DRAFT UNITED STATES POSITIONS (CURRENT THINKING) FOR THE 14TH SESSION OF THE CODEX COMMITTEE ON CONTAMINANTS IN FOODS (CCCF) (CANCELLED/TO BE RESCHEDULED)

The documents referenced here are available from the Codex Alimentarius website at www.codexalimentarius.net at the link to CCCF14 for the meeting of the Codex Committee on Contaminants in Foods in Utrecht, The Netherlands, originally scheduled April 20-24, 2020, but now to be rescheduled.

Agenda Item 2

Matters referred to the Committee by the Codex Alimentarius Commission and/or its subsidiary bodies

Current Documents: CX/CF 20/14/2 (available)

MATTERS FOR INFORMATION

Standards and related texts adopted at Step 8, 5/8, and 5

- Codex Alimentarius Commission 42 (CAC42) (July 2019) adopted the following MLs and related texts:
  - Maximum Limits (ML) for lead in selected commodities: wines and fortified/liqueur wines (from grapes harvested after the adoption of the ML by CAC); edible offal (cattle, pig and poultry) in the General Standard for Contaminants for Toxins in Food and Feed (GSCTFF) – adopted at Step 5/8 (final adoption)
  - Code of practice (COP) for the reduction of 3-MCPDEs and GEs in refined oils and food products made with refined oils – adopted at Step 8 (final adoption)
  - Guidelines for rapid risk analysis following instances of detection of contaminants in food where there is no regulatory level – adopted at Step 8 (final adoption)
  - ML for cadmium for chocolate containing or declaring <30% total cocoa solids on a dry matter basis – adopted at Step 5 (allowing for further consideration by CCCF)

Revocation of standards and related texts

- CAC42 revoked MLs for lead in selected commodities in the GSCTFF following adoption of revised MLs

New Work

- CAC42 approved the following new work:
  - Establishment of MLs for lead in certain food categories
  - Revision of the code of practice for the prevention and reduction of lead contamination in foods (CXC 56-2004)
  - Development of a code of practice for the prevention and reduction of cadmium contamination in cocoa beans
  - Establishment of MLs for aflatoxins in certain cereal and cereal-based products including foods for infants and young children

MATTER FOR ACTION

- Executive Committee of the Codex Alimentarius Commission 78 (CCEXEC78) (February 2020) requested that the Codex Secretariat bring the information (CX/EXEC 20/78/8) on the timeliness of Codex working documents, reports and the availability of adopted standards to the attention of subsidiary bodies for their review and suggestions.
- Codex Committee on Methods and Analysis and Sampling 40 (CCMAS40) (May 2019) agreed to:
  - Inform all Codex committees of the current work of CCMAS regarding the review and update of CXS 234 and the development of a database for methods of analysis and sampling endorsed by CCMAS and adopted by CAC.
  - Remind CCCF of the decision that CXS 234 is the single reference for methods of analysis and request CCCF to consider the appropriateness of the methods identified in CXS 228 so

that the methods could be transferred to CXS 234 or to identify more updated methods or methods performance criteria for endorsement by CCMAS and inclusion in CXS 234 in order to revoke CXS 228.

- The FAO/WHO Coordinating Committee for North America and the South West Pacific 15 (CCNASWP15) (September 2019) agreed to request CCCF to retain scopoletin on the priority list and to call upon Codex members to generate and submit data to support the conduct of the safety evaluation byJoint FAO/WHO Expert Committee on Food Additives (JECFA).

Agenda Item 3

Matters of interest arising from FAO and WHO (including Joint FAO/WHO Expert Committee on Food JECFA)

Current Documents: CX/CF 20/14/3 (available)

Joint FAO/WHO Expert Committee on Food Additives (JECFA)
Since CCCF13 (April 2019), two JECFA meetings have been convened. These meetings addressed food additives and residues of veterinary drugs.

Future meetings:
The 89th JECFA will be held June 2-11, 2020 in Geneva, Switzerland. The meeting is dedicated to the evaluation of a number of food additives.

The 90th JECFA will be held October 27 – November 5, 2020 in Geneva, Switzerland. The meeting is dedicated to the evaluation of ergot alkaloids and trichothecenes. JECFA90 will also consider whether a group of listed substances will be suitable as previous cargos on request from the Codex Committee on Fats and Oils (CCFO).

The following additional items are described in the document:

- Ad-hoc FAO/WHO Expert Meeting on (-)-hyoscyamine, (+)-hyoscyamine and (-)-scopolamine
- Ad-hoc FAO/WHO Expert Meeting on ciguatera fish poisoning
- Global Food Consumption Databases and ongoing activities to support countries to generate and to use data for risk analysis purposes
- Risk Assessment Methods and Principles
- FAO's publication on Food Safety and Climate Change
- Other issues of potential interest to the Committee
    - FAO's work on bivalve mollusk monitoring
    - Microplastics
    - Seaweed and chemical safety
    - Marine biotoxins in water from desalinization plants

Agenda Item 5

Draft ML for cadmium for chocolates containing or declaring <30% total cocoa solids on a dry matter basis (at Step 7)

Current Status:

Current Documents: CL 2019/81-CF (available), CX/CF 20/14/5 (not available)
Comments at Step 6: CX/CF 20/14/5-Add.1 (available)

Lead Country: No EWG established

U.S. CURRENT THINKING:
The United States supports final adoption of the draft Maximum Limit (ML) of 0.3 mg/kg for chocolates containing or declaring <30% total cocoa solids on a dry matter basis, as agreed to at CCCF13 and CAC42.

- CAC42 (2019) concluded that if new additional information provided does not justify a change to the draft ML, currently at Step 5, CCCF14 (2020) will recommend the adoption of the draft ML of 0.3 mg/kg by CAC43 (2020).
- Based on our review of data submitted to GEMS in 2019, 100 percent of 69 chocolate samples identified as containing < 30 % cocoa solids (and/or as milk chocolate, with no inclusions) were below the draft ML of 0.3 mg/kg. These 69 samples included samples from Australia, Canada, Cuba, Ecuador, Singapore, and the United States, including 38 samples from Latin America.
- The new information supports finalizing the ML of 0.3 mg/kg for chocolates containing <30 % cocoa solids at Step 8.
- The draft ML is based on proportionality to the established MLs of 0.8 m/kg and 0.9 mg/kg for chocolates containing or declaring ≥50% to <70% and ≥70% total cocoa solids, respectively.
- The draft ML is based on data with good geographical distribution obtained from several rounds of data calls, with a relatively low rejection rate on a worldwide basis.
- Although the draft ML would result in a higher rejection rate for some Latin American and Caribbean countries, it represents a global compromise.
- As noted by the FAO representative at CAC42, (1) the draft ML does not pose a safety concern based on JECFA77 (2013) and (2) cadmium intake from consumption of chocolate and cocoa-derived products was insignificant compared to other sources of dietary exposure to cadmium.

BACKGROUND:
At CCCF13 (April 2019), there was general support for the proposed ML of 0.3 mg/kg for chocolate containing or declaring <30% total cocoa solids on a dry matter basis and the Committee agreed to advance the ML for adoption at Step 5/8 by CAC42, noting the reservations of the EU, Norway, and Ecuador to this decision.

At CAC42 (July 2019), there was extensive discussion on the proposed ML of 0.3 mg/kg for chocolates containing or declaring <30% total cocoa solids on a dry matter basis. As there was no consensus on the final adoption, the proposed ML was adopted at Step 5 which would allow further discussion at CCCF14.

CAC42 noted the reservations of the EU, Norway, and Switzerland. If new additional information provided does not justify a change to the ML, CCCF14 will recommend the adoption of the ML of 0.3 mg/kg by CAC at its next session.

CAC42 confirmed that upon such recommendation by CCCF14, CAC43 “shall adopt” the ML without further discussion. Benin, European Union, Nigeria, Norway, and Switzerland expressed their reservations based on their view that this was not an outcome of the informal discussion, and that CAC42 could not dictate the outcome nor discussions of the next CAC.

Agenda Item 6

Proposed draft maximum levels for cadmium in chocolate and cocoa-derived products containing or declaring ≥30% to <50% total cocoa solids on a dry matter basis; and cocoa powder (100% total cocoa solids on a dry matter basis) (at Step 4)

Current Status: Final document posted on CCCF14 website

Current Documents: CL 2020/19-CF, CX/CF 20/14/6 (available)
Comments at Step 3: CX/CF 20/14/6-Add.1 (not available)

Lead Country: Ecuador (The United States participated as a member of the EWG.)

Recommendations in CX/CF 20/14/6

- CCCF14 is invited to consider the following:
  - The proposed ML ranging from 0.6 mg/kg to 0.7 mg/kg for chocolates and chocolates products containing or declaring ≥30% to <50% total cocoa solids on a dry matter basis.
  - The proposed ML of 2.0 mg/kg to 3.0 mg/kg for cocoa powder (100% total cocoa solids on a dry matter basis) ready for consumption.
  - The proportionality approach when setting MLs for different categories, the MLs previously adopted at CAC41 (2018), and the discussion held on the proposed ML for chocolates containing or declaring <30% total cocoa solids on a dry matter basis at CCCF13 and CAC42 in 2019 (for consideration under Agenda Item 5).

APPENDIX I
(For comments)

Commodity / Product Name	Maximum Level (ML) (mg/kg)	Notes/Remarks
Chocolate and chocolate products containing or declaring ≥30% to <50% total cocoa solids on a dry matter basis,	0.6 – 0.7	Including sweet chocolate, Gianduja chocolate, semi – bitter table chocolate, Vermicelli chocolate / chocolate flakes, bitter table chocolate, couverture chocolate.
Cocoa powder (100% total cocoa solids on a dry matter basis) ready for consumption.	2.0 – 3.0	Product sold for final consumption

U.S. CURRENT THINKING:
Chocolates containing ≥30% to <50% total cocoa solids: Proposed ML of 0.6-0.7 mg/kg

- The United States does not object to an ML in the range of 0.6-0.7 mg/kg. MLs of 0.6 and 0.7 mg/kg have worldwide rejection rates of 12.6% and 6.8% and Latin American rejection rates of 15.4% and 8.95%, respectively.
- The United States also can agree to an ML of 0.5 mg/kg, based on previous proposals.

- The proposed MLs of 0.6-0.7 mg/kg align with the proportionality approach, given the MLs of 0.8 mg/kg and 0.9 mg/kg for chocolates containing or declaring ≥50% to <70% and >70% total cocoa solids.
- Although the proposed MLs of 0.6-0.7 mg/kg would result in higher rejection rates for some Latin American and Caribbean countries, they are based on data provided from several data calls and represent a global compromise.

Cocoa powder containing 100% total cocoa solids: Proposed ML of 2-3 mg/kg

- The United States considers the proposed ML range of 2.0-3.0 mg/kg to be too high based on proportionality to established MLs.
- The United States did not object to the ML of 1.5 mg/kg proposed in 2018 (CCCF12) and 2019 (CCCF13).

BACKGROUND:
At CCCF8 (March 2014), the Delegation of Ecuador introduced a proposal for new work on MLs for cadmium in chocolate and cocoa-derived products. The Delegation informed the Committee that the proposal had been discussed in the in-session Working Group on Priorities, which had proposed that a project document be presented to the plenary. The Delegation noted that while the evaluation of the JECFA77 (June 2013) had noted that the intake of cadmium from the consumption of chocolate and cocoa derived products is not a health concern, the lack of an ML for cadmium in cocoa and its derived products could threaten exports from some member countries, especially developing countries who were the major exporters of cocoa.

The Committee agreed to initiate new work on MLs for cadmium in chocolate and cocoa-derived products, which was approved by CAC37 (July 2014). Since 2014, an EWG led by Ecuador, co-chaired by Ghana and Brazil, has led the work on proposing draft MLs for cadmium in chocolate and cocoa-derived products.

At CCCF12 (March 2018), the Committee agreed to:

- Advance the ML of 0.8 mg/kg for chocolate containing or declaring ≥ 50% to < 70% total cocoa solids on a dry matter basis for final adoption at Step 5/8 (adopted by CAC41, July 2018).
- Advance the ML of 0.9 mg/kg for chocolate containing or declaring ≥ 70% total cocoa solids on a dry matter basis for final adoption at Step 5/8 (adopted by CAC41, July 2018).
- Continue work on the categories of chocolate and chocolate products containing or declaring the following:
    - < 30% total cocoa solids on a dry matter basis,
    - ≥ 30% to < 50% cocoa solids on a dry matter basis, and to assess if it is feasible to merge the <30% and ≥ 30% to < 50% cocoa solids categories to derive one ML for chocolate containing or declaring < 50% cocoa solids on a dry matter basis, and
    - Cocoa powder (100% total cocoa solids on a dry matter basis) taking into consideration MLs established for other product categories.

Most recently, at CCCF13 (April 2019), the Committee agreed to:

- Continue work on MLs for the categories for chocolates and chocolate products containing or declaring ≥30% to <50% total cocoa solids on a dry matter basis and cocoa powder (100% total

cocoa solids on a dry matter basis) for consideration by CCCF14 (2020) using a proportional approach,

- Re-establish the Electronic Working Group (EWG) chaired by Ecuador and co-chaired by Ghana for the continuation of the work, and
- If no consensus were reached at CCCF14 for the remaining chocolate categories the work would be discontinued until the COP for the prevention and reduction of cadmium contamination in cocoa was finalized and implemented.

Agenda Item 7

Proposed draft Code of practice for the prevention and reduction of cadmium contamination in cocoa beans (at Step 4)

Current Status: Final document posted on CCCF14 website

Current Documents: CL 2020/20-CF, CX/CF 20/14/7 (available)
Comments at Step 3: CX/CF 20/14/7-Add.1 (not available)

Lead Country: Peru (The United States participated as a member of the EWG.)

Recommendations in CX/CF 20/14/7

- CCCF is invited to consider the COP as set out in Appendix I of the final document together with the comments submitted in reply to CL 2020/20-CF.

U.S. CURRENT THINKING:

- The United States supports the progress made in developing the COP, which will be an important contribution to lowering cadmium levels in cocoa beans and supporting international trade in cocoa. The United States provided extensive comments and information to the EWG to support this work.
- The United States recommends further revision of the COP before moving forward in the Step process and will provide a tracked changes version of the draft to the Chair of the EWG. The recommended changes include focusing on proven mitigation techniques, clear identification of proposed techniques that are experimental, and removal of Appendix II.

BACKGROUND:
At CCCF11 (April 2017), Peru introduced a proposal to develop the draft Code of Practice and explained that the proposed COP aimed to guide Member States and the cocoa production industry in preventing and reducing cadmium contamination in cocoa beans during the production and processing phases.

The Committee agreed to establish an EWG, led by Peru, working in English, to prepare a discussion paper and project document for discussion on the opportunity to develop such a COP and the risk mitigation measures available that would support the development of a COP.

At CCCF12 (March 2018), after further discussion on the discussion paper presented by Peru, the Committee agree to re-establish an EWG chaired by Peru, co-chaired by Ghana and Ecuador, to further elaborate the discussion paper to:

1) Determine whether mitigation measures available at present would support the development of the COP, and
2) Identify the scope of the COP (e.g., whether the COP will cover the whole production chain or only primary production) based on replies to a CL on a survey to gather information on validated practices throughout the food chain for prevention and reduction of cadmium contamination in cocoa.

If conditions under 1) and 2) above are met, the EWG should provide a project document and a first draft of a COP.

The EWG should focus on mitigation measures that are proven to be cost-effective and applicable

worldwide by large and small-scale producers.

At CCCF13 (April 2019), after further discussion on the discussion paper presented by Peru, the Committee agreed to:

1) Submit a project document to CAC42 for approval as new work, and
2) Established an EWG, chaired by Peru and co-chaired by Ghana and Ecuador to prepare, subject to the approval of CAC42, a draft COP.

CAC42 (July 2019) approved the new work.

Agenda Item 8

Proposed draft MLs for lead in selected commodities for inclusion in the GSCTFF (CXS 193-1995) (at Step 4)

Current status: Final document posted on CCCF14 website

Current Document: CL 2020/21-CF, CX/CF 20/14/8 (available)
Comments: CX/CF 20/14/8-Add. 1 (not available)

Lead Country: Brazil (The United States participated as a member of the EWG.)

Recommendations in CX/CF 20/14/8
CCCF is invited to consider the following proposals:

1. Establish a ML of 0.1 mg/kg for eggs
2. Establish a ML of 1.5 or 2 mg/kg for preserved eggs
3. Establish a ML of 0.2 mg/kg for fresh culinary herbs
4. Establish a ML of 2.0 mg/kg for dried culinary herbs
5. Establish the following MLs for spices
    - 0.6 mg/kg for fruits and berries
    - 2.5 mg/kg for rhizomes, bulbs and roots (dried)
    - 0.8 mg/kg for rhizomes, bulbs and roots (fresh)
    - 3.0 mg/kg for bark
    - 1.0 mg/kg for floral parts
    - 0.9 mg/kg for seed
6. Postpone to next year the establishment of MLs for lead in food for infants and young children and sugar and confectionery, and extracts to analyze again occurrence data addressing the inconsistencies identified.
7. When working on food for infants and young children, consider establishing MLs for cereal-based products in infants and young children "as consumed" to align with other food categories in the GSCTFF.

U.S. CURRENT THINKING:

- Based on industry input, the proposed MLs for dried culinary herbs; dried rhizomes, bulbs, and roots; dried bark; and dried floral parts are achievable; for the categories "fruits and berries" and "seed, MLs of 1.0 mg/kg would be achievable.
- We have some concerns with the proposed MLs for bark (e.g., cinnamon), and for dried rhizomes, bulbs, and roots (e.g., turmeric) on a health basis.
- We are currently reviewing additional data to refine positions on the proposed MLs for dried culinary herbs and spices, fresh culinary herbs, and eggs.
- We question whether an ML for preserved eggs is needed, given that most samples are from China and Singapore. Preserved eggs may not be an important commodity in international trade.
- We agree with further review of the MLs for lead in sugars and confectionery.
- We agree with further review of the MLs for lead in food for infants and young children. We also have specific comments on the following categories:
    - Fruit juice for infants and young children: An ML may not be needed. Data on lead in fruit juice for infants and young children were included in the recent reassessment of

existing lead MLs, and these products are covered by the revised MLs in the GSCTFF.
- Herbal teas for infants and young children: An ML may not be needed. Herbal tea for infants and young children appears to be a regionally consumed food, based on the small number of data available from only one region.
- Dairy products: It may be possible to consolidate the dairy product subcategories. If there are still not enough data or if consolidation is not appropriate, these foods may not be important in international trade, and establishing MLs may not be needed.
- Cereals: MLs for cereal-based products for infants and young children should be based on an "as is"/dry basis, comparable to deoxynivalenol MLs for cereal-based foods for infants and young children. Lead concentrations measured on an "as consumed" basis will vary depending on preparation method.

BACKGROUND:
At CCCF11 (April 2017), the Committee noted that current work on the revision of the MLs for lead is limited to those food categories listed in the General Standard for Contaminants and Toxins in Food and Feed (GSCTFF). There was however wide support to continue working on new MLs for lead for a range of categories. An EWG, led by Brazil, was established to prepare a discussion paper on a structured approach to prioritize commodities not included in the GSCTFF and proposed new MLs.

At CCCF12 (March 2018), the Committee agreed to re-establish an EWG led by Brazil to prepare for CCCF13 a revised discussion paper and project document which took into consideration exposure data (in addition to other criteria for prioritization of commodities) in establishing the prioritization of the categories, and to propose MLs for food categories identified as high priority.

At CCCF13 (April 2019), the Committee agreed with the selection and prioritization criteria presented and decided to focus on proposing MLs for food for infants and young children (except those for which MLs have already been established in the GSCTFF), spices and aromatic herbs, eggs and sugars and confectionery, excluding cocoa.

The Committee also agreed to:
- Submit a revised project document to CAC42 for approval as new work,
- Establish an EWG, chaired by Brazil, to prepare, subject to approval of CAC42, proposed draft MLs for comment and consideration at CCCF14, and
- Issue a call for data on the agreed categories in order to identify sub-categories for which MLs could be proposed for consideration by CCCF14

CAC42 (July 2019) approved the new work.

Agenda Item 9

Proposed draft revision of the *Code of Practice for the prevention and reduction of lead contamination in foods* (CXS 56-2004) (at Step 4)

Current status: Final document posted on CCCF14 website

Current Document: CL 2020/22-CF, CX/CF 20/14/9 (available)
Comments at Step 3: CX/CF 20/14/9-Add. 1 (not available)

Lead Country: United States

Recommendations in CX/CF 20/24/9
CCCF14 should:

- Note the revisions made to the COP based on the discussion held and comments submitted at CCCF13 as well as the submissions made to the EWG
- Consider the revised COP as set out in Appendix I of the final document together with comments submitted in reply to CL 2020/22-CF

U.S. CURRENT THINKING:

- The United States supports advancement of the COP for final adoption at Step 5/8.
- The United States drafted the revisions, in close cooperation with the U.K. and Japan.
- The COP provides additional information on sources of lead that include lead paint, corrosion of lead pipes, damaged or unused fencing batteries, and consumption of waterfowl that have ingested lead pellets.
- The COP provides additional information on measures to reduce lead that include:
    - Securing fencing and housing for livestock
    - Considering testing soil if gardens are located in areas with potentially high lead levels
    - Referencing WHO Guidelines for Drinking-Water Quality
    - Adding an example of an alternative filtration method for juices, wine, and beer
    - Using an alternative water source for food preparation that does not contain lead
    - Using x-ray detection to identify and facilitate removal of lead shot

BACKGROUND:
At CCCF12 (March 2018), the United States introduced a proposal for new work on the revision of the 2004 COP.

- The purpose of the new work is to reflect new information available on measures to reduce lead during agricultural production and food processing.
- A revised COP would complement work by CCCF on lead, including revision of MLs for lead in selected commodities in the GSCTFF and future work on MLs for lead for inclusion in the GSCTFF.
- The scope of the new work would encompass updating the existing COP to add new information on lead reduction in the areas of:
    - Agricultural production (e.g., techniques to address lead contamination in soil and water).
    - Food processing (e.g., filtration aids for juice manufacture, measures to reduce lead in food during cooking, and minimizing introduction of lead from food processing equipment).
- The Committee agreed to establish an EWG chaired by the United States, co-chaired by the United

Kingdom, to prepare a discussion paper, including a project document, for a proposal for new work on the revision of the COP for consideration by CCCF13.

At CCCF13 (April 2019), the United States presented the discussion paper that was intended to provide additional information on sources of lead in food and updated measures for reducing lead in food that had become available since the publication of the COP.

CCCF14 generally agreed with the discussion paper and agreed to (1) submit a project document to CAC42 for approval as new work and (2) establish an EWG chaired by the United States and co-chaired by UK and Japan, to prepare, subject to approval of CAC42, a revised version of the COP for comments and consideration at CCCF14. CAC42 (July 2019) approved the proposal for new work.

Agenda Item 10

Proposed draft MLs for total aflatoxins in certain cereals and cereal-based products including foods for infants and young children (at Step 4)

Current Status: Final document posted on CCCF14 website

Current Documents: CL 2020/23-CF, CX/CF 20/14/10 (available)
Comments at Step 3: CX/CF 20/14/10-Add.1 (not available)

Lead Country: Brazil (The U.S participated as a member of the EWG)

Recommendations in CX/CF 19/13/8

PROPOSED DRAFT MAXMUM LEVELS FOR TOTAL AFLATOXINS IN CERTAIN CEREALS AND CEREAL-BASED PRODUCTS INCLUDING FOODS FOR INFANTS AND YOUNG CHILDREN

Food category	Proposal 1		Proposal 2	
	ML	Sample rejection (%)	ML	Sample rejection (%)
Maize grain, destined for further processing[a]	20 µg/kg	4.5	15 µg/kg	5.4
Flour, meal, semolina and flakes derived from maize	15 µg/kg	1.1	10 µg/kg	1.5
Husked rice	20 µg/kg	2.2	15 µg/kg	2.7
Polished rice	8 µg/kg	0.5	4 µg/kg	1.2
Sorghum grain, destined for further processing[a]	10 µg/kg	2.0	8 µg/kg	2.7
Cereal-based Food for infants and young children[b]	2 µg/kg	0.4	1 µg/kg	0.7

[a]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; [b]All cereal-based foods intended for infants (up to 12 months) and young children (12 to 36 months).

OTHER MATTERS

Codex members and observers are also invited to provide comments or information on the following:

a) Whether sampling plans and performance criteria for the analysis of total aflatoxins for the food categories listed above, considering each of the MLs should be developed;

In the affirmative, please consider the following questions:

b) Whether performance criteria for AFs should consider 70% of total aflatoxins would be AFB1 and the remaining 30% would be distributed equally between AFB2, AFG1 and AFG2;

c) Provide information on analytical methods and sampling plans for the analysis of AFs in cereals and cereal-based products in order to inform the discussion on the associated sampling plans and performance criteria.

U.S. CURRENT THINKING:

General Comments

- Impact Assessment: CCCF should ask JECFA for evaluation of exposure and risk reduction for various proposed MLs, including to determine if similar health impacts could be achieved at lower sample rejection rates. This follows the precedent set in the peanut aflatoxin MLs impact assessment.
- Proposed MLs and Method Limit of Quantitation (LOQ) consideration: Several proposed MLs, namely 4 µg/kg for polished rice and 1-2 µg/kg for infant cereals, are below the LOQs for collaboratively validated aflatoxin methods. As a result, there may not be fit for purpose methods available to test foods at the proposed MLs.
    - For a method to be fit for purpose, the analytical range which encompasses the ML should be captured in a collaborative study protocol.
    - Available AOAC (collaborative) methods for the determination of aflatoxins in grains, nuts, and corn specify 5 ng/g (or higher) as the lower end of the analytical range of the method.
    - While individual laboratories may report LOQ values lower than the concentration stated in the compendial method, and such results may be included in the Global Environment Monitoring System (GEMS)/Food database, individual lab performance does not supersede the analytical range established in the collaborative study.
    - The recommendation for collaborative studies to determine method reproducibility (Codex *Procedural Manual* (p. 78, 26th Ed)) still applies when numeric criteria are used instead of method endorsement.
    - While there are sensitive mass spectrometric methods that can determine total aflatoxin at very low concentrations, we are not aware of these methods undergoing collaborative studies that included appropriate matrices at the proposed MLs. Also, mass spectrometric methods may not be available to laboratories in all regions of the world.
- Year to year variation: The proposal presents but does not take into account year to year variations in aflatoxin levels.

Comments on proposed MLs

Maize grain, destined for further processing: Proposed ML of 15 µg/kg or 20 µg/kg

- We potentially would not object to the proposed ML of 20 µg/kg.
- On a yearly basis, the 95th percentile of the global dataset exceeded the proposed ML of 15 µg/kg in 4 of 14 years.
- We recommend an accompanying note that an ML does not apply to maize for wet milling or animal feed.

Flour, meal, semolina, and flakes derived from maize: Proposed ML of 10 µg/kg or 15 µg/kg

- We potentially would not object to the proposed ML of 15 µg/kg.

- The proposed MLs of 10 µg/kg and 15 µg/kg have similar levels of intake reduction, but 15 µg/kg would have less impact on trade.

Husked rice: Proposed ML of 15 µg/kg or 20 µg/kg

- The United States potentially would not object to the proposed ML of 20 µg/kg.
- However, we are concerned with the lack of data from major rice producing and consuming countries in Asia. We suggest gathering more globally representative data before establishing MLs.

Polished rice: Proposed ML of 4 µg/kg or 8 µg/kg

- The United States would not support the proposed ML of 4 µg/kg.
- As noted in general comments, we are not aware of collaboratively validated methods with an LOQ that will support this ML.
- In addition, the proposed ML of 4 µg/kg is below the LOQ of methods used in rapid inspections for bulk grain.
- While United States can meet the proposed ML of 8 µg/kg based on review of GEMS data presented, we are concerned with the lack of data from major rice producing and consuming countries. We suggest gathering more globally representative data before establishing MLs.

Sorghum grain, destined for further processing: Proposed ML of 8 µg/kg or 10 µg/kg

- The United States does not support CCCF establishing an ML for sorghum without considering data on sorghum for human food use from Africa, which is a primary sorghum-consuming region.
- We note that 99% of the data in the document are from the United States, and the remaining data are only from Indonesia, Japan, and Korea.

Cereal-based food for infants and young children: Proposed ML of 1 µg/kg or 2 µg/kg

- The United States does not support the proposed MLs of 1 µg/kg or 2 µg/kg based on current data and approach.
- As noted in general comments, we are not aware of collaboratively validated methods with an LOQ that will support an ML of 1 to 2 µg/kg in cereal-based foods for infants and young children.
- The data are not globally representative, with 76% of data from the EU, which already has a limit of 0.1 µg/kg in place for aflatoxin B1.
- The approach used was to convert all data to 0 for results with LOQs < 8 ug/kg and omit data for results with an LOQ > 8 µg/kg. This approach could potentially eliminate samples with values > 2 µg/kg, and present a misleading picture of whether the MLs of 1-2 µg /kg are globally achievable on the proposed 95th percentile basis.

Response to Other Matters

a) Sampling plans and performance criteria for the analysis of total aflatoxins should be developed for food categories for which MLs are adopted.
b) Because total aflatoxins is a "sum of components," CCMAS will need to be consulted on the best approach for the criteria.
c) Numeric criteria and not the endorsement of specific methods should be used. The proposed 70 percent value may not be appropriate for all cereal grains.

BACKGROUND:

At CCCF12 (March 2018), Brazil, as the Chair of the EWG, introduced a Discussion Paper on Aflatoxins and Sterigmatocystin (STC) Contamination in Cereals (CX/CF 18/12/15) with the following

recommendations:

- Due to the toxicity and occurrence of aflatoxins, a proposal was made to set MLs for aflatoxins in cereals and cereal-based foods, including foods for infants and young children,
- It was premature to set MLs for STC due to the lack of an internationally validated analytical method and reference material for this mycotoxin, and
- Consideration could be given to development of an annex to the *Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals* (CXC 51-2003) if there are specific management practices available for STC in cereals.

After further discussion, the Committee agreed to:

- Establish an EWG, chaired by Brazil and co-chaired by India, to further develop the discussion paper and provide proposed MLs for total aflatoxins in wheat, maize, sorghum and rice (specifying the categories) for grains for human consumption, and also propose MLs for flour and cereal-based foods for infants and young children,
- Inform Standard Developing Organizations of the need for an internationally validated method of analysis for STC through CCMAS, and because there was insufficient information for the development of an annex for STC, no action was needed at this stage.

At CCCF13 (April 2019), Brazil as Chair of the EWG introduced the discussion paper and, after extensive discussion, the Committee agreed to:

- Submit a project document for new work to establish ML for total aflatoxins in certain cereals and cereal-based products, including food for infants and young children,
- Establish an EWG, chaired by Brazil and co-chaired by India to present at CCCF14 a proposal for MLs for total aflatoxins in:
  - Maize grain destined for further processing
  - Flour, meal, semolina and flakes derived for maize
  - Husked and polished rice (excluding parboiled rice)
  - Sorghum
  - Cereal-based food for infants and young children,
- Issue a call for data for all discussed food categories for submission to GEMS/Food, and
- Consider other cereals and cereal-based products once the work on the MLs for the current set of commodities was completed

Agenda Item 11*

Proposed draft ML for total aflatoxins in ready-to-eat peanuts and associated sampling plan (Held at Step 4)

Current Documents: REP18/CF, para.115, Appendix VII (available)

Lead Country: India

*This agenda item is not for discussion according to the decision of CCCF12 (March 2018) to hold the ML to ensure the implementation of the *Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Peanuts* (CXC 55-2004) to generate additional data to be assessed by JECFA in three years' time (REP18/CF, paragraph 115).

In considering the decision on the ML for total aflatoxins in ready-to-eat peanuts during Critical Review, CCEXEC75 recommended that CCCF accelerate the process to finalize the ML and sampling plan for this contaminant/commodity combination (REP18/EXEC2-Rev.1, paragraph 23)

Agenda Item 12*

Proposed draft MLs for total aflatoxins and ochratoxin A in nutmeg, dried chili and paprika, ginger, pepper and turmeric and associated sampling plans (Held at Step 4)

Current Documents: REP18/CF, para.119, Appendix VIII (available)

Lead Country: India

*This agenda item is not for discussion according to the decision of CCCF12 (March 2018) to hold the MLs to ensure the implementation of the *Code of Practice for the Prevention and Reduction of Mycotoxins in Spices* (CXC 78-2017) to generate additional data to be assessed by JECFA in three years' time (REP18/CF, paragraph 119).

Agenda Item 18

Discussion paper on the approach to identity the need for revision of standards and related texts developed by CCCF

Current status: Final document posted on CCCF14 website

Current Documents: CX/CF 20/14/16 (available)

Lead Country: Canada (The United States participated as co-chair of the EWG)

Proposed Options and Recommendations in CX/CF 20/14/16

PROPOSED OPTIONS

Option 1 – Status quo: Existing Codex standards would continue to be reviewed on an *ad hoc* basis, upon nomination by Member countries and/or CCCF on the basis of new and adequate data and scientific information.

Option 2 – Tracking lists: Establish tracking lists of Codex standards > 15 and > 25 years old and of standards recommended for re-evaluation by CCCF, CAC, or a Member country. The review of existing Codex standards would continue on an *ad hoc* basis, as described in paragraph 43 of CX/CF 20/14/16.

Option 3 – Tracking & prioritization lists: Establish tracking lists of Codex standards > 15 and > 25 years old and of standards recommended for re-evaluation by CCCF, CAC, or a Member country. Any Codex standards meeting the "25-year rule" would be prioritized for assessment by a Member country for the availability of adequate new data and scientific information in order to determine if such information is sufficient to warrant a review of the standard. If a Member country does not volunteer for the assessment, the work would be assigned to a Member country by CCCF or Codex Secretariat. Option 3 would help ensure that the availability of new data or scientific information is considered for all Codex Maximum Limits (MLs), Guidance Limits (GLs), and Code of Practices (CoPs) every 25 years, at a minimum. Codex standards could still be reviewed on an ad hoc basis, as described in paragraph 43.

RECOMMENDATIONS

CCCF is invited to consider implementing Option 2, as described in paragraph 43. It is proposed that Option 2 be implemented for 3 years, after which time its effectiveness could be reviewed and discussed in 2023 by CCCF17.

The process by which Option 2 could be implemented and how this could be integrated with the process related to new Codex standard development is outside the scope of this discussion document. However, a possible approach for Option 2 could involve:

- Establishing an EWG to generate, and annually maintain, the following lists:
  - List(s) of contaminant standards established or most recently updated > 15 and > 25 years ago.
  - List of Codex standards that have been recommended for re-evaluation by CCCF, CAC, or a Member country within a certain period of time or at an unspecified future date.
- The above tracking lists would be shared with CCCF in advance of each meeting. An in-session working group at the annual CCCF meeting could summarize the current review status, if any, and make any recommendations to CCCF for review priorities from the tracking lists. CCCF would then consider how to balance these priorities with new Codex standard development.
- Member countries that nominate existing Codex standards for review or new Codex standards for elaboration would take the item on as new work and present their findings in the form of a

discussion paper.

U.S. CURRENT THINKING:

- The United States was co-chair of the EWG and supports the proposal for CCCF to consider implementing Option 2 for three years.

BACKGROUND:
At CCCF11 (April 2017), the Codex Secretariat highlighted the need for CCCF to develop a forward work plan to strategically establish or prioritize items within its workload. The Committee agreed that the Codex Secretariat and Host Country Secretariat would develop a plan to address this issue and report back at CCCF12.

At CCCF12 (March 2018), a discussion paper regarding the forward workplan of CCCF was presented. The WHO Representative underlined the value of longer-term forward planning to identify areas of concern for public health with trade implications, allowing for data gathering well in advance. The Committee agreed that a further discussion paper would be prepared by the Codex, JECFA and the Host Country Secretariats with assistance of EU. The paper would focus on whether CCCF covered the main staple foods moving in international trade and the related presence of contaminants being of public health concern.

At CCCF13 (April 2019), a discussion paper was presented to identify areas of work that CCCF could prioritize for future meetings. The focus was on the reduction of health risks resulting from chemical contamination of food. The importance of the identified commodities in trade was to be identified in a later stage. Four key areas were presented in the appendices to the discussion paper. Appendix C focused on the review of existing Codex standards, that is, Maximum Levels (MLs) and Guideline Levels (GLs) in the *General Standard for Contaminants and Toxins in Food and Feed* (CXS 193-1995), and Codes of Practice (CoPs).

Appendix C of the discussion paper outlined that CCCF, and the Codex Committee on Food Additives and Contaminants (CCFAC) before it, established numerous standards, namely MLs, GLs, and CoPs. Some standards were established long ago and have not been revised since, and for some contaminants CoPs have been established and no MLs have been developed to date. At this time, updates to Codex standards stem from discussions at CCCF, JECFA evaluations, and when new information becomes available. CCCF was invited to consider if a structured approach with criteria on when and why to update/supplement existing standards should be developed and if yes, what this approach should entail.

The Committee noted that keeping existing standards up to date was important, a work plan would be needed, the proposed approach should not lead to too much administrative burden and should not preclude *ad hoc* decisions to revise the existing standards. The Committee agreed to establish an EWG, chaired by Canada and co-chaired by Japan and the United States to prepare a proposal for an approach to identify the need for review of existing CCCF standards for consideration at CCCF14.

Agenda items with no documents posted and not for discussion

Agenda Item 4: Matters of interest arising from other international organizations

Agenda Item 13: Discussion paper on MLs for methylmercury in additional fish species

Agenda Item 14: Discussion paper on MLs for HCN in cassava and cassava-based products and COP for the prevention and reduction of mycotoxin contamination in cassava and cassava-based product

Agenda Item 15: Discussion paper on MLs for cadmium and lead in quinoa

Agenda Item 16: Discussion paper on radioactivity in feed and food (including drinking water) in normal circumstances

Agenda Item 17: General guidance on data analysis for ML development and for improved data collection

Agenda Item 19: Forward work-plan for CCCF

- Agenda Item 19(a): Review of staple food-contaminant combination for future work of CCCF
- Agenda Item 19(b): Project plan for the evaluation of implementation of COPs of CCCF

Agenda Item 20: JECFA Evaluations

- Agenda Item 20(a): Priority list of contaminants and naturally occurring toxicants for evaluation by JECFA
- Agenda Item 20(b): Follow-up work to the outcome of JECFA evaluations