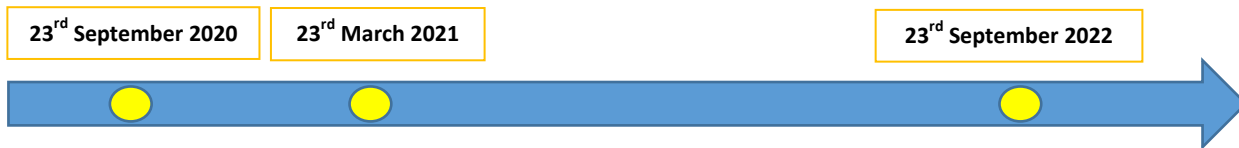




# COMMISSION REGULATION (EU) 2020/1245, amending and correcting Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food



- 23<sup>rd</sup> September 2020** Commission Regulation (EU) 2020/1245 has entered into force
- 23<sup>rd</sup> March 2021** Plastic materials and articles complying with Regulation (EU) No 10/2011 as applicable before the entry into force of Regulation 2020/1245 can still be placed on the market up till this date. Since this date new materials and articles shall be evaluated according to the new rules.
- 23<sup>rd</sup> September 2022** Plastic materials and articles complying with Regulation (EU) No 10/2011 as applicable before the entry into force of Regulation 2020/1245 and 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.

## THE MOST IMPORTANT CHANGES IN THE SCOPE OF TESTING

**ITC labs is prepared to evaluate the articles according to the new requirements of Commission Regulation (EU) 2020/1245**

### 1. Specific migration of metals (Annex II – Table 1):

Previous version of 10/2011		Actual version 10/2011 (as amended by 2020/1245)		
Metal	SML (mg/kg)	Metal	SML (mg/kg)	Note
Aluminium	1	Aluminium	1	Limited metals according to the 10/2011 as amended before 23 <sup>rd</sup> of September 2020 (before Commission Regulation 2020/1245)
Barium	1	Barium	1	
Cobalt	0,05	Cobalt	0,05	
Copper	5	Copper	5	
Iron	48	Iron	48	
Lithium	0,6	Lithium	0,6	
Manganese	0,6	Manganese	0,6	
Nickel	0,02	Nickel	0,02	
Zinc	5	Zinc	5	
		Antimony	0,04	
		Europium	0,05	<b>Lanthanides</b> Sum of all migrating lanthanides into food or food simulants shall not exceed 0,05 mg/kg
		Gadolinium	0,05	
		Lanthanum	0,05	
		Terbium	0,05	<b>Non authorized heavy metals (ND = not detected)</b> Limit for chromium is valid for hexavalent chromium (Cr <sup>VI+</sup> ). If the presence of Cr <sup>VI+</sup> is excluded the limit 3,6 mg/kg can be used.
		Arsenic	ND = 0,01	
		Cadmium	ND = 0,002	
		Chromium	ND = 0,01	
		Lead	ND = 0,01	
		Mercury	ND = 0,01	<b>Elements (substances) from allowed salts of authorized acids, phenols or alcohols</b>
		Ammonium	-	
		Calcium	-	
		Magnesium	-	
		Potassium	-	
		Sodium	-	

## 2. Change of limits and scope of the testing for primary aromatic amines - PAA (Annex II):

### New Regulation requirement:

- specific migration limits for individual PAA (0,002 mg/kg) listed in entry 43 of Appendix 8 to Annex XVII to Regulation (EC) No 1907/2006 „Azocolourants“ – see the following table
- sum of all other PAA must meet migration limit 0,01 mg/kg

PAA	CAS	SML (mg/kg)	Note
4-Aminobiphenyl	92-67-1	0,002	PAA listed in entry 43 of Appendix 8 to Annex XVII to Regulation (EC) No 1907/2006 „Azocolourants“
Benzidine	92-87-5	0,002	
4-Chloro-o-toluidine	95-69-2	0,002	
2-Naphthylamine	91-59-8	0,002	
o-Aminoazotoluene	97-56-3	0,002	
5-Nitro-o-toluidine	99-55-8	0,002	
4-Chloroaniline	106-47-8	0,002	
4-methoxy-m-phenylenediamine	615-05-4	0,002	
4,4'-Diamino-diphenylmethane	101-77-9	0,002	
3,3'-Dichloro-benzidine	91-94-1	0,002	
3,3'-Dimethoxy-benzidine	119-90-4	0,002	
3,3'-Dimethyl-benzidine	119-93-7	0,002	
3,3'-Dimethyl-4,4'-diaminodiphenylmethane	838-88-0	0,002	
p-Cresidine	120-71-8	0,002	
4,4'-Methylene-bis(2 chloro-aniline)	101-14-4	0,002	
4,4'-Oxy-dianiline	101-80-4	0,002	
4,4'- Thio-dianiline	139-65-1	0,002	
o-Toluidine	95-53-4	0,002	
4-Methyl-m-phenylenediamine	95-80-7	0,002	
2,4,5-Trimethyl-aniline	137-17-7	0,002	
o-Anisidine	90-04-0	0,002	
o-Aminoazobenzene	60-09-3	0,002	

## 3. Testing of materials and articles intended into the repeated use (Annex V, point 2.1.6):

The regulation strictly requires proof of the stability of the plastic article (material) during the repeated use and therefore three subsequent overall and also specific migration tests are requested for articles intended to repeated use.

The results of the third migration test shall fulfill the migration limits. In addition the level of migration shall not increase from the first migration test to the third migration test. Otherwise compliance of the material shall not be established even in case the specific migration limit is not exceeded in any of the three tests.