PRINTING INKS FOR FOOD PACKAGING MATERIALS

Elaine Campling provides an introduction to European Legislation governing food contact materials, with a focus on the printing industry

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Printing inks are used on food packaging materials for decoration, to provide consumer information, as well as for marketing and identification purposes. Inks are designed for use with many different packaging materials, such as plastics, paper and board, and may be printed directly onto the substrate, or on labels for subsequent application.

Without proper controls, ink components may come into inadvertent contact with the contained food through set-off or migration from the print. Ink set-off can occur on the reverse side of the substrate e.g. printed labels, either in a stack, or in the reel after printing. Low molecular weight substances may then be transferred to the unprinted surface of the packaging that comes into direct contact with the food item.

The use of recycled paper and board as packaging materials has also been associated with contamination of food through the migration of mineral oils. Inks used for printing newspapers contain mineral oils as an important part of the formulation. The paper absorbs the mineral oil during printing and consequently contaminates the mix when recycled.

Although there are other sources for the contamination of food with mineral oils, this is one of the recognised routes within the printing industry.

Different substrates have different permeabilities and therefore offer different levels of protection. Glass is generally considered to be a particularly effective means of containment. The use of aluminium and other functional barriers can allow other packaging materials to be used.

REGULATING FOOD CONTACT MATERIALS

Various legislative instruments are in place to regulate food contact materials (FCMs). The topic is wide-reaching, making it only possible to provide an overview here. Regulation (EC) 2019/1381, otherwise known as the 'Transparency Regulation' came into force on 27 March 2021 with the aim of improving the transparency of risk assessment in the food chain. Another goal of the legislation is to improve the reliability of studies used by the European Food Safety Authority (EFSA) and amend the General Food Law, Regulation (EC) No. 178/2002, originally put in place to establish EFSA.

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The activities of EFSA are now subject to greater public scrutiny, with improved access to scientific data and studies, which must now be published on the EFSA website in an easily accessible electronic format. The Transparency Regulation also makes provision for public consultation on authorisation applications for regulated products.

A public consultation was recently issued by EFSA on a draft scientific opinion proposing a revised tolerable daily intake (TDI) limit for BPA, a substance that has been in fairly wide use within the print industry. The TDI is an estimate of the amount of a substance that can be ingested daily over a lifetime without appreciable risk. In an earlier risk assessment (2015), EFSA set a temporary TDI of 4 micrograms per kilogram of body weight per day.

Following the latest evaluation published mid-December 2021, EFSA's expert Panel on Food Contact Materials, Enzymes and Processing Aids determined a TDI of 0.04 nanograms per kilogram of body weight per day.

SAFETY PRINCIPLES

Regulation (EC) No. 1935/2004 (as amended), known as the 'Framework Regulation' is another significant piece of legislation that was put in place to establish general safety principles covering FCMs. The regulation sets out an underlying principle that any material or article intended to come into contact with food, directly or indirectly: "must be sufficiently inert to preclude substances from being transferred to food in quantities large enough to endanger human health or to bring about an unacceptable change in the composition of the food or a deterioration in its organoleptic properties." The term organoleptic is associated with taste and odour.

A procedure to perform safety assessments and rules on labelling is set out in the Regulation, along with the concept of good manufacturing practice (GMP). The GMP Regulation (EC) No. 2023/2006 sets out measures to prevent the transfer of 'materials and articles, specifically referencing printing inks:

"Printing inks applied to the non-food contact side of materials and articles shall be formulated and/or applied in such a manner that substances from the printed surface are not transferred to the food-contact side: (a) through the substrate or; (b) by set-off in the stack or the reel, in concentrations that lead to levels of the substance in the food which are not in line with the requirements of Article 3 of Regulation (EC) No 1935/2004."

MIGRATION LIMITS

Certain FCMs are governed by specific legislation, for example ceramic materials, regenerated cellulose film, plastics (including recycled plastic), as well as active and intelligent materials. Active and

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intelligent materials extend the shelf-life of packaged food by releasing or absorbing substances to or from the food or its surrounding environment. The requirements for active and intelligent materials are set out in Commission Regulation (EC) No. 450/2009.

Regulation (EU) No. 10/2011 establishes a Union List of substances that are permitted for use in the manufacture of plastic FCMs. The Regulation also sets out specific migration limits (SML) for the substances on the Union List that are established by EFSA. The overall migration to a food of all substances together may not exceed the Overall Migration Limit of 60mg/kg food, or 10mg/dm^2 of surface area.

Migration is usually evaluated using simulants representative of a food category, for example acetic acid 3% (w/v) is used for acidic foods. Migration testing is performed under standardised conditions (time, temperature) for a certain food use and is conducted to take account of the maximum shelf life of the packaged food. There have been several amendments to the Regulation and the Union List of substances permitted for use.

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Before concluding, it is worth mentioning that EU Member State countries are permitted to maintain or adopt their own national provisions on FCMs in accordance with Article 6 of Regulation 1935/2004: "In the absence of specific measures referred to in Article 5, this Regulation shall not prevent Member States from maintaining or adopting national provisions provided they comply with the rules of the Treaty."

EU LEGISLATION

National legislation is in place in most EU Member States with varying sophistication. In Germany, the Consumer Goods Ordinance regulates the use of printing inks and varnishes. The Ordinance has been recently updated, with the main change relating to the positive list of substances, essentially a list of monomers, additives, colorants, solvents and photoinitiators that may be used in printing inks and varnishes.

One of the most advanced instruments on FCM resides with the Swiss Federal Department of Home Affairs (FDHA) Food Safety

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and Veterinary Office (FSVO). The Swiss 'Ordinance on Materials and Articles' (817.023.21) is complemented by several Annexes of 'positive' lists of permitted substances for different uses, including ceramics, cellulose films, glass, plastics, ceramics, silicone and printing inks. ■

Further reading:

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02004R1935-20210327
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32006R2023

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