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European Commission

# EVALUATION ROADMAP

Roadmaps aim to inform citizens and stakeholders about the Commission's plans in order to allow them to provide feedback on the intended initiative and to participate effectively in future consultation activities. Citizens and stakeholders are in particular invited to provide views on the Commission's understanding of the problem and possible solutions and to make available any relevant information that they may have, including on possible impacts of the different options.

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|---|---|
| **TITLE OF THE EVALUATION** | Evaluation of Food Contact Materials (FCM) |
| **LEAD DG – RESPONSIBLE UNIT – AP NUMBER** | DG SANTE – Unit E2 – PLAN/2016/436 |
| **INDICATIVE PLANNING (PLANNED START DATE AND COMPLETION DATE)** | PLANNED START DATE: Q1 2018<br>PLANNED COMPLETION DATE: Q2 2019 |
| **ADDITIONAL INFORMATION** | https://ec.europa.eu/food/safety/chemical_safety/food_contact_materials/consultation_en |

**The Roadmap is provided for information purposes only. It does not prejudge the final decision of the Commission on whether this initiative will be pursued or on its final content. All elements of the initiative described by the document, including its timing, are subject to change.**

## A. Context, Purpose and Scope of the evaluation

### Context

Food contact materials (FCMs) are all materials that come into contact with food including packaging as well as every-day items such as kitchen and table ware and those used in professional food manufacturing, preparation, storage and distribution. Regulation (EC) No 1935/2004 (the FCM Regulation) provides that these materials shall not transfer their components into food in quantities that could endanger human health or change the composition, or organoleptic properties of the food. The principal objectives of the legislation are to:

1. Provide the basis for securing a high level of protection of human health and the interests of consumers;
2. Ensure the effective functioning of the internal market.

The Regulation complements other EU legislation related to the safety of chemical substances such as REACH, as well as other legislation on the safety of the food chain, including the General Food Law.

The size of the industry is significant (circa. €100 billion) and the Regulation has never been systematically assessed since the inception of its basic provisions set out in 1976. On the basis of evidence presented, including a recent JRC study it also appears that there are issues concerning the disparity between detailed harmonised EU rules on plastic FCMs and the absence of EU rules for many other materials, which in turn may negatively affect the correct functioning of the internal market due to national divergent rules as well as potentially the safety of FCMs.

In light of this and the inefficiencies that have also been highlighted in the existing approach to regulating FCMs including plastic FCMs, a need has been identified to evaluate how the current Regulation has performed in relation to its original objectives.

### Purpose and Scope

The purpose of this evaluation is to assess whether the current EU legislative framework for FCMs is fit for purpose and delivers as expected. It will assess the overall effectiveness, efficiency, relevance, coherence including coherence with other chemicals and food legislation, and EU added value of the FCM Regulation. The evaluation will cover the functioning of the FCM Regulation in its entirety and the rules and tools provided for by this legislation (see intervention logic in annex) applicable in the European Union. For example this will include the relevant aspects of specific implementing measures. It will also examine the situation concerning materials for which there are no EU specific measures and which are subject to national measures which are permitted.

The period of the evaluation will start from when the FCM Regulation entered into force in 2004 as regards those elements that were introduced or modified in this Regulation. However, the evaluation will also cover the period concerning the general rules that have been maintained since the introduction of the earliest FCM legislation in the EU.

## B. Better Regulation

### Consultation strategy

Consultations will be carried out to engage all relevant stakeholders and seek their opinion on the main evaluation criteria (relevance, efficiency, effectiveness, coherence and EU added-value). It will also seek a general view on the scope and approach set in the FCM Regulation and aims to identify any unexpected impacts or issues as a consequence of the current Regulation.

Relevant stakeholders for which this consultation may be relevant include, but are not restricted to:

- Member States' national authorities including central competent authorities, local or regional enforcement bodies and control laboratories;
- FCM professional associations including those that represent small and medium sized enterprises (SMEs);
- Professional associations or individuals representing any relevant parts of the supply chain including chemicals industry, importation of goods from third countries and the food industry;
- Individual businesses operators including food business operators, and in particular SMEs and microbusinesses not represented by professional associations;
- The European Parliament;
- EU citizens and members of the general public (consumers);
- Non-governmental organisations (NGOs) including consumer watchdogs;
- Relevant European bodies including the European Food Safety Authority (EFSA);
- Scientific experts relevant to the field of FCMs including those in the field of research or academia;
- Other relevant professional bodies e.g. consultancies, think tanks and law firms.

An extensive consultation process will be undertaken structured around three main axes of actions:

- A 12-week internet based public consultation will take place to ensure transparency and accountability and give any interested party the possibility to contribute. The questionnaire will be available in all official EU languages and the replies can also be submitted in all official EU languages. This is provisionally planned to take place in the second or third quarter of 2018;
- A set of targeted consultation activities tailored for particular stakeholders' groups, including surveys, interviews and case studies will be conducted in the context of the evaluation study run by a consultant;
- A stakeholder conference/ workshop/ seminar is also foreseen to take place during the evaluation to complement the process, gather views and ensure that all relevant interested parties are included.

The consultation will be published on the Commission's Public Consultations database. Further information on the consultation will be published on the Food Contact Materials - Consultation web page.

### Data collection and methodology

No formal evaluation work or reports on Regulation (EC) No 1935/2004 have been carried out to date by the European Commission. The JRC has recently completed a base-line study focussing on those FCMs for which no specific measures exist at the EU level. The report provides a comprehensive picture on the state of play concerning both regulation and markets in Europe.

The Commission also holds information concerning audit and fact-finding work carried out by DG SANTE Directorate F as well as recently gathered information on the use of compliance documentation in the supply chain.

In May 2016, a European Implementation Assessment report on Regulation (EC) No 1935/2004 was published by the European Parliament, which concluded that the lack of specific measures at EU level for some food contact materials negatively impacts the functioning of the internal market for the relevant material or article and its food safety.

The evaluation will also complement other evaluations or assessments that have been carried out or are ongoing by the European Commission, in particular those in the areas of chemicals legislation and food safety.

**Annex – Intervention logic**

| BASIC PROBLEMS | | DRIVERS (WHY PROBLEMS EXIST) | | POLICY OBJECTIVES | | TOOLS | | ANTICIPATED RESULTS |
|---|---|---|---|---|---|---|---|---|
| Substances in FCMs may endanger human health or bring about an unacceptable change in the composition or taste | → | FCMs are not inert and substances with hazardous properties may within them be transferred to food in sufficient quantities to cause a risk to consumers | → | Secure a high level of protection of human health and the interests of the consumer by requiring that FCMs do not endanger human health or change the composition or organoleptic qualities in an adverse way | → | National measures may be introduced by Member States alongside EU measures | → | FCMs are safe for human health |
| | | | | | | General requirements | | |
| | | | | | | Possibility of safeguard measures | | |
| | | | | | | Labelling requirements | | |
| Free movement of FCMs on the internal market may be hindered, creating conditions of unequal and unfair competition | → | Differences which exist or may evolve between national laws, regulations and administrative provisions concerning the safety assessment and authorisation of substances used in the manufacture of FCMs | → | Ensure the free movement of FCMs on the market | → | DoC for specific measures | → | Effective functioning of the internal market |
| | | | | | | New specific measures may be introduced | | |
| **IDENTIFIED PROBLEMS (PRE-2004)** | | | | | | | → | Consumers use FCMs appropriately and safely |
| Some new types of FCMs and processes introduced to the market or identified as relevant. Unclear if these were covered at national or EU level | → | Technological progress in the area of food packaging is rapid and intense with new types of packaging developed including active & intelligent materials (AIM) and recycled plastics | → | Take into account important technological developments in the area of food packaging | → | A revised list of materials for which specific measures can be made | → | AIM are safe and new materials on the market are specifically regulated |
| | | | | | | Special rules for AIM | | |
| Procedures for the safety assessment of FCM substances not transparent or detailed enough | → | Not set out sufficiently in the previous Directive. Establishment of and need to involve EFSA | → | Improve transparency of the authorisation process by specifying the various phases of the procedure | → | Procedure set out including EFSA for establishment of positive authorised list of substances | → | EFSA assesses risk from all substances to be placed on positive authorised list. Authorisation process is fully transparent |
| Uniform and timely application of the rules not ensured | → | No possibility to implement Decisions or Regulations | → | Give powers to the Commission to adopt Decisions and Regulations | → | Implementation of Regulation | → | Measures apply without delay |
| Traceability is not ensured along the supply chain | → | Provisions on traceability established in Regulation 178/2002 do not apply to FCMs | → | Ensure better traceability | → | Rules on traceability | → | Traceability of FCMs is ensured at all stages |
| Enforceability at the technical level is not ensured | → | Provisions for European Union-Reference laboratory (EU-RL) or National Reference Laboratories (NRLs) do not exist | → | Ensure better enforceability of the rules through establishment of EU-RL/ NRL | → | Requirement to carry out controls and have sanctions | → | MSs carry out official controls on FCMs and can enforce rules |
| | | | | | | Regulation 882/2004 | → | EU-RL and NRLs are established for FCMs |