

Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs (Text with EEA relevance) (repealed)

[^{X1}Article 1

1 This Directive is a specific Directive within the meaning of Article 3 of Directive 89/109/EEC.

[^{F1}]^{X2} This Directive shall apply to the following materials and articles which, in the finished product state, are intended to come into contact or are brought into contact with foodstuffs and are intended for that purpose (hereafter referred to as ‘plastic materials and articles’):

- a materials and articles and parts thereof consisting exclusively of plastics;
- b plastic multi-layer materials and articles;
- c plastic layers or plastic coatings, forming gaskets in lids that together are composed of two or more layers of different types of materials.]]

3 For the purposes of this Directive, ‘plastics’ shall mean the organic macromolecular compounds obtained by polymerisation, polycondensation, polyaddition or any other similar process from molecules with a lower molecular weight or by chemical alteration of natural macromolecules. Other substances or matter may be added to such macromolecular compounds.

However, the following shall not be regarded as ‘plastics’:

- a varnished or unvarnished regenerated cellulose film, covered by Commission Directive 93/10/EEC⁽¹⁾;
- b elastomers and natural and synthetic rubber;
- c paper and paperboard, whether modified or not by the addition of plastics;
- d surface coatings obtained from:
 - paraffin waxes, including synthetic paraffin waxes, and/or micro-crystalline waxes,
 - mixtures of the waxes listed in the first indent with each other and/or with plastics;
- e ion-exchange resins;
- f silicones.

[^{F1}]^{X2} Without prejudice to paragraph 2(c), this Directive shall not apply to materials and articles composed of two or more layers, one or more of which does not consist exclusively of plastics, even if the one intended to come into direct contact with foodstuffs does consist exclusively of plastics.]]

Editorial Information

- X1 Substituted by [Corrigendum to Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs \(Official Journal of the European Communities L 220 of 15 August 2002\)](#).
- X2 Substituted by [Corrigendum to Commission Directive 2007/19/EC of 30 March 2007 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food and Council Directive 85/572/EEC laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs \(Official Journal of the European Union L 91 of 31 March 2007\)](#).

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Textual Amendments

- F1** Substituted by [Commission Directive 2007/19/EC of 30 March 2007 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food and Council Directive 85/572/EEC laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs \(Text with EEA relevance\).](#)

^{F2} ^{X3}Article 1a

For the purpose of this Directive the following definitions shall apply:

- (a) ‘plastic multi-layer material or article’ means a plastic material or article composed of two or more layers of materials, each consisting exclusively of plastics, which are bound together by means of adhesives or by other means;
- (b) ‘plastic functional barrier’ means a barrier consisting of one or more layers of plastics which ensures that the finished material or article complies with Article 3 of Regulation (EC) No 1935/2004 of the European Parliament and of the Council⁽²⁾ and with this Directive;
- (c) ‘non-fatty foods’ means foods for which in migration testing simulants other than simulant D are laid down in Directive 85/572/EEC.]]

Editorial Information

- X1** Substituted by [Corrigendum to Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs \(Official Journal of the European Communities L 220 of 15 August 2002\).](#)
- X3** Inserted by [Corrigendum to Commission Directive 2007/19/EC of 30 March 2007 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food and Council Directive 85/572/EEC laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs \(Official Journal of the European Union L 91 of 31 March 2007\).](#)

Textual Amendments

- F2** Inserted by [Commission Directive 2007/19/EC of 30 March 2007 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food and Council Directive 85/572/EEC laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs \(Text with EEA relevance\).](#)

^{F1}^{X2}Article 2

1 Plastic materials and articles shall not transfer their constituents to foodstuffs in quantities exceeding 60 milligrams of the constituents released per kilogram of foodstuff or food simulant (mg/kg) (overall migration limit).

However, this limit shall be 10 milligrams per square decimetre of surface area of material or article (mg/dm²) in the case of the following:

- a articles which are containers or are comparable to containers or which can be filled, with a capacity of less than 500 millilitres (ml) or more than 10 litres (l);
- b sheet, film or other material or articles which cannot be filled or for which it is impracticable to estimate the relationship between the surface area of such material or article and the quantity of food in contact therewith.

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2 For plastic materials and articles intended to be brought into contact with or already in contact with food intended for infants and young children, as defined by Commission Directives 91/321/EEC⁽³⁾ and 96/5/EC⁽⁴⁾, the overall migration limit shall always be 60 mg/kg.]]

Editorial Information

- X1** Substituted by [Corrigendum to Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs \(Official Journal of the European Communities L 220 of 15 August 2002\)](#).
- X2** Substituted by [Corrigendum to Commission Directive 2007/19/EC of 30 March 2007 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food and Council Directive 85/572/EEC laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs \(Official Journal of the European Union L 91 of 31 March 2007\)](#).

Textual Amendments

- F1** Substituted by [Commission Directive 2007/19/EC of 30 March 2007 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food and Council Directive 85/572/EEC laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs \(Text with EEA relevance\)](#).

Article 3

[^{F3}1 Only those monomers and other starting substances listed in Annex II, section A may be used for the manufacture of plastic materials and articles subject to the restrictions set out therein.

2 By way of derogation from paragraph 1, the monomers and other starting substances listed in Annex II, section B may continue to be used until 31 December 2004 at the latest, pending their evaluation by the European Food Safety Authority (hereinafter referred to as the Authority).]

3 The list in Annex II, Section A, may be amended:

- either by adding substances listed in Annex II, Section B, according to the criteria in Annex II of Directive 89/109/EEC, or
- by including ‘new substances’, i.e. substances which are listed neither in Section A nor in Section B of Annex II, according to Article 3 of Directive 89/109/EEC.

4 No Member State shall authorise any new substance for use within its territory except under the procedure in Article 4 of Directive 89/109/EEC.

5 The lists appearing in Annex II, Sections A and B, do not yet include monomers and other starting substances used only in the manufacture of:

- surface coatings obtained from resinous or polymerised products in liquid, powder or dispersion form, such as varnishes, lacquers, paints, etc.,
- epoxy resins,
- adhesives and adhesion promoters,
- printing inks.

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Editorial Information

- X1** Substituted by [Corrigendum to Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs \(Official Journal of the European Communities L 220 of 15 August 2002\)](#).

Textual Amendments

- F3** Substituted by [Commission Directive 2004/19/EC of 1 March 2004 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs \(Text with EEA relevance\)](#).

[^{F3} Article 4

[^{F41} A Community list of additives which may be used for the manufacture of plastic materials and articles, together with the restrictions and/or specifications on their use, is set out in Annex III.

Until 31 December 2009, additives which are not included in the Community list of additives may continue to be used subject to national law.

As from 1 January 2010, only additives included in the Community list of additives may be used for the manufacture of plastic materials and articles (positive list).]

2 For the additives listed in Annex III, section B, the verification of compliance with the specific migration limits in simulatant D or in test media of substitute tests as laid down in Article 3(1), second subparagraph of Directive 82/711/EEC and Article 1 of Directive 85/572/EEC shall apply from [^{F1}[^{X2}1 May 2008]].

- 3 The lists in Annex III, sections A and B do not yet include the following additives:
- a additives used only in the manufacture of:
 - surface coatings obtained from resinous or polymerised products in liquid, powder or dispersion form, such as varnishes, lacquers, paints,
 - epoxy resins,
 - adhesives and adhesion promoters,
 - printing inks;
 - b colorants;
 - c solvents.]

Editorial Information

- X1** Substituted by [Corrigendum to Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs \(Official Journal of the European Communities L 220 of 15 August 2002\)](#).
- X2** Substituted by [Corrigendum to Commission Directive 2007/19/EC of 30 March 2007 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food and Council Directive 85/572/EEC laying down the list of simulatants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs \(Official Journal of the European Union L 91 of 31 March 2007\)](#).

Textual Amendments

- F1** Substituted by [Commission Directive 2007/19/EC of 30 March 2007 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food and Council Directive](#)

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85/572/EEC laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs (Text with EEA relevance).

- F3** Substituted by Commission Directive 2004/19/EC of 1 March 2004 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs (Text with EEA relevance).
- F4** Substituted by Commission Directive 2008/39/EC of 6 March 2008 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food (Text with EEA relevance).

[^{F5} Article 4a

1 A new additive may always be added to the list of substances referred to in Article 4(1) following an evaluation of its safety by the Authority.

2 Member States shall provide that any person interested in the inclusion in the list referred to in Article 4(1) of an additive, which is already placed on the market in one or more of the Member States, shall submit data for the evaluation of its safety by the Authority by 31 December 2006 at the latest.

For the submission of the required data, the applicant shall consult the ‘Guidelines of the European Food Safety Authority for the presentation of an application for safety assessment of a substance to be used in food contact materials prior to its authorisation’.

[^{F43} A provisional list of additives that are under evaluation by the Authority shall be made public by the Commission by 11 April 2008 at the latest. It shall be kept updated.

4 By derogation from the third subparagraph of Article 4(1), additives not included in the Community list referred to in that Article may continue to be used subject to national law after 1 January 2010 for as long as they are included in the provisional list.]

5 The inclusion of an additive in the provisional list is subject to the following conditions:

- a the additive must be permitted in one or more of the Member States no later than 31 December 2006;
- b the data referred to in paragraph 2 concerning that additive must have been supplied in accordance with the Authority requirements no later than 31 December 2006.

[^{F66} An additive shall be removed from the provisional list:

- a when it is included in the Community list of additives; or
- b when a decision is taken by the Commission not to include it in the Community list of additives; 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.]

Editorial Information

- X1** Substituted by Corrigendum to Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs (Official Journal of the European Communities L 220 of 15 August 2002).

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Textual Amendments

- F4** Substituted by [Commission Directive 2008/39/EC of 6 March 2008 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food](#) (Text with EEA relevance).
- F5** Inserted by [Commission Directive 2004/19/EC of 1 March 2004 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs](#) (Text with EEA relevance).
- F6** Inserted by [Commission Directive 2008/39/EC of 6 March 2008 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food](#) (Text with EEA relevance).

Article 4b

Without prejudice to Article 4 of Directive 89/109/EEC, Member States may not authorise after 31 December 2006 additives referred to in Article 4(1) which were never evaluated by the Scientific Committee on Food or the Authority.]

Editorial Information

- X1** Substituted by [Corrigendum to Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs](#) (Official Journal of the European Communities L 220 of 15 August 2002).

Textual Amendments

- F5** Inserted by [Commission Directive 2004/19/EC of 1 March 2004 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs](#) (Text with EEA relevance).

^{F2} x3 Article 4c

For the use of additives for the manufacture of plastic layers or plastic coatings in lids referred to in Article 1(2)(c), the following rules shall apply:

- (a) for the additives listed in Annex III, the restrictions and/or specifications on their use set out in that Annex shall apply, without prejudice to Article 4(2);
- (b) by way of derogation from Article 4(1) and Article 4a(1) and (5), additives not listed in Annex III may continue to be used, until further review, subject to national law;
- (c) by way of derogation from Article 4b Member States may continue to authorise additives for the manufacture of plastic layers or plastic coatings in lids referred to in Article 1(2)(c) at national level.

Editorial Information

- X1** Substituted by [Corrigendum to Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs](#) (Official Journal of the European Communities L 220 of 15 August 2002).
- X3** Inserted by [Corrigendum to Commission Directive 2007/19/EC of 30 March 2007 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food and Council Directive 85/572/EEC laying down the list of simulants to be used for testing migration of](#)

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constituents of plastic materials and articles intended to come into contact with foodstuffs (Official Journal of the European Union L 91 of 31 March 2007).

Textual Amendments

- F2** Inserted by [Commission Directive 2007/19/EC of 30 March 2007 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food and Council Directive 85/572/EEC laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs \(Text with EEA relevance\).](#)

Article 4d

For the use of additives exclusively acting as polymerisation production aids which are not intended to remain in the finished article (hereinafter PPAs), for the manufacture of plastic materials and articles, the following rules shall apply:

- (a) for the PPAs listed in Annex III, the restrictions and/or specifications on their use set out in Annex III shall apply, without prejudice to Article 4(2);
- (b) by way of derogation from Article 4(1) and Article 4a(1) and (5), the PPAs not listed in Annex III may continue to be used, until further review, subject to national law;
- (c) by way of derogation from Article 4b, Member States may continue to authorise PPAs at national level.

Editorial Information

- X1** Substituted by [Corrigendum to Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs \(Official Journal of the European Communities L 220 of 15 August 2002\).](#)
- X3** Inserted by [Corrigendum to Commission Directive 2007/19/EC of 30 March 2007 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food and Council Directive 85/572/EEC laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs \(Official Journal of the European Union L 91 of 31 March 2007\).](#)

Textual Amendments

- F2** Inserted by [Commission Directive 2007/19/EC of 30 March 2007 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food and Council Directive 85/572/EEC laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs \(Text with EEA relevance\).](#)

Article 4e

The use of azodicarbonamide, Ref. No 36640 (CAS No 000123-77-3) in the manufacture of plastic materials and articles is prohibited.]]

Editorial Information

- X1** Substituted by [Corrigendum to Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs \(Official Journal of the European Communities L 220 of 15 August 2002\).](#)
- X3** Inserted by [Corrigendum to Commission Directive 2007/19/EC of 30 March 2007 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food and](#)

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Council Directive 85/572/EEC laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs (Official Journal of the European Union L 91 of 31 March 2007).

Textual Amendments

- F2** Inserted by Commission Directive 2007/19/EC of 30 March 2007 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food and Council Directive 85/572/EEC laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs (Text with EEA relevance).

Article 5

Only the products obtained by means of bacterial fermentation listed in Annex IV may be used in contact with foodstuffs.

Editorial Information

- X1** Substituted by Corrigendum to Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs (Official Journal of the European Communities L 220 of 15 August 2002).

[^{F5}Article 5a

1 Additives referred to in Article 4, which are authorised as food additives by Council Directive 89/107/EEC⁽⁵⁾ or flavourings by Council Directive 88/388/EEC⁽⁶⁾ shall not migrate into:

- a foodstuffs in quantities having a technological function in the final foodstuffs;
- b foodstuffs for which their use is authorised as food additives or flavourings, in quantities exceeding the restrictions provided for in Directive 89/107/EEC or in Directive 88/388/EEC or in Article 4 of this Directive, whichever is the lower;
- c foodstuffs for which their use is not authorised as food additives or flavourings, in quantities exceeding the restrictions set out in Article 4 of this Directive.

[^{F1}[^{X2} At the marketing stages other than the retail stages, plastic materials and articles which are intended to be placed in contact with foodstuffs and which contain additives referred to in paragraph 1 shall be accompanied by a written declaration containing the information referred to in Article 9.]]

3 By way of derogation from paragraph 1, when the substances referred to in point (a) of paragraph 1 are used as active components of active food contact materials and articles, they may be subject to national provisions pending the adoption of Community provisions.]

Editorial Information

- X1** Substituted by Corrigendum to Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs (Official Journal of the European Communities L 220 of 15 August 2002).
- X2** Substituted by Corrigendum to Commission Directive 2007/19/EC of 30 March 2007 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food and Council Directive 85/572/EEC laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs (Official Journal of the European Union L 91 of 31 March 2007).

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Textual Amendments

- F1** Substituted by [Commission Directive 2007/19/EC of 30 March 2007 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food and Council Directive 85/572/EEC laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs \(Text with EEA relevance\).](#)
- F5** Inserted by [Commission Directive 2004/19/EC of 1 March 2004 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs \(Text with EEA relevance\).](#)

Article 6

1 General specifications related to plastic materials and articles are laid down in Annex V, Part A. Other specifications related to some substances appearing in Annexes II, III and IV are laid down in Annex V, Part B.

2 The meaning of the numbers between brackets appearing in the column ‘Restrictions and/or specifications’ is explained in Annex VI.

Editorial Information

- X1** Substituted by [Corrigendum to Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs \(Official Journal of the European Communities L 220 of 15 August 2002\).](#)

^{F3}Article 7

The specific migration limits in the list set out in Annexes II and III are expressed in mg/kg. However, such limits are expressed in mg/dm² in the following cases:

- (a) articles which are containers or are comparable to containers or which can be filled, with a capacity of less than 500 ml or more than 10 l;
- (b) sheet, film or other material or articles which cannot be filled or for which it is impracticable to estimate the relationship between the surface area of such material or article and the quantity of food in contact therewith.

In those cases, the limits set out in Annexes II and III, expressed in mg/kg shall be divided by the conventional conversion factor of 6 in order to express them in mg/dm².

^{F2}^{X3}For 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 91/321/EEC and 96/5/EC, the SMLs shall always be applied as mg/kg.]]]]

Editorial Information

- X1** Substituted by [Corrigendum to Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs \(Official Journal of the European Communities L 220 of 15 August 2002\).](#)
- X3** Inserted by [Corrigendum to Commission Directive 2007/19/EC of 30 March 2007 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food and Council Directive 85/572/EEC laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs \(Official Journal of the European Union L 91 of 31 March 2007\).](#)

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Textual Amendments

- F2** Inserted by [Commission Directive 2007/19/EC of 30 March 2007 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food and Council Directive 85/572/EEC laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs \(Text with EEA relevance\).](#)
- F3** Substituted by [Commission Directive 2004/19/EC of 1 March 2004 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs \(Text with EEA relevance\).](#)

[^{F2}] *^{X3}Article 7a*

1 In a plastic multi-layer material or article, the composition of each plastic layer shall comply with this Directive.

2 By way of derogation from paragraph 1, a layer which is not in direct contact with food and is separated from the food by a plastic functional barrier, may, provided that the finished material or article complies with the specific and overall migration limits specified in this Directive:

- a not comply with the restrictions and specifications set in this Directive,
- b be manufactured with substances other than those included in this Directive or in the national lists concerning the plastic materials and articles intended to come into contact with food.

3 The migration of the substances referred to in paragraph 2(b) into food or simulant 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⁽⁷⁾. This limit shall always be expressed as concentration in foods or simulants. It 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 referred to in paragraph 2(b) shall not belong to either of the following categories:

- a substances classified as proved or suspect ‘carcinogenic’, ‘mutagenic’ or ‘toxic to reproduction’ substances in Annex I to Council Directive 67/548/EEC⁽⁸⁾;
- b substances classified under the self-responsibility criteria as ‘carcinogenic’, ‘mutagenic’ or ‘toxic to reproduction’ according to the rules of Annex VI to Directive 67/548/EEC.]]

Editorial Information

- X1** Substituted by [Corrigendum to Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs \(Official Journal of the European Communities L 220 of 15 August 2002\).](#)
- X3** Inserted by [Corrigendum to Commission Directive 2007/19/EC of 30 March 2007 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food and Council Directive 85/572/EEC laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs \(Official Journal of the European Union L 91 of 31 March 2007\).](#)

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- F2** Inserted by [Commission Directive 2007/19/EC of 30 March 2007 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food and Council Directive 85/572/EEC laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs \(Text with EEA relevance\).](#)

Article 8

1 Verification of compliance with the migration limits shall be carried out in accordance with the rules laid down in Directives 82/711/EEC and 85/572/EEC and the further provisions set out in Annex I.

[^{F32} The verification of compliance with the specific migration limits provided for in paragraph 1 shall not be compulsory, if the value of overall migration determination implies that the specific migration limits referred to in that paragraph are not exceeded.]

3 The verification of compliance with the specific migration limits provided for in paragraph 1 shall not be compulsory, if it can be established that, by assuming complete migration of the residual substance in the material or article, it cannot exceed the specific limit of migration.

4 The verification of compliance with the specific migration limits provided for in paragraph 1 may be ensured by the determination of the quantity of a substance in the finished material or article provided that a relationship between that quantity and the value of the specific migration of the substance has been established either by an adequate experimentation or by the application of generally recognised diffusion models based on scientific evidence. To demonstrate the non-compliance of a material or article, confirmation of the estimated migration value by experimental testing is obligatory.

[^{F2} Notwithstanding paragraph 1, for phthalates (Ref. No 74640, 74880, 74560, 75100, 75105) referred to in Annex III Section B, the verification of the SML shall only be performed in food simulants. However, verification of the SML may be performed in food where the food has not already been in contact with the material or article and is pre-tested for the phthalate and the level is not statistically significant or greater than or equal to the limit of quantification.]]

Editorial Information

- X1** Substituted by [Corrigendum to Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs \(Official Journal of the European Communities L 220 of 15 August 2002\).](#)
- X3** Inserted by [Corrigendum to Commission Directive 2007/19/EC of 30 March 2007 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food and Council Directive 85/572/EEC laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs \(Official Journal of the European Union L 91 of 31 March 2007\).](#)

Textual Amendments

- F2** Inserted by [Commission Directive 2007/19/EC of 30 March 2007 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food and Council Directive 85/572/EEC laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs \(Text with EEA relevance\).](#)

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- F3** Substituted by [Commission Directive 2004/19/EC of 1 March 2004 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs \(Text with EEA relevance\)](#).

[^{F1}]^{X2} Article 9

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

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

3 Appropriate documentation to demonstrate that the materials and articles as well as the substances intended for the manufacturing of those materials and articles comply with the requirements of this Directive shall be made available by the business operator to the national competent authorities on request. That documentation shall contain the conditions and results of testing, calculations, other analysis, and evidence on the safety or reasoning demonstrating compliance.]]

Editorial Information

- X1** Substituted by [Corrigendum to Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs \(Official Journal of the European Communities L 220 of 15 August 2002\)](#).
- X2** Substituted by [Corrigendum to Commission Directive 2007/19/EC of 30 March 2007 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food and Council Directive 85/572/EEC laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs \(Official Journal of the European Union L 91 of 31 March 2007\)](#).

Textual Amendments

- F1** Substituted by [Commission Directive 2007/19/EC of 30 March 2007 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food and Council Directive 85/572/EEC laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs \(Text with EEA relevance\)](#).

Article 10

1 Directive 90/128/EEC, as amended by the Directives set out in Annex VII, Part A, is hereby repealed without prejudice to the obligations of the Member States in respect of the deadlines for transposition and application laid down in Annex VII, Part B.

2 References to the repealed Directives shall be construed as references to this Directive and be read in accordance with the correlation table set out in Annex VIII.

Editorial Information

- X1** Substituted by [Corrigendum to Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs \(Official Journal of the European Communities L 220 of 15 August 2002\)](#).

Status: EU Directives are being published on this site to aid cross referencing from UK legislation. After IP completion day (31 December 2020 11pm) no further amendments will be applied to this version.

Article 11

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

Editorial Information

- X1** Substituted by [Corrigendum to Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs \(Official Journal of the European Communities L 220 of 15 August 2002\)](#).

Article 12

This Directive is addressed to the Member States.]

Editorial Information

- X1** Substituted by [Corrigendum to Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs \(Official Journal of the European Communities L 220 of 15 August 2002\)](#).

Status: EU Directives are being published on this site to aid cross referencing from UK legislation. After IP completion day (31 December 2020 11pm) no further amendments will be applied to this version.

- (1) [^{X1}OJ L 93, 17.4.1993, p. 27. Directive amended by Directive 93/111/EC (OJ L 310, 14.12.1993, p. 41).
- (2) [^{F2}[^{X3}OJ L 338, 13.11.2004, p. 4.]]
- (3) [^{F1}[^{X2}OJ L 175, 4.7.1991, p. 35.
- (4) OJ L 49, 28.2.1996, p. 17.]]
- (5) [^{F5}OJ L 40, 11.2.1989, p. 27.
- (6) OJ L 184, 15.7.1988, p. 61.]
- (7) [^{F2}[^{X3}OJ L 165, 30.4.2004, p. 1, as corrected by OJ L 191, 28.5.2004, p. 1.
- (8) OJ 196, 16.8.1967, p. 1.]]]

Editorial Information

- X1** Substituted by Corrigendum to Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs (Official Journal of the European Communities L 220 of 15 August 2002).
- X2** Substituted by Corrigendum to Commission Directive 2007/19/EC of 30 March 2007 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food and Council Directive 85/572/EEC laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs (Official Journal of the European Union L 91 of 31 March 2007).
- X3** Inserted by Corrigendum to Commission Directive 2007/19/EC of 30 March 2007 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food and Council Directive 85/572/EEC laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs (Official Journal of the European Union L 91 of 31 March 2007).

Textual Amendments

- F1** Substituted by Commission Directive 2007/19/EC of 30 March 2007 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food and Council Directive 85/572/EEC laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs (Text with EEA relevance).
- F2** Inserted by Commission Directive 2007/19/EC of 30 March 2007 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food and Council Directive 85/572/EEC laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs (Text with EEA relevance).
- F5** Inserted by Commission Directive 2004/19/EC of 1 March 2004 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs (Text with EEA relevance).