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Subject: Preparation for the 38th Session of the Codex Committee on Food Additives and Contaminants (CCFAC) the Hague, the Netherlands 24-28 April 2006

Delegations will find attached the declassified version of the above document.

The text of this document is identical to the previous version.

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CODEX 11

REPORT

from : Codex Alimentarius Working Party
to : COREPER

Subject : Preparation for the 38th Session of the Codex Committee on Food Additives and Contaminants (CCFAC) the Hague, the Netherlands 24-28 April 2006

1. At its meeting on 27 March 2006, in preparing the above session, the Codex Alimentarius Working Party was unable to reach an EC position on Agenda Item 13c) of this session, which concerns the maximum level for aflatoxins in processed almonds, hazelnuts and pistachios.
2. Aflatoxins are highly toxic contaminants. However, there is a significant disparity between the maximal level laid down in EC legislation (4µg/kg) and the level currently on the table in the Codex Committee on Food Additives (15µg/kg).

Given the risk that the totally unacceptable level of (15µg/kg) might be adopted in Codex, in case the EC would show no willingness to compromise, most delegations accepted to support a compromise EC position which consists:

- in advancing provisionally a maximum level of 8µg/kg to step 5 in the Codex procedure, pending consultation of the European Food Safety Authority,

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- in inviting producing countries to present at the next session detailed evidence as regards the implementation of the "Code of Practice for the prevention of aflatoxin contamination",
- in convening that a level of 10µg/kg be acceptable as an ultimate fallback position.

However, two delegations entered a reservation on this compromise, the UK considering it inappropriate to indicate the EU negotiating position in the EU comments and BE not accepting the fallback position of 10µg/kg.

3. Consequently the Working Party has decided to submit to COREPER for a decision:

- in Annex I hereafter, the draft European Community comments for the Codex Committee, indicating in particular that the EC would be able to accept for aflatoxins in processed nuts a level of 8µg/kg;¹
- in Annex II, an internal note developing a fallback position of 10µg/kg maximum level in order to avoid that the EC would be forced to accept a higher level in the future.

¹ This position would be sent prior to the session of the CCFAC, in writing, to the Codex Secretariat.

28/03/06

DRAFT

European Community comments for the CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS

38th Session, The Netherlands, 24-28 April 2006

DRAFT MAXIMUM LEVEL FOR TOTAL AFLATOXINS IN UNPROCESSED ALMONDS,
HAZELNUTS AND PISTACHIOS AND PROPOSED DRAFT MAXIMUM LEVEL FOR TOTAL
AFLATOXINS IN PROCESSED ALMONDS, HAZELNUTS AND PISTACHIOS (ALINORM
05/28/12, APP XXII)
AND DISCUSSION PAPER WITH PROPOSALS FOR A MAXIMUM LEVEL FOR TOTAL
AFLATOXINS IN PROCESSED ALMONDS, HAZELNUTS PISTACHIOS (CX/FAC 05/37/23)

Agenda Item 13 (c)

**European Community Competence
European Community Vote**

Background

The CCFAC decided at its 37th session to circulate for comments at Step 3 the proposed draft maximum level of total aflatoxins of 15 µg/kg in processed almonds, hazelnuts, and pistachios (ALINORM 05/28/12, § 141 and Appendix XXII)

The European Community (EC) reiterates its comments made at previous sessions of CCFAC on this subject.

Aflatoxins are genotoxic carcinogens. For substances of this type, no tolerable daily intake can therefore be set. Current scientific and technical knowledge and improvements in production and storage techniques do not 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 reasonably achievable (= ALARA principle).

No evidence has yet been submitted which indicates that the level of 4 µg/kg total aflatoxins proposed by the EC for processed almonds, hazelnuts and pistachios is not reasonably achievable when prevention and reduction measures are applied to minimize the presence of aflatoxins in tree nuts.

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A Code of practice for the prevention and reduction of aflatoxin contamination in tree nuts has been adopted by the Codex Alimentarius Commission at its 28th session in 2005 (CAC/RCP 59-2005).

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.

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 processed almonds, hazelnuts and pistachios, should be significantly lower than those set for unprocessed nuts.

Position of the EC as regards the maximum level for total aflatoxin in processed almonds, hazelnuts and pistachios

Taking into account the comments made by other Member Countries in CCFAC on this issue, the EC is in favour of finding a common solution which meets to a large extent the concerns and comments made by the different member Countries.

Therefore, the EC will not oppose the forwarding of **a level of 8 µg/kg total aflatoxins in processed almonds, hazelnuts and pistachios for adoption at Step 5** by the Codex Alimentarius Commission.

However concern has been expressed as regards the possible public health consequences given that this level signifies a significant increase compared to the current EU maximum level of 4 µg/kg. Therefore the EC will request its scientific body, the European Food Safety Authority (EFSA), to provide a risk assessment in order to clarify if acceptance of this higher level would not entail unacceptable risks for the EU consumer, taking into account vulnerable groups in the population and also the significant increase in tree nut consumption in recent years in the EU.

Therefore, it is clearly stated that a **possible final acceptance** of that level at Step 8 will **depend on the outcome of this risk assessment** which is expected to be available prior to the next session of Codex Committee dealing with Contaminants in Food.

In addition, the EC is of the opinion that it is necessary that **producing countries shall be required** to provide the Codex Committee dealing with Contaminants in Food, by its next session, with **detailed information as regards the implementation** of the “Code of Practice for the prevention and reduction of aflatoxin contamination in tree nuts” adopted by the Codex Alimentarius Commission at its 28th session in 2005 (CAC/RCP 59-2005).

Position of the EC as regards the maximum level for total aflatoxin in unprocessed almonds, hazelnuts and pistachios

The 28th Session of the Codex Alimentarius Commission adopted the proposed maximum level for total aflatoxin in unprocessed almonds, hazelnuts, and pistachios at Step 5 and advanced it to Step 6. (ALINORM 05/28/41, § 71 and Appendix VIII)

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The European Community indicated that a possible future acceptance of this level for unprocessed almonds hazelnuts and pistachios at Step 8 of the Codex uniform procedure will depend on the outcome of the ongoing discussions on the maximum level for total aflatoxins in processed almonds, hazelnuts, and pistachios (ALINORM 05/28/41, § 76)

Therefore the EC is of the position that **the draft maximum level of 15 µg/kg for total aflatoxin in unprocessed almonds, hazelnuts and pistachios should be retained at step 6** until the next Session of Codex Committee dealing with Contaminants in Food.

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Internal note

for the Member States as regards the proposed position on a maximum level for total aflatoxin in processed almonds, hazelnuts and pistachios and the ultimate fall-back position

Please find enclosed the position paper as discussed on 27 March 2006 in the Council co-ordination working group.

From previous discussions, it appears that it might be difficult, although not impossible, to achieve an agreement at Codex on a level of 8 µg/kg. A level of 10µg/kg on the other hand seems to have reasonable chances to get accepted by the Codex

Therefore, delegations of Member States are requested to agree upon an **ultimate fall back position of 10 µg/kg for total aflatoxins only to be used as “safety brake”** in case no agreement has been reached on the level of 8 µg/kg and **the Chair of CCFAC, in the absence of an agreed compromise level, is proposing to forward a level of 15 µg/kg of aflatoxin total in processed almonds, hazelnuts and pistachios for adoption at Step 5 or even Step 5/8 by the Codex Alimentarius Commission.**

Delegations of Member States should consider the important benefits, also as regards consumer protection, a compromise level will have:

* The acceptance of a compromise level 8 µg/kg (10 µg/kg eventually as ultimate fall-back) will avoid that the EU would be forced to accept a level of 15 µg/kg in the future.

* The application of strict enforcement measures with consignments not complying with the Codex level to be destroyed (or eventually sorted on the spot), as these cannot be returned neither re-exported when non-complying with a worldwide safety standard. This will significantly increase the cost of non-compliance for the exporter compared to the current situation as now export to another third country is in most cases allowed. Given the current high levels of aflatoxins found in non-complying consignments, this will be major driving force for producing countries to accelerate and improve the implementation of the codes of practice. This will improve the overall safety of the tree nuts also for domestic consumption in the developing countries. In addition the improvement of the overall situation as regards aflatoxins will enable Member States to redirect control resources to other food safety issues.

The acceptance of a compromise level of 8 µg/kg (10 µg/kg eventually as ultimate fall-back) is inextricably bound up with following conditions to guarantee consumer protection:

- the European Food Safety Authority (EFSA), will be provided to provide a risk assessment in order to clarify if acceptance of this higher level would not entail unacceptable risks for the EU consumer, taking into account vulnerable groups in the population and also the significant increase in tree nut consumption in recent years in the EU
- producing countries shall be required to provide the Codex Committee dealing with Contaminants in Food, by its next session, with detailed information as regards the implementation of the “Code of Practice for the prevention and reduction of aflatoxin contamination in tree nuts”