CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Items 7, 8, 11, 13, 16 **CRD16**

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ORIGINAL LANGUAGE ONLY

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON CONTAMINANTS IN FOODS

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Comments of European Union

Agenda Item 7: CX/CF 22/15/7

Request for comments at step 3 on maximum levels for lead in certain food categories.
(Codex Circular Letter CL 2022/16-CF)

European Union Competence
European Union Vote

The European Union (EU) welcomes and appreciates the work on the maximum levels (MLs) for lead by the electronic Working Group chaired by Brazil.

In general, the EU considers that the MLs for lead should be lowered wherever possible. A rejection rate of 5% is a good target for proposing MLs, however for each commodity also particular specificities as regards consumer groups, consumption volumes, possible mitigation measures and the available data, should be considered.

The EU believes that MLs should be established on the basis of data sets, from which clear outliers were removed, which has not yet been done, because CCCF hasn't agreed yet on a procedure to do so. A distribution of the concentrations per commodity or commodity group should be provided to allow to identify whether the proposed ML is driven by outliers or not.

As regards the proposed MLs for the individual commodities, the EU would like to present the following position:

For **eggs** the EU considers that in view of the lower concentration of lead in chicken eggs, compared to duck eggs, and in view of the higher consumption of chicken eggs, it would be appropriate to set separate MLs for chicken eggs and duck eggs.

- For **chicken eggs**, taking into account the occurrence data for the global data set, there is margin to set an ML of 0.05 mg/kg, which is closer to a 5% rejection rate. LOQs for lead of 0.02 mg/kg (2/5 of the ML), which are required according to the Codex Alimentarius Procedural Manual, are sufficiently achievable to allow the establishment of such ML.
- For **duck eggs**, taking into account the occurrence data for the global data set, there is margin to set a lower ML of 0.15 mg/kg, which is closer to a 5% rejection rate.

For **culinary herbs,** the EU prefers to establish separate MLs for the dried herbs and the fresh herbs.

- For **fresh culinary herbs**, the EU has data available, which indicate that for specific herbs such as oregano and thyme the proposed ML of 0.25 mg/kg would be too low (25 samples of fresh oregano P95 0.6 mg/kg – 18 samples of fresh thyme P95 0.6 mg/kg). Taking into account the EU data and because thyme and oregano are just like rosemary culinary herbs with a lower moisture content, the EU would support an ML of 0.5 mg/kg for fresh rosemary, fresh thyme and fresh oregano. The EU could support an ML of 0.25 mg/kg for fresh culinary herbs except rosemary, thyme and oregano.
- For **dried culinary herbs**, the EU can support the proposed ML of 2.0 mg/kg.

For **dried floral part spices (cloves, excluding saffron),** the EU considers that at the moment insufficient data are available to establish an ML. It also needs to be checked whether the current limited data set contains outliers.

Therefore, it is requested to provide a distribution of the concentrations.

For **dried fruits and berry spices (excluding star anise and sumac),** the EU considers that taking into account the global data set, a lower ML of 0.6 mg/kg would be more appropriate. According to the global data set in sumac and star anise the lead concentrations seem higher than in the other spices, however it should be checked whether this is not cause by outliers.

For **dried rhizomes, bulbs and roots spices**, taking into account the EU data, an ML of 1.5 mg/kg seems appropriate. As the concentrations for the Codex samples are significantly higher, it needs to made sure that the Codex data were obtained from products for which good practices were used. It should also be avoided that data for turmeric, which was fraudulently coloured with lead chromate, or other outliers would bias the conclusions. Therefore the EU would be in favour of an ML of 1.5 mg/kg for dry rhizomes and roots spices. For fresh garlic a Codex ML of 0.1 mg/kg is established. It needs to be ensured that compliant fresh garlic, which is dried, would be compliant with the proposed ML of 0.4 mg/kg for dry garlic. As the ML for dry garlic can be calculated on the basis of the ML for fresh garlic and a processing factor, the EU would prefer not to establish an ML for dry garlic/ dry bulbs spices and to only establish an ML for dried rhizomes and roots spices of 1.5 mg/kg.

For **bark spices,** taking into account the EU data for bark spices from various origins, an ML of 2.0 mg/kg seems appropriate. As the concentrations for the Codex samples are higher, it needs to made sure that the Codex data were obtained from products for which good practices were used. The EU is in favour of an ML of 2.0 mg/kg for bark spices.

For **dried seeds spices (excluding carom, celery, dill, mahlab, mustard and poppy),** the EU could support an ML of 0.8 mg/kg. The EU notes that for celery seeds limited data are available from only 2 regions. Therefore the EU suggests to not yet establish an ML for celery seeds, awaiting the availability of more data from different regions, to confirm the higher concentrations of lead in celery seeds.

For **white, refined, raw and brown sugar,** the EU can support the proposed ML of 0.1 mg/kg.

For **honey** the EU can support an ML of 0.06 mg/kg.

For **molasses** the EU can support an ML of 0.3 mg/kg.

For **corn and maple syrups,** the EU can support an ML of 0.1 mg/kg.

For **hard candies, soft candies, gummies and jellies,** the EU would prefer a single ML for the entire group, in order to avoid enforcement problems, because it might be difficult to determine whether certain candies belong to the category of soft or hard candies. Taking into account the occurrence data, the EU can support an ML of 0.07 mg/kg for hard candies, soft candies, gummies and jellies.

For **candy powder** the EU wonders whether there is an explanation why in candy powder more lead is present than in other candies. Taking into account the limited data set, originating from one country, it could be considered to collect more data, before establishing an ML.

For **cereal-based products for infants and young children (as is),** the EU notes that in CX/CF/21/14/8 2537 samples for cereal based foods for infants and young children (expressed as is) were reported with a rejection rate of 3.0% for an ML of 0.01 mg/kg. Now only 634 samples are reported and the rejection rate for an ML of 0.01 mg/kg is 44.8%. An explanation should be given for the discrepancies between the rejection rates in CX/CF/21/14/8 and CX/CF/22/15/7. As children are a more vulnerable consumer group, ingredients of these foods should be selected, to ensure that the lead content is as low as reasonably achievable. The available EU data show that an ML of 0.02 mg/kg is achievable through a careful selection of the ingredients. It is not clear whether the data mentioned in CX/CF/22/15/7 were collected from products for which ingredients with low lead concentrations were used. The EU is in favour of an ML of 0.02 mg/kg for cereal based foods for infants and young children, in order to provide a higher level of health protection for this vulnerable consumer group.

For **ready-to-eat meals for infants and young children,** the EU considers that, because children are a more vulnerable consumer group, ingredients of these foods should be selected, to ensure that the lead content is as low as reasonably achievable. On the basis of the available data an ML of 0.02 mg/kg is achievable. Therefore the EU supports a lower ML of 0.02 mg/kg in order protect children, which are a vulnerable consumer group.

Agenda Item 8 and 13: CX/CF 22/15/8

Request for comments on MLs for methyl mercury in certain fish species and associated sampling plans and additional related matters
(Codex Circular Letter CL 2022/17-CF)
European Union Competence
European Union Vote

The European Union (EU) welcomes and appreciates the work done on the discussion paper on methylmercury in fish by the electronic Working Group led by New Zealand and Canada.

The EU would like to make following comments:

a) Proposed maximum levels (MLs) for orange roughy and pink cusk-eel

The EU could support an ML of 0.8 mg/kg methylmercury of orange roughy and an ML of 1.0 mg/kg, for pink-cusk eel. The EU can agree to advance these MLs for final adoption by the Codex Alimentarius Commission.

b) Feasibility of ML for Patagonian toothfish

As in the previous data calls not sufficient data were made available for toothfish, the EU supports a further data collection in 2-3 years' time for methylmercury in Antarctic and Patagonian toothfish. In case no member countries can commit to generate the required data, the EU can also support a discontinuation of the discussion on an ML for methylmercury in toothfish.

c) Sampling plans

The EU agrees to progress the further development of the sampling plan and agrees to request via a circular letter or a call for data information on national and regional sampling plans for mercury or other contaminants in fish. The EU agrees to develop sampling plans for different weight/ size classes of fish. The EU doesn't agree to link the sampling plans to the value of the fish, as this fluctuates and doesn't ensure a consistent approach over time. As typically, the larger size fishes have the highest value, size-based sampling methods are appropriate to limit economic losses in high value fish.

d) Risk-management measures for methylmercury in fish

The EU welcomes a guidance on risk-management measures and therefore agrees to postpone assessing the feasibility of such paper for one year, in order to collect further information via a circular letter.

If insufficient information on risk management measures would become available, the EU can agree that information, which relates to sorting and reconditioning, is taken into consideration in the sampling plan.

Agenda Item 11: CX/CF 22/15/11

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 2016[1].

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.

The European Food Safety Authority (EFSA) has recently performed a comprehensive risk assessment of aflatoxins in food[2]. 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.

JECFA[3] 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 food[4]. 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.

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[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

[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 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 sublot 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 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

Agenda Item 16: CX/CF 22/15/15

Request for comments on the review of methods of analysis for contaminants: proposed numeric method performance criteria for lead and cadmium in foods.
(Codex Circular Letter CL 2022/22-CF)

European Union Competence
European Union Vote

The European Union (EU) welcomes and appreciates the work done on the review of methods of analysis for contaminants by Brazil, the United States and Japan.

The EU would like to make following comments:

The EU agrees to apply the performance criteria from the Procedural Manual of the Codex Alimentarius Commission to set method performance criteria for lead and cadmium (listed in Appendix I) to be submitted to CCMAS for consideration of inclusion in the General Standard for Recommended Methods of Analysis and Sampling (CXS 234-1999).

The EU agrees to recommend to CCMAS the revocation of the Standard for General Methods of Analysis for Contaminants (CXS 228-2001), including the methods for copper, iron and zinc, because analytical methods for these metals in foods are already listed in CXS 234.

The EU agrees to request CCMAS to remove the analytical methods listed in Appendix II for lead from CXS 234 and sees no need to transfer these methods as example methods for the analysis of lead and cadmium in the table in Appendix I for inclusion in CXS 234-1999, because the establishment of performance criteria for the analytical methods provides sufficient guarantees for the appropriateness of the methods. Therefore, the EU also doesn't consider it necessary the request CCMAS to identify ad suggest further examples of methods, which meet the performance criteria.

The EU agrees to request CCMAS to evaluate the appropriateness of replacing the existing performance criteria in CXS 234 for lead and cadmium in natural mineral waters according to Appendix I.