

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 I

**GENERAL PROVISIONS**

*Article 3*

**Definitions**

For the purpose of this Regulation, the following definitions shall apply:

- (1) 'plastic materials and articles' means:
  - (a) materials and articles referred to in points (a), (b) and (c) of Article 2(1); and
  - (b) plastic layers referred to in Article 2(1)(d) and (e);
- (2) 'plastic' means polymer to which additives or other substances may have been added, which is capable of functioning as a main structural component of final materials and articles;
- (3) 'polymer' means any macromolecular substance obtained by:
  - (a) a polymerisation process such as polyaddition or polycondensation, or by any other similar process of monomers and other starting substances; or
  - (b) chemical modification of natural or synthetic macromolecules; or
  - (c) microbial fermentation;
- (4) 'plastic multi-layer' means a material or article composed of two or more layers of plastic;
- (5) 'multi-material multi-layer' means a material or article composed of two or more layers of different types of materials, at least one of them a plastic layer;
- (6) 'monomer or other starting substance' means:
  - (a) a substance undergoing any type of polymerisation process to manufacture polymers; or
  - (b) a natural or synthetic macromolecular substance used in the manufacture of modified macromolecules; or
  - (c) a substance used to modify existing natural or synthetic macromolecules;
- (7) 'additive' means a substance which is intentionally added to plastics to achieve a physical or chemical effect during processing of the plastic or in the final material or article; it is intended to be present in the final material or article;
- (8) 'polymer production aid' means any substance used to provide a suitable medium for polymer or plastic manufacturing; it may be present but is neither intended to be

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*Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011, Article 3. (See end of Document for details)*

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- present in the final materials or articles nor has a physical or chemical effect in the final material or article;
- (9) ‘non-intentionally added substance’ means an impurity in the substances used or a reaction intermediate formed during the production process or a decomposition or reaction product;
- (10) ‘aid to polymerisation’ means a substance which initiates polymerisation and/or controls the formation of the macromolecular structure;
- (11) ‘overall migration limit’ (OML) means the maximum permitted amount of non-volatile substances released from a material or article into food simulants;
- (12) ‘food simulant’ means a test medium imitating food; in its behaviour the food simulant mimics migration from food contact materials;
- (13) ‘specific migration limit’ (SML) means the maximum permitted amount of a given substance released from a material or article into food or food simulants;
- (14) ‘total specific migration limit’ (SML(T)) means the maximum permitted sum of particular substances released in food or food simulants expressed as total of moiety of the substances indicated;
- (15) ‘functional barrier’ means a barrier consisting of one or more layers of any type of material which ensures that the final material or article complies with Article 3 of Regulation (EC) No 1935/2004 and with the provisions of this Regulation;
- (16) [<sup>F1</sup>‘non-fatty food’ means a food for which in migration testing only food simulants other than food simulants D1 or D2 are laid down in Table 2 of Annex III to this Regulation;]
- (17) ‘restriction’ means limitation of use of a substance or migration limit or limit of content of the substance in the material or article;
- (18) [<sup>F1</sup>‘specification’ means composition of a substance, purity criteria for a substance, physico-chemical characteristics of a substance, details concerning the manufacturing process of a substance or further information concerning the expression of migration limits;]
- (19) [<sup>F2</sup>‘hot-fill’ means the filling of any article with a food with a temperature not exceeding 100 °C at the moment of filling, after which the food cools down to 50 °C or below within 60 minutes, or to 30 °C or below within 150 minutes.]

#### **Textual Amendments**

- F1** 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 \(Text with EEA relevance\)](#).
- F2** 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 \(Text with EEA relevance\)](#).

**Changes to legislation:**

There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011, Article 3.