

codex alimentarius commission



FOOD AND AGRICULTURE
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Agenda Item 16 (b)

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**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: Argentina, European Community, Japan, International Tree Nut Council (ITNC)

Argentina

Argentina appreciates the opportunity to make comments on this paper.

The 15 µg/kg maximum level for total Aflatoxins proposed at the 36th Session of the Codex Committee on Food Additives and Contaminants is supported, taking into consideration the risk assessment conducted by JECFA (1988).

European Community:

The European Community welcomes the discussion on maximum levels for aflatoxins in almonds, hazelnuts and pistachios.

At the 36th session of the CCFAC, Rotterdam, The Netherlands, 22-26 March 2004, 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 consideration at its next Session (ALINORM 04/27/12, § 155).

Aflatoxins are amongst the most potent mutagenic and carcinogenic substances known and are genotoxic carcinogens, therefore possible maximum levels must be set at a level as low as reasonable achievable (= ALARA principle).

The four main aflatoxins (B1, B2, G1, and G2) usually occur together in varying ratios but normally aflatoxin B1 is the major component.

The Codex Alimentarius Commission adopted at its 23rd session, Rome, July 1999, a maximum level of 15 µg/kg for total aflatoxins in peanuts intended for further processing. No level was adopted for aflatoxin B1 separately.

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. The EC is therefore in favour of setting a maximum level for total aflatoxins and a lower maximum level for aflatoxin B1 separately. In accordance with the ALARA principle the EC proposes a maximum level of 10 µg total aflatoxin/kg and 5 µg aflatoxin B1/kg for almonds, hazelnuts and pistachios intended for further processing.

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

Therefore significantly lower maximum levels should be set for processed almonds, hazelnuts and pistachios for direct human consumption or use as food ingredient. The EC proposes for these food products a maximum level of 2 µg aflatoxin B1/kg and 4 µg total aflatoxin/kg and **opposes the setting of a maximum level of 15 µg/kg total aflatoxin especially for processed almonds, hazelnuts and pistachios.**

Japan:

1. A maximum level of 15 ppb in tree nuts for total aflatoxins has been proposed and circulated for comments at Step 3. We, the Government of Japan, appreciate the opportunity to provide the following comments.

2. It has been known that aflatoxin B1 shows higher toxicity and carcinogenicity than other aflatoxins (B2, G1 and G2). For this reason, we strongly recommend that appropriate risk management options, including establishing two separate maximum levels for aflatoxin B1 and total aflatoxins, should be carefully considered by the CCFAC on a basis of available scientific data on aflatoxin B1 in tree nuts and on the correlation between the concentrations of aflatoxin B1 and total aflatoxins.

3. In order to facilitate discussions, we are planning to provide in due course the results of studies conducted in Japan on concentrations of individual aflatoxins in tree nuts to the CCFAC.

ITNC:

At the 36th session of the CCFAC¹, a proposed draft maximum level of 15 µg/kg total aflatoxins was proposed for unprocessed and processed almonds, hazelnuts and pistachios and circulated for comments at Step 3. Further consideration will be given at the next CCFAC Session (ALINORM 04/27/12, § 155).

Members of the International Tree Nut Council (INC) include producers, exporters and importers of the nine tree nuts in more than 40 countries.

Contaminants are an important food safety issue, and should be controlled to the extent possible at all levels of production – utilizing good agricultural practices in the orchard, harvesting practices in the wild and good manufacturing practices in processing/storage facilities. However,

- *what is reasonably achievable at the producer level, without significant destruction of food, is limited by the significant heterogeneity of contamination.*

At its 23rd session in Rome, July 1999, the Codex Alimentarius Commission adopted a maximum level of 15 µg/kg for total aflatoxins in peanuts intended for further processing. This level was adopted after the conduct of a risk assessment by JECFA, which took into consideration peanut per capita consumption levels and the long-term effects of aflatoxin exposure. JECFA determined that moving from 20 ppb to 10 ppb (B1) resulted in negligible additional consumer health protection, particularly in populations that are not immune-compromised.

- *Given the fact that tree nut consumption is less than peanuts, it is unlikely that consumer exposure considerations would necessitate more restrictive aflatoxin levels.*

With reference to comments suggesting establishing a level for both total aflatoxin and aflatoxin B1, there is no precedent in Codex to establish a separate tolerance for B1. While B1 has been established as the more toxic of the 4 components (B1, B2, G1, G2), the JECFA evaluation established that setting a tolerance for total aflatoxin was sufficiently protective.

¹ Rotterdam, The Netherlands, 22-26 March 2004

- *The proportion of B1 to total aflatoxin varies by tree nut, by producing country, and by crop year, and can range from a low of 19% to 100%.²*
- *Setting a limit for B1 in international trade has been shown to result in a greater number of rejections, negatively affecting trade without providing additional consumer health protection.*

With reference to comments suggesting setting a tolerance for both processed and unprocessed tree nuts, there is limited information (other than for almonds) that additional processing such as sorting, blanching, etc., results in reduced aflatoxin contamination. Since many tree nuts are consumed in their natural state, they are often considered “consumer-ready” when entered into international commerce. There is also significant commercial cost to establishing a lower aflatoxin level for processed tree nuts moving in international trade, as has been demonstrated by European surveillance data.

EU Rapid Alert notifications between 1998-2002 indicated 572 rejections of tree nuts exceeded EU limits of 4 ppb total/2 ppb B1 (no information is available on what percentage of total imports this represents). The following chart indicates the additional percentage of consignments that **would have been accepted** if alternative limits had been applied:

4 ppb total (if no B1 limit)	10 ppb total 5 ppb B1	10 ppb total (if no B1 limit)	15 ppb total 8 ppb B1	15 ppb total (if no B1 limit)
18%	28%	44%	34%	44%

A 15 MT consignment of tree nuts has a value of approximately \$66-90,000³. Costs when a consignment is rejected include unstuffing/re-stuffing the container, cost of demurrage while awaiting analytical results, cost of appeal samples/analyses (and further demurrage charges), shipment cost back to origin and replacement cost of shipping another container. In total, a rejection could mean a loss of more than \$8,000 per container – assuming the goods can be utilized in another market.

- *The commercial cost of strict limits in Europe between 1998-2002 was a minimum of \$4.5 million, without taking into consideration the cost of any of the tree nuts that may have been destroyed. If a limit of 15 ppb total aflatoxin, similar to that approved by Codex for peanuts, had been applied in Europe, there would have been a savings of more than \$2 million (not including the cost of the tree nuts) without compromising consumer health.*

It is important to note that most of the tree nut producing countries are developing economies 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.

² Analysis of EU Rapid Alert notifications for 1998-2002 indicated that the reported proportion of B1 to total aflatoxin in tree nuts varied considerably. In almonds, the proportion tended to be 70-100%; for pistachios, the range was 66% to 93%; for hazelnuts the proportion was about 50% or less while Brazil nuts were 40-60%.

³ Average price of \$2.00-\$2.75 per pound.