



European Commission's FCM rules in the future

EDQM-AESAN SYMPOSIUM ON FOOD CONTACT MATERIALS AND ARTICLES

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EU legislation applicable to all FCMs

'Framework' Regulation (EC) No 1935/2004 (basic act)

- Objectives:
 1. Provide a basis for securing a high level of protection of human health and the interests of consumers
 2. Ensure the effective functioning of the internal market in relation to the placing of FCMs on the EU market
- Sets out general rules and procedures for FCMs including safety, definitions, labelling, traceability, inspection and control
- Good Manufacturing Practice (GMP) for all FCMs (Reg 2023/2006)
- Basis for specific measures

Current regulation of FCMs in EU

- Basic FCM legislation is approaching 50 years old (originally Directive 76/893/EEC)
 - EU authorised lists of substances since 1980s (RCF) and 1990s (plastics)
 - Rules on lead and cadmium but also old (1984)
 - Substance specific rules (BADGE, BPA, VCM)
 - More recently specific measures being implemented on recycled plastic
- Support from all stakeholders to improve the current EU FCM legislation and for more EU harmonised rules beyond plastics
- Evaluation carried out 2017 – 2020. European Commission [Staff Working Document](#) published 2022



Why revise FCM legislation?

- Issues raised
 - Beyond plastics, little or no harmonisation → **lack of functioning of EU market and uncertainty over safety**
 - Issues with authorised list approach inc. **lack of prioritisation of the most hazardous substances, up-to-date assessments** and **lack of focus on the final article**
 - **Exchange of safety and compliance information** in the supply chain is poor and ability to ensure compliance is compromised; enforcement of rules on FCMs is generally poor
 - Rules do not sufficiently take into account the **specificity of SMEs**
 - Rules do not encourage development of safer and more **sustainable alternatives**
- Causes are inherent with the present regulatory system → somewhat **fundamental change to present system are required** to address issues

Other relevant activities and policies



- Initiatives along the life cycle of products on design of products, circularity, waste prevention
 - Compostable, biodegradable, natural,
 - Recycling: sorting, quality and safety
 - Reduce over-packaging and packaging waste
 - Innovative and sustainable packaging solutions including re-use
- A toxic-free environment to better protect citizens, environment; boost innovation for safe and sustainable chemicals
 - Coherence of assessment: “1S1A”
 - Reduce use of most hazardous chemicals: ban CMRs, EDs, PBTs
 - “Safe and sustainable” materials by design
 - Combination effects of chemicals



Revision: Objectives

1. Ensure appropriate **harmonisation**
 - **Improve safety**
 - **Improve functioning of the EU market**
2. Rebalance **focus on final food contact articles**; producers responsible
 - (materials and articles likely to become two different concepts)
3. **Prioritise** the most harmful substances
4. **Simplify rules** - more **practicable, enforceable** and **achievable**
 - Taking into account resources available
5. High level of **transparency** over migratable substances for compliance and controls
6. Increase **sustainability** of materials

EU FCM revision: Main policy themes and pillars

Safety and sustainability of food contact materials (FCMs)

A + B together to become the core of the future risk management approach + new material categories to apply that approach

- A + B together to become the core of the future risk management approach
- + new material categories to apply that approach

C. Supporting more sustainable alternatives

Information exchange, compliance and enforcement of FCMs

To verify safety, sustainability and ensure smooth functioning of the internal market

D. Improving quality and accessibility of supply chain information

E. System for verifying compliance and undertaking of official controls

F. Analytical methods

A: Rebalance focus: final food contact article



1. FCMs should be inert

- Migration allowed as exception, if demonstrated to be safe but 'limits' no longer driver
- Rules should drive innovation towards safer [and more sustainable] materials

2. Comprehensive assessment of the final food contact article

- All substances that may migrate and in what quantities are known to the producer of the final article
- Substances have been risk assessed – exposure below resulting limit

3. EU to define the level of safety that needs to be achieved

- Both rules and possibility of industry input on how to achieve this (recognising sector specificity)
- GMP and adequate transfer of supply chain data required

4. Broader material types

- Synthetic organic type materials (plastics, rubbers, coatings, inks, adhesives); natural organic type materials (paper, wood, fibres, plant-based); inorganic based materials including metals; recycled materials, active FCM) and composite and multi-materials
- Grouping done on basis of similarities between groups and practicable and achievable approaches for RA and RM; not to set different safety standards

B: Prioritisation of substances

1. Substances are no longer prioritised for risk assessment and risk management purely based on the need to authorise their use in the manufacture of FCMs

- No difference between non-intentionally added substances (NIAS) and IAS
- Groups of substances as relevant

2. Tiered approach, with **precedence given to certain hazard classes**

- 1. Generic risk approach/ hazard-based: CMRs, EDs, PBTs and vPvBs.
- 2. Generic risk approach/ hazard-based or specific risk assessments: with specific concern e.g. neurotoxins, immunotoxins, nano materials or substances that migrate in high amounts
- 3. More benign substances and those migrating in low amounts
 - Other criteria to be discussed and elaborated: Use, migration, exposure, grouping and combination effects, vulnerable populations, essentiality - also to be elaborated

3. Dialogue with and input required from **EFSA and MS/ national risk assessment bodies** to inform on priorities and capacity for future risk assessments

EU/ public risk
assessment
bodies

Self-
assessment

Pillar C: 'Sustainable FCMs'

1. This pillar to focus on rules that **would facilitate sustainability** through:
 - production of FCM, e.g. information on impact / prioritisation
 - use of FCM, e.g. re-use, hygiene, support food systems
 - disposal of FCM, e.g. recycling (focus likely on natural fibres)
2. Study underway to
 - articulate what sustainability means in context of FCMs
 - consider gaps, needs and opportunities in present and future Union legislation and policies
 - list potential policy measures, characterise promising policy measures
3. Resulting measures *may* then be integrated in FCM legislation

Pillar D: Information in the supply chain

1. Ensure that the objectives of pillars A and B can be met
 - A. transfer information in supply chain **digitally** / provide access to supporting documentation
 - B. provide access to existing risk assessments
2. Challenges: To design a system and manage proprietary information
 - the information is (largely) to be provided by the supply chain - high level of transparency required
3. Implicit requirement on supply chain: **no information, no market**
4. Knowledge of FINAL producers
 - Expertise in chemistry or of consultants

Pillar E: Compliance and controls

1. Role of **business operators**
 - What can be achieved
 - SMEs
 - Possible use of **Notified Bodies** tasked with conformity assessment
2. Role of **Member States** in controls and enforcement
 - Documentary checks
 - Physical checks and laboratory controls
 - Available resources
 - Need for prioritisation
 - Point of control
 - Possible use of **Delegated Bodies** under Official Control Regulation 2017/625



Pillar F: Analytical methods

1. Present: focus on enforcement of migration limits under OCR
 - in practice, only a very limited number of substances is routinely subject to verification of compliance by competent authorities on the basis of analytical methods
 - in many cases methods do not exist, or accreditation does not exist
2. Future:
 - lower importance of migration testing (→A)
 - rules to be made specific to the tiered approach (→B)
 - **Tier 1: confirm absence**
 - **Tier 2: the present approach?**
 - **Tier 3: screening**
 - consider novel approaches (e.g. screening / non-targeted approaches)
 - rework migration testing (Annex III + V to R 10/2011) to become generally applicable

Important Disclaimer!




- The previous slides describe the ‘aspirations’ of the revision
- These do not necessarily reflect the reality of what will be final legislation
- Some of these aspirations may not be achieved, or be differently achieved
- Discussions with EFSA, Member States and Stakeholders will be very important
- Success also relies on you!

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Where are we up to?

- Revision of EU FCM rules announced as part of the previous Commission's 'Farm to fork' strategy
 - Roadmap/ inception impact assessment: December 2020 – January 2021
 - Summary of feedback from stakeholders on the roadmap: January 2022
 - Public consultation: October 2022 – January 2023
 - Summary of consultation published: June 2023
 - Citizen engagement study published: October 2023
 - Study concerning information exchange, compliance and enforcement: in completion
 - Study on sustainability in the context of food contact materials: ongoing

Going forwards

- Priorities are shifting onto the actual revision work
 - Other work increasingly being minimised in favour of revising the FCM legislation 
- Present Activities
 - Scoping paper being prepared internally → internal discussion → external elaboration
 - External elaboration being prepared → elaboration by groups of independent experts
 - Sustainability study (2nd phase has started, long list of measures + market mapping)
- Foreseen timing
 - Scoping paper 2024, developed policy paper late 2025, IA 2026 + validated + legislative proposal 2027
 - Validation by new Commission first step

Other ongoing matters

- Risk management measures for metals in ceramics, enamels and glass (part of the revision)
- Regulation 10/2011 on plastic FCMs
- Implementation of Regulation 2020/1616 on plastic recycling
 - 56 Authorisation Decisions prepared
 - To be voted on this autumn (+/- additional Decisions)
 - Matters to be considered after the first 'batch':
 - Possible amendment to Regulation (EU) 2022/1616
 - BTSF course
 - Novel technologies
 - Miscellaneous inc. the register, enforcement issues, international trade

Thank You



European Commission webpages on FCMs

http://ec.europa.eu/food/food/chemicalsafety/foodcontact/index_en.htm

Contact us: SANTE-FCM-revision@ec.europa.eu

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