

FCM Evaluation

- 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
- Key problems identified with functioning of current legislation
 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

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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

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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

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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

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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

Self-
assessment

2. Other substances with specific properties such as those in nano-form
3. More benign substances and those migrating in low amounts

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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

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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

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Legislative pathways

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



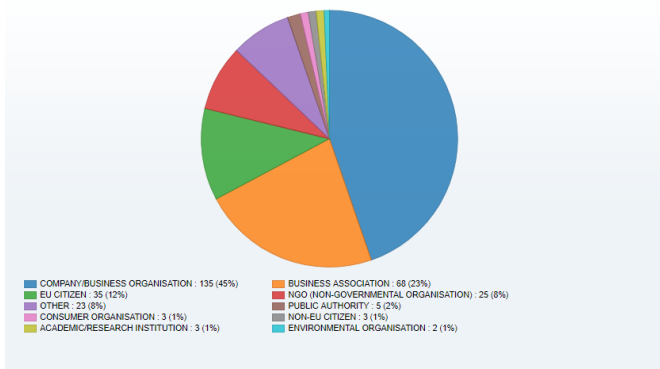
Option 2: Develop a new regulatory framework, replacing the current Regulation

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Demographic of stakeholders who contributed to feedback

USER TYPE



- 302 respondents in total
- 60% from artisanal producers and ceramics including specific issues related to revision of Directive 84/500/EEC

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Next steps

- **Ongoing:** Assess feedback and contributions from stakeholders
- **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

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