

**CODEX COMMITTEE ON CONTAMINANTS IN FOOD
14th Session**

Virtual session, 3-7 and 13 May 2021

Agenda Item 10 (a):

CL 2021/15/OCS-CF

Request for comments at Step 3 on maximum levels for total aflatoxins in certain cereals and cereal-based foods including foods for infants and young children (CX/CF 21/14/10 – Part I)

*European Union Competence
European Union Vote*

The European Union (EU) welcomes and appreciates the 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.

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. 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.

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 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.

REPLY TO THE QUESTIONS RAISED IN CX/CF 21/14/10 – Part I, paragraph 11.1

In reply to the questions raised in CX/CF 21/14/10-Part I, paragraph 11.1, the EU has following comments:

a. Should the rejection rates adopted be the same for grains and for processed products? (Grains may have another destination, such as animal feed). What is the more appropriate rejection rate, considering the different types of products and contaminants?

The EU is of the opinion that the maximum levels for total aflatoxins in cereal grains can be set taking into account higher rejection rates than for processed products, considering that cereal grains can be used for other purposes than for (direct) human consumption, such as for animal feed.

This is particularly relevant for those cereals such as maize, barley of which large part of the production is already destined for uses other than for human consumption, regardless the contamination level. Use of these cereals for purposes other than human consumption will not necessarily result in economic loss.

For other cereals, such as durum wheat, this has to be handled with caution as a very large part of the whole production of these cereals is used for human consumption. Use of such cereals for purposes other than for human consumption might in these cases result in economic loss.

Even if for processed cereal products, the use for purposes other than human consumption might result in an economic loss, this does not mean that automatically (very) low rejection rates should be taken into account for the setting of maximum levels for total aflatoxins. No aflatoxins are formed during the processing of cereals, so with the application of good practices, i.e. a careful selection of raw materials with low levels of aflatoxins after appropriate cleaning and sorting, will result in low levels of aflatoxins in the processed product.

Proposing a concrete figure for a rejection rate considering the types of products and contaminants than the usually applied rejection rate of 5 % is not straightforward as it depend also on the data under consideration and how outliers are handled. But taking into account the considerations above, it can be considered that for raw materials for which use for other purposes would not necessarily result in economic loss, maximum levels can be set at rejection rates higher than 5 % and for processed products, for which use for other purposes would result in economic loss, maximum levels can be set at rejection rates lower than 5 %.

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>

b. How the outliers should be treated, since there is no harmonized procedure available in the Committee?

Outliers are data which fall outside the normal range of variation in levels in a certain food produced following good practices.

As maximum levels should be set as low as reasonably achievable, maximum levels should be set at a level which is (slightly) higher than the normal range of variation in levels in food and feed that are produced with current adequate technological methods, in order to avoid undue disruptions of food and feed production and trade (Criteria for the establishment of maximum levels in food and feed, Annex I to the General Standard for Contaminants and Toxins in Food and Feed, CXS 193-1995).

The EU is of the opinion that it would be appropriate to present the frequency distribution curves of the occurrence data as outlined above in order to be able to identify possible clear outliers. The EU is of the opinion that it is appropriate to investigate the reasons for these outliers to verify if these outliers are related to e.g. specific climatic conditions, specific regions and if they are to be considered as unavoidable despite the application of good practices. In that case outliers should not be excluded. In case no or no acceptable explanation can be provided for these unusual high levels, the EU is of the opinion that it should be considered not to take into account these outliers for the setting of the maximum levels as these outliers, clearly not reflecting the application of good practices to prevent aflatoxin contamination³, should be excluded from further consideration.

c. How should the maize data be evaluated, since the available data are related to the marketing of the products and there is no guarantee that they are intended exclusively for human consumption and not for animal feed?

It is correct that the occurrence data for maize in the GEMS/Food database are related to the marketing of the products and there is not necessarily a guarantee that they are intended for human consumption. Taking into account the reply given to questions a) and b), the occurrence data for total aflatoxins in maize could be evaluated by applying a higher rejection rate and excluding the outliers.

³ Code of Practice for the prevention and reduction of mycotoxin contamination in cereals (CXC 51-2003).

d. Are there any methods available that have already been validated in collaborative assays that meet the limits proposed in this document?

Yes, there are validated methods of analysis available that can quantitatively determine the proposed and lower levels

	Matrix	Mycotoxin(-s)	Method / link	Description
1	Cereals, shell fruits & derived products	Aflatoxin B1 Aflatoxin B2 Aflatoxin G1 Aflatoxin G2	EN 12955:1999	Foodstuffs - Determination of aflatoxin B1, and the sum of aflatoxins B1, B2, G1 and G2 in cereals, shell-fruits and derived products - High performance liquid chromatographic method with post column derivatisation and immunoaffinity column clean up
2	Cereals, nuts & derived products	Aflatoxin B1 Aflatoxin B2 Aflatoxin G1 Aflatoxin G2	ISO 16050:2003	Foodstuffs - Determination of aflatoxin B1, and the total content of aflatoxins B1, B2, G1 and G2 in cereals, nuts and derived products. High-performance liquid chromatographic method
3	Cereals, nuts & derived products	Aflatoxin B1 Aflatoxin B2 Aflatoxin G1 Aflatoxin G2	EN ISO 16050:2011	Foodstuffs - Determination of aflatoxin B1, and the total content of aflatoxins B1, B2, G1 and G2 in cereals, nuts and derived products - High-performance liquid chromatographic method (ISO 16050:2003)
4	Food	Aflatoxins Deoxynivalenol Fumonisin Ochratoxin A T-2 toxin HT-2 toxin Zearalenone	prEN 7641	Foodstuffs - Multimethod for the determination of aflatoxins, deoxynivalenol, fumonisins, ochratoxin A, T-2 toxin, HT-2 toxin and zearalenone by LC-MS/MS The results of the study are also published by: Bessaire T, Mujahid C, Mottier P, Desmarchelier A. 2019. Multiple mycotoxins determination in food by LC-MS/MS: An international collaborative study. Toxins 11. doi:10.3390/toxins11110658

e. Should CCCF request JECFA to carry out a dietary exposure assessment considering the MLs proposed in this document?

The EU does not object to request JECFA to carry out a dietary exposure assessment. It is however noted that JECFA updated the aflatoxin risk assessment at its 83rd meeting in November 2016⁴ and 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. Therefore it is of major importance for the protection of public health that the maximum levels for total aflatoxins are set at a level as low as reasonably achievable taking into account the application of good practices.

⁴ 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>

f. What limits does CCCF consider that can move forward in this meeting?

The EU agrees with the setting of maximum levels for total aflatoxins in the food products currently under consideration. However the EU does not agree with most of the levels as proposed (proposal 1 and proposal 2) and can therefore not agree to move forward in the Step procedure most of these levels with the exception of the proposed level of 4 µg/kg for polished rice and of 8 µg/kg for sorghum grain, destined for further processing.

SPECIFIC 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 maximum levels as proposed in Appendix I of CX/CF 20/14/10, proposal 1 as well proposal 2, are in the view of the EU in most cases not established according to the ALARA principle and therefore to a large extent not acceptable for the EU. More details are hereby provided.

Maximum level proposed for maize grain, destined for further processing

- The data for the years 2011, 2012 and 2013 show an unusual high contamination level compared to the data for the other years in the period 2007-2019 (table 2).
- The EU is of the opinion that it would be appropriate to present the frequency distribution curve of the occurrence data in order to be able to identify possible clear outliers. These outliers, in case no or no acceptable explanation can be provided for these unusual high levels, the EU is of the opinion that it should be considered not to take into account these outliers for the setting of the maximum levels (see reply to point b above).
- The EU notes, according to table 4, the same rejection rate of 5.4 % for a hypothetical ML of total aflatoxins of 10 µg/kg and 15 µg/kg.
- Given that the EU considers it of major importance to establish maximum levels for total aflatoxins as low as reasonably achievable (ALARA), the EU proposes to establish the ML of 10 µg/kg for total aflatoxins in maize grain destined for further processing.

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

- The EU is of the opinion that it would be appropriate to present the frequency distribution curve of the occurrence data as outlined above in order to be able to identify possible clear outliers. These outliers, in case no or no acceptable explanation can be provided for these unusual high levels, the EU is of the opinion that it should be considered not to take into account these outliers for the setting of the maximum levels (see reply to point b above).
- The EU proposes to recalculate the effect on exposure and rejection rate of hypothetical MLs on total aflatoxins through the consumption of flour, meal, semolina and flakes derived from maize (table 8) after the exclusion of the outliers, for which no or no acceptable explanation can be provided.
- 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.
- The EU proposes therefore to establish a maximum level of 4 µg/kg for aflatoxin total in flour, meal, semolina and flakes derived from maize resulting in an acceptable rejection rate of 3.3 % and with significant reduction of the human exposure to aflatoxins (table 8).

Maximum level proposed for husked rice

- The EU is of the opinion that it would be appropriate to present the frequency distribution curve of the occurrence data as outlined above in order to be able to identify possible clear outliers. These outliers, in case no or no acceptable explanation can be provided for these unusual high levels, the EU is of the opinion that it should be considered not to take into account these outliers for the setting of the maximum levels (see reply to point b above).
- The EU furthermore proposes to recalculate the effect of hypothetical MLs on aflatoxins through the consumption of husked rice (table 12) after the exclusion of the outliers, for which no or no acceptable explanation can be provided.
- 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.
- The EU proposes therefore to establish a maximum level of lower than 8 µg/kg for aflatoxin total in husked rice following the above mentioned recalculation after exclusion of the outliers. On the basis of the current calculation, a maximum level of 8 µg/kg results in an acceptable rejection rate of 4.9 % and with significant reduction of the human exposure to aflatoxins compared to the proposed maximum levels of 20 or 15 µg/kg (table 12). It is expected that after exclusion of the outliers, a lower maximum level can be proposed with an acceptable rejection rate and resulting in a significant reduction of the human exposure to aflatoxins

Maximum level proposed for polished rice

- The EU is of the opinion that it would be appropriate to present the frequency distribution curve of the occurrence data as outlined above in order to be able to identify possible clear outliers. These outliers, in case no or no acceptable explanation can be provided for these unusual high levels, the EU is of the opinion that it should be considered not to take into account these outliers for the setting of the maximum levels (see reply to point b above).
- The EU furthermore proposes to recalculate the effect on exposure and rejection rate of hypothetical MLs of total aflatoxins through the consumption of polished rice (table 16) after the exclusion of the outliers for which no or no acceptable explanation can be provided.
- The EU can agree with establishment of 4 µg/kg for aflatoxins total in polished rice (proposal 2) resulting in an acceptable rejection rate of 1.2 % with a reduction of the human exposure to aflatoxins (table 16).

Maximum level proposed for sorghum grain destined for further processing

- The EU is of the opinion that it would be appropriate to present the frequency distribution curve of the occurrence data as outlined above in order to be able to identify possible clear outliers. These outliers, in case no or no acceptable explanation can be provided for these unusual high levels, the EU is of the opinion that it should be considered not to take into account these outliers for the setting of the maximum levels (see reply to point b above).
- The EU furthermore proposes to recalculate the effect on exposure and rejection rate of hypothetical MLs of total aflatoxins through the consumption of sorghum grain for further processing (table 20) after the exclusion of the outliers for which no or no acceptable explanation can be provided.
- The EU can agree with establishment of 8 µg/kg for aflatoxins total in sorghum grain destined for further processing (proposal 2) resulting in an acceptable rejection rate of 2.7 % with a reduction of the human exposure to aflatoxins (table 20).

Maximum level proposed for cereal based foods for infants and young children

- The EU is of the opinion that it would be appropriate to present the frequency distribution curve of the occurrence data as outlined above in order to be able to identify possible clear outliers. These outliers, in case no or no acceptable explanation can be provided for these unusual high levels, the EU is of the opinion that it should be considered not to take into account these outliers for the setting of the maximum levels (see reply to point b above).
- The EU furthermore proposes to recalculate the effect on exposure and rejection rate of hypothetical MLs of total aflatoxins, including hypothetical MLs lower than 1 µg/kg through the consumption of cereal-based foods for infants and young children (table 24) after the exclusion of the outliers for which no or no acceptable explanation can be provided.
- The EU proposes to discuss a maximum level lower than 1 µg/kg for aflatoxin total in cereal based foods for infants and young children following the above mentioned recalculation after exclusion of the outliers.