

Commission Regulation (EC) No 466/2001 of 8 March 2001 setting maximum
levels for certain contaminants in foodstuffs (Text with EEA relevance) (repealed)

Article 1

1 The foodstuffs indicated in Annex I must not, when placed on the market, contain higher contaminant levels than those specified in that Annex.

[^{F1}1a By way of derogation from paragraph 1, Sweden and Finland are authorised for a transitional period, up to 31 December 2006, to place on the market fish, originating from the Baltic region, which is intended for consumption in their territory with dioxin levels higher than those set in point 5.2. of section 5 of Annex I, provided that a system is in place to ensure that consumers are fully informed of the dietary recommendations with regard to the restrictions on consumption of fish from the Baltic region by identified vulnerable groups of the population in order to avoid potential health risks.

Any future application of this derogation will be considered in the framework of the review of section 5 of Annex I, provided for in Article 5(3).

Finland and Sweden shall communicate to the Commission by 31 December each year, the results of their monitoring of the levels of dioxins in fish from the Baltic region and report on the measures taken to reduce human exposure to dioxins from fish from the Baltic region.]

[^{F2}1b By way of derogation from paragraph 1, the Commission may authorise Estonia for a transitional period, up to 31 December 2006, to place on its market fish, originating from the Baltic region, which is intended for consumption in its territory with dioxin levels higher than those set in point 5.2. of Section 5 of Annex I. This derogation will be granted in accordance with the procedure laid down in Article 8 of Council Regulation (EEC) No 315/93 laying down Community procedures for contaminants in food⁽¹⁾. To this end, Estonia shall demonstrate that the conditions applicable to Finland and Sweden laid down in paragraph 1a are fulfilled and that human exposure to dioxins in Estonia is not higher than the highest average level in any of the Member States of the Community as constituted on 30 April 2004.

If such a derogation is granted to Estonia, any future application of it will be considered in the framework of the review of Section 5 of Annex I, provided for in Article 5(3).

Notwithstanding the above, Estonia shall implement the necessary measures to ensure that fish or fish products not complying with point 5.2 of Section 5 of Annex I are not marketed in other Member States.]

2 The maximum levels specified in Annex I shall apply to the edible part of the foodstuffs mentioned.

3 The sampling and analysis methods applied shall be those specified in Annex I.

Textual Amendments

- F1** Inserted by [Council Regulation \(EC\) No 2375/2001 of 29 November 2001 amending Commission Regulation \(EC\) No 466/2001 setting maximum levels for certain contaminants in foodstuffs \(Text with EEA relevance\)](#).
- F2** Inserted by [Act concerning the conditions of accession of the Czech Republic, the Republic of Estonia, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Republic of Hungary,](#)

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the Republic of Malta, the Republic of Poland, the Republic of Slovenia and the Slovak Republic and the adjustments to the Treaties on which the European Union is founded.

Article 2

1 In the case of products, other than those mentioned under Article 4(1), which are dried, diluted, processed or composed of more than one ingredient, the maximum level applicable shall be that laid down in Annex I, taking into account respectively:

- a changes of the concentration of the contaminant caused by drying or dilution processes,
- b changes of the concentration of the contaminant caused by processing,
- c the relative proportions of the ingredients in the product and
- d the analytical limit of quantification.

The first subparagraph shall apply in so far as no specific maximum levels are fixed for these dried, diluted, processed or compound products.

[^{F32} The maximum levels specified in Annex I shall apply also to food intended for infants and young children covered by Directive 91/321/EEC and Directive 96/5/EC, taking into account respectively, the changes of the concentration of the contaminant caused by drying, dilution or processing and the relative concentrations of the ingredients in the product. This does not apply to the contaminants for which specific Community maximum levels have been set for the specified foods or to the cases where in the absence of Community maximum levels, stricter levels have been set by national legislation for the specified foods.]

[^{F43} Without prejudice to Articles 3(1) and 4(3), the following shall be prohibited

- a to use products, which do not comply with the maximum levels set out in Annex I, as food ingredients for the production of compound or other foodstuffs;
- b to mix products complying with the maximum levels with products exceeding the maximum levels set out in Annex I;
- c to deliberately detoxify products by chemical treatments in the case of contaminants listed in section 2 (Mycotoxins) of Annex I.]

Textual Amendments

- F3** Substituted by [Commission Regulation \(EC\) No 683/2004 of 13 April 2004 amending Regulation \(EC\) No 466/2001 as regards aflatoxins and ochratoxin A in foods for infants and young children \(Text with EEA relevance\)](#).
- F4** Substituted by [Commission Regulation \(EC\) No 856/2005 of 6 June 2005 amending Regulation \(EC\) No 466/2001 as regards Fusarium toxins \(Text with EEA relevance\)](#).

^{F5}Article 3

Textual Amendments

- F5** Deleted by [Commission Regulation \(EC\) No 1822/2005 of 8 November 2005 amending Regulation \(EC\) No 466/2001 as regards nitrate in certain vegetables \(Text with EEA relevance\)](#).

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[^{F6}Article 3a

Member States shall monitor nitrate levels in vegetables containing significant levels, in particular green leafy vegetables, and communicate the results to the Commission by 30 June each year.]

Textual Amendments

F6 Inserted by [Commission Regulation \(EC\) No 1822/2005 of 8 November 2005 amending Regulation \(EC\) No 466/2001 as regards nitrate in certain vegetables \(Text with EEA relevance\)](#).

[^{F6}Article 3b

1 By way of derogation from Article 1(1), Belgium, Ireland, the Netherlands and the United Kingdom are authorised until 31 December 2008 to place on the market fresh spinach grown and intended for consumption in their territory with nitrate levels higher than the maximum levels set out in point 1.1 of Annex I.

2 By way of derogation from Article 1(1), Ireland and the United Kingdom are authorised until 31 December 2008 to place on the market fresh lettuce grown and intended for consumption in their territory and harvested throughout the year with nitrate levels higher than the maximum levels set out in point 1.3 of Annex I.

By way of derogation from Article 1(1), France is authorised until 31 December 2008 to place on the market fresh lettuce grown and intended for consumption in its territory and harvested from 1 October to 31 March with nitrate levels higher than the maximum levels set out in point 1.3 of Annex I.]

Textual Amendments

F6 Inserted by [Commission Regulation \(EC\) No 1822/2005 of 8 November 2005 amending Regulation \(EC\) No 466/2001 as regards nitrate in certain vegetables \(Text with EEA relevance\)](#).

Article 4

1 The maximum limits of aflatoxins applicable to the products, as laid down in points 2.1.1.1 and 2.1.2.1 of Annex I shall also be applicable to processed products thereof in so far as no specific maximum limits are fixed for such processed products.

2 [^{F7}With regard to aflatoxins and ochratoxin A in products mentioned in points 2.1 and 2.2 of Annex I, it is prohibited:]

- a to mix products complying with the maximum levels laid down in Annex I with products exceeding these maximum levels or to mix products to be subjected to a sorting technique or physical treatment with products intended for direct human consumption or as an ingredient in foodstuffs,
- b to use products which do not comply with the maximum levels laid down in points 2.1.1.1, 2.1.2.1 [^{F7}, 2.1.3, 2.1.4, 2.2.1 [^{F8}, 2.2.2, 2.2.3, 2.2.4 and 2.2.5]] of Annex I as an ingredient for the manufacture of other foodstuffs,
- c to detoxify products by chemical treatments.

[^{F93} Groundnuts, nuts and dried fruit not complying with the maximum levels of aflatoxins laid down in point 2.1.1.1 of Annex I and maize not complying with the maximum levels laid down in point 2.1.2.1 of that Annex can be placed on the market provided that these products:

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- a are not intended for direct human consumption or used as an ingredient in foodstuffs;
- b comply with the maximum levels laid down in point 2.1.1.2 of Annex I for groundnuts, in point 2.1.1.3 of Annex I for nuts and dried fruit and in point 2.1.2.3 of Annex I for maize;
- c are subjected to a secondary treatment involving sorting or other physical treatment and that after this treatment the maximum limits laid down in points 2.1.1.1 and 2.1.2.1 of Annex I are not exceeded, and this treatment does not result in other harmful residues;
- d are labelled clearly showing their destination, and bearing the indication ‘product must be subjected to sorting or other physical treatment to reduce aflatoxin contamination before human consumption or use as an ingredient in foodstuffs’.]

Textual Amendments

- F7** Substituted by [Commission Regulation \(EC\) No 472/2002 of 12 March 2002 amending Regulation \(EC\) No 466/2001 setting maximum levels for certain contaminants in foodstuffs \(Text with EEA relevance\)](#).
- F8** Substituted by [Commission Regulation \(EC\) No 123/2005 of 26 January 2005 amending Regulation \(EC\) No 466/2001 as regards ochratoxin A \(Text with EEA relevance\)](#).
- F9** Substituted by [Commission Regulation \(EC\) No 2174/2003 of 12 December 2003 amending Regulation \(EC\) No 466/2001 as regards aflatoxins \(Text with EEA relevance\)](#).

[^{F1}Article 4a

With regard to dioxins in products referred to in section 5 of Annex I, it shall be prohibited:

- (a) to mix products complying with the maximum levels with products exceeding these maximum levels;
- (b) to use products, which do not comply with the maximum levels as an ingredient for the manufacture of other foodstuffs.]

Textual Amendments

- F1** Inserted by [Council Regulation \(EC\) No 2375/2001 of 29 November 2001 amending Commission Regulation \(EC\) No 466/2001 setting maximum levels for certain contaminants in foodstuffs \(Text with EEA relevance\)](#).

Article 5

1 On the basis of the results of controls carried out by the Member States to check compliance with the maximum levels of nitrates laid down in section 1 of Annex I, the reports with regard to the application and improvement of codes of good agricultural practice to reduce nitrate levels and the evaluation of the data on which the Member States have based their good agricultural practice, the Commission shall proceed, every five years, and before 1 January 2002 for the first time, to a review of the maximum levels with the overall objective of reducing the said levels.

2 On the basis of new scientific data and the results of controls carried out by the Member States to check compliance with the maximum levels of heavy metals and 3-MCPD in sections 3 and 4 of Annex I, the Commission shall proceed, every five years, and before 5 April 2003 for the first time, to a review of the maximum levels with the overall objective of ensuring a high level of consumer health protection.

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[^{F8}2a The Commission shall, based on an up-to-date risk assessment on ochratoxin A (OTA) performed by the EFSA and taking into account the prevention measures applied to reduce the OTA content, review the provisions under the heading 2.2 of section 2 of Annex I by 30 June 2006 at the latest. This review will concern in particular the maximum level for OTA in dried vine fruit and grape juice and the consideration of setting a maximum level for OTA in green coffee, dried fruit other than dried vine fruit, beer, cocoa and cocoa products, liqueur wines, meat and meat products, spices and liquorice.

For this purpose, Member States and interested parties shall communicate each year to the Commission the results of the investigations undertaken and the progress with regard to the application of prevention measures to avoid contamination by OTA. The Commission will make these results available to the Member States.]

[^{F13} The Commission shall review section 5 of Annex I for the first time by 31 December 2004 at the latest in the light of new data on the presence of dioxins and dioxin-like PCBs, in particular with a view to the inclusion of dioxin-like PCBs in the levels to be set.

Section 5 of Annex I shall be further reviewed by 31 December 2006 at the latest with the aim of significantly reducing the maximum levels and possibly laying down maximum levels for other foodstuffs.]

[^{F10}4 The Commission shall review the maximum levels for patulin laid down in points 2.3.1 and 2.3.2 of section 2 of Annex I by 30 June 2005 at the latest with a view to reducing them to take account of the progress in scientific and technological knowledge and the implementation of the 'Code of practice for the prevention and reduction of patulin contamination in apple juice and apple juice ingredients in other beverages' .]

[^{F11}5 The Commission shall review points 2.4, 2.5, 2.6 and 2.7 of section 2 of Annex I by 1 July 2008 as regards the maximum limits for deoxynivalenol, zearalenone and fumonisin B₁+B₂ and with a view to including a maximum level for T-2 and HT-2 toxin in cereals and cereal products.

For that purpose, the Member States and interested parties shall communicate each year to the Commission the results of investigations undertaken including occurrence data and the progress with regard to the application of prevention measures to avoid contamination by deoxynivalenol, zearalenone, T-2 and HT-2 toxin and fumonisin B₁+B₂.]

Textual Amendments

- F1** Inserted by [Council Regulation \(EC\) No 2375/2001 of 29 November 2001 amending Commission Regulation \(EC\) No 466/2001 setting maximum levels for certain contaminants in foodstuffs \(Text with EEA relevance\)](#).
- F8** Substituted by [Commission Regulation \(EC\) No 123/2005 of 26 January 2005 amending Regulation \(EC\) No 466/2001 as regards ochratoxin A \(Text with EEA relevance\)](#).
- F10** Inserted by [Commission Regulation \(EC\) No 1425/2003 of 11 August 2003 amending Regulation \(EC\) No 466/2001 as regards patulin \(Text with EEA relevance\)](#).
- F11** Inserted by [Commission Regulation \(EC\) No 856/2005 of 6 June 2005 amending Regulation \(EC\) No 466/2001 as regards Fusarium toxins \(Text with EEA relevance\)](#).

Article 6

Regulation (EC) No 194/97 shall be repealed with effect from 5 April 2002.

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References to the repealed Regulation shall be construed as references to this Regulation and shall be read in accordance with the correlation table in Annex II.

Article 7

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

It shall apply from 5 April 2002. Sections 3 (heavy metals) and 4 (3-MCPD) of Annex I shall not apply to products which have been lawfully placed on the Community market before this date.

[^{F12}The maximum levels established in point 2.3. Patulin of section 2 (Mycotoxins) of Annex I shall not apply to products which have been lawfully placed on the Community market before 1 November 2003. The burden of proving when the products were placed on the market shall be borne by the food business operator.]

Textual Amendments

F12 Inserted by [Commission Regulation \(EC\) No 455/2004 of 11 March 2004 amending Regulation \(EC\) No 466/2001 as regards patulin \(Text with EEA relevance\)](#).

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

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Changes to legislation: There are currently no known outstanding effects for the
Commission Regulation (EC) No 466/2001 (repealed). (See end of Document for details)

(1) [^{F2}OJ L 37, 13.2.1993, p. 1.]

Textual Amendments

- F2** Inserted by Act concerning the conditions of accession of the Czech Republic, the Republic of Estonia, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Republic of Hungary, the Republic of Malta, the Republic of Poland, the Republic of Slovenia and the Slovak Republic and the adjustments to the Treaties on which the European Union is founded.

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