

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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Agenda Item10 (a)

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ORIGINAL LANGUAGE ONLY

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

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MAXIMUM LEVELS FOR TOTAL AFLATOXINS IN CERTAIN CEREALS AND CEREAL-BASED PRODUCTS INCLUDING FOODS FOR INFANTS AND YOUNG CHILDREN

(at Step 4)

Comments at Step 3 submitted by Australia, Canada, Chile, Cuba, Ecuador, Egypt, Iraq, Kazakhstan, Philippines, Thailand, Uganda, United States of America (USA), Venezuela (Bolivarian Republic of), ACF International (Action Contre la Faim), International Atomic Energy Agency (IAEA), International Special Dietary Food Industries (ISDI), Médecins Sans Frontières International (MSF), United Nations Children's Fund (UNICEF) and World Food Programme (WFP)

Background

1. This document compiles comments received in response to CL 2021/15/OCS-CF issued in March 2021.

Explanatory notes on the Annex

2. The comments are hereby compiled in the Annex and are presented in table format.

**COMMENTS AT STEP 3 ON THE MLs FOR AFT IN CERTAIN CEREALS AND CEREAL-BASED PRODUCTS
INCLUDING FOOD FOR INFANTS AND YOUNG CHILDREN**

GENERAL COMMENTS

COMMENTS	MEMBER/OBSERVER
Australia does not have any comments on this Circular Letter.	Australia
<p>Table "Food Category" - 6th category - Cereal-based foods for infants and children, comments on ML: For cereal-based foods for infants and young children, given that neither of the MLs proposed have rejection rates approaching the target 95% value (1 µg/kg, rejection rate of 7.9%; 2 µg/kg, rejection rate 0.2%). Canada questions if MLs in increments between the MLs proposed could be considered (e.g. 1.2-1.8 µg/kg).</p> <p>It appears from the data tables presented and in Canada's experience that analytical methods can detect aflatoxins in the tenths of parts per billion, however, whether such sensitive methods are consistently available globally may require further discussion by CCCF.</p> <p>Table "Food Category" 5th category - Technical and Substantive: Sorghum grain, destined for further processing, comments on ML: For sorghum, Canada questions why MLs lower than 8 µg/kg are not presented for consideration. Based on the information in Tables 17-19 of the discussion paper, 6 µg/kg is the lower bound p95 concentration, and therefore would best approach the target 95% rejection rate.</p> <p>Canada also notes that the rejection rates in the discussion paper for sorghum for further processing for the proposed MLs of 10 or 8 µg/kg are lower (2 and 2.7%, respectively) than the rejection rates associated with the MLs proposed for maize for further processing (20 and 15 µg/kg; 4.5 and 5.4%, respectively). Canada requests that rationale be provided for this difference.</p> <p>Table "Food Category" 1st category - destined for further processing: Technical and Substantive: Maize grain, destined for further processing, comment on ML: Processing is known to reduce aflatoxin concentrations in grain significantly, as discussed in CX/CF 14-8-15 and articles cited below. The MLs proposed for maize and rice are based only on occurrence data from GEMS/Food. Any proposed MLs should be confirmed to be supported, if possible, by data and information from Codex members and the primary literature on the expected reductions in AFT concentrations due to processing maize into flour, meal, semolina and flakes and husked rice to polished rice. Although for other Codex MLs for cereal grains processing factors were not employed quantitatively in ML elaboration (e.g. due to differences in food processing and preparation worldwide, variability in results of studies examining processing factors (e.g. CX/CF 11/5/6)), the effects of processing were discussed and at least considered by other CCCF EWGs elaborating MLs for arsenic in polished and husked rice (CX/CF 14/8/6) and DON in cereal grains (CX/CF 11/5/6 & CX/CF 13/7/7). Canada also recommends that a section be included in the discussion paper on the temperature, pressure, and moisture stability of AFT in maize and rice.</p> <p>Amra, H.A. et al., 1996. Mycotoxin Research 12: 99-104.</p> <p>Bol, E.K. et al. 2016. Food and Chemical Toxicology 89: 85-91.</p> <p>Brekke, et al. 1975. Cereal Chemistry 52: 205-211.</p> <p>Hwang, J.H. et al. 2006. Food Chemistry 98: 71-75.</p>	Canada
Agree	Iraq

COMMENTS	MEMBER/OBSERVER
<p>The Philippines would like to thank the Electronic Working Group, chaired by Brazil and co-chaired by India, for preparing the proposals for the Maximum Levels for Total Aflatoxins in certain cereals and cereal-based products including food for infants and young children.</p> <p>The Philippines would like to support the proposed ML in Proposal 2 in the following food category:</p> <p><u>Food category Proposal 2</u></p> <p>ML Sample rejection (%)</p> <p>Flour, meal, and flakes derived from maize 10 µg/kg 1.5</p> <p><u>RATIONALE:</u></p> <p>This is consistent with the local data collected from the Philippines specific to this food category.</p>	<p>Philippines</p>
<p>In general, Thailand notes that the establishment of MLs for lead in selected commodities considered using the ALARA principle and the sample rejection (range between 2%-5%), which depends on the types of products. Other factors such as safety effects, impacts on trade, vulnerable groups, and population in some regions will also be considered case by case.</p> <p>In terms of the outliers in datasets, members who submit the data must consider their data and decide to cut outlier by themselves if they found unusual results in their samples, such as very damaged grain or moldy rice, before submitting to GEMS/Food. Otherwise, the data analyzer could not decide whether those data were contaminated with a high level of AFs or outliers.</p> <p>Additionally, Thailand agrees with the recommendation from the EWG to request JECFA to carry out a dietary exposure assessment considering the proposed MLs for the establishment.</p>	<p>Thailand</p>
<p>Uganda agrees that the draft is important and should be developed.</p> <p>Appendix 1; Maximum levels of aflatoxins; Uganda proposes need to consider adoption of maximum levels for aflatoxins for Maize grain destined for further processing, Maize grain destined for further processing, Husked rice, polished rice, Flour, meal, semolina and flakes derived from maize based on the existing East African standards for example; (10 µg/kg AFT for maize grains, 10 µg/kg AFT for Milled maize products, 10 µg/kg AFT for whole sorghum grains and 10 µg/kg AFT for paddy rice). These maximum levels are data generated on the regional products.</p> <p><u>Appendix 1</u>; Maximum levels of aflatoxins; Uganda agrees with the maximum levels of 2 µg/kg AFT or 1 µg/kg AFT for cereal-based foods for infants and young children.</p> <p><u>Table 1</u>. Subdivision of maize sub lots according to lot weight; Uganda proposes need to include a note that 100 increment is based on the sub lots, for example; when you sub lot, samples must be taken from all the sub lots.</p> <p><u>Table 3</u>. Performance criteria for Total Aflatoxins; Uganda proposes need to adjust minimum applicable range to commensurate with the respective ML suggested as per the changed maximum limits for aflatoxin as proposed above.</p> <p><u>Table 3</u>. Performance criteria for Total Aflatoxins; Uganda seeks for clarity on the double commodities naming under table 3, both having sample commodity name but different MLs and other parameters.</p> <p><u>Table 3</u>. Performance criteria for Total Aflatoxins; Uganda seeks for clarity on detection methods used, the LOD is too high. That would mean the method is not a good one (cannot easily detect aflatoxins) yet there are methods that can detect as low as 0.01 µg/kg (ppb).</p>	<p>Uganda</p>

COMMENTS	MEMBER/OBSERVER
<p><u>General Comments</u></p> <ul style="list-style-type: none"> • The United States supports re-establishment of the EWG to continue work for CCCF15. For CCCF15, the EWG may want to consider: <ul style="list-style-type: none"> ○ Whether additional notes would be needed to accompany the MLs (e.g., for all grains, that the ML does not apply to animal feed and that the ML does not apply for maize intended for wet milling). ○ How to address concerns raised by member countries where grains are consumed directly. This issue was also raised at CCCF08 (REP14/CF, paragraphs 63-66). • CCCF14 should focus on addressing questions raised by the EWG, rather than moving forward with the proposed MLs. • Impact Assessment: CCCF should ask JECFA for evaluation of exposure and risk reduction for various proposed MLs, including to determine if similar health impacts could be achieved at lower sample rejection rates. This follows the precedent set in the peanut aflatoxin MLs impact assessment. • Proposed MLs and Method Limit of Quantitation (LOQ): Several proposed MLs, namely 4 µg/kg for polished rice and 1-2 µg/kg for infant cereals for all grains, appear to be below the LOQs for available collaboratively validated aflatoxin methods. As a result, there may not be fit for purpose methods available to test foods at the proposed MLs. <ul style="list-style-type: none"> ○ Since the ML is for total aflatoxins, the method criteria fall under the category of “sum of components” (Codex Procedural Manual p. 78, 27th Ed). The Codex method criteria approach requires CCCF to specify the ratio of isomers in order to determine the required LOQ for each isomer. Since the ML is a sum of four isomers, the required LOQ for each isomer will be at least (0.1) (ML). If a ratio is chosen that reflects the natural abundance of isomers where B1 is 70% of the total isomers, the LOQ requirement for B2, G1, and G2 would be (0.04) (ML). Method performance requirements are more demanding for an ML that involves a sum of components. ○ For a method to be fit for purpose, the analytical range which encompasses the ML should be captured in a collaborative study protocol. ○ While individual laboratories may report LOQ values lower than the concentration stated in the compendial method, and such results may be included in the GEMS/Food database, individual lab performance does not supersede the analytical range established in the collaborative study. ○ The recommendation for collaborative studies to determine method reproducibility (Codex Procedural Manual (p. 76, 27th Ed)) still applies when numeric criteria are used instead of method endorsement. ○ While there are sensitive mass spectrometric methods that can determine total aflatoxins at very low concentrations, we are not aware of any collaboratively studied methods that are endorsed by an international standards-developing organization. (For example, available AOAC collaborative methods for the determination of aflatoxins in grains, nuts, and corn specify 5 ng/g (µg/kg) or higher as the lower end of the analytical range.) Also, mass spectrometric methods capable of determining total aflatoxins at very low concentrations may not be available to laboratories in all regions of the world. • Year to year variation: The proposal presents but does not take into account year to year variations in aflatoxin levels. 	<p>USA</p>

COMMENTS	MEMBER/OBSERVER
<p>UNICEF does not support the proposed ML of 1 µg/kg or 2 µg/kg for cereal-based food for infants and young children:</p> <p>UNICEF maintains a generic specification for a specially formulated corn soy cereal with added milk called Super Cereal plus and also a Lipid-based Supplement Food used in humanitarian and emergency response and the set maximum limit of aflatoxin total at 10 µg/kg. This is the same specification is utilized by Humanitarian Agencies around the world, including WFP. We rely on producers based in countries such as africa, where local grain and soy are used. the quality is carefully controlled, and the aflatoxin limit is consistently achievable at 10 µg/kg. Lowering the limit will impact our supply chains and our ability to respond to emergencies.</p>	<p>UNICEF</p>
<p>World Food Programme does not support progressing the draft as it is.</p> <p><u>Introduction:</u></p> <p>The World Food Programme of the United Nations (WFP) is the world's largest humanitarian organization, working to save and change the lives of 100 million people in 88 countries.</p> <p>WFP is among the first on the scene in an emergency, providing food and other assistance to the victims of conflict, drought, floods, earthquakes, hurricanes and crop failures, as well as pandemics such as the current global outbreak of COVID-19. At the same time, WFP keeps a sharp focus on sustainable development, providing governments with the support and skills to manage food security in the long term.</p> <p>In 2020, WFP was awarded the Nobel Peace Prize "for its efforts to combat hunger, for its contribution to bettering conditions for peace in conflict-affected areas and for acting as a driving force in efforts to prevent the use of hunger as a weapon of war".</p> <p>The Coronavirus (COVID-19) pandemic has disrupted the world, with a heavy toll on human lives and economic activities. Its rapid global spread threatens millions of people already made vulnerable by food insecurity, malnutrition and the effects of conflict and disasters.</p> <p>In 2017, the global number of people marching towards the brink of starvation was 80 million. In 2020, pre-COVID -19, the number had already risen to 135 million people. COVID-19 has caused the predicted number to grow to 270 million people in 2021.</p> <p>WFP relies on a number of food procurement strategies to respond to food insecurity and they heavily rely on local procurement of food in countries of operation, as well as cash-based transfers that allow access to foods which are available in local retail markets.</p> <p>WFP tests purchased foods to ensure their compliance to applicable and highest food standards to the extent possible. CODEX is generally the reference adopted for food specifications.</p> <p>Local supply chains in the developing world are often fragmented and inefficient, resulting in higher prices, greater losses and less access to food for the poorest. Millions of small and medium-sized businesses and smallholder farmers are made poorer by the inability to access markets and support themselves.</p> <p>Every year, the World Food Programme (WFP) spends more than US\$ 2 billion in locations where it runs operations. As a large buyer of commodities and services, WFP's purchasing power allows strengthening of markets in a way that promotes development and resilience to shocks, while addressing the root causes of food insecurity.</p>	<p>WFP</p>

COMMENTS	MEMBER/OBSERVER
<p><u>General comments:</u></p> <p>At the outset, WFP appreciates the concrete actions taken by the committee to further the guidance on MRLs for aflatoxins. We strongly believe that these efforts will pave the way to globally reduce exposure to aflatoxins in human diets.</p> <p>WFP would like to offer its internally generated data for aflatoxin in various foods, conveyed by regions, and suggests that the committee also considers the data from locations in which prevalence of aflatoxin is higher, as to define limits that include the impact on food security as well as food safety.</p> <p>The draft proposed maximum limits for aflatoxins will limit WFP's capacity of to purchase and distribute foods to the most vulnerable populations.</p> <p>In a joint effort towards achieving SDG-2 (Zero Hunger) and linking it to SDG-3 (Good Health and Well-being), the consideration of WFP's inputs would be highly appreciated.</p>	

SPECIFIC COMMENTS

(a) Should the rejection rates adopted be the same for grains and for processed products? (Grains may have another destination, such as animal feed). What is the more appropriate rejection rate, considering the different types of products and contaminants?

COMMENTS	MEMBER/OBSERVER
Canada is not aware that different rejection rates have ever been applied depending on the product, contaminant, or degree of processing, when other Codex MLs (e.g. DON) were established. Canada is of the opinion that it's consistent with CCCF processes to target a 5% or lower rejection rate for all food commodities and contaminants under consideration for ML elaboration.	Canada
Proposal 2 is the more appropriate for rejection rate.	Egypt
According to the Technical Regulations ML for total aflatoxins in cereals for feed purposes is higher than ML of maize grain destined for further processing, husked rice, flour, meal, semolina and flakes derived from maize. We consider that the rejection rate of 5% should be left which is currently in force. In order to establish a specific deviation rate based on product types and contaminants, as opposed to 5%, it is necessary to analyze the data on the identified outliers and the processing of the outliers and contaminants. It is necessary to take into account the facts that, feeding animals with an increased content of contaminants (aflatoxins) leads to the death of animals.	Kazakhstan
<p>Las tasas de rechazo para cereales y productos procesados a base de cereales para lactantes, niños y niñas pequeños no deben ser las mismas, ya que al someter los granos de cereal a un posterior procesamiento lo que implica cada una de las operaciones unitarias correspondientes (secado, almacenamiento, procesamiento y manufactura en producto terminado), encontramos de acuerdo a la literatura correspondiente que se evidencia una disminución de la tasa de aflatoxinas presentes en comparación con el grano sin procesar.</p> <p>Los cereales si pueden tener otro destino como alimento para animales como es el caso del maíz amarillo y el arroz, de la producción total solo un porcentaje muy bajo tiene como destino final alimento para animales en Venezuela. Solo podemos hablar de maíz y arroz porque nuestro país no es productor de trigo.</p> <p>De acuerdo a lo presentado en la carta CIRCULAR CL 2020/23/OCS-CF y con el universo de muestras correspondientes a los países de los cuales se obtuvo datos para elaborar las tablas correspondientes con un límite de cuantificación superior a 8 µg/kg, no se observó muestras positivas, por lo que podría tomarse ese valor como la tasa de rechazo. Sin embargo, como también se acordó en la reunión es imperativo conocer los valores que manejan aquellos países con producción de cereales para lactantes y niños pequeños que no fueron incluidos.</p>	Venezuela (Bolivarian Republic of)
What is meant by processed products? is it processed and used as an ingredient? or is it processed and final product?	Action Contre la Faim
MSF suggests that the rejection rates could be adapted to the purpose of the product (i.e. different for grains and for processed products), but should be clearly defined for each purpose (e.g. MLs clearly defined per category: grains for animal feed, ingredient for food for general population, ingredient for food for infants or other vulnerable population...)	MSF

(b) How the outliers should be treated, since there is no harmonized procedure available in the Committee?

COMMENTS	MEMBER/OBSERVER
<p>Outliers should not be excluded as long as there is information available on the LOD and LOQ of the method of analysis, and the method is deemed fit for purpose. Aflatoxins in unprocessed grains are expected to be highly heterogeneous and the presence of outliers in the dataset reflects this.</p> <p>Fewer outliers would be expected in processed products (e.g. flour, flakes) as processing reduces the distributional heterogeneity of aflatoxins.</p> <p>1b): Canada is interested in the discussion at CCCF14, "Agenda Item 17: Guidance on data analysis for development of MLS and improved data collection", which will address treatment of outliers.</p>	Canada
<p>En el caso puntual de la determinación de NM realizado en aflatoxinas, no deben ser eliminados del análisis de datos, ya que la presencia de aflatoxinas tampoco sigue una distribución normal.</p>	Ecuador
<p>It is preferable not to remove potential outliers from the dataset, since the presence of potential outliers in the suggested maxima did not affect 95% and that aflatoxin contamination does not follow a normal distribution as it is affected by several factors, for example climatic factors, which can change from year to year.</p>	Egypt
<p>The outliers can be caused by various factors. It is important to determine the factor: anthropogenic or natural-climatic to analyze how much it is possible to prevent mycotoxin contamination. This determines whether the outliers should be rejected or still be included.</p>	Kazakhstan
<p>En este punto estamos de acuerdo con el comité, en no excluir los atípicos de los datos trabajados. La razón es que la distribución de aflatoxinas en el grano de cereal no es homogénea por lo que a nivel de planta es conocido que puede ocurrir contaminación con altos niveles de aflatoxinas y en ocasiones pueden presentarse "picos" atípicos del comportamiento real y regular del contenido de aflatoxinas en los cereales.</p>	Venezuela (Bolivarian Republic of)

(c) How should maize data be evaluated, since the available data are related to the marketing of the products and there is no guarantee that they are intended exclusively for human consumption and not for animal feed?

COMMENTS	MEMBER/OBSERVER
<p>Calls for data should indicate that the maize grain data be provided for maize in the human food stream. If maize grain later leaves the human food stream or is in the animal food stream and then enters the human food stream, this should not matter if the maize is at any time intended for human consumption.</p>	Canada
<p>Chile revisó las recomendaciones de esta carta circular y sus comentarios se exponen a continuación:</p> <p>En relación a cómo deben evaluarse los datos sobre el maíz, ya que los datos disponibles están relacionados con la comercialización de los productos y no hay garantía de que se destinen exclusivamente al consumo humano y no a piensos para animales, en opinión de Chile, podría ser necesario detener el trabajo y hacer una eventual revisión de los datos ya disponibles, o en defecto, llevar a cabo, una nueva solicitud de datos en donde se especifique el destino del maíz, de tal forma de poder evaluar lo que se requiere.</p>	Chile
<p>En este punto estamos de acuerdo en que debe incluirse una nota a pie de tabla que indique, que los datos presentados en la tabla corresponden con el maíz sometido a posterior procesamiento para consumo humano y no para alimentación animal.</p>	Venezuela (Bolivarian Republic of)

(d) Are there any methods available that have already been validated in collaborative assays that meet the limits proposed in this document?

COMMENTS	MEMBER/OBSERVER
AOAC has some "Performance Tested Methods" that are immune-based simple test kits that have been evaluated for maize according to AOAC processes (which may not be considered collaboratively validated; the test kit manufacturers submit a data package for AOAC to review). The sensitivity of these appear to be applicable to the proposed maize grain MLs. There are some AOAC "Official Methods of Analysis" that use liquid chromatography and non-mass spectrometric detection that seem to include maize. These would have undergone a more collaborative validation. The sensitivity of these methods would need to be verified with the AOAC.	Canada
In Egypt we use the following method: Rapid Analysis of Aflatoxins in Corn, Cereals, and Almonds Using ACQUITY UPLC H-Class System with Fluorescence Detection.	Egypt
There are methods to determine lower levels of aflatoxins than proposed in this document.	Kazakhstan
En este punto desconocemos si en Venezuela se han realizado ensayos colaborativos por parte de las Universidades y de las Industrias que fabrican y comercializan cereales para lactantes y niños pequeños.	Venezuela (Bolivarian Republic of)
This shouldn't be limited to collaborative methods/assays, as long as a method is fit for purpose	IAEA

(e) Should CCCF request JECFA to carry out a dietary exposure assessment considering the MLs proposed in this document?

COMMENTS	MEMBER/OBSERVER
Canada is of the opinion that a request for JECFA to conduct an impact assessment on the proposed MLs is not needed. JECFA49 (2017) conducted a risk assessment for aflatoxins that indicated the cereals that contributed most to dietary exposure (wheat, rice, maize, sorghum), and identified grains are being prioritized for ML elaboration.	Canada
Sí, el Comité puede solicitar al JECFA que realice la evaluación de la exposición alimentaria de los NM propuestos.	Ecuador
It is preferred that JECFA assesses the risks within the maximum limits suggested in this document.	Egypt
Si, en este punto es recomendable que el Comité Mixto FAO/OMS de Expertos en Aditivos Alimentarios (JECFA), participe y realice una evaluación considerando que está dentro de sus funciones de trabajo.	Venezuela (Bolivarian Republic of)
It would be useful to carry out dietary exposure assessment; to reinforce market contamination assessment (global assessment) and as well as to continue research on effects of aflatoxin as new developments seem to be produced regularly	Action Contre la Faim
MSF International agrees that a request from CCCF to JECFA to carry out a dietary exposure assessment considering the MLs proposed in this document would be helpful.	MSF
To ensure the protection of this vulnerable population, ISDI would support conducting a dietary exposure assessment to inform the decision on the appropriate ML for this food category	ISDI

(f) What limits does CCCF consider that can move forward in this meeting?

COMMENTS	MEMBER/OBSERVER
Canada is of the opinion that further discussion and analysis is needed before ML elaboration progresses on a variety of topics, in addition to those in the various technical questions posed to CCCF14 by the EWG.	Canada
<p>En cuanto a la carta circular: CL 2021/15/OCS-CF Solicitud de observaciones en el trámite 3 sobre niveles máximos para el total de aflatoxinas en algunos cereales y productos a base de cereales, incluidos alimentos para lactantes y niños pequeños y teniendo en cuenta el documento: CX/CF 21/14/10-Parte I NIVELES MÁXIMOS PARA EL TOTAL DE AFLATOXINAS EN ALGUNOS CEREALES Y PRODUCTOS A BASE DE CEREALES, INCLUIDOS ALIMENTOS PARA LACTANTES Y NIÑOS PEQUEÑOS (En el trámite 4)</p> <ul style="list-style-type: none"> <input type="checkbox"/> Cuba agradece a Brasil y a la India por tan importante trabajo, y en principio nuestro país apoyaría NM más bajos que los propuestos, teniendo en cuenta que en la Norma Cubana 1205:2017 Norma general para los contaminantes y las toxinas presentes en los alimentos y piensos, expone NM más bajos. Se sugiere que sería posible aplicar NM más bajos basándose en las cifras presentadas para proteger la salud pública. <input type="checkbox"/> El párrafo 7, expone que “los datos de cada categoría de alimentos se organizaron en tres cuadros diferentes que contienen información sobre la presencia de AF a nivel mundial...”, sin embargo, este criterio sobre los NM propuestos no se basan en datos representativos a nivel mundial para determinar la ingesta de aflatoxinas. <input type="checkbox"/> En el Cuadro 1. Datos de SIMUVIMA/Alimentos sobre la presencia y las concentraciones de AF en el maíz en grano destinado a su posterior procesamiento, Finlandia ofrece resultados datos extremadamente altos, se debería revisar esta información, pues con ello alteraría los resultados de los análisis descritos en el documento y, por ende las propuestas presentarían errores. <input type="checkbox"/> Cuba recomienda que se recopile más información para poder considerar una mejor distribución de los datos, pues quedan sin exponer datos de otros países que son grandes productores de cereales y que por su ubicación geográfica presentan un alto grado de exposición a las aflatoxinas totales en toda la cadena productiva. 	Cuba
En este punto le corresponde a la industria evaluar esta propuesta.	Venezuela (Bolivarian Republic of)
Efforts to reduce exposure to aflatoxin and therefore work on agricultural practices should continue. As far a maximal limits are concerned; Action Contre la Faim, WFP, UNICEF, MSF, USAID and ICRC are working together to harmonise their requirements in order to ease collaboration. Today, and based on the numerous testings and data collected, it is estimated sourcing would be dramatically impaired with the proposed ML below	Action Contre la Faim
ISDI would support first waiting for the finalization of JECFA exposure assessment before discussing limits.	ISDI

Provide comments on the MLs

COMMENTS	MEMBER/OBSERVER
<p><u>General comment:</u> There are no occurrence data for any food commodity under consideration for ML elaboration from African countries and limited data from South America. The majority of the data submitted for all foods considered for ML elaboration are from Europe and North America. More geographically representative data would improve the global applicability of the MLs proposed.</p>	Canada
<ul style="list-style-type: none"> • <u>Maíz en grano, destinado a su posterior procesamiento:</u> Chile apoya la propuesta 2, correspondiente a un nivel máximo de 15 µg/kg. • <u>Harina, sémola, semolina y hojuelas de maíz / arroz descascarillado / ¿arroz pulido / Sorgo / Alimentos a base de cereales para lactantes y niños pequeños</u> Chile podría apoyar la propuesta 2, para estar matrices alimentarias, no obstante, atendiendo a lo planteado por el Programa Mundial de Alimentos (PMA), Chile cree que sería recomendable solicitar al JECFA que realice una evaluación de la exposición alimentaria teniendo en cuenta, tanto los niveles máximos propuestos en el documento CX/CF 21/14/10-Parte I, como también los NM que actualmente maneja el PMA, para determinar si es posible tener niveles que permitan resguardar la seguridad alimentaria y a la vez la inocuidad de estas matrices. 	Chile
<p>Egypt adopts the following limits:</p> <ul style="list-style-type: none"> • Maize grain, destined for further processing ML: 10 µg/kg - Sample rejection (%): 5.4 • Flour, meal, semolina ML: 4 µg/kg - Sample rejection (%): 1.5 • flakes derived from maize ML: 10 µg/kg - Sample rejection (%): 1.5 • Husked rice ML: 10 µg/kg - Sample rejection (%): 2.7 • Polished rice ML: 4 µg/kg - Sample rejection (%): 1.2 • Sorghum grain, destined for further processing ML: 8 µg/kg - Sample rejection (%): 2.7 	Egypt
<p>As mentioned above there are sensitive methods for mycotoxins and the need to apply the ALARA approach to protect consumers' health, so we think the suggested MLs are high.</p>	Kazakhstan
<p><u>Maize grain, destined for further processing:</u> Thailand does not object to the proposed ML for AFs of 15 µg/kg. Although the rejection rate is higher than 5%, most sample data came from the USA. Thus, Thailand would like to recommend that selecting appropriate ML should also consider the data representing geographical distribution.</p> <p><u>Flour, meal, semolina and flakes derived from maize:</u> Thailand does not object to the proposed ML for AFs of 10 µg/kg, showing an appropriate rejection rate of 1.5% and consistency with the proposed ML at 15 µg/kg for AFs in maize grain, destined for further processing higher ML than products derived from maize.</p> <p><u>Husked rice:</u> Thailand does not object to the proposed ML for AFs of 20 µg/kg, showing an appropriate rejection rate of 2.1%</p> <p><u>Polished rice:</u> Thailand does not object to the proposed ML for AFs of 4 µg/kg.</p>	Thailand

COMMENTS	MEMBER/OBSERVER
<p><u>Sorghum grain, destined for further processing:</u> Thailand does not object to the proposed ML for AFs of 10 µg/kg, showing an appropriate rejection rate of 2.0%</p> <p><u>Cereal-based Food for infants and young children:</u> Thailand strongly agrees to restrict the ML as it will protect the infant and young children's health. However, it is noticed that both proposed MLs as 2 µg/kg and 1 µg/kg have rejection rates of 0.2% and 7.8%, respectively, which are not in the range of considered sample rejection between 2%-5%</p>	
<p>Con respecto a esta tabla solo podemos decir lo siguiente:</p> <p>a) El nivel máximo (NM) establecido en la propuesta 1 para el maíz en grano, destinado a su posterior procesamiento está acorde con lo discutido por el subcomité 01 ALIMENTOS PARA NIÑOS, en relación con la norma venezolana COVENIN 1452 ALIMENTOS ELABORADOS A BASE DE CEREALES PARA NIÑOS DE PECHO Y NIÑOS DE CORTA EDAD, resultado de las consultas internas realizadas por los representantes de las empresas miembros. No se ha acordado aun un nivel máximo para los productos contemplados en la norma es un punto pendiente para discutir en las próximas reuniones.</p> <p>b) En cuanto a cereales como arroz el subcomité no ha establecido aun acuerdos, las empresas que manufacturan productos para lactantes y niños pequeños como crema de arroz no han aportado aún ninguna información.</p>	Venezuela (Bolivarian Republic of)
<p><u>Maize grain, destined for further processing:</u> Proposed ML of 15 µg/kg or 20 µg/kg</p> <ul style="list-style-type: none"> • The United States would not object to the proposed ML of 20 µg/kg. • On a yearly basis, the 95th percentile of the global dataset exceeded the proposed ML of 15 µg/kg in 4 of 14 years. • We recommend an accompanying note that an ML does not apply to maize for wet milling (i.e., processing for starch, ethanol, and other fractions) or animal feed. <p><u>Flour, meal, semolina, and flakes derived from maize:</u> Proposed ML of 10 µg/kg or 15 µg/kg</p> <ul style="list-style-type: none"> • The proposed MLs of 10 µg/kg and 15 µg/kg have similar levels of intake reduction, but 15 µg/kg would have less impact on trade. <p><u>Husked rice:</u> Proposed ML of 15 µg/kg or 20 µg/kg</p> <ul style="list-style-type: none"> • The United States would not object to the proposed ML of 20 µg/kg. • However, we are concerned with the lack of data from major rice producing and consuming countries in Asia. We suggest gathering more globally representative data before establishing MLs. <p><u>Polished rice:</u> Proposed ML of 4 µg/kg or 8 µg/kg</p> <ul style="list-style-type: none"> • The United States does not support the proposed ML of 4 µg/kg. • As noted in general comments, we are not aware of widely available, collaboratively validated methods with an LOQ that will support this ML. • In addition, the proposed ML of 4 µg/kg is below the LOQ of methods used in rapid inspections for bulk grain. • We are concerned with the lack of data from major rice producing and consuming countries. We suggest gathering more globally representative data before establishing MLs. 	USA

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<p><u>Sorghum grain, destined for further processing</u>: Proposed ML of 8 µg/kg or 10 µg/kg</p> <ul style="list-style-type: none"> The United States does not support CCCF establishing an ML for sorghum without considering data on sorghum for human food use from Africa, which is a primary sorghum-consuming region. We note that 99% of the data in the document are from the United States, and the remaining data are only from Indonesia, Japan, and Korea. <p><u>Cereal-based food for infants and young children</u>: Proposed ML of 1 µg/kg or 2 µg/kg</p> <ul style="list-style-type: none"> The United States does not support the proposed MLs of 1 µg/kg or 2 µg/kg based on current data and approach. As noted in general comments, we are not aware of widely available, collaboratively validated methods with an LOQ that will support an ML of 1 to 2 µg/kg in cereal-based foods for infants and young children. The data are not globally representative, with 76% of data from the European Union, which already has a limit of 0.1 µg/kg in place for aflatoxin B1. The approach used was to convert all data to 0 for results with LOQs < 8 µg/kg and omit data for results with an LOQ > 8 µg/kg. This approach could potentially eliminate samples with values > 2 µg/kg and present a misleading picture of whether the MLs of 1-2 µg/kg are globally achievable at the proposed 95th percentile. 	
<p><u>Maize grain for further processing</u>: Proposal 1 seems fair</p> <p><u>Flour, Meal, Semolina</u>: current max limit used by ACF is 20ppb. Currently there is no request to change this value</p> <p><u>Husked rice</u>: proposal 1 is fair</p> <p><u>Cereal-based food for infant and young children</u>: the proposed ML seem too low and hardly achievable, Proposed ML is 10 ppb</p>	Action Contre la Faim
<p>MSF International distributes super cereals and super cereals plus to victims of conflict, natural disasters, epidemics or healthcare exclusion. Super cereals and super-cereals plus are fortified cereal-based products for infants and young children. The MSF specifications for specialised nutrition food distributed in MSF programmes are based on an interagency collaboration between UNICEF, WFP, USAID, Action Against Hunger, ICRC and MSF. In this group, WFP (the World Food Programme) leads the work on specifications for super cereals and super cereals plus, as WFP is the main buyer worldwide for these specific products.</p> <p>For Cereal-based food for infants and young children, MSF International does not support the proposed ML of 1 µg/kg or 2 µg/kg, because this would have a significant impact on the availability of super cereals and super cereals plus.</p> <p>WFP (the World Food Programme) has generated a considerable amount of data for aflatoxins level, by regions, in super cereals and super cereals plus. MSF International suggests that the committee considers the data from locations in which prevalence of aflatoxin is higher, as to define limits that include the impact on food security as well as food safety.</p>	MSF

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<p><u>Cereal-based food for infants and young children</u>: Proposed ML of 1 µg/kg or 2 µg/kg</p> <ul style="list-style-type: none"> The World Food Programme does not support the proposed MLs of 1 µg/kg or 2 µg/kg. WFP 2018-2020 pre-shipment inspection data showed 7% (12 out of 170 samples) of cereal-based infant foods originated from Eastern Africa did not meet the ML of 2 µg/kg, and 14% (24 out of 170 samples) did not meet the ML of 1 µg/kg. The World Food Programme generic specification of Super Cereal plus and Lipid-based Supplement Foods set maximum limit of aflatoxin total at 10 µg/kg. The same specification is utilized by Humanitarian Agencies such as UNICEF. <p><u>Flour, meal, semolina, and flakes derived from maize</u>: Proposed ML of 10 µg/kg or 15 µg/kg</p> <ul style="list-style-type: none"> The World Food Programme does not support the proposed ML of 10 µg/kg. WFP 2020 Market Assessment in West Africa and East Africa showed 37.5% samples (3 out of 8 samples) did not meet the proposed ML. World Food Programme generic maize meal specification sets maximum limit of aflatoxin total at 20 µg/kg. <p><u>Maize grain, destined for further processing</u>: Proposed ML of 15 µg/kg or 20 µg/kg</p> <ul style="list-style-type: none"> The World Food Programme does not support the proposed MLs of 15 µg/kg. In 2021, WFP pre-shipment inspection showed 14.4% maize (136 MT out of 941 MT) from East African did not meet the proposed MLs of 15 µg/kg. The World Food Programme generic maize specification sets maximum limit of aflatoxin total at 20 µg/kg. <p><u>Sorghum grain, destined for further processing</u>: Proposed ML of 8 µg/kg or 10 µg/kg</p> <ul style="list-style-type: none"> The World Food Programme does not support the proposed MLs. WFP 2020/2021 pre-shipment inspection data showed 20% (2 out of 10 samples) of sorghum originated from India will not meet the ML of 8 µg/kg. Additionally, WFP has limited data on sorghum originated from India and Africa to support the ML of 10 µg/kg. WFP noted the current data considered are from the United States, Indonesia, Japan, and Korea, and urges the committee to also take into account data from countries where the prevalence of aflatoxins will be higher. The World Food Programme generic sorghum specification sets maximum limit of aflatoxin total at 20 µg/kg. 	<p>WFP</p>