Commission Regulation (EU) No 165/2010 of 26 February 2010 amending Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs as regards aflatoxins (Text with EEA relevance)

COMMISSION REGULATION (EU) No 165/2010

of 26 February 2010

amending Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs as regards aflatoxins

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

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,

Whereas:

(1) Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs[(2)] sets maximum levels for aflatoxin B1 and aflatoxin total (aflatoxin B1 + G1 + B2 + G2) in a range of foodstuffs.

(2) It is necessary to amend certain maximum levels for aflatoxins in certain foodstuffs to take into account developments in Codex Alimentarius and new information contained in recent scientific advice.

(3) Codex Alimentarius established a level of 15 μg/kg aflatoxin total in almonds, hazelnuts and pistachios intended for further processing and a level of 10 μg/kg aflatoxin total in almonds, hazelnuts and pistachios 'ready-to-eat'[(3)].

(4) The Scientific Panel on Contaminants in the Food Chain (Contam Panel) of the European Food Safety Authority (EFSA) adopted on 25 January 2007 an opinion on the potential increase of consumer health risk by a possible increase of the existing maximum levels for aflatoxins in almonds, hazelnuts and pistachios and derived products[(4)]. The Contam Panel concluded that changing the maximum levels for total aflatoxins from 4 to 8 or 10 μg/kg in almonds, hazelnuts and pistachios would have minor effects on the estimates of dietary exposure, cancer risk and the calculated margins of exposure (MOEs). The Panel furthermore concluded that exposure to aflatoxins from all sources should be as low as reasonably achievable, because aflatoxins are genotoxic and carcinogenic. The data indicate that reduction of total dietary exposure to aflatoxins could be achieved by reducing the number of highly contaminated foods reaching the market through more effective enforcement and reducing exposure from food sources other than almonds, hazelnuts and pistachios.

(5) The Contam Panel adopted on 16 June 2009 a statement on the effects on public health of an increase of the levels for aflatoxin total from 4 μg/kg to 10 μg/kg for tree nuts

other than almonds, hazelnuts and pistachios[5]. The Panel concluded that based on the information which was available in 2007 public health would not be adversely affected by increasing the levels for total aflatoxins from 4 μg/kg to 10 μg/kg for other tree nuts, including Brazil nuts. Given the current discussions in Codex Alimentarius on the maximum levels for aflatoxins in Brazil nuts, it is appropriate to align the level for aflatoxins in Brazil nuts with the Codex level for almonds, hazelnuts and pistachios.

(6) Codex Alimentarius established only a maximum level for aflatoxin total. The corresponding aflatoxin B1 level was determined by making use of the database on occurrence of aflatoxins in food used by EFSA for the exposure assessment.

(7) In the EFSA opinion on aflatoxins it is observed that oilseeds and derived products are an important contributor to the human aflatoxin exposure. EFSA concluded that exposure to aflatoxins from all sources should be as low as reasonably achievable. Furthermore, notifications in the Rapid Alert System for Food and Feed (RASFF) indicate high levels of aflatoxins in oilseeds such as sunflower seeds, melon seeds etc. It is therefore proposed to also set a maximum level for oilseeds other than groundnuts (peanuts), in line with the existing maximum levels for groundnuts (peanuts). However, as aflatoxins are nearly completely removed by the process for producing refined vegetable oils, it is appropriate to exclude oilseeds, including groundnuts (peanuts), intended for crushing for refined vegetable oil and refined vegetable oil.

(8) A maximum level of 2 μg/kg for aflatoxin B1 and 4 μg/kg aflatoxin total has been established in all cereals and all products derived from cereals with the exception of maize to be subjected to sorting or other physical treatment before human consumption for which a maximum level of 5 μg/kg for aflatoxin B1 and 10 μg/kg for aflatoxin total has been established. Rice in husk regularly contains levels of aflatoxins slightly above the maximum levels. After milling, a process which removes the husk, the levels of aflatoxins in the white milled rice are below the maximum levels. It is therefore appropriate to apply the same approach for rice as the existing approach for maize, and to set a higher maximum level of aflatoxin B1 and aflatoxin total for rice to be subjected to sorting or other physical treatment before human consumption or use as an ingredient in foodstuffs.

(9) The maximum levels refer to the edible part of the tree nuts. However, recent scientific evidence has demonstrated that a part of the aflatoxin contamination can be found on the shell of Brazil nuts. Therefore, it is appropriate to modify the footnote in the Annex, indicating the procedure to be followed in case tree nuts ‘in shell’ are analysed, to take into account this recent scientific information.

(10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 1881/2006 is amended as follows:

1. Article 4 is replaced by the following:

Article 4

Specific provisions for groundnut, other oilseeds, tree nuts, dried fruit, rice and maize

Groundnuts (peanuts), other oilseeds, tree nuts, dried fruit, rice and maize not complying with the appropriate maximum levels of aflatoxins laid down in points 2.1.5, 2.1.6, 2.1.7, 2.1.8, 2.1.10 and 2.1.11 of the Annex can be placed on the market provided that these foodstuffs:

(a) are not intended for direct human consumption or use as an ingredient in foodstuffs;

(b) comply with the appropriate maximum levels laid down in points 2.1.1, 2.1.2, 2.1.3, 2.1.4, 2.1.9 and 2.1.12 of the Annex;

(c) are subjected to a treatment involving sorting or other physical treatment and that after this treatment the maximum levels laid down in points 2.1.5, 2.1.6, 2.1.7, 2.1.8, 2.1.10 and 2.1.11 of the Annex are not exceeded, and this treatment does not result in other harmful residues;

(d) are labelled clearly showing their use, and bearing the indication "product shall be subjected to sorting or other physical treatment to reduce aflatoxin contamination before human consumption or use as an ingredient in foodstuffs". The indication shall be included on the label of each individual bag, box etc. and on the original accompanying document. The consignment/ batch identification code shall be indelibly marked on each individual bag, box etc. of the consignment and on the original accompanying document.;

2. Article 5 is replaced by the following:

Article 5

Specific provisions for groundnuts (peanuts), other oilseeds, derived products thereof and cereals

A clear indication of the intended use must appear on the label of each individual bag, box, etc. and on the original accompanying document. This accompanying document must have a clear link with the consignment by means of mentioning the consignment identification code, which is on each individual bag, box, etc. of the consignment. In addition the business activity of the consignee of the consignment given on the accompanying document must be compatible with the intended use.

In the absence of a clear indication that their intended use is not for human consumption, the maximum levels laid down in points 2.1.5 and 2.1.11 of the Annex shall apply to all groundnuts (peanuts), other oilseeds and derived products thereof and cereals placed on the market.

As regards the exception of groundnuts (peanuts) and other oilseeds for crushing and the application of the maximum levels laid down in point 2.1.1 of the Annex, the exception only applies to consignments which are clearly labelled showing their use and bearing the indication "product to be subject to crushing for the production of refined vegetable oil". The indication shall be included on the label of each individual

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bag, box etc. and on the accompanying document(s). The final destination must be a crushing plant.;

3. the Annex is amended as follows:

(a) subsection 2.1 (Aflatoxins) is replaced by the text in the Annex to this Regulation;

(b) footnote 5 is replaced by the following:

([5]) The maximum levels refer to the edible part of groundnuts (peanuts) and tree nuts. If groundnuts (peanuts) and tree nuts "in shell" are analysed, it is assumed when calculating the aflatoxin content all the contamination is on the edible part, except in the case of Brazil nuts.;

(c) the following footnotes are added:

([40]) Oilseeds falling under codes CN 1201, 1202, 1203, 1204, 1205, 1206, 1207 and derived products CN 1208; melon seeds fall under code ex 1207 99.

([41]) In case derived/processed products thereof are derived/processed solely or almost solely from the tree nuts concerned, the maximum levels as established for the corresponding tree nuts apply also to the derived/ processed products. In other cases, Article 2(1) and 2(2) apply for the derived/processed products.

Article 2

This Regulation shall not apply to apricot kernels, oilseeds, other than groundnuts (peanuts) and processed products thereof, which were placed on the market at a date prior to the date of application in conformity with the provisions applicable at such date.

The burden of proving when the products were placed on the market shall be borne by the food business operator.

Article 3

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

It shall apply from the date of entry into force.

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

Done at Brussels, 26 February 2010.

For the Commission

The President

José Manuel BARROSO

***Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EU) No 165/2010. (See end of Document for details)*

ANNEX

Foodstuffs ([1])		**Maximum levels (µg/kg)**		
‘2.1.	**Aflatoxins**	B_1	Sum of B_1, B_2, G_1 and G_2	M_1
2.1.1.	Groundnuts (peanuts) and other oilseeds ([40]), to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs, with the exception of: — groundnuts (peanuts) and other oilseeds for crushing for refined vegetable oil production	8,0 ([5])	15,0 ([5])	—
2.1.2.	Almonds, pistachios and apricot kernels to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs	12,0 ([5])	15,0 ([5])	—
2.1.3.	Hazelnuts and Brazil nuts, to be subjected to sorting, or other physical treatment,	8,0 ([5])	15,0 ([5])	