

# CODEX COMMITTEE ON CONTAMINANTS IN FOOD

## 15<sup>th</sup> Session

### Agenda Item 9

Maximum levels for total aflatoxins in certain cereals and cereal-based products including foods for infants and young children and associated sampling plans  
(CX/CF 22/15/9 and CL 2022/18-CF)

#### **European Union Competence** **European Union Vote**

The European Union (EU) welcomes and appreciates the huge work done on the setting of maximum levels (MLs) for aflatoxins total by the electronic Working Group chaired by Brazil and co-chaired by India.

#### **I. BACKGROUND**

Aflatoxins are genotoxic and carcinogenic substances. The Joint FAO/WHO Expert Committee on Food Additives (JECFA) updated the aflatoxin risk assessment at its 83<sup>rd</sup> meeting in November 2016<sup>1</sup>.

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. Five food commodities (maize, peanuts, rice, sorghum and wheat) were identified to contribute each more than 10% to international dietary exposure estimates for more than one GEMS/Food cluster diet, for either AFT or AFB1. 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. Maize and groundnuts are a traditional focus for aflatoxin management. Based on their contribution to dietary aflatoxin exposure in some areas of the world, JECFA recommended that rice, wheat and sorghum would need to be considered in future risk management activities for aflatoxins.

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<sup>1</sup> 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 risk assessment of aflatoxins in food<sup>2</sup>. 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.

## II. COMMENTS ON PROPOSED MAXIMUM LEVELS

In order to ensure a high level of human protection, the EU is of the opinion that it is of major importance that maximum levels for aflatoxin total are established as low as reasonably achievable (ALARA) by applying good practices to prevent contamination.

The position of the EU on the maximum levels as proposed in Appendix I of CX/CF 22/15/9 is hereby provided in detail.

### a) Maximum level proposed for maize grain, destined for further processing

- The data analysis shows a very large geographical variation and a very large year-to-year variation (Table 1, 2 and 3 in CX/CF 22/15/9). However, it is unclear if this large year-to-year variation is observed in all regions for which sufficient data have been provided. No further explanations are provided explaining these large variations.
- The EU notes, according to table 4, the sample rejection rate between a hypothetical ML of total aflatoxins of 20 µg/kg versus 30 µg/kg does not differ significantly and is in both cases acceptable (< 5 %). It is, however also noted that the differences in rejection rates can be larger when considering specific regions or specific years (table 5).
- Table 4 also demonstrates that lower hypothetical maximum levels of aflatoxins have a very significant positive effect on lowering the human exposure to aflatoxins, without an unacceptable increase in sample rejection rates.
- Given that the EU considers it of major importance to establish maximum levels for total aflatoxins as low as reasonably achievable (ALARA), the EU cannot agree on the proposed maximum level of 30 µg/kg for aflatoxin total in maize grain, destined for further processing.

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<sup>2</sup> 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>

**b) Maximum level proposed for flour, meal, semolina and flakes derived from maize**

- The data analysis shows a large geographical variation and a large year-to-year variation (Table 6, 7 and 8 in CX/CF 22/15/9). However, it is unclear if this large year-to-year variation is observed in all regions for which sufficient data have been provided. No further explanations are provided explaining these large variations.
- Referring to the information provided in §14 of the document CX/CF 22/15/9, the EU is questioning the appropriateness of setting a Codex maximum level based on data originating from one country (Singapore), in which according to information available, maize is not grown to a significant extent.
- The EU does not agree to establish a maximum level resulting in a very low rejection rate while setting a lower maximum level with still an acceptable rejection rate (< 5%) would result in a significant reduction of the human exposure to aflatoxins.
- Given that the EU considers it of major importance to establish maximum levels for total aflatoxins as low as reasonably achievable (ALARA), the EU cannot agree on the proposed maximum level of 20 µg/kg for aflatoxin total in flour, meal, semolina and flakes derived from maize.
- Taking into account the information provided in CX/CF 22/15/9, the EU is of the opinion that the maximum level of 2.5 µg/kg for aflatoxin total in flour, meal, semolina and flakes derived from maize would result in a significant reduction of the human exposure to aflatoxins with still an acceptable sample rejection rate (4.1 %) (Table 9)

**c) Maximum level proposed for husked rice**

- The data analysis shows a large geographical variation and a large year-to-year variation (Table 10, 11 and 12 in CX/CF 22/15/9). No further explanations are provided explaining these large variations.
- The EU does not agree to establish a maximum level resulting in a low rejection rate while setting a lower maximum level with still an acceptable rejection rate (< 5%) would result in a significant reduction of the human exposure to aflatoxins (table 13).
- Given that the EU considers it of major importance to establish maximum levels for total aflatoxins as low as reasonably achievable (ALARA), the EU cannot agree on the proposed maximum level of 25 µg/kg for aflatoxin total in husked rice.

**d) Maximum level proposed for polished rice**

- The data analysis show only a limited geographical variation and a limited year-to-year variation (Table 14, 15 and 16 in CX/CF 22/15/9).
- The EU can agree with the proposed maximum level of 5 µg/kg for aflatoxins total in polished rice resulting in an acceptable sample rejection rate of 0.8 % with a reduction of the human exposure to aflatoxins (table 17).

**e) Maximum level proposed for sorghum grain destined for further processing**

- The data analysis show a geographical variation and a year-to-year variation (Table 18, 19 and 20 in CX/CF 22/15/9).
- The relative low number of positive samples is noted.
- Given that the EU considers it of major importance to establish maximum levels for total aflatoxins as low as reasonably achievable (ALARA), the EU cannot agree on the proposed maximum level of 15 µg/kg for aflatoxin total in sorghum grain destined for further processing.
- Taking into account the information provided in CX/CF 22/15/9, the EU is of the opinion that the maximum level of 5 µg/kg for aflatoxin total in sorghum grain destined for further processing would result in a significant reduction of the human exposure to aflatoxins with still an acceptable sample rejection rate (4.9 %) (Table 21)

**f) Maximum level proposed for cereal based foods for infants and young children**

Given that the EU considers it of major importance to establish maximum levels for total aflatoxins as low as reasonably achievable (ALARA), and in particular in foods destined for infants and young children, the EU cannot agree on the proposed maximum level of 10 µg/kg for aflatoxin total in cereal based foods for infants and young children.

**III. SAMPLING PLANS**

*To suspend the development of sampling plans until finalization of the MLs and in addition, provide advice on the points raised in paragraph 25(i-ii) of CX/CF 22/15/9 i.e.:*

*i. If the sampling plan and the decision rule should be aligned with the sampling plans for mycotoxins already mentioned in General Standard for Contaminants and Toxins in Food and Feed (CXS 193-1995) or with the General Guidelines on Sampling (CXG 50-2004) once they are finalized by the Codex Committee on Methods of Analysis and Sampling (CCMAS).*

*ii. If CCMAS should be consulted regarding how to establish performance criteria for a sum of components (AFB1, AFB2, AFG1 and AFG2) in the different matrices considering that AFB1, AFB2, AFG1 and AFG2 are not distributed equally and presents different profile in the various cereal grains.*

**EU POSITION**

The EU is of the opinion that the sampling plans and methods performance criteria should be discussed in parallel with the discussion on MLs to ensure that the sampling plans and method performance criteria are available once the MLs are established. For a contaminant that can heterogeneously be distributed in a given lot, as is the case for aflatoxins in cereal grains, it is important that an appropriate method of sampling is specified so that the maximum level is applied to a representative sample of the lot.

The EU is of the opinion that the sampling plan and decision rule should be aligned with the sampling plans already provided in CXS 193-1995 for the control of Codex MLs for deoxynivalenol and for fumonisins (B1 + B2). As the maximum levels for total aflatoxins in cereals and cereal products under consideration and the established maximum levels for deoxynivalenol and fumonisins (B1 + B2) relates to a certain extent, it is important that the sampling procedures are aligned so that the same representative sample of the lot can be analysed for total aflatoxins, deoxynivalenol and fumonisins (B1 + B2). In addition, it is appropriate to consider to extend the sampling procedure also for the control of the Codex MLs for ochratoxin A in wheat barley and rye.

The EU is of the opinion that it is not necessary to consult CCMAS regarding the establishment of criteria for a sum of components.

In case the maximum level applies to a sum of different components, then the criteria for precision apply to both the sum and the individual components.