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Regulatory Developments EC Begins Public Consultation on Evaluation of FCMs

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The European Commission (EC) began a public consultation on February 11, 2019, on the evaluation of food contact materials (FCM). The purpose of the evaluation is to assess whether the current European Union (EU) legislative framework for FCMs is fit for purpose and delivers as expected. The evaluation covers the functioning of Regulation (EC) No 1935/2004 (Regulation) in its entirety and the rules and tools provided for by the legislation, such as specific implementing measures. It also examines the situation concerning materials for which there are no EU measures and which are subject to permitted national measures. Comments are due **May 6, 2019**.

Article By Bergeson & Campbell, P.C.
ACTA Group
The ACTA Group Regulatory Developments
Administrative & Regulatory
Biotech, Food, Drug
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Background

As reported in our January 22, 2019, memorandum, "EC Evaluates Performance of FCM Legislation: What You Need to Know and How to Respond," the Regulation provides the legislative framework for FCMs 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.

Target Audience

The consultation targets all stakeholders groups with an interest in the FCM legislation, including:

- The general public;
- All businesses at any stage of the FCM supply chain and their European or national representatives;
- Non-governmental associations and consumer organizations; and

- Public authorities, including public enforcement laboratory and regional/local enforcement offices.

Why the EC Is Consulting

The EC states that the FCM legislation provides a harmonized legal EU framework for FCMs and sets out the general principles of the safety of FCMs, as well as rules on labeling, compliance documentation, and traceability. The legislation provides the basis for securing a high level of protection of human health and the interests of consumers, and to ensure the effective functioning of the internal market as regards to placing FCMs on the market.

The consultation is a part of the EC evaluation of the EU legislation on FCMs. The evaluation aims to assess to what extent the current EU legislative framework for FCMs is fit for purpose and delivers as expected; and to identify any unexpected impacts or issues as a consequence of the current legislation. In addition, the evaluation will show whether the objectives and tools of the FCM legislation are still relevant and coherent.

The consultation aims to gather views and evidence from a wide range of stakeholders on the functioning of the FCM legislation and the requirements that the legislation sets for businesses and public authorities. The EC will take into account the feedback received from the consultation. Once it completes its evaluation of the FCM legislation, it will publish a synopsis report of all consultation activities.

Responding to the Questionnaire

Stakeholders can contribute to the consultation by filling in the online questionnaire. Questionnaires are available in some or all official EU languages. Responses can be submitted in any official EU language. For reasons of transparency, the EC asks organizations and businesses taking part in public consultations to register in the EU's Transparency Register.

Commentary

As we noted in our January memorandum, 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.

The review now underway is as significant for U.S.-based FCM manufacturers as it is for EU entities.

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