codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 13 (c) **CX/FAC 06/38/23**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS

Thirty-eighth Session

The Hague, the Netherlands, 24 – 28 April 2006

DISCUSSION PAPER WITH PROPOSAL FOR A MAXIMUM LEVEL FOR AFLATOXINS IN PROCESSED ALMONDS, HAZELNUTS AND PISTACHIOS

Prepared by Iran and the European Community wit the assistance of Japan, Turkey, United Kingdom, United States 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.

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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. As a result of the extensive discussion, the Committee recognized at its 37th session that it could only make progress with the maximum level of 15 µg/kg (total aflatoxins) for unprocessed tree nuts (almonds, hazelnuts and pistachios). The Committee also decided to postpone the discussion on maximum level for processed tree nuts (almond, hazelnuts and pistachios) to the next session and established an electronic Working Group, led by the European Community and Iran[4], to prepare a discussion paper with a proposal for a maximum level for aflatoxins in processed almonds, hazelnuts and pistachios, with appropriate justification, for circulation, comments and consideration at its next session.

4. The Committee agreed to forward a maximum level of total aflatoxins in unprocessed almonds, hazelnuts, and pistachios to the 28th Session of the Codex Alimentarius Commission for adoption at Step 5. The Committee also decided to circulate for comments at Step 3 the proposed draft maximum level of total aflatoxins in processed almonds, hazelnuts, and pistachios[5]

ELEMENTS TO CONSIDER RELATIVE TO THE DIFFERENT ASPECTS

A. Toxicological aspects

5. 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.

6. 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.

7. 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

8. 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.

B. Maximum levels for aflatoxin total versus aflatoxin B1

9. 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.

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4 With the assistance of Japan, Turkey, United Kingdom, United States and INC

5 ALINORM 05/28/12, para 141

10. 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[6, 7]. Additionally, the ratio of B_1 to total aflatoxins has been noted to vary in some nut species by lot, region and crop year.[8]. 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 maximum level for aflatoxins in tree nuts should be based on the total aflatoxin level. The high ratio of aflatoxin B1, the most toxic compound of all aflatoxins, to total aflatoxin should be taken into account for the setting of a maximum level for total aflatoxin.

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

11. 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".

12. 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 in their natural state, they should be considered "consumer ready" when entered into international commerce. Hence there is no safety reason for establishing a lower maximum level for aflatoxins in processed nuts than for unprocessed nuts.

13. Risk associated with aflatoxin-contaminated foods can be reduced through the use of specific processing 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 seriously 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

14. 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.

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

7 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.

8 USDA/ARS sampling and distribution research for hazelnuts, almonds and pistachios..

15. 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.

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

16. 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.

17. 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.

18. On the other hand, 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.

19. 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 aflatoxinsl 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.

E. Commercial impact of maximum levels

20. 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 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

21. 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

22. However, different recent World Bank reports such as "Food Safety and Agricultural Health Standards, Challenges and Opportunities for Developing Country Exports[9]" and "Global Agricultural Trade and Developing Countries[10]" 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.

CONCLUSIONS AND RECOMMENDATIONS

Taking into account the abovementioned elements following conclusions and recommendations can be put forward for discussion

23. A possible CODEX maximum level for aflatoxins in pistachios, almonds and hazelnuts should be set for aflatoxin total only.

24. Given that there are sorting and physical treatments available which reduce the presence of aflatoxins in unprocessed nuts, it might be appropriate to consider setting a separate maximum level for aflatoxins in processed almonds, hazelnuts and pistachios, lower than the level for unprocessed almonds, hazelnuts and pistachios. Nevertheless it should be noted that these sorting and physical treatments are not applied and/or effective in all tree nuts.

25. Maximum levels of 4 µg/kg, 10µg/kg and 15 µg/kg for aflatoxin total in processed pistachios, almonds and hazelnuts have been suggested considering the discussion elements mentioned in this document. A different importance is attached to the different elements resulting in the suggestion of different levels. It is recommended to continue the discussion within CCFAC by carefully considering all the elements and all the viewpoints in order to come to a common viewpoint on the appropriate maximum level for aflatoxin total in processed almonds, hazelnuts and pistachios.

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

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