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I

(Acts whose publication is obligatory)

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:

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.

(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

(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.

⁽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.

- (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.
- (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.
- (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 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*.

⁽¹⁾ OJ L 144, 16.6.1993, p. 23.

- (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.
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

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 and 1.3 of Annex I provided that codes of good agricultural practice are applied to achieve gradual progress towards the levels laid down in this Regulation.

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

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. With regard to aflatoxins in products mentioned in point 2.1 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 and 2.1.3 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'.

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.

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*.

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.

Done at Brussels, 8 March 2001.

For the Commission

David BYRNE

Member of the Commission

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
1.1. Fresh spinach ⁽²⁾ (<i>Spinacia oleracea</i>)	Harvested 1 November to 31 March: Harvested 1 April to 31 October:	3 000 ⁽³⁾ 2 500 ⁽³⁾	Commission directive 79/700/EEC ⁽⁴⁾	
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)	Harvested 1 October to 31 March: Harvested 1 April to 30 September: with the exception of open-grown lettuce harvested from 1 May to 31 August	4 500 ⁽³⁾ 3 500 ⁽³⁾ ⁽⁵⁾ 2 500 ⁽³⁾ ⁽⁵⁾	Directive 79/700/EEC. However, the minimum number of units per laboratory sample is 10	

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⁾	—	Commission directive 98/53/EC	Directive 98/53/EC

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		
2.1.1.3. 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⁾ ⁽⁸⁾	10 ⁽⁶⁾ ⁽⁸⁾	—	Directive 98/53/EC	Directive 98/53/EC
2.1.2. Cereals (including buckwheat, <i>Fagopyrum</i> sp.)					
2.1.2.1. Cereals (including buckwheat, <i>Fagopyrum</i> sp.) 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
2.1.2.2. Cereals (including buckwheat, <i>Fagopyrum</i> sp.) 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

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

Product	Maximum level (mg/kg wet weight)	Performance criteria for sampling	Performance criteria for methods of analysis
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
3.1.4. Muscle meat of fish as defined in category (a), (b) and (e) of the list in Article 1 of Council Regulation (EC) No 104/2000 ⁽¹⁸⁾ , excluding fish species listed in point 3.1.4.1	0,2	Directive 2001/22/EC	Directive 2001/22/EC
3.1.4.1. Muscle meat of wedge sole (<i>Dicologlossa cuneata</i>), eel (<i>Anguilla anguilla</i>), spotted seabass (<i>Dicentrarchus punctatus</i>), horse mackerel or scad (<i>Trachurus trachurus</i>), grey mullet (<i>Mugil labrosus labrosus</i>), common two-banded seabream (<i>Diplodus vulgaris</i>), grunt (<i>Pomadour benneti</i>), European plichard or sardine (<i>Sardina pilchardus</i>)	0,4	Directive 2001/22/EC	Directive 2001/22/EC
3.1.5. Crustaceans, excluding brown meat of crab	0,5	Directive 2001/22/EC	Directive 2001/22/EC
3.1.6. Bivalve molluscs	1,0	Directive 2001/22/EC	Directive 2001/22/EC
3.1.7. Cephalopods (without viscera)	1,0	Directive 2001/22/EC	Directive 2001/22/EC
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 Council Regulation (EEC) No 1601/91, 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

Product	Maximum level (mg/kg wet weight)	Performance criteria for sampling	Performance criteria for methods of analysis
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 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	0,05	Directive 2001/22/EC	Directive 2001/22/EC
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 of fish as defined in category (a), (b) and (e) of the list in 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 of wedge sole (<i>Dicologlossa cuneata</i>), eel (<i>Anguilla anguilla</i>), European anchovy (<i>Engraulis encrasicolus</i>), louvar or luvar (<i>Luvius imperialis</i>), horse mackerel or scad (<i>Trachurus trachurus</i>), grey mullet (<i>Mugil labrosus labrosus</i>), common two-banded seabream (<i>Diplodus vulgaris</i>), European pilchard or sardine (<i>Sardina pilchardus</i>)	0,1	Directive 2001/22/EC	Directive 2001/22/EC
3.2.6. Crustaceans, excluding brown meat of crab	0,5	Directive 2001/22/EC	Directive 2001/22/EC
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

Product	Maximum level (mg/kg wet weight)	Performance criteria for sampling	Performance criteria for methods of analysis
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</i> spp.) atlantic catfish (<i>Anarhichas lupus</i>) bass (<i>Dicentrarchus labrax</i>) blue ling (<i>Molva dipterygia</i>) bonito (<i>Sarda</i> spp.) eel (<i>Anguilla</i> spp.) halibut (<i>Hippoglossus hippoglossus</i>) little tuna (<i>Euthynnus</i> spp.) marlin (<i>Makaira</i> spp.) pike (<i>Esox lucius</i>) plain bonito (<i>Orcynopsis unicolor</i>) portuguese dogfish (<i>Centroscyrmnes coelolepis</i>) rays (<i>Raja</i> spp.) 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 (<i>Lepidocybium flavobrunneum</i> , <i>Ruvettus pretiosus</i> , <i>Gempylus serpens</i>) sturgeon (<i>Acipenser</i> spp.) swordfish (<i>Xiphias gladius</i>) tuna (<i>Thunnus</i> spp.)	1,0	Directive 2001/22/EC	Directive 2001/22/EC

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

⁽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.

⁽³⁾ Subject to review before 1 January 2002 pursuant to the provisions of Article 5(1).

⁽⁴⁾ OJ L 207, 15.8.1979, p. 26.

⁽⁵⁾ 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.

⁽⁸⁾ The maximum limits shall be reconsidered before 1 July 2001 according to the progress of scientific and technological knowledge.

⁽⁹⁾ In as far as no specific limit will be fixed before 1 July 2001, the limits laid down in point 2.1.2.1 of the table will apply thereafter to the cereals referred to in this point.

⁽¹⁰⁾ OJ L 268, 14.9.1992, p. 1.

⁽¹¹⁾ OJ L 368, 31.12.1994, p. 33.

⁽¹²⁾ See page 14 of this Official Journal.

⁽¹³⁾ Maximum level applies to the product as proposed ready for consumption or as reconstituted according to the instructions of the manufacturer.

⁽¹⁴⁾ OJ 121, 29.7.1964, p. 2012.

⁽¹⁵⁾ OJ L 243, 11.10.1995, p. 7.

⁽¹⁶⁾ OJ L 55, 8.3.1971, p. 23.

⁽¹⁷⁾ OJ L 24, 30.1.1998, p. 31.

⁽¹⁸⁾ OJ L 17, 21.1.2000, p. 22.

⁽¹⁹⁾ OJ L 350, 14.12.1990, p. 71.

⁽²⁰⁾ OJ L 197, 3.8.2000, p. 26.

⁽²¹⁾ OJ L 244, 30.9.1993, p. 23.

⁽²²⁾ OJ L 179, 14.7.1999, p. 1.

⁽²³⁾ 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.

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'

COMMISSION DIRECTIVE 2001/22/EC**of 8 March 2001****laying down the sampling methods and the methods of analysis for the official control of the levels of lead, cadmium, mercury and 3-MCPD 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 Directive 85/591/EEC of 20 December 1985 concerning the introduction of Community methods of sampling and analysis for the monitoring of foodstuffs intended for human consumption⁽¹⁾, and in particular Article 1 thereof,

Whereas:

(1) Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food⁽²⁾ provides that maximum levels must be set for certain contaminants in foodstuffs in order to protect public health.

(2) Commission Regulation (EC) No 466/2001 of 8 March 2001 setting maximum levels for certain contaminants in foodstuffs⁽³⁾ establishes, besides others, maximum levels for lead, cadmium, mercury and 3-monochloropropane-1,2-diol (3-MCPD) in foodstuffs and makes reference to the measures laying down the sampling and analysis methods to be used.

(3) Council Directive 89/397/EEC of 14 June 1989 on the official control of foodstuffs⁽⁴⁾ lays down the general principles for the performance of control of foodstuffs. Council Directive 93/99/EEC of 29 October 1993 on the subject of additional measures concerning the official control of foodstuffs⁽⁵⁾ introduces a system of quality standards for laboratories entrusted by the Member States with the official control of foodstuffs.

(4) Sampling plays a crucial role in obtaining representative results for the determination of the levels of the contaminants which may be heterogeneously distributed in a lot.

(5) Directive 85/591/EEC has fixed general criteria for methods of sampling and analysis but in certain cases more specific criteria become necessary in order to ensure that laboratories, in charge of the control, use methods of analysis with comparable levels of performance.

(6) The provisions for the sampling and methods of analysis have been drawn up on the basis of present knowledge and they may be adapted to take account of advances in scientific and technological knowledge.

(7) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee for Foodstuffs,

HAS ADOPTED THIS DIRECTIVE:

Article 1

The Member States shall take all measures necessary to ensure that the sampling for the official control of the levels of lead, cadmium, mercury and 3-MCPD in foodstuffs is carried out in accordance with the methods described in Annex I to this Directive.

Article 2

The Member States shall take all measures necessary to ensure that sample preparation and methods of analyses used for the official control of the levels of lead, cadmium, mercury and 3-MCPD in foodstuffs comply with the criteria described in Annex II to this Directive.

⁽¹⁾ OJ L 372, 31.12.1985, p. 50.

⁽²⁾ OJ L 37, 13.2.1993, p. 1.

⁽³⁾ See page 1 of this Official Journal.

⁽⁴⁾ OJ L 186, 30.6.1989, p. 23.

⁽⁵⁾ OJ L 290, 24.11.1993, p. 14.

Article 3

The Member States shall, not later than 5 April 2003, bring into force the laws, regulations or administrative provisions necessary to comply with the provisions of this Directive. They shall forthwith notify the Commission thereof.

When Member States adopt these provisions, the provisions shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted by Member States.

Article 4

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

This Directive is addressed to the Member States.

Done at Brussels, 8 March 2001.

For the Commission

David BYRNE

Member of the Commission

ANNEX I

METHODS OF SAMPLING FOR OFFICIAL CONTROL OF THE LEVELS OF LEAD, CADMIUM, MERCURY AND 3-MCPD IN CERTAIN FOODSTUFFS**1. PURPOSE AND SCOPE**

Samples intended for the official control of the levels of lead, cadmium, mercury and 3-MCPD contents in foodstuffs shall be taken according to the methods described below. Aggregate samples thus obtained shall be considered as representative of the lots or sublots from which they are taken. Compliance with maximum levels laid down in Regulation (EC) No 466/2001 shall be established on the basis of the levels determined in the laboratory samples.

2. DEFINITIONS

Lot:	an identifiable quantity of food delivered at one time and determined by the official to have common characteristics, such as origin, variety, type of packing, packer, consignor or markings. In the case of fish, also the size of fish shall be comparable.
Sublot:	designated part of a large lot in order to apply the sampling method on that designated part. Each sublot must be physically separated and identifiable.
Incremental sample:	a quantity of material taken from a single place in the lot or sublot.
Aggregate sample:	the combined total of all the incremental samples taken from the lot or sublot.
Laboratory sample:	sample intended for the laboratory

3. GENERAL PROVISIONS**3.1. Personnel**

Sampling shall be performed by an authorised qualified person as specified by the Member States.

3.2. Material to be sampled

Each lot which is to be examined must be sampled separately.

3.3. Precautions to be taken

In the course of sampling and preparation of laboratory samples precautions must be taken to avoid any changes which would affect the lead, cadmium, mercury and 3-MCPD contents, adversely affect the analytical determination or make the aggregate samples unrepresentative.

3.4. Incremental samples

As far as possible incremental samples shall be taken at various places distributed throughout the lot or sublot. Departure from this procedure must be recorded in the record provided for under 3.8.

3.5. Preparation of the aggregate sample

The aggregate sample is made up by uniting all incremental samples. It shall be at least 1 kg unless not practical, e.g. when a single package has been sampled.

3.6. Subdivision of aggregate sample in laboratory samples for enforcement, defence and referee purposes

The laboratory samples for enforcement, trade (defence) and referee purposes shall be taken from the homogenised aggregate sample unless this conflicts with Member States' regulations on sampling. The size of the laboratory samples for enforcement shall be sufficient to allow at least for duplicate analyses.

3.7. Packaging and transmission of aggregate and laboratory samples

Each aggregate and laboratory sample shall be placed in a clean, inert container offering adequate protection from contamination, from loss of analytes by adsorption to the internal wall of the container and against damage in transit. All necessary precautions shall be taken to avoid change of composition of the aggregate and laboratory samples which might arise during transportation or storage.

3.8. Sealing and labelling of aggregate and laboratory samples

Each sample taken for official use shall be sealed at the place of sampling and identified following the Member States' regulations. A record must be kept of each sampling, permitting each lot to be identified unambiguously and giving the date and place of sampling together with any additional information likely to be of assistance to the analyst.

4. SAMPLING PLANS

Sampling should ideally take place at the point where the commodity enters the food chain and a discrete lot becomes identifiable. The sampling method applied shall ensure that the aggregate sample is representative for the lot that is to be controlled.

4.1. Number of incremental samples

In the case of liquid products for which a homogeneous distribution of the contaminant in question can be assumed within a given lot, it is sufficient to take one incremental sample per lot which forms the aggregate sample. Reference to the lot number shall be given. Liquid products containing hydrolysed vegetable protein (HVP) or liquid soya sauce shall be shaken well, or homogenised by other suitable means, before the incremental sample is taken.

For other products, the minimum number of incremental samples to be taken from the lot shall be as given in Table 1. The incremental samples shall be of similar weight. Departure from this procedure must be recorded in the record provided for under 3.8.

Table 1: Minimum number of incremental samples to be taken from the lot

Weight of lot (kg)	Minimum number of incremental samples to be taken
< 50	3
50 to 500	5
> 500	10

If the lot consists of individual packages, then the number of packages which shall be taken to form the aggregate sample is given in Table 2.

Table 2: Number of packages (incremental samples) which shall be taken to form the aggregate sample if the lot consists of individual packages

Number of packages or units in the lot	Number of packages or units to be taken
1 to 25	1 package or unit
26 to 100	About 5 %, at least 2 packages or units
> 100	About 5 %, at maximum 10 packages or units

5. COMPLIANCE OF THE LOT OR SUBLOT WITH THE SPECIFICATION

The control laboratory shall analyse the laboratory sample for enforcement at least in two independent analyses, and calculate the mean of the results. The lot is accepted if the mean conforms to the respective maximum level as laid down in Regulation (EC) No 466/2001. It is rejected if the mean exceeds the respective maximum level.

ANNEX II

SAMPLE PREPARATION AND CRITERIA FOR METHODS OF ANALYSIS USED IN OFFICAL CONTROL OF THE LEVELS OF LEAD, CADMIUM, MERCURY AND 3-MCPD IN CERTAIN FOODSTUFFS**1. INTRODUCTION**

The basic requirement is to obtain a representative and homogeneous laboratory sample without introducing secondary contamination.

2. SPECIFIC SAMPLE PREPARATION PROCEDURES FOR LEAD, CADMIUM AND MERCURY

There are many satisfactory specific sample preparation procedures which may be used for the products under consideration. Those described in the draft CEN Standard 'Foodstuffs — Determination of trace elements — Performance criteria and general consideration' have been found to be satisfactory ^(a) but others may be equally valid.

The following points must be noted for any procedure used:

- bivalve molluscs, crustaceans and small fish: where these are normally eaten whole, the viscera are to be included in the material to be analysed,
- vegetables: only the edible portion of is to be tested, with note to be taken of the requirements of the Regulation (EC) No 466/2001.

3. METHOD OF ANALYSIS TO BE USED BY THE LABORATORY AND LABORATORY CONTROL REQUIREMENTS**3.1. Definitions**

A number of the most commonly used definitions that the laboratory will be required to use are given below:

r = repeatability, the value below which the absolute difference between two single test results obtained under repeatability conditions (i.e., same sample, same operator, same apparatus, same laboratory, and short interval of time) may be expected to lie within a specific probability (typically 95 %) and hence $r = 2,8 \times s_r$.

s_r = standard deviation, calculated from results generated under repeatability conditions.

RSD_r = relative standard deviation, calculated from results generated under repeatability conditions [$(s_r / \bar{x}) \times 100$], where $\bar{x}$ is the average of results over all laboratories and samples.

R = reproducibility, the value below which the absolute difference between single test results obtained under reproducibility conditions (i.e., on identical material obtained by operators in different laboratories, using the standardised test method), may be expected to lie within a certain probability (typically 95 %); $R = 2,8 \times s_R$.

s_R = standard deviation, calculated from results under reproducibility conditions.

$RSD_R =$	relative standard deviation calculated from results generated under reproducibility conditions $[(s_R / \bar{x}) \times 100]$
$HORRAT_r =$	the observed RSD_r divided by the RSD_r value estimated from the Horwitz equation using the assumption $r = 0,66R$
$HORRAT_R =$	the observed RSD_R value divided by the RSD_R value calculated from the Horwitz equation ^(b) .

3.2. General requirements

Methods of analysis used for food control purposes must comply whenever possible with the provisions of paragraphs 1 and 2 of the Annex to Directive 85/591/EEC.

For the analysis of lead in wine, Commission Regulation (EEC) No 2676/90⁽¹⁾ determining Community methods for the analysis of wines lays down the method to be used in Chapter 35 of its Annex.

3.3. Specific requirements

3.3.1. Lead, cadmium and mercury analyses

Specific methods for the determination of lead, cadmium and mercury contents are not prescribed. Laboratories shall use a validated method that fulfils the performance criteria indicated in Table 3. Where possible, the validation shall include a certified reference material in the collaborative trial test materials.

Table 3: Performance criteria of methods for lead, cadmium and mercury analyses

Parameter	Value/comment
Applicability	Foods specified in Regulation (EC) No 466/2001
Detection limit	No more than one tenth of the value of the specification in Regulation (EC) No 466/2001, except if the value of the specification for lead is less than 0,1 mg/kg. For the latter, no more than one fifth of the value of the specification
Limit of quantification	No more than one fifth of the value of the specification in Regulation (EC) No 466/2001, except if the value of the specification for lead is less than 0,1 mg/kg. For the latter, no more than two fifths of the value of the specification
Precision	$HORRAT_r$ or $HORRAT_R$ values of less than 1,5 in the validation collaborative trial
Recovery	80-120 % (as indicated in the collaborative trial)
Specificity	Free from matrix or spectral interferences

3.3.2. 3-MCPD analysis

Specific methods for the determination of 3-MCPD contents are not prescribed. Laboratories shall use a validated method that fulfils the performance criteria indicated in Table 4. Where possible, the validation shall include a certified reference material in the collaborative trial test materials. A specific method has been validated by collaborative trial and has been shown to meet the requirements of Table 4 ^(c).

⁽¹⁾ OJ L 272, 3.10.1990, p. 1.

Table 4: Performance criteria of methods for 3-MCPD analysis

Criterion	Recommended value	Concentration
Field blanks	Less than the detection limit	—
Recovery	75-110 %	All
Limit of quantification	10 (or less) µg/kg on a dry matter basis	—
Standard deviation of the field blank signal	Less than 4 µg/kg	—
In-house precision estimates — standard deviation of replicate measurements at different concentrations	< 4 µg/kg	20 µg/kg
	< 6 µg/kg	30 µg/kg
	< 7 µg/kg	40 µg/kg
	< 8 µg/kg	50 µg/kg
	< 15 µg/kg	100 µg/kg

3.4. Estimation of the analytical trueness and recovery calculations

Wherever possible the trueness of the analysis shall be estimated by including suitable certified reference materials in the analytical run.

The 'Harmonised Guidelines for the Use of Recovery Information in Analytical Measurement' ^(d) developed under the auspices of IUPAC/ISO/AOAC shall be taken into account.

The analytical result shall be reported corrected or uncorrected. The manner of reporting and the level of recovery must be reported.

3.5. Laboratory quality standards

Laboratories must comply with Directive 93/99/EEC.

3.6. Expression of results

The results shall be expressed in the same units as the maximum levels laid down in Regulation (EC) No 466/2001.

REFERENCES

- (a) Draft Standard prEN 13804, 'Foodstuffs — Determination of Trace Elements — Performance Criteria and General Considerations', CEN, Rue de Stassart 36, B-1050 Brussels.
- (b) W Horwitz, 'Evaluation of Analytical Methods for Regulation of Foods and Drugs', Anal. Chem., 1982, No 54, 67A-76A
- (c) Method of Analysis to determine 3-Monochloropropane-1,2-Diol in Food and Food Ingredients using Mass Spectrometric Detection, submitted to CEN TC 275 and AOAC International (also available as 'Report of the Scientific Cooperation task 3.2.6: Provision of validated methods to support the Scientific Committee on Food's recommendations regarding 3-MCPD in hydrolysed protein and other foods').
- (d) ISO/AOAC/IUPAC Harmonised Guidelines for the Use of Recovery Information in Analytical Measurement. Edited Michael Thompson, Steven L R Ellison, Ales Fajgelj, Paul Willetts and Roger Wood, Pure Appl. Chem., 1999, No 71, 337-348

II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DECISION

of 8 March 2001

repealing Decision 93/351/EEC determining analysis methods, sampling plans and maximum limits for mercury in fishery products

(notified under document number C(2001) 672)

(Text with EEA relevance)

(2001/182/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 91/493/EEC of 22 July 1991 laying down the health conditions for the production and placing on the market of fishery products ⁽¹⁾, as last amended by Directive 97/79/EC ⁽²⁾ and in particular chapter V, part II, point 3.C of the Annex thereto.

Whereas:

- (1) Commission Regulation (EC) No 466/2000 ⁽³⁾ provides for the setting of maximum levels for certain contaminants in foodstuffs in order to protect public health and, for reasons of transparency, maximum limits for concentrations of mercury in fishery products intended for human consumption covered by Decision 93/351/EEC ⁽⁴⁾ have been integrated in that Regulation. It follows that Decision 93/351/EEC should be repealed.
- (2) The measures provided for in this Decision are in accordance with the opinion of the Standing Veterinary Committee,

HAS ADOPTED THIS DECISION:

Article 1

Decision 93/351/EEC is repealed with effect from 5 April 2002.

⁽¹⁾ OJ L 268, 24.9.1991, p. 15.

⁽²⁾ OJ L 24, 30.1.1997, p. 31.

⁽³⁾ See page 1 of this Official Journal.

⁽⁴⁾ OJ L 144, 16.6.1993, p. 236.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 8 March 2001.

For the Commission

David BYRNE

Member of the Commission
