A Tailored Risk Assessment for Food Contact Materials and Articles

Our material world (plastic, glass, paper and cardboard, rubber, metals, waxes, coatings, recyclates, inks and varnishes etc..) offer almost endless possibilities to combine a wide array of starting substances to produce materials and articles in a way that these are safe for contact with food.

Food Contact materials and articles (FCMAs) are carefully manufactured according to procedures to control any migration of substances into food. This applies to everyday tableware and cutlery, kitchen appliances and cooking utensils, food packaging and its labels, as well as the surface materials used in food manufacturing, preparation, storage, transport and distribution. The Regulation (EC) 1935/2004 is a comprehensive framework that sets out the general safety requirements for all food contact materials (FCM) placed on the EU market.

The risk assessment and management of substances migrating from the final FCM is critical to ensure consumer protection. The risk assessments are strengthened by assuring the adequate information flow along the supply chain to enable each actor in the chain to complete his part of the assessment for safety and compliance of the final FCM. The risk assessment and management approach also enable the implementation of the GMP according to Regulation 2023/2006.

Future FCM in a changing regulatory environment

Various European legislation and new initiatives put forward a reflection on how to identify and evaluate hazards. For instance, the Commission's Evaluation Report[1] of July 2020 concludes that the current EU legislative approach does not consistently prioritise the most hazardous substances in all FCMs. The EU Green Deal and its Farm to Fork Strategy have committed to revise the FCM legislation in order to improve food safety and public health (in particular by reducing the use of hazardous chemicals). More currently, the COVID-19 pandemic has once again highlighted the importance of FCMs in safeguarding food supply chains and ensuring food security in the EU.

Positive impulses are seen in the Chemical Strategy for Sustainability which envisions better coordination and distribution of tasks between EU agencies concerning the hazard and risk assessment of substances, and the cumulative risk from all uses of the same chemical. Such an approach can offer benefits as the EU's agencies and scientific bodies move towards a process of '**one substance – one assessment**' to provide greater transparency when prioritising actions to deal with chemicals. This proposal is described in the ECHA and EFSA joint position paper[2] and will require enabling access to all available data in the same structured format for all EU authorities.

Our joint task is to improve the assessment process for substances used in FCM across Europe for the future. Currently, the EU's agencies and scientific bodies work with different approaches

[1] https://op.europa.eu/en/publication-detail/-/publication/3ae0294b-bc0c-11ea-811c-01aa75ed71a1/language-en
[2] https://www.efsa.europa.eu/en/corporate/pub/osoa

leading to different assessments for the same substance depending on the context they are operating and on the scope of evaluation.

The packaging value chain contributes with industry-made risk assessments, generates data, and offers solutions to warrantee the safety of FCM. This is common practice and industry will continue to do so.

Striking the best balance for FCM evaluations and their specific uses

The strengths of risk-based and hazard-based approaches must be well understood in order to have a tailored assessment of substances used in FCM. This needs to be done in the appropriate sequence by the EU agency with the relevant expertise and using the MS scientific bodies. A complete risk assessment can only be achieved by accounting for identified hazardous properties, specific use of the substances, migration potential and resulting exposure for a relevant and specific evaluation.

One core element of risk assessments for FCM is that they allow for the evaluation of the migration of a substance into food and the potential consumers exposure along the FCM supply chain considering the specific conditions and requirements.

Furthermore, risk-based assessment of FCM:

- builds on the hazard assessment and also includes the evaluation of exposure, which is key for minimizing the risk to human health;
- allows for evaluation of contaminants followed by management actions to mitigate the risk;
- is based on scientific methods used to derive safe levels of exposure via the oral route;
- is already well established and widely used by authorities and industry for FCM and food.

When focusing on the hazard-based assessment it is important to consider that:

- it is based on the intrinsic properties of the substance, but does not consider whether these properties still represent a risk in the final FCM;
- it disregards in particular the duration, frequency, and level of potential exposure resulting from use of the substance in the final FCM;
- it often omits oral ingestion as most relevant route of exposure for FCM.

Our proposal

We propose an approach where substances undergo a **"one substance - one assessment"**, consisting of a first step **"one substance- one hazard assessment**" in which the hazard is defined by the intrinsic properties of the substance. This should be followed by a second step of a **"FCM specific risk assessment and management"** for food contact materials and articles, in which the risk resulting from potential oral exposure is assessed. We believe that EFSA is best positioned to provide such specific FCM assessment due to their extensive experience in food safety-related matters, and in the assessment of substances in dietary exposure.

5 April 2022

This paper is supported by the following associations:

ACE – Alliance for Beverage Cartons and the Environment

APEAL – Association of European Producers of Steel for Packaging

CEPE – European Council of the Paint, Printing Ink, and Artist's Colours Industry

CEPI – Confederation of European Paper Industries

CES – Silicones Europe, a Sector group of Cefic

CITPA – International Confederation of Paper and Board Converters

CPME – Committee of PET Manufacturers in Europe

ECMA – European Carton Makers Association

ESIG – European Solvents Industry Group, a Sector group of Cefic

EUROFER – European Steel Association

EuPC – European Plastics Converters Confederation

EuPIA – European Printing Ink Association, a Sector of CEPE

EWF – European Wax Federation

FCA – Food Contact Additives, a Sector group of Cefic

FEC – Federation of European manufacturers of Cookware and cutlery

FEFCO – European Federation of Corrugated Board Manufacturers

FEICA – Association of the European Adhesive & Sealant Industry

FoodDrinkEurope – The organisation of the European food and drink manufacturing industry

FPE – Flexible Packaging Europe

GAE – Glass Alliance Europe

Intergraf – European Federation for Print and Digital Communication

I&P Europe – Imaging and Printing Association

MPE – Metal Packaging Europe

NI – Nickel Institute

PlasticsEurope – European Association of Plastics Manufacturers

WBT – World association of manufacturers of bottles and teats