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Revision of EU rules on food contact materials: Inception Impact Assessment

The Food Packaging Forum (FPF) is a charitable, science-based organization dedicated to raising awareness for hazardous chemicals in all types of food contact materials and articles (FCMs and FCAs). We welcome the opportunity to provide input on the EU's plans for modernizing its FCM rules.

1. The Problem

Definition of Safety:

The Inception Impact Assessment (IIA) describes the challenges related to the existing FCM regulation. However, in our opinion, not only the absence of specific EU rules is of concern, but also the way that safety is currently defined in Art. 3 of the Framework Regulation 1935/2004 is not aligned with the current scientific understanding. The Framework Regulation's generalized threshold concept of chemical safety needs to be replaced with an approach anchored in current knowledge. Assuming there are safe thresholds for chemicals that migrate as default is outdated and not in line with current scientific understanding. Therefore, instead of implicitly assuming that for all chemicals there are safe exposure levels ("quantities which could endanger human health"), modern science needs to be reflected in a revised safety definition that is aligned with the EU Chemical Strategy for Sustainability (CSS).

In particular, the safety definition should acknowledge that (1) some chemicals have effects at low levels (mutagens, carcinogens, endocrine disrupters) and therefore all chemicals migrating from FCMs need to be tested for the hazard properties of most concern. Further, chemicals with hazard properties of most concern shall not be present in FCMs (neither intentionally added, nor non-intentionally added). (2) Some chemicals have effects at low levels on young children, but they also cross the placenta and affect the developing fetus. Therefore, it is insufficient to remove these chemicals only from children's products- instead, they need to be removed from all FCMs because of fetal exposure via mothers. And (3), the mixture toxicity of all chemicals migrating from FCMs is of serious concern for human health and needs to

be assessed for finished FCMs and FCAs—moving away from the current "substance-by-substance" assessment. We have summarized the relevant scientific evidence and compiled options for policy makers moving forward, including an iterative multi-stakeholder dialogue to identify solutions https://www.foodpackagingforum.org/news/scientific-consensus-statement-on-food-contact-chemicals-and-human-health.

2. The Objectives

Hazard-based Approach: When prioritizing the assessment and management of substances, not only the risk to consumers should be of interest, but also (1) the human health hazards of the chemicals as such (regardless of migration and consumer exposure) and (2) the environmental hazards of chemicals. FCMs may inadvertently enter the environment and become sources of chemical contamination in different environmental compartments. Therefore, in our opinion environmental hazards must also be addressed for the finished FCMs and FCAs (such as PBT, vPvB, PMT and vPvM). What is more, in a circular economy, where FCMs are increasingly reused and recycled, chemical risk management becomes an even greater challenge. Therefore, a more conservative approach to managing chemicals, that is also aligned with the values of the EU, and that is outlined in the CSS, is to focus on the intrinsic hazard properties of chemicals and to avoid the use of hazardous chemicals where possible and feasible. The CSS points to the essential use concept which should consequently also be adopted in the FCM regulation, to guide companies when selecting and developing chemicals for FCM use. This would also simplify the rules considerably and likely facilitate enforcement. A hazard-based approach to FCM chemicals management will be critical for enabling a clean circular economy.

Moreover, the inception impact assessment describes the positive list approach and states that it is almost impossible to address all substances in non-harmonised materials at the present capacity of risk assessments and subsequent EU authorization. We certainly agree with the Commission's conclusion that shifting the focus from only the starting substances to the final material is needed. However, the assessment of starting substances is essential and should remain mandatory. Therefore, we welcome strategies on how to handle the steadily increasing complexity of food contact materials and would like to see more focus on limiting the number of chemicals used in a defined set of food contact materials. This approach would further help to develop materials that are easier and safer to be recycled, and contribute to an achievable enforcement of FCMs.

Modern Science: the prioritization of substances of concern should be carried out in a systematic, transparent way and it should be updated regularly, based on the most current knowledge. At FPF, we have recently published a prioritization of intentionally added substances likely used in FCMs, using a

peer-reviewed methodology https://www.foodpackagingforum.org/news/fpf-publishes-food-contact-chemicals-database and drawing from different hazard-data sources.

In our hazard-based prioritization of chemicals, we sorted chemicals in our recently published *Food Contact Chemicals Database* (FCCdb; https://zenodo.org/record/4296944#.YArwyuhKhjU) using *Generally Harmonized System* hazard data (EU 1272/2008 Classification, Labelling and Packaging (CLP) Regulation). With this approach, we identified 608 priority substances. Of these, 395 compounds are also included in the EU-funded *FACET* list (Food Flavorings, Food Additives and Food Contact Materials Exposure Tool) which was compiled by EU industry, and 85 of the priority substances are currently authorized in the EU for use in plastic food contact (EU 10/2011). Therefore, we assume that more than half of our priority substances – or more – are indeed of relevance in the EU.

We encourage the EU Commission and its agencies to review this methodology and welcome the opportunity for further exchange. We stress that any prioritization of chemical substances should be done in a concise, but also systematic, reproducible, and transparent way that reflects current knowledge and is aligned with scientific principles.

We further urge the EU Commission to provide sufficient funds for developing novel methods to analyze migrating chemicals from finished FCMs and FCAs. Testing for hazard properties of concern, as defined in the CSS, will require adequate and sufficiently sensitive assays that can be used for FCMs. But to achieve this in practice, the EU Commission must prioritize investment in the development of these test methods that can be used by industry and enforcement. Thereby, it is important to make these tests transparent and reproducible for other stakeholders, like in academia and the civil society who play an important role controlling the market, in addition to government. Therefore, the EU Commission should not rely exclusively on industry stakeholders for the development of novel test methods but instead make funding available under its various research funding schemes (like Horizon Europe).

Again, we thank the Commission for the opportunity to provide input. FPF is available for supporting the EU Commission's work to identify priority substances, and for providing expertise on other matters relating to the chemical safety of FCMs. We trust that the modernisation of the EU's FCM rules will lead to a better protection of public health, if changes are based on current scientific understanding.

Best regards,

Jane Muncke, Managing Director