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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

Agenda Item 7(c) **CX/CF 07/1/9**
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CODEX COMMITTEE ON CONTAMINANTS IN FOODS
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The Hague, the Netherlands, 24 – 28 April 2006

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

Governments and international organizations are invited to submit comments on the following subject matters no later than 9 April 2007, preferably in electronic format, for the attention of Ms. Tanja Åkesson, the Netherlands Secretariat of the Codex Committee on Contaminants in Foods, Fax No.:+31 70 3786141; E-mail:info@codexalimentarius.nl with a copy to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Viale delle Terme di Caracalla, 00153 Rome, Italy (Fax +39.06.5705.4593; E-mail: Codex@fao.org).

This document has been prepared by the electronic working group led by the European Community as agreed by the 38th Session of the Codex Committee on Food Additives and Contaminants (CCFAC) (see ALINORM 06/29/12, para 129) The electronic working group includes Brazil, Iran, Indonesia, Sri Lanka, Turkey, United kingdom, United States (lead on sampling plan), WHO and INC[1]

BACKGROUND

1. The 36th Session of the 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[2].

2. At the 37th session of the CCFAC, discussion on the maximum level for aflatoxins included the following aspects[3]

- 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 (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 total aflatoxins 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.

[1] **Members of the electronic working group have actively contributed to the elaboration of this discussion paper and contributions have been included as much as possible. However the final version of the discussion paper has not been submitted for approval to the members of the working group prior to submission to the Codex secretariat.**
[2] ALINORM 04/27/12, para. 155
[3] ALINORM 05/28/12, para 133-141

3. At the 38th session of the CCFAC, the Committee decided to establish an electronic Working Group, led by the European Community[4], 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. The electronic Working Group will work in English[5].

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[6]

5. In this discussion paper the relevant information from the discussion paper CX/FAC 06/38/23 as discussed at the 38th session of CCFAC is taken over in this discussion paper and expanded with the elements as decided at the 38th session (see §3 above)

[4] With the assistance of Brazil, Iran, Indonesia, Sri Lanka Turkey, United Kingdom, United States (lead on Sampling Plan), WHO and INC

[5] ALINORM 06/29/12, para 129

[6] ALINORM 06/29/12, para 130, para 206-208 and Appendix XXXII.

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PART A

RELEVANT INFORMATION CONTAINED IN DISCUSSION PAPER CX/FAC 06/38/23

I. Toxicological aspects

1. Aflatoxins are mycotoxins produced by certain species of Aspergillus, which develop at high temperatures and humidity levels. Aflatoxins are amongst the most potent mutagenic and carcinogenic substances known and have been shown to be genotoxic carcinogens in rodent bioassays. Human epidemiology studies have shown that hepatitis is a co-risk factor. For substances of this type there is no threshold below which no harmful effect is observed. No tolerable daily intake can therefore be set. Current scientific and technical knowledge and improvements in production and storage techniques do not completely prevent the development of these moulds and consequently do not enable the presence of the aflatoxins in food to be eliminated entirely. It is, therefore, advisable to set limits as low as reasonable achievable (ALARA principle). In applying the ALARA principle, consideration should also be given to the science-based risk assessments performed by JECFA.

2. At the 49th meeting of the FAO/WHO Joint Expert Committee on Food Additives (JECFA) in Rome, in 1997, available aflatoxin exposure data from around the world was used in evaluating the risk associated with aflatoxins in foods. A major conclusion from that risk assessment was that there was no significant difference in the health risk between standards of 10 and 20 µg/kg aflatoxin in foods including maize and peanuts. Worldwide tree nut consumption is much less than peanuts and cereals. Tree nut consumption was estimated in 2004 to be 8.4 million metric tons while peanuts and cereals were estimated to be 35.7 and 2,264 million metric tons, respectively. However, the report accepts that there were limitations to the data used and that the analysis only provides a qualitative comparison between regulator options.

3. In previous exposure assessments, it was considered that tree nuts constitute only a very small portion of the daily food intake in different regions of the world (1 to 17.5 g/person/day). It is however to be noted that a very significant increase in tree nut consumption can be observed in recent years in some regions in the world and this very significant increase of consumption should be duly taken into account in any dietary exposure assessment (see more extensive information on this in II.1.1.2. in the part B of this discussion paper).

4. The estimated dietary intake of aflatoxins via almonds, hazelnuts and pistachio consumption in the UK, is approximately ten times greater than for intakes estimated from groundnuts in the 1998 JECFA report, based on the same hypothetical limit of 10 µg/kg (see more extensive information on this in II.1.2.2. in the part B of this discussion paper).

II. Maximum levels for aflatoxin total versus aflatoxin B1

5. The four main aflatoxins (B1, B2, G1, and G2) usually occur together in varying ratios but normally aflatoxin B1 is the major component. Because aflatoxin B1 is the most toxic compound of all aflatoxins, setting a separate (lower) level for aflatoxin B1 offers an extra guarantee for public health.

6. A review of the literature reveals that the relationship between the percentage of aflatoxin B_1 to the total aflatoxin level in tree nuts is variable and has not been fully explored. It has even been reported in some cases that the level of aflatoxin G_1 can exceed the level of B_1 in the total aflatoxin load on a tree nut species[7, 8]. Additionally, the ratio of B_1 to total aflatoxins has been noted to vary in some nut species by lot, region and crop year.[9]. Examination of tree nut aflatoxin data from regulatory sources suggests that B_1 averages about 85% of total aflatoxins (more details have been provided indicating that the ratio of B1 to total aflatoxin was a mean of 0.85 and median of 0.91 for almonds, while for pistachios, the mean and the median ratios were 0.90 and 0.93, respectively) but the ratio of B_1 /total aflatoxins is extremely variable and the distribution of ratio values is highly skewed with the median ratio being about 92%. Therefore, the setting of maximum level for total aflatoxin in tree nuts should take into account the proportion of aflatoxin B1, which is the most toxic compound of all aflatoxins, and is normally present at high ratio relative to total aflatoxin.

III. Setting different maximum levels for unprocessed and processed nuts/ effects of processing

7. 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”.

8. 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.

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[7] Cheeke, P.R. and Shull, L.R., 1985. Natural toxicants in feed and poisonous plants. Pp. 393-477. Connecticut: Avi Publishing Company.

[8] Nagashiro, C.W., Saucedo, A., Alderson, E., Wood, C.D., Nagler, M.J., 2001. Chemical composition, digestibility and aflatoxin content of Brazil nut (*Bertholletia excelsa)* cake produced in north-eastern Bolivia. *Livestock Research for Rural Development* **13:**2.

[9] USDA/ARS sampling and distribution research for hazelnuts, almonds and pistachios..

9**.** 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

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

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

IV. Impact of Codes of Practice (COP)/Good Agricultural Practices (GAP)/Good Manufacturing Practices (GMP) in reducing aflatoxin contamination

11. Using GAPs, GMPs and COPs at an agricultural level 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, e.g. pistachios from Iran, has enabled significant reduction in the level of aflatoxins but could not completely avoid the presence of aflatoxins.

There are ongoing projects such as Green Corridor in Iran, which according to the first results, indicate that the level of contamination in pistachios have reduced significantly by using Good Agricultural Practices and precautionary measures such as early harvest. Doing these significant efforts, the project indicates that low levels (< 4 µg/kg aflatoxin total) are indeed achievable (see more extensive information on this in IV.2 and IV.3. in part B of this discussion paper)..

12. No evidence has yet been submitted which would indicate that the lower levels proposed by some delegations are not reasonably achievable when prevention and reduction measures are applied to minimize the presence of aflatoxins in tree nuts. The information on what levels are achievable when applying prevention and reduction measures is of major importance and is an indispensable condition to determine the levels which are reasonably achievable across a wide range of production conditions.

13. Extensive control data in the EU in the period 2003-2005 demonstrate that more than 95 % of the imports of almonds and hazelnuts do comply with current EU legislation. With pistachios, the compliance rate is lower. However, when analysing the levels of aflatoxins found in non-complying consignments only a minor part, particularly in the case of pistachios, contained levels in the range between and 4 and 15 µg/kg; the majority of the non-complying levels had aflatoxin levels significantly above 15 µg/kg. These data indicate that efforts still have to be made by the producing countries to apply the prevention measures as outlined in the Code of Practice.

V. Commercial impact of maximum levels

14. In many countries, aflatoxin contamination in tree nuts may be unavoidable due to many factors including climatic conditions and traditional practices. Adoption of a maximum level lower than 15 µg/kg will require implementation of GAPs / GMPs in order for those countries to prevent a detrimental effect on trade and national economies. An analysis of regulatory and industry aflatoxin testing data, performed by the International Nut Council (INC), indicates that reducing the aflatoxin limit from 15 to 10 µg/kg or from 15 to 5 µg/kg will increase rejections by 33 and 144%, respectively. This increase in consignments rejected would certainly have considerable economic impact on the commercial trade of tree nuts. However other data sets do not indicate such a significant impact between the levels of 5 and 15 µg/kg.

15. An indication of the impact of applying different limits has been calculated by the International Tree Nut Council (INC). One study of aflatoxin distribution in almonds estimated that 94% of lots would test below 15 ppb, 92% below 10 ppb and 86% below 4 ppb. Applying these rejection rates to the total trade of almonds, hazelnuts and pistachios (52,800 containers with an average value of €90,000) and assuming that an average of 15% of consignments are controlled on import, the potential impact that various global aflatoxin levels would have on rejections were estimated as follows by INC

At 15 ppb	Rejected consignments valued at € 3,847,500
At 10 ppb	Rejected consignments valued at € 5,130,000
At 4 ppb	Rejected consignments valued at € 8,977,500

16. However, different recent World Bank reports such as “Food Safety and Agricultural Health Standards, Challenges and Opportunities for Developing Country Exports[10]” and “Global Agricultural Trade and Developing Countries[11]” 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.

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

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

PART B

NEW INFORMATION EXPANDING THE DISCUSSION PAPER AS REGARDS ADDITIONAL ASPECTS FOR CONSIDERATION, AS AGREED AT THE 38th SESSION OF CCFAC CONTAINED IN DISCUSSION PAPER CX/FAC 06/38/23 (see para 3 above)

I. Description of occurrence data

I.1. General information on the frequency of aflatoxin concentration in nuts compared to other food commodities

Unlike various other commodities, aflatoxins in nuts are not only found at low and high levels, which can be separated by setting a limit, but can occur with equal frequency at all concentrations, up to concentrations of 10 mg/g[12]. Figure 1 demonstrates this schematically showing the frequency of aflatoxin concentrations normally found in nuts with those normally found in some other commodities, such as spices, and relates these to the impact of increasing Regulatory limits. In the case of nuts, owing to the pattern of aflatoxin occurrence, more aflatoxin contaminated produce will enter the food chain if the Regulatory limit is increased from level A to level B (graph i). In comparison, an increase from level A to level B for some other commodities would not be expected to result in a significant rise in aflatoxins in the food chain as the toxins occur mainly in low or high concentrations (graph ii).

(i) Nuts **(ii) Other commodities (e.g. spices)**

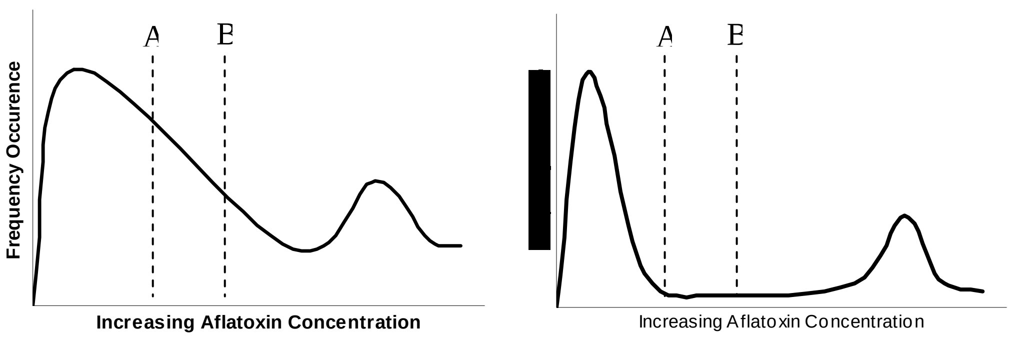


Figure 1. Schematic representation of aflatoxin concentration occurrence

In the UK, a recent survey for aflatoxins in nuts available to consumers found that seven percent of these samples exceeded the regulatory limit for total aflatoxin (4µg/kg) with exceedances in the range of 15 - 710 µg/kg. The lower bound mean aflatoxin level of the samples analysed was 10.4 µg/kg. The majority of the exceedances found were from pistachios and almonds.

[12] Schatzki, T.F. (1995). Distribution of Aflatoxins in Pistachios. 2. Distribution in Freshly Harvested Pistachios, Journal of Agricultural Food Chemistry, **43**, 1566-1569.

I.2. Data gathered by the EC in 2006 in view of the EFSA[13] assessment[14].

I.2.1. Data submitted by EC Member States

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.

Submissions were also received from Turkey and FRUCOM (European Federation of the Trade in Dried Fruit, Edible Nuts, Processed Fruit & Vegetables, Processed Fishery Products, Spices, Honey and Similar Foodstuffs).

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. FRUCOM 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 1). 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 1 with special emphasis on almonds, hazelnuts and pistachios.

[13] EFSA is the European Food Safety Authority

[14] 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

Table 1: Distribution of samples over year and food category.

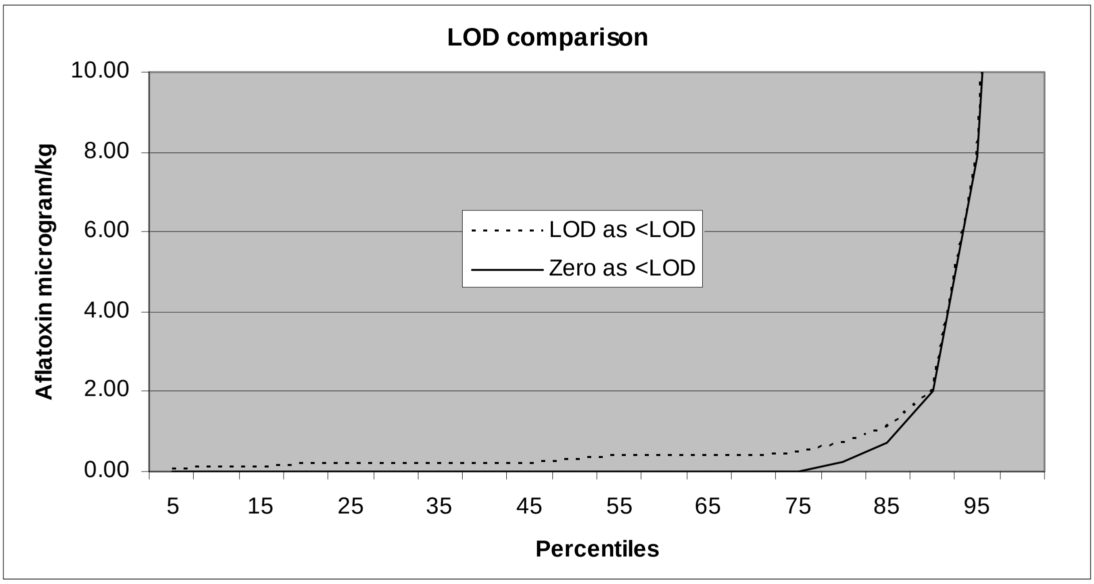
Food category	Number of samples						
	2000	2001	2002	2003	2004	2005	2006
All data	2883	3609	4386	5605	8313	6638	2890
Almonds	112	108	206	362	347	287	344
Hazelnuts	100	170	569	673	739	642	270
Pistachios	246	384	428	680	1062	917	352
Baby foods	0	0	42	282	113	134	21
Brazil nuts	28	181	142	130	61	71	9
Cashews	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

Reporting of aflatoxin concentrations

Aflatoxin concentrations were reported as below the limit of detection (LOD) for 25,451 of the European samples while aflatoxins above the LOD were found in 8,875 or 26% of samples. For the samples where aflatoxins were not detected it has to be assumed that concentrations ranged between zero and the LOD. As recommended by the FAO/WHO (1995) for materials where the majority of results are below the limit of detection, both lower and upper bound values were calculated to provide an estimate of a concentration range.

Thus, the respective LOD was entered as the actual value (upper bound) or replaced by zero (lower bound). The impact of the two methods is illustrated in Figure 2 for total aflatoxins in the European samples. There is a maximum difference of 0.46 µg/kg at the 80th percentile after which the difference levels out as the levels reach the LOD. The lower bound mean is 5% lower than the upper bound mean, or 4.28 and 4.53 µg/kg, respectively.

Figure 2: Comparison of the impact of using the LOD or zero for all total aflatoxin values <LOD.

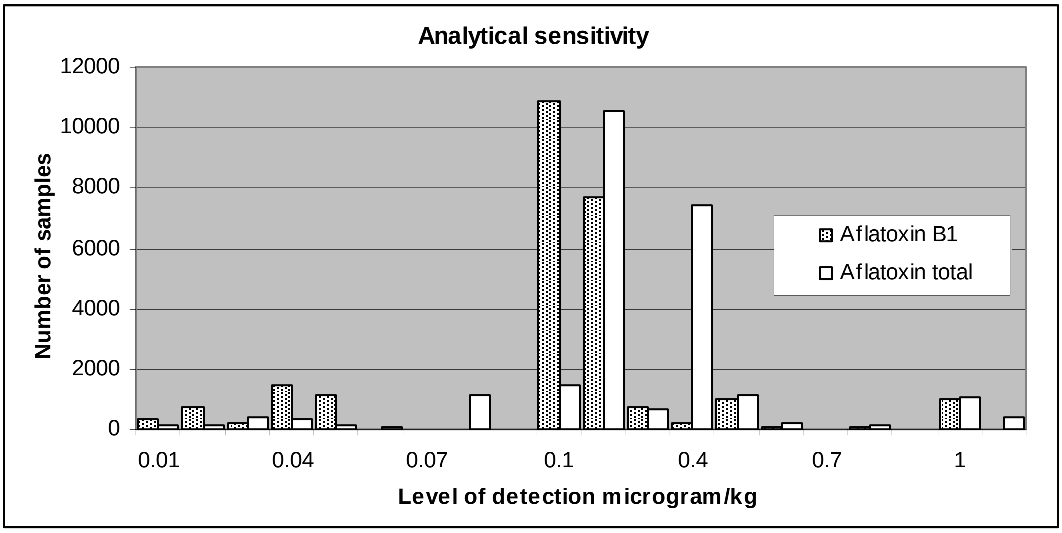


The LOD for the aflatoxins varied considerably between laboratories, different foods, methods used and over time in that more sensitive methods were adopted. The minimum LOD reported for AFB1 was 0.0002 µg/kg and the maximum 10 µg/kg, but usually the LOD was reported at around 0.1 µg/kg. Some laboratories reported only the limit of quantification (LOQ). LOD is most often equal to three times the standard deviation of a blank or a low concentration sample while LOQ is ten times the standard deviation or 3.3 times the LOD. Results reported as less than the LOQ were thus transformed to LOD using this relationship and assuming there were no detected concentrations of aflatoxins. Furthermore, samples with a LOD above 1 µg/kg for AFB1 (equivalent to 2 µg/kg of for total aflatoxins as shown below) were excluded from the analysis as recommended by the FAO/WHO (1995)[15] since the sensitivity was too close to or above the level of interest for the study. Thus, around 4,000 results from mainly the use of screening methods had to be discarded.

The distribution of the LOD for all samples remaining in the analysis is shown in Figure 3. The most common LOD was 0.1 or 0.2 µg/kg for AFB1 and 0.2 or 0.4 µg/kg for total aflatoxins after the adjustment indicated below.

[15] FAO/WHO. 1995. Evaluation of certain food additives and contaminants. World Health Organisation Tech.Rep.Ser. 859, 1-54.

Figure 3: The limit of detection as applied by laboratories for all samples in the study.



The LOD for total aflatoxins as reported by Member States was comprised of the sum of the separate LODs for aflatoxins B1, B2, G1 and G2 and was often four times the level for AFB1 or more. In the experience of the Panel, AFB1 most often dominated the mix of aflatoxins in food samples and it was expected that simply adding together the LODs for all aflatoxins would considerably overstate the total aflatoxin level. To check this assumption, the relationship between AFB1 and total aflatoxins was calculated through linear regression for values above the limit of detection (Table 2).

Table 2: 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 3 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.

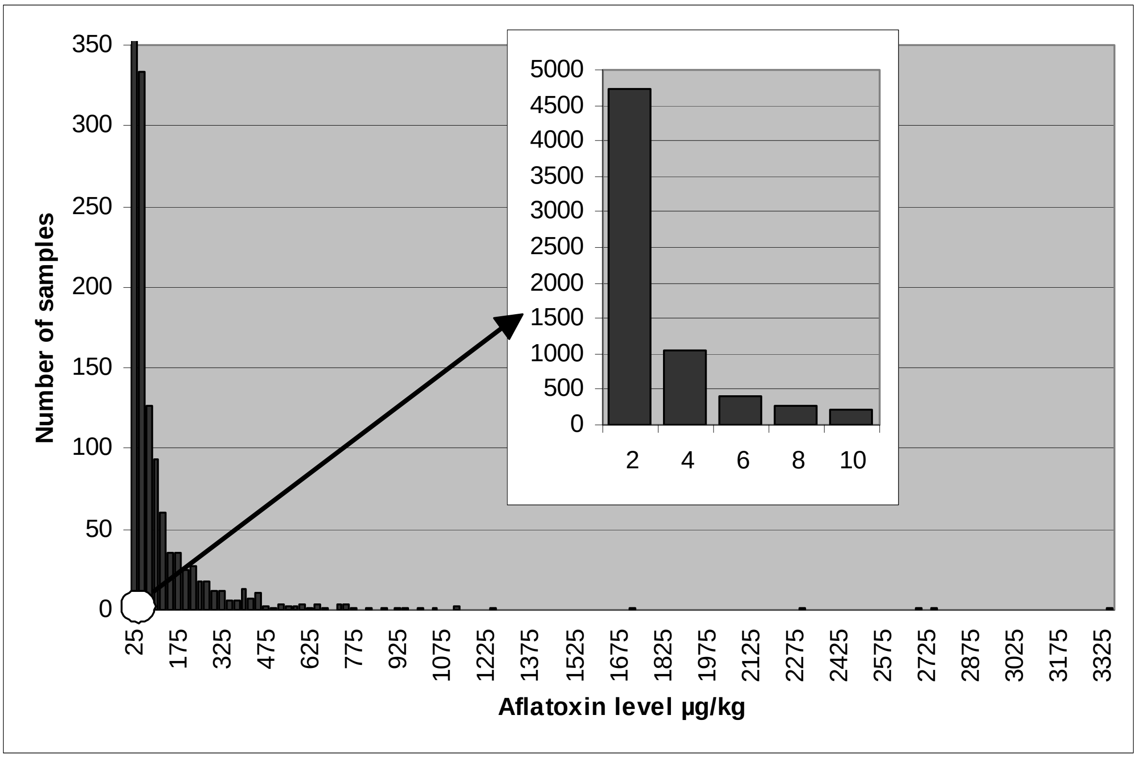
An attempt was made to illustrate the distribution of total aflatoxin levels above LOD in all European samples tested in Figure 4. However, since the material is heavily skewed towards very low values the graph is difficult to read. Each bar in the main Figure represents an increment of 25 µg/kg and to improve readability the y-axes has been set at a maximum of 350 observations. The first bar is thus outside the scale with a total of 7,248 observations. To refine the low-level part of the graph, an insert has been produced where each bar represents an increment of 2 µg/kg. The first bar represents 4,735 observations followed by 1,035, 397, 259, and 208, respectively, for each increment of 2 µg/kg.

Table 3: 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*

Figure 4: Histogram of the distribution of total aflatoxin levels in all samples above the limit of detection (LOD)



Of the 168 samples with levels above 200 µg/kg, 110 comprised of pistachios, 30 of Brazil nuts, 23 of peanuts, 3 of other nuts and 2 of almonds. There were five unevenly distributed very high outlier values among the 168 samples, all pistachios and Brazil nuts, which clearly biased the overall distribution. Although a rare occurrence, the heterogeneous distribution of aflatoxins with occasionally very high values is a concern that will be addressed later.

In general, for skewed data the median would give a robust and adequate measure of contamination. However the median could not be used to describe the aflatoxin data in this opinion because the majority of the observations were below the LOD. This means that the median is highly dependent on assumptions related to the LOD and to the approach to values below the LOD, with minimal impact of the actual measured data. Use of high percentile occurrence data would be relevant to assessment of acute risks, but for long term risks, the mean concentrations are more likely to be relevant.

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 4.

Table 4: 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.

Type of sampling

Samples were selected within four types of control system: export, import, company, and market control. There were also a large number of samples that lacked information on the control system.

Company control data refer to results for products before placing them on the market as reported by companies. Import control data refer to results from border control before entering the European Union reported by Member States. An analysis of the findings from the three different control systems and for the unspecified monitoring is presented in Table 5 for total aflatoxin and values of less than LOD set to the LOD.

Table 5: Number of samples reported by type of control and the respective total aflatoxin levels with values less than the LOD set to the LOD (upper bound).

Type	No. of samples	Range µg/kg	Total aflatoxins µg/kg					
			Median	Mean	90th %	95th %	97.5th %	Max
Company control	*2,782 (96%)*	**0-4**	0.20	0.41	0.96	1.78	2.60	4
	2,826 (97%)	**0-8**	0.20	0.49	1.00	2.20	3.48	8
	2,849 (98%)	**0-10**	0.20	0.56	1.00	2.50	3.90	10
	2,903	**All**	0.20	2.06	1.50	3.50	8.23	426
Import control	*13,507 (92%)*	**0-4**	0.20	0.40	0.72	1.20	2.10	4
	13,754 (94%)	**0-8**	0.20	0.50	1.00	1.80	3.40	8
	13,841 (95%)	**0-10**	0.20	0.55	1.00	2.00	3.98	10
	14,653	**All**	0.30	5.06	2.20	12.50	38.30	2680
Market control	*10,603 (94%)*	**0-4**	0.20	0.45	1.00	2.00	2.40	4
	10,806 (95%)	**0-8**	0.20	0.55	1.30	2.00	3.50	8
	10,878 (96%)	**0-10**	0.20	0.60	1.50	2.40	4.10	10
	11,255	**All**	0.20	4.19	2.00	5.24	16.29	2740
Unknown	*5,015 (92%)*	**0-4**	0.40	0.60	1.25	2.00	2.66	4
	5,171 (95%)	**0-8**	0.40	0.75	1.80	2.92	4.52	8
	5,202 (96%)	**0-10**	0.40	0.80	1.91	3.10	5.08	10
	5,440	**All**	0.40	4.92	2.70	7.83	24.45	3337

It should be noted that the type of product tested, and the sampling procedure, could be different between the different control systems which could influence the results.

I.2.2. Data submitted by Turkey

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.

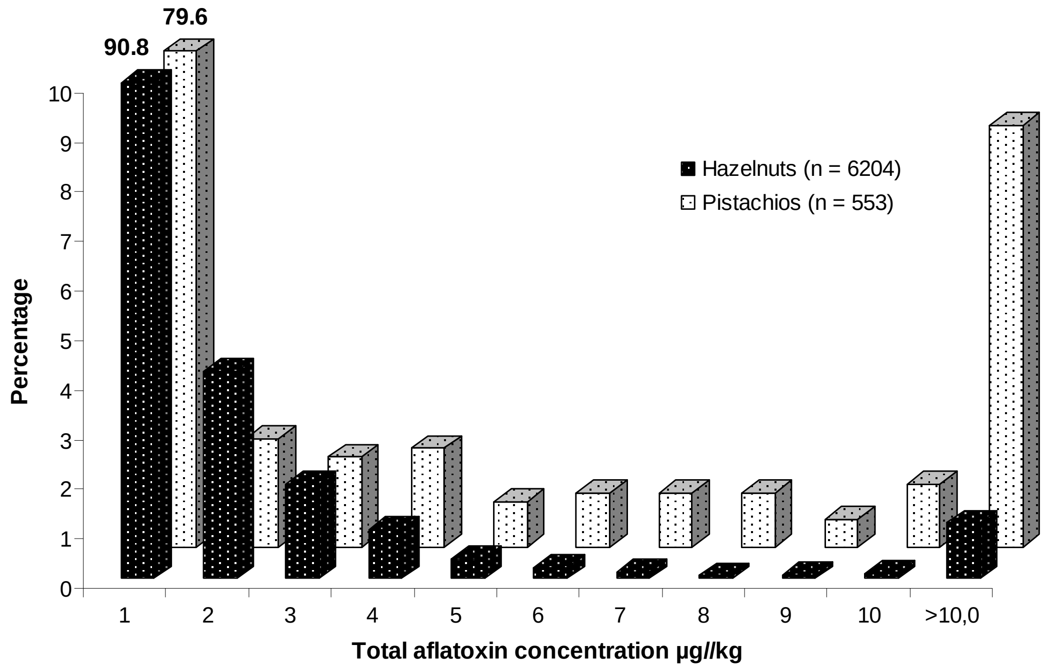
Food Category	Proportion of samples with total aflatoxins (T) within indicated ranges (µg/kg)						
	Type	**<LOD**	**>LOD-2**	**>2-4**	**>4-8**	**>8-10**	**>10**
Hazelnuts	AFB1	85.9%	12.2%	0.9%	0.4%	0.1%	0.6%
	T	83.2%	11.7%	2.9%	0.8%	0.2%	1.1%
Pistachios	AFB1	76.4%	7.2%	3.1%	4.9%	2.0%	6.2%
	T	76.1%	5.6%	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 5.

Figure. 5: 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	90th %	95th %	97.5th %	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.2.3. Data on aflatoxins in pistachios from Iran

Information on the presence of aflatoxins in pistachios in Iran can be found in an article to be published in Food and Chemical Toxicology[16]. In this study, incidence of aflatoxins in Iranian pistachio intended for export to the EU was investigated. Therefore the data in this study do not reflect the whole Iranian production of pistachios but only part of it which was pre-selected for export.
It was mentioned that the Iranian Codex Contact Point submitted a more comprehensive and more representative data collection on the presence of aflatoxins in pistachios to FAO for evaluation by the 68th meeting of JECFA. However these data were not submitted in the frame of the elaboration of this discussion paper and can therefore not be considered in this discussion paper;

Pistachio nuts, produced in Iran during March 2002 – February 2003 were analyzed for aflatoxin B1 (AFB1), aflatoxin B2 (AFB2), aflatoxin G1 (AFG1) and aflatoxin G2 (AFG2) using immunoaffinity column and quantified by HPLC and/or TLC-scanner.

In this regard, 3356 pistachio nut samples were collected. After dividing samples to sub-samples, 10068 AF analyses were done. Among 10068 samples analyzed, AFB1 was detected in 3699 samples (36.7% of the total) with the mean and median of 5.9 (± 41.7) ng/g and 0.1 ng/g, respectively. Total AF (AFT) was detected in 2852 samples (28.3% of the total) with the mean and median of 7.3 (± 53.2) ng/g and 0.4 ng/g, respectively.

Table 8: Mean, standard deviation, median and percentiles 25% and 75% of aflatoxin B1 and total aflatoxins (ng/g) in Iran pistachio nut samples analyzed by Food Control Labs during March 2002 – February 2003

	No. of samples analyzed	Samples without AF (<LOD)*	Mean	STD	Median	Percentile 25%	Percentile 75%
AFB1	10068	6369 (63.3%)**	5.9	41.7	0.1	0.1	0.5
AFT	10068	7216 (71.7%)**	7.3	53.2	0.4	0.4	0.6

*LOD of HPLC method for AFB1: 0.1 ng/g and AFT: 0.4 ng/g; LOD of TLC method for AFB1: 0.2 ng/g and AFT: 1 ng/g.
** Percentage of non-contaminated samples

[16] Cheraghali et al. Incidence of aflatoxin in Iran Pistachio Nuts, Food and Chemical Toxicology (2006), doi 10.1016/j.fct.2006.10.026

Figure 6. Incidence of AFB1 in Iran pistachio nut samples analyzed by Food Control Labs during March 2002 – February 2003

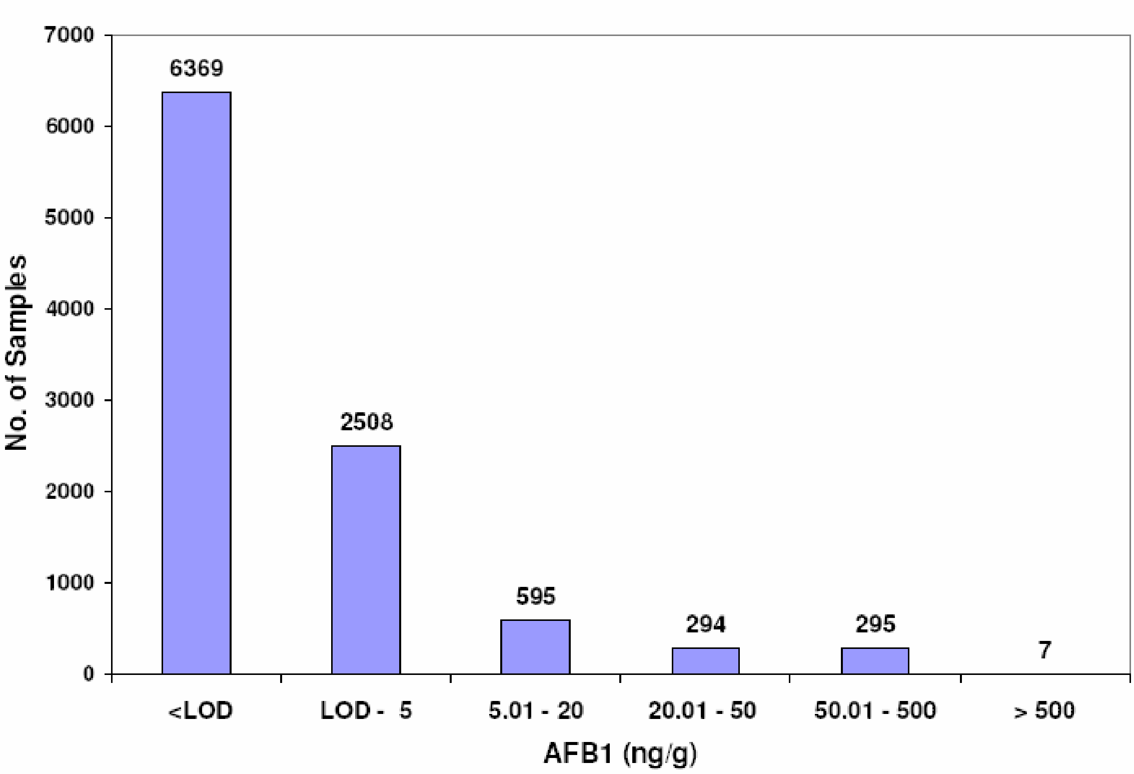
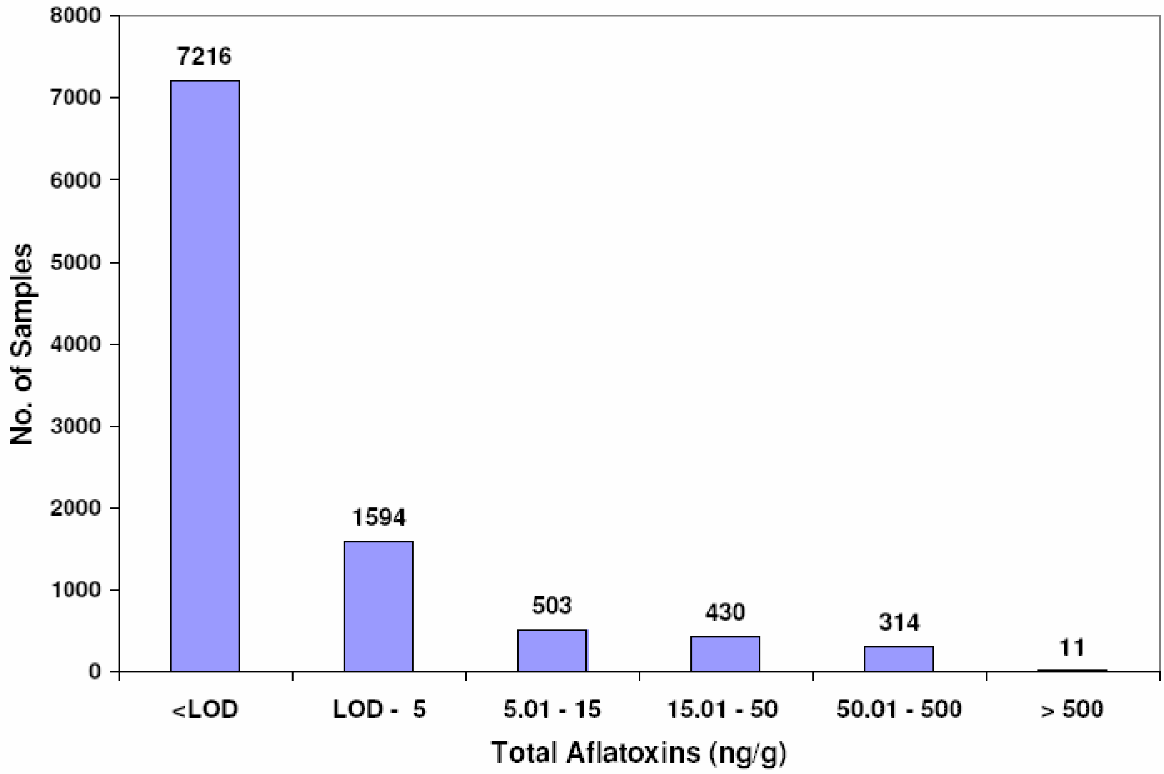


Figure 7: Incidence of AFT in Iran pistachio nut samples analyzed by Food Control Labs during March 2002 – February 2003



I.3. Data submitted by the members of the working group in view of this discussion paper

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. Data submitted by other Codex member countries in view of this discussion paper.

No additional data have been received.

II. Consumer health risk assessment of different levels of aflatoxins in ready-to-eat tree nuts

On 25 January 2007, the Scientific Panel on Contaminants in the Food Chain (CONTAM Panel) adopted an opinion related to the potential increase of consumer health risk by a possible increase of the existing maximum levels for aflatoxins in almonds, hazelnuts and pistachios and derived products. The opinion is available on the EFSA website[17]. This section contains the main conclusions of this opinion.

JECFA will conduct at its 68th meeting of JECFA, which will take place from 19-28 June 2007, 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. This section will be completed with the outcome of this assessment once available.

II.1. Exposure assessment and impact of different levels of aflatoxins

II.1.1. Food consumption

II.1.1.1. Information extracted from the EFSA opinion

II.1.1.1.1 GEMS/Food database

The GEMS/Food Consumption Cluster Diets are based on national food balance sheets of annual food production as well as import and export for individual countries, aggregated into clusters according to similar consumption behaviour. The main advantage of the data is the good comparability between different countries because the same methodology and standardised food classification system of the Codex Alimentarius were used. However, data from food balance sheets do not give information on consumption at individual consumer level, therefore only the mean consumption can be derived from GEMS. Information on high percentiles of the population and on selected population subgroups (age-groups, vulnerable subgroups) cannot be derived from these data. Table 9 lists all the clusters used in the EFSA opinion.

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17 http://www.efsa.europa.eu/en/science/contam/contam_opinions/ej446_aflatoxins.html (general page)
http://www.efsa.europa.eu/etc/medialib/efsa/science/contam/contam_opinions/ej446_aflatoxins.Par.0001.File.dat/CONTAM%20_op_ej446_aflatoxins_en.pdf (full opinion)
http://www.efsa.europa.eu/etc/medialib/efsa/science/contam/contam_opinions/ej446_aflatoxins.Par.0002.File.dat/CONTAM%20_op_ej446_aflatoxins_summary_en.pdf (summary)

Table 9: Composition of GEMS/Food Consumption Cluster Diets that include European Member States [18].

Cluster B	Cluster E		Cluster F
Cyprus	Austria	Luxembourg	Estonia
Greece	Belgium	Malta	Finland
Israel	Croatia	Netherlands	Iceland
Italy	Czech Republic	Poland	Latvia
Lebanon	Denmark	Slovakia	Lithuania
Portugal	France	Slovenia	Norway
Spain	Germany	Switzerland	Sweden
Turkey	Hungary	United Kingdom	
United Arab Emirates	Ireland		

In Table 10, the mean consumption amounts from the GEMS/Food database for the three nuts (almonds, hazelnuts and pistachios) together with consumption figures for other foods relevant for assessment of total dietary exposure are listed.

Table 10: Consumption of nuts and other food items relevant for the exposure assessment according to the GEMS/ Food Consumption Cluster Diets database in gram per day (mean of all population, ingredients included).

	Cluster B	Cluster E	Cluster F
Almonds	1.9	1.0	0.8
Hazelnuts	2.1	1.3	0.3
Pistachios	0.7	0.3	<0.1
Consumption of other food items	239.5	110.3	67.5
Other nuts (including groundnuts shelled, except coconuts)	6.2	5.0	1.5
Maize[19] (including oil, sweet corn, kernels and pop corn)	150.6	39.9	14.8
Oilseeds[20] (except groundnuts)	62.1	58.1	38.0
Dried fruits (including coconuts)	19.5	5.5	12.1
Spices	1.1	1.8	1.1

The definition of exposure from other food items in this opinion includes nuts other than almonds, hazelnuts and pistachios, maize, oilseeds, dried fruits and spices. The category “oilseeds” in the submitted occurrence data contains food commodities like sunflower seeds, sesame seeds, pumpkin seeds and poppy seeds. To match these values with the GEMS/Food classification the consumption values for groundnuts in GEMS/Food were excluded from the “oilseeds” category and added to the category “other nuts”.

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

[19] The value for consumption of maize corresponds to a calculated value obtained from food balance sheet transformed product back to raw product using the converting factors of the FAO (maize is the maximum of 1.2 x maize flour or 16.7 x maize germ and 0.2 x beer of maize; germ maize is the maximum of germ maize and 2.2 x maize oil.

[20] This food category takes into account declared food balance sheet for oil using different factors, according to the type of seed, in converting back to the raw seed (linseed, melon, sunflower, mustard, poppy, rape, safflower, palm, olive and sesame).

II.1.1.1.2. Consumption figures based upon national surveys performed by EU Member States

The following tables can be found in the Annex to this discussion paper

Table 11: Consumption figures of almonds taken from food surveys of the EU-Member States and GEMS/Food Consumption Cluster Diets database for adult population

Table 12: Consumption figures of hazelnuts taken from food surveys of the EU-Member States and GEMS/Food Consumption Cluster Diets database for adult population

Table 13: Consumption figures of pistachios taken from food surveys of the EU-Member States and GEMS/Food Consumption Cluster Diets database for adult population

Table 14: Consumption figures of almonds taken from food surveys of the EU-Member States for children.

Table 15: Consumption figures of hazelnuts taken from food surveys of the EU-Member States for children.

Table 16: Consumption figures of pistachios taken from food surveys of the EU-Member States for children.

II.1.1.2. Information provided by members of the electronic working group and which is not contained elsewhere in this paper.

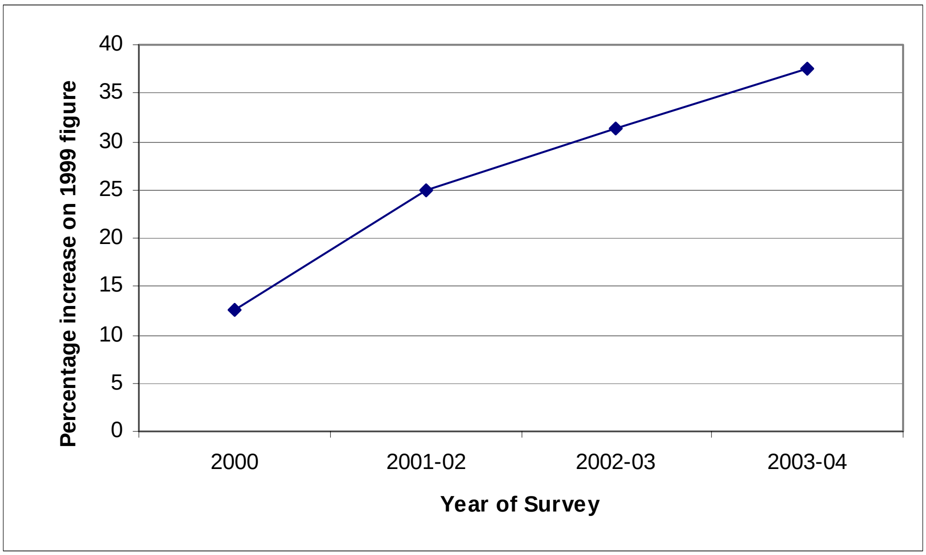
Recent emphasis on healthy eating has seen a marked increase in sales of nut varieties by up to 70% in the past year as consumers opt for dried fruit, nuts and cereal bars over potato crisp snacks[21]. Numerous studies in recent years have reported that almonds, hazelnuts, macadamia nuts, peanuts, pecans, 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%)[22]. 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[23].

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 8.

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

Figure 8. Percentage increase in average purchases in UK per person per week of nuts, edible seeds & peanut butter relative to 1999 figures.



A nut consumption survey conducted in the UK in 2006 found adults to consume on average 31 grams of nuts per day, with a high-level consumption of 159 grams per day (Table 17)

Table 17: Summary of UK nut consumption data collected in 2006

Consumption Survey	**Mean** (g/person/day)	**97.5th%ile** (g/person/day)	**Max Total Nut Consumption** (g/person/day)	**Highest Reported Consumption of One Type of Nut** (g/person/day)
2006 UK Adults	31	159	273	178 (almonds)
2006 UK Children	6	44	63	40 (mixed nuts)

II.1.2. Exposure

II.1.2.1. Information extracted from the EFSA opinion

Intakes from almonds, hazelnuts and pistachios have been assessed 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
- scenario 3: high level exposure for hazelnuts
- scenario 4: high level exposure for pistachios

The details on the different scenarios and the resulting aflatoxin exposure can be found in Tables 18 and 19 and figure 9 in Annex to this discussion paper

Figure 9: Percentage contribution of other foods to total exposure based on GEMS/Food consumption data and collected occurrence data from Member States

Table 18: Scenario 1 “average exposure” to total aflatoxins in ng/kg b.w. per day truncating occurrence data at its current EU MLs for adults

Table 19: 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

Table 20: 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

These scenarios involve a number of assumptions. Firstly, mean levels of aflatoxin contamination were assumed to be of most relevance for long-term exposures. The Panel considered whether high level occurrence data should be used, but found no evidence that particular sources of nuts were consistently highly contaminated and therefore brand preference would not affect average long-term exposure.

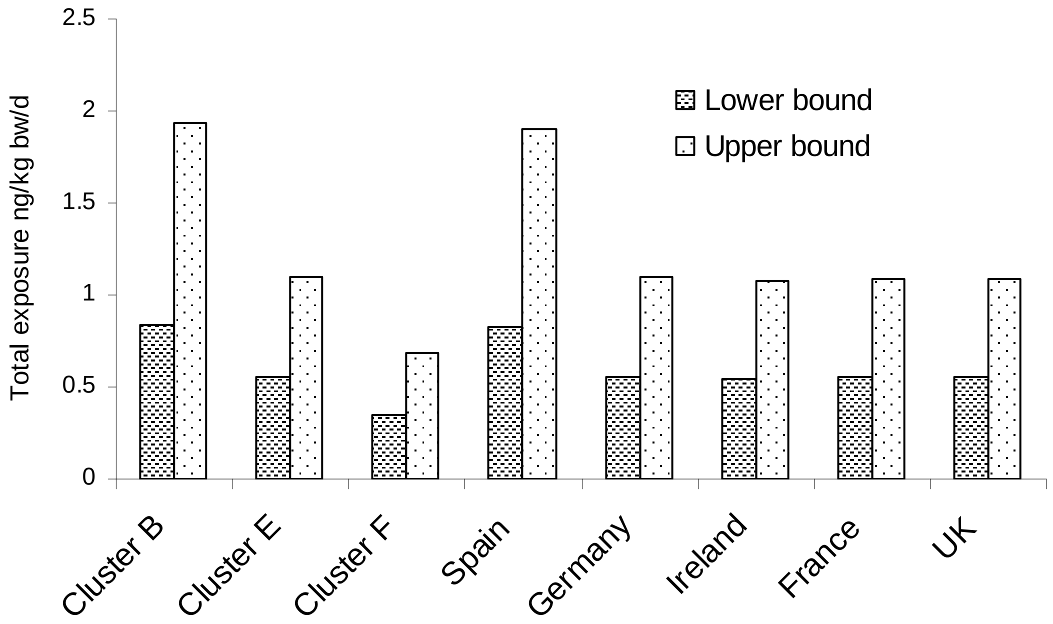
To estimate exposure under the current legislation, occurrence data with levels below or at the MLs were used assuming that all other foods were detected by food surveillance and prevented from reaching the market and therefore not consumed. This assumption does not reflect the true situation, but since there is no information on which to base assumptions of the effects of surveillance systems before and after any change to the permitted MLs, this assumption provides the best basis for a comparison of the current situation with hypothetical future scenarios.

Influence of setting the LOD

In tables 18 to 20, two standard approaches were used in dealing with the LOD-values. Use of the upper bound gives an overestimation of the occurrence levels and therefore of exposure, whereas lower bound gives an underestimation. Actual exposure will be within this range of values and as it is illustrated in Figure 10, changes in the handling of values below the LOD have a relatively high impact. This can be explained by the high numbers of values below the LOD in the data used for estimation of intake from other foods other than almonds, hazelnuts and pistachios.

The over-estimation resulting from the use of the upper bound entails a precautionary approach to assessment of exposure and hence of potential health effects. However, this over-estimation will mask the relative potential impact of increasing the MLs and therefore the lower bound approach is also important.

Figure 10: Total exposure to total aflatoxins in ng/kg b.w. per day dependent on different handling of values below LOD/LOQ.



Conclusions

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.

II.1.2.2. Information provided by members of the electronic working group and which is not contained elsewhere in this paper.

UK aflatoxin exposure assessments show that consumption of nuts and peanuts can contribute over 90 percent of the daily intake of aflatoxins for an average consumer (Table 21).

Table 21. Comparison of contribution to UK aflatoxin exposures by nuts and the rest of the diet

Population	Dietary exposures to total aflatoxins (ng/person/day) **Nuts and Peanuts**		Dietary exposures to total aflatoxins (ng/person/day) **Rest of diet** *		**Contribution to mean total dietary intake by nuts (%)**
	Mean	97.5^{th}%ile	Mean	97.5^{th}%ile	
Adults	320	1650	30	110	**91**
Young people	70	460	42	132	**62**

* Occurrence based on upper bound means from UK surveys on maize products, spices (B1) and rice. Using JECFA's approach, levels reported below the limit of quantification (LOQ) were considered as the LOQ divided by 2, to reduce the bias.

II.1.3. Potential impact of different maximum levels

II.1.3.1. Information extracted from the EFSA opinion

- 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 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 22.

Table 22: 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.1.3.2. Information provided by members of the electronic working group and which is not contained/reflected elsewhere in this paper.

Table 23 compares exposures to aflatoxins in nuts at the current EU-limit of 4 µg/kg with proposed limits of 8 and 10 µg/kg. The calculation assumes that all nuts consumed contain aflatoxins at the regulatory limit. Although this initially may appear an overestimate of exposure, it is actually an underestimate as mean aflatoxin levels in nuts have been found to exceed the current regulatory limit.

Table 23. Contribution of nuts to total dietary exposures of aflatoxins in proportion to increasing regulatory limits**.**

(a) Adult Consumers

Proposed aflatoxin limit (µg/kg)	Aflatoxin Exposure (ng/person/day)*
4	124
8	248
10	310

* Based on contribution from 31 grams of nuts per day (2006 UK adults)

(b) Young Consumers

Proposed aflatoxin limit (µg/kg)	Aflatoxin Exposure (µg/person/day) *
4	24
8	48
10	60

* Based on contribution from 6 grams of nuts per day (2006 UK children)

If the regulatory limits are increased, the economic and commercial pressures are such that the majority of nuts on the market will be at or above this higher limit. The increased exposure estimates above are therefore realistic in the case of nuts, unlike many other foods where regulatory limits serve to exclude highly contaminated from entering the market.

II.2. Risk characterisation

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[24]. Also, in line the opinions of the EFSA Scientific Committee[25] and of the JECFA[26] 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 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.2.1. Intake estimates and calculations of MOEs for the average EU population

The intake of aflatoxins from foods other than almonds, hazelnuts and pistachios was predominant in the estimates of population average intakes of aflatoxins. Applying the JECFA cancer potency estimates to the range of lower bound to upper bound estimates of mean exposure provides an indication of anticipated cancer incidence in different EU regions (Table 24). These take into account the lowest and highest reported prevalences of chronic HBV infection in the ranges reported by the WHO for Europe, which are 0.2% and 7%, respectively.

[24] 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

[25] 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.

[26] FAO/WHO. 2005. Evaluation of certain food additives. World Health Organ Tech.Rep.Ser. 928, 1-156.

Table 24. Estimated cancer rates in different EU regions (data truncated at a ML of 4 µg/kg for almonds, hazelnuts and pistachios)

GEMS/ Food cluster	Total aflatoxin intake [a] Lower bound – upper bound (ng/kg b.w. per day)	Lowest HBV prevalence Cancers/yr per 100,000 [b]	Highest HBV Prevalence Cancers/yr per 100,000 [c]
F	0.352 – 0.687	0.0037 – 0.0073	0.011 – 0.021
B	0.838 – 1.934	0.0089 – 0.0205	0.025 – 0.059

[a] Based on population average consumption and mean occurrence data taken from Table 26
[b] assuming 0.2 % have a risk of 0.3 cancers/year per 100,000, and 99.8% have a risk of 0.01 cancers/year per 100,000 per 1 ng/kg b.w. per day
[c] assuming 7 % have a risk of 0.3 cancers/year per 100,000, and 93% have a risk of 0.01 cancers/year per 100,000 per 1 ng/kg b.w. per day

MOEs calculated on the basis of the BMDL values from the animal and human data are shown in Table 25. 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 25. 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[27]	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 based on data from table 26
[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 (see section 4.1.8)
[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

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

II.2.2. Vulnerable groups

High level consumers of nuts

The highest estimated aflatoxin intakes were derived for high level consumers of pistachios. These data are based on consumption data from a survey with a very low proportion of consumers and are therefore likely to overestimate long term exposure. The Panel used a worst case scenario, in which the upper end of the range of estimates for high level pistachio consumers, which were derived from limited consumption data, in a precautionary approach to assessing the risk to high level consumers. Table 26 shows the cancer risk estimates derived by applying the JECFA cancer potency estimates to the estimated intakes associated with MLs of 4, 8 and 10 µg/kg, again taking into account the lowest and highest reported prevalences of chronic HBV infection. These are slightly higher than the estimates for GEMS/food cluster B, in table 21 and show small increases associated with increasing MLs, but are all still at least two orders of magnitude lower than the reported incidences of HCC in Europe.

Table 26. Estimated cancer rates 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)	Highest total aflatoxin intake [a] Lower bound – upper bound (ng/kg b.w. per day)	Lowest HBV prevalence Cancers/yr per 100,000 [b]	Highest HBV prevalence Cancers/yr per 100,000 [c]
4	0.980 – 2.251	0.010 – 0.024	0.030 – 0.068
8	1.115 – 2.386	0.012 – 0.025	0.034 – 0.072
10	1.187 – 2.450	0.013 – 0.026	0.036 – 0.074

[a] Based on high level consumer consumption and mean occurrence data

[b] assuming 0.2 % have a risk of 0.3 cancers/year per 100,000 per 1 ng/kg b.w. per day, and 99.8% have a risk of 0.01 cancers/year per 100,000 per 1 ng/kg b.w. per day

[c] assuming 7 % have a risk of 0.3 cancers/year per 100,000 per 1 ng/kg b.w. per day, and 93% have a risk of 0.01 cancers/year per 100,000 per 1 ng/kg b.w. per day

Similarly, the Panel used these worst case data in calculating MOEs (table 27). The MOEs are smaller than for the average population estimates in table 25, but show a minimal impact of changing the ML, regardless of whether the focus is on the lower bound or upper bound estimates.

Children

The available data do not indicate that children have higher dietary exposure to aflatoxins than adults and therefore do not provide a basis for a different risk characterisation. However, the exposure estimates use the GEMS/Food data for dietary sources other than almonds, hazelnuts and pistachios, which are not specifically based of children’s consumption patterns. Therefore this conclusion is tentative and better exposure data are required.

Table 27. 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

Vegetarians and vegans

The limited available exposure estimates for vegetarians and vegans are lower than for the highest national estimates for high level consumers of nuts. Therefore, these data also do not provide a basis for a different risk characterisation.

Subgroups with chronic hepatitis infection

No specific data are available for this subgroup regarding consumption of nuts and other foods potentially contaminated with aflatoxins.

II.3. Overall conclusion 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.
.
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.

III. Sampling plan for aflatoxin contamination in almonds, Brazil nuts, hazelnuts and pistachios.

III.1. Background

The 36th Session of the Codex Committee on Food Additives and Contaminants (CCFAC) agreed to commence work on the development of sampling plans for aflatoxins in almonds, Brazil nuts, hazelnuts, and pistachios, subject to approval as new work by the Codex Alimentarius Commission.

Aflatoxin, and mycotoxins in general, are contaminants which are heterogeneously spread within the lot of a certain commodity. Because of the nature of this contamination, it is impossible to exactly determine the location and concentration of all the “hot spots” where the mycotoxins have been produced. It is therefore essential, when testing a lot for mycotoxin contamination, to have an appropriate sampling plan to generate the sample that best represents that lot and the level of contamination present.

An aflatoxin-sampling plan is defined by an aflatoxin test procedure and an accept/reject limit. The accept/reject limit is a threshold value that is usually equal to the maximum limit. The aflatoxin test procedure for tree nuts consists of a sampling, sample preparation, and analytical steps. Because of the uncertainty associated with each step, the true aflatoxin concentration of a bulk lot can’t be determined with 100% certainty. As a result, there is a chance that some lots with concentration greater than the maximum limit will be accepted by the sampling plan and some lots with concentration below the maximum limit will be rejected by the sampling plan. The performance (risk of misclassifications) of a sampling plan depends, in part, on the amount of uncertainty associated with each step of the aflatoxin test procedure.

The United States suggested that aflatoxin sampling plans recommendations for the four tree nuts be based upon the measurement of uncertainty and distribution among sample test results for each tree nut. From the uncertainty and distributional information, the performance of sampling plans can be estimated, which will help the electronic working group to design aflatoxin-sampling plans for each tree nut.

The U.S., Turkey, Iran, and Brazil agreed to conduct sampling studies to determine the uncertainty and distribution among sample test results for almonds, hazelnuts, pistachios, and Brazil nuts, respectively. As of April 2007 (1st session of the Codex Committee on Contaminants in Foods, CCCF), sampling data has been developed for almonds, hazelnuts, and pistachios. Brazil anticipates that sampling data for Brazil nuts will be available for statistical analysis in October 2007.

From the uncertainty and distributional data, the chances of accepting (or rejecting) a lot at a given aflatoxin concentration can be predicted for a specific sampling plan design (sample size, sample preparation method, analytical method, and maximum limit). The performance of sampling plan designs is described by operating characteristic (OC) curves.

III. 2. Sampling plan design considerations

Over and above consideration for consumer safety, the design of an aflatoxin-sampling plan is a compromise between costs of the sampling plan and the benefits of minimizing the risks of misclassifying of lots and effectively removing contaminated lots from the market. The previous discussions by the CCFAC sampling-working group considered the following practical aspects:

1. Two separate maximum limits and two separate sampling plans need to be established, one for raw shelled tree nuts destined for further processing and one for consumer-ready (also called ready-to-eat) shelled tree nuts.
2. Maximum limits need to be defined for raw tree nuts destined for further processing and consumer-ready tree nuts before a final decision can be made about a sampling plan design.
3. Codex established a 20 kg sample size and a 15 ng/g total aflatoxin maximum limit for raw shelled peanuts destined for further processing.
4. Should the sampling statistics be based upon in-shell nuts or shelled kernels. Either can be used knowing the hull-kernel mass ratio?
5. Tree nuts are more expensive than peanuts making the cost of equivalent sampling plans more expensive.
6. There appears to be more uncertainty associated with the sampling step for tree nuts than for peanuts requiring larger samples for tree nuts to get an equivalent level of performance to peanuts.
7. Can the same sampling plan design be used for two or more type of tree nuts? This will depend upon the similarity of uncertainty data for the four tree nuts.

III. 3. Results of Sampling Studies

Uncertainty - The aflatoxin test procedure used for each tree nut study along with the sampling, sample preparation, and analytical variance equations are shown in Annex I, Table 1. Where possible, the experimental design was similar (Brazil nut studies have not yet started). Generally, the uncertainty was measured using a 10 kg samples, dry grinding the sample with vertical cutter type mills (VCM), selection of a 25 to 100 g subsample from the comminuted sample, and HPLC analytical methods to quantify the aflatoxin in the comminuted subsample. Almond and hazelnut studies used 10 kg samples of shelled kernels while the pistachio study used 10 kg of inshell nuts, which is equivalent to 5 kg of shelled kernels. The count per unit mass for shelled almonds, hazelnuts, and pistachios is 773, 1000, and 1600 kernels per 1 kg, respectively.

The sampling, sample preparation, and analytical variances were found to be a function of aflatoxin concentrations (C). Variance equations were developed for each tree nut showing the effect of aflatoxin concentration and quantity inspected on the magnitude of each variance.

Using the variance equations in Table 1, the sampling, sample preparation, and analytical variance associated with the specific test procedure are shown in Tables 2 and 3 for each tree nut when sampling a lot at 8 and 15 ng/g total aflatoxin. Tables 2 and 3 show that the sampling step contributes most of the uncertainty associated with the test procedure. The effect of uncertainty associated with sampling, sample preparation, and analytical steps of the aflatoxin test procedure for all three tree nuts are approximately the same magnitude.

Effect of type tree nut on the performance of aflatoxin sampling plan design - Because the variance equations associated with the sampling, sample preparation, and analytical steps are slightly different for each tree nut (Table 1, Annex I), the performance or OC curves for the same sampling plan design will be slightly different for each of the three tree nuts. As an example, three OC curves for the same sampling plan that uses a 20 kg sample, dry grind, 50 g subsample, HPLC analytical method, and 8 ng/g maximum limit is shown in Annex II, Figure 1 using uncertainty data measured for almonds, hazelnuts, and pistachios. Figure 2 shows three OC curves for the same sampling plan design, but for a maximum limit of 15 ng/g total aflatoxin.

The OC curves for hazelnuts and pistachios (either maximum limit) are similar, while the OC curve for almonds is slightly different. The OC curve for almonds reflects more uncertainty in the aflatoxin test procedure than for hazelnuts and pistachios (Table 1, Annex I). Because there appears to be slightly more uncertainty with the aflatoxin test procedure used for almonds, the uncertainty associated with sampling almonds for aflatoxin could be used to predict the performance of aflatoxin sampling plans for all three tree nuts. Performance estimates for pistachio and hazelnut sampling plans would be slightly more conservative.

Effects of Sample Size on the Performance of Sampling Plans - To help the electronic working group recommend a sampling plan for tree nuts, operating characteristic curves were developed for the following design parameters:
Using uncertainty equations for almonds in Table 1, Annex I for all three tree nuts;
Sampling plans were developed for raw shelled tree nuts destined for further processing and for consumer-ready shelled tree nuts;

1. Maximum limits of 15 ng/g total aflatoxin for raw shelled tree nuts destined for further processing and 8 ng/g total aflatoxin for consumer-ready shelled tree nuts;
2. Three sample sizes of 10, 20, and 30 kg;
3. Because the uncertainty of the sampling step accounts for a major portion of the total uncertainty associated the overall aflatoxin test procedure, the following sample preparation and analytical parameters were considered: dry grind, 50 g subsample, and use of HPLC to quantify aflatoxin in one aliquot taken from the subsample/solvent blend.

An OC curve describes the performance or the chances of accepting lots at a given aflatoxin concentration using a specific sampling plan design. Three OC curves representing the performance of sampling plans that use 10, 20, and 30 kg samples of raw shelled tree nuts destined for further processing (maximum limit of 15 ng/g total aflatoxin) are shown in Figure 1, Annex III. Three OC curves representing the performance of sampling plans that use 10, 20, and 30 kg samples of consumer-ready shelled tree nuts (maximum limit of 8 ng/g total aflatoxin) are shown in Figure 2, Annex III.

The relative effect of sample size on the OC curve (or the performance of a sampling plan design) is the same for both maximum limits of 8 and 15 ng/g. As sample size (ns) increases, the variance (Table 1, Annex I) decreases and fewer lots are misclassified by the sampling plan. In Figure 1, Annex III, as sample size increases, the slope of the OC curve increases. As a result, more good lots (lot <=15 ng/g maximum limit) are accepted and fewer bad lots (lot <= 15 ng/g maximum limit) are accepted by the sampling plan as sample size increases. Increasing sample size has the same effect for consumer-ready shelled tree nuts.

<u>Effect of maximum limit on the performance of aflatoxin sampling plans</u> – The effect of using a 4, 8, 10, and 15 ng/g maximum limit on the performance of sampling plans that use either a 10, 20, or 30 kg sample are shown in Annex IV, Figures 1, 2, and 3, respectively. For a given sample size, as maximum limit decreases from 15 to 4 ng/g, the OC curves shift to the left. The results of reducing the maximum limit are both good and bad. As the maximum limit decreases, fewer lots at low concentrations are accepted and fewer lots at high concentrations are accepted. For a given sample size, as the maximum limit decreases, fewer lots are accepted (more lots are rejected), but overall aflatoxin in the accepted lots decreases. Choosing a maximum limit is a balance between not interrupting international trade (rejecting too many lots) and removing contaminated lots to protect public health.

III. 4. Conclusions

Sampling studies have been completed for almonds, hazelnuts, and pistachios. Several sampling plan designs were evaluated to demonstrate the effect of type tree nut, sample size, and maximum limit on the risk of misclassifying lots. As part of the electronic working group, the U.S. delegation can evaluate other sampling plan designs for the electronic working group as maximum limits and sample sizes are discussed.

III. 5. Acknowledgement

The United States delegation wishes to thank and acknowledge parties in the United States, Turkey, and Iran for conducting the sampling studies and providing the sampling data and statistical analyses so the United States could evaluate the performance of sampling plans for almonds, hazelnuts, and pistachios, respectively, for the CCCF Electronic Working Group.

ANNEX I to part B.III.

Uncertainty associated with sampling, sample preparation, and analytical steps of the aflatoxin test procedure used to estimate aflatoxin in almonds, hazelnuts, and pistachios.

Table 1. Experimental test conditions and uncertainty results for each treenut.

Test Procedure	Almonds	Hazelnuts	Pistachios
Sampling	$S^2_s = (10/ns)5.759C^{1.561}$	$S^2_s = (10/ns)4.291C^{1.609}$	$S^2_s = (5/ns)7.913C^{1.475}$
Sample Prep	$S^2_{sp} = (100/nss)0.170C^{1.646}$	$S^2_{sp} = (50/nss)0.021C^{1.545}$	$S^2_{sp} = (25/nss)2.334C^{1.522}$
Analytical	$S^2_a = (1/na)0.0041C^{1.966}$	$S^2_a = (1/na)0.0028C^{1.990}$	$S^2_a = (1/na)0.0368C^{1.598}$
Sample Product	shelled kernels	shelled kernels	In-shell (5 kg shelled kernels)
Sample size ns kg	10	10	10 kg inshell/ 5kg shelled
Sample Prep (mill)	Hobart (dry grind)	Robot Coupe (dry grind)	Marjaan Khatam (dry grind)
Subsample size nss g	100	50	25
Analytical method	HPLC (na = 1 aliquot)	HPLC (na = 1 aliquot)	HPLC (na = 1 aliquot)
Total variance	$S^2_s + S^2_{sp} + S^2_a$	$S^2_s + S^2_{sp} + S^2_a$	$S^2_s + S^2_{sp} + S^2_a$

Note: All sampling variances reflect shelled kernels. Pistachio sampling study was conducted on 10 kg of in-shell nuts. Hull represents about 50% of the total inshell mass. Sampling data for almonds, hazelnuts, and pistachios supplied by the United States, Turkey, and Iran, respectively. S^2 = variance, ns = sample size in kg, nss = subsample size in g, na = number of aliquots quantified, and C = aflatoxin concentration (ng/g).

Table 2. Uncertainty associated with the aflatoxin test procedure to estimate aflatoxin in bulk lots of almonds, hazelnuts, and pistachios at 8 total ng/g using equations in Table 1.

Test Procedure	Size	Variance			Coeff of Variation (%)			Variance Ratio (Component/Total)		
		Almonds	Hazelnuts	Pistachios	Almonds	Hazelnuts	Pistachios	Almonds	Hazelnuts	Pistachios
Sample (kg)	10	147.93	121.80	84.99	152.04	137.95	115.24	93.27	99.43	74.78
Sample Prep (g)	50	10.42	0.52	27.64	40.35	9.03	65.72	6.57	0.43	24.32
Analysis HPLC	1	0.24	0.18	1.02	6.18	5.24	12.63	0.15	0.14	0.90
Total		158.60	122.49	113.65	157.42	138.35	133.26	100.00	100.00	100.00

Table 3. Uncertainty associated with the aflatoxin test procedure to estimate aflatoxin in bulk lots of almonds, hazelnuts, and pistachios at 15 total ng/g.

Test Procedure	Size	Variance			Coeff of Variation (%)			Variance Ratio (Component/Total)		
		Almonds	Hazelnuts	Pistachios	Almonds	Hazelnuts	Pistachios	Almonds	Hazelnuts	Pistachios
Sample (kg)	10	394.66	334.88	214.81	132.44	122.00	97.71	92.90	99.41	74.19
Sample Prep (g)	50	29.33	1.38	71.96	36.11	7.83	56.55	6.90	0.41	24.85
Analysis HPLC	1	0.84	0.61	2.79	6.12	5.22	11.13	0.20	0.18	0.96
Total		424.83	336.87	289.55	137.41	122.36	113.44	100.00	100.00	100.00

Size = 1 for analysis indicates that 1 aliquot was quantified by HPLC

ANNEX II to Part B.III

Comparing performance of sampling plans using almond, hazelnut, and pistachio sampling data.

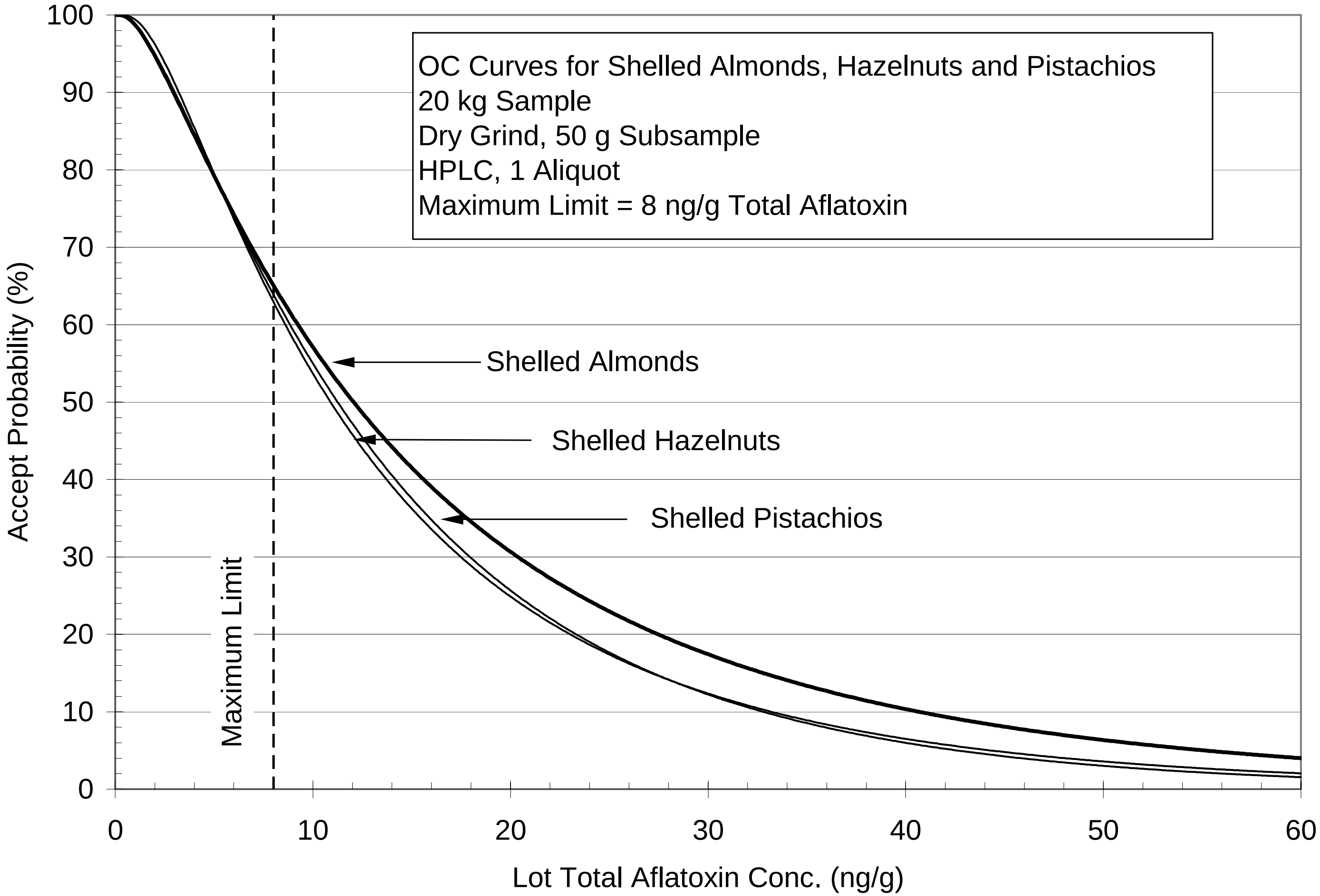


Figure 1. Operating characteristic curves based upon consumer-ready almond, hazelnut, and pistachio uncertainty data for a 20 kg sample, dry grinding, 50 g subsample, using HPLC to quantify aflatoxin in 1 aliquot, and 8 ng/g maximum limit.

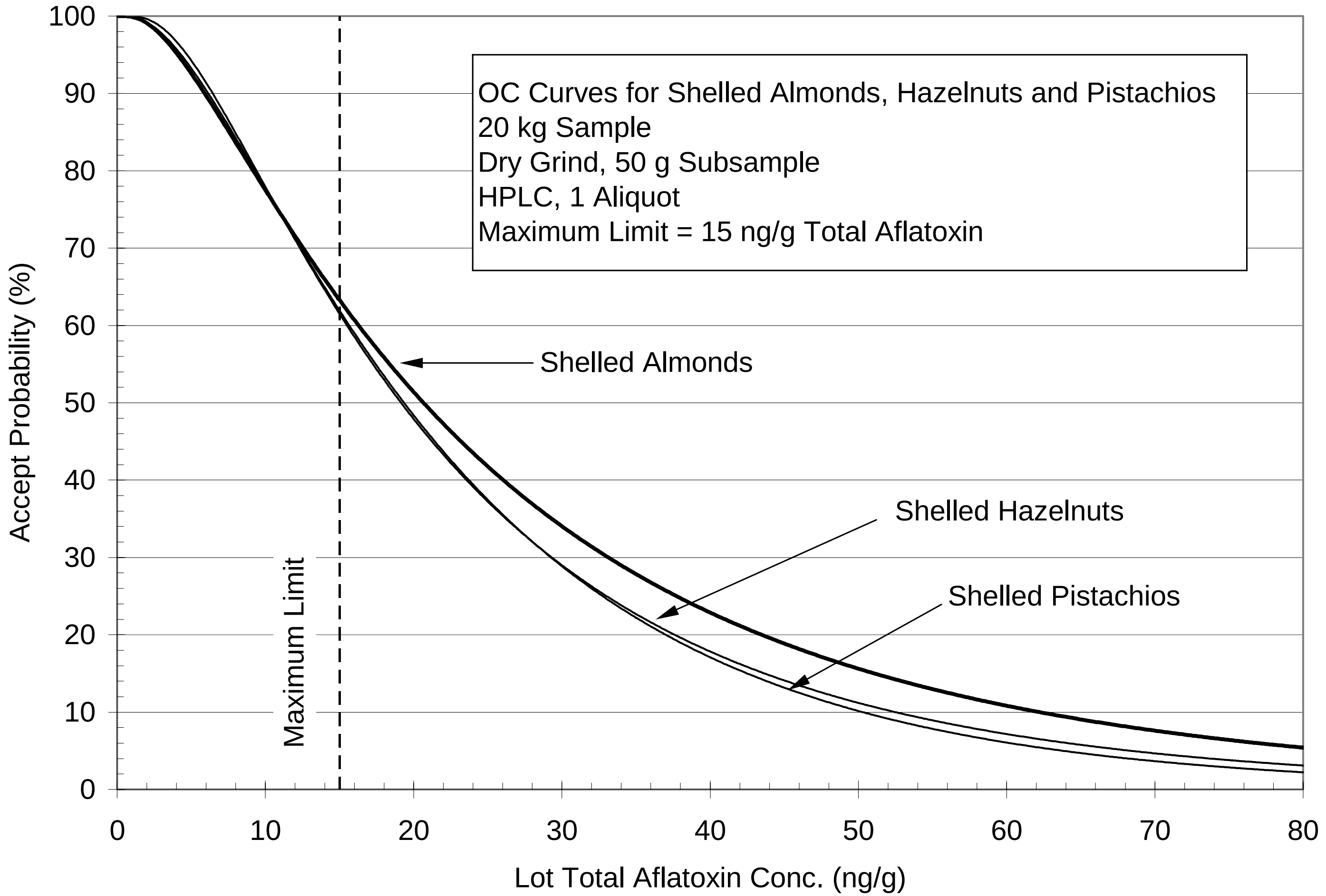


Figure 2. Operating characteristic curves based upon raw shelled almond, hazelnut, and pistachio uncertainty data for a 20 kg sample, dry grinding, 50 g subsample, using HPLC to quantify aflatoxin in 1 aliquot, and 15 ng/g maximum limit.

ANNEX III to part B.III

Effect of sample size on performance of aflatoxin sampling plans for three tree nuts (almonds, hazelnuts, and pistachios).

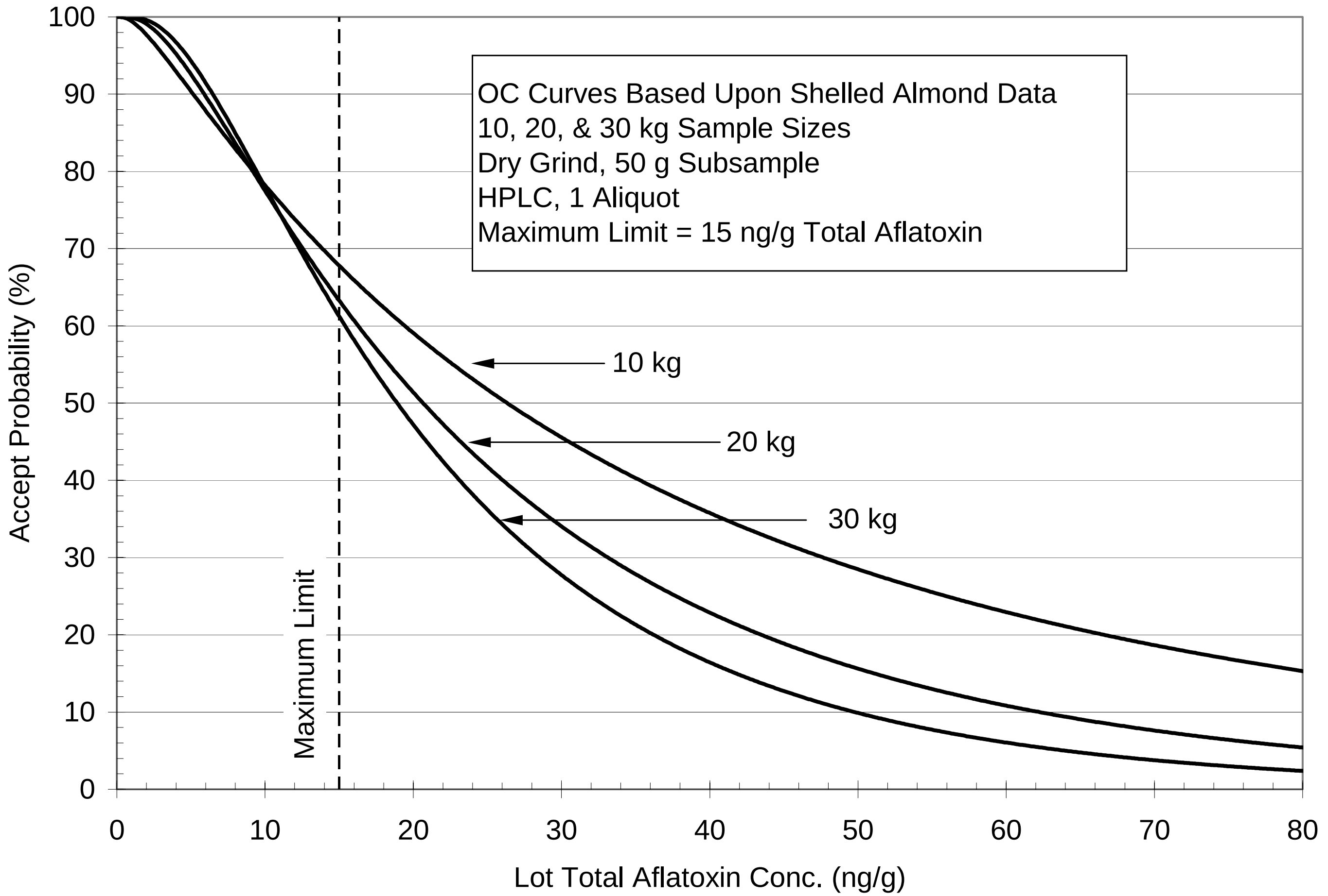


Figure 1. Three OC curves showing the effect of sample size on reducing the risk of misclassifying raw shelled treenut lots destined for further processing. The maximum limit for all three sampling plans is 15 ng/g total aflatoxin.

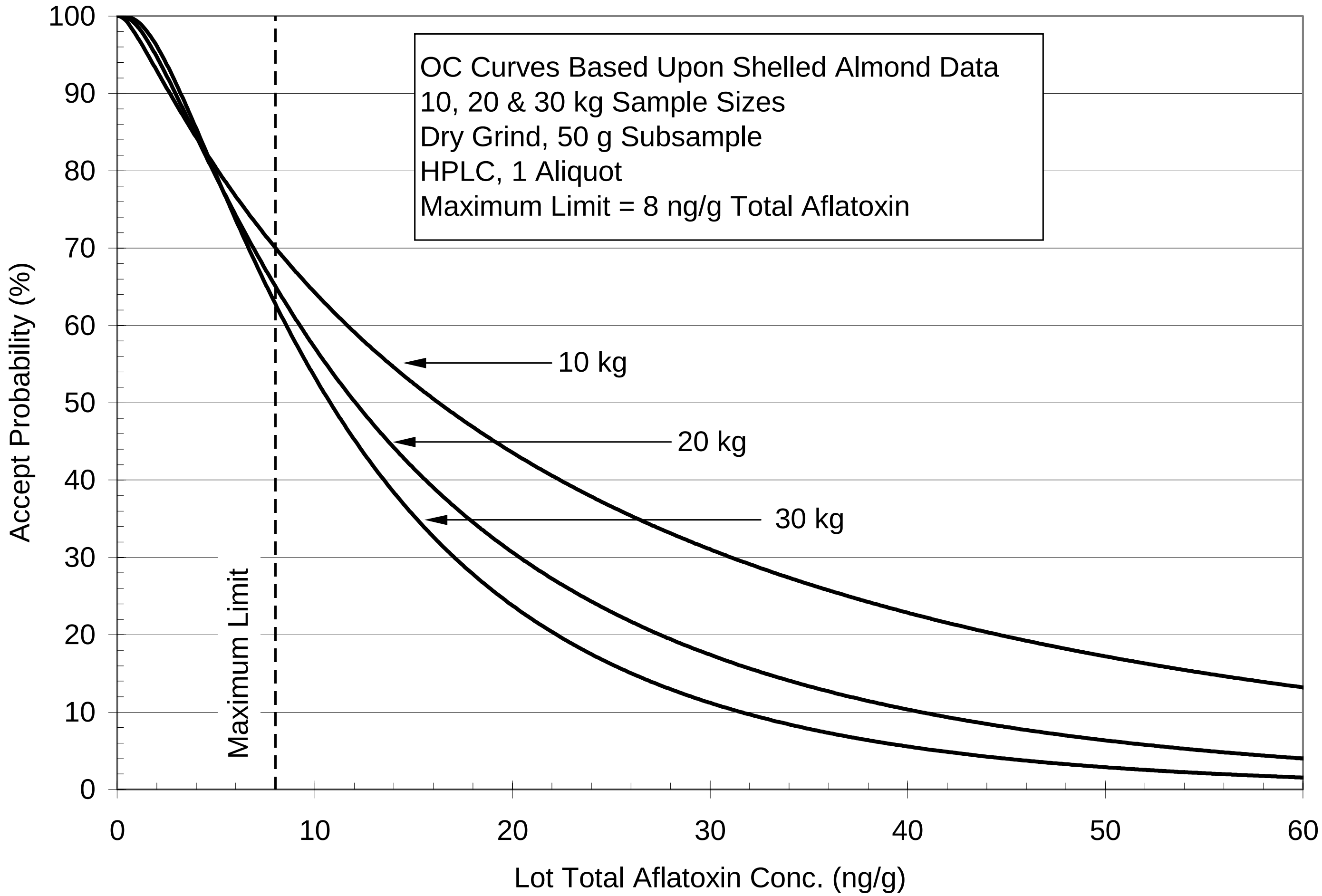


Figure 2. Three OC curves showing the effect of sample size on reducing the risk of misclassifying shelled consumer-ready treenut lots. The maximum limit for all three sampling plans is 8 ng/g total aflatoxin.

Annex IV to Part B.III

Effect of maximum limit on the performance of aflatoxin sampling plans for treenuts.

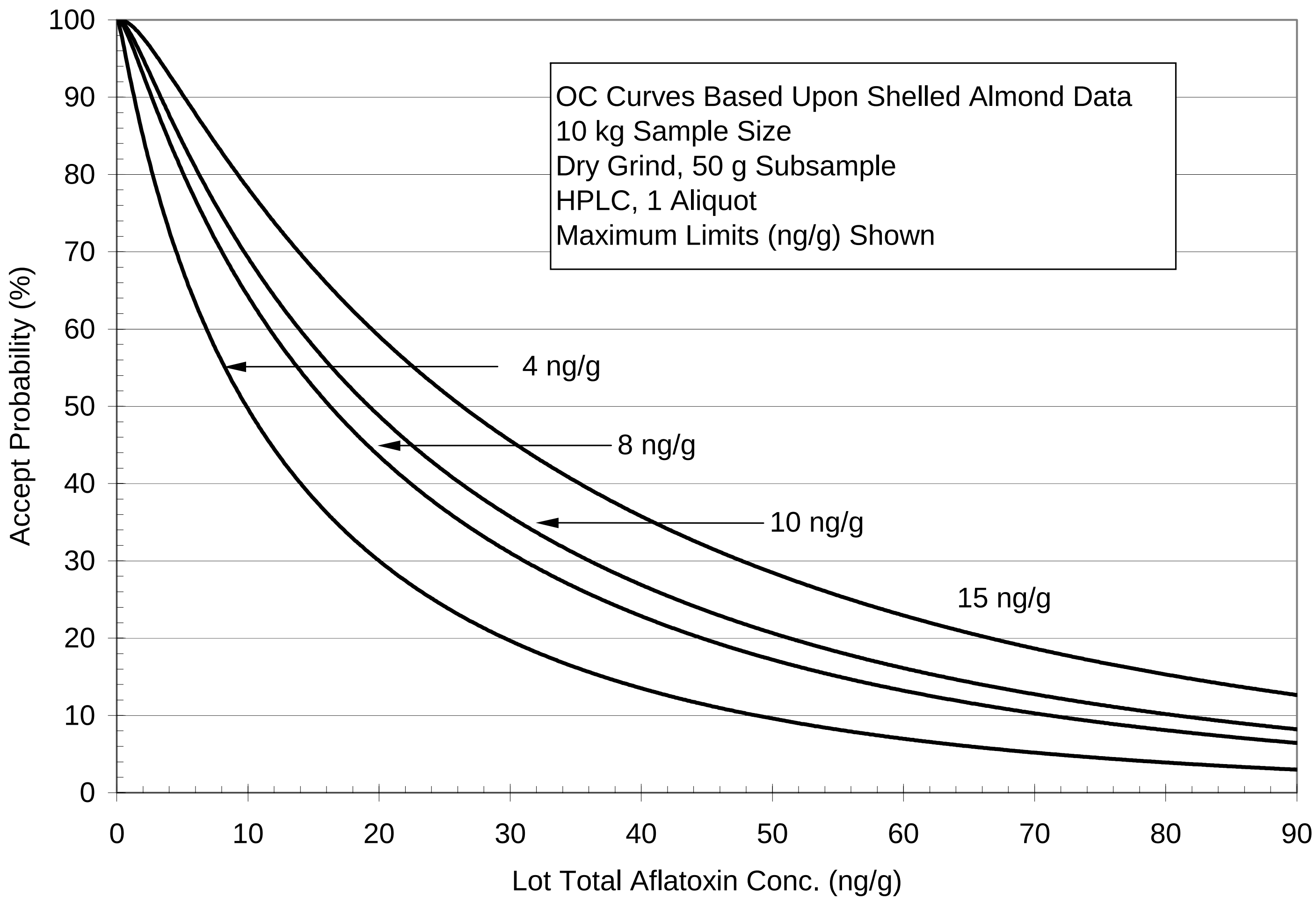


Figure 1. Performance of four-aflatoxin sampling plans for treenuts using 4, 8, 10, and 15 ng/g maximum limits. All sampling plans use a 10 kg sample.

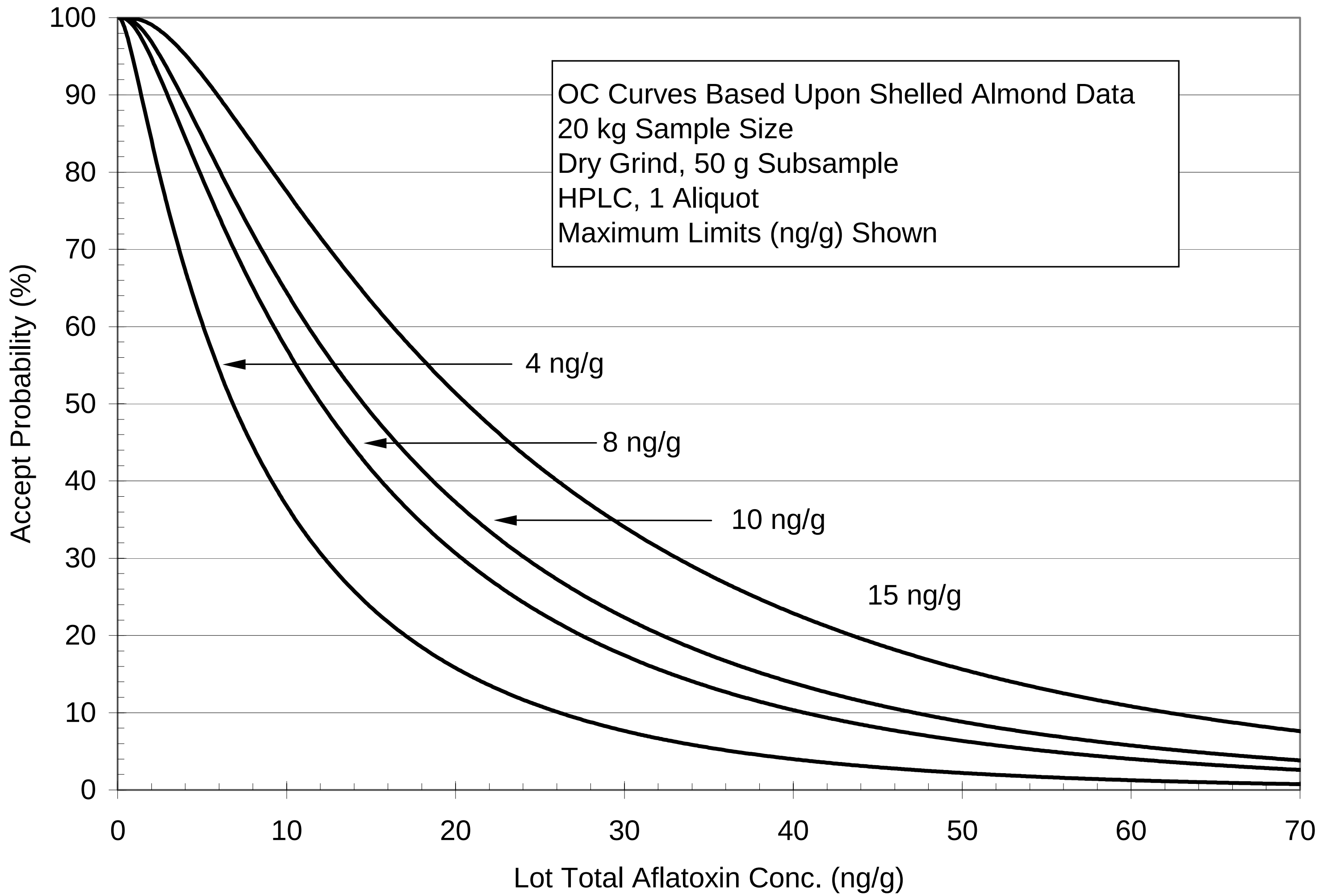


Figure 2. Performance of four-aflatoxin sampling plans for tree nuts using 4, 8, 10, and 15 ng/g maximum limits. All sampling plans use a 20 kg sample.

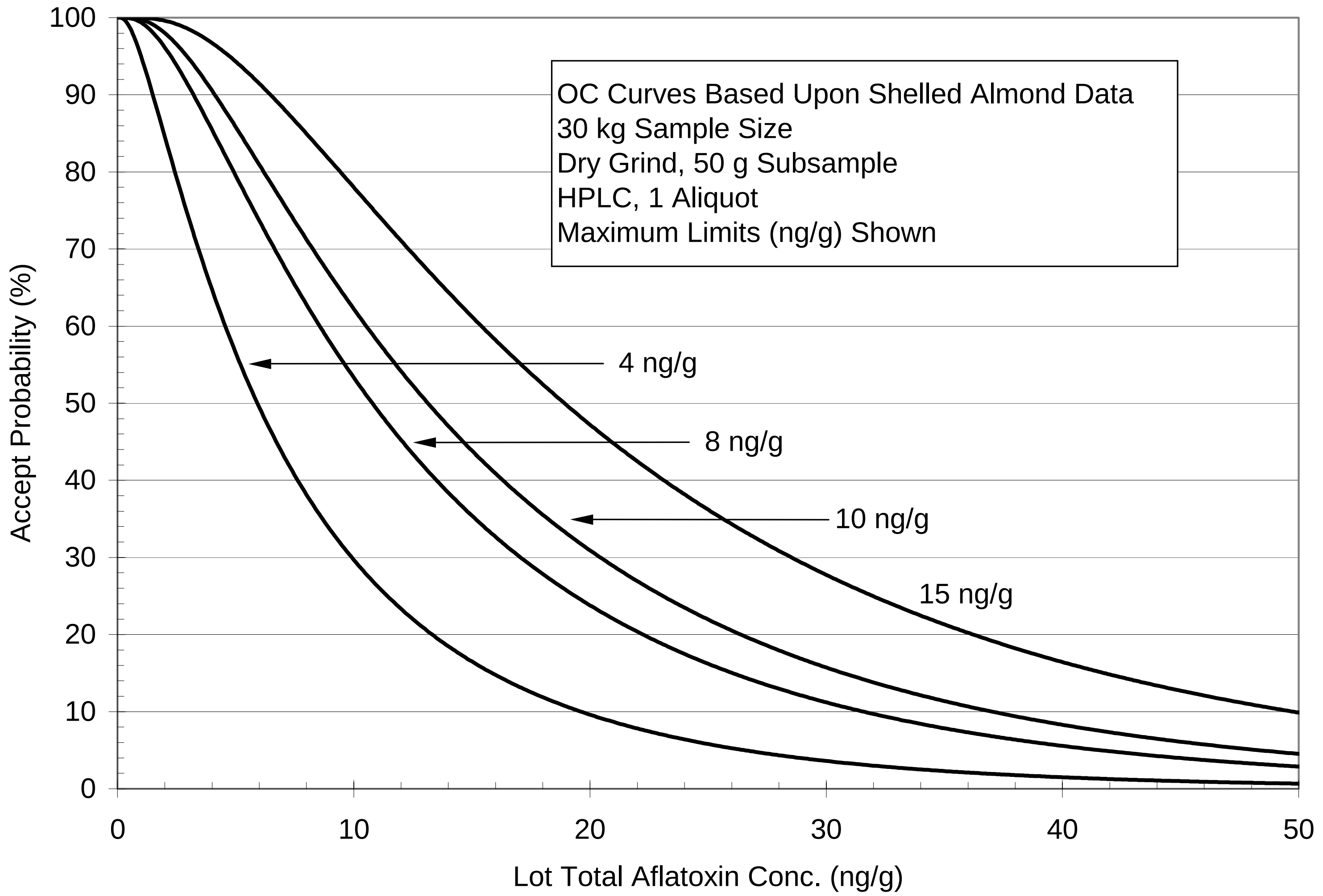


Figure 3. Performance of four-aflatoxin sampling plans for tree nuts using 4, 8, 10, and 15 ng/g maximum limits. All sampling plans use a 30 kg sample.

IV. Effects of codes of practice

IV.1. 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.

Our data, reflecting this progress, was given in the codex document, *CX/FAC 05/37/22-Add. 1* in 2005

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
% 20th value	0	0	0	0	0	0	0	0	0	0	0	0
% 80th value	0	0	0	0	0,23	0,63	0,30	0,70	0,3	0,60	0	0
% 90th value	0	0	0,63	0,85	1,25	2,5	0,98	1,94	1,00	1,98	0,30	0,33
% 95th value	0	0	1,38	2,05	1,70	3,37	1,60	3,40	1,60	3,30	0,60	1,18
% 99th 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.

IV.2. 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.3. Information provided by INC

Origin producers have been revising Good Agricultural Practices (GAPs) and Good Manufacturing Practices (GMPs) in order to comply with stricter food safety requirements worldwide. Following are examples of measures which have been implemented by origin producers:

Green Corridor Project (cf. also information provided by Iran under IV.2). An extensive project has been implemented over 2 years 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.

Almond in-edible program. In the U.S., standards have been tightened on percentages of damaged kernels that are permitted to enter the commercial stream. The standards resulted in an additional 3,400 mtons of potentially contaminated kernels removed from edible channels. Furthermore, stricter standards for damage allowed in consignments are being reviewed. Even by significantly reducing the % of “serious damage” allowed in a consignment of almonds, there are still unavoidable risks associated with aflatoxin due to the heterogeneity of contamination. As an example, an average consignment contains 15,500,000 almond kernels. If only 1% are potentially contaminated, that is still 155,000 kernels disbursed throughout the consignment.

Also on hazelnut kernels from Turkey, in spite of very deep and accurate study supported by INC and application of GAP and GMP, we have a not linear casuality which is subject to weather conditions.

Origin Testing and Certification. Methodologies for sampling and testing nuts prior to shipment have been implemented for peanuts and pistachios in the U.S. These measures have resulted in reduced rejections on arrival in importing countries, since it is possible to divert or resort a number of consignments prior to shipment. This approach also provides additional assurance for import authorities, reducing the need for extensive surveillance on arrival – which can be more expensive as well as potentially a food safety risk if proper warehousing is not available in which to hold goods which are being inspected. However, a certain percentage of contamination is unavoidable, resulting in the potential for false positives (exporters risk) or false negatives (buyers risk) on arrival at port of entry.

<u>V. Terminology of “ready-to-eat” and “for further processing”</u>

"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**

"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 sorting by size, specific gravity, and colour (damage),

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

<u>Specific information as regards pistachio nuts:</u>

Processes applied to "in-shell pistachio nuts for further processing" include processing which removes discoloured nuts, deformed nuts, adhering hull, nuts closed in shell, damaged pistachio kernels, mouldy nuts and nuts damaged by storage pests. It might also involve the sorting out of very small pistachio nuts (pistachios passing the 11/12/13 mm sieve)

Processes applied to "pistachio kernels for further processing" include processing which removes particles (small pieces of endocarp of kernel and which passes a 2 mm sieve), dust, kernel pieces, damaged kernels, mouldy kernels and kernels damaged by storage pests and shriven kernels.

In-shell pistachio nuts and pistachio kernels which have undergone the abovementioned processes result in "ready-to-eat" in-shell pistachio nuts and pistachio kernels.

VI. ANNEX

Table 11: Consumption figures of almonds taken from food surveys of the EU-Member States and GEMS/Food Consumption Cluster Diets database for adult population

Country	All population				Consumers only				Remark
	N	Mean (g/day)	95th perc.	97.5th perc.	%	Mean (g/day)	95th perc.	97.5th perc.	
GEMS/ Food Cluster B		1.9							ingredients included
GEMS/ Food Cluster E		1.0							
GEMS/ Food Cluster F		0.8							
Spain	1,060	0.2	2.6	3.1	1.5	9.8	21.9	24.2	unshelled, ingredients not included
Spain	1,060	0.5	4.9	5.8	5.7	8.6	21.2	23.7	shelled, ingredient not included
Germany	4,030	0.4	2.0	-	29.0	1.3	5.4	-	ingredients included
Ireland	1,379	0.1	-	-	10.5	0.8	-	5.9	ingredients included
France	1,474	0.5	2.1	-	29.8	1.6	3.7	-	ingredients included
United Kingdom	1,724	0.1	-	-	2	3.3	-	15.9	ingredients not included
United Kingdom	1,724	0.5	-	-	32	1.6	-	8.3	ingredients included

Table 12: Consumption figures of hazelnuts taken from food surveys of the EU-Member States and GEMS/Food Consumption Cluster Diets database for adult population

Country	All population				Consumers only				Remark
	N	Mean (g/day)	95th perc.	97.5th perc.	%	Mean (g/day)	95th perc.	97.5th perc.	
GEMS/ Food Cluster B		2.1							ingredients included
GEMS/ Food Cluster E		1.3							
GEMS/ Food Cluster F		0.3							
Spain	1,060	0.1	2.2	2.6	2.0	7.2	15.7	17.3	ingredients not included
Germany	4,030	1.4	8.0	-	37.6	3.6	14.3	-	ingredients included
Ireland	1,379	0.2	-	-	9.9	2.0	-	12.3	ingredients included
France	1,474	0.4	2.2	-	17.8	2.2	7.1	-	ingredients included
United Kingdom	1,724	0.04	-	-	0.6	6.2	-	(max 30.7)	ingredients not included
United Kingdom	1,724	0.2	-	-	15.8	1.3	-	5.4	ingredients included

Table 13: Consumption figures of pistachios taken from food surveys of the EU-Member States and GEMS/Food Consumption Cluster Diets database for adult population

Country	All population				Consumers only				Remark
	N	Mean (g/day)	95th perc.	97.5th perc.	%	Mean (g/day)	95th perc.	97.5th perc.	
GEMS/ Food Cluster B		0.7							ingredients included
GEMS/ Food Cluster E		0.3							ingredients included
GEMS/ Food Cluster F		<0.1							ingredients included
Spain	1,060	0.3	5.8	6.9	1.7	19.9	47.5	52.8	ingredients not included
Germany	4,030	0.2	0.2	-	11.4	1.4	7.5	-	ingredients included
Ireland	1,379	<0.1	-	-	0.3	2.8	-	5.7	ingredients included
France	1,474	0.1	0.0	-	3.5	2.7	7.2	-	ingredients included
United Kingdom	1,724	0.07	-	-	0.7	9.3	-	(max 35.7)	ingredients not included
United Kingdom	1,724	0.07	-	-	1.1	6.3	-	25.9	ingredients included

Table 14: Consumption figures of almonds taken from food surveys of the EU-Member States for children.

Country	All population				Consumers only				Remark
	N	Mean (g/day)	95th perc.	97.5th perc.	%	Mean (g/day)	95th perc.	97.5th perc.	
Spain	90	<0.1	1.1	1.3	0.2	12.5	23.0	25.0	unshelled, ingredients not included
Spain	90	0.2	2.5	3.0	1.6	9.8	20.8	22.9	shelled, ingredient not included
Germany	47	0.5	2.6	-	46.9	1.0	3.3	-	ingredients included
Ireland	59	<0.1	<0.1	0.2	2.9	1.1	3.8	5.5	ingredients included
France	1,018	0.2	1.2	-	21.2	0.9	-	-	ingredients included
United Kingdom (4-18y)	1,701	<0.1	-	-	0.4	2.1	-	-	ingredients not included
United Kingdom (4-18y)	1,701	0.4	-	-	33.0	1.3	-	4.8	ingredients included
United Kingdom (1.5-4.5y)	1,675	0	-	-	0.2	1.4	-	-	ingredients not included
United Kingdom (1.5-4.5y)	1,675	0.1	-	-	12.0	0.9	-	3.3	ingredients included
United Kingdom	22	0.2	-	-	92.9	0.2	-	-	ingredients not included

Table 15: Consumption figures of hazelnuts taken from food surveys of the EU-Member States for children.

Country	All population				Consumers only				Remark
	N	Mean (g/day)	95th perc.	97.5th perc.	%	Mean (g/day)	95th perc.	97.5th perc.	
Spain	903	<0.1	1.1	1.3	0.4	8.8	17.6	19.3	ingredient not included
Germany	475	1.3	5.0	-	81.7	1.6	5.2	-	ingredients included
Ireland	594	<0.1	<0.1	<0.1	1.9	1.0	2.2	2.9	ingredients included
France	1,018	0.8	3.4	-	47.3	1.7	-	-	ingredients included
United Kingdom (4-18y)	1,701	0	-	-	0.1	4.3	-	-	ingredients not included
United Kingdom (4-18y)	1,701	0.2	-	-	21.0	0.9	-	3.8	ingredients included
United Kingdom (1.5-4.5y)	1,675	0	-	-	0.2	1.0	-	-	ingredients not included
United Kingdom (1.5-4.5y)	1,675	<0.1	-	-	11.0	0.7	-	2.7	ingredients included
United Kingdom	225	0.2	-	-	96.9	0.2	-	-	ingredients not included

Table 16: Consumption figures of pistachios taken from food surveys of the EU-Member States for children.

Country	All population				Consumers only				Remark
	N	Mean (g/day)	95th perc.	97.5th perc.	%	Mean (g/day)	95th perc.	97.5th perc.	
Spain	903	0.1	1.3	1.5	0.6	9.4	16.5	17.9	ingredient not included
Germany	475	< 0.1	<0.1	-	1.9	0.3	1.1	-	ingredients included
Ireland	594	<0.1	<0.1	<0.1	0.7	4.8	7.9	7.9	ingredients included
France	1,018	0.1	<0.1	-	2.7	3.8	-	-	ingredients included
United Kingdom (4-18y)	1,701	0.01	-	-	0.3	3.4	-	-	ingredients not included
United Kingdom (4-18y)	1,701	0	-	-	0.5	2.6	-	-	ingredients included
United Kingdom (1.5-4.5y)	1,675	<0.1	-	-	0.2	4.3	-	-	ingredients not included
United Kingdom (1.5-4.5y)	1,675	<0.1	-	-	0.4	3.5	-	-	ingredients included
United Kingdom	225	0.5	-	-	93.3	0.6	-	-	ingredients not included

Accompanying information to Tables 18, 19 and 20 (including Figure 9)

All data were combined in four scenarios for the exposure assessment. In general, a scenario is characterised by the following decisions:

- Consumption
    a) taking into account “all population” or “consumers only”;
    b) mean or high percentile of a);
    c) GEMS/Food Consumption Cluster Diets data or data from individual surveys;
    d) definition of exposure from other food sources;
    e) selection of a subgroup.

- Occurrence data
    f) aflatoxin B1 or total aflatoxins;
    g) upper bound or lower bound estimates to handle values below the LOD;
    h) mean or high percentiles for f);
    i) different cut off points to simulate the MLs.

It was not feasible to present results of all possible combinations for all Member States and subgroups. Therefore, the following four scenarios were explored:

- **Scenario 1 - Average exposure -**
    a) “all population” for hazelnuts, almonds and pistachios;
    b) population mean consumption data for all three nuts;
    c) GEMS/Food Consumption Cluster Diets data and data from individual surveys;
    d) exposure from other food sources from GEMS/Food Consumption Cluster Diets database mean for all population and mean of the aflatoxin occurrence data;
    e) adults, children and vegetarians;
    f) total aflatoxins;
    g) upper bound and lower bound estimates;
    h) mean values for occurrence data;
    i) cut off points of 4, 8 and 10 µg/kg to simulate different proposed MLs

- **Scenario 2 - High level exposure for almonds -**
    a) taking into account “all population” for hazelnuts and pistachios and “consumers only” for almonds;
    b) mean for hazelnuts and pistachios, but high level for almond consumption;
    c) data from individual surveys;
    d) same as Scenario 1;
    e) adults;
    f) total aflatoxins total;
    g) to i) same as Scenario 1;

- **Scenario 3 - High level exposure for hazelnuts -**
  a) taking into account "all population" for almonds and pistachios and "consumers only" for hazelnuts;
  b) mean for almonds and pistachios, but high level for hazelnut consumption;
  c) same as Scenario 2;
  d) same as Scenario 1;
  e) same as Scenario 2;
  f) total aflatoxins;
  g) to i) same as Scenario 1;

- **Scenario 4 - High level exposure for pistachios -**
  a) taking into account "all population" for almonds and hazelnuts and "consumers only" for pistachios;
  b) mean for almonds and hazelnuts, but high level of pistachios consumption;
  c) same as Scenario 2;
  d) same as Scenario 1;
  e) same as Scenario 2;
  f) total aflatoxins;
  g) to i) same as Scenario 1.

The composition of exposure from other foods differed in the three GEMS/Food regions. The fractions of exposure from other nuts and spices were low in all regions. In the southern countries the exposure from maize was highest and in northern countries oilseeds, were the most important exposure source for exposure from other foods. All there results are illustrated in Figure 9.

Figure 9: Percentage contribution of other foods to total exposure based on GEMS/Food consumption data and collected occurrence data from Member States

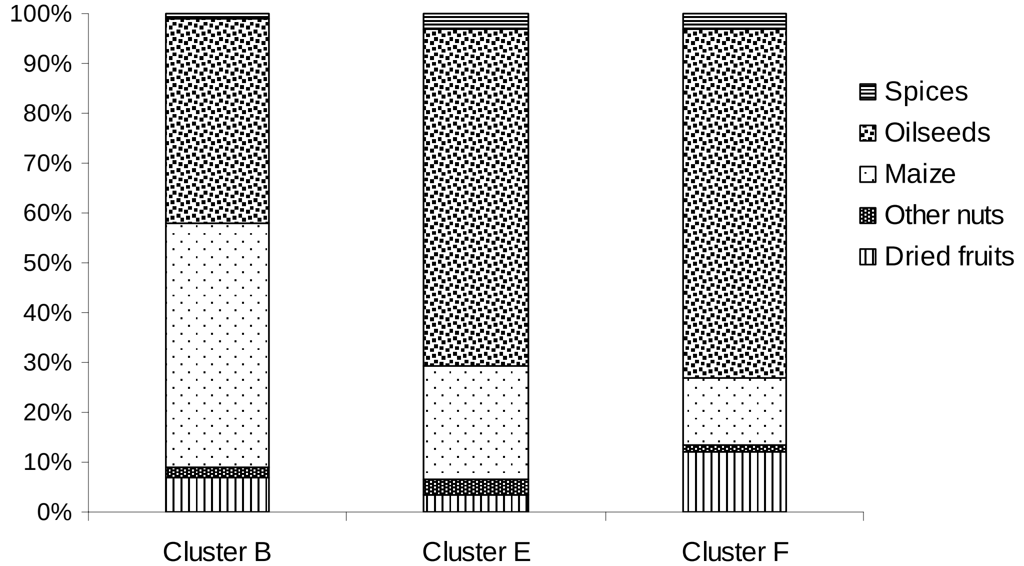


Table 18: Scenario 1 “average exposure” to total aflatoxins in ng/kg b.w. per day truncating occurrence data at its current EU MLs for adults

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 19: 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 20: 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**
