Webinar on the evaluation and revision of the EU rules on Food Contact Materials

Wednesday, 20 January 2021

Thank you for your patience, the meeting will start at 14:00

Technical issues?

- Send an email to SANTE VISIO (sante-visio@ec.europa.eu)

Questions on the topics?

- Write your question in the chat box (to All Participants or to Everyone)
- Please try to identify your organisation if relevant

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Wednesday, 20 January 2021

- **Event is open to all interested parties**
- **Event is being recorded**
- **This presentation made available afterwards**
- **Approximate running time 1.5 hours**
- **Q&A session at end of presentation**
- **DG SANTE presenters/ panellists: Jonathan BRIGGS, Bastiaan SCHUPP, Greta BORG, Michael LATSCH, Bruno GAUTRAIS**

What are food contact materials (FCMs)?

Any material:

- Already in contact with food and intended for that purpose
  - Primarily food packaging

- Intended to be brought into contact with food
  - For example, kitchenware, tableware and food processing equipment

- Can reasonably be expected to be brought into contact with food or transfer constituents to food under normal or foreseeable conditions of use
  - Such as paper napkins or table mats although case-by-case basis

EU legislation applicable to all FCMs

'Framework' Regulation (EC) No 1935/2004

- Purpose of the legislation:
  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
- Basis for specific measures
  - ➢ Focus on authorised lists of substances and role of EFSA
- Requires Good Manufacturing Practice (GMP) for all FCMs (Reg 2023/2006)

Examples of EU specific measures

AUTHORISED LISTS

(Referred to as ***'Union Lists'*** in legislation)

1. Plastic monomers and additives
2. Substances in regenerated cellulose film (cellophane)
3. Active and intelligent substances *(future)*

Individual decisions, registry

4. Authorization of plastic recycling processes *(future)*

RESTRICTIONS OF USE

- Migration limits in plastics
- Leaching limits for cadmium & lead ceramics
- Nitrosamines limits in rubber teats and soothers
- BADGE limits in plastics, coatings and adhesives
- BPA limits in plastics, varnishes and coatings
- Residual content of substances in plastics or cellophane
- Migration limits for biocides *(future)*

PROHIBITION OF USE

- BFDGE and NOGE in plastics, coatings and adhesives
- Bisphenol A in plastic bottles for infants and young children
- Certain phthalates in FCMs intended for infants & young children
- **Substances which are not on a positive authorised list that are not covered by a derogation**

Main ongoing FCM policy work at EU level

- Commission Regulation (EU) No 10/2011 on plastics FCMs
  - Assessment and authorisation of substances, update restrictions, rules on compliance
- Commission Regulation (EC) 282/2008 on recycled plastic for FCMs
  - Amendment + authorisations of processes
- Revision of rules on lead, cadmium and possibly other metals from ceramic and vitreous FCMs
  - Impact assessment being carried out. Public consultation + webinar in Q2/Q3 this year
- **Evaluation and revision of EU rules on FCMs**
  - **Concerns Regulation (EC) No 1935/2004 and approach for setting harmonised rules**
  - **Subject of today's webinar**

Evaluation of FCM legislation: rational and background

- Basic FCM legislation is over 44 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
- 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

Evaluation commenced in 2018, consultation activities included:

- 12 week public consultation (February – May 2019)
- Targeted interviews addressed to:
  - MSs' Authorities, including enforcement bodies and control laboratories;
  - Consumer representatives and NGOs;
  - Businesses including specifically SMEs and microbusinesses;
  - Scientific experts in the field of FCM (e.g. EFSA, analytical laboratories, etc.)
- Surveys mainly targeting SMEs
- Focus group meetings gathering representatives
- Case studies
- Workshops (September 2018 and September 2019)

FCM Evaluation

- Supporting documents published on Commission website
  - JRC “baseline report” on non-harmonised food contact materials in the EU: regulatory and market situation
  - Ecorys study supporting the Evaluation of Food Contact Materials (FCM) legislation: Final report, executive summary and supporting annexes
  - BTSF Workshop report on strengthening Member States' response to Union audits on FCM
  - Study on the use of compliance documentation in official controls and in the supply chain
- Staff Working Document in 2021 to conclude the evaluation exercise and feed into the next steps. Further data and supporting evidence welcome for clear problem definition and to inform on the revision of EU rules
- Nevertheless, several issues apparent with functioning of current legislation

Key problems identified

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

EU revision of rules on FCMs announced in 2020

European Commission's "Farm to Fork" strategy

"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)

Packaging

- Reducing (over)packaging and packaging waste, including by setting targets and other waste prevention measures
- Driving design for re-use and recyclability of packaging
- Considering reducing the complexity of packaging materials, including the number of materials and polymers used

Plastics

- Use of biodegradable or compostable plastics
- New Directive on Single Use Plastic Products
- Recycling e.g. sorting quality

Related EU initiatives: Chemicals Strategy for sustainability

Materials

- “Safe and sustainable” by design
- Non-toxic material cycles and clean recycling

Substances

- Banning the most harmful chemicals in consumer products - allowing their use only where essential
- Criteria for EDs applicable to FCMs
- Account for combination effects of chemicals

Assessment

- Establishment of a ‘One substance, one assessment’ process to coordinate the hazard/risk assessment on chemicals across chemical legislation

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

- Published 18 December 2020
- Feedback on the roadmap from all stakeholders welcome. Feedback period open for 6 weeks until 29 January 2021
- Sets out context, problem definition, objectives and broad policy options; summary of expected impacts, evidence base, data collection and consultation with stakeholders

Moving forwards: Possible approach for harmonising legislation

- Refocussing on broader material types e.g.
  - ‘organic/ synthetic’ FCM: plastics, rubbers, coatings, inks, adhesives …
  - ‘natural’ FCM: wood, paper and board, other fibres …
- Avoid current issues e.g.
  - with composites and multi-material materials
  - with complexities related to definitions
- Less focus in this IA
  - Inorganic materials → present work on ceramic and vitreous materials → regulation of metals and alloys could follow logically from this work
  - Recycled materials → present work on recycled plastic FCM → regulation of recycled paper and board could follow logically from this work

Possible options/ solutions for FCM rules

Safety and sustainability of FCMs

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 or by industry (needs to recognize sector specificity)
- Strengthening of rules on GMP

Possible options/ solutions for FCM rules

Safety and sustainability of FCMs

B. Prioritisation of substances

- All substances that may pose a risk to consumers, including non-intentionally added substances (NIAS) and groups of substances
- Tiered approach, with precedence given to certain hazard classes

Public risk assessment authorities

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 such as those in nano-form

Self-assessment

3. More benign substances and those migrating in low amounts

Possible options/ solutions for FCM rules

Safety and sustainability of FCMs

C. Supporting safer and more sustainable alternatives

- Development of methodology to assess and specific rules to ensure safety and incentivise more sustainable production sources and methods, such as 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 environmental legislation

Possible options/ solutions for FCM rules

Information exchange, compliance and enforcement

D. Improving quality and accessibility of supply chain information

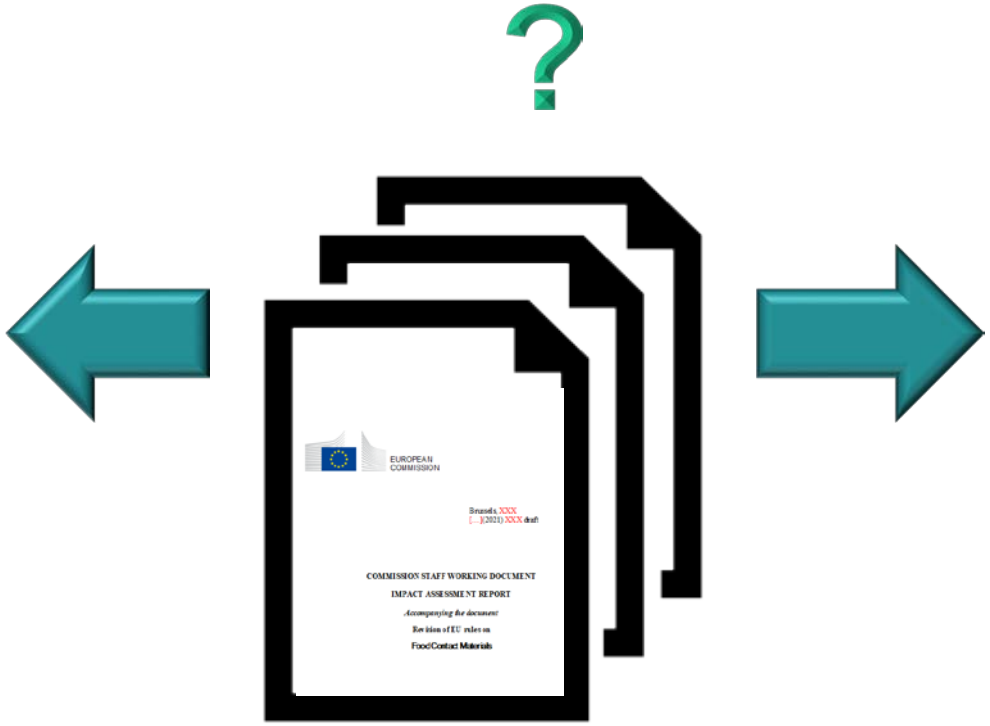
- Clear and consistent rules on data requirements and information transfer throughout the supply chain, including a Declaration of Compliance (DoC) for all FCMs
- Digitalisation to help businesses, especially SMEs to ensure compliance and for Member States to enforce

E. System for verifying compliance

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

Legislative pathways

Option 1: Use the current regulatory framework (with Regulation (EC) No 1935/2004 as a cornerstone)



Option 2: Develop a new regulatory framework, replacing the current Regulation

What are the expected impacts?

- More effectively and efficiently prevent health risks through increased transparency and prioritisation in risk assessment; decreased burden on health services due to higher standards of protection for consumers
- Simpler and clearer rules for all businesses trading in FCMs, including SMEs
- Overall reduction in costs for businesses e.g. harmonization of testing regimes and compliance costs. Initial increase in costs for some sectors can be envisaged
- Increased global competitiveness of EU businesses due to higher standards
- Contribute to environmental objectives including increase in use of sustainable and renewable materials and reduction in waste

Next steps

- **Ongoing**: Inception Impact Assessment (roadmap) setting out problem definition and broad options
- **2021 – 2022**: Development of Impact Assessment (IA) setting out policy options in more detail
  - 12 week public consultation
  - Targeted consultation activities e.g. interviews, working groups
- **By end 2022**: Completion of IA work and 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

Questions?

Questions from stakeholders

Options part A (focus on final materials)

- How would this function in practice and will the potential impact be carefully assessed?
- How would final materials be defined? Is it for example the individual films in a multi-layer or is it the final multi-layer consisting of several films and maybe adhesive and printing inks?
- Is the focus going to be on the final material or on substances? The IIA seems contradictory
- Will it be EU rules or industry that determine *how* to achieve the right level of safety?

Questions from stakeholders

Options part B (substances)

- What does “one substance, one assessment” mean?
- How will substances be assessed under the tiered approach? How will it be implemented in practice? Will there be a hazard-based approach in the future?
- How will the NIAS be included in the Tier 1, 2 and 3 grouping of substances?

Questions from stakeholders

Options part D (improving supply chain information)

- Has there been any study on how a digitalized compliance system would look like and how it might work?
- Will there be a DoC even if there are no specific rules for materials?
- How would the be DoC be structured?

Questions from stakeholders

Option E (delegated/ notified bodies)

- How will the system with delegated bodies/notified bodies work and how will it benefit SMEs? Would it be instead of self-assessment by industry?
- Why does the Commission think that this would work better than the current system on Mutual Recognition for non-harmonized materials?
- Would a product checked on one MS need to be checked in another if national laws still exist?
- Would the assessment account for repeat use articles made from different materials?

Other questions

- What will the sub-options look like, referred to in the IIA?
- When can we expect that the EU will have harmonised legislation?
- What actions will the Commission take already now to improve the safety of FCM?
- The Chemicals Strategy foresees a new roadmap for group restrictions under REACH which is to include FCM. What is the current timing for these plans?
- Are you aware of the 5 Key principles developed by key NGOs? Will you let these help you guide the development of the new legislation?