



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

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DISCUSSION PAPER ON AFLATOXINS AND STERIGMATOCYSTIN CONTAMINATION IN CEREALS

(Prepared by the Electronic Working Group led by Brazil)

BACKGROUND

1. At the 23rd Session of the Committee on Food Additives and Contaminants (CCFAC23) (1991), a maximum level (ML) of 10 µg/kg total aflatoxins (B₁ + B₂ + G₁ + G₂) was proposed for all foods. As there was no consensus over the issue among country members, the development of an ML for aflatoxins (AFs) in foods was discontinued and the Committee decided¹ to discuss the issue on a commodity-by-commodity basis.
2. At the 6th Session of the Committee on Contaminants in Foods (CCCF06) (2012), the Committee agreed² to develop a discussion paper on AFs in cereals through an electronic Working Group (eWG) led by Brazil and co-chaired by the United States of America. At CCCF07, a summary of data available in the literature was presented to the Committee in the discussion paper on AFs in cereals and CCCF agreed³ that it would be necessary to have original occurrence data on AFs in cereal grains to conduct a sounder evaluation of the current situation, the exposure levels and the impact on human health.
3. At CCCF08, the updated discussion paper on AFs in cereals was presented, showing a preliminary risk assessment and an exposure assessment based on data submitted to GEMS/Food, including information on maize, sorghum, wheat and rice. Rice was the commodity with the largest dataset presented (66%) and the cereal with both the highest AF incidence (17.7%) and level of contamination (total upper bound mean of 2.4 µg/kg). A preliminary risk assessment showed that rice and wheat contributed the most to aflatoxin exposure through the consumption of cereals evaluated in most Cluster Diets (13 of 17 Cluster Diets). At that time, the Committee agreed to: prioritize the revision of the *Code of practice for the Prevention and Reduction of Mycotoxin in Cereals* (CXC 51-2003) (Annex on AFs in cereals); to request that occurrence data on AF in cereals be submitted to the GEMS/Food database; and to discontinue the work of establishing MLs for AFs in cereals. The revised *Code of practice for the prevention and reduction of mycotoxin in cereals*, including special provisions for AFs, was finalized at CCCF10 (2016) and approved by CAC39 (2016).
4. Also at CCCF08, the progress report of the FAO/WHO project on mycotoxins in sorghum was presented to the Committee, showing that only a small number of samples had detectable concentration of mycotoxins and that those most frequently detected were: aflatoxins, fumonisins, ochratoxin A, sterigmatocystin (STC) and diactoxyscirpenol. Since the two latter mycotoxins had not been evaluated by JECFA yet, they were added to the priority list of contaminants and naturally occurring toxicants for JECFA evaluation. At this same meeting, it was also noted that the last JECFA assessment for AFs had been conducted in 1998 and that a lot of new data were available to update this evaluation. The Committee agreed⁴ to add AFs to the priority list of contaminants, but not to be considered as a high priority.
5. At CCCF11 (2017), the findings of the JECFA evaluation of AFs and STC were presented and it was recommended that a discussion paper on aflatoxins and sterigmatocystin in cereals (mainly maize, rice, sorghum and wheat) should be prepared. CCCF agreed⁵ to establish an eWG, chaired by Brazil, to prepare this discussion paper to support the Committee to take a decision on the appropriate risk management actions for AFs and STC in cereals.

¹ ALINORM 91/12A, paras. 9, 113-118

² REP12/CF, para. 175

³ REP13/CF, paras. 134-140

⁴ REP14/CF, paras. 100-103

⁵ REP17/CF, para. 151

KEY POINTS DISCUSSED IN THE ELETRONIC WORKING GROUP

6. In developing this discussion paper, the following points were raised by the eWG:
- A few countries questioned why there was a food category for cereals and cereal based products and other categories for specific cereals such maize, rice, wheat, and sorghum.
Those products were grouped considering similarities in mycotoxins incidence and contamination, thus, products with different patterns of contamination remained in a specific category. Furthermore, food products were also grouped in accordance to information available in the GEMS/Food database and, therefore, when the cereal was not specified it remained in the food group named as cereal and cereal based product.
 - Two countries considered premature the establishment of MLs for STC in cereals.
The suggestion was accepted considering the lack of internationally validated analytical methods and certified reference materials for STC in cereals.
 - Three countries suggested that raw products should be separated from the processed food category when establishing MLs.
Data currently available do not support this recommendation, since the patterns of contamination of raw and processed products were very similar or even worse for processed foods (Annex I). Moreover, documents recently discussed at this Committee also focused in establishing MLs for processed foods when it is necessary (lead in several processed products and cadmium in cocoa products).
 - One country questioned about the absence of data submitted to the GEMS/Food database in this document.
Samples submitted to the GEMS/Food database that did not fulfill the requirements used in the elaboration of this discussion paper (samples that included an inedible portion, samples that were cooked before analysis in the laboratories and aggregated samples) were excluded from the dataset at this moment.

CONCLUSIONS

7. Occurrence data on AFs in cereals and cereal products obtained from the GEMS/Food database were preliminary grouped into food categories according to their profile of contamination (incidence and levels of contamination). The food category named as cereal and cereal-based products included products such as: cereal grains and cereal based products (cereals not specified), bran, bread and other cooked cereal products, buckwheat, snack food, etc.). Samples submitted to the GEMS/Food database showed that rice and rice-based products, maize and maize-based products and cereal and cereal-based products were the most contaminated food categories evaluated. Sorghum and sorghum-based products and maize and maize-based products had the highest AF concentration, respectively 51.4 and 10.6 µg/kg.
8. A total of 37 941 samples were analyzed during the period evaluated, with 14% of them being positive for one or more AFs. Samples had been submitted to the GEMS/Food database from countries belonging to eight different GEMS/Food clusters diets (C06, C07, C08, C09, C10, C11, C13 and C15).
9. The dietary exposure assessment conducted to illustrate the current scenario showed that cereal and cereal-based products, maize and maize-based products, rice, sorghum and sorghum-based products and wheat and wheat-based products contributed the most to total AFs exposure, mainly due to high patterns of consumption of these foods in all cluster diets (except for sorghum, where exposure was driven by its high AF level).
10. The evaluation of the impact of hypothetical MLs for AFs in the food categories that contributed the most to total AF intake showed that the establishment of the highest MLs considered could greatly reduce total AFs exposure, with a minimum increase in sample rejection. Food categories and the hypothetical limits shown in this document reflects data available at this moment and were defined to illustrate the importance of setting MLs for these products. Thus, when the discussion on the establishment of the ML starts, food categories and MLs should be revised according to data available.
11. Only 6.6% of samples analyzed for STC had detectable concentrations (N=5234). The highest incidence was found in cereal-based snacks (33%), sorghum flour (16%) and rice and rice-based products (11%). Both the largest dataset and the highest level of contamination were found in the sorghum flour category. Occurrence data on STC in cereal and cereal products were very limited, being submitted only by nine different countries. However, data for sorghum flour came mostly from countries belonging to the cluster with the highest consumption of this product and the establishment of an ML for STC for this category could greatly reduce the intake in populations with high pattern of consumption of sorghum and sorghum-based products. Nevertheless, the establishment of an ML for STC was considered premature due to the lack of internationally validated analytical methods and certified reference materials.
12. Aflatoxins and sterigmatocystin 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 JECFA.

RECOMMENDATIONS

13. Consistent with the information provided in this discussion paper, the eWG recommends the following:
- Start new work to set an ML for AFs in cereal and cereal-based products and in food for infants and small children, according to the project document (Appendix I). Specific levels should be set for other cereal food groups if data available at the time show it is essential to do so.
 - To encourage standards development organizations (SDO) to provide a validated method of analysis for STC.
 - Discuss whether there are specific management practices for STC in cereals and if it is necessary to include an annex in the revised *Code of practice for the prevention and reduction of mycotoxin contamination in cereals*.

PROJECT DOCUMENT**PROPOSAL FOR NEW WORK ON MAXIMUM LEVELS FOR AFLATOXINS IN CEREALS
AND CEREAL-BASED PRODUCTS FOR INCLUSION IN THE
GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOOD AND FEED (CXS 193-1995)****(For consideration by CCCF)****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 maximum levels (MLs) for aflatoxins (AFs) in cereal and cereal-based products.

2. Its relevance and timeliness

Toxicological data and human dietary exposure to AFs were evaluated by 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 AFs 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, JECFA also noted that rice, wheat and sorghum needed to be considered in future risk management activities for AFs, 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 AFs contamination in these products could significantly contribute to total AFs exposure. Currently, there is no ML for AFs in cereal and cereal-based products, thus, new work on the establishment of MLs in this category, with specific limits for some food products if it is necessary, could greatly contribute to AFs dietary exposure reduction.

3. The main aspects to be covered

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

- a) Results of discussions of CCCF
- b) Risk assessments conducted by JECFA
- c) Data availability
- d) AFs occurrence in the food category
- e) Achievability of the MLs
- f) Rejection rates
- g) 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 ML(s) 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 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).

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 Codex Alimentarius Commission in 2018, the following working plan:

- The proposed draft ML(s) for AFs in cereal and cereal-based products will be considered at CCCF13 and CCCF14 with a view to its finalization in 2021.

BACKGROUND INFORMATION

(For information to Codex Members and Observers
when considering the conclusions and recommendations)

INTRODUCTION

1. Aflatoxins (AFs) are considered the most important group of mycotoxins in the world's food supply and are produced in nature primarily by *Aspergillus flavus*, *A. parasiticus* and related species. AFs B₁, B₂, G₁ and G₂ are the four major naturally produced AFs. The B and G designations refer to the blue and green fluorescence colours produced under UV light (Pitt and Hocking, 2009).
2. *A. flavus* is often found in food produced in tropical countries, having special affinity with maize, peanuts and cottonseed. Usually, *A. flavus* produces only B aflatoxins and yet is considered the main source of AFs. *A. parasiticus* produces both B and G aflatoxins and is commonly isolated from peanuts, being quite rare to find it in other foods (Frisvad et al., 2006). Optimum conditions for AFs production by these species are 33°C and 0.99 a_w (Sanchis and Magan, 2004). At least fourteen other *Aspergillus* species are known to produce AFs, but only two of them are of possible importance in foods: *A. nomius* and *A. minisclerotigenes*. Both resemble *A. flavus* in culture but *A. nomius* produces bullet shaped sclerotia, as distinct from the large spherical sclerotia produced by many *A. flavus* isolates, while *A. minisclerotigenes* produces small spherical sclerotia. Both species produce B and G aflatoxins (Taniwaki & Pitt, 2013). 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).
3. Sterigmatocystin (STC) is a toxic fungal metabolite, produced in food mainly by *A. versicolor* (Pitt and Hocking, 1997). *Chaetomium* ssp., *Emericella* ssp., *Monocillium nordinii* and *Humicola fuscoatra* can produce STC, although they are not likely to contaminate foods (Frisvad et al., 2006). Sterigmatocystin is an intermediate in the biosynthetic pathway of aflatoxin and therefore they are structurally closely related (Figure 1) (FAO/WHO, 2017; Mol et al., 2015). Despite this, only *Aspergillus ochraceoroseus* and some *Emericella* species (*Aspergillus*) are confirmed to accumulate both STC and AFs (Frisvad et al., 2004). The major aflatoxin producers, species in *Aspergillus* section *Flavi*, efficiently convert STC into 3-methoxysterigmatocystin and then into AFs (Frisvad et al., 1999).
4. Sterigmatocystin has been found in grains and grain-based products, green coffee beans, spices, nuts, beer and on the surface of cheese during ripening and storage (Pitt and Hocking, 1997; Mol et al., 2015). Fungal infection by STC producers occurs mainly at post-harvest stage (Mol et al., 2015).

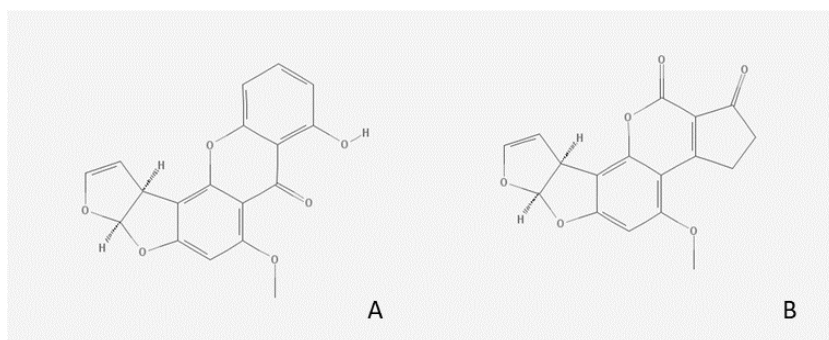


Figure 1 – Chemical structures of sterigmatocystin (A) and aflatoxin B₁ (B).

TOXICOLOGICAL ASPECTS

5. JECFA49 (1998) evaluated toxicological data and human dietary exposure to aflatoxins (B₁, B₂, G₁ and G₂; AFs) (FAO/WHO, 1998). JECFA reviewed a wide range of studies, in both animals and humans, and concluded that AFs are genotoxic human liver carcinogens, AFB₁ being the most potent carcinogen. As is typical for genotoxic carcinogens, no tolerable daily intake was proposed.
6. The risks arising from exposure to AFs were evaluated through potency estimates for human liver cancer derived from epidemiological and toxicological studies. The potency of AFs was defined by JECFA to be 30 times higher in carriers of hepatitis B virus (HBsAg⁺; about 0.3 cancers/year/100,000 individuals based on aflatoxin intake of 1 ng/kg bw/day) than in non-carriers of hepatitis B virus (HBsAg⁻; about 0.01 cancers/year/100,000 individuals based on aflatoxin intake of 1 ng/kg bw/day). Thus, reduction of AFs intake in populations with a high prevalence of hepatitis B carriers would have a greater impact on reducing liver cancer rates than in populations with a low prevalence of carriers.

7. JECFA64 (FAO/WHO, 2005) decided that evaluations of compounds that are both genotoxic and carcinogenic, such as AFs, should be based on the estimation of Margins of Exposure (MOEs). The MOE is defined as the ratio between a toxicological threshold (such as the benchmark dose) and the estimated intake. MOEs lower than 10000 may indicate a public health concern (EFSA, 2005). A benchmark dose of 170 ng/kg bw per day for a 10% increase in cancer incidence in rodents (BMDL₁₀) has been used for AFs risk assessments (EFSA, 2007).
8. JECFA83 (FAO/WHO, 2017) re-evaluated toxicological data and dietary exposure to AFs and reaffirmed the conclusions of the JECFA49 meeting (FAO/WHO, 1998), namely, that AFs are among the most potent mutagenic and carcinogenic substances known and that hepatitis B virus infection is a critical contributor to the potency of AFs in inducing liver cancer. JECFA also noted that rice, wheat and sorghum needed to be considered in future risk management activities for AFs, considering their contribution to aflatoxin exposure in some parts of the world.
9. Also JECFA83 (FAO/WHO, 2017) evaluated for the first-time toxicological data and dietary exposure for sterigmatocystin. The Committee concluded that STC is genotoxic and carcinogenic and the critical effect was determined to be carcinogenicity. The Committee also noted that STC and AFB₁ have the same main target organ (the liver) and that STC is less potent than AFB₁, based on limited comparative carcinogenic animal data. JECFA selected a BMDL₁₀ of 0.16 mg/kg bw per day as the point of departure for risk assessment evaluations. No tolerable intake was proposed since this compound was found to be a genotoxic carcinogen. JECFA conducted a dietary exposure assessment to STC through the consumption of sorghum. The lowest MOEs were found for the African Region (from 4700 [upper bound] to 5000 [LB] for the high-exposure range), what may indicate a human health concern.

METHOD OF ANALYSIS

10. Methods typically used for AFs analysis were recently reviewed in the JECFA83 evaluation (FAO/WHO, 2017). Quantitative analysis has been widely conducted using mostly high-performance liquid chromatography (HPLC), with fluorescence (HPLC-FD) or mass spectrometer detectors (LC-MS or LC-MS/MS).
20. In general, analytical methods used for AFs were divided into four categories:: 1) quantitative methods – Thin layer chromatography (TLC), HPLC, LC-MS, LC-MS/MS and capillary electrophoresis; 2) semi quantitative methods – Enzyme-Linked Immunosorbent Assay (ELISA), lateral flow tests, direct fluorescence, fluorescence polarization immunoassay and biosensors; 3) indirect methods – spectroscopy; and 4) emerging technologies – hyperspectral imaging, electronic nose, aptamer-based biosensors and molecularly imprinted polymers. Thus, the limits of quantification of the methods vary considerably, depending on the aflatoxin analyzed and on the method chosen.
30. Analytical methods used for the determination of STC were also reviewed at the JECFA83 meeting and included mostly chromatographic techniques such as TLC, GC, GC-MS, and HPLC with ultraviolet fluorescence or mass spectrometer detection (LC-MS, LC-MS/MS). Sterigmatocystin determination has also been included in multi-mycotoxins analysis using LC-MS/MS, but still with high LOQs ($\geq 2\mu\text{g}/\text{kg}$) (FAO/WHO, 2017). Although analytical methods for STC were reported in the literature, there is no internationally validated analytical method nor certified reference materials available for STC in cereals.
40. For accurate mycotoxins analysis, it is very important that the method chosen meets performance criteria such as selectivity, limit of quantification, precision, trueness and ruggedness. These criteria should be addressed when establishing maximum levels (MLs) and should be considered in accordance with the Codex Procedural Manual (CAC, 2016). Another difficulty in mycotoxins analysis is the establishment of sampling plans, which should be developed during the establishment of MLs, with the support of the FAO mycotoxin sampling tool (FAO, 2014).

OCCURRENCE IN FOOD

14. Worldwide occurrence of AFs and STC in cereals and products thereof was evaluated using data extracted from the GEMS/Food database. Data regarding samples analyzed between 2007 and 2017 were extracted from the database and exported into Microsoft Excel spreadsheets.

15. First, data were individually analyzed 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 contamination profile of individual groups, that is, samples with similar incidence and levels of contamination were put in the same category. For example, raw maize and maize-based products were put in the same category, since their incidence of positive samples and level of contamination were very similar. Individual categories, before grouping, are shown in Annex 1. Food category named as cereal and cereal-based products included products with no specification of which cereal it was made and products with similarities in mycotoxins incidence and levels of AFs contamination. Samples that included an inedible portion, samples that were cooked before analysis in the laboratories and aggregated samples were excluded from the dataset.
16. For aflatoxins, some samples included information on individual aflatoxins (AFB₁, AFB₂, AFG₁, AFG₂), the sum of AFB₁ plus AFB₂ 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 AFB₂, AFG₁ or AFG₂ were excluded when it was not possible to sum individual concentrations to yield a total aflatoxin concentration using the “serial number”. Samples with data only for AFB₁ or the sum of AFB₁ and AFB₂ were corrected for total aflatoxin concentration using the representative percentage of contamination of each aflatoxin, as obtained from the GEMS/Food dataset (AFB₁= 90% AF; AFB₁+AFB₂=93% AF). This correction was not made individually for each food group since there was no information available for all of them. This percentage was very similar across all products evaluated, except for sorghum and sorghum-based products (AFB₁= 78% AF; AFB₁+AFB₂= 83%).
17. Data on total AFs (hereafter referred to as ‘AF’) occurrence and levels of contamination for each food category are shown in Table 1. The food category listed as cereal and cereal-based products includes samples of cereal grains and cereal based products (cereals not specified), cereal bars, baking mixtures, bran, bread and other cooked cereal products, breakfast cereals, buckwheat, pasta, pastries, snack food, etc.
18. A total of 37941 samples were analyzed for one or more AFs, with wheat and wheat-based products, cereal and cereal-based products, maize and maize-based products and rice accounting for almost 75% of the dataset. Samples were submitted from 26 different places, including: Australia, Bulgaria, Burkina Faso, Canada, China, Czech Republic, Ethiopia, European Union, France, Germany, Hungary, Japan, Lithuania, Luxembourg, Mali, New Zealand, Philippines, Republic of Korea, Romania, Singapore, Slovakia, Slovenia, Sudan, Sweden, Thailand and United States of America. Most samples were submitted from the European Union (53%), Singapore (14%) and Canada (12%).

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 - µg/kg (range)	Mean of all samples (lower bound) (µg/kg) ^a
Barley and barley-based products	59/1172 (5.0)	1.4 (0.09-14.8)	0.1
Buckwheat	31/458 (6.8)	4.0 (0.1-49.7)	0.3
Cereal and cereal-based products	1056/7101 (14.9)	2.0 (0.01-206.4)	0.3
Food for infants and small children	93/2455 (3.8)	0.3 (0.004-4.7)	0.01
Maize and maize-based products	1354/6900 (19.6)	10.6 (0.02-743.6)	2.1
Millet and millet-based products	16/169 (9.5)	1.2 (0.08-15.0)	0.1
Oat and oat-based products	115/1512 (7.6)	0.5 (0.05-6.1)	0.04
Quinoa and quinoa-based products	0/46	ND	ND
Rice	1520/6500 (23.4)	3.7 (0.002-347.0)	0.9
Rice products	311/1219 (25.5)	0.9 (0.04-23.9)	0.2
Rye and rye-based products	14/543 (2.6)	0.5 (0.14-1.1)	0.01
Sorghum and sorghum-based products	127/1651 (7.7)	51.4 (0.07-1092)	4.0
Spelt and spelt-based products	0/531	ND	ND
Wheat and wheat-based products	641/7684 (8.3)	1.5 (0.05-95.5)	0.1
Total	5337/37941 (14.1)	5.7 (0.002-1092)	0.8

^a mean of all samples (samples below LOD or LOQ were considered as zero); cereal and cereal-based products includes samples of cereal grains and cereal based products (cereals not specified), cereal bars, baking mixtures, bran, bread and other cooked cereal products, breakfast cereals, buckwheat, pasta, pastries, snack food, etc.; food for infants and small children includes samples of cereal-based food such as baby's biscuits, baby's pasta, breakfast cereals, cereals powder, fermented rice powder, oatmeal, porridge, rusks, etc.

19. 14% of all samples were positive for AFs, with the highest incidence found in rice-based products (25%), followed by rice (23%), maize and maize-based products (20%) and cereal and cereal-based products (15%). Positive samples were submitted mainly from the European Union (53%) and Singapore (17%), which submitted the largest dataset. No positive samples were found in quinoa and quinoa-based products nor in spelt and spelt-based products. Sorghum and sorghum-based products had the highest mean level of AFs (51.4 µg/kg) and the most contaminated sample (1092 µg/kg; Mali). The mean of all samples, reported with the concentrations in samples below the LOQ set to zero, ranged from ND (quinoa and quinoa-based products nor in spelt and spelt-based products) to 4.0 µg/kg (sorghum and sorghum-based products). LOQs ranged from 0.001 µg/kg (barley and barley-based products, cereal and cereal-based products, food for infants and small children, maize and maize-based products, oat and oat-based products, rye and rye-based products and wheat and wheat-based products) to 70 µg/kg (maize and maize-based products).
20. Table 2 shows GEMS/Food data on STC occurrence in cereals and cereal products. The food category listed as cereal and cereal-based products includes samples of cereal grains and cereal based products (cereals not specified), cereal bars, baking mixtures, bran, bread and other cooked cereal products, breakfast cereals, buckwheat, pasta, pastries, etc. The food group "cereal-based snacks" was not included in the cereal and cereal-based products category due to its high incidence level, despite of the low number of samples analyzed (n=9).

21. A total of 5234 samples were analyzed for STC, 6.6% of them being positive. Data were submitted from only nine different places (Burkina Faso, Canada, Czech Republic, Ethiopia, European Union, Mali, Singapore, Sudan and United Kingdom). Most data came from Canada (46%) and the European Union (20%). The largest datasets were available for sorghum flour (29%), followed by cereal and cereal-based products (21%), wheat and wheat-based products (19%) and food for infants and small children (10%).

Table 2. GEMS/Food data on the occurrence and concentrations of STC in different types of cereals and cereal products.

Samples	Number and proportion of positive samples (%)	Mean of positive samples - µg/kg (range)	Mean of all samples (lower bound) (µg/kg)^a
Barley and barley-based products	1/63 (1.6)	1.9	0.03
Buckwheat and buckwheat-based products	2/33 (6.1)	5.6 (2.4-8.8)	0.3
Cereal and cereal-based products	14/1119 (1.3)	1.7 (0.5-4.6)	0.02
Cereal-based snacks	3/9 (33.3)	1.1 (1.1)	0.4
Food for infants and small children	18/553 (3.3)	3.2 (0.5-10.4)	0.1
Maize and maize-based products	1/241 (0.4)	0.6	0.003
Millet and millet products	0/13	ND	ND
Oat and oat-based products	18/277 (6.5)	4.5 (0.4-32.9)	0.3
Quinoa and quinoa-based products	0/35	ND	ND
Rice and rice-based products	33/304 (10.9)	1.5 (0.5-5.5)	0.2
Rye and rye-based products	2/87 (2.3)	2.2 (0.7-3.7)	0.1
Sorghum flour	246/1536 (16.0)	56.0 (2.5-1189)	9.0
Spelt and spelt products	0/31	ND	ND
Wheat and wheat-based products	9/933 (1.0)	1.3 (0.7-4.0)	0.01
Total	347/5234 (6.6)	40.4 (0.4-1189)	2.7

^a mean of all samples (samples below LOD or LOQ were considered as zero). ND=not detected. Cereal and cereal-based products includes samples of cereal grains and cereal based products (cereals not specified), cereal bars, baking mixtures, bran, bread and other cooked cereal products, breakfast cereals, buckwheat, pasta, pastries, etc.; food for infants and small children includes samples of cereal-based food such as baby's biscuits, baby's pasta, breakfast cereals, cereals powder, fermented rice powder, oatmeal, porridge, rusks, etc.

22. The highest incidence of positive samples was found in cereal-based snacks (33%), sorghum flour (16%) and rice and rice-based products (11%). However, only nine samples of cereal-based snacks were analyzed, while for sorghum flour and rice and rice-based products the dataset was much more representative.

23. LOQs ranged from 0.3 µg/kg (barley and barley-based products, cereal and cereal-based products, food for infants and small children, maize and maize-based products, oat and oat-based products, rice and rice-based products, rye and rye-based products, spelt and spelt-based products and wheat and wheat-based products) to 16.6 µg/kg (barley and barley-based products, cereal and cereal-based products, cereal-based snacks, oat and oat-based products, rye and rye-based products, spelt and spelt-based products and wheat and wheat-based products). No positive detections of STC were found in millet and millet-based products, quinoa and quinoa-based products and spelt and spelt-based products, although methods that analyzed the first two groups had higher LOQ (5 µg/kg). Both the highest mean level of positive samples (56 µg/kg) and the most contaminated sample (1189 µg/kg; Ethiopia) were found in the sorghum flour category.
24. The mean for all samples, reported with concentrations in samples below the LOQ set to zero, was 2.7 µg/kg, detected samples ranging from not detected (millet and millet-based products, quinoa and quinoa-based products and spelt and spelt-based products) to 9 µg/kg (sorghum flour). Most positive samples for STC came from Ethiopia (36%), followed by Burkina Faso (18%), European Union (17%), Mali (12%) and Canada (13%). For the European Union and Canada this was mainly because of the largest dataset submitted, however, for the African countries this fact was also accompanied by higher STC levels in positive samples (32.6 to 68.4 µg/kg). Sorghum flour samples were submitted mainly by African countries (only 3 samples were submitted by the European Union) and data for rice and rice-based products came mainly from Canada and the European Union.

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25. A dietary exposure to AFs through the consumption of cereals and cereal products was conducted using the GEMS/Food occurrence data (Table 1) and mean consumption data obtained from the 17 Cluster Diets (Annex 2). Quinoa and quinoa-based products and spelt and spelt-based products were not included in the exposure assessment since there were no positive samples for these two food categories. 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.
26. Table 3a and 3b shows AF intake through the consumption of cereals and cereals products for each of the 17 Cluster Diets. Individual commodities that contributed, on average, less than 1% to the total AFs exposure were not shown in tables 3a and 3b (barley and barley-based products, buckwheat, millet and millet-based products, oat and oat-based products, rice products, rye and rye-based products).

Table 3a. AFs intake through the consumption of cereals and cereals products for GEMS/Food Clusters C01 to C08 (ng/kg bw per day).

Food category	Mean AF (µg/kg)	C01	C02	C03	C04	C05	C06	C07	C08
Cereal and cereal-based products	0.3	2.5	2.4	1.3	2.5	2.4	3.1	1.8	2.0
Maize and maize-based products	2.1	1.0	1.5	3.8	1.8	2.1	2.6	0.6	0.9
Rice	0.9	0.7	0.2	1.2	1.6	2.8	1.4	0.3	0.2
Sorghum and sorghum-based products	4.0	0.3	0.0	1.1	1.0	0.7	0.2	NC	NC
Wheat and wheat-based products	0.1	0.8	0.7	0.1	0.6	0.4	0.9	0.5	0.5
Total		5.3	4.9	7.5	7.6	8.4	8.2	3.3	3.7

NC= no consumption data available; AFs exposure through the consumption of barley and barley-based products, buckwheat, millet and millet-based products, oat and oat-based products, rice products, rye and rye-based products were omitted from table 3a (food categories that contributed to less than 1% of total exposure).

Table 3b. AFs intake through the consumption of cereals and cereals products for GEMS/Food Clusters C09 to C17 (ng/kg bw per day).

Food	Mean AF (µg/kg)	C09	C10	C11	C12	C13	C14	C15	C16	C17
Cereal and cereal-based products	0.3	2.8	2.0	1.5	1.8	2.1	2.1	2.0	1.0	1.3
Maize and maize-based products	2.1	1.0	1.4	0.3	2.2	4.0	0.4	1.3	2.7	1.2
Rice	0.9	5.4	1.1	0.2	1.3	0.8	4.2	0.3	0.3	1.1
Sorghum and sorghum-based products	4.0	0.1	0.1	NC	0.5	5.9	0.1	NC	2.3	NC
Wheat and wheat-based products	0.1	0.3	0.5	0.5	0.4	0.1	0.2	0.6	0.1	0.3
Total	1.0	9.6	5.2	2.5	6.2	13.0	7.0	4.3	6.4	3.9

NC= no consumption data available; AFs exposure through the consumption of barley and barley-based products, buckwheat, millet and millet-based products, oat and oat-based products, rice products, rye and rye-based products were omitted from table 3b (food categories that contributed to less than 1% of total exposure).

27. The highest exposures were found to be from clusters C13 (13 ng/kg bw per day) and C09 (9.6 ng/kg bw per day), high consumers of sorghum and sorghum-based products and rice, respectively. Consumption of cereal and cereal-based products contributed the most to the total intake in 10 Clusters (C01, C02, C04, C06, C07, C08, C10, C11, C15 and C17), maize and maize-based products in 3 Clusters (C03, C12 and C16), rice also in 3 Clusters (C05, C09, C14) and sorghum and sorghum-based products in 1 Cluster only (C13). Countries that submitted samples to the GEMS/Food database represented 8 different Clusters (C06, C07, C08, C09, C10, C11, C13 and C15), if all European Union members were considered.
28. Considering all Cluster Diets, the food categories that most contributed to AF exposure across all clusters were cereal and cereal-based products (36%), maize and maize-based products (26%), rice (19%), sorghum and sorghum-based products (11%) and wheat and wheat-based products (9%). From these products, the impact came mostly from high patterns of consumption, rather than from high contamination concentrations, except for sorghum and sorghum-based products, which reported the highest level of AFs contamination (4.0 µg/kg).
29. Aflatoxins are both genotoxic and carcinogenic, thus exposure should be as low as reasonably achievable (CAC,1995). Since complete elimination of AFs from food supply is not feasible, measures should be taken to control and manage worldwide contamination. Recently, the *Code of practice for the prevention and reduction of mycotoxin contamination in cereals* was revised and new annexes were included for mycotoxins and cereals that required specific management practices, including AFs in cereals (CAC, 2003).
30. The impact of the establishment of hypothetical MLs for AFs on aflatoxin dietary intake and sample rejection rate were analyzed for those food categories that had the greatest contribution to total AFs exposure. Hypothetical MLs were chosen according to the contamination distribution profile of each group. Tables 4 to 8 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 4. Effect of the implementation of hypothetical MLs on AFs intake through the consumption of cereal and cereal-based products for cluster C06 (highest consumption pattern).

ML (µg/kg)	Mean AF (µg/kg)	Intake (ng/kg bw per day)	Intake reduction (%)	Sample rejection (%) ^a
No limits	0.3	3.11	-	-
10	0.15	1.54	50.7	0.6
5	0.10	1.07	65.7	1.2
2	0.06	0.63	79.9	2.6
1	0.04	0.43	86.2	3.8

Consumption data used: cereal grains, raw, (incl processed); C06=614.04 g/person (mean consumption).

^aPercentage 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 AFs intake through the consumption of maize and maize-based products for cluster C13 (highest consumption pattern).

ML (µg/kg)	Mean AF (µg/kg)	Intake (ng/kg bw per day)	Intake reduction (%)	Sample rejection (%) ^a
No limits	2.1	4.037	-	-
12	0.40	0.773	80.9	2.7
8	0.30	0.592	85.3	3.7
4	0.18	0.344	91.5	6.0
2	0.10	0.197	95.1	8.5

Consumption data used: maize, raw (incl glucose & dextrose & isoglucose, incl flour, incl oil, incl beer, incl germ, incl starch); C13= 116.66 g/person (mean consumption). ^aPercentage 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 AFs intake through the consumption of rice for cluster C09 (highest consumption pattern).

ML (µg/kg)	Mean AF (µg/kg)	Intake (ng/kg bw per day)	Intake reduction (%)	Sample rejection (%) ^a
No limits	0.9	5.4	-	-
10	0.25	1.5	71.9	1.3
5	0.18	1.1	79.7	2.2
2	0.11	0.7	87.6	4.5
1	0.06	0.4	92.7	7.6

Consumption data used: rice, husked, dry (incl polished, excl flour, excl oil, excl beverages, excl starch); C09=338.58 g/person (mean consumption). ^aPercentage 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 AFs intake through the consumption of sorghum and sorghum-based products for cluster C13 (highest consumption pattern).

ML (µg/kg)	Mean AF (µg/kg)	Intake (ng/kg bw per day)	Intake reduction (%)	Sample rejection (%) ^a
No limits	4.0	5.88	-	-
20	0.38	0.57	90.3	4.1
15	0.29	0.43	92.8	4.7
8	0.04	0.06	99.0	6.8
1	0.002	0.002	100.0	7.3

Consumption data used: sorghum, raw (incl flour, incl beer); C13= 89.16 g/person (mean consumption).

^aPercentage 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 AFs intake through the consumption of wheat and wheat-based products for cluster C06 (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	0.921	-	-
5	0.09	0.632	31.5	0.3
2	0.06	0.426	53.7	1.5
1	0.02	0.109	88.1	4.5
0.5	0.01	0.044	95.2	5.6

Wheat, raw (incl bulgur, incl fermented beverages, incl germ, incl whole meal bread, incl white flour products, incl white bread); C06= 434.07 g/person (mean consumption). ^aPercentage of samples above proposed MLs for AFs considering samples from all Clusters Diets for this food category.

31. For the five food categories evaluated (Tables 4 to 8), the establishment of even the highest ML evaluated could reduce AF exposure by up to 90% (sorghum and sorghum-based products), with a maximum rejection rate of only 4% (sorghum and sorghum-based products), considering individual exposures assessments. If the total AFs exposure is considered (Tables 9a and 9b), the reduction could reach up to 78% (Cluster C13) when adopting the highest ML evaluated for each one of these food categories. 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 9a. Aflatoxins intake through the consumption of cereals and cereals products for GEMS/Food Clusters C01 to C08 (ng/kg bw per day) with establishment of hypothetical MLs.

Food category	Mean AF (µg/kg)	C01	C02	C03	C04	C05	C06	C07	C08
Cereal and cereal-based products	0.15	1.2	1.2	0.7	1.2	1.2	1.5	0.9	1.0
Maize and maize-based products	0.4	0.2	0.3	0.7	0.3	0.4	0.5	0.1	0.2
Rice	0.25	0.2	0.1	0.3	0.5	0.8	0.4	0.1	0.1
Sorghum and sorghum-based products	0.38	0.0	0.0	0.1	0.1	0.1	0.0	NC	NC
Wheat and wheat-based products	0.09	0.6	0.5	0.1	0.4	0.3	0.6	0.4	0.4
Total		2.2	2.1	1.9	2.5	2.7	3.1	1.5	1.6

NC= no consumption data available. Scenario of establishment of maximum levels for cereal and cereal-based products (10 µg/kg), maize and maize-based products (12 µg/kg), rice (10 µg/kg), sorghum and sorghum-based products (20 µg/kg) and wheat and wheat-based products (5 µg/kg).

Table 9b. Aflatoxins intake through the consumption of cereals and cereals products for GEMS/Food Clusters C09 to C17 (ng/kg bw per day) with establishment of hypothetical MLs.

Food	Mean (µg/kg)	AF	C09	C10	C11	C12	C13	C14	C15	C16	C17
Cereal and cereal-based products	0.15		1.4	1.0	0.7	0.9	1.0	1.0	1.0	0.5	0.7
Maize and maize-based products	0.4		0.2	0.3	0.0	0.4	0.8	0.1	0.3	0.5	0.2
Rice	0.25		1.5	0.3	0.1	0.4	0.2	1.2	0.1	0.1	0.3
Sorghum and sorghum-based products	0.38		0.01	0.01	NC	0.05	0.6	0.01	NC	0.2	NC
Wheat and wheat-based products	0.09		0.2	0.3	0.3	0.2	0.1	0.2	0.4	0.0	0.2
Total			3.3	2.0	1.2	2.0	2.8	2.5	1.8	1.4	1.4

NC= no consumption data available. Scenario of establishment of maximum levels for cereal and cereal-based products (10 µg/kg), maize and maize-based products (12 µg/kg), rice (10 µg/kg), sorghum and sorghum-based products (20 µg/kg) and wheat and wheat-based products (5 µg/kg).

32. Foods for infants and small 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. Data on AFs in food for infants and small children were submitted by fourteen different places, coming mostly from European Union (66%) and Canada (22%). However, infants and small 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 10). Sample rejection rate was obtained considering the percentage of samples above the proposed MLs – no distinction was made for different regions.

Table 10. Effect of the implementation of hypothetical MLs for AFs in food for infants and small children.

ML (µg/kg)	Mean AF (µg/kg)	Sample rejection (%)
No limits	0.01	-
2	0.007	0.1
1	0.005	0.3
0.5	0.005	0.3
0.3	0.005	1.1
0.1	0.002	1.7

33. Several countries have already established regulatory limits to control the presence of AFs in cereals, including Brazil, the European Union, Iran and the United States. Table 11 shows a summary of those limits.

Table 11. MLs established for AFs in cereals in in several countries.

Country	Food category	ML	Comments
Brazil (ANVISA, 2011)	Cereals and cereals based products	5 µg/kg	AFs; Except maize
	Processed cereal-based foods and baby formulas for infants	1 µg/kg	AFs
	Maize and maize based products	20 µg/kg	AFs
European Union (EC, 2006)	Cereals and products derived from cereals	4 µg/kg	AFs; Except maize and rice to be subjected to sorting
	Maize and rice to be subjected to sorting	10 µg/kg	AFs
	Processed cereal-based foods and baby foods for infants	0.1 µg/kg	AFB1
Iran (National Standard No. 5925)	Rice and corn	30 µg/kg	AFs
		5 µg/kg	AFB1
	Wheat	15 µg/kg	AFs
		5 µg/kg	AFB1
	Barley	50 µg/kg	AFs
	10 µg/kg	AFB1	
United States (USFDA, 2000)	All foods	20 µg/kg	AFs

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34. A dietary exposure for STC was not conducted due to a lack of representative occurrence data. Only nine different countries submitted data to the GEMS/Food database and there was limited data for several food categories. However, in the JECFA83 evaluation, a dietary exposure assessment was carried out for those WHO regions for which data on consumption and contamination were available (using the GEMS/Food occurrence database and GEMS/Food cluster diets, respectively). The worst-case scenario was found in Africa (C13), with a mean exposure of 16 ng/kg bw per day, considering only one food commodity (sorghum).
35. Sorghum flour samples submitted to the GEMS/Food database came mostly from Burkina Faso, Ethiopia, Mali and Sudan, countries belonging to cluster C13. Thus, there was representative data for this food commodity for the region with higher consumption of sorghum-based products.
36. The effect of establishing a hypothetical ML for sorghum flour was evaluated for cluster C13 and is shown on Table 17. The implementation of the highest ML proposed (30 µg/kg), would reduce STC intake in that cluster by 87%, with 4.4% of samples being withdrawn from the market.

Table 17. Effect of the implementation of hypothetical MLs on STC intake through the consumption of sorghum flour for cluster C13 (highest consumption pattern).

ML (µg/kg)	Level (µg/kg)	Intake (ng/kg bw per day)	Intake reduction (%)	Sample rejection (%)
No limits	9.0	11.4	-	-
30	1.2	1.5	87.0	4.4
25	1.0	1.2	89.1	5.1
20	0.8	1.0	91.1	5.9
10	0.4	0.5	95.2	8.5
5	0.2	0.2	97.9	11.7

Sorghum, flour (white flour and whole meal flour); C13= 75.99 g/person (mean consumption).

Annex I of Appendix II**DATA ON AFS IN CEREALS AND CEREAL PRODUCTS****Table 1** - GEMS/Food data on the occurrence and concentrations of Afs in different types of cereals and cereal products (before grouping into the categories used in this discussion paper).

Food category	Number and proportion of positive samples	Mean of positive samples - µg/kg (range)	Mean of all samples (lower bound) (µg/kg) ^a
Barley	58/1151 (5.0)	1.4 (0.09-14.8)	0.07
Barley products	1/21 (4.8)	0.3	0.01
Bread and other cooked products	532/3687 (14.4)	0.9 (0.01-26.7)	0.13
Buckwheat	31/458 (6.8)	4.0 (0.1-49.7)	0.27
Buckwheat products	21/228 (9.2)	0.8 (0.05-6.7)	0.08
Cereal and cereal-based products	501/3171 (15.8)	3.3 (0.05-206.4)	0.52
Food for infants and small children	93/2455 (3.8)	0.3 (0.004-4.7)	0.01
Maize	509/2494 (20.4)	9.6 (0.1-319.6)	1.95
Maize products	845/4406 (19.2)	11.2 (0.02-743.6)	2.15
Millet	14/142 (9.9)	1.3 (0.08-15.0)	0.13
Millet products	2/27 (7.4)	0.5 (0.2-0.8)	0.04
Oat	0/238	ND	ND
Oat products	115/1274 (9.0)	0.5 (0.05-6.1)	0.04
Quinoa	0/32	ND	ND
Quinoa products	0/14	ND	ND
Rice	1520/6500 (23.4)	3.7 (0.002-347.0)	0.87
Rice products	311/1219 (25.5)	0.9 (0.04-23.9)	0.23
Rye	6/271 (2.2)	0.3 (0.2-0.5)	0.01
Rye products	8/272 (2.9)	0.6 (0.14-1.1)	0.02
Snacks	2/15 (13.3)	0.3 (0.16-0.44)	0.04
Sorghum	10/115 (8.7)	4.7 (0.07-12.0)	0.41
Sorghum products	117/1536 (7.6)	55.4 (3.0-1092)	4.22
Spelt	0/385	ND	ND
Spelt products	0/146	ND	ND
Wheat	349/3658 (9.5)	1.5 (0.05-3.3)	0.14
Wheat products	292/4026 (7.3)	1.6 (0.05-95.5)	0.12
Total	5337/37941 (14.1)	5.7 (0.002-1092)	0.8

ND = not detected.

Table 2 - GEMS/Food data on the occurrence and concentrations of STC in different types of cereals and cereal products (before grouping into the categories used in this discussion paper).

Food category	Number and proportion of positive samples (%)	Mean of positive samples - µg/kg (range)	Mean of all samples (lower bound) (µg/kg)^a
Barley	1/55 (1.8)	1.9	0.03
Barley products	0/8	ND	ND
Bread and other cooked products	9/994 (0.9)	1.6 (0.5-4.0)	0.01
Buckwheat	0/16	ND	ND
Buckwheat products	2/17 (11.8)	5.6 (2.4-8.8)	0.66
Cereal products	5/125 (4.0)	2.0 (0.8-4.6)	0.08
Food for infants and small children	18/553 (3.3)	3.2 (0.5-10.4)	0.1
Maize	1/26 (3.8)	0.6	0.02
Maize products	0/215	ND	ND
Millet and its products	0/13	ND	ND
Oat	8/104 (7.7)	5.2 (0.6-33)	0.4
Oat products	10/173 (5.8)	3.9 (0.4-17.6)	0.22
Quinoa	0/25	ND	ND
Quinoa products	0/10	ND	ND
Rice	29/191 (15.2)	1.6 (0.5-5.5)	0.24
Rice products	4/113 (3.5)	0.9 (0.6-1.9)	0.03
Rye	1/29 (3.4)	0.7	0.03
Rye products	1/58 (1.7)	3.7	0.06
Snacks	3/9 (33.3)	1.1 (1.1)	0.37
Sorghum flour	246/1536 (16.0)	56 (2.5-1189)	9.0
Spelt and its products	0/31	ND	ND
Wheat	2/117 (1.7)	0.7 (0.6-0.8)	0.01
Wheat products	7/816 (0.9)	1.5 (0.7-4.0)	0.01
Total	347/5234 (6.6)	40.4 (0.4-1189)	2.7

ND = not detected.

Annex II of Appendix II
GEMS/FOOD CONSUMPTION DATA

Table 1a. Consumption data obtained from the GEMS/Food Cluster Diets - C01 to C08 (g/person/day).

Food category	C01	C02	C03	C04	C05	C06	C07	C08
Barley and barley-based products	19.9	31.2	5.0	3.1	9.8	4.3	36.2	53.5
Buckwheat	NC	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Cereal and cereal-based products	484.3	464.6	262.4	486.8	469.6	614.0	345.6	386.2
Maize and maize-based products	29.8	44.8	108.9	52.4	60.3	75.7	18.5	26.2
Millet and millet-based products	1.5	2.3	5.8	0.9	16.2	0.1	0.1	0.2
Oat and oat-based products	0.1	7.0	0.1	1.7	1.0	0.1	7.5	6.3
Rice	45.3	14.7	84.9	111.1	194.1	93.1	19.7	15.5
Rice products	0.3	0.3	0.1	0.6	0.7	0.2	1.0	0.4
Rye and rye-based products	0.1	19.4	0.1	0.1	0.1	2.1	3.2	35.4
Sorghum and sorghum-based products	4.3	0.1	16.2	15.8	11.0	2.9	NC	NC
Sorghum, flour (white flour and wholemeal flour)	3.9	NC	11.6	14.2	9.9	2.6	NC	NC
Wheat and wheat-based products	381.1	341.5	38.3	281.9	172.8	434.1	253.1	244.7

NC = no consumption data available.

Table 1b. Consumption data obtained from the GEMS/Food Cluster Diets - C09 to C17 (g/person/day).

Food category	C09	C10	C11	C12	C13	C14	C15	C16	C17
Barley and barley-based products	9.4	35.2	46.7	15.9	11.6	2.3	46.7	3.7	16.3
Buckwheat	0.1	0.1	NC	NC	0.1	2.8	0.1	0.1	NC
Cereal and cereal-based products	514.3	402.7	295.3	360.0	407.0	417.0	402.8	195.3	263.3
Maize and maize-based products	26.0	40.0	7.4	64.6	116.7	10.5	38.5	76.6	34.4
Millet and millet-based products	1.7	0.7	NC	NC	61.1	0.8	NC	33.5	NC
Oat and oat-based products	0.1	4.9	3.2	3.0	0.4	0.1	2.8	0.1	NC
Rice	338.6	74.8	16.6	86.0	52.5	285.2	18.4	19.7	75.1
Rice products	1.1	3.0	0.2	0.2	0.2	0.8	0.2	0.1	0.0
Rye and rye-based products	0.2	6.5	1.5	NC	0.1	0.1	13.9	0.1	0.9
Sorghum and sorghum-based products	1.4	1.1	NC	7.1	89.2	2.0	NC	35.4	NC
Sorghum, flour (white flour and wholemeal flour)	1.3	0.1	NC	NC	76.0	1.8	NC	19.8	NC
Wheat and wheat-based products	134.4	235.1	216.4	167.4	57.2	110.5	272.6	25.8	132.0

NC = no consumption data available.

REFERENCES

- ANVISA, 2011. Brazilian Sanitary Surveillance Agency: Resolução n° 7, de 18 de fevereiro de 2011.
- Codex Alimentarius Commission (CAC), 1995. Codex general standard for contaminants and toxins in food and feed – Codex Standard 193-1995. Available at: <http://tinyurl.com/mpkehpr>.
- Codex Alimentarius Commission (CAC), 2003. Code of practice for the prevention and reduction of mycotoxin contamination in cereals. CAC/RCP 51-2003. Adopted in 2003. Amendment: 2014, 2017. Revision: 2016. Available at: http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?Ink=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252Fstandards%252FCAC%2BRCP%2B51-2003%252FCXP_051e.pdf
- Codex Alimentarius Commission (CAC), 2016. Procedure Manual 21st ed– Joint FAO/WHO Food Standards Programme. Available at: <http://www.codexalimentarius.org>
- EC, 2006. Commission regulation (EC) No 1881/2006 of 19 December 2006 - Setting maximum levels for certain contaminants in foodstuffs. Official Journal of the European Union.
- EFSA, 2005. Opinion of the scientific committee on a request from EFSA related to a harmonized approach for risk assessment of substances which are both genotoxic and carcinogenic., vol. 282. The EFSA Journal, p. 31.
- EFSA, 2007. Opinion of the scientific panel on contaminants in the food chain on a request from the commission related to the potential increase of consumer health risk by a possible increase of the existing maximum levels for aflatoxins in almonds, hazelnuts and pistachios and derived products. The EFSA Journal, vol. 446, p. 127.
- FAO/WHO, 1998. Joint FAO/WHO Expert Committee on Food Additives - Evaluation of certain food additives and contaminants: forty-ninth report of the Joint FAO/WHO Expert Committee on Food Additives. vol. 40. WHO Food Additives Series, p. 73.
- FAO/WHO, 2005. Joint FAO/WHO Expert Committee on Food Additives - Evaluation of certain food contaminants: sixty-fourth report of the Joint FAO/WHO Expert Committee on Food Additives. vol. 930. WHO technical report series, Rome, Italy, p. 100.
- FAO/WHO, 2017. Joint FAO/WHO Expert Committee on Food Additives - Evaluation of certain food contaminants: eighty-third report of the Joint FAO/WHO Expert Committee on Food Additives. vol. 1002. WHO technical report series, Rome, Italy, p. 182.
- Food and Agriculture Organization of the United Nations (FAO), 2014. Mycotoxin Sampling Tool – User Guide. Available at: <http://tools.fstools.org/mycotoxins/Documents/UserGuide.pdf>
- Frisvad, J. C., and Samson, R. A., 2004, *Emericella venezuelensis*, a new species with stellate ascospores producing sterigmatocystin and aflatoxin B1, *System. Appl. Microbiol.* **27**:672-690
- Frisvad, J. C., Houbraken, J., and Samson, R. A., 1999, *Aspergillus* species and aflatoxin production: a reappraisal, in: *Food Microbiology and Food Safety into the Next Millennium*, A. C. J. Tuijtelaars, R. A. Samson, F. M. Rombouts and S. Notermans, eds, Foundation Food Micro '99, Zeist, Netherlands. pp. 125-126
- Frisvad, J.C., Thrane, U., Samson, R.A., Pitt, J.I., 2006. Important mycotoxins and the fungi which produce them. In: Hocking, A.D., Pitt, J.I., Samson, R.A., Thrane, U. (Eds.) *Advances in Experimental Medicine and Biology - Advances in Food mycology*, vol. 571. Springer Science + Business Media, New York.
- Miraglia, M., Marvin, H.J.P., Kleter, G.A., Battilani, P., Brera, C., Coni, E., Cubadda, F., Croci, L., De Santis, B., Dekkers, S., Filippi, L., Hutjes, R.W.A., Noordam, M.Y., Pisante, M., Piva, G., Prandini, A., Toti, L., van den Born, G.J., Vespermann, A., 2009. Climate change and food safety: An emerging issue with special focus on Europe. *Food and Chemical Toxicology* **47**, 1009-1021.
- Mol, H.G.J, Pietri, A., MacDonald, S.J., Anagnostopoulos, C., Spanjer, M. 2015. Survey on sterigmatocystin in food. EFSA supporting publication 2015: EN-774. 56 pp.
- Pitt, J. I., and Hocking, A. D., 1997, *Fungi and Food Spoilage*, 2nd edition, Blackie Academic and Professional, London.
- Pitt, J.I., Hocking, A.D., 2009. *Fungi and Food Spoilage*. Springer Science + Business Media, New York.
- Sanchis, V., Magan, N., 2004. Environmental conditions affecting mycotoxins. In: Magan, N., Olsen, M. (Eds.) *Mycotoxins in food - Detection and control*. Woodhead Publishing Limited, Cambridge, England, p. 471.
- Taniwaki, M.H. & Pitt, J.I. 2013. Mycotoxins. Chapter 23. p. 597-618. In: *Food Microbiology: Fundamentals and Frontiers*. Doyle, M.P. & Buchanan, R.L. eds. 4th ed. ASM Press: Washington, D.C. doi: 10.1128/9781555818463.ch23.
- USFDA, 2000. U.S. Food and Drug Administration - Guidance for Industry: Action levels for poisonous or deleterious substances in human food and animal feed.

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