codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 16 (b) **CX/FAC 05/37/22-Add. 1**
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ORIGINAL LANGUAGE ONLY

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS

Thirty-seventh Session

The Hague, the Netherlands, 25 – 29 April 2005

PROPOSED DRAFT MAXIMUM LEVEL FOR AFLATOXIN IN UNPROCESSED AND PROCESSED ALMONDS, HAZELNUTS AND PISTACHIOS

COMMENTS AT STEP 3 (IN RESPONSE TO CL 2004/9-FAC)

The following comments have been received from: Cuba, European Community, Iran, Turkey, and USA

Cuba:

Estamos de acuerdo con un nivel máximo de 15 microgramos/kg del total de aflatoxinas ens Nueces de Árbil, pero consideramos conveniente incluir un nivel máximo especifíco para aflatoxina B1

EGNLISH TRANSLATION

We agree to a maximum level for the total content of aflatoxins in tree nuts of 15 µ/kg but consider that it would be appropriate to include a specific maximum level for aflatoxin B1.

European Community:

In addition to comments from the European Community contained in document CX/FAC 05/37/22, the European Community wishes to provide following information as regards the comments made by INC (also contained in document CX/FAC 05/37/22).

1) Comments as regards the statement ***"Given the fact that tree nut consumption is less than peanuts, it is unlikely that consumer exposure considerations would necessitate more restrictive aflatoxin levels"***

The European Community wishes to draw the attention of CCFAC that the maximum level for aflatoxin total in peanuts intended for further processing, adopted by the Codex Alimentarius Commission at its 23rd session in Rome in July 1999 is for peanuts which **requires further processing before human consumption**. It is generally known that several processing steps significantly reduce the aflatoxin **content resulting in peanuts for direct human consumption with much lower levels of aflatoxin total** than the adopted CODEX maximum level of 15 µg/kg for aflatoxin total in peanuts intended for further processing.

The currently proposed draft maximum level for aflatoxin total in unprocessed and processed almonds, hazelnuts and pistachios applies to almonds, hazelnuts and pistachios for further processing but also to almonds, hazelnuts and pistachios for direct human consumption.

It is therefore unjustified to draw conclusions as regards the appropriate maximum level to be established for processed almonds, hazelnuts and pistachios for the protection of public health by referring to an adopted CODEX maximum level for peanuts intended for further processing for which it is well known that through processing the aflatoxin level can be very significantly reduced resulting in much lower levels of aflatoxins in peanuts for direct human consumption.

It is moreover not correct to state in a general way that tree nut consumption is less than peanuts as it can be observed from food consumption studies that in several cases the consumption of tree nuts (almonds, pistachios, and hazelnuts) and derived products is larger than of peanuts and derived products.

2) Comments as regards the statement ***"It is important top note that most of the tree nut producing countries are developing countries that rely heavily on the economic returns from tree nut crops. The commercial ramifications of rejections are quite significant to these countries, with no scientifically-based consumer health benefit. ALARA is an important principle, but its practical application must be based on what is truly "reasonably achievable" across a wide range of production conditions, without the risk of destroying nutritious foods that do not pose any consumer health risk."***

The European Community wishes to stress that no evidence has yet been submitted which would indicate that the levels the EC is proposing (see position of the EC contained in document CX/FAC 05/37/22) 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 "*truly "reasonably achievable" across a wide range of production conditions*"

The European Community seizes this opportunity to re-iterate its comments made at the 21st session of the Codex Committee on General Principles which was held at Paris, France from 8-12 November 2004 and which are related to this topic.

"The main purposes of the Codex Alimentarius are protecting health of the consumers and ensuring fair trade practices. In the field of contaminants, these objectives are pursued through a policy of elaborating of codes of practice on the one hand and standards on the other hand.

The adoption of codes of practice for the prevention and reduction of contaminants in the food chain is the first important pillar. The adoption of standards, maximum levels at a level, achievable and stimulating the effective application of these codes of practice are the second important pillar.

It is major importance for the achievement of the objectives that Codex Alimentarius follows a consistent policy on the prevention and reduction of contaminants in the food chain. The setting of maximum levels, standards must provide a strong incentive for the application of the Codes of practice."

As regards the commercial ramifications and costs of rejections and strict limits in Europe and of rejections, the European Community wishes to draw the attention to information contained in most recent World Bank reports.

The report "Saving two in a billion: A case study to quantify the trade effect of European food safety standards on African exports"[1] predicted that the aflatoxin levels in European Union would result in a loss of hundreds of millions of dollars for African exports.

However in a very recent World Bank report "Food Safety and Agricultural Health Standards, Challenges and Opportunities for Developing Country Exports[2] », it is acknowledged that the actual experience has been much different than projected and that the African share of the EU market for dried fruit has actually increased. This is also confirmed in another very recent World Bank report "Global Agricultural Trade and Developing Countries [3] » which indicates that for dried fruit, the more stringent EU standards and enforcement at the border worked to the competitive advantage of Africa's leading suppliers.

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1 Otsuki et al, 2001

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

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

In the abovementioned World Bank report “Food Safety and Agricultural Health Standards, Challenges and Opportunities for Developing Country Exports” it is furthermore mentioned 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 EU market share for these products, indicating that these border rejections do not necessarily affect the economic return for the developing countries.

This is also confirmed in the other recent World Bank report “Global Agricultural Trade and Developing Countries» which mentions that *“border rejections attributable to food safety concerns represent only a small part of the constraint on international trade in agricultural and food products associated with food safety and agricultural health measures”*.

Iran

a. The 35th session of CCFAC on the bases of sufficient available data agreed to the elaboration of maximum levels for aflatoxins only in almonds , hazelnuts and pistachios. The remaining data for other varieties of tree nuts was considered insufficient for such elaboration. The original mandate back to the 33rd session of CCFAC was the establishment of maximum limits for Aflatoxin B1 (AFB1) and total Aflatoxins in pistachios for further processing and pistachios for direct consumption. The 26th Session of Codex Alimentarius Commission approved the elaboration of maximum levels for these tree nuts as new work for the Committee.

b. The 36th session of the CCFAC , observed a very detailed discussion by a large number of delegations.

c. The European Community , stated that maximum levels for aflatoxins should be set by following the ALARA principle and proposed to have two separate levels for total aflatoxins and aflatoxin B1 same levels as currently adopted by EU members (5 and 10 µg/kg aflatoxin B1 and total aflatoxins in tree nuts for further processing and 2 and 4 µg/kg B1 and total aflatoxins for direct human consumption.)

d. Other delegations such as Iran and United States ; supported by a number of delegations including Australia , Argentina , Brazil , Canada , Cuba , Ghana , India , Kenya , Morocco , Turkey , South Africa , Sudan , indicated that the ALARA Principle should be based on JECFA risk assessment that in its 49th meeting indicated that reducing the hypothetical standard from 20 to 10 µg/kg in both Maize and peanuts yields a very small reduction in cancer in estimated population risk , and on the bases of the low associated risk due to the low dietary exposure through the consumption of tree nuts and the fact that tree nuts are mainly not to go for further processing , proposed the maximum level of 15 µg/kg for both unprocessed and non processed almonds , hazelnuts and pistachios .

e. Based on the proposal of Delegation of Iran supported by a number of delegations including Aregentina , Brazil , India , Kenya , Turkey and South Africa , the Committee agreed to set up a proposed draft maximum level of 15 µg/kg (total aflatoxins) for unprocessed and processed almonds , hazelnuts and pistachios and to circulate it for comments at Step 3 and considration at its next Session.

f. This proposal same was very similar to the level of 15 µg/kg for total aflatoxins in peanuts intended for further processing adopted by 23rd session of CAC where no separate level was adopted for aflatoxin B1.

g. The CCFAC informed that after initial processing present sorting techniques , can not considerably decrease the aflatoxin content therefore one level should be set for both unprocessed and processed almonds , hazelnuts and pistachios.

h. Iran will support the setting of a maximum level of 15 µg/kg total aflatoxin for both unprocessed and processed almonds , hazelnuts and pistachios .

i. Iran proposes a new JECFA risk assessment to study that reducing the hypothetical standard from 15 µg/kg (the proposed CCFAC level) to 4 µg/kg (the EU currecnt level) in almonds , hazelnuts and pistachios will produce any reduction in cancer and in what magnitude.

Turkey:

As it is known, mycotoxins are secondary metabolites produced by moulds. Four types of aflatoxin (B_1, B_2, G_1, G_2) naturally exist in foodstuffs, among which aflatoxin B_1 forms a major part. It is possible to reduce the formation and amount of mycotoxins in foodstuffs, however once they are produced in foodstuffs it is not possible to remove them completely. Therefore, mycotoxins may be found in measurable amounts, at a certain frequency, especially in foodstuffs such as cereals, dried fruits, peanuts, hazelnuts, almonds and walnuts.

Mycotoxin levels in foodstuffs can change considerably from one year to another depending on adverse conditions which give way to mould formation during both primary production stage and storage period,. From a global-scale perspective, one of the important trade barriers for dried fruits is that a maximum residue limit for mycotoxins has not been determined yet. Since it is not possible to remove toxins completely from foodstuffs, limits that will not pose a threat to human health should be determined with risk analysis based on scientific data. The principle of ALARA *(As Low As Reasonably Achievable)* should be taken into consideration when limits are determined for chemical genotoxic carcinogens. However, factors such as the economic value of the foodstuff, consumption amount, whether or not the country proposing the limits is a potential producer, protection of producer-consumer interests and methods of analysis play an important role.

Aflatoxins were evaluated for the first time at the 31st JECFA meeting in 1997. Aflatoxin B_1 was accepted by the Committee as the most potent primary liver carcinogen known. It has been concluded that it is difficult to make an assessment of the correlation between exposure to aflatoxin and the frequency of liver cancer because although valid data from experiments conducted on animals is available concerning the relation between aflatoxin levels, exposure period and its carcinogenicity, the data regarding dietary intake amounts of aflatoxin, hepatitis B virus prevalence, culture, nutritional conditions and habits are insufficient. In the light of scientific data, JECFA has decided that the correlation between exposure to aflatoxin and increase of liver cancer in population is inadequate. Due to these kinds of uncertainties, the Committee has not been able to determine the tolerable intake level of mycotoxins (1).

The concept “acceptable risk” applies in the risk management of all chemicals. In terms of toxicological risk assessment concerning a substance, a risk of 1/100.000-1/1.000.000 is generally accepted as a negligible risk for humans(1).

At JECFA’s 49th meeting, it was determined that primary liver cancer frequency is 0.01/100.000 person/year in individuals with hepatitis B surface antigen negative (HBsAg- individuals), 0.3/100.000 person/year in HBsAg+ individuals, if exposed to AFB_1 with an amount of 1 ng/kg body weight/day *(Evaluation of Certain Mycotoxins in Food, Technical Reports Series 906).*

At the 49th meeting of the Committee, it was concluded that reducing the permitted quantity of AFB_1 in peanuts from 20 ppb to 10 ppb did not lead to any noticeable difference in the frequency of liver cancer. A similar situation is also the case for pistachios(2).

It was stated that among societies consuming Hepatitis B+ low (prevalence 1%) European diet, for those who consume foodstuffs containing 20 ppb residue liver cancer frequency is 41/1.000.000.000 person/year and for those who consume foodstuffs containing 10 ppb residue liver cancer frequency is 39/1.000.000.000 person/year. A one-fold increase in the amount of aflatoxin causes only an increase of 2/1.000.000.000 person/year in cancer frequency.

Special arrangements are being implemented in certain countries for aflatoxin limits. The limits for aflatoxin B_1 vary in countries between 1-20 ppb (Figure 1) and the limits for total aflatoxin vary between 0-35 ppb (Figure 2). The distribution of total aflatoxin amounts according to countries is shown on the following graphic (FAO, 2003).

Figure 1: Worldwide limits for aflatoxin B_1 in food

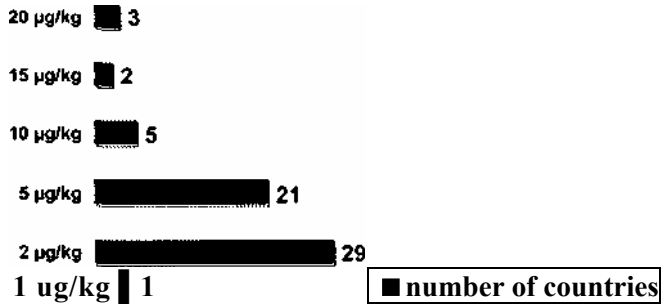
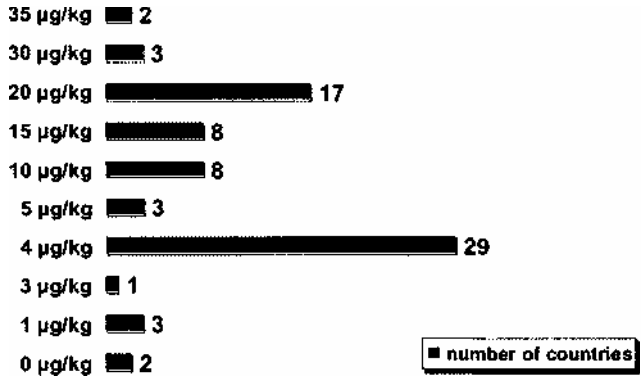


Figure 2: Worldwide limits for total aflatoxins in food



Production Amounts of Hazelnuts, Pistachios and Almonds in Turkey and Their Place in World Trade

Turkey is among leading countries in terms of production of hazelnuts and pistachios. Information regarding those products has been presented below.

1. Hazelnuts

Turkey ranks first in worldwide hazelnut production in terms of quality and production amount. In spite of annual variations, Turkey comprises about 68-78 % of world production with its annual average of 500-600 thousand tons of hazelnuts in shell.

Turkey exports hazelnuts to more than 50 countries and holds 70-80 % of the world hazelnut exports volume (Table 1)

Table 1. World Hazelnut Production and Primary Producer Countries (1000 Tons)

Countries	1998	1999	2000	2001	2002
Turkey	**580**	**530**	**470**	**570**	**600**
Italy	128,137	118,388	98,54	119,48	122,565
Spain	17,667	27,8	17,8	26,2	22,4
USA	14,06	36,29	20,41	43,54	16
Azerbaijan	9,477	12,635	13,334	15,945	16,121
Georgia	2,4	1,836	2,22	1,676	1,7
Greece	2,653	2,5	2,5	2,5	2,5
France	4,191	4,87	5,113	3,959	5,064
Russia	2	2	2	2	2
World	**790,317**	**766,712**	**659,103**	**870,125**	**842,981**

Source: www.fao.org

Ways of Consumption for Hazelnuts

Hazelnut consumption in the world is generally as follows:

- About 10 % in packaged form (in packages of 50, 100, 200, 250g used for household pastry making mostly in the form of natural flour, partially natural flour, roasted, ground, sliced)
- About 30 % in pastry and cookie industry and in the pastry shop sector
- About 60% in chocolate industry (including chocolate spread with hazelnut cream)

Thus, approximately 90% of hazelnuts consumed in the world are offered to consumers after being processed in various ways. The daily consumption amount of hazelnuts is considerably low among other processed products.

2. Pistachios

Pistachios is a species included in the genus *Pistacia vera* L., (Pistacia), which comprises 10 or more species, which has a commercial value, is bought and sold as dried fruit having edible kernel. Pistachios have two homelands: One is Near Eastern gene center which is spread about Anatolia, the Caucasus, Iran and high mountain ranges of Turkmenistan; and the other is Central Asia gene center. It is known that the gene center of pistachios' culture forms is Anatolia, Iran, Syria, Afghanistan and Palestine. Today pistachios are being cultivated between 30-45 South and North parallels and generally in northern hemisphere, in areas which can be referred to as microclimatic dispositions (Table 2). Hybrids such as *Pistacia khinjuk*, *Pistacia terebinthus*, *Pistacia atlantica*, *Pistacia palestina* and *Pistacia vera* are cultivated widely in Turkey (3, 4). Pistachios are a species having a tendency for periodicity.

Table 2. World Pistachios Plantation Area, Production and Yield (Average of 1997 - 2002)

Countries	Plantation Area		Production		Yield
	Ha	%	Ton	%	kg/ha
Iran	266.374	65,49	212.238	42,78	792,2
USA	31.595	7,77	88.872	17,91	2436,7
Turkey	**37.408**	**9,2**	**48.333**	**9,74**	**1566**
Syria	18.750	4,61	35.302	7,12	1868,6
Greece	5.099	1,25	7.618	1,54	1494,8
China	15.250	3,75	26.500	5,34	1747,3
Italy	3.674	0,9	2.655	0,54	945,5
World	**406.709**	**100**	**496.148**	**100**	**1119,8**

Source: www.fao.org

It is seen that generally a balance exists between pistachio production and consumption in the world and that producing countries are at the same time a consumer of this product (Table 3, Table 4). Generally 60-70 % of pistachios produced worldwide are being consumed as salty roasted dried fruit and 30-40 % in confectionary and pastry sector whereas 90% of pistachios in the USA and Europe are being consumed as snacks.

Table 3. Pistachios Exports in the World (Average of 1996 - 2001)

Countries	Exports	
	Amount (Ton)	%
Iran	106.764	60,37
Germany	16.368	9,26
USA	14.841	8,39
China, Hong Kong	12.483	7,06
Syria	6.683	3,78
Belgium, Luxembourg	5.963	3,37
China	2.522	1,43
England	2.100	1,19
Turkey	**1.987**	**1,12**
Italy	900	0,51
World	**170.610**	**100**

Source: www.fao.org

Table 4. Pistachio Imports in the World (Average of 1996-2001)

Countries	Imports	
	Amount (Ton)	%
Germany	31.740	18,89
China, Hong Kong	15.412	9,17
China	12.176	7,25
Italy	11.658	6,94
France	10.056	5,98
Spain	10.030	5,97
Lebanon	9.353	5,57
Mexico	7.003	4,17
Russian Federation	5.744	3,42
England	4.699	2,8
Turkey	**344**	**0,2**
World	**118.216**	**100**

Source: www.fao.org

3. Almonds

Almonds (*Prunus dulcis)* are a species of fruit which belong to the Rosacae family and originate from southeastern Asia. Total almond plantation area in the world was 1.7 million hectares in 2002 as compared to 1.6 million hectares in 1998, which shows an increase of 9%. In 2002, the total amount of almonds produced worldwide was 1.4 million tons. Among top producers are: USA, Spain, Iran, Morocco, Syria, Italy, Greece and Turkey (Table 5)

Table 5. World Almond Production and Primary Producers (tons)

Countries	1998	1999	2000	2001	2002
USA	393.000	377.840	318.880	376.480	444.520
Spain	220.439	279.100	223.300	257.000	315.400
Iran	111.992	95.900	89.637	97.144	100.000
Morocco	52.700	81.304	65.044	81.820	80.000
Syria	67.150	57.697	62.288	49.487	74.838
Italy	87.998	103.100	104.755	112.812	56.000
Greece	40.344	46.319	47.184	55.267	52.000
Turkey	36.000	43.000	47.000	42.000	50.000
World	1.304.114	1.393.312	1.246.239	1.330.321	1.419.725

Source: Istanbul Chamber of Commerce (ITO) http//www.ito.org

Almonds are one of the most important fruits in hard shell exported all over the world. Total value of exported almonds, in shell or shelled, in 2001 was 1 billion USD. USA and Spain rank the top two in terms of export volume and represent 83% of the world export. Shelled almonds within worldwide importation of almonds have a higher share both in terms of quantity and value. Within the worldwide importation of almonds in 2001 which totaled to 363,907 tons, shelled almonds had a share of 81.1 % as compared to almonds in shell having a share of 18.9 %.

Table 6. World Foreign Trade by Countries for Almonds in Shell and Shelled Almonds

Exports of Shelled Almonds

Countries	1998	1999	2000	2001
USA	164.174	177.419	190.572	213.563
Spain	42.146	43.023	38.885	52.868
China	2.132	4.548	8.338	6.888
World	226.802	246.903	261.088	304.084

Exports of Almonds in Shell

Countries	1998	1999	2000	2001
USA	22.531	22.294	42.340	52.193
China	593	1.623	6.805	5.332
Spain	1.743	1.483	1.766	1.975
World	37.395	37.942	68.378	82.655

Imports of Shelled Almonds

Countries	1998	1999	2000	2001
Germany	55.327	55.088	62.527	59.789
Spain	23.233	31.054	29.112	34.855
France	20.865	21.100	24.343	24.194
Japan	18.795	17.299	21.175	23.946
World	227.723	254.695	278.055	295.287

Imports of Almonds in Shell

Countries	1998	1999	2000	2001
India	16.677	17.632	24.367	21.334
Pakistan	1.294	2.734	7.516	11.452
China	840	2.591	10.587	10.379
World	33.074	35.371	58.740	68.620

Source: Istanbul Chamber of Commerce (ITO) http//www.ito.org

4. The Results of statistical evaluation of aflatoxin analysis conducted in Turkey

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

When products are evaluated in the light of ALARA principle;

- Considering the results of statistical evaluation of data from 1998-2002 (Table 7), in case aflatoxin limit is15 ppb in hazelnuts, product loss will be at a level of **1 %** (6.000 tons /year).
- Considering the results of statistical evaluation of data from 1998-2003 (Table 8), in case aflatoxin limit is 15 ppb in pistachios, product loss will be at a level of **5 %** (2,400 tons /year).

In both cases lower limit levels will lead to an increase in product loss. With regard to worldwide production, this production loss should be taken into consideration when limits are being determined.

In addition, 90 % of hazelnuts are not directly consumed. Instead they are consumed after being processed (shelling, grinding, roasting and peeling etc). Similarly pistachio is also consumed after being shelled, salted and roasted. The fact that the amount of aflatoxin can be reduced or partially removed from these products through the aforementioned processes has been determined as a result of scientific studies.

Although Good Agricultural Practices (GAP), Good Hygiene Practices (GHP), Good Manufacturing Practices (GMP), Good Storage Practices (GSP) and Hazard Analysis and Critical Control Points (HACCP) are being applied for the purpose of controlling the formation of aflatoxin in products carrying aflatoxin risk, it may not always be possible to fully implement control criteria because of external factors such as unforeseen rainfall, climate variations, drought etc that can occur during harvest. Accordingly, aflatoxin levels in the said products can vary from one year to another due to climate and other reasons. Therefore, taking into consideration human health, it would be very beneficial to determine these limits in line with the ALARA principle and in the light of JECFA data, in order to reduce product losses to a minimum on a worldwide basis. Moreover, it is well known that the daily consumption amounts of the said products are quite low. It is also stated in data obtained as a result of studies conducted by JECFA that 20 ppb alfatoxin B_1 might not create a risk in terms of human health.

CONCLUSION

According to the multifaceted scientific and epidemiological evaluations made concerning aflatoxins during JECFA's 49th Meeting, and in the light of the above mentioned data and in line with ALARA principles, it is considered that a total aflatoxin amount of 15 ppb, which will be permitted in pistachios, hazelnuts and almonds, as proposed in CCFAC's 36th Session, will not cause any risks in terms of human health.

In addition, the fact that a 15 ppb limit that has been determined for further processing of peanuts because peanuts are a product of soil origin leads to the idea that this limit should be higher for other dried fruits such as hazelnuts, pistachios and almonds.

Sources:

(1) Kuiper-Goodman, T. 1999. Approaches to the risk analysis of mycotoxins in the food supply. FNA/ANA 23. www.fao.org/waicent/faoinfo/economic/esn/nutri.htm

(2) Boutrif, E. 1998. Prevention of aflatoxin in pistachios. FNA/ANA21 www.fao.org/waicent/faoinfo/economics/esn/nutri.htm

(3) Arpacı, S., Atlı, H.S. 1999. T.R. Prime Ministry's Office, State Planning Organization (DPT) V. Five-Year Development Plan Special Commission's Pistachios Report Ankara.

(4) Aksoy, A., Atsan, T., Yavuz, F. 2002. "Econometric Analysis of Pistachio Sector in Turkey". Turkey V. Agricultural Economy Congress, Erzurum.

USA:

This responds to CL 2004/9-FAC which requests comments on the Proposed Draft Maximum Level for Total Aflatoxins in Processed and Unprocessed Almonds, Hazelnuts, and Pistachios at Step 3 (para. 155 and Appendix XXV). The United States of America appreciates the opportunity to provide the following comments for consideration at the forthcoming 37th Session of the Codex Committee on Food Additives and Contaminants (CCFAC).

At the 36th Session of the CCFAC (Rotterdam, The Netherlands, 22-26 March 2004) the Committee agreed to a proposed draft maximum level of 15 µg/kg (total aflatoxins) for unprocessed and processed almonds, hazelnuts and pistachios for circulation and comment at Step 3 and consideration at the next CCFAC Session (ALINORM 04/27/12, para 155).

The United States (U.S.) supports the establishment of a maximum level of 15 µg/kg (total aflatoxins) for unprocessed and processed almonds, hazelnuts and pistachio nuts traded internationally based on the reasons given below.

- 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. Specifically, it has been reported that the level of aflatoxin G_1 can exceed the level of B_1 in the total aflatoxin load on a tree nut species.[4, 5] Additionally, the ratio of B_1 to total aflatoxins has been noted to vary in some nut species by lot, region and crop year.[6] Therefore, the maximum level for aflatoxins in tree nuts should be based on the total aflatoxin level.

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

5 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.

6 EU Rapid Alert notifications for 1998-2002.

- 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. The total annual per capita consumption of tree nuts in many regions of the world is much lower than that of maize and peanuts. In view of this, a maximum level of 15 µg/kg total aflatoxins would be adequate to protect the public health of consumers of tree nuts.
- 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 microorganisms in amounts which may be toxic". This implies that unprocessed and processed nuts are held to the same standard of hygienic practices. Although limited, the available information suggests that additional processes such as blanching (except for almonds) will not significantly reduce aflatoxin contamination levels in tree nuts.
- A Draft Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Tree Nuts is currently being considered by the CCFAC at Step 6. If this Code is adopted by the CAC and implemented properly by countries, it will complement the principles and guidelines in the Code of Hygienic Practice for Tree Nuts and result in additional safety and health protection to the consumers of tree nuts. Since many tree nuts are shipped and consumed in their natural state, they should be considered "consumer ready" when entered into international commerce. Hence there is no safety reason for establishing a maximum level below 15 µg/kg for aflatoxins in unprocessed or processed nuts.
- 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 than15 µg/kg could result in the rejection of many otherwise safe export consignments from those countries, resulting in a detrimental effect on trade and national economies.

Based on the reasons stated above, the U.S. strongly supports establishing a maximum level of 15 µg/kg for total aflatoxins in unprocessed and processed almonds, hazelnuts and pistachio nuts designated for international trade.