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**SME Panel Questionnaire – Evaluation of Food Contact Material Legislation**

Food Contact Materials (FCMs) are all materials and articles which are intended or can be expected to come into contact with food. This includes materials used in professional food manufacturing, preparation, storage and distribution, and also food packaging, kitchenware or tableware. A wide range of materials may be used to make FCM such as glass, metal, paper, plastics. But also adhesive, printing inks and coatings are used in the final articles, as well as composite materials.

Regulation (EC) No 1935/2004 of the European Parliament and Council provides a harmonised legal EU framework for FCMs. It sets out the principal objectives of the FCM legislation: firstly, to secure a high level of protection of human health and the interests of consumers. Secondly, to ensure the effective functioning of the European Union market, i.e. to avoid restrictions or tariffs or the creation of conditions of unequal and unfair competition.

Besides, Article 3 of Regulation (EC) No 1935/2004 sets out the general requirements which require all FCMs to be manufactured in compliance with good manufacturing practices (GMP) so that under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could:

* Endanger human health; or
* Bring about unacceptable change in the composition of the food; or
* Bring about a deterioration in the organoleptic properties – taste and smell, for example – of the food.

To take into account technological developments, Regulation (EC) No 1935/2004 introduced an updated list of materials for which specific measures can be adopted. Moreover, Article 5 provides for the establishment at EU level of specific measures. One type of specific measure that the Regulation allows for is the establishment of authorised lists of substances to be used to manufacture FCMs. Articles 8 to 14 of the Regulation therefore set out specific procedures for the safety assessment and authorisation of such substances. Anyone who wants to place an FCM manufactured with an unlisted substance on the market needs to apply to the Competent Authority of a Member State. The European Food Safety Authority (EFSA) provides an opinion on the safety of the substance. If the opinion is favourable, the Commission can authorise the substance.

Article 6 allows Member States – in the absence of specific measures at EU level – to maintain or adopt national provisions. Member States need to implement the [mutual recognition principle](http://ec.europa.eu/growth/single-market/goods/free-movement-sectors/mutual-recognition_en)[[1]](#footnote-1): any product that is lawfully sold in one EU country can be sold in another. This applies even if the product does not fully comply with the technical rules of the other country.

Article 16 and 17 of regulate the compliance documentation for FCMs and traceability requirements. These measures were introduced to promote traceability and self-control for businesses operators. They also ensure the transparency and flow of information throughout the manufacturing chain. Besides, FCMs must be traceable by means of labelling, relevant documentation or information. These provisions – and the documentation of compliance – aim at ensuring the free movement of FCMs on the market.

The Regulation concerns only the chemical safety of FCM in relation to human health. It doesn’t provide for hygienic, waste management or environmental requirements.

In addition to the Regulation, a series of measures have been established for specific materials and substances. Specific measures exist for plastic FCMs (including recycled plastic), ceramics, and active and intelligent materials. Besides, Regulation No 2023/2006 sets out rules on Good Manufacturing Practices (GMP) that apply to all stages in the manufacturing chain of FCM, except starting substances. To ensure the safety of plastic food contact materials, Regulation (EU) No 11/2011 defines migration limits which specify the maximum amount of chemical substances allowed to transfer from the food contact material to food.

The European Commission has launched the evaluation of the FCM Regulation to further improve the legislation. The overall purpose of this evaluation is to assess whether the current EU legislative framework for FCMs is working and delivers as expected.

The analysis aims at evaluating how the approaches, the procedures and the processes of the Regulation and its implementation contribute to protecting human health and ensure the effective functioning of the internal market for FCM. The analysis focuses on the major requirements of Regulation (EC) No 1935/2004. Namely, the analysis covers the positive authorised listing approach, the risk assessment and risk management processes of authorities and business operators, and the implementation of GMP, including information sharing along the FCM supply chains.

This survey gathers data from small and medium enterprises (SMEs) for this evaluation. It explores the awareness of SMEs of the general requirements of the FCM legislation and their views on the functioning of the legislation. The survey further collects information on how the legislation affects businesses. This survey addresses businesses along the FCM supply chain. this includes (but is not limited to) manufacturers of starting materials, distributers, laboratories specialising in compliance, caterers, and retailers.

Once the evaluation of the FCM legislation is completed, a synopsis report of all consultation activities, including this survey, will be published on the following consultation page:

<https://ec.europa.eu/food/safety/chemical_safety/food_contact_materials/evaluation_en>

1. <http://ec.europa.eu/growth/single-market/goods/free-movement-sectors/mutual-recognition_en> [↑](#footnote-ref-1)