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## ANALYSIS OF AGENDA ITEMS IN PREPARATION FOR THE 15<sup>th</sup> SESSION OF THE CODEX COMMITTEE ON CONTAMINANTS IN FOOD

9<sup>th</sup> – 13<sup>th</sup> and 24<sup>th</sup> MAY 2022 Virtual Meeting

### 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 (at step 4)*

#### Objectives

This document offers a review and analysis of the agenda items planned for discussion at the 15<sup>th</sup> session of the **Codex Committee on Contaminants in Food (CCCF)**, scheduled to take place virtually May 9<sup>th</sup> – 13<sup>th</sup> and 24<sup>th</sup>, 2022. This document is intended for possible use by the Codex communities of practice, promoted by [GForSS](#) and [PARERA](#), as part of their contribution to enhancing awareness and supporting effective participation in international food standard setting meetings (Codex meetings) by representatives from members and observers.

The analysis provided in this document offers a factual review of agenda items, their background and a discussion of some considerations. This analysis is indicative in nature and does not represent an official position of the organizations mentioned above ([PARERA](#) and [GForSS](#)), their membership or their management. It provides a synthesis and analysis of the work currently under discussion by the CCCF, which may be useful for delegations from Arab countries to prepare their positions taking into account the needs and specificity of the region and the potential impact of the proposed food standards.

This analysis is prepared as part of the **Codex Initiative for the Arab Region: Arab Codex Initiative**, implemented by [PARERA](#) and [GForSS](#), hosted and coordinated by the Arab Industrial Development, Standardization and Mining Organization (AIDSMO) and funded by the US Codex Office, US Department of Agriculture.

The focus of the analysis of agenda items 9, 10 and 11 of CCCF15, relates to **total aflatoxins and ochratoxin A** in food commodities: **establishing maximum levels and associated sampling plans**.

*\*It is important to note that experts – members of the Expert Working Group (EWG) – do not represent the organizations and / or jurisdictions to which they are affiliated. The selection and participation in the EWG proceedings is based on each expert's own credentials and experience which should not be misconstrued as the country's / delegation's / organization's position to which they belong.*

## 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 (at Step 4)

### Document

#### ❖ CX/CF 22/15/9

CCCF15 is invited to consider the proposed MLs for total aflatoxins in the selected cereals and cereal-based products including foods for infants and young children and to suspend the development of the associated sampling plans until finalization of the MLs.

### Background

Aflatoxins (AFs) are considered as the most important naturally occurring group of mycotoxins in the world's food supply. AFs (B1, B2, G1 and G2) were classified as human liver carcinogens by an evaluation conducted by JECFA, with AFB1 being considered the most potent one (FAO/WHO, 2017).<sup>1</sup>

**Maximum Levels (MLs)** for total aflatoxins have been already established by the Codex Alimentarius Commission (CAC) for almonds, Brazil nuts, hazelnuts, peanuts intended for further processing, pistachios, and dried figs (CXS 193-1995). The Codex Committee on Contaminants in Food (CCCF) is however aiming to extend these MLs to cover additional MLs for **total aflatoxins (AFT)** in cereals and cereal-based products, including food for infants and young children.

Since 2013, the CCCF has been discussing the establishment of these MLs for AFT in cereal and cereal based products, where **total aflatoxins (AFT)** refer to the **sum of aflatoxins B1, B2, G1 and G2**.

In the following, all discussions, comments and decisions are summarized, as discussed and agreed upon since the launching of this work during the CCCF13 (2019) and afterwards at the CCCF14 (2021).

The work **was initiated by a discussion paper**, where a large dataset was available on the occurrence of AFs in cereals and cereal-based products in the GEMS/Food Database (more than 17 000 samples). However, the majority of data was submitted by the European Union (EU), Singapore and Canada. The discussion paper also demonstrated that the establishment of MLs for AFT in the targeted cereal and cereal-based products could greatly reduce AFT exposure worldwide. In this context, CCCF13 agreed to:

- ❖ Establish an Electronic Working Group (EWG) chaired by Brazil and co-chaired by India to present proposals for MLs for total AFs in maize grain destined for further processing, flour, meal, semolina and flakes derived from maize, husked and polished rice (excluding parboiled rice), cereal based food for infants and young children and to include sorghum in the list noting that it was a staple food in many parts of the world, relying on a more geographically representative data;
- ❖ Consider the proposal of MLs for other cereals and cereal-based products once the work on the MLs for the food categories mentioned above were completed;
- ❖ Issue a call for data on whole wheat flour and parboiled rice to better assess whether these food categories should be added later.

CAC42 (2019) approved the new work.

<sup>1</sup> FAO/WHO, 2017. Joint FAO/WHO Expert Committee on Food Additives (JECFA) - Evaluation of certain food contaminants: eighty-third report of the Joint FAO/WHO Expert Committee on Food Additives. vol. 1002. WHO technical report series, Rome, Italy, p. 182.



After discussing the report of the EWG, CCCF14 (2021) agreed to:

- ❖ Pursue the work on the targeted food categories. This would include consideration of a wider range of MLs and rejection rates, especially up to and about 5%, which would also apply to maize grain, and to include considerations on the effect of processing on the reduction of aflatoxins contamination.
- ❖ Assess the data to:
  - verify the outliers and whether they should be excluded or not;
  - analyze year to year and regional variations;
  - consider whether the ML would be set for maize for further processing or maize for direct human consumption and;
  - assess the impact of lower MLs on food aid/food security particularly cereal products for infants and young children.
- ❖ Try to gather more geographically representative data, including details on food and feed;
- ❖ Request JECFA to issue a call for data and, in case no data was submitted, the MLs would be finalized on the existing data set.
- ❖ Liaise with the WHO JECFA Secretariat on whether it would be possible to further segregate data available on GEMS/Food to differentiate between maize grain for food or feed.

### Analysis

- ❖ JECFA did not propose a **tolerable daily intake for aflatoxins** since they are genotoxic carcinogens. And since their complete elimination from the food supply is not feasible, measures should be taken to control and manage worldwide contamination. The risk management approach to propose MLs is therefore based on the **ALARA principle “as low as reasonably achievable”**, considering the occurrence data and the trade rejection rates of samples.
- ❖ The rationale used to propose the various MLs was based on the previous approach adopted by CCCF in recent years, to accept a maximum rejection rate of 5% (i.e. rejection rates of 5% or less may offer room for reduction of exposure to be implemented), with the caution that such rate, may lead to higher rejecting rates for some producing countries.
- ❖ In response to the discussed issue about the lack of geographical representativeness of the pre-submitted data, JECFA issued another call for data on all categories under discussion. This call included a special request to indicate the country of origin and to provide any information that could allow the differentiation between maize for food or feed. The new data set, extracted from the GEMS / Food Database, was as follows:
  - Data for samples analyzed between 2011 and 2021 were considered;
  - Worldwide occurrence of aflatoxins in cereals and cereal-based products was evaluated, submitted from the following countries: African Union, Republic of Montenegro, Rwanda, Former Yugoslavia, Indonesia, Mali, Canada (sorghum), European Union, India, Thailand, Brazil, Philippines, Singapore, USA. **From the Arab region, only Saudi Arabia answered this call for data.** However, most of the data originated from the European Union and the USA, which constitutes a limitation, since it may not be representative of AFs occurrence in cereal-based staple foods across all the GEMS/Food Cluster Diets.



- ❖ All MLs proposed were based both on the **intake reduction** and **sample rejection (less than 5%)**. Those MLs are a reasonable choice for the food categories selected, since they greatly contributed to AFs intake reduction and did not result in a large withdrawal of samples from international trade.

### *Comments and Considerations*

Upon the development of this document, the deadline of the new circular letter (CL 2022/18-CF) related to this agenda item was not reached (28/04/2022). More comments are therefore still being received by the Codex Secretariat. However, the majority of comments expressed until now focus on the following:

- ❖ It was noted that occurrence data in cereals used for the analysis and the subsequent proposal for new work, relied heavily on data from only a few countries and regions. Although calls for data on the occurrence of AFs in cereals and cereal-based products have been made since 2014. The Committee pointed out that the available data were not sufficiently representative of cereal-based foods from all GEMS/Food cluster diets.
- ❖ MLs proposed may constrain the capacity of humanitarian agencies of purchasing and delivering foods all over the world.
- ❖ There was general support for the categories other than maize grain but views diverged on the MLs that should apply to these categories.
- ❖ The following was also noted:
  - How the considerations given for maize grain would impact processed products e.g. geographical distribution of data, year to year variations, regional variation, treatment of outliers, etc.
  - How processing, including cleaning and sorting, could help to reduce aflatoxin contamination in processed products to allow lower MLs with acceptable rejection rates.
  - MLs for processed products should be supported by data and information on the expected aflatoxin reductions due to processing.
- ❖ Flour, meal, semolina and flakes derived from maize: wider ranges of MLs and rejection rates, up to and about 5% should be presented and consideration should be given to processes that could reduce contamination in this category, including polished rice, similar to the considerations taken for DON in flour, meal, semolina and flakes derived from wheat, maize or barley, and arsenic in rice, respectively.
- ❖ For cereal-based food for infants and young children: data should be analyzed to determine if the ML should be set for the product “as is” or “on a dry matter basis”. A comment was made to set the ML on “as is” basis as the most straightforward method that would not require an adjustment of the moisture content in the products.
- ❖ The ML of **2 µg/kg for cereal-based foods for infants and young children was not considered viable**, mainly because the constraints faced by Food Aid Agencies to purchase products within this limit. Therefore, higher limits are being suggested eliminating such methodological problems. Nevertheless, some countries reported that lower MLs are in force, so it is possible that the results of collaborative assays for the methods used are available.



*Recommendations formulated by the EWG chaired by Brazil and co-chaired by India***In its 15<sup>th</sup> session, CCCF is therefore considering:**

- A. To endorse the establishment of the following MLs (**table 1**) for the selected food categories.
- B. To suspend the development of sampling plans until finalization of the MLs.

**Table 1:** Proposed MLs for AFT in certain cereals and cereal-based products including foods for infants and young children.

Food	ML <sup>a</sup> (µg/kg)
Maize grain, destined for further processing <sup>b,c</sup>	30
Flour, meal, semolina and flakes derived from maize	20
Husked rice	25
Polished rice	5
Sorghum grain, destined for further processing <sup>a</sup>	15
Cereal-based Food for infants and young children <sup>d</sup>	10

<sup>a</sup> Limits proposed on an “as is” basis;

<sup>b</sup> “Destined for further processing” means intended to undergo an additional processing/treatment that has proven to reduce level of AFs before being used as an ingredient in foodstuffs, otherwise processed or offered for human consumption. Codex members may define the processes that have been shown to reduce levels;

<sup>c</sup> Does not apply to maize destined for animal feed;

<sup>d</sup> All cereal-based foods intended for infants (up to 12 months) and young children (12 to 36 months).

Moreover, the EWG recommended to have the discussions focused **on these additional questions:**

- ❖ Whether the proposed MLs may constrain the capacity of humanitarian agencies of purchasing and delivering foods all over the world.
- ❖ If CCCF agrees to adopt lower limits, such as 2 µg/kg for cereal-based foods for infants and young children, it is suggested that the Codex Committee on Methods of Analysis and Sampling (CCMAS) should be questioned about the availability of validated analytical methods allowing to quantify these limits.
- ❖ Whether to set MLs before moving forward with the sampling plans and the methods of analysis, because they depend on the MLs and:
  - 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).
  - 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.

*Considerations for the Arab Region*

- ❖ The data submitted and included in Appendix II of working document CX/CF 22/15/9 does not seem to contain significant input from the Arab region, except for few data provided by Saudi Arabia on maize grain destined for further processing, polished rice and cereal-based food for infants and young children.



- ❖ It would be important to document the possible impacts and in particular the achievability of several MLs on the designated food products from the Arab region.
- ❖ It would also be important to document the feedback from representatives of the Food industry in the region, on the feasibility of these MLs, in particular for importers and processors of the region.
- ❖ Most MLs proposed would be considered acceptable for the region, in that they would offer a contribution to reduction of exposure to Aflatoxins from the targeted commodities. However, some MLs may gain to be reduced, because of the potential higher level of achievability (e.g. Maize grain, destined for further processing) or the fact that the commodities are directed to more vulnerable groups. A proposed ML for Maize grain destined to further processed would gain to be set at **20 µg/kg (ppb)**, with a rejection rate not exceeding 5% (4.7%).
- ❖ The ML for Cereal-based Food for infants and young children would also gain to be reduced, because of the public health impact of these toxins and the contribution of this commodity to the overall exposure for this sub-category of the population. **Values such 5 or 2.5 µg/kg (ppb) should be considered**, while ensuring that that would not challenge the work of humanitarian aid agencies.
- ❖ It may be recommended also that the Arab region considers:
  - examining monitoring data related to AFT in cereal and cereal-based products sold and produced in the region,
  - reviewing current risk management measures, in particular regulatory measures related to AFT in cereal and cereal-based products in the Arab region,
  - Developing proposed approaches for MLs of AFT for possible consideration in the Arab region, based on data collected from the region, while Codex is in the process of establishing these new MLs and aim for regional harmonization and alignment with international standards,
  - Establishing a regional (Arab) Expert Working Group, who could help in examining the above proposal and develop a risk analysis for AFT in cereal and cereal-based products, in the Arab region.
- ❖ It may be recommended to support the adjournment of the discussion on sampling plan, since its establishment is intimately linked to the MLs to be agreed on.

### Conclusion

The proposed MLs to be considered by CCCF15 on total aflatoxins (AFT) in cereal and cereal-based products rely on data submitted to GEMS/Food and collected between 2011 and 2021, noting a poor geographical representativeness. The ALARA approach was adopted in the setting of the proposed MLs. These MLs were defined considering hypothetical MLs, which were chosen following a geometric progression (the CL 2021/78-CF) and relying on subsequent suggestions from the EWG. The proposed MLs were selected considering both AFs intake reduction and samples rejection. Year to year, and geographic variation and Food Aid data were considered when proposing MLs to ensure food security (MLs that did not reject more than 5% of samples in most groups).

Most MLs proposed would be considered acceptable for the Arab region. However, some MLs may gain to be reduced, with a possible proposed alternative for the ML for Maize grain destined to further processed which could be set at **20 µg/kg (ppb)**, leading to a rejection rate not exceeding 5% (4.7%). Similarly, the ML for Cereal-based Food for infants and young children would also gain to be reduced, with a proposed level of 5 or 2.5 µg/kg, while ensuring that that would not challenge the work of humanitarian aid agencies.

Moreover, it is proposed to suspend the development of sampling plans until finalization and adoption of the MLs.

