



## Amendment EU 2020/1245 of Regulation (EU) No 10/2011 on food contact plastic materials

The legislation on food contact materials is extensive and complex, and it is crucial to know exactly which requirements a product must comply with before it is placed on the market

### Regulation (EC) no. 1935/2004

In Europe, these type of articles are regulated by Regulation (EC) no. 1935/2004, which specifies the basic requirements for materials and articles intended to come into contact with food. According to the regulation, materials and articles intended to come into contact with food must not bring about a deterioration of the organoleptic properties of the food or bring about an unacceptable change in the composition of the food. Accordingly, they need to be manufactured at a constant quality (Good Manufacturing Practice, GMP) and most importantly, they must not endanger human health.



### Plastic materials or articles intended to come into contact with food

The migration of remaining monomers, additives, plasticizers and solvents in plastic materials and articles intended to come into contact with food are regulated by Regulation No (EU)10/2011, based on the toxicity of the individual material or article. It establishes limits for the transfer (migration) of substances from packaging to food. Annex I contains a list for approved substances and also gives individual limits for their migration into food, based on their toxicological profile.

### 15<sup>th</sup> amendment to Regulation (EU) 10/2011

On September 2<sup>nd</sup> 2020, the 15<sup>th</sup> amendment to Regulation (EU) 10/2011 was officially published as:

*'Commission Regulation (EU) 2020/1245 amending Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food'.*

Based on scientific assessments by the European Food Safety Authority (EFSA), amendments are now proposed to

Annexes I and II to Regulation (EU) No 10/2011 on plastic food contact materials. At the same time, changes are added to the migration scenarios and the text on the testing of products for repeated use is clarified, among other things.

The amendment addresses, among others points:

- Adding a detection limit of 0.002 mg/kg for specific primary aromatic amines;
- Adding a note 28 that the limit value for FCM # 236 is 0.002 mg/kg;
- Adding FCM Nos. 1075, 1076 and 1077 to Annex I;
- Addition of 4 lanthanides: Lanthanum (La), Europium (Eu), Gadolinium (Gd) and Terbium (Tb) to Annex II;
- General update of Annex II, in which metals referred to in Article 6 (3) (a) and Annex I are included in Annex II;
- Arsenic (As), Cadmium (Cd), Chromium (Cr), Lead (Pb) and Mercury (Hg) are added to Annex II as they can be found as impurities in plastics;
- Requirements for migration from repeated use products are clarified to make it clear that a product does not meet the requirements if an increasing migration is seen from 1<sup>st</sup>

to 2<sup>nd</sup> to 3<sup>rd</sup> migration, although all results are below the limit value;

- OM0 (30 minutes at 40 ° C) is added to test products with short contact at low temperatures;
- OM4 can now be used at reflux temperatures;
- Further clarification of the requirements for the testing of process equipment, where several components come into contact with the food.

The amendment came into force on 23<sup>rd</sup> September 2020 with a transition period of two years, until 23 September 2022. For Plastic materials and articles that comply with Regulation (EU) No 10/2011 and which are first placed on the market before 23 March 2021, they will remain on the market until the exhaustion of stocks.

### **Producing new plastic products or packaging in contact with food**

When a manufacturer, supplier, distributor or retailer places on the market a plastic material and/or article intended to be in contact with food, they must comply the requirements of Regulation (EC) N° 1935/2004 and Regulation





N° 10/2011 and its amendments, such as the compositional requirements, specific provisions for certain materials and articles, declaration, documentation requirements, etc.

With this new amendment, it is very important that the Declaration of Compliance (DoC) and the supporting documents are updated with the conditions and results of testing, calculations, analysis and evidence on the safety or reasoning demonstrating compliance of the product or the raw material, especially where it concerns metals and primary aromatic amines requirements. Until now, it was acceptable for the manufacturers to state that the metals listed in Annex II were not present in the raw materials, but now the list has been expanded with new metals and restriction limits. Various metals that are only present as contaminations are introduced in the annex. Another important point in Annex II is the reduction of the non-detection limit for the specific migration of primary aromatic amines. Thus, testing metals and primary aromatic amines is necessary to check that the raw material and/or product comply with the Regulation N° 10/2011 and the 15<sup>th</sup> amendment.

## Services

Eurofins offers the full breadth of our services and expertise to the entire supply chain, from raw materials to the finished product – delivering complete documentation of regulatory compliance.

## Testing services

Eurofins offers testing of materials and articles intended to come into contact with food, in accordance with current legislation, and can assist you in establishing a test program that meets your needs for regulatory requirements and testing. We are, of course, ISO-17025 accredited and are highly focused on delivering high- quality service and products.

## Regulatory compliance service

Understanding varied applicable regulatory demands can be challenging, with several different legal requirements to be potentially considered on a European level alone, with EU member states having additional requirements in some instances. Eurofins can facilitate the evaluation of your raw materials and final articles for their compliance according to the national, European and international standards and legislation. Eurofins can help you to put your products on the market, through which you can keep your focus on your priority: satisfying customers and growing business.

