

Legislation – Food Packaging – EU - Plastics Regulation

The Plastics Regulation (EU) No. 10/2011 is a specific measure under the EU Food Contact Materials Framework Regulation EC 1935/2004 covering plastic food contact materials and articles in contact with food. It sets out rules on the composition of plastic FCMs, including the establishment of a positive list of component monomers and additives that are permitted for use in the manufacture of plastic FCMs (Union List). The Regulation specifies restrictions on the use of these substances and sets out rules to determine the compliance of plastic materials and articles. It also applies to plastic layers in multi-material multi-layer FCMs.

An important mechanism to ensure the safety of plastic materials is the use of migration limits. These limits specify the maximum amount of substances allowed to migrate to food. For the substances on the Union List the Regulation sets out 'Specific Migration Limits' (SML). These are established by the European Food Safety Authority (EFSA) on the basis of toxicity data of each specific substance. To ensure the overall quality of the plastic, the overall migration to a food of all substances together may not exceed the Overall Migration Limit (OML) of 60 mg/kg food, or 10 mg/dm² of the contact material.

Substances used in the manufacture of plastic layers in plastic materials and articles shall be of a technical quality and a purity suitable for the intended and foreseeable use of the materials or articles. The composition shall be known to the manufacturer of the substance and made available to the competent authorities on request.

Not all substances are required to be included in the Union List, for example colourants, solvents and polymer production aids may be used in the manufacture of plastic layers in plastic FCMs subject to national law. The migration limits apply also to migration from the printed plastic packaging, but the printing inks and coatings are not themselves directly covered. The specific migration limit of a substance on the Union List which migrates from the print or coating must be met, but other non-listed substances can be used in the manufacture of a printing ink or coating.

The Regulation sets out detailed migration testing rules. Although migration testing in the food prevails, migration is usually tested using 'simulants'. These simulants are representative for a food category, e.g., acetic acid 3 % (w/v) is assigned for acidic foods. The migration testing is done under standardised time / temperature conditions, representative for a certain food use, and covers the maximum shelf life of packed food.

To ensure the safety, quality and compliance of plastic materials, adequate data on the composition of (intermediate) materials has to be communicated via the manufacturing chain, up to but not including the retail stage. For this purpose, a 'Declaration of Compliance' (DoC) needs to be provided. The DoC is based on supporting documentation which documents the reasoning on the safety of a plastic food contact material, and which must be provided to enforcement Authorities on their request. The supporting documentation also provides an important link to the manufacturer's responsibility under the Good Manufacturing Practice (GMP) Regulation (EC No 2023/2006).

The Plastics Regulation requires that substances not included in the Union List, including the presence of non-intentionally added substances (NIAS), be assessed in accordance with internationally recognised scientific principles on risk assessment to demonstrate compliance with Article 3 of the Framework Regulation (EC) No 1935/2004 (which specifies that constituents do not transfer to food in quantities which could endanger human health).

The Regulation has legal status in all EU Member States and is regularly amended. The consolidated version is a convenient tool but may not contain all the most recent amendments and is not legally binding.

Regulation (EU) No 2018/213 on the [use of bisphenol A \(BPA\) in varnishes and coatings](#) intended to come into contact with food, which amends the Plastics Regulation (EU) No 10/2011 and sets a revised specific migration limit (SML) of 0.05 mg/kg food, applying from 6th September 2018. In addition, no migration of BPA is allowed from varnishes or coatings applied to materials and articles specifically intended to come into contact with infant formula, follow-on formula, baby food or similar products intended for infants and young children. The Commission has also published a [Questions & Answers](#) document on BPA.

The most recent [15th Amendment to the EU Plastics Regulation](#) (EU) No 2020/1245 introduces new restrictions on plastic food contact materials, in particular, changes to Annex II covering metals and primary aromatic amines, and some changes to testing conditions for repeated use articles and overall migration limit (OML) compliance. The lanthanide metals europium, gadolinium, lanthanum and terbium are added with a group migration limit of 0.05 mg/kg food, and limits are set for several heavy metal impurities. Primary aromatic amines (PAAs) which are listed in entry 43 to Appendix 8 of Annex XVII to the REACH Regulation (EC) No 1907/2006 are given a generic not detectable migration limit with a limit of detection of 0.002 mg/kg food or food simulant applied to each individual primary aromatic amine. The sum of other (not listed) PAAs shall not exceed 0.01 mg/kg in food or food simulant.

The European Commission has issued two guidance documents for the EU Plastics Regulation. The first covers [information in the plastics supply chain](#), and describes the purpose and content of the Declaration of Compliance, as well as the roles and obligations within the supply chain. Although a Declaration of Compliance is not required for non-plastic intermediates, such as adhesives, coatings and printing inks, the document also provides recommendations on the content of the Adequate Information that is expected to be provided. Sun Chemical provides this information by way of our Statements of Composition, which give details on the components with a potential to migrate from the print. The second document provides more [general guidance on the Plastics Regulation](#), including explanations regarding the scope and definitions, why substances are included or exempted from the Union List, and information on dual-use additives and biocides. Sun Chemical was an active participant in the working group drafting these documents, and ensured that the description of the expectations and obligations for printing inks accurately reflected the legal requirements.

EFSA has issued [administrative guidance](#) for applicants seeking to authorise substances for use in plastic food contact materials. The procedures from submission of the application to adoption and publication of the scientific opinion are described. The [Note for Guidance](#) provides the specific instructions on how to prepare a dossier for safety assessment. The EFSA Note for Guidance is often referred to by Member State Competent Authorities when evaluating substances to be used in national food contact materials.

The information contained herein is based on data believed to be up-to-date and correct at the time writing. It is provided to our customers in order that they are able to comply with all applicable health and safety laws, regulations, and orders. In particular, customers are under an obligation to carry out a risk assessment under relevant Good Manufacturing Practices (GMP) in line with legislation and as a result take adequate measures to protect consumers.

