

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)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food ⁽¹⁾, and in particular Article 2(3) thereof,

After consulting the Scientific Committee for Food (SCF),

Whereas:

- (1) Regulation (EEC) No 315/93 provides that maximum levels must be set for contaminants in foodstuffs in order to protect public health.
- (2) Commission Regulation (EC) No 466/2001 ⁽²⁾, as last amended by Regulation (EC) No 257/2002 ⁽³⁾, sets maximum levels for certain contaminants in foodstuffs to apply from 5 April 2002.
- (3) Some Member States have adopted, or plan to adopt, maximum levels for aflatoxins in spices and maximum levels for ochratoxin A in certain foodstuffs. In view of the disparities between Member States and the consequent risk of distortion of competition, Community measures are necessary in order to ensure market unity while abiding by the principle of proportionality.
- (4) Aflatoxins, in particular aflatoxin B1, are genotoxic carcinogenic substances. For substances of this type there is no threshold below which no harmful effect is observed and therefore no admissible daily intake can be set. Current scientific and technical knowledge and improvements in production and storage techniques do not prevent the development of these moulds and consequently do not enable the presence of the aflatoxins in spices to be eliminated entirely. Limits should therefore be set which are as low as reasonably achievable.
- (5) The results of a coordinated control programme, performed by the Member States in accordance with Commission Recommendation 97/77/EC of 8 January 1997 concerning a coordinated programme for the official control of foodstuffs for 1997 ⁽⁴⁾ have become avail-

able since the maximum levels for aflatoxins in other foodstuffs were established. They show that several species of spices contain a high level of aflatoxins. It is therefore appropriate to establish maximum limits for the species of spices which are used in large quantity and which have a high incidence of contamination.

- (6) The maximum limits should be reviewed and, if necessary, reduced before 31 December 2003 taking into account possibilities to reduce aflatoxin contamination in spices by improvements in production, harvesting and storage methods and the progress of scientific and technological knowledge.
- (7) Ochratoxin A is a mycotoxin produced by several fungi (*Penicillium* and *Aspergillus* species). It occurs naturally in a variety of plant products, such as cereals, coffee beans, cocoa beans, and dried fruit, all over the world. It has been detected in products such as cereal products, coffee, wine, beer, spices and grape juice but also in products of animal origin, namely pig kidneys. Investigations of the frequency and levels of occurrence of ochratoxin A in food and human blood samples indicate that foodstuffs are frequently contaminated.
- (8) Ochratoxin A is a mycotoxin with carcinogenic, nephrotoxic, teratogenic, immunotoxic and possibly neurotoxic properties. It has been linked to nephropathy in humans. Ochratoxin A may have a long half-life in humans.
- (9) The Scientific Committee for Food considered in its opinion on ochratoxin A of 17 September 1998 that it would be prudent to reduce exposure to ochratoxin A as much as possible, ensuring that exposures are towards the lower end of the range of tolerable daily intakes of 1,2-14 ng/kg bw/day which have been estimated by other bodies, e.g. below 5 ng/kg bw/day.
- (10) With current scientific and technical knowledge, and despite improvements in production and storage techniques, it is not possible to prevent the development of these moulds altogether. Consequently ochratoxin A cannot be eliminated from food entirely. Limits should therefore be set which are as low as reasonably achievable.

⁽¹⁾ OJ L 37, 13.2.1993, p. 1.

⁽²⁾ OJ L 77, 16.3.2001, p. 1.

⁽³⁾ OJ L 41, 13.2.2002, p. 12.

⁽⁴⁾ OJ L 22, 24.1.1997, p. 27.

- (11) The main contributors to the dietary intake of ochratoxin A are cereals and cereal products. Prevention is of major importance to avoid contamination as much as possible and to protect the consumer. In addition, it is appropriate to establish maximum limits for cereals and cereal products at a level reasonably achievable on condition that preventive actions to avoid contamination at all stages in the production and commercialisation chain are applied.
- (12) Dried vine fruit (currants, raisins and sultanas) has been found to be highly contaminated. Dried vine fruit is an important dietary source of ochratoxin A for people with high levels of consumption, in particular children. While it is therefore appropriate to establish for the time being a limit at a level which is technologically achievable, it is imperative to further improve practices to reduce contamination.
- (13) The presence of ochratoxin A has also been observed in coffee, wine, beer, grape juice, cocoa and spices. Investigations and research should be undertaken by Member States and interested parties (such as professional organisations) to determine the different factors involved in the formation of ochratoxin A and to determine the prevention measures to be taken to reduce the presence of ochratoxin A in these foodstuffs. For these products every effort should be made with regard to research and prevention measures to reduce ochratoxin A content as much as possible pending the establishment of maximum limits on the basis of the 'as low as reasonably achievable' (ALARA) principle. If no effort is undertaken to reduce the ochratoxin A content for certain products, it will be necessary to establish a maximum limit for these products in order to protect public health, without being able to assess the technological feasibility.
- (14) Regulation (EC) No 466/2001 should therefore be amended accordingly.
- (15) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 466/2001 is amended as follows:

1. Article 4(2) is amended as follows:

- (a) the introductory phrase is replaced by the following: 'With regard to aflatoxins and ochratoxin A in products mentioned in points 2.1 and 2.2 of Annex I, it is prohibited:';
- (b) in point (b), 'and 2.1.3' is replaced by ' ; 2.1.3, 2.1.4, 2.2.1 and 2.2.2'.

2. In Article 5, the following paragraph 2a is inserted:

'2a. The Commission shall review the maximum limits for aflatoxins laid down in point 2.1.4 of section 2 of Annex I by 31 December 2003 at the latest and, if appropriate, reduce them to take account of the progress of scientific and technological knowledge.

The Commission shall review the provisions in points 2.2.2 and 2.2.3 of section 2 of Annex I by 31 December 2003 at the latest as regards the maximum limits for ochratoxin A in dried vine fruit and with a view to including a maximum limit for ochratoxin A in green and roasted coffee and coffee products, wine, beer, grape juice, cocoa and cocoa products and spices taking into account the investigations undertaken and the prevention measures applied to reduce the presence of ochratoxin A in these products.

For this purpose, Member States and interested parties shall communicate each year to the Commission the results of investigations undertaken and the progress with regard to the application of prevention measures to avoid contamination by ochratoxin A.'

3. Annex I is amended as set out in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the 10th day following its publication in the *Official Journal of the European Communities*.

It shall apply from 5 April 2002.

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

Done at Brussels, 12 March 2002.

For the Commission
David BYRNE
Member of the Commission

ANNEX

In Section 2 (Mycotoxins) of Annex I to Regulation (EC) No 466/2001 the following is added:

Product	Maximum level (µg/kg)			Sampling method	Performance criteria for methods of analysis
	B ₁	B ₁ + B ₂ + G ₁ + G ₂	M ₁		
2.1.4. Following species of spices: — <i>Capsicum</i> spp. (dried fruits thereof, whole or ground, including chillies, chilli powder, cayenne and paprika) — <i>Piper</i> spp. (fruits thereof, including white and black pepper) — <i>Myristica fragrans</i> (nutmeg) — <i>Zingiber officinale</i> (ginger) — <i>Curcuma longa</i> (turmeric)	5	10	—	Directive 98/53/EC	Directive 98/53/EC'

Product	Maximum levels (µg/kg or ppb)	Sampling method	Reference analysis method
2.2. OCHRATOXIN A			
2.2.1. Cereals (including rice and buckwheat) and derived cereal products			
2.2.1.1. Raw cereal grains (including raw rice and buckwheat)	5	Commission Directive 2002/27/EC (*)	Directive 2002/27/EC
2.2.1.2. All products derived from cereals (including processed cereal products and cereal grains intended for direct human consumption)	3	Directive 2002/27/EC	Directive 2002/27/EC
2.2.2. Dried vine fruit (currants, raisins and sultanas)	10	Directive 2002/27/EC	Directive 2002/27/EC
2.2.3. Green and roasted coffee and coffee prod- ucts, wine, beer, grape juice, cocoa and cocoa products and spices	—		

(*) OJ L 75, 16.3.2002, p. 44.'