

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 I

GENERAL PROVISIONS

Article 1

Subject matter

This Regulation establishes specific requirements for the marketing of active and intelligent materials and articles intended to come into contact with food.

These specific requirements are without prejudice to Community or national provisions applicable to the materials and articles to which active or intelligent components are added or into which they are incorporated.

Article 2

Scope

This Regulation shall apply to active and intelligent materials and articles which are placed on the market within the Community.

Article 3

Definitions

For the purpose of this Regulation, the following definitions shall apply:

- (a) ‘active materials and articles’ means materials and articles that are intended to extend the shelf-life or to maintain or improve the condition of packaged food; they are designed to deliberately incorporate components that would release or absorb substances into or from the packaged food or the environment surrounding the food;
- (b) ‘intelligent materials and articles’ means materials and articles which monitor the condition of packaged food or the environment surrounding the food;
- (c) ‘component’ means an individual substance or a combination of individual substances which cause the active and/or intelligent function of a material or article, including the products of an *in situ* reaction of those substances; it does not include the passive parts, such as the material they are added to or incorporated into;
- (d) ‘functional barrier’ means a barrier consisting of one or more layers of food contact materials which ensures that the finished material or article complies with Article 3 of Regulation (EC) No 1935/2004 and with this Regulation;

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- (e) ‘releasing active materials and articles’ are those active materials and articles designed to deliberately incorporate components that would release substances into or onto the packaged food or the environment surrounding the food;
- (f) ‘released active substances’ are those substances intended to be released from releasing active materials and articles into or onto the packaged food or the environment surrounding the food and fulfilling a purpose in the food.

Article 4

Placing on the market of active and intelligent materials and articles

Active and intelligent materials and articles may only be placed on the market if they:

- (a) are suitable and effective for the intended purpose of use;
- (b) comply with the general requirements set out in Article 3 of Regulation (EC) No 1935/2004;
- (c) comply with the special requirements set out in Article 4 of Regulation (EC) No 1935/2004;
- (d) comply with the labelling requirements set out in Article 15(1)(e) of Regulation (EC) No 1935/2004;
- (e) comply with the composition requirements set out in Chapter II of this Regulation;
- (f) comply with labelling and declaration requirements set out in Chapters III and IV of this Regulation.

CHAPTER II

COMPOSITION

SECTION 1

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;

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- 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 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.

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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.

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.

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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⁽²⁾.

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.

CHAPTER III

LABELLING

Article 11

Additional rules on labelling

1 To allow identification by the consumer of non-edible parts, active and intelligent materials and articles or parts thereof shall be labelled, whenever they are perceived as edible:

- a with the words 'DO NOT EAT'; and
- b always where technically possible, with the symbol reproduced in Annex I.

2 The information required by paragraph 1 shall be conspicuous, clearly legible and indelible. It shall be printed in characters of a font size of at least 3 mm and comply with the requirements set out in Article 15 of Regulation (EC) No 1935/2004.

3 Released active substance shall be considered as ingredients within the meaning of Article 6(4)(a) of Directive 2000/13/EC of the European Parliament and of the Council⁽³⁾ and shall be subject to the provisions of that Directive.

CHAPTER IV

DECLARATION OF COMPLIANCE AND DOCUMENTATION

Article 12

Declaration of compliance

1 At the marketing stages other than at the point of sale to the final consumer, active and intelligent materials and articles, whether or not they are in contact with food, or the components intended for the manufacturing of those materials and articles or the substances intended for the manufacturing of those components, shall be accompanied by a written declaration in accordance with Article 16 of Regulation (EC) No 1935/2004.

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2 The declaration referred to in paragraph 1 shall be issued by the business operator and shall contain the information set out in Annex II.

Article 13

Supporting documentation

Appropriate documentation to demonstrate that the active and intelligent materials and articles and the components intended for the manufacturing of those materials and articles comply with the requirements of this Regulation shall be made available by the business operator to the national competent authorities on request.

That documentation shall contain information on the suitability and effectiveness of the active or intelligent material or article, the conditions and results of testing or calculations or other analysis, and evidence on the safety or the reasoning demonstrating compliance.

CHAPTER V

FINAL PROVISIONS

Article 14

Entry into force and application

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

Article 4(e), and Article 5 shall apply from the date of application of the Community list. Until that date, and without prejudice to the requirements set out in Article 4(2) of Regulation (EC) No 1935/2004 and Articles 9 and 10 of this Regulation, national provisions in force concerning the composition of active and intelligent materials and articles shall continue to apply.

Article 4(f), Article 11(1) and (2) and Chapter IV shall apply from 19 December 2009. Until that date, and without prejudice to the requirements set out in Article 4(5) and (6) of Regulation (EC) No 1935/2004 and Article 11(3) of this Regulation, national provisions in force concerning the labelling and declaration of compliance of active and intelligent materials and articles shall continue to apply.

The placing on the market of active and intelligent materials and articles labelled in accordance with Article 4(5) of Regulation (EC) No 1935/2004 prior to the date of application of Article 11(1) and (2) of this Regulation shall be permitted until the exhaustion of stocks.

Until the date of application of the Community list, released active substances shall be authorised and used in accordance with the relevant Community provisions applicable to food, and shall comply with the provisions of Regulation (EC) No 1935/2004 and its implementing measures.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

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Done at Brussels, 29 May 2009.

For the Commission

Androulla VASSILIOU

Member of the Commission

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- (1) [OJ L 353, 31.12.2008, p. 1.](#)
- (2) [OJ L 165, 30.4.2004, p. 1.](#)
- (3) [OJ L 109, 6.5.2000, p. 29.](#)

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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
- Annex 1 omitted by S.I. 2022/1351 reg. 17(3)
- Annex 2 point 5 word omitted by S.I. 2019/704 reg. 64(a)
- Annex 2 point 6 word omitted by S.I. 2019/704 reg. 64(b)(ii)
- Annex 2 point 6 words substituted by S.I. 2019/704 reg. 64(b)(i)
- Art. 1 words omitted by S.I. 2019/704 reg. 52
- Art. 2 words omitted by S.I. 2019/704 reg. 53
- Art. 5 heading word omitted by S.I. 2019/704 reg. 56(c)
- Art. 5(1) words omitted by S.I. 2019/704 reg. 56(a)(ii)
- Art. 5(1) words substituted by S.I. 2019/704 reg. 56(a)(i)
- Art. 5(2) word omitted by S.I. 2019/704 reg. 56(c)
- Art. 6 heading word omitted by S.I. 2019/704 reg. 57
- Art. 6 word omitted by S.I. 2019/704 reg. 57
- Art. 7 heading word omitted by S.I. 2019/704 reg. 58
- Art. 7 word omitted by S.I. 2019/704 reg. 58
- Art. 8 word omitted by S.I. 2019/704 reg. 59(a)
- Art. 8 heading word omitted by S.I. 2019/704 reg. 59(a)
- Art. 8 words substituted by S.I. 2019/704 reg. 59(b)
- Art. 8(2) words substituted by S.I. 2019/704 reg. 59(c)(i)
- Art. 8(2) words substituted by S.I. 2019/704 reg. 59(c)(ii)
- Art. 8(5) words substituted by S.I. 2019/704 reg. 59(d)
- Art. 8(6) words substituted by S.I. 2019/704 reg. 59(e)
- Art. 9(1) words substituted by S.I. 2019/704 reg. 61(a)
- Art. 9(2) word omitted by S.I. 2019/704 reg. 61(b)
- Art. 9(3) words substituted by S.I. 2019/704 reg. 61(c)(i)
- Art. 9(3) words substituted by S.I. 2019/704 reg. 61(c)(ii)
- Art. 11(1) words substituted by S.I. 2022/1351 reg. 17(2)(a)
- Art. 11(3) words substituted by S.I. 2022/1351 reg. 17(2)(b)(i)
- Art. 11(3) words substituted by S.I. 2022/1351 reg. 17(2)(b)(ii)
- Art. 13 word omitted by S.I. 2019/704 reg. 62

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)