

# CODEx ALIMENTARIUS COMMISSION



Food and Agriculture  
Organization of the  
United Nations



World Health  
Organization

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Agenda Item 10

CX/CF 22/15/10-Add.1

April 2022

ORIGINAL LANGUAGE ONLY

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEx COMMITTEE ON CONTAMINANTS IN FOODS

15th Session

Virtual

9-13 and 24 May 2022

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

Comments in reply to CL 2022/19-CF

*Comments of Canada, Chile, Egypt, European Union (EU), Kazakhstan, Kenya, Peru, Philippines, Rwanda,  
Saudi Arabia, Singapore, Uganda, United States of America (USA),  
African Union (AU), FoodDrinkEurope and International Confectionery Association (ICA)*

#### Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2022/19-CF<sup>1</sup> issued in March 2022. Under the OCS, comments are compiled in the following order: general comments are listed first, followed by comments on specific sections.

#### Explanatory notes on the appendix

2. The comments submitted through the OCS are hereby attached in the **Annex** and are presented in table format.

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<sup>1</sup> Codex circular letter, including CL 2021/87-CF, are available on the Codex webpage/Circular Letters:

<http://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/>

or on the dedicated Codex webpage/CCCF/Circular Letters:

<http://www.fao.org/fao-who-codexalimentarius/committees/committee/related-circular-letters/en/?committee=CCCF>

**GENERAL AND SPECIFIC COMMENTS****MAXIMUM LEVEL**

COMMENT	MEMBER/ OBSERVER				
<p>Canada continues to have questions regarding the achievability of the proposed MLs of 10 and 12 µg/kg and the lack of quantitative analysis presented for the proposed ML of 12 µg/kg. In last year's report, the CCCF agreed that the EWG would prepare revised ML proposals for total aflatoxins in RTE Peanuts for consideration by CCCF15 (2022), taking into consideration the impact assessment of JECFA83 and the new and old datasets available on GEMS/Food (REP21/CF, Para. 143). Consideration of the new (i.e. after 2017) data is complicated by the fact that the large majority of data submitted from 2019 and 2020 appear to be from jurisdictions whose results are very low in aflatoxins due to their exclusion of shipments which do not comply with their existing MLs (CX/CF 22/15/10, para. 5 of Appendix II).</p> <p>The JECFA83 assessment had also reported biases in the geographic representation of the data, and difficulty differentiating between peanuts intended for further processing and those that are ready-to-eat; it is unclear if either of these challenges have been rectified. It is noted that the available data support an ML of 15 µg/kg in RTE peanuts based on a rejection rate of 5%, and that this would also protect the health of consumers (CX/CF 22/15/10 para. 6 of Appendix II). In light of the concerns about achievability and the difficulty distinguishing the two commodities in the data set, Canada recommends that the existing ML of 15 µg/kg for peanuts destined for further processing could be extended to also include ready-to-eat peanuts at this time.</p> <p>Canada further notes that, as part of the existing work to prioritize Contaminant Standards for possible review by CCCF (CL 2021/90-CF; comments in reply to CL 2021/90-CF in CX/CF 22/15/17), the existing ML of 15 µg/kg aflatoxins in peanuts destined for further processing is identified in List A.2 given that it was established in 1999, which is ≥15 and &lt;25 years ago and, in 2024 it will meet the criteria to be put on list A.1 (established ≥ 25 years ago). If prioritized for future review, the MLs for peanuts could be reconsidered if necessary in the context of available data and proportionality.</p>	Canada				
<p>Chile agradece la oportunidad de presentar observaciones sobre el nivel máximo para el contenido total de aflatoxinas en el maní (cacahuete) listo para el consumo y plan de muestreo asociado.</p> <p>Al respecto, Chile quisiera apoyar el nivel máximo de 10 µg/kg para su aprobación final, lo anterior en consonancia con el modelo ya adoptado por el Codex para determinar los niveles máximos de aflatoxinas totales para las nueces de árbol, y teniendo en cuenta la carcinogenicidad de estas micotoxinas.</p>	Chile				
<p>Egypt appreciates the work and efforts done by the EWG in drafting of this circulated document; and in this regard, Egypt adopts the following limits:</p> <table border="1" data-bbox="98 1082 1912 1225"> <thead> <tr> <th data-bbox="98 1082 1120 1118">Commodity / Product Name</th> <th data-bbox="1120 1082 1912 1118">Maximum Level (ML) µg/kg</th> </tr> </thead> <tbody> <tr> <td data-bbox="98 1118 1120 1225">Groundnuts (peanuts) and other oilseeds and processed products thereof, (2) intended for direct human consumption or use as an ingredient in foodstuffs, with the exception of: crude vegetable oils destined for refining and refined vegetable oils</td> <td data-bbox="1120 1118 1912 1225">4</td> </tr> </tbody> </table>	Commodity / Product Name	Maximum Level (ML) µg/kg	Groundnuts (peanuts) and other oilseeds and processed products thereof, (2) intended for direct human consumption or use as an ingredient in foodstuffs, with the exception of: crude vegetable oils destined for refining and refined vegetable oils	4	Egypt
Commodity / Product Name	Maximum Level (ML) µg/kg				
Groundnuts (peanuts) and other oilseeds and processed products thereof, (2) intended for direct human consumption or use as an ingredient in foodstuffs, with the exception of: crude vegetable oils destined for refining and refined vegetable oils	4				
<p>The European Union (EU) welcomes and appreciates the work done by India to prepare the document CX/CF 22/15/10 related to the proposed draft maximum level for aflatoxins in ready-to-eat peanuts and associated sampling plans.</p> <p>Aflatoxins are genotoxic and carcinogenic substances. The Joint FAO/WHO Expert Committee on Food Additives (JECFA) updated the aflatoxin risk assessment at its 83rd meeting in November 2016.</p>	EU				

COMMENT	MEMBER/ OBSERVER
<p>JECFA reaffirmed the conclusions of previous assessment that aflatoxins are among the most potent mutagenic and carcinogenic substances known and that the reduction of dietary total aflatoxin exposure is an important public health goal. Five food commodities (maize, peanuts, rice, sorghum and wheat) were identified to contribute each more than 10% to international dietary exposure estimates for more than one GEMS/Food cluster diet, for either AFT or AFB1. The Committee recommends that efforts continue to reduce aflatoxin exposure using valid intervention strategies, including the development of effective, sustainable and universally applicable pre-harvest prevention strategies. Maize and groundnuts are a traditional focus for aflatoxin management.</p> <p>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 µg/kg in peanuts and processed products thereof, intended for direct human consumption or use as an ingredient in foodstuffs. 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 µg/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.</p> <p>The European Food Safety Authority (EFSA) has recently performed a comprehensive risk assessment of aflatoxins in food. The CONTAM Panel noted that the calculated Margins of Exposure MOEs are less than 10,000, which raises a health concern. The estimated cancer risks in humans following exposure to AFB1 are in-line with the conclusion drawn from the animal data. This conclusion also applies to AFM1 and AFT + AFM1.</p>	
<p>The EU cannot agree on the proposed ML of 10 µg/kg or 12 µg/kg for aflatoxin total in ready-to-eat peanuts because:</p> <ul style="list-style-type: none"> <li>– the presence of aflatoxins in food is a health concern;</li> <li>– the level of aflatoxins in peanuts can be minimized by the application of the Codex Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Peanuts (CAC/RCP 55-2004);</li> <li>– a careful selection of peanuts destined to be marketed as ready-to-eat peanuts should ensure that peanuts ready-to-eat contain lower levels of aflatoxins;</li> <li>– an application of sorting and other physical treatments shall further reduce the presence of aflatoxins in ready-to-eat peanuts.</li> </ul> <p>A combination of the application of the code of practice, a careful selection of peanuts destined to be marketed as ready-to-eat peanuts and the application of sorting and other physical treatments shall result in lower levels of aflatoxins and it is therefore in the interest of public health protection to set lower levels for aflatoxin total than the current proposed 10 or 12 µg/kg.</p>	EU
<p>AFTs are recognized as carcinogens, and aflatoxin B1, often found in peanuts, is the most toxic of them. The cost of peanuts in Kazakhstan is lower compared to tree nuts, so they are consumed more often and more quantity. And the proposed ML is higher than in the Technical Regulations in force in the country.</p> <p>In addition, the tables presented by EWG with new data revealed that the application of the CoP for the Prevention and Reduction of Aflatoxin Contamination in Peanuts significantly reduced the amount of aflatoxins in peanuts.</p> <p>In this regard, Kazakhstan cannot support the proposed ML of AFTs in RTE peanuts.</p>	Kazakhstan
<p><u>Comment:</u> Kenya supports MLs of 10 µg/kg <u>Justification:</u> Based on our EAC Standards</p>	Kenya
<p>Solicitud de observaciones en el trámite 3 sobre un nivel máximo de aflatoxinas totales en los cacahuates listos para el consumo y el plan de muestreo asociado.</p> <p>El Perú desea agradecer a la presidencia del GTe por todo el trabajo realizado para la determinación de nivel máximo para el contenido de aflatoxinas en el maní (Cacahuete) para el consumo y el plan de muestreo asociado.</p> <p>En esta ocasión, el Perú apoya el nivel máximo de 12 mcg/kg para el total de aflatoxinas en el maní (Cacahuete) listo para el consumo.</p>	Peru

COMMENT	MEMBER/ OBSERVER								
<p><u>Recommendation</u> An ML of AFT in ready-to-eat peanuts either 10µg/kg or 12µg/kg based on the considerations provided in paragraph 17 and the data/ information provided in Annex II.</p> <p><u>POSITION:</u> The Philippines would like to thank the Electronic Working Group led by India, for preparing the recommendation for the Maximum Level for Total Aflatoxins in ready-to-eat peanuts and associated sampling plan.</p> <p>The Philippines supports the following recommendation for ready-to-eat peanuts:</p> <table border="1" data-bbox="96 512 1912 639"> <thead> <tr> <th data-bbox="96 512 472 544"><u>Commodity/ Product Name:</u></th> <th data-bbox="472 512 853 544"><u>Maximum Level (ML) µg/kg:</u></th> <th data-bbox="853 512 1608 544"><u>Portion of the Commodity/ Product to which the ML applies:</u></th> <th data-bbox="1608 512 1912 544"><u>Notes/ Remarks:</u></th> </tr> </thead> <tbody> <tr> <td data-bbox="96 544 472 576">Peanuts</td> <td data-bbox="472 544 853 576">10 µg/kg</td> <td data-bbox="853 544 1608 608">Unless specified, seed or kernels with or without shell</td> <td data-bbox="1608 544 1912 639">The ML applies to peanuts labelled as “ready-to-eat”</td> </tr> </tbody> </table> <p>Advancement of the ML to final adoption by CAC45 (2022)</p> <p><u>POSITION:</u> The Philippines supports the adoption of the ML of 10 µg/kg in ready-to-eat peanuts at Step 5/8 for final adoption by CAC45.</p>	<u>Commodity/ Product Name:</u>	<u>Maximum Level (ML) µg/kg:</u>	<u>Portion of the Commodity/ Product to which the ML applies:</u>	<u>Notes/ Remarks:</u>	Peanuts	10 µg/kg	Unless specified, seed or kernels with or without shell	The ML applies to peanuts labelled as “ready-to-eat”	Philippines
<u>Commodity/ Product Name:</u>	<u>Maximum Level (ML) µg/kg:</u>	<u>Portion of the Commodity/ Product to which the ML applies:</u>	<u>Notes/ Remarks:</u>						
Peanuts	10 µg/kg	Unless specified, seed or kernels with or without shell	The ML applies to peanuts labelled as “ready-to-eat”						
<p>Rwanda supports adoption of an ML of 10µg/kg for total aflatoxins in RTE peanuts.</p> <p><u>Rationale:</u> Considering the fact that aflatoxin in peanuts intended for further processing has already an ML of 15 µg/kg, a limit of 10µg/kg for total aflatoxins in RTE peanuts is fair as processing can further reduce the contamination level</p>	Rwanda								
<p>Saudi Arabia support the ML For Total Aflatoxins In Ready-To-Eat Peanuts And Associated Sampling Plan</p>	Saudi Arabia								
<p>Singapore does not support either of the MLs proposed (i.e. 10 µg/kg or 12 µg/kg).</p> <p>Singapore notes that the implementation of the CoP for the prevention and reduction of aflatoxin contamination in peanuts (CXC 55-2004) has been very effective in reducing the aflatoxin contamination of RTE peanuts. In 2020, the percentage of peanut samples with aflatoxins greater than 4 µg/kg was even lower than 3% indicating that lower aflatoxin contaminations and substantial reduction in aflatoxin dietary exposures can be reasonably achieved without compromising food security.</p> <p>In line with the ALARA principle and the demonstration in the most recent years that lower aflatoxin levels in RTE peanuts can be reasonably achieved, this justifies for a lower ML to be established. Therefore, Singapore does not support the establishment of either 10 or 12 µg/kg as the ML for total aflatoxins in RTE peanuts.</p>	Singapore								
<p>Uganda to seeks clarity on the terms “shell, testa and husk” from the EWG.</p> <p>Uganda further proposes adoption of maximum levels of 10 µg/kg aflatoxin in ready to eat peanut.</p> <p><u>Justification:</u> The available limited data in Uganda supports the set limit of 10 µg/kg in according to the East African Community standard for peanut thus the limit is implementable/achievable in Uganda.</p>	Uganda								
<ul style="list-style-type: none"> <li>• The United States does not support the proposed ML of 10 µg/kg for total aflatoxins (AFT) in ready-to-eat peanuts. <ul style="list-style-type: none"> <li>o Based on the analysis in CX/CF 22/15/10, the average rejection rate is significantly higher at 10 µg/kg (8.9%) than at 15 µg/kg (5.1%). No reduction in dietary exposure is expected with an ML of 10 versus 15 µg/kg, based on the 2016 JECFA impact assessment.</li> </ul> </li> </ul>	USA								

COMMENT	MEMBER/ OBSERVER
<ul style="list-style-type: none"> <li>• The United States does not support the new proposed ML of 12 µg/kg. The document does not present data or analysis to support this proposal.</li> <li>• The United States does not object to an ML of 15 µg/kg for AFT in RTE peanuts, based on the November 2016 impact assessment by JECFA, the risk assessment body for CCCF.</li> <li>• The United States recalls that the JECFA83 (November 2016) impact assessment concluded that:               <ul style="list-style-type: none"> <li>o There would be no reduction in dietary exposure to AFT if an ML was set at 10 µg/kg compared with 15 µg/kg.</li> <li>o The mean AFT exposure for all GEMS/Food cluster diets was 5.0-8.0 (Lower Bound-Upper Bound, ng/kg bw per day) at MLs of 15 µg/kg and 10 µg/kg.</li> <li>o The rejection rate of RTE peanuts would be significantly higher at an ML of 10 µg/kg (12.6%) versus an ML of 15 µg/kg (9.7%).</li> </ul> </li> <li>• For CCCF12 (2018), the United States peanut industry calculated that an increase in rejection rate from 9.7% to 12.6% would result in loss from international trade of about 100,000 metric tons of RTE peanuts, with a trade value of about \$140 million (Global Trade Information Services for Calendar Year 2016).</li> <li>• In 2022, the United States peanut industry reported, based on an independent analysis of GEMS data, that an ML of 15 µg/kg versus 10 µg/kg would result in an increase in rejection rate of peanuts of 4.1% internationally.</li> <li>• The United States recommends additional consideration of year-to-year variation before setting an ML. The data presented for 2017-2020 show significant year to year variation (e.g., the rejection rate at 10 µg/kg is 9.79% in 2017 versus 1.58% in 2020).</li> <li>• The United States recommends additional consideration of geographical variation before setting an ML. The data are not globally representative, with 80% of 2020 data from the WHO European Region, where the EU has a limit of 4 µg/kg in place for total aflatoxins. In addition, very few data from major peanut exporters in Africa, South America, and parts of Asia are included.</li> <li>• The United States has additional technical concerns with the data analysis in the current document (CX/CF 22/15/10). Further data analysis before considering an ML would be appropriate.               <ul style="list-style-type: none"> <li>o The timeframe after implementation of the COP should be 2018 – 2021, rather than 2017-2020.</li> <li>o U.S. data for 2019 were not included.</li> <li>o The document does not include an analysis by year of data prior to the adoption of the COP, which would help illustrate the impact of year-to-year variation.</li> <li>o The document does not include an analysis by geographical region, which would help illustrate the impact of producer data versus importer data.</li> <li>o The document does not include a summary of samples included and excluded in the data pull.</li> <li>o Presentation of data in ranges (e.g., 10-15 µg/kg) does not provide a clear picture of rejection rates at the proposed MLs (10 µg/kg and 12 µg/kg).</li> <li>o Consideration of all available data could result in significantly higher rejection rates than reported in CX/CF 22/15/10; this should be explored in a new analysis.</li> </ul> </li> </ul>	
<p><u>Comments:</u> African Union supports the ML of 10µg/kg for total aflatoxins in ready-to-eat (RTE) peanuts.</p> <p><u>Rationale:</u> Africa Union supports an ML of 10 µg/kg for total aflatoxin in RTE peanuts based on the following reasons:</p> <ol style="list-style-type: none"> <li>1. MLs for RTE peanuts should be lower than that set for peanuts for further processing (15 µg/kg) given that processing can further reduce contamination level.</li> <li>2. Our position is consistent with the approach already taken by Codex for establishing MLs of total aflatoxins for tree nuts (i.e. 10 µg/kg for RTE &amp; 15 µg/kg for further processing).</li> </ol>	<p><b>AU</b></p>

COMMENT	MEMBER/ OBSERVER
<p>FoodDrinkEurope thanks the electronic working group (EWG) led by India, and the working group members, for the opportunity to provide comments on the document CL 2022/19-CF (March 2022).</p> <p>The JECFA risk assessment concluded that an ML of 10, 8 or 4 µg/kg in ready-to-eat peanuts would have little further impact on dietary exposure to aflatoxin. There are no data provided to support any additional health benefit for 12 µg/kg, but data has shown the economic impact on trade. The number of datapoints for 2019 and 2020 are low and not statistically representative of the global situation.</p> <p>We believe that the current Codex standard for peanuts for further processing at a maximum aflatoxin level of 15 µg/kg provides for consumer safety and that the limit for ready-to-eat peanuts should not be any lower.</p> <p>We thank the Committee for taking these points into account and look forward to further discussion at the CCCF15 session.</p>	FoodDrinkEurope
<p>We support the EWG and Committee making quicker progress on this item, to facilitate international trade and to provide a single harmonized standard to simplify the complicated global compliance challenges.</p> <p>CCCF has delayed finalizing the ML for AFT in RTE peanuts, pending further uptake on the Code of Practice and further data collection by the EWG.</p> <p>As stated in our previous comments on the first EWG draft report, we believe there are several inconsistencies in the data which we are still concerned about. A harmonized level will eventually help achieve global alignment. The current global analytical data or health concerns of the general population does not support the establishment of either a 10 µg/kg or 12 µg/kg ML.</p> <p>ICA can support the establishment of a 15 µg/kg ML which will facilitate international trade without jeopardizing the health of the general population.</p> <p>The following are the reasons ICA believes the current data do not support the proposed 10 µg/kg or 12 µg/kg ML, but instead a 15 µg/kg ML:</p> <ol style="list-style-type: none"> <li>1) The data presented in the EWG Report does not differentiate health or economic impacts between 10 µg/kg and 15 µg/kg and therefore does not support an ML of 10 µg/kg or 12 µg/kg.</li> <li>2) Setting an ML of 10 µg/kg or 12 µg/kg AFT in RTE peanuts will result in a reduction in available peanut supply due to unacceptably high rejection rates, will increase food waste, and will impact export and international trade.</li> <li>3) The long-term feasibility of establishing either 10 µg/kg or 12 µg/kg as the ML has not been considered with regards to high stress environmental impacts on crop yield and crop quality.</li> <li>4) Tables 3, 4 and 5 present GEMS/Food data (2017-2020) at the hypothetical MLs of 4, 10 and 15 µg/kg, respectively, along with the resulting % rejection rates at these MLs. However, since there is no data presented for a hypothetical ML of 12 µg/kg, we question why an ML of 12 µg/kg is even being considered here.</li> <li>5) Table 5 (which is mislabeled as Table 4 in the sequence of these three tables) contains data showing a rejection rate of 5.10% for the four combined years if a hypothetical ML of 15 µg/kg were to be established. Since Codex generally agrees that a 5% rejection rate is an acceptable level, we believe that an ML of 15 µg/kg (based on a huge number of data points (over 65,000) from 2017-2020 testing) can be justified.</li> <li>6) The JECFA83 (83rd Meeting of JECFA, 2016) risk assessment concluded that: <ol style="list-style-type: none"> <li>a) There would be minimal further reduction in dietary exposure to AFT if an ML was set at 10 µg/kg compared to 15 µg/kg; and</li> <li>b) A reduction to a 10 µg/kg ML AFT in RTE peanuts would have very little health impact for the general population.</li> </ol> </li> </ol>	ICA

**SAMPLIN PLAN**

<b>COMMENT</b>	<b>MEMBER/ OBSERVER</b>
Canada supports applying the sampling plan for AFT in peanuts intended for further processing to RTE peanuts provided that an EWG be established at CCCF15 to present an updated sampling plan to CCCF16 (2023) that includes provisions for RTE peanuts as well as those for further processing. Any new sampling plan or amendments to the existing sampling plan in the GSCTFF would need to clearly identify the criteria by which peanuts destined for further processing would be distinguished from RTE peanuts in international trade.	<b>Canada</b>
It is proposed to apply the same sampling plan established for aflatoxin total in peanuts intended for further processing, as described in General Standard for Contaminants and Toxins in Food and Feed (CXS 193-1995), also to ready-to-eat peanuts. A different sample preparation procedure has been established for the control of aflatoxins in treenuts destined for further processing and ready-to-eat treenuts with a different decision rule(CXS 193-1995). The EU is of the position that it is appropriate to have for ready-to-eat peanuts instead of one laboratory sample to have two laboratory samples from the aggregate sample and with the decision rule that in case the aflatoxin test result is less than or equal to the maximum level in both test samples, then the lot is accepted. Otherwise the lot is rejected.	<b>EU</b>
The sampling plan for AFT in peanuts intended for further processing also applies as for RTE peanuts.	<b>Kazakhstan</b>
<u>Comment:</u> Kenya proposes the sampling plan to be modified. <u>Justification:</u> The sampling plan does not address the occurrence of aflatoxin in small packages of RTE Peanuts.	<b>Kenya</b>
The recommendation to apply the sampling plan for AFT in peanuts intended for further processing, as describe in the General Standards for Contaminants and Toxins in Food and Feed (CXS 193-1995), also to RTE peanuts, based on the recommendations provided in paragraph 17 <u>POSITION:</u> The Philippines agrees with the recommendation of applying the sampling plan for AFT in peanuts for further processing, as describe in the General Standards for Contaminants and Toxins in Food and Feed, in RTE peanuts. <u>RATIONALE:</u> Applying the sampling plan for RTE peanuts will ensure accurate assessment of the risk of AFT in RTE peanuts. Furthermore, it will improve the conduct of product inspection.	<b>Philippines</b>
Rwanda supports the EWG recommendation of requesting the Codex Committee on Methods of Analysis and Sampling (CCMAS) to determine an appropriate sampling plan for AFT in RTE peanuts once a limit is adopted.	<b>Rwanda</b>
The proposed sampling plan (existing Codex methods of sampling for peanuts for further processing) does not address retail packages. RTE peanuts may be available in this form.	<b>USA</b>