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Kinetic Modeling of Chemical Migration from Polyethylene Packaging Film: A Comparative Study of Regulatory Methods

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***Abstract* – An awareness of chemical migration kinetics from the packaging to food is critical to determine consumer exposure and measure regulatory compliance. This paper analyzes the migration kinetics of the chemical residues of monolayer low density polyethylene (LDPE) package films under US 21 CFR and JETRO 2009 guidelines. LDPE film specimens were extracted with n-heptane at 21 °C for 30 minutes (US CFR) and 25 °C for 60 minutes (JETRO 2009). Migration data were modeled with zero-, first-, and second-order kinetic models. The results indicated poor correlation ($R^2 < 0.1$) for all the models, with second-order kinetics providing marginally better fits for low-concentration samples. High-concentration samples showed high variability, revealing complicated migration mechanisms outside classical kinetics. Residual analysis indicated uniform underprediction by zero- and first-order models. Generally, none of the conventional kinetic models sufficiently described migration behavior, which indicated shortcomings of traditional modeling strategies and the need for more appropriate modeling strategies in food safety evaluation.**

I. INTRODUCTION

Polyethylene (PE), including low-density polyethylene (LDPE), high-density polyethylene (HDPE), and linear low-density polyethylene (LLDPE), is still the most widely used polymer for food packaging purposes because of its cost-effectiveness, mechanical properties, and processability [1], [2]. Nevertheless, the wide applications of PE in food contact materials have become a concern regarding the migration of chemical compounds into food matrices under high temperature or long-term storage conditions [3]–[6]. Migration, the movement of chemical substances from packaging materials into foods, is a process determined by polymer structure, food type, contact time, and environmental conditions [7]–[9].

Recent research has shown that PE packaging can leach a wide variety of substances, ranging from additives to monomers, as well as non-intentionally added substances (NIAS) [10]–[12]. Systematic review revealed that 211 of the 377 food contact chemicals were found to migrate from PE-based packaging materials and a few with some over the safety levels [13]. Common kinetic models like zero-order and first-order kinetic models frequently fall short to appropriately model the complexity of chemical migration from plastics [14], [15]. Consequently, newer or alternative modeling methodologies have been proposed to improve migration kinetics prediction and risk assessment accuracy better [16].

Regulatory bodies around the world have established guidelines to manage chemical migration from the packaging. In the United States, the Code of Federal Regulations Title 21 regulates food contact materials by the Food and Drug Administration (FDA) [17]. Japan also set its standards via the Japan External Trade Organization (JETRO), laying down precise migration limits and testing protocols [18]. Although these regulatory approaches are extensively cited, comparative assessments in terms of their predictive capability for migration kinetics remain limited. This research hopes to fill this knowledge gap by comparing the kinetic modeling results of chemical migration from monolayer PE films according to two international regulatory approaches: US 21 CFR and JETRO (2009). By comparing extraction protocols and fitting kinetic models, this research hopes to clarify the limitations of existing migration tests and identify opportunities for enhancing predictive abilities in food packaging safety evaluations.

II. MATERIALS AND METHODS

A. Materials and Reagents

Monolayer low-density polyethylene (LDPE) food contact packaging films were obtained from local Metro Manila, Philippines. The films were selected because of their wide marketing coverage and regular application in

packaging for fatty and oily foods. An analytical grade n-heptane with a minimum purity of 99.9% was obtained from Sigma-Aldrich (USA) and used as the simulant of fatty foodstuffs for food contact by standard regulatory procedures. All glassware and sample containers were thoroughly cleaned with ethanol and distilled water before use to prevent contamination. Food contact monolayer low-density polyethylene (LDPE) packaging films were collected from some public markets throughout Metro Manila, Philippines. The samples included a broad range of commercially purchased brands. Samples were coded for traceability, and Global Positioning System (GPS) coordinates were taken at each sampling location.

B. Sample Screening and Residue Profiling

To assess the preliminary contamination levels in food-contact packaging, a selection was made on gathered polyethylene (PE) packing samples. Only one representative sample of monolayered PE from each noted brand was taken for thorough lab analysis. Initial polymeric identities of these films were determined via Fourier Transform Infrared Spectroscopy (FTIR), on a Shimadzu IR-Prestige-21 spectrometer, following established polymer characterization methodologies. This process made sure that only LDPE samples—widely applied in domestic food uses—were utilized in the kinetic modeling study. Following polymer identification, all samples were screened for extractable residues with the 2009 Japan External Trade Organization (JETRO) established protocol. The procedure entailed cutting the film to uniform sizes (5 cm × 10 cm) and immersing it in 100 mL of n-heptane, a food fat simulant solvent. The experiment was carried out in ambient laboratory conditions (~25 °C), and the contact time between the simulant and the sample was defined as one hour.

For reproducibility and accuracy, the extraction was conducted in duplicate. Once the extraction time had passed, a 50 mL aliquot of the simulant was transferred carefully into pre-weighed borosilicate glass beakers. These beakers were kept under a fume hood and warmed gradually to evaporate the solvent to dryness so that any migrated compounds would leave as residue. The beakers were then taken to a convection oven (Labtech LDO-150N) with 105 °C maintained inside, where further drying was carried out to remove residual traces of the solvent. Final weighing was done with a calibrated analytical balance (Shimadzu AUX220) to a constant weight, so only non-volatile migrated components were quantified. The levels of these residues were computed and presented in mg/L. From this data set, two reference samples were chosen, one with the lowest and one with the highest recorded levels of residues. These two samples were then utilized for the kinetic migration study under two regulation protocols to permit a comparative examination of chemical migration with time.

C. Migration Test Protocols

Migration experiments were conducted following international regulatory guidelines adapted for kinetic study purposes:

1. JETRO 2009 Protocol: Extraction using n-heptane at 25 °C for 30 minutes and 1 hour.
2. US FDA 21 CFR §177.1520(c): Extraction using n-heptane at 21 °C for 30 minutes and 1 hour.

Each film sample was immersed in 100 mL of freshly prepared n-heptane inside sealed glass vessels to minimize solvent evaporation. Extractions were conducted in triplicates for each time point (30 min and 1 hr) under tightly controlled temperature conditions (±1 °C), using thermostatic water baths. After the designated extraction time, a 50 mL aliquot of the simulant was carefully transferred to pre-weighed glass beakers. Solvents were evaporated to dryness under a fume hood, and the residual substances were further dried at 105 °C using a vacuum oven until a constant weight was achieved. Residual weights were recorded using an analytical balance with 0.1 mg sensitivity. The amount of migrated substances (mg/L) was calculated using the formula:

$$\text{Residue concentration} = \frac{(W_R - W_E - W_{blk})}{V_S} \times 10^6 \qquad (1)$$

Where:
W_R = weight of beaker with residue (g)
W_E = weight of empty beaker (g)
W_{blk} = average blank residue (g)
V_S = volume of simulant used (mL)

D. Kinetic Modeling

Residue migration data from both low- and high-concentration samples were modeled using standard kinetic equations:

$$\text{Zero-order kinetics}: C_t = C_0 + kt \qquad (2)$$

$$\text{First-order kinetics}: \ln(C_t) = \ln(C_0) + kt \qquad (3)$$

$$\text{Second-order kinetics}: \frac{1}{C_t} = \frac{1}{C_0} - kt \qquad (4)$$

To account for limited time points (only 30 min and 60 min), bootstrap resampling was applied to simulate intermediate time points (35-55 min, 5 min gradient) between 30 and 60 minutes and to quantify variability. This enabled better resolution and fitting across a wider temporal range during kinetic modeling. Figure 1 shows the oversimplified coding steps for implementation of bootstrapping in R.

1. Load the necessary data handling libraries
2. Load the original dataset from a CSV
3. Define new time points where additional data will be simulated
4. Set the number of bootstrapped samples

5. Initialize random seed
6. For each unique combination of Protocol + Level in the original dataset, resample concentration at each point with replacement and compute their means to simulate intermediate time points.
7. Merge the original dataset with bootstrapped dataset

Fig.1. Workflow for Simulated Data Generation

E. Statistical Analysis

Datasets from replicate experiments were visually inspected for outliers using box-and whisker plots. Instead of Grubbs' test for outlier detection, only visual inspection via box-and-whisker plots was used in this study to preserve data variability. Migration profiles for every sample were individually fitted to zero-order, first-order, and second-order kinetic models via least-squares regression. The goodness of each fit was evaluated by deriving the coefficient of determination (R^2), which was the principal criterion in deciding the best-fitting kinetic description. To compare outcomes between regulatory approaches or across time points (30 min vs. 1 hr), the effect size was approximated by Cohen's d statistic to determine the practical relevance of the detected differences. A p-value less than 0.05 was taken as a sign of statistical significance. All the statistical calculations and model fittings were carried out by employing R version 4.2.3 (The R Foundation for Statistical Computing, Vienna, Austria) and Python 3.11 (SciPy and NumPy libraries). Graphs representing migration kinetics and residual distributions were produced to visually support quantitative results.

III. RESULTS AND DISCUSSIONS

A. Residue Profiling and Sample Screening

The box-and-whisker plot in Figure 2 shows the levels of residue migration in two commonly employed regulatory protocols—US CFR at 21°C and JETRO at 25°C—at 60- and 30-minute time points. Several outliers can be seen at both points in time, but no outliers were removed from the sample at this stage because they could be reflective of real instances of possible increase in migration, particularly on longer exposure.

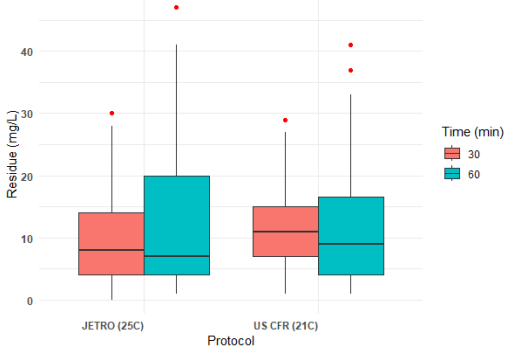

Fig. 2. Residue Concentration by Protocol and Time

Figure 3 is the boxplot showing the residue concentration at the low concentration level, where both protocols showed similar distributions at each time point, with residue values generally below 20 mg/L. JETRO exhibited a few high-end outliers at 60 minutes, suggesting that under warmer exposure conditions, occasional spikes in migration can occur—possibly due to local variations in film composition or surface interaction with the simulant. The range was broader under JETRO, which may suggest a slightly more variability compared to US CFR. In contrast, the High concentration level plots (Figure 4) presented more pronounced differences.

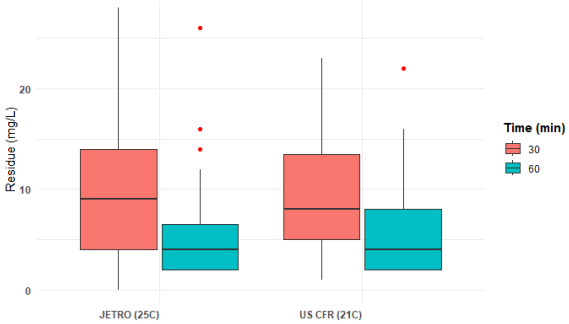

Fig. 3. Residue Concentration at Low Level

At the high-level concentration shown in Figure 4, it can easily be seen that JETRO (25 °C) conditions have the tendency to have larger mean migration values compared to the US CFR (21 °C) protocol at the same time scales. For instance, at 60 minutes, the mean residue for high-level JETRO samples was 20.50 mg/L, which is approximately 17% higher than the US CFR's 17.50 mg/L.

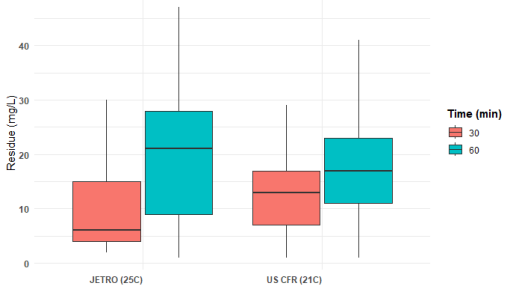

Fig. 4. Residue Concentration at High Level

This is consistent with the understanding that higher test temperatures tend to promote greater diffusion or migration of materials from polymer matrices which might be explained by the excess thermal energy promoting the mobility of residual chemicals. The descriptive statistics illustrated in Table 1 provide helpful information on the way chemical residue migration acts within polyethylene packaging under different regulatory test protocols (US CFR at 21 °C vs. JETRO at 25 °C), time exposure (30 vs. 60 minutes), and concentration levels (high vs. low). Several interesting observations are worthy of discussion.

For instance, the interquartile range (IQR) and standard deviation values of 60 minutes for JETRO (19.00 and 12.20, respectively) are significantly greater than their counterparts for US CFR (12.00 and 9.46), indicating greater variability in residue measurement under high temperature.

JETRO at 30 minutes has a mean residue of 10.00 mg/L, higher than the US CFR value of 9.45 mg/L under the same conditions, but this trend is reversed after 60 minutes, where JETRO mean drops to 5.55 mg/L compared to the value of the US CFR at 6.05 mg/L.

Table 1. Summary of Descriptive Statistics

Protocol	Level	Time	Mean	Median	Std_dev	IQR
JETRO (25C)	High	30	9.71	6.00	7.18	11.00
JETRO (25C)	High	60	20.50	21.00	12.20	19.00
US CFR (21C	High	30	13.30	13.00	6.87	10.00
US CFR (21C	High	60	17.50	17.00	9.46	12.00
JETRO (25C)	Low	30	10.00	9.00	6.95	10.00
JETRO (25C)	Low	60	5.55	4.00	4.95	4.50
US CFR (21C	Low	30	9.45	8.00	6.08	8.50
US CFR (21C	Low	60	6.05	4.00	7.74	6.00

The reversal might be due to sample fluctuation or likely saturation values at low levels, where prolonged exposure at 21 °C still shows significant migration.

B. Migration Trends Under Regulatory Protocols

Figure 5 illustrates the time-dependent migration behavior of residues under two regulatory protocols—JETRO (25°C) and US CFR (21°C), evaluated separately at high and low concentration levels. These line plots provide a side-by-side look at how exposure time influences residue migration, while also highlighting protocol-specific differences. Under the high concentration conditions, both protocols indicate a clear rise in residue concentration between 30 and 60 minutes. But the increase is significantly more pronounced for the JETRO protocol. The average residue value goes up from a level of about 10 mg/L to a level above 20 mg/L, whereas under the US CFR protocol, it is a relatively slower rise with the plateau lying just below 18 mg/L. This steeper slope in the JETRO group could be attributed to the slightly higher test temperature (25°C compared to 21°C), which has the effect of increasing diffusion rates in LDPE packaging materials.

In contrast, the low level of concentration reveals another trend. Both methods exhibit a slight decrease in mean residue concentration between 30 and 60 minutes. This reversal in the slope may be attributed to adsorption of the analyte, chemical instability of the simulant over time, or simply the natural variability encountered at trace levels. Interestingly, the similarity of trend direction and magnitude between the two protocols suggests that in low concentration testing conditions, regulatory temperature and exposure differences can have less impact on overall migration behavior.

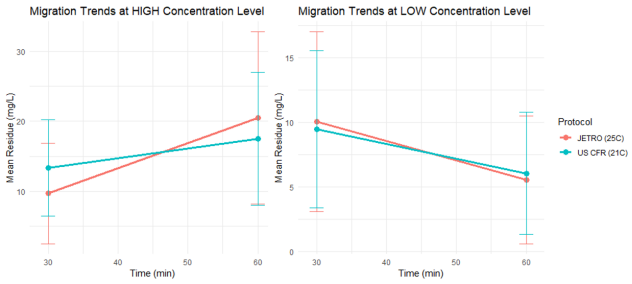

Fig. 5. Migration Trends Over Time at High and Low Levels with Different Protocols

Building on this need for kinetic modeling, Figure 6 illustrates the interaction between regulatory protocol and time of exposure on polyethylene packaging residue migration. A descriptive interaction and not from an analysis of variance (ANOVA) interaction nor from an inferential statistical interaction, this plot indicates how the effect of time on residue concentration depends on the method of regulation applied, i.e., JETRO (25°C) and US CFR (21°C). The JETRO condition line has a steeper slope, indicating that migration increases more steeply with time under this protocol. There was an observed increase in the mean residue level from less than 10 mg/L to above 13 mg/L when going through 30 to 60 minutes — a demonstration that higher test temperature of JETRO facilitates greater molecular movement and product diffusion from package material to simulant. In contrast, the US CFR line is relatively flat, reflecting minimal change in mean residue level during the same period. This near horizontal trend indicates a less inclined or even saturated curve of migration in the lower test temperature of 21°C. The lack of curvature or slope here may imply that the system is quick to equilibrate, or migration proceeds at a slower but regular pace within the time span evaluated. The slope difference between the two protocols emphasizes a primary interaction effect: the impact of time on migration is not consistent across protocols.

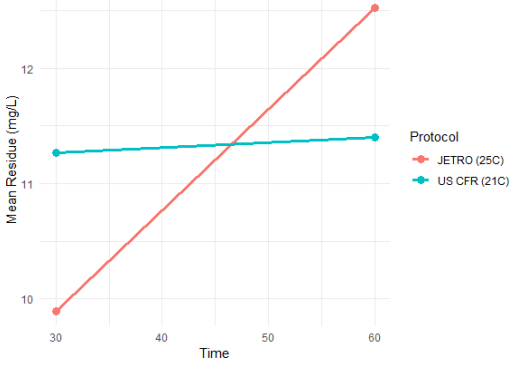

Fig. 6. Interaction Effect: Protocol x Time on Migration

To better quantify the magnitude of differences observed between protocols and exposure times, the effect size statistic Cohen's d was calculated. The results, summarized in Table 2, provide a practical metric beyond statistical significance to understand the influence of regulatory conditions on migration behavior.

Table 2. Effect Size Comparison Between Protocols

Comparison	Time (min)	Level	Cohen's d
JETRO vs US CFR	30	Low	0.229 (small effect)
JETRO vs US CFR	60	Low	-0.174 (negligible)
JETRO vs US CFR	30	High	0.380 (small–moderate)
JETRO vs US CFR	60	High	0.495 (moderate effect)

At the high concentration and 60-minute exposure condition, the Cohen's d value was approximately 0.495, indicating a moderate practical difference in residue migration between the JETRO and US CFR protocols. In contrast, most low-level conditions exhibited only small or negligible effect sizes, reinforcing the notion that protocol differences are more pronounced under elevated residue loads or extended contact times.

C. Bootstrapping and Kinetic Modeling

Bootstrapped kinetic models' performance is shown in Table 3. Results indicate the difficulty of describing chemical migration from polyethylene (PE) films using conventional zero- (mg/L·min^{-1}), first- (min^{-1}), or second- (L/mg·min) order kinetic models—especially under regulatory settings. For JETRO (25 °C) and US CFR (21 °C) protocols, R^2 values for zero-order and second-order models consistently were less than 0.1, indicating extremely poor linear or nonlinear correlation between residue concentration and migration time. The first-order model performed quite poorly in reality, with all negative R^2 values ranging from -1.44 to -3.32 revealing that it was not capable of replicating even a substantial trend and tended to forecast worse than a horizontal mean line. Even at the low concentration level, model performance did improve but to a small degree, particularly under the US CFR protocol when the second-order model produced an R^2 of 0.0125 reflecting marginal but non-trivial explanatory ability.

Table 3. Kinetics Fit Summary

Protocol	Level	R^2_Zero	R^2_First	R^2_Second
JETRO (25C)	High	0.091703	-1.437874	0.091703
JETRO (25C)	Low	0.079797	-1.549669	0.079797
US CFR (21C)	High	0.086207	-3.318279	0.086207
US CFR (21C)	Low	0.059239	-2.106631	0.012496

Despite this, both the zero- and second-order models under JETRO low-level conditions both produced R^2 values of about 0.08, indicating a weak—but slightly more positive—correlation. In contrast, high concentration levels were dominated by equally bad fit as evidenced by R^2 values of zero and second-order models being about 0.09. This is consistent with the implication that migration behavior at high concentrations introduces variability or mechanistic complexity not adequately described or captured by conventional kinetic assumptions. Figure 7 shows the bootstrapped distribution of rate constants for zero-, first-, and second-order kinetic models.

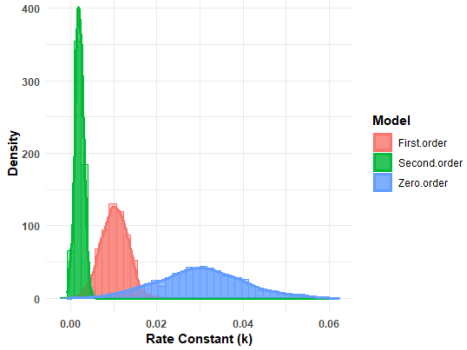

Fig. 7. Bootstrapped Distributions of Rate Constant by Kinetic Modeling

The plot indicates that the second-order kinetics exhibits the most consistent distribution with a sharp peak near 0.002 min^{-1}, suggesting better model stability. In contrast, zero-order shows wide variability, indicating poor fit for the migration data.

IV. CONCLUSION

This study was intended to determine if classical kinetic models could describe the migration pattern of chemical residues from polyethylene packaging films under two different regulatory test conditions. Experimental data from both US CFR and JETRO protocols were fitted with zero-order, first-order, and second-order models. To enhance the limited temporal resolution of the initial data set, a bootstrapping approach was utilized to create intermediate time points between 30 and 60 minutes to maximize the capability to evaluate model fit across a wider range. However, none of the kinetic models offered consistently strong correlations between time and residue concentration. Second-order kinetics performed a little better—particularly in low concentration groups—but R^2 values generally remained well below acceptable levels, reflecting poor explanatory power. These findings reflect the inherent complexity of chemical migration in real LDPE packaging systems, where processes such as interfacial interactions, matrix-dependent diffusion, and simulant absorption cannot be represented by the simplifying assumptions of fixed-rate kinetic models. In particular, the observed deviations may reflect non-Fickian diffusion behavior, where polymer relaxation and local physicochemical interactions dominate the migration process. The findings reveal that deterministic kinetic models are insufficient to describe the dynamic nature of

migration phenomena in polyethylene matrices. They suggest the necessity to develop alternative or hybrid modeling strategies—potentially utilizing empirical observation, diffusion theory, and data-driven numerical procedures—to improve the prediction of migration behavior and strengthen the scientific basis for food safety assessments. Additionally, effect size analysis using Cohen's d supported the conclusion that residue migration differences between protocols, particularly at high concentration and longer exposures, can be moderately significant.

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