

Status: Point in time view as at 31/12/2020.

*Changes to legislation: There are currently no known outstanding effects for the
Commission Regulation (EU) No 10/2011, ANNEX II. (See end of Document for details)*

[^{F1}ANNEX II

Restrictions on plastic materials and articles

Textual Amendments

- F1** Substituted by [Commission Regulation \(EU\) 2020/1245 of 2 September 2020 amending and correcting Regulation \(EU\) No 10/2011 on plastic materials and articles intended to come into contact with food \(Text with EEA relevance\).](#)

The following restrictions on plastic materials and articles apply:

1. Plastic materials and articles shall not release the substances in Table 1 below in quantities exceeding the specific migration limits expressed in mg/kg food or simulant specified in column (3), and subject to the remarks in Column (4).

Substances listed in Table 1 shall only be used in accordance with the compositional requirements set out in Chapter II. If Chapter II does not provide a basis for the authorised use of such a substance, that substance may only be present as an impurity subject to the restrictions specified in Table 1.

Table 1

General list of migration limits for substances migrating from plastic materials and articles

(1)	(2)	(3)	(4)
Name	Salts allowed in accordance with Article 6(3)(a)	SML [mg/kg food or food simulant]	Remark
Aluminium	yes	1	
Ammonium	yes		(1)
Antimony	no	0,04	(2)
Arsenic	no	ND	
Barium	yes	1	
Cadmium	no	ND (LOD 0,002)	
Calcium	yes		(1)
Chromium	no	ND	(3)
Cobalt	yes	0,05	
Copper	yes	5	
Europium	yes	0,05	(4)
Gadolinium	yes	0,05	(4)
Iron	yes	48	
Lanthanum	yes	0,05	(4)
Lead	no	ND	

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Table 1

General list of migration limits for substances migrating from plastic materials and articles

Lithium	yes	0,6	
Magnesium	yes		(1)
Manganese	yes	0,6	
Mercury	no	ND	
Nickel	no	0,02	
Potassium	yes		(1)
Sodium	yes		(1)
Terbium	yes	0,05	(4)
Zinc	yes	5	

ND: Not Detectable; detection limit assigned in accordance with second subparagraph of Article 11(4); LOD: specified Limit of Detection.

Remarks

(1) The migration is subject to Article 11(3) and Article 12

(2) The note in Annex I, Table 1, FCM No 398 applies: SML might be exceeded at very high temperature

(3) To verify compliance with the Regulation, the detection limit of 0,01 mg/kg shall apply for total chromium. However if the operator that placed the material on the market can prove on the basis of pre-existing documentary evidence that the presence of hexavalent chromium in the material is excluded because it is not used or formed or during the entire production process, a limit for the total chromium of 3,6 mg/kg food shall apply.

(4) The lanthanide substances europium, gadolinium, lanthanum, and/or terbium can be used in accordance with Article 6(3)(a) provided that:

- (a) The sum of all lanthanide substances migrating to the food or food simulant does not exceed the specific migration limit of 0,05 mg/kg; and
- (b) analytical evidence using a well described methodology demonstrating that the lanthanide substance(s) used are present in dissociated ionic form in the food or the food simulant, forms part of the documentation referred to in Article 16.

2. Primary aromatic amines ('PAAs') listed in entry 43 to Appendix 8 of Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council⁽¹⁾ and for which no migration limit is specified in Table 1 of Annex I shall not migrate or shall not otherwise be released from plastic materials and articles into food or food simulant. They shall not be detectable using analytical equipment with a limit of detection of 0,002 mg/kg food or food simulant applied to each individual primary aromatic amine ('PAA'), in accordance with Article 11(4).

For PAAs not listed in entry 43 to Appendix 8 of Annex XVII to Regulation (EC) No 1907/2006, but for which no specific migration limit is specified in Annex I, compliance with Article 3 of Regulation (EC) No 1935/2004 shall be verified in accordance with Article 19. The sum of those PAAs shall however not exceed 0,01 mg/kg in food or food simulant.]

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- (1) [^{F1}Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).:]

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