

Supporting document 2

International regulations for food contact materials – P1034

Chemical Migration from Packaging into Food

Regulations in place in the EU and US are the most widely used international regulations for food contact materials (FCMs), although other countries, such as Canada, China and Japan have their own regulations.

European Union

In Europe, the Framework Regulation (EC) No 1935/2004 is the basic legislation that applies to all FCMs. It sets out that FCMs shall be safe and not change the properties of food in unacceptable ways. Essentially, the European approach is based on a premise that all materials should be explicitly approved and publicised in the regulations and that all approvals should be based on a toxicological evaluation of the listed substances. Article 3 of this legislation sets out that materials and articles shall be manufactured in compliance with Good Manufacturing Practice (GMP) and sets out three basic criteria for FCMs which are;

- they shall not endanger human health,
- they shall not change the composition of the food in an unacceptable way, and
- they shall not change the taste, odour or texture of the food.

Regulation (EC) No. 2023/2006 defines GMP and ties it into the general requirement of Article 3, of the 2004 Regulation. This regulation applies to all sectors and to all stages of manufacture, processing and distribution of FCMs. However, it does not apply to the production of the starting substances used in the manufacture of food contact materials and articles. The Annex to EC2023/2006 requires that printing inks applied to the non-food contact side of materials and articles shall not be transferred into foods at concentrations that are inconsistent with Article 3.

Article 5 authorizes the Commission to maintain a register of authorized materials and the adoption of specific procedural rules applicable to individual authorization of substances or materials. For example, it authorizes the application of specific migration limits (SMLs) and overall migration limits (OMLs); and the promulgation of rules to check on compliance, sample collection, record retention, and labelling for active and intelligent packaging. Notably, where specific measures apply to materials and articles in Article 5, those materials must be accompanied by a written declaration stating that those materials comply with the rules applicable to them.

The Regulation also establishes that the European Food Safety Authority (EFSA) shall conduct a conventional risk assessment and prescribes the way in which an application for a listing in some suitable regulation is to be submitted, noting the need for a technical dossier to comply with the guidelines published to indicate what is needed to demonstrate safety. The EFSA opinion should include the designation of the substance and any specifications and recommendations for any conditions or restrictions on use.

Safety assessment is followed by a risk management decision as to whether the substance should be entered on a Community list. Authorisations are applicable to all parties, not just the submitter.

A streamlined approach to the EU legislative framework for hazardous chemicals is provided by EC Regulation No. 1907/2006 through the Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH¹). REACH aims to ensure protection of human health and the environment from the risks posed by chemicals, the promotion of alternative test methods and promote market access.

REACH makes industry responsible for assessing and managing the risks posed by chemicals and provides appropriate safety information to their users. The EU can also take additional measures on highly dangerous substances, where required.

Annex 1 of the Framework sets out 17 materials which may be covered by specific measures. At present there are specific measures only for ceramics, regenerated cellulose, plastics, recycled plastics and active and intelligent materials and articles. These are discussed in more detail below. However for the majority of FCMs in Annex 1 (paper and board, glass, wood, cork, metals and alloys, textiles, ion-exchange resins, printing inks, silicones, varnishes and coatings, waxes) there are no specific EU measures in place. National provisions may exist in areas for which Community legislation has not been adopted. These can be found at http://ec.europa.eu/food/food/chemicalsafety/foodcontact/eu_legisl_en.htm.

Plastics

The use of plastic materials and articles intended to contact food in the EU is governed by Plastics Regulation (EU) No. 10/2011. It includes a positive list of permissible monomers and other starting substances and additives. While the EU regulation establishes that SMLs may be adopted for 17 types of materials, at this stage specific measures exist for only a few materials (eg plastics, regenerated cellulose, active and intelligent materials).

Plastic materials and articles were the first FCMs covered by Community legislation. Commission Regulation (EU) No 10/2011 establishes specific rules for plastic materials and articles to be applied for their safe use. In general, it is foreseen that potential health risks may occur from non- or incompletely reacted monomers or other starting substances or additives that may migrate from packaging into the food. Therefore, these substances need to undergo a risk assessment before their use in the manufacture of plastic materials.

Risk assessment is performed by EFSA considering likely reaction and degradation products. Based on the risk assessment, EFSA recommends specifications for the substance and any restrictions of use and migration limits to ensure the safety of the material. Annex I of the regulation establishes a Union list of authorised monomers, other starting substances, additives, polymer production aids and macromolecules obtained from microbial fermentation that may be used in the manufacture of plastic food contact materials of articles.

In the EU, migration tests are requested only for plastic packaging. In this system, the migrants are measured in food simulants with the total dose of migrant absorbed per day that could be derived from 1 kg of food in contact with the plastic is determined, noting this amount of food is assumed to be composed either of 1 kg of fatty food or 1 kg of one of the other types of food, but never by the sum of the various types of food. The highest migration found across the different simulants is used to estimate exposure assessment. A surface area of 6 dm² (600 cm²) represents the surface of a cube of 1 kg (or 1 litre) of food.

¹ http://ec.europa.eu/enterprise/sectors/chemicals/reach/index_en.htm

An overall maximum limit of migration of 60 mg/kg applies for all packaging materials, i.e. any migration of chemicals from plastic into food above this limit is not permitted (equivalent to 10 mg of substances per 1 dm² of surface area of the plastic material).

As mentioned, Article 3 of Regulation (EC) No 1935/2004 prescribes that the release of substances from food contact materials and articles should not bring about unacceptable changes in the composition of the food. According to GMP it is feasible to manufacture plastic materials in such a way that they are not releasing more than 10 mg of substances per 1 dm² of surface area of the plastic material.

If the risk assessment of an individual substance does not indicate a lower level, this level is set as a generic limit for the inertness of a plastic material, the OML. In addition, on the basis of a toxicological risk assessment, a specific migration limit may be established. The SML means the maximum permitted amount of a given substance released from a material or article into food or food simulants. Annex 1 establishes SMLs for various phthalate compounds that may migrate into food.

The regulation also sets out rules in relation to the expression of migration test results and assessing compliance with migration limits.

Recycled plastic materials

It is recognised that recycled plastic packaging waste may contain residues from previous use, contaminants, including household, garden or automotive chemicals, and contaminants from non-authorised substances. As such, industry in Europe had pressed for harmonisation of EU controls since the early 1990's.

Commission Regulation (EC) No 282/2008 establishes rules to ensure the safety of recycled plastics in food contact packaging. Article 3 of the regulation requires that recycled plastic materials and articles should only be placed on the market if they contain recycled plastic from an authorised recycling process.

EFSA conducts an assessment of the safety of the recycling process and the EC determines an appropriate risk management decision. These authorisations are process specific and recycling facilities are subject to inspection and control by the Member State.

Other food contact materials

For the majority of food contact materials (eg paper and board, printing inks², coatings, rubber, colourants, wood and cork) there are no specific EU measures in place. In the absence of EU measures for specific materials, national legislation is often relied upon³. National legislation is in place in 19 Member States with a varying range of scope and detail, but no member state covers all materials. This gap in FCM requirements and lack of harmonised approach by Member States is currently being addressed through an EC roadmap⁴ for the implementation of specific provisions for materials other than plastics.

² Switzerland has specific legislation regulating food-contact printing inks, Swiss Ordinance RS 817.023.21. This positive list contains 5104 substances however not all of the materials on this list have undergone a risk assessment. The non-evaluated substances are only permitted if they do not migrate to food at a level of 0.01 mg/kg or above. Germany has recently published a Draft Ordinance on printing inks based on the Swiss Ordinance. In addition Romania, the Czech Republic and Slovakia have purity requirements for colorants used in printing ink applications.

³ Veraart, R. and Coulier, L. (2007) Compliance testing of chemical migration from food contact materials Ch 5 In Chemical migration and food contact materials Ed. Karen A. Barnes, C. Richare Sinclair and D.H. Watson CRC Press

⁴ http://ec.europa.eu/governance/impact/planned_ia/docs/2014_sanco_005_fcm_specific_provisions_for_materials_other_than_plastics_en.pdf

The roadmap will also review limitations in the performance of risk assessment at the manufacturer/user level in combination with the non-application of GMP requirements; the lack of transparency throughout the production chain of FCMs and the non-functioning of the internal market leading to barriers in trade. The roadmap draws on information from an EFSA Scientific Cooperation (ESCO) Working Group⁵ report which collated information from all Member States on non-plastic FCMs with no harmonised risk assessment.

United States of America

Food contact packaging has a long history of regulation in the US. The US Food and Drug Administration (FDA) enforces the Federal Food, Drug and Cosmetic Act (FFDCA) from 1958. This is the basic regulation on food contact materials which has a pre-clearance requirement that any substance that is intended to become a component of food (eg. migrates from packaging into food) must be: generally recognised as safe (GRAS), used in accordance with a sanction of approval issued prior to 1958, the subject of a “Threshold of Regulation” exemption letter or cleared by a Food Contact Notification or a food additive regulation. Requirements for food contact materials are briefly summarised below. Detailed information is available at <http://www.fda.gov/Food/FoodIngredientsPackaging/FoodContactSubstancesFCS/ucm064161.htm>.

The US Congress granted authority to the FDA to regulate food additives in 1958 by adding section 409 to the Federal Food Drug and Cosmetic Act (FFDCA). A food additive is defined as ‘any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of food.’

As a result, the FDA established a petition process through which individuals could petition the FDA requesting approval of a food additive. However, experience showed that the promulgation of a regulation for a food additive was an unnecessarily lengthy and resource intensive process. This led to the development of two additional processes intended to largely supplant the petition process. Those processes are the Threshold of Regulation (ToR) exemption process and the Food Contact Notification (FCN) process.

The ToR process, established in 1995, exempts certain substances used in food contact articles from the requirement for an authorising regulation prior to use in contact with food. It is an abbreviated review process that can result in a faster approval. However the approval is not proprietary. To obtain this exemption, the following criteria must be met:

- the estimated daily intake from the proposed substance must be less than or equal to 1.5 µg per person per day (equivalent to less than or equal to less than 0.5 µg per kg of food consumed). The method of estimating daily intake is different to that used in the EU and relies on market share information on packaging use in different types of food matrices; OR
- cleared as a direct additive (part 172) and exposure from the food-contact use is less than 1% of the ADI; AND
- the substance must not be known to be a carcinogen in man or animals. The FDA may decline to grant an exemption if the substance is known to be a potent toxin, or based on the chemical structure the substance may be suspected to be a carcinogen. The substance must also not contain a carcinogenic impurity above specified levels.

⁵European Food Safety Authority; Report of ESCO WG on non-plastic Food Contact Materials. Supporting Publications 2012:139 [63 pp.]. Available online: www.efsa.europa.eu

The FCN process was established in 1997 through an amendment to Section 409 of the FFDCFA. This established a process by which food additives that are food contact substances could be deemed to be safe without going through the petition process. The FFDCFA defines a food contact substance (FCS) as 'any substance intended for use as a component of materials used in the manufacturing, packing, packaging, transporting or holding food if such use is not intended to have any technical effect in such food.' This process is designed as the primary method of authorising new uses of the FCS, however there are circumstances where a petition can still be used. Notably, the FCN process results in an authorisation only for the notifier and manufacturer listed in the FCN, in contrast to a ToR or petition. For a petition a Code of Federal Regulation listing is generated, whereas an effective list of ToR exemptions and FCNs is maintained on the FDA website.

Regardless of the process involved, the submitter must demonstrate that the intended use of the FCM is safe, meaning that there must be a reasonable certainty of no harm. This means that the data and information required are generally comparable under the three processes for a given level of exposure. The FDA has received and processed hundreds of ToR reception requests and FCN applications. Notably, the FDA will not accept an FCN, a ToR exemption submission or a petition for review in the absence of an environmental component.

Product classes specifically regulated under Title 21 of the Code of Federal Regulations

Regulations for FCM primarily relate to substances in 21 CFR 174 – 178 which are functionally separated into lists of specific polymers or classes of polymers, a list of FCM by use or function, and a list based on the type of packaging that they may be used in. These are:

- 175 Adhesives and coatings
- 176 Paper and paperboard
- 177 Polymers
- 178 Adjuvants and production aids

Information about a particular substance in a regulation, ToR exemption or FCN Agency letters generally include a unique chemical descriptor, specifications for the FCM and restrictions related to its use. For FCMs that are the subject of petitions, those specifications ensure that the FCM marketed by the manufacturer is equivalent to the FCM that was subjected to safety assessment.

Recycled materials

In the US, recycled products are not considered to be a new use and, as such, if the recycled product meets the specifications for the virgin material, the recycler is not required to get FDA approval prior to marketing the recycled material for food contact use. There is formal guidance for recycled plastics⁶ and opinion letters are issued by the FDA. There is currently no regulation in the US for recycled paper, and it is considered an undeclared Generally Recognized As Safe (GRAS) material. Draft guidance to evaluate recycled paper products is under development.

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<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/IngredientsAdditivesGRASPackaging/ucm120762.htm>

Canada

In Canada, regulations prohibit the sale of foods that may impart harmful substances to their contents and, similar to Australia/New Zealand requirements, the responsibility lies with the manufacturer or distributor to ensure the safety of their products. However, in the absence of positive lists⁷, voluntary submissions can be made to the Food Directorate for a premarket safety assessment (Magnuson et al. 2013). In terms of data requirements, food packaging submissions are divided into two categories: those on 'formulated products and finished articles' (normally submitted by converters and formulators) and those on 'specific constituents or single additives' (from raw material suppliers). The Food Directorate may then issue a 'no objection' letter which can be used by submitters to reassure their clients that their products are acceptable in terms of safety. Notably, in a legal sense, the letter does not relieve the manufacturer from their responsibilities in terms of food safety.

Asia and the Pacific Rim

The laws and regulations of Asian and Pacific Rim countries that relate to food-packaging materials are diverse. While most countries impose a general safety requirement, there is no common approach to regulation beyond that similarity (Nielsen and Ng Clark 2004; Magnuson et al. 2013). Some countries have established positive lists for polymers that can be used, while others have essentially adopted the requirements of the US FDA. Companies choosing to introduce food-packaging components into Asia need to continue to understand and comply with each country's requirements prior to entering the market.

China

China's requirements for packaging materials utilise a composite of both EU and US regulations. GB 9685-2008 Hygienic Standard⁸ for Use of Additives in Food Containers and Packaging Materials specifies a positive list of more than 1500 permitted food contact additives (including monomers), application scope, specific migration limits, maximum permitted quantity and other restrictions. The standard does not specify whether the material comes in direct or indirect contact with food. Therefore some inks and adhesives used in food packaging not destined for primary packaging are also covered by this standard. Unapproved substances not on the positive list are not allowed unless a food contact notification has been submitted and approved by the Ministry of Health. Many of the substances on the Chinese positive list are taken from the EU regulations and share the same SML. However, there are some differences in regulations, for example, the Chinese regulations apply to plastics, paper, ink, coatings and rubber whereas the EU regulations are only applicable to plastics.

Japan

Japan currently regulates FCMs under the Food Sanitation Law which sets out general food safety standards including food packaging materials (Ettinger and Ng Clark 2012). There is no positive list of permitted substances for use in FCMs, but the Food Sanitation Law authorises the establishment of specifications for food containers and packaging and the raw materials used to manufacture these articles. Examples of these specifications are the use of certain metals (particularly lead) and prohibition of the use of di(2-ethylhexyl) phthalate as a plasticiser for polyvinyl chloride (PVC) used in contact with food containing edible fats and oils.

⁷ http://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._870/page-174.html#docCont

⁸ http://www.cirs-reach.com/China_Chemical_Regulation/China_GB_9685_Hygienic_Standard_for_Use_of_Additives_in_Food_Containers_and_Packaging_Materials.html

Japan also has many voluntary industry standards which are sanctioned by specific well established trade associations (e.g. The Japan Hygienic Olefin and Styrene Plastics Association and the Japan Paper Association). Positive lists exist for food additives for most standards, though the Japan Printing Ink Makers Association holds a negative list excluding substances classified as carcinogenic, mutagenic or acutely toxic. New substances can be added by filing a petition to the relevant association. Only members of these associations (or sponsored companies) can apply for a voluntary standard on an FCM. The Japanese Ministry of Health Labour and Welfare is also now considering introducing a positive list for monomers and additives for food contact plastics.

References

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