

FCA additional comments to Commission public consultation on the evaluation of the FCM legislation

Dear all,

Further to our input to the above questionnaire, FCA – the Food Contact Additives Sector Group of Cefic, the European Chemical Industry Council, would like to offer additional comments.

Regulation (EC) No 1935/2004 provides an excellent framework to ensure a high level of food safety

The main objective of Framework Regulation (EC) No 1935/2004 is to ensure a high level of human health and consumer protection. This Regulation is consistent and fully coherent with the approach, principles and methodology laid down in General Food Law Regulation (EC) No 178/2002, which is internationally recognised as providing EU citizens with a high level of food safety.

In this respect, we believe that Regulation (EC) No 1935/2004 – and its subsequent implementation – has continued to achieve its objectives by providing the basis for this high level of protection of human health and the interests of consumers in relation to Food Contact Materials (FCMs). We believe that the Regulation is extensive, clear and provides a scientifically sound baseline and expert advice for ensuring the safety assessment of FCMs.

Regulation (EC) No 1935/2004 provides an excellent harmonised framework applicable to all FCMs and sets the basis for a full harmonisation of the materials listed in Annex I. Currently however, the functioning of the European internal market is negatively affected by the absence of this full harmonisation of FCMs at EU level, except for certain materials, e.g. plastics.

Lack of full harmonisation fragments EU Single Market

In the absence of this full harmonisation, the EU subsidiarity principle allows Member States to step forward with national specific FCM legislation for the non-EU harmonised materials. In this regard, one should keep in mind that a given Member State can only act within geographical boundaries to set up national legislation and may discuss issues only with the corresponding industry residing in that Member State. In today's globally organised value chains, this means that not all stakeholders are consulted, because they are not present or represented in that specific Member State. In addition, language barriers inhibit a fruitful working opportunity on such national specific legislation. We strongly believe that at present, only the EU provides sufficient resources and consultation power for a single market approach.

The fact that individual countries have specific legislation on FCMs results in repeating petition obligations for industry. While in theory, the risk assessment follows the same principles, i.e. the EFSA note for guidance for FCMs, practice has shown that the criteria differ across Member

FCA (Food Contact Additives)

Avenue E. van Nieuwenhuysse 4 B-1160 Brussels Belgium
Tel. +32.2.436.93.00 map@cefic.be <http://fca.cefic.org/>

A sector group of Cefic 

European Chemical Industry Council - Cefic aisbl

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States. The petition dossiers need to be adapted to meet national evaluation specificities. There is a general trend of some Member States not accepting new scientific elements supporting the risk assessment methodologies, e.g. acceptance of in-silico tools. In addition to that, the deviating Member State's specific measures hamper mutual recognition, which should be the main element in the single market concept. The current "non-harmonisation" creates internal market barriers, even though the safety of the FCM is ensured by the Framework Regulation (EC) No 1935/2004.

This leads to increased costs of compliance for businesses, particularly SMEs which do not always have the resources to ensure cross-border compliance.

In a non-harmonised landscape, legal complexity, costs, need of resources and expertise, as well as language barriers are issues for all companies, including SMEs. If no official translation is available, legal compliance is difficult, due to unofficial translations and interpretations.

Full harmonisation for all FCMs is needed

To support the functioning of the internal market, Regulation (EC) No. 1935/2004 should be either the sole basis for ensuring the safety of FCMs or otherwise supported by harmonised specific measures for non-plastics materials. Harmonisation would support the speed of authorisation with only one petition for all Member States in contrast to several petitions for different Member States.

Substances are risk assessed following internationally recognised scientific principles

In those cases where the legislation requires industry risk assessment (e.g. Art 19 of the plastics regulation (EU) No 10/2011) for specific types of substances, the general approach follows both EFSA and internationally recognised risk assessment principles. Industry has developed and published these principles in various guidelines (e.g. FCA Guidelines on Risk Assessment of non-listed substances (NLS) and non-intentionally added substances (NIAS) under the requirements of Article 3 of the Framework Regulation (EC) 1935/2004 ¹). The outcomes and details of such assessments are available to competent authorities.

¹ https://fca.cefic.org/images/FCA_Risk_Assessment_Guidelines_v2.0.pdf

