Plastic food contact materials: good manufacturing practice

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EU strengthens rules on the purity of plastic food contact materials

Commission Regulation (EU) 2025/351 of 21 February 2025 amending Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food, amending Regulation (EU) 2022/1616 on recycled plastic materials and articles intended to come into contact with foods, and repealing Regulation (EC) No 282/2008, and amending Regulation (EC) No 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food as regards recycled plastic and other matters related to quality control and manufacturing of plastic materials and articles intended to come into contact with food

Update

The European Union has set new rules for plastic food contact materials (FCM) to improve quality control. In particular, it aligns existing rules on plastic FCM with legislation on recycled plastic FCM. It introduces purity requirements for substances obtained from waste and natural materials, and adds quality control rules on good manufacturing practice.

What is changing?

Plastic FCM

Regulation 10/2011 sets requirements for plastic materials intended to come into contact with foods. The changes introduced by the new Regulation 2025/351 include the following (Articles cited are in Regulation 10/2011).

Reinforcing purity requirements

- High degree of purity: substances used to manufacture plastic materials must be of a “high degree of purity”, as defined in new Art. 3a.
- Purity of substances present in plastic: substances in the final plastic materials, including those manufactured from waste, also have to comply with of a high degree of purity (new Art. 8).

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- Substances of natural origin: specific rules on purity requirements are introduced for substances from biological and mineral sources known as “UVCB” (substances of unknown or variable composition, complex reaction products, or a material of a biological or other natural origin) (new Art. 8).
- Demonstrating purity: in addition to the documentation currently required to demonstrate compliance with manufacturing requirements, on request from competent authorities, operators must make available documentation to demonstrate compliance with purity requirements, and competent authorities must be able to take samples of materials to verify purity and composition (Art. 16).

Increasing information for food businesses

Food operators must be able to provide on request a written declaration of compliance, with information that allows easy identification of the plastic materials “or articles or products from intermediate stages of their manufacturing or the substances intended for the manufacturing of those materials and articles” (Art. 15; detail in Annex IV). The new rules extend these requirements to include information on all non-intentionally added substances (impurities) if they could be present in amounts that endanger human health, unacceptably change the composition of food, or worsen its organoleptic characteristics.

Other amendments

- Reprocessed plastic: conditions are set for the use of reprocessed plastic in plastic materials, including migration limits and prohibited constituents (new Art. 10).
- Biocidal products: in addition to those substances authorised for use in plastic materials (Annex I), Regulation 10/2011 previously allowed the temporary use of other substances (Art. 6(5)). The new rules confirm the possibility to incorporate products with a biocidal function into plastic material, provided the substances and products are authorised under the Biocidal Products Regulation (528/2012).
- Migration limits: these limits now apply to plastic layers in multi-layer materials where the layer in direct contact with food is a plastic layer (new Art. 14(4)).
- Good manufacturing practices: detailed rules are established on good manufacturing practices for reprocessing and recycling plastics (amendment to Regulation 2023/2006).
- Clarification on plastic layers: Regulation 10/2011 referred to “plastic layers”, which has created confusion about whether compositional requirements (Chapter II) also apply to non-plastic layers (adhesives, printing inks, varnishes, and coatings). To clarify that Chapter II does not apply to non-plastic layers, the reference to “plastic layers” is deleted in that Chapter of the new Regulation. The term is still used (in Chapter III) to distinguish between plastic and non-plastic layers in multi-layer materials.

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- Clarification on additives: there is sometimes uncertainty about whether solid materials added to plastics should be considered “additives”. The definition of additives now includes these materials (new Art. 3(7)).

Recycled plastic FCM

The revised requirements of Regulation 10/2011 regarding composition (Chapter II), certain materials (Chapter III), and compliance (Chapter V) also generally apply to recycled plastic materials and articles. However, the new Regulation 2025/251 clarifies that the high purity requirement does not apply to substances contained in the input, and remaining in the output of the plastic waste decontamination process (Regulation 10/2011, Art. 8(1)). The high purity requirement therefore only applies to any substance that was added during the recycling process and is still present in the material produced.

Why?

The EU aims to reduce risks to consumers associated with substances passing from plastic materials into foods, especially taking into account the increased production of plastic from reprocessed plastics and waste.

Several problems were identified with the previous rules on **recycled plastic FCM**.

- Regulations 282/2008 and 10/2011 did not apply to all recycling technologies and recycled plastic materials, leaving a gap which created a potential risk to human health.
- Regulation 282/2008 excluded chemical depolymerisation, the use of offcuts and scraps, and the use of barrier layers. Although the safety of these technologies fell under Regulation 10/2011 on plastic materials, the risk assessment under that Regulation was not sufficient.
- Regulation 10/2011 requires that substances used to manufacture plastic materials are of a suitable purity and that any remaining impurities can be risk assessed. However, certain recycling technologies generate substances in an intermediate recycling stage with incidental contamination that is difficult to determine in final plastic materials, again leaving a gap that created a potential risk to human health.

Timeline

The new Regulation applies from **16 March 2025**.

A transition period is foreseen for products complying with the rules in Regulation 10/2011: plastic materials placed on the EU market for the first time before 16 September 2026 can continue to be placed on the market until stocks are exhausted.

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What are the major implications for exporting countries?

Plastic FCM

Under the new rules, manufacturers of FCM will have to review whether all substances used in plastic materials, including substances manufactured from waste and substances of natural origin, meet the high degree of purity required. They will also have to review the information that they provide to food businesses through labelling and in their declaration of compliance.

Recycled plastic FCM

Exporters to the EU of prepacked food products using recycled plastics have to comply with the rules in Regulations 2022/1616 and 10/2011. Recycling installations located outside the EU must be on the EU register and must fully comply with the new Regulation if their recycled plastic is used on food products on the EU market.

Recommended Actions

Plastic FCM

Exporters to the EU of food products packaged in plastic should inform their packaging suppliers of the changes to rules on plastic FCM.

Recycled plastic FCM

Exporters to the EU of food products packaged in recycled plastic must ensure that any recycled plastic FCM are produced by recycling facilities that are registered with the EU, and must provide the necessary declaration of compliance.

Background

Plastic FCM

Regulation 1935/2004 provides the framework for EU rules on FCM. This Regulation states that FCM should not:

- release their constituents into food at levels harmful to human health
- change the composition, taste, or odour of food in an unacceptable way.

Regulation 1935/2004 is modified by Regulation 2019/1381 on the transparency and sustainability of the EU risk assessment in the food chain.

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Good manufacturing practices for materials intended to come into contact with food are set by Regulation 2023/2006.

There are specific rules for certain FCM: active and intelligent materials (Regulation 450/2009), ceramics (Directive 84/500/EEC), and regenerated cellulose film (Directive 2007/42/EEC).

Specific EU rules also apply to certain substances, including bisphenol A (BPA) and other bisphenols and bisphenol derivatives (Regulation 2024/3190); epoxy derivatives (Regulation 1895/2005/EC); N-nitrosamines and N-nitrosatable substances from rubber teats and soothers (Directive 93/11/EEC); and vinyl chloride monomer (Council Directive 78/142/EEC).

The new rules for plastic and recycled plastic FCM increase the safety of these materials. The European Commission asked for feedback from stakeholders before proposing new rules that respond to growing concerns about the potential health impacts of chemicals used in FCM.

Recycled plastic FCM

The EU's Circular Economy Package (2015) identified the need to increase plastic recycling, which led to the adoption of a European Plastics Strategy in 2018. This strategy aims to increase plastic recycling and the recycled content of plastic products and packaging. Food packaging represents a significant proportion of all packaging materials.

Even where recycled plastic materials originate from food use, there may be incidental contamination. In particular, as the input material in the recycling process comes from waste, there is an increased risk of microbiological contamination. Plastic should always be decontaminated during recycling to ensure that any remaining contaminants cannot endanger human health or affect the food with which the plastic comes into contact. Decontamination can take place at waste management or recycling facilities.

Resources

Online resources from the European Commission:

- Circular Economy Package
- Food Contact Materials
- Plastics Strategy
- Union Guidelines on Regulation 10/2011 on plastic materials and articles intended to come into contact with food (2014)
- Union Guidance on Regulation 10/2011 on plastic materials and articles intended to come into contact with food as regards information in the supply chain (2013)

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Commission Regulation (EC) 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food

Commission Regulation (EU) 2022/1616 of 15 September 2022 on recycled plastic materials and articles intended to come into contact with foods, and repealing Regulation (EC) No 282/2008

Commission Regulation (EU) 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food

Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food

Sources

Regulation 2025/351 amending Regulation 10/2011 on plastic materials and articles intended to come into contact with food, amending Regulation 2022/1616 on recycled plastic materials and articles intended to come into contact with foods, and repealing Regulation 282/2008, and amending Regulation 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food as regards recycled plastic and other matters related to quality control and manufacturing of plastic materials and articles intended to come into contact with food

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