

Publication of 15th amendment of Commission Regulation (EU) No 10/2011.

Customer information 09/2020.

On September 2, 2020, the European Commission published Commission Regulation (EU) 2020/1245, amending Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food.

Several changes are made which could be interesting for our valued customers to know, please see below for some noteworthy points related to this amendment.

Update of the Union list in Annex I according to recent scientific opinions from the European Food Safety Authority (EFSA):

- Addition of 3 substances, namely Montmorillonite clay modified with hexadecyltrimethylammonium bromide (FCM No 1075), Phosphorous acid, triphenyl ester, polymer with alpha-hydro-omega-hydroxypoly[oxy(methyl-1,2-ethanediy)], C10-16 alkyl ester (FCM No 1076) and Titanium dioxide surface-treated with fluoride-modified alumina (FCM No 1077)
- Amendment of 2 substances regarding their SML, namely 1,3-phenylenediamine (FCM No 236) and antimony trioxide (FCM No 398)

Update the restrictions on plastic materials and articles in Annex II:

- Specific migration of heavy metals
 - Keeping the existing 9 elements and expanding the list to total 24 elements with specific migration limits (SML)
 - This updated list serves as an uniform approach for verification of compliance for all relevant elements instead of case by case assessment from authorities and industries
- Specific migration of primary aromatic amines (PAAs)
 - Detection limit of PAAs to be reduced to 0.002 mg/kg due to availability of improved analytical methods
 - This lower detection limit is applicable to PAAs listed in entry 43 to Appendix 8 of Annex XVII to Regulation (EC) No 1907/2006 and they shall not be detectable referred to

the single substance with a detection limit of 0.002 mg/kg

- For PAAs not listed in entry 43 to Appendix 8 of Annex XVII to Regulation (EC) No 1907/2006, the requirement remains the same as "not detectable" with sum of PAA less than 0.01 mg/kg

Update in Annex IV for declaration of compliance:

- With the update in Annex II mentioned above, Annex IV sets additional declaration needed to meet the specification set out in Annex II, therefore it is important that evidence of compliance as supporting document(s) is available at request from authority by demand
- There is also at the same time a focus on upstream responsibility. Based on the substances that are used in the formulation and manufacturing of the intermediate material, intermediate material producers need in addition to declare information about Annex II as well as if genotoxicity of an added substance cannot be ruled out.

Update in Annex V related to compliance testing:

- Migration test using the whole equipment or appliance
 - A subparagraph is added in Chapter 2 for allowing complete product assessment for articles which contain plastic part(s) in a food processing equipment or appliance. Important is that the actual use during such assessment can be properly simulated and the final collected food simulant is representative to the worst foreseeable condition(s) of use.
 - This approach can confirm compliance only. If a test result exceeds the allowed limit(s), further investigation is needed to track if the non-compliance is coming from the plastic material or not.
- Introduction of OM0 for overall migration
 - OM0 test condition (30 minutes at 40°C) is introduced to represent conditions of use at cold or ambient temperatures for a short duration
 - As original available OM2 and OM3, which come closest in simulating the above described conditions of

use, they are significantly more severe than the real life conditions. This new OM0 helps to fill up the gap.

- With this more suitable option for assessment, some items (e.g. a plastic garlic press) can be tested with OM0 instead of OM2 or OM3
- Verification of compliance for OM and SM on articles and materials that are placed in repeated contact with food
 - When a repeated use article is tested, the results of the 3rd migration test should be used to verify compliance with the migration limits. Under normal circumstances for plastic with resistant character to foodstuffs and food simulants, the residues from such migration tests should decrease per migration.
 - In this sense is now specified, that the result in the 2nd migration shall not exceed the level observed in the 1st migration, and the result in the 3rd migration shall not exceed the level observed in the 2nd migration.
 - Moreover, if the decreasing trend is not shown in the test results, even if 3rd migration result is below the limit, then it still cannot be concluded as compliant.

This amendment shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union. Plastic materials and articles complying with Regulation (EU) No 10/2011 as applicable before the entry into force of this Regulation, and which were first placed on the market before 23 March 2021 may continue to be placed on the market until 23 September 2022 and remain on the market until the exhaustion of stocks. With the update above, TÜV Rheinland Group can support customers finding the right approach and testing for the compliance requirements. Please feel free to contact your local TÜV Rheinland for further information.

Reference link:

[https://eur-lex.europa.eu/legal-content/EN/TX-T/?uri=uriserv:OJ.L_.2020.288.01.0001.01.ENG&toc=O-J:L:2020:288:TOC](https://eur-lex.europa.eu/legal-content/EN/TX/T/?uri=uriserv:OJ.L_.2020.288.01.0001.01.ENG&toc=O-J:L:2020:288:TOC)

**FOR FURTHER TECHNICAL INFORMATION,
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