

COMMISSION REGULATION (EC) No 1525/98
of 16 July 1998
amending 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 some Member States have adopted, or plan to adopt, maximum levels for aflatoxins in certain foodstuffs;

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 consequently Commission Regulation (EC) No 194/97 of 31 January 1997 setting maximum levels for certain contaminants in foodstuffs⁽²⁾ has to be added to;

Whereas aflatoxins are mycotoxins produced by certain species of *Aspergillus*, which develop at high temperatures and humidity levels; whereas aflatoxins may be present in a large number of foods;

Whereas aflatoxins, in particular aflatoxin B₁, are genotoxic carcinogenic substances; whereas for substances of this type there is no threshold below which no harmful effect is observed; whereas no admissible daily intake can therefore be set; whereas 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; whereas it is, therefore, advisable to set limits as low as possible;

Whereas rules have to be set concerning the maximum limits which are acceptable in single dried and/or processed agricultural products and in compound foodstuffs in order to ensure proper human health protection

as well as proper functioning of the single market with regard to such products;

Whereas efforts to improve production, harvesting and storage methods in order to reduce the development of moulds should be encouraged;

Whereas the aflatoxins group includes a number of compounds of varying toxicity and frequency in food; whereas aflatoxin B₁ is by far the most toxic compound; whereas it is advisable, for safety reasons, to limit both the total aflatoxin content of food (compounds B₁, B₂, G₁ and G₂) and aflatoxin B₁ content;

Whereas aflatoxin M₁ is a metabolic product of aflatoxin B₁, and is present in milk and milk products from animals which have consumed contaminated feed; whereas 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;

Whereas it is recognised that the sorting or other physical treatment methods make it possible to reduce the aflatoxin content of the groundnuts, nuts and dried fruit; that in order to minimise the effects on trade, it is advisable consequently to admit higher aflatoxin contents for those products which are not intended for direct human consumption or as an ingredient in foodstuffs; that, in these cases, the maximum limits for aflatoxins were fixed by taking at the same time into consideration the known possible effects of the abovementioned treatments respectively for the groundnuts, the nuts and the dried fruit 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. That according to the progress of scientific and technological knowledge, the limits for the raw nuts and dried fruit could be reconsidered within a defined period of time;

Whereas in the case of the cereals, it cannot be excluded that sorting methods or other physical treatments can reduce the level of contamination of aflatoxins; that in order to be able to check the real effectiveness of these methods and, if necessary, to fix specific maximum limits

⁽¹⁾ OJ L 37, 13. 2. 1993, p. 1.

⁽²⁾ OJ L 31, 1. 2. 1997, p. 48.

for the unprocessed cereals, it is foreseen for a limited period to apply the maximum limits as laid down in the Annex only for the cereals and processed products thereof intended for direct human consumption or as an ingredient in foodstuffs; that 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 the cereals and the processed products thereof intended for direct human consumption or as an ingredient of food, will also apply to the unprocessed cereals;

Whereas to allow effective control of the respect of the various limits fixed for the products in question, it is appropriate to know the exact destination by suitable labelling;

Whereas 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;

Whereas 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;

Whereas it suffices for the moment to lay down general provisions for processed and compound foodstuffs; whereas specific maximum limits for aflatoxins in processed and compound foodstuffs could be fixed in case of need;

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

Regulation (EC) No 194/97 is amended as follows:

1. Article 2(1) is replaced by the following:

- '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.'

2. In Article 2, paragraphs 4 and 5 are added as follows:

- '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,
 - 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".

3. The following text is inserted under point I 'Agricultural contaminants' of the Annex:

'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 (4) | 4 (4) | — | 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 (4) | 15 (4) | — | 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 (4) (5) | 10 (4) (5) | — | Directive 98/53/EC | Directive 98/53/EC |

| Products | Aflatoxins: maximum admissible levels (*) (µg/kg) | | | Sampling method | Reference analysis method |
|--|---|---|----------------|--------------------|---------------------------|
| | B ₁ | B ₁ + B ₂ + G ₁ + G ₂ | M ₁ | | |
| 2.1.2. Cereals (including buckwheat, <i>Fagopyrum sp.</i>) | | | | | |
| 2.1.2.1. Cereals (including buckwheat, <i>Fagopyrum sp.</i>) 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 sp.</i>) to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs | — ^(*) | — ^(*) | — | 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 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 |

(*) 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.

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

(‡) 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.

(§) See page 93 of this Official Journal.

Article 2

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 1 January 1999.

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

Done at Brussels, 16 July 1998.

For the Commission

Franz FISCHLER

Member of the Commission