

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 III

**SPECIFIC PROVISIONS FOR CERTAIN MATERIALS AND ARTICLES**

*Article 13*

**Plastic multi-layer materials and articles**

- 1 In a plastic multi-layer material or article, the composition of each plastic layer shall comply with this Regulation.
- 2 By derogation from paragraph 1, a plastic layer which is not in direct contact with food and is separated from the food by a functional barrier, may:
  - a not comply with the restrictions and specifications set out in this Regulation except for vinyl chloride monomer as provided in Annex I; and/or
  - b be manufactured with substances not listed in the Union list or in the provisional list.
- 3 The migration of the substances under paragraph 2(b) into food or food simulant shall not be detectable measured with statistical certainty by a method of analysis set out in Article 11 of Regulation (EC) No 882/2004 with a limit of detection of 0,01 mg/kg. That limit shall always be expressed as concentration in foods or food simulants. That limit shall apply to a group of compounds, if they are structurally and toxicologically related, in particular isomers or compounds with the same relevant functional group, and shall include possible set-off transfer.
- 4 The substances not listed in the Union list or provisional list referred to in paragraph 2(b) shall not belong to either of the following categories:
  - a substances classified as ‘mutagenic’, ‘carcinogenic’ or ‘toxic to reproduction’ in accordance with the criteria set out in sections 3.5, 3.6. and 3.7 of Annex I to Regulation (EC) No 1272/2008 of the European Parliament and the Council<sup>(1)</sup>;
  - b substances in nanoform.
- 5 The final plastic multi-layer material or article shall comply with the specific migration limits set out in Article 11 and the overall migration limit set out in Article 12 of this Regulation.

*Article 14*

**Multi-material multi-layer materials and articles**

- 1 In a multi-material multi-layer material or article, the composition of each plastic layer shall comply with this Regulation.
- 2 By derogation from paragraph 1, in a multi-material multi-layer material or article a plastic layer which is not in direct contact with food and is separated from the food by a functional barrier, may be manufactured with substances not listed in the Union list or the provisional list.
- 3 The substances not listed in the Union list or provisional list referred to in paragraph 2 shall not belong to either of the following categories:

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*Status: This is the original version (as it was originally adopted).*

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- a substances classified as ‘mutagenic’, ‘carcinogenic’ or ‘toxic to reproduction’ in accordance with the criteria set out in sections 3.5, 3.6. and 3.7 of Annex I to Regulation (EC) No 1272/2008;
- b substances in nanoform.

4 By derogation from paragraph 1, Articles 11 and 12 of this Regulation do not apply to plastic layers in multi-material multi-layer materials and articles.

5 The plastic layers in a multi-material multi-layer material or article shall always comply with the restrictions for vinyl chloride monomer laid down in Annex I to this Regulation.

6 In a multi-material multi-layer material or article, specific and overall migration limits for plastic layers and for the final material or article may be established by national law.

(1) [OJ L 353, 31.12.2008, p. 1.](#)