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SCIENTIFIC OPINION

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[1]

Statement of the Panel on Contaminants in the Food Chain

(Question No EFSA-Q-2009-00675)

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PANEL MEMBERS

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SUMMARY

Aflatoxins can occur in food and feed as a result of fungal contamination by moulds, primarily by *Aspergillus flavus* and *A. parasiticus* under warm and humid conditions. They are most likely to contaminate tree nuts (e.g. almonds, hazelnuts, pistachios, Brazil nuts, cashew nuts, walnuts, pecan nuts), ground nuts (e.g. peanuts), figs and other dried fruits, spices, crude vegetable oils, cocoa beans and maize. Aflatoxins are genotoxic and carcinogenic, and already in 1998 the European Union (EU) introduced maximum levels for certain food commodities based on the principle as low as reasonably achievable (ALARA).

The Scientific Panel on Contaminants in the Food Chain (CONTAM Panel) of the European Food Safety Authority (EFSA) adopted an opinion related to 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 in January 2007. This risk assessment was requested by the European Commission following discussions at the Codex Committee for Food Additives and Contaminants (CCFAC) where the setting of higher levels than the 4 µg/kg, the current EU maximum level for aflatoxins in almonds, hazelnuts and pistachios, had been proposed. The CONTAM Panel concluded in its assessment that changing the maximum levels for total aflatoxins from 4 to 8 or 10 µg/kg in almonds, hazelnuts and pistachios would

[1] For citation purposes: Statement of the Scientific Panel on Contaminants in the Food Chain on a request from the European Commission 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. *The EFSA Journal* (2009) 1168, 1-11.

have a minor impact on the estimates of dietary exposure, cancer risk and the calculated margin of exposures.

Recently, the European Commission asked EFSA to elaborate further on the potential adverse effects on public health of increasing the level for total aflatoxins from 4 µg/kg to 10 µg/kg for tree nuts other than almonds, hazelnuts and pistachios. This request was triggered by discussions with Members States on the alignment of European Community legislation for aflatoxin to the Codex decision (10 µg/kg total aflatoxins for almonds, hazelnuts and pistachios ready-to-eat). Risk managers noted that this would facilitate the enforcement of maximum levels, particularly for nut mixtures.

For the current statement the CONTAM Panel took into account the nearly 35,000 results on the occurrence of aflatoxins in various food commodities, including tree nuts other than almonds, hazelnuts and pistachios, which were submitted by 20 Member States for the risk assessment in 2006. The short deadline of the Commission request for the current statement did not allow EFSA to issue a complementary call for further information, thus EFSA relied on existing information on aflatoxin in food collected in 2006.

Robust consumption data for tree nuts other then almonds, hazelnuts and pistachios from Member States were not available to the CONTAM Panel and thus the information from the Global Environment Monitoring System - Food Contamination Monitoring and Assessment Program (GEMS/Food) Consumption Cluster Diets database of the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) were used for estimating dietary exposure to aflatoxins in tree nuts (FAO/WHO, 2006).

The previous estimates indicated that increasing the maximum levels for total aflatoxins in almonds, hazelnuts and pistachios from 4 to 8 or 10 µg/kg would result in an increase in average total dietary exposure to aflatoxins in the region of 1 %. In reviewing a potential increase of total aflatoxin in other tree nuts from 4 to 10 µg/kg it was noted that only about 0.5 % of such nuts would have concentrations in this range except for Brazil nuts with 2.4 %. For the three GEMS/Food Consumption Cluster Diets, the impact of such an increase would be even less than for the three tree nuts in the initial opinion. Thus the proposed increase in the legislated maximum level is expected to increase total dietary exposure by less than 2 % for the majority of the respective population. Furthermore, if as is expected, tree nuts exceeding the maximum aflatoxin levels are occasionally consumed, the long term average dietary total aflatoxin exposure would be higher, but in turn the impact of raising the maximum level for all tree nuts from 4 to 10 µg/kg would be less.

Based on the information which was available in 2007 the CONTAM Panel concluded that public health would not be adversely affected by increasing the levels for total aflatoxins from 4 µg/kg to 10 µg/kg for all tree nuts. The CONTAM Panel, however, reiterated its previous conclusion that exposure to aflatoxins from all sources should be as low as reasonably achievable, because aflatoxins are genotoxic and carcinogenic, and that priority should be given to reducing the numbers of highly contaminated foods reaching the market, irrespective of the commodity involved.

Key words: **tree nuts, aflatoxins, consumption of nuts, exposure assessment, public health**

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BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

The discussions on maximum levels and associated sampling plans for aflatoxins in almonds, hazelnuts and pistachios started in 2003 in the Codex Committee for Food Additives and Contaminants (CCFAC) and continued from 2007 onwards within the Codex Committee on Contaminants in Food (CCCF).

Within the European Community (EC), it was acknowledged that acceptance of the existing EC maximum levels for aflatoxins in these tree nuts at the Codex Alimentarius could be excluded. To avoid Codex maximum levels for aflatoxins to be set not at all taking into account the EC concerns, it was agreed within the EC to actively participate in the discussions with a co-operative attitude by demonstrating flexibility as regards existing EC legislation. During the discussions the EC continuously stressed that the maximum level has to be set at a level as low as reasonably achievable, providing a strong incentive for the application of prevention measures and ensuring a high level of consumer protection.

Therefore, the European Commission requested the European Food Safety Authority (EFSA), to provide a risk assessment in order to clarify if acceptance of this higher level would not entail unacceptable risks for the EU consumer, taking into account vulnerable groups in the population and also the significant increase in tree nut consumption in recent years in the EU (Question N° EFSA-Q-2006-174).

The Scientific Panel on Contaminants in the Food Chain (CONTAM Panel) adopted on 25 January 2007[2] an opinion related to the potential increase of the existing maximum levels for aflatoxins in almonds, hazelnuts and pistachios and derived products.

In July 2008, the Codex Alimentarius Commission adopted maximum levels and associated sampling plan for aflatoxin total (AFTOT) in almonds, hazelnuts and pistachio's, higher than the current EC maximum levels. The EC accepted this decision as EC concerns were to a satisfactory extent taken into account and the CONTAM Panel concluded in its abovementioned opinion that such an increase of maximum levels of aflatoxin total in almonds, hazelnuts and pistachios would have only minor effects on the estimates of dietary exposure and cancer risk.

During the discussions on the alignment of EC legislation to the Codex decision, it was considered to align the level for aflatoxins also for other tree nuts with the Codex level for almonds, hazelnuts and pistachios (i.e. 10 µg/kg AFTOT for other tree nuts ready-to-eat and 15 µg/kg AFTOT for other tree nuts for further processing). This will facilitate the enforcement of the maximum levels, in particular as regards mixtures of nuts.

However, it is appropriate and necessary that EFSA assesses if the conclusions of the abovementioned opinion remain valid in case of a possible increase of the maximum level of AFTOT for tree nuts other than almonds, hazelnuts and pistachios.

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

In accordance with Art. 29 (1) of Regulation (EC) No 178/2002, the European Commission asks the European Food Safety Authority to assess

[2] Opinion of the Scientific Panel on Contaminants in the Food Chain (CONTAM Panel) on a request from the Commission related to 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. Adopted on 25 January 2007 http://www.efsa.europa.eu/EFSA/Scientific_Opinion/CONTAM%20_op_ej446_aflatoxins_en.pdf?ssbinary=true

- the effect on public health of an increase of the level for aflatoxin total from 4 µg/kg to 10 µg/kg for tree nuts other than almonds, hazelnuts and pistachios.
- if the conclusions of its Scientific Opinion related to 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, adopted on 25 January 2007, remain valid in case of a possible increase of the maximum level for aflatoxin total from 4 µg/kg to 10 µg/kg in tree nuts other than almonds, hazelnuts and pistachios.

ACKNOWLEDGEMENTS

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ASSESSMENT

1. Introduction

Aflatoxins can be found as a result of fungal contamination with *Aspergillus flavus* or *A. parasiticus* at both pre- and post-harvest in the following food commodities: ground nuts (e.g. peanuts), tree nuts (e.g. almonds, hazelnuts, pistachios, brazil nuts, cashew nuts, walnuts, pecan nuts), dried fruit, spices, figs, crude vegetable oils, cocoa beans, maize, rice, cottonseed and copra. The degree of contamination depends on temperature, humidity, soil and storage conditions for the crop.

Aflatoxins are genotoxic and carcinogenic, and the health effects have been reviewed by a number of expert groups including the Scientific Panel on Contaminants in the Food chain (CONTAM Panel) of the European Food Safety Authority (EFSA). In January 2007 the CONTAM Panel adopted an opinion related to the potential increase in consumer health risk by a possible raising of the existing maximum levels for aflatoxins in almonds, hazelnuts and pistachios and derived products.

Recently, the European Commission asked EFSA to elaborate further on the effect on public health when increasing the maximum level of total aflatoxin from 4 µg/kg to 10 µg/kg also for tree nuts other than almonds, hazelnuts and pistachios. This request was triggered by discussions with Members States on the alignment of European Community legislation for aflatoxin to the Codex Alimentarius Committee decision (10 µg/kg total aflatoxins for almonds, hazelnuts and pistachios ready-to-eat) for the same level of 10 µg/kg of total aflatoxins to apply for all tree nuts. Risk managers noted that this would facilitate the enforcement of maximum levels, particularly for nut mixtures.

2. Legislation

A summary of the European Union (EU) legislation is given in the CONTAM opinion of 2007 (EFSA, 2007), but it should be noted that current EU legislation for total aflatoxin for almonds, hazelnuts and pistachios are currently being discussed to be aligned to the Codex decision (higher levels than currently in EU legislation). In addition, discussions will take place to align the new proposed maximum levels not only for almonds, hazelnuts and pistachios but to all tree nuts.

3. Occurrence data

For this statement EFSA relied on existing information on aflatoxin in food collected in 2006 for the previous opinion on aflatoxin in almonds, hazelnuts and pistachios. The short deadline of the Commission request did not allow EFSA to issue a complementary call for further information. Total aflatoxin concentrations for different tree nuts as collected for the CONTAM opinion of 2007 is presented in Table 1. Peanut data are included for information only since it is a ground nut and not considered in the current review.

Table 1. Number of nut samples and the distribution in defined concentration ranges of total aflatoxin (µg/kg) for different tree nuts.

		Proportion of samples with total aflatoxin within the indicated µg/kg ranges			
Food category	**No of samples**	**<LOD[(a)]**	**>LOD-4**	**>4-10**	**>10**
Almonds	1766	73.3 %	22.9 %	1.6 %	2.3 %
Hazelnuts	3163	70.3 %	22.9 %	3.9 %	2.9 %
Pistachios	4069	56.2 %	24.3 %	3.4 %	16.1 %
Brazil nuts	622	56.4 %	22.0 %	2.4 %	19.1 %
Cashews	336	90.2 %	8.3 %	0.6 %	0.9 %
Other tree nuts	1131	86.0 %	12.4 %	0.5 %	1.1 %
Peanuts [(b)]	8929	79.5 %	15.7 %	1.6 %	3.2 %

(a) LOD = limit of detection
(b) Peanuts are not tree nuts but ground nuts

In reviewing a potential increase of total aflatoxin maximum levels in tree nuts other than almonds, hazelnuts and pistachios from 4 to 10 µg/kg it was noted that only about 0.5 % of such nuts would have concentrations in this range except for Brazil nuts with 2.4 %.

A detailed statistical description of the expected aflatoxin levels in the nut categories should the maximum level be increased from 4 to 10 µg/kg is given in Table 2 indicating median, mean, 95th and 99th percentiles, and maximum concentrations. These data assume that all nuts exceeding the current or proposed maximum level are not available to the consumer and that changes in maximum levels only impact the tail of the distribution.

Table 2. Estimated total aflatoxin concentrations µg/kg for lower bound (LB) and upper bound (UB) at a maximum level (ML) of 4 or 10 µg/kg, assuming nuts with higher levels are not available to the consumer.

		Aflatoxin concentration in µg/kg									
	ML	Median		Mean		95th %		99th %		Max	
		LB [a]	UB [b]	LB	UB	LB	UB	LB	UB	LB	UB
Almonds	**4**	0	0.20	0.18	0.40	1.28	1.30	1.90	2.00	3.92	3.92
	10	0	0.22	0.29	0.50	1.50	1.60	5.54	5.54	9.80	9.80
Hazelnuts	**4**	0	0.20	0.32	0.54	2.30	2.30	3.60	3.60	4.00	4.00
	10	0	0.26	0.57	0.79	3.60	3.60	8.50	8.50	10.00	10.00
Pistachios	**4**	0	0.20	0.20	0.44	1.38	2.00	3.10	3.10	4.00	4.00
	10	0	0.20	0.46	0.69	3.10	3.10	7.92	7.92	10.00	10.00
Three tree nuts [c]	**4**	0	0.20	0.24	0.47	1.70	2.00	3.50	3.50	4.00	4.00
	10	0	0.20	0.46	0.69	3.10	3.10	8.00	8.00	10.00	10.00
Brazil nuts	**4**	0	0.40	0.29	0.65	1.90	2.00	3.44	3.44	3.93	3.93
	10	0	0.40	0.47	0.82	2.90	2.90	6.30	6.30	9.50	9.50
Cashews	**4**	0	0.20	0.08	0.34	0.20	1.20	2.30	2.30	3.94	3.94
	10	0	0.20	0.12	0.37	0.40	1.60	3.66	3.66	6.00	6.00
Other tree nuts	**4**	0	0.20	0.08	0.32	0.40	1.00	2.10	2.10	3.90	3.90
	10	0	0.20	0.11	0.35	0.48	1.00	2.70	2.70	8.20	8.20
Tree nuts other than almonds, hazelnuts, pistachios [d]	**4**	0	0.20	0.13	0.41	0.96	2.00	2.70	2.86	3.94	3.94
	10	0	0.20	0.20	0.48	1.20	2.00	4.98	4.98	9.50	9.50

(a) Lower bound means that the respective limit of detection was replaced by zero.
(b) Upper bound means that the respective limit of detection was entered as the actual value.
(c) The three tree nuts are almonds, hazelnuts and pistachios which have been considered in the assessment of 2007 (EFSA, 2007).
(d) Combination of brazil nuts, cashews and other tree nuts excluding almonds, hazelnuts and pistachios.

The percentage increase in mean total aflatoxin concentration for the first three tree nuts in the table (i.e. almonds, hazelnuts and pistachios combined) is 47-92 % between a maximum level of 4 and a maximum level of 10 µg/kg, while for other tree nuts the increase is 17-54 %. The higher ends of these ranges are derived from the lower bound approach, assuming that levels below the limit of detection are zero, and therefore likely to overestimate the actual relative increase.

4. Consumption data

Consumption data were obtained from the GEMS/Food Consumption Cluster Diets database covering the EU Member States as indicated in Table 3. The CONTAM Panel previously concluded that evaluation of the few available national dietary exposure data indicated that the GEMS/Food Consumption Cluster diets provided a reasonable approximation of European diets (EFSA, 2007). Coconuts, which are strictly speaking classified as a tree nut, were included in the dried fruit classification in the initial EFSA opinion. They are not included in Table 3.

Table 3. Consumption in g/day for tree nuts as given by GEMS/Food for the three European cluster diets.

	Consumption g/day		
GEMS/Food	**Cluster diet B**	**Cluster diet E**	**Cluster diet F**
Almonds	1.9	1	0.8
Hazelnuts	2.1	1.3	0.3
Pistachios	0.7	0.3	0
Three tree nuts [(a)]	**4.7**	**2.6**	**1.1**
Cashew nuts	0.1	0.3	0
Chestnuts	1.7	0.3	0
Brazil nut	0	0.1	0
Kolanuts	0	0	0
Walnuts	1.3	0.3	0.1
* Nuts prepared (except ground nuts)	0.4	0.6	0.9
* Nuts nes [(b)]	0.2	0.1	0.1
Pecan nuts	0	0.1	0
Other tree nuts [(c)]	**3.7**	**1.8**	**1.1**

(a) The three tree nuts are almonds, hazelnuts and pistachios
(b) Nuts not elsewhere specified (nes)
(c) Tree nuts other than almonds, hazelnuts and pistachios

Only information from GEMS/Food is available with the necessary level of detail. This database does not include high percentile consumers since it is based on production statistics and thus it is not possible to calculate the 95th percentile consumption.

5. Exposure assessment

The potential increase in aflatoxin exposure presented in Table 4 was calculated based on the estimated total aflatoxin upper bound concentrations given in Table 2, and consumption information presented in Table 3.

Table 4. Estimated exposure to total aflatoxin for adults (ng/kg body weight (b.w.) per day assuming a b.w. of 60 kg) at the current and proposed maximum levels (4 and 10 µg/kg) for the initial three tree nuts (almonds, hazelnuts and pistachios) and for other tree nuts.

Maximum level	Upper bound mean occurrence of total aflatoxin µg/kg	Consumption g/day		
		Cluster diet B	Cluster diet E	Cluster diet F
		4.7	**2.6**	**1.1**
Three tree nuts [(a)]		Exposure ng/kg b.w. per day		
4 **µg/kg**	0.47	0.037	0.020	0.009
10 **µg/kg**	0.69	0.054	0.030	0.013
		Consumption g/day		
		3.7	**1.8**	**1.1**
Other tree nuts [(b)]		Exposure ng/kg b.w. per day		
4 **µg/kg**	0.41	0.025	0.012	0.008
10 **µg/kg**	0.48	0.030	0.014	0.009
		Exposure from previous opinion ng/kg b.w. per day		
Other food [(c)]		1.896	1.076	0.677

(a) The three tree nuts are almonds, hazelnuts and pistachios which have been considered in the assessment of 2007 (EFSA, 2007)
(b) Tree nuts other than almonds, hazelnuts and pistachios
(c) Contribution from other food groups as presented in the assessment of 2007 (EFSA, 2007)

Estimates in the previous aflatoxin assessment of 2007 (EFSA, 2007) indicated that increasing the maximum levels for total aflatoxins in almonds, hazelnuts and pistachios from 4 to 10 µg/kg would result in an increase in average total dietary exposure to aflatoxins in the region of 1 % when compared to the contribution from all possible sources. For all three of the GEMS/Food cluster diets, the estimated aflatoxin exposure from almonds, hazelnuts and pistachios is greater than that from other tree nuts, and increasing the maximum level for total aflatoxin in other tree nuts from 4 to 10 µg/kg would result in a smaller increase in total dietary exposure to total aflatoxins than for the three tree nuts in the initial assessment. Thus, by allowing the suggested increase in the legislated maximum limit, exposure is expected to increase by less than 2 % for the majority of the population. Such an increase is considered marginal in relation to the estimated total aflatoxin exposure from all dietary sources. Furthermore, if as is expected, tree nuts exceeding the maximum aflatoxin levels are occasionally consumed, the total long term average dietary aflatoxin exposure would be higher, but the impact of raising the maximum level for all tree nuts from 4 to 10 µg/kg would be less.

CONCLUSIONS

Based on the information which was available in 2007 the CONTAM Panel concluded that public health would not be adversely affected by increasing the levels for total aflatoxins from 4 µg/kg to 10 µg/kg for all tree nuts. The CONTAM Panel, however, reiterated its previous conclusion that exposure to aflatoxins from all sources should be as low as reasonably achievable, because aflatoxins are genotoxic and carcinogenic. Priority should be given to reducing the numbers of highly contaminated foods reaching the market, irrespective of the commodity involved.

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EFSA (European Food Safety Authority), 2007. Opinion of the Scientific Panel on Contaminants in the Food chain on a request from the European Commission related to the potential increase of consumer health risk by a possible of the existing maximum levels for aflatoxins in almonds, hazelnuts and pistachios and derived products. The EFSA Journal 446, 1-127.

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ABBREVIATIONS

AFTOT	Aflatoxin total
ALARA	As low as reasonably achievable
b.w.	Body weight
EU	European Union
CCCF	Codex Committee on Contaminants in Food
CCFAC	Codex Committee for Food Additives and Contaminants
CONTAM Panel	The Scientific Panel on Contaminants in the Food Chain
EFSA	European Food Safety Authority
GEMS/Food	Global Environment System – Food Contaminantion Monitoring and Asssessment Program
LB	Lower bound
LOD	Limit of detection
ML	Maximum level
UB	Upper bound
WHO	World Health Organization