CODEX ALIMENTARIUS COMMISSION

E

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 **CX/CF 23/16/9**

February 2023

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON CONTAMINANTS IN FOODS

16th Session

17-21 April 2023 (physical plenary meeting)

26 April 2023 (virtual report adoption)

MAXIMUM LEVELS FOR TOTAL AFLATOXINS AND OCHRATOXIN A IN NUTMEG, DRIED CHILI AND PAPRIKA, GINGER, PEPPER AND TURMERIC AND ASSOCIATED SAMPLING PLANS

(At Step 4)

(Prepared by the Electronic Working Group chaired by India)

Codex members and observers wishing to submit comments at Step 3 on the MLs and sampling plans should do so as instructed in CL 2023/24-CF available on the Codex webpage[1]

I. Background

1. During the 11th Session (April 2017) of the Committee on Contaminants in Foods (CCCF11, 2017), India submitted a new work proposal for the establishment of individual maximum levels (MLs) for total aflatoxins (AFT) and ochratoxin A (OTA) for five spices: nutmeg, chilli and paprika, ginger, pepper and turmeric. Based on this, the Committee agreed to start new work on MLs for AFT and OTA in nutmeg, chilli and paprika, ginger, pepper and turmeric through an Electronic Working Group (EWG) chaired by India. The 40th Session of the Codex Alimentarius Commission approved the new work.[2]

2. The work was suspended in 2018 to ensure implementation of the *Code of practice for the prevention and reduction of mycotoxins in spices* (CXC 17-2017) and to resume discussion in 3 years' time to reconsider the MLs based on new/additional data submitted to GEMS/Food Database. The Secretariat further recalled that the JECFA Secretariat would issue a call for data in 3 years' time to assist the work of the EWG following their re-establishment by CCCF.[3] This call for data was issued on 22nd July 2021 and sought data until 15th October 2021.

3. The EWG presented a paper suggesting possible MLs, which was discussed at CCCF15 (2022).

   CCCF noted that there was no consensus on a single ML for AFT in all spices and noted the following comments:

   - Delegations supporting a single ML noted that a much lower ML could be set and proposed an ML of 10 µg/kg.
   - The proposed ML for AFT could be divided into two groups, one for dried chilies and paprika, nutmeg and ginger at 20 µg/kg and another for dried pepper and turmeric at an ML lower than 20 µg/kg.
   - An ML of 20 µg/kg could be established noting that spices were consumed in low amounts and had a lesser impact on public health concerns, but its trade was significant and that a harmonized ML for AFT in spices (and also an ML for OTA) would prevent trade impediments.

[1] Codex webpage/Circular Letters: http://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/. Codex webpage/CCCF/Circular Letters: http://www.fao.org/fao-who-codexalimentarius/committees/committee/related-circular-letters/en/?committee=CCCF

[2] REP17/CF11, paras. 118-124

[3] REP18/CF12, paras. 116-119

- Further work was needed before a decision could be made and that a paper should be prepared for CCCF16 (2023) that includes a more elaborate data analysis and presentation thereof. In doing so, the following points should be clearly indicated:
    - which data were included or excluded,
    - whether the data were for ground or whole spices, and if possible, ground and whole spices should be examined separately;
    - the year-to-year variation by region; and
    - revised groupings could be proposed once the occurrence data were more carefully looked at and consideration should be given to whether MLs were needed for spices with very low rejection rates, such as turmeric and pepper.

CCCF15 considered the appropriateness of ISO 948 as proposed by the EWG. CCCF however noted that ISO 948 was not an appropriate sampling plan for the control of heterogeneously distributed contaminants, such as AFT and OTA and that the sampling plan had a number of shortcomings, e.g. it did not provide incremental sample size and size of the bulk aggregate sample, amongst others. CCCF noted an alternative proposal for a sampling plan addressing the shortcomings was presented in CRD16.

4. CCCF15 agreed[4]

I. To return the MLs and sampling plan to Step 2/3 for further consideration;

II. To re-establish the EWG chaired by India, working in English to prepare:

a. new proposals for MLs for AFT and OTA in spices: nutmeg, dried chili and paprika, ginger, pepper and turmeric; and

b. an associated sampling plan.

III. That the EWG should carefully consider all the data and prepare a paper that clearly presents a more elaborate data analysis, taking into account written comments submitted to and all comments made during this Session, in particular those in paragraphs 185 and 191 of REP22/CF15; and

Iç. To request the Codex Secretariat to issue a CL requesting comments on the sampling plan presented in CRD16 and information on other sampling plans for consideration by the EWG.

II. Objective

5. The main objective of the work is to facilitate fair practices in international food trade and to protect public health by harmonizing the MLs of mycotoxins, specifically AFs and OTA, in dried/dehydrated forms of black and white pepper, dried chili pepper and paprika, ginger, nutmeg, and turmeric. The MLs for various mycotoxins in spices vary widely across the world (Table 6) and the lack of harmonization affects global trade of spices. Some countries have regulations for mycotoxins specifying different tolerated levels for individual foods, while others have set only one tolerated level for instance for “all foods” which also include spices.

III. Relevance

6. Nutmeg (*Myristica fragrans*.), chilli and paprika (*Capsicum annuum L*.), ginger (*Zingiber officinale L.),* pepper *(Piper nigrum L.),* and turmeric *(Curcuma longa L.)* in dried or dehydrated forms are spices prominently produced and traded globally in both whole and ground forms. These spices are reported to have higher susceptibility towards mycotoxin contamination compared to other spices.

7. AFs were evaluated by JECFA at its 36th (1990), 46th (1996), 49th (1997), 56th (2001) and 68th (2007) meetings. Recently at its 83rd meeting in 2016 JECFA reaffirmed the conclusions of the 49th meeting of JECFA that AFs are among the most potent mutagenic and carcinogenic substances known, based on studies in test species and human epidemiological studies, Ochratoxin A (OTA) was evaluated by the JECFA at its 37th (1990), 44th (1995) and 56th (2001) meetings.

8. The hazardous nature of mycotoxins to humans and animals has necessitated the need for establishment of control measures and tolerance levels by national and international authorities. Many countries in the world have MLs for AFT and OTA in spices. But different regulations (MLs) for AFs in various countries are a potential impediment to the international trade.

[4] REP22/CF15, paras 181-193

IV. **Related Codex Standards for AFs and OTA in spices.**

9. There are no Codex MLs for mycotoxins in spices set by the Codex Alimentarius Commission (CAC). Relevant Codex Commodity Standards to which MLs would apply include CXS 326-2017 and CXS 343-2021. Code of Practice for the Prevention and Reduction of Mycotoxins in Spices (CXC 78-2017) was adopted in 2017.

V. **JECFA "summary and conclusions"**

10. In the JECFA83 report, it is mentioned that the high consumption of rice and wheat in some countries means that these cereals may account for up to 80% of dietary aflatoxin exposure for those GEMS/Food cluster diets. In the report, there is no mention about mycotoxins in spices.

VI. Occurrence and Consumption Data:

11. Data available in the GEMS/Food database

VII. Observation:

Based on Total Aflatoxins and Ochratoxin A data available GEMS/Food database during 2011-2021

12. It is observed that there were data submitted without limit of quantification (LOQ), such data were excluded from the data analysis.

13. Data for only total Aflatoxins and Ochratoxin A were considered.

14. Data with Values 0 and ND were summed together, since various limits of detection (LODs) were reported, and it is not possible to assign any value.

15. It is observed that

a. For total Aflatoxins, a total of 3385 data points Viz. 565 Pepper Chili, dried, 888 Nutmeg, 416 Ginger, 1443 Pepper (Black and White), and 73 Turmeric were available in GEMS/Food database excluding those that were mentioned in para 12 and 13 (Table 4a).

b. For Ochratoxin A, a total of 4379 data points Viz. 532 Pepper Chili, dried, 1342 Nutmeg, 485 Ginger, 1919 Pepper (Black and White), and 101 Turmeric (Table 4b) were available in GEMS/Food database excluding those that were mentioned in para 12 and 13 (Table 4b).

16. The range of Total Aflatoxins and Ochratoxin A reported in Spices- **Table 1**

Spices	Total Aflatoxin (µg/kg)	Ochratoxin A (µg/kg)
Black and White Pepper	0.03-24.04	0.44-910
Dried Chili Pepper	0.06-318.25	0.11 - 1770
Ginger	0.05 – 60	0.1 – 29
Nutmeg	0.03-310.45	0.1 -355
Turmeric	0.06 – 6.59	0.21 – 6.21

17. The data were analyzed for total data spice wise and spice forms/styles (Viz. Whole/Ground etc.) wise and percentage rejections were calculated by keeping hypothetical MLs (Table 4a and 4b).

18. Percentage rejections were noted to be higher for the Dried Chili Pepper and Nutmeg; however, for Ginger, Black and White Pepper and Turmeric the percentage rejections were lower.

19. The following regions and countries submitted the data for Total Aflatoxins and Ochratoxin A:

Eastern Mediterranean Region (Saudi Arabia, Iran), European Region, The Former Yugoslav Republic of Macedonia, South-East Asia Region (Thailand, Indonesia), Western Pacific region (New Zealand, Singapore), Region of the Americas (United States of America, Canada, Brazil).

Region wise Yearly Data of Total Aflatoxins: Table 2

Region	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	TOTAL
SEARO	0	0	0	30	185	135	36	71	178	117	127	**879**
WPRO	0	0	0	1	1	24	21	25	81	0	7	**160**
PAHO	0	0	0	0	4	59	29	25	18	2	3	**140**
EURO	357	214	151	191	230	310	324	201	96	98	0	**2172**
EMRO	0	0	0	0	0	0	0	0	0	17	0	**17**
CCNE	0	0	0	0	0	0	0	0	0	17	0	**17**
TOTAL	**357**	**214**	**151**	**222**	**420**	**528**	**410**	**322**	**373**	**251**	**137**	**3385**

SEAR: South-East Asia region; WPR: Western Pacific region; PAHO- Region of the Americas; EUR: Europe; EMR-Eastern Mediterranean Region; CCNE- Codex Committee Near-East

Region wise Yearly Data of Ochratoxin A: Table 3

Region	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	TOTAL
SEARO	0	0	30	0	185	96	5	17	138	91	7	**569**
WPRO	0	6	9	15	3	19	11	18	75	0	4	**160**
PAHO	0	0	38	157	185	47	4	17	66	26	3	**543**
EURO	491	267	234	177	429	387	437	292	170	217	0	**3101**
EMRO	0	0	0	0	0	0	0	0	0	3	0	**3**
CCNE	0	0	0	0	0	0	0	0	0	3	0	**3**
TOTAL	**491**	**273**	**311**	**349**	**802**	**549**	**457**	**344**	**449**	**340**	**14**	**4379**

SEAR: South-East Asia region; WPR: Western Pacific region; PAHO- Region of the Americas; EUR: Europe; EMR-Eastern Mediterranean Region; CCNE- Codex Committee Near-East

20. Data submitted region wise year wise shows that 64.2% of the data for Total Aflatoxins and 70.8% of the data for Ochratoxin A was from EURO region, rest of the data was received from SEARO, WPRO, PAOH, EMRO and CCNE regions. Data submitted by these regions are of global representation.

21. It is also noted that based on GEMS/Food cluster diets-the global average consumption of spices is 2.6 g/day which is very less as compared to tree nuts with an average consumption of 36.9 g/day (Table 5). The Codex MLs for Total Aflatoxin are set at 10 µg/kg for ready to eat tree nuts and 15 µg/kg for tree nuts destined for further processing. Since the consumption of spices is very low setting a higher MLs may not affect consumer health, however considering many spices are a high value commodity in international trade, a harmonized ML would ensure fair practices in trade as it is noted that there are different MLs set by various countries (Table 6).

VIII. Recommendations:

See Appendix I, Part I.

Table 4a. Expected Percentage rejection (%) for the Hypothetical Maximum Limit of Total Aflatoxin for certain spices

Hypothetical ML of Total Aflatoxin (µg/kg)	Expected percentage rejection, % (Number of samples)															
	Pepper (Black, White)			Pepper Chili, Dried				Ginger, Root			Nutmeg			Turmeric, Root		
	Whole	Powder/ Crushed/ Ground	Total	Whole	Powder/ Crushed/ Ground	Paprika	Total	Whole	Powder/ Crushed/ Ground	Total	Whole	Powder/ Crushed/ Ground	Total	Whole	Powder/ Crushed/ Ground	Total
0 (ND)	81.5	97.0	82.5	60.1	27.4	78.9	47.4	70.7	30.8	64.4	57.2	0.0	56.5	97.1	71.8	83.6
	(1093)	(98)	(1191)	(172)	(66)	(30)	(268)	(248)	(20)	(268)	(502)	(0)	(502)	(33)	(28)	(61)
0.01 - 4.99	17.1	3.0	16.1	23.8	49.4	21.1	34.5	16.2	61.5	23.3	31.2	60.0	31.5	2.9	25.6	15.1
	(229)	(3)	(232)	(68)	(119)	(8)	(195)	(57)	(40)	(97)	(274)	(6)	(280)	(1)	(10)	(11)
≥ 5	1.5	0.0	1.4	16.1	23.2	0.0	18.1	13.1	7.7	12.3	11.6	40.0	11.9	0.0	2.6	1.4
	(20)	(0)	(20)	(46)	(56)	(0)	(102)	(46)	(5)	(51)	(102)	(4)	(106)	(0)	(1)	(1)
≥ 10	0.5	0.0	0.5	11.2	10.8	0.0	10.3	5.7	7.7	6.0	7.0	30.0	7.2	0.0	0.0	0.0
	(7)	(0)	(7)	(32)	(26)	(0)	(58)	(20)	(5)	(25)	(61)	(3)	(64)	(0)	(0)	(0)
≥ 15	0.4	0.0	0.4	7.3	6.2	0.0	6.4	2.6	1.5	2.4	5.1	20.0	5.3	0.0	0.0	0.0
	(5)	(0)	(5)	(21)	(15)	(0)	(36)	(9)	(1)	(10)	(45)	(2)	(47)	(0)	(0)	(0)
≥ 20	0.2	0.0	0.1	5.6	4.2	0.0	4.6	2.0	0.0	1.7	4.0	20.0	4.2	0.0	0.0	0.0
	(2)	(0)	(2)	(16)	(10)	(0)	(26)	(7)	(0)	(7)	(35)	(2)	(37)	(0)	(0)	(0)
≥ 30	0.0	0.0	0.0	3.5	2.5	0.0	2.8	1.1	0.0	1.0	2.3	10.0	2.4	0.0	0.0	0.0
	(0)	(0)	(0)	(10)	(6)	(0)	(16)	(4)	(0)	(4)	(20)	(1)	(21)	(0)	(0)	(0)
Total number of samples	1342	101	1443	286	241	38	565	351	65	416	878	10	888	34	39	73

Table 4b. Expected Percentage rejection (%) for the Hypothetical Maximum Limit of Ochratoxin A for certain spices

Hypothetical ML of Total Ochratoxin A (µg/kg)	Expected percentage rejection, % (Number of samples)															
	Pepper (Black, White)			Pepper Chili, Dried				Ginger, Root			Nutmeg			Turmeric, Root		
	Whole	Powder/ Crushed/ Ground	Total	Whole	Powder/ Crushed/ Ground	Paprika	Total	Whole	Powder/ Crushed/ Ground	Total	Whole	Powder/ Crushed/ Ground	Total	Whole	Powder/ Crushed/ Ground	Total
0 (ND)	74.5	86.2	75.0	35.9	13.6	10.0	17.5	66.1	35.1	63.7	55.7	50.0	55.7	56.5	50.0	55.5
	(1365)	(75)	(1440)	(42)	(36)	(15)	(93)	(296)	(13)	(309)	(744)	(3)	(747)	(48)	(8)	(56)
0.01 - 4.99	21.3	10.3	20.8	23.9	43.4	16.0	31.6	26.8	48.7	28.5	31.2	0.0	31.1	40.0	50.0	41.6
	(391)	(9)	(400)	(28)	(115)	(25)	(168)	(120)	(18)	(138)	(417)	(0)	(417)	(34)	(8)	(42)
≥ 5	4.2	3.5	4.2	40.2	43.0	73.0	50.9	7.1	16.2	7.8	13.1	50.0	13.3	3.5	0.0	3.0
	(76)	(3)	(79)	(47)	(114)	(110)	(271)	(32)	(6)	(38)	(175)	(3)	(178)	(3)	(0)	(3)
≥ 10	1.2	1.2	1.2	29.1	24.5	54.0	33.8	1.8	2.7	1.9	8.0	50.0	8.2	0.0	0.0	0.0
	(22)	(1)	(23)	(34)	(65)	(81)	(180)	(8)	(1)	(9)	(107)	(3)	(110)	(0)	(0)	(0)
≥ 15	0.6	1.2	0.6	23.9	17.7	45.0	26.9	0.7	2.7	0.8	5.5	50.0	5.7	0.0	0.0	0.0
	(11)	(1)	(12)	(28)	(47)	(68)	(143)	(3)	(1)	(4)	(73)	(3)	(76)	(0)	(0)	(0)
≥ 20	0.5	1.2	0.5	18.0	13.2	36.0	20.7	0.2	2.7	0.4	4.4	50.0	4.6	0.0	0.0	0.0
	(9)	(1)	(10)	(21)	(35)	(54)	(110)	(1)	(1)	(2)	(59)	(3)	(62)	(0)	(0)	(0)
≥ 30	0.2	1.2	0.3	12.8	6.4	25.3	13.2	0.0	0.0	0.0	3.3	33.3	3.4	0.0	0.0	0.0
	(4)	(1)	(5)	(15)	(17)	(38)	(70)	(0)	(0)	(0)	(44)	(2)	(46)	(0)	(0)	(0)
Total number of samples	1832	87	1919	117	265	150	532	448	37	485	1336	6	1342	85	16	101

Table 5. Cluster diet of Spices and Tree nuts*

Lev1 CODE	Lev2 CODE	Lev2NAME	G01	G02	G03	G04	G05	G06	G07	G08	G09	G10	G11	G12	G13	G14	G15	G16	G17
			g/day	g/day	g/day	g/day	g/day	g/day	g/day	g/day	g/day	g/day	g/day	g/day	g/day	g/day	g/day	g/day	g/day
2	22	Tree nuts (excl. groundnut)	3.6	3.3	5.1	8.6	15.9	9.3	5.2	7.0	13.2	4.2	9.2	28.3	6.7	157.2	4.0	0.0	347.3
5	53	Spices & condiments	2.1	1.3	2.0	6.5	4.4	2.0	1.3	1.3	1.8	1.9	3.3	2.5	2.2	7.0	3.3	0.5	1.4

*Source: GEMS/ Food cluster diets- 2012

(https://www.who.int/data/gho/samples/food-cluster-diets)

Average Consumption of Spices & Condiments = 2.6 g/day

Average Consumption of Tree nuts = 36.9 g/day

G01, Afghanistan, Algeria, Azerbaijan, Iraq, Jordan, Libya, Mauritania, Mongolia, Morocco, Occupied Palestinian Territory, Pakistan, Syrian Arab Republic, Tunisia, Turkmenistan, Uzbekistan, Yemen

G02, Albania, Bosnia and Herzegovina, Georgia, Kazakhstan, Kyrgyzstan, Montenegro, Republic of Moldova, Ukraine

G03, Angola, Benin, Burundi, Cameroon, Congo, Côte d'Ivoire, Democratic Republic of the Congo, Ghana, Guinea, Liberia, Madagascar, Mozambique, Paraguay, Togo, Zambia

G04, Antigua and Barbuda, Bahamas, Barbados, Brunei Darussalam, French Polynesia, Grenada, Israel, Jamaica, Kuwait, Netherlands Antilles, Saint Kitts and Nevis, Saint Lucia, Saint Vincent and the Grenadines, Saudi Arabia, United Arab Emirates

G05, Argentina, Bolivia Plurinational State of , Brazil, Cape Verde, Chile, Colombia, Costa Rica, Djibouti, Dominican Republic, Ecuador, El Salvador, Guatemala, Guyana, Honduras, India, Malaysia, Maldives, Mauritius, Mexico, New Caledonia, Nicaragua, Panama, Peru, Seychelles, South Africa, Suriname, Tajikistan, The former Yugoslav Republic of Macedonia, Trinidad and Tobago, Venezuela Bolivarian Republic of

G06, Armenia, Cuba, Egypt, Greece, Iran Islamic Republic of , Lebanon, Turkey

G07, Australia, Bermuda, Finland, France, Iceland, Luxembourg, Norway, Switzerland, United Kingdom, Uruguay

G08, Austria, Germany, Poland, Spain

G09, Bangladesh, Cambodia, China, Democratic People's Republic of Korea, Guinea Bissau, Indonesia, Lao People's Democratic Republic, Myanmar, Nepal, Philippines, Sierra Leone, Thailand, Timor Leste, Viet Nam

G10, Belarus, Bulgaria, Canada, Croatia, Cyprus, Estonia, Italy, Japan, Latvia, Malta, New Zealand, Republic of Korea, Russian Federation, United States of America

G11, Belgium, Netherlands

G12, Belize, Dominica

G14, Comoros, Fiji Islands, Kiribati, Papua New Guinea, Solomon Islands, Sri Lanka, Vanuatu

G13, Ethiopia, Erythrea, South Sudan, Botswana, Burkina Faso, Central African Republic, Chad, Ethiopia PDR, Gambia, Haiti, Kenya, Malawi, Mali, Namibia, Niger, Nigeria, Senegal, Somalia, Sudan, Swaziland, United Republic of Tanzania, Zimbabwe

G16, Gabon, Rwanda, Uganda

G17, Samoa, Sao Tome and Principe

G15, Serbia, Czech Republic, Denmark, Hungary, Ireland, Lithuania, Portugal, Romania, Serbia and Montenegro, Slovakia, Slovenia, Sweden

Table 6: Maximum levels of Total Aflatoxins and Ochratoxins A set by some countries for spices/all food products

Sl. No.	Country/ Organization	Product	Aflatoxin Total (µg/kg)	Ochratoxin A (µg/kg)
1	Armenia	All foods		10
2	Barbados	All foods	20	
3	Brazil	Spices	20	30
4	Bulgaria	Spices	5	
5	Chile	Spices	10	
6	Colombia	All foods	10	
7	Cuba	All Foods	5	
8	European Union	Spices*	10	15a
				20b
9	Finland	All Spices	10	
10	Honduras	All Food Stuffs	1	
11	Hong Kong (SAR of China)	All Food Stuffs	15	
12	Iceland	Spices	10	15
13	India	All Spices	30	
14	Indonesia	Spices powder	20	
15	Iran (Islamic Republic of)	Spices	10	
16	Jamaica	Food and Grains	20	
17	Japan	All Foods	10	
18	Liechtenstein	Spices	10	
19	Malaysia	Other foods not specified, including spices	5	
20	Mauritius	All foods	10	
21	Norway	Spices	10	
22	Pakistan	Chilli	30	
23	Salvador	All foods	20	
24	Singapore	All foods except food for infants or young children	5	
25	South Africa	All food stuffs	10	
26	Sri Lanka	All foods	30	
27	Switzerland	Spices excluding Nutmeg	10	20
		Nutmeg	20	
28	Thailand	All foods	20	
29	Turkey	Spices	10	
30	USA	All food except milk	20	
31	Uruguay	All foods and spices	20	
32	Vietnam	All foods	10	

Spices*: Capsicum spp. (dried fruits thereof, whole or ground, including chillies, chilli powder, cayenne and paprika); Piper spp. (fruits thereof, including white and black pepper); Myristica fragrans (nutmeg); Zingiber officinale (ginger);

Curcuma longa, based on Commission Regulation (EC) No 2174/2003. a - Spices mentioned in footnote*, except from Capsicum spp. (Ref: Commission Regulation (EC) No 2015/1137) b - Spices mentioned in footnote* from dried fruits of Capsicum spp. (Ref: Commission Regulation (EC) No 2015/1137

Source: Worldwide regulations for mycotoxins in food and feed in 2003 (FAO); Pakistan Standard and Quality Control Authority (PSQCA) standard # PS: 1742- 2010;, Agri-Food and Veterinary Authority of Singapore; Commission Regulation (EU) No 105/2010 of 5 February 2010 amending Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs as regards Ochrwww.ava.gov.sgatoxin A: www.anvisa.gov.br; The National Agency on Drugs and Food Control, Republic of Indonesia: # HK. 00.06.1.52.4011-2009. Chilean Sanitary Food Regulation http://web.minsal.cl/sites/default/files/files/DECRETO_977_96%20actualizado%20a%20Enero%202015(1).pdf

APPENDIX I

PARTI I: MAXIMUM LEVELS

(For comments)

Total Aflatoxins

Proposed MLs for:

1. Dried Chili Pepper and Nutmeg: 20 µg/kg
2. Ginger, Black & White pepper and Turmeric: Since majority of the samples are reported ND and percentage of rejections are also not a major concern; it is redundant to fix any MLs for these spices.

Ochratoxin A

Proposed MLs for:

3. Dried Chili Pepper and Nutmeg: 20 µg/kg
4. Ginger, Black & White Pepper and Turmeric Since majority of the samples are reported ND and percentage of rejections are also not a major concern; it is redundant to fix any MLs for these spices.

APPENDIX I

PART II: SAMPLING PLAN

(For comments)

A) Spices with large particle size

In case of large lots and on condition that the sublot can be separated physically, each lot shall be subdivided into sublots following table 1. Taking into account that the weight of the lot is not always an exact multiple of the weight of the sublots, the weight of the sublot may exceed the mentioned weight by a maximum of 20 %.

Table 1

Subdivision of lots into sublots depending on product and lot weight

Commodity	Lot weight (tonne)	Weight or number of sublots	No incremental samples	Aggregate sample weight (kg)
spices with large particle size	≥ 500	100 tonnes	100	20
	> 125 and < 500	5 sublots	100	20
	≥ 15 and ≤ 125	25 tonnes	100	20
	< 15	—	10-100 (*)	≤ 20
(*) Depending on the lot weight — see table 2.				

Each sub-lot shall be sampled separately

Number of incremental samples: 100

Weight of the aggregate sample = 20 kg which shall be mixed and to be divided into two equal laboratory samples of 10 kg before grinding.

Each laboratory sample of 10 kg shall be separately ground finely and mixed thoroughly to achieve complete homogenisation

(*) The number of incremental samples of 100 g to be taken depends on the weight of the lot, with a minimum of 10 and a maximum of 100.

The figures in the following table 2 may be used to determine the number of incremental samples to be taken and the subsequent division of the aggregate sample.

Table 2

Number of incremental samples to be taken depending on the weight of the lot and number of subdivisions of the aggregate sample

Lot weight (tonnes)	No of incremental samples	Aggregate sample weight (kg)	No of laboratory samples from aggregate sample
≤ 0.1	10	2	1 (no division)
> 0.1 – ≤ 0.2	15	3	1 (no division)
> 0.2 – ≤ 0.5	20	4	1 (no division)
> 0.5 – ≤ 1.0	30	6	1 (no division)
> 1.0 – ≤ 2.0	40	8 (- < 12 kg)	1 (no division)
> 2.0 – ≤ 5.0	60	12	2
> 5.0 – ≤ 10.0	80	16	2
> 10.0 – ≤ 15.0	100	20	2

No of incremental samples

Weight of the aggregate sample = 20 kg which shall be mixed and if necessary divided into two equal laboratory samples of 10 kg before grinding

In cases where the aggregate sample weights are less than 20 kg, the aggregate sample shall be divided into laboratory samples according to following guidance:

< 12 kg: no division into laboratory samples;

> 12 kg division into two laboratory samples.

Each laboratory sample shall be separately ground finely and mixed thoroughly to achieve complete homogenisation

Decision rule: If the aflatoxin test result is less than or equal to the ML in both test samples, then accept the lot.

Otherwise reject the lot.

B) Spices with small particle size

In the case of large lots and on condition that the sublot can be separated physically, each lot shall be subdivided into sublots following Table 3. Taking into account that the weight of the lot is not always an exact multiple of the weight of the sublots, the weight of the sublot may exceed the mentioned weight by a maximum of 20 %.

Table 3

In case of large lots, subdivision of lots into sublots depending on product and lot weight

Commodity	Lot weight (tonnes)	Weight or number of sublots	Number of incremental samples	Aggregate sample weight (kg)
Spices	≥ 15	25 tonnes	100	10
	< 15	—	5-100 (*)	0,5-10
(*) Depending on the lot weight — see Table 4				

Each sublot shall be sampled separately.

Number of incremental samples: 100. Weight of the aggregate sample = 10 kg.

(*) For lots of spices less than 15 tonnes the sampling plan shall be used with 5 to 100 incremental samples, depending on the lot weight, resulting in an aggregate sample of 0,5 to 10 kg.

The figures in the following Table 4 can be used to determine the number of incremental samples to be taken.

Table 4

Number of incremental samples to be taken depending on the weight of the lot of spices

Lot weight (tonnes)	Number of incremental samples	Aggregate sample weight (kg)
≤ 0.01	5	0.5
> 0.01-≤ 0.1	10	1
> 0.1-≤ 0.2	15	1.5
> 0.2-≤ 0,5	20	2
> 0,5-≤ 1.0	30	3
> 1.0-≤ 2.0	40	4
> 2.0-≤ 5.0	60	6
> 5.0-≤ 10.0	80	8
> 10.0-≤ 15.0	100	10

C. Powdered spices

In the case of large lots and on condition that the sublot can be separated physically, each lot shall be subdivided into sublots following Table 5. Taking into account that the weight of the lot is not always an exact multiple of the weight of the sublots, the weight of the sublot may exceed the mentioned weight by a maximum of 20 %.

Table 5

Subdivision of lots into sublots depending on lot weight

Commodity	Lot weight (tonnes)	Weight or number of sublots	Number of incremental samples	Aggregate sample Weight (kg)
Powdered spices	≥ 15	25 tonnes	50	2
	< 15	—	3 – 50 (*)	0.1 – 2.0
(*) Depending on the lot weight — see Table 6				

- each sublot shall be sampled separately

- number of incremental samples: 50. Weight of the aggregate sample: 2 kg

(*) For lots of powdered spices less than 15 tonnes the sampling plan shall be used with 3 to 50 incremental samples, depending on the lot weight, resulting in an aggregate sample of 0,1 to 2.0 kg.

The figures in the following Table 6 can be used to determine the number of incremental samples to be taken.

Table 6

Minimum number of incremental samples to be taken depending on the weight of the lot of powdered spices

Lot weight (tonnes)	Minimum number of incremental samples	Minimum aggregate sample weight (kg)
≤ 0.1	3	0.1
> 0.1 - ≤ 0.5	10	0.4
> 0.5 - ≤ 5.0	25	1.0
> 5.0 - ≤ 10.0	35	1.4
> 10.0 - ≤ 15.0	50	2.0

APPENDIX II

Comments in reply to CL 2022/45-CF

(For information)

Original Language Only

GENERAL AND SPECIFIC COMMENTS

MEMBER/OBSERVER - COMMENT
Brazil Brazil thanks you for the excellent work and informs you that it has no additional comments om the proposal.
Canada The sampling plan proposed appears to be identical to that presented by the EU in CF15/CRD16 for spices, and takes into consideration similar factors as sampling plans for mycotoxins in other commodities (e.g. heterogeneity, sample size). However, Canada questions whether the proposed sample weights of 20 kg for large-particle spices and 10 kg for small-particle spices could pose a problem for sampling and sample preparation (e.g. homogenization), as 10 kg or 20 kg of spices, whether fresh or ground, would occupy orders of magnitude greater volume than other commodities (e.g. grain or nut products). Furthermore, Canada questions whether the comparatively higher cost of spices per kg relative to that of grain would result in large costs to the importer/manufacturer and whether there is potential that this could become a trade impediment. Canada recommends that when the draft discussion document is being circulated, the eWG discuss whether a smaller sample weight might be more appropriate or practical. Canada is not a significant producer of the spices under consideration for ML elaboration, but should other member countries have data on sampling variability and heterogeneity of mycotoxin contamination specific to spices that would inform an appropriate sampling weight, this information may be useful to discuss at the eWG.
Egypt Egypt appreciates the approach taken by EWG on the document. In this regard, we would like to inform you that ; Egypt agrees on the document with the following general recommendation : Take into consideration what is mentioned in codex standard no. 193/1995 (Rev.2019) " General Standard for Contaminants and Toxins in Food and Feed" , and provide the method with introduction , definition , incremental sample selection , static lot , and dynamic lot , ...etc. which are related to spices as same as to what is stated for the rest of the commodities stipulated in the aforementioned standard
European Union The European Union (EU) wishes to make the following comments on the proposed sampling plan: The EU is indeed of the opinion that ISO 948 – Spices and Condiments – Sampling is not an appropriate sampling plan for the control of aflatoxins and ochratoxin A in spices as mentioned in §1 of CL 2022 /45 – CF, given that it does not provide for -sampling provisions traded in bulk. -incremental sample size and size of the bulk (aggregate) sample. -a distinction in sampling provisions for spices with larger particle size (e.g. nutmeg) and spices with low particle size (e.g. spices in powder) -it is not appropriate for sampling of spices with large particle size with heterogeneous contamination of total aflatoxins and ochratoxin A. The EU has no comments and agrees to the proposed alternative sampling plan attached as Annex to CL 2022/45-CF. Given that the heterogeneity of contamination with aflatoxins and ochratoxin A in spices with small particle size is lower than in spices with larger particle size, it is indeed appropriate to propose a lighter sampling procedure for spices with small particle size than for spices with larger particle size. The fine grinding of spices into powder will also further homogenize the contamination by aflatoxins and ochratoxin A and therefore, in addition to the sampling procedure for spices with large particle size and the sampling procedure for spices with small particle size, the following lighter sampling procedure for powdered spices could be considered: **C. Powdered spices** In the case of large lots and on condition that the sublot can be separated physically, each lot shall be subdivided into sublots following Table 5. Taking into account that the weight of the lot is not always an exact multiple of the weight of the sublots, the weight of the sublot may exceed the mentioned weight by a maximum of 20 %.

MEMBER/OBSERVER - COMMENT

Table 5

Subdivision of lots into sublots depending on lot weight

Commodity	Lot weight (tonnes)	Weight or number of sublots	Number of incremental samples	Aggregate sample Weight (kg)
Powdered spices	≥ 15	25 tonnes	50	2
	< 15	—	3 – 50 (*)	0,1 – 2.0
(*) Depending on the lot weight — see Table 6				

- each sublot shall be sampled separately

- number of incremental samples: 50. Weight of the aggregate sample: 2 kg

(*) For lots of powdered spices less than 15 tonnes the sampling plan shall be used with 3 to 50 incremental samples, depending on the lot weight, resulting in an aggregate sample of 0,1 to 2.0 kg.

The figures in the following Table 6 can be used to determine the number of incremental samples to be taken.

Table 6

Minimum number of incremental samples to be taken depending on the weight of the lot of powdered spices

Lot weight (tonnes)	Minimum number of incremental samples	Minimum aggregate sample weight (kg)
≤ 0,1	3	0,1
> 0,1 - ≤ 0,5	10	0.4
> 0.5 - ≤ 5,0	25	1.0
> 5,0 - ≤ 10,0	35	1.4
> 10,0 - ≤ 15,0	50	2.0

Peru

El Perú desea agradecer a la Secretaría de la Comisión del Codex Alimentarius, Programa Conjunto FAO/OMS sobre Normas Alimentarias, respecto a la Solicitud de observaciones e/o informaciones sobre planes de muestreo: Niveles máximos para el total de aflatoxinas y de ocratoxina A en las especias.

De acuerdo a la reunión del CCCF en el que se acordó que se necesita más trabajo para desarrollar un plan de muestreo que también debe tener en cuenta el NM a establecer, el Perú considera que se debe realizar una adecuación del plan de muestreo que forma parte del anexo de la CL, así como determinar los puntos que deben tenerse en cuenta que pueden mejorar este plan de muestreo para garantizar la adecuación de los NM sobre AFT y OTA en especias.

Republic of Korea

It is appropriate to set sampling plan depending on the particle size, therefore it is necessary to clarify the criteria for each particle size(ex, range of large/small size)

Saudi Arabia

The Kingdom of Saudi Arabia respectfully submit the following comments on Request for comments and/or information on sampling plans: Maximum levels for total aflatoxins and ochratoxin A in spices

When estimating mycotoxin contents in foods, sample variance is typically the major source of inaccuracy. To figure out how safe mycotoxins are, sampling plans is needed to give values that are close enough to the true levels of contamination in different batches or lot of products. Food and feed have a skewed or uneven distribution of mycotoxin concentrations, which makes it very hard to obtain a sample that accurately shows the mean batch concentration. The sampling plans may depend on the kind of mycotoxin being analysed and the kind of food. In general, the sampling variance decreases when sample size increases.

The attached sampling plan is appropriate and we have the following point to be taking into account by EWG:

-We recommended to provide information or data on the variation in sampling for spices.
- We suggested weight of the test portion need to be mentioned in sample plan

MEMBER/OBSERVER - COMMENT
Unites States of America The United States appreciates the opportunity to provide comments in response to CL 2022/45-CF, which requests comments on a) the appropriateness of the sampling proposed sampling plan for AFT and OTA in spices, b) points that need to be taken into account that can improve the sampling plan to ensure appropriateness for MLs on AFT and OTA in spices, c) to provide information on other sampling plans. The proposed sampling plan described in CL 2022/45-CF appears to be similar to Codex sampling plans for aflatoxin contamination in ready-to-eat tree nuts and tree nuts destined for further processing (General Standard for Contaminants and Toxins in Food and Feed, CXS 193-1995, as amended in 2019, page 34), as well as the European Union sampling plan for mycotoxins in spices (European Commission Regulation No 401/2006). While a potentially useful resource, this sampling plan will be challenging to implement if importing countries require exporting countries to sample and test for total aflatoxins according to this plan before exporting large lots of spices. The plan proposes 80 increments for all lots between 5 and 10 tons. For similar lots of tree nuts, CXS 193-1995 recommends 50 incremental samples. In addition, for lots greater than 15 tons, various numbers of sublots are provided. Both the number and size of the increments as well as the sublot provisions may make this sampling plan impractical to implement by exporters. The sample schedule used by FDA for mycotoxins in foods (including spices) can be found at the following link: https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/investigations-operations-manual Investigations Operations Manual | FDA, Sample Schedule 6, page 4-104. Other comments: • Replace commas with periods to indicate decimal points. • Clarify the meaning of 8 (-< 12 kg). • Provide examples of large and small particle size spices.

APPENDIX III

List of Participants

EWG Chair
Dr. Dinesh Singh Bisht, Scientist C
Quality Evaluation Laboratory,
Spices Board (Ministry of Commerce & Industry, Govt. of India)
India

BELGIUM

Frans Verstraete
European Commission
Directorate General for Health and Food Safety

CANADA

Ian Richard
Scientific Evaluator
Food Contaminants Section
Bureau of Chemical Safety, Health Canada

Elizabeth Elliott
Scientific Evaluator
Food Contaminants Section
Bureau of Chemical Safety, Health Canada

CHINA

Yongning Wu
Professor, Chief Scientist
NHC Key Laboratory of Food Safety Risk Assessment
China National Center of Food Safety Risk Assessment (CFSA)

Yi Shao
Associate Professor
Division II of Food Safety Standards
China National Center of Food Safety Risk Assessment (CFSA)

Shuang Zhou
Professor
NHC Key Laboratory of Food Safety Risk Assessment
China National Center for Food Safety Risk Assessment (CFSA)

INDIA

Perumal Karthikeyan
Joint Director
Science and Standards Division
Food Safety and Standards Authority of India

Ratish Ramanan K
Technical Officer
Science and Standards Division
Food Safety and Standards Authority of India

Alok Dhawan
Director
Centre of Bio-Medical Research (CBMR)

Ramachandra Koodli Subbarao
Ex-Principal Scientist
ICAR – National Institute of Animal Nutrition and Physiology

Sandeep Sharma
Senior Scientist
CSIR – Indian Institute of Toxicology Research

Vakdevi Validandi
ICMR – National Institute of Nutrition

Shashi Prakash Tripathi
Technical Officer
Export Inspection Council

Wasi Asghar
Assistant Director (Technical)
Export Inspection Council

Kannan B
AM - Regulatory Affairs
ITC Limited

Ganesh Ramamurthi
COO
NCML

Prashant Bagade
Head – R & D
NCML

Ritika
Research Associate
FICCI

Varsha Yadav
Research Associate
FICCI

IRAN

Mansooreh Mazaheri
Ph.D. of Biophysics
Director of Applied Research and Technology
Iran Secretariat of CCCF
Standard Research Institute

JAPAN

Naofumi Iizuka
Deputy Director
Ministry of Health, Labour and Welfare

Mr. Tomoaki Miura
Associate Director
Ministry of Agriculture, Forestry and Fisheries

MEXICO
Tania Daniela Fosado Soriano
Punto de Contacto CODEX México
Secretaría de Economía

NETHERLANDS
Weiluan Chen
RIVM

NEW ZEALAND
Jeane Nicolas
Senior Adviser Toxicology
Ministry for Primary Industries

Fiapaipai Auapaau (Ruth)
Adviser Risk Assessment
Ministry for Primary Industries

REPUBLIC OF KOREA
Yeon Ju Kim
Codex researcher
Ministry of Food and Drug Safety

SINGAPORE
Joachim Chua
Specialist Team Lead (Foodborne and Natural Toxins)
Singapore Food Agency

Wilson Toh Ghim Hon
Scientist
Singapore Food Agency

SOUTH AFRICA
Juliet
Medical Biological Scientist
Department of Health

THAILAND
Chutiwan Jatupornpong
Standards officer
Office of Standard Development
National Bureau of Agricultural Commodity and Food Standards

Nisachol Pluemjai
Standards officer
Office of Standard Development
National Bureau of Agricultural Commodity and Food Standards

UNITED KINGDOM
Craig Jones
Senior Policy Advisor
Food Standards Agency

Holly Howell-Jones
Policy Advisor
Food Standards Agency

UNITED STATES OF AMERICA
Anthony Adeuya
Chemist
FDA

Lauren Posnick Robin
Branch Chief
FDA

Quynh-Anh Nguyen
Consumer Safety Office
FDA

International Organization of Spice Trade Associations (IOSTA)
Shannen Kelly
Senior Manager
Regulatory and Scientific Affairs
American Spice Trade Association