



## Report of the United States Delegate to the 12th Session of the Codex Committee on Contaminants in Food

March 12-16, 2018  
Utrecht, Netherlands

The United States believes the 12<sup>th</sup> Session of the Codex Committee on Contaminants in Food (CCCF) was a productive session, with multiple maximum levels (MLs), Codes of Practice (COPs), and Guidelines sent forward for adoption or endorsement by the 41<sup>st</sup> Codex Alimentarius Commission (CAC41, July 2018), consistent with U.S. positions and comments. Notably, the Committee recommended final adoption of draft MLs for lead in a number of foods (work chaired by the United States), approved formation of an electronic working group chaired by the United States and co-chaired by the United Kingdom to prepare a discussion paper and project document for new work on revising the COP for Prevention and Reduction of Lead Contamination in Foods, agreed to suspend work on setting an ML for aflatoxin in ready-to-eat peanuts and issue a call for additional data in three years, and postponed consideration on revised MLs for lead in wine pending collection and analysis of additional data.

CCCF12 was attended by 59 Member Countries, one Member Organization (the European Union), and Observers from 18 international organizations. The U.S. Delegation was led by Dr. Lauren Posnick Robin (Head of Delegation) from the U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, and Mr. Terry Dutko (Alternate Delegate) from the U.S. Department of Agriculture, Food Safety and Inspection Service, supported by five government advisors and one non-government advisor.

The following summarizes the Committee's actions and the discussion of key significant agenda items and issues from the 12th Session. The full report of the Session will be published on the CCCF webpage at the "Related Meetings" tab: <http://www.fao.org/fao-who-codexalimentarius/committees/committee/en/?committee=CCCF>.

### MEETING SUMMARY

#### Texts for final adoption at CAC 41:

The Committee sent the following draft MLs and COPs to CAC41 for adoption at Step 5/8 (final adoption):

- Draft MLs for lead in various foods in the General Standard for Contaminants and Toxins in Food and Feed (GSCSTFF) (work chaired by the United States),
- Draft MLs for cadmium in several categories of chocolate products,
- Draft MLs for methylmercury in various fish species, with footnotes consistent with U.S. comments, and
- A revised COP for the prevention and reduction of dioxins, dioxin-like PCBs, and non-dioxin-like PCB contamination in food and feed.

#### Ongoing and new work:

The Committee sent the following draft COP and Guidelines to CAC41 for adoption at Step 5 (to be reviewed again at the next session of CCCF):

- A draft COP for the reduction of 3-monochloropropane-1,2-diol esters (3-MCPDE) and glycidyl esters (GE) in refined oils and food products made with refined oils, and
- Draft Guidelines for risk analysis of contaminants in food that lack an established regulatory level or risk management framework.

The Committee also agreed to continue or start work on the following for the next session:

- Work chaired by the United States on revising MLs in the GSCSTFF for lead in wine and edible offal,
- Work chaired by Ecuador, and co-chaired by Brazil and Ghana, on MLs for cadmium in additional chocolate products,
- A new discussion paper, chaired by New Zealand and co-chaired by Canada, on MLs for methylmercury for additional fish species,
- Work chaired by the United States, and co-chaired by the European Union (EU) and Malaysia, on the draft COP on 3-MCPDE and GE in refined oils and food products made with refined oils,



- A revised discussion paper, chaired by Brazil, on future work on MLs for lead,
- A revised discussion paper, chaired by Brazil and co-chaired by India, on MLs for total aflatoxins in wheat, maize, sorghum, and rice for grains for human consumption, and for flour and cereal-based foods for infants and young children,
- A revised discussion paper, chaired by Peru and co-chaired by Ghana and Ecuador, on a COP for the prevention and reduction of cadmium contamination in cocoa,
- A discussion paper on a forward work plan for CCCF,
- A discussion paper, chaired by the EU, and co-chaired by the United States, the Netherlands, and Japan, on general guidance on data analysis for ML development, and
- A discussion paper, chaired by the United States and co-chaired by the United Kingdom, on revision of the COP for the prevention and reduction of lead contamination in foods.

#### **Agenda Item 5: Proposed Draft Revision of the Maximum Levels for Lead in Selected Commodities in the *General Standard for Contaminants and Toxins in Food and Feed (CXS 193-1995)***

The U.S. has chaired work reviewing MLs for lead in selected commodities in the GSCTFF since 2012. As chair of the electronic working group (EWG), the United States presented the recommendations of the EWG.

- **Grape juice.** The EWG proposed a revised ML of 0.04 mg/kg. Turkey expressed concern that the proposed ML would be applied to concentrates. The U.S. stated that the ML applies to juices ready to drink. The Committee agreed to forward a revised draft ML of 0.04 mg/kg.
- **Processed tomato concentrates.** The EWG proposed a revised ML of 0.08 mg/kg. After consideration, the Committee agreed to a suggestion by the EU to revoke the ML, since the ML for fruiting vegetables (including fresh tomatoes) of 0.05 mg/kg could be used to derive, with concentration factors, appropriate levels for tomato concentrates and that such an approach would be in line with the desire of CCCF to consolidate MLs where possible.
- **Mango chutney.** The EWG proposed a revised ML of 0.3 mg/kg. India and Thailand supported an ML of 0.5 mg/kg based only on Indian data as the major mango chutney producer. The Committee agreed to a suggestion by the Chair to compromise at 0.4 mg/kg. The EU proposed merging the categories of mango chutney and jams/jellies, but the United States supported India in retaining mango chutney as a standalone category, based on a decision taken at CCCF12.
- **Canned brassica vegetables.** The EWG proposed and the Committee agreed to include canned brassica vegetables in the canned vegetables category with an ML of 0.1 mg/kg.
- **Fresh farmed mushrooms.** The EWG proposed a revised ML of 0.2 mg/kg. China, Japan, Chile, and the EU supported an alternate proposal of 0.3 mg/kg. The Committee agreed to forward a revised draft ML of 0.3 mg/kg.
- **Wine.** The EWG proposed an ML of 0.05 mg/kg, and noted comments from several countries that wines are not produced with the intention of being consumed by infants and young children, and are not as frequently consumed as non-alcoholic drinks. The EU recommended a reduction of the Codex ML for lead in wine from grapes from 0.2 mg/kg to 0.15 mg/kg, which would mirror the limit currently recommended by the International Organisation of Vine and Wine (OIV). OIV commented that, based on the 2011 evaluation of lead by the Joint FAO/WHO Expert Committee on Food Additives (JECFA), a concerned OIV group of experts has already engaged in discussion on the potential reduction of the current OIV limit (0.15 mg/L) and would share new data. OIV expressed concerns that a limit that is too low could have important consequences in international trade. Argentina requested an extension, more geographically representative data, and a focus on grapes. After consideration, CCCF agreed to postpone a decision until the next session to allow time for collection of additional data, to be submitted to the GEMS/Food database, including geographically diverse data. The new analysis and proposal will (a) focus on wines made from grapes, (b) consider fortified wines separately, and (c) apply to wine made from grapes harvested after the date of the establishment of the revised ML.
- **Salt:** The EWG proposed a revised ML of 1.0 mg/kg. The EU proposed excluding marsh salt. The Committee agreed to lower the ML from 2.0 mg/kg to 1.0 mg/kg, excluding marsh salt.
- **Fat spreads and blended spreads:** The EWG proposed a revised ML of 0.04 mg/kg. The Committee agreed to lower the ML from 0.1 mg/kg to 0.04 mg/kg.
- **Edible fats and oils:** The EWG proposed a revised ML of 0.07 mg/kg. Thailand, supported by Malaysia, Indonesia, Japan, India and Nepal, proposed 0.08 mg/kg, because of potential trade impacts. The Committee agreed to lower the ML from 0.1 mg/kg to 0.08 mg/kg.

#### **Proposed draft Maximum Levels for Cadmium in Chocolate and Cocoa-derived Products**

Ecuador, as Chair of the EWG, presented the EWG recommendations as follows.



- **Chocolate containing or declaring  $\geq 50\%$  to  $< 70\%$  total cocoa solids on a dry matter basis.** The EWG recommended an ML of 0.8 mg/kg. CCCF agreed to advance the proposed ML for adoption by CAC41, as there was wide support for the ML.
- **Chocolate containing or declaring  $\geq 70\%$  total cocoa solids on a dry matter basis.** The EWG recommended an ML of 1.0 mg/kg. The United States, Chile, International Council of Grocery Manufacturers Association (ICGMA), Cuba, and Ghana supported the proposal, while the EU and an observer group (the National Health Federation) supported 0.8 mg/kg. CCCF agreed to compromise on an ML of 0.9 mg/kg.
- **Chocolate products containing or declaring  $< 30\%$  total cocoa solids on a dry matter basis.** The EWG recommended an ML of 0.4 mg/kg. Delegations supporting 0.4 mg/kg (Canada, Colombia, Chile, Corte d'Ivoire, Mali, the United States, Ecuador) agreed there was no added health benefit in setting lower MLs for cadmium in this category of cocoa-derived products, consistent with the JECFA evaluation. Other delegations supported 0.1 mg/kg or 0.2 mg/kg (the EU, Brazil, Senegal, the Russian Federation) and expressed concern about potential adverse effects on vulnerable populations at the proposed ML of 0.4 mg/kg. Because of diverging views, CCCF postponed discussion to the next session.
- **Chocolate and chocolate products containing or declaring  $\geq 30\%$  to  $< 50\%$  total cocoa solids on a dry matter basis.** The EWG proposed an ML of 0.5 mg/kg. This proposal was supported by Colombia, Canada, and Cuba. The EU supported MLs of 0.3 mg/kg, while Peru proposed 0.7 mg/kg, in light of trade impacts. Because of varying views, the Chair proposed that the EWG continue working on this category and to assess if it was feasible to merge the  $< 30\%$  and  $\geq 30\%$  to  $< 50\%$  total cocoa solids categories to derive one ML. The United States questioned this approach, since data from the  $< 30\%$  category would dominate the combined data set. The Chair indicated that the ML proposal for  $\geq 30\%$  to  $< 50\%$  was derived differently than for  $< 30\%$ , but Ecuador stated that the analysis for both categories was based on actual data and that Ecuador would need data to see if the categories could be merged.
- **Dry mixtures of cocoa and sugars sold for final consumption.** CCCF agreed to discontinue work, since it would be possible to derive values from a value for cocoa powder.
- **Cocoa powder (100% total cocoa solids on a dry matter basis).** The EWG proposed an ML of 1.5 mg/kg. The EU could not support this ML and suggested discontinuing work in this category based on low significance in international trade. ICGMA stated it was important to establish an ML for trade reasons. The United States supported continued work on an ML for cocoa powder, given the establishment of MLs for other chocolate categories. Canada supported the proposed ML of 1.5 mg/kg and the United States said it could support Canada's position or a lower level, if the chosen level was proportional to total cocoa solids. Brazil noted that cocoa powder should have a higher ML than chocolate with lower total cocoa solids. CCCF agreed to continue working on cocoa powders (100%) taking into consideration MLs to be established for other chocolate categories to be consistent across categories of cocoa-derived products.

### Proposed draft Maximum Levels for Methylmercury in Fish

The Netherlands, as Chair of the EWG, introduced the proposed MLs as indicated below.

- **ML for tuna.** The EWG proposed 1.2 mg/kg, based on a rejection rate of  $< 5\%$  for all tuna species. The United States, although supporting consumption advice as more appropriate for addressing methylmercury in fish than MLs, recommended 1.4 mg/kg based on bigeye/bluefin tuna. CCCF agreed on an ML of 1.2 mg/kg for all tuna after considering lower and higher MLs for various tuna species. The EU, Switzerland, and Norway recorded reservations, stating that they could not agree with any of the MLs proposed for methylmercury as the levels were higher than those established in the EU.
- **ML for alfonsino, marlin, and shark.** The EWG proposed MLs of 1.5 mg/kg for alfonsino, 1.7 mg/kg for marlin, and 1.6 mg/kg for shark. CCCF agreed with these proposed MLs and noted the reservation of the EU, Switzerland, and Norway.
- **ML for amberjack.** CCCF noted that based on new dataset used by the EWG, the average and median concentration of total mercury and methylmercury fall below the 0.3 mg/kg used as the selection criterion for selection of fish species for setting MLs, and therefore the Committee agreed to discontinue work on the ML for amberjack.
- **ML for swordfish.** The EWG proposed an ML of 2.4 mg/kg. After discussion, CCCF noted that although the methylmercury concentrations in swordfish were high, which was of health concern when consuming this fish, no consensus could be reached on an appropriate ML and therefore CCCF agreed to discontinue work on the ML for swordfish.
- **Notes to the MLs.**
- **Existing note attached to the current guideline levels.** CCCF considered whether to carry over a note regarding applicability to fish products (canned fish) from the current guideline levels (GLs) in the GSCTFF to the new MLs. The United States expressed concern that the MLs should not apply to canned tuna, as was agreed at CCCF11. Other delegations generally shared this viewpoint, but some also expressed concern about possible diversion of tuna with high methylmercury to canning. The Committee agreed to include a note that the ML applied to fresh or frozen fish



intended for further processing, which would not make the ML applicable to canned tuna, but also ensure that fish not complying with the ML would not be used for canning.

**Consumer advice supplemental to ML.** The EWG reminded the Committee that there was agreement last year to include a footnote for additional risk management measures, namely consumer advice, to protect public health because the MLs were based on an as low as reasonably achievable approach. In the EWG, the United States proposed, "For fish species high in methylmercury, countries should consider developing nationally relevant consumer advice for women of child-bearing age and young children to supplement these MLs" as an alternative to the footnote proposed by the EWG chair. This alternate footnote was widely supported and accepted by the Committee.

- **Sampling Plan.** CCCF agreed to send an amended sampling plan to the Codex Committee on Methods of Analysis and Sampling for endorsement and to request advice on the following issues, including the latter two points, which were raised by the United States in the EWG:
- The necessary performance criteria for the MLs,
- Whether there is evidence that methylmercury can vary widely between individual fish sampled at the same time. How the plan would apply to large fish sold as individual units and whether the sampling plan is adequate to deal with variation, and
- Whether the whole fish should be analyzed or only specific fractions of edible portions. (Currently, only sampling the mid-section of some large fish is mentioned.)

#### **Proposed draft Revision of the Code of Practice for the Prevention and Reduction of Dioxins, Dioxin-Like PCBs and Non-Dioxin-Like PCBs in Food and Feed**

The EU, as Chair of the EWG, introduced the item and noted that all comments submitted had, to the extent possible, been incorporated into the revised text. The Committee considered the revised COP and noted that pentachlorophenol may be allowed in fence treatment by national authorities (based on a U.S. comment); that the COP dealt with PCBs specifically in food and feed; and that situations where, for example, animals were put out to pasture, would be covered by source-directed measures in the COP. The Committee agreed to forward the proposed draft Code of Practice to CAC41 for final adoption at Step 5/8.

#### **Proposed draft Code of Practice for the Reduction of 3-MCPDE and GE in Refined Oils and Food Products Made with Refined Oils**

The United States, as Chair of the EWG and on behalf of co-chairs the EU and Malaysia, introduced the item and highlighted the proposed revisions based on comments on the posted document, including removing "infant formula" from the title. Some additional changes were proposed in the plenary, including broadening the scope to include non-vegetable oils (fish oil) and technical revisions to the text regarding specific issues such as low lipase activity, irrigation water, polar solvent, degumming, agricultural practices, and bleaching clay deodorization.

The Committee agreed to forward the proposed draft COP to CAC41 for adoption at Step 5; the text will be reviewed by the next session of CCCF.

#### **Proposed draft Maximum Level for Total Aflatoxins in Ready-To-Eat (RTE) Peanuts**

India, as chair of the EWG, proposed an ML of 10 µg/kg total aflatoxins in RTE peanuts. Delegates supporting the proposed ML of 10 µg/kg stated that the level matched what was achievable in their countries, that it was consistent with the ML established for RTE tree nuts, and that in their view it was important to have a different ML than the ML of 15 µg/kg that applies to peanuts for further processing. Japan, China, Australia, Argentina, Kenya, Uganda, Thailand, Malaysia, Brazil, Colombia, Mali, Chile, Cuba, Ghana, Thailand, and India supported 10 µg/kg.

The EU and European Union member states supported 4 µg/kg, noting that this level was established in their national or regional legislation, that the European Food Safety Authority had determined there would be an increased in cancer risk at the level of 10 µg/kg, and that there would be no difficulty in achieving 4 µg/kg.

The United States, Canada and Senegal supported an ML of 15 µg/kg, and observed that the JECFA83 (November 2016) impact assessment determined that there would be no additional public health benefit at lower levels. An ML of 10 µg/kg could result in higher rejection rates, leading to food waste, especially for developing countries where peanuts are mainly produced. Because the JECFA assessment was dominated by data from the EU, the rejection rates could actually be higher if data from other countries were included.



Noting lack of consensus, the Committee considered a compromise ML of 12 µg/kg. (Sudan also proposed a compromise ML of 12.5 µg/kg.) The United States and Canada could support the compromise ML, but also supported the collection of additional data in the future. The Committee could not reach consensus for the reasons outlined above. After extensive discussion, the Committee agreed to hold the ML of 10 µg/kg at Step 4 to give time to countries to implement the COP for the Prevention and Reduction of Aflatoxin Contamination in Peanuts (CXC 55-2004), and further concluded that JECFA would issue a data call in three years and an EWG would be re-established once the data were submitted to prepare a proposal for consideration by CCCF15 and 16.

### **Proposed draft Maximum Level for Total Aflatoxins and Ochratoxin A in Nutmeg, Chili and Paprika, Ginger, Pepper, and Turmeric**

India, as Chair of the EWG, proposed consideration of MLs of 20 or 30 µg/kg total aflatoxins (AFT) and 20 µg/kg ochratoxin A (OTA) for nutmeg, chili and paprika, ginger, pepper and turmeric. Sri Lanka, China, Nepal, Chile, and Kenya supported India. The EU supported the proposed level for AFT only. The United States and Canada noted the older data and high rejection rates for some spices. Japan and Egypt supported collecting new occurrence data. The Chair proposed postponing work since the COP for mycotoxins in spices was recently adopted. Although some countries, including India, supported finalizing work on some spices, others, such as Brazil, supported the Chair's proposal. The Committee agreed to suspend work and to hold the MLs of 20/30 µg/kg for AFT and 20 µg/kg for OTA for all specified spices at Step 4 to give time for countries to implement the Code of Practice for the Prevention and Reduction of Mycotoxins in Spices (CXC 78-2017), and further concluded that JECFA would issue a data call in three years and an EWG would be re-established once the data were submitted to prepare a proposal for consideration by a future session of CCCF.

### **Proposed draft Guidelines for Risk Analysis of Instances of Contaminants in Food Where There is no Regulatory Level or Risk Management Framework Established**

The Committee agreed to forward the draft Guidelines to CAC41 for adoption at Step 5; to re-establish the EWG, chaired by New Zealand and co-chaired by The Netherlands, working in English only, to further develop the Guidelines, especially those sections in brackets; and to keep open the possibility of a physical working group to meet immediately before the next session of the Committee, to consider written comments and prepare a revised proposal for consideration.

### **Discussion Paper on Maximum Levels for Hydrocyanic Acid in Cassava and Cassava-based Products and Mycotoxin Contamination in These Products**

The Committee deferred discussion until next year due to the absence of Nigeria, the EWG Chair, and encouraged Codex members to continue submitting data to GEMS/Food.

### **Discussion Paper on Future Work on Maximum Levels for Lead for Inclusion in the GSCTFF**

Brazil, as EWG chair, presented a summary of the paper, which prioritized work on new MLs for lead in the GSCTFF based on occurrence data and trade. Brazil proposed to update the paper for next year with new data on food categories identified as high priorities, as well as spices and seaweed. The United States recommended prioritizing foods by exposure, so that the Committee focuses on the most important foods. The EU supported this approach. Canada also supported consideration of consumption data. The Committee agreed to establish an EWG, chaired by Brazil, to prepare a revised discussion paper that takes into consideration exposure data (in addition to other criteria) in establishing the prioritization categories for MLs, and to propose, if feasible, MLs for the categories indicated, with a focus on high priority commodities.

### **Discussion Paper on Aflatoxins and Sterigmatocystin Contamination in Cereals**

Brazil, as EWG chair, presented a summary of the work, including a proposal to start new work on MLs for aflatoxins in cereals and cereal-based foods and foods for infants and young children. Thailand, supported by India and Japan, indicated that this issue needed careful consideration, considering geographic variation and the importance of grains as food, and suggested waiting several years given that the revised COP on mycotoxins in grains had been completed in 2016. The JECFA Secretariat recommended that work proceed on some MLs because of the importance of these grains as staple foods and considering potential health impacts. The United States requested that the scope be clarified to include cereal grains, but not products. The EU supported excluding products, with the exception of flours and possibly foods for infants and young children. Japan and Thailand stressed the importance of identifying the fraction of rice grain to which proposed MLs would apply. The United States requested that the EWG consider food grains, not feed grains, and also consider geographic impact of proposed MLs on grain availability. The



Committee agreed to establish an EWG, chaired by Brazil and co-chaired by India, to further develop the discussion paper and develop proposed MLs for total aflatoxins in wheat, maize, sorghum, and rice (specifying the categories) for grains for human consumption, and for flour and cereal-based foods for infants and young children.

### **Discussion Paper on the Development of a Code of Practice for the Prevention and Reduction of Cadmium Contamination in Cocoa**

The Committee agreed to establish an EWG, chaired by Peru and co-chaired by Ghana and Ecuador, to further elaborate the discussion paper on the development of a COP to determine whether mitigation measures available at present would support the development of the COP and identify the scope of the COP (e.g., whether it will cover the production chain or only primary production). If these conditions are met, the EWG should provide a project document and a first draft of a COP for consideration at the next session.

### **Priority list of contaminants and naturally occurring toxicants for evaluation by JECFA**

The United States chaired the Priority In-Session Working Group. The Committee endorsed the current list of contaminants and naturally occurring toxicants for JECFA evaluation.

### **Forward Workplan and Guidance for Data Analysis**

The Committee agreed that a discussion paper, focusing on whether CCCF covered the main staple foods in international trade and of public health concern, would be prepared by the Codex, JECFA, and Host Country Secretariats with the assistance of EU. CCCF also agreed to establish an EWG, chaired by the EU, and co-chaired by the United States, the Netherlands, and Japan, to prepare a discussion paper on development of general guidance on data analysis for ML development.

### **Other Business and Future Work**

The United States introduced a proposal for a discussion paper on the revision of the Code of Practice for the Prevention and Reduction of Lead Contamination in Foods (CXC 56-2004), citing new information on lead mitigation practices, such as in the production of wine and juice. The Committee agreed to establish an EWG, chaired by the United States and co-chaired by the United Kingdom, to prepare a discussion paper, including a project document for a proposal for new work, for consideration by the next session of CCCF.

### ***Date and Place of the Next Session***

The 13<sup>th</sup> Session of the Committee will meet in Yogyakarta, Indonesia, in approximately one year's time, the final arrangements being subject to confirmation by the Host Country and the Codex Secretariat.