Food Contact Material (FCM) Migration Testing: Novel Assay for Ensuring Food Safety

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Abstract

The safety of food is fundamental, and a pivotal aspect of this is the prospect for chemical substances to transmit from food contact materials (FCMs) into food. This approach, known as migration, can drive harmful compounds, change food quality, and institute a risk to human health. Consequently, migration testing of FCMs is a crucial component of food safety regulations globally. This article furnishes a comprehensive overview of FCM migration assay, comprising its primary principles, the analytical procedures utilized, and the global food safety standards that control it. It also discusses neoteric research trends, compliances, and, highlighting the developing nature of this critical field.

Keywords: Food Contact Materials, Food Safety, Chemical Migration, Migration Testing, Non-Intentionally Added Substances (NIAS).

Introduction

The Concept of Migration

Food contact materials involve a broad range of materials or articles, such as packaging, kitchen utensils, and processing equipment that proposed to come into contact with food products (Muncke *et al.,* 2020). This concept, known as migration, can drive to food contamination, influencing both the quality and safety of food. The safety of FCMs is a vital issue due to the possible for chemical components to transmit from the material into the foodstuffs (Muncke *et al.,* 2021). Although, they serve necessary functions like protection and preservation, they are not inert. Migration is a physical procedure campaigned by a concentration gradient, whereby low molecular weight components, such as additives, contaminants and monomers transmit from the FCM into the food (Urbelis and Cooper, 2021).

Factors affect the extent of the migration:

i. Material features: The chemical composition, porosity, and diffusion coefficients of the FCM.
ii. Migrant characteristics: Concentration of the substance in the material, the molecular weight, and polarity.

iii. Food merits: The composition of the food, particularly its acid, fat, and water content.
iv. Environmental circumstances: Temperature, surface area of contact and, contact time.
v. Migration testing is planned to simulate these real-world conditions under regulated laboratory settings to evaluate the safety of FCMs.

Consequently, strict regulations and standardized assessment protocols have been instituted globally to govern and diminish the migration of harmful materials (HQTS., 2025).

This review aims to construct the present knowledge on FCM migration assay, addressing its different facets and underscoring its significance in protecting public health.

Regulatory Frameworks and Migration Restrictions

A robust legal framework is necessary to assert FCM safety. Key standards and regulations realize the needing for migration assay, involving migration restraints and testing protocols.

1. European Union (EU) has a highly developed regulatory system for FCMs (EU, 2022).
2. Regulation (EC) No 1935/2004: This "Framework Regulation" constructs general principles, revealing that FCMs must not imperil human health, induce an unacceptable alteration in food composition, or change its odor and taste (EC, 1935/2004).
3. Regulation (EU) No 10/2011: This is the particular regulation for plastic FCMs. It involves a "Union List" of authorized materials and sets both Overall Migration Limits (OML) and Specific Migration Limits (SML) (EU, No 10/2011).
4. Overall Migration Limit (OML): The total amount of non-volatile substances (NVS) migrating from the substance. The limit is typically 60 mg/kg of food or 10 mg/dm of the contact surface. This is beholded a quality, not a safety, measure.
5. Specific Migration Limit (SML): The maximum allowed amount of a specific substance that can transfer into food, relied on its toxicological risk evaluation.
6. The US regulatory system is primarily controlled by the Food and Drug Administration (FDA) under the Code of Federal Regulations (CFR) Title 21, Parts 170-199. The FDA employs different mechanisms, involving Generally Recognized as Safe (GRAS) status and Food Contact Notifications (FCNs), to assess the safety of FCMs. In similar to the EU, the FDA does not have a sole, unified OML (FDA, Title 21).

Migration Testing Methodologies

Due to the impracticality of assaying every FCM with every potential food product, standardized assaying protocols are utilized. These comprise the employ of "food simulants" and particular test circumstances (Gupta *et al.,* 2024).

1. Food Simulants (Paseiro-Cerrato *et al.,* 2019)

Food simulants are liquids planned to imitate the extractive approach of various food types. The choice of simulant relies on the proposed use of the FCM. Common food simulants realized in EU regulations involve:

Simulant A: 10% ethanol (w/v), for aqueous and acidic foods.

Simulant B: 3% acetic acid (w/v), for acidic foods with a pH below 4.5.

Simulant C: 20% ethanol (w/v), for alcoholic foods.

Simulant D2: Vegetable oil (e.g., olive oil), for fatty foods.

Simulant E: Modified Polyphenylene Oxide (MPPO), a solid material employed for dry foods.

2. Testing circumstances

Test circumstances, comprising temperature and time, are standardized to display the most intense, worst-case scenario of contact between the FCM and food. These circumstances are typically realized by the particular regulations and can scoop from short-term contact at high temperatures (e.g., for microwave use) to long-term storage at ambient temperature.

3. Analytical Methods

A vast range of analytical techniques are used to determine and quantify migrating materials. The choice of the method relies on the nature of the material being analyzed (Paseiro-Cerrato *et al.,* 2006).

4. Chromatographic Methods: backbone of the migration testing

- Gas Chromatography (GC): Often coupled with Mass Spectrometry (MS) (GC-MS) for the analysis of volatile and semi-volatile compounds.

- High-Performance Liquid Chromatography (HPLC): Frequently used with detectors like Diode-Array Detection (DAD) or fluorescence detection (FLD) for non-volatile and heat-sensitive substances. HPLC coupled with MS/MS (LC-MS/MS) provides high sensitivity and selectivity, making it ideal for targeted analysis of specific migrants.

4. Spectroscopic Methods:

It is highly sensitive for the recognition and quantification of metal migration.

5. Other Techniques:

- Gravimetric analysis: The standard method for OML testing, where the residue after evaporation of the food simulant is weighed.

- Non-targeted screening: This involves advanced techniques like High-Resolution Mass Spectrometry (HRMS) to identify and quantify Non-Intentionally Added Substances (NIAS), which are substances present in the FCM but not part of the formulation (e.g., impurities, degradation products).

Emerging Challenges and Future Directions

The field of FCM migration testing is constantly evolving to address new challenges.

- Micro-plastic and Nano-plastic Migration: current research has highlighted the migration of micro- and nano- plastics from plastic FCMs, especially beneath thermal stress. This is a significant issue because of the prospect for these particles to accumulate in the body. Emerging standardized testing protocols for these particles is a prime area of present research (Geueke *et al.,* 2018).

- Non-Intentionally Added Substances (NIAS): NIAS are an evolving threat as they are often unlisted and can have unknown toxicological impacts. The move towards non-targeted screening and improved toxicological assessments is pivotal for addressing this concern (Groh M. E. *et al.,* 2018).

- Recycled Materials: The growing use of recycled plastics in FCMs presents a new challenge. Migration testing for recycled materials must assert that contaminants from the recycling process do not pose a risk to consumers (Ong *et al.,* 2020).

- Bio-based and Novel Materials: The evolving of new materials, such as bio-based polymers and active/intelligent packaging, needs the creation of novel, material-specific testing methods and regulations to ensure their safety (Seref and Cufaoglu, 2025).

Conclusion

FCM migration testing is a fundamental tool for asserting the safety and compliance of materials that get into contact with food. By augmenting standardized protocols with advanced analytical methods, it is possible to evaluate the risk of chemical migration and guard public health. The regulatory landscape, especially in the EU and US, beholds a clear framework for compliance. However, the field continues to emerge in response to novel materials, novel contaminants like microplastics, and the requirement to screen for NIAS. Future research will be substantial in developing more comprehensive and robust techniques to keep step with innovation in the food packaging industry and assert consumer safety.

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