

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relating to plastic materials and articles intended to come into contact with foodstuffs (Text with EEA relevance) (repealed)

XI Article 1

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

2 This Directive shall apply to plastic materials and articles and parts thereof:

- a consisting exclusively of plastics; or
- b composed of two or more layers of materials, each consisting exclusively of plastics, which are bound together by means of adhesives or by any other means,

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.

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.

4 This Directive shall not apply, until further action by the Commission, 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 \(Official Journal of the European Communities L 220 of 15 August 2002\)](#).

Article 2

Plastic materials and articles shall not transfer their constituents to foodstuffs in quantities exceeding 10 milligrams per square decimetre of surface area of material or article (mg/dm²) (overall migration limit). However, this limit shall be 60 milligrams of the constituents released per kilogram of foodstuff (mg/kg) in the following cases:

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- (a) articles which are containers or are comparable to containers or which can be filled, with a capacity of not less than 500 millilitres (ml) and not more than 10 litres (l);
- (b) articles which can be filled and for which it is impracticable to estimate the surface area in contact with foodstuffs;
- (c) caps, gaskets, stoppers or similar devices for sealing.

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 3

[^{F1} 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.

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

- F1** 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 \(Text with EEA relevance\)](#).

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[^{F1}Article 4

1 A 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.

That list of additives shall be considered to be an incomplete list until the Commission decides, in accordance with Article 4a, that it shall become a positive Community list of authorised additives, to the exclusion of all others.

The Commission shall establish, by 31 December 2007 at the latest, the date when that list shall become a 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 1 July 2006.

- 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 \(Official Journal of the European Communities L 220 of 15 August 2002\)](#).

Textual Amendments

- F1** 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}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’.

3 If during the examination of the data referred to in paragraph 2, the Authority calls for supplementary information, the additive may continue to be used subject to national law until

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the Authority has issued an opinion, provided that the information is submitted within the time limits specified by the Authority.

4 The Commission shall establish, by 31 December 2007 at the latest, a provisional list of additives which may continue to be used after 31 December 2007 subject to national law until the Authority has evaluated them.

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.

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

- F2** 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 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

- F2** 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 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 \(Official Journal of the European Communities L 220 of 15 August 2002\)](#).

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[^{F2}Article 5a

5 Additives referred to in Article 4, which are authorised as food additives by Council Directive 89/107/EEC⁽²⁾ or flavourings by Council Directive 88/388/EEC⁽³⁾ 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.

2 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(1)(b).

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 \(Official Journal of the European Communities L 220 of 15 August 2002\)](#).

Textual Amendments

- F2** 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 \(Official Journal of the European Communities L 220 of 15 August 2002\)](#).

[^{F1}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:

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- (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.]

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

- F1** 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 \(Text with EEA relevance\)](#).

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.

[^{F12} 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.

Editorial Information

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Textual Amendments

- F1** 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 \(Text with EEA relevance\)](#).

Article 9

[^{F1} At the marketing stages other than the retail stages, plastic materials and articles which are intended to be placed in contact with foodstuffs shall be accompanied by a written declaration, which shall:

- a be in accordance with Article 6(5) of Directive 89/109/EEC;
- b provide, for substances which are subject to a restriction in food, adequate information obtained by experimental data or theoretical calculation about the level of their specific migration and, where appropriate, purity criteria in accordance with Commission Directives 95/31/EC⁽⁴⁾, 95/45/EC⁽⁵⁾ and 2002/82/EC⁽⁶⁾ to enable the user of these materials and articles to comply with the relevant Community provisions or, in their absence, with national provisions applicable to food.]

^{F3}2

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

- F1** 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** Deleted 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 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 \(Official Journal of the European Communities L 220 of 15 August 2002\)](#).

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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 \(Official Journal of the European Communities L 220 of 15 August 2002\)](#).

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- (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}OJ L 40, 11.2.1989, p. 27.
- (3) OJ L 184, 15.7.1988, p. 61.]
- (4) [^{F1}OJ L 178, 28.7.1995, p. 1.
- (5) OJ L 226, 22.9.1995, p. 1.
- (6) OJ L 292, 28.10.2002, 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 \(Official Journal of the European Communities L 220 of 15 August 2002\)](#).

Textual Amendments

- F1** 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** 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 \(Text with EEA relevance\)](#).