European Commission (DG SANTE) activities including on the revision of the FCM framework legislation

EFSA NETWORK ON THE COOPERATION AND HARMONISATION OF RISK ASSESSMENT OF FOOD CONTACT MATERIALS (FCM)

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Revision of EU rules on FCMs

European Commission

FCM revision – where are we up to?

- Evaluation of current EU rules on FCMs 2017 – published 2022
- Revision of EU FCM rules announced in 2020
  - 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
- Political ‘revalidation’ – start of current mandate 2024 – 2029

Why revise FCM legislation?

- **Fundamental problems**
  - Beyond plastics, little or no harmonisation → **lack of functioning of EU market and uncertainty over safety** and how to demonstrate it
  - 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

What are the objectives (‘aspirations’)

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 in principal 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
   - All substances to which consumers may be exposed have equal ‘weighting’
   - Groups of substances as relevant
2. Tiered approach, with **precedence given to certain hazard classes**

EU/ public risk assessment bodies

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

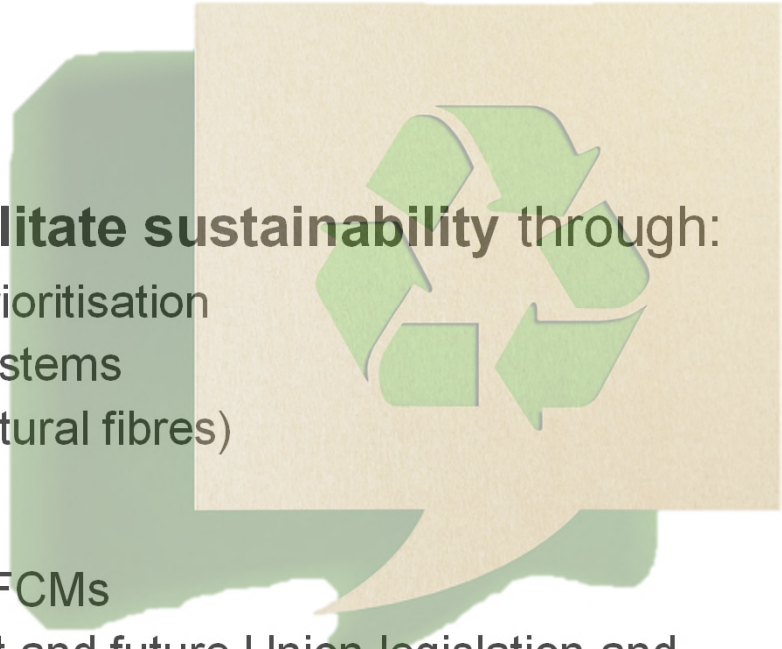
Self-assessment

3. More benign substances and those migrating in low amounts

- Other criteria also important: 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

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

Pillars D, E and F: To support pillars A – C

D. Information in the supply chain

- Digital transfer of information in supply chain including existing work e.g. risk assessments
- High level of transparency required, information largely to be supplied by businesses
- Implicit requirement on supply chain: no information, no market

E. Compliance and controls

- Role of businesses including SMEs and possible use of Notified Bodies tasked with conformity assessment
- Role of Member States in controls – capacity, prioritization, point of control and possible use of Delegated Bodies under Official Control Regulation 2017/625

F. Analytical methods

- Currently a very limited number of substances are routinely checked by competent authorities on the basis of analytical methods; in many cases methods or accreditation is lacking
- Future depends on tier of substance – confirmation of absence (tier 1) but also screening (novel approaches)

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

Main ongoing implementation work

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‘Quality’ amendment to Regulation 10/2011

- Change of ‘plastic layer’ concept
- Address biocidal substances
- Major change considered to general requirements on substance (Article 8)
  - all substances to be of high degree of purity – including those originating from chemical recycling
  - clarification of natural origin – high degree of purity if extracted substance
  - potential significant impact if Article 19 has not been given sufficient consideration
- Substances are additives even if their surface is covalently bound to polymers
- SML and OML to apply multi-material multi-layer materials if plastic food surface

‘Quality’ amendment to Regulation 10/2011

- Reprocessing of plastics only to be allowed if certain conditions are met
  - subject to new GMP requirements on collection only if by-product under waste legislation
  - no constituents from foods, inks, coatings, adhesives, and lubricants
- Aging condition for plastics intended for plastics intended for repeat use
  - no long-term increase in migration, instructions to users
  - report in supporting documentation under Article 16
- Annex III – New assignment for cheeses
- Annex IV – Declaration of compliance
  - stricter reporting requirements for the presence of NIAS
  - Compliance statement that the reprocessed plastic complies with Articles 10(1) and (2) (e.g. no functional barrier can be present)
  - provisions to indicate recycled content if under Article 1(3) of Regulation (EU) 2022/1616
- Annex V
  - performance criteria for testing – calibration range and standard measurement uncertainty
  - clarified criteria for repeated use

‘Quality’ amendment to Regulation 10/2011

- Feedback March – April 2024
- PAFF 20 September 2024
- Scrutiny EP and Council to commence shortly
- Adoption and publication Q1 2025

New EU measure on BPA and other bisphenols

- Bans use of BPA and its salts [as a monomer or other starting substance] in the manufacture of FCM
  - ➢plastic
  - ➢varnishes and coatings
  - ➢inks
  - ➢adhesives
  - ➢rubbers
  - ➢ion-exchange resins
  - ➢silicones
- Removes authorisation of BPA in FCM plastic from Commission Regulation (EU) No 10/2011
- Two derogations for the use of BPA as monomer or other starting substance:
- FCMs manufactured using other bisphenols or derivatives e.g. BADGE must not contain residual BPA from the manufacturing process

New EU measure on BPA and other bisphenols

- Bans use of other bisphenols and derivatives subject to harmonised classification as CMR category 1A or 1B in the manufacture of FCM
  - bisphenol S (BPS)
  - 2,2-bis(4'-hydroxyphenyl)-4-methylpentane
  - bisphenol F (BPAF)
- Unless for a specific FCM application that does not present a risk
- Possible applications foreseen after EFSA, in consultation with ECHA, has informed on the information necessary for assessing the risk (max 2 years after the Regulation takes effect)

Application for use of other bisphenols: Article 5 and 6

- As of the date EFSA updates its guidelines or otherwise informs on the information necessary, applications for FCM articles already on the market at that point should be made within 9 months
- Use of other bisphenols that are also subject to the relevant harmonised classification in the future will also need to be assessed
- Business operators will need to provide information to EFSA on current uses of bisphenols and derivatives to support EFSA's work on developing risk assessment guidelines

Transitional periods for packaging: Article 11

- A fixed transition period of 18 months is foreseen for the placing on the market of affected single use final food contact articles from the date of entry into force of the measure
- Exceptionally 36-month transitional period
  - Canned fish and fruit and vegetables
  - Exterior of cans
- In practice, this means mainly the finished production of empty cans
- A further 12-months is allowed for filling with food
- Thereafter, no withdrawal of packaged food already placed on the market

Transitional periods for repeat use FCM: Article 12

- A fixed transition period of 18 months is foreseen for the first placing on the market of affected repeat use final food contact articles from the date of entry into force of the measure
- Exceptionally 36-month transitional period
  - ➢ Professional food production equipment
- A further 12-months is allowed for remaining on the market in order for manufacturers to sell to food businesses or for retail to sell to consumers
- Thereafter, no withdrawal of the articles used by food businesses

Estimated remaining timeline

- Scrutiny period (3-months) by EP and Council ends 24 October
- Adoption by the Commission November this year
- Entry into force by the end of the year
- First transitional period ends mid 2026

Implementation of Regulation (EU) 2022/1616

- No detailed discussion today
  - this Regulation concerns recycled plastics suitable for contact with food
- Present activities:
  - Preparation of authorisation Decisions for PET recycling processes
    - vote on first 56 Decisions on 17 October
  - Register of recycling installations, facilities, and operators is on-line and functioning
  - Work on novel technologies on-going
- Please be aware of specific terminology, such as definitions

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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