

CODEX COMMITTEE ON CONTAMINANTS IN FOOD

15th Session

Agenda Item 11

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)

(CL 2022/20-CF and CX/CF 22/15/11)

European Union Competence **European Union Vote**

The European Union (EU) welcomes and appreciates the work done by India to prepare the document CX/CF 22/15/11 related to the proposed draft maximum levels for total aflatoxins and ochratoxin A in nutmeg, dried chili and paprika, ginger, pepper and turmeric and associated sampling plans.

The EU wishes to make the following comments as regards the proposed maximum levels and the proposed sampling plan.

BACKGROUND

Aflatoxins are genotoxic and carcinogenic substances. The Joint FAO/WHO Expert Committee on Food Additives (JECFA) updated the aflatoxin risk assessment at its 83rd meeting in November 2016¹.

JECFA reaffirmed the conclusions of previous assessment that aflatoxins are among the most potent mutagenic and carcinogenic substances known and that the reduction of dietary total aflatoxin exposure is an important public health goal. The Committee recommends that efforts continue to reduce aflatoxin exposure using valid intervention strategies, including the development of effective, sustainable and universally applicable pre-harvest prevention strategies.

¹ Eighty-third meeting of the Joint FAO/WHO Expert Committee on Food Additives Rome, 8–17 November 2016. WHO Food Additives Series: 74 – Safety evaluation of certain contaminants in food. <http://apps.who.int/iris/bitstream/handle/10665/276868/9789241660747-eng.pdf?ua=1>

The European Food Safety Authority (EFSA) has recently performed a comprehensive risk assessment of aflatoxins in food². The CONTAM Panel noted that the calculated Margins of Exposure MOEs are less than 10,000, which raises a health concern. The estimated cancer risks in humans following exposure to AFB1 are in-line with the conclusion drawn from the animal data. This conclusion also applies to AFM1 and AFT + AFM1.

JECFA³ concluded that the mechanism by which ochratoxin A causes carcinogenicity is unknown, although both genotoxic and non-genotoxic modes of action have been proposed. The Committee retained the previously established PTWI of 100 ng/kg bw per week, pending the results of on-going studies on the mechanisms of nephrotoxicity and carcinogenicity.

In 2020, the European Food Safety Authority (EFSA) adopted an update of the scientific opinion on ochratoxin A in food⁴. The CONTAM Panel considered that it was not appropriate to establish a health based guidance value for ochratoxin A and that the Tolerable Weekly Intake of 120 ng/kg body weight (bw) as established by the Authority in 2006 is consequently no longer valid. It further concluded that the calculated margins of exposure for carcinogenic effects of ochratoxin A indicate a possible health concern for certain consumer groups.

COMMENTS ON THE PROPOSED MAXIMUM LEVELS AND SAMPLING PLANS

1. Aflatoxin Total

The EU is in principle in favour of setting a single maximum level for all the considered spices but cannot agree on the proposed ML of 20 µg/kg.

Only very low rejection rates are observed with a hypothetical maximum level of 10 µg/kg for total aflatoxins for pepper and turmeric and also with a hypothetical maximum level of 5 µg/kg low acceptable rejection rates are observed. Therefore the EU can support the maximum level of 10 µg/kg for aflatoxin total for pepper and turmeric.

As regards dried chillies, nutmeg and ginger, hypothetical maximum levels lower than 20 µg/kg, do not increase significantly the rejection rate. Given the health concern related to the presence of aflatoxins in food, a maximum level of 20 µg/kg for dried chillies, nutmeg and ginger is not acceptable. The EU proposes a maximum level of 10 µg/kg.

² EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), Schrenk D, Bignami M, Bodin L, Chipman JK, del Mazo J, Grasl-Kraupp B, Hogstrand C, Hoogenboom LR, Leblanc J-C, Nebbia CS, Nielsen E, Ntzani E, Petersen A, Sand S, Schwerdtle T, Vleminckx C, Marko D, Oswald IP, Piersma A, Routledge M, Schlatter J, Baert K, Gergelova P and Wallace H, 2020. Scientific opinion – Risk assessment of aflatoxins in food. EFSA Journal 2020;18(3):6040, 112 pp. <https://doi.org/10.2903/j.efsa.2020.6040>

³ Fifty-sixth meeting of the Joint FAO/WHO Expert Committee on Food Additives Rome, 2001 . WHO Food Additives Series: 47. <https://inchem.org/documents/jecfa/jecmono/v47je04.htm>

⁴ Scientific Opinion on the risk assessment of ochratoxin A in food. EFSA Journal 2020; 18(5):6113, 150 pp. <https://doi.org/10.2903/j.efsa.2020.6113>.

2. Ochratoxin A

For dried chillies the EU can agree on a maximum level of 20 µg/kg for ochratoxin A.

For nutmeg, ginger, pepper and turmeric a hypothetical maximum levels of ochratoxin A lower than 20 µg/kg, e.g. 15 µg/kg, do not increase significantly the rejection rate. Given the health concern related to the presence of ochratoxin A in food, a maximum level of 15 µg/kg for nutmeg, ginger, pepper and turmeric is proposed.

3. Sampling Plans

The EU is 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 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.

An alternative sampling plan, addressing the abovementioned shortcomings of the sampling provisions in the ISO standard 948, is presented in Annex for consideration.

ANNEX

A) Spices with large particle size

In case of large lots and on condition that the subplot 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 subplot 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 subplot 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

- 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 subplot 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 subplot 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 subplot 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