

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 1*

Regulation (EU) No 10/2011 is amended as follows:

- (1) Article 3 is amended as follows:
  - (a) point 16 is replaced by the following:
    - (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 III to this Regulation;;
  - (b) point 18 is replaced by the following:
    - (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;;
  - (c) a new point 19 is added:
    - (19) “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.;
- (2) in Article 6(3), point (a) is replaced by the following:
  - (a) all salts of aluminium, ammonium, barium, calcium, cobalt, copper, iron, lithium, magnesium, manganese, potassium, sodium, and zinc of authorised acids, phenols or alcohols;;
- (3) Article 11 is amended as follows:
  - (a) paragraph 2 is deleted;
  - (b) paragraph 3 is replaced by the following:
    3. 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.;
  - (c) the following paragraph 4 is added:

---

**Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EU) 2016/1416, Article 1. (See end of Document for details)

---

4. 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.;

(4) in Article 13, paragraph 3 is replaced by the following:

3. Substances under paragraph 2(b) shall not migrate into food or food simulant, in accordance with Article 11(4). The detection limit set out in the second subparagraph of Article 11(4) shall apply to groups of substances if they are structurally and toxicologically related, including isomers or substances with the same relevant functional group, or to individual substances that are not related, and shall include possible set-off transfer.;

(5) in Article 17(3), point (a) is replaced by the following:

(a) mg/kg using the actual content of the container for which the closure is intended applying the total contact surface of sealing article and sealed container if the intended use of the article is known, while taking into account the provisions of paragraph 2.;

(6) Article 18 is amended as follows:

(a) paragraph 4 is replaced by the following:

4. For materials and articles not yet in contact with food verification of compliance with the overall migration limit shall be carried out in food simulants as set out in Annex III in accordance with the rules set out in Chapter 3 of Annex V.;

(b) paragraph 7 is replaced by the following:

7. Before comparing specific and overall migration test results with the migration limits the correction factors set out in point 3 of Annex III and Chapter 4 of Annex V shall be applied in accordance with the rules set out therein.;

(7) Annexes I, II, III, IV and V are amended in accordance with the Annex to this Regulation.

**Changes to legislation:**

There are currently no known outstanding effects for the Commission Regulation (EU) 2016/1416, Article 1.