

# CODEX ALIMENTARIUS COMMISSION



Food and Agriculture  
Organization of the  
United Nations



World Health  
Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: [codex@fao.org](mailto:codex@fao.org) - [www.codexalimentarius.org](http://www.codexalimentarius.org)

**Agenda Item 8**

**CX/CF 17/11/8  
March 2017**

**ORIGINAL LANGUAGE ONLY**

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

**Eleventh Session  
Rio De Janeiro, Brazil, 3-7 April 2017**

**PROPOSED DRAFT MAXIMUM LEVEL FOR TOTAL AFLATOXINS IN READY-TO-EAT PEANUTS  
(AT STEP 4)**

*Comments submitted at Step 3 (in response to CL2017/26-CF by Canada, Chile, Costa Rica, Cuba, Egypt, EU, Japan, Nicaragua, Republic of Korea, USA, AU and ICGMA)*

**CANADA**

Canada wishes to express its appreciation to India for once again leading the electronic Working Group (eWG) **on the Proposed Draft Maximum Level for Total Aflatoxins in Ready-to-Eat Peanuts**. Canada would like to express its agreement with the proposed maximum level (ML) of 15 µg/kg for total aflatoxins (AFT) in ready-to-eat peanuts, which is consistent with Canada's regulatory ML of 15 µg/kg for AFT in nut and nut products calculated on the basis of the nut meat portion.

**CHILE**

Chile agradece la oportunidad de presentar observaciones sobre el anteproyecto de Nivel máximo para el contenido total de aflatoxinas en el maní (cacahuete) listo para el consumo y el plan de muestreo asociado.

Chile revisó la recomendación de esta carta circular y su comentario se expone a continuación:

- A pesar de los argumentos entregados por el documento revisado, Chile considera que no es coherente que el nivel máximo propuesto para maní listo para el consumo, sea el mismo que el que actualmente posee el maní para ulterior elaboración, de acuerdo al CODEX STAN 193-1995 (2016)

**COSTA RICA**

Costa Rica agradece al grupo de trabajo la oportunidad de emitir comentarios. En ese sentido; y sobre la base de la evaluación del JECFA, apoya que el Comité considere un ML de 15 µg / kg, para el maní.

**CUBA**

Cuba tiene reservas sobre las recomendaciones emitidas en el documento y continua revisando el mismo. En este momento no hace otro comentario adicional.

**EGYPT**

We would like to inform you that Egypt supports the low level to protect the health of consumers, so we propose the following maximum levels:

- 4 µg/kg MLs of total aflatoxins in ready-to-eat peanuts.

**EU**

The European Union (EU) welcomes and appreciates the work done by India to prepare the document CL 2017/26 – CF related to the proposed draft maximum level for total aflatoxins in ready-to-eat peanuts.

The EU wishes to make the following comments as regards the proposed maximum level (ML) of 15 µg/kg for aflatoxin total in ready-to-eat peanuts:

- the establishment of MLs is not only to be based on exposure assessment by JECFA but has to take into account all the criteria for the establishment of maximum levels in food and feed mentioned in point 1.3.3 and more elaborated in detail in the Annex I of the General Standard for Contaminants and Toxins in Food and Feed (CODEX STAN 193-1995);

- no justification is given as to why the previously proposed draft ML of 10 µg/kg, held at Step 4 pending the outcome of the JECFA exposure assessment for health impact, (REP15/CF § 100) could not be maintained and is changed to 15 µg/kg for aflatoxin total;

- no information nor justification is provided regarding the ML of 15 µg/kg being the level that is as low as reasonably achievable (one of the criteria for the establishment of MLs in food and feed referred to in CODEX STAN 193-1995). The information provided on the difference in rejection rate between a hypothetical ML of 4 µg/kg and 15 µg/kg is not a justification as to why the previously proposed ML of 10 µg/kg cannot be maintained;

- in the Codex STAN 193-1995, it is stated that additional processing/treatment has proven to reduce the presence of aflatoxins in consignments of peanuts. Processes that have proven to reduce levels of aflatoxins are shelling, blanching followed by colour sorting, and sorting by specific gravity and colour (damage). These processes are applicable to peanuts. Therefore, it is not justified to establish the same ML for ready-to-eat peanuts as the existing Codex ML for aflatoxins total in peanuts intended for further processing, as this is not in accordance with the criterion that MLs should be based on Good Manufacturing Processes (GMP) (CODEX STAN 193-1995).

**For the reasons outlined above, the EU cannot accept the proposed ML of 15 µg/kg of aflatoxin total in ready-to-eat peanuts.**

In addition the EU is of the opinion that the sampling plan for aflatoxins total in peanuts for further processing has to be reviewed to be applicable to ready-to-eat peanuts, not only for those traded in packs but also for ready-to-eat peanuts traded in bulk.

#### JAPAN

Japan would like to submit the following comments in response to the request for comments at Step 3.

##### **Recommendation for ML**

The summary of the 83<sup>rd</sup> JECFA meeting does not provide sufficiently detailed information about the impact on dietary exposure and the proportion rejected at each proposed ML. Such information is necessary to estimate economic impact and determine appropriate sampling plan. As 10 µg/kg was proposed at CCCF9, the estimated violation rate at 10 µg/kg should be referred to as well as 4 µg/kg and 15 µg/kg. The committee should wait for the full report of JECFA evaluation and the monograph.

##### **Sampling plans**

- Japan proposes that the committee should discuss methods of sampling after the ML for total aflatoxins in RTE peanuts is agreed.
- As the sampling plans for “ready-to-eat tree nuts” and “tree nuts destined for further processing” are different, the sampling plan for ready-to-eat peanuts should be discussed separately from that for peanuts intended for further processing.

#### NICARAGUA

##### **(i) Comentarios generales**

CODEX Nicaragua agradece al GTE por la elaboración del documento y por brindarnos la oportunidad de presentar observaciones.

##### **(ii) Comentarios específicos**

Tomando como referencia el resultado de la evaluación de la exposición para el impacto en la salud, realizada por **JECFA**, Nicaragua apoya el establecimiento de un Nivel Máximo de 15 µg / kg de Aflatoxina en el maní listo para el consumo, sin embargo, considerando la toxicidad y efectos cancerígenos de la Aflatoxina **B<sub>1</sub>**, proponemos se establezca un Nivel Máximo igual o menor a 8 µg/kg para ésta.

#### REPUBLIC OF KOREA

The Republic of Korea supports the proposed ML of 15 µg/kg for total aflatoxins in ready-to-eat peanuts.

#### USA

The United States appreciates the work that India has done in preparing this document and submits the following comments for consideration.

- The U.S. supports the recommendation in paragraph 9 that an ML of 15 µg/kg for total aflatoxins in ready to eat (RTE) peanuts be considered by the Committee, based on the results of the JECFA83 evaluation. JECFA83 concluded that enforcing an ML of 10, 8, or 4 µg/kg for RTE peanuts would have little further impact on dietary exposure to total aflatoxins for the general population, compared with setting an ML of 15 µg/kg.
- There is no term or definition for RTE peanuts in the GSCTFF. To be consistent with the definition for RTE tree nuts and RTE dried figs in the GSCTFF, the U.S. recommends the following definition for RTE peanuts: “peanuts, which are not intended to undergo an additional processing/treatment that has proven to reduce levels of aflatoxins before being offered for direct human consumption.”
- The Committee needs to clarify whether the ML is intended to apply to peanuts shipped in packages for consumers. If so, the U.S. agrees that a sampling plan for total aflatoxins in packaged RTE peanuts should be developed before moving forward with a proposed ML in the Step process. We note that we do not consider raw shelled peanuts and raw in-shell peanuts as ready to consume.
- The U.S. recommends using the existing “Sampling Plan for Total Aflatoxins in Peanuts Intended for Further Processing” in Schedule 1, Annex 1 of the General Standard for Contaminants and Toxins in Food and Feed (GSCTFF) (CODEX STAN 193-1995) for bulk RTE peanuts.

## AU

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

**Position 2:** Based on the findings of the 83<sup>rd</sup> JECFA evaluation of aflatoxins, AU supports the maximum level of 15 ppb for total aflatoxins in ready-to-eat peanuts proposed for discussion at CCCF11, despite a Codex ML of 15 ppb already agreed for peanuts intended for further processing.

**Position 3:** AU recommends that CCCF should consider setting a ML for aflatoxin B1 (AFB1) at 8 ppb for ready-to-eat peanuts.

**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 in Africa, have experienced difficulties in accessing export markets, particularly those in Europe where a ML for total aflatoxins of 4 ppb is applied. At the 9th CCCF (2015), a ML of 10 ppb (in line with that previously agreed for tree nuts) was proposed but it was agreed to forward a request to JECFA to conduct a new risk assessment on aflatoxin and consider the health and trade impact (violation rates) of levels between 4 and 15 ppb.

The evaluation was conducted by the 83<sup>rd</sup> JECFA in November 2016. A quantitative risk assessment was performed using newly derived cancer potency estimates. Highest aflatoxin-induced cancer rates were in GEMS/Food dietary cluster 13, including many sub-Saharan countries. Estimated cancer rates using central and upper-bound potencies were 0.21 and 3.94 cancers per year per 100 000 population. These same countries also have high HBsAg positive rates of 5.2 to 19%. However, importantly, the JECFA evaluation established overall that the primary source of aflatoxin exposure in all dietary cluster areas was from cereals and not nuts and that in the sub-Saharan countries, maize and sorghum were the primary source of exposure. Consequently, MLs below 15 ppb for peanuts offer little additional health protection, but impact heavily on trade. The JECFA reported rejections at a ML of 15 ppb as being 10%, whereas lowering of the limit to 4 ppb doubled this figure. Consequently, the choice of ML between 4 and 15 ppb would appear to be an issue in trade rather than carrying public health consequences.

Although in the past Codex has set MLs, only for total aflatoxin, most countries have enacted regulations that set MLs for both AFB1 and total aflatoxin. AFB1 is the most toxic and carcinogenic of the aflatoxins, and is classified as a group 1 carcinogen by the International Agency for Research on Cancer (IARC). Toxicological evaluation of the other forms of aflatoxin is less well developed. It is known that the ratio of AFB1 to total aflatoxin is not fixed and can be quite variable. It is thus important to have regulation for both combined aflatoxin and for its most toxic form.

## ICGMA

Based on the JECFA83 Evaluation, the International Council of Grocery Manufacturers Association (ICGMA) is in support of the proposed ML of 15µg/kg of AFT in RTE Peanuts to be considered by the Committee.