CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda Item 9 **CRD25**

May 2022

ORIGINAL LANGUAGE ONLY

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON CONTAMINANTS IN FOODS

15th Session
Virtual
9-13 and 24 May 2022

MAXIMUM LEVELS FOR TOTAL AFLATOXINS IN CERTAIN CEREALS AND CEREAL-BASED PRODUCTS INCLUDING FOODS FOR INFANTS AND YOUNG CHILDREN AND ASSOCIATED SAMPLING PLANS (At Step 4)

(Prepared by Brazil as Chair of the EWG)

BACKGROUND

1. CCCF14 (2021) agreed that Brazil, with the assistance of India, should keep working on the proposal of Maximum Levels for Total Aflatoxins in Certain Cereals and Cereal-Based Products Including Food For Infants and Young Children and Associated Sampling Plans.
2. Maximum levels for total aflatoxins in maize grain (destined for further processing), flour, meal, semolina and flakes derived from maize, husked rice, polished rice, sorghum grain (destined for further processing) and cereal-based food for infants and young children were proposed in CX/CF 22/15/9 (Appendix I).
3. Comments received in response to CL 2022/18-CF can be found in CX/CF 22/15/9-Add.1, CRD 11, CRD 12, CRD 18, CRD 19 and CRD 20. In general, there was support for the establishment of lower MLs than those proposed in the document. Therefore, this CRD was elaborated to discuss the points raised in the comments as well as to suggest a proposal that could accommodate those suggestions.

KEY POINTS

4. Most comments received in response to CL 2022/18-CF showed that countries were willing to consider lower limits for most of the categories since in some cases rejection rates did not reach 5% for the limits proposed in CX/CF 22/15/9.
5. It is important to state that in CCCF14 (2021) the Committee decided that the EWG should also take into account year-to-year and regional variations of data submitted and also to consider whether the MLs proposed would influence the ability of food aid programs to purchase and provide food to vulnerable populations.
6. Limits proposed in in CX/CF 22/15/9 (Appendix I) were chosen taking into account the intake reduction and the rejection rate (up to 5%). Considering cereals are staple food worldwide, the limits of the proposal were selected considering the value that contributed to a great intake reduction, while withdrawn the minimal % of samples from the market, also bearing in mind food security. Therefore, in some cases, the proposed limits were not indicated as the P95 for the overall data, because it was also considered the rejection rates of samples submitted for individual countries and the year-to-year variation (CCCF14 recommendations).

CONCLUSIONS

7. Data presented in CX/CF 22/15/9 showed that the establishment of even the highest MLs could greatly reduce aflatoxins exposure at an international level.
8. Considering CCCF aim to finalize the MLs for total aflatoxins maize grain (destined for further processing), flour, meal, semolina and flakes derived from maize, husked rice, polished rice, sorghum grain (destined for further processing) and cereal-based food for infants and young children at CCCF15, Brazil prepared this proposal to be discussed in the plenary. The proposal considers both CCCF14 recommendations and comments received by members countries and observers in response to CL 2022/18-CF.
9. The proposed MLs for the selected food categories can be found in Appendix I and the rationale used to reach this proposal in Appendix II.

APPENDIX I

(For comments)

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

Food category	ML	Sample rejection (%)
Maize grain, destined for further processing[a,b]	20 µg/kg	4.7
Flour, meal, semolina and flakes derived from maize[c]	10 µg/kg	1.7
Husked rice[c]	20 µg/kg	2.7
Polished rice[c]	5 µg/kg	0.8
Sorghum grain, destined for further processing[a]	10 µg/kg	1.9
Cereal-based Food for infants and young children[c,d]	5 µg/kg	4.9

[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] Does not apply to maize destined for animal feed; [c] Limits proposed on an "as is" basis [d] All cereal-based foods intended for infants (up to 12 months) and young children (12 to 36 months).

APPENDIX II

(For information)

Maize grain destined for further processing

1. The limit proposed in CX/CF22/15/9 for this food category was 30 µg/kg and only a few countries supported that value. Most countries supported lower values, such as 20 and 10 µg/kg. A ML of 10 µg/kg for maize grain destined for further processing was not considered appropriate since it would remove 7.1% of samples submitted to the GEMS/Food database.

2. To accommodate some countries' requests for lower MLs, a limit of 15 µg/kg was also evaluated, as show in Table 1. A ML of 15 µg/kg would reduce the intake in 92.5% (like a ML of 20 µg/kg – 89.7%) and would reject 5.7% of samples submitted to the GEMS/Food database. Looking into year-to-year variation and regional distribution (Table 2), its possible to observe that a ML of 15 µg/kg would reject up to 40% of samples submitted in 2021, while a ML of 20 µg/kg would reject a maximum of 20.7% (2021). Even though high rejection rates were observed in a few years and regions, the Committee should consider that cereal grains that eventually does not meet the MLs may have other destination such as raw material for animal feed.

3. Considering CCCF recommendation to investigate year-to-year variation and geographic distribution, and also aiming a consensus at CCCF15, the EWG suggests the adoption of a ML of 20 µg/kg for maize grain destined for further processing (a reduction of at least 50% of AFs content is achievable after cleaning, sorting and milling, as shown in Appendix III)

Table 1. Effect of hypothetical MLs on aflatoxins intake through the consumption of maize grain for Cluster G06 (highest consumption pattern).

ML (µg/kg)	Mean lower bound AF (µg/kg)	Intake (ng/kg bw per day)[a]	Intake reduction (%)	Sample rejection (%)[b]
No limits	6.236	1.2815	-	-
40	1.030	0.2117	83.5	3.4
30	0.904	0.1859	85.5	3.7
20	0.643	0.1321	89.7	4.7
15	0.4685	0.0963	92.5	5.7
10	0.280	0.0576	95.5	7.1
5	0.058	0.0119	99.1	9.8
2.5	0.001	0.0001	100	10.6

[a]Consumption data used: maize, raw; G06=12.33 g/person (mean consumption) (see Annex II). [b]Percentage of samples above proposed MLs for AFs considering data submitted by all member countries for this food category.

Table 2. Rejection rates (%) estimated for MLs under consideration for aflatoxins in maize grain destined for further processing*.

GEMS/Food data (Country/Region/year)[a]	ML (µg/kg)				
	40	30	20	15	10
African Union	12.5	12.5	18.8	25.0	25.0
Philippines	0.0	0.0	0.0	0.0	14.3
Rwanda	10.2	13.5	20.5	37.3	88.1
USA	3.3	3.7	4.6	5.5	6.6
2011	6.5	6.9	8.2	9.0	10.2
2012	12.5	13.6	17.4	19.6	22.3
2013	3.1	3.7	4.9	7.0	9.3
2020	9.1	12.0	18.3	33.1	77.9
2021	10.6	13.8	20.7	39.9	96.8

*Only contains rejection rates estimated for country/region/year that exceed 5%; [a]Country or region that submitted the data to GEMS/Food; this may not be the country of origin of the food in question.

Flour, meal, semolina and flakes derived from maize

4. The ML proposed in CX/CF22/15/9 for this category was 20 µg/kg. Most countries that did not supported the ML proposed, suggested the adoption of a ML of 10 µg/kg. A few countries suggested even lower MLs, such as 5, 4 or 2.5 µg/kg. A ML of 5 µg/kg, or even lower, was not considered suitable since the rejection rate in Phillipines, Singapore and USA would exceed 5%, being 33.3%, 7.5% and 7.8%, respectively (ML = 5 µg/kg). The same would happen with samples analysed in 2021 (6.9%). Even though higher rejection rates were considered for maize grain while analysing year-to-year and regional variations, a more conservative approach should be taken for flour, meal, semolina and flakes derived from maize, since for processed products withdrawn from the market, its destination would be challenging if they are not suitable for human consumption.

5. When comparing the MLs of 20 µg/kg and 10 µg/kg, the first limit would reduce the intake in 84.9% while the second one would reduce in 90.3 %. Estimated rejection rates would be lower than 5% for both limits (1.0% and 1.7%, respectively). However, when considering year-to-year and regional variation, a ML of 10 µg/kg could be considered since only one country (Singapore, 6.3%) and one year (2021, 5.7%) had rejection rates above 5%.

6. Appendix III summarizes papers that studied the fate of aflatoxins during processing. They showed that sorting, cleaning and milling process can greatly reduce aflatoxins contamination. Therefore, this reduction of aflatoxin content achieved during processing also supports the establishment of a ML of 10 µg/kg for flour, meal, semolina and flakes derived from maize, since a reduction of 50% in AFs content for maize destined for further processing (ML = 20 µg/kg) could be achieved with sorting, cleaning and milling process.

Table 3. Rejection rates (%) estimated for MLs under consideration for aflatoxins in flour, meal, semolina and flakes derived from maize*.

GEMS/Food data (Country/Region/year)[a]	ML (µg/kg)		
	20	**10**	**5**
Philippines	0.0	0.0	33.3
Singapore	5.1	6.3	7.5
USA	2.8	5.0	7.8
2012	0.9	2.7	4.9
2021	2.3	5.7	6.9

*Only contains rejection rates estimated for country/region/year that exceed 5%; [a]Country or region that submitted the data to GEMS/Food; this may not be the country of origin of the food in question.

Husked rice

7. The ML proposed in CX/CF22/15/9 for this category was 25 µg/kg. Most countries that did not support the ML proposed, suggested the adoption of a ML of 20 µg/kg or even a lower value such as 10 µg/kg. A ML of 10µg/kg was not considered adequate since it would reject 24.1% of samples submitted by Mali, 6.0 % from Thailand, 6.8 % from USA, besides from 7.0% samples collected in 2011, 10.0% in 2018 and 7.4% in 2019 (Table 4). A compromise for a ML of 20 µg/kg seems to be suitable, since it would exceed 5% rejection rate for Mali (10.3%) and in samples analysed in 2018 (6.3%) only.

Table 4. Rejection rates (%) estimated for MLs under consideration for aflatoxins in husked rice*.

GEMS/Food data (Country/Region/year)[a]	ML (µg/kg)		
	25	**20**	**10**
Mali	3.4	10.3	24.1
Thailand	3.7	3.7	6.0
USA	3.9	4.9	6.8
2011	0.8	2.3	7.0
2018	5.0	6.3	10.0
2019	5.3	5.3	7.4

*Only contains rejection rates estimated for country/region/year that exceed 5%; [a]Country or region that submitted the data to GEMS/Food; this may not be the country of origin of the food in question.

Polished rice

8. For polished rice the ML proposed in CX/CF22/15/9 received general support (5 µg/kg), therefore, the EWG maintains its recommendation for adoption. It is important to state that if the Committee agrees with the ML suggested, the rejection rate would not exceed 5% for any set of samples submitted to the GEMS/Food database.

9. Appendix III summarize a study that showed a reduction up to 90% from the initial concentration of AFs in the raw grain during the production of polished rice (after dehulling and whitening process), what also supports the establishment of a ML of 5 µg/kg while a ML of 20 µg/kg is being proposed for husked rice (reduction of 75%).

Sorghum

10. Although 98.6% of samples were submitted by The United States the EWG, African countries supported establishing a ML of 10 µg/kg. Considering that Africa is the primary consumer of sorghum as food, this ML is being proposed. Even though high rejection rate were observed in 2011, the Committee should consider that cereal grains that eventually does not meet the MLs may have other destination such as raw material for animal feed.

Table 5. Rejection rates (%) estimated for MLs under consideration for aflatoxins in sorghum*.

GEMS/Food data (Country/Region/year)[a]	**ML (µg/kg)**	
	15	**10**
India	0.0	54.5
2011	5.1	9.1
2021	0.0	21.4

*Only contains rejection rates estimated for country/region/year that exceed 5%; [a]Country or region that submitted the data to GEMS/Food; this may not be the country of origin of the food in question.

*Only contains rejection rates estimated for country/region/year that exceed 5%; [a]Country or region that submitted the data to GEMS/Food; this may not be the country of origin of the food in question.

Cereal-based food for infants and young children

11. The ML proposed in CX/CF22/15/9 for this category was 10 µg/kg. Most countries that did not supported the ML proposed suggested the adoption of a ML of 4 µg/kg or even a lower value such as 2 µg/kg. A ML of 2 µg/kg does not seem to be adequate as it excludes almost 60% samples submitted by Rwanda and 75% samples analysed in 2011 (Table 6). The same situation can be observed in samples presented by Food Aid (Table 7), a ML of 2 would withdraw 15.4% of samples purchased by food aid programs, and this rejection rate would reach 54.5% in samples analysed in 2017.

12. For the hypothetical MLs of 10 µg/kg, 5 µg/kg and 4 µg/kg, the intake reduction was 10.4 %, 14.6% and 20%, respectively. Between the limits of 5 µg/kg and 4 µg/kg, the rejection rates were similar both in the GEMS/Food dataset as well as in Food Aid data. The limit of 5 µg/kg is being suggested since, many countries have expressed concerns about the adoption of limits lower than 5 µg/kg for total aflatoxins, considering the performance criteria of methods of analysis that should also be established along with the ML.

Table 6. Rejection rates (%) estimated for MLs under consideration for aflatoxins in cereal-based food for infants and young children (data submitted to the GEMS/Food database)*.

GEMS/Food data (Country/Region/year)[a]	**ML (µg/kg)**			
	10	**5**	**4**	**2**
Rwanda	1.3	2.1	3.3	57.8
2011	0.0	0.0	0.0	74.5

*Only contains rejection rates estimated for country/region/year that exceed 5%; [a]Country or region that submitted the data to GEMS/Food; this may not be the country of origin of the food in question.

Table 7. Rejection rates (%) estimated for MLs under consideration for aflatoxins in cereal-based food for infants and young children (Food aid data)*.

Food Aid data (Region/year)	**ML (µg/kg)**			
	10	**5**	**4**	**2**
Africa	3.7	5.3	5.3	15.4
2017	36.4	54.5	54.5	54.5
2020	0.0	1.3	1.3	12.5
2021	12.2	14.6	14.6	43.9

*Only contains rejection rates estimated for country/region/year that exceed 5%.

APPENDIX III
(Summary of references)

1. The fate of aflatoxins during processing was reviewed in CX/CF 13/7/18. The main points reported at that time are resumed above and a few new references were also included.
2. AFs are relatively stable compounds that are not completely destroyed by most food processes, and therefore, cereal based foods ready for consumption may still be contaminated. Sorting, cleaning, milling and thermal processing (cooking, baking, roasting, flaking, extrusion) may reduce AFs content in food products.
3. Sorting and cleaning usually remove the contaminated parts of the cereals, lowering AF concentration. Johansson et al. (2006) demonstrated that AFs are concentrated in the poor-quality grade components of shelled corn. About 60% of AF mass was found in damage kernels (DM), broken kernels and foreign materials (BCFM), representing only 5% of total mass. This study also found a correlation (0.964) between AF mass in the combined DM and BCFM components with AF concentration in the lot, indicating its potential value as a screening method to predict AF in a bulk lot of corn.
4. Pearson et al. (2004) tested a high-speed dual-wavelength sorter for removing corn contaminated with AFs. Reduction in AF content reached 82% in samples of yellow corn with initial AF level higher than 10 µg/kg, and 38% in samples contaminated with less than 10 µg/kg. The same approach was applied in white corn, reducing 46% of the AF content in the first sorting and 88% after a re-sorting (Pearson et al., 2010).
5. Stasiewicz et al. (2017) evaluated the potential use of a low-cost, cost, multi-spectral sorter in identification and removal of aflatoxin- and fumonisin contaminated single kernels from a bulk of mature maize kernels. Reduction was statistically significant ($p < 0.001$), achieving an 83% mean reduction in each toxin evaluated.
6. The same occurs in the milling process, where AFs may be redistributed and concentrated in certain fractions. Siwela et al. (2005) showed that AF concentration in corn meal was reduced by approximately 92% after dehulling of corn grains.
7. Several studies investigated the distribution of AFs during the corn wet-milling process (CRA, 2011). These studies demonstrated that AFs are mostly found into the aqueous phase of the process, due to their relatively high solubility in the water fraction. Therefore, starch, the fraction commonly used for food, is essentially aflatoxin-free.
8. Park et al. (2018) investigated the distribution of twelve mycotoxins (aflatoxins B1, B2, G1, and G2; ochratoxin A; fumonisins B1 and B2; deoxynivalenol; nivalenol; zearalenone; T-2 toxin; and HT-2 toxin) in corn and corn by-products (corn bran, cornstarch, corn gluten, corn gluten feed, corn germ, light steep water, and corn steep liquor) produced by wet-milling in Korea. AFB1 was mainly carried over into corn gluten feed (65.0% of the total AFB1).
9. The distribution of AFs in dry-milled corn fractions was evaluated by Castells et al. (2008). The authors found higher levels of AFs in the outer layers of the kernels, while processed products from the inner parts of grain, such as corn meal and flaking grits, had decreased mycotoxin levels. Pietri et al. (2009) found reductions of 8.0% (from a 5 µg/kg contaminated corn lot) and 57.0% (from a 120 µg/kg lot) of AF levels after cleaning steps. The subsequent removal of bran and germ led to a further decrease in contamination levels in the products destined for human consumption. In both papers, the most contaminated parts were those usually intended for animal feed production.
10. To estimate the effect of the technological process on the distribution of aflatoxins and zearalenone throughout the milled fractions, two different corn lots (one conventional and one organic) processed in the described industrial plant were evaluated. A quantitative estimate of the fate of the two toxins from the raw grain to the end products leads to a reduction factor for aflatoxins of roughly four times and of roughly 10 times for zearalenone in conventional and organic lots. Conversely, for the byproducts such as germ, bran, and animal flour, where a concentration factor occurred, an increase of three times for aflatoxins and zearalenone was obtained as a minimum in the conventional lot; roughly eight times for aflatoxin B1 and four times for zearalenone in the organic lot (Brera et al., 2006)
11. Coradi et al. (2016) evaluated the distribution of aflatoxins and fumonisins in different corn fractions obtained by physical separation (size, density, screen and aspiration) from a dry milling, and in the feed processing steps using two different treatments (high and low levels of contaminated corn) for three conditional times in the pellet mill (30, 45 and 60 s) in a temperature con-trolled setting at 82 C, and in the final feed. The distributions of aflatoxin and fumonisin levels were inversely proportional to the results of density. The coarse, the fine screen and aspiration represented 54.44% of all contamination of aflatoxins. The authors concluded that physical separation of corn is a good alternative to reduce the aflatoxin and fumonisin distribution in dry milling.

12. Massarolo et al. (2022) compared the distribution of aflatoxins B1 and B2, and fumonisin B1 in corn fractions obtained by dry and wet milling. After the wet milling 68% and 58% of the aflatoxin B1 and B2, respectively, were quantified in the germ and 31% and 41% of these aflatoxins in the pericarp. After dry milling, aflatoxin B1 and B2 were detected in all fractions of the kernel. Regarding aflatoxin B1, 54.5% was quantified in the pericarp, 38% in the endosperm and only 6.7% in the germ. Dry and wet milling processing resulted in a concentration of both fumonisins and aflatoxins in pericarp and germen, which is widely used in the production of animal feeds

13. During the production of polished rice (after dehulling and whitening process), AF reduction of 92-97% from the initial concentration of the raw grain was observed by Castells et al. (2007). AFs were found throughout all fractions, but higher contamination levels were detected in hull and bran fractions.

14. Trucksess et al. (2011) evaluated the distribution of aflatoxins in rice milling fractions. Samples were milled into four fractions (hulls, brown rice, bran and white rice) and analysed for aflatoxins (B1, B2, G1 and G2) using a validated method. Brown rice contained 92.9% of the aflatoxins in paddy rice, whereas white rice contained only 27.9%.

15. Zhong et al (2015) also evaluated the distribution of aflatoxin B1, B2, G1 and G2 in various fraction of rice. The rough rice samples were dehulled and milled at three milling degrees (30, 45, and 60 s of millings). Milling rice samples for 60 s reduced the concentration of aflatoxin B1 5-fold and completely removed all the aflatoxin B2. Aflatoxins were found mostly in the rice bran, and were highly concentrated especially in the outer bran layers.

REFERENCES

- Johansson, A.S., Whitaker, T.B., Hagler, W.M., Bowman, D.T., Slate, A.B., Payne, G., 2006. Predicting aflatoxin and fumonisin in shelled corn lots sing poor-quality grade components. Journal of Aoac International 89.
- Pearson, T.C., Wicklow, D.T., Pasikatan, M.C., 2004. Reduction of aflatoxin and fumonisin contamination in yellow corn by high-speed dualwavelength sorting. Cereal Chemistry 81.
- Pearson, T.C., Wicklow, D.T., Brabec, D.L., 2010. Characteristics and sorting of white food corn contaminated with mycotoxins. Applied Engineering in Agriculture 26.
- Siwela, A.H., Siwela, M., Matindi, G., Dube, S., Nziramasanga, N., 2005. Decontamination of aflatoxin-contaminated maize by dehulling. Journal of the Science of Food and Agriculture 85.
- Castells, M., Ramos, A.J., Sanchis, V., Marin, S., 2007. Distribution of total aflatoxins in milled fractions of hulled rice. Journal of Agricultural and Food Chemistry 55.
- CRA, 2011. Corn Refiners Association–Mycotoxins. Food Safety Information papers, p.15.
- Castells, M., Marin, S., Sanchis, V., Ramos, A.J., 2008. Distribution of fumonisins and aflatoxins in corn fractions during industrial cornflake processing. International Journal of Food Microbiology 123.
- Pietri, A., Zanetti, M., Bertuzzi, T., 2009. Distribution of aflatoxins and fumonisins in dry-milled maize fractions. Food Additives and Contaminants Part a-Chemistry Analysis Control Exposure & Risk Assessment.
- Park, J.; Kim, D.-H.; Moon, J.-Y.; An, J.-A.; Kim, Y.-W.; Chung, S.-H.; Lee, C. Distribution Analysis of Twelve Mycotoxins in Corn and Corn-Derived Products by LC-MS/MS to Evaluate the Carry-Over Ratio during Wet-Milling. Toxins 2018, 10, 319. https://doi.org/10.3390/toxins10080319
- Coradi, P.C., Maier, D.E., Channaiah, L.H. and Campabadal, C. (2016), Mycotoxin levels in corn fractions and feeds. J Food Process Eng, 39: 215-225. https://doi-org.ez54.periodicos.capes.gov.br/10.1111/jfpe.12212
- Matthew J. Stasiewicz, Titilayo D.O. Falade, Murithi Mutuma, Samuel K. Mutiga, Jagger J.W. Harvey, Glen Fox, Tom C. Pearson, James W. Muthomi, Rebecca J. Nelson, Multi-spectral kernel sorting to reduce aflatoxins and fumonisins in Kenyan maize, Food Control, Volume 78, 2017, Pages 203-214, ISSN 0956-7135, https://doi.org/10.1016/j.foodcont.2017.02.038.
- BRERA, Carlo et al. Effect of industrial processing on the distribution of aflatoxins and zearalenone in corn-milling fractions. Journal of Agricultural and Food Chemistry, v. 54, n. 14, p. 5014-5019, 2006.
- Massarolo, K. C., Rodrigues, P., Ferreira, C. F. J., Kupski, L., & Badiale-Furlong, E. (2022). Simultaneous distribution of aflatoxins B1 and B2, and fumonisin B1 in corn fractions during dry and wet-milling. Journal of Food Science and Technology, 1-9.
- Zhong, H., Atungulu, G. G., Bench, B. J., Wilson, S., & Nguyen, V. T. (2015). Distribution of aflatoxin B1, B2, G1, and G2 in various fractions of rice. In 2015 ASABE Annual International Meeting (p. 1). American Society of Agricultural and Biological Engineers.