

CODEx ALIMENTARIUS COMMISSION



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ANALYSIS OF OCCURRENCE DATA OF AFLATOXINS IN CEREALS

(Prepared by the FAO/WHO JECFA Secretariat)

BACKGROUND

1. The 15th Session of the Codex Committee on Contaminants in Foods (CCCF15, 2022) finalized several maximum levels (MLs) for total aflatoxins in certain cereals and cereal-based products, including foods for infants and young children.¹
2. The 45th Session of the Codex Alimentarius Commission (CAC45, 2022) agreed with the final adoption of these MLs, however, because of the reservations expressed by Codex members on these MLs, the Commission requested CCCF to undertake a review of all the MLs for total aflatoxins for these products within three years, if Members submitted sufficient data through GEMS/Food, but in any event to undertake this review in no more than five years.²
3. The MLs for total aflatoxins in certain cereals and cereal-based products, including foods for infants and young children, were published in the *Codex General Standard for Contaminants in Food and Feed* (CXS 193-1995) and are reproduced in the Annex to this document for easy reference.
4. In addition, CAC46 (2023) noted the intention of the CCCF Chairperson to issue a letter that sets out an approach for the potential review of MLs for total aflatoxins in various cereal products as agreed by CAC45, subject to the availability of data; and that this approach would provide flexibility to consider proposals for additional MLs for which no Codex references were yet available.³
5. Following on this matter, at CCCF17 (2024), the Chairperson of the Committee clarified that a review of the MLs depended on the availability of data and that it was initially necessary to determine whether there was enough data to proceed. The Chairperson further noted that the Committee could request the Secretariat of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) to issue a call for data on the MLs for total aflatoxins in various cereals and cereal products agreed upon at CCCF15 and prepare an overview to facilitate a decision on a possible review of the MLs at CCCF18. The Chairperson concluded her intervention by explaining that if not enough data were available for a review of the MLs, the same process would be repeated after two years.
6. CCCF7 therefore agreed to request the JECFA Secretariat to issue a call for data to support the review of the MLs for total aflatoxins in various cereal products and prepare an overview to facilitate a decision at CCCF18 on a possible review of the MLs.⁴
7. On 31 July 2024, the JECFA Secretariat issued a call for data on total aflatoxins in cereals and cereal-based products, with a deadline for submitting data before 31 October 2024.

¹ REP22/CF15, paras. 113-155, Appendix VI, Part I

² REP22/CAC45, paras. 66-73, Appendix II

³ REP23/CAC46, para. 75

⁴ REP24/CF17, paras. 8 and 13 (v)

OCCURRENCE DATA

Data retrieved from the Global Environment Monitoring System

Food Contamination Monitoring and Assessment Programme (GEMS/Food database)

8. The JECFA Secretariat retrieved 8,196 results of aflatoxins occurrence from the GEMS/Food database, based on samples of cereals, reported as commodities rather than in their prepared form. The data submitted in the framework of the call represented 64% of the data used in this analysis. The samples included rice, polished (n=4425), rice, husked (n=340), maize (n=839), maize flour (n=718), wheat (n=794), wheat flour (n=475), barley (n=170), sorghum (n=145), rye (n=77), oats (n=63), millet (n=58), spelt (n=47), buckwheat (n=44), quinoa (n=1). The GEMS food categories with less than 200 samples were grouped into other cereals (n=605).
9. Sampling period ranged from 2014 to 2024. Submitted data on Aflatoxins included results from Kenya (n=3,887), USA (n=1,039), Thailand (n=920), EU (n=770), Saudi Arabia (n=530), Singapore (n=489), Canada (n=166), Indonesia (n=158), Japan (n=136), Mali (n=77), and Montenegro (n=14), with additional data from 16 other countries each contributing fewer than 10 results. The limits of detection (LOD) and quantification (LOQ) ranged from 0.001 to 1.12 µg/kg and 0.003 to 3.36 µg/kg, respectively. Aflatoxins were not detected (ND) in 92% of the samples.
10. The distribution of the total aflatoxins' contamination is described in **Table 1**. Noting the high proportion of ND, the data are presented according to two scenarios: lower-bound (LB), which uses an aflatoxins concentration of zero for non-detects, and LOD for non-quantified results, and upper-bound (UB), which uses an aflatoxins concentration equal to the LOD for non-detects, and the LOQ for non-quantified results.

Table 1: Distribution of total aflatoxins (AFT) in cereals

Cereal	GEMS Food Name	Data points	ND (%)	AFT concentration 5 th Percentile (µg/kg)		AFT concentration 50 th Percentile (µg/kg)		Mean AFT concentration (mg/kg)		AFT concentration 75 th Percentile (mg/kg)		AFT concentration 95 th Percentile (mg/kg)		AFT concentration 97.5 th Percentile (mg/kg)		Maximum AFT concentration (mg/kg)
				LB	UB	LB	UB	LB	UB	LB	UB	LB	UB	LB	UB	LB=UB
Rice	Rice, polished	4425	97	0.00	0.04	0.00	0.80	0.06	0.67	0.00	0.80	0.00	0.80	0.33	0.80	28.89
	Rice, husked	340	90	0.00	0.00	0.00	0.06	1.29	1.41	0.00	0.33	1.52	1.52	13.98	13.98	104.02
Maize	Maize	839	82	0.00	0.02	0.00	0.06	10.06	10.67	0.00	0.50	12.22	12.22	82.65	82.65	1600.00
	Maize flour	718	76	0.00	0.02	0.00	0.25	9.62	9.80	0.00	0.50	15.42	15.42	71.50	71.50	1281.15
Wheat	Wheat	794	93	0.00	0.10	0.00	0.80	0.10	0.86	0.00	1.00	0.80	1.00	1.09	2.60	9.86
	Wheat flour	475	94	0.00	0.02	0.00	0.05	1.34	1.63	0.00	0.80	0.05	1.00	0.87	1.24	520.00
Other Cereals	Barley, Buckwheat, Millet, Oats, Rye, Sorghum, Spelt and Quinoa	605	92	0.00	0.01	0.00	0.70	2.31	2.78	0.00	1.00	0.06	1.00	1.86	2.47	520.00
All	15 GEMS food names above	8196	92	0.00	0.03	0.00	0.80	2.22	2.71	0.00	0.80	0.70	1.00	2.39	2.60	1600.00

Legend:

ND: Non detected

AFT: Aflatoxins (total)

LB: lowerbound (uses zero for non detects and LOD for non quantified results)

UB: upper bound (uses LOD for non detects and LOQ for non quantified results)

11. **Table 1** shows that the distributions of aflatoxins concentrations in the sampled cereals are right-skewed (mean > median or 50th percentile). Except for maize, all cereals have both mean and 95th percentile aflatoxin concentrations below 5 µg/kg, which is the most stringent level currently set in CXS 193-1995 for cereal-based foods intended for infants and young children. This standard refers to the “*Whole commodity as sold; not reconstituted or otherwise prepared for consumption*”, as stated in the general standard.
12. **Table 1** indicates that the observed aflatoxin concentrations in husked rice are higher than in polished rice, wheat, and other cereals (excluding maize) under both lower and upper bound scenarios. Nonetheless, the 97.5th percentile of aflatoxins concentrations in husked rice at 14 µg/kg remains well below the current maximum level (20 µg/kg), with a mean of 1.4 µg/kg (UB), and a 95th percentile of 1.5 µg/kg. It is important to note the relatively limited number of data points (n=340) for husked rice.
13. **Table 1** presents the mean of aflatoxin concentrations in maize and maize flour. The aflatoxins concentration of 12-15 µg/kg at the high 95th percentile exceeds the current Codex ML of 10 µg/kg for flour, meal, semolina, and flakes, but aligns with the current ML of 15 µg/kg for Maize grain, destined for further processing. According to CXS 193-1995, “*Destined for further processing means intended to undergo an additional processing/treatment that has proven to reduce levels of AFs before being used as an ingredient in foodstuffs, otherwise processed or offered for human consumption.*”
14. The proportion of rejected samples based on existing and possible new MLs was calculated for the CCCF discussion. **Table 2** reflects the number of samples, which comply with a certain ML. The application of an ML of 5 µg/kg would imply a rejection rate of 0.25% (polished rice), 0.13% (wheat and wheat flour), and 2.3% (other cereals).
15. Applying the current Codex ML for husked rice (20 µg/kg) results in a rejection rate of 1.8%. This would rise to 2.4% if a stricter ML of 15 µg/kg were applied. Reducing the ML from 20 to 15 µg/kg would also lower the mean aflatoxins contamination of husked rice by 26%.
16. The data on aflatoxins in maize and in maize flour show very similar distribution patterns. Implementing an ML of 15 µg/kg would result in rejection rates of 4.5% for maize and 5.2% for maize flour, with a reduction in the mean aflatoxin concentration of 93%. A stricter ML of 10 µg/kg is projected to increase rejection rates of 5.5% for maize and 6.0% for maize flour, while further reducing the average contamination by 15-22%.

Table 2: Projection of rejection rates based on ML scenarios

Cereal	ML Scenario (µg/kg)	Data points	Mean AFT concentration (µg/kg)	High AFT concentration 95 th Percentile (µg/kg)	Rejection rate (%)
Maize flour	No ML	718	9.80	15.42	0
	ML: 15	681	0.69	2.84	5.2
	ML: 10 (CXS-193-1995)	675	0.59	2.39	6.0
Maize	No ML	839	10.25	12.22	0
	ML: 15 (CXS-193-1995)	801	0.54	1.74	4.5
	ML: 10	793	0.42	1.14	5.5
Polished rice	No ML	4425	0.67	0.80	0
	ML: 5 (CXS-193-1995)	4414	0.64	0.80	0.25
Husked rice	No ML	340	1.41	1.52	0
	ML: 20 (CXS-193-1995)	334	0.38	0.75	1.8
	ML: 15	332	0.28	0.70	2.4
Wheat	No ML	794	0.86	1.00	0
	ML: 5	793	0.85	1.00	0.13
Wheat flour	No ML	475	1.63	1.00	0
	ML: 5	469	0.33	1.00	0.13
Other cereals	No ML	605	2.78	1.00	0
	ML: 5	591	0.50	1.00	2.3

CONSUMPTION DATA

Consumption data of cereals from the GEMS/Food cluster diet

17. Cereals across 17 clusters covering the world a food availability of 288 g/day per capita, spanning from 137 g/d for cluster G16 up to 479 g/d in cluster G06. It is understood that this broad category does not reflect.

Table 3: Availability per capita of the cereals food group across GEMS/Food cluster diets

FOOD AVAILABILITY (g/day)	G01	G02	G03	G04	G05	G06	G07	G08	G09	G10	G11	G12	G13	G14	G15	G16	G17
Cereal grains & flours	372,4	337,8	205,9	355,3	358,4	479,2	216,7	245,0	391,9	260,7	183,6	247,0	330,5	321,3	262,3	136,8	182,9

FAO/Stat Food Supply Utilization Accounts

18. The food balance sheets per capita of the FAOSTAT for 2022 reflect the availability of food within countries. The percentiles are shown in Table 4.

Table 4: Distribution of national availability of cereals per capita

Availability (g/cap/d)	Maize	Rice	Wheat	Sorghum	Millet	Barley	Rye	Oats
Max	386	764	551	199	240	78	70	27
P95	222	504	490	125	62	37	28	16
P90	153	381	432	65	28	19	17	10
P75	73	201	360	13	4	9	2	6
Mean	54	141	302	19	12	9	5	5
P50	25	66	291	2	1	4	0.1	3
P5	0.1	10	176	0.0	0.0	0.7	0.0	0.5

Consumption data of cereals from the FAO/WHO Chronic Individual Food Consumption database (CIFOCoss)

19. Countries (46) have reported consumption of cereal in the CIFOCoss database. The data represented in **Table 5** are consumption for consumers only. The data do not reflect all the cereals consumed by the survey subjects, and exclude, for example, breads and noodles. The inclusion of foods prepared as consumed in CIFOCoss presents a challenge due to the dilution factor compared to the raw agricultural commodity.

In addition, the fact that adding up food categories using summary statistics would be incorrect, as the number of consumers varies from one food to another.

Table 5: Consumption of a selection of cereals from the CIFOCoss database

Consumption (g/d/person?)	Parameter	Maize flour	Rice grain	Wheat flour	Sorghum	Millet	Barley	Rye	Oats
Children	Mean	62	24	20	85	34	5	8	10
	Max	204	36	157	249	121	41	27	40
Adults	Mean	117	28	32	88	50	20	20	25
	Max	514	81	198	467	229	61	60	141

DIETARY EXPOSURE ESTIMATES

20. Mean aflatoxin concentrations under various ML scenarios were combined with per capita food availability, reflecting plausible consumption patterns. Diets were simulated by adding the average intake of all cereals except one, for which the 95th percentile intake was applied. This analysis focuses specifically on maize (**Table 6**) and rice (**Table 7**) as they are likely high contributors. Risk characterization followed the method proposed by JECFA 83 (2016), which considers the dose-response relationship for aflatoxin B1 (AFB1). Total aflatoxins were assumed to be equivalent to AFB1, acknowledging that some sources estimated AFB1 accounts for 80% of total aflatoxin occurrence due to potency as a genotoxic carcinogen. In the absence of an ML, estimated dietary exposure from cereals was 50 µg/kg bw/day in maize-rich diets and 31 ng/kg bw/day in diets essentially consisting of husked rice.

21. The assessment considers a morbidity factor to estimate the liver cancer risk associated with the dietary exposure to AFB1 expressed in ng/kg bw/d. A factor of 0.3 is applied to the fraction of the population exposed to the hepatitis B virus, and a factor of 0.01 is applied to the remainder of the population. This morbidity factor represents the number of additional liver cancer cases per 100,000 capita per year. The prevalence of [HBV Ag]⁺ varies across regions, as reported by the Global Burden of Disease collaborators (2022)⁵, with rates below 2% in high-income countries, Latin America and the Caribbean, Central Europe, Eastern Europe, and Central Asia, and above 6% in Southeast Asia, East Asia, Oceania, and Sub-Saharan Africa.
22. In settings where maize is the major staple, Case 1 (**Table 6**) reflects a scenario with no ML applied. The associated risk translates into a morbidity factor of 0.66 (high-income countries) to 1.60 (South-East Asia and Oceania) additional liver cancer cases per 100,000 capita per year. Case 2 assumes the implementation of an ML of 15 µg/kg for maize, 20 µg/kg for husked rice, and no ML for wheat and other cereals. This scenario results in a 72% reduction in dietary exposure and aflatoxin-related risk from cereals. Case 3 simulates a more stringent scenario, applying an ML of 10 µg/kg for maize, 15 µg/kg for husked rice, and 5 µg/kg for wheat and other cereals. Compared to Case 1, this leads to a 90% reduction in dietary exposure and risk, and 66% compared to Case 2.
23. In settings where rice is the primary staple, Case 4 (**Table 7**) reflects a scenario without application of MLs. The associated risk translates into an estimated morbidity of 0.41 (high-income countries) to 0.99 (South-East Asia and Oceania) additional liver cancer cases per 100,000 capita per year. Case 5 assumes the implementation of an ML of 15 µg/kg for maize and of 20 µg/kg for husked rice and no ML for wheat and other cereals. This scenario results in a 54% reduction in dietary exposure and aflatoxin-related risk from cereals. Case 6 presents a more stringent scenario, with MLs of 10 µg/kg for maize, 15 µg/kg for husked rice, and 5 µg/kg for wheat and other cereals. Compared to Case 4, this results in an 84% reduction in dietary exposure and risk from aflatoxins, and a 64% reduction compared to Case 5.

⁵ GBD Collaborators. *Lancet Gastroenterology and Hepatology* 2022; 7: 796–829

Table 6: Impact of different ML scenarios on dietary exposure to aflatoxins and risk, considering high maize consumption.

JECFA 83 methodology for AFB1		ML Scenario (µg/kg)	Rejection rate	Cereal consumption scenario	Cereal consumption (proxy from FAOSTAT Food Balance Sheets) (g/d)	AFT contamination scenario	AFT concentration (µg/kg)	Contributions to dietary exposure to AFT from cereal (ng/kg bw/d)	%	Hepatitis B prevalence, according to Lancet Gastroenterology & Hepatology 2022; 7: 796–830				
										Central Europe, Eastern Europe and Central Asia	High Income	Latin America and Caribbean	South East Asia and Oceania	Sub-Saharan Africa
										1,3	1,1	1,8	7,6	6,7
Case 1	Maize	No ML	0%	High (P95)	222	Mean	9,80	36,26	73%	Additional cases of liver cancer per 100 000 capita per year				
	Rice		0%	Mean	141	Mean	1,41	3,31	7%					
	Wheat		0%	Mean	302	Mean	1,63	8,20	16%					
	Other cereals		0%	Mean	46	Mean	2,78	2,13	4%					
	SUM					711	SUM		49,91	100%	0,69	0,66	0,76	1,60
Case 2	Maize	15	5,2%	High (P95)	222	Mean	0,69	2,55	19%	Additional cases of liver cancer per 100 000 capita per year				
	Rice	20	1,8%	Mean	141	Mean	0,38	0,89	6%					
	Wheat	No ML	0%	Mean	302	Mean	1,63	8,20	60%					
	Other cereals	No ML	0%	Mean	46	Mean	2,78	2,13	15%					
	SUM					711	SUM		13,78	100%	0,19	0,18	0,21	0,44
Case 3	Maize	10	6,0%	High (P95)	222	Mean	0,59	2,18	45%	Additional cases of liver cancer per 100 000 capita per year				
	Rice	15	2,4%	Mean	141	Mean	0,28	0,66	13%					
	Wheat	5	0,13%	Mean	302	Mean	0,33	1,66	34%					
	Other cereals	5	2,3%	Mean	46	Mean	0,50	0,38	8%					
	SUM					711	SUM		4,89	100%	0,07	0,06	0,07	0,16

Table 7: Impact of different ML scenarios on dietary exposure to aflatoxins and risk, considering high rice consumption.

JECFA 83 methodology for AFB1		ML Scenario (µg/kg)	Rejection rate	Cereal consumption scenario	Cereal consumption (proxy from FAOSTAT Food Balance Sheets) (g/d)	AFT contamination scenario	AFT concentration (µg/kg)	Contributions to dietary exposure to AFT from cereal (ng/kg bw/d)	%	Hepatitis B prevalence, according to Lancet Gastroenterology & Hepatology 2022; 7: 796–830				
										Central Europe, Eastern Europe and Central Asia	High Income	Latin America and Caribbean	South East Asia and Oceania	Sub-Saharan Africa
										1,3	1,1	1,8	7,6	6,7
Case 4	Maize	No ML	0%	Mean	54	Mean	9,80	8,82	28%	Additional cases of liver cancer per 100 000 capita per year				
	Rice		0%	High (P95)	504	Mean	1,41	11,84	38%					
	Wheat		0%	Mean	302	Mean	1,63	8,20	26%					
	Other cereals		0%	Mean	46	Mean	2,78	2,13	7%					
	SUM				906	SUM			31,00	100%	0,43	0,41	0,47	0,99
Case 5	Maize	15	5,2%	Mean	54	Mean	0,69	0,62	4%	Additional cases of liver cancer per 100 000 capita per year				
	Rice	20	1,8%	High (P95)	504	Mean	0,38	3,19	23%					
	Wheat	No ML	0%	Mean	302	Mean	1,63	8,20	58%					
	Other cereals	No ML	0%	Mean	46	Mean	2,78	2,13	15%					
	SUM				906	SUM			14,15	100%	0,19	0,19	0,22	0,45
Case 6	Maize	10	6,0%	Mean	54	Mean	0,59	0,53	11%	Additional cases of liver cancer per 100 000 capita per year				
	Rice	15	2,4%	High (P95)	504	Mean	0,28	2,35	48%					
	Wheat	5	0,13%	Mean	302	Mean	0,33	1,66	34%					
	Other cereals	5	2,3%	Mean	46	Mean	0,50	0,38	8%					
	SUM				906	SUM			4,93	100%	0,07	0,06	0,07	0,16

CONCLUSIONS

24. The JECFA Secretariat has arrived at the following conclusions:

- (i) The assessment highlights public health concerns in the absence of risk management measures. In particular, the reliance on maize in parts of Sub-Saharan Africa and on rice in South-East Asia and Oceania is associated with realistic estimates of approximately 1,500 and 1,000 additional liver cancer cases per 100 million people per year, respectively.
- (ii) The implementation of the current Codex ML for aflatoxins in maize (Case 2) and rice (Case 5) is expected to reduce risk by a factor of 3, with rejection rates of 5.2% for maize and 1.8% for rice.
- (iii) Approximately a nine-fold risk reduction could be achieved with stricter MLs: 10 µg/kg for maize (aligned with the current Codex ML for maize flour), 15 µg/kg for husked rice, and new MLs of 5 µg/kg for wheat and other cereals; projected rejection rates would be 6% for maize, 2.4% for husked rice, 0.13% for wheat, and 2.3% for other cereals.

RECOMMENDATIONS

25. Based on the assessment of the JECFA Secretariat, CCCF is invited to consider:

- (i) Whether there is a need to establish a specific ML for total aflatoxins in cereals, other than maize and rice, for example, of 5 µg/kg, as is currently the case for polished rice.
- (ii) Whether the current ML for husked rice (20 µg/kg) could be reduced to, for example, 15 µg/kg without jeopardizing the food supply and major trade interests.
- (iii) Whether further investigation of the evidence is required for consideration by CCCF18 (2025).

ANNEX

Commodity/ Product Name	Maximum Level (µg/kg)	Portion of the Commodity/Product to which the ML applies	Notes/Remarks
Maize grain, destined for further processing	15	Whole commodity	“Destined for further processing” means intended to undergo an additional processing/treatment that has proven to reduce levels 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. The ML does not apply to maize destined to animal feed or wet milling.
Flour, meal, semolina and flakes derived from maize	10	Whole commodity	
Husked rice	20	Whole commodity	
Polished rice	5	Whole commodity	
Sorghum grain, destined for further processing	10	Whole commodity	“Destined for further processing” means intended to undergo an additional processing/treatment that has proven to reduce levels 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.
Cereal-based foods for infants and young children	5	Whole commodity as sold; not reconstituted or otherwise prepared for consumption.	Relevant Codex commodity standard is CXS 74-1981. The ML applies to all cereal-based foods intended for infants (up to 12 months) and young children (12 to 36 months).
Cereal-based foods for infants and young children	10	Whole commodity as sold; not reconstituted or otherwise prepared for consumption.	Relevant Codex commodity standard is CXS 74-1981. The ML applies to cereal-based foods destined for food aid programs intended for infants (6 to 12 months) and young children (12 to 36 months).