CODEX ALIMENTARIUS COMMISSION





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Agenda Item 10

CF12/CRD10

JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON CONTAMINANTS IN FOODS

12th Session Utrecht, The Netherlands, 12 - 16 March 2018

PROPOSED DRAFT MAXIMUM LEVEL FOR TOTAL AFLATOXINS IN READY-TO-EAT PEANUTS AND ASSOCIATED SAMPLING PLAN

Comment submitted by EU, Uganda and AU

EUROPEAN UNION (EU)

The European Union (EU) welcomes and appreciates the work done by India to prepare the document CX/CF 18/12/10 related to the proposed draft maximum level for aflatoxins in ready-to-eat peanuts and associated sampling plans.

The EU wishes to make the following comments as regards the proposed maximum level (ML) of 10 μ g/kg for aflatoxin total in ready-to-eat peanuts.

As this proposed ML of 10 μ g/kg for aflatoxin total in ready-to-eat peanuts is higher than the current EU ML of 4 μ g/kg for aflatoxin total in ready-to-eat peanuts, the European Food Safety Authority (EFSA) has been requested to assess the impact on public health of a possible increase of the current EU ML of 4 μ g/kg for aflatoxin total in peanuts and processed products thereof, intended for direct human consumption or use as an ingredient in foodstuffs to 10 μ g/kg of aflatoxin total taking into account vulnerable groups of the population and the EU consumption patterns.

Following this request, EFSA adopted on 23 January 2018 a statement on the effect on public health of a possible increase of the ML for aflatoxin total from 4 to 10 μ g/kg in peanuts and processed products thereof, intended for direct human consumption or use as an ingredient in foodstuffs¹. EFSA concluded that for consumers of peanuts and peanut butter, based on estimates of current exposure to aflatoxins, the cancer risk is higher than the excess lifetime cancer risk of 10^{-5} . A ML for aflatoxin total of 10 μ g/kg in ready-to-eat peanuts would further increase the cancer risk by a factor of 1.6 to 1.8 based on a simulation of the possible dietary exposure to aflatoxins.

Taking into account this significant increase of the cancer risk, then EU cannot agree on the proposed ML of $10 \mu g/kg$ for aflatoxin total in ready-to-eat peanuts. The EU further notes that no associated sampling plan is proposed.

UGANDA

Uganda supports the proposed ML of 10 ppb for total aflatoxin in ready-to-eat peanuts. This is consistent with the total aflatoxin MLs set for similar products in the East African region for which there is a high dietary exposure.

AFRICAN UNION (AU)

Position 1: African Union supports the setting of ML for total aflatoxins in ready-to-eat peanuts.

Position 2: Although African Union had previously supported an ML of 15 ppb for total aflatoxin in ready-to-eat (RTE) peanuts and the setting of a separate ML for aflatoxin B1, we can support a compromise ML of 10 ppb for total aflatoxin in RTE peanuts and to follow Codex practice of only setting MLs for total aflatoxin, as expressed by a majority of participants at previous CCCF.

Position 3: African Union wishes to propose the revision and updating of the CoP for prevention and reduction of aflatoxin in peanuts, CAC/RCP 55-2004 as new measures developed after the adoption of this COP in 2004 need to be included.

¹ Statement available at: http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2018.5175/epdf

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Issue & Rationale: Currently, the only Codex ML for total aflatoxins in peanuts is applied to those intended for further processing (ML of 15 ppb). Over a number of years, many producing countries, especially India and those in Africa, have experienced difficulties in accessing export markets, particularly those in Europe where a ML for total aflatoxins of 4 ppb is applied.

Work on setting a ML for total aflatoxins in RTE peanuts began at the 7th session of CCCF. Initially, a ML of 10 ppb was proposed, whereupon a request was made to JECFA to conduct an exposure assessment to determine the health impact and potential violation rates based on hypothetical MLs of 4, 8, 10 and 15 ppb. Subsequent to the JECFA report, a new ML of 15 ppb was proposed. However, it has proved extremely difficult to reach a consensus between those supporting adoption of a ML of 15 ppb and those calling for a ML of 10 ppb. The arguments generally raised by the two sides to support their positions were as follows:

- 1. Arguments in favour of a ML of 10 ppb:
 - MLs should be established on the basis of the ALARA (as low as reasonably achievable) principle.
 - ML for RTE peanuts should be lower than that set for peanuts for further processing (15 ppb) as this implies that processing can further reduce the contamination level.
 - The approach for setting ML for RTE peanuts should be comparable to those used to set MLs for almonds, Brazil nuts, hazelnuts and pistachios in which there is a distinction between RTE and further processing.
 - The ML for aflatoxins should be as low as possible due to their genotoxicity.
 - Consideration needs to be given to population groups that are extremely vulnerable.
 - Because the GEMS/Food data that was used in the JECFA exposure assessment did not distinguish between RTE peanuts and those for further processing and also was biased with a predominance of data from developed countries, the overall assessment is subject to bias and uncertainty, which implies a possible underestimation of the health benefits that could result from a lower ML.
- 2. Arguments in favour of a ML of 15 ppb:
 - As concluded by JECFA, there would be minimal further reduction in exposure in lowering the ML from 15 ppb to 10 ppb.
 - As concluded by JECFA, rejection rates at 10 ppb are higher than at 15 ppb. This difference would be nearly 3% (12.6% vs 9.7%), which was estimated to equate to trade loss of 100000 metric tonnes with a value of US\$ 140 million.
 - Lower rejection rates increase supply and would be expected to lower prices in favour of consumers.
 - A higher rejection rate would contribute to food wastage and impact trade without any corresponding public health benefit.

In order to reach a compromise on this divided issue, the electronic working group has returned to their original proposal and proposed adoption of a ML of 10 ppb applied to peanuts "ready-to-eat". The adoption of this ML would be expected to improve the export potential of African countries, while still protecting public health, taking into account the absence of a recognized safe level for this genotoxin.