

02/04/2007

**European Community comments for the  
CODEX COMMITTEE ON CONTAMINANTS IN FOODS**

**1<sup>st</sup> Session, Beijing, China, 16-20 April 2007**

**Agenda Item 7(a), 7 (b), 7(c) and 7 (d)**

**Agenda items related to draft maximum levels and sampling for total  
aflatoxins in almonds hazelnuts and pistachios for further processing  
and "ready-to-eat".**  
**(CX/CF 07/1/9)**

*European Community Competence.  
European Community Vote.*

JECFA will conduct at its 68<sup>th</sup> 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, pistachios, and 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.

The European Community is of the opinion that it is appropriate to await the outcome of the JECFA assessment is available before continuing the discussion on the maximum level. Consequently the European Community proposes not to have a discussion on agenda item 7(a) and (b) at this session of the CCCF.

As regards the discussion paper, much of the information has been taken from the opinion that the European Food Safety Authority (EFSA) published in March 2007 on the implications of increasing the maximum permitted levels for almonds, hazelnuts and pistachios. Such opinion was requested by the European Commission and it includes a large number of occurrence data, as well as consumption data, compiled mainly by the EC Member States. The information given in the discussion paper does not provide much information as regards the rest of the world. This will be considered in the JECFA assessment in June 2007.

The EFSA Scientific Panel on Contaminants in the Food Chain (CONTAM Panel) has performed a very detailed assessment on 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. This assessment is available on the EFSA website<sup>1</sup>.

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<sup>1</sup> [http://www.efsa.europa.eu/en/science/contam/contam\\_opinions/ej446\\_aflatoxins.html](http://www.efsa.europa.eu/en/science/contam/contam_opinions/ej446_aflatoxins.html) (general page)

The CONTAM Panel calculated aflatoxin exposures by setting several scenarios with limits at 4, 8 and 10 µg/kg and 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 for the mean population.

However, the Panel noted that this was not true for population groups with high nut consumption, where increasing the maximum level from 4 to 10 µg/kg, could result in an increase of aflatoxin exposure of up to 20 %.

Additionally, the CONTAM Panel **could not accurately evaluate the exposures for other population sub-groups expected to be more vulnerable**, such as children, vegetarians and vegans and subgroups with chronic hepatitis infection due to the very few data available for these sub-groups.

Because aflatoxins are genotoxic carcinogenic compounds, a careful risk characterisation needed to be derived. In its opinion, the CONTAM Panel decided to use an approach based on the use of the Margin of Exposure (MOEs) to assess the possible increase of cancer incidence following the introduction in the market of nuts with higher levels of contamination.

The 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 that **the presence of aflatoxins in food is a potential concern for human health**. Such concern is not equally evident when considering human epidemiological data, for which MOEs indicate lower risk. Additionally, EFSA indicated that **the increase on risk could not accurately estimated** due to the lack of accurate exposure data for certain sub-groups such as those with chronic hepatitis infection.

The CONTAM Panel concluded that **exposure to aflatoxin from all sources should be as low as reasonably achievable, because aflatoxins are genotoxic and carcinogenic**. The overall 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. To this effect, EFSA have recommended that measures to apply Good Agricultural Practice by producing countries are required in order to reduce incidents of highly contaminated products being consumed and that improved pre-export controls are also required to reduce incidents of highly contaminated products.

The European Community notes that a Code of Practice for the Prevention and Reduction of aflatoxin contamination in Tree nuts was adopted by the Codex Alimentarius Commission (CAC) at its 28<sup>th</sup> Session and an appendix specific for Brazil nuts was adopted by the CAC at its 29<sup>th</sup> Session.

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[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](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](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)

In the preamble to the Codex General Standard for Contaminants and Toxins in Foods (CODEX STAN 193-1995 – rev 2-2005) one of the criteria to be applied for the establishment of maximum levels is the following:

*“Maximum levels shall be set as low as reasonably achievable. Providing it is acceptable from the toxicological point of view, maximum levels shall be set at a level which is (slightly) higher than the normal range of variation in levels in foods that are produced with current adequate technological methods, in order to avoid undue disruptions of food production and trade. Where possible, maximum levels shall be based on GMP and/or GAP considerations in which the health concerns have been incorporated as guiding principle to achieve contaminant levels as low as reasonably achievable.”*

The European Community is of the opinion that the information provided in the discussion paper on the impact of the application of Codes of Practice on the level of aflatoxins in almonds, hazelnuts and pistachios is very limited and it is not demonstrated what levels are reasonably achievable. It is evident from the scientific opinion of EFSA that, although 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, the overall exposure to aflatoxin is a potential reason for concern and therefore levels should be as low as reasonable achievable, also in almonds, hazelnuts and pistachios.

**The European Community stresses that it is indispensable to have more detailed, concrete information on the impact of the application of Codes of Practice on the level of aflatoxins in almonds hazelnuts and pistachios in order to be able to evaluate what levels of aflatoxins are achievable by applying good practices in view of setting maximum levels as low as reasonably achievable, and this in accordance with the outcome of the EFSA assessment.**

As regards the **sampling plan**, the European Community is of the opinion that it is appropriate to determine **one sampling plan for the control of aflatoxins in hazelnuts, pistachios and almonds** to ensure practicability of the sampling by enforcement officers despite differences in performance characteristics.

Since the maximum level to be controlled could influence the performance of aflatoxin sampling plan, a sampling plan would be best finalised once the maximum levels are established. However based upon the information provided in the discussion paper on the performance of different sampling plans, it appears **that a minimum sample weight of 20 kg is necessary** to obtain an acceptable low level of misclassifications (good lots rejected and bad lots accepted) to protect public health and to minimize the adverse effect on international trade.

Furthermore the European Community is of the opinion that the size of the lot to be sampled and the number and size of incremental samples constituting the aggregate sample are parameters of major importance for the determination of the effectiveness of a sampling procedure and of the representativeness of the resulting sample for the sampled lot. The European Community is therefore of the opinion that these parameters should be integrated in the evaluation of and determination of a sampling procedure for the control of aflatoxins in hazelnuts, pistachios and almonds.

**As regards the terminology of "ready-to-eat" and "for further processing", the European Community agrees with the proposed definition in the discussion paper for "consumer-ready nuts" or "ready-to-eat nuts" and "nuts for further processing"**