

Regulation (EU) 2025/351 – Amendments on several important EU regulations for food contact materials

TÜV Rheinland LGA Products – Information

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On 24th of February 2025 the Commission Regulation (EU) 2025/351 was published. This Regulation contains several amendments to some of the most important food contact material (FCM) legislations, such as Regulation (EU) No. 10/2011, Regulation (EC) No. 2023/2006 and Regulation (EU) 2022/1616. While there is no update included on the positive list in this Regulation, it addresses some important topics related to (including but not limited to) requirements of labelling, declaration of compliance, recycled and reprocessed plastics.

“High degree of purity” is another important topic and its requirements are further defined within this Regulation to assure stronger consumer product safety.

Additional labelling requirements are included, which are needed for food contact articles intended for repeated use and/or not yet in contact with food.

The Declaration of Compliance (DoC) for plastic materials also has been updated and customers are highly recommended to take this into consideration.

Some important aspects of the Regulation are introduced below with further details.

HIGH DEGREE OF PURITY

Regulation (EU) No. 10/2011 has been updated via article 3a with the “high degree of purity” requirements on substance level. All substances used shall correspond to their identity whereby the accompanying non-intentionally added substances (NIAS) will meet one of the below conditions:

- Comply with the assigned specifications and restrictions, or
- Comply with article 19 following risk assessment per internationally recognised scientific principles, or
- If genotoxicity can be ruled out, potential migration must not exceed 0.05 mg/kg
- If genotoxicity cannot be ruled out, potential migration must not exceed 0.00015 mg/kg

Consequently, this leads to final plastic food contact materials, which are produced from substances of high degree of purity, also need to comply with the purity criteria (updated in Article 8).

REPROCESSING PLASTIC FROM OFF-CUTS AND SCRAPS

Reprocessed plastics which are made from plastic off-cuts and scraps are taken under the scope of Regulation (EU) No. 10/2011 via article 10 and the newly added Annex C of Regulation (EC) No. 2023/2006. The collection and use are specified in Annex C of Regulation (EC) No. 2023/2006 and they must comply with the compositional requirements set out in Chapter II of Regulation (EU) No. 10/2011. At the same time, it may not contain substances in any amount which could exceed any of the SML or endanger human health.

UPDATES IN LABELLING REQUIREMENTS

New labelling requirements have been added to article 14 of Regulation (EU) 10/2011. For food contact articles which are intended for repeated use, the labelling information shall include the following:

- Appropriate instructions to slow down deterioration of the article
- Description of observable changes of the article that may indicate deterioration
- A warning in case specific damages or foreseeable misuse would cause increased migration or cause the article to be unsuitable for use in contact with food

For materials and articles not yet in contact with food it is needed to add information based on the substances used, for which limitations of use apply in specific types of foods, contact time and/or temperature of contact and/or heating conditions such as oven and microwave use.

ADJUSTMENT ON S/V RATIO FOR COMPLIANCE

Article 17 paragraph 2 of Regulation (EU) No. 10/2011 previously listed the derogations for which the Surface to Volume (S/V) ratio was set out at a fixed ratio of 6 dm² per kg of foodstuff. Under the new amended part, it allows business operators to choose to verify compliance with an actual ratio than higher than 6 dm² per kg. This applies for example particularly towards small food packaging.

RECYCLED PLASTIC MATERIALS

Article 4 of Regulation (EU) 2022/1616 is updated and further clarified that final recycled plastic food contact materials should meet the same requirements as plastic food contact materials of Regulation (EU) No. 10/2011 (specifically requirements mentioned in chapter II, III and V) ~~w-~~With the exemption, that high degree of purity requirements do not apply to the contaminants of the input and the output of the decontamination process.

Regulation (EC) No. 2023/2006 is further amended in Annex B for recycled plastics and emphasizes that the quality assurance system implemented must contain specific “Quality Assessment Stages” at which the quality shall be verified for each batch of material.

DECLARATION OF COMPLIANCE

An important update is related to Annex IV of Regulation (EU) No. 10/2011, which has updated the requirement to list important information to downstream users to include NIAS, which could be present in quantities that could cause non-compliance to article 3 of Regulation (EC) No. 1935/2004.

Additionally, two points (10 and 11) are added where compliance confirmation is needed if the material is intended for reprocessing use or when the materials is using substances recovered from waste, this substance is conforming to the high degree of purity requirements.

OTHER UPDATES

Aside from the above-mentioned updates, also readjustment of cheese related food simulants, new defined rules for assessing compliance to SML and stability, responsibility of business operators to have supporting documentation and samples available on request by authorities are added.

HINTS FOR ACTION

This Regulation has brought plentiful of changes and one of the most important could be the definition of high degree of purity, which is pushing forward to investigate presence of NIAS and whether these may cause concern to safety to consumers. Presence of such NIAS needs to be declared to downstream users via updated DoC requirements, and consumer safety is further enhanced by labelling obligations directly towards end consumers.

The transitional period is up to 16th September 2026, on or after this date all articles placed on the market must comply with Regulation (EU) 2025/351.

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