

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 - www.codexalimentarius.org

Agenda Item 9

CX/CF 22/15/9-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 LEVELS FOR TOTAL AFLATOXINS IN CERTAIN CEREALS AND CEREAL-BASED PRODUCTS INCLUDING FOODS FOR INFANTS AND YOUNG CHILDREN AND ASSOCIATED SAMPLING PLANS (At Step 4)

Comments in reply to CL 2022/18-CF

Comments of Canada, Ecuador, Egypt, European Union (EU), Iraq, Kazakhstan, Kenya, Peru, Rwanda, Saudi Arabia, Singapore, Uganda, United States of America (USA), African Union (AU), International Commission for Uniform Methods of Sugar Analysis (ICUMSA), Institute of Food Technologists (IFT), Médecins Sans Frontières International (MSF), United Nations International Children's Emergency Fund (UNICEF) and World Food Programme (WFP)

Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2022/18-CF¹ 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.

¹ 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 COMMENTS

COMMENT	MEMBER/ OBSERVER
<p>Canada continues to have questions regarding the effects of processing on the concentration of aflatoxins in raw relative to refined cereal grains. REP21/CF, Para. 131 indicates that the EWG should include considerations on the effect of processing on the reduction of aflatoxins contamination. This does not appear to have been elaborated on in CX/CF 22/15/9 in proposing the MLs for maize and rice, though para. 12 of Appendix II mentions the review conducted in the discussion paper on this topic presented at CCCF8. Reviewing and updating the available information on the effects of processing from that paper (CX/CF 14/8/15) may allow for the derivation of processing factors that would support the ratio between the proposed ML for maize destined for further processing relative to that of flour, meal, semolina and flakes derived from maize, and likewise for husked versus polished rice. While geographic representativeness of the data set has been improved for some commodities, it is still lacking for others such as sorghum, but it is unclear whether additional data would be forthcoming to fill this data gap.</p> <p>Canada notes that the MLs proposed in CX/CF 22/15/9 all fall within the target rejection rate of $\leq 5\%$ according to the data presented and most would be expected to reduce total aflatoxins exposure considerably (50 to 85%). In addition, Canada appreciates that previous comments regarding the consideration of a wider range of potential MLs and rejection rates, the potential impacts of proposed MLs on humanitarian aid, and the lack of exposure estimates for infant foods have been addressed.</p>	Canada
<p>En respuesta a la Carta Circular CL 2022/18-CF, Ecuador agradece al Presidente y Copresidente del Grupo de Trabajo por Medios Electrónicos - Gte por preparar y presentar la propuesta de niveles máximos para el total de aflatoxinas en algunos cereales y productos a base de cereales, incluidos alimentos para lactantes y niños pequeños, y planes de muestreo asociados (en el trámite 4).</p> <p>Ecuador desea apoyar los NM propuestos en el APÉNDICE I referente a niveles máximos para el total de aflatoxinas. De igual manera, se sugiere suspender el desarrollo de planes de muestreo hasta que se concluyan los NM.</p>	Ecuador
<p>The European Union (EU) welcomes and appreciates the huge work done on the setting of maximum levels (MLs) for aflatoxins total by the electronic Working Group chaired by Brazil and co-chaired by India.</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> <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.</p> <p>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. Based on their contribution to dietary aflatoxin exposure in some areas of the world, JECFA recommended that rice, wheat and sorghum would need to be considered in future risk management activities for aflatoxins.</p> <p>The European Food Safety Authority (EFSA) has recently performed a 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>	EU
<p>In order to ensure a high level of human protection, the EU is of the opinion that it is of major importance that maximum levels for aflatoxin total are established as low as reasonably achievable (ALARA) by applying good practices to prevent contamination.</p>	EU
<p>Agree with proposal</p>	Iraq

COMMENT	MEMBER/ OBSERVER
<p>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 planes de muestreo asociados.</p> <p>El Perú desea agradecer a Brasil e India por el trabajo realizado respecto a la determinación de niveles máximos para el total de aflatoxinas en algunos cereales y productos a base de cereales, incluidos alimentos para lactantes y niños pequeños, y planes de muestreo asociados.</p> <p>En esta ocasión, el Perú evaluando los porcentajes de rechazo para las categorías de alimentos de acuerdo al apéndice I, considera que los niveles propuestos sean aceptados para su adopción definitiva en la CAC 45.</p>	Peru
<p>French document appears to not have superscripts for the descriptions of a, b, c, d but superscripts are in the text for the English and Spanish documents.</p>	ICUMSA
<p>Saudi Arabia support the Proposed Maximum Levels For Total Aflatoxins In Certain Cereals And Cereal-Based Products Including Foods For Infants And Young Children</p>	Saudi Arabia
<p>The United Nations World Food Programme (WFP) is the world's largest humanitarian organization, saving lives in emergencies and using food assistance to build a pathway to peace, stability and prosperity for people recovering from conflict, disasters and the impact of climate change.</p> <p>Powered by the passion, dedication and professionalism of 20,000 staff worldwide, WFP works in 117 countries and territories to bring life-saving food to people displaced by conflict and made destitute by disasters, and help individuals and communities find life-changing solutions to the multiple challenges they face in building better futures. 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 COVID-19 pandemic has disrupted the world, taking a heavy toll on human lives and global economies. It continues to spread rapidly, threatening the lives of millions of people already made vulnerable by food insecurity, malnutrition and the effects of conflict and disaster.</p> <p>The State of Food Security and Nutrition in the World 2021 estimates that between 720 and 811 million people in the world faced hunger in 2020 – as many as 161 million more than in 2019. Furthermore, more than three billion people cannot afford a healthy, nutritious diet, a root cause of malnutrition. Additionally, large numbers of children under five years of age were affected by stunting (149.2 million, or 22%), wasting (45.4 million) or were overweight (38.9 million). Child malnutrition continues to be a challenge, particularly in Africa and Asia. Efforts to eradicate malnutrition in all its forms have been challenged by disruptions in essential nutrition interventions and negative impacts on dietary patterns during the COVID-19 pandemic.</p> <p>WFP relies on a number of food procurement strategies to address the twin challenges of food insecurity and malnutrition quickly and efficiently, including local procurement of foods in countries of operation and supporting cash-based transfers that enable affected populations to choose and purchase food in local retail markets. WFP tests all purchased food intended for in-kind distribution by WFP and partners to ensure their compliance to the highest food standards possible. CODEX is generally the reference adopted for WFP's food specifications.</p> <p>Local supply chains in low-to-middle-income countries are often fragmented and inefficient, resulting in higher prices, greater losses and reduced/limited 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, WFP spends more than US\$2 billion on commodities and services in locations where it runs operations. WFP's purchasing power supports local markets in a way that promotes development and resilience of producers, manufacturers, retailers and consumers while addressing the root causes of food insecurity and malnutrition.</p> <p>WFP appreciates the concrete steps taken by the EWG to further the guidance on maximum limits (MLs) for aflatoxins. We strongly believe that these efforts will help to significantly reduce people's exposure to aflatoxins in their diets worldwide.</p>	WFP
<p>UNICEF thanks the EWG for the work done on contaminants to this date. As suppliers of a fortified cereal intended for children aged 6 to 59 months, we support the limit of aflatoxin in the proposal. We also agree to the suspension of sampling plan development until after the MLs are finalized.</p>	UNICEF

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

COMMENT	MEMBER/ OBSERVER						
<p><u>Limits proposed on an “as is” basis</u></p> <p><u>Editorial:</u> Canada recommends double-checking that the footnotes apply to the appropriate commodities. Canada's prior comment requesting the addition of the footnote on an "as-is basis" was intended to apply to the ML for cereal-based foods for infants and young children. The footnote associated with sorghum grain should be the one defining "destined for further processing."</p> <p>Canada notes that the Codex ML for DON in cereal-based foods for infants and young children in the GSCTFF “applies to the commodity on a dry matter basis”. The wording used to describe the MLs for both DON and aflatoxins in cereal-based foods for infants and young children should align, if indeed they apply to the same format/basis of the same food commodities.</p> <p>Further, Canada suggests that the wording “as is” does not clearly describe the format/basis of the food commodities to which this ML applies. Canada also questions if the wording that qualifies the DON ML for this commodity, that is, “on a dry matter basis”, could also be edited for clarity so that it is clear that the ML does not apply to fully desiccated food products containing 0% moisture, but rather to the format in which it is typically sold, which might for instance contain between 1 and 9% moisture depending on the food; Canada believes this was the intent when the ML was established, but this detail would have to be confirmed. A potentially more suitable wording that could be used to describe the application of the ML to cereal-based foods for infants and young children that could be added to the GSCTFF for the ML for DON and that for aflatoxins, should the latter be elaborated, is: “as sold; not reconstituted or otherwise prepared for consumption”.</p>	Canada						
<p>Egypt appreciates the work and efforts done by the EWG in drafting of this circulated document; and in this regard, Egypt would like Provide comments on:</p> <table border="0" data-bbox="94 831 851 927"> <tr> <td>Food category</td> <td>ML</td> </tr> <tr> <td>Maize grain, destined for further processing</td> <td>10 µg/kg</td> </tr> <tr> <td>Flour, meal, semolina</td> <td>4 µg/kg</td> </tr> </table>	Food category	ML	Maize grain, destined for further processing	10 µg/kg	Flour, meal, semolina	4 µg/kg	Egypt
Food category	ML						
Maize grain, destined for further processing	10 µg/kg						
Flour, meal, semolina	4 µg/kg						
<table border="0" data-bbox="94 948 985 979"> <tr> <td><u>Maize grain, destined for further processing</u>^{b,c}</td> <td>30 µg/kg</td> <td>3.7</td> </tr> </table> <ul style="list-style-type: none"> The data analysis shows a very large geographical variation and a very large year-to-year variation (Table 1, 2 and 3 in CX/CF 22/15/9). However, it is unclear if this large year-to-year variation is observed in all regions for which sufficient data have been provided. No further explanations are provided explaining these large variations. The EU notes, according to table 4, the sample rejection rate between a hypothetical ML of total aflatoxins of 20 µg/kg versus 30 µg/kg does not differ significantly and is in both cases acceptable (< 5 %). It is, however also noted that the differences in rejection rates can be larger when considering specific regions or specific years (table 5). Table 4 also demonstrates that lower hypothetical maximum levels of aflatoxins have a very significant positive effect on lowering the human exposure to aflatoxins, without an unacceptable increase in sample rejection rates. Given that the EU considers it of major importance to establish maximum levels for total aflatoxins as low as reasonably achievable (ALARA), the EU cannot agree on the proposed maximum level of 30 µg/kg for aflatoxin total in maize grain, destined for further processing. 	<u>Maize grain, destined for further processing</u> ^{b,c}	30 µg/kg	3.7	EU			
<u>Maize grain, destined for further processing</u> ^{b,c}	30 µg/kg	3.7					

COMMENT	MEMBER/ OBSERVER
<p><u>Cereal-based Food for infants and young children</u> 10 µg/kg 0.14</p> <p>Aflatoxins have carcinogenic and genotoxic effect. So, they can affect on the consumers' health. That's why we consider the proposed MLs are high. A cause of particular concern is the proposed ML for total ATFs of food for infants and young children, as children are the most vulnerable population groups.</p> <p>The proposed MLs are higher than the given indicators in the Technical Regulations in force in Kazakhstan, excluding polished rice.</p>	Kazakhstan
<p><u>Flour, meal, semolina and flakes derived from maize</u> 20 µg/kg 1.0</p> <p>Kenya does not accept the proposed maximum levels for the cereals and cereal based products.</p> <p><u>Rationale:</u> The levels in the EAC region has been set at a maximum level of 10µg/Kg based on the regional consumption and total aflatoxin monitoring data for all grains.</p>	Kenya
<p><u>Cereal-based Food for infants and young children</u> 10 µg/kg 0.14</p> <p>Rwanda does not support adoption of the ML 10 µg/kg in cereal-based food for infants and young children as recommended by EWG. Rwanda proposes the ML of 4 µg/kg in cereal-based food for infants and young children.</p> <p><u>Rationale:</u> Since aflatoxin predominance in the whole of Africa and particularly in Rwanda, the following are reasons for supporting the ML of 4 µg/kg:</p> <ul style="list-style-type: none"> ☐ The ML of 4 µg/kg has little or no impact on the lives of infants and young children considering some research conducted ☐ The shifting of total aflatoxin from 4 µg/kg to 10 µg/kg has a big impact considering effort done so far to reduce the aflatoxin levels. Given the high vulnerability of infants and young children to aflatoxin exposure, 4 µg/kg is fair and practical to protect the health of infants and young children. ☐ Most of specific key criteria considered when developing MLS were not respected while setting the MLs of 10 µg/kg, some of those criteria are Toxicological Information, Analytical Data, intake data, ☐ When considering the ML of 4µg/kg, the rejection rate is 0.61% with intake reduction of 20.0% <p>Rwanda is one of biggest producer for fortified infant food for young children through Africa Improved Foods with production capacity of 45,000 metric Tons per annum intended for WFP and government of Rwanda use.</p> <p>Note that those products are taken to Centrafrica, South Soudan, Ethiopia, Uganda and DRC.</p> <p>To discuss this, we are considering 3 important aspects:</p> <ol style="list-style-type: none"> 1. Availability of raw materials based on data we generated in 5 years 2. Risk associated to the exposed-on aflatoxin for the targeted group (Vulnerable group) 3. Sampling and testing methodologies available <p><u>Availability of raw material:</u></p> <p>Raw materials used (Maize) are sourced locally and regionally, considering the production capacity. Among countries we source from Uganda, Tanzania, Zambia, Malawi, etc While the requirement for our client on finished products was 5 µg/kg, AIF set the intake maize aflatoxin level at 5µg/kg in order to minimize any risk of rejection, while the EAC standard on maize was at 10 µg/kg.</p> <p>While the review of MLs Was being suggested by CODEX, Rwanda submitted data at GEMS for total aflatoxin in maize intake and finished products (Cereal based food for infant and young children).Those data backed up from 2017-2021 and showed different rates of rejection on different aflatoxin levels</p> <p>Briefly, the levels of aflatoxin in fortified cereal foods for infant and young children usually range between 3 and 4 µg/kg</p>	Rwanda

COMMENT	MEMBER/ OBSERVER
<p>Rejection rate at 2µg/kg was 98% in 2020 and 97% in 2021. Rejection rate at 3µg/kg was 40% in 2020 and 38% in 2021. Rejection rate at 4µg/kg was 1% in 2020 and 0% in 2021.</p> <p><u>Risk associated to aflatoxin intake to the vulnerable group:</u></p> <p>Rwanda recognizes the risk associated to the intake of aflatoxin containing foods, investigated into some research conducted before whereby the aflatoxicosis (disease due to high level of aflatoxin consumption) were discussed.</p> <p><u>Effect on human health/Acute toxicity:</u></p> <p>The disease was characterized by high fever, high colored urine, vomiting, and edema of feet, Jaundice, rapidly developing ascitis, portal hypertension and a high mortality rate</p> <p>The diseased was conformed to the very poor, who were forced by economic circumstances to consume badly molded corn containing aflatoxin between 6.25-15.6 ppm. On average the daily intake per person was 2-6 mg of aflatoxin.</p> <p><u>Sampling and testing methods:</u></p> <p>To bring to your attention that validated method need to have limit of detection and quantification. Most of techniques used to quantify total aflatoxin in cereal based products have LOD of 2 and LOQ of 3µg/kg. It is therefore ridiculous to have a requirement that is the same as limit of quantification</p> <p><u>CONCLUSION:</u> Codex should consider all voices of members, consider having the fair MLs in order to have every member included. Rwanda proposes ML of 4µg/kg for total aflatoxin in cereal based foods for infants and young children</p> <p><u>Maize grain, destined for further processing</u> 30 µg/kg 3.7</p> <p>Rwanda does not support setting MLs for maize grain for further processing at 30 µg/kg . Rwanda proposes the limits of 10 µg/kg for maize grain for human consumption, not for further processing.</p> <p><u>Rationale:</u> In Rwanda, a huge proportion of maize grain is sold as such for human consumption and we propose setting limits for such products. This is more suitable for human health protection where maize is a staple food and is traded as maize regardless of whether it would be going for further processing or meant for direct human consumption.</p> <p>In the same context, Rwanda as member of East African Community has already adopted 10 µg/kg for maize grains regardless of whether it is destined for further processing or direct human consumption. In this case, the ML for the whole category of maize should be 10 µg/kg in line with already existing East African standards.</p> <p><u>Flour, meal, semolina and flakes derived from maize</u> 20 µg/kg 1.0</p> <p>Rwanda does not support the adoption of a MLs of 20µg/kg proposed by EWG on flour, meal, semolina and flakes derived from maize. Rwanda proposes the ML of 10 µg/kg for flour, meal, semolina and flakes derived from maize</p> <p><u>Rationale:</u> The ML of 10 µg/kg is being enforced in Rwanda as well as in East African Community for all these food categories for the general population. Efforts to comply with those ML of 10 µg/kg have been made by the country and those limits are fair.</p> <p><u>Husked rice</u> 25 µg/kg 1.9</p> <p>Rwanda does not support the adoption of a MLs of 25µg/kg proposed by EWG on husked rice. Rwanda proposes the ML of 10 µg/kg for husked rice</p> <p><u>Rationale:</u> The ML of 10 µg/kg is being enforced in Rwanda as well as in East African Community for all husked rice. Efforts to comply with those ML of 10 µg/kg have been made by the country and those limits are fair.</p>	

COMMENT	MEMBER/ OBSERVER
<p><u>Polished rice</u> 5 µg/kg 0.8</p> <p>Rwanda does not support the adoption of a MLs of 5µg/kg proposed by EWG on polished rice. Rwanda proposes the ML of 10 µg/kg for polished rice</p> <p><u>Rationale:</u> The ML of 10 µg/kg is being enforced in Rwanda as well as in East African Community for all polished rice.</p> <p><u>Sorghum grain, destined for further processing</u> 15 µg/kg 0.9</p> <p>Rwanda does not support setting MLs for sorghum grains for further processing at 15 µg/kg . Rwanda proposes the limits of 10 µg/kg for sorghum grain for human consumption, not for further processing.</p> <p><u>Rationale:</u> In Rwanda, a huge proportion of sorghum grain is sold as such for human consumption and we propose setting limits for such products. This is more suitable for human health protection where sorghum is traded as sorghum regardless of whether it would be going for further processing or meant for direct human consumption. In the same context, Rwanda as member of East African Community has already adopted 10 µg/kg for sorghum grains regardless of whether it is destined for further processing or direct human consumption. In this case, the ML for the whole category of sorghum should be 10 µg/kg in line with already existing East African standards.</p>	
<p><u>Flour, meal, semolina and flakes derived from maize</u> 20 µg/kg 1.0</p> <p>Singapore does not support the 20 µg/kg ML proposed for flour, meal, semolina and flakes derived from maize.</p> <p>Singapore's ML for aflatoxins in food is 5 µg/kg. Aflatoxins are genotoxic carcinogens and the levels should be ALARA. The assessment provided by the EWG in CX/CF 22/15/9 showed that there is further significant 10% reduction in dietary exposure from reducing the MLs from 20 µg/kg to 5 µg/kg.</p> <p>Singapore notes that CX/CF 22/15/9 mentioned that the proposed MLs considered that lower MLs would lead to higher percentage of samples withdrawn from the Singapore market. However, for most other countries considered in the EWG's assessment, the rejection rates were low. At Singapore's current ML of 5 µg/kg, the global rejection rate is only 2.5% as given in CX/CF 22/15/9. In line with the ALARA principle, the data justifies for a lower ML to be established. Therefore, Singapore does not support the establishment of 20 µg/kg as the ML for flour, meal, semolina and flakes derived from maize.</p> <p><u>Cereal-based Food for infants and young children</u> 10 µg/kg 0.14</p> <p>Singapore does not support the 10 µg/kg ML proposed for cereal-based food for infants (< 12 months) and young children (12 – 36 mths).</p> <p>In many countries, infant cereals are the first solid food in an infant's diet and they play an important role in the complementary feeding period of an infant. Singapore is concerned that the proposed ML of 10 µg/kg offers limited health protection to infants and young children who constitute a vulnerable subpopulation.</p> <p>The proposed ML of 10 µg/kg is even higher than the 5 µg/kg ML for polished rice which is consumed by adults. For infant and young children food, Singapore has a ML of 0.1 g/kg for aflatoxin B1 and the ML was established based on the ALARA principle.</p>	Singapore
<p><u>Maize grain, destined for further processing</u> 30 µg/kg 3.7</p> <p>Uganda proposes maximum limits for total aflatoxin as 10 µg/kg AFT for cereals and 2 µg/kg AFT for cereal based products for infants and young children.</p> <p><u>Justification:</u> Due to repeated exposure in consumption of the food category that could subject high risk to consumers in Uganda. This is because the cereals and cereal based foods are staple food consumed in Uganda by all age groups on a daily basis thus need for lower limits of AFT.</p> <p>Vulnerability of the target population (infants and young children) that possess it to a high risk of aflatoxin toxicity effects, if the infants and young children consume foods contaminated with aflatoxins hence a much lower ML needed for this category of food.</p>	Uganda

COMMENT	MEMBER/ OBSERVER
<p><u>Maize grain, destined for further processing</u> 30 µg/kg 3.7</p>	USA
<p>Maize grain, destined for further processing: 30 µg/kg</p> <ul style="list-style-type: none"> • The United States does not support 30 µg/kg, but would not object to an ML of 20 µg/kg, which was proposed at CCCF14. An ML of 20 µg/kg will provide some protection from year-to-year variation in aflatoxin, while also ensuring that maize consumed without further processing will be at an acceptable aflatoxin level. • The United States recommends an accompanying note that the ML does not apply to maize for wet milling, as maize with levels above 30 µg/kg can be diverted to wet milling, which produces ingredients for human food use. 	
<p><u>Flour, meal, semolina and flakes derived from maize</u> 20 µg/kg 1.0</p>	
<p>Flour, meal, semolina, and flakes derived from maize: 20 µg/kg</p> <ul style="list-style-type: none"> • The United States does not object to the proposed ML of 20 µg/kg. 	
<p><u>Husked rice</u> 25 µg/kg 1.9</p>	
<ul style="list-style-type: none"> • The United States does not support 25 µg/kg, but would not object to an ML of 20 µg/kg. Husked rice is often consumed without further processing and greater intake reduction is achieved at 20 µg/kg versus 25 µg/kg. 	
<p><u>Polished rice</u> 5 µg/kg 0.8</p>	
<p>Polished rice: 5 µg/kg</p> <ul style="list-style-type: none"> • The United States objected to the previous proposed ML (4 µg/kg) on technical grounds. This concern is addressed with an ML of 5 µg/kg, which aligns with grain testing methods used in official grain inspections in the United States. The United States remains concerned, however, about setting an ML without polished rice data from major rice-producing countries, including in Asia and Africa. The United States also notes that the mean AFT level is lowest for polished rice versus all other commodities. CCCF may want to consider asking JECFA for an evaluation of exposure and risk reduction related to the proposed polished rice ML. 	
<p><u>Sorghum grain, destined for further processing</u> 15 µg/kg 0.9</p>	
<p>Sorghum grain, destined for further processing: 15 µg/kg</p> <ul style="list-style-type: none"> • The United States notes that 98.6% of the data is from the United States. There are very limited data from Africa, the primary consumer of sorghum as food. • The United States continues to believe that CCCF should not set an ML for sorghum without considering a larger body of data from Africa. 	
<p><u>Cereal-based Food for infants and young children</u> 10 µg/kg 0.14</p>	
<p>Cereal-based food for infants and young children: 10 µg/kg</p> <ul style="list-style-type: none"> • The United States can meet the proposed ML of 10 µg/kg based on review of GEMS data presented and can also meet a lower ML of 5 µg/kg. • The United States notes that the data are not globally representative, with about 64% of the data from the European Union, which has a limit of 0.1 µg/kg for aflatoxin B1. 	

COMMENT	MEMBER/ OBSERVER
<ul style="list-style-type: none"> <p><u>Comment:</u> African Union does not support setting MLs for maize grain destined for further processing. AU can however support ML of 10µg/kg for total aflatoxins in maize grain, destined for direct human consumption.</p> <p><u>Rationale:</u> African Union had previously expressed concern that It would be difficult to segregate data for maize for human consumption from data for maize intended for animal feed or intended for direct human consumption, as its intended purpose is not always indicated on the lot. In light of this, it will be appropriate to establish an ML only for ready-to-eat maize based on the whole dataset. This is more suitable for human health protection, especially in the African region where maize is a major staple food and is traded as maize regardless of whether it is destined for further processing or is meant for direct human consumption.</p> <p><u>Comment:</u> African Union supports the adoption of an ML of 10 µg/kg for flour, meal, semolina, and flakes derived from maize.</p> <p><u>Rationale:</u> The ML of 10 µg/kg is based on the high (up to 400g/person/day) consumption of cereal-based foods in the region. The consumption levels used by the EWG to estimate aflatoxin exposures from maize were about one-tenth of the average mean consumption (up to 400g/person/day) in Africa. For maize, the EWG used the mean consumption of 12.33 g/person obtained from GEMS/Food Cluster 6. Thus, the proposed ML of 20µg/kg is not consistent with the exceptionally high consumption patterns in Africa.</p> <p><u>Comment:</u> African Union supports the adoption of 10µg/kg for total aflatoxins in sorghum grain, destined for direct human consumption.</p> <p><u>Rationale:</u> African Union had previously expressed concern that It would be difficult to segregate data for sorghum for human consumption from data for maize intended for animal feed or intended for direct human consumption, as its intended purpose is not always indicated on the lot. In light of this, it will be appropriate to establish an ML only for ready-to-eat maize based on the whole dataset. This is more suitable for human health protection, especially in the African region where sorghum is a major staple food and is traded as sorghum regardless of whether it is destined for further processing or is meant for direct human consumption.</p> <p><u>Comment:</u> African Union does not support the adoption of an ML of 10 µg/kg for total aflatoxins in cereal-based food for infants and young children and recommends further review of this ML with the view to proposing a higher ML.</p> <p><u>Rationale:</u> Given the high vulnerability of infants and young children to aflatoxins exposure, it is necessary to protect infants and young children against aflatoxin exposure by setting an ML that is protective of this group of consumers.</p> 	AU
<p><u>Cereal-based Food for infants and young children</u> 10 µg/kg 0.14</p> <p>The IFT supports the proposed ML's for aflatoxins for general use, but recommends changing the ML for Cereal-based food for infants and young children due to the lower ML set for polished rice (currently 5 ug/kg) being below the one for Cereal-based food for infants and young children. IFT believes that having the polished rice ML lower than that of Cereal-based food for infants and young children ML could lead to non-polished rice (husked rice) being used in Cereal-based foods for infants and young children, thereby increasing the risk of impaired growth and potential toxicity in infants and young children. Infants and young children consume substantially more of such cereals as a percentage of their diet than do adults, have less developed ability to remove toxic components like aflatoxins in the liver, and are at substantially higher health risk than the general population due to being in a high growth phase of life. Therefore, IFT believes that more data collection on global production capabilities, particularly in Asia and Africa, and further data on the risk profile for aflatoxins, particularly for infants and children, should be pursued to evaluate the feasibility of lowering the level for Cereal-based foods for infants and young children to 5 ug/kg as a next step. IFT also recommends clarifying that the standard for use of rice in Cereal-based foods for infants and young children be made 5 ug/kg in line with that of the polished rice proposal.</p> <p>IFT would propose that the lowest ML achievable for polished rice should also be the ML for rice used in Cereal-based food for infants and young children, regardless of the challenges associated with aflatoxin in other grains. IFT recommends that FAO focus on improvements to agricultural practices in the most challenged regions in order to reduce the risk of aflatoxin contamination, in particular targeting the Cereal-based foods for infants and young children category.</p>	IFT
<p>MSF supports the new proposed ML and appreciates the consideration by the EWG of the concerns raised during the CCCF 14. The new proposed MLs will not affect availability of food for food aid, and will allow food aid agencies to procure foods locally, regionally and internationally for the most vulnerable populations in need.</p>	MSF

COMMENT	MEMBER/ OBSERVER
<ul style="list-style-type: none"> • Flour, meal, semolina and flakes derived from maize 20 µg/kg 1.0 The proposed ML will enable WFP to purchase foods locally, regionally and internationally and also distribute food to the most vulnerable populations in need. • Cereal-based Food for infants and young children 10 µg/kg 0.14 The proposed ML will enable WFP to purchase foods locally, regionally and internationally and also distribute foods to the most vulnerable populations in need. This is particularly crucial given the current global food crisis triggered by the situation in Ukraine. <p>WFP implements nutrition programmes in 75 countries worldwide. In 2020, WFP provided specially formulated complementary foods to 6 million infant and young children (6-59 months) suffering from malnutrition, and to 5.8 million at-risk of malnutrition.</p> <p>The products distributed in WFP Nutrition Programmes, namely Super Cereal plus (cereal-based foods for infant and young children) and Lipid-based Supplementary Foods, are chosen because they comply with the WHO Technical note: supplementary foods for the management of moderate acute malnutrition (MAM) in infants and children 6–59 months of age. To WFP’s knowledge, there are no comparative food products readily available in the commercial market for MAM management.</p> <p>In conflict situations, WFP uses food assistance as a way to build pathways to peace and stability. WFP is a key player in global efforts to end hunger achieve food security and improved nutrition as part of Sustainable Development Goal 2: Zero Hunger and to contribute to the advancement of SDG 3: good health and wellbeing.</p> <p>To strengthen joint international efforts to achieve peace and prosperity in line with the 2030 Agenda for Sustainable Development, your consideration of WFP’s inputs would be greatly appreciated.</p>	<p>WFP</p>

SAMPLING PLANS

COMMENT	MEMBER/ OBSERVER
<p>According to the Codex website, the next meeting for CCMAS is scheduled for June 12-16, 2023; as such, consulting CCMAS would not yield an answer until after next year's CCCF16 meeting (April 17-21, 2023). Canada therefore recommends that this EWG be re-established for CCCF16 to develop the sampling plan and performance criteria for aflatoxins in cereals to accompany the proposed MLs.</p> <p>The EWG could consult the Information Document on Criteria Approaches for Methods which use a Sum of Components (INF_CCMAS_SOC) developed by CCMAS in 2017 (REP17/MAS App. IV). Notably, this document clarifies that "Consideration of the ratio of components, toxicity, and properties of matrices (commodities) are outside of the terms of reference of CCMAS, but rather fall under the responsibilities of Codex Commodity Committees."</p> <p>Work at the EWG level over the coming year could summarize from JECFA83, GEMS/Food, and other available information the relative abundance of aflatoxins in each commodity for which MLs are being proposed, the relative toxicity of AFB1 versus the other aflatoxins, required sampling parameters to account for the heterogeneous distribution of aflatoxins, and validated analytical methods that can meet the proposed MLs. Ongoing work from CCMAS on the revisions of the General Guidelines on Sampling (CXG 50-2004), including the apps to aid in the development of sampling plans being developed in CX/MAS 21/41/9, could be helpful as well. CCCF could then consult CCMAS on the assembled information after CCCF16 if appropriate.</p> <p>Canada is of the opinion that work on the sampling plan and performance criteria should progress in concert with the work to elaborate new MLs. Although the final ML values would be needed to finalize these, knowing the proposed MLs may aid in continuing with this work, and there are other aspects that would comprise a sampling plan that could be worked on.</p> <p>While the General Guidelines on Sampling (CXG 50-2004) are indeed under revision by CCMAS, they do provide considerations and information that informs the development of sampling plans, and that information should be reviewed and considered when any new sampling plan is developed (see CX/MAS 21/41/9). The sampling plans in the GSCTFF for mycotoxins in cereal grains would act as a good reference for the development of a sampling plan for aflatoxins in cereal grains, although it is not expected that the subject sampling plan would be entirely aligned with an existing one. The International Association for Cereal Science and Technology (ICC) also has a relatively new standard "Sampling of Cereal Grains" (ICC Standard No. 101/2) that provides a more critical description of sampling tools and processes which could be considered as well.</p> <p>The biological aspects of fungal infection and production of aflatoxins can be different as compared to fungal infection and production of fumonisins in maize and DON in cereals. DON and fumonisins are formed in the field during plant development, while AFs can be formed after harvest when grain is in storage. Production during storage leads to a higher degree of heterogeneity with respect to the AFs in grain, as compared to DON and fumonisins (Whitaker et al. 1979, 2000). Harmonizing sampling plans for AFs in maize with those of other mycotoxins in maize or other cereals (DON in cereals; fumonisins in maize) is therefore not recommended.</p>	Canada
<p>Egypt agrees to suspend the development of sampling plans until finalization of the MLs, And the sampling plan and the decision rule should be aligned with the sampling plans for Mycotoxins already mentioned in General Standard for Contaminants and Toxins in Food and Feed (CXS 193-1995).</p>	Egypt

COMMENT	MEMBER/ OBSERVER
<p>The EU is of the opinion that it is not necessary to consult CCMAS regarding the establishment of criteria for a sum of components.</p> <p>In case the maximum level applies to a sum of different components, then the criteria for precision apply to both the sum and the individual components.</p> <p>The EU is of the opinion that the sampling plans and methods performance criteria should be discussed in parallel with the discussion on MLs to ensure that the sampling plans and method performance criteria are available once the MLs are established. For a contaminant that can heterogeneously be distributed in a given lot, as is the case for aflatoxins in cereal grains, it is important that an appropriate method of sampling is specified so that the maximum level is applied to a representative sample of the lot.</p> <p>The EU is of the opinion that the sampling plan and decision rule should be aligned with the sampling plans already provided in CXS 193-1995 for the control of Codex MLs for deoxynivalenol and for fumonisins (B1 + B2). As the maximum levels for total aflatoxins in cereals and cereal products under consideration and the established maximum levels for deoxynivalenol and fumonisins (B1 + B2) relates to a certain extent, it is important that the sampling procedures are aligned so that the same representative sample of the lot can be analysed for total aflatoxins, deoxynivalenol and fumonisins (B1 + B2). In addition, it is appropriate to consider to extend the sampling procedure also for the control of the Codex MLs for ochratoxin A in wheat barley and rye.</p>	EU
<p>We suppose an advice from CCMAS regarding how to establish performance criteria for ATFs sum in the different matrices will help CCCF to move forward.</p>	Kazakhstan
<ul style="list-style-type: none"> • <u>Comment</u>: Kenya does not support suspension of the sampling plans. <u>Justification</u>: The sampling plans are important in establishing the correct levels of contamination which are crucial for determining the MLs for monitoring purposes. To suspend the development of sampling plans until finalization of the MLs and in addition, provide advice on the points raised in paragraph 25(i-ii) of CX/CF 22/15/9 i.e. • <u>Comment</u>: Kenya supports the sampling plan and the decision rule being aligned with the sampling plan for mycotoxins in the General Standard for Contaminants and Toxins in Food and Feed (CXS 193-1995) <u>Justification</u>: CXS 193 -1995 is adopted by most EAC Standards. 	Kenya
<p>Rwanda supports the EWG recommendation of suspending the development of sampling plans until finalization of the MLs</p>	Rwanda
<p>B. Sampling plans</p> <ul style="list-style-type: none"> • The United States can agree to suspension of development of sampling plans, but this work should resume when the first ML is finalized. i. The United States agrees that the sampling plan and the decision rule should be aligned with the sampling plans for mycotoxins in the GSCTFF (CXS 193-1995) and the General Guidelines on Sampling (CXG 50-2004). ii. The United States agrees that the Codex Committee on Methods and Sampling (CCMAS) should be consulted regarding how to establish performance criteria. Further, the United States notes that analytical methods for aflatoxins are normally based on the detection of individual isomers (AFB1, AFB2, AFG1, AFG2) and require that the contribution of each aflatoxin isomer be defined for a sum of components approach before establishing method performance requirements. Different ratios will result in different limits of detection (LODs) and limits of quantitation (LOQs) for each isomer, as shown in the following examples: <ul style="list-style-type: none"> a. For an ML = 20 µg/kg and a target ratio of 1:1:1:1 <ul style="list-style-type: none"> i. LOD = 1 µg/kg and LOQ = 2 µg/kg for all isomers. b. For an ML = 20 µg/kg and a target ratio of 15:1:0.01:0.05 (typical of U.S. maize) <ul style="list-style-type: none"> i. LOD = 3.7 µg/kg and LOQ = 7.5 µg/kg for AFB1 ii. LOD = 0.25 µg/kg and LOQ = 0.5 µg/kg for AFB2. 	USA