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COMMISSION REGULATION (EC) No 194/97
of 31 January 1997
setting maximum levels for certain contaminants in foodstuffs

(Text with EEA relevance)

(OJ L 31, 1.2.1997, p. 48)

Amended by:

		Official Journal		
		No	page	date
►**M1**	Commission Regulation (EC) No 1525/98 of 16 July 1998	L 201	43	17.7.1998
►**M2**	Commission Regulation (EC) No 864/1999 of 26 April 1999	L 108	16	27.4.1999

Corrected by:

►**C1**	Corrigendum, OJ L 138, 29.5.1997, p. 31 (194/97)

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COMMISSION REGULATION (EC) No 194/97

of 31 January 1997

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 thereof,

Whereas Regulation (EEC) No 315/93 provides that maximum levels must be set for certain contaminants in order to protect public health; whereas 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 and analytical detection limits; whereas the sampling and analysis methods to be applied may be specified;

Whereas it is essential, in order to protect public health, to keep contaminant levels at contents which are toxicologically acceptable; whereas contaminants must be eliminated more thoroughly wherever possible by means of good professional practice;

Whereas vegetables have an essential nutritional function and play an important role in health protection; whereas the consumption of vegetables should therefore be encouraged by improving the quality of the products on offer;

Whereas some Member States have adopted, or are planning to adopt, maximum levels for nitrates in certain vegetables;

Whereas, in view of the disparities between Member States and the consequent risk of distortion of competition, Community measures are necessary in order to ensure market unity while abiding by the principle of proportionality;

Whereas specific measures designed to provide better control of the sources of agricultural contamination together with codes of good practice may help to reduce the contaminant levels of certain vegetables and in particular the nitrate levels;

Whereas climatic conditions, production methods and eating habits vary widely in different parts of the Community; whereas different maximum nitrate levels should therefore be fixed for vegetables depending on the season; whereas, moreover, Member States should be allowed for a transitional period to authorize the marketing of lettuces and spinach grown and intended for consumption in their territory with nitrate levels higher than those fixed in point 1.1 of Part I of the Annex, provided, however, that the quantities present remain acceptable from the point of view of public health;

Whereas lettuce and spinach producers established in the Member States which have given the abovementioned authorizations should progressively modify their farming methods by applying the good practice recommended at national level so as to comply at the end of the transitional period with the maximum levels laid down at Community level;

Whereas it is desirable to achieve common values as soon as possible;

Whereas a study should be made, based on the available scientific data, as to whether maximum contaminant levels should be set for baby food for infants and young children;

([1]) OJ No L 37, 13. 2. 1993, p. 1.

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Whereas the free movement throughout the Community of foodstuffs with contaminant levels below or equal to those fixed in the Annex should be guaranteed;

Whereas the Member States must adopt appropriate surveillance measures regarding the presence of contaminants in foodstuffs;

Whereas any maximum level adopted at Community level will have to be revised to take account of the advance of scientific and technical knowledge and improvements in production practice;

Whereas the levels set for lettuce and spinach should be reviewed and, if necessary, reduced before 1 October 1998; whereas the review will be based on the results of controls carried out by the Member States;

Whereas the Scientific Committee for Food has been consulted, in accordance with Article 3 of Regulation (EEC) No 315/93, on the provisions liable to affect public health;

Whereas 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

This Regulation sets maximum levels for certain contaminants present in various foodstuffs.

Article 2

▼M1

1. (a) The products indicated in the Annex to this Regulation must not, when placed on the market, contain higher contaminant levels than those specified therein.

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

(c) For milk products which are dried, processed or composed of more than one ingredient, the maximum limit applicable shall be that laid down in point I.2.1.3 of the Annex for milk, taking into account respectively the concentration caused by the drying process, by processing or the relative concentrations of the ingredients in the product, in so far as no specific maximum limits are fixed for these dried, processed or compound milk products.

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2. Member States may, where justified, authorize for a transitional period the placing on the market of lettuces and spinach grown and intended for consumption in their territory with nitrate levels higher than those set in point 1.1 of Part I of the Annex provided codes of good practice are applied to achieve gradual progress towards the levels laid down at Community level.

3. Member States shall inform the other Member States and the Commission each year of steps taken to implement paragraph 2.

▼M1

4. With regard to the products mentioned at point I.2.1 of the Annex, it is prohibited:

— to mix products complying with the maximum limits laid down in the Annex with products exceeding these maximum limits 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,

— to use products which do not comply with the maximum limits laid down in point I.2.1.1.1, I.2.1.2.1 and I.2.1.3 as an ingredient for the manufacture of other foodstuffs,

▼M1

— to detoxify products by chemical treatments.

5. Groundnuts, nuts and dried fruit not complying with the maximum limits laid down in point I.2.1.1.1 of the Annex and cereals not complying with the maximum limits laid down in point I.2.1.2.1 can be placed on the market provided that:

(a) these products:

— are not intended for direct human consumption or use as an ingredient in foodstuffs,

— comply with the maximum limits laid down in point I.2.1.1.2 of the Annex for groundnuts and point I.2.1.1.3 of the Annex for nuts and dried fruit, and

— are subjected to a secondary treatment involving sorting or other physical treatments and that after this treatment the maximum limits laid down in points I.2.1.1.1 and I.2.1.2.1 of the Annex are not exceeded, and this treatment does not result in other harmful residues;

(b) the destination of these products is demonstrated clearly by labelling comprising 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'.

▼M2

Article 3

Member States shall each year communicate to the Commission by 30 June, 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 practices to reduce nitrate levels. This information shall also contain the data on which their codes of good practice are based.

The Member States, who do not apply Article 2(2) of this Regulation, shall carry out the monitoring and the application of good practices using means proportionate to the desired objective, the obtained monitoring results and, particularly, in the light of the risks and of experience gained.

On the basis of the results of controls carried out by the Member States to check compliance with the maximum limits laid down in the Annex, the reports with regard to the application and improvement of codes of good practice to reduce nitrate levels and the evaluation of the data on which the Member States have based their good agricultural practices, the Commission shall proceed each three years and before 31 December 2001 for the first time, to a review of the provisions of this Regulation.

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Article 4

The sampling and analysis methods applied shall be those specified in the Annex hereto.

Article 5

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 15 February 1997. Notwithstanding Article 2, the products referred to in point 1.2 of Part I of the Annex which are already on the market on the date from which this Regulation applies and which do not conform to the provisions of this Regulation may continue to be marketed until stocks are exhausted.

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

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ANNEX

MAXIMUM LEVELS FOR CERTAIN CONTAMINANTS IN FOODSTUFFS

I. **Agricultural contaminants**

▼M2 1. Nitrates

1.1. Fresh vegetables

Product	Maximum nitrate levels (1) (mg NO_3/kg fresh product)		Sampling method	Reference analysis method
Spinach (7) *(Spinacia oleracea)*	Harvested 1 November to 31 March	3 000 (2)	Commission Directive 79/700/EEC (3)	
	Harvested 1 April to 31 October	2 500 (2)		
Lettuce *(Lactuca sativa* L.) (protected and open-grown lettuce)	Harvested 1 October to 31 March	4 500 (2)	Directive 79/700/EEC However, the minimum number of units per laboratory sample is 10	
	Harvested 1 April to 30 September	3 500 (2) (8)		
	with the exception of open grown lettuce harvested from 1 May to 31 August	2 500 (2) (8)		

1.2. Other processed vegetables for consumption

Product	Maximum nitrate levels (1) (mg NO_3/kg processed product)		Sampling method	Reference analysis method
Preserved, deep-frozen or frozen spinach		2 000	Directive 79/700/EEC	

(1) The maximum levels do not apply to food particularly prepared for babies and young children.

(2) Subject to review before 31 December 2001 pursuant to the provisions of Article 3.

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

(7) The maximum limits 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.

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

▼M1

2. Mycotoxins

2.1. Aflatoxins

	Products	Aflatoxins: maximum admissible levels (1) (μg/kg)			Sampling method	Reference analysis method
		B_1	$B_1 + B_2 + G_1 + G_2$	M_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 (1)	4 (1)	—	Directive 98/53/EC (4)	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 (1)	15 (1)	—	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 (1) (2)	10 (1) (2)	—	Directive 98/53/EC	Directive 98/53/EC
2.1.2.	Cereals (including buckwheat, Fagopyrum sp.)					
2.1.2.1.	Cereals (including buckwheat, Fagopyrum 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, Fagopyrum sp.) to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs	— (3)	— (3)	—	Directive 98/53/EC	Directive 98/53/EC

▼M1

	Products	Aflatoxins: maximum admissible levels (1) (μg/kg)			Sampling method	Reference analysis method
		B_1	$B_1 + B_2 + G_1 + G_2$	M_1		
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 of 16 June 1992 laying down the health rules for the production and placing on the market of raw milk, heat-treated milk and milk-based products)	—	—	0,05	Directive 98/53/EC	Directive 98/53/EC

(1) 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.

(2) The maximum limits shall be reconsidered before 1 July 1999 according to the progress of scientific and technological knowledge.

(3) In as far as no specific limit will be fixed before 1 July 1999, the limits laid down in point 2.1.2.1 of the table will apply thereafter to the cereals referred to in this point.

(4) See page 93 of this Official Journal.

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II. **Other contaminants**