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CODEX ALIMENTARIUS COMMISSION

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World Health Organization

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON CONTAMINANTS IN FOODS

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DISCUSSION PAPER ON THE ESTABLISHMENT OF MAXIMUM LEVELS FOR TOTAL AFLATOXINS IN CEREALS (WHEAT, MAIZE, SORGHUM AND RICE), FLOUR AND CEREAL-BASED FOODS FOR INFANTS AND YOUNG CHILDREN

(Prepared by the Electronic Working Group led by Brazil and India)

BACKGROUND

1. The Codex Committee on Contaminants in Foods (CCCF) has been discussing the establishment of maximum levels (MLs) for total aflatoxins (AFs) in cereals and cereal based foods since 2013. At the 7th Session of the CCCF (CCCF07, 2013), a summary of data available in the literature was presented to the Committee in a discussion paper on aflatoxins in cereals.[1]

2. At CCCF08 (2014), an updated discussion paper on aflatoxins in cereals showed a preliminary risk assessment and an exposure assessment based on data submitted to GEMS/Food, including information on maize, sorghum, wheat and rice. At that time, due to the large amount of new data available and the planned revision of the *Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals* to include a new annex on aflatoxins, the Committee agreed to discontinue the work of establishing MLs for aflatoxins in cereals and to request that occurrence data on AF in cereals be submitted to the GEMS/Food database.[2]

3. At CCCF11 (2017), JECFA presented the findings of the evaluation on aflatoxins and sterigmatocystin (STC) (83rd JECFA, 2016). Regarding AFs, JECFA83 noted that only five food commodities (maize, peanuts, rice, sorghum and wheat) contributed to more than 10% each to international dietary exposure estimation, for more than one GEMS/Food Cluster Diet, for either AFs or AFB_1. The JECFA evaluation also pointed out that lower levels of aflatoxins were found in rice and wheat, compared to maize and groundnuts, but the high consumption of rice and wheat in some countries led to a greater contribution to the dietary aflatoxins intake, up to 80%, in some GEMS/Food cluster diets. Based on the information generated, the JECFA recommended that rice, wheat and sorghum should be considered in future risk management activities for aflatoxins. At that moment, the CCCF agreed that a discussion paper on the occurrence of these mycotoxins in cereals (mainly maize, rice, sorghum and wheat) should be prepared and presented on the following meeting.[3]

4. At CCCF12 (2018), a discussion paper on aflatoxins and sterigmatocystin in cereals was presented to the Committee. The document showed that maize, rice, wheat and their derived products, contributed the most to total dietary AFs exposure. The discussion paper also showed that the establishment of any MLs for these food categories would greatly reduce AFs exposure worldwide. At that time, the Committee agreed that new work on the establishment of MLs for AFs in cereals should be developed. It also concluded that it was premature to set MLs for STC in cereals due to limited data and lack of internationally validated analytical methods and certified reference materials.

[1] REP13/CF, paras. 134 - 140
[2] REP14/CF, paras. 100 - 103
[3] REP17/CF, para. 151

5. CCCF12 agreed to establish an electronic working group (EWG) chaired by Brazil and co-chaired by India to present at the CCCF13 a discussion paper on a proposal for establishment of MLs for total aflatoxins in cereals and cereal products, including cereal-based food for infants and young children, and focusing on maize, rice, sorghum, wheat and flours of these cereals. The document was prepared based on the most recent data available in the GEMS/Food database (2008-2018) and was structured as follows: occurrence in food (data grouped into food categories specified in the last CCCF meeting, detailing type of products whenever possible); dietary exposure (to illustrate different scenarios of AFs exposure worldwide); risk management considerations (to evaluate the impact of the establishment of hypothetical MLs for AFs, considering both exposure and samples rejection rate).[4]

6. The aim of this discussion paper was to demonstrate the impact of the establishment of MLs for total aflatoxins in maize, rice, sorghum, wheat and flours of these cereals on the reduction of aflatoxins exposure worldwide and also to show that there is sufficient data available in the GEMS/Food database to start a new work on the establishment of MLs for total aflatoxins in these food categories.

KEY POINTS DISCUSSED IN THE ELETRONIC WORKING GROUP

7. In developing this discussion paper, the following points were raised by the eWG:

- A few countries questioned the inclusion and/or exclusion of some food categories from the scope of the new work.
  Those points were included in the recommendation section of this discussion paper to be further discussed and defined by the Committee.

- Some countries questioned information related to the method of analysis, performance criteria, sampling plans and outliers of data submitted to the GEMS/Food database.

  At this point, considering the discussion raised in the eWG, the aim of this paper was to agree on the food categories that MLs should be established on the new work and, therefore, the discussion regarding quality assurance of data used will be addressed next year.

- A few countries agreed to exclude sorghum grain from the food categories selected based on its low contribution to exposure estimated in this paper. However, another country pointed out that the JECFA's evaluation showed that sorghum contributed 16-59% of dietary exposure in six GEMS/Food clusters.

  Considering that the dietary exposure assessment presented in this paper was simple and straightforward and that the JECFA recently conducted an assessment on aflatoxins exposure, the inclusion of sorghum on the food categories selected was pointed out in the recommendation section for discussion and definition by the Committee.

CONCLUSIONS

8. A total of 17,899 samples were analysed during the period evaluated, with 16% of them being positive for one or more AFs. Samples had been submitted to the GEMS/Food database mainly by the European Union (EU), Singapore and Canada. Although there is a large dataset, data available in the GEMS/Food database did not cover all GEMS/Food cluster diets, as already shown in the last JECFA evaluation.

9. Food categories were chosen based on the JECFA's recommendation and on the last CCCF meeting. Groups were created according to the information available in the GEMS/Food database. If new information becomes available in the future, the food categories could be reorganized.

10. The dietary exposure assessment conducted to illustrate the current scenario showed that polished rice and maize flour contributed the most to total AFs exposure, due to both high patterns of consumption of these foods in all cluster diets and high levels of AFs contamination.

11. The evaluation of the impact of hypothetical MLs for AFs were carried out for food groups that were defined in the last Codex meeting (wheat, maize, sorghum, types of rice, cereal-based flours and cereal-based foods for infants and small children) and for food that contributed the most to total AFs intake (>10% of total intake).

[4] REP18/CF, paras. 132-140

12. Although Codex usually considers the importance of the commodity on international trade during prioritization of food commodities to the establishment of ML, this discussion paper did not evaluate the economic impact of the food categories chosen, since the scope of the discussion paper was already determined in the last CCCF meeting, based on JECFA's recommendation.

13. The dietary exposure showed that the establishment of MLs proposed in this document could greatly reduce total AFs exposure from the grains considered in this assessment (from 82% for countries in GEMS/Food cluster diet G11 to 97% for cluster diets G09 and G14), with a minimum increase in sample rejection (maximum of 4.3% for maize flour). No MLs were proposed for sorghum grain and parboiled rice, since MLs did not significantly impact the total exposure (< 3% in all Cluster Diets).

14. Although the dietary exposure assessment was conducted in a very simplified way in this document, the outcomes were mostly the same found by the JECFA, except for sorghum. This assessment was only prepared to illustrate the impact of the establishment of hypothetical MLs on AFs intake and it was never considered to replace JECFA's evaluation.

15. It is important to encourage countries to submit data on representative sample of the food categories discussed in this document, so that MLs can be proposed from a representative dataset. The sample should be analysed by validated analytical methods in quality assurance system implemented laboratories. Final MLs will be proposed considering the available dataset and will take into account the specificity of data and limits of quantification (LOQs) of methods used. Information on appropriate sampling methods should be provided as AFs are not homogeneously distributed in cereals.

16. Aflatoxins are genotoxic carcinogens and, therefore, actions should be taken to reduce the exposure to these contaminants to levels as low as reasonably achievable (ALARA principle) as already recommended by the JECFA.

RECOMMENDATIONS

17. Based on the conclusions above and the technical information provided in Appendix II, CCCF is invited to consider the following recommendations:

- To start new work on the establishment of MLs for total aflatoxins and associated sampling plans for the food categories described below (see also the project document in Appendix I):

Food category
Maize grain, destined for further processing[a]
Flour, meal, semolina and flakes derived from maize
Husked rice
Polished rice
Wheat grain, destined for further processing[a]
Flour, meal, semolina and flakes derived from wheat, excluding whole wheat flour
Cereal-based Food for infants and young children[b]

[a] Destined for further processing" means intended to undergo an additional processing/treatment that has proven to reduce level of AFs before being used as an ingredient in foodstuffs, otherwise processed or offered for human consumption. Codex members may define the processes that have been shown to reduce levels; [b] All cereal foods intended for infants (up to 12 months) and young children (12 to 36 months).

- To decide whether rice flour should be included in the food categories listed above, considering its low impact on aflatoxins exposure worldwide, but its importance to coeliacs; If the committee agrees to include rice flour, to discuss whether grouping rice flour with polished rice and applying the same ML;
- To decide if a call for data should be launched to gather information on AFs occurrence in whole wheat flour and, if new data becomes available, whether this food category should be added to the categories selected for the new work;
- To consider the inclusion of sorghum in the food categories selected for the new work since JECFA's evaluation showed that sorghum contributes to 16-59% of dietary exposure in six GEMS/Food clusters;
- To launch a call for data on AFs occurrence for the food categories selected for the new work on the establishment of MLs for total aflatoxins to ensure that the proposed limits are estimated using a representative dataset. Data should be submitted specifying exactly the type of product (for example, whole or white flour);
- To encourage Codex members to submit information on analytical methods and sampling plans for collecting occurrence data on AFs in cereals and cereal products in order to discuss associated sampling plans and analytical methods.

APPENDIX I

PROJECT DOCUMENT
(For consideration by CCCF)

MAXIMUM LEVELS FOR AFLATOXINS IN CEREALS AND CEREAL-BASED PRODUCTS, INCLUDING FOOD FOR INFANTS AND YOUNG CHILDREN

1. Purpose and scope

The purpose of this work is to protect public health and to ensure fair practices in the international food trade by establishing MLs for aflatoxins in cereal and cereal-based products.

2. Its relevance and timeliness

Toxicological data and human dietary exposure to aflatoxins (AFs) were evaluated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) at its 49th and 83rd meetings. The findings showed that AFs are genotoxic human liver carcinogens, being among the most potent mutagenic and carcinogenic substances known so far. Hepatitis B virus was shown to be a critical contributor to the potency of aflatoxins in inducing liver cancer, AFs potency being 30 times higher in carriers of hepatitis B virus than in non-carrier of hepatitis B virus. No tolerable daily intake was proposed for AFs, as is typical for genotoxic carcinogens. At its last evaluation, JECFA83 also noted that rice, maize, wheat and sorghum needed to be considered in future risk management activities for aflatoxins, considering their great contribution to aflatoxin exposure in some parts of the world.

Cereal and cereal-based products are highly consumed worldwide and therefore any level of aflatoxin (AFs) contamination in these products could significantly contribute to total AFs exposure. Currently, there is no maximum level (ML) for AFs in cereal and cereal-based products, thus, a new work on the establishment of MLs for the categories listed below, could greatly contribute to AFs dietary exposure reduction.

- Maize grain destined for further processing and flour, meal, semolina and flakes derived from maize
- Husked and polished rice
- Wheat grain destined for further processing and f lour, meal, semolina and flakes derived from wheat, excluding whole wheat flour
- Cereal-based Food for infants and young children

3. The main aspects to be covered

MLs for aflatoxins in cereal and cereal-based products, considering the following:

a) Results of discussions of the CCCF
b) Risk assessments conducted by JECFA
c) Data availability
d) AFs occurrence
e) Achievability of the MLs
f) Rejection rates
g) Methods of analysis and sampling plans

4. An assessment against the criteria for the establishment of work priorities

a) Consumer protection from the point of view of health, food safety, ensuring fair practice in the food trade and taking into account the identified needs of the developing countries.

The new work will establish MLs for AFs in cereal and cereal-based products.

b) Diversification of national legislations and apparent resultant or potential impediments to international trade.

The new work will provide harmonized international maximum levels.

c) Work already undertaken by other organizations in this field

The risk assessment has already been done for AFs by JECFA83.

5. Relevance to the Codex Strategic Objectives

The work proposed falls under the following Codex Strategic Goals of the Codex Strategic Plan 2014-2019:

Strategic goal 1 Establish international food standards that address current and emerging food issues

This work was proposed in accordance to the JECFA recommendation to reduce AFs dietary exposure.

Strategic goal 2 Ensure the application of risk analysis principles in the development of Codex standards

The establishment of MLs for AFs in cereal and cereal-based products will contribute to the reduction of AFs intake what was already indicated as mandatory in the risk assessment performed by JECFA.

6. Information on the relation between the proposal and other existing Codex documents

This new work is recommended following the Procedural Manual and the General Standard for Contaminants and Toxins in Food and Feed (GSCTFF) (CXS 193-1995).

7. Identification of any requirement for and availability of expert scientific advice

Expert scientific advice has been already provided by JECFA.

8. Identification of any need for technical input to the standard from external bodies so that this can be planned for the proposed timeline for completion of the new work

Currently, there is no need for additional technical input from external bodies.

9. Proposed timeline for completion of work

Subject to the approval by the 42nd Session of the Codex Alimentarius Commission in 2019, the following working plan is proposed:

- The MLs for AFs in cereal and cereal-based products will be considered at CCCF14 (2020) and CCCF15 (2021) with a view to its finalization in 2022 or earlier.

APPENDIX II

BACKGROUND DOCUMENT
(For information)

INTRODUCTION

1. Aflatoxins (AFs) are considered the most important naturally occurring group of mycotoxins in the world's food supply. They are produced primarily by *Aspergillus flavus, A. parasiticus* and related species. AFs B_1, B_2, G_1 and G_2 are the four majors naturally produced AFs. The B and G designations refer to the blue and green fluorescence colours produced under UV light (Pitt and Hocking, 2009). *A. flavus* is often found in various foods produced in tropical countries, and has special affinity for maize, peanuts and cottonseed while *A. parasiticus* which is commonly isolated from peanuts and rarely found in other foods, produces both B and G AFs (Frisvad et al., 2006). At least fourteen other *Aspergillus* species are known to produce aflatoxins, but only two of them are of possible importance in foods: *A. nomius* and *A. minisclerotigenes*. AFs could be produced by fungi either before and/or after harvesting of cereals, and the level of contamination is influenced by several environmental factors such as temperature, relative humidity, insect damage, drought and stress condition of the plants (Miraglia et al., 2009). Among the four AFs, AFB_1 is usually found in greatest amounts in the food supply, with the exception of dairy products where AFM_1 typically predominates and also the majority of the toxicological data documented relate to AFB_1.

2. AFs (B_1, B_2, G_1 and G_2) were evaluated by the JECFA at its 49th Meeting (1998) and concluded that aflatoxins are human liver carcinogens with AFB_1 as the most potent one. No tolerable daily intake was proposed since they were considered genotoxic carcinogens. Thus, adoption of the ALARA (as low as reasonably achievable) principle was recommended in order to reduce the potential risk. At its 83rd meeting, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) (FAO/WHO, 2017) re-evaluated toxicological data and dietary exposure to AFs and reaffirmed the conclusions of the JECFA49 meeting (FAO/WHO, 1998). The JECFA also noted that rice, wheat and sorghum needed to be considered in future risk management activities for aflatoxins, considering their contribution to aflatoxin exposure in some parts of the world where they are consumed as staple cereals/foods in the diet.

3. Since the complete elimination of aflatoxins from food supply is not feasible, measures should be taken to control and manage worldwide contamination.

OCCURRENCE IN FOOD

4. Worldwide occurrence of aflatoxins in cereals and products thereof was evaluated using data extracted from the GEMS/Food database in July 2018. Data regarding samples analysed between 2008 and 2018 were extracted from the database and exported into Microsoft Excel spreadsheets. Only samples intended for human consumption were considered.

5. First, data were individually analysed and grouped into categories according to their listed "food category, food name, food code and local food name". Final food categories were created considering the data available in the GEMS/Food database and the last CCCF grouping recommendations. Rice grain category included samples that were not specified for the type of rice, which may include husked and polished rice. Parboiled rice was maintained in a single food category since there are studies that show AFs migration into the starchy endosperm during the parboiling process and higher AFs levels in the parboiled rice than in the polished rice (Dors et al., 2009; Bandara et al., 1991; Firdous et al., 2014; Iqbal et al., 2012). Most data available from the GEMS/Food database did not specify whether the wheat flour was white or whole wheat, thus, for this discussion paper all data was considered to refer to white wheat flour.

6. Samples that included an inedible portion, samples that were cooked before analysis in the laboratories and aggregated samples were excluded from the dataset. Samples that were cooked before analysis were excluded since Codex MLs are proposed for raw foods, in such a way as they are internationally commercialized.

7. For aflatoxins, some samples included information on individual aflatoxins (AFB_1, AFB_2, AFG_1, AFG_2), the sum of AFB_1 plus AFB_2 and total aflatoxins, which generated up to 6 entries per sample. In such cases, data were gathered according to the "serial number" provided. Samples that reported results only for AFB_2, AFG_1 or AFG_2 were excluded when it was not possible to sum individual concentrations to yield a total aflatoxin concentration using the "serial number".

8. Data on total aflatoxins (hereafter referred to as 'AFs') occurrence and levels of contamination for each food category are shown in Table 1. Since the AFs risk assessment was already conducted by the JECFA and the purpose of this document was to illustrate AFs exposure scenarios in order to facilitate the proposition of MLs, only the lower bound AF concentrations were estimated (samples below the limit of detection - LOD or the limit of quantification - LOQ were considered as zero). Data with high LOQs were not excluded at this moment since there is no ML established yet, thus the dataset will be reworked when guidelines become available.

9. A total of 17,899 samples were analysed for one or more AFs, with maize grain, rice grain, wheat grain, wheat flour and cereal-based food for infants and young children accounting for almost 87% of the dataset. Samples were submitted by 33 different countries, including: Australia, Austria, Belgium, Brazil, Bulgaria, Canada, China, Cyprus, Czech Republic, European Union, Finland, France, Germany, Hungary, Ireland, Italy, Japan, Lithuania, Luxembourg, Mali, Malta, Philippines, Poland, Portugal, Republic of Korea, Romania, Singapore, Slovakia, Slovenia, Spain, Sweden, Thailand and United States of America. Most samples were submitted from the European Union (61%), Singapore (12%) and Canada (6%).

Table 1. GEMS/Food data on the occurrence and concentrations of AFs in different types of cereals and cereal products.

Food category	Number and proportion of positive samples (%)	Mean of positive samples (range) - µg/kg	Lower bound[a] (µg/kg)	
			Mean	95th percentile
Maize				
Grain[b]	528/2502 (21.1)	10.8 (0.1 – 800)	2.3	5.9
Flour	112/468 (23.9)	21.5 (0.05 – 476)	5.2	4.5
Rice				
Grain[b,c]	1173/5230 (22.4)	7.0 (0.002 – 800)	1.6	1.7
Husked	44/190 (23.2)	19.7 (0.004 – 800)	4.6	1.7
Parboiled	7/119 (5.9)	0.4 (0.2 – 0.8)	0.02	0.2
Polished	231/813 (15.9)	21.4 (0.002 – 800)	6.1	0.8
Flour	127/568 (22.4)	1.2 (0.05 – 23.9)	0.3	1.0
Sorghum				
Grain[b]	6/104 (5.8)	3.8 (0.3 -10.8)	0.2	0.3
Wheat				
Grain[b]	345/4027 (8.6)	1.5 (0.05 – 3.3)	0.1	1.3
Flour	179/1392 (12.9)	0.9 (0.05 – 95.5)	0.1	0.3
Food for infants and young children[d]	94/2486 (3.8)	5.6 (0.004 – 50)	0.2	0.0
Total	2846/17899 (15.9)	8.3	1.3	1.5

[a] LB: mean of all samples (samples below LOD or LOQ were considered as zero);
[b] destined for further processing; [c] long grain, grain (not specified); [d] only cereal based foods.

10. 16% of all samples were positive for AFs, with the highest incidence found in maize flour (24%), followed by husked rice (23%), rice grain and rice flour (22%), maize grain (21%) and polished rice (16%). Positive samples were submitted mainly from the European Union (60%) and Singapore (15%), which submitted the largest datasets. Maize flour, polished rice and husked rice had the highest mean level of AFs in positive samples, respectively 21.5 µg/kg, 21.4 µg/kg and 19.7µg/kg. The mean of all samples, reported with the concentrations in samples below the LOQ set to zero, ranged from 0.1 (wheat grain and wheat flour) to 6.1 µg/kg (polished rice). LOQs ranged from 0.002 µg/kg (food for infants and young children) to 70 µg/kg (maize grain). The 95th percentiles were, in some cases, higher than the mean estimated for the lower bound, what could be explained by the occurrence of a few data with very high levels of contamination (outliers), that were not treated at this point. When the work on the establishment of MLs for total aflatoxins in the food categories selected starts, this should be taken into account, as well as methods of analysis with high LOQ/LOD.

RISK MANAGEMENT CONSIDERATIONS FOR AFLATOXINS CONSIDERING DIETARY EXPOSURE

11. Dietary exposure to aflatoxins was estimated in this discussion paper to demonstrate different scenarios of AFs exposure worldwide and to support the risk management decisions. Dietary exposure to aflatoxins through the consumption of maize, rice, sorghum, wheat, and their flours was estimated using the GEMS/Food occurrence data (Table 1) and mean consumption data obtained from the 17 Cluster Diets (Annex I). Consumption data were chosen in order to best represent the food categories evaluated. Since the exact food group was not available from the GEMS/Food database, a more complete description was chosen. Rice grain was not included in the estimation since the data was not specified and could include husked and/or polished rice. The concentration used in the estimation was the mean level for each category shown in Table 1 when concentrations below the LOQ were set to zero (LB).

12. Tables 2a and 2b shows AF intake through the consumption of cereals and cereals products for each of the 17 Cluster Diets. The highest exposures were found to be from Clusters G09 (31.5 ng/kg bw per day), G14 (23.6 ng/kg bw per day) and G05 (20.1 ng/kg bw per day), all high consumers of rice. Consumption of polished rice contributed the most to the total intake in 11 Clusters (G01, G04, G05, G06, G07, G09, G10, G11, G12, G14 and G17) and maize flour in 6 Clusters (G02, G03, G08, G13, G15 and G16).

Table 2a. Aflatoxins intake through the consumption of cereals and cereals products for GEMS/Food Clusters G01 to G08 (ng/kg bw per day).

Food category	Mean AF (µg/kg)	GO1	G02	G03	G04	G05	G06	G07	G08
Maize									
Grain	2.3	0.07	0.04	0.07	0.36	0.11	0.58	0.04	0.39
Flour	5.2	1.95	3.06	7.50	3.00	4.01	4.22	1.23	1.11
Rice									
Husked	4.6	0.09	0.10	2.36	0.36	0.05	0.16	0.18	0.12
Parboiled	0.02	0.001	0.001	0.013	0.002	0.0004	0.001	0.002	0.001
Polished	6.1	3.47	1.05	4.24	8.36	15.25	7.15	1.36	1.10
Flour	0.3	0.0005	0.001	0.0005	0.002	0.001	0.0005	0.004	0.002
Sorghum									
Grain	0.2	0.02	0.0004	0.06	0.06	0.04	0.01	NC	NC
Wheat									
Grain	0.1	0.81	0.72	0.08	0.60	0.37	0.92	0.54	0.52
Flour	0.1	0.59	0.52	0.06	0.43	0.26	0.67	0.39	0.38
Total		**7.0**	**5.5**	**14.4**	**13.2**	**20.1**	**13.7**	**3.7**	**3.6**

NC= no consumption data available;

Table 2b. Aflatoxins intake through the consumption of cereals and cereals products for GEMS/Food Clusters G09 to G17 (ng/kg bw per day).

Food category	Mean AF (μg/kg)	G09	G10	G11	G12	G13	G14	G15	G16	G17
Maize										
Grain	2.3	0.08	0.93	0.08	0.02	0.03	0.02	0.15	0.30	NC
Flour	5.2	1.85	1.08	0.36	4.49	8.11	0.70	2.41	4.81	2.41
Rice										
Husked	4.6	0.05	0.13	NC	0.38	1.03	0.31	0.15	0.01	0.67
Parboiled	0.02	0.001	0.001	0.0001	0.002	0.006	0.002	0.001	0.00004	0.004
Polished	6.1	29.03	5.80	1.30	6.37	3.07	22.17	1.30	1.55	5.21
Flour	0.3	0.004	0.0005	0.001	0.0005	0.0005	0.001	0.001	0.0005	NC
Sorghum										
Grain	0.2	0.01	0.004	NC	0.03	0.32	0.01	NC	0.13	NC
Wheat										
Grain	0.1	0.31	0.50	0.46	0.35	0.12	0.23	0.58	0.05	0.28
Flour	0.1	0.23	0.36	0.33	0.26	0.09	0.17	0.42	0.04	0.2
Total		**31.5**	**8.8**	**2.5**	**11.9**	**12.8**	**23.6**	**5.0**	**6.9**	**8.8**

NC= no consumption data available;

13. Figure 1 shows the contribution of each food category to total AFs intake among all cluster diets. The food categories that most contributed to AF exposure across all clusters were polished rice (50%) and maize flour (33%). From these products, the impact came both from high consumption rates and high AF concentrations (highest AFs levels among food categories considered).

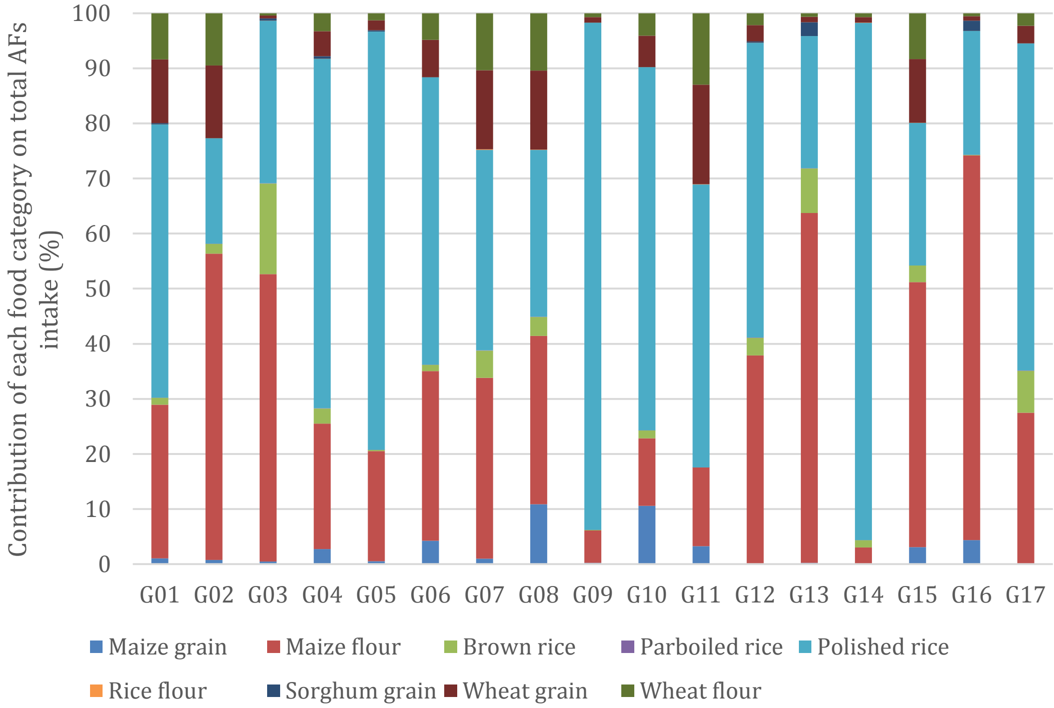

Figure 1. Impact of each food category on the total aflatoxin intake for each cluster.

14. The impact of the establishment of hypothetical MLs for AFs on aflatoxin dietary intake and sample rejection rate were analysed. Based on JECFA's safety recommendation, MLs were proposed for food categories that contributed to more than 10% of the total AFs intake, in at least one GEMS/Food cluster diet. Rice flour had little impact on total aflatoxin dietary intake, however, MLs were also discussed for this food category considering that specific population groups, such as people with celiac disease, could be high consumers of rice flour and its products. MLs were also proposed for whole wheat flour, considering that whole flour is usually more contaminated than white flour, as shown by Trombete et al. (2014). It also is important to state that wet milling of maize grain isolates most mycotoxins from the starch fraction used as food ingredients and the processing of maize may cause reduction in aflatoxin levels. Wet milling reduces the concentration of aflatoxin in maize starch to 1% of the levels found in the raw grain. Therefore, cereal starches and starch-derived products were not considered and no MLs for these products were proposed.

15. Hypothetical MLs were proposed according to the contamination distribution profile of each food group. Tables 3 to 11 show the impact of hypothetical MLs for AFs in each food category for the Cluster Diet with the highest consumption pattern for that group (worst case scenario).

Table 3. Effect of the implementation of hypothetical MLs on aflatoxins intake through the consumption of maize grain for Cluster G10 (highest consumption pattern).

ML (µg/kg)	Mean AF (µg/kg)	Intake (ng/kg bw per day)	Intake reduction (%)	Sample rejection (%)[a]
No limits	2.3	0.93	-	-
20	0.6	0.25	73.1	2.3
15	0.5	0.2	78.8	3.0
10	0.4	0.16	83.0	3.8
5	0.3	0.11	87.9	5.4

Consumption data used: cereal grains, raw, (incl processed); G10=24.59 g/person (mean consumption). [a]Percentage of samples above proposed MLs for AFs considering samples from all Clusters Diets for this food category.

Table 4. Effect of the implementation of hypothetical MLs on aflatoxins intake through the consumption of maize flour for cluster G03 (highest consumption pattern).

ML (µg/kg)	Mean AF (µg/kg)	Intake (ng/kg bw per day)	Intake reduction (%)	Sample rejection (%)[a]
No limits	5.2	7.5	-	-
20	0.4	0.65	91.3	1.9
10	0.4	0.52	93.1	2.6
5	0.2	0.34	95.5	4.3
2	0.1	0.14	98.1	8.3

Consumption data used: maize, flour (white flour and wholemeal); G03= 87.27 g/person (mean consumption). [a] Percentage of samples above proposed MLs for AFs considering samples from all Clusters Diets for this food category.

Table 5. Effect of the implementation of hypothetical MLs on aflatoxins intake through the consumption of husked rice for cluster G03 (highest consumption pattern).

ML (µg/kg)	Mean AF (µg/kg)	Intake (ng/kg bw per day)	Intake reduction (%)	Sample rejection (%)[a]
No limits	4.6	2.36	-	-
10	0.3	0.16	93.3	1.1
5	0.1	0.07	97.0	3.2
2	0.1	0.04	98.4	4.7
1	0.04	0.02	99.1	6.8

Consumption data used: rice, husked, dry (incl oil, incl beverages, excl polished, excl flour); G03=31.05 g/person (mean consumption). [a] Percentage of samples above proposed MLs for AFs considering samples from all Clusters Diets for this food category.

Table 6. Effect of the implementation of hypothetical MLs on aflatoxins intake through the consumption of parboiled rice for cluster G03 (highest consumption pattern).

ML (µg/kg)	Mean AF (µg/kg)	Intake (ng/kg bw per day)	Intake reduction (%)	Sample rejection (%)[a]
No limits	0.02	0.01	-	-
5	0.02	0.01	0.0	0.0
3	0.02	0.01	0.0	0.0
1	0.02	0.01	0.0	0.0
0.5	0.01	0.004	71.9	2.5

Consumption data used: rice, husked, dry (incl flour, incl oil, incl beverages, incl starch, excl polished); G03= 31.05 g/person (mean consumption). [a] Percentage of samples above proposed MLs for AFs considering samples from all Clusters Diets for this food category.

Table 7. Effect of the implementation of hypothetical MLs on aflatoxins intake through the consumption of polished rice for cluster G09 (highest consumption pattern).

ML (µg/kg)	Mean AF (µg/kg)	Intake (ng/kg bw per day)	Intake reduction (%)	Sample rejection (%)[a]
No limits	6.1	29.03	-	-
8	0.18	0.90	96.9	0.7
5	0.16	0.78	97.3	1.1
3	0.14	0.68	97.7	1.7
1	0.10	0.49	98.3	4.1

Consumption data used: rice, polished, dry; G09= 262.1 g/person (mean consumption). [a] Percentage of samples above proposed MLs for AFs considering samples from all Clusters Diets for this food category.

Table 8. Effect of the implementation of hypothetical MLs on aflatoxins intake through the consumption of rice flour for cluster G07 (highest consumption pattern).

ML (µg/kg)	Mean AF (µg/kg)	Intake (ng/kg bw per day)	Intake reduction (%)	Sample rejection (%)[a]
No limits	0.27	0.0045	-	-
4	0.11	0.0018	60.9	1.6
3	0.10	0.0016	65.0	1.9
2	0.09	0.0014	67.9	2.3
1	0.05	0.0008	81.5	4.9

Consumption data used: rice flour; G07=0,98 g/person (mean consumption). [a] Percentage of samples above proposed MLs for AFs considering samples from all Clusters Diets for this food category.

Table 9. Effect of the implementation of hypothetical MLs on aflatoxins intake through the consumption sorghum grain for cluster G13 (highest consumption pattern).

ML (µg/kg)	Mean AF (µg/kg)	Intake (ng/kg bw per day)	Intake reduction (%)	Sample rejection (%)[a]
No limits	0.2	0.32	-	-
8	0.02	0.03	90.6	1.9
2	0.02	0.03	90.6	1.9
1	0.02	0.03	90.6	1.9
0.5	0.01	0.01	96.7	3.8

Consumption data used: sorghum, raw (incl flour, incl beer) (i.e. Chicken corn Dari seed, Durra, Feterita); G13= 89.16 g/person (mean consumption). [a] Percentage of samples above proposed MLs for AFs considering samples from all Clusters Diets for this food category.

Table 10. Effect of the implementation of hypothetical MLs on aflatoxins intake through the consumption wheat grain for cluster G06 (highest consumption pattern).

ML (µg/kg)	Mean AF (µg/kg)	Intake (ng/kg bw per day)	Intake reduction (%)	Sample rejection (%)[a]
No limits	0.13	0.92	-	-
5	0.13	0.92	0.0	0.0
2	0.09	0.62	32.2	1.8
1	0.01	0.06	93.7	7.1
0.5	0.001	0.01	98.9	7.9

Consumption data used: wheat, raw (incl bulgur, incl fermented beverages, incl germ, incl wholemeal bread, incl white flour products, incl white bread); G06=434.07 g/person (mean consumption). [a] Percentage of samples above proposed MLs for AFs considering samples from all Clusters Diets for this food category.

Table 11. Effect of the implementation of hypothetical MLs on aflatoxins intake through the consumption wheat flour for cluster G06 (highest consumption pattern).

ML (µg/kg)	Mean AF (µg/kg)	Intake (ng/kg bw per day)	Intake reduction (%)	Sample rejection (%)[a]
No limits	0.1	0.67	-	-
8	0.05	0.28	58.6	0.1
5	0.04	0.23	65.9	0.2
2	0.04	0.20	70.0	0.4
1	0.03	0.17	74.2	0.7

Consumption data used: wheat, white flour (incl white flour products: starch, gluten, macaroni, pastry). G06=343.12 g/person (mean consumption). [a] Percentage of samples above proposed MLs for AFs considering samples from all Clusters Diets for this food category.

16. Considering the data described above, the MLs described above are being suggested for total AFs. Since sorghum grain and parboiled rice did not significantly impact the total exposure (< 3% in all Cluster Diets), no limits were proposed for these food categories. The dataset did not specify values for whole wheat flour, therefore a ML of 2 µg/kg is being suggested considering the wheat grain profile of AFs contamination.

Food category	ML (µg/kg)[a]
Maize grain, destined for further processing	10
Flour, meal, semolina and flakes derived from maize	5
Husked rice	5
Polished rice	3
Rice flour	3
Wheat grain, destined for further processing	2
Flour, meal, semolina and flakes derived from wheat	1
Whole wheat flour	2

[a] MLs suggested are not definitive, they may change if new data become available.

17. Evaluating the scenario considering the establishment of the MLs suggested, AFs exposure is reduced by up to 97% (G09 and G14), with a maximum rejection rate of 4.3% (maize flour). (Tables 12a and 12b). Since the same dataset of samples were used for estimation of dietary exposure for all Cluster Diets, the worst-case scenario was found in Cluster Diets with higher consumption pattern of the food groups evaluated.

Table 12a. Aflatoxins intake through the consumption of cereals and cereals products for GEMS/Food Clusters G01 to G08 (ng/kg bw per day) with establishment of hypothetical MLs.

Food category	Mean AF (µg/kg)	GO1	G02	G03	G04	G05	G06	G07	G08
Maize									
Grain	0.4	0.01	0.01	0.01	0.06	0.02	0.10	0.01	0.07
Flour	0.2	0.09	0.14	0.34	0.14	0.18	0.19	0.06	0.05
Rice									
Husked	0.1	0.003	0.03	0.07	0.01	0.001	0.005	0.01	0.004
Parboiled	0.02	0.001	0.001	0.013	0.002	0.0004	0.001	0.002	0.001
Polished	0.14	0.08	0.02	0.10	0.20	0.36	0.17	0.03	0.03
Flour	0.1	0.0002	0.0004	0.0002	0.001	0.0004	0.0002	0.002	0.001
Sorghum									
Grain	0.2	0.02	0.0004	0.06	0.06	0.04	0.01	NC	NC
Wheat									
Grain	0.1	0.55	0.49	0.06	0.40	0.25	0.62	0.36	0.35
Flour	0.03	0.15	0.14	0.02	0.11	0.07	0.17	0.10	0.10
Total		**0.9**	**0.8**	**0.7**	**1.0**	**0.9**	**1.3**	**0.6**	**0.6**

NC= no consumption data available. Scenario of establishment of maximum levels for maize grain, destined for further processing (10 µg/kg), Flour, meal, semolina and flakes derived from maize (5 µg/kg), husked rice (5 µg/kg), polished rice (3 µg/kg), rice flour (3 µg/kg), wheat grain, destined for further processing (2 µg/kg), Flour, meal, semolina and flakes derived from wheat (1 µg/kg).

Table 12b. Aflatoxins intake through the consumption of cereals and cereals products for GEMS/Food Clusters G09 to G17 (ng/kg bw per day) with establishment of hypothetical MLs.

Food category	Mean AF (µg/kg)	G09	G10	G11	G12	G13	G14	G15	G16	G17
Maize										
Grain	0.4	0.01	0.16	0.01	0.03	0.01	0.004	0.03	0.05	NC
Flour	0.2	0.08	0.05	0.02	0.20	0.37	0.03	0.11	0.22	0.11
Rice										
Husked	0.1	0.001	0.004	NC	0.01	0.03	0.01	0.004	0.0002	0.02
Parboiled	0.02	0.001	0.001	0.0001	0.002	0.006	0.002	0.001	0.00004	0.004
Polished	0.14	0.68	0.14	0.03	0.15	0.07	0.52	0.03	0.04	0.12
Flour	0.1	0.001	0.0002	0.0004	0.0002	0.0002	0.0002	0.0003	0.0002	NC
Sorghum										
Grain	0.2	0.01	0.004	NC	0.03	0.32	0.01	NC	0.13	NC
Wheat										
Grain	0.1	0.21	0.34	0.31	0.24	0.08	0.16	0.39	0.04	0.19
Flour	0.03	0.06	0.09	0.08	0.07	0.02	0.04	0.11	0.01	0.05
Total		**1.1**	**0.8**	**0.5**	**0.7**	**0.9**	**0.8**	**0.7**	**0.5**	**0.5**

NC= no consumption data available. Scenario of establishment of maximum levels for maize grain, destined for further processing (10 µg/kg), Flour, meal, semolina and flakes derived from maize (5 µg/kg), husked rice (5 µg/kg), polished rice (3 µg/kg), rice flour (3 µg/kg), wheat grain, destined for further processing (2 µg/kg), Flour, meal, semolina and flakes derived from wheat (1 µg/kg).

18. Cereal based foods for infants and young children were not included in the total AFs exposure estimates since this food category is intended for consumption by a specific population group and worldwide consumption data for this group is not available. However, infants and young children are of great concern regarding contaminants exposure and, therefore, the effect of establishment of a ML on sample rejection was also evaluated for this food category (Table 14).

Table 13. Effect of the implementation of hypothetical MLs for aflatoxins in food for infants and young children (only cereal based foods).

ML (µg/kg)	Mean AF (µg/kg)	Sample rejection (%)
No limits	0.21	-
50	0.01	0.4
2	0.01	0.5
1	0.004	0.6
0.5	0.004	0.7
0.1	0.001	1.9

19. If a ML of 0.1 µg/kg was established, 1.9% of the samples of cereal based food for infants and young children currently available would be withdrawn from the market. When analysing the data for grains, at least 10% of each cereal considered in this document would meet the AFs concentration needed to allow production of the cereal-based foods for food for infants and young children, assuring continuity of production of this food category if the ML was applied. However, if the performance criteria of methods of analysis approved for aflatoxins are considered, a ML of 0.5 µg/kg should be suggested for food for infants and young children.

20. MLs proposed at this moment reflect data available at the GEMS/Food database. If new data become available, MLs could change in order to represent the real occurrence data.

Annex I of Appendix I: GEMS/Food Consumption Data

Table 1a. Consumption data obtained from the GEMS/Food Cluster Diets - G01 to G08 (g/person/day).

Food category	GO1	G02	G03	G04	G05	G06	G07	G08
Maize								
Grain	1.9	1.1	1.9	9.5	3.0	15.4	1.0	10.4
Flour	22.7	35.6	87.3	34.9	46.7	49.1	14.3	12.9
Rice								
Husked	1.2	1.3	31.0	4,8	0.6	2.2	2.4	1.6
Parboiled	1.3	1.6	31.0	5.4	0.9	2.2	3.7	2.1
Polished	34.2	10.4	41.7	82.4	150.2	70.5	13.4	10.8
Flour	0.1	0.2	0.1	0.5	0.2	0.1	1.0	0.4
Sorghum								
Grain	4.3	0.1	16.2	15.8	11.0	2.9	NC	NC
Wheat								
Grain	381.1	341.5	38.3	281.9	172.8	434.1	253.1	244.7
Flour	301.2	268.6	30.21	222.5	134.7	343.1	198.1	193.0

NC= no consumption data available.

Table 1b. Consumption data obtained from the GEMS/Food Cluster Diets - G09 to G17 (g/person/day).

Food category	G09	G10	G11	G12	G13	G14	G15	G16	G17
Maize									
Grain	1.9	24.6	2.2	0.4	0.9	0.6	4.0	8.0	NC
Flour	19.7	12.5	4.2	52.3	94.3	8.1	28.0	55.9	28.1
Rice									
Husked	0.6	1.7	NC	5.0	13.5	4.1	2.0	0.1	8,8
Parboiled	1.5	1.7	0.3	5.1	13.6	4.3	2.2	0.1	8.8
Polished	262.1	57.2	12.8	62.8	30.2	218.3	12.8	15.2	51.3
Flour	0.7	0.1	0.2	0.1	0.1	0.1	0.2	0.1	NC
Sorghum									
Grain	1.4	1.1	NC	7.1	89.2	2.0	NC	35.4	NC
Wheat									
Grain	133.4	235.1	216.4	167.4	57.2	110.5	272.6	25.8	132.0
Flour	106.2	185.1	168.7	131.6	44.8	86.9	214.0	20.3	103.6

NC= no consumption data available.

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