



The latest trends, services & promotions

EUROPEAN UNION REVISES (EU) NO 10/2011 FOR FOOD CONTACT PLASTICS

On September 3, 2020, the European Union published **Regulation (EU) No 2020/1245** to amend and correct Regulation (EU) 10/2011 on food contact plastics. This regulation contains, inter alia, important changes to Annexes I, II, IV, and V to the Regulation (EU) No 10/2011.

The new law will enter into force on the twentieth day after its publication in the Official Journal of the EU. Food contact plastics complying with the old regulation before the entry into force of the new regulation, and which were first placed on the market before March 23, 2021 may continue to be placed on the market until September 23, 2022 and remain on the market until the exhaustion of stocks.



The highlights of the new regulation are summarized as follows:

Changes on specific migration:

- The new regulation provides specific migration limits (SMLs) for 24 Heavy Metals as below:

HEAVY METAL	LIMIT (MG/KG)	HEAVY METAL	LIMIT (MG/KG)
Aluminium (Al)	1	Iron (Fe)	48
Ammonium	-	Lanthanum (La)	0.05
Antimony (Sb)	0.04	Lead (Pb)	ND
Arsenic (As)	ND	Lithium (Li)	0.6
Barium (Ba)	1	Magnesium (Mg)	-
Cadmium (Cd)	ND (0.002)	Manganese (Mn)	0.6
Calcium (Ca)	-	Mercury (Hg)	ND
Chromium (Cr)	ND (0.01)	Nickel (Ni)	0.02
Cobalt (Co)	0.05	Potassium (K)	-
Copper (Cu)	5	Sodium (Na)	-
Europium (Eu)	0.05	Terbium (Tb)	0.05
Gadolinium (Gd)	0.05	Zinc (Zn)	5

- The SML for each primary aromatic amine (PAA) listed in entry 43 of REACH Annex XVII but no SML in (EU) No 10/2011 shall be ≤ 0.002 mg/kg, while the sum of PAAs not listed in entry 43 of Annex XVII in REACH regulation and no SML in (EU) No 10/2011 shall be ≤ 0.01 mg/kg.



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Provisions on migration tests and plastic materials or articles for repeated use:

- Defining new rules for the migration of plastic materials or components in food processing equipment or appliances, where migration tests may be carried out by determining the specific migration into the food or food simulant produced or processed by the final equipment or appliance or the part as appropriate in accordance with the worst foreseeable conditions
- The migration test(s) for repeated use food contact materials and articles are obliged to be carried out three times on a single sample using a fresh portion of simulant on each occasion
- The result of specific migration for each occasion must not be higher than the value in the preceding migration test. Although compliance for migration is based on the third test, compliance cannot be established if the result of migration increases from the first migration test to third migration test even if the SML is not exceeded in any of the three tests

Update on overall migration conditions:

- New Test Number OM0 (40°C, 30 min) for any food contact at cold or room temperatures with no more than 30 minutes
- The words "or at reflux" added to the testing conditions in OM4 for the situation when testing at 100°C is technically difficult

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