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EC Evaluates Performance of FCM Legislation: What You Need to Know and How to Respond

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As Brexit is eclipsing nearly all other developments in Europe these days, we write to alert you to *another* important development underway in the European Union (EU). As discussed in detail below, the European Commission (EC) has initiated a process to evaluate and likely revise the EU framework addressing the regulation of food contact materials (FCM). Regulation (EC) No 1935/2004 (Regulation) provides this framework and has done so since its adoption in October 2004 with varying degrees of success given the divergence of national standards sprinkled throughout the EU. The framework provides for special rules on active and intelligent materials; powers to enact additional EU measures for specific materials; a procedure to perform safety assessments of substances used to manufacture FCMs involving the European Food Safety Authority (EFSA); rules on labeling, including an indication for use, either by language or the appropriate symbol; and compliance documentation and

traceability. The EC has wisely (and bravely given the complexity of the process) concluded there is a need to evaluate how the current Regulation has performed in relation to its original objectives, which were (1) to facilitate the free movement of FCMs and articles within the European Economic Community (EEC); and (2) to expand the scope of the previous legislation (Directives 80/590/EEC and 89/109/EEC) to include new types of materials and articles such as active ingredients and intelligent food contact materials, "for reasons of clarity and legal certainty," all while protecting public health and the interests of consumers.

The purpose of the evaluation now underway will be to assess the general effectiveness, efficiency, relevance, coherence, and EU added value of the FCM legislation. The evaluation will cover the functioning of the FCM Regulation in its entirety and the rules and tools provided for by this legislation, including the way in which the specific implementing measures regulate FCMs. The evaluation will also examine the situation concerning materials for which there are no EU specific measures and that are subject to national measures.

We wish to bring this evaluation process to your attention for three reasons. First, too little attention has been devoted to this initiative on this side of the pond. Second, many of our clients have significant commercial interests in FCMs, and an initiative of this scale will have major implications for the EU market and beyond. Third, when a significant trading partner like the EU decides to evaluate and likely amend a foundational legal framework, it is almost certain to have precedent-setting implications for other regulatory and standard-setting bodies elsewhere. Following our summary below, we offer suggestions on how best to engage to ensure your business interests are protected.

Joint Research Center Baseline Study

In January 2017, the Joint Research Center (JRC) published a baseline study that provides an EU-wide review at the national and sectorial levels on FCMs for which there are no specific measures at the EU level. The JRC study reviewed the frameworks for food safety compliance and the burden of having only national legislation. It found four principal shortcomings to the current situation:

1. There is a lack of common guidelines and transparency in undertaking risk assessment work across EU Member States. Schemes and requirements for the authorization of substances are not the same in all Member States and often differ from that of EFSA. The potential of risk assessment tools developed in the EU is not fully exploited;

2. National measures can be difficult to access and are not always consistently structured or sufficiently detailed. Standards on common food safety requirements that are applicable to all FCMs and uniform Good Manufacturing Practices (GMP) are needed;

3. Measures are based on lists of authorized substances (with a total of close to 8,000), but show disparities among Member States in the nature of substances considered, the type of restrictions imposed, and their numerical values. This leads to multiple testing requirements and further complicates mutual

recognition; and

4. Testing methods lack uniformity and consistent standards for demonstration of efficacy -- making compliance, demonstration of food safety, and enforcement more difficult to ensure consistently throughout the EU.

The baseline study mapped the industry supply chain and national frameworks in place for these materials. According to JRC, this information will allow the EC to assess the efficiency and effectiveness of the current regulation, including the benefits and administrative burdens on businesses. It will support the EC's evaluation to consider what, if any, possible steps need to be taken in the future concerning the regulation of FCMs in the EU.

Roadmap

According to the EC's web page on the evaluation of FCMs, the starting point for the evaluation is a November 2017 roadmap intended to inform citizens and stakeholders about the EC's plans and to allow them to provide feedback and participate in future consultation activities. The roadmap states that the period of the evaluation will start from the October 2004 entry into force of the FCM Regulation as regards those elements that were introduced or modified with the repeal of the previous legislation, Directive 80/590/EEC, including its multiple Adaptations to Technical Progress. This approach, while covering the period and general rules that have been maintained since the introduction of the earliest FCM legislation in the EU, will structure an extensive consultation process 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. 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; and

- 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.

Stakeholder Workshop

In September 2018, the EC Directorate-General for Health and Food Safety (DG SANTE) held an introductory stakeholder workshop as the first major step in the consultation process. According to the EC, there was involvement from a wide range of stakeholders representing all interests on FCMs. The EC has posted the following workshop materials:

- Agenda;
- Workshop document;
- Summary;
- Video-recording;
- List of participating organizations;
- **Presentations:**
  - Part 1(a) FCMs background and evaluation;
  - Part 1(b) Baseline study;
  - Part 1(c) EFSA risk assessment;
  - Part 2(a) Stakeholder perspectives (non-governmental organizations (NGO));
  - Part 2(b) Stakeholder perspectives (Plastics Coordination Group (PCG));
  - Part 2(c) Stakeholder perspectives (Cross Sector Group (CSG));
  - Part 2(d) Stakeholder perspectives enforcement; and
  - Part 3 Study approach and consultation.

Evaluation Questions

The EC prepared ten questions covering the five evaluation criteria:

Effectiveness

1. To what extent has Regulation (EC) No 1935/2004 and subsequent implementation achieved its objective of providing the basis for securing a high level of protection of human health and the interests of consumers in relation to FCMs?

2. To what extent has Regulation (EC) No 1935/2004 and subsequent implementation ensured the effective functioning of the internal market in relation to the placing on the market in the EU of FCMs?

Efficiency

3. What are the quantifiable benefits, taking into account resources (cost, time) to stakeholders, including:

a. Consumers (*e.g.*, health and safety benefits);

b. Business operators, including specifically for small- and medium-sized enterprises (SME) and microbusinesses (*e.g.*, in demonstrating compliance, market access); and

c. Member States' Competent Authorities (*e.g.*, in ensuring safety and control of FCMs)?

4. What are the quantifiable burdens, taking into account resources (cost, time) to stakeholders and are there aspects that could be simplified to improve efficiency?

5. Taking into account the answers to questions 3 and 4, how efficient is Regulation (EC) No 1935/2004 and its implementation tools in ensuring the safety of FCMs?

Relevance

6. What are the needs, interests, and expectations of the following stakeholders and to what extent does the current legislation address them:

   a. Consumers and their representative organizations?

   b. Business operators including food business operators?

   c. Member States' Competent Authorities?

7. To what extent has Regulation (EC) No 1935/2004 and its subsequent implementation allowed for evolving science, prioritization, and innovation?

Coherence

8. To what extent is Regulation (EC) No 1935/2004 internally coherent, including all of its implementing acts?

9. To what extent are Regulation (EC) No 1935/2004 and its subsequent implementation including the risk assessment and risk management approaches taken, externally coherent with other relevant legislation and policies?

EU Added Value

10. What is the EU added value of Regulation (EC) No 1935/2004 in relation to its main objectives?

Timing

The EC states that it will launch a 12-week open public consultation on its Better Regulation Portal as part of the stakeholder consultation process. The consultation will be available in all official EU languages, aimed at capturing opinions and views of the general public, including consumers, to answer the evaluation questions. The EC foresees that it will complete its evaluation in **early 2020**, including dissemination activities and preparation of the Staff Working Document.

Stakeholder Consultation

The consultation process is intended to engage all stakeholders and to collect supporting information, data, and knowledge on the functioning and application of Regulation (EC) No 1935/2004 and its associated and implementing measures. According to the EC, the consultation activities intend to seek stakeholders' experiences and views on the scope and the approaches set in the Regulation, as well as to identify any positive or negative effects, including unexpected impacts, and any emerging issues as a consequence of the current legislation. Consultation activities will be designed in such a way that they will support the EC in answering the evaluation questions.

The EC will consult stakeholders on the following key aspects: the positive authorized listing approach; authorization procedures; risk assessment and risk management processes; enforceability of the Regulation and enforcement practices; GMPs including transparency and traceability practices; costs of implementation of the Regulation and its associated measures; and regulation of FCMs by Member States at the national level and for which no specific measures exist at the EU level.

The EC will record and summarize all stakeholder activities, including consultation methods, outcomes, and results, in a synopsis report that will be published online.

Commentary

The review now underway is as significant for U.S. based FCM manufacturers as it is for EU entities. The Acta Group (Acta®), with offices in Brussels, Belgium; Manchester, United Kingdom; Beijing, China; and Washington, D.C., is well suited to assist our clients and interested others in monitoring and engaging in this vitally important and quite momentous initiative. Our practice consists of seasoned professionals and scientists intimately familiar with the close interplay between domestic and EU FCM law and regulation, and the important regulatory and trade implications the FCM evaluation invites.

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