

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}3 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).

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011, SECTION 1. (See end of Document for details)

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;

- 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, SECTION 1.