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**COMMISSION REGULATION (EC) No 466/2001
of 8 March 2001
setting maximum levels for certain contaminants in foodstuffs
(Text with EEA relevance)
(OJ L 77, 16.3.2001, p. 1)**

Amended by:

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► <u>M1</u> Council Regulation (EC) No 2375/2001 of 29 November 2001	L 321	1	6.12.2001
► <u>M2</u> Commission Regulation (EC) No 221/2002 of 6 February 2002	L 37	4	7.2.2002
► <u>M3</u> Commission Regulation (EC) No 257/2002 of 12 February 2002	L 41	12	13.2.2002
► <u>M4</u> Commission Regulation (EC) No 472/2002 of 12 March 2002	L 75	18	16.3.2002
► <u>M5</u> Commission Regulation (EC) No 563/2002 of 2 April 2002	L 86	5	3.4.2002
► <u>M6</u> Commission Regulation (EC) No 1425/2003 of 11 August 2003	L 203	1	12.8.2003

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- **C1** Corrigendum, OJ L 313, 30.11.2001, p. 60 (466/2001)
- **C2** Corrigendum, OJ L 80, 23.3.2002, p. 42 (472/2002)
- **C3** Corrigendum, OJ L 155, 14.6.2002, p. 63 (563/2002)



COMMISSION REGULATION (EC) No 466/2001
of 8 March 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 certain contaminants in foodstuffs in order to protect public health. These maximum levels must be adopted in the form of a non-exhaustive Community list which may contain levels for the same contaminant in different foodstuffs. The sampling and analysis methods to be applied may be specified.
- (2) Commission Regulation (EC) No 194/97 of 31 January 1997, setting maximum levels for certain contaminants in foodstuffs ⁽²⁾, as last amended by Regulation (EC) No 1566/1999 ⁽³⁾, has been amended substantially several times. Since further amendments are to be made, it should be recast in the interests of clarity.
- (3) It is essential, in order to protect public health, to keep contaminants at levels which are toxicologically acceptable. The presence of contaminants must be reduced more thoroughly wherever possible by means of good manufacturing or agricultural practices, in order to achieve a higher level of health protection, especially for sensitive groups of the population.
- (4) In view of disparities between the laws of Member States in regard to the maximum levels for contaminants in certain foodstuffs 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.
- (5) Member States must adopt appropriate surveillance measures regarding the presence of contaminants in foodstuffs.
- (6) So far, Community legislation does not set maximum levels for contaminants in food intended for infants and young children covered by Commission Directive 91/321/EEC ⁽⁴⁾, as last amended by Directive 1999/50/EC ⁽⁵⁾, and Commission Directive 96/5/EC ⁽⁶⁾, as last amended by Directive 1999/39/EC ⁽⁷⁾. After having consulted the SCF, specific maximum levels for those foodstuffs should be established as soon as possible. Until then the levels set in this Regulation should also apply to those foodstuffs in so far as no stricter level has been set by national legislation.
- (7) Food ingredients used for the production of compound foodstuffs should comply with the maximum levels set in this Regulation prior to addition to the said compound foodstuff in order to avoid dilution.

⁽¹⁾ OJ L 37, 13.2.1993, p. 1.

⁽²⁾ OJ L 31, 1.2.1997, p. 48.

⁽³⁾ OJ L 184, 17.7.1999, p. 17.

⁽⁴⁾ OJ L 175, 4.7.1991, p. 35.

⁽⁵⁾ OJ L 139, 2.6.1999, p. 29.

⁽⁶⁾ OJ L 49, 28.2.1996, p. 17.

⁽⁷⁾ OJ L 124, 18.5.1999, p. 8.

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- (8) Vegetables are the major source of nitrates for human intake. The SCF in its opinion of 22 September 1995 stated that the total intake of nitrates is normally well below the acceptable daily intake. It recommended, however, continuation of efforts to reduce exposure to nitrates via food and water since nitrates can be converted into nitrites and nitrosamines, and urged that good agricultural practices are adopted to ensure nitrate levels are as low as reasonably achievable. The SCF emphasised that concern about the presence of nitrates should not discourage increase in the consumption of vegetables since vegetables have an essential nutritional function and play an important role in health protection.
- (9) Specific measures designed to provide better control of the sources of nitrates together with codes of good agricultural practice may help to reduce the nitrate levels in vegetables. However, climatic conditions also influence the levels of nitrates in certain vegetables. Different maximum nitrate levels should therefore be fixed for vegetables depending on the season. The climatic conditions vary widely in different parts of the Community. Therefore, Member States should be allowed, for a transitional period, to authorise the marketing of lettuces and spinach grown and intended for consumption in their territory with nitrate levels higher than those fixed in points 1.1 and 1.3 of Annex I, provided, that the quantities present remain acceptable from the point of view of public health.
- (10) Lettuce and spinach producers established in the Member States which have given the abovementioned authorisations should progressively modify their farming methods by applying the good agricultural practices recommended at national level, so as to comply with the maximum levels laid down at Community level at the end of the transitional period. It is desirable to achieve common values as soon as possible.
- (11) The levels set for lettuce and spinach should be reviewed and, if possible, reduced before 1 January 2002. This review will be based on monitoring carried out by the Member States and the application of codes of good agricultural practice in order to fix the maximum levels as low as reasonably achievable.
- (12) The monitoring of nitrate levels in lettuce and spinach and the application of good agricultural practices shall be carried out using means proportionate to the desired objective, the monitoring results obtained and, particularly, in the light of the risks and of experience gained. The application of codes of good agricultural practice in some Member States will be closely observed. It is therefore appropriate that each year Member States communicate the results of their monitoring and report on the measures taken and the progress with regard to the application of codes of good agricultural practice to reduce nitrate levels and that an exchange of views with the Member States on these reports will take place annually.
- (13) Lower limits are fixed for open-grown lettuce than for lettuce grown under glass, and in order to allow effective control the limits set for open-grown lettuce should apply also to lettuce grown under glass in the absence of precise labelling.
- (14) Aflatoxins are mycotoxins produced by certain species of *Aspergillus*, which develop at high temperatures and humidity levels. Aflatoxins are genotoxic carcinogenic substances and may be present in a large number of foods. For substances of this type there is no threshold below which no harmful effect is observed. No tolerable daily intake can therefore 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 food to be eliminated entirely. It is, therefore, advisable to set limits as low as reasonably achievable.

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- (15) Efforts to improve production, harvesting and storage methods in order to reduce the development of moulds should be encouraged. The aflatoxins group includes a number of compounds of varying toxicity and frequency in food. Aflatoxin B₁ is by far the most toxic compound. It is advisable, for safety reasons, to limit both the total aflatoxin content of food (compounds B₁, B₂, G₁ and G₂) and the aflatoxin B₁ content. Aflatoxin M₁ is a metabolic product of aflatoxin B₁, and is present in milk and milk products from animals which have consumed contaminated feed. Even if aflatoxin M₁ is regarded as a less dangerous genotoxic carcinogenic substance than aflatoxin B₁, it is necessary to prevent the presence thereof in milk and milk products intended for human consumption and for young children in particular.
- (16) It is recognised that sorting or other physical treatment methods make it possible to reduce the aflatoxin content of groundnuts, nuts and dried fruit. In order to minimise the effects on trade, it is consequently advisable to admit higher aflatoxin content for those products which are not intended for direct human consumption or as an ingredient in foodstuffs. In these cases, the maximum limits for aflatoxins were fixed by taking into consideration at the same time the known possible effects of the above-mentioned treatments for groundnuts, nuts and dried fruit respectively and the need to comply after treatment with the maximum limits fixed for these products intended for direct human consumption or to be used as an ingredient in foodstuffs. In the case of cereals, it cannot be excluded that sorting methods or other physical treatments can reduce the level of contamination of aflatoxins. In order to be able to check the real effectiveness of these methods and, if necessary, to fix specific maximum limits for the unprocessed cereals, it is foreseen for a limited period to apply the maximum limits as laid down in Annex I only for cereals and processed products thereof intended for direct human consumption or as an ingredient in foodstuffs. In the absence of data justifying the fixing of a specific maximum limit for unprocessed cereals, after a well-defined period of time, the maximum limit laid down for cereals and the processed products thereof intended for direct human consumption or as an ingredient of food, will also apply to unprocessed cereals.
- (17) To allow effective control of the respect of the various limits fixed for the products in question, it is necessary to know the exact destination by means of suitable labelling. Products with levels of aflatoxin exceeding the maximum limit may not be brought into circulation, either as such, after mixture with other foodstuffs or as an ingredient in other foodstuffs. Under Article 5 of Regulation (EEC) No 315/93, Member States may maintain their national provisions concerning the maximum limits for aflatoxins in certain foodstuffs for which no Community provisions have been adopted.
- (18) Lead absorption may constitute a serious risk to public health. Lead may induce reduced cognitive development and intellectual performance in children and increased blood pressure and cardiovascular diseases in adults. Over the past decade the levels in food have decreased significantly owing to the awareness of lead as a health problem and source-related efforts to reduce the emission of lead and improvements in quality assurance of chemical analysis. The SCF concluded in its opinion of 19 June 1992 that the mean level of lead in foodstuffs does not seem to be a cause for alarm, however, longer-term action should follow with the objective of further lowering the mean levels of lead in foodstuffs. Therefore, the maximum levels should be as low as reasonably achievable.
- (19) Cadmium may accumulate in the human body and may induce kidney dysfunction, skeletal damage and reproductive deficiencies. It cannot be excluded that it acts as a human carcinogen. The SCF, in its opinion of 2 June 1995, recommended greater efforts to reduce dietary exposure to cadmium since foodstuffs

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are the main source of human intake of cadmium. Therefore, maximum levels should be set as low as reasonably achievable.

- (20) Methylmercury may induce alterations in the normal development of the brain of infants and at higher levels may induce neurological changes in adults. Mercury contaminates mostly fish and fishery products. To protect public health, maximum levels of mercury in fishery products are laid down by Commission Decision 93/351/EEC ⁽¹⁾. For reasons of transparency, the relevant measures laid down by that Decision should be transferred to the present Regulation and updated. The levels should be as low as reasonably achievable, taking into account that for physiological reasons certain species concentrate mercury more easily in their tissues than others.
- (21) 3-monochloropropane-1,2-diol (3-MCPD) is created during food processing under certain conditions. In particular, it may be produced during the manufacture of the savoury food ingredient 'hydrolysed vegetable protein' that is produced through the acid hydrolysis method (acid-HVP). By adjusting production processes, a significant decrease of 3-MCPD in the abovementioned product has been achieved over the past years. Recently, several Member States have also reported high levels of 3-MCPD in certain samples of soy sauce. In order to enforce good manufacturing practice and to protect the health of consumers, maximum levels of 3-MCPD should be set. The SCF advised, in its opinion of 16 December 1994, which was confirmed on 12 June 1997, that 3-MCPD should be regarded as a genotoxic carcinogen and that residues of 3-MCPD in food products should be undetectable. Recently performed toxicological studies indicate that the substance acts as a non-genotoxic carcinogen *in vivo*.
- (22) The maximum levels set in Annex I for 3-MCPD are based on the SCF opinion. The SCF will reevaluate the toxicity of 3-MCPD in the light of new studies. The adequacy of the maximum levels should be reconsidered as soon as the new SCF opinion is available. Member States are requested to examine other foodstuffs for the occurrence of 3-MCPD in order to consider the need to set maximum levels for additional foodstuffs.
- (23) Any maximum level adopted at Community level will have to be reviewed regularly to take account of the advance of scientific and technical knowledge and improvements in manufacturing or agricultural practices with the objective of achieving steadily decreasing levels.
- (24) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Foodstuffs,

HAS ADOPTED THIS REGULATION:

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.

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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

⁽¹⁾ OJ L 144, 16.6.1993, p. 23.

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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.

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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.

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.

2. 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 in so far as no stricter level has been set by national legislation for the specified food products, 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. Specific maximum levels of contaminants for those foodstuffs shall be established by 5 April 2004 at the latest.

3. Without prejudice to Articles 3(1) and 4(3), it is prohibited to use products as food ingredients for the production of compound foodstuffs which do not comply with the maximum levels set in Annex I.

*Article 3***▼M5**

1. Member States may, where justified, authorise for a transitional period the placing on the market of fresh lettuces and fresh spinach, grown and intended for consumption in their territory, with nitrate levels higher than those set as maximum levels in points 1.1, 1.3 and 1.4 of the Annex provided that codes of good agricultural practice are applied to achieve gradual progress towards the levels laid down in this Regulation.

The transitional period:

- (a) with regard to lettuces, shall cease on 1 January 2005;
- (b) with regard to spinach, shall be reviewed not later than 1 January 2005.

Member States shall inform the other Member States and the Commission each year of steps taken to implement the first sub-paragraph.

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2. Member States shall communicate to the Commission by 30 June of each year, the results of their monitoring and report on the measures taken and the progress made with regard to the application and improvement of codes of good agricultural practice to reduce nitrate levels in lettuce and spinach. This information shall also contain the data on which their codes of good agricultural practice are based.

3. The Member States, who do not apply paragraph 1, shall carry out the monitoring of nitrate levels in lettuce and spinach and apply good agricultural practices using means proportionate to the desired objective, the monitoring results obtained, particularly in the light of the risks and of experience gained.

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. ►**M4** 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 ►**M4**, 2.1.3, 2.1.4, 2.2.1 and 2.2.2 ◀ of Annex I as an ingredient for the manufacture of other foodstuffs,
- (c) to detoxify products by chemical treatments.

3. 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 cereals not complying with the maximum levels laid down in point 2.1.2.1 can be placed on the market provided that these products:

- (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 and point 2.1.1.3 of Annex I for nuts and dried fruit,
- (c) are subjected to a secondary treatment involving sorting or other physical treatments 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'.

▼M1*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.

▼B*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.

▼M4

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.

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3. 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.

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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'.

▼B*Article 6*

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

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*.

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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.

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

ANNEX I

MAXIMUM LEVELS FOR CERTAIN CONTAMINANTS IN FOODSTUFFS

Section 1: Nitrates ⁽¹⁾

Product	Maximum level (mg NO ₃ / kg)		Sampling method	Reference analysis method
	Harvested 1 November to 31 March	Harvested 1 April to 31 October		
1.1. Fresh spinach ⁽²⁾ (<i>Spinacia oleracea</i>)		3 000 2 500	Commission Directive 79/700/EEC ⁽³⁾	
1.2. Preserved, deep-frozen or frozen spinach		2 000	Directive 79/700/EEC	
1.3. Fresh Lettuce (<i>Lactuca sativa</i> L.) (protected and open-grown lettuce) excluding lettuce listed in point 1.4.	Harvested 1 October to 31 March:		Directive 79/700/EEC. However, the minimum number of units per laboratory sample is 10	
	— lettuce grown under cover	4 500 ⁽⁵⁾		
	— grown in the open air	4 000 ⁽⁵⁾		
	Harvested 1 April to 30 September:			
— lettuce grown under cover	3 500 ⁽⁵⁾			
— lettuce grown in the open air	2 500 ⁽⁵⁾			
1.4. 'Iceberg' type lettuces ⁽²⁷⁾	Lettuce grown under cover	2 500 ⁽⁵⁾	Directive 79/700/EEC. However, the minimum number of units per laboratory sample is 10	
	Lettuce grown in the open air	2 000 ⁽⁵⁾		

Section 2: Mycotoxins

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. AFLATOXINS (1)					
2.1.1. Groundnuts, nuts and dried fruit					
2.1.1.1. Groundnuts, nuts and dried fruit and processed products thereof, intended for direct human consumption or as an ingredient in foodstuffs	2 (6)	4 (6)	—	Directive 98/53/EC (7)	Directive 98/53/EC
2.1.1.2. Groundnuts to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs	8 (6)	15 (6)		Directive 98/53/EC	Directive 98/53/EC
2.1.1.3. Nuts and dried fruit to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs	5 (6)	10 (6)	—	Directive 98/53/EC	Directive 98/53/EC
2.1.2. Cereals (including buckwheat, <i>Fagopyrum</i> spp.)					
2.1.2.1. Cereals (including buckwheat, <i>Fagopyrum</i> spp.) and processed products thereof intended for direct human consumption or as an ingredient in foodstuffs	2	4	—	Directive 98/53/EC	Directive 98/53/EC

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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		
2.1.2.2. Cereals (including buckwheat, <i>Fagopyrum</i> spp.), with the exception of maize, to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs	2	4	—	Directive 98/53/EC	Directive 98/53/EC
2.1.2.3. Maize to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs	— ⁽⁹⁾	— ⁽⁹⁾	—	Directive 98/53/EC	Directive 98/53/EC
2.1.3. Milk (raw milk, milk for the manufacture of milk-based products and heat-treated milk as defined by Council Directive 92/46/EEC ⁽¹⁰⁾ , as last amended by Council Directive 94/71/EC ⁽¹¹⁾).	—	—	0,05	Directive 98/53/EC	Directive 98/53/EC
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

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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 ► C2 Directive 2002/26/EC ◄ ⁽³⁶⁾	► C2 Directive 2002/26/EC ◄
2.2.1.2. All products derived from cereals (including processed cereal products and cereal grains intended for direct human consumption)	3	► C2 Directive 2002/26/EC ◄	► C2 Directive 2002/26/EC ◄
2.2.2. Dried vine fruit (currants, raisins and sultanas)	10	► C2 Directive 2002/26/EC ◄	► C2 Directive 2002/26/EC ◄
2.2.3. Green and roasted coffee and coffee products, wine, beer, grape juice, cocoa and cocoa products and spices	—		

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Products	Patulin: maximum levels (µg/kg or ppb)	Sampling method	Reference analysis method
2.3. PATULIN			
2.3.1. — Fruit juices and fruit nectar, in particular apple juice, and fruit juice ingredients in other beverages ⁽³⁶⁾ — Concentrated fruit juice ⁽³⁶⁾ after reconstitution as instructed by the manufacturer	50,0	Directive 2003/78/EC	Directive 2003/78/EC
2.3.2. Spirit drinks ⁽³⁷⁾ , cider and other fermented drinks derived from apples or containing apple juice	50,0	Directive 2003/78/EC	Directive 2003/78/EC
2.3.3. Solid apple products, including apple compote, apple puree intended for direct	25,0	Directive 2003/78/EC	Directive 2003/78/EC

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Products	Patulin: maximum levels (µg/kg or ppb)	Sampling method	Reference analysis method
consumption			
2.3.4. — Apple juice and solid apple products, including apple compote and apple puree, for infants and young children ⁽³⁸⁾ and labelled and sold as intended for infants and young children — other baby food ⁽⁴⁰⁾	10,0 ⁽³⁹⁾	Directive 2003/78/EC	Directive 2003/78/EC

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Section 3: Heavy metals

Product	Maximum level (mg/kg wet weight)	Performance criteria for sampling	Performance criteria for methods of analysis
3.1. LEAD (Pb)			
3.1.1. Cows' milk (raw milk, milk for the manufacture of milk-based products and heat-treated milk as defined by Directive 92/46/EEC)	0,02	Commission directive 2001/22/EC ⁽¹²⁾	Directive 2001/22/EC
3.1.2. Infant formulae and follow-on formulae as defined in Directive 91/321/EEC ⁽¹³⁾	0,02	Directive 2001/22/EC	Directive 2001/22/EC
3.1.3. Meat of bovine animals, sheep, pig and poultry as defined in Article 2(a) of Council Directive 64/433/EEC ⁽¹⁴⁾ , as last amended by Directive 95/23/EC ⁽¹⁵⁾ , and Article 2(1) of Council Directive 71/118/EEC ⁽¹⁶⁾ , as last amended by Directive 97/79/EC ⁽¹⁷⁾ , excluding offal as defined in Article 2(e) of Directive 64/433/EEC and Article 2(5) of Directive 71/118/EEC	0,1	Directive 2001/22/EC	Directive 2001/22/EC
3.1.3.1. Edible offal of cattle, sheep, pig and poultry as defined in Article 2(e) of Directive 64/433/EEC and Article 2(5) of Directive 71/118/EEC	0,5	Directive 2001/22/EC	Directive 2001/22/EC

▼ <u>B</u>	Product	Maximum level (mg/kg wet weight)	Performance criteria for sampling	Performance criteria for methods of analysis
▼ <u>M2</u>	3.1.4. Muscle meat ⁽²⁵⁾ of fish as defined in categories (a), (b) and (e) of the list of Article 1 of Council Regulation (EC) No 104/2000 (OJ L 17, 21.1.2000, p. 22), excluding fish species listed in 3.1.4.1	0,2	Directive 2001/22/EC	Directive 2001/22/EC
▼ <u>B</u>	3.1.4.1. Muscle meat ⁽²⁵⁾ of: bonito (<i>Sarda sarda</i>), common two-banded seabream (<i>Diplodus vulgaris</i>), eel (<i>Anguilla anguilla</i>), grey mullet (<i>Mugil labrosus labrosus</i>), grunt (<i>Pomadasyss benneti</i>), horse mackerel or scad (<i>Trachurus trachurus</i>), sardine (<i>Sardina pilchardus</i>), sardinops (<i>Sardinops species</i>), spotted seabass (<i>Dicentrarchus punctatus</i>), tuna (<i>Thunnus species</i> and <i>Euthymys species</i>), wedge sole (<i>Dicologlossa cuneata</i>)	0,4	Directive 2001/22/EC	Directive 2001/22/EC
▼ <u>B</u>	3.1.5. Crustaceans, excluding brown meat of crab	0,5	Directive 2001/22/EC	Directive 2001/22/EC
▼ <u>M2</u>	3.1.6. Bivalve molluscs	1,5	Directive 2001/22/EC	Directive 2001/22/EC
▼ <u>B</u>	3.1.7. Cephalopods (without viscera)	1,0	Directive 2001/22/EC	Directive 2001/22/EC
▼ <u>B</u>	3.1.8. Cereals (including buckwheat), legumes and pulses	0,2	Directive 2001/22/EC	Directive 2001/22/EC



Product	Maximum level (mg/kg wet weight)	Performance criteria for sampling	Performance criteria for methods of analysis
3.1.9. Vegetables as defined in Article 1 of Council Directive 90/642/EEC ⁽¹⁹⁾ , as last amended by Directive 2000/48/EC ⁽²⁰⁾ , excluding brassica, leafy vegetables, fresh herbs and all fungi. For potatoes the maximum level applies to peeled potatoes	0,1	Directive 2001/22/EC	Directive 2001/22/EC
3.1.9.1. Brassica, leafy vegetables and all cultivated fungi	0,3	Directive 2001/22/EC	Directive 2001/22/EC
3.1.10. Fruit as defined in Article 1 of Directive 90/642/EEC, excluding berries and small fruits	0,1	Directive 2001/22/EC	Directive 2001/22/EC
3.1.10.1. Berries and small fruits as defined in Article 1 of Council Directive 90/642/EEC	0,2	Directive 2001/22/EC	Directive 2001/22/EC
3.1.11. Fats and oils, including milk fat	0,1	Directive 2001/22/EC	Directive 2001/22/EC
3.1.12. Fruit juices, concentrated fruit juices (for direct consumption) and fruit nectars as defined in Council Directive 93/77/EEC ⁽²¹⁾	0,05	Directive 2001/22/EC	Directive 2001/22/EC
3.1.13. Wines as defined in Council Regulation (EC) No 1493/1999 ⁽²²⁾ (including sparkling wines and excluding liqueur wines), aromatised wines, aromatised wine-based drinks and aromatised wine-product cocktails as defined in ► CFI Council Regulation (EEC) No 1601/91 ⁽²³⁾ ◀, and ciders, perry and fruit wines. Maximum level applies to products produced from the 2001 fruit harvest onwards	0,2	Directive 2001/22/EC	Directive 2001/22/EC
3.2. CADMIUM (Cd)			
3.2.1. Meat of bovine animals, sheep, pig and poultry as defined in Article 2(a) of Directive 64/433/EEC and Article 2(1) of	0,05	Directive 2001/22/EC	Directive 2001/22/EC

Product	Maximum level (mg/kg wet weight)	Performance criteria for sampling	Performance criteria for methods of analysis
Directive 71/118/EEC excluding offal as defined in Article 2(e) of Directive 64/433/EEC and Article 2(5) of Directive 71/118/EEC			
3.2.2. Horsemeat	0,2	Directive 2001/22/EC	Directive 2001/22/EC
3.2.3. Liver of cattle, sheep, pig and poultry	0,5	Directive 2001/22/EC	Directive 2001/22/EC
3.2.4. Kidney of cattle, sheep, pig and poultry	1,0	Directive 2001/22/EC	Directive 2001/22/EC
3.2.5. Muscle meat ⁽²⁵⁾ of fish as defined in categories (a), (b) and (c) of the list of Article 1 of Regulation (EC) No 104/2000, excluding fish species listed in 3.2.5.1	0,05	Directive 2001/22/EC	Directive 2001/22/EC
3.2.5.1. Muscle meat ⁽²⁵⁾ of: bonito (<i>Sarda sarda</i>), common two-banded seabream (<i>Diplodus vulgaris</i>), eel (<i>Anguilla anguilla</i>), European anchovy (<i>Engraulis encrasicolus</i>), grey mullet (<i>Mugil labrosus labrosus</i>), horse mackerel or scad (<i>Trachurus trachurus</i>), louvar or luvar (<i>Luvarus imperialis</i>), sardine (<i>Sardina pilchardus</i>), sardinops (<i>Sardinops species</i>), tuna (<i>Thunnus</i> and <i>Euthynnus species</i>), wedge sole (<i>Dicologlossa cuneata</i>)	0,1	Directive 2001/22/EC	Directive 2001/22/EC
3.2.6. Crustaceans, excluding brown meat of crab and excluding head and thorax meat of lobster and similar large crustaceans (<i>Nephropidae</i> and <i>Palinuridae</i>)	0,5	Directive 2001/22/EC	Directive 2001/22/EC

Product	Maximum level (mg/kg wet weight)	Performance criteria for sampling	Performance criteria for methods of analysis
3.2.7. Bivalve molluscs	1,0	Directive 2001/22/EC	Directive 2001/22/EC
3.2.8. Cephalopods (without viscera)	1,0	Directive 2001/22/EC	Directive 2001/22/EC
3.2.9. Cereals, excluding bran, germ, wheat grain and rice	0,1	Directive 2001/22/EC	Directive 2001/22/EC
3.2.9.1. Bran, germ, wheat grain and rice	0,2	Directive 2001/22/EC	Directive 2001/22/EC
3.2.10. Soybeans	0,2	Directive 2001/22/EC	Directive 2001/22/EC
3.2.11. Vegetables and fruits as defined in Article 1 of Directive 90/642/EEC, excluding leafy vegetables, fresh herbs, all fungi, stem vegetables, root vegetables and potatoes	0,05	Directive 2001/22/EC	Directive 2001/22/EC
3.2.11.1. Leafy vegetables, fresh herbs, celeriac and all cultivated fungi	0,2	Directive 2001/22/EC	Directive 2001/22/EC
3.2.11.2. Stem vegetables, root vegetables and potatoes, excluding celeriac. For potatoes the maximum level applies to peeled potatoes	0,1	Directive 2001/22/EC	Directive 2001/22/EC
3.3. MERCURY			
3.3.1. Fishery products, except those in 3.3.1.1	0,5	Directive 2001/22/EC	Directive 2001/22/EC
3.3.1.1. Anglerfish (<i>Lophius species</i>), Atlantic catfish (<i>Anarhichas lupus</i>), bass (<i>Dicentrarchus labrax</i>), blue ling (<i>Molva dipterygia</i>), bonito (<i>Sarda sarda</i>), eel (<i>Anguilla species</i>), emperor or orange roughy (<i>Hoplostethus</i>	1,0	Directive 2001/22/EC	Directive 2001/22/EC

▼ M2

Product	Maximum level (mg/kg wet weight)	Performance criteria for sampling	Performance criteria for methods of analysis
<p><i>atlanticus</i>), grenadier (<i>Coryphaenoides rupestris</i>), halibut (<i>Hippoglossus hippoglossus</i>), marlin (<i>Makaira species</i>), pike (<i>Esox lucius</i>), plain bonito (<i>Orcynopsis unicolor</i>), portuguese dogfish (<i>Centroscymnus coelolepis</i>), rays (<i>Raja species</i>), redfish (<i>Sebastes marinus</i>, <i>S. mentella</i>, <i>S. viviparus</i>), sail fish (<i>Istiophorus platypterus</i>), scabbard fish (<i>Lepidopus caudatus</i>, <i>Aphanopus carbo</i>), shark (all species), snake mackerel or butterfish (<i>Lepidocybium flavobrunneum</i>, <i>Ruvettus pretiosus</i>, <i>Gempylus serpens</i>), sturgeon (<i>Acipenser species</i>), swordfish (<i>Xiphias gladius</i>), tuna (<i>Thunnus species</i> and <i>Euthynnus species</i>)</p>			

▼ B

Section 4: 3-monochloropropane-1,2-diol (3-MCPD)

Product	Maximum level (mg/kg)	Performance criteria for sampling	Performance criteria for methods of analysis
4.1. Hydrolysed vegetable protein (²⁴)	0,02	Directive 2001/22/EC	Directive 2001/22/EC
4.2. Soy sauce (²⁴)	0,02	Directive 2001/22/EC	Directive 2001/22/EC

Section 5: Dioxin (sum of polychlorinated dibenzo-*para*-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs) expressed in World Health Organisation (WHO) toxic equivalents, using the WHO-TEFs (toxic equivalency factors, 1997)

Products	Maximum levels (PCDD + PCDF) ⁽²⁸⁾ (pg WHO-PCDD/F-TEQ/g fat or product)	Performance criteria for sampling	Performance criteria for the methods of analysis
5.1.1. Meat and meat products ⁽³¹⁾ originating from <ul style="list-style-type: none"> — Ruminants (bovine animals, sheep) — Poultry and farmed game — Pigs 	3 pg WHO-PCDD/F-TEQ/g fat ⁽²⁹⁾ ⁽³⁰⁾	Directive 2001/.../EC (*)	Directive 2001/.../EC (*)
5.1.2. Liver and derived products	2 pg WHO-PCDD/F-TEQ/g fat ⁽²⁹⁾ ⁽³⁰⁾ 1 pg WHO-PCDD/F-TEQ/g fat ⁽²⁹⁾ ⁽³⁰⁾ 6 pg WHO-PCDD/F-TEQ/g fat ⁽²⁹⁾ ⁽³⁰⁾	Directive 2001/.../EC (*) Directive 2001/.../EC (*) Directive 2001/.../EC (*)	Directive 2001/.../EC (*) Directive 2001/.../EC (*) Directive 2001/.../EC (*)
5.2. Muscle meat of fish and fishery products ⁽³²⁾ and products thereof	4 pg WHO-PCDD/F-TEQ/g fresh weight ⁽²⁹⁾	Directive 2001/.../EC (*)	Directive 2001/.../EC (*)
5.3. Milk ⁽³³⁾ and milk products, including butter fat	3 pg WHO-PCDD/F-TEQ/g fat ⁽²⁹⁾ ⁽³⁰⁾	Directive 2001/.../EC (*)	Directive 2001/.../EC (*)
5.4. Hen eggs and egg products ⁽³⁴⁾ ⁽³⁵⁾	3 pg WHO-PCDD/F-TEQ/g fat ⁽²⁹⁾ ⁽³⁰⁾	Directive 2001/.../EC (*)	Directive 2001/.../EC (*)
5.5. Oils and fats <ul style="list-style-type: none"> — Animal fat <ul style="list-style-type: none"> — from ruminants — from poultry and farmed game — from pigs — mixed animal fat — Vegetable oil — fish oil intended for human consumption 	3 pg WHO-PCDD/F-TEQ/g fat ⁽²⁹⁾ 2 pg WHO-PCDD/F-TEQ/g fat ⁽²⁹⁾ 1 pg WHO-PCDD/F-TEQ/g fat ⁽²⁹⁾ 2 pg WHO-PCDD/F-TEQ/g fat ⁽²⁹⁾ 0,75 pg WHO-PCDD/F-TEQ/g fat ⁽²⁹⁾ 2 pg WHO-PCDD/F-TEQ/g fat ⁽²⁹⁾	Directive 2001/.../EC (*) Directive 2001/.../EC (*) Directive 2001/.../EC (*) Directive 2001/.../EC (*) Directive 2001/.../EC (*) Directive 2001/.../EC (*)	Directive 2001/.../EC (*) Directive 2001/.../EC (*) Directive 2001/.../EC (*) Directive 2001/.../EC (*) Directive 2001/.../EC (*) Directive 2001/.../EC (*)

(1) This section is already included in Regulation (EC) No 194/97 and is repeated here without changes.

(2) The maximum levels for fresh spinach do not apply for fresh spinach to be subjected to processing and which is directly transported in bulk from field to processing plant.

► **MS** ◀

(3) OJ L 207, 15.8.1979, p. 26.

(4) In the absence of appropriate labelling, indicating the production method, the limit established for open-grown lettuce applies.

- (6) The maximum limits apply to the edible part of groundnuts, nuts and dried fruits. If nuts 'in shell' are analysed, it is assumed when calculating the aflatoxin content all the contamination is on the edible part.
- (7) OJ L 201, 17.7.1998, p. 93.
- **M3** —
- **M3** (*) If no specific level is fixed before 1 July 2003, the levels laid down in point 2.1.2.1 of the table will apply thereafter to maize referred to in this point. ▼
- (8) OJ L 268, 14.9.1992, p. 1.
- (9) OJ L 368, 31.12.1994, p. 33.
- (10) See page 14 of this Official Journal.
- (11) Maximum level applies to the product as proposed ready for consumption or as reconstituted according to the instructions of the manufacturer.
- (12) OJ L 121, 29.7.1964, p. 2012.
- (13) OJ L 243, 11.10.1995, p. 7.
- (14) OJ L 55, 8.3.1971, p. 23.
- (15) OJ L 24, 30.1.1998, p. 31.
- (16) OJ L 17, 21.1.2000, p. 22.
- (17) OJ L 350, 14.12.1990, p. 71.
- (18) OJ L 197, 3.8.2000, p. 26.
- (19) OJ L 244, 30.9.1993, p. 23.
- (20) OJ L 179, 14.7.1999, p. 1.
- (21) OJ L 149, 14.6.1991, p. 1.
- (24) Maximum level is given for the liquid product containing 40 % dry matter, corresponding to a maximum level of 0,05 mg/kg in the dry matter. The level needs to be adjusted proportionally according to the dry matter content of the products.
- **M2** (*) Where fish are intended to be eaten whole, the maximum level shall apply to the whole fish. ▼
- **M4** (*) OJ L 75, 16.3.2002, p. 38. ▼
- **M5** (*) Described in Commission Regulation (EC) No 1543/2001 of 27 July 2001, laying down the marketing standard for lettuces and curled-leaved and broad-leaved (Batavian) endives (OJ L 203, 28.7.2001, p. 9). ▼
- **M1** (*) Commission Directive to be adopted before 1 July 2002.
- (26) Upperbound concentrations; upperbound concentrations are calculated assuming that all values of the different congeners less than the limit of determination are equal to the limit of determination.
- (28) These maximum levels shall be reviewed 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 and will be further reviewed by 31 December 2006 at the latest with the aim of significantly reducing the maximum levels.
- (30) The maximum levels are not applicable for food products containing < 1 % fat.
- (31) Meat of bovine animals, sheep, pig, poultry and farmed game as defined in Article 2(a) of Council Directive 64/433/EEC (OJ L 121, 29.7.1964, p. 2012/64), as last amended by Directive 95/23/EC (OJ L 243, 11.10.1995, p. 7) and Article 2(1) of Council Directive 71/118/EEC (OJ L 55, 8.3.1971, p. 23), as last amended by Directive 97/64/EC (OJ L 24, 30.1.1998, p. 31), and Article 2(2) of Council Directive 91/495/EEC (OJ L 268, 24.9.1991, p. 41) as last amended by Directive 64/433/EEC (OJ L 368, 31.12.1994, p. 10), excluding edible offal as defined in Article 2(e) of Directive 64/433/EEC and Article 2(5) of Directive 71/118/EEC.
- (32) Muscle meat of fish and fishery products as defined in categories (a), (b), (c), (e) and (f) of the list in Article 1 of Council Regulation (EC) No 104/2000 (OJ L 17, 21.1.2000, p. 22). The maximum level applies to crustaceans excluding the brown meat of crab and to cephalopods without viscera.
- (33) Milk (raw milk, milk for the manufacture of milk-based products and heat treated milk as defined in Council Directive 92/46/EEC (OJ L 268, 14.9.1992, p. 1) as last amended by Council Directive 96/23/EC (OJ L 125, 23.5.1996, p. 10)).
- (34) Hen eggs and egg products as defined in Article 2 of Council Directive 89/437/EEC (OJ L 212, 22.7.1989, p. 87), as last amended by Council Directive 96/23/EC (OJ L 125, 23.5.1996, p. 10).
- (35) Free-range or semi-intensive eggs as defined in Article 18 of Commission Regulation (EEC) No 1274/91 (OJ L 121, 16.5.1991, p. 11), as last amended by Commission Regulation (EC) No 1651/2001 (OJ L 220, 15.8.2001, p. 5), must comply with the maximum level laid down as from 10 January 2004. ▼
- **M6** (*) Fruit juices, including fruit juices from concentrates, concentrated fruit juice and fruit nectar as defined in Annex 1 and 2 to Council Directive 2001/112/EC of 20 December 2001 relating to fruit juices and certain similar products intended for human consumption (OJ L 10, 12.1.2002, p. 58).
- (37) Spirit drinks as defined in Article 1 of Council Regulation (EEC) No 1576/89 of 29 May 1989 laying down general rules on the definition, description and presentation of spirit drinks (OJ L 160, 12.6.1989, p. 1), as last amended by Regulation (EC) No 3378/94 of the European Parliament and of the Council of 22 December 1994 (OJ L 366, 31.12.1994, p. 1).
- (38) Infants and young children as defined in Article 1 of Commission Directive 91/321/EEC of 14 May 1991, on infant formulae and follow-on formulae (OJ L 175, 4.7.1991, p. 35), as last amended by Directive 2003/14/EC (OJ L 41, 14.2.2003, p. 37) and Article 1 of Commission Directive 96/5/EC of 16 February 1996 on processed cereal based foods and baby foods for infants and young children (OJ L 49, 28.2.1996, p. 17), as last amended by Directive 2003/13/EC (OJ L 41, 14.2.2003, p. 33).



- (³⁹) A method of analysis will be validated by an international collaborative ring trial which will be performed before 1 November 2003 in order to demonstrate that the level of 10 µg/kg patulin can be reliably determined. In case there is no evidence by 1 November 2003 that the level of 10 µg/kg patulin can be reliably determined, the level of 25 µg/kg will apply.
- (⁴⁰) Baby food as defined in Article 1 of Commission Directive 96/5/EC of 16 February 1996 on processed cereal based foods and baby foods for infants and young children (OJ L 49, 28.2.1996, p. 17), as last amended by Directive 2003/13/EC (OJ L 41, 14.2.2003, p. 33). ▼



ANNEX II

CORRELATION TABLE

This Regulation	Regulation (EC) No 194/97
—	Article 1
Article 1 (1)	Article 2 (1)(a)
Article 2 (1)	Article 2 (1)(b)
Article 2 (1)	Article 2 (1)(c)
Article 3 (1)	Article 2 (2)
Article 3 (1)	Article 2 (3)
Article 4 (2)	Article 2 (4)
Article 4 (3)	Article 2 (5)
Article 3 (2)	Article 3, first paragraph
Article 3 (3)	Article 3, second paragraph
Article 5 (1)	Article 3, third paragraph
Article 1 (3)	Article 4
Annex I, section 1 'Nitrates'	Annex I, agricultural contaminants, point 1 'Nitrates'
Annex I, section 2 'Mycotoxins'	Annex, I. agricultural contaminants, point 2 'Mycotoxins'
—	Annex, II. 'Other contaminants'