

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 <sup>F1</sup>... 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 <sup>F1</sup>... 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 <sup>F2</sup>... provisions applicable to printing inks, adhesives or coatings.

---

**Textual Amendments**

- F1** Word in [Art. 2](#) omitted (31.12.2020) by virtue of [The Materials and Articles in Contact with Food \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/704\)](#), regs. 1, **66(b)**; 2020 c. 1, Sch. 5 para. 1(1)

---

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

---

**F2** Words in Art. 2(3) omitted (31.12.2020) by virtue of [The Materials and Articles in Contact with Food \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/704\)](#), regs. 1, **66(a)**; 2020 c. 1, Sch. 5 para. 1(1)

### 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) [<sup>F3</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>F3</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>F4</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**

- F3** 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 \(Text with EEA relevance\)](#).
- F4** 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 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

---

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

---

- (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.

---

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

---

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

**Changes to legislation:**

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