

Advice 03-2014 of the Scientific Committee of the FASFC on the risk assessment of migration from food contact materials: explorative case studies

In this opinion, the issue of migrating components from food contact materials (FCM; packaging, but also e.g. utensils, pipes, storage tanks) is discussed by means of a number of exploratory case studies. Risk assessment of components migrating from FCM is complex since it is not only about packaging, but also objects and other materials that come into contact with food. Moreover, different substances may be used to provide FCM the desired functionality and the identity and toxicity of potentially migrating substances are not always known (cf. NIAS or 'Non-Intentionally Added Substances', such as contaminants, impurities, reaction or degradation products). Additionally, migration is a dynamic phenomenon that is influenced by several variables (not only by the contact surface between FCM and food product, but also by the nature of the food, storage conditions, processing, etc.). The exposure assessment of FCM components includes consequently a number of uncertainties. Data are often scarce or missing (e.g. market data on the type of packaging of food consumed) and/or are based on an extrapolation of data available for comparable FCM components with a similar functionality. To determine whether the exposure to an FCM component entails a risk to human health, a tiered approach can be followed, starting from the most conservative scenario.

As explorative case studies, the risk of the daily (chronic) exposure to ESBO (Epoxidized soya bean oil; CAS n° 8013-07-8) and to the phthalates DEHP (di(2-ethylhexyl) phthalate; CAS n° 000117-81-7), DiNP (di-isononyl phthalate; CAS n° 068515-48-0//028553-12-0) and DiDP (di-isodecyl phthalate; CAS n° 068515-49-1//026761-40-0), plasticizers used amongst others in the seals of lids of glass jars, is evaluated based on the results of the FASFC monitoring program 2008 – 2012. Given that DiNP and DiDP were hardly detected, an estimation of the exposure to these phthalates appeared to make little sense.

For adults, the exposure to ESBO and the evaluated phthalates seems to hold no significant health risk, even for the most pessimistic scenario where a high consumption and contamination of the food were assumed. For infants (<1 year), however, the exposure to ESBO may exceed the tolerable daily intake (TDI) in case of a frequent or of a large consumption of baby food packed in glass jars. On the other hand, since (i) ESBO is neither carcinogenic nor genotoxic and has no detrimental effect on development, and since (ii) the consumption of baby food in jars significantly decreases after the first year of life, as a result of which such potentially large exposure shall only occur for a limited time, a limited risk can be assumed. The exposure of infants to DEHP is below 50% of the TDI, even when baby food in jars is frequently consumed. In addition to FCM, however, other sources of contamination (e.g. the environment) and other sources of exposure (e.g. plastic toys and dust which are taken into the mouth) are possible. Furthermore, DEHP has endocrine disrupting properties (for which a classical toxicological approach, such as for example based on the TDI, is inadequate).

For the risk assessment of an incidental (acute) exposure, the same methodology as for the risk assessment of a chronic exposure, is followed. This was illustrated in annex of the advice by a number of examples, including a high (or non-compliant) migration of ESBO from the seal lids of glass jars, of DEHA (di (2-ethylhexy) adipate; CAS No. 103-23-1) from a plastic film and of 4,4'-methylene dianiline (4,4'-diaminodiphenylmethane or 4,4'-MDA; CAS 101-77-9) from kitchen utensils.

Based on this study, the main bottlenecks occurring when assessing the risk of migrating FCM components were identified and a number of recommendations in regarding control and research were formulated.

The full text is available on this website in dutch and in french, respectively under the section "Wetenschappelijk Comité/Adviezen" and "Comité scientifique/Avis".