

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 1*

**Subject matter**

- 1 This Regulation is a specific measure within the meaning of Article 5 of Regulation (EC) No 1935/2004.
- 2 This Regulation establishes specific requirements for the manufacture and marketing of plastic materials and articles:
  - a intended to come into contact with food; or
  - b already in contact with food; or
  - c which can reasonably be expected to come into contact with food.

*Article 2*

**Scope**

- 1 This Regulation shall apply to materials and articles which are placed on the EU market and fall under the following categories:
  - a materials and articles and parts thereof consisting exclusively of plastics;
  - b plastic multi-layer materials and articles held together by adhesives or by other means;
  - c materials and articles referred to in points a) or b) that are printed and/or covered by a coating;
  - d plastic layers or plastic coatings, forming gaskets in caps and closures, that together with those caps and closures compose a set of two or more layers of different types of materials;
  - e plastic layers in multi-material multi-layer materials and articles.
- 2 This Regulation shall not apply to the following materials and articles which are placed on the EU market and are intended to be covered by other specific measures:
  - a ion exchange resins;
  - b rubber;
  - c silicones.
- 3 This Regulation shall be without prejudice to the EU or national provisions applicable to printing inks, adhesives or coatings.

### 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 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) ‘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 V 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) ‘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.

#### *Article 4*

### **Placing on the market of plastic materials and articles**

Plastic materials and articles may only be placed on the market if they:

- (a) comply with the relevant requirements set out in Article 3 of Regulation (EC) No 1935/2004 under intended and foreseeable use; and
- (b) comply with the labelling requirements set out in Article 15 of Regulation (EC) No 1935/2004; and
- (c) comply with the traceability requirements set out in Article 17 of Regulation (EC) No 1935/2004; and
- (d) are manufactured according to good manufacturing practice as set out in Commission Regulation (EC) No 2023/2006<sup>(1)</sup>; and
- (e) comply with the compositional and declaration requirements set out in Chapters II, III and IV of this Regulation.

- (1) OJ L 384, 29.12.2006, p. 75.