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DISCUSSION PAPER ON MANAGING FOOD CONTACT MATERIALS (FCMs)

FOOD REGULATORY PRACTICES AND THE ROLE OF CODEX

Submitted by the State of Qatar, the Arab Industrial Development, Standardization and Mining Organization (AIDSMO) and the International Union of Food Science and Technology (IUFoST)¹

Executive Summary

Food contact materials (FCMs), including packaging, kitchenware, processing equipment surfaces, inks, adhesives, and coatings, are indispensable for safe, efficient, and sustainable food systems. Yet regulatory oversight of FCMs remains uneven worldwide. Many jurisdictions lack the infrastructure, legal tools, or scientific capacity to evaluate and manage migration risks, particularly those linked to non-intentionally added substances (NIAS) and the growing use of recycled materials. In Codex, FCMs are only indirectly addressed in hygiene texts, with no dedicated cross-cutting framework or harmonized positive-list system in place.

This paper invites discussion among CCNE countries on how Codex could better support regulators in assessing FCMs and making evidence-based decisions that foster regional and global convergence. A phased Codex program is proposed for consideration, aimed at: (1) developing horizontal guidance on FCM risk assessment and good manufacturing practices (GMP); (2) preparing fit-for-purpose guidance for recycled materials; and (3) piloting a harmonized “Codex-cleared applications” list, beginning with plastics and adhesives/coatings, anchored in transparent data and reliance on competent evaluations. To advance this agenda, a time-bound ad hoc mechanism is recommended to coordinate the work, strengthen capacity, and shape this new Codex domain. This work aligns with broader discussions among Codex members and stakeholders across different regions, aiming to provide the most effective responses—whether at the regional or global level. The objective is to enhance guidance for regulators and food producers on the oversight and selection of food contact applications that not only meet safety criteria but also respond to the growing demand for sustainable solutions.

1. Background and Problem Statement

FCMs can transfer intentionally and non-intentionally added substances to food. This migration must be controlled to protect health and preserve food quality. Rapid growth in sustainability policies (e.g., recycled content mandates) and innovation in materials (active/intelligent packaging, multilayers, novel polymers) adds complexity.

¹ Through its Disciplinary Group for Food Regulatory Science: the Global Food Regulatory Science Society (GFoRSS).

Moreover, national/international divergence in definitions, pre-market oversight, migration testing, and NIAS approaches creates trade friction and inconsistent consumer protection.

Many regulators, particularly in emerging markets, face limited specialized evaluation and laboratory capabilities, as well as restricted access to consolidated positive lists.

Countries across the CCNE region face wide variability in the oversight of FCMs, compounded by limited access to accredited laboratories and harmonized testing methods. At the same time, the region is becoming increasingly reliant on imports of pre-packaged foods and packaging materials, while also confronting rising sustainability demands such as the use of recycled materials and the shift toward circularity.

2. Relevance to Codex

Codex currently provides broad hygiene principles and risk-analysis foundations that cover packaging and FCMs, but these remain high-level and do not provide the specificity needed for standardized assessment or decision-making. At CAC46, the Commission acknowledged this gap and agreed to explore possible guidance on recycled food packaging, initiating a Circular Letter to gather information from Members and Observers. This development demonstrates both recognition of the issue and an entry point for broader Codex engagement.

Building on this momentum, Codex could:

- Establish a cross-cutting framework for FCM safety principles, anchored in risk analysis;
- Promote convergence of migration testing methods and documentation practices, including Declarations of Compliance, traceability, and GMP;
- Develop regionally or globally coordinated, science-based approaches to create a harmonized list of “cleared” applications, reducing duplication of evaluations, safeguarding health, and facilitating trade. A regional focus could further support producers by providing guidance on applications that are better adapted to local production practices.

3. International Regulatory Landscape (Concise Profile)

The following provides a concise overview of the key features of regulatory oversight of food contact materials (FCMs) worldwide, with specific reference to the Near East region.

3.1 European Union

- Horizontal framework with GMP, specific measures for plastics (including recycled), ceramics, regenerated cellulose film, and active/intelligent materials; The European Food Safety Authority (EFSA) is mandated to conduct risk assessments, supporting decisions and approvals.
- The European Reference Laboratory (EURL-FCM) coordinates methods and proficiency testing. Some gap areas include the absence of harmonized EU measures for several material classes (e.g., paper/board) and the challenge of NIAS assessment.

3.2 United States of America

- Mixture of material- and substance-specific provisions in 21 CFR (e.g., Parts 175–178; 176 paper/board; 177 polymers).
- Food Contact Notifications and “threshold of regulation” exemptions.
- Strong practice of migration testing and chemistry/toxicology dossiers.

3.3 Canada

- General legal prohibition on injurious migration.
- Voluntary pre-market Letters of No Objection for materials/additives/articles.
- Reliance on migration studies and exposure estimates.

3.4 Australia/New Zealand

- Food Standards Code requires packaging to be fit for purpose.
- State legislation and AS 2070 for plastics support compliance; more performance-based, with responsibility on food businesses.

3.5 China

- Comprehensive, positive-list system administered under the National Food Safety Standards (GB standards). The core text is GB 4806.1-2016 (General Safety Requirements for FCMs), supported by material-specific standards (e.g., GB 4806.7 for plastics, GB 4806.8 for paper/board).
- Positive lists of permitted additives and resins are maintained, with specific migration limits (SMLs) and overall migration limits (OMLs).
- New substances require pre-market review and approval by the National Health Commission (NHC). GMP principles are codified in GB 31603-2015. NIAS remain an emerging challenge, with increasing attention to risk-assessment methodology.

3.6 Gulf Cooperation Council (GCC)

- The GCC Standardization Organization (GSO)'s standards broadly mirror EU horizontal principles for materials in contact with food.
- Additional plastic packaging standard and general requirements for food packages.
- Adoption into national law of member countries may vary.

3.7 Egypt

Egypt has introduced a binding framework for FCMs through the National Food Safety Authority (NFSA) Decision No. 17 of 2022, establishing one of the most comprehensive systems in the region. It sets requirements across the full supply chain, from manufacturing to food business operators, with NFSA as the central authority for oversight and enforcement.

- Scope: Wide coverage including plastics (recycled and virgin), metals, ceramics, paper, glass, coatings, inks, silicones, wood, waxes, and active/intelligent materials.
- Business Operators: Obligated to use only approved substances, apply GMP, ensure traceability, and issue Declarations of Compliance.
- Food Businesses: Must verify packaging and equipment comply with requirements.
- Compliance Tools: labelling, documentation, traceability systems, and restrictions/prohibitions on certain substances.

4. Discussion of Global and Regional Gaps and “Pain-Points”

4.1 Lack of global definitions and architecture

- There is no internationally agreed set of definitions distinguishing food contact substances (FCS), food contact materials (FCM), and final food contact articles. This may be the source of inconsistencies in scope across jurisdictions.
- Documentation and Declarations of Compliance (DoCs) are often required, but formats and content vary widely.
- Migration testing conditions are fragmented, with differing time/temperature regimes and simulant choices, leading to non-comparable results and regulatory uncertainty.
- Exposure assumptions (e.g., default consumption factors) are also not aligned, complicating reliance and mutual recognition.

4.2 Non-Intentionally Added Substances (NIAS)

- Regulators face growing challenges with NIAS, which can arise from impurities, breakdown products, or interactions during manufacturing and use.
- There is no harmonized framework for hazard screening, prioritization, or tiered risk assessment. Current approaches range from case-by-case evaluations to broad default limits.
- Regulators with limited toxicology or analytical capacity struggle to implement proportionate, science-based strategies.

4.3 Recycled materials

The circular economy is driving rapid expansion of recycled plastics and other recycled inputs. However, clear requirements for feedstock quality, process validation, and verification of decontamination efficiency are lacking globally. Criteria linking specific recycling technologies (e.g., mechanical vs. chemical recycling) to predictable safety outcomes are not harmonized. This creates uncertainty for both industry and regulators and increases the risk of trade disruptions.

4.4 Capacity limitations

Many jurisdictions, particularly in emerging markets, lack accredited laboratories capable of performing sophisticated migration and NIAS analyses. Training opportunities for regulators and laboratory staff are scarce, and technical guidance is often inaccessible. In addition, reliance mechanisms, through which authorities can make use of evaluations conducted by trusted regulators, are weak or absent, leading to duplication of effort and slower decision-making.

5. Options for Proposed Codex Action

5.1 Option A — Use existing committees (no new structure)

Commission targeted Guidelines on FCM Risk Assessment & GMP (horizontal) and a Code of Practice for Recycled Materials through existing Codex pathways; create EWGs drawing expertise from CCFH/CCFA/CCCF.

- **Pros:** minimal structural change; leverages established processes.
- **Cons:** diffuse ownership; limited bandwidth for multi-material scope and technical depth; slower consolidation of “cleared” lists.

5.2 Option B — Establish an Ad hoc Intergovernmental Task Force on FCMs (time-bound, 4 years)

The proposed Taskforce would have the mandate to develop (1) General Guidelines for FCMs (definitions; safety objectives; documentation; GMP; NIAS), (2) Guidance on Recycled Materials (feedstock/process criteria; verification), (3) an architecture and initial content for a Codex Harmonized List of Cleared Applications (begin with plastics and adhesives/coatings). A proposed outline of the outputs of such a taskforce is presented in Annex 1.

- **Pros:** clear locus of expertise; faster, coherent package; strong visibility for capacity-building; easier to pilot a “cleared applications” list.
- **Cons:** requires consensus of Codex members and resourcing;

5.3 Option C — Phased approach (recommended)

2025: Commission a comprehensive discussion paper and circulate a CL to map Member/Observer FCM frameworks beyond recycling; convene a FAO/WHO expert meeting to propose a tiered NIAS/RA methodology and test-method baseline.

2027–2028: Launch an ad hoc Task Force to draft the core texts and pilot the harmonized list (plastics + adhesives/coatings) with reliance on trustworthy evaluations (e.g., EFSA/FDA/Health Canada), while ensuring Codex-specific exposure assumptions and documentation.

2029: Deliverables for Commission adoption; agree a continued maintenance pathway under an existing Codex structure e.g., CCFA.

6. Recommendations for CCNE12

CCNE12 is invited to:

- First take note of this proposal and consider its endorsement with a view to working towards consensus on the most suitable way to advance Codex oversight of Food Contact Materials (FCMs).
- CCNE member countries could also consider the following:
 - Establish a regional network to facilitate the exchange of expertise on NIAS screening, dossier evaluation, and migration testing requirements (including solvent systems, simulants, and validation), coordinate proficiency testing, and ultimately advance toward harmonization of methodologies.
 - Establish a framework for mutual recognition of competent evaluations, supporting joint reviews and shared templates.
 - Improve transparency and data availability by supporting open access to monographs, migration data, and Declarations of Compliance (DoC) reports.

Annex 1: Proposed Codex Outputs to Support Management of FCM

Proposed Codex Work Products (Scopes & Outlines)

General Guidelines for FCMs (Horizontal) aiming to agree on definitions (FCS, FCM, article), to define general safety objectives, GMP, requirements of Demonstration of Compliance (DoC), traceability; migration principles (OML/SML concept and exposure assumptions); NIAS management; modelling acceptance; labelling if relevant for consumer safety (e.g., non-edible inserts).

Guidance on Recycled Materials in FCMs aiming to define recycling technology categories; feedstock requirements; decontamination performance verification; process authorization/notification concepts; links to migration compliance; documentation chains; special cases for closed-loop vs. open-loop; material-specific considerations (plastics; metals; paper/board).

Codex Harmonized List of “Cleared Applications” (Pilot) aiming to establish a living, Codex-managed compendium of cleared material/substance uses tied to conditions and SMLs/OML where applicable.

- Phase 1 materials: plastics (monomers/additives/processing aids) and adhesives/coatings; Phase 2: paper/board; Phase 3: metals and others.
- Governance: Reliance model using transparent criteria to incorporate evaluations from recognized authorities; Codex-specific exposure assumptions and migration-test mapping; cyclic updates; public database with versioning and DoC templates.