

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⁽¹⁾;
 - (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

Changes to legislation: There are outstanding changes not yet made to Commission Regulation (EC) No 450/2009. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

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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(1) [OJ L 353, 31.12.2008, 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\(b\)](#)