11th March 2021

Position on the Roadmap (IIA) on the Revision of EU rules on FCMs

A. CONTEXT, PROBLEM DEFINITION AND SUBSIDIARITY CHECK

While in general agreement with the conclusions of the Ecorys report on the central role of Regulation 1935/2004, and the gaps identified in the overall structure of the EU FCM legislation, we believe that the primary objective of such legislation should not change, i.e. guarantee a high degree of protection of consumers and ensure proper functioning of the EU internal market.
Addressing potential risks from migrating substances from FCM can be efficiently made by testing properly the final FCM&A and developing reliable processes for risk assessment.

1. Lack of functioning of the internal market and possible safety issues for non-plastics FCMs

Harmonization of rules for all FCM remains the best option to ensure that the primary objectives of R 1935/2004 are met. This would close gaps derived from different implementation of non-harmonized rules in Member States and would grant proper functioning of the internal market. In addition, harmonization can provide an answer to the perceived lack of safety in countries where rules for certain materials are scanty or non-existing.
It is important to outline that lack of harmonized rules does not mean that FCM&A are unsafe, but that the corresponding national rules are insufficient to provide evidence of safety for the corresponding FCM&A.

Industry has adopted and triggered during the course of the years several measures to fill the gap created by lack of legislation. One example is the ISO standard on ceramic articles and enamels, that was promoted by the relevant industries missing a legislation in this sector. These experiences should be considered and possibly integrated in future harmonized legislation.

2. The positive authorised list approach and lack of focus on the final article

We agree on the statement that with the current EFSA assessment process, developing positive lists for all the non-harmonized FCM&A would represent an extremely resources intensive exercise. We believe that the focus should be strictly kept on those substances that have a potential to become part of the consumers' diet, and address them through a harmonized an scientifically sound risk assessment procedure.

3. Lack of prioritisation of the most hazardous substances and up-to-date assessments

We do not agree that prioritization should be made exclusively on hazard properties of substances. Exposure plays an important role in risk assessment, in facts there are numerous examples of substances with intrinsically hazardous properties, that are safely used in FCM&A because their migration, hence exposure of consumers, is virtually none.

Any collaboration between ECHA and EFSA in prioritization of substances should consider the different roles, whereas ECHA is well suited to gather comprehensive hazard data on substances while risk assessment should be left to EFSA. In facts, exposure in the context of FCM&A relates to the oral route. In the context of the "one substance, one assessment approach" it should be made sure that the most appropriate route of exposure is used to establish potential limitations.

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Prioritization of hazardous substances may imply the use of the precautionary principle in the case that evidence of threat to health exists. The precautionary principle however should not be used as a blanket solution when hazard information is missing. Its use should be done within the meaning of its definition, i.e. when a reasonable evidence of threat is demonstrated.

4. Exchange of safety and compliance information in the supply chain is poor and the ability to ensure compliance is compromised

Although very important progresses has been made in the exchange of information in the last decade, we would welcome an extension of the use of the DoC to non-harmonized FCM&A, along with clearer rules on the information that should be reported in this document.
Our experience shows that it is strongly required to receive sufficient information from suppliers outside the EU, therefore the enforcement of the EU legislation towards importers has to be strengthened.

5. Enforcement of rules on FCMs is generally poor

We generally agree that in several Member Countries the enforcement of FCM legislation is insufficient. This represents a problem as it causes the false perception of lack of safety for FCM&A that is in fact lack of control. We would welcome a significant increase of resources and expertise at Member States level.

Regarding the availability of standards for testing substances , although it is true that a limited number of accredited test methods are available, we believe that methods for substances subject to the process of application to EFSA can be available as a result of such process. These methods should be considered and possibly adopted.
Also, several existing standards currently used in FCM&A are available and ready to be adopted horizontally, one example being the rules utilized in risk assessment, such as the Threshold of Toxicological Concern.

6. Rules do not sufficiently take into account the specificity of SMEs

SMEs should have the same obligations towards safety of FCM&A than all other companies. It is important, however, to avoid complex and bureaucratic rules in order to help all business operators, not only SME, to remain competitive in the global market.

7. Rules do not encourage development of safer and more sustainable alternatives

The concept of “safer alternatives” should be clarified; it is necessary that safety of FCM&A is objectively defined, not based on perception of risk. FEC Members has always invested in the development of fully compliant products with the highest standards of safety, on the other hands we have no evidence that border controls in the EU has been always capable to detect non-compliant materials imported from other countries.

We are in favour of encouraging more sustainable alternatives, and in this context we urge the Commission to take measures to rule the use of recycled plastics in FCM&A, and to extend the rules in order to foster innovation, such as new recycling technologies (chemical recycling, physical recycling, etc.).

In no case, however, FCM&A with more sustainable profiles should make compromises on safety.

8. The subject matter is not always clear and definitions need to be reviewed

Better definition of the field of application is required, especially to clarify the meaning of “reasonably be expected to be brought into contact with food” set by art 1(2), leaving large room for interpretation. Cases of unintended use of articles should not lead to unnecessary limitations.

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B. OBJECTIVES AND POLICY OPTIONS

1. Shifting the focus onto final materials

The focus on final materials can only be enforced properly if a more efficient system is put in place allowing the manufacturers and users of the final materials to access the information they need. It is important that reliable exposure models and agreed risk assessment guidelines are developed, adopted and made public.

In any case, shifting the focus on final materials should also include that a proper assessment is made by each relevant stakeholder in the supply chain, and that all relevant information is duly communicated downstream.

2. Prioritising the assessment and management of substances

While we recognize the limitations of the positive lists and the need of prioritization and more efficient management of substances, we outline that

- Prioritization should primarily concern substances that have a critical hazard profile and to which consumers are exposed through ingestion (via migration from FCM&A)
- Assessment of groups of substances should be done when these substances show common characteristics, such as same or similar migration behaviour, same or similar hazard profile etc.
- We do not agree on prioritization that does not consider the actual exposure of consumers to the concerned substances. This can only introduce unnecessary burden and represent an obstacle to innovation.
- The precautionary principle should not be used to compensate lack of information on hazard and exposure.

The approach "one substance one assessment" must take into consideration the different way of exposure of a chemical substance. For FCM, oral exposure is relevant, and we disagree on using different routes of exposure as a proxy for oral intake. This is scientifically incorrect and may lead to unnecessary limitation.

3. Supporting safer and more sustainable alternatives

Development of more sustainable FCM&A must not be driven forward at the expense of food safety. In particular, recycling of plastics in food contact applications must be backed-up by clear guidance on how to perform safety evaluation of the recycled packaging.

Ensure exchange of information in the supply chain, support for SMEs and enforcement of the rules.

4. Improving quality and accessibility of supply chain information for compliance and enforcement

We welcome the improvement of information communicated in the supply chain, enabling FCM&A manufacturers to carry out a proper risk assessment. Adoption of more detailed format for DoC, as well as extension to non-harmonized FCM&A would be of help. These DoCs should ideally include information on NLS and NIAS, impurities, degradation products, etc. so that downstream users can do an appropriate risk assessment of their final articles.

Establishing a new system for digital DoCs should be weighed against the benefit that it can provide, and its design should involve multiple stakeholders, including industry. It also should take in due consideration the need of protection of confidential business information. This should ideally allow not only authorities but also downstream users to access the information necessary for compliance and risk assessment.

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5. System for ensuring compliance of the final FCM

It is of utmost importance that the responsibility for compliance and assessment of the products introduced in the market is maintained by the relevant business operators. For such reason we believe that the use of notified bodies in charge for pre-market approval for FCM&A would be detrimental, adding a layer of burden without any benefit for consumers.

Outsourcing of market surveillance may be helpful in countries where enforcement is insufficient, however there must be clear rules on responsibilities, attention should be paid to avoid conflicts of interest, and a full EU harmonization of the procedures used to carry out such surveillance should be in place. Delegated bodies may represent a viable solution, and may be of help especially for SME to properly understand and fulfil their compliance duties.

Options

In line with the findings of the Ecorys investigation, we believe that the current Regulation (EC) 1935/2004 already defines the safety objectives that should be met by FCM&A. A clear proof of the above is that such regulatory scheme has been widely adopted by other jurisdictions around the world, such as Mercosur, China, Turkey and several other countries. We are therefore in favour to maintain the existing regulatory framework and concentrate the efforts in the material specific legislation and in the flow of information within the supply chain. It may also be worthwhile developing horizontal specific rules that would enable a wider harmonization, such as rules for risk assessment, transmission of information, DoC, testing standards, etc.

C. PRELIMINARY ASSESSMENT OF EXPECTED IMPACTS

1. Economic Impact

We disagree linking “decreased health costs and reduced cancer incidences” to FCM&A. This not only lacks of evidence, but contributes to building the false perception that FCM&A would increase cancer risk.
On the contrary, health risks can more likely arise from inadequate distribution, preparation and consumption of food (decay, infestations, consumption of inappropriately cooked food, etc). This is likely much higher than risks associated with substances migrating from FCM&A.

FEC welcomes a simplified and harmonized food contact rules, as this will improve competitiveness, growth and innovation. It will also promote development of circular economy and more sustainable articles.

2. Likely Social Impact

Agreed

3. Likely Environmental Impact

We do not disagree with the idea that FCM&A should contribute to circular economy, however we outline that environmental objectives and safety objectives should not be mixed in the same legislative framework. In particular no compromise should be made on safety of FCM&A trying to meet environmental objectives.

4. Likely impacts on fundamental rights

Agree

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5. Likely impacts on Simplification and/or administrative burden

It is important to make sure that digitalization does not add extra burden in an area where demonstration of compliance is already very complex.

D. EVIDENCE BASE, DATA COLLECTION AND BETTER REGULATION INSTRUMENTS

1. Impact assessment

We agree that running a full Impact Assessment is necessary before taking decisions on the regulatory measures to be proposed. We believe that industry should be consulted and included in the policy discussion, to make sure that no excessive burden is added to a sector that is already delivering safe and high performance products to the market. All possible policy options should be such as to make sure that the European industry remains competitive on a global market.

2. Evidence base and data collection

No particular comments on this paragraph.

3. Consultation of citizens and stakeholders

We welcome a wide public consultation with all relevant stakeholders, including professional associations and individual business operators.

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