

Supporting document 4

Risk assessment approaches to chemical migration from packaging into food – P1034

Chemical Migration from Packaging into Food

The risk of adverse health effects to consumers from any chemical present in food depends on the hazard characteristics of the chemical and the dietary exposure resulting from consumption of foods containing the chemical. So called ‘tiered’ approaches to the risk assessment of chemical migration from packaging into food are followed in the US and the EU (SD2).

EFSA guidelines state that, as a general principle, the greater the level of migration the greater the extent of toxicological information required (EFSA 2008). If migration can be shown to be less than 0.05 mg chemical/kg food, EFSA requires *in vitro* genotoxicity data only. In the case of “high” migration (defined by EFSA as 5 to 60 mg/kg food), an extensive set of toxicological data is needed to establish safety, while for intermediate migration levels (0.05-5 mg/kg food) EFSA states that a reduced data set may suffice. A similar tiered approach to the risk assessment of packaging chemicals is also used by the US FDA, with the additional provision that no toxicity data are required if migration is less than 0.0005 mg/kg food (i.e. 0.5 parts per billion, the “threshold of regulation”¹). However carcinogens, or substances suspected to be carcinogenic based on chemical structure, are excluded from this provision.

Tiered approaches are increasingly recognised as sound approaches for chemical risk assessment, which not only offer consumers reasonable certainty of no harm, but also avoid unnecessary toxicological testing (Barlow 2009). Such approaches can be particularly valuable for the risk assessment of CMPF issues that require a rapid response from regulatory authorities (SD3). For example, hazard information on a chemical newly detected in food may not be extensive, but may be considered sufficient to indicate a minimal risk in cases of very low migration.

A major factor which complicates risk assessment is the large number of chemicals used in food packaging materials, many of which are not yet subject to regulation and for which no, or only limited, food migration information is available. For example, the EU has legislation in place for plastics, regenerated cellulose film, ceramics, active and intelligent materials, and recycled plastics. However, as stated in a recent report, there is no specific legislation for a range of other food packaging materials including printing inks, coatings, adhesives, paper and board (EC 2012).

For printing inks alone the report states that over 6000 substances have been notified to the Swiss authorities since the establishment of their food packaging legislation in 2009. For many of these chemicals there are limited or no toxicity data and this has resulted in consideration of the use of toxicological data on chemicals with related structures (“read-

¹ US Code of Federal Regulations, § 170.39 Threshold of regulation for substances used in food-contact articles.

across approach”; Blackburn and Stuard 2014) and/or use of the Threshold of Toxicological Concern (TTC) concept which categorises chemicals into various levels of safe expected exposure depending on chemical structure features (Kroes et al 2000; Canady et al 2013). Such approaches are already used by JECFA and EFSA for the safety evaluation of the large number of flavouring agents that are used by the food industry.

Read-across and TTC approaches may also be useful for the safety evaluation of chemical species other than the known starting materials used in the production of food packaging, such as oligomers, reaction products and impurities (Koster et al 2014), and chemicals that may arise in packaging due to a recycling process, for example if contaminated plastics or paper are used as source materials. The use of read-across and/or TTC approaches still requires an estimate of dietary exposure to the chemical, and this requires data on levels of the chemical in food(s)/food simulants. The US FDA states that it is currently attempting to collect and review data for approximately 3000 food contact substances for addition to the >1300 chemicals currently present in its dietary exposure database (US FDA 2014).

There have been specific concerns regarding the use of recycled materials in food packaging. For example, Biedermann and Grob (2013) analysed recycled paperboard sourced from several manufacturing plants in Germany and concluded that the number of substances potentially migrating into food above 0.01 mg/kg was too large to be realistically “brought under control”. However, they also stated that a barrier that reduces migration by a factor of 100 could be adequate to render recycled paperboard suitable for food packaging without the need for toxicological evaluation of all potential migrants.

Finally, as indicated by Barlow (2009), prioritisation of packaging chemicals for evaluation might include aspects such as high migration levels (e.g. >5 mg/kg food), high levels of fat in food in contact with packaging, use in packaging for foods specifically made for infants and young children, and suspect chemical structures (e.g. those with structural alerts for genotoxicity).

In developing an approach to the risk assessment of CMPF, FSANZ will consider such prioritisation criteria as well as developments in the use of read-across and TTC approaches in chemical risk assessment (EFSA 2012).

References

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