

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 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:

- 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).

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*Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011, SECTION 2. (See end of Document for details)*

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<sup>F12</sup> .....

[<sup>F23</sup> By derogation from paragraph 1, 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.]

[<sup>F34</sup> Where it is specified that no migration of a particular substance is permitted, compliance shall be established using appropriate migration test methods selected in accordance with Article 11 of Regulation (EC) No 882/2004 that can confirm the absence of migration above a specified limit of detection.

For the purposes of the first subparagraph, unless specific detection limits have been set for particular substances or groups of substances, a detection limit of 0,01 mg/kg shall apply.]

#### Textual Amendments

- F1** Deleted by [Commission Regulation \(EU\) 2016/1416 of 24 August 2016 amending and correcting Regulation \(EU\) No 10/2011 on plastic materials and articles intended to come into contact with food \(Text with EEA relevance\).](#)
- F2** Substituted by [Commission Regulation \(EU\) 2016/1416 of 24 August 2016 amending and correcting Regulation \(EU\) No 10/2011 on plastic materials and articles intended to come into contact with food \(Text with EEA relevance\).](#)
- F3** Inserted by [Commission Regulation \(EU\) 2016/1416 of 24 August 2016 amending and correcting Regulation \(EU\) No 10/2011 on plastic materials and articles intended to come into contact with food \(Text with EEA relevance\).](#)

### 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 dm<sup>2</sup> of food contact surface (mg/dm<sup>2</sup>).

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<sup>(1)</sup> and 2006/125/EC<sup>(2)</sup>, 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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**Changes to legislation:** There are currently no known outstanding effects for the  
Commission Regulation (EU) No 10/2011, SECTION 2. (See end of Document for details)

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

**Changes to legislation:**

There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011, SECTION 2.