

Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance)

CHAPTER II

COMPOSITIONAL REQUIREMENTS

SECTION 1

Authorised substances

Article 5

Union list of authorised substances

- 1 Only the substances included in the Union list of authorised substances (hereinafter referred to as the Union list) set out in Annex I may be intentionally used in the manufacture of plastic layers in plastic materials and articles.
- 2 The Union list shall contain:
 - a monomers or other starting substances;
 - b additives excluding colorants;
 - c polymer production aids excluding solvents;
 - d macromolecules obtained from microbial fermentation.
- 3 The Union list may be amended in accordance with the procedure established by Articles 8 to 12 of Regulation (EC) No 1935/2004.

Article 6

Derogations for substances not included in the Union list

- 1 By way of derogation from Article 5, substances other than those included in the Union list may be used as polymer production aids in the manufacture of plastic layers in plastic materials and articles subject to national law.
- 2 By way of derogation from Article 5, colorants and solvents may be used in the manufacture of plastic layers in plastic materials and articles subject to national law.
- 3 The following substances not included in the Union list are authorised subject to the rules set out in Articles 8, 9, 10, 11 and 12:
 - a salts (including double salts and acid salts) of aluminium, ammonium, barium, calcium, cobalt, copper, iron, lithium, magnesium, manganese, potassium, sodium, and zinc of authorised acids, phenols or alcohols;
 - b mixtures obtained by mixing authorised substances without a chemical reaction of the components;
 - c when used as additives, natural or synthetic polymeric substances of a molecular weight of at least 1 000 Da, except macromolecules obtained from microbial fermentation,

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complying with the requirements of this Regulation, if they are capable of functioning as the main structural component of final materials or articles;

- d when used as monomer or other starting substance, pre-polymers and natural or synthetic macromolecular substances, as well as their mixtures, except macromolecules obtained from microbial fermentation, if the monomers or starting substances required to synthesise them are included in the Union list.

4 The following substances not included in the Union list may be present in the plastic layers of plastic materials or articles:

- a non-intentionally added substances;
- b aids to polymerisation.

5 By derogation from Article 5, additives not included in the Union list may continue to be used subject to national law after 1 January 2010 until a decision is taken to include or not to include them in the Union list provided they are included in the provisional list referred to in Article 7.

Article 7

Establishment and management of the provisional list

1 The provisional list of additives that are under evaluation by the European Food Safety Authority (hereinafter referred to as the Authority) that was made public by the Commission in 2008 shall be regularly updated.

2 An additive shall be removed from the provisional list:

- a when it is included in the Union list set out in Annex I; or
- b when a decision is taken by the Commission not to include it in the Union list; or
- c if during the examination of the data, the Authority calls for supplementary information and that information is not submitted within the time limits specified by the Authority.

SECTION 2

General requirements, restrictions and specifications

Article 8

General requirement on substances

Substances used in the manufacture of plastic layers in plastic materials and articles shall be of a technical quality and a purity suitable for the intended and foreseeable use of the materials or articles. The composition shall be known to the manufacturer of the substance and made available to the competent authorities on request.

Article 9

Specific requirements on substances

1 Substances used in the manufacture of plastic layers in plastic materials and articles shall be subject to the following restrictions and specifications:

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- a the specific migration limit set out in Article 11;
 - b the overall migration limit set out in Article 12;
 - c the restrictions and specifications set out in column 10 of Table 1 of point 1 of Annex I;
 - d the detailed specifications set out in point 4 of Annex I.
- 2 Substances in nanoform shall only be used if explicitly authorised and mentioned in the specifications in Annex I.

Article 10

General restrictions on plastic materials and articles

General restrictions related to plastic materials and articles are laid down in Annex II.

Article 11

Specific migration limits

- 1 Plastic materials and articles shall not transfer their constituents to foods in quantities exceeding the specific migration limits (SML) set out in Annex I. Those specific migration limits (SML) are expressed in mg of substance per kg of food (mg/kg).
- 2 For substances for which no specific migration limit or other restrictions are provided in Annex I, a generic specific migration limit of 60 mg/kg shall apply.
- 3 By derogation from paragraphs 1 and 2, additives which are also authorised as food additives by Regulation (EC) No 1333/2008 or as flavourings by Regulation (EC) No 1334/2008 shall not migrate into foods in quantities having a technical effect in the final foods and shall not:
- a exceed the restrictions provided for in Regulation (EC) No 1333/2008 or in Regulation (EC) No 1334/2008 or in Annex I to this Regulation for foods for which their use is authorised as food additive or flavouring substances; or
 - b exceed the restrictions set out in Annex I to this Regulation in foods for which their use is not authorised as food additive or flavouring substances.

Article 12

Overall migration limit

- 1 Plastic materials and articles shall not transfer their constituents to food simulants in quantities exceeding 10 milligrams of total constituents released per dm² of food contact surface (mg/dm²).
- 2 By derogation from paragraph 1, plastic materials and articles intended to be brought into contact with food intended for infants and young children, as defined by Commission Directives 2006/141/EC⁽¹⁾ and 2006/125/EC⁽²⁾, shall not transfer their constituents to food simulants in quantities exceeding 60 milligrams of total of constituents released per kg of food simulant.

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- (1) [OJ L 401, 30.12.2006, p. 1.](#)
- (2) [OJ L 339, 6.12.2006, p. 16.](#)