codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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JOINT OFFICE: Viale delle Terme di Caracalla 00153 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

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DISCUSSION PAPER ON MAXIMUM LEVELS FOR TOTAL AFLATOXINS IN "READY-TO-EAT" ALMONDS, HAZELNUTS AND PISTACHIOS

1. This document incorporates a report of the electronic working group (led by the European Community) to prepare a discussion paper on maximum levels for total aflatoxins in "ready-to-eat" almonds, hazelnuts and pistachios as presented in ANNEX I) as agreed by the Codex Committee on Contaminants in Foods (CCCF) at its First Session[1]. The discussion paper is presented in ANNEX II. The electronic working group includes members from Brazil, Iran, Japan, Spain, Sweden, The Netherlands, Turkey, United Kingdom, United States of America, WHO, FAO and INC. A list of participants is presented in ANNEX III.

2. The Terms of Reference of the electronic working group[2] is

"To update the discussion paper covering following aspects:
- a) the detailed data on distribution of aflatoxins between lots;
- b) consumer health risk assessment of different levels of aflatoxins in ready-to-eat tree nuts;
- c) effects of codes of practice; and
- d) terminology of “ready-to-eat” and “for further processing".

[1] ALINORM 07/30/41 para. 58
[2] ALINORM 07/30/41 para. 58 and ALINORM 06/29/12 para.129

ANNEX I

REPORT OF THE ELECTRONIC WORKING GROUP TO PREPARE A DISCUSSION PAPER ON MAXIMUM LEVELS FOR TOTAL AFLATOXINS IN "READY-TO-EAT" ALMONDS, HAZELNUTS AND PISTACHIOS

BACKGROUND

1. The 36th Session of the Codex Committee on Food Additives and Contaminants (CCFAC) agreed to circulate for comments at Step 3 a proposed draft maximum level of 15 µg/kg (total aflatoxins) for unprocessed and processed almonds, hazelnuts, and pistachios, for consideration at its next session[3].

2. At the 37th session of the CCFAC, discussion on the maximum level for aflatoxins included the following aspects[4]

- as to whether maximum levels should be established for processed and unprocessed tree nuts (almonds, hazelnuts and pistachios) individually or in combination.
- the establishment of a maximum level for aflatoxin B1 only, since aflatoxin B1 was the most toxic aflatoxin and it was easier to analyze than total aflatoxins versus the establishment of a maximum level for total aflatoxins, reflecting the wide variation observed in the ratio between aflatoxin B1 and total aflatoxins, caused by several factors (associated fungal species, crop year, variety, weather)
- the conclusions of the JECFA evaluation on the differences in health risks in a normal population derived from maximum levels between 10 and 20 µg/kg for aflatoxin B1 in groundnuts, maize and their products
- the setting of maximum levels following the ALARA principle taking into account the application of the Codex Code of Practice for the prevention and Reduction of Aflatoxin in Tree Nuts.

3. At the 38th Session of the CCFAC, the Committee decided to establish an electronic Working Group, led by the European Community[5,6], to expand the discussion paper on the aflatoxin level in ready-to-eat tree nuts, considering

i) the detailed data on distribution of aflatoxins between lots,
ii) consumer health risk assessment of different levels of aflatoxins in ready-to-eat tree nuts,
iii) sampling plan for aflatoxin contamination in almonds, Brazil nuts, hazelnuts and pistachios,
iv) effects of codes of practice, and
v) terminology of “ready-to-eat” and “for further processing”

for circulation, comments and consideration at the next session.

4. The Committee also agreed at its 38th Session to request JECFA to conduct a dietary exposure assessment on tree nuts (ready to-eat), in particular, almonds, hazelnuts, and pistachios, Brazil nuts, and impact on exposure taking into account hypothetical levels of 4, 8, 10 and 15 µg/kg, putting in the context of exposure from other sources and previous exposure assessments on maize and groundnuts[7]

5. At the First session of the Codex Committee on Contaminants in Foods (CCCF), the Representative of WHO, speaking on behalf of the FAO and WHO JECFA Secretariats, clarified that the JECFA Secretariat, on request of a delegation, requested to JECFA to consider in addition of the hypothetical levels of 4, 8, 10 and 15 µg/kg also the hypothetical maximum level of 20 µg/kg if the data were sufficient to permit this. This would also allow to put the assessment in the context of the previous JECFA assessment which included 20 µg/kg. The Representative of WHO also explained that countries were entitled to make requests for

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[3] ALINORM 04/27/12, para. 155
[4] ALINORM 05/28/12, paras 133-141
[5] With the assistance of Brazil, Iran, Indonesia, Sri Lanka Turkey, United Kingdom, United States (lead on Sampling Plan), WHO and INC
[6] ALINORM 06/29/12, para. 129
[7] ALINORM 06/29/12, para. 130, paras 206-208 and Appendix XXXII.

evaluation directly to JECFA and that the JECFA Secretariat itself could forward a request to JECFA, as appropriate, without formal request from the Committee on Contaminants in Foods[8].

6. The CCCF agreed at its First session to establish an electronic working group[18] led by the European Community working in English, to update the discussion paper which would provide useful information for further discussion on the maximum levels at its next session.

STRUCTURE OF THE DOCUMENT

7. This discussion paper contains the following 4 chapters in accordance with the identified topics to be addressed in the discussion paper at the 38th session of CCFAC and conclusions and recommendations. This paper does not contain the topic on sampling as the issue is the subject of a separate Document CX/CF 08/2/10 prepared under the lead of the United States of America.

a) the detailed data on distribution of aflatoxins between lots (Chapter I)
b) consumer health risk assessment of different levels of aflatoxins in ready-to-eat tree nuts (Chapter II)
c) effects of codes of practice (Chapter III), and
d) terminology of “ready-to-eat” and “for further processing” (Chapter IV)

Conclusions on these topics are provided in a separate chapter (Chapter VII).

8. Thanks to the contribution from FAO and WHO to the electronic working group, this discussion paper can contain all relevant information from the 68th JECFA assessment and consequently provide a full picture on the different topics that needs to be addressed by the Committee, despite the draft pre-publication of the report of the 68th JECFA meeting has not yet been posted on the JECFA website at the time when this discussion paper was drafted.

9. Given that also information has been provided as regards the economical implications following the setting of maximum levels for aflatoxins in almonds hazelnuts and pistachios, a separate heading has been devoted to this topic. In addition the rationale for setting different levels for "ready-to-eat" and "for further processing" nuts is also subject of a separate chapter

10. Given the size of the document the numbering of the tables and figures restarts at each chapter.

[8] ALINORM 07/30/41 para. 65

DISCUSSION POINTS IN THE ELECTRONIC WORKING GROUP ON WHICH NO CONSENSUS COULD BE ACHIEVED.

11. A number of issues were discussed within the electronic working group but not on all points a consensus could be achieved. However the points where a large majority of the working group could agree on are mentioned hereafter as it is considered appropriate that the Plenary session of CCCF is informed hereof

12. The majority of the working group could agree on the following statement which could be used as a starting point for discussion at the 2nd session of the CCCF:

> JECFA concluded that for tree nuts, other than pistachios, the presence of a maximum level has no effect on the aflatoxin total dietary exposure. Moreover JECFA concluded that enforcing a maximum level of 4, 8, 10 or 15 µg/kg aflatoxin total would have little further impact on the overall dietary exposure to aflatoxin total compared to setting an maximum level of 20 µg/kg.
>
> The JECFA noted that the reduction of aflatoxin total dietary exposure is an important public health goal, particularly in populations who consume high levels of any potentially aflatoxin contaminated food. Therefore from a public health point of view, an in light of uncertainties and limitations of the analysis, a limit should be proposed as low as reasonably technically achievable by applying good practices.
>
> The current draft maximum levels of 8 µg/kg for almonds, hazelnuts and pistachios "ready to eat" and 15 µg/kg for almonds, hazelnuts and pistachios "for further processing" should be assessed in this context.
>
> Based on the information contained in this discussion paper, it might be appropriate to discuss a (slightly) higher maximum level for pistachios, almonds and hazelnuts "ready to eat" in the context of achievability and impact of GAP and GMP on the levels of aflatoxin total.

One delegation of the working group opposed the abovementioned statement and expressed the opinion that the CCCF at its 2nd meeting should consider all levels assessed by JECFA higher than the current draft maximum level of 8 µg/kg because JECFA concluded that enforcing an maximum level of 4, 8, 10 or 15 µg/kg aflatoxin total would have little further impact on the overall dietary exposure to aflatoxin total compared to setting an maximum level of 20 µg/kg.

13. A majority of the members of the working group agreed that the inclusion of the Chapter V as regards the economic impact was appropriate although several members were of the opinion that the reference to the World Bank reports (V.2) was not appropriate. The Chair of the working group decided, in the interest of keeping the document balanced through reflecting the different views, to keep the Chapter V in its entirety in the discussion paper.

14. Some members of the working group were of the opinion that the discussion paper contained too many details and should be more limited to the conclusions which could be drawn from the data. Also some members were of the opinion that too much attention was paid to the information contained in the EFSA risk assessment. The chair of the working group decided to maintain to a certain extent the data from the JECFA and EFSA assessment in the discussion paper.

15. One member of the working group disagreed with the use of the term "ready-to-eat" nuts. According to this member the use of term "ready-to-eat" when applied to pistachios in the context of commercial trade would be misleading to the consumer, since in the context of this discussion paper it refers to nuts that are not intended to undergo a further sorting or physical treatment to reduce the aflatoxin content. The choice of wording ("ready-to-eat") would mislead the consumer into believing that pistachios so defined are ready for direct consumption which is not a correct assumption in the case of raw pistachios. The reason is that pistachio processing is not only done to reduce aflatoxins through sorting techniques, but also to reduce the possibility of microbial contamination of the in-shell pistachio nut, where roasting is used as an essential step in the process, as the heat involved in roasting at 135-180 °C effectively destroys any existing microbial contamination in the raw product.

Raw in-shell pistachios should therefore not be considered ready-to-eat, since roasting is mandatory step in the process of making this nut safe for consumption, even though it may not lead to significant reduction in aflatoxin contamination levels. Roasting has the added benefit of making raw pistachios more palatable to the consumer, by enhancing taste Therefore, this member of the electronic working group proposes that the term "ready-to-eat" should be replaced by the term "ready-for-roasting", at the very least in the case of raw in-shell pistachios.

ANNEX II

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I. DETAILED DATA ON DISTRIBUTION OF AFLATOXINS BETWEEN LOTS

I.1. Data gathered by JECFA in view of the JECFA[9] assessment[10] - assessment of the data performed by JECFA

In the JECFA assessment, the sum of AFL B1, B2, G1 and G2 (AFB1, AFB2, AFG1 and AFG2) is referred to as AFT. JECFA agreed that the assessment applies to the edible parts of almonds (Codex food and feed classification number TN 0660) of cultivars grown from *Prunus amygdalus*, to Brazil nuts (TN 0662) ("white almonds") from *Bertholletia excelsa*, to the "common edible hazelnuts" (TN 0666) from *Corylus avellana* intended for direct consumption and to pistachio nuts (TN 0675) of cultivars grown from *Pistacia vera*.

Additionally, the evaluation considered dried figs (DF 0297) from ripe fruits of cultivars grown from *Ficus carica* and intended for direct consumption. It does not apply to dried figs intended for processing.

Aflatoxin occurrence data on almonds, Brazil nuts, hazelnuts, pistachios and dried figs were obtained by JECFA from both producing and importing countries. The aflatoxin occurrence and concentration data, submitted from 22 EU Member States for the European Food Safety Authority (EFSA) risk assessment requested by the European Commission in 2006, were available for the JECFA evaluation. Australia, Brazil, the Islamic Republic of Iran, Japan, Turkey, United Arab Emirates and the USA also submitted data on aflatoxin contamination. In total, JECFA had access to over 100 000 data points for its analyses.

JECFA decided to base the assessment of the impact of different maximum levels (MLs) for aflatoxin total (AFT) for almonds, Brazil nuts, hazelnuts, pistachios and dried figs (4, 8, 10, 15 and 20 µg/kg) on data provided by producing countries, as these are more likely to represent the actual occurrence of aflatoxins in the commodities.

As the discussion paper relates to almonds, hazelnuts and pistachios only the information from the EFSA assessment relevant for these three nuts will be mentioned.

The primary producing countries[11] were, for almonds, the USA (42% of the world market); for hazelnuts, Turkey (70%); for pistachios, the Islamic Republic of Iran (65%). Turkey is the primary producing country for hazelnuts, but JECFA received no data on AFT levels in hazelnuts from Turkey. Therefore, JECFA used all of the submitted data supplied by the EU (see I.3.1 and I.3.2) the USA and Japan for its analyses.

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[9] JECFA is the Joint FAO/WHO Expert Committee on Food Additives

[10] The information contained in this section of the discussion paper is extracted from the assessment performed by JECFA as regards the impact of different hypothetical limits for almonds, Brazil nuts, hazelnuts, pistachios and dried figs. WHO Technical Report Series, 947, Evaluation of certain food additives and contaminants. Sixty-eight report of the Joint FAO/WHO Expert Committee on Food Additives

[11] FAOSTAT 2007 (http://faostat.fao.org)

The mean concentrations of aflatoxin total (AFT) in nuts in the main producing countries were, for almonds, 2 µg/kg; for hazelnuts, 2 µg/kg; for pistachios, 54 µg/kg. The effects of the theoretical full enforcement of MLs (all samples above the ML would be excluded from the distribution) at 20, 15, 10, 8 and 4 µg/kg are shown in Table 1. The reduction in mean AFT concentrations would be approximately 2- to 3-fold for almonds, 2- to 4-fold for hazelnuts, 10- to 50-fold for pistachios. The corresponding proportion of rejected samples would be 1–3% for almonds, 1–7% for hazelnuts, 40–60% for pistachios.

Table 1: Impact of different hypothetical ML scenarios for AFT on the mean AFT level and the corresponding proportion of rejected samples from the producing countries on the world market for tree nuts

	Mean AFT level, µg/kg (proportion of rejected samples, %)					
Scenario µg/kg	**No MLs**	**ML 20 µg/kg**	**ML 15 µg/kg**	**ML 10 µg/kg**	**ML 8 µg/kg**	**ML 4**
Almonds	2.0 (0)	0.8 (1)	0.7 (2)	0.7 (2)	0.6 (3)	0.6 (3)
Hazelnuts	1.9 (0)	1.0 (1)	0.9 (2)	0.8 (3)	0.7 (4)	0.6 (7)
Pistachios	54 (0)	4.4 (40)	3.4 (44)	2.4 (49)	2.0 (53)	1.2 (61)

I.2. Data gathered by the EC in 2006 in view of the EFSA[12] assessment[13].

I.2.1. Data submitted by EC Member States – assessment of the data performed by EFSA

A total of 49,748 analytical results on occurrence of aflatoxins were submitted from 22 EU Member States in response to a call for information issued by the European Commission. The close to 5,700 data from the Netherlands could not be used because only aggregated data were submitted and the nearly 700 data from Lithuania were incomplete and only showed approval or rejection of imported lots. Due to incomplete product description, approximately 4,700 data from two Italian regions could also not be used. Overall 38,648 sample results from Member States were entered into the database. On close analysis a further 4,332 sample results had to be discarded because of deficiencies in the way results were presented or the limit of detection of the method used was not adequate for the analysis (see limit of detection below).

In total, 34,326 analytical results submitted by Austria (1,453), Belgium (434), Cyprus (212), Czech Rep (1,464), Denmark (340), Estonia (349), Finland (1,419), France (2,719), Germany (5,287), Greece (4,847), Hungary (3,750), Ireland (1,765), Italy (6,959), Latvia (549), Luxembourg (320), Slovakia (939), Slovenia (402), Spain (229), Sweden (211) and United Kingdom (678) were included in the following analysis.

[12] EFSA is the European Food Safety Authority

[13] The information contained in this section of the discussion paper can also be found in the opinion of the Scientific Panel on Contaminants in the Food Chain 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. The opinion is available on the EFSA website: http://www.efsa.europa.eu/EFSA/Scientific_Opinion/CONTAM%20_op_ej446_aflatoxins_en,0.pdf

Details on sampling were provided in most of the cases but not all. However it was requested that only analytical results of samples representatively taken from the consignment would be submitted. Most of the samples were taken in accordance with the official EC sampling procedure[14]

Turkey reported individual analytical results from testing of 6,762 hazelnut and pistachio samples from the official pre-export control that were analysed in 2005 and 2006 (see the analysis of the data by EFSA under I.3.2).

FRUCOM (European Federation of the Trade in Dried Fruit, Edible Nuts, Processed Fruit & Vegetables, Processed Fishery Products, Spices, Honey and Similar Foodstuffs) reported internal food business compliance testing results from 2002 to 2006 covering approximately 3,500 samples consisting of mainly aggregated data with an indicated non conformity rate of about 1%. Because of the data aggregation, the FRUCOM results could not be incorporated into further analysis.

In the call for information, Member States were asked to indicate what type of control the respective samples related to (import, market or company control) and if the product was market ready or would undergo further processing before being sold, since the latter would allow some further sorting and thus reduction of aflatoxin levels. The country of origin of the product was also requested. All such requested information was not made available for all samples tested and analyses of such factors have thus been performed on a sub-sample of the overall material, but only those for which a sufficient amount of data was available.

The information covers seven years from 2000 to 2006 (Table 2). Information for 2006 was incomplete as the deadline for submission was the end of September 2006.

Results were grouped into 14 food categories as shown in Table 2 with special emphasis on almonds, hazelnuts and pistachios.

[14] Commission Regulation (EC) No 401/2006 of 23 February 2006 laying down methods of sampling and analysis for the official controlof the levels of mycotoxins in foodstuffs. Official Journal of the European Union, L 70, 9.3.2006, p. 12

Table 2: Distribution of samples over year and food category.

Food category	Number of samples						
	2000	2001	2002	2003	2004	2005	2006
All data	2883	3609	4386	5605	8313	6638	2890
Almonds	112	108	206	362	347	287	344
Hazelnuts	100	170	569	673	739	642	270
Pistachios	246	384	428	680	1062	917	352
Baby foods	0	0	42	282	113	134	21
Brazil nuts	28	181	142	130	61	71	9
Cashews	7	23	21	51	77	107	50
Figs	85	145	301	444	571	431	90
Maize	70	66	55	306	258	122	66
Other cereals	417	479	207	240	539	618	510
Other dried fruits	107	75	179	242	283	347	163
Other foodstuffs	159	138	135	250	444	345	133
Other nuts	88	104	119	204	233	274	109
Peanuts	1260	1600	1451	1057	1640	1366	555
Spices	204	136	531	684	1947	977	219

Table 3: Calculation of the relationship between concentrations of AFB1 and total aflatoxins in the different food categories utilising all samples above the LOD.

Food category	No of samples All	No of samples >LOD	Linear regression coefficient[1]	R^2
Almonds	*1766*	*471 (27%)*	1.07	0.99
Hazelnuts	*3163*	*940 (30%)*	1.23	0.83
Pistachios	*4069*	*1783 (44%)*	1.10	0.97
Baby foods	*592*	*23 (4%)*	1.06	0.82
Brazil nuts	*622*	*271 (43%)*	1.73	0.98
Cashews	*336*	*33 (10%)*	1.14	0.99
Figs	*2067*	*618 (30%)*	1.43	0.73
Maize	*943*	*136 (14%)*	1.03	0.95
Other cereals	*3010*	*207 (7%)*	1.08	0.93
Other dried fruits	*1396*	*114 (8%)*	1.13	0.78
Other foodstuffs	*1604*	*303 (19%)*	1.03	0.97
Other nuts	*1131*	*158 (14%)*	1.06	1.00
Peanuts	*8929*	*1830 (20%)*	1.14	0.93
Spices	*4698*	*1988 (42%)*	1.02	0.81
All	*34326*	*8875 (26%)*	1.24	0.93

[1)] *Thirty five samples with total aflatoxins only were excluded from the regression analysis*

The slope of the equation as indicated by the linear regression coefficient is of most interest since it has to be assumed that the real intercept will be zero, i.e. a majority of samples had neither AFB1 nor total aflatoxins present. On average total aflatoxin levels were 24% higher than AFB1 levels but with a variation of 2% to 73% for different food categories. Brazil nuts in particular but also figs seemed to have a different aflatoxin profile from the rest of the food groups. The ratio of AFB1 to total aflatoxins will vary depending on the *Aspergillus* spp. since AFB1 and AFB2 are produced by *A. flavus* and AFB1, AFB2, AFG1 and AFG2 are produced by *A. parasiticus*. The occurrence of these fungal species will vary geographically and by food commodity. As a conservative estimate, values below the LOD for total aflatoxins were set at a maximum of twice the LOD for AFB1.

Aflatoxin concentrations across food categories

Statistical descriptors for each food category with a range defined by the lower and upper bound values are presented in Table 4 for AFB1 and total aflatoxin concentrations. The number of decimals given has been adjusted for ease of reading and the food groups are sorted from high to low mean values with the three product categories of special interest at the top of the table.

The results for Brazil nuts and pistachios are clearly different with much higher mean and upper percentile values than for the other food groups. Also figs, peanuts, spices, hazelnuts and almonds have 97.5th percentile values above 2 µg/kg for AFB1 and above 4 µg/kg for total aflatoxins. There are some high maximum values for most food categories except for baby foods and maize.

Chemical food contaminants often have a lognormal distribution with most values at the low concentration end and a few high or very high values. This is obvious here with the median lower or much lower than the mean and the maximum often 10 to 100 times higher than the 95th percentile indicating a tail end of very high values.

Table 4: Distribution statistics for different food commodities obtained in the European Union in the period 2000 to 2006 for lower to upper bound AFB1 and total aflatoxin (T) concentrations in µg/kg.

Food category	Lower to upper bound aflatoxin concentrations in µg/kg						
	Type	**Median**	**Mean**	**90th %**	**95th %**	**97.5th %**	**Max**
Pistachios	AFB1	0-0.20	16.7-16.8	27.8[1]	85.0	177.9	2625
	T	0-0.40	19.2-19.4	32.7	103.6	212.3	2680
Almonds	AFB1	0-0.20	1.36-1.46	0.78-0.80	2.00	7.2	575
	T	0-0.28	1.61-1.82	1.00	2.64	8.6	579
Hazelnuts	AFB1	0-0.16	0.85-0.95	1.40	3.00	5.6	200
	T	0-0.30	1.50-1.70	2.80	6.20	11.8	200
Brazil nuts	AFB1	0-0.20	22.0-22.2	43.6	96.9	182.6	1897
	T	0-0.40	39.3-39.6	76.24	188.8	379.3	3337
Peanuts	AFB1	0-0.10	1.80-1.93	0.60-1.00	2.34	9.8	935
	T	0-0.20	2.44-2.69	1.00-1.60	3.76	16.8	985
Spices	AFB1	0-0.20	1.33-1.46	3.10	6.60	10.9	96
	T	0-0.40	1.65-1.88	4.10	7.80	14.1	96
Figs	AFB1	0-0.15	1.25-1.36	1.20	4.80	13.0	130
	T	0-0.24	2.02-2.22	1.72-1.80	7.97	18.2	151
Other nuts	AFB1	0-0.10	1.04-1.16	0.02-0.23	0.46-1.00	1.2	385
	T	0-0.20	1.18-1.41	0.04-0.46	0.62-1.41	2.1	402
Other foodstuffs	AFB1	0-0.10	0.35-0.53	0.12-1.00	0.54-1.00	1.5	99
	T	0-0.20	0.43-0.75	0.30-1.20	0.90-2.00	2.4	99
Cashews	AFB1	0-0.10	0.29-0.42	0-0.23	0.24-1.00	1.9	36
	T	0-0.20	0.35-0.60	0-0.48	0.47-1.85	2.3	39
Other cereals	AFB1	0-0.20	0.14-0.35	0-0.50	0.10-1.00	0.7-1.0	109
	T	0-0.40	0.19-0.51	0-0.50	0.18-1.00	1.1-1.8	117
Other dried fruits	AFB1	0-0.10	0.07-0.26	0-0.40	0.04-1.00	0.3-1.0	20
	T	0-0.24	0.17-0.51	0-0.80	0.10-1.33	0.5-2.0	90
Maize	AFB1	0-0.12	0.12-0.26	0.22-0.50	0.69-0.73	1.1	8
	T	0-0.24	0.16-0.41	0.34-0.50	1.00	1.7-1.8	9
Baby foods	AFB1	0-0.02	0-0.07	0-0.10	0-0.15	0.03-1.0	0.2-1
	T	0-0.04	0-0.14	0-0.20	0-0.30	0.03-2.0	0.2-2
All foods	AFB1	0-0.15	3.32-3.46	1.30	5.50	19.8	2625
	T	0-0.30	4.28-4.53	2.00	7.90	25.9	3337

[1] *One value only is given when the lower and upper bounds are the same*

Distribution of aflatoxins in set ranges

Using the collected data, the distribution of aflatoxin levels across food categories was further explored by analysing the proportion of samples within set ranges using MLs of 2, 4, 8, and 10 µg/kg for AFB1 and total aflatoxins as presented in Table 5.

Table 5: Distribution of levels for AFB1 and total aflatoxins(T) in defined concentration ranges across all food categories.

Food category	Proportion of samples with aflatoxins within indicated µg/kg range [1]						
	Type	<LOD	>LOD-2	>2-4	>4-8	>8-10	>10
Pistachios	AFB1	56.2%	22.7%	2.0%	2.8%	0.9%	15.4%
	T	56.2%	22.2%	2.1%	2.6%	0.8%	16.1%
Almonds	AFB1	73.3%	21.7%	1.4%	1.5%	0.3%	1.7%
	T	73.3%	20.6%	2.3%	1.1%	0.5%	2.3%
Hazelnuts	AFB1	70.3%	22.3%	4.0%	1.9%	0.4%	1.3%
	T	70.3%	17.3%	5.6%	2.7%	1.2%	2.9%
Brazil nuts	AFB1	56.4%	20.4%	2.6%	2.6%	1.0%	17.0%
	T	56.4%	18.5%	3.5%	1.9%	0.5%	19.1%
Peanuts	AFB1	79.5%	15.1%	1.3%	1.2%	0.4%	2.5%
	T	79.5%	13.8%	1.9%	1.2%	0.4%	3.2%
Spices	AFB1	57.7%	27.1%	7.4%	4.0%	1.0%	2.7%
	T	57.7%	23.7%	8.5%	5.2%	1.4%	3.4%
Figs	AFB1	70.1%	22.1%	2.3%	2.2%	0.2%	3.1%
	T	70.1%	20.6%	2.2%	2.1%	0.6%	4.4%
Other nuts	AFB1	86.0%	12.4%	0.2%	0.5%	0.1%	0.8%
	T	86.0%	11.3%	1.1%	0.4%	0.1%	1.1%
Other foodstuffs	AFB1	81.1%	17.0%	0.7%	0.3%	0.1%	0.7%
	T	81.1%	16.1%	1.5%	0.4%	0.1%	0.9%
Cashews	AFB1	90.2%	7.4%	0.9%	0.6%	0.3%	0.6%
	T	90.2%	6.5%	1.8%	0.6%	0.0%	0.9%
Other cereals	AFB1	93.1%	6.0%	0.3%	0.2%	0.0%	0.3%
	T	93.1%	5.6%	0.4%	0.4%	0.1%	0.3%
Other dried fruits	AFB1	91.8%	7.4%	0.2%	0.3%	0.1%	0.1%
	T	91.8%	7.1%	0.4%	0.3%	0.1%	0.3%
Maize	AFB1	85.6%	13.4%	0.5%	0.5%	0.0%	0.0%
	T	85.6%	12.5%	1.3%	0.5%	0.1%	0.0%
Baby foods	AFB1	96.1%	3.9%	0.0%	0.0%	0.0%	0.0%
	T	96.1%	3.9%	0.0%	0.0%	0.0%	0.0%

[1)] *The EU MLs for some spices are set at 5 and 10 µg/kg for AFB1 and total aflatoxins, respectively. Different MLs also apply for some products to undergo further sorting. However, for the purpose of comparison the same ranges are used for all products.*

Although there are some slight variations between the proportion of samples within the set MLs for AFB1 and total aflatoxins, the distributions are basically the same. The number of samples with total aflatoxin levels of 4 µg/kg or less varied from 78.5% for Brazil nuts to 100% for baby foods. In fact, baby foods had no samples above 1 µg/kg. Apart from having the least number of samples at or below 4 µg/kg, Brazil nuts also had the most samples (19.1%) above 10 µg/kg. The situation for pistachios was similar with 80.5% of samples at or below 4 µg/kg and 16.1% above 10 µg/kg.

I.2.2. Data submitted by Turkey – assessment of the data performed by EFSA

A total of 553 individual results of pre-export checks of pistachios produced in Turkey in 2005 and 2006 could be accessed. Moreover, Turkey provided 6204 results for aflatoxins in **hazelnuts** analysed before export in 2005 and 2006. Turkey is the greatest exporter of hazelnuts and also a major producer and exporter of pistachios into the EU.

The results of the Turkish pre-export controls were grouped into various concentration ranges (0-4, 4-8, 8-10, and >10 µg/kg) in order to estimate the impact on aflatoxin occurrence in hazelnuts and pistachios in response to proposed change of the MLs. Table 6 gives an overview of the percentage distribution.

Table 6: Distribution of AFB1 and total aflatoxin (T) levels in defined concentration ranges for Turkish hazelnuts and pistachios tested before export in 2005/2006.

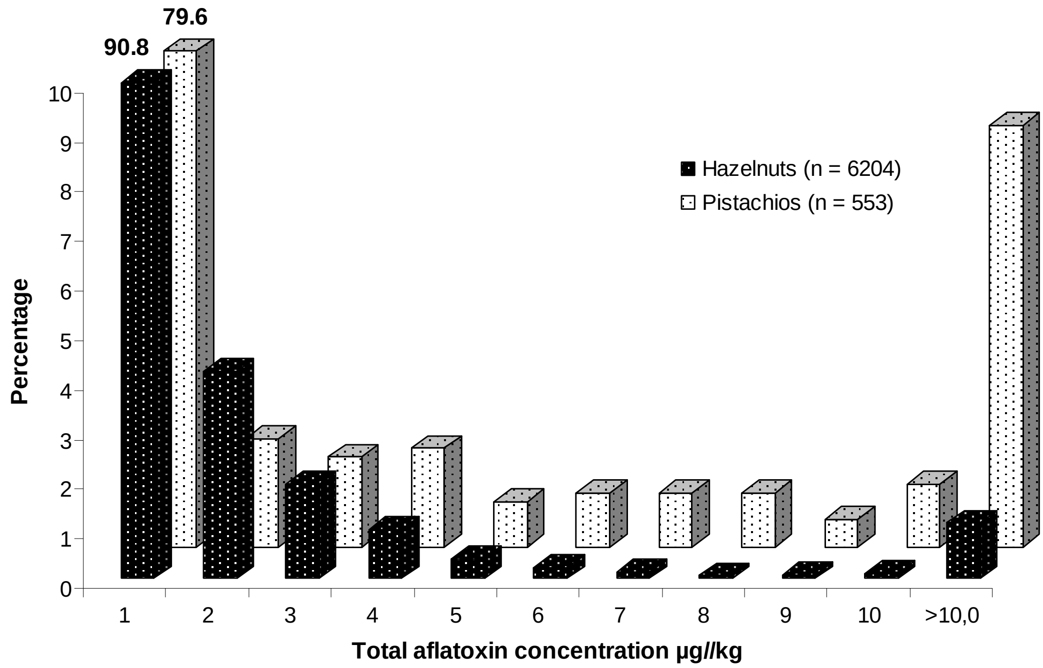
Food Category	Proportion of samples with total aflatoxins (T) within indicated ranges (µg/kg)						
	Type	<LOD	>LOD-2	>2-4	>4-8	>8-10	>10
Hazelnuts	AFB1	85.9%	12.2%	0.9%	0.4%	0.1%	0.6%
	T	83.2%	11.7%	2.9%	0.8%	0.2%	1.1%
Pistachios	AFB1	76.4%	7.2%	3.1%	4.9%	2.0%	6.2%
	T	76.1%	5.6%	3.8%	4.2%	1.8%	8.5%

As can be seen, 83.2% of all hazelnut lots tested were below the limit of detection of 0.20 µg/kg and 97.8% of all hazelnut consignments were below the current EU ML of 4 µg/kg for total aflatoxins. Another 0.8% and 0.2% were between 4-8 and 8-10µg/kg, respectively. A total of 1.1% of the hazelnut samples tested before export in 2005/2006 exceeded 10 µg/kg for total aflatoxins.

A somewhat different situation can be observed for pistachios. Although the total number of pistachio export lots tested (n=553) was considerably lower than hazelnuts (n=6204), the number of samples that exceeded the current ML for total aflatoxins was substantially higher. Almost 15% of the pistachio lots tested in Turkey before export in 2005/2006 were not compliant with the current EU Regulation. Moreover, 8.5% of the pistachio lots tested before export was exceeding 10 µg/kg, in comparison to only 1.1% of the hazelnut samples. On the other hand, 76.1% of the pistachio lots were below the limit of detection of 0.20 µg/kg for total aflatoxins.

Detailed histograms illustrating the different distributions of total aflatoxin occurrence data in Turkish hazelnuts and pistachios analysed before export in 2005/2006 are depicted in Figure 1.

Figure. 1: Frequency histograms for total aflatoxins in Turkish hazelnuts and pistachios tested before export 2005/2006.



The LOD for AFB1 in hazelnuts and pistachios was given by the Turkish authorities as 0.10 µg/kg. Taking into account that AFB1 in hazelnuts and pistachios amounts on average to around 75% of total aflatoxins, for a worst case scenario the limit of detection for total aflatoxins was set as twice (0.20 µg/kg, upper bound) the LOD for AFB1. For comparison, a second evaluation was performed for which the LOD was set to zero (lower bound). Based on these assumptions, distribution statistics were calculated for the two types of nuts. Table 7 presents these descriptions for AFB1 and total aflatoxins as determined in the Turkish pre-export controls performed in 2005/2006.

Table 7: Distribution statistics for hazelnut and pistachio pre-export controls 2005/2006 for lower to upper bound AFB1 and total aflatoxin (T) concentrations in µg/kg.

Food category	Type	Lower bound/upper bound aflatoxin concentrations (µg/kg)					
		Median	Mean	90^{th} %	95^{th} %	97.5^{th} %	Max
Hazelnuts	AFB1	0.00-0.10	0.36-0.44	0.45	0.85	1.55	218
	T	0.00-0.20	0.71-0.87	0.84	2.05	3.59	243
Pistachios	AFB1	0.00-0.10	3.31-3.39	6.07	17.3	36.6	119
	T	0.00-0.20	4.79-4.94	8.60	32.6	52.8	164

Only one value is given if the lower bound and upper bound values are the same

I.3. Data on aflatoxins in pistachios provided by the delegation of Iran for this discussion paper – assessment of the data performed by Iran

I.3.1. Occurrence data on the presence of aflatoxins in pistachios in Iran, representative for the production in Iran in 2004-2006 (data also submitted to JECFA in view of the JECFA assessment)

a) **Sample Analysis**: Measurements of aflatoxin total in laboratory samples were made according to the Iranian Institute of Standards guideline #5179 and the European Directive 98/53/EC (replaced by Regulation (EC) 2006/401 containing similar provisions on sampling and analysis as Directive 98/53/EC.

b) **Sample size**: 5200, including 1619 cases with NA or ND measurements.
NA implies: Aflatoxin measurement lower than the limit of detection, i.e. less than 0.4 ppb
ND indicates: Not Detected.
Uniform random numbers between 0.0 and 0.4 were assigned to NA and ND observations to complete the sample set.

c) **Descriptive Statistics**: descriptive statistics for the complete sample set are provided in Tables 8 and 9, below. Table 8 shows the valid and missing cases. Since only 1% of sample had missing values, they were ignored. The following analyses are based on 5200 valid cases.

Table 8.

Case Processing Summary

	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
TOTAL	5200	99.0%	50	1.0%	5250	100.0%

Table 9.

Descriptives

			Statistic	Std. Error
Total Aflatoxin	Mean		46.772599	1.831971
	95% Confidence Interval for Mean	Lower Bound	43.181166	
		Upper Bound	50.364032	
	5% Trimmed Mean		22.960772	
	Median		2.400000	
	Variance		17451.807	
	Std. Deviation		132.1053	
	Minimum		.0000	
	Maximum		2108.530	
	Range		2108.530	
	Interquartile Range		24.216234	
	Skewness		5.411	.034
	Kurtosis		40.644	.068

Table 9 provides the summary statistics. Thus, the mean value of aflatoxin total (AFT) is 46.77 ppb with a standard error of 1.83 ppb. With 95% confidence, AFT is between 43.18 to 50.36 ppb.

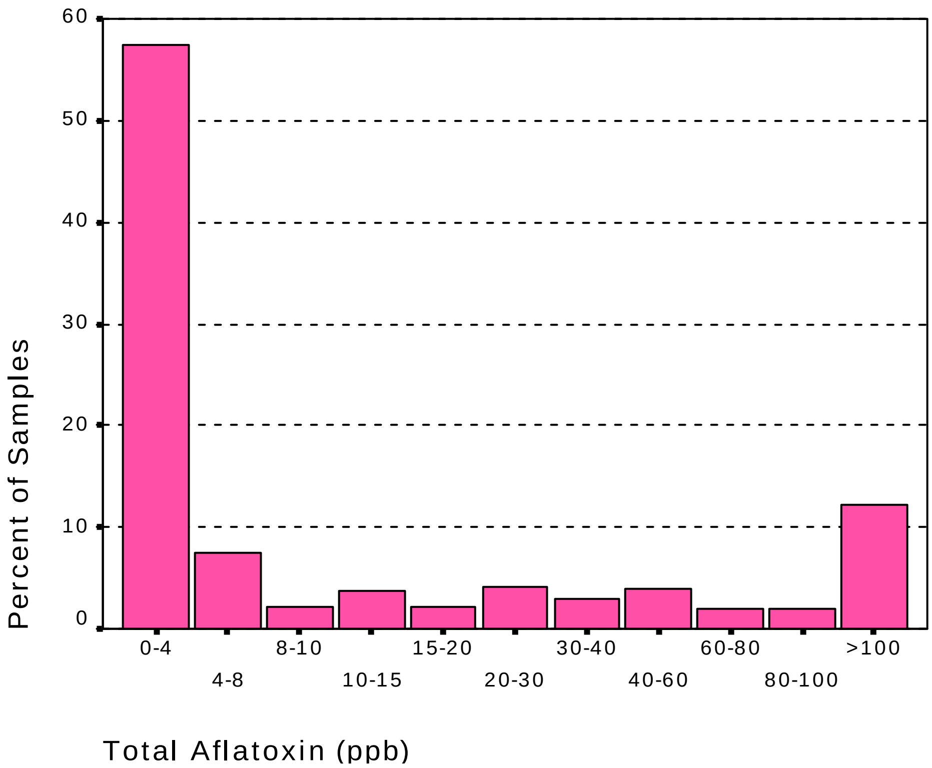
The median value of AFT is 2.40 ppb, much lower than the mean. The variance of AFT is 17451.81, (standard deviation equal to 132.11 ppb).

The above statistics along with their skew and kurtosis reveal that we are dealing with a very unusual distribution.

While 50% of measurements are below 2.40 ppb, there are a few huge measurement values of about 2000 ppb.

Considering these facts, if we use a 5% trimmed mean, leaving the 2.5% smallest, as well as the 2.5% largest values out, a mean value of 22.96 ppb was obtained, about half of the mean obtained by using the complete dataset. .
If the most contaminated cases are excluded from the dataset, the picture will be completely different.
To see the distribution of AFT has been computed (see Table 10), and the results are illustrated in figure 2, below.

Figure 2. The histogram of the relative frequency distribution of analytical results on aflatoxin total in samples of Iranian pistachios.



The cumulative percent column in Table 10 below, and the histogram in Figure 2, above, show that 57.4% of samples have less than 4 ppb AFT. The higher values of AFT are quite rare, except for values larger than 100 ppb, which comprise 12% of the sample values. Again, this is indicative of the unusual distribution of AFT. One can conclude that there are two types of consignments giving rise to two distinct sample values. Firstly, those with AFT of up to 100 ppb, whose distribution is consistent with our expectations: The more contamination, the less frequent the samples. Secondly, those which are highly contaminated with AFT content >100 ppb.

Table. 10 The relative frequencies distribution of sample observations (11 classes)

	Frequency	Percent	Cumulative Percent
0 - 4	2985	57.4	57.4
4 - 8	389	7.5	64.9
8 - 10	116	2.2	67.1
10 - 15	192	3.7	70.8
15 - 20	115	2.2	73.0
20 - 30	211	4.1	77.1
30 - 40	150	2.9	80.0
40 - 60	205	3.9	83.9
60 - 80	100	1.9	85.8
80 - 100	102	2.0	87.8
> 100	635	12.2	100.0
Total	5200	100.0	

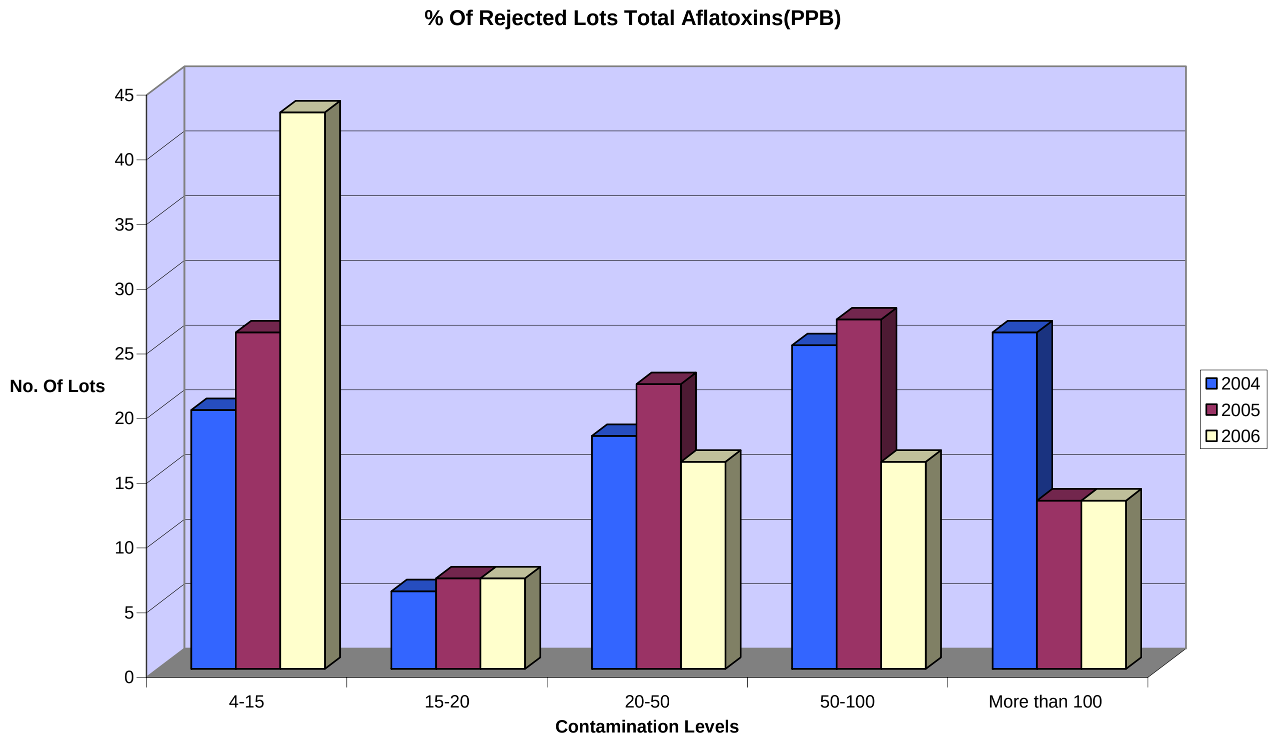
I.3.2. Evaluation of the levels of aflatoxin total in consignments of pistachios from Iran rejected by the EU in the period 2004-2006.

The Iranian delegation has provided information on the levels of aflatoxin total found in consignments of pistachios from Iran rejected for import by the EU and reported through the Rapid Alert System for Food (RASFF). This information is presented in Table 11 and graphically presented in Figure 3.

Table 11. Evaluation of the levels of aflatoxin total in consignments of pistachios from Iran rejected by the EU in the period 2004-2006

	Contamination Level (Total Aflatoxins)																	
	More than 100			50-100ppb			20-50ppb			15-20ppb			4-15ppb					
Year	**2006**	**2005**	**2004**	**2006**	**2005**	**2004**	**2006**	**2005**	**2004**	**2006**	**2005**	**2004**	**2006**	**2005**	**2004**	**2006**	**2005**	**2004**
No.of Lots	33	58	148	27	124	139	41	103	104	18	33	32	86	119	112	253	464	560
Weight (Tn)	723	1340	3320	570	2846	3210	1336	2685	2466	395	747	670	1846	2751	2457	5430	10659	12679
% of Rejected Lots	13	13	26	16	27	25	16	22	18	7	7	6	43	26	20			

Figure 3. Graphical presentation of the data presented in table 11



I.4. Data submitted by INC (International Nut and Dried Fruit Council Foundation)

I.4.1. Data submitted by INC in preparation of the 1st session of the CCCF

Pistachio (mainly in shell) – food business operator own checks

year	origin	Type*	Number	Number of data < LOD (0.5 ppb)	Data > LOD Levels (ppb)
2001	Iran	FFP	36	27	19.8; 12.3; 6.3; 14.0; 39.4; 12.7; 104.0; 39.4; 7.9;
2001	US	FFP	9	9	---
2002	Iran	FFP	54	45	48.8; 44.5; 2.2; 58.3; 22.7; 145.9; 41.6; 22.8; 54.3;
2002	US	FFP	17	17	---
2002	Italy	FFP	9	9	---
2002	Italy	RTE	5	5	---
2003	Iran	FFP	41	28	2.0; 3.2; 124.9; 58.0; 1.2; 120.5; 30.1; 31.8; 61.7; 3.7; 11.2; 55.9; 7.5;
2003	US	FFP	13	13	---
2003	Italy	FFP	9	9	---
2004	Iran	FFP	69	42	66.4; 3.4; 10.6; 31.4; 38.1; 11.8; 98.4; 61.2; 2.0; 11.9; 59.3; 34.5; 79.9; 68.4; 25.8; 155.6; 5.2; 130.7; 152.3; 137.9; 105.7; 2.8; 138.9; 147.8; 30.5; 44.2; 1.8;
2004	US	FFP	19	18	8.6;
2004	Italy	FFP	12	9	1.5; 66.0; 2.1;
2004	Turkey	FFP	2	2	---
2005	Iran	FFP	68	48	35.7; 72.1; 137;8; 121.9; 132.3; 70.7; 8.0; 29.6; 31.1; 2.2; 1.2; 168.7; 177.6; 59.5; 165.8; 25.0; 1.5; 26.9; 16.4; 62.7;
2005	US	FFP	26	25	55.2;
2005	Italy	FFP	5	3	4.2; 1.5;
2005	Turkey	FFP	1	0	15.6;
2006	Iran	FFP	48	37	147.3; 145.2; 3.0; 222.0; 70.8; 8.9; 5.1; 19.5; 117.0; 2.2; 23.4;
2006	US	FFP	13	13	---
2006	Italy	FFP	1	1	---
2006	Turkey	FFP	1	1	---

* FFP: for further processing
* RTE ready-to-eat

Hazelnuts (shelled) – food business operator own checks

year	origin	Type*	Number	Number of data < LOD (0.5 ppb)	Data > LOD Levels (ppb)
2003	Italy	RTE	3	3	---
2003	Turkey	RTE	19	19	---
2004	Turkey	RTE	17	18	5.9
2005	Turkey	RTE	28	27	8.1
2006	Turkey	RTE	10	10	---

* FFP: for further processing
* RTE ready-to-eat

Almonds (shelled, limited number peeled) – food business operator own checks

year	origin	Type*	Number	Number of data < LOD (0.5 ppb)	Data > LOD Levels (ppb)
2003	Italy	RTE	8	8	---
2003	US	RTE	7	7	---
2004	Italy	RTE	40	40	---
2004	US	RTE	54	54	---
2004	Spain	RTE	11	11	---
2005	Italy	RTE	22	21	18.3;
2005	US	RTE	58	58	---
2005	Spain	RTE	8	8	---
2005	Chile	RTE	2	2	---
2006	Italy	RTE	10	10	---
2006	US	RTE	11	11	---
2006	Spain	RTE	4	4	---

* FFP: for further processing
* RTE ready-to-eat

I.4.2. Data submitted by INC in preparation of the 2nd session of the CCCF.

I.4.2.1 Explanatory notes to the data submitted by INC

The information presented in the following tables is based on the data provided by various sources as indicated in the tables. The data were then subdivided into 4/8/10/15/20 ppb contamination intervals. The percentage of samples/lots within those intervals is then calculated.

Percentage of samples under current limits (<4ppb total Aflatoxin) are compared to those under the industry recommended limit (<10ppb total Aflatoxin) and the additional percentage of lots that would be accepted is indicated.

Five control steps are identified in the following tables:

1. Producer internal controls
2. Producer country export controls
3. Importer/Processors EU
4. Official laboratory EU import controls
5. Official EU market controls

At step 4, the official laboratory imports controls, 100% of the lots indicated in the RASFF are rejected. The official EU sampling and analytical methodology however requires for nuts for direct human consumption for dividing the aggregate sample into 3 sub samples and reporting all three results. This is not always the case and rejections are in many cases due to the interpretation of the analysis results “if only one of the 3 sub-samples is above the limit the whole lot is rejected”.

However the methodology involves taking 100 individual 300g samples throughout the lot and analyzing three 10kg sub samples. According to INC, it is the average of these 3 sub samples which is most representative of the lot. The percentages shown in the table are calculated from the average of the 3 sub-samples (when the three results are reported by the authorities). In such a case one finds that a significant number of currently rejected lots would be accepted even without raising the current 4ppb total Aflatoxin limit (in 21% of cases for pistachios, 16% for hazelnuts and 40% for almonds), and even more if the current total Aflatoxin levels were raised to 10ppb (in 60% of cases for pistachios, 69% for hazelnuts and 54% for almonds).

I.4.2.2 Data on pistachios

Place of sampling	Organization reporting	Origin	Reporting period	TOTAL AFLATOXIN (percentage of lots within indicated levels)					
				<4 ppb	**>4 to <8ppb**	**>8 to <10ppb**	**>10 to <15ppb**	**>15ppb Total**	Comments
Producer Internal Controls	companies	Iran	Green corridor Aug-Dec 2005 Wet process	**61,0%**	**7,0%**	**2,0%**	4,0%	26,0%	(1)
Producer Internal Controls	companies	Iran	Green corridor Aug-Dec 2005 dry process	**80,0%**	**4,0%**	**1,0%**	3,0%	12,0%	(2)
Producer Internal Controls	companies	USA	1/6/06-31/3/07	**98,4%**	**0,5%**	**0,2%**	0,2%	0,7%	(3)
Producer country export controls	Health authorities exporting countries	USA	Not required						(4)
		Turkey	Not available						
		Iran	Not available						
EU importers/EU industry	Companies	US	13/3/07-26/6/07	**100%**	**0%**	**0%**	**0%**	**0%**	(5)
		Turkey	Not available						
		Iran	Not available						
				Mean of 3 sub-samples					
Official laboratory Import controls	Health authorities Importing countries	RASFF-Rejected lots	12/04/07-16/10/7	**21%**	**33%**	**6%**	15%	24%	(6)
Official market controls	Health authorities Importing countries	RASFF-Market withdrawals	12/04/07-16/10/7	0	**22%**		0	78%	('7)

(1)	*Green corridor 2005 field study data shows that 39% of the samples processes in the terminal at harvest (before dry sorting) have aflatoxin values >4ppb*
(2)	*Green corridor 2005 field study data shows that 20% of the samples still have aflatoxin values >4ppb despite sorting and preparation for export*
(3)	*2414 samples from lots prepared for export, internal control from US pistachios industry*
(4)	*Not available or not required*
(5)	*EU industry (18 lots from USA) reporting no lots above current EU- limits*
(6)	*Based on 33 RASFF notifications: Using mean Total aflatoxin across 3 sub-samples (where data was available for 15 lots) and a 10ppb limit, 61% of lots currently rejected would be accepted.*
(7)	*9 market withdrawals all based on a single sample analysis reported, 22% of them would no longer be withdrawn at a new 10ppb total aflatoxin limit*

I.4.2.3 Data on almonds

Place of sampling	Organisation reporting	Origin	Reporting period	TOTAL AFLATOXIN (percentage of lots within indicated levels)					Comments
				<4 ppb	**>4 to <8ppb**	**>8 to <10ppb**	**>10 to <15ppb**	**>15ppb Total**	
Producer Internal Controls	Export Companies	USA	1/6/06-31/3/07	**97,4%**	**1,3%**	**0,0%**	0,2%	1,1%	(1)
Producer country export controls	VASP	USA	1/6/06-31/10/07	**99,2%**	**0,6%**	**0,0%**	0,2%	0,0%	(2)
EU importers/EU industry	Importing Companies	EU	13/3/07-26/6/07	**96,9%**	**0,0%**	**0,0%**	0,4%	2,8%	(3)
				Mean of 3 sub-samples					
Official laboratory Import controls	Health authorities Importing countries	RASFF-Rejected lots	12/04/07-16/10/7	**40,0%**	**7%**	**7%**	0%	47%	(4)
Official market controls	Health authorities Importing countries	RASFF-Market withdrawals							(5)

(1)	*The reported lots (529) are prepared for export*
(2)	*Of the reported lots (532) Very few (0.6%) are above current limit*
(3)	*EU industry (255 lots) have very few lots above current limit and **raising the limit to 10ppb would have no effect at the EU industry level***
(4)	*Using mean Total aflatoxin across 3 sub-samples (15 lots) and **a 10ppb limit,*** **53% of lots currently rejected would be accepted.**
(5)	*No market withdrawals*

I.4.2.4 Data on hazelnuts

Place of sampling	Organisation reporting	Origin	Reporting period	TOTAL AFLATOXIN (percentage of lots within indicated levels)					Comments
				<4 ppb	**>4 to <8ppb**	**>8 to <10ppb**	**>10 to <15ppb**	**>15ppb Total**	
Producer/raw material intake	Producing companies	Turkey	1/9/06-31/5/07	91,5%	0,0%	2,6%	0,6%	5,6%	(1)
Producer country export controls	Health authorities exporting country	Turkish authorities	Not available						(2)
EU importers/EU industry	EU companies	FRUCOM	14/3/07-26/6/07	92,9%	0,0%	0,0%	1,2%	5,9%	(3)
				Mean of 3 sub-samples					
Official laboratory Import controls	Health authorities Importing countries	RASFF-Rejected lots	12/04/07-16/10/7	**16,0%**	**32%**	21%	21%	**11,0%**	(4)
Official market controls	Health authorities Importing countries	RASFF-Market withdrawals	12/04/07-16/10/7	**0%**	**0%**	**0%**	**0%**	**100%**	(5)

(1)	*1196 samples*
(2)	*Not available*
(3)	*85 samples*
(4)	*Using mean Total aflatoxin across 3 sub-samples (where data was available for 19 lots) and a 10ppb limit, 70% of lots currently rejected would be accepted.*
(5)	*Two market controls with only one sample analyzed*

II. CONSUMER HEALTH RISK ASSESSMENT OF DIFFERENT LEVELS OF AFLATOXINS IN READY-TO-EAT-NUTS

II.1 JECFA assessment

II.1.1. Assessment of dietary exposure

Published studies reported that estimated mean dietary exposures to AFT for the general population from all food sources were 0.93–2.4 ng/kg bw per day in Europe, 3.5–180 ng/kg bw per day in Africa, 0.3–53 ng/kg bw per day in Asia and 2.7 ng/kg bw per day in the USA.

In the JECFA assessment, mean lower- and upper-bound scenarios have been used in making the dietary exposure estimates employing the 13 GEMS/Food Consumption Cluster Diets (Tables 2, 3 and 4). The lower bound was calculated using 0 for non-detects or the LOD for trace values, whereas the upper bound was calculated using either the LOD or LOQ, as appropriate. Table 1 contains information on the countries assigned to the 13 GEMS/Food Consumption Cluster Diets.

Table 1: Country Assignments to the 13 GEMS/Food Consumption Cluster Diets

Cluster	Countries assigned to the cluster
A	Angola; Burundi; Cameroon; Central African Republic; Comoros; Côte d'Ivoire; Djibouti; Eritrea; Ethiopia; Gabon; Guinea; Guinea Bissau; Liberia; Mauritius; Rwanda; Sao Tome & Principe; Seychelles; Sierra Leone; Somalia; Uganda; Yemen;
B	Cyprus; Greece; Israel; Italy; Lebanon; Portugal; Spain; Turkey; United Arab Emirates;
C	Algeria; Egypt; Iraq; Jordan; Kuwait; Libya Arab Jamahiriya; Morocco; Saudi Arabia; Syrian Arab Republic; Tunisia;
D	Albania; Armenia; Azerbaijan; Belarus; Bosnia and Herzegovina; Bulgaria; Georgia; Iran, Islamic Rep of; Kazakhstan; Kyrgyzstan; Moldova, Republic of; Romania; Russian Federation; Serbia and Montenegro; Tajikistan; The former Yugoslav Republic of Macedonia; Turkmenistan; Ukraine; Uzbekistan;
E	Austria; Belgium; Croatia; Czech Republic; Denmark; France; Germany; Hungary; Ireland; Luxembourg; Malta; Netherlands; Poland; Slovakia; Slovenia; Switzerland; United Kingdom
F	Estonia; Finland; Iceland; Latvia; Lithuania; Norway; Sweden
G	Afghanistan; Bangladesh; Cambodia; China; India; Indonesia; Laos; Malaysia; Mongolia; Myanmar; Nepal; Pakistan; Sri Lanka; Thailand; Viet Nam;
H	Bolivia; El Salvador; Guatemala; Haiti; Honduras; Mexico; Nicaragua; Panama; Paraguay; Peru; Saint Kitts & Nevis; St. Vincent & Grenadine;
I	Benin Botswana; Cape Verde; Ghana; Kenya; Lesotho; Malawi; Mozambique; Namibia; South Africa; Swaziland; Togo; United Republic of Tanzania; Zambia; Zimbabwe;
J	Burkina Faso; Chad; Congo, Democratic Republic of; Congo, Republic of; Gambia; Mali; Mauritania; Niger; Nigeria; Senegal; Sudan;
K	Antigua & Barbuda; Bahamas; Barbados; Belize; Brazil; Colombia; Costa Rica; Cuba; Dominica; Dominican Republic; Ecuador; Grenada; Guyana; Jamaica; Saint Lucia; Suriname; Trinidad and Tobago; Venezuela
L	Brunei Darussalam; Fiji; Japan; Kiribati; Democratic People's Republic of Korea; Republic of Korea; Madagascar; Maldives; Papua New Guinea; Philippines; Solomon Islands; Vanuatu;
M	Argentina; Australia; Canada; Chile; New Zealand; United States; Uruguay;

The JECFA employed the 13 GEMS/Food Consumption Cluster Diets to make international estimates of dietary AFT exposure from all sources. These were estimated to range from 0.4–0.7 ng/kg bw per day (cluster K) to 3.0–3.7 ng/kg bw per day (cluster J), by assuming a body weight of 60 kg and using the lower-bound/upper-bound approach. The mean total dietary exposure to AFT from maize, groundnuts, oilseeds and cocoa products made the greatest contribution to total exposure in all cluster diets (Table 2).

Dietary AFB1 exposure ranged from 0.3–0.5 ng/kg bw per day to 2.3–2.8 ng/kg bw per day for the same clusters (Table 3)

Almonds, hazelnuts and pistachios

The mean contribution to dietary AFT exposure from consumption of almonds, hazelnuts, Brazil nuts and pistachios ranged from 0 ng/kg bw per day (clusters A, G, I and J; nut consumption reported as zero for these clusters) up to 0.8 ng/kg bw per day (clusters B and D). In five cluster diets (B, C, D, E and M), the contribution from almonds, Brazil nuts, hazelnuts and pistachios was higher than 5% of the overall dietary exposure to AFT (Table 4).

Pistachios were the main contributor to dietary AFT exposure from tree nuts in all five cluster diets, ranging from 0.2 to 0.8 ng/kg bw per day, equivalent to 7–45% of the total AFT from all sources (Table 4). Almonds, Brazil nuts and hazelnuts contributed up to 0.1 ng/kg bw per day in all Consumption Cluster Diets.

Foods other than tree nuts

In order to evaluate the relative contribution of tree nuts to the overall AFT exposure, the JECFA considered other foods known to contribute to the overall exposure to AFT in humans. Occurrence data and dietary exposures to AFT from these other foods were described. Food commodities included in the mean overall exposure were maize, groundnuts (i.e. peanuts) and other nuts (i.e. walnuts, cashews, chestnuts, macadamia nuts, pecans), dried fruits other than figs (apricots, plums, grapes, dates and others), spices, cocoa and cocoa products (cocoa mass, cocoa butter, cocoa powder), peanut butter, peanut cream, oilseeds and butter of Karité nut.

The majority of the data included in the estimation of dietary AFT exposure from other food sources came from the EU. The JECFA noted that the European data do not reflect the actual mean values in other world regions for some foods considered here, as the mean concentration of AFT in the EU takes into account fewer highly contaminated samples due to existing EU MLs compared with regions with higher MLs or lack of enforcement. The mean concentrations of AFB1 and AFT were less than 1 µg/kg for most foods, except spices, cocoa products, groundnuts and butter of Karité nut, where mean levels ranged between 2 and 4 µg/kg.

The JECFA noted that different concentrations in rice were reported in different regions (producing and non-producing countries), with mean AFT levels around 0.6–1.0 µg/kg in the EU, 0.2–1.2 µg/kg in the Republic of Korea and 0.1–0.2 µg/kg in Qatar, with no reports of detected levels in other regions, including Japan and Argentina. High AFT levels, such as those for peanuts or maize, have never been reported in rice; the highest reliably reported levels are less than 10 µg/kg. Because of uncertainties in the data, rice was not included in estimating overall dietary exposures to AFT for comparison with the contribution from almonds, Brazil nuts, hazelnuts, pistachios and dried figs. In regions where rice is a major component of the diet, any low levels of AFT in rice may lead to its being a major contributor to total dietary exposure to AFT, even though that exposure may be low when compared with other regions.

Table 2
Mean estimates of dietary exposure to AFB1 and AFT from all food sources for the 13 GEMS/Food Consumption Cluster Diets taking into consideration hypothetical ML scenarios for AFT (no MLs; 4, 8, 10, 15 and 20 µg/kg) in tree nuts and the contribution of tree nuts to total AFT dietary exposure

Scenario(a)		Mean dietary exposure (ng/kg bw per day) for the 13 GEMS/Food Consumption Cluster Diets												
		A	B	C	D	E	F	G	H	I	J	K	L	M
No ML	AFB1	0.9–1.2	1.7–2.3	1.1–1.7	1.2–1.4	1.3–1.7	0.6–0.8	1.0–1.1	1.0–1.9	1.1–1.8	2.3–2.8	0.3–0.5	0.6–0.9	1.3–1.8
	AFT	1.1–1.7	2.1–3.2	1.5–2.5	1.4–1.8	1.7–2.3	0.7–1.1	1.3–1.6	1.4–2.8	1.4–2.7	3.0–3.7	0.4–0.7	0.8–1.3	1.7–2.5
	All tree nuts (% AFT)	0.0	24.6	20.0	45.0	16.8	3.7	0.0	3.3	0.0	0.0	4.3	0.8	9.3
ML 20 µg/kg	AFB1	0.9–1.2	1.1–1.7	0.8–1.3	0.5–0.7	1.0–1.4	0.6–0.8	1.0–1.1	1.0–1.8	1.1–1.8	2.3–2.8	0.3–0.5	0.6–0.9	1.2–1.6
	AFT	1.1–1.7	1.5–2.5	1.1–2.0	0.7–1.1	1.3–2.0	0.7–1.1	1.3–1.6	1.3–2.7	1.4–2.7	3.0–3.7	0.4–0.7	0.8–1.3	1.5–2.3
	All tree nuts (% AFT)	0.0	4.7	2.6	6.3	3.2	1.6	0.0	0.3	0.0	0.0	0.6	0.3	1.1
ML 15 µg/kg	AFB1	0.9–1.2	1.1–1.7	0.7–1.3	0.5–0.7	1.0–1.4	0.6–0.8	1.0–1.1	1.0–1.8	1.1–1.8	2.3–2.8	0.3–0.5	0.6–0.9	1.2–1.6
	AFT	1.1–1.7	1.4–2.5	1.1–2.0	0.6–1.1	1.3–2.0	0.7–1.1	1.3–1.6	1.3–2.7	1.4–2.7	3.0–3.7	0.4–0.7	0.8–1.3	1.5–2.3
	All tree nuts (% AFT)	0.0	4.1	2.2	5.0	2.8	1.5	0.0	0.3	0.0	0.0	0.5	0.3	0.9
ML 10 µg/kg	AFB1	0.9–1.2	1.1–1.7	0.7–1.3	0.5–0.7	1.0–1.4	0.6–0.8	1.0–1.1	1.0–1.8	1.1–1.8	2.3–2.8	0.3–0.5	0.6–0.9	1.2–1.6
	AFT	1.1–1.7	1.4–2.5	1.0–2.0	0.6–1.1	1.3–2.0	0.7–1.1	1.3–1.6	1.3–2.7	1.4–2.7	3.0–3.7	0.4–0.7	0.8–1.3	1.5–2.3
	All tree nuts (% AFT)	0.0	3.3	1.7	3.6	2.3	1.4	0.0	0.2	0.0	0.0	0.4	0.2	0.7
ML 8 µg/kg	AFB1	0.9–1.2	1.1–1.7	0.7–1.3	0.5–0.7	1.0–1.4	0.6–0.8	1.0–1.1	1.0–1.8	1.1–1.8	2.3–2.8	0.3–0.5	0.6–0.9	1.2–1.6
	AFT	1.1–1.7	1.4–2.5	1.1–2.0	0.6–1.1	1.3–2.0	0.7–1.1	1.3–1.6	1.3–2.7	1.4–2.7	3.0–3.7	0.4–0.7	0.8–1.3	1.5–2.3
	All tree nuts (% AFT)	0.0	2.9	1.5	3.0	2.1	1.2	0.0	0.2	0.0	0.0	0.4	0.2	0.7
ML 4 µg/kg	AFB1	0.9–1.2	1.1–1.7	0.7–1.3	0.4–0.7	1.0–1.4	0.6–0.8	1.0–1.1	1.0–1.8	1.1–1.8	2.3–2.8	0.3–0.5	0.6–0.9	1.2–1.6
	AFT	1.1–1.7	1.4–2.5	1.1–2.0	0.6–1.1	1.3–2.0	0.7–1.1	1.3–1.6	1.3–2.7	1.4–2.7	3.0–3.7	0.4–0.7	0.8–1.3	1.5–2.3
	All tree nuts (% AFT)	0.0	2.3	1.1	1.9	1.7	1.1	0.0	0.1	0.0	0.0	0.4	0.2	0.5

(a) Lower- and upper-bound scenarios have been used in making the dietary exposure estimates for overall exposure and all tree nuts. The lower bound was calculated using 0 for non-detects or the LOD for trace values, whereas the upper bound was calculated using either the LOD or LOQ, as appropriate. “All tree nuts” includes dried figs, which contributed less than 0.3% of the AFT dietary exposure in all scenarios. % AFT is the contribution from almonds, Brazil nuts, hazelnuts, pistachios and dried figs to total AFT dietary exposure (upper-bound scenario only).

Table 3
Summary of the mean overall estimates of international dietary exposure to AFT from other contributing food sources (lower- and upper-bound scenarios) for the 13 GEMS/Food Consumption Cluster Diets and the corresponding exposure from each food commodity

		Dietary exposure to AFT (ng/kg bw per day) for the 13 GEMS/Food Consumption Cluster Diets												
		A	B	C	D	E	F	G	H	I	J	K	L	M
Overall exposure from other sources		1.1–1.7	1.3–2.4	1.0–2.0	0.6–1.0	1.3–1.9	0.7–1.1	1.3–1.6	1.3–2.7	1.4–2.7	3.0–3.7	0.4–0.7	0.7–1.3	1.5–2.2
Mean dietary exposure to AFT from individual food sources (a)	Maize	0.2–0.7	0.4–1.0	0.3–0.9	0.1–0.2	0.1–0.3	0.04–0.10	0.1–0.2	0.8–2.1	0.6–1.7	0.2–0.4	0.2–0.5	0.2–0.4	0.3–0.7
	Groundnuts	0.7–0.7	0.4–0.4	0.3–0.3	0.1–0.1	0.5–0.5	0.2–0.2	0.9–1.0	0.3–0.3	0.6–0.6	2.6–2.9	0.1–0.1	0.1–0.1	0.8–0.9
	Oilseeds	0.1–0.2	0.4–0.6	0.2–0.3	0.3–0.5	0.4–0.6	0.2–0.3	0.1–0.2	0.1–0.2	0.1–0.2	0.1–0.1	0.02–0.04	0.4–0.6	0.1–0.2
	Cocoa products	0.02–0.04	0.1–0.2	0.03–0.1	0.04–0.1	0.2–0.4	0.2–0.4	0.02–0.04	0.1–0.1	0.03–0.04	0.02–0.03	0.1–0.1	0.1–0.1	0.2–0.3
	Other nuts	0.0–0.0	0.04–0.1	0.0–0.0	0.0–0.01	0.01–0.02	0.0–0.0	0.01–0.02	0.01–0.01	0.0–0.0	0.0–0.0	0.0–0.0	0.02–0.03	0.01–0.02
	Dried fruits other than figs	0.0–0.01	0.02–0.1	0.1–0.3	0.02–0.1	0.01–0.03	0.01–0.03	0.0–0.01	0.0–0.0	0.0–0.0	0.01–0.04	0.0–0.0	0.0–0.01	0.01–0.04
	Butter of Karité nut	0.01–0.02	0.0–0.0	0.0–0.0	0.0–0.0	0.0–0.0	0.0–0.0	0.0–0.0	0.0–0.0	0.0–0.0	0.0–0.02	0.0–0.0	0.0–0.0	0.0–0.0
	Peanut oil	0.02–0.03	0.01–0.01	0.01–0.01	0.0–0.0	0.02–0.02	0.01–0.01	0.04–0.05	0.0–0.0	0.02–0.02	0.1–0.1	0.0–0.0	0.0–0.0	0.01–0.01
	Spices	0.07–0.08	0.03–0.03	0.07–0.07	0.02–0.03	0.1–0.1	0.03–0.03	0.1–0.1	0.1–0.1	0.04–0.04	0.04–0.04	0.01–0.01	0.02–0.02	0.1–0.1

(a) Lower- and upper-bound scenarios have been used in making the dietary exposure estimates for overall exposure and individual food sources. The lower bound was calculated using 0 for non-detects or the LOD for trace values, whereas the upper bound was calculated using either the LOD or LOQ, as appropriate.

Table 4
Mean estimates of dietary exposure to AFT from almonds, Brazil nuts, hazelnuts and pistachios for the 13 GEMS/Food Consumption Cluster Diets, taking into consideration the impact of different hypothetical ML scenarios for AFT (no MLs; 4 and 20 µg/kg) in tree nuts

		Dietary exposure to AFT (ng/kg bw per day) for the 13 GEMS/Food Consumption Cluster Diets												
		A	B	C	D	E	F	G	H	I	J	K	L	M
Overall exposure from other sources (a)		1.1–1.7	1.3–2.4	1.0–2.0	0.6–1.0	1.3–1.9	0.7–1.1	1.3–1.6	1.3–2.7	1.4–2.7	3.0–3.7	0.4–0.7	0.7–1.3	1.5–2.2
Scenario (b)														
No ML	All tree nuts	0.0–0.0	0.8–0.8	0.5–0.5	0.8–0.8	0.4–0.4	0.04–0.04	0.0–0.0	0.1–0.1	0.0–0.0	0.0–0.0	0.03–0.03	0.01–0.01	0.2–0.2
	Pistachios (% AFT)	0.0	20.1	18.4	44.8	12.0	0.0	0.0	3.2	0.0	0.0	0.0	0.0	7.4
	Other tree nuts (% AFT)	0.0	4.4	1.7	0.2	4.9	3.7	0.0	0.1	0.0	0.0	4.3	0.8	1.9
ML 20 µg/kg	All tree nuts	0.0–0.0	0.1–0.1	0.1–0.1	0.1–0.1	0.1–0.1	0.02–0.02	0.0–0.0	0.01–0.01	0.0–0.0	0.0–0.0	0.0–0.0	0.0–0.0	0.03–0.03
	Pistachios (% AFT)	0.0	2.0	1.8	6.1	1.1	0.0	0.0	0.3	0.0	0.0	0.0	0.0	0.6
	Other tree nuts (% AFT)	0.0	2.7	0.8	0.2	2.1	1.6	0.0	0.0	0.0	0.0	0.6	0.3	0.5
ML 4 µg/kg	All tree nuts	0.0–0.0	0.1–0.1	0.02–0.02	0.02–0.02	0.03–0.03	0.01–0.01	0.0–0.0	0.0–0.0	0.0–0.0	0.0–0.0	0.0–0.0	0.0–0.0	0.01–0.01
	Pistachios (% AFT)	0.0	0.6	0.5	1.8	0.3	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.2
	Other tree nuts (% AFT)	0.0	1.7	0.6	0.1	1.4	1.1	0.0	0.0	0.0	0.0	0.4	0.2	0.3

(a) Mean concentration as reported for other contributing food sources to the overall dietary exposure to AFT and the corresponding food consumption from the 13 GEMS/Food Consumption Cluster Diets.

(b) Lower- and upper-bound scenarios have been used in making the dietary exposure estimates for overall exposure and all tree nuts. The lower bound was calculated using 0 for non-detects or the LOD for trace values, whereas the upper bound was calculated using either the LOD or LOQ, as appropriate. “All tree nuts” includes dried figs, which contributed less than 0.3% of the AFT dietary exposure in all scenarios. % AFT is the contribution from almonds, Brazil nuts, hazelnuts, pistachios and dried figs to the total AFT dietary exposure (upper-bound scenario only).

II.1.2. Effect of hypothetical MLs in almonds, hazelnuts, pistachios on dietary exposure

The JECFA evaluated the impact on dietary exposure to AFT of setting hypothetical MLs of 4, 8, 10, 15 or 20 µg/kg for AFT in almonds, Brazil nuts, hazelnuts, pistachios and dried figs. For tree nuts other than pistachios, the contribution to total AFT dietary exposure is less than 5%, regardless of whether an ML is in place or not. This is explained by the fact that the main part of the dietary exposure to AFT comes from other food sources (Tables 2, 3 and 4).
Using the five cluster diets where almonds, Brazil nuts, hazelnuts, pistachios and dried figs contribute more than 5% to dietary AFT exposure (clusters B, C, D, E and M), and assuming a body weight of 60 kg, the JECFA estimated that an enforced ML of 20, 15, 10, 8 or 4 µg/kg results in dietary exposures to AFT ranging from 0.12, 0.10, 0.08, 0.07 and 0.06 ng/kg bw per day in the cluster with the highest exposure (D) to 0.03, 0.02, 0.02, 0.02 and 0.01 ng/kg bw per day in the cluster with the lowest exposure (M).

United Kingdom food consumption data for vegetarians and vegans showed that for high level consumers of almonds, Brazil nuts, hazelnuts and pistachios, enforcing an ML of 20 µg/kg reduces total AFT dietary exposure when compared with no ML. Setting a lower ML would have little impact compared with the ML of 20 µg/kg. The dietary exposure from tree nuts assuming no ML was estimated to be 5.8 ng/kg bw per day. The estimate with an ML of 20 µg/kg would be 0.5 ng/kg bw per day, and with an ML of 4 µg/kg would be 0.2 ng/kg bw per day.

In these analyses, the contribution from tree nuts to the total AFT dietary exposures in all five cluster diets, whatever the ML scenario (4, 8, 10, 15 or 20 µg/kg), will remain below 0.1 ng/kg bw per day, compared with <0.8 ng/kg bw per day for the scenario with no MLs. The highest decrease in AFT exposure results from the contribution from pistachios to total AFT dietary exposure when setting an ML at 20 µg/kg in comparison with no ML.

JECFA also noted that in all these different ML scenarios, dried figs were included (dietary exposures not shown in tables). However, the contribution of dried figs (<0.01 ng/kg bw per day) to total AFT dietary exposure estimates in all Consumption Cluster Diets, whatever the ML scenario, would be less than 0.3% of the overall dietary AFT exposure.
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JECFA noted the previous assessments of exposure to AFT made by JECFA in 1998 and EFSA in 2007. The estimates made at the 68th JECFA meeting for EU dietary exposures (0.7–2.5 ng/kg bw per day for European clusters B, E and F, with MLs from 4 to 20 µg/kg for tree nuts) were in the range of those reported in the EFSA opinion, where AFT exposures ranged from 1.0 to 2.5 ng/kg bw per day (with MLs from 4 to 10 µg/kg for tree nuts, and including high-level consumers of these nuts), compared with 0.8 ng/kg bw per day reported by JECFA in 1998 (with MLs from 10 to 20 µg/kg in groundnuts).In these estimates, groundnuts and maize were the main contributors to AFT exposure, ranging from 0.2 to 1.4 ng/kg bw per day at the current meeting, compared with 1.1–2.0 ng/kg bw per day in the 1998 JECFA evaluation and 0.03–1.0 ng/kg bw per day in the EFSA opinion.

II.1.3. Evaluation/conclusions from JECFA as regards hazelnuts, pistachios and almonds

JECFA noted that the majority of data included in the estimation of dietary AFT exposure from foods other than almonds, Brazil nuts, hazelnuts, pistachios and dried figs came from the EU and that these data do not reflect the actual mean values in other world regions. This probably results in an underestimate of dietary AFT exposure and overstates the relative contribution of dietary AFT exposure from tree nuts.

JECFA decided to base the assessment of the impact of different MLs for AFT on data provided by producing countries, noting that these better represent the materials in commerce and result in a robust estimate of dietary AFT exposure from tree nuts.

JECFA calculated that the consumption of almonds, Brazil nuts, hazelnuts, pistachios and dried figs contributes greater than 5% of the dietary AFT exposure in only five cluster diets (clusters B, C, D, E and M). If fully enforced, an ML at 20 µg/kg in almonds, Brazil nuts, hazelnuts, pistachios and dried figs would have an impact on the relative contribution to dietary AFT exposure only in these clusters, including high-level consumers of the tree nuts. This is due solely to the elevated AFT level in pistachios. For the tree nuts other than pistachios, the presence of an ML has no effect on dietary AFT exposure.

Moreover, JECFA concluded that enforcing an ML of 15, 10, 8 or 4 µg/kg would have little further impact on the overall dietary exposure to AFT in all five of the highest exposed population groups, compared with setting an ML of 20 µg/kg. The proportion of rejected samples from the world market would be between 1% (ML 20 µg/kg) and 3% (ML 4 µg/kg) for almonds, 1% and 7% for hazelnuts and 40% and 60% for pistachios, respectively.

The Committee noted that the reduction of dietary AFT exposure is an important public health goal, particularly in populations that consume high levels of any potentially AFT contaminated food.

II.2 EFSA assessment

II.2.1. Assessment of dietary exposure

Intakes from almonds, hazelnuts and pistachios have been assessed by the CONTAM panel from EFSA by the use of aggregated data from the GEMS/Food Consumption Cluster Diets database or national survey information at an individual level. Data from the GEMS/Food Consumption Cluster Diets database enabled extrapolation to other non-reporting Member States, whilst national survey information allowed a more accurate assessment and identification of groups of high level consumers. The exposure from food sources other than the three nuts could only be calculated by using the GEMS/Food Consumption Cluster Diets database because not all Member States provided data for all food groups of interest.

Body weights were not available for all countries, so it was decided to use 60 kg body weight for adults and 15 kg for children as standard values

In the EFSA opinion 4 scenarios were explored for the exposure assessment:
- scenario 1: average exposure
- scenario 2: high level exposure for almonds (other tree nuts average exposure)
- scenario 3: high level exposure for hazelnuts (other tree nuts average exposure)
- scenario 4: high level exposure for pistachios (other tree nuts average exposure)

From tables 5, 6 and 7 it can be concluded that high level consumers of pistachios were calculated to have the highest total dietary exposure to aflatoxins, with an upper bound estimate in the range of 1.1 to 2.3 ng/kg b.w. per day. The ranges of upper bound estimates for high level consumers of almonds were 1.1-2.1 ng/kg b.w. per day and for hazelnuts 1.1-2.0 ng/kg b.w. per day. The highest values were all from Spain with a survey methodology that was not fully appropriate for chronic exposure assessments. The second highest values were in the range of 1.2 to 1.3 ng/kg b.w. per day for all three types of nuts. No unique picture was apparent for children or for vegetarians.

Table 5: Scenario 1 “average exposure” to total aflatoxins in ng/kg b.w. per day truncating occurrence data at its current EU MLs for adults

Food	Values below LOD	Cluster B	Cluster E	Cluster F	Spain	Germany	Ireland	France	UK
Almonds	lower bound	0.006	0.003	0.002	0.002	0.001	0.000	0.002	0.002
	upper bound	0.013	0.007	0.005	0.003	0.003	0.001	0.003	0.003
Hazelnuts	lower bound	0.011	0.007	0.002	0.001	0.007	0.001	0.002	0.001
	upper bound	0.019	0.011	0.003	0.001	0.012	0.002	0.004	0.002
Pistachios	lower bound	0.002	0.001	0.000	0.001	0.001	0.000	0.000	0.000
	upper bound	0.005	0.002	0.001	0.002	0.001	0.001	0.001	0.001
Other food items	lower bound	0.819	0.546	0.348	0.819			0.546	
	upper bound	1.898	1.077	0.678	1.898			1.077	
Other nuts	lower bound	0.014	0.012	0.004	0.014			0.012	
	upper bound	0.042	0.034	0.010	0.042			0.034	
Maize	lower bound	0.301	0.080	0.030	0.301			0.080	
	upper bound	0.929	0.246	0.091	0.929			0.246	
Oilseeds	lower bound	0.445	0.416	0.272	0.445			0.416	
	upper bound	0.776	0.726	0.475	0.776			0.726	
Dried fruits	lower bound	0.042	0.012	0.026	0.042			0.012	
	upper bound	0.130	0.037	0.081	0.130			0.037	
Spices	lower bound	0.016	0.027	0.016	0.016			0.027	
	upper bound	0.021	0.034	0.021	0.021			0.034	
Total	**lower bound**	**0.838**	**0.557**	**0.352**	**0.822**	**0.556**	**0.548**	**0.550**	**0.549**
	upper bound	**1.934**	**1.097**	**0.687**	**1.904**	**1.094**	**1.080**	**1.085**	**1.083**

Table 6: Scenario 2-4 "high level exposure" to total aflatoxins in ng/kg b.w. per day truncating occurrence data at MLs of the current European legislation for adults

Food	**Values below LOD**	**Spain**	**Germany**	**Ireland**	**France**	**UK**
Scenario 2 "high level exposure almonds"						
Almonds	lower bound	0.066	0.016	0.018	0.011	0.025
	upper bound	0.146	0.036	0.039	0.025	0.055
Hazelnuts	*lower bound*	*0.001*	*0.007*	*0.001*	*0.002*	*0.001*
	upper bound	*0.001*	*0.012*	*0.002*	*0.004*	*0.002*
Pistachios	*lower bound*	*0.001*	*0.001*	*0.000*	*0.000*	*0.000*
	upper bound	*0.002*	*0.001*	*0.001*	*0.001*	*0.001*
Other food items	*lower bound*	*0.819*		*0.546*		
	upper bound	*1.898*		*1.077*		
Total	**lower bound**	**0.887**	**0.571**	**0.566**	**0.560**	**0.573**
	upper bound	**2.047**	**1.127**	**1.119**	**1.106**	**1.135**
Scenario 3 "high level exposure hazelnuts"						
Almonds	*lower bound*	*0.002*	*0.001*	*0.000*	*0.,002*	*0.002*
	upper bound	*0.003*	*0.003*	*0.001*	*0.003*	*0.003*
Hazelnuts	lower bound	0.081	0.074	0.064	0.037	0.028
	upper bound	0.139	0.126	0.109	0.063	0.048
Pistachios	*lower bound*	*0.001*	*0.001*	*0.000*	*0.000*	*0.000*
	upper bound	*0.002*	*0.001*	*0.001*	*0.001*	*0.001*
Other food items	*lower bound*	*0.819*		*0.546*		
	upper bound	*1.898*		*1.077*		
Total	**lower bound**	**0.903**	**0.622**	**0.611**	**0.585**	**0.576**
	upper bound	**2.042**	**1.207**	**1.187**	**1.144**	**1.129**
Scenario 4 "high level exposure pistachios"						
Almonds	*lower bound*	*0.002*	*0.001*	*0.000*	*0,002*	*0.002*
	upper bound	*0.003*	*0.003*	*0.001*	*0,003*	*0.003*
Hazelnuts	*lower bound*	*0.001*	*0.007*	*0.001*	*0,002*	*0.001*
	upper bound	*0.001*	*0.012*	*0.002*	*0,004*	*0.002*
Pistachios	lower bound	0.158	0.025	0.019	0,024	0.086
	upper bound	0.348	0.055	0.042	0,053	0.190
Other food items	*lower bound*	*0.819*		*0.546*		
	upper bound	*1.898*		*1.077*		
Total	**lower bound**	**0.980**	**0.580**	**0.567**	**0,574**	**0.635**
	upper bound	**2.251**	**1.147**	**1.121**	**1,137**	**1.272**

Table 7: Scenario 1 "average exposure" to total aflatoxins in ng/kg b.w. per day truncating occurrence data at MLs of the current European legislation - children and vegetarian in comparison to minimum and maximum adult exposure values

Food	Values below LOD	Adults			Children				Vegetarian
		Min	**Max**	**Spain**	**Germany**	**Ireland**	**France**	**UK**	**UK**
Almonds	lower bound	0.000	0.006	0.002	0.006	0.001	0.002	0.002	0.013
	upper bound	0.001	0.013	0.005	0.013	0.003	0.005	0.005	0.029
Hazelnuts	lower bound	0.001	0.011	0.002	0.027	0.002	0.017	0.004	0.009
	upper bound	0.001	0.019	0.004	0.046	0.004	0.028	0.007	0.016
Pistachios	lower bound	0.000	0.002	0.001	0.001	0.001	0.001	0.007	0.003
	upper bound	0.001	0.005	0.003	0.003	0.003	0.003	0.015	0.007
Other foods	lower bound	0.348	0.819	0.819	0.546				0.546
	upper bound	0.678	1.898	1.898	1.077				1.077
Other nuts	lower bound	0.004	0.014	0.014	0.012				0.012
	upper bound	0.010	0.042	0.042	0.034				0.034
Maize	lower bound	0.030	0.301	0.301	0.080				0.080
	upper bound	0.091	0.929	0.929	0.246				0.246
Oilseeds	lower bound	0.272	0.445	0.445	0.416				0.416
	upper bound	0.475	0.776	0.776	0.726				0.726
Dried fruits	lower bound	0.012	0.042	0.042	0.012				0.012
	upper bound	0.037	0.130	0.130	0.037				0.037
Spices	lower bound	0.016	0.027	0.016	0.027				0.027
	upper bound	0.021	0.034	0.021	0.034				0.034
Total	**lower bound**	**0.352**	**0.838**	**0.825**	**0.592**	**0.563**	**0.578**	**0.571**	**0.572**
	upper bound	**0.687**	**1.934**	**1.910**	**1.139**	**1.086**	**1.114**	**1.104**	**1.310**

II.2.2. Effect of hypothetical MLs in almonds, hazelnuts, pistachios on dietary exposure

- Impact on mean level of "compliant" batches

A change in the hypothetical maximum level for **almonds** from 4 to 8 or 10 µg/kg total aflatoxins would add another 1.1% or 1.6% of lots as compliant and would result in an increase in the mean level for total aflatoxins from 0.40 to 0.46 or 0.50 µg/kg for upper bound and from 0.18 to 0.24 or 0.29 µg/kg for lower bound values.

A change in the hypothetical maximum level for **hazelnuts** from 4 to 8 or 10 µg/kg total aflatoxins would add another 2.7% or 3.9% of lots as compliant and would result in an increase in the mean level for total aflatoxins from 0.53 to 0.68 or 0.78 µg/kg for upper bound and from 0.31 to 0.46 or 0.57 µg/kg for lower bound values.

A change in the hypothetical maximum level for **pistachios** from 4 to 8 or 10 µg/kg total aflatoxins would add another 2.6% or 3.4% of lots as compliant and would result in an increase in the mean level for total aflatoxins from 0.44 to 0.61 or 0.69 µg/kg for upper bound and from 0.20 to 0.37 or 0.46 µg/kg for lower bound values.

- Impact on exposure

The impact of changing regulatory limits for total aflatoxin in almonds, hazelnuts and pistachios have been evaluated by the EFSA CONTAM Panel for the EU consumers, including the different population sub-groups such as children, high level consumers and vegetarians. Increase in the exposures to total aflatoxin varies considerably depending on the group of population considered.

Hence for the average European consumer, raising the ML from 4 to 10 µg/kg for total aflatoxins in almonds, hazelnuts and pistachios would result in an increase in total dietary aflatoxin exposure of about 1%.

On the other hand, population groups with high nut consumption are exposed to higher levels of aflatoxins in all assessments. Different MLs for the three nut products could have a higher impact for some of these groups, with a potential maximum increase of up to 20% (from 0.98 to 1.19 ng/kg b.w. per day) when comparing the effect of an hypothetical ML of 4 µg/kg with an hypothetical ML of 10 µg/kg and strictly enforced. Assuming that nuts exceeding the maximum levels are occasionally eaten, the relative impact of increasing the limits for the three nuts would be numerically low, but the total long term average dietary aflatoxin exposures would be never-the-less higher.

Estimates of exposures for children are in the same range of exposures for adults. However, such estimates are severely affected by the very limited data available on children's dietary patterns and therefore the robustness of the results is partly compromised.

In the cases of high consumption patterns for one of the three nuts and mean occurrence levels aflatoxin exposure from nuts initially seemed to be low in relation to the aflatoxin exposure from other foods. The proportion of aflatoxin exposure from the three nuts increased in importance in some of the calculated scenarios particularly for some Member States.

However, it should be noted that the use of the mean is conservative compared to the median and the mean is more sensitive to changes in the ML.

A summary of the effect of different MLs on exposure for the 4 abovementioned exposure scenarios (1- average exposure, 2- high level exposure for almonds – 3- high level exposure for hazelnuts and 4 – high level exposure for pistachios) can be found in Table 8.

These estimates indicated that increasing the maximum levels for total aflatoxins from 4 to 8 or 10 µg/kg could increase total dietary exposure to aflatoxins by up to 20% in consumers with the highest level of consumption. If, as is expected, nuts exceeding the maximum levels are occasionally consumed, the total long term average dietary exposures might be higher, but the relative impact of raising the maximum level from 4 to 8 or 10 µg/kg in the three nuts would be less.

Table 8: Overview of maximal and minimal lower and upper bound exposure estimates in ng/kg b.w. per day.

Limit of truncation of occurrence data	Values below LOD	Scenario 1	Scenario 2	Scenario 3	Scenario 4
Minimal Case		Ireland	France	UK	Ireland
4	lower bound	0.548	0.560	0.576	0.567
	upper bound	1.080	1.106	1.129	1.121
8	lower bound	0.549	0.565	0.590	0.584
	upper bound	1.081	1.111	1.143	1.138
10	lower bound	0.550	0.569	0.601	0.593
	upper bound	1.082	1.114	1.153	1.146
Maximal Case		Spain	Spain	Spain	Spain
4	lower bound	0.822	0.887	0.903	0.980
	upper bound	1.904	2.047	2.042	2.251
8	lower bound	0.824	0.910	0.944	1.115
	upper bound	1.906	2.070	2.083	2.386
10	lower bound	0.825	0.928	0.973	1.187
	upper bound	1.907	2.085	2.110	2.450

II.2.3. Risk characterisation performed by EFSA as regards the consumption of almonds, hazelnuts and pistachios

The EFSA CONTAM Panel evaluated whether the increase in dietary exposure to aflatoxins, predicted to result from altered regulatory MLs for almonds, hazelnuts and pistachios, would result in an increased risk based on the cancer potency estimates for AFB1 identified by the JECFA[15]. Also, in line the opinions of the EFSA Scientific Committee[16] and of the JECFA[17] on substances that are genotoxic and carcinogenic, Margins of Exposure (MOEs) were calculated by dividing the BMDL values for AFB1 derived from animal (rat) carcinogenicity and human epidemiological data by the estimates of dietary exposure. The Panel derived MOEs from the lowest BMDL10 (10% extra cancer risk) value of 170 ng/kg b.w. per day

[15] FAO/WHO 1998. Evaluation of certain veterinary drug residues in food. Forty-seventh report of the joint FAO/WHO Expert Committee on Food Additives (JECFA). World Health Organ Tech.Rep.Ser. 876, 1-85
[16] EFSA 2005. Opinion of the Scientific Committee on a request from EFSA related to A Harmonised Approach for Risk Assessment of Substances Which are both Genotoxic and Carcinogenic. The EFSA Journal 282, 1-31.
[17] FAO/WHO. 2005. Evaluation of certain food additives. World Health Organ Tech.Rep.Ser. 928, 1-156.

derived from the animal data and the lowest BMDL10 value of 870 ng/kg b.w. per day or the lowest BMDL1 (1% extra cancer risk) value of 78 ng/kg b.w. per day derived from epidemiological data. The EFSA Scientific Committee proposed that a MOE of 10,000 or higher, based on a BMDL10 from an animal study, would be of low concern from a public health point of view. To date there have been no conclusions on the magnitude of an MOE based on human data that would be of low concern.

II.2.3.1. Calculations of MOEs for the average EU population

MOEs calculated on the basis of the BMDL values from the animal and human data are shown in Table 9. The MOE based on the animal BMDL10 indicate a potential concern regarding aflatoxin intakes in all regions of the EU, even taking into account the uncertainty with respect to the large number of samples with aflatoxins below the LOD. However, the BMDL10 and BMDL1 values calculated based on human data from studies of sensitive populations (men only) having a high prevalence of HBV infection suggest that humans may be less sensitive than the rat strain used to derive the animal BMDL10.

Table 9. Estimated MOEs in different EU regions (data truncated at a MLs of 4 µg/kg for almonds, hazelnuts and pistachios)

GEMS/Food consumption cluster diets[18]	Aflatoxins intake (ng/kg b.w. per day) [a]		MOE for animal BMDL10 [b]		MOE for human BMDL10 [c]		MOE for human BMDL1[d]	
	LB	UB	LB	UB	LB	UB	LB	UB
F	0.352	0.687	483	247	2472	1266	222	114
B	0.838	1.934	203	88	1038	450	93	40

[a] Based on population average consumption and mean occurrence data

[b] Rodent BMDL10 of 170 ng/kg b.w. per day divided by estimated lower bound-upper bound intake

[c] Human BMDL10 of 870 ng/kg b.w. per day, obtained from a study of a population (men only) with a high proportion of individuals being carriers of hepatitis B surface antigen and having a very high background incidence of hepatocellular carcinomas (app. 10%), divided by estimated lower bound-upper bound intake

[d] Human BMDL1 of 78 ng/kg b.w. per day, obtained from a study of a population (men only) with a high proportion of individuals being carriers of hepatitis B surface antigen and having a background incidence of hepatocellular carcinomas of <1%, divided by estimated lower bound-upper bound intake

LB = lower bound, UB = upper bound

[18] FAO/WHO. 2006. GEMS/Food Consumption Cluster Diets database. Available at. URL: http://www.who.int.foodsafety/chem/gems/en/index1.html.

II.2.3.2. Calculations of MOEs for the vulnerable groups

The highest estimated aflatoxin intakes were derived for high level consumers of pistachios. The CONTAM Panel used these intakes as a worst case in calculating MOEs (table 10). The MOEs are smaller than for the average population estimates in table 8, but show a minimal impact of changing the ML, regardless of whether the focus is on the lower bound or upper bound estimates.

Table 10. Estimated MOEs for adult high level consumers of pistachios based on exposure estimates at different MLs for almonds, hazelnuts and pistachios

Maximum total aflatoxin level (microg/kg)	Aflatoxin intake (ng/kg b.w.per day) [a]		MOE for animal BMDL10[b]		MOE for human BMDL10 [c]		MOE for human BMDL1[d]	
	LB	UB	LB	UB	LB	UB	LB	UB
4	0.980	2.251	173	76	888	386	80	35
8	1.115	2.386	152	71	780	365	70	33
10	1.187	2.450	143	69	733	355	66	32

[a] Based on high level consumer consumption and mean occurrence data
[b] Rodent BMDL10 of 170 ng/kg b.w. per day divided by estimated lower bound-upper bound intake
[c] Human BMDL10 of 870 ng/kg b.w. per day, obtained from a study of a population (men only) with a high proportion of individuals being carriers of hepatitis B surface antigen and having a very high background incidence of hepatocellular carcinomas (app. 10%), divided by estimated lower bound-upper bound intake
[d] Human BMDL1 of 78 ng/kg b.w. per day, obtained from a study of a population (men only) with a high proportion of individuals being carriers of hepatitis B surface antigen and having a background incidence of hepatocellular carcinomas of <1%, divided by estimated lower bound-upper bound intake
LB = lower bound, UB = upper bound

II.2.4. Overall evaluation/conclusions from the CONTAM panel of EFSA

The EFSA CONTAM Panel's calculated margins of exposure (MOEs) for all estimated intakes compared with the 95% lower confidence limit of the benchmark dose for a 10% increase in cancer incidence (BMDL10) based on animal data indicated a potential concern for human health.

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The EFSA 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 MOEs.

The EFSA CONTAM Panel concluded that exposure to aflatoxin 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 and reducing exposure from food sources other than almonds, hazelnuts and pistachios.

II.3. Other provided information as regards consumption of almonds, hazelnuts and pistachio nuts and the resulting exposure to aflatoxins

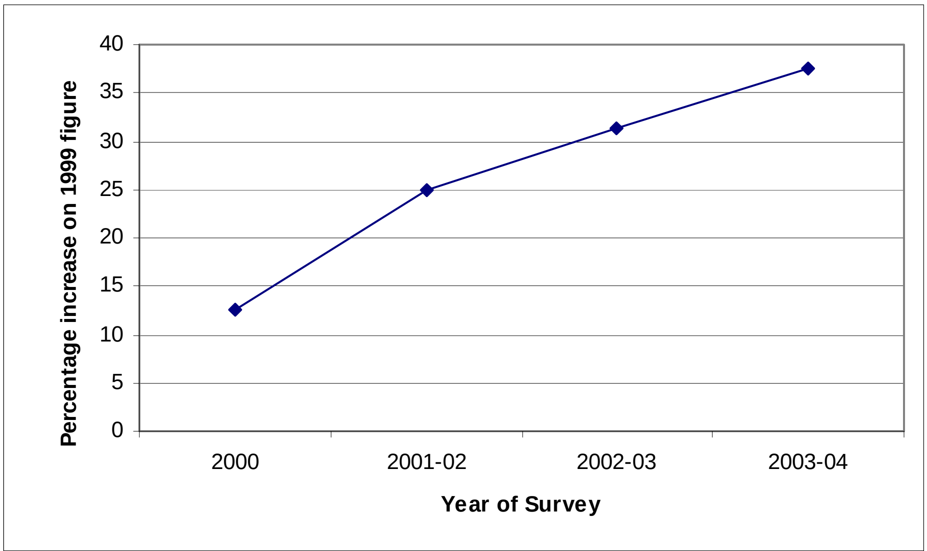
II.3.1 Consumption of tree nuts (information provided by UK)

Recent emphasis on healthy eating has seen a marked increase in sales of nut varieties by up to 70% in the past year as consumers opt for dried fruit, nuts and cereal bars over potato crisp snacks[19]. Numerous studies in recent years have reported that almonds, hazelnuts, macadamia nuts, peanuts, pecans, pistachios and walnuts significantly reduce cardiovascular disease risk factors and articles in the popular press in the UK regularly pick up on this. In July 2003, the US Food and Drug Administration (FDA) approved the first qualified health claim for conventional food, saying: "Scientific evidence suggests but does not prove that eating 1.5 ounces (42g) per day of most nuts, such as almonds, as part of a diet low in saturated fat and cholesterol may reduce the risk of heart disease".

A leading supermarket chain reported an increase in demand for nuts of 81% between June 2004 and June 2005. Individual increases were: almonds (91%), hazelnuts (46%) and pistachios (36%)[20]. This finding was supported by market analysis conducted in 2006 by MINTEL showing 50% growth since 2001 in the nuts, seeds and dried fruit market with a 99% increase in premium nuts, which includes almonds[21]. Data from MINTEL has not been used to estimate dietary exposure.

The increase in nut consumption can be demonstrated further by a UK Survey, which is derived from both household and eating-out food and drink.
The results show an increase in nuts purchased per person per week over a 5-year period ending March 2004, as indicated in Figure 1.

Figure 1. Percentage increase in average purchases in UK per person per week of nuts, edible seeds & peanut butter relative to 1999 figures.



[19] Curtis, P.; The Guardian; Crisp sales down as snackers choose health; June, 2005. Retrieved from http://www.guardian.co.uk
[20] Barnett, L; The Press Association. *Nation Goes Nuts for Nuts*. June, 2005
[21] MINTEL Report. Nuts, seeds and dried fruit – UK (2006).

UK consumption data (2006 survey of vegetarians and vegans)

	Adults 2006				Children 2006			
	Pop.	Consumers			Pop.	Consumers		
	Mean	Mean	97.5th % ile	Max	Mean	Mean	97.5th %ile	Max
Almonds	4.74	7.49	39.18	178	0.19	1.22	8.26	25
Hazelnuts	1.73	4.16	25	30	0.22	1.83	9.86	25
Pistachios	1.09	1.94	16.53	28	0.14	0.65	4.13	4

These figures do not include the contribution from recipes containing nuts. Consumption from recipes is expected to be significant for vegetarians and vegans, as this group of the population relies on nuts and nut products such as nut cutlets to ensure protein intake.

This data was collected in order to fulfil a call for data on nut consumption from the European Commission in 2006, the UK Food Standards Agency commissioned a survey on nut consumption by children aged 4 to 14 years and also vegetarians and vegans. Children were chosen as, owing to their body weight to food consumption ratio, they are considered to be at more risk from contaminants. Vegans and vegetarians were expected to be high consumers of nuts and therefore likely to be exposed to higher levels of aflatoxins. As vegetarians and vegans are also likely to consume higher levels of maize and seeds, in addition to nuts, information on the type, quantity and frequency of seed and maize products was also requested.

II.3.2 Consumption of tree nuts (information provided by INC)

MAJOR CONSUMING COUNTRIES, 2006	Production* (MT)	Imports ** (MT)	Exports** (MT)	Total supply for consump.	Population (1000)	Consumption/cap/kg/ year	Consumption/cap only 25% of population	Consumption/cap only 33% of population	Consumption/cap only 40% of population
ALMONDS (Sh)									
Belgium		10.658	5.668	4.990	10.446	0,478	1,911	1,433	1,194
France		27.531	6.526	21.005	63.588	0,330	1,321	0,991	0,826
Germany* **		71.323	6.541	64.782	82.422	0,786	3,144	2,358	1,965
Italy* **	12.000	29.917	7.270	34.647	58.462	0,593	2,371	1,778	1,482
Netherlands		16.793	6.639	10.154	16.407	0,619	2,476	1,857	1,547
Spain* **	60.000	55.676	49.633	66.043	45.061	1,466	5,863	4,397	3,664
United Kingdom		12.583	1.951	10.632	60.776	0,175	0,700	0,525	0,437
TOTAL	**72.000**	**224.481**	**84.228**	**212.253**	**337.162**	**0,630**	**2,518**	**1,889**	**1,574**
HAZELNUTS (Sh)									
Belgium** **		12.334	226	12.108	10.446	1,159	4,636	3,477	2,898
France		7.520	986	6.534	63.588	0,103	0,411	0,308	0,257
Germany** **		42.121	3.398	38.723	82.422	0,470	1,879	1,409	1,175
Italy** **	65.000	36.306	7.364	93.942	58.462	1,607	6,428	4,821	4,017
Netherlands		2.582	2.467	115	16.407	0,007	0,028	0,021	0,018
Spain	14.000	3.966	2.114	15.852	45.061	0,352	1,407	1,055	0,879
United Kingdom		2.247	484	1.763	60.776	0,029	0,116	0,087	0,073
TOTAL	**79.000**	**107.076**	**17.039**	**169.037**	**337.162**	**0,501**	**2,005**	**1,504**	**1,253**
PISTACHIOS									
Belgium		4.646	3.571	1.075	10.446	0,103	0,412	0,309	0,257
France		9.966	542	9.424	63.588	0,148	0,593	0,445	0,371
Germany		32.177	19.029	13.148	82.422	0,160	0,638	0,479	0,399
Italy	3.000	12.412	2.969	12.443	58.462	0,213	0,851	0,639	0,532
Netherlands		13.482	10.911	2.571	16.407	0,157	0,627	0,470	0,392
Spain		12.569	1.318	11.251	45.061	0,250	0,999	0,749	0,624
United Kingdom		14.305	104	14.201	60.776	0,234	0,935	0,701	0,584
TOTAL	**3.000**	**99.557**	**38.444**	**64.113**	**337.162**	**0,190**	**0,761**	**0,570**	**0,475**

MAJOR CONSUMING COUNTRIES, 2006	Production* (MT)	Imports ** (MT)	Exports** (MT)	Total supply for consump.	Population (1000)	Consumption/cap/kg/year	Consumption/cap only 25% of population	Consumption/cap only 33% of population	Consumption/cap only 40% of population
BRAZIL NUTS									
Belgium		403	398	5	10.446	0,000	0,002	0,001	0,001
France		362	17	345	63.588	0,005	0,022	0,016	0,014
Germany		2.424	281	2.143	82.422	0,026	0,104	0,078	0,065
Italy		1.107	498	609	58.462	0,010	0,042	0,031	0,026
Netherlands		1.319	788	531	16.407	0,032	0,129	0,097	0,081
Spain		486	10	476	45.061	0,011	0,042	0,032	0,026
United Kingdom		6.568	539	6.029	60.776	0,099	0,397	0,298	0,248
TOTAL	**0**	**12.669**	**2.531**	**10.138**	**337.162**	**0,030**	**0,120**	**0,090**	**0,075**

* Source: INC

** Source: FAO

***: Large manufacturers of marzipan and turron to be exported.
****: Large manufacturers of hazelnuts cream to be exported.

Total consumption/capita of the largest consuming countries

	Produc.* (MT)	Imports ** (MT)	Exports** (MT)	Total supply for consump.	Consumption /cap/gr/year	Consumption /cap/gr/day	Consumption/cap only 25% of population	Consumption/cap only 33% of population	Consumption/cap only 40% of population
Almonds (Sh)	72.000	224.481	84.228	212.253	630	1,725	6,899	5,174	4,312
Hazelnuts (Sh)	79.000	107.076	17.039	169.037	501	1,374	5,494	4,121	3,434
Pistachios	3.000	99.557	38.444	64.113	190	0,521	2,084	1,563	1,302
Brazil nuts	0	12.669	2.531	10.138	30	0,082	0,330	0,247	0,206
TOTAL	**154.000**	**443.783**	**142.242**	**455.541**	**1351**	**3,702**	**14,807**	**11,105**	**9,254**

* Source: INC

** Source: FAO

II.3.3. Explanation on differences on consumption provided by UK and INC

As can be observed, consumption values found by the INC for all three nuts are low compared to those obtained from the UK data. This can be attributed to the fact the UK data is from a consumption survey while the INC data has been derived from an estimation of the trade versus percentage of the population which may or may not consume nuts.

III. EFFECTS OF CODES OF PRACTICE

III.1 Information provided by INC

Industry efforts to minimize aflatoxin contamination have been sustained in the last 15 years through supporting basic and agronomic research on the growth of the mould and production of the mycotoxin as well as improving GAP and GMP. The INC has been working in direct collaboration with international and national bodies, organizations, institutions and laboratories. Competence and commitment in this area is amply demonstrated by the involvement of the INC in forums on regulatory issues and continued support to scientific progress.

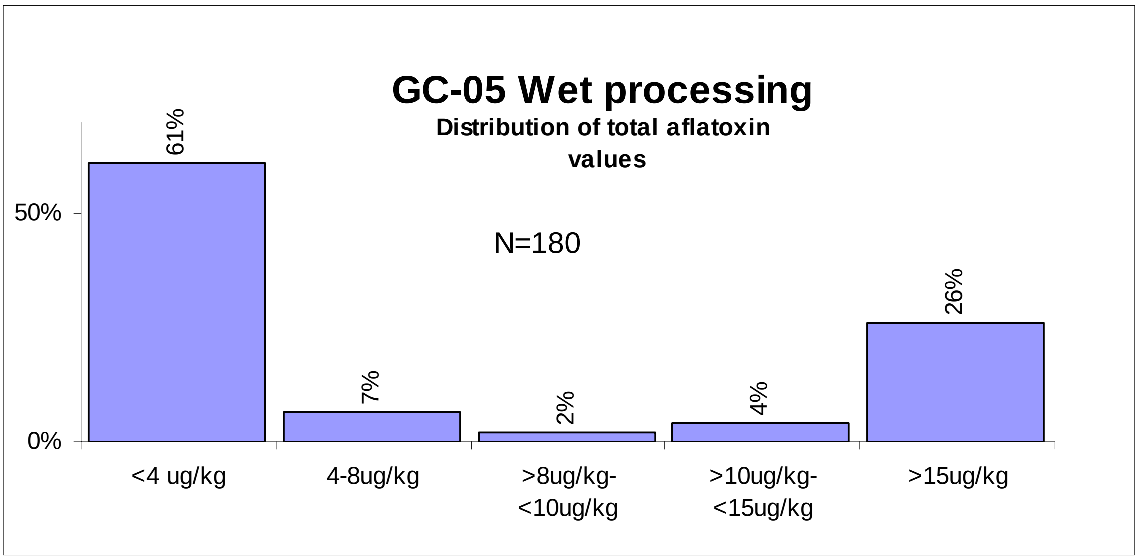
World production of almonds, hazelnuts and pistachios is concentrated in five countries (USA, Spain, Italy, Turkey and Iran) which produce:
88% of almonds
94% of hazelnuts
74% of pistachios

Contamination levels of nuts in the field have been found to be variable depending on meteorological conditions and geography. Good agricultural practices applied in producing countries aim to reduce the occurrence of the mould in the orchard and avoid the conditions favourable to their production of the mycotoxin. Research shows that contamination in the field is widespread and industry efforts in the export country, using the most thorough sorting technologies to eliminate contaminated nuts, are insufficient to reduce contamination to consistently reach the lowest limits set by certain import countries.

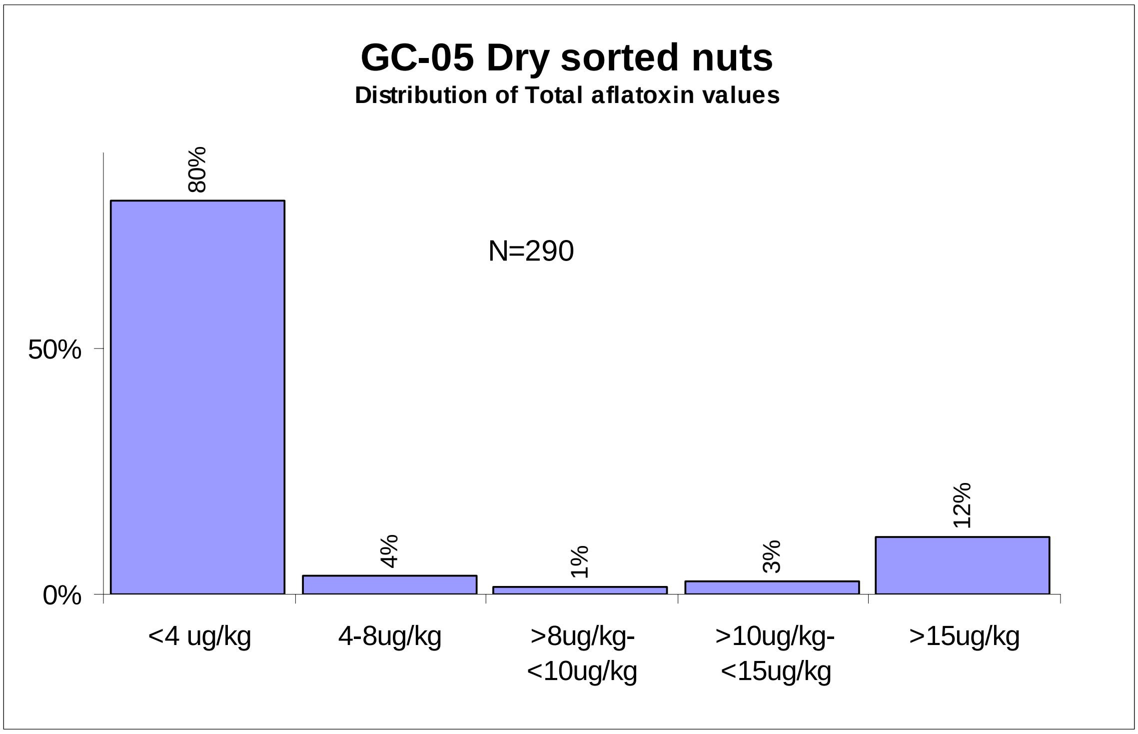
The INC through its Centre of excellence has supported a number of research projects (Green Corridor in Iran, Hazelnuts in Turkey, The SDTF-SafeNut Project for Brazil nuts in Brazil) with the objective to better understand the conditions leading to contamination and the means to reduce it.

In particular the Green Corridor work illustrates how challenging the task of the sheller/producer is in light of the level of contamination in the field and how challenging the reduction in Aflatoxin contamination can be as shown by the results obtained after applying Good Manufacturing Practices and expensive sorting processes.

The Green Corridor Project (cf. also information provided by Iran under III.3) is an extensive project has been implemented in Iran. The program involves closely monitored agricultural practices, aflatoxin sampling and analysis at several points in the processing stream. The project identified that one of the key vectors for aflatoxin contamination is field infestation and insect vectorial propagation. Of particular importance is the fact that consignments shipped under the Green Corridor Project were rejected in Europe at a rate of 9% as compared to non-Green Corridor pistachios, which were rejected at a rate of 25%. This demonstrates that even with the most extensive of control measures, there is still a potential for aflatoxin rejections on arrival in Europe. On the other hand, with the application of good agricultural practices (GAP) and good manufacturing practices (GMP) a significant decrease of the of the rejection rate has been obtained which is a clear proff of the effectiveness of GAP and GMP to reduce aflatoxin contamination.



Samples taken in the wet processing phase include steps from arrival to the terminal and hulling, flotation tank and drying phases all occurring within hours of harvest. At this stage 39% of samples have Aflatoxin values that exceed existing 4ug/kg total Aflatoxin values. This shows how extensive the Aflatoxin contamination is in the environment.



Samples taken in the dry processing phase have undergone multiple mechanical and manual sorting steps in preparation for export to markets with low Aflatoxin levels. At this stage 20% of samples still have Aflatoxin values that exceed existing 4ug/kg total Aflatoxin values. One can conclude that despite industry efforts samples with Aflatoxin values >4ug/kg can only be reduced from 39% in the field to 20% after careful sorting in preparation for export.

Another example is illustrated in the Hazelnut industry where processors have reported Aflatoxin levels in incoming raw material from the field with between 10% and 20% of lots exceeding a 4ug/kg total Aflatoxin level. Turkish hazelnut exporters contributing to the INC study have carefully sorted, selected and analyzed lots prepared for export to markets with <4ug/kg total Aflatoxin limits and cleared them for those markets. Despite these efforts the rejection rates for Turkish hazelnuts from EU authorities remain at a high 9%.

Imports into countries with a limit of 4ppb total have been problematic and despite all the industry efforts, at production stage we could have rejection levels in the last 9 months still estimated about

- 9% for hazelnut
- 6,5 % for almonds
- 10% in pistachios

The continuing and unavoidable rejections are due to factors that cannot be controlled such as the adverse climatic conditions that exert direct or indirect effects on the toxigenic fungi, or substrate suitability and consequent Aflatoxin formation. Factors such as variety, fungal and insect load are also important. Current conditions and limits have tremendously increased the risks at producer level and consequently have socio-economic impacts on distributional patterns.

The top 5 producing countries, despite applying the most up to date and efficient agricultural practices and good manufacturing processes, are unable to meet the most stringent regulatory levels (4 ppb aflatoxin total).
This result is due to factors that cannot be controlled such as the adverse climatic conditions that exert direct or indirect effects on the toxigenic fungi, or substrate suitability and consequent Aflatoxin formation.

The hazelnut crop in the Black Sea Region of Turkey for example, has been intensively studied for the last 4 years and, despite excellent meteorological conditions during the warm and dry August 2006 harvest, Aflatoxin levels are higher than those found in the wet September 2006 harvest.

In the U.S. efforts of identifying where contamination can occur in the field confirm a correlation with insect damage. But eliminating this vector is not possible; it can only be reduced with insect control throughout the production area thanks to individual efforts aimed at eradicating the pest at regional level at origin. Evaluation of aflatoxin control results in the US have shown higher association with insect damage, but even high quality product without insect damage has shown positive results for aflatoxin.

All this makes it impossible to reliably achieve contamination levels below 10 ppb.
The implications of a low regulatory limit for other producing countries, those with less sophisticated means than the top 5 producing countries, are economically ruinous and eliminate them from the market.

III.2. Information provided by Turkey

Turkey, the largest country in the hazelnut production and one of the leading country in the pistachios production, has applied its code of practices, developed as country based and compatible with Codex Standard *CAC/RCP 59 -2005* in order to reduce and prevent aflatoxin formation in the tree nuts since 2001. Especially, the aflatoxin level of hazelnut and pistachios has been reduced to considerable level since then.

The data, reflecting this progress, was already provided in the Codex document, *CX/FAC 5/37/22-Add. 1* in 2005 (extract from this document is provided hereafter)

The results of statistical evaluation of aflatoxin analysis conducted in laboratories of the Ministry of Agriculture and Rural Affairs on hazelnuts, pistachios and almonds over the last six years are shown in Table 7, Table 8 and Table 9.

Table 7. The Results Of Statistical Evaluation On Aflatoxin In Hazelnut And Its Products In Turkey (The samples analyzed for inspection, export, reference, monitoring projects and upon request were included in the evaluation)

HAZELNUT and ITS PRODUCTS	1998-1999		2000		2001		2002 (10 months)		5 YEARS (1998-2002)		2003	
	B_1 (Ppb)	Total (PPb)	B_1 (PPb)	Total (PPb)	B_1 (PPb)	Total (PPb)	B_1 (PPb)	Total (PPb)	B_1 (PPb)	Total (PPb)	B_1 (PPb)	Total (PPb)
N	351	351	243	243	1572	1572	11636	11636	13802	13802	15454	15454
Minimum	0	0	0	0	0	0	0	0	0	0	0	0
Maximum	3,2	11,2	26,4	61,1	149,9	210,4	138,2	141,2	149,9	210,4	441	451,07
Mean	0,018	0,055	0,315	0,705	0,520	1,154	0,445	0,911	0,440	0,913	0,18	0,31
Median	0	0	0	0	0	0	0	0	0	0	0	0
Standard Deviation	0,196	0,659	1,882	4,655	5,061	8,130	3,026	4,943	3,272	5,342	4,813	5,301
% 20^{th} value	0	0	0	0	0	0	0	0	0	0	0	0
% 80^{th} value	0	0	0	0	0,23	0,63	0,30	0,70	0,3	0,60	0	0
% 90^{th} value	0	0	0,63	0,85	1,25	2,5	0,98	1,94	1,00	1,98	0,30	0,33
% 95^{th} value	0	0	1,38	2,05	1,70	3,37	1,60	3,40	1,60	3,30	0,60	1,18
% 99^{th} value	0,75	1,60	8,13	25,41	4,24	21,02	6,58	14,69	6,20	15,40	1,90	4

N : Number of analyses
0 : Not detected
Not : The extraneous values were included in the statistical evaluation.
Total: $B_1+B_2+G_1+G_2$

Analysis methods:

1998-1999	TLC
2000	Mostly TLC and some HPLC
2001	Mostly HPLC and some TLC
2002-	HPLC

Table 8. The Results Of Statistical Evaluation On Aflatoxin In Pistachio And Its Products In Turkey (The samples analyzed for inspection, export, reference, monitoring projects and upon request were included in the evaluation)

PISHTACHIO and ITS PRODUCTS	1998-1999		2000		2001		2002 (10 months)		5 YEARS (1998-2002)		2003	
	B_1 (PPb)	Total (PPb)	B_1 (PPb)	Total (PPb)	B_1 (PPb)	Total (PPb)	B_1 (PPb)	Total (PPb)	B_1 (ppb)	Total (PPb)	B_1 (PPb)	Total (PPb)
N	37	37	35	35	94	94	357	357	523	523	488	488
Minimum	0	0	0	0	0	0	0	0	0	0	0	0
Maximum	113	120,8	35	37	93,6	116,4	62	64,4	113	120,8	450,23	460
Mean	3,786	4,078	1	1,057	1,812	2,321	1,054	1,225	1,380	1,613	4,84	5,60
Median	0	0	0	0	0	0	0	0	0	0	0	0
Standard Deviation	18,312	19,559	5,831	6,164	1 0,240	12,640	5,203	5,885	7,990	9,089	36,022	37,848
% 20th value	0	0	0	0	0	0	0	0	0	0	0	0
% 80th value	0	0,8	0	0	0	0	0	0	0	0	0	0
% 90th value	3,68	3,92	0	0	0	0,08	1,60	1,70	1,39	1,68	2,48	4,79
% 95th value	7,04	7,04	0	0	7,76	11,37	4,47	5,05	4,87	6,49	10,15	12,51
% 99th value	85,64	90,63	35	36,32	93,63	95,57	31,17	36,18	34,43	36,87	82,56	88,69

N : Number of analyses

0 : Not detected

Not : The extraneous values were included in the statistical evaluation.

Total: B_1,+B_2+G_1+G_2

Analysis methods:	1998-1999	TLC
	2000	Mostly TLC and some HPLC
	2001	Mostly HPLC and some TLC
	2002-	HPLC

Table 9. The Results Of Statistical Evaluation On Aflatoxin In Almond And Its Products In Turkey (The samples analyzed for inspection, export, reference, monitoring projects and upon request were included in the evaluation)

ALMOND and ITS PRODUCTS	2003	
	B_1 (ppb)	Total (ppb)
N	21	21
Minimum	0	0
Maximum	1,01	1,27
Mean	0,05	0,06
Median	0	0
Standard Deviation	0,215	0,270
% 20th value	0	0
% 80th value	0	0
% 90th value	0	0
% 95th value	0	0
% 99th value	0,81	1,02

N : Number of analyses
0 : Not detected
Not : The extraneous values were included in the statistical evaluation.
Total : $B_1+B_2+G_1+G_2$

Analysis methods:	
1998-1999	TLC
2000	Mostly TLC and some HPLC
2001	Mostly HPLC and some TLC
2002-	HPLC

But sometimes application of code of practice is not enough to overcome the problem of aflatoxin totally. As it is known aflatoxin formation can occur at every stage of relevant foodstuffs from farm to fork. Especially, climatic condition is the most important factor concerning aflatoxin formation. So, merely application of the code of practice is not enough to prevent aflatoxin formation.

III.3. Information provided by Iran

The Green Corridor 2005 Codes of Practice, which have been drawn up after careful review of the most recently available credible scientific literature on the subject of controlling aflatoxin contamination in tree nuts, including the International Code of Hygienic Practice for Tree Nuts (CAC/RCP 6-1972, Codex Alimentarius Volume 5A-1994).

The Green Corridor 2005 Codes of Practice were implemented during a high contamination risk season in Iran, the 2005 crop year, yielding a success rate of 97% for commercial lot compatibility with the 4 ppb (total) aflatoxins, as well as 2 ppb aflatoxin B1 maximum levels set by the EU, given that all lots were tested at EU border.
Similar rates of compatibility can be expected to be achievable for the 2006 crop year, given proper implementation of the same code of practice by Green Corridor 2006 participants. So it is clear that at least on a relatively small scale, with the proper organizational structures in place, compliance with strict maximum levels can be achieved, even in challenging operating environments such as those to be found in some developing countries.
It was stressed that this is a pilot project at a small scale and that the achieved positive results need to be assessed further. An introduction of the Green Corridor at a larger scale will require significant changes to current practices. In Iran the most effective way to reduce the aflatoxin content was the introduction of early harvest and to keep the harvesting period and drying time as short as possible, which required employing significantly more human resources at harvest time. The success of this strategy at larger scale is limited by the availability of sufficient human resources and the increased cost related to the drying process and necessary storage capacity in good conditions. Also the early harvest has a negative influence on the production yield.

IV. TERMINOLOGY OF "READY-TO-EAT" AND "FOR FURTHER PROCESSING"

IV. 1. General terminology

"Consumer-ready nuts" or "ready-to-eat nuts" – nuts, which are not intended to undergo **an additional processing/treatment that has proven to reduce levels of aflatoxins. This applies also to nuts used as ingredient in other foods.**

"Nuts for further processing" – nuts, which are intended to undergo an additional processing/treatment **that has proven to reduce levels of aflatoxins** before being used as ingredient in foodstuffs, otherwise processed or offered for human consumption

Processes that have been proven to reduce aflatoxin are shelling, blanching, and sorting by size, specific gravity, colour (damage),

Processes that haven't been proven to reduce aflatoxin are packaging, foreign material removal, drying, salting, flavouring and roasting.

IV. 2. Specific terminology as regards pistachio nuts

a) In-Shell Pistachio Nuts:

Refers to the pistachio nuts after harvesting, hulling, washing and drying have been completed; and the moisture content has been reduced to a maximum of 6 %.

b) Pistachio Kernel:

Refers to a pistachio in which the hull and shell have been removed.

c) Pistachio Nuts Skins:

The pistachio nut has three types of skins (protective tissues), which surround and protect the embryo from the outside environment, namely:

- First skin: (Hull, Epicarp)
  Refers to the soft outer layer of skin.

- Second skin (Shell, Mesocarp)
  Refers to the hard textured (bonny) tissue layer which underlies the first skin.

- Third skin (Seed Coat, Endocarp)
  Refers to the thin innermost tissue layer that surrounds the kernel.

d) Pistachio Nut Shell Colour:

Refers to the natural colour of the shell. Shell colour primarily depends on the pistachio variety, and post-harvest processes. The natural shell colour may vary from light to dark cream. In certain varieties of pistachio, light grey lines are seen on the shell surface.

e) Stained Pistachio Nuts:

Refers to a discoloration of the natural nut shell color that covers over ¼ of total shell surface, or ½ of one shell half.
There is a specific stain indicating ealry split. Growth splits give a different stain pattern.

f) Deformed Pistachio Nuts:

Refers to pistachio nuts which have malformed or wrinkled hard shells that do not have the natural smooth shape; Or nuts with cracks on their shells that occur outside of the shell's normal suture line.

g) Adhering Hull Pistachio Nut:

Refers to a pistachio nut whose shell is covered on at least ¼ of its surface with the dried remains of the hull.

h) Damaged Pistachio Kernels:

Refers to pistachio kernels that have been either cut, broken, or physically damaged in an observable manner.

i) Shriveled Pistachio Kernels:

Refers to pistachio kernels that have not developed fully.

j) Pest Damaged Pistachio Nuts:

Refers to damage on the surface of the nut kernel which is caused by pests, and that is visible to the naked eye without the removal of the seed coat; the effect of such damage usually forms a cavity on the surface of the kernel.

k) Mouldy Pistachio Nuts:

Refers to pistachio nuts that are visibly contaminated by fungi.

l) Nut Particles and Dust:

Refers to particulate matter consisting of small pieces of the nut shell and seed coat which are produced as a result of erosive contact during nut processing, and which will pass through a 2 mm sieve.

m) Closed In-Shell Pistachio Nuts:

Refers to the pistachio nuts, where the shells have not opened naturally, nor mechanically along their natural suture lines. If there is an opening along the natural suture line, the length of that opening should be less than ¼ of the circumstance of the nut, so that a gauge of 0.4 mm thickness and 6 mm width will not pass through it easily.

n) Sorting by Size:

Refers to the process which removes very small pistachio nuts from the product stream during processing.

- Very Small Long Variety Pistachio Nuts
Refers to the long variety pistachio nuts which will pass through a 10 mm sieve.

- Very Small Round Variety Pistachio Nuts
Refers to the round variety pistachio nuts which will pass through an 11 and 13 mm sieve for Round and Jumbo nuts respectively.

o) Processing:

Is referred to the actions taken to ensure the following non-conforming types of nuts and/or items are removed from the product stream: stained nuts, deformed nuts, adhering hull nuts, damaged pistachio kernels, shriveled pistachio kernels, mouldy nuts, pest damaged nuts, nut particles and dust, closed in-shell nuts and in addition sorting by size and salting & roasting.

p) Ready to Eat Open In-Shell Pistachio Nuts:

Refers to the pistachio nuts for which all of the processes listed in definition number (o) have been completed (with the exception of sorting by size, roasting and salting as these processes have not been proven to reduce the aflatoxin content).

q) In-Shell Pistachio Nuts for Further Processing:

Refers to the pistachio nuts for which one or more of the processes listed in definition number (o) have not been completed (with the exception of sorting by size, roasting and salting as these processes have not been proven to reduce the aflatoxin content).

r) Early split

Refers to the atypical situation whereby pistachio nuts rupture both their hulls and shells in the orchard, exposing the kernel to invasion by fungi and insects while pistachio nuts typically split their shells, but do not split their surrounding hull and have an intact hull until after harvest.

V. ECONOMIC IMPACT

V. 1. Production of hazelnuts, pistachios, almonds and other edible nuts: producing countries and production volume (metric tons, source INC)

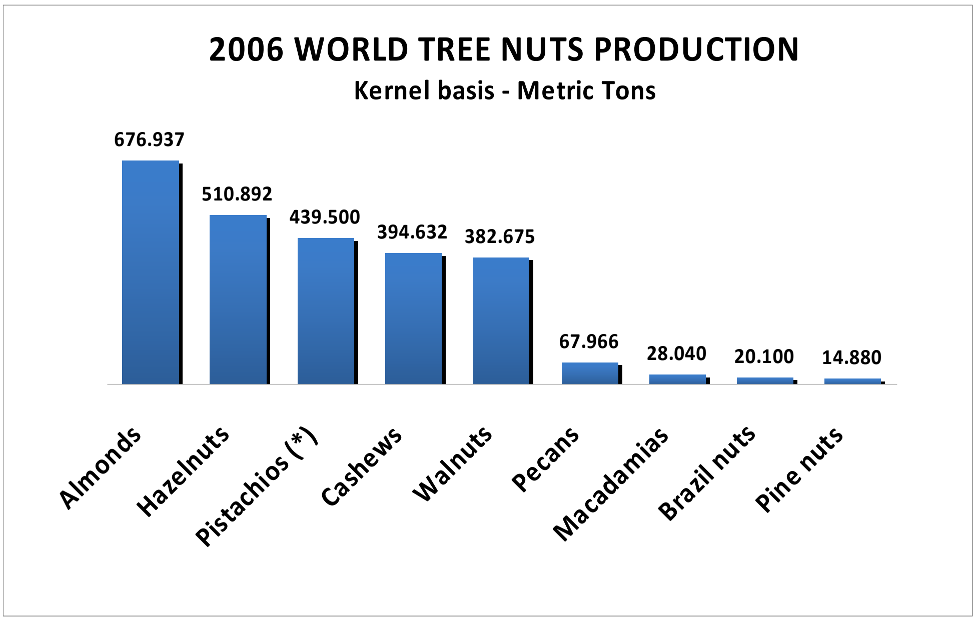
HA	Hazelnuts
WA	Walnuts
BR	Brazil nuts
CA	Cashews
AL	Almonds
PIN	Pine nuts
PE	Pecans
PI	Pistachios
MA	Macadamias

(Metric Tons)
Source: INC

ALMONDS, Shelled	2004	2005	2006	2007	4 Year Average
USA, California	440.000	414.000	485.000	603.277	
Spain	15.000	45.000	60.000	40.000	
Italy	9.000	10.000	12.000	18.144	
TOTAL	**464.000**	**469.000**	**557.000**	**661.421**	**537.855**
WORLD TOTAL	**504.000**	**530.000**	**676.937**	**784.805**	**623.936**
% Total / World Total	**92,06%**	**88,49%**	**82,28%**	**84,28%**	**86,78%**

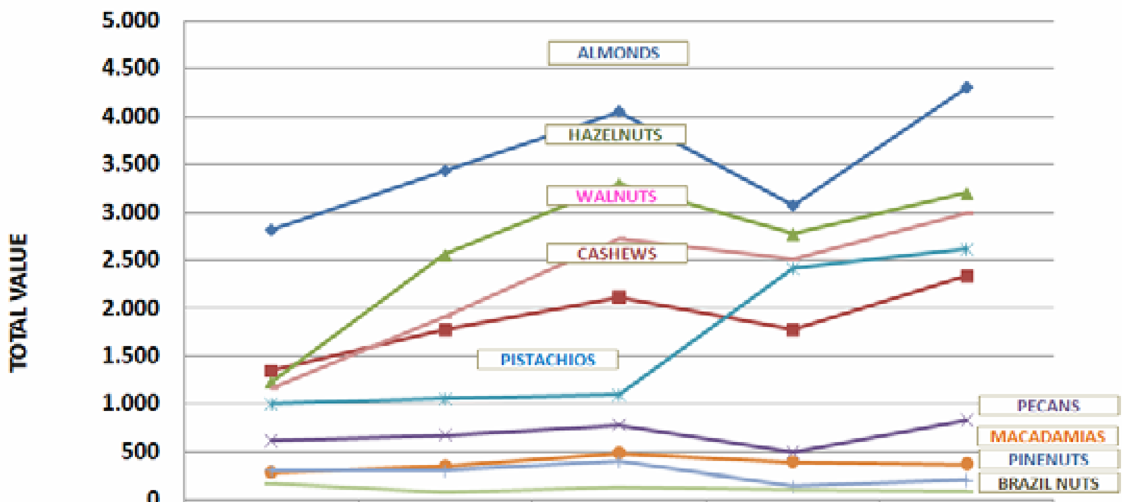
HAZELNUTS, Shelled	2004	2005	2006	2007	4 Year Average
Turkey	190.000	315.000	395.000	277.500	
Italy	67.500	32.500	65.000	47.000	
Spain	12.500	9.000	14.000	10.500	
USA, Oregon	16.750	12.700	15.292	11.500	
TOTAL	**286.750**	**369.200**	**489.292**	**346.500**	**372.936**
WORLD TOTAL	**304.250**	**389.200**	**510.892**	**369.650**	**393.498**
% Total / World Total	**94,25%**	**94,86%**	**95,77%**	**93,74%**	**94,65%**

PISTACHIOS, In shell	2004	2005	2006	2007	4 Year Average
Iran	180.000	175.000	174.000	220.000	
USA, California	160.600	130.000	130.000	150.000	
Italy	4.000	3.000	3.000	3.600	
TOTAL	**344.600**	**308.000**	**307.000**	**373.600**	**333.300**
WORLD TOTAL	**418.492**	**438.500**	**437.800**	**437.800**	**433.148**
% Total / World Total	**82,34%**	**70,24%**	**70,12%**	**85,34%**	**77,01%**



V. 2. Production of hazelnuts, pistachios, almonds and other edible nuts: value (source INC)

WORLD TREE NUTS SUPPLY- VALUE 2003-2007 ($ BILLION) (source INC)



	2003	2004	2005	2006	2007
TOTAL SUPPLY VALUE ALMOND	2.815	3.432	4.050	3.071	4.300
TOTAL SUPPLY CASHEWS	1.346	1.775	2.112	1.775	2.332
TOTAL SUPPLY VALUE HAZELNUTS	1.229	2.555	3.294	2.773	3.200
TOTAL SUPPLY VALUE PECANS	618	672	777	495	828
TOTAL SUPPLY VALUE PISTACHIOS	1.000	1.049	1.095	2.412	2.614
TOTAL SUPPLY VALUE MACADAMIAS	288	352	486	396	372
TOTAL SUPPLY VALUE PINENUTS	308	308	396	148	207
TOTAL SUPPLY VALUE WALNUTS	1.157	1.905	2.724	2.508	2.995
TOTAL SUPPLY VALUE BRAZIL NUTS	175	80	132	101	88
TOTAL	8.935	12.128	15.066	13.679	14.508

2006 WORLD TREE NUTS PRODUCTION (source INC)

		Value ex-farm	
Products	**MT**	**Million $**	**Million €**
Walnuts (kernels)	385.894	2.508	1.929
Almonds (kernels)	682.500	3.071	2.362
Cashews (kernels)	394.632	1.775	1.365
Hazelnuts (kernels)	504.292	2.773	2.133
Pistachios (inshell)	438.500	2.412	1.855
Pecans (kernels)	70.780	495	381
Macadamia (kernels)	28.320	396	305
Brazils (kernels)	20.100	101	78
Pinenuts (kernels)	11.400	148	114

Peanuts	29.778.000	32.756	25.197

V. 3. Farms and people directly and indirectly involved in the production of hazelnuts, pistachios and almonds (source INC)

ALMONDS

Country	Farms	People working in the farms	TOTAL People involved within sector
Greece			
Iran			
Italy	12.700	50.000	63.000
China			
USA	21.037	85.000	93.962
Spain	88.000	117.500	137.200
Chile			
Argentina			
Tunisia			
Morocco			
Total	**121.737**	**252.500**	**294.162**

HAZELNUTS

Country	Farms	People working in the farms	TOTAL People involved within sector
Russia	5	250	520
Spain	2.000	2.500	2.800
Turkey	900.000	1.600.000	2.500.000
Italy	29.400	120.000	145.000
USA	650	1.300	2.400
Georgia	18.000	34.000	160.000
Azerbaijan	21.500	73.000	200.000
Total	**971.555**	**1.831.050**	**3.010.720**

PISTACHIOS

Country	Farms	People working in the farms	TOTAL People involved within sector
Iran	40.000	250.000	2.000.000
Turkey	200.000	75.000	300.000
China			
Italy	1.200	3.600	7.200
USA	750	2.500	8.700
Syria			
Total	**241.950**	**331.100**	**2.315.900**

Source: INC and FAO

Work in progress

V. 4. Estimated costs involved at various hypothetical regulatory limits with 2 assumptions of frequency of controls (source INC).

The latest economic evaluations estimate that the **additional economic cost** of rejected goods, handling, transport costs, and official controlling fees add up to a **350,4 million USD (240 million EUR**) for total Aflatoxin limits at 4 ppb compared to 10 ppb.

		$/lb	2204 lbs MT Value			Total Value
Almond intl trade	625.000	$2,29	$5.047	€ 5.047		$3.154.475.000
Hazel intl trade	395.000	$3,19	$7.031	€ 7.031		$2.777.150.200
Pistachio intl trade	455.000	$2,22	$4.893	€ 4.893		$2.226.260.400
MT	**1.475.000**				**Total**	**$8.157.885.600**
Total Containers (CNT)	**73.750**	20	**MT/CNT**		**Avg €/CNT**	$110.615

ASSUMPTIONS

% tested	10%
Containers Inspected	7.375
Cost of Cnt Rejects	$9.000

	Cost Rejections (freight/acc		**Inspected CNT Only**		**Raw Material + accessories cost at origin/consuming c. ALL Containers**	
	Rejects at 15 ppb	3,70%	**273**	$2.455.875	$24.558.750	
	Rejects at 10 ppb	5,30%	**391**	$3.517.875	$35.178.750	
	Rejects at 8 ppb	6,00%	**443**	$3.982.500	$39.825.000	
	Rejects at 4 ppb	9,60%	**708**	$6.372.000	$63.720.000	
	Value of Goods Rejected					
D	**Rejects at 15 ppb**		$48.131.525	$30.184.177	$301.841.767	$481.315.250
C	**Rejects at 10 ppb**		$35.078.908	$43.236.794	$432.367.937	$350.789.081
B	**Rejects at 8 ppb**		$29.368.388	$48.947.314	$489.473.136	$293.683.882
A	**Rejects at 4 ppb**			$78.315.702	$783.157.018	

A minus B
A minus C
A minus D

ASSUMPTIONS

% tested	5%
Containers Inspected	3.688
Cost of Cnt Rejects	$9.000

	Cost Rejections (freight/acc		**Inspected CNT Only**		**Raw Material + accessories cost at origin/consuming c. ALL Containers**	
	Rejects at 15 ppb	3,70%	**136**	$1.227.938	$24.558.750	
	Rejects at 10 ppb	5,30%	**195**	$1.758.938	$35.178.750	
	Rejects at 8 ppb	6,00%	**221**	$1.991.250	$39.825.000	
	Rejects at 4 ppb	9,60%	**354**	$3.186.000	$63.720.000	
	Value of Goods Rejected					
D	**Rejects at 15 ppb**		$24.065.763	$15.092.088	$301.841.767	$481.315.250
C	**Rejects at 10 ppb**		$17.539.454	$21.618.397	$432.367.937	$350.789.081
B	**Rejects at 8 ppb**		$14.684.194	$24.473.657	$489.473.136	$293.683.882
A	**Rejects at 4 ppb**			$39.157.851	$783.157.018	

A minus B
A minus C
A minus D

V. 5. Estimated impact according to World Bank reports.

Different recent World Bank reports such as "Food Safety and Agricultural Health Standards, Challenges and Opportunities for Developing Country Exports[22]" and "Global Agricultural Trade and Developing Countries[23]" acknowledge that while border rejections are undoubtedly an irritant to exporters, it can be observed that some of the producing countries affected by these border rejections are simultaneously increasing their market share for these products, indicating that these border rejections do not necessarily affect the economic return for the developing countries.

[22] Food Safety and Agricultural Health Standards, Challenges and Opportunities for Developing Country Exports, World Bank Report No 31207, January 10, 2005

[23] Global Agricultural Trade and Developing Countries, M. Ataman Aksoy and John C. Beghin, World Bank, 2005.

VI. SETTING DIFFERENT MAXIMUM LEVELS FOR UNPROCESSED AND PROCESSED NUTS/ EFFECTS OF PROCESSING

The Recommended International Code of Hygienic Practice for Tree Nuts (CAC/RCP 6-1972, Codex Alimentarius Volume 5A-1994) provides basic hygienic requirements for orchards, farm processing and/or commercial shelling or in-shell operations for all tree nuts and tree nut products. One of the end-product specifications indicated in the Code is that “when tested by appropriate methods of sampling and examination, the product should not contain any substance originating from micro-organisms in amounts which may be toxic”.

The available information suggests that additional processes such as sorting and blanching do reduce aflatoxin contamination in some tree nuts, but it seems that these processes are not customarily used for all tree nuts. Since many tree nuts are shipped and consumed shelled, they should be considered “consumer ready” when entered into international commerce.

Risk associated with aflatoxin-contaminated foods can be reduced through the use of specific processing, code of practices, good manufacturing practices and decontamination procedures. Factors, which influence the effectiveness of a specific process or procedure, include the heat stability of the mycotoxin(s), nature of the process, type and interaction with the food matrix and interaction with multiple mycotoxins if present. In addition to the capability of a process to degrade the toxin to safe levels, it should meet the following requirements.

- It must not result in the formation of other toxic substances or leave any harmful residues that might diminish the overall safety of the treated product.
- The nutritional quality of the product should not be suppressed.
- It should not adversely affect desirable physical and sensory properties and acceptability or the technological properties of the product.
- It has to be economically feasible, and technically applicable.
- It must be capable of destroying the spores and mycelia of aflatoxigenic fungi, if they are present in the product, which might, under favourable conditions, proliferate and reproduce the toxin.
- It must be approved by the appropriate authorities of the importing country.

For aflatoxins, multiple processing and/or decontamination schemes have been successful in reducing aflatoxin concentration to acceptable levels. Physical cleaning and separation procedures, where the mold-damaged kernel/seed/nut is removed from the intact commodity, can result in 40-80 % reduction in aflatoxins levels. However, this is not always the case. Processes such as dry and wet milling result in the distribution of aflatoxin residues into fractions of commodity, less used for human consumption but used for other purposes such as for animal feeding

According information provided by INC, existing sorting processes have been shown to allow the reduction of aflatoxin levels. In addition from evolving scientific research and food industry efforts, new systems are being developed which confirm the possible reduction of lots containing aflatoxin levels in excess of 10ppb into good and safe edible food. These new processes can be applied in country of origin or country of consumption

As it is known that sorting techniques and other physical treatments carried out on unprocessed almonds, hazelnuts to obtain the final consumer product can considerably decrease the aflatoxin content, and aflatoxins are genotoxic carcinogens, maximum levels for almonds, hazelnuts for direct human consumption or use as food ingredient, should be significantly lower than those set for unprocessed nuts.

VII. CONCLUSIONS

1. On the basis of a comprehensive amount of data, available to JECFA, and making use of only data provided by producing countries, the mean aflatoxin total level in almonds was 2.0 µg/kg, in hazelnuts 1.9 µg/kg and in pistachios 54 µg/kg.

Mean AFT level excluding samples above a certain level (percentage of samples above that level

Scenario	**No MLs**	**ML 20 µg/kg**	**ML 15 µg/kg**	**ML 10 µg/kg**	**ML 8 µg/kg**	**ML 4 µg/kg**
Almonds	2.0 (0)	0.8 (1)	0.7 (2)	0.7 (2)	0.6 (3)	0.6 (3)
Hazelnuts	1.9 (0)	1.0 (1)	0.9 (2)	0.8 (3)	0.7 (4)	0.6 (7)
Pistachios	54 (0)	4.4 (40)	3.4 (44)	2.4 (49)	2.0 (53)	1.2 (61)

~~2.~~In the EFSA assessment, the same pattern ~~, but less pronounced as regards pistachios,~~ can be seen in case only samples originating from countries where the nuts are consumed are taken into account (EFSA assessment). However, this pattern is less pronounced as regards pistachios, compared to the data used in the JECFA assessment.

Food category	**Proportion of samples with levels of aflatoxin total within indicated µg/kg range**				
	<LOD	**>LOD-4**	**>4**	**>8**	**>10**
Pistachios	56.2%	24.3%	19.5%	16.9 %	16.1%
Almonds	73.3%	22.9%	3.9%	2.8%	2.3%
Hazelnuts	70.3%	22.9%	6.8%	4.1%	2.9%

2. JECFA concluded that the consumption of almonds, Brazil nuts, hazelnuts, pistachios, and dried figs contributes greater than 5% of the total aflatoxin dietary exposure in only five of the 13 GEMS/Food cluster diets. If fully enforced, an ML at 20 µg/kg in hazelnuts, almonds, pistachios, Brazil nuts, and dried figs would only have an impact on the relative contribution to aflatoxin dietary exposure in these clusters, including high-level consumers of tree nuts. This contribution is due solely to the elevated aflatoxin level in pistachios. For tree nuts other than pistachios, the presence of an ML has no effect on AFL dietary exposure. Moreover, the Committee concluded that enforcing an ML of 15, 10, 8, or 4 µg/kg, would have little further impact on the overall dietary exposure to aflatoxin in all five of the highest exposed population groups compared to setting an ML of 20 µg/kg.

3. JECFA concluded further that the reduction of AFL dietary exposure is an important public health goal; particularly in populations who consume high levels of any potentially aflatoxin contaminated food. This concurs with the conclusion of the CONTAM Panel of EFSA, that exposure to aflatoxins from all sources should be as low as reasonably achievable, because aflatoxins are genotoxic and carcinogenic.

4. Using GAPs, GMPs and COPs will assist in reducing the presence of aflatoxins in raw nuts, particularly the proportion of highly contaminated nuts. However, given the heterogeneous nature of contamination, it is impossible to completely avoid the presence of aflatoxins. Using best agricultural practices, it is still anticipated that aflatoxin levels will be found in a certain proportion of shipments. Applying very strict production controls on have shown to result in a significant reduction in the level of aflatoxins but could not completely avoid the presence of aflatoxins.
According to the International Nut and Dried Fruit Council Foundation (INC), a level of 10 µg/kg aflatoxin total is an achievable level in pistachios, almonds and hazelnuts by applying GAP, COPs, good storage practices and GMP.

5. "**Consumer-ready nuts**" or "**ready-to-eat nuts**" can be defined as "nuts, which are not intended to undergo an additional processing/treatment that has proven to reduce levels of aflatoxins".
"Nuts for further processing" can be defined as nuts, which are intended to undergo an additional processing/treatment that has proven to reduce levels of aflatoxins before being used as ingredient in foodstuffs, otherwise processed or offered for human consumption

Processes that have been proven to reduce aflatoxin are shelling, blanching sorting by size, specific gravity, and colour (damage), while processes that haven't been proven to reduce aflatoxin are packaging, foreign material removal, drying, salting, flavouring and roasting.

ANNEX III

LIST OF PARTICIPANTS
LISTE DES PARTICIPANTS
LISTA DE PARTICPANTES
CHAIRPERSON/PRESIDENT/PRESIDENTE

Mr Frans VERSTRAETE
Administrator
European Commission, Health and Consumer
Protection DG
Rue Froissart 101
1049 Brussels
BELGIUM
Tel.: +32 2 295.6359
Fax.: +32 2 299 1856
E-mail: frans.verstraete@ec.europa.eu

MEMBER COUNTRIES

BRAZIL - BRÉSIL - BRASIL

Ms Ligia SCHREINER
Expert on Regulation
National Health Surveillance Agency
SEPN 511, BLOCO A, Edifício Bittar II
70750-541 Brasilia
BRAZIL
Tel.: +55 613 448 6292
Fax.: +55 613 448 6274
E-mail: ligia.schreiner@anvisa.gov.br

IRAN (ISLAMIC REPUBLIC OF)
IRAN (RÉPUBLIQUE ISLAMIQUE D')
IRÁN (REPÚBLICA ISLÁMICA DEL)

Mr Navid ARJMAND
Iran Codex Committee for Contaminants in Food
(Head Office)
Apt.5, #37 Babak Bahrami St., Africa Ave.
Tehran
IRAN (ISLAMIC REPUBLIC OF)
Tel.: +98 913 340 1158
Fax.: +98 218 896 6518
E-mail: arjmand_n@hotmail.com

JAPAN - JAPON - JAPÓN

Dr. Yasuhiro NISHIJIMA
Deputy Director
Ministry of Health, Labour and Welfare
Standards and Evaluation Division
Department of Food Safety
Pharmaceutical and Food Safety Bureau
1-2-2 Kasumigaseki, Chiyoda-ku
100-8916 Tokyo
JAPAN
Tel.: +81 335 952 341
Fax.: +81 335 014 868
E-mail: codexj@mhlw.go.jp

NETHERLANDS - PAYS-BAS – PAÍSES BAJOS

Mr Harrie STORMS
Policy Advisor
Ministry of Health, Welfare and Sport
P.O. Box 20350
2500 EJ The Hague
NETHERLANDS
Tel.: +31 70 340 6225
Fax.: +31 70 340 5554
E-mail: hf.storms@minvws.nl

Dr Martien C. SPANJER
Senior Analytical Chemist
Food and Consumer Product Safety Authority
Hoogte Kadijk 401
1018 BK Amsterdam
THE NETHERLANDS
Tel.: +31 20 524 4703
Fax.: +31 20 524 4700
E-mail: martien.spanjer@vwa.nl

SPAIN
ESPAGNE
ESPAÑA

Mrs Almudena DE ARRIBA HERVÁS
Jefe de Servicio de Gestión de Contaminantes. Spanish
Food Safety and Nutrition Agency (AESAN),
C/Alcalá, 56,
Madrid
SPAIN
Tel: +34 91 3380455
Fax:+34 91 3380169
Email: contaminantes@msc.es

Mrs Ana LÓPEZ-SANTACRUZ SERRALLER
Técnico Superior de Gestión de Contaminantes.
Spanish Food Safety and Nutrition Agency (AESAN),
C/Alcalá, 56,
Madrid
SPAIN
Tel: +34 91 3380017
Fax:+34 91 3380169
Email: contaminantes@msc.es

SWEDEN
SUÈDE
SUECIA

Mrs Monica OLSEN
National Food Administration
P.O. Box 622
SE – 751 26 Uppsala
SWEDEN
Tel.: +46 181 755 98
Fax.: +46 181 058 48
E-mail: mool@slv.se

TURKEY
TURQUIE
TURQUÍA

Mr. Nevzat ARTIK
Deputy of General Directorate
Ministry of Agriculture and Rural Affairs
Akay Cad. 3, Bakanliklar
006640 Ankara
TURKEY
Tel: +90 312 418 7022
Fax: 90 312 418 3246
E-mail: nartik@kkgm.gov.tr

Mr. Halis KORKUT
Head of Department
Ministry of Agriculture and Rural Affairs
General Directorate of Protection and Control
Akay Cad. 3, Bakanliklar
006640 Ankara
TURKEY
Tel: +90 312 425 1915
Fax: 90 312 425 4416
Email: halisk@kkgm.gov.tr

Mrs. M. Nurseren BUDAK
Division Manager
Ministry of Agriculture and Rural Affairs
General Directorate of Protection and Control
Akay Cad. 3, Bakanliklar
006640 Ankara
TURKEY
Tel: +90 312 417 4176 ext. 6213
Fax: 90 312 425 4416
Email: nurb@kkgm.gov.tr

Mr. Ramazan TOKER
Food Engineer
Ministry of Agriculture and Rural Affairs
General Directorate of Protection and Control
Akay Cad. 3, Bakanliklar
006640 Ankara
TURKEY
Tel: +90 312 417 4176 ext. 6202
Fax: 90 312 425 4416
Email: ramazant@kkgm.gov.tr
codex@kkgm.gov.tr

UNITED KINGDOM
ROYAUME-UNI
REINO UNIDO

Ms Wendy MATTHEWS
Head of Branch, Food Standards Agency
Chemical Safety Division
Room 702c, Aviation House, Kingsway, 125
WC2B 6NH London
UNITED KINGDOM
Tel.: +44 207 276 8707
Fax.: +44 207 276 8717
E-mail: wendy.matthews@foodstandards.gsi.gov.uk

Ms Simona ORIGGI
Senior Scientific Officer
Food Standards Agency, Chemical Safety Division
Room 707c, Aviation House, Kingsway, 125
WC2B 6NH London
UNITED KINGDOM
Tel.: +44 207 276 8722
Fax.: +44 207 276 8717
E-mail: simona.origgi@foodstandards.gsi.gov.uk

UNITED STATES OF AMERICA
ÉTATS-UNIS D'AMÉRIQUE
ESTADOS UNIDOS DE AMÉRICA

Mr. Nega BERU
Director, ,Office of Food Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway, College Park
MD 20740
UNITED STATES OF AMERICA
Tel.: +1 301 436 1700
Fax.: +1 301 436 2651
E-mail: nega.beru@fda.hhs.gov

INTERNATIONAL GOVERNMENTAL ORGANIZATIONS
ORGANISATIONS GOUVERNEMENTALES INTERNATIONALES
ORGANIZACIONES GUBERNAMENTALES INTERNACIONALES

FAO

Ms Annika WENNBERG
Senior Officer
FAO JECFA Secretary
Food and Nutrition Division
Food and Agriculture Organization
of the United Nations
Viale delle Terme di Caracalla
Roma
ITALY
Tel.: +39 6 5705 3612
Fax.: +39 6 5705 4593
E-mail: annika.wennberg@fao.org

WORLD HEALTH ORGANIZATIONS (WHO)
Organisation Mondiale de la Santé (OMS)/Organización Mondial de la Salud (OMS)

Ms Angelika TRITSCHER
WHO JECFA Secretary
International Programme on Chemical Safety
World Health Organization
Avenue Appia 20
CH-1211 Geneve 27
SWITZERLAND
Tel.: +41 22 791 3569
Fax.: +41 22 791 4848
E-mail: tritschera@who.int

Mr Gerald G. MOY
GEMS/Food Manager
Food Safety Department Zoonoses and Foodborne Diseases
World Health Organization
Avenue Appia, 20
CH-1211 Geneva 27
SWITZERLAND
Tel.: +41 227 913 698
Fax.: +41 227 914 807
E-mail: moyg@who.int

INTERNATIONAL NON-GOVERNMENTAL ORGANIZATIONS
ORGANISATIONS NON-GOUVERNEMENTALES INTERNATIONALES
ORGANIZACIONES INTERNACIONALES NO GUBERNAMENTALES

INC

Ms. Goretti Guasch
Executive Director
INC-International Nut and Dried Fruit Council Foundation
Calle Boule 2
43201 Reus, Spain
Tel.: +34 977 331 416
Fax.: +34 977 315 028
E-mail goretti.guasch@nutfruit.org

Mr Giuseppe CALCAGNI
Chairman Scientific and Government Affairs Committee
INC
Via Ferrovia 210
80040 San Gennaro Vesuviano
ITALY
Tel.: +39 818 659 111
Fax.: +39 818 657 651
E-mail: giuseppe.calcagni@besanagroup.com

Ms Julie ADAMS
Senior Director
Almond Board of California
1150 9th Street, Svite 1500
95354 Modesto CA
UNITED STATES OF AMERICA
Tel.: +1 209 343 3238
Fax.: +1 209 549 8267
E-mail: jadams@almondboard.com