Overview of the evaluation and revision of the EU FCM legislation

2021 Food Packaging Forum (FPF) Workshop

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EU legislation on FCMs

- Objectives of **'Framework' Regulation (EC) No 1935/2004**
  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
- Applicable to **all FCMs**
  - already in contact with food (e.g. packaging)
  - intended to be brought into contact (kitchenware, food processing equipment)
  - that can reasonably be expected to be brought into contact with food or transfer constituents to food under normal or foreseeable conditions of use (e.g. napkins but subjective)
- Sets out general rules and procedures for FCMs including safety, definitions, labelling, traceability, inspection and control
- Basis for specific measures (e.g. Regulation 10/2011 on plastic FCM)
  - Including authorised substances and the role of EFSA
  - Also restrictions (e.g. SMLs) and prohibitions
- Requires Good Manufacturing Practice (GMP) for all FCMs (Commission Regulation 2023/2006)

Evaluation of FCM legislation: rational and background

- Basic FCM legislation is almost 45 years old (originally Directive 76/893/EEC, now Regulation 1935/2004) and has never been systematically evaluated
- EU authorised list of substances (for plastics) since 1990
- Support from all stakeholders to improve the current EU FCM legislation and in particular for more EU “harmonised” rules
  - Concerns over safety and functioning of the internal market
- JRC ‘baseline’ study on supply chain and national legislation published January 2017
  - Highlights the complexities of the supply chains
  - Many national rules in place in Member States, often divergent

FCM Evaluation: Process and output

- Commenced in 2018, consultation work led by Ecorys (12 week public consultation targeted interviews, surveys, focus groups, case studies, workshops)
- Commission Staff Working Document (SWD) is definitive output from the evalution and is based on:
  - Ecorys report
  - JRC baseline study
  - Workshop report on strengthening Member States' response to Union audits on FCM
  - SANTE study on the use of compliance documentation in official controls and in the supply chain
- SWD is currently under internal COM consultation to conclude the evaluation exercise and feed into the next steps (see problem definition in roadmap for revision).

European Commission's "Farm to Fork" strategy

May 2020: "Food packaging plays a key role in the sustainability of food systems.

The Commission will revise the food contact materials legislation

- *to improve food safety and public health (in particular in reducing the use of hazardous chemicals)*
- *support the use of innovative and sustainable packaging solutions using environmentally-friendly, re-usable and recyclable materials, and contribute to food waste reduction*
- *In addition, under the sustainable products initiative announced in the CEAP, it will work on a legislative initiative on re-use in food services to substitute single-use food packaging and cutlery by re-usable products."*

Related EU initiatives

Circular Economy Action Plan (CEAP)

- Reducing (over)packaging and packaging waste, driving design for re-use and recyclability of packaging and considering reducing the complexity of packaging materials, including the number of materials and polymers used
- New Directive on single use plastic products, addressing use of biodegradable or compostable plastics and recycling e.g. sorting quality

Chemicals Strategy for Sustainability

- “Safe and sustainable” materials by design, non-toxic material cycles and clean recycling
- Prohibiting the most hazardous chemicals in consumer products including endocrine disruptors (EDs) and better addressing combination effects of substances
- Establishment of a ‘one substance, one assessment’ process to coordinate the hazard/risk assessment on chemicals across chemical legislation

Key problems identified in IIA (roadmap)

1. Lack of functioning of the internal market and possible safety issues for non-plastics FCMs
2. Positive authorised list approach and lack of focus on the final article
3. Lack of prioritisation of the most hazardous substances and up-to-date assessments
4. Exchange of safety and compliance information in the supply chain is poor and the ability to ensure compliance is compromised
5. Enforcement of rules on FCMs is generally poor
6. Rules do not sufficiently take into account the specificity of SMEs
7. Rules do not encourage development of safer and more sustainable alternatives
8. The subject matter is not always clear and definitions need to be reviewed

Possible options for FCM rules: Safety and sustainability

A. Shifting the focus onto the final material

- Rules better aimed at addressing the full characteristics of all final materials and articles
- Define the level of safety that needs to be achieved
- How to achieve this determined in EU legislation and/ or by industry (needs to recognize sector specificity)
- Possible strengthening of rules on GMP
- Refocus on broader material types e.g. (1) ‘organic/ synthetic’ type materials (plastics, rubbers, coatings, inks, adhesives), (2) inorganic based materials including metals (3) ‘natural’ or plant-based FCM: wood, paper and board, other fibres
    - Synergy and efficiency gains
    - Avoid current issues e.g. with composites and multi-material materials
    - Avoid complexities related of needing to specifically define very similar materials

Possible options for FCM rules: Safety and sustainability

B. Prioritisation of substances

- All migrating substances including non-intentionally added substances (NIAS) and where relevant groups of substances
- Tiered approach, with precedence given to certain hazard classes

Public risk assessment bodies (principally EFSA taking account of OSOA)

1. Carcinogenic, mutagenic and reprotoxic substances (CMRs), endocrine disruptors (EDs) persistent, bioaccumulative and toxic substances ('PBTs' and 'vPvBs').
   - Criteria and information requirements to be elaborated
   - Generic approach based on relevant hazardous properties with possibility for limited exceptions
2. Other substances with specific properties that may justify closer scrutiny by public risk assessment bodies e.g. substances with other types of specific hazard properties, in nano-form or that migrate in high amounts

Self-assessment

3. More benign substances including those migrating in low amounts

Possible options for FCM rules: Safety and sustainability

C. Supporting safer and more sustainable alternatives

- Development of methodology to harmonise assessment of ‘natural’ materials with unknown composition, to ensure safety whilst facilitating and incentivising more sustainable production sources and methods, including those using plant or bio-based technology
- Expand rules to prioritise and support all forms of safe re-use and recycling, to exclude risks from contamination and to include all recycling technologies
- Ensure consistency and coherence with EU environmental legislation e.g. packaging and packaging waste, SUP

Possible options for FCM rules: Information exchange, compliance and enforcement

D. Improving quality and accessibility of supply chain information

- Clear and consistent rules on data requirements and information transfer throughout the supply chain, including a Declaration of Compliance (DoC) for all FCMs
- Digitalisation to help businesses, including SMEs to ensure compliance and for Member States to enforce

E. System for verifying compliance

- Delegated bodies under Official Control Regulation 2017/625
- Notified Bodies tasked with conformity assessment
- Further development of test methods and technical standards as required

Inception Impact Assessment (IIA)/ roadmap for the revision of EU FCM rules

- Open for feedback 18 December 2020 - 29 January 2021 (6 weeks)
- IIA sets out context, problem definition, **objectives and broad policy options**, summary of expected impacts, evidence base, data collection and consultation with stakeholders
- Webinar 20 January 2021 presented by SANTE
- ~ 300 stakeholders submitted feedback

Revision process and consultation

- **Dec 2020**: Inception Impact Assessment (roadmap) setting out problem definition and broad options. Six week feedback + presentation Jan 2021
- **2021 – 2023**: Development of policy options and legislation in more detail, supported by Impact Assessment (IA)
  - 12 week public consultation in early 2022 to gain further views from stakeholders
  - Targeted activities: expert groups, interviews, surveys, workshops
  - Study work e.g. to support economic and practical implications
  - Continuation of cross-cutting exercises e.g. CSS, CEAP
  - Above all, further data and working examples needed to support problem definition and to inform on the revision of EU rules
- **By mid 2023**: Planned Commission adoption of new legislation

Contact and further information

European Commission webpages on FCMs
http://ec.europa.eu/food/food/chemicalsafety/foodcontact/index_en.htm

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