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ORIGINAL PAPER

Method validation and profiling of total UV-absorbing contaminants migrating from monolayered low-density polyethylene used for aqueous foods in the Philippines

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ABSTRACT

The widespread consumption of disposable plastics as food contact articles (FCAs) in the Philippines has raised concerns about food safety due to the potential chemical migration of contaminants. In this study, validation of the modified 21 code of federal regulations (CFR) Part 177 method was performed through preliminary screening, determination of validation parameters, and profiling. 18 randomly screened low-density polyethylene (LDPE) bags from 16 brands across Philippine markets were analyzed to identify low and high absorbance levels of total UV-absorbing contaminants (TACs) to be considered for method validation. Validation parameters demonstrated limit of detection (LOD) and quantification (LOQ) of 0.013 AU and 0.033 AU per 50 cm^2, ensuring reliable detection at low levels. Results from profiling 47 samples presented variability in migration of TACs across brands and locations. However, all samples were within the maximum allowable limit (MAL) of 0.300 AU set by the food and drug administration (FDA) Philippines for aqueous foods. These findings account for the potential migration of contaminants throughout production, transportation, environmental conditions, and storage processes. Comparison between food simulants, n-Heptane to mimic fatty and oily foods and water for aqueous foods, was conducted through statistical analysis using previously reported same-laboratory data for n-Heptane. An independent nonparametric Mann–Whitney U test indicated a statistically significant difference between TACs levels of the two simulants. Comprehensive research on yet to be specified contaminants is proposed to further explore probable adverse health effects associated with their toxicokinetics and toxicodynamics. **Polyolefins J (2025) 12: 259-272**

Keywords: Food contact articles; food safety; migration; low-density polyethylene; total UV-absorbing contaminants.

INTRODUCTION

An increasing trend in the usage of plastics in the Philippines has been identified over the past decade, with at least 2.7 million metric tons of plastic waste generated every year [1]. Intensive use of single-use food contact articles (FCAs) made of monolayered low-density polyethylene (LDPE), locally recognized as plastic *labo* or plastic *yelo* depending on their use, can be considered one of the major culprits. Favored for their accessibility, affordability, and versatility, freshly baked products, soupy viands, and potables are habitually packaged in these plastic bags. Some common products are *pandesal* (salt bread/soft roll) and *monay* (nun's bread/bread roll) from *panaderias* or local bakeries; variations of stews from *carinderias* or local eateries; and iced water, soda, and flavored popsicles from *sari-sari* or retail stores.

However, chemical migration, which is the transfer of chemical contaminants from packaging to food products [2], poses food safety and health concerns. The majority of these contaminants are monomers,

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oligomers, plasticizers, additives, and adhesives, associated with cardiovascular diseases, endocrine disruption, and carcinogenic effects [2-5]. Two classifications of migration can be identified–overall and specific. Overall migration (OM) is defined as the total migrating chemical compounds from the packaging into the food, while specific migration refers to the distinct migrant typically determined through advanced analytical methods [2,4]. Factors influencing migration include the nature of food products (e.g., fatty and oily [6], alcoholic [7], acidic or dried), processes in the supply chain (e.g., production, distribution, or storage), environmental conditions, and handling practices which include the misuse and abuse of FCAs.

To address this concern, regulatory agencies, like the food and drug administration (FDA) Philippines issued a guideline for the voluntary application and issuance of FCAs under circular no. 2022-0011 [8]. The guideline aims to assess and evaluate FCAs' material safety and suitability through various testing parameters conducted by FDA-accredited or recognized laboratories. While the guideline is aligned with the Philippines' Food Safety Act of 2013 [9], voluntary testing does not completely guarantee consumer protection. As per the proponent's recent meeting with FDA Philippines' representatives, only approximately a hundred FCA stakeholders request certification annually, a small percentage from the Philippine Statistics Authority's 2022 tally of 7,162 registered food manufacturing businesses i.e., excluding unregistered establishments and packaging companies [10]. In addition, the FDA Philippines follows a modified procedure of the 21 code of federal regulations (CFR) Part 177 [11] for the determination of total UV-absorbing contaminants (TACs) therefore requiring method development and validation to ensure suitability, reliability, and reproducibility.

Moreover, there is limited scientific data on the migration of TACs from LDPE to food products with high moisture content. Giacin and Brzozowska [12], and Gupta *et al*. [2], despite the 40 year gap in their studies, mentioned 21 CFR Part 177 in their paper but only as an entry to their respective inventories of global regulations and legislations for FCAs. Being one of the few established directives specific to polymers, the method dedicates a section to polyolefins such as polyethylene (PE) and polystyrene (PS), justifying its validity as a reference and providing an avenue for broader research such as this study. Meanwhile, de Anda-Flores *et al*. [13] cited 21 CFR Part 177 to single out the applicability of di(2-ethylhexyl) phthalate (DEHP) as a plasticizer for food contact materials (FCMs) of high water content, similar to the type of food investigated in this study. The main difference between the previous and current research is that the former deals with specific migration while the latter on total transfer. A non-targeted technique, UV-Vis spectroscopy, was performed to initially screen and determine TACs. This method of overall migration analysis provides rapid results yet introduces limitations such as overlapping of absorption bands within the same wavelength [14]. Due to the method's non-specificity, further qualification and quantification of specific migrants require advanced analytical techniques such as liquid chromatography-mass spectrometry (LC-MS), gas chromatography-mass spectrometry (GC-MS), and their tandem mass spectrometry (MS/MS) counterpart for selectivity and sensitivity through the fragmentation of target precursor ion into product ions [2]. In addition, it is interesting to highlight that the current study could be used as an initial assessment to verify the absence of DEHP in plastic FCAs, eliminating the use of high-order GC-MS and additional consumables thus, reducing operational costs. However, DEHP confirmatory tests are beyond the scope of this paper. Lastly, Kailo *et al*. [15] only peeked into the appropriateness of 21 CFR Part 177 for 3D printed food packaging and utensils. Unlike microbial and mechanical tests, chemical investigations were not performed, leaving the research area untouched.

As a result, this study intends to explore the development, validation, and utilization of the method to create a better profile of Philippine FCAs made from monolayered polymers such as LDPE bags. It is the first to systematically investigate the migration of absorbing contaminants when in contact with high-moisture food products, distinguishing it from the recently published study of Alejandro *et al*. [6] on fatty and oily commodities. Although non-specific, the study also aims to present the feasibility of using 21 CFR Part 177 as a preliminary screening procedure for plasticizers [13,16], organic pesticides [17], and polymer residues [18] in aqueous medium. This study builds on the lack of localized evidence to support the crafting of science-based policies on FCAs and strengthens the research-to-policy collaboration between the Packaging Safety Laboratory (PSL) of the Department of Science and Technology - Industrial Technology Development Institute - Packaging Technology Division (DOST-ITDI-PTD) and the FDA Philippines as a regulatory agency under the Department of Health (DOH).

EXPERIMENTAL

Sample collection

Non-stratified purposive sampling was performed by purchasing suspected LDPE bags from cities and a municipality in Metro Manila. Retail stores in each city's public market were chosen based on either the high volume of customers present or the variety of brands available during the time of sampling. Partnered stakeholder, manufacturer A, also submitted one LDPE sample. A total of 47 unused LDPE samples, covering 16 different brands from 17 cities were randomly acquired. All samples were coded per brand and location to maintain strict confidentiality between retailers and a manufacturer.

FTIR-ATR analysis

Obtained samples were analyzed through Shimadzu IR-Prestige-21 Fourier Transform Infrared Spectroscopy - Attenuated Total Reflectance (FTIR-ATR) to confirm polymer composition.

Sample extraction

The samples were measured and cut into 5 cm x 10 cm films, wiped with lint-free paper, and each placed in a 250 mL beaker. One hundred mL of distilled water was measured and added to each beaker, ensuring the sample's total immersion. Beakers were covered with aluminum foil and placed in the incubator, following the extraction conditions for room temperature filled and stored (no thermal treatment in the container), 24 hours at 49 ± 0.43 ºC. After extraction, plastic films were removed using tweezers and the extracting solutions were left to reach room temperature.

Preliminary screening

Shimadzu UV-1800 UV/Vis Spectrophotometer, in the range of 220-360 nm, was used to analyze the extracting solutions. From the spectrum, the highest peak was recorded as the maximum absorbance. A minimum of one sample per brand was randomly surveyed, with a total of 18 sample representatives screened. Low and high absorbance values were determined among selected samples tested.

Method validation

Limit of detection (LOD) and limit of quantification (LOQ)

The determination of LOD was performed to identify the lowest absorbance of an analyte that can be detected and to distinguish background noise from the detection of TACs in samples. Whereas, LOQ was conducted to determine the absorbance level quantifiable with precision and accuracy. At least 10 method reagent blanks were tested, and LOD and LOQ were calculated using the following formulas [19]:

LOD = Average Absorbance + (3 × Corrected Standard Deviation)

LOQ = Average Absorbance + (10 × Corrected Standard Deviation)

Repeatability and intermediate precision

To verify the repeatability and reproducibility of samples with low and high absorbance levels identified during the preliminary screening, a series of repeatability and intermediate precision tests was conducted and performed separately by two analysts. Both analysts performed repeatability, with 2 method reagent blanks and at least 6 replicates for sample extraction. The average of the method reagent blanks was used to calculate the corrected absorbance. The average absorbance, standard deviation, and percentage relative standard deviation (% RSD) were calculated. Intermediate precision was conducted between the 2 analysts through the calculation of pooled average and pooled %RSD.

The formulas can be expressed as:

%RSD = (Standard Deviation / Average Absorbance) × 100

Pooled %RSD =

$$\sqrt{\frac{(n_1-1)RSD_1^2+(n_2-1)RSD_2^2+\ldots+(n_k-1)RSD_k^2}{n_1+n_2+\ldots+n_k-k}}$$

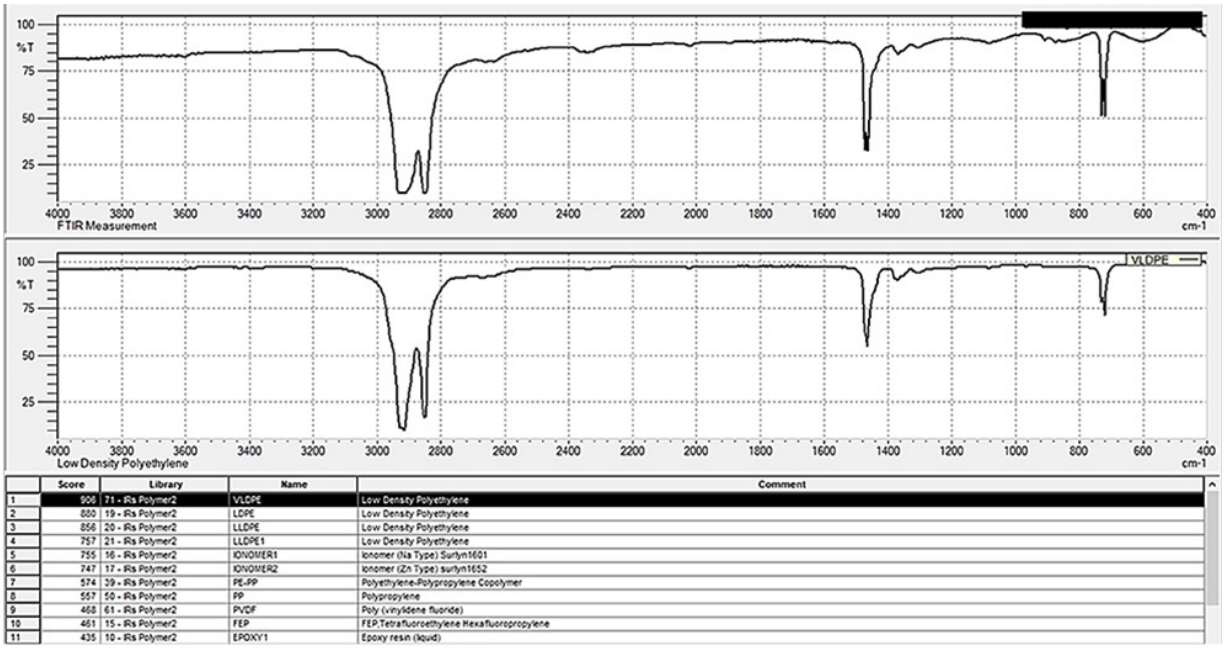
Profiling

All 47 LDPE samples were tested using the validated method with an established permissible range. Additional samples were employed to enhance reliability and accuracy, testing triplicate (n = 3) per sample. Average absorbance of the profiled samples was then assessed with the maximum allowable limit (MAL) set by FDA Philippines (0.300 AU) for chemical migrations to aqueous foods.

RESULTS AND DISCUSSION

FTIR-ATR Analysis

The FTIR-ATR spectra, as shown in Figure 1, displayed major absorption peaks corresponding to C-H stretching and bending vibrations. This revealed characteristic alkyl functional groups associated with non-polar hydrocarbons. Distinct absorption features within the fingerprint region (500–1500 cm^{-1}) further



	Score	Library	Name	Comment
1	906	71 - IRs Polymer2	VLDPE	Low Density Polyethylene
2	880	19 - IRs Polymer2	LDPE	Low Density Polyethylene
3	856	20 - IRs Polymer2	LLDPE	Low Density Polyethylene
4	757	21 - IRs Polymer2	LLDPE1	Low Density Polyethylene
5	755	16 - IRs Polymer2	IONOMER1	Ionomer (Na Type) Surlyn1601
6	747	17 - IRs Polymer2	IONOMER2	Ionomer (Zn Type) surlyn1652
7	574	39 - IRs Polymer2	PE-PP	Polyethylene-Polypropylene Copolymer
8	557	50 - IRs Polymer2	PP	Polypropylene
9	468	61 - IRs Polymer2	PVDF	Poly (vinylidene fluoride)
10	461	15 - IRs Polymer2	FEP	FEP,Tetrafluoroethylene Hexafluoropropylene
11	435	10 - IRs Polymer2	EPOXY1	Epoxy resin (liquid)

Figure 1. FTIR Result of LDPE-0015.

substantiated the LDPE structure. The resulting spectrum exhibited a close match with the reference spectrum, yielding a high similarity score of 906. These findings ensured that all analyzed samples used in subsequent procedures were LDPE.

Preliminary screening

Among the 17 LDPE bags surveyed from various brands, one (1) exhibited an absorbance value of at least 66.7% higher than the rest, suggesting possible variability of composition and processes across brands. Despite this observed variability, data from Table 1 showed full compliance with FDA's MAL of 0.300 AU for high-moisture foods. Survey results revealed LDPE-0013 from Caloocan City having the lowest absorbance (0.000 AU), while LDPE-0004 from the City of Manila generated the highest value with 0.025 AU. Figure 2 presents the summarized results in the form of a scatter plot, and provides a graphical overview of the range and distribution across surveyed samples.

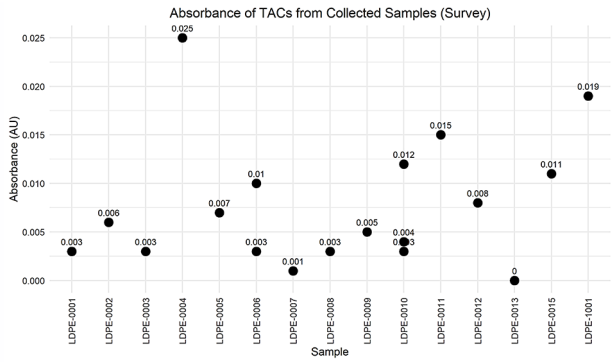


Figure 2. Scatter plot of absorbance values of analyzed LDPE samples from different brands and locations.

Method Validation

Limits of detection and quantification

The obtained LOD value of 0.013 AU defines the smallest absorbance of the analyte that can be detected by the method, while the LOQ of 0.033 AU describes the level at which the analyte can be quantified

Table 1. Survey Results of LDPE Samples from Different Brands and Locations.

Sample Code	Location	Absorbance (AU) (n = 2)	%RSD
LDPE-0001	Taguig City	0.003	117.9
LDPE-0002	Pasig City	0.006	58.9
LDPE-0003	Valenzuela City	0.003	56.6
LDPE-0004	City of Manila	0.025	8.66
LDPE-0005	Makati City	0.007	54.4
LDPE-0006	Quezon City	0.010	22.3
LDPE-0006	Municipality of Pateros	0.003	0.00
LDPE-0007	Malabon City	0.001	0.00
LDPE-0008	Mandaluyong City	0.003	28.3
LDPE-0009	Valenzuela City	0.005	15.7
LDPE-0010	Marikina City	0.004	60.6
LDPE-0010	Municipality of Pateros	0.003	28.3
LDPE-0010	Navotas City	0.012	6.15
LDPE-0011	Muntinlupa City	0.015	18.9
LDPE-0012	Pasig City	0.008	17.7
LDPE-0013	Caloocan City	0.000	-
LDPE-0015	Makati City	0.011	12.9
LDPE-1001	Malabon City	0.019	3.82

Table 2. LOD and LOQ Results.

	Results (AU)	Criteria	Remarks
Average absorbance	0.005	-	-
SD	0.003	-	-
% RSD	55.8	-	-
LOD	0.013	< 10% MAL (0.300 AU)	Passed
LOQ	0.033	-	-

with accuracy [20]. Determination was performed by analyzing at least 10 method reagent blanks with readings above 0.000 AU. While a low-level sample was initially considered, its replicates yielded inconsistent results potentially implying material inhomogeneity influenced by blend composition and production processes [21]. Nevertheless, Table 2 attests that the computed LOD from method reagent blanks was deemed suitable for purpose, having a value that is less than 10% of the MAL (0.300 AU) established by the regulatory body.

Repeatability and intermediate precision

In theory, results of surveyed samples must produce repeatable trials at selected low and high absorbance levels to be considered for method validation. However, the samples with the lowest and highest values from the preliminary screening, LDPE-0013 from Caloocan City (0.000 AU) and LDPE-0004 from the City of Manila (0.025 AU) respectively, were not repeatable. As a consequence, a trial-and-error approach was employed to select the alternate samples for low and high levels, i.e., LDPE-0015 from Makati City having a low absorbance value of 0.011 AU with a relatively low %RSD and LDPE-1001 from Malabon City having a high absorbance value of 0.019 AU with a relatively low %RSD, respectively. Both materials meet the required levels while showing a better spread of results compared with the others.

Table 3. Repeatability of Absorbance Measurements for Two Analysts.

Low		High	
Analyst A (AU)	**Analyst B (AU)**	**Analyst A (AU)**	**Analyst B (AU)**
0.013	0.017	0.019	0.019
0.014	0.013	0.024	0.019
0.018	0.013	0.023	0.018
0.016	0.014	0.028	0.018
0.013	0.013	0.020	0.018
0.016	0.016	0.025	0.018
0.016	0.014	0.024	0.023

As shown in Tables 3 and 4, repeatability results obtained by Analyst A were 12.7 %RSD for low level and 13.1 %RSD for high level, whereas Analyst B demonstrated slightly lower variability, with %RSD values of 11.2 and 9.6 for the corresponding levels. The results of Analyst B illustrate the theory which predicts that the variability increases as the analyte concentration decreases [22]. Moreover, the difference between Analyst A and Analyst B's average absorbance value for low level is 0.001 AU while 0.004 AU for high level. The closeness of results may have been influenced by the operators' familiarity and competence with the method, proper maintenance of the equipment, and favorable environmental conditions [23]. A supplementary investigation may be undertaken to confirm whether the observed difference between the two analysts verifies that the deviation is statistically insignificant. The calculation of the pooled average and pooled %RSD (Table 5) were instrumental in establishing acceptable criteria for the developed method (Table 6).

Table 4. Results of repeatability for two levels and two analysts.

Analyst	Level	Absorbance (AU)	%RSD
Analyst A	Low	0.015±0.002	12.7
	High	0.023±0.003	13.1
Analyst B	Low	0.014±0.002	11.2
	High	0.019±0.002	9.6

Gaps on trueness and future interventions

While the assessment of limits and repeatability support the fitness-for-purpose of the method, the utilization of certified reference materials (CRMs), participation in proficiency testing (PT) schemes, and interlaboratory comparisons (ILC) are strongly encouraged to further support method reliability and align with international practices. The limited availability of these in the local setting compromises the method validation. Thus, interventions are encouraged, including partnering with local and global CRM producers and accredited PT providers (e.g., National Metrology Laboratory of

Table 5. Results of Intermediate Precision.

Level	Absorbance (AU)		Pooled average (AU)	Pooled % RSD
	Analyst A	Analyst B		
Low	0.015±0.002	0.014±0.002	0.014	12.0
High	0.023±0.003	0.019±0.002	0.021	11.5

Table 6. Established Acceptable Criteria by Single Extraction (24 hours at 49 ± 0.43ºC) and Qualitative Spectral Scanning (λ = 220 - 360 nm, 5 cm path length).

AU/TACs migrated from 50 cm^2 LDPE films	% RSD
0.014≤AU<0.021	12.0
0.021≤AU	11.5

the Philippines, National Institute of Standards and Technology, LGC Standards, European Commission's Joint Research Centre, and other metrological institutes), as well as collaborating with several reputable laboratories for comparative studies.

Through validation of the procedure, the detection

Table 7. Results of Profiling using Established Acceptable Criteria.

Sample Code	Location	Absorbance (AU) (n = 3)	%RSD	Average AU per Brand	%RSD
LDPE-0001	Muntinlupa City	0.031	0.00	0.031	-
LDPE-0001	Taguig City	ND (0.008)	18.7		
LDPE-0002	Pasig City	ND (0.009)	51.3	ND	-
LDPE-0003	Valenzuela City	ND (0.005)	22.2	ND	-
LDPE-0004	City of Manila	ND (0.005)	43.1	ND	-
LDPE-0005	Makati City	ND (0.006)	26.2	ND	-
LDPE-0005	Taguig City	ND (0.009)	28.5		
LDPE-0005	Valenzuela City	ND (0.010)	0.00		
LDPE-0006	Las Piñas City	ND (0.012)	8.70	0.023	59.7
LDPE-0006	Navotas City	0.032	6.57		
LDPE-0006	Pasay City	0.013	35.4		
LDPE-0006	Municipality of Pateros	ND (0.009)	11.1		
LDPE-0006	Quezon City	ND (0.007)	45.8		
LDPE-0006	San Juan City	ND (0.005)	28.6		
LDPE-0006	Valenzuela City	ND (0.011)	33.4		
LDPE-0007	Malabon City	0.026	9.81	0.026	-
LDPE-0007	City of Manila	ND (0.005)	78.1		
LDPE-0008	Mandaluyong City	0.024	10.3	0.025	5.66
LDPE-0008	City of Manila	ND (0.004)	35.3		
LDPE-0008	Marikina City	ND (0.005)	32.7		
LDPE-0008	Paranaque City	0.026	3.85		
LDPE-0008	Taguig City	ND (0.002)	0.00		
LDPE-0008	Valenzuela City	ND (0.007)	68.6		
LDPE-0009	Valenzuela City	0.027	3.70	0.027	-
LDPE-0010	Caloocan City	ND (0.007)	60.6	ND	-
LDPE-0010	Las Piñas City	ND (0.004)	41.7		
LDPE-0010	Malabon City	ND (0.007)	0.00		
LDPE-0010	City of Manila	ND (0.006)	27.0		
LDPE-0010	Marikina City	ND (0.003)	33.3		
LDPE-0010	Navotas City	ND (0.010)	14.8		
LDPE-0010	Municipality of Pateros	ND (0.004)	70.5		
LDPE-0010	Quezon City	0.021	12.6		
LDPE-0010	Taguig City	ND (0.002)	89.2		
LDPE-0010	Valenzuela City	ND (0.003)	40.0		
LDPE-0011	Muntinlupa City	ND (0.004)	79.7	ND	-
LDPE-0012	Pasig City	ND (0.004)	54.3	ND	-
LDPE-0013	Caloocan City	ND (0.006)	18.2	ND	-
LDPE-0013	Mandaluyong City	ND (0.002)	83.3		
LDPE-0013	Navotas City	ND (0.005)	72.1		
LDPE-0013	Paranaque City	ND (0.001)	229.1		
LDPE-0013	Pasay City	ND (0.006)	0.00		
LDPE-0013	Taguig City	ND (0.004)	110.2		
LDPE-0014	Navotas City	ND (0.004)	56.8	ND	-
LDPE-0014	San Juan City	ND (0.008)	70.7		
LDPE-0014	Valenzuela City	ND (0.006)	47.1		
LDPE-0015	Makati City	0.017	4.29	0.017	-
LDPE-1001	Malabon City	0.020	5.56	0.020	-

limit was found acceptable for routine testing and regulatory assessment, while criteria for precision within and between analysts were established. While the gaps in method trueness are yet to be addressed, these preliminary results help build confidence in ensuring the integrity of succeeding measurements and reliability of follow-through studies.

Profiling

Table 7 summarizes the absorbance values of 47 samples subject to the validated method and assessed against set precision criteria. Approximately 4.26% of the profiled samples were found within the established low and high range of the method, while 14.9% exceeded the high absorbance value of 0.021 AU. Only 21.3% of the profiled samples were equivalent to and above the detection limit, implying that the absorbance values of the remaining samples were Not Detected (ND) by the method. Although these absorbance values were below the 0.300 AU MAL for high-moisture food products, TACs were still detected under these conditions, suggesting a potential hazard. Trace amounts of toxic contaminants such as phthalates and non-phthalate additives influence OM values [13] and are potentially present in the tested samples. Therefore, targeted analysis of specific migrants must be pursued to further evaluate the risks associated with chemical migration.

By Brand

Average absorbance per brand

Regardless of the spread of results, computation of the average absorbance of each brand (represented by a sample code) revealed that 46.7% (7 of the 15) were above the set detection limit. This suggests that almost half of the brands commercially available to the public are demonstrating migration of trace amounts of chemicals. And while the values fall approximately ten times lower than the established MAL, this presents an opportunity for manufacturers to receive technical assistance in further reducing their products' values through review, analysis and modifications, if necessary, of their raw materials and processes [24]. Both of which may be contributory to the slight transfer of unknown chemicals, which constant exposure to may lead to chronic effects [2-5].

Discrepancies in a single brand across various locations were substantially observed. LDPE-0008, for example, obtained from Manila, Marikina, Taguig, and Valenzuela resulted in having no detections, while those from Mandaluyong and Parañaque exhibited distinct (and repeatable) absorbance values of 0.024 and 0.026 AU, respectively. This resulted in LDPE-0008 placing third among the 16 profiled brands, slightly trailing behind LDPE-0001 (0.031 AU) and LDPE-0009 (0.027 AU). However, it should be emphasized that the average absorbance cannot be used to conclude the chemical migration behavior of a brand considering the spread of results and ratios of detectable and non-detectable units. This pattern of variability in a lone brand was also evident in LDPE-0010 (9 ND: 1 detected), LDPE-0006 (5 ND: 2 detected), LDPE-0001 (1 ND: 1 detected), and LDPE-0007 (1 ND: 1 detected). The difference in the AU readings of a single brand sourced from different locations can be associated with the influence of external factors.

Raw material sourcing and production

Significant inconsistencies may be observed due to raw material sourcing and variations during production which introduced batch-related discrepancies. As stated by Doganaksoy and Hahn [25], blending of polymers from various sources unintentionally affects the uniformity and quality consistency of the finished product. Thermal and mechanical degradation during film extrusion forms low molecular weight compounds that promote leaching into food [26]. Leachables formed during these processes can accelerate dissolution and diffusion behavior [27] which manifest elevated absorbance values. The discrepancy in LDPE-0008 may have been influenced by this particular type of external factor. The values from four locations being below LOD and the other two within the 0.024-0.026 range may imply two production batches differentiated by a change in sourced resin or additive, or a variation in the company's manufacturing process, e.g., slight changes in ambient and extrusion temperatures, replacement of mixer lining or rollers in contact with product, etc.

Distribution and storage

Transportation and storage procedures greatly vary from suppliers, manufacturers, retailers, and consumers. All of which could also influence disparities among AU readings across a single brand purchased from different locations. Exposure to sunlight can increase the leaching of aldehydes and ketones from plastic [28]. Meanwhile, endocrine-disrupting chemicals were released from plastic containers at temperatures close to 40°C [29]. During recent years, Metro Manila has experienced an increasing heat index due to high

surface temperatures, and urban heat island effects depending on the thermal characteristics of the urban morphology and the closeness of an area to bodies of water (e.g., Manila Bay, Laguna Lake, Pasig River) and vegetation (e.g. Arroceros Forest Park, La Mesa Nature Reserve) [30]. This could explain the presence of variations in certain brands such as LDPE-0006. LDPE-0006 sourced from Pasay and Navotas cities yielded detectable values. The presence of reclamation activities in these cities have decreased the size of Manila Bay and may have affected its cooling effect on the west coast of Metro Manila, where both are located [31]. In addition, both cities are also undergoing major infrastructure construction which may have raised surface temperatures. Further, Pasay's proximity to the Ninoy Aquino International Airport and Navotas' shipbuilding and industrial activities may also be contributing to urban heat island effects [32].

In contrast, LDPE-0005, LDPE-0013, and LDPE-0014 depict TACs migration below the detection limit across locations per brand. The formulation and composition of the brands may be correlated with the TACs migration. For instance, some manufacturers enhance their product by incorporating antioxidants to prevent oxidation of polymers. This delays the onset of oxidation of polymers caused by exposure to light, extreme temperatures, and loss of volatile compounds or diffusion of volatiles from the environment. Several antioxidants like tocopherols are effective stabilizers for polymer processing and reducing oxidation [33,34]. Such can be partnered with another antioxidant to influence migration profile and release rate, e.g., complexation of alpha-tocopherols and beta-cyclodextrin to control the release of alpha-tocopherols from LDPE packaging [33]. The complexation of antioxidants illustrates that incorporation of additives in LDPE bags is being performed. Formulation of LDPE bags per brand is undisclosed, and some manufacturers may have included stabilizing additives to at least lessen oxidation. As composition plays a critical role in chemical migration, raw material analysis and investigation of processes should be administered to explore the different chemical interactions of FCAs and FCMs towards food. The need for specific migration after overall migration lies in further identifying the derivatives of contaminants that cannot be determined by using a UV-Vis Spectrophotometer. Specifying contaminants will focus on the toxicological aspect and aid in knowing which derivative is more abundant than others. Identifying specific additives present in the food packaging enables a better understanding and control of the contaminants.

Comparison with literature (fatty and oily foods compared against aqueous foods)

Findings from Alejandro *et al*.'s [6] reported literature highlighted a major non-compliance rate of TACs absorbance values extracted from monolayered LDPE packaging. With 58.7% of samples exceeding FDA's 0.100 AU MAL for fatty and oily foods, the need to identify the effects of two different simulants on the migration behavior was explored. Data obtained in the study were tabulated with those of previously published findings (Table 8) and an assessment of normality was employed as a basis for subsequent statistical analyses. The Shapiro-Wilk test was chosen to verify normality due to its suitability for small to moderate sample sized data ($n < 50$). The test provided evidence ($p < 0.001$) that the two independent groups, TACs in n-Heptane and TACs in Water, were not normally distributed and violated the assumption of a parametric test. As such, the use of a nonparametric test, the Mann-Whitney U test, was appropriate to determine whether there is a statistically significant difference between the two independent groups without assuming normal distribution.

The Mann-Whitney U test depicted in Figure 3 resulted in a U value of 2209 and a p-value of < 0.001, indicating a statistically significant difference between the TACs absorbance of the two different simulants. The effect size was large with a matched rank biserial correlation of 1.000—highlighting that one group consistently had higher ranks than the other. A standard error (SE) of 0.119 and 95% confidence interval (CI) (Lower = 1.000, Upper = 1.000) further supports that the effect size estimate has no variability, with groups having a complete separation in the distribution of ranks. The relationship between the two independent groups suggests not only statistical significance but also extreme consistency and robustness among observed data points. These results suggest that monolayered LDPE bags may pose higher chemical migration into fatty and oily foods, warranting closer monitoring and stringent regulatory controls than that of aqueous foods.

The descriptive statistics, found in Figure 4, showed that the mean level of TACs was substantially higher in n-Heptane compared to water, indicating greater migration of contaminants into the fatty and oily food simulant. The standard deviation (SD) was also notably higher in n-Heptane (0.144) than in water (0.008),

Table 8. Profiled Data Comparison Between TACs in n-Heptane and Water.

Sample Code	TACS in n-Heptane (n = 3)	TACs in Water (n = 3)
LDPE-0001	0.063	0.031
LDPE-0001	0.111	0.008
LDPE-0002	0.050	0.009
LDPE-0003	0.150	0.005
LDPE-0004	0.226	0.005
LDPE-0005	0.136	0.006
LDPE-0005	0.146	0.009
LDPE-0005	0.221	0.010
LDPE-0006	0.075	0.012
LDPE-0006	0.105	0.032
LDPE-0006	0.074	0.013
LDPE-0006	0.096	0.009
LDPE-0006	0.106	0.007
LDPE-0006	0.101	0.005
LDPE-0006	0.104	0.011
LDPE-0007	0.106	0.026
LDPE-0007	0.133	0.005
LDPE-0008	0.145	0.024
LDPE-0008	0.102	0.004
LDPE-0008	0.113	0.005
LDPE-0008	0.114	0.026
LDPE-0008	0.128	0.002
LDPE-0008	0.152	0.007
LDPE-0009	0.049	0.027
LDPE-0010	0.084	0.007
LDPE-0010	0.121	0.004
LDPE-0010	0.093	0.007
LDPE-0010	0.044	0.006
LDPE-0010	0.098	0.003
LDPE-0010	0.097	0.010
LDPE-0010	0.124	0.004
LDPE-0010	0.046	0.021
LDPE-0010	0.100	0.002
LDPE-0010	0.120	0.003
LDPE-0011	0.103	0.004
LDPE-0012	0.110	0.004
LDPE-0013	0.117	0.006
LDPE-0013	0.091	0.002
LDPE-0013	0.115	0.005
LDPE-0013	0.081	0.001
LDPE-0013	0.139	0.006
LDPE-0013	0.093	0.004
LDPE-0014	0.064	0.004
LDPE-0014	0.063	0.008
LDPE-0014	0.078	0.006
LDPE-0015	0.229	0.017
LDPE-1001	1.056	0.020

suggesting more variability among the samples. While both simulants had relatively low SE, the coefficient of variation was slightly higher in n-Heptane (1.116) than in water (0.853), reflecting greater relative variability in the data. These findings support the observation that packaging materials release more contaminants into fatty and oily simulant than into aqueous simulant. This further suggests the incompatibility of LDPE bags used for fatty and oily foods. Foods with high content of fat and oil penetrate or swell the LDPE matrix, leading to greater TACs migration. Their similar polarity interacts, as non-polar substances exhibit solubility in non-polar solvent due to their comparable intermolecular forces. In contrast, polar substances such as aqueous foods, demonstrated lower chemical migration when subjected to the LDPE samples under the performed conditions. The composition of FCAs remarkably influenced the TACs migration between different simulants which was evidently seen through the obtained absorbance levels and statistical analyses performed. These findings, however, propose intensive research on different types of solvents that are suitable, and match the foods and viands commonly used in LDPE bags in the Philippines. Method validation and profiling through various simulants under elevated temperatures is also recommended to mimic different conditions and food types, namely, acidic, dry, and alcoholic food products. This will explore the effects of storage temperatures with common household and retail practices in the Philippines—ice water in plastic *yelo* stored inside the refrigerator or freezer, freshly cooked soup-based viands from *carinderias* or local eateries, and such. Enhanced comprehension of numerous immersion times and temperatures would provide insights into the complexities between interactions of compounds and their corresponding effects–thermally induced degradation that could instigate mechanical and physical stress [34,35,36]. Data analysis also highly depends on the accuracy and standardization of sample collection. The collection of locally available samples must be further explored in broader areas and varying environmental conditions to account for induced chemical migration during production, transportation, and storage. Types of FCAs such as High-Density Polyethylene (HDPE), Polypropylene (PP), PS, Polycarbonate (PC), Polyethylene Terephthalate (PET), blends, papers, and biodegradables may react distinctively with various food types and environmental conditions. This should be addressed especially with the increasing demand for sustainable packaging [35,36].

These findings underscore the need to come up with effective regulatory policies on FCAs and FCMs that are specific to the Philippines. These policies should be developed through collaborative efforts between the government and the private sector since food safety

Independent Samples T-Test

	U	df	p	Rank-Biserial Correlation	SE Rank-Biserial Correlation	95% CI for Rank-Biserial Correlation	
						Lower	Upper
TACs of Two Simulants	2209.000		< .001	1.000	0.119	1.000	1.000

Note. For the Mann-Whitney test, effect size is given by the rank biserial correlation.
Note. Mann-Whitney U test.

Figure 3. Mann-Whitney U Test.

Descriptives

Group Descriptives

	Group	N	Mean	SD	SE	Coefficient of variation
TACs of Two Simulants	TACS in Heptane	47	0.129	0.144	0.021	1.116
	TACs in Water	47	0.010	0.008	0.001	0.853

Figure 4. Descriptive Statistics of Two Simulants.

and packaging regulation require shared responsibility. While the government provides the legal basis and enforcement, the private sector brings in resources, technical expertise, and innovation. By working together, both can ensure that standards of regulation are achievable, widely adopted, and harmonized with international scientific and regulatory systems. Strict enforcement of such policies—particularly through the establishment of precise migration limits and the frequent testing of FCAs and FCMs—would be critical in ensuring consumer safety. National standards for FCAs and FCMs remain limited in coverage compared to international counterparts such as EU Regulation No. 10/2011 [37], China's National Food Safety Standard GB 31604.1-2023 [38], and the U.S. FDA 21 CFR standards [11]. The path forward is to combine the establishment of specific chemical migration limits and routine testing with collaborative efforts among regulatory agencies, research institutions, and private industry. Such partnerships can assist with laboratory capacity building, foster open compliance mechanisms, and incentivize the industry.

Involvement and urgency of the Philippines' regulatory enforcement is advised, as results from using LDPE bags in public markets, *carinderias*, retail or *sari-sari* stores, and bakeries contributed to elevated chemical migration of various additives and contaminants at ambient temperature. Public's exposure to contaminants caused by chemical migration from FCAs and their adverse effects remains unclear and an area of concern. As practice-based usage of FCAs is not yet explored, laboratory-based results provide an initial overview of possible local and global impacts. Industry partners could also have serious repercussions on food safety and quality, as changes in taste, appearance, and nutritional value are affected by FCAs' formulation [39]. Economic losses as damage in reputation, and market and trade impacts can ripple, losing trade opportunities and eventually reducing national revenue [40]. Therefore, collaborations with local industry stakeholders through a Memorandum of Agreement (MOA) encourage feedback and improvement of samples, along with enhanced analytical reliability due to the provision of representative samples. Efforts from partnerships would also influence the knowledge and perception of consumers and the public on chemical migration and regulations, emphasizing the risks of improper usage of FCAs with certain food types. Local government units (LGUs) in the Philippines must strengthen their regulation on banning single-use plastic bags and containers as the majority of the samples used in this study were purchased in public markets and are accessible to the community despite ordinances [41-46]. Consumers may have limited awareness of the consequences of using FCAs, which may be due to the lack of migration studies in the Philippines. Only one study by Encarnacion *et al*. [47] focused on per- and polyfluoroalkyl substances (PFAS) content in paper-based fast food packaging through LC-MS. Therefore, the need for strict regulations for locally available FCAs and FCMs is advised not just for the safety of the consumers but also for compliance with international standards and environmental impact. Prospective studies on exposure assessment, specific migration, and toxicological studies are crucial to comprehensively evaluate health implications of chemical contaminants migrating from food packaging.

CONCLUSIONS

The study accomplished the validation of modified 21 CFR Part 177 using the UV-Vis spectrophotometric method for the determination of TACs in LDPE in contact with high-moisture foods. Established acceptable criteria were also achieved through preliminary screening; LOD = 0.013 AU, LOQ = 0.033 AU per 50 cm^2, repeatability, and intermediate precision. Profiling results revealed that TACs levels of locally available LDPE samples were below the 0.300 AU MAL for aqueous foods set by the FDA Philippines, implying compliance with guidelines. TACs levels differ by brands and locations due to variables that could greatly contribute to the migration of chemical contaminants present in the FCAs. Comparison between n-Heptane as simulant for fatty and oily foods, and water as simulant for aqueous foods showed statistically significant difference in TACs absorbance levels and therefore indicate that fatty and oily foods may have higher chemical migration from monolayered LDPE. Local regulatory bodies and policymakers must establish strict and mandatory testing of FCAs and FCMs with specific migration limits. This would ensure the protection of consumers and promotion of trading. Hence, continuous local testing of FCAs and FCMs is obliged to monitor TACs levels for consumer safety, international standards, and a harmonized industry.

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CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

AUTHOR CONTRIBUTION

Rizel Marie S.M. Ting (Method Validation, Data Analysis and Collection, Writing–original draft, review and editing), Elyson Keith P. Encarnacion (Conceptualization, Supervision, Funding Acquisition, Project Administration, Writing–review and editing), Anne C. Alcantara (Project Administration, Data Analysis, Writing–review and editing), David J. Alcarde Jr. (Writing–review and editing), Harold E. Armario (Data Analysis, Writing–review and editing), Winnie P. Alejandro (Data Analysis and Collection, Writing–review and editing), Agaseve F. Del Rosario (Writing–review and editing), April Star L. Canonizado (Data Collection, Writing–review and editing).

ABBREVIATIONS

%RSD Percentage Relative Standard Deviation
AU Absorbance Units
CFR Code of Federal Regulations
CI Confidence Interval
CRM Certified Reference Material
DEHP di(2-ethylhexyl) phthalate
DOH Department of Health
DOST-ITDI-PTD Department of Science and Technology - Industrial Technology Development Institute - Packaging Technology Division
FCA Food Contact Article
FCM Food Contact Material

FDA Food and Drug Administration
FTIR-ATR Fourier-Transform Infrared Spectroscopy-Attenuated Total Reflectance
GC-MS Gas Chromatography - Mass Spectrometry
HDPE High-Density Polyethylene
ILC Interlaboratory Comparison
LC-MS Liquid Chromatography - Mass Spectrometry
LDPE Low-Density Polyethylene
LGU Local Government Unit
LOD Limit of Detection
LOQ Limit of Quantification
MAL Maximum Allowable Limit
MOA Memorandum of Agreement
MS/MS Tandem Mass Spectrometry
ND Not Detected
OM Overall Migration
PC Polycarbonate
PE Polyethylene
PFAS Per- and Polyfluoroalkyl Substances
PET Polyethylene Terephthalate
PP Polypropylene
PS Polystyrene
PSL Packaging Safety Laboratory
PT Proficiency Testing
SD Standard Deviation
SE Standard Error
TACs Total UV-Absorbing Contaminants

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