

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

^{F1} ... List of authorised substances

1 Only the substances included in the ^{F2}... list of authorised substances (hereinafter referred to as the ^{F2}... list) set out in Annex I may be intentionally used in the manufacture of plastic layers in plastic materials and articles.

- 2 The ^{F2}... 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.

[^{F3} The appropriate authority may prescribe amendments to the list.]

Textual Amendments

- F1** Word in *Art. 5* heading 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, **67(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F2** Word in *Art. 5* 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, **67(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F3** *Art. 5(3)* substituted (31.12.2020) by *The Materials and Articles in Contact with Food (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/704)*, regs. 1, **67(b)**; 2020 c. 1, Sch. 5 para. 1(1)

[^{F4} *Article 5A*

Regulations and devolved powers

1. Any power to make regulations under this Regulation—
 - a so far as exercisable by a Minister of the Crown, is exercisable by statutory instrument;
 - b so far as exercisable by the Welsh Ministers, is exercisable by statutory instrument.
2. For regulations made under this Regulation by the Scottish Ministers, see also section 27 of the Interpretation and Legislative Reform (Scotland) Act 2010 (Scottish statutory instruments).

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3. Any power to make regulations under this Regulation includes power—
 - a to make different provision in relation to different cases or classes of case (including different provision for different areas or different classes of business); and
 - b to provide for such exceptions, limitations and conditions, and to make such supplementary, incidental, consequential or transitional provisions, as the appropriate authority considers necessary or expedient.
4. Any statutory instrument or Scottish statutory instrument containing regulations made under this Regulation is subject to annulment in pursuance of a resolution—
 - a in the case of England, of either House of Parliament;
 - b in the case of Wales, of Senedd Cymru;
 - c in the case of Scotland, of the Scottish Parliament.
5. In this Regulation, any power—
 - a of the Secretary of State to make regulations is limited to regulations which apply in relation to England only;
 - b of the Welsh Ministers to make regulations is limited to regulations which apply in relation to Wales only;
 - c of the Scottish Ministers to make regulations is limited to regulations which apply in relation to Scotland only.]

Textual Amendments

- F4** [Art. 5A](#) inserted (31.12.2020) by The Materials and Articles in Contact with [Food \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/704\)](#), regs. 1, **68**; 2020 c. 1, [Sch. 5 para. 1\(1\)](#) (as amended by S.I. 2020/1504, regs. 1(2), **16(7)**)

Article 6

Derogations for substances not included in the ^{F5}... list

1 By way of derogation from Article 5, substances other than those included in the ^{F6}... list may be used as polymer production aids in the manufacture of plastic layers in plastic materials and articles subject to [^{F7}any relevant enactment].

[^{F8}2 By way of derogation from Article 5, colorants and solvents which were capable of lawful use in the manufacture of plastic layers in plastic materials and articles prior to adoption of the list may continue to be so used subject to any relevant enactment.]

3 The following substances not included in the ^{F6}... list are authorised subject to the rules set out in Articles 8, 9, 10, 11 and 12:

- [^{F9}a all salts of substances for which ‘ yes ’ is indicated in column 2 in Table 1 of Annex II of authorised acids, phenols or alcohols, and subject to the restrictions set out in column 3 and 4 of that table;]
- 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, complying with the requirements of this Regulation, if they are capable of functioning as the main structural component of final materials or articles;

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Commission Regulation (EU) No 10/2011, CHAPTER II. (See end of Document for details)

- 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 ^{F6}... list.
- 4 The following substances not included in the ^{F6}... 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 ^{F6}... 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 ^{F6}... list provided they are included in the provisional list referred to in Article 7.

Textual Amendments

- F5** Word in Art. 6 heading 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, **69(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F6** Word in Art. 6 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, **69(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F7** Words in Art. 6(1) substituted (31.12.2020) by The Materials and Articles in Contact with Food (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/704), regs. 1, **69(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F8** Art. 6(2) substituted (31.12.2020) by The Materials and Articles in Contact with Food (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/704), regs. 1, **69(c)**; 2020 c. 1, Sch. 5 para. 1(1)
- F9** Substituted by Commission Regulation (EU) 2020/1245 of 2 September 2020 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).

^{F10} Article 7

Establishment and management of the provisional list

1. The appropriate authority must regularly prescribe updates to the provisional list of additives that that was published by the European Commission in 2008.
2. An additive must be removed from the provisional list—
 - a when it is included in the list set out in Annex 1;
 - b when a decision is taken by the appropriate authority not to include it in the list; or
 - c if during the examination of the data, the appropriate authority calls for supplementary information and that information is not submitted within the time limits specified by the appropriate authority.]

Textual Amendments

- F10** Art. 7 substituted (31.12.2020) by The Materials and Articles in Contact with Food (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/704), regs. 1, **70**; 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 II. (See end of Document for details)

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).

^{F112}

[^{F123} 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.]

[^{F134} 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

- F11** 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).
- F12** 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).
- F13** 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 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.

Changes to legislation: There are currently no known outstanding effects for the
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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, CHAPTER II.