CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 10 **CX/CF 20/14/10-Add.1**

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON CONTAMINANTS IN FOODS

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

Comments submitted at Step 3 by Canada, Chile, Cuba, Egypt, European Union (EU), India, Iran, Iraq, Mexico, Republic of Korea, Syrian Arab Republic, Thailand, Uganda, United States of America (USA), International Special Dietary Food Industries (ISDI) and World Food Program (WFP)

NOTE: CCCF14 has been postponed to 3 – 7 May 2021. The comments compiled in this document will be made available to the EWG chaired by Brazil and co-chaired by India for further consideration and preparation of a revised version of the document for consideration by CCCF14.

Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2020/23/OCS-CF issued in February 2020. Under the OCS, comments are compiled in the following order: general comments are listed first, followed by comments on specific paragraphs.

Explanatory notes on the appendix

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

ANNEX I

COMMENTS ON THE PROPOSED DRAFT MLs FOR TOTAL AFLATOXINS IN CERTAIN CEREALS AND CEREAL-BASED PRODUCTS INCLUDING FOODS FOR INFANTS AND YOUNG CHILDREN

GENERAL COMMENTS	MEMBER/OBSERVER
Canada wishes to express its appreciation to the chair, Brazil, and co-chair, India, for once again leading the electronic working group (eWG) on the Proposed draft maximum levels for total aflatoxins in certain cereals and cereal-based products, including foods for infants and young children (CX/CF 20/14/10). Canada would like to offer the following comments for the consideration of the Committee. Two MLs for each food category are proposed for consideration. The rationale used to propose MLs for each food category is: "…MLs were proposed considering a maximum rejection rate of 5%. …a ML was recommended based on the combination of intake reduction and a minimum sample rejection." The rejection rates of the proposed MLs for the various food categories range from 0.4 to 5.4% and it is unclear why the rejection rates are not more comparable across categories. It is suggested that rationale for the proposed MLs be explained for each commodity and that quantitative information on the effects of processing on aflatoxin (AF) levels be presented when MLs are proposed for minimally processed and processed commodities (i.e. husked and polished rice; maize destined for further processing and flour, meal, semolina and flakes derived from maize) so that proportionality of the MLs for different products of the same food type can be considered. The limited geographic representation of the samples in countries that widely consume certain commodities (e.g. sorghum data from Africa) may be a concern as the majority of samples submitted for most commodities is from Europe and the United States. If geographically representative data are not available when MLs are elaborated, a call for data could be reissued 3 years after the MLs are established.	**Canada**
Please see the following editorial changes to CX/CF 20/14/10: Para 6 – "Analysis of data grouped by continent, country and year of sampling showed that the mean level of AFs (lower bound) and the resulting impact of the proposed MLs for each food category did not significantly vary." "A preliminary exposure assessment was carried out to illustrate the expected intake reduction of each ML proposed in order to support risk management decisions. After that, a ML was recommended based on the combination of expected intake reduction and sample rejection rates." "Considering that the Committee has not yet agreed upon a procedure to deal with outliers in datasets of heterogeneous distributed contaminants, and considering the possibility of samples being contaminated with high levels of AFs, it was decided not to remove the possible outliers from the data sets considered in this document. Furthermore, the presence of the possible outliers in the dataset did not impacted the proposal of MLs since they had no effect on the 95 percentiles." Para 7 – "CCCF is invited to consider the proposed MLs for the selected food categories as shown in Appendix I as well as the issues raised under the OTHER MATTERS section. The CCCF is also encouraged to take into account the information provided in paragraph 6 above and in Appendix II, and comments submitted in reply to the circular letter issued regarding this Agenda Item (CL 2020/23-CF)." Appendix II Para 4g. – "Outliers were not removed since aflatoxins are not homogeneously distributed and therefore it is possible that samples with high AFs concentration could be found in the market. Besides that, the few high values maintained in the dataset did not impact the proposal of MLs since they had no effect on the 95 percentiles. The treatment of outliers in the data for mycotoxins should be further discussed taking into account mycotoxins' heterogeneous distribution in food samples."	
Appendix II, Table 1 – The Canadian data shows a mean of positive samples of 0.1 µg/kg based on 29 positive samples despite a range listed as being from 0.1 to 90 µg/kg, and a lower bound mean of 2.9 µg/kg. It is not possible for the mean of positives to be lower than the lower bound mean (which includes zero values).	
Chile welcomes the opportunity to provide comments on the draft maximum levels with a total of aflatoxins in some cereals and cereal products, including foods for infants and young children. Chile would like to comment on the possibility of further encouraging countries from other geographical areas not reflected in the data analysed, to compile and share the results, especially in those geographical areas whose particular climatic conditions could provide new contributions to the statistical analysis. Chile reviewed the recommendations in this circular letter and has the following comments to make (see specific comments):	**Chile**

GENERAL COMMENTS	MEMBER/OBSERVER
Chile agrees with the changes offered in the draft and supports their progress.	
European Union Competence European Union Vote The EU welcomes and appreciates the 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. BACKGROUND 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. 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 AFB (1). 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. The European Food Safety Authority (EFSA) has recently performed a risk assessment of aflatoxins in food (2) . 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. PROPOSED MAXIMUM LEVELS 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. The maximum levels as proposed in Appendix I of CX/CF 20/14/10, proposal 1 as well proposal 2, are in the view of the EU not established according to the ALARA principle and therefore to a large extent not acceptable for the EU. More details are provided. (1) Eighty-third meeting of the Joint FAO/WHO Expert Committee on Food Additives Rome, 8–17 November 2016. WHO Food Additives Series: 74 – Safety evaluation of certain contaminants in food. http://apps.who.int/iris/bitstream/handle/10665/276868/9789241660747-eng.pdf?ua=1 (2) EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), Schrenk D, Bignami M, Bodin L, Chipman JK, del Mazo J, Grasl-Kraupp B, Hogstrand C, Hoogenboom LR, Leblanc J-C, Nebbia CS, Nielsen E, Ntzani E, Petersen A, Sand S, Schwerdtle T, Vleminckx C, Marko D, Oswald IP, Piersma A, Routledge M, Schlatter J, Baert K, Gergelova P and Wallace H, 2020. Scientific opinion – Risk assessment of aflatoxins in food. EFSA Journal 2020;18(3):6040, 112 pp. https://doi.org/10.2903/j.efsa.2020.6040	**EU**
India strongly supports proposal 1 for all categories of cereal and cereal based products to address any immediate concern of trade while taking due note of the lack of truly representative data at present. We also reiterate that the final MLs should be established after analysing more representative data from different geographies while taking in to account all the environmental stress factors at different climatic conditions worldwide. Rationale: We propose this based on following: 1) For finalising the MLs, data needs to be compiled while take into consideration both tropical and temperate climatic conditions as the risk of aflatoxin contaminations increases with hot and dry climates. 2) The data considered at present was submitted mainly by European Union and the USA, hence it is not geographically representative of spices producing countries.	**India**

GENERAL COMMENTS	MEMBER/OBSERVER
Considering above two facts, it will be appropriate to establish MLs which would have least trade restrictions/ rejections and be reflective of the situation in the cereal producing countries on account of their climatic conditions that might have an impact on aflatoxins levels in the produce.	
Iran National Committee of CCCF thanks for the efforts of Brazil and India in preparing the proposed draft of ML for AF in cereals. The data have come mostly from the United States of America (USA) and European Union and many information of others countries, especially African and Asian countries have not been included in this proposed drafts. Since aflatoxins has always been a major issue in maize crops in many countries, therefore,it's important to make a decision to include contamination data in all area such as Asia countries. So, since data is not globally representative and need to gather more data from all region of the world for MLs suggestion.	**Iran**
We agree with proposed draft without any comments.	**Iraq**
Describe the analytical methods and laboratory measurement instruments used to obtain the data used in statistics. Analytical methods and measurement instruments may vary between official laboratories in each country, so the bias of statistical data may affect their analysis.	**Mexico**
Add the official sources of each participating country to consult the AFs MLs Official sources can be useful for comparing the MLs of each country compared to the CODEX MLs	
Approval	**Syrian Arab Republic**
For specifity, Uganda is in agreement with data submitted on proposal 2. Uganda agrees with the data given in the document.	**Uganda**
• Impact Assessment: The United States recommends that CCCF ask JECFA for evaluation of exposure and risk reduction for various proposed MLs when agreed by CCCF, 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 LOQ consideration: The United States considers several proposed MLs, namely 4 µg/kg for polished rice and 1-2 µg/kg for infant cereals, are below the LOQs for collaboratively validated aflatoxin methods. As a result, there may not be "fit for purpose" methods available to test foods at the proposed MLs. o For a method to be "fit for purpose," the analytical range which encompasses the ML should be captured in a collaborative study protocol. o Available AOAC (collaborative) methods for the determination of aflatoxins in grains, nuts, and corn specify 5 ng/g (or higher) as the lower end of the analytical range of the method. o 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. o The recommendation for collaborative studies to determine method reproducibility (Codex Procedural Manual (p. 78, 26th Ed)) still applies when numeric criteria are used instead of method endorsement. o While there are sensitive mass spectrometric methods that can determine total aflatoxin at very low concentrations, we are not aware of these methods undergoing collaborative studies that included appropriate matrices at the proposed MLs. Also, mass spectrometric methods may not be available to laboratories in all regions of the world. • Year to year variation: The United Sates notes that the proposal presents but does not take into account year to year variations in aflatoxin levels.	**USA**
ISDI supports of the Codex Committee on Contaminants in Food on mycotoxins and views food safety as a top priority. We would like to provide the below comments in relation to circular letter CL 2020/23/OCS-CF. ISDI members are committed to providing foods for infants and young children (IYC) with the highest levels of quality and safety and putting great efforts to mitigate the levels of mycotoxins in our foods through the application of intense selection process to the raw materials.	**ISDI**

GENERAL COMMENTS	MEMBER/OBSERVER
We strongly believe that all MLs set for mycotoxins need to be feasible and realistic for the final products. Several mycotoxins are being reviewed at various levels for standards/regulations: aflatoxins (AFB1, AFB2, AFG1 and AFG2), fumonisins, zearalenone, ergot alkaloids, citrinin, ochratoxin A and trichothecenes. The cumulative impact of changes in all these standards and legislative proposals on mycotoxins (including CCCF work on aflatoxins) has to take into account the following aspects: 1. Supply chain considerations At agricultural level, many factors affect the contamination level of the crops which vary by cereal type, origin and crop year. Additionally, climatic conditions change from year to year with each cereal type being impacted differently. The setting of MLs should account for reduction of crop yields due to volatile and harsh climatic conditions, such as drought, leading on the one hand to shortage of compliant raw materials due to the presence of higher levels of mycotoxins, and on the other hand to challenges ensuring conformity in finished products with unnecessary economic impact on the whole food chain. 2. Limited control measures There is no effective agronomic mitigation currently available and further research in this area across all cereal crops is required. In the case of raw materials for baby food there are special limitations in the plant protection products that can be applied. Measures can be taken by the suppliers to mitigate the risk; however, these measures will not provide an absolute guarantee that all those contaminants will be removed even if control processes are followed well. An efficient control is further impacted by the inhomogeneous distribution of mycotoxins over the cereal grains. 3. Lack of robust analytical methodologies Current analytical methods still have high uncertainty leading to highly variable and potentially misleading results. Moreover, there are a lot of concerns regarding LOQs and there are no effective proven rapid tests and sampling plans. Therefore, any proposed legislation needs to define the preferred methodology for testing prior to setting MLs. 4. Inconsistencies MLs for primary ingredients and final products MLs for primary ingredients and final products must be correlated and proportional. The major factors affecting a ML in cereals are the toxicity of the respective mycotoxin, its occurrence in a certain cereal and the intake of the concerned cereal by the population. Hence, the same mycotoxin may have different MLs in different cereals. Moreover, MLs depend on the state of processing. Cereal based food can contain several types of ingredients with different MLs according to the above factors. Establishing significantly different MLs for cereal and other raw materials and finished products can create disruptions along the supply chain, with suppliers being compliant and manufacturers of cereal based food struggling to meet the legal MLs. ISDI strongly believes that the introduction of new MLs and reduction of current MLs without carefully considering current limitations in control measures by farmers specially in raw materials for the baby food industry, the problem of no homogeneous distribution, the changing climatic conditions and environmental control aspects at the farm level, would have an overall negative impact on the whole food chain and we look forward to continuing working with all relevant Institutions to ensure proportionate regulatory measures and avoid the situation of running out of alternatives and compliant raw materials for the production of processed cereal-based foods and baby foods for IYC.	
Introduction: WFP is the largest humanitarian agency worldwide, working to save and change the lives of 86.7 million people in 83 countries each year. With yearly 3 million metric ton foods purchased from both developed and developing markets, WFP aspire to increase food security, safety and quality. WFP Food Safety and Quality Unit tests purchased foods to ensure their compliance to applicable and highest food standards to the extent possible. **Comments:** At the outset, WFP appreciates the concrete actions taken by the committee to further the guidance on Maximum Residue Levels for aflatoxins. We strongly believe that these efforts will pave the way to globally reduce exposure to aflatoxins in human diets.	**WFP**

<table>
<tr><th>GENERAL COMMENTS</th><th>MEMBER/OBSERVER</th></tr>
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Based on WFP's historical experience in purchasing foods, especially in countries where WFP serves, producers may not be able to meet the proposed maximum levels for total aflatoxin, as explained in Table-1 below:
Table-1: Comparing WFP specifications to Codex Committee Proposals
<table>
<tr><th rowspan="2">Type of food</th><th>WFP Requirement
Max ppb</th><th>Codex Proposal 1
Max ppb</th><th>Codex Proposal 2
Max ppb</th></tr>
<tr><td>Super Cereal plus (infant foods)</td><td>10</td><td>1</td><td>2</td></tr>
<tr><td>Lipid-based Nutrient Supplement</td><td>10</td><td>1</td><td>2</td></tr>
<tr><td>Maize flour/meal</td><td>20</td><td>10</td><td>15</td></tr>
<tr><td>Polished rice</td><td>20</td><td>4</td><td>8</td></tr>
<tr><td>Sorghum</td><td>20</td><td>8</td><td>10</td></tr>
</table>
The proposed maximum limits will constrain WFP's capacity of purchasing and delivering foods to the most vulnerable populations.
WFP also takes note of the following sentence in the report: "The discussion paper showed that there is a large dataset available on the occurrence of AFs in cereals and cereal-based products in the GEMS/Food database (more than 17000 samples), submitted mainly by the European Union (EU), Singapore and Canada."
WFP urges the committee to also take into account data from countries where the prevalence of aflatoxins will be higher; and further take into consideration the balance between food safety and food security.
In a joint effort towards SDG-2 (Zero Hunger) and linking it to SDG-3 (Good Health and Well-being), your consideration of our inputs would be highly appreciated. WFP has several years of analytical data by testing foods at accredited laboratories using accredited methods, that the organization is willing to present to the committee. Additionally, the report also mentioned setting potential limits for Aflatoxin B1. It would be our pleasure to generate and share data on mycotoxins levels in WFP purchases.
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SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer**
MAXIMUM LEVELS	
Maize grain, destined for further processing: Chile supports proposal 2, for a maximum level of 15 µg/kg. **Flour, meal, semolina and flakes derived from maize / husked rice**: For these two categories Chile would like to express its concern about the proposed maximum levels, given that the rejection rates given both in proposal 1 and 2, in both categories, are much lower than 5%. Bearing in mind the toxicity level of these mycotoxins, Chile believes that these values should be further revised, so as to provide greater consumer protection. **Polished rice**: Chile supports proposal 2, for a maximum level of 4 µg/kg. **Sorghum grain, destined for further processing:** Chile supports proposal 2, for a maximum level of 8 µg/kg. **Cereal-based foods for infants and young children**: Chile supports proposal 2, for a maximum level of 1 µg/kg. - For the category of cereal-based foods for infants and young children, Chile supports proposal 2, for a maximum level of 1 µg/kg.	**Chile**
Cuba thanks Brazil and India for producing the draft maximum levels with a total of aflatoxins in some cereals and cereal products, including foods for infants and young children. Nevertheless, our standard for Contaminants and toxins in food and feed G(NC: 1205: 2017) presents Maximum Levels (MLs) below those proposed in the document. • **Maize (destined for further processing or as an ingredient in other products)** B1 5.0 µg/kg, total aflatoxins (B1+B2+G1 and G2) 10 µg/kg. • **Cereals (including buckwheat, Fagopyrum sp.), and products derived from its processing, except maize (ready to eat or as ingredients in other products)** B1 2.0 µg/kg, total aflatoxins (B1+B2+G1 and G2) 4 µg/kg. • **Infant food and cereal-based foods for infants and young children**. B1 0.10 µg/kg and for total aflatoxins (B1+B2+G1 and G2) no presence. Consequently, the values proposed in document CX/CF 20/14/10 are high considering the risk to consumer health. These foods are highly consumed worldwide. Consequently, we request an evaluation of the proposals for levels of aflatoxins in the foods in question.	**Cuba**
1) For the following food category, Egypt adopts the following limits: Maximum Levels (µg/Kg) B1 M1 • Maize destined for sorting or other physical treatment before human consumption or being used as an ingredient in foodstuffs Maximum Levels (µg/Kg) B1 = 5.0 Sum of B1,B2,G1,G2 = 10.0 • Husked rice B1 = 5.0 Sum of B1,B2,G1,G2 = 10.0 • Polished rice B1 = 2.0 Sum of B1,B2,G1,G2 = 4.0 • Processed cereal-based foods and baby foods for infants and young children* B1 = 0.10 Sum of B1,B2,G1,G2 = -- * Infants are from day one to 12 months, while young children are up to 12 months	**Egypt**

SPECIFIC COMMENTS		
Section/paragraph		**Member/Observer**
2) For food categories (Flour, meal, semolina and Flakes derived from maize) and (Sorghum grain, destined for further processing) Egypt supports the proposal 2 as it is safer than proposal 1.		
Contemplate types of treatment according to food category in the table in Appendix 1 Describing food treatments will allow to see which ones are applicable, for example; thermal, drying, nixtamalization, etc		**Mexico**
Maize grain, destined for further processing **Flour, meal, semolina and flakes derived from maize** **Husked rice** **Polished rice** **Sorghum grain, destined for further processing**	India supports Proposal 1	**India**
Maximum level proposed for maize grain, destined for further processing: • The data for the years 2011, 2012 and 2013 show an unusual high contamination level compared to the data for the other years in the period 2007-2019 (table 2). The EU is of the opinion that it is appropriate to investigate the reasons for these unusual high levels in these years to verify if these high levels could be related to e.g. specific climatic conditions in these years. In case no or no acceptable explanation can be provided for these unusual high levels in these years, the EU is of the opinion that it should be considered not to take into account the occurrence data of these years for the setting of the maximum levels. • Occurrence data on contaminants in food are provided to GEMS/Food database by EFSA on behalf of all EU Member States. The origin of the few data reported in Table 1 for individual EU Member States (Belgium, Bulgaria, Cyprus, Finland, France, Germany, Hungary Ireland, Italy, Poland, Romania, Slovakia, Slovenia, Spain) is therefore unclear. The EU proposes not to use these data for the discussion on the establishment of maximum levels. • The EU is of the opinion that it would be appropriate to present the frequency distribution curve of the occurrence data as outlined above in order to be able to identify possible clear outliers. These outliers, clearly not reflecting the application of good practices to prevent aflatoxin contamination (3) , should be excluded from further consideration. • The EU furthermore proposes to recalculate the effect of hypothetical MLs on aflatoxins through the consumption of maize grain (table 4) on the basis of the occurrence data, after the possible exclusion of the data for the years 2011, 2012 and 2013 and after the exclusion of the outliers and the few data in the table as reported to be originating from individual EU Member States. • The EU consequently proposes to re-discuss the maximum level proposed for maize grain, destined for further processing on this basis taking into account an acceptable rejection rate (<5 %) and the reduction of human exposure to aflatoxins. _____(3) Code of Practice for the prevention and reduction of mycotoxin contamination in cereals (CXC 51-2003). **Maximum level proposed for flour, meal, semolina and flakes derived from maize:** • The EU is of the opinion that it would be appropriate to present the frequency distribution curve of the occurrence data as outlined above in order to be able to identify possible clear outliers. These outliers, clearly not reflecting the application of good practices to prevent aflatoxin contamination, should be excluded from further consideration. • The EU proposes to recalculate the effect of hypothetical MLs on aflatoxins through the consumption of flour, meal, semolina and flakes derived from maize (table 8) after the exclusion of the outliers. • The EU does not agree to establishing a maximum level resulting in a very low rejection rate while setting a lower maximum level with still an acceptable rejection rate (< 5%) would result in a significant reduction of the human exposure to aflatoxins. • The EU consequently proposes to re-discuss the maximum level proposed for flour, meal, semolina and flakes derived from maize on this basis taking into account an acceptable rejection rate (< 5 %) and the reduction of the human exposure to aflatoxins.		**EU**

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer**
Maximum level proposed for husked rice: • Occurrence data on contaminants in food are provided to GEMS/Food database by EFSA on behalf of all EU Member States. The origin of the few data reported in Table 9 for individual EU Member States (Austria, Finland, France, Lithuania, Romania, Slovakia, Spain, Sweden) is therefore unclear. The EU proposes not to use these data for the discussion on the establishment of maximum levels. • The EU is of the opinion that it would be appropriate to present the frequency distribution curve of the occurrence data as outlined above in order to be able to identify possible clear outliers. These outliers, clearly not reflecting the application of good practices to prevent aflatoxin contamination, should be excluded from further consideration. • The EU furthermore proposes to recalculate the effect of hypothetical MLs on aflatoxins through the consumption of husked rice (table 12) after the exclusion of the outliers and the few data in the table as reported to be originating from individual EU Member States. • The EU does not agree to establishing a maximum level resulting in a low rejection rate while setting a lower maximum level with still an acceptable rejection rate (< 5%) would result in a significant reduction of the human exposure to aflatoxins. • The EU consequently proposes to re-discuss the maximum level proposed for husked rice on this basis taking into account an acceptable rejection rate (up to 5 %) and the reduction of the human exposure to aflatoxins. **Maximum level proposed for polished rice:** • Occurrence data on contaminants in food are provided to GEMS/Food database by EFSA on behalf of all EU Member States. The origin of the few data reported in Table 13 for individual EU Member States (Bulgaria, Czech Republic, Finland, Hungary Ireland, Luxembourg, Romania, Slovakia, Spain) is therefore unclear. The EU proposes not to use these data for the discussion on the establishment of maximum levels. • The EU is of the opinion that it would be appropriate to present the frequency distribution curve of the occurrence data as outlined above in order to be able to identify possible clear outliers. These outliers, clearly not reflecting the application of good practices to prevent aflatoxin contamination, should be excluded from further consideration. • The EU furthermore proposes to recalculate the effect of hypothetical MLs on aflatoxins through the consumption of polished rice (table 16) after the exclusion of the outliers and the few data in the table as reported to be originating from individual EU Member States. • The EU does not agree to establishing a maximum level resulting in a very low rejection rate while setting a lower maximum level with still an acceptable rejection rate (< 5%) would result in a significant reduction of the human exposure to aflatoxins. • The EU consequently proposes to re-discuss the maximum level proposed for polished rice on this basis taking into account an acceptable rejection rate (up to 5 %) and the reduction of the human exposure to aflatoxins. **Maximum level proposed for sorghum grain destined for further processing:** • The EU is of the opinion that it would be appropriate to present the frequency distribution curve of the occurrence data as outlined above in order to be able to identify possible clear outliers. These outliers, clearly not reflecting the application of good practices to prevent aflatoxin contamination, should be excluded from further consideration. • The EU furthermore proposes to recalculate the effect of hypothetical MLs on aflatoxins through the consumption of sorghum grain for further processing (table 20) after the exclusion of the outliers. • The EU does not agree to establishing a maximum level resulting in a low rejection rate while setting a lower maximum level with still an acceptable rejection rate (< 5%) would result in a significant reduction of the human exposure to aflatoxins. • The EU consequently proposes to re-discuss the maximum level proposed for sorghum grain on this basis taking into account an acceptable rejection rate (up to 5 %) and the reduction of the human exposure to aflatoxins.	

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer**
Maximum level proposed for cereal based foods for infants and young children: • Occurrence data on contaminants in food are provided to GEMS/Food database by EFSA on behalf of all EU Member States. The origin of the few data reported in Table 21 for individual EU Member States (Bulgaria, Czech Republic, Finland, France, Germany, Hungary, Ireland, Italy, Lithuania, Luxembourg, Malta, Poland, Portugal, Romania, Slovenia, Spain) is therefore unclear. The EU proposes not to use these data for the discussion on the establishment of maximum levels. • The EU is of the opinion that it would be appropriate to present the frequency distribution curve of the occurrence data as outlined above in order to be able to identify possible clear outliers. These outliers, clearly not reflecting the application of good practices to prevent aflatoxin contamination, should be excluded from further consideration. • The EU furthermore proposes to recalculate the effect of hypothetical MLs on aflatoxins through the consumption of cereal-based foods for infants and young children (table 24) after the exclusion of the outliers and the data in the table as reported to be originating from individual EU Member States. • The EU does not agree to establishing a maximum level resulting in a very low rejection rate while setting a lower maximum level with still an acceptable rejection rate (< 5%) would result in a significant reduction of the human exposure to aflatoxins. • The EU consequently proposes to re-discuss the maximum level proposed for cereal-based foods for infants and young children on this basis taking into account an acceptable rejection rate (up to 5 %) and the reduction of the human exposure to aflatoxins.	
Republic of Korea would like to express its agreement with the proposed draft maximum levels(MLs): **Maize grain, destined for further processing**: 15 (µg/kg)· **Flour, meal, semolina and flakes derived from maize**: 15 (µg/kg)· **Husked rice**: 15 (µg/kg)· **Polished rice / sorghum grain destined for further processing**: Republic of Korea would like to suggest to establish the higher ML for polished rice and sorghum grain destined for further processing. The ML for polished rice and sorghum grain destined for further processing is low, so the rejection rate seem to be too low. **Cereal-based Food for infants and young children**: 1 (µg/kg)	**Republic of Korea**
Thailand would like to express the appreciation to Brazil as the chair, and India as co-chair, for analyzing and preparing the proposed draft MLs for total aflatoxins in certain cereals and cereal-based products including foods for infants and young children. We are pleased to provide specific comments about the following matters. **Maize grain, destined for further processing**: Thailand supports the establishment of ML for aflatoxins in this category at 15 µg/kg. However, we note that the big number of data submitted by USA could lead to the ML that would be only based on USA data. We believe that it is important to consider the ML by using the data in appropriate proportion from every region which could be lower the sample rejection rate. **Flour, meal, semolina and flakes derived from maize**: Thailand supports the establishment of ML in this category at 10 µg/kg which has appropriate sample rejection rate. **Husked rice**: Thailand supports the establishment of ML in this category at 20 µg/kg which has appropriate intake reduction and sample rejection rate as 69.7% and 2.2%, respectively. **Polished rice**: Thailand supports the establishment of ML in this category at 8 µg/kg which has appropriate intake reduction and sample rejection rate as 70.2% and 0.4%, respectively. **Sorghum grain, destined for further processing**: Thailand supports the establishment of ML in this category at 10 µg/kg which has appropriate intake reduction of 63.7% and sample rejection rate of 2.0%. **Cereal-based Food for infants and young children**: For safety and health protection of infant and children, Thailand supports the establishment of ML in this category at 1 µg/kg which has sample rejection rate for 0.7%.	**Thailand**

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer**
Maize grain, destined for further processing: Proposed ML of 15 µg/kg or 20 µg/kg • The United States potentially 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 four of 14 years. • We recommend an accompanying note that an ML does not apply to maize for wet milling or animal feed. **Flour, meal, semolina, and flakes derived from maize**: Proposed ML of 10 µg/kg or 15 µg/kg • The United Sates potentially would not object to the proposed ML of 15 µg/kg. • 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. **Husked rice**: Proposed ML of 15 µg/kg or 20 µg/kg • The United States potentially 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. **Polished rice:** Proposed ML of 4 µg/kg or 8 µg/kg • The United States does not support the proposed ML of 4 µg/kg. • As noted in general comments, we are not aware of 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. • While the United States can meet the proposed ML of 8 µg/kg based on review of GEMS data presented, 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. **Sorghum grain, destined for further processing:** Proposed ML of 8 µg/kg or 10 µg/kg • 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. **Cereal-based food for infants and young children**: Proposed ML of 1 µg/kg or 2 µg/kg • 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 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 on the proposed 95th percentile basis.	**USA**

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer**
OTHER MATTERS	
Question (a): Canada supports that sampling plans and performance criteria for the analysis of total AF for the food categories under consideration should be developed. The most critical food categories for sampling plan development will be maize grain, husked rice, and sorghum grain, as the heterogeneity of AF in whole grain that has undergone minimal processing will be greater than for food matrices that are processed such as flour, meal, and cereal-based foods. Milling to produce flour, meal, semolina, and flakes, as well as production of cereal-based foods and dehusking of rice will reduce AF concentrations and/or heterogeneity throughout the food matrix. Therefore, resources should be prioritised for developing sampling plans for the unprocessed grain types. Question (b): Applying the same performance criteria that assumes 70% of total AF would be AFB1 and the remaining 30% would be distributed equally between AFB2, AFG1 and AFG2 for all food commodities may not be supported by the available data. Table 26 shows that AFB1 represents 78 to 95% of the total AF content of the individual food categories for which MLs are being elaborated. Canadian data demonstrate that typically only AFB1 is detected in grain and grain products, and that for the small percentage of samples where multiple aflatoxins are detected, the proportion of AFB1 in grain samples can vary significantly. Furthermore, making an assumption about the relative proportions of four different AF compounds in foods assumes that methods used for analysis will be able to distinguish between the different AF compounds. A significant number of analyses are performed using antibody-based tests (such as ELISAs). Since AFB1 is the predominant AF, method performance criteria should include a minimum LOD/LOQ for this compound no matter what technology is used for an analytical method. Criteria of accuracy and precision of analytical methods should also be developed on the basis of total AFs. Question (c): Canada has analytical methods for the analysis of AF (total and individual) in foods that can be provided, but Canada is not aware of any data currently available that can be used to develop sampling plans. Canada does not have a sampling plan for cereal-based foods that is appropriate for compliance purposes as, at this time, Canada does not have maximum levels for AF in these foods. Data from international proficiency testing programs such as the Bureau Inter-Professionnel d'Études Analytiques (BIPEA) and the Food Analysis Performance Assessment Scheme (FAPAS) should be used to develop realistic method performance criteria for methods using a range of technologies. Method performance criteria should not solely be developed for mass spectrometric-based methods.	**Canada**
Question (b) As Aflatoxin B1 is classified by the International Agency for Research on Cancer (IARC) carcinogenic to human (Group 1) and recognized as one of the most potent liver genotoxic carcinogens, therefore Egypt supports that AFB1 should be considered 50% of total aflatoxins. Question (c) 1. Screening by ELISA. 2. Detection quantity of Aflatoxin by Fluorometer (VICAM fluorometer) procedure for wheat midds, oats, dried distillers grain: The Procedure: Assay range to (series 4, 4EX range 0-300 ppb) Sample Extraction: • Using a blender, combine 50 g sample, 10 g sodium chloride, and 200 mL of a 80:20 methanol:water (HPLC grade). • Mix at high speed for 1 min. • Filter the mixture through fluted Whatman filter paper.	**Egypt**

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer**
Extract Dilution: • Mix well 10 mL of filtrate with 40 mL purified water. • Filter diluted extract through glass microfibre filter into a glass syringe barrel using markings on barrel to measure 4 mL. Column chromatography: • Pass 4 mL filtered diluted extract completely through AflaTest® affinity column at a rate of 1-2 drops/second until air comes through column. • Pass 5 mL of purified water through the column at a rate of about 2 drops/second. • Repeat the previous step once more until air comes through column. • Elute affinity column by passing 1.0 mL HPLC grade methanol through column at a rate of 1-2 drops/second and collecting all of the sample eluate (1 mL) in a glass cuvette. • Add 1.0 mL of AflaTest® Developer to eluate in the cuvette. • Mix well and place cuvette in a calibrated fluorometer. • Read aflatoxin concentration after 60 seconds. 3. UPLC (Ultra performance Liquid Chromatography) by fluorometer detection: To detect total Aflatoxin and there individuals (B1, B2, G1, G2), use the previous procedure except last step, instead of adding 1 mL of AflaTest® Developer, add 1% acetic acid. Detection of Aflatoxin for corn, Ref. (AOAC) 991.3	
a) The EU is of the opinion that sampling plans and performance criteria for the analysis of total aflatoxins for the food categories for which an ML is proposed to be established should be developed. b) The EU does not agree to establishing performance criteria for AFs that consider 70% of total aflatoxins would be AFB1 and the remaining 30% to be distributed equally between AFB2, AFG1 and AFG2. The EU proposes to establish performance criteria for aflatoxins total. c) The EU provides has extensive legislation on the sampling and analysis of aflatoxins in food. All information on analytical methods and sampling plans for the analysis of aflatoxins in cereals and cereal-based products is provided in Commission Regulation (EC) No 401/2006 of 23 February 2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs (Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02006R0401-20140701&from=EN). Relevant provisions in Commission Regulation (EC) No 401/2006: ANNEX I - Methods of sampling A) General provisions B) Methods of sampling for cereals and cereal products J) Methods of sampling for baby foods and processed cereal based foods for infants and young children L) Method of sampling for very large lots or lots stored or transported in a way whereby sampling throughout the lot is not feasible ANNEX II – Criteria for sample preparation and for methods of analysis used for the official control of the levels of mycotoxins in foodstuffs 1) Introduction 1.1. Precautions 2) Treatment of the sample as received by the laboratory 3) Replicate samples	**EU**

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer**
4) Methods of analysis to be used by the laboratory and laboratory control requirements 4.1. Definitions 4.2. General requirements 4.3. Specific requirements 4.3.1.1. a) Performance criteria for aflatoxins 4.3.1.1. i) Notes to the performance criteria for the mycotoxins 4.3.1.2. 'Fitness-for-purpose' approach 4.3.2. Specific requirements for semi-quantitative screening methods 4.4. Estimation of measurement uncertainty, recovery calculation and reporting of results	
a) Aflatoxins, being a pollutant that disperses heterogeneously in products, makes it necessary to establish and standardize sampling methods for the different types of samples and batch sizes in question, in order to obtain representative samples for the reliable analysis of these pollutants.	**Mexico**
a) The United States recommends that sampling plans and performance criteria for the analysis of total aflatoxins be developed for food categories for which MLs are adopted. b) Because total aflatoxins is a "sum of components," we recommend that CCCF consults with CCMAS on the best approach for the criteria. The proposed "70 percent of total aflatoxins would be AFB1 and the remaining 30 percent would be distributed equally between AFB2, AFG1 and AFG2" may not be appropriate for all cereal grains. c) The United States recommends that numeric criteria and not the endorsement of specific methods be used.	**USA**