

Supporting document 3

International responses to chemical migration from packaging into food – P1034

Chemical Migration from Packaging into Food

There are a number of examples in the last 25 years where food contact packaging materials have been detected in foods requiring a risk assessment or response from regulatory authorities.

Printing inks and mineral oils

Consumers may be exposed to mineral oil hydrocarbons which may migrate into food from food packaging, as well as other sources. These substances are typically divided into mineral oil saturated hydrocarbons (MOSH) and mineral oil aromatic hydrocarbons (MOAH)¹. In 2012, EFSA concluded that exposures to MOSH and MOAH in food in Europe were of potential health concern.

In 2010 the US FDA notified the recall of 28 million boxes of cereal due to elevated levels of hydrocarbons (including methyl naphthalene) leaching from package liners causing products to be tainted. It was reported that customers had complained of an ‘off-taste and smell’ and that some people had complained of nausea.

Benzophenone and 4-methylbenzophenone are used as initiators for printing inks. Because of their volatility, these compounds can migrate through the packaging to the food. On 2 February 2009, the German authorities notified the migration of 4-methylbenzophenone from packaging into certain cereal products through the Rapid Alert System for Food and Feed (RASFF) at a concentration of 798 µg/kg. Belgian Authorities later provided data showing concentrations of 4-methylbenzophenone in cereals of up to 3729 µg/kg. An EFSA evaluation based on the limited exposure data, and extrapolating from the toxicity of benzophenone, concluded that short term consumption of contaminated breakfast cereals should not pose a risk to most people. However, it was noted that the margin of exposure was low and recommended that more data on the occurrence of the substance in foods should be provided as well as appropriate toxicity data corresponding to the level of exposure to enable a full risk assessment².

In 2005 a notification from the Italian authorities on the RASFF showed the presence of the ink photoinitiator 2-isopropyl thioxanthone (ITX) at a concentration of 250 µg/l in liquid milk for babies packaged in printed carton. Industry later reported the migration of another ink photoinitiator, 2-ethylhexyl-4-dimethylaminobenzoate (EHDAB), at lower levels than ITX and that other milk products and cloudy fruit juices packaged in cartons were also affected. As a result the European Commission requested that EFSA conduct a risk assessment on ITX and EHDAB.

¹ report available at <http://www.efsa.europa.eu/en/efsajournal/pub/2704.htm>

² report available at <http://www.efsa.europa.eu/en/efsajournal/pub/1104.htm>

In this case, it was concluded that the occurrence of EHDAB in food from its use in inks applied to food packaging materials was of no safety concern. However, the Panel concluded that in view of the lack of toxicity data an assessment of the safety of ITX could not be made³. EFSA re-evaluated ITX in 2007 and concluded that an assessment of potential health risks in relation to the possible presence of ITX in food, would require additional data on ITX effects after longer term administration⁴. FSANZ is not aware of a subsequent risk assessment on ITX.

Monomers

As stated in Section 3, bisphenol A (BPA), a chemical used in the production of polycarbonate plastics and coatings/resins used in some food packaging materials (e.g. protective linings of cans), is by far the most well characterised packaging chemical in regard to both hazard characterisation and dietary exposure, and is the subject of a growing number of epidemiology studies. The most recent EFSA assessment concluded that dietary exposure to BPA for all population groups was below the Tolerable Daily Intake (TDI) derived from animal toxicity data (EFSA 2014). However, the validity of the TDI has been challenged by some scientists on the basis of so called “low-dose” effects reported in some animal studies which differ in design to the guideline-compliant toxicity studies typically required by regulators. In addition, several published epidemiological studies have reported associations between BPA exposure and adverse health outcomes such as obesity, type II diabetes and cardiovascular disease. FSANZ, other regulators, and academic scientists have highlighted flaws in the design and interpretation of these studies, and a recent systematic review of the epidemiological data concluded that assertions about a causal link between BPA and obesity, type II diabetes, or cardiovascular disease are unsubstantiated (Lakind et al 2014). Despite the extensive toxicological characterisation of BPA, regulators are awaiting the results of a large chronic toxicity study in rats currently being conducted in the USA as a collaborative effort between academic and regulatory scientists (Schug et al 2013).

Notwithstanding the weight of scientific evidence indicating that the TDI for BPA is appropriate, there has been a range of management options employed on the use of BPA in polycarbonate baby bottles. Canada, the EU, France and certain US States and Counties have phased out the use of BPA.

Plasticisers

In 2004, EFSA was asked to give an opinion on the risk for infants of epoxidised soybean oil (ESBO) and, for the consumer in general, ESBO-derivatives. It was estimated exposure of infants aged 6-12 months to ESBO migrating into baby foods packaged in glass jars and bottles with metal lids sealed with PVC gaskets could sometimes exceed the TDI by up to 4- to 5-fold. It was considered that this situation was undesirable because it could reduce on a regular basis, the safety margin between exposure and adverse effects. It was therefore recommended to develop a specific migration limit for ESBO in baby foods⁵. The report noted that limited information was available on ESBO derivatives and that a program should be developed to address this situation. EFSA subsequently provided an opinion of the exposure of adults to ESBO used in food contact materials. Using conservative exposure estimates, the Panel noted that the potential dietary exposure to ESBO from foods packaged in glass jars and cling films for the adult population was below the TDI for ESBO⁶.

³ report available at <http://www.efsa.europa.eu/en/efsajournal/pub/293.htm>.

⁴ report available at <http://www.efsa.europa.eu/en/efsajournal/pub/1064.htm>.

⁵ report available at <http://www.efsa.europa.eu/en/efsajournal/pub/64.htm>.

⁶ report available at: <http://www.efsa.europa.eu/en/efsajournal/doc/332.pdf>

Information on the toxicology and migration levels of phthalates is included in Section 3. Like phthalates, esters of adipic acid (adipates) are also used as plasticizers in packaging materials. A Canadian analytical survey of foods sampled between 1985 and 1989 found di-2-ethylhexyl adipate (DEHA) in store wrapped meat, poultry, fish, cheese and ready to eat foods at concentrations of up to 310 mg/kg (Page and Lacroix, 1995). In 1987, a UK survey of DEHA levels in retail foods packaged in plasticised PVC showed DEHA levels ranging from 1.0 to 72.8 mg/kg in uncooked meat and poultry, 9.4 to 48.6 mg/kg in cooked chicken portions, 27.8 to 135.0 mg/kg in cheese, and 11 to 212 mg/kg in baked goods and sandwiches (Castle et al, 1987). These values were well in excess of the current SML for DEHA which is 18 mg/kg food and, in some cases, in excess of the overall migration limit for plastic FCMs in the EU (60 mg/kg). A UK Government report found that dietary exposure to DEHA was 16 mg per person per day and should be significantly reduced. A later report estimated that the maximum exposure had been reduced to 8.2 mg per person per day as a direct consequence of reformulation of films by manufacturers (reviewed in Robertson, 1993).

Coatings

In the 1990's high amounts of Bisphenol A diglycidyl ether (BADGE) were discovered in fish oil in tins as a result of its use as an additive. It was reported that BADGE levels were up to 600 mg/kg in the oil (Grob et al, 1999). There was concern at the time that BADGE may be carcinogenic, however EFSA subsequently assessed newly available animal toxicity data and concluded that BADGE does not raise carcinogenicity concerns. As a result of this issue, measures were taken to reduce the migration of BADGE and Bisphenol F diglycidyl ethers (BFDGE) and Novolac glycidyl ethers (NOGE) and there is now legislation in the EU related to BADGE, BFDGE and NOGE in coated materials, plastics and adhesives.

Decomposition products

Semicarbazide (SEM) is a molecule that belongs to the hydrazine group of chemicals that was first reported to have been found in food as a result of migration from food packaging in 2003. It was found in a number of food products from different manufacturers that were packaged in glass jars and bottles with metal lids, sealed with plastic PVC gaskets. These gaskets were used for the packaging for a range of foods in jars and bottles, for example fruit juices, baby food, mayonnaise, mustard and sauces. The presence of SEM was found to be due to the permitted use of azodicarbonamide (ADC) as a blowing agent to make a foamed plastic. At the time ADC was listed in Commission Directive 2002/72/EC relating to plastics materials and articles intended to come into contact with foodstuffs. Commission Directive 2004/1/EC of 6th January 2004 amended Directive 2002/72/EC such that the use of ADC as an additive in food contact materials was prohibited in the European Union from 2nd August 2005⁷.

Other non-plastic materials

In response to some of the reports where migration occurred from non-plastic materials, an EFSA scientific cooperation working group was set up to anticipate emergency situations where FCMs were released from materials for which no EU regulations existed and where no harmonised risk assessment was available. A list of 2800 substances used in the manufacture of paper and board, printing inks, coatings, rubber, colorants, wood and cork was established. Of these, 230 substances were evaluated following publication of the Scientific Committee of Food Guidelines for Food Contact Materials (1991).

⁷ report available at: <http://www.efsa.europa.eu/en/efsajournal/doc/219.pdf>

This provides an indication of the number of substances that could potentially migrate into food, but have yet to undergo full toxicological evaluation. The working group proposed strategies to prioritise the evaluations of substances and for providing urgent advice⁸. Measures include toxicity and exposure assessment tools and the establishment of a network of experts to be mobilised in case of the need for urgent advice.

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⁸ report available at <http://www.efsa.europa.eu/en/supporting/pub/139e.htm>