



**JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON CONTAMINANTS IN FOODS**

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**Comments submitted by the United States
Agenda Items 5, 6, 7, 8, 9, 10, 11, 12 and 13**

**Agenda Item 5
(CL 2017/23-CF)**

Proposed draft and draft revised maximum levels for lead in selected fruits and vegetables (fresh and processed) and other selected food categories in the *General Standard for Contaminants and Toxins in Food and Feed (CODEX STAN 193-1995)* (at Steps 7 and 4)

- The U.S. agrees with the recommendations in paragraphs 15 to 24 of the document.

**Agenda Item 6
(CL 2017/24-CF)**

Proposed draft maximum levels for cadmium in chocolate and cocoa-derived products (at Step 4)

- JECFA concluded in 2013 that total cadmium exposure, including for high consumers of cocoa and cocoa products, was not considered to be of concern. In 2014, Ecuador proposed work on MLs because the lack of MLs for cadmium in cocoa and its products could threaten the exports of some member countries, especially developing countries.
- Since there is no health concern from exposure to cadmium in chocolate and cocoa products based on the JECFA assessment, it is important that the proposed new MLs do not negatively impact exports from these countries.
- At this time, the U.S. cannot recommend that the proposed MLs move forward in the step process.
 1. The U.S. is concerned that the data presented to support MLs for dry cocoa mixtures and chocolate products may not capture differences in cadmium levels due to geographic origin. Failure to consider geographic origin could negatively impact countries with cocoa beans that contain higher levels of cadmium, such as some Latin American countries. Although Appendix I identifies countries that contributed data for specific chocolate categories, it is not possible to determine from the data presented if certain countries (or regions) are associated with higher cadmium levels and thus negatively impacted by proposed MLs, or if particular countries (or regions) are underrepresented in the data collection.
 2. The U.S. is concerned that some of the proposed MLs may not be achievable. For example, in a small U.S. Food and Drug Administration (FDA) survey of chocolate bars collected at retail in the United States, 13% of chocolate bars with >70% total dry cocoa solids exceeded the proposed ML of 0.8 mg/kg. All of the samples of known origin that exceeded this ML were from Latin America.
 3. Additional (or subset) product categories of MLs may be needed, including for chocolate with very high cocoa solids content; dry mixtures of cocoa and sugars with higher levels of cocoa solids, e.g., > 50 percent; and for cocoa powder (without sugar) sold at retail.
- The U.S. suggests the Committee consider two options:

1. Reestablish the EWG for development of a revised draft paper for comments and consideration at the 12th Session of CCCF in 2018. The Committee should renew the request to member countries and organizations for new data, including data on country of origin and percent total cocoa solids.
2. Request that JECFA conduct an impact assessment of proposed MLs. In its analysis, the EWG stated that MLs established for cocoa-derived products should be based primarily on practical achievability worldwide using a 95 percent cutoff. However, given JECFA's conclusion that total cadmium exposure is not of concern, including for high consumers of cocoa and cocoa products, the U.S. recommends that the Committee ask JECFA to conduct an impact assessment of proposed MLs (including possible higher alternate MLs). The results of the impact assessment should be used to guide ML selection, rather than achievability alone. As with Option 1, the Committee should renew the request to member countries and organizations for new data, including data on country of origin and percent total cocoa solids.

Agenda Item 7

(CL 2017/25-CF)

Proposed draft Code of practice for the prevention and reduction of arsenic contamination in rice (at Step 4)

General Comments

- The United States recommends advancing the Code of Practice to Step 5/8 for adoption by the 40th Session of the Commission.
- The U.S. supports finalizing the draft Code of Practice, which includes source directed measures (such as identifying sources of pollution and elevated arsenic in irrigation water), agricultural measures (such as aerobic growth, intermittent ponding, and identifying rice cultivars that contain or absorb arsenic at low levels), and risk communication for reducing arsenic during processing and cooking (such as use of water containing low arsenic levels for washing and cooking and cooking in large volumes of water).
- The U.S. recommends that CCCF finalize a short, simple Code of Practice in 2017, as originally proposed in the project document. The U.S. does not support postponing the Code of Practice.
- The U.S. considers establishing a Code of Practice in 2017 important to support MLs for inorganic arsenic in polished and husked rice, which have already been adopted by the Commission.
- CCCF should update the Code of Practice in the future, as additional information and data become available.

Specific Comments on Appendix I

- Paragraph 1.1. The U.S. recommends the following revised first sentence: "Arsenic is a toxic metalloid that can be found in various foods, including rice."
- Paragraph 2.1. The U.S. recommends the following revised sentence: "The Code intends to provide national or relevant food control authorities, producers, manufacturers and other relevant bodies with guidance to prevent and reduce arsenic contamination in rice as follows:"
- Paragraph 3.6. The U.S. recommends inclusion of the following sentence in square brackets: "Inorganic arsenic is considered the significant toxic form of arsenic in rice."
- Paragraph 3.7. The U.S. recommends the following revised sentence: "**Flooded condition** is a condition in which a paddy field is filled or covered with water during growth."
- Paragraph 3.8. The U.S. recommends the following revised sentence: "**Aerobic condition** is a condition in which rice is grown in well drained, non-flooded and unsaturated soils."
- Paragraph 3.10. The U.S. recommends deletion of this sentence that states: "**Production under irrigation** means any type of irrigation such as sprinkler or drip irrigation, except flooding irrigation."
- Paragraph 4.1. The U.S. recommends inclusion of this paragraph that states: "Inorganic arsenic is the most toxic form of arsenic. Measures to reduce arsenic (e.g., flooding/aerobic growth) may affect inorganic and organic arsenic differently. The most important goal is to reduce inorganic arsenic."
- Paragraph 5.1. The U.S. recommends the following revised sentence: "The effectiveness of measures to prevent or reduce inorganic arsenic should be monitored by determining the concentrations of inorganic arsenic in rice."
- Paragraph 5.2. The U.S. recommends the following revised sentence: "If agricultural land or ground waters used for growing rice are widely contaminated by natural sources, non-point source or historical activities, monitoring of arsenic concentrations in soil and/or irrigation water may also be necessary."
- Paragraph 6.1. The U.S. recommends the following revised sentence: "National or relevant food control authorities should consider sharing information on risks and benefits of consuming polished and/or husked rice among stakeholders in light of arsenic concentrations and nutrient components, considering concerns regarding arsenic concentrations and the nutritional benefits of rice consumption."

- Paragraph 6.2. The U.S. recommends the following revised sentence: “National or relevant food control authorities should consider sharing the following information with rice producers, distributors and consumers and consider encouraging them to implement practices that would reduce arsenic concentration during processing and cooking.”
- Paragraph 6.3. The U.S. recommends the following revised paragraph: “Polished rice contains less inorganic arsenic than husked rice because polishing removes inorganic arsenic in the bran layer. Husked rice polished at the higher polishing rate results in polished rice with lower arsenic concentrations. However, there are also benefits associated with consumption of husked rice.”

Agenda Item 8

(CL 2017/26-CF)

Proposed draft maximum level for total aflatoxins in ready-to-eat peanuts (at Step 4)

- The U.S. supports the recommendation in paragraph 9 that an ML of 15 µg/kg for total aflatoxins in ready to eat (RTE) peanuts be considered by the Committee, based on the results of the JECFA83 evaluation. JECFA83 concluded that enforcing an ML of 10, 8, or 4 µg/kg for RTE peanuts would have little further impact on dietary exposure to total aflatoxins for the general population, compared with setting an ML of 15 µg/kg.
- There is no term or definition for RTE peanuts in the GSCTFF. To be consistent with the definition for RTE tree nuts and RTE dried figs in the GSCTFF, the U.S. recommends the following definition for RTE peanuts: “peanuts, which are not intended to undergo an additional processing/treatment that have proven to reduce levels of aflatoxins before being offered for direct human consumption.”
- The Committee needs to clarify whether the ML is intended to apply to peanuts shipped in packages for consumers. If so, the U.S. agrees that a sampling plan for total aflatoxins in packaged RTE peanuts should be developed before moving forward with a proposed ML in the Step process. We note that we do not consider raw shelled peanuts and raw in-shell peanuts as ready to consume.
- The U.S. recommends using the existing “Sampling Plan for Total Aflatoxins in Peanuts Intended for Further Processing” in Schedule 1, Annex 1 of the General Standard for Contaminants and Toxins in Food and Feed (GSCTFF) (CODEX STAN 193-1995) for bulk RTE peanuts.

Agenda Item 9

(CL 2017/27-CF)

Proposed draft annex on the prevention and reduction of ergot and ergot alkaloids contamination in cereal grains (for inclusion in the Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals (CAC/RCP 51-2003)) (at Step 4)

Specific Comments:

- Paragraph 6.e. states: “Where low and zero tillage crop rotation practices are normally followed, other mitigation measures take on greater importance.”
 - The U.S. recommends providing illustrative examples of “other mitigation measures” that take on greater importance.
- Paragraph 12 states: “It is important that ergot sclerotia and dust particles are eliminated at each stage of the food processing chain to prevent carryover to the next stage of processing.”
 - The U.S. considers it impractical and impossible to “eliminate” or “completely remove” ergot sclerotia and dust particles and suggests the following revision:
 - “Where possible and practical, eliminate as many ergot sclerotia and dust particles as possible at each stage of the food processing chain to reduce carryover to the next stage of processing.”
- Paragraph 18 states: “Ensure that any dust is removed well before the milling process including, the option of removing and replacing the flour filter in the crusher are of the mill unit.”
 - The U.S. suggests the following revision for clearer understanding:
 - “To prevent ergot dust from accumulating in milled flour, consider removing and replacing, as needed, the flour filter in the crusher area of the mill unit.”

Agenda Item 10

(CL 2017/28-CF)

Proposed draft Code of practice for the prevention and reduction of mycotoxin contamination in spices (at Step 4)

General Comments:

The U.S. appreciates the work that Spain, India, and The Netherlands have done in preparing this draft Code of Practice and considers this Code of Practice important as it would help governments, farmers, industry and consumers in reducing mycotoxin levels in spices.

Specific Comments:

- The U.S. agrees with the conclusions in APPENDIX II, paragraphs 2.i. to 2.vii. In particular, paragraph 2.i that states “The scope of the COP (Part B of the Introduction) has been narrowed to “Spices” (as opposed to “dried aromatic herbs or culinary herbs”) by deleting “leaf/leaves or herbs” in accordance with the discussion held at CCCF10 and the Classification of Food and Feed (CAC/MISC 4-1989).”
- The U.S. agrees with the following recommendation in APPENDIX II, paragraph 3: To propose the Committee to consider the proposed draft code of practice for the prevention and reduction of mycotoxins in spices for advancement in the step procedure (Step 5 or Step 5/8).
- The U.S. does not agree with the following recommendation in APPENDIX II, paragraph 3: To propose the Committee on Food Hygiene to consider the possibility of including some general practices for spices on hygienic practices during transportation (Section 2.3.4.2) and packaging (Section 2.3.5) mentioned in paragraph 2 (points v. and vi.) within the Code of Hygienic Practice for Low Moisture Foods, Annex III on spices and dried aromatic herbs (CAC/RCP 75-2015).
 - The Code of Hygienic Practice for Low Moisture Foods, Annex III on spices and dried aromatic herbs already includes some general (non-mycotoxin related) practices for spices related to transportation (Section VIII – TRANSPORTATION) and packaging (Section 5.4 Packaging).
 - The U.S. believes the hygienic practices specifically related to mycotoxins mentioned in paragraph 2 (points v. and vi.) are appropriate for this Code of Practice, but are not needed in Annex III of the Code of Hygienic Practice for Low Moisture Foods, which addresses contamination by pathogenic microorganisms.
- The U.S. does not object to the following recommendation in APPENDIX II, paragraph 3: “To propose the Committee on Food Labeling to endorse the part of this Code of Practice dealing with Labeling and distribution/information to consumers (Section 2.3.6), already mentioned in paragraph 2 (point vii.)”
- The U.S. agrees with the following recommendation in APPENDIX II, paragraph 7: To stop work on specific Annexes to the General Code of Practice at this stage until more information on specific management practices becomes available.

Agenda Item 11 **(CX/CF 17/11/11)**

Discussion paper on maximum levels for mycotoxins in spices

General

- The U.S. agrees with the Priority List of Spices (Nutmeg, Chili and Paprika, Ginger, Pepper, Turmeric) in Annex V for consideration for the establishment of MLs for total aflatoxins.
- The U.S. would not object to establishment of MLs for ochratoxin A for individual spices in the Priority List of Spices in Annex V.
- The U.S. supports requesting JECFA to perform an exposure assessment for health impact on proposed MLs for spice(s)/mycotoxin(s) combinations mentioned in Annex V for total aflatoxins and ochratoxin A, but not for aflatoxin B1.
- The U.S. reiterates its position on establishing MLs for total aflatoxins, rather than total aflatoxins and aflatoxin B1, for the following reasons:
 - Establishing an ML only for total aflatoxin is sufficient because total aflatoxins include B1, B2, G1, and G2, and a separate ML for B1 is not necessary.
 - Establishing MLs only for total aflatoxins is consistent with MLs only for total aflatoxins that have been established for other commodities, i.e., peanuts, tree nuts, and dried figs, by CCCF and the Commission.

Individual versus group MLs

- The U.S. continues to recommend establishment of MLs for total aflatoxins and ochratoxin A in individual spices in the Priority List of Spices in dried or dehydrated form based on consumption and occurrence data.
- However, if the agreement of the Committee is to develop the same ML for all of the individual spices, they should be consolidated in a broad category of “spices” in the GSCTFF, with the possibility of addressing individual spices in the Notes section.
- If more than one ML is proposed for total aflatoxins or ochratoxin A in individual spices, and CCCF cannot agree on an ML, the U.S. recommends that CCCF requests JECFA to evaluate the impact on dietary exposure for total aflatoxins and ochratoxin A at various MLs proposed by CCCF.

Agenda Item 12**(CX/CF 17/11/12)****Discussion paper on methylmercury in fish**

- The U.S. believes that consumption advice is more appropriate for addressing methylmercury in fish than setting maximum levels.
- The U.S. agrees with the conclusion in the document, based on review of occurrence and consumption data, that setting an ML for canned tuna is not appropriate.
- As the Committee continues to work on establishing MLs for methylmercury in fish, the U.S. believes that:
 - Additional collection of worldwide occurrence and consumption data are needed, and the analysis should clearly identify countries that have contributed data.
 - Greater consideration and analysis should be given to assess whether MLs should be set for a single species, for a group of fish species, or for a single species based on highest mercury levels in a subspecies (“generic ML”).
 - Attention needs to be given to the sampling plan and methodology during the development of MLs, e.g., testing for methylmercury vs total mercury, sampling large lots of small fish vs large predator fish, sampling consumer ready packaged fish vs whole fish, etc.
 - The preliminary analysis that forms the basis of recommendations in paragraph 15 for additional species for ML development is not sufficient as a basis for future work, e.g., fish with low average concentrations were targeted for future MLs based solely on high maximum concentrations.
 - An ALARA approach to establish MLs may be more compatible with the use of national fish consumption advice than health-based MLs. National fish consumption advice would more appropriately reflect the variability in fish consumption levels worldwide, and the variability in mercury concentrations in different fish species.
- The U.S. recommends the following specific next steps:
 - The Committee should identify a limited number of specific fish in the project document on which to begin work, i.e., the highest priority fish in paragraph 16 under Recommendations. Reasons for limiting the scope to these fish include:
 - Many technical issues remain to be resolved, e.g., the correct approach to setting MLs, sampling plans, testing for methylmercury versus total mercury, etc.
 - The Committee needs to consider whether the current Codex GLs would still apply to fish species other than specific fish species for which new MLs may be established.
 - If the Committee decides that an EWG should consider both the ALARA and risk benefit approaches, this should be stated clearly in the Project Document, e.g., “3d. Achievability of the Approach” should read, “3d. The EWG will consider which approach is appropriate, an ALARA or risk-benefit approach.”

Agenda Item 13**(CX/CF 17/11/13)****Discussion paper on non-dioxin like PCBs in the Code of Practice for the Prevention and Reduction of Dioxin and Dioxin-like PCB Contamination in Food and Feeds (CAC/RCP 62-2006)**

The U.S. supports the following recommendations made by the EWG in paragraph 16:

- To propose the review and update of the *Code of Practice for the Prevention and Reduction of Dioxin and Dioxin-like PCB Contamination in Food and Feeds (CAC/RCP 62-2006)* to include non-dioxin-like PCBs (NDL-PCBs) in its scope as new work for approval by CCEXEC/CAC and to agree on the project document enclosed as Appendix I to this discussion paper.
- To agree that the elements mentioned in paragraph 14 a) to d) are to be considered for the update and review and to agree explicitly on the elements mentioned in paragraph 14 e), f) and g) to be considered for the update and review of the Code of Practice.