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Position paper by Food Packaging Forum on the European food contact regulation

Food Packaging Forum is a charitable foundation dedicated to raising awareness for the presence of hazardous chemicals in all types of food contact materials and articles. We are committed to balanced and independent science communication and research in the interest of protecting the general public from avoidable, harmful chemical exposures to hazardous chemicals present in all types of food contact materials and articles. We welcome this opportunity to provide scientific background information on current European food contact regulations.

The European food contact framework regulation 1935/2004, with its specific measures, aims to ensure both (1) the protection of public health from harmful chemical exposures and (2) the functioning of the inner European market. Both aspects are not functioning well, according to a 2016 report of the European Parliament (EU Parliament 2016). In this position paper, the Food Packaging Forum highlights aspects of the current regulatory approach in light of the most recent scientific understanding. We have also published a detailed analysis of the scientific challenges in the risk assessment of food contact chemicals which addresses many other relevant aspects in detail (Muncke et al. 2017), and commented on the draft Scientific Opinion on "Recent developments in the risk assessment of chemicals in food and their potential impact on the safety assessment of substances used in food contact materials" (FPF 2015). Both documents are relevant for this consultation, in addition to this position paper.

1. Safety requirement and definition of safety

The framework regulation 1935/2004, Art. 3 states that food contact materials (FCMs) and food contact articles (FCAs) "shall be manufactured [. . .] so that they do not transfer their constituents to food in quantities which could endanger human health". This requirement applies to all food contact materials and articles, however specific guidance on how safety shall be assessed is momentarily provided only for plastic food contact materials, as detailed in the European Food Safety Authority's (EFSA) guidance which is based on the Scientific Committee on Food's (SCF) guidance of 2001. A more recent EFSA Scientific Opinion made suggestions on how safety assessments can be updated (EFSA 2016), and we have commented on the detailed scientific aspects (FPF 2015).

In brief, safety should be assessed for all migrating compounds, regardless of whether they are starting substances, additives, or non-intentionally added substances (NIAS), and for all types of food contact materials and articles. It is important, that specific guidance is provided to stakeholders on how safety shall be assessed, but this is currently not the case except for plastics and this guidance is not based on the most recent scientific understanding. Therefore, we urgently propose to provide the necessary guidance which should be based on the most current scientific understanding and should, for example, justify any cut-offs or thresholds: For example, the assumption that chemicals larger than 1000 Da molecular weight are always toxicologically irrelevant has been questioned (Groh et al. 2017); therefore, if a molecular size exclusion is applied for migrating substances, case-specific justification should be provided.

Importantly, safety assessments need to be aligned with current scientific understanding of relevant hazards. Currently, the focus of hazard assessments is on mutagenic and/or genotoxic substances. The purpose of this is to assess the property of a chemical to cause or contribute to the generation of cancer.

Cancer is a highly relevant and prevalent type of chronic disease in the human population, and associations with chemical exposures have been shown. Prevention of cancer is of utmost societal importance and deserves a strong focus. However, other chronic diseases with even higher prevalence in the human population are cardiovascular and metabolic diseases, as well as disease clusters related to the nervous, immune and endocrine systems. For these types of chronic disease, associations with chemical exposures have also been shown and mechanistic understanding has been established in both animal studies and in cell-based assays. Of particular concern are endocrine disrupting chemicals that interact with the endocrine system and contribute to the development of various diseases. Therefore, we strongly suggest that the assessment of safety for any kind of chemical migrating from food contact materials, regardless of the level of migration, addresses these potential hazards that are highly relevant to human health. Screening only for mutagenicity and genotoxicity is insufficient, based on current scientific understanding. Prevention of all highly prevalent chronic diseases that are associated with harmful chemical exposures needs to be the aim. Notably, this will require additional investments into research and development and we urge the Commission to make funding available for this purpose.

2. Addressing mixture toxicity and aggregate exposures

Regulation 10/2011 for plastic food contact materials defines an overall migration limit (OML) of 60 mg/kg food (60 ppm). This OML is a qualitative descriptor of FCM inertness. But the OML also highlights that chemicals migrate in mixtures from plastic FCAs, and indeed from all types of food contact materials and articles. Therefore, the current safety approach which focuses on a single migrating substance's safety assessment is insufficient because it does not address the reality of mixture toxicity. Further, we question whether the level of 60 ppm is adequate or if it should be set lower like this is custom in other countries (e.g. 30 ppm in Japan), hence an explanation for the selected level should be provided. And, we stress the fact that mixtures of chemicals have been shown to cause adverse outcomes in toxicological studies. For this reason, it has been suggested that regulators address this reality to better protect public health (Bopp et al. 2019; Kortenkamp and Faust 2018). This means, that safety assessments and risk management for single substances are incomplete for prevention of harmful effects of chemical exposures, when it is an acknowledged fact that chemicals migrate in (predictable) mixtures from food contact articles.

The 1000 Da cut-off is also relevant in the context of mixture toxicity: some substances are permeation enhancers and can facilitate transport of other, larger chemicals across the gut epithelial layer. If such permeation enhancing substances are present in the overall migrate, substances larger than 1000 Da can potentially be taken up and should be assessed for their safety (Groh et al. 2017).

At present, authorisation of new substances for plastic food contact (starting substance or additives) are usually based on EFSA scientific opinions that are based on a likely very detailed assessment ("likely", because the detailed assessment is not made publicly available). In its scientific opinions, EFSA addresses not only the main substance but also related NIAS (including oligomers). However, in the authorisation, this very relevant information is not included and it is also not made publicly available, even though EFSA is publicly funded. For mixture risk assessment, this information is also highly relevant and should be available to all stakeholders.

Further, it is known that humans are exposed to chemicals not only from food contact articles, but also from many other sources, mostly outside the food chain, such as personal care products, textiles, electronics, building materials and furniture. In many instances the same chemicals are used in both

food contact and other, non-food applications, since similar materials (such as plastics or lacquers) are used. Therefore, humans may be exposed to the same chemical from different sources. This aspect of aggregate exposure needs to be taken into consideration in all safety assessments (Bopp et al. 2019).

3. Substances intentionally used in the manufacture of food contact materials and articles

Regulation EU 10/2011, Art. 13 defines the functional barrier concept, and specifies that unauthorised substances can be used behind functional barriers, if their migration into food does not exceed 10 µg/kg food (10 ppb or 0.01 mg/kg). Exemptions apply to chemicals that are known to be carcinogenic, mutagenic or toxic to reproduction (CMR; EU 1272/2008, Annex I), and substances in nanoform. The 10 ppb detection limit is often interpreted by industry stakeholders as "threshold of toxicological concern," thus for chemicals that migrate below this level, often no safety assessments are performed. But this assumption is not based on current scientific understanding. Therefore, we urge the Commission to (1) clarify why a threshold of 10 ppb has been set (i.e. to justify this level of detection) and (2) make explicit the conditions when it applies. In particular, for compliance work on non-plastic FCMs or for migrating chemicals from plastics that are not authorized, such a clarification is urgently needed to ensure that no hazardous chemicals transfer from food contact articles into foods that pose a risk to human health. Again, the issue of potential mixture toxicity needs to be taken into account.

In Europe, the Regulation on the Registration, Evaluation, Authorisation and restriction of Chemicals (REACH), EU 1907/2006 introduced the concept of Substances of Very High Concern (SVHC). SVHCs are substances that are intended for phase-out or substitution with substances of less concern. While substances used in food contact are exempted from REACH for human health safety assessments, all substances produced or imported need to be assessed for environmental safety under REACH and therefore, also all food contact-relevant substances are subject to registration. But an SVHC listing of a substance has no legal consequences for its use in food contact. Several food contact-relevant substances that are authorised for use in plastics are now classified as SVHCs. As consequence, some large food producers have issued their own list of chemicals that should not be used for food packaging, and all SVHCs are included (FPF 2018). We therefore urge the Commission to proactively address this aspect. For example, the list of authorised substances for use in plastic FCMs could be revised based on actual use of a substance in FCMs (e.g. using registration data from REACH). In a next step, substances could be prioritised for reassessment based on hazard e.g. if a substance is already listed as SVHC, or if it fulfils SVHC criteria implying that SVHC classification in the near future is probable, it should be of highest priority for reassessment.

4. Enforcement

According to stakeholders tasked with enforcement, the current system does not allow for effective enforcement, implying that non-compliant food contact articles are presently on the market and that human health is likely to be at risk (Grob 2014; Grob 2017a; Grob 2017b; Daniel et al. 2019). However, enforcement is the most critical aspect for ensuring the protection of public health. Therefore, we urge the Commission and the Member States to introduce suitable means (including funding and tools) for appropriate enforcement and control of compliance. This implies that non-compliance is systematically addressed and penalised with suitable measures. These measures need to be aimed at faulty business operators across the supply chain, instead of being ignored, as is the case at present (Grob 2017; McCombie et al. 2016; Daniel et al. 2019). Ensuring that the gap between legal requirements and market reality is closed efficiently and adequately is a critical task for the Commission and the Member States. It

is essential for ensuring the public's trust in FCM regulations.

Many food business operators are small and medium enterprises (SMEs). But oftentimes, SMEs lack the knowledge and means to perform proper compliance work as legally required, and the information they receive from their suppliers is mostly inadequate. Therefore, we urge the Commission to actively raise awareness for chemical migration and the obligatory compliance work, especially with small and medium business operators. The Commission and the Member States have an important role to play here, and there is an urgent need for improvement. This aspect is especially pertinent in light of the circular economy, where reuse and recycling of food contact articles is commonly perceived as beneficial, but a deeper understanding of the involved chemical risks is most often absent. For this reason, more educational outreach is required aiming at SMEs and the general public, and appropriate funds should be allocated for this important purpose.

5. Circular economy

Inappropriate recycling processes may contaminate FCMs made out of secondary raw materials. For example, several food contact articles composed of black plastics have recently been found on the European market, containing brominated flame retardants (BFRs) (Turner 2018; Puype et al. 2017; Samsonek and Puype 2013). BFRs are present in Waste Electric and Electronic Equipment (WEEE), but they are not authorised for plastic food contact and due to their hazard properties should not be present in any kind of food contact article. As consequence, more controls of imports, especially for the presence of heavy metals and persistent organic pollutants, such as BFRs, should be put in place, and appropriate measures should be taken in response to detection of non-compliance (i.e. removal of these articles from the market). The hypothesis for the presence of BFRs in black plastics food contact materials is that WEEE plastics are illicitly recycled into new articles intended for food contact, likely outside of Europe (Hahladakis et al. 2018).

The waste-food packaging interface is a challenge and it is currently being addressed. Chemical safety of food packaging is one of the main obstacles in transitioning to a circular economy (Geueke et al. 2018), but more efforts need to be taken to ensure it. Therefore, we urge the Commission to invest appropriate funds into research and development of safe recycled food contact articles. Tools ensuring the chemical safety of these materials could include (high-throughput) bioassays (Groh and Muncke 2017) or automated chemical screening.

These approaches are important first steps in developing improved new regulation that will ensure adequate protection of public health, based on the precautionary principle. We thank the Commission for this opportunity to provide input.

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