DISCUSSION PAPER

Managing Food Contact Material – Food Regulatory Practices and the Role of Codex

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Executive Summary

Food contact materials (FCMs)—including packaging, 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. Within Codex, FCMs are only indirectly referenced in hygiene texts; there is no dedicated cross-cutting framework or harmonized positive-list system.

This paper invites discussion among CCASIA 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; (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 position CCASIA countries at the forefront of shaping this new Codex domain.

1. Background and Problem Statement

FCMs can transfer intentionally and non-intentionally added substances to food; 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.

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

Many regulators—especially in emerging markets—lack specialized evaluation capacity, validated methods, and access to consolidated positive lists.

Implications for CCASIA: wide heterogeneity in FCM oversight across the region; limited access to accredited laboratories and harmonized methods; increasing reliance on imports for pre-packaged foods and packaging materials; growing sustainability pressures (recycled content; circularity).

2. Relevance to Codex

Codex currently provides broad hygiene principles and risk-analysis foundations that touch on packaging and food contact materials, 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;
- Create a global, science-based reliance pathway toward a harmonized list of “cleared” applications, reducing duplication of evaluations while safeguarding health and facilitating trade.

3. International Regulatory Landscape (Concise Profile)

3.1 European Union

- Horizontal framework with GMP, specific measures for plastics (including recycled), ceramics, regenerated cellulose film, and active/intelligent materials; EFSA conducts risk assessments.
- 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 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 may vary.

3.6 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.

3.7 Japan

- Historically relied on a negative list system under the Food Sanitation Act, but from 2020 has moved to a positive list framework for synthetic resins.
- The Ministry of Health, Labour and Welfare (MHLW) maintains the positive list of approved substances, with conditions of use and migration limits.
- Compliance is supported by guidance on testing, with responsibility resting on business operators.
- Other material classes remain under general safety provisions without full positive lists, though technical standards and industry codes are widely used.

3.8 Singapore

- Singapore's Food Regulations prohibit packaging that may render food unsafe;
- Regulation is mainly performance-based. The Singapore Food Agency (SFA) does not maintain its own positive list but recognizes and relies on assessments and clearances from other jurisdictions (e.g., US FDA, EU, Japan).
- Declarations of compliance and testing evidence are expected when new materials are introduced.

- Singapore's approach highlights regulatory reliance and international alignment.

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)

Mandate: 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).

- **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.

Annex 1: Proposed Codex Outputs to Support Management of FCM and Role of CCASIA countries

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.

Capacity-Building & CCASIA Leadership

- CCASIA could pilot a network modelled on the European network of reference laboratories such as EU's Reference Laboratory (EURL-FCM) and its network of National Reference Laboratories (NRLs) to harmonize migration testing, organize proficiency trials, and maintain method notes.
- CCASIA countries could agree to exchange experience and expertise in relation with NIAS screening, exposure estimation, dossier review; packaging for small/regional labs (solvent systems, simulants, validation).
- CCASIA countries could agree on framework to recognize competent evaluations and Codex-cleared uses; countries could support joint reviews and shared templates.
- CCASIA countries can further contribute to Dat availability to Transparency: support open access to monographs, migration data, and DoC reports