

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 I

GENERAL PROVISIONS

Article 1

Subject matter

- 1 This Regulation is a specific measure within the meaning of Article 5 of Regulation (EC) No 1935/2004.
- 2 This Regulation establishes specific requirements for the manufacture and marketing of plastic materials and articles:
 - a intended to come into contact with food; or
 - b already in contact with food; or
 - c which can reasonably be expected to come into contact with food.

Article 2

Scope

- 1 This Regulation shall apply to materials and articles which are placed on the EU market and fall under the following categories:
 - a materials and articles and parts thereof consisting exclusively of plastics;
 - b plastic multi-layer materials and articles held together by adhesives or by other means;
 - c materials and articles referred to in points a) or b) that are printed and/or covered by a coating;
 - d plastic layers or plastic coatings, forming gaskets in caps and closures, that together with those caps and closures compose a set of two or more layers of different types of materials;
 - e plastic layers in multi-material multi-layer materials and articles.
- 2 This Regulation shall not apply to the following materials and articles which are placed on the EU market and are intended to be covered by other specific measures:
 - a ion exchange resins;
 - b rubber;
 - c silicones.
- 3 This Regulation shall be without prejudice to the EU or national provisions applicable to printing inks, adhesives or coatings.

Status: Point in time view as at 14/01/2011.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011. (See end of Document for details)

Article 3

Definitions

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

- (1) 'plastic materials and articles' means:
 - (a) materials and articles referred to in points (a), (b) and (c) of Article 2(1); and
 - (b) plastic layers referred to in Article 2(1)(d) and (e);
- (2) 'plastic' means polymer to which additives or other substances may have been added, which is capable of functioning as a main structural component of final materials and articles;
- (3) 'polymer' means any macromolecular substance obtained by:
 - (a) a polymerisation process such as polyaddition or polycondensation, or by any other similar process of monomers and other starting substances; or
 - (b) chemical modification of natural or synthetic macromolecules; or
 - (c) microbial fermentation;
- (4) 'plastic multi-layer' means a material or article composed of two or more layers of plastic;
- (5) 'multi-material multi-layer' means a material or article composed of two or more layers of different types of materials, at least one of them a plastic layer;
- (6) 'monomer or other starting substance' means:
 - (a) a substance undergoing any type of polymerisation process to manufacture polymers; or
 - (b) a natural or synthetic macromolecular substance used in the manufacture of modified macromolecules; or
 - (c) a substance used to modify existing natural or synthetic macromolecules;
- (7) 'additive' means a substance which is intentionally added to plastics to achieve a physical or chemical effect during processing of the plastic or in the final material or article; it is intended to be present in the final material or article;
- (8) 'polymer production aid' means any substance used to provide a suitable medium for polymer or plastic manufacturing; it may be present but is neither intended to be present in the final materials or articles nor has a physical or chemical effect in the final material or article;
- (9) 'non-intentionally added substance' means an impurity in the substances used or a reaction intermediate formed during the production process or a decomposition or reaction product;
- (10) 'aid to polymerisation' means a substance which initiates polymerisation and/or controls the formation of the macromolecular structure;

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- (11) ‘overall migration limit’ (OML) means the maximum permitted amount of non-volatile substances released from a material or article into food simulants;
- (12) ‘food simulant’ means a test medium imitating food; in its behaviour the food simulant mimics migration from food contact materials;
- (13) ‘specific migration limit’ (SML) means the maximum permitted amount of a given substance released from a material or article into food or food simulants;
- (14) ‘total specific migration limit’ (SML(T)) means the maximum permitted sum of particular substances released in food or food simulants expressed as total of moiety of the substances indicated;
- (15) ‘functional barrier’ means a barrier consisting of one or more layers of any type of material which ensures that the final material or article complies with Article 3 of Regulation (EC) No 1935/2004 and with the provisions of this Regulation;
- (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 V to this Regulation;
- (17) ‘restriction’ means limitation of use of a substance or migration limit or limit of content of the substance in the material or article;
- (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.

Article 4

Placing on the market of plastic materials and articles

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

- (a) comply with the relevant requirements set out in Article 3 of Regulation (EC) No 1935/2004 under intended and foreseeable use; and
- (b) comply with the labelling requirements set out in Article 15 of Regulation (EC) No 1935/2004; and
- (c) comply with the traceability requirements set out in Article 17 of Regulation (EC) No 1935/2004; and
- (d) are manufactured according to good manufacturing practice as set out in Commission Regulation (EC) No 2023/2006⁽¹⁾; and
- (e) comply with the compositional and declaration requirements set out in Chapters II, III and IV of this Regulation.

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Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011. (See end of Document for details)

CHAPTER II

COMPOSITIONAL REQUIREMENTS

SECTION 1

Authorised substances

Article 5

Union list of authorised substances

1 Only the substances included in the Union list of authorised substances (hereinafter referred to as the Union list) set out in Annex I may be intentionally used in the manufacture of plastic layers in plastic materials and articles.

2 The Union list shall contain:

- a monomers or other starting substances;
- b additives excluding colorants;
- c polymer production aids excluding solvents;
- d macromolecules obtained from microbial fermentation.

3 The Union list may be amended in accordance with the procedure established by Articles 8 to 12 of Regulation (EC) No 1935/2004.

Article 6

Derogations for substances not included in the Union list

1 By way of derogation from Article 5, substances other than those included in the Union list may be used as polymer production aids in the manufacture of plastic layers in plastic materials and articles subject to national law.

2 By way of derogation from Article 5, colorants and solvents may be used in the manufacture of plastic layers in plastic materials and articles subject to national law.

3 The following substances not included in the Union list are authorised subject to the rules set out in Articles 8, 9, 10, 11 and 12:

- a salts (including double salts and acid salts) of aluminium, ammonium, barium, calcium, cobalt, copper, iron, lithium, magnesium, manganese, potassium, sodium, and zinc of authorised acids, phenols or alcohols;
- b mixtures obtained by mixing authorised substances without a chemical reaction of the components;
- c when used as additives, natural or synthetic polymeric substances of a molecular weight of at least 1 000 Da, except macromolecules obtained from microbial fermentation, complying with the requirements of this Regulation, if they are capable of functioning as the main structural component of final materials or articles;
- d when used as monomer or other starting substance, pre-polymers and natural or synthetic macromolecular substances, as well as their mixtures, except macromolecules obtained from microbial fermentation, if the monomers or starting substances required to synthesise them are included in the Union list.

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4 The following substances not included in the Union list may be present in the plastic layers of plastic materials or articles:

- a non-intentionally added substances;
- b aids to polymerisation.

5 By derogation from Article 5, additives not included in the Union list may continue to be used subject to national law after 1 January 2010 until a decision is taken to include or not to include them in the Union list provided they are included in the provisional list referred to in Article 7.

Article 7

Establishment and management of the provisional list

1 The provisional list of additives that are under evaluation by the European Food Safety Authority (hereinafter referred to as the Authority) that was made public by the Commission in 2008 shall be regularly updated.

2 An additive shall be removed from the provisional list:

- a when it is included in the Union list set out in Annex I; or
- b when a decision is taken by the Commission not to include it in the Union list; or
- c if during the examination of the data, the Authority calls for supplementary information and that information is not submitted within the time limits specified by the Authority.

SECTION 2

General requirements, restrictions and specifications

Article 8

General requirement on substances

Substances used in the manufacture of plastic layers in plastic materials and articles shall be of a technical quality and a purity suitable for the intended and foreseeable use of the materials or articles. The composition shall be known to the manufacturer of the substance and made available to the competent authorities on request.

Article 9

Specific requirements on substances

1 Substances used in the manufacture of plastic layers in plastic materials and articles shall be subject to the following restrictions and specifications:

- a the specific migration limit set out in Article 11;
- b the overall migration limit set out in Article 12;
- c the restrictions and specifications set out in column 10 of Table 1 of point 1 of Annex I;
- d the detailed specifications set out in point 4 of Annex I.

2 Substances in nanoform shall only be used if explicitly authorised and mentioned in the specifications in Annex I.

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Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011. (See end of Document for details)

Article 10

General restrictions on plastic materials and articles

General restrictions related to plastic materials and articles are laid down in Annex II.

Article 11

Specific migration limits

- 1 Plastic materials and articles shall not transfer their constituents to foods in quantities exceeding the specific migration limits (SML) set out in Annex I. Those specific migration limits (SML) are expressed in mg of substance per kg of food (mg/kg).
- 2 For substances for which no specific migration limit or other restrictions are provided in Annex I, a generic specific migration limit of 60 mg/kg shall apply.
- 3 By derogation from paragraphs 1 and 2, 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.

Article 12

Overall migration limit

- 1 Plastic materials and articles shall not transfer their constituents to food simulants in quantities exceeding 10 milligrams of total constituents released per dm² of food contact surface (mg/dm²).
- 2 By derogation from paragraph 1, plastic materials and articles intended to be brought into contact with food intended for infants and young children, as defined by Commission Directives 2006/141/EC⁽²⁾ and 2006/125/EC⁽³⁾, shall not transfer their constituents to food simulants in quantities exceeding 60 milligrams of total of constituents released per kg of food simulant.

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⁽⁴⁾;
- 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:

- 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.

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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.

CHAPTER IV

DECLARATION OF COMPLIANCE AND DOCUMENTATION

Article 15

Declaration of compliance

1 At the marketing stages other than at the retail stage, a written declaration in accordance with Article 16 of Regulation (EC) No 1935/2004 shall be available for plastic materials and articles, products from intermediate stages of their manufacturing as well as for the substances intended for the manufacturing of those materials and articles.

2 The written declaration referred to in paragraph 1 shall be issued by the business operator and shall contain the information laid down in Annex IV.

3 The written declaration shall permit an easy identification of the materials, articles or products from intermediate stages of manufacture or substances for which it is issued. It shall be renewed when substantial changes in the composition or production occur that bring about changes in the migration from the materials or articles or when new scientific data becomes available.

Article 16

Supporting documents

1 Appropriate documentation to demonstrate that the materials and articles, products from intermediate stages of their manufacturing as well as the substances 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.

2 That documentation shall contain the conditions and results of testing, calculations, including modelling, other analysis, and evidence on the safety or reasoning demonstrating compliance. Rules for experimental demonstration of compliance are set out in Chapter V.

CHAPTER V

COMPLIANCE

Article 17

Expression of migration test results

1 To check the compliance, the specific migration values shall be expressed in mg/kg applying the real surface to volume ratio in actual or foreseen use.

2 By derogation from paragraph 1 for:

- a containers and other articles, containing or intended to contain, less than 500 millilitres or grams or more than 10 litres,
- b materials and articles for which, due to their form it is impracticable to estimate the relationship between the surface area of such materials or articles and the quantity of food in contact therewith,
- c sheets and films that are not yet in contact with food,
- d sheets and films containing less than 500 millilitres or grams or more than 10 litres,

the value of migration shall be expressed in mg/kg applying a surface to volume ratio of 6 dm² per kg of food.

This paragraph does not apply to plastic materials and articles intended to be brought into contact with or already in contact with food for infants and young children, as defined by Directives 2006/141/EC and 2006/125/EC.

3 By derogation from paragraph 1, for caps, gaskets, stoppers and similar sealing articles the specific migration value shall be expressed in:

- a mg/kg using the actual content of the container for which the closure is intended or in mg/dm² 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;
- b mg/article if the intended use of the article is unknown.

4 For caps, gaskets, stoppers and similar sealing articles the overall migration value shall be expressed in:

- a mg/dm² applying the total contact surface of sealing article and sealed container if the intended use of the article is known;
- b mg/article if the intended use of the article is unknown.

Article 18

Rules for assessing compliance with migration limits

1 For materials and articles already in contact with food verification of compliance with specific migration limits shall be carried out in accordance with the rules set out in Chapter 1 of Annex V.

2 For materials and articles not yet in contact with food verification of compliance with specific migration limits shall be carried out in food or in food simulants set out in Annex III in accordance with the rules set out in Chapter 2, Section 2.1 of Annex V.

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3 For materials and articles not yet in contact with food screening of compliance with the specific migration limit can be performed applying screening approaches in accordance with the rules set out in Chapter 2, Section 2.2 of Annex V. If a material or article fails to comply with the migration limits in the screening approach a conclusion of non-compliance has to be confirmed by verification of compliance in accordance with paragraph 2.

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 A, B, C, D1 and D2 as set out in Annex III in accordance with the rules set out in Chapter 3, Section 3.1 of Annex V.

5 For materials and articles not yet in contact with food screening of compliance with the overall migration limit can be performed applying screening approaches in accordance with the rules set out in Chapter 3, Section 3.4 of Annex V. If a material or article fails to comply with the migration limit in the screening approach a conclusion of non-compliance has to be confirmed by verification of compliance in accordance with paragraph 4.

6 The results of specific migration testing obtained in food shall prevail over the results obtained in food simulant. The results of specific migration testing obtained in food simulant shall prevail over the results obtained by screening approaches.

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

Article 19

Assessment of substances not included in the Union list

Compliance with Article 3 of Regulation (EC) No 1935/2004 of substances referred to in Articles 6(1), 6(2), 6(4), 6(5) and 14(2) of this Regulation which are not covered by an inclusion in Annex I to this Regulation shall be assessed in accordance with internationally recognised scientific principles on risk assessment.

CHAPTER VI

FINAL PROVISIONS

Article 20

Amendments of EU acts

The Annex to Council Directive 85/572/EEC⁽⁵⁾ is replaced by the following:

‘The food simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with a single food or specific groups of foods are set out in point 3 of Annex III to Commission Regulation (EU) No 10/2011.’

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Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011. (See end of Document for details)

Article 21

Repeal of EU acts

Directives 80/766/EEC, 81/432/EEC, and 2002/72/EC are hereby repealed with effect from 1 May 2011.

References to the repealed Directives shall be construed as references to this Regulation and shall be read in accordance with the correlation tables in Annex VI.

Article 22

Transitional provisions

1 Until 31 December 2012 the supporting documents referred to in Article 16 shall be based on the basic rules for overall and specific migration testing set out in the Annex to Directive 82/711/EEC.

2 As from 1 January 2013 the supporting documents referred to in Article 16 for materials, articles and substances placed on the market until 31 December 2015, may be based on:

- a the rules for migration testing set out in Article 18 of this Regulation; or
- b the basic rules for overall and specific migration testing set out in the Annex to Directive 82/711/EEC.

3 As from 1 January 2016, the supporting documents referred to in Article 16 shall be based on the rules for migration testing set out in Article 18, without prejudice to paragraph 2 of this Article.

4 Until 31 December 2015 additives used in glass fibre sizing for glass fibre reinforced plastics which are not listed in Annex I have to comply with the risk assessment provisions set out in Article 19.

5 Materials and articles that have been lawfully placed on the market before 1 May 2011 may be placed on the market until 31 December 2012.

Article 23

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*.

It shall apply from 1 May 2011.

The provision of Article 5 as regards the use of additives, others than plasticisers, shall apply for plastic layers or plastic coatings in caps and closures referred to in Article 2(1) (d), as from 31 December 2015.

The provision of Article 5 as regards the use of additives used in glass fibre sizing for glass fibre reinforced plastics, shall apply from 31 December 2015.

The provisions of Articles 18(2), 18(4) and 20 shall apply from 31 December 2012.

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*Changes to legislation: There are currently no known outstanding effects for
the Commission Regulation (EU) No 10/2011. (See end of Document for details)*

This Regulation shall be binding in its entirety and directly applicable in the Member States in accordance with the Treaties.

Done at Brussels, 14 January 2011.

For the Commission

The President

José Manuel BARROSO

Status: Point in time view as at 14/01/2011.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011. (See end of Document for details)

- (1) OJ L 384, 29.12.2006, p. 75.
- (2) OJ L 401, 30.12.2006, p. 1.
- (3) OJ L 339, 6.12.2006, p. 16.
- (4) OJ L 353, 31.12.2008, p. 1.
- (5) OJ L 372, 31.12.1985, p. 14.

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