9 January 2023

FEFCO supports the review of the FCM legislation

The European Commission's review of Regulation (EC) 1935/2004 on food contact materials is essential to ensuring the safety of consumers and the well-functioning of the internal market.

FEFCO supports increased harmonisation of the legislation on food contact materials and articles (FCMs). By introducing a unified approach across the EU, the Commission will ensure clarity and improved efficiency while safeguarding safety. Additionally, this will streamline the development and use of innovative packaging solutions.

Key policy recommendations:

1. Shifting the focus onto final articles requires a coordinated approach and shared responsibility throughout the value chain
2. Specific regulation for paper & board materials and articles is paramount
3. Prioritisation of substances should follow a specific risk assessment
4. Improving quality and accessibility of supply chain information is key for ensuring compliance

1. Shifting the focus onto final articles requires a coordinated approach and shared responsibility throughout the value chain

The producers of final articles are already required to ensure the safety of their products with respect to Regulation 1935/2004, article 3 on food contact materials and articles. The ongoing review must ensure that the risk assessment and risk management procedures cover the impact throughout the entire value chain; from starting substances through intermediate materials to final products.

Every step along the value chain should have a well-defined responsibility to evaluate the risks associated with this step on the process and pass on the adequate information to the next actor in the value chain, so he can perform his own risk assessment. The regulation should legally define the approach of shared responsibility to streamline cooperation, communication and compliance. This would ultimately benefit all actors, SMEs in particular. Adequate information sharing is vital for the converters to perform a cost-effective risk assessment for the final article. The Commission should also define the level of safety for starting substances and intermediate materials.

2. Specific regulation for paper & board materials and articles is paramount

The lack of EU specific measures for paper and board created uneven level playing field and unfair competition on the market for products of paper & board, especially recycled paper. The application of divergent national requirements further increases the inconsistency of legal rules and creates mistrust by consumers. To overcome this situation, the paper and board value chain have developed broadly accepted Food Contact Guidelines[1]. They aim to strengthen the level of safety of paper and board FCMs and support industry in compliance evaluation. The guidelines also prioritise risk assessment steps and communication in the value chain so that FCMs produced are safe

[1] Food Contact Guidelines_2019_final.pdf (citpa-europe.org)

for use. We would therefore like to propose that these be used as a starting point for the development of specific regulation or guidance for paper & board materials and articles. Additionally, the Commission should strengthen the rules on Good Manufacturing Practices (GMP). We firmly believe these play a crucial role in controlling the production process of food contact materials and articles to ensure safety of the final product. However, the new set of rules will also have to be carefully designed so as not to create unnecessary additional administrative burdens.

3. Prioritisation of substances should follow a specific risk assessment

We support the Commission's intent to consider a tiered approach for the prioritisation of substances in the evaluation of FCM. For certain hazard classes, like genotoxic or CMR substances, stricter rules could be considered to ensure that such substances do not enter the food contact materials value chain. However, the rules should be based on scientific evidence and risk evaluation instead of relying on a "*generic approach to risk management*" based entirely on hazard classification, as proposed.

The most relevant approach for food contact materials and articles is the specific risk assessment, which allows the consideration of both hazard properties and the evaluation of possible migration or exposure to the substances. A hazard assessment of substances is an indispensable part of the risk assessment but should not be an end decision point for FCM or any other use of that substance. Industry self-assessment as an alternative approach with respect substances considered as Tier 3 (or Priority) should be also allowed. In that context, we would welcome the development of a harmonized approach that supports and guides business operators in their self-risk assessments.

We therefore believe that harmonised specific legislation and an agreed approach for risk assessment, with specific evaluation criteria at EU level, would be beneficial for the safety and compliance assessment of all FCM and articles.

4. Improving quality and accessibility of supply chain information

We support a mandatory declaration of compliance (DoC) for all FCMs based on a fixed format with an optional section to allow differentiation per sector. This will enhance transparency and improve compliance communication within the value chain, while respecting confidentiality rules (where needed). DoC should be mandatory for all actors in the supply chain to enable harmonization and risk assessment at the next step in the chain.

The upstream suppliers need to communicate the necessary and adequate information for the risk assessment at the next step of the chain and should bear responsibility for the migration of substances where information is not properly communicated.

In that context, we fully support the work of the Packaging Inks Joint Industry Task Force, where industry actors across the entire value chain have already agreed on an appropriate communication of adequate information.

The revision of the FCM Regulation will have a lastingng impact on European industry and the internal market. FEFCO is committed to work with policymakers to ensure a balanced and . With respect to the public consultation on the revision of EU rules on food contact materials (FCM), further clarification on specific questions is available in the annex.

Annex

Further clarification on specific questions from the Public consultation on the revision of EU rules on food contact materials (FCMs) published on 5 October 2022

Part for FCM stakeholders

Question 1:
It is very important to address the safety of the items listed in this question via specific legislation rather than the Framework Regulation.

Question 2:
Many hazards mentioned in this question are managed via the GMP and risk assessment, meaning that adequate information should be passed in the supply chain.

Question 3:
We understand the aim of the Commission to regulate the most hazardous substances. However, the hazard information available in REACH very often does not include the specific end points relevant for food contact materials. Furthermore, the potential risk for consumers is associated with exposure to substances, not their mere presence in the final FCMs. Therefore, for FCMs the most appropriate regulatory approach is via specific risk assessment.
Regarding Priority 1 substances, where the GRA approach is suggested, it should apply only to intentionally added substances (or mixtures) and not to substances that could be naturally occurring in raw materials.
Considering the number of substances to be evaluated and the resources required, certain hazard classes and substances which classification is in the group of "suspected" should be subject to industry risk assessment but following a harmonized EU approach.

Question 4(a):
This question is not answered as it presents a biased approach not allowing an adequate response. The most important substances for FCMs are those that migrate. Therefore, the "*substance(s) that migrate from the final FCM article into food*" should be subject to prohibition or restriction across all categories, including Priority 1, 2 and 3 substances.
On the other side, "*use of substance(s) to manufacture FCM, even if they are not present in the final FCM article*" should NOT be subject to any prohibition or restriction.
Finally, "*substance(s) that may be present in the final FCM, even if ….migration is safe*" are already part of the risk assessment and risk management, and should NOT be prohibited or restricted.

Question 4(b):
The most appropriate tool (parameter) for the risk management of FCM substances is specific migration limit (SML), which is currently not included in the questionnaire.
While OML can provide interesting information, it cannot replace the SML.
Purity criteria are relevant only for substances that migrate from the FCMs to the food.
Labelling requirements play a specific role at different stages of the supply chain, including the final consumer and should be attained according to the "*end user*" needs.

Question 6:
The answer was selected only because this question is mandatory, not because this aspect should be assessed in this legislation. EU sustainability legislation is already well developed and continuously improved, like for example taxonomy. Food contact

packaging is already subject to the Packaging & Packaging Waste Regulation which revision is ongoing, the new Eco-design for Sustainable Products Regulation, the Waste Framework Directive, Waste Shipping regulation, etc.
The FCM Regulation should focus on regulating the product safety aspects of FCMs and should not include sustainability requirements to avoid regulatory red tape and unnecessary administrative burdens.

Question 9:
We do not believe that "*approval step*" of the final FCM will improve compliance, while it will for sure increase administrative burden and cost for the business. However, we do believe that verification of the risk assessment approach used for the industry risk assessment will support compliance efforts.
Disallowing disclaimers on permitted uses will ultimately restrict the possible uses of FCMs and inevitably increase food waste. The final article producer does not have a control over the use and all the information about the potential use, which makes the use of disclaimers absolutely necessary to prevent potential misuse and ensure appropriate responsibility in the supply chain. One such example is the disclaimer on temperature limits, like for microwave applications.

Question 10(a):
"*The identify of substance(s) used in the processing or conversion of FCM*" is only relevant if those substances have the potential to migrate.

Question 11:
Supporting documentation should be retained in a digital or paper-based format, but it should not be transferred in the supply chain, unless agreed with a non-disclosure agreement.

Question 12:
The use of "*delegated bodies*" to support Member States authorities should be carefully considered and discussed with all stakeholders. Such bodies cannot be given ultimate power leading to potential misuse of role or position. A good example could be taken from the GMP regulation, where accredited bodies perform audits of the system.