

Commission Regulation (EC) No 450/2009 of 29 May 2009  
on active and intelligent materials and articles intended to  
come into contact with food (Text with EEA relevance)

CHAPTER II

COMPOSITION

SECTION I

*Community list of authorised substances*

*Article 5*

**Community list of substances that may be used in active and intelligent components**

1 Only substances which are included in the ‘Community list’ of authorised substances (hereinafter referred to as the Community list) may be used in components of active and intelligent materials and articles.

2 By way of derogation from paragraph 1, the following substances may be used in components of active and intelligent materials and articles without being included in the Community list:

- a released active substances provided that they comply with the conditions set out in Article 9;
- b substances falling within the scope of Community or national provisions applicable to food, which are added to or incorporated into active materials and articles by techniques such as grafting or immobilisation in order to have a technological effect in the food, provided that they comply with the conditions set out in Article 9;
- c substances used in components which are not in direct contact with food or the environment surrounding the food and are separated from the food by a functional barrier provided that they comply with the conditions set out in Article 10 and that they do not fall within either of the following categories:
  - (i) 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 of the Council<sup>(1)</sup>;
  - (ii) substances deliberately engineered to particle size which exhibit functional physical and chemical properties that significantly differ from those at a larger scale.

*Article 6*

**Conditions for inclusion of substances in the Community list**

In order to be included in the Community list, substances which constitute the components of active and intelligent materials and articles must satisfy the requirements

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of Article 3 and, where they apply, Article 4 of Regulation (EC) No 1935/2004 for the intended condition of use of the active or intelligent material or article.

#### *Article 7*

#### **Content of the Community list**

The Community list shall specify:

- (a) the identity of the substance(s);
- (b) the function of the substance(s);
- (c) the reference number;
- (d) if necessary, the conditions of use of the substance(s) or component;
- (e) if necessary, restrictions and/or specifications of use of the substance(s);
- (f) if necessary, conditions of use of the material or article to which the substance or component is added or into which it is incorporated.

#### *Article 8*

#### **Conditions for the establishment of the Community list**

1 The Community list shall be drawn up on the basis of applications made pursuant to Article 9 of Regulation (EC) No 1935/2004.

2 The deadline for submitting applications shall be 18 months following the date of publication of the guidelines of the European Food Safety Authority (the Authority) for the safety assessment of substances used in active and intelligent materials and articles.

The Authority shall publish those guidelines at the latest six months after the date of publication of this Regulation.

3 The Commission shall make available to the public a register which contains all substances for which a valid application has been submitted in accordance with paragraph 2.

4 The Community list shall be adopted by the Commission in accordance with the procedure laid down in Articles 10 and 11 of Regulation (EC) No 1935/2004.

5 Where the Authority requests supplementary information and the applicant fails to provide the additional data within the set time limit, the substance shall not be evaluated by the Authority for inclusion in the Community list as the application cannot be considered a valid application.

6 The Commission shall adopt the Community list after the Authority has delivered its opinion on all substances included in the register for which a valid application has been submitted pursuant to paragraphs 2 and 5.

7 For the addition of new substances to the Community list, the procedure laid down in Articles 9, 10 and 11 of Regulation (EC) No 1935/2004 shall apply.

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## SECTION 2

### **Conditions of use for substances not to be included in the Community list**

#### *Article 9*

##### **Substances referred to in Article 5(2)(a) and (b)**

1 Released active substances, as referred to in Article 5(2)(a) of this Regulation and substances added or incorporated by techniques such as grafting or immobilisation, as referred to in Article 5(2)(b) of this Regulation, shall be used in full compliance with the relevant Community and national provisions applicable to food, and shall comply with the provisions of Regulation (EC) No 1935/2004 and, when applicable, its implementing measures.

2 The amount of a released active substance shall not be included in the value of the measured overall migration, in cases where an overall migration limit (OML) is established in a specific Community measure for the food contact material in which the component is incorporated.

3 Without prejudice to Article 4(1) and (3) of Regulation (EC) No 1935/2004, the amount of a released active substance may exceed the specific restriction established for that substance in a specific Community or national measure on the food contact materials in which the component is incorporated provided it complies with the Community provisions applicable to food, or, where no such provisions exist, with the national provisions applicable to food.

#### *Article 10*

##### **Substances referred to in Article 5(2)(c)**

1 The migration into food of the substances from components which are not in direct contact with food or the environment surrounding the food, as referred to in Article 5(2)(c) of this Regulation, shall not exceed 0,01 mg/kg, measured with statistical certainty by a method of analysis in accordance with Article 11 of Regulation (EC) No 882/2004 of the European Parliament and of the Council<sup>(2)</sup>.

2 The limit provided for in paragraph 1 shall always be expressed as a concentration in foods. It shall apply to a group of substances, if they are structurally and toxicologically related, in particular isomers or substances with the same relevant functional group, and shall include possible set-off transfer.

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- (1) [OJ L 353, 31.12.2008, p. 1.](#)
- (2) [OJ L 165, 30.4.2004, p. 1.](#)

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**Changes and effects yet to be applied to :**

- Ch. 2 s.0001 heading word omitted by [S.I. 2019/704 reg. 55](#)

**Changes and effects yet to be applied to the whole legislation item and associated provisions**

- s. 2 heading word omitted by [S.I. 2019/704 reg. 60](#)
- Signature words omitted by [S.I. 2019/704 reg. 63](#)
- Art. 3(g) inserted by [S.I. 2019/704 reg. 54](#)
- Art. 5(2)(b) words substituted by [S.I. 2019/704 reg. 56\(b\)](#)