

DRAFT U.S. POSITIONS

NOTE: This is a draft document and the U.S. positions in this document are subject to change.

*U.S. Positions for
the issues on the
Agenda of the 41st
Session of the Codex
Alimentarius
Commission*

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Agenda item 1: Adoption of the Agenda (CX/CAC 18/41/1)

U.S. Position:

- Currently, the United States has no plans to offer amendments to the Agenda. However, there is an expectation that the Executive Committee (CCEXEC) will refer certain issues to the Codex Alimentarius Commission for discussion. If this happens, it may result in changes to the Agenda.

Positions of Other Countries:

- We are not aware of any country that plans to put forth amendments to the Agenda.

Agenda Item 2: Report by the Chairperson on the 74th and 75th Sessions of the Executive Committee (REP 18/EXEC1 and REP 18 EXEC2)

- This report will be available after the 75 CCEXEC Session, June 26 – 29, 2018.

Agenda Item 3: Amendments to the Procedural Manual (CX /CAC 18/41/2)

CCRVDF: Codex Committee on Residues of Veterinary Drugs in Foods

- ***Risk Analysis Principles Applied by the Codex Committee of Residues of Veterinary Durqs in Foods (REP 18/RVDF, para. 3, 84(i), Appendix V***

Background:

- CCRVDF24 (2018) noted that the *Risk Analysis Principles Applied by CCRVDF* in the *Procedural Manual* required that extrapolation of MRLs to one or more species could only be recommended where JECFA had identified that it is scientifically justifiable and the uncertainties have been clearly defined. To provide more autonomy to CCRVDF as the risk manager, the Committee agreed to amend this section of the *Risk Analysis Principles*.
- The Committee agreed to revise Section 3.4 of the *Risk Analysis Principles*, specifically the second bullet point of paragraph 30, to read, “recommend extrapolation of MRLs to one or more other species.”

U.S. Position:

- The United States supports adoption of the revision to the *Procedural Manual*.

Agenda Item 4: Final Adoption of Codex Texts (CX/CAC 18/41/3)

CCFFV: Codex Committee on Fresh Fruits and Vegetables

- **Standard for Aubergines (Draft) REP 18 FFV, Para. 19, Appendix II, Step 8**

Background:

- The 19th CCFFV Session (2015) submitted this Standard to the 39th Codex Alimentarius Commission (CAC) (2016) for final adoption at Step 5/8.
- The 39th CAC did not adopt the Draft Standard due to objections from several countries regarding the inclusion of tolerances for “soft rot, decay and internal breakdown” in Extra Class. The CAC returned the Standard to the CCFFV for further discussion.
- At the 20th CCFFV (2017), despite general agreement on most sections of the Draft Standard, the discussions on the tolerances for “soft rot, decay and internal breakdown” were again contentious. The Committee devoted more time to the discussion of these issues than any other issue.
- During the 20th CCFFV session there was growing support for inclusion of the tolerances for decay, with 43 delegations in support and only 8 opposing. The Committee adopted the Draft Standard at Step 8 for approval by the CAC.

U.S. Position:

- The United States supports adoption of the Standard for Aubergines.

CCFL: Codex Committee on Food Labelling

- **Revision of the General Standard for the Labelling of Prepackaged Foods: date marking (CX 1-1085 (Draft) REP 18/FL Para. 32, Appendix II, Step 8**

Background:

- The current provisions of the General Standard for the Labelling of Prepackaged Food (GSLPF) do not provide any criteria for exempting foods from the application of a date mark. The United States supported the development of general criteria to assist countries. CCFL has been working to complete the date marking revisions for several years.
- At the 43rd Session of CCFL (2016), the Committee concluded that the draft revisions were ready to progress to Step 5, as the only outstanding issues needing further consideration were the draft criteria for exemptions from date marking. The Committee agreed to focus its discussions on this section of the document. At its 44th Session (CCFL44, 2017), the Committee had discussions on these sections,

both in Plenary and during an in-session working group led by Canada.

- The Committee extensively discussed the wording of the exemption criteria and agreed that the wording of the chapeau implied that foods meant to be consumed before a certain date due to food safety reasons could inadvertently be exempted from date marking. The Committee amended the chapeau section to clarify that exemptions would not apply if food safety were compromised, and to provide flexibility to competent authorities to apply the criteria depending on their needs. This was intended to address concerns expressed that the exemptions might apply to foods for which such exemptions were not intended.
- The Committee considered the language submitted by the Codex Committee on Food Hygiene (CCFH) to combine Sections 1.1. and 1.2 and agreed to language with several minor modifications: add a reference to the “intended” storage conditions and remove “preserving” when referencing the nature of the food. (Final text of this section: “1. Where safety is not compromised and quality does not deteriorate because the nature of the food is such that it cannot support microbial growth (e.g. alcohol, salt, acidity, low water activity under intended or stated storage conditions.”)
- The Committee also included a footnote, supported by the United States and others, to clarify that the list of exempted foods was intended to be illustrative only.
- The Committee agreed to forward the proposed draft revision to CAC41 for final adoption at Step 8.

U.S. Position:

- The United States strongly supports adoption.
- The list of identified exempted foods is short and has remained unchanged for over 20 years. It should be interpreted as an illustrative list, not the only allowable exemptions. The illustrative list includes foods for which any change in quality is minimal over a long period of time. Quality in some products may actually improve based on longer storage periods. Foods such as salt, sugar and honey are not susceptible to microbial or chemical deterioration over time and are appropriately included in the list of exempted foods. Date marks would add little value beyond a simple visual inspection of the product.

CCFH: Codex Committee on Food Hygiene

- **[Revision of the Code of Practice for Fish and Fishery Products \(CXC 52- 2003\): Guidance for histamine control \(Proposed Draft\) REP 18/FH, Para. 40, Appendix II, Step 5/8](#)**

Background:

- The 39th session of the CAC (2016) assigned work on histamine control guidance and sampling plans [formerly proposed in the Codex Committee on Fish and Fishery Products (CCFFP)] to the Codex Committee on Food Hygiene (CCFH).
- CCFH48 (November 2016) decided to proceed with the drafting of the histamine control guidance for the Code of Practice for Fish and Fishery Products before beginning work on the sampling plan/guidance for the commodity standards.

- CCFH48 established an electronic Working Group chaired by Japan and co-chaired by the United States to lead the development of the control guidance for histamine and, among other terms of reference, to consider, based on an FAO/WHO scientific review on histamine-related illness in Salmonidae, the inclusion of Salmonidae in the list of susceptible species.
- The main and most contentious issue at CCFH49 (2017) was the decision as to whether Salmonidae should be included in the list of susceptible species. The Chair of the Committee summarized that the key findings of FAO indicated: (i) there had been few confirmed cases of illness over a long period of time - 40 years; (ii) Salmonidae contained low levels of histidine; (iii) formation of histamine had occurred, albeit at levels generally below the existing Codex limit; and (iv) there is a high volume of production and trade with no identified rejections linked to histamine, suggesting that the family Salmonidae do not present a significant risk of histamine poisoning.
- The Committee agreed to keep a list of susceptible species in the guidance but delegations were divided into two main opinions regarding the content of the list. Some delegations wanted to include only species that presented the highest potential for developing histamine and causing Scombrotoxin Fish Poisoning (SFP), which would mean excluding Salmonidae from the list. Others wanted to include an exhaustive list with all species identified in Table 2.3 of a Joint FAO/WHO Expert Meeting report on the Public Health Risks of Histamine and Other Biogenic Amines from Fish and Fishery Products (2013), thus including Salmonidae.
- To resolve the differences, the Committee agreed to adopt a list of six families of fish that were already referenced as being associated with SFP in existing sections of the Code of Practice for Fish and Fishery Products (CAC/RCP 52-2003). The wording in Section 13: Smoked fish, smoke-flavored fish and smoke-dried fish was selected for inclusion because it was the most recent applicable section completed by CCFFP. Section 13 states “This applies only to susceptible species (e.g., Scombridae, Clupeidae, Engraulidae, Coryphaenidae, Pomatomidae, Scomberesocidae)”. The committee noted that the list could be expanded in the future.

U.S. Position:

- The United States supports the adoption of the revision of the Code of Practice. This document is important to be sure the Code of Practice for Fish and Fishery Products provides clear guidance on the application of histamine control measures to fish that present a significant risk for histamine poisoning in order to enhance public health.

CCCF: Codex Committee on Contaminants in Food

- **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) REP 18/CF Para. 45, Appendix II**

Background:

- Since the 6th Session of CCCF (CCCF06, March 2012), the United States has led work to review and revise the maximum levels (MLs) for lead in multiple food categories in the General Standard for Contaminants and Toxins in Food and Feed (GSCTFF) CXS 193-1995).
- This work was undertaken in response to the new toxicological evaluation of lead in food conducted by Joint Expert Committee on Food Additives (JECFA) at its 73rd (June 2010) meeting, at the request of CCCF. In the evaluation, JECFA stated that exposure to lead is associated with a wide range of effects, including various neurodevelopmental effects, impaired renal function, hypertension, impaired fertility and adverse pregnancy outcomes.
- Because of the neurodevelopmental effects, fetuses, infants and children are the subgroups that are most sensitive to lead. JECFA withdrew the previously established provisional tolerable weekly intake (PTWI) of 25 µg/kg bw and concluded that it was not possible to establish a new PTWI that would be considered to be health protective. JECFA also concluded that, in populations with prolonged dietary exposures to higher levels of lead, measures should be taken to identify major contributing sources and foods and, if appropriate, to identify methods of reducing dietary exposure that are commensurate with the level of risk reduction.
- Since no safe level of lead has been identified by JECFA, the focus of this work has been to review occurrence data to determine what percentage of samples can meet proposed new MLs.
- At its 12th Session (CCCF12, March 2018), CCCF agreed to:
 - Forward the following proposed revised draft MLs to the 41th Session of the Codex Alimentarius Commission (CAC41) for final adoption at Step 5/8:
 - Grape juice - 0.04 mg/kg
 - Mango chutney - 0.4 mg/kg
 - Fresh farmed mushrooms (common mushrooms (*Agaricus bisporous*), shiitake mushrooms (*Lentinula edodes*), and oyster mushrooms (*Pleurotus ostreatus*)) - 0.3 mg/kg
 - Salt (excluding salt from marshes) - 1 mg/kg
 - Fat spreads and blended spreads - 0.04 mg/kg
 - Edible fats and oils - 0.08 mg/kg
 - Propose that CAC41:
 - amend the canned vegetables category to remove the exclusion for canned brassica vegetables,
 - revoke the existing ML of 1.5 mg/kg in processed tomato concentrates 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
- revoke the existing MLs for the categories proposed for adoption at 5/8, as well as for processed tomato concentrates.

U.S. Position:

- The United States supports adoption of the proposed revised draft MLs at Step 5/8 and the amendments and revocations proposed by the Committee.
- **Proposed draft Maximum Levels for Cadmium in Chocolate and Cocoa-derived Products (REP 18/CF para 67, Appendix III)**

Background:

- At CCCF08 (March 2014), the Delegation of Ecuador introduced a proposal for new work on Maximum Levels (MLs) for cadmium in chocolate and cocoa-derived products, noting that while the evaluation of the 77th JECFA (June 2013) had concluded 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 (2014). Since 2014, an electronic Working Group led by Ecuador, and co-chaired by Ghana and Brazil, has worked on draft MLs for cadmium in chocolate and cocoa-derived products.
- Most recently, CCCF12 agreed to forward:
 - the proposed draft ML of 0.8 mg/kg for cadmium in chocolate containing or declaring $\geq 50\%$ to $< 70\%$ total cocoa solids on a dry matter basis to CAC41 for final adoption at Step 5/8, and
 - the proposed draft ML of 0.9 mg/kg for cadmium in chocolate containing or declaring $\geq 70\%$ total cocoa solids on a dry matter basis to CAC41 for final adoption at Step 5/8.

U.S. Position:

- The United States supports adoption of the proposed draft MLs at Step 5/8.
- **Proposed draft Maximum Levels for Methylmercury in Fish REP 18/CF, para. 91, Appendix IV**

Background:

- The 38th Session (April 2006) of the Codex Committee on Food Additives and Contaminants requested CAC29 (July 2006) to seek scientific advice from FAO and WHO on the risks and benefits of fish consumption: specifically, advice on the nutritional health benefits compared to the risks of consuming fish that may be contaminated with methylmercury and dioxins (<http://www.who.int/foodsafety/chem/meetings/jan2010/en/index.html>).
- As a follow-up to the Expert Consultation, CCCF6 (2012) agreed to the development

of a discussion paper on the review of the guideline levels (GLs) for methylmercury in fish and predatory fish through an electronic Working Group (eWG) led by Norway and co-chaired by Japan.

- After several years of extensive discussions and revisions of the discussion paper, in an eWG chaired by the Netherlands and co-chaired by New Zealand and Canada, CCCF11 (2017) agreed to establish draft Maximum Levels (MLs) for methylmercury in tuna (but not canned tuna), alfonsino, kingfish/amberjack, marlin, shark, dogfish and swordfish.
- Most recently, CCCF12 (2018) agreed to forward the following proposed draft MLs to CAC41 for final adoption at Step 5/8:
 - Tuna – 1.2 mg/kg
 - Alfonsino – 1.5 mg/kg
 - Marlin – 1.7 mg/kg
 - Shark – 1.6 mg/kg
- The Committee also proposed the following Notes/Remarks to CAC41 (2018) for adoption at Step 5/8:
 - Countries or importers may decide to use their own screening when applying the ML for methylmercury in fish by analyzing total mercury in fish. If the total mercury concentration is below or equal to the ML for methylmercury, no further testing is required and the sample is determined to be compliant with the ML. If the total mercury concentration is above the ML for methylmercury, follow-up testing shall be conducted to determine if the methylmercury concentration is above the ML.
 - The ML also applies to fresh or frozen fish intended for further processing.
 - Countries should consider developing nationally relevant consumer advice for women of childbearing age and young children to supplement the ML.

U.S. Position:

- The United States believes that consumption advice is more appropriate for addressing methylmercury in fish than MLs, but does not object to adoption of the proposed draft MLs and the proposed draft Notes/Remarks at Step 5/8. The note on processing is intended to ensure that fish not complying with the ML are not diverted to canning, and would not make the ML applicable to canned tuna. The note on consumer advice is consistent with U.S. comments.

- **[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 \(CXC 62-2006\) \(REP 18/CF para 98, Appendix V\)](#)**

Background:

- At CCCF10 (April 2016), the Committee agreed that an electronic Working Group chaired by the EU, would prepare a discussion paper on possible inclusion of non-dioxin like PCBs in the *Code of Practice (COP) for the Prevention and Reduction of Dioxin and Dioxin-like PCB Contamination in Food and Feeds* (CAC/RCP 62-2006).
- At CCCF11 (2017), the Committee agreed to start new work and to establish an

eWG, chaired by the EU, working in English only, to revise the COP for comments and consideration at its next session. CAC40 (2017) approved the new work.

- Most recently, CCCF12 (2018) agreed to forward the proposed draft revised COP to CAC41 for final adoption at Step 5/8.

U.S. Position:

- The United States supports adoption of the proposed draft revised COP at Step 5/8.

CCFA: Codex Committee on Food Additives

- **Proposed Draft Specifications for the Identity and Purity of Food Additives (CAC/MISC 6) (REP 18/FA para. 30(i, ii) and Appendix III)**

Background:

- As part of its mission, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) establishes specifications of identity and purity for food additives, including flavorings, used in food. JECFA is the expert risk assessment body that provides scientific advice to CCFA, and ultimately the Codex Alimentarius Commission (CAC), which are responsible for setting standards based on scientific criteria. Therefore, CCFA considers JECFA's food additive specifications of identity and purity to represent the minimum criteria necessary to establish food grade quality for an additive. The CCFA provides recommendations to the CAC for adoption of the JECFA specifications of identity and purity as Codex specifications (CAC/MISC 6).
- The 50th CCFA (2018):
 - forwarded full specifications for 10 food additives (8 revised and 2 new) to the 41st CAC (2018) for adoption at Step 5/8 as Codex specifications (REP 18/FA Appendix III).
 - forwarded revisions to existing provisions in multiple Codex texts to reflect the revision of INS 554 from "sodium aluminosilicate" to "sodium aluminium silicate" (REP 18/FA para 30(ii))– consequential changes in other Codex texts are discussed in the relevant sections of this document.
 - revised the List of Codex Specifications of Food Additives (CXM 6-2017) to reflect the entry of Rebaudioside A from multiple gene donors expressed in *Yarrowia lipolytica* (INS 960b(i)) and to replace the entry steviol glycosides (INS 960) with Steviol glycosides from *Stevia rebaudiana* Bertoni (Steviol glycosides from *Stevia*) (960a) (REP 18/FA para 121(ii)) – consequential changes in other Codex Text are discussed in the relevant sections of this document.

U.S. Position:

- The United States supports adoption of the specifications in REP 18/FA Appendix III.

• Draft and Proposed Draft Food Additive Provisions of the General Standard for Food Additives (GSFA) at Steps 8 and 5/8 (REP 18/FA paras. 30(ii), 111(i), 121(iii), and Appendix V)

Background:

- The Codex General Standard for Food Additives (GSFA), CODEX STAN 192-1995, is intended to be the single reference for food additives in Codex. The GSFA sets forth the conditions under which food additives are recognized as suitable for use in all foods, whether standardized by Codex or not. In order for a food additive to be listed in the GSFA, it must have been assigned an Acceptable Daily Intake (ADI) by the Joint FAO/WHO Expert Committee on Food Additives (JECFA), and assigned an International Numbering System (INS) number.
- In the GSFA, food additive provisions are presented in three tables:
 - Table 1 lists, in alphabetical order, the food categories in which the additive is recognized for use, the maximum use level, and its technological function for each food additive or food additive group with a numerical ADI. Table 1 also includes the uses of those additives with non-numerical ADI (which are found in Table 3) for which the use is specified in accordance with the Annex to Table 3.
 - Table 2 contains the same information as Table 1, listed by food category number.
 - Table 3 lists additives that have been assigned a non-numerical ADI (“not specified” or “not limited”) by JECFA that are acceptable for use in foods in general in accordance with Good Manufacturing Practices (GMP).
 - The Annex to Table 3 lists food categories and individual foods that are excluded from the general conditions of Table 3. Provisions for use of Table 3 additives in the food categories listed in the Annex to Table 3 are specifically listed in Tables 1 and 2.
- As of the 40th CAC (2017), approximately 4000 food additive provisions have been adopted, and approximately 1800 food additive provisions remain in the step process.
- Every year an electronic Working Group, led by the United States reviews a subset of provisions currently in the step process for adoption in the GSFA and provides recommendations. Those recommendations are discussed at a physical Working Group, also led by the United States which meets for 2 days prior to the CCFA session to formulate final proposals for the Committee to consider.
- Current Issue: adoption of new provisions or provisions currently in the step process:
 - The 50th CCFA (2018) forwarded for final adoption (at Step 8 or 5/8) approximately 181 provisions for food additives in Tables 1 and 2 of the GSFA and 2 provisions for Table 3 (REP 18/FA, Paras 30(ii), 111(i), 121(iii), and Appendix V).

U.S. Position:

- The United States supports adoption of the food additive provisions in REP 18/FA Appendix V,

Current Issue: revision of provisions already adopted in the GSFA

- Revisions to provisions for INS 554 (REP18/FA para 30(ii)): The 84th JECFA (2017) revised the specifications for INS 554 from “sodium aluminosilicate” to “sodium aluminium silicate”. The 50th CCFA (2018) forwarded the revised specifications to the 41st CAC (2018) for adoption.
- The 50th CCFA also forwarded to the 41st CAC consequential revisions to existing provisions in the GSFA to reflect this change. Revision of Note 301 attached to the provision for benzoates in FC 14.1.4 (REP18/FA paras 129 and 134(iii)): Based on the result of an exposure estimate on Benzoates (INS 210-213) conducted by the 80th JECFA (2016), the 48th CCFA (2016) lowered the ML for Benzoates (INS 210-213) in Food Category 14.1.4 “Water-based flavoured drinks, including “sport”, “energy” or “electrolyte” drinks and particulated drinks” and added a new Note 301 “Interim maximum level until CCFA 49” to indicate the revised ML was interim pending the discussion of an appropriate use level and subsequent revision at the 49th CCFA (2017).
- At the 49th CCFA, Industry offered to begin the process of conducting new toxicology studies to allow for a re-evaluation of the ADI by JECFA in the future. The 49th CCFA decided to keep the ML for benzoates in FC 14.1.4 at the current 250 mg/kg and revise Note 301 to read “Interim maximum level until CCFA 50” to indicate that industry would confirm their commitment to conduct additional testing by submitting a research plan to the CL requesting proposals for addition to the JECFA priority list at the 50th CCFA. At the 50th CCFA (2017) the Committee noted that the data sponsor had confirmed that data would be provided by December 2019 and that JECFA could not provide advice on the matter before the 53rd CCFA (2021). The Committee recommended the revision of Note 301 accordingly to read “Interim maximum level until CCFA53”.

U.S. Position:

- The United States supports:
 - the consequential revisions to applicable provisions in the GSFA as a result of the JECFA specifications name change for INS 554 from “sodium aluminosilicate” to “sodium aluminium silicate” as discussed in para. 30(ii) of REP 18/FA.
 - the revision of the provision for benzoates in FC 14.1.4 as discussed in para. 129 and 134(iii) of REP18/FA.
- ***Proposed Draft Revision of the Class Names and the International Numbering System (INS) for Food Additives (CAC/GL 36-1989) (REP 18/FA para. 30(ii), 121(i) and Appendix IX, part A2)***

Background:

- The need for the identification of food additives on food labels arises from the provisions of the Codex General Standard for the Labeling of Prepackaged Foods (GSLPF) (CODEX STAN 1 - 1985). The *Codex Class Names and the International Numbering System for Food Additives* (CAC/GL 36-1989) was prepared by the

Codex Committee on Food Additives and Contaminants (CCFAC) to provide a voluntary, harmonized international numerical system for identifying food additives in ingredient lists as an alternative to the specific name, which may be lengthy. The 18th CAC (1989) adopted the INS as a Codex Advisory Text on the basis that the list would be an open one, and that proposals for inclusion of further additives would be considered (ALINORM 89/40, para. 297).

- Inclusion of a food additive in the INS does not imply approval by Codex for use in food. The list includes additives that have not been evaluated by JECFA. The INS does not include flavors, since the GSFLP does not require these to be specifically identified in the list of ingredients, and since flavors have a JECFA number as an identifier. Further, it does not include chewing gum bases, and dietetic and nutritive additives. However, it does include enzymes that function as food additives.
- The INS serves as the official source of additive names, INS numbers and functional classes for use in the GSFA. The INS also provides a list of technological purposes for each additive contained in the INS.
- The 50th CCFA (2018) recommended two new additives for inclusion in the INS (including name, INS number, functional class and technological purpose), and the revision of functional classes and technological purposes for five existing additives in the *Codex Class Names and the International Numbering System for Food Additives* (CAC/GL 36-1989), as outlined in REP 18/FA Appendix IX. These proposals were forwarded to the 41st CAC (2018) for adoption at Step 5/8.
- The 50th CCFA (2018) recommended the replacement of the entry steviol glycosides (INS 960) with Steviol glycosides from *Stevia rebaudiana* Bertoni (Steviol glycosides from Stevia)(INS 960a) and consequential amendments to the GSFA in respect of listing steviol glycosides (INS 960) as a group food additive with steviol glycosides from *Stevia rebaudiana* Bertoni (Steviol glycosides from Stevia) (INS 960a) and Rebaudioside A from multiple gene donors expressed in *Yarrowia lipolytica* (INS 960b(i)) as discussed in REP 18/FA para 121 (iii).

U.S. Position:

- The United States supports:
 - adoption of the proposed amendments to the INS in REP 18/FA para 121 (ii) and Appendix IX
 - listing steviol glycosides (INS 960) as a group food additive with steviol glycosides from *Stevia rebaudiana* Bertoni (Steviol glycosides from Stevia) (INS 960a) and Rebaudioside A from multiple gene donors expressed in *Yarrowia lipolytica* (INS 960b(i)) as discussed in REP 18/FA para 121 (iii).
- **[Revised Food Additives Section of the Codex Standards for Standards for Various Fish Products](#)**
- Canned Salmon (CODEX STAN 3-1981), Canned Shrimp or Prawns (CODEX STAN 37-1991), Canned Tuna and Bonito (CODEX STAN 70-1981), Canned Crab Meat (CODEX STAN 90-1981), Canned Sardines and Sardine-Type Products (CODEX STAN 94-1981), Canned Finfish (CODEX STAN 119-1981), Salted Fish and Dried Salted Fish of the Gadidae Family of Fishes (CODEX STAN 189-1993), Dried Shark

- Fins (CODEX STAN 189-1993), Crackers from Marine and Freshwater Fish, Crustacean and Molluscan Shellfish (CODEX STAN 222-2001), Boiled Dried Salted Anchovies (CODEX STAN 236-2003), Salted Atlantic Herring and Salted Sprat (CODEX STAN 244-2004), Sturgeon Caviar (CODEX STAN 291-2010), Fish Sauce (CODEX STAN 302-2001), and Smoked Fish, Smoke-Flavoured Fish and Smoke-Dried Fish (CODEX STAN 311-2013) and Certain Canned Citrus Fruits (CODEX STAN 319- 2015) (REP 18/FA para. 48(i) points a, and b, 30(ii) and Appendix IV);
- and the related revised food additive provisions of the GSFA related to the alignment of the standards for fish and fish products and of the annexes on canned mangoes, canned pears and canned pineapples of the Standard for Certain Canned Citrus Fruits (CODEX STAN 319- 2015), (REP 18/FA para. 48(i) points c, and d and Appendix V Part B)

Background:

- The 49th CCFA (2017) established an eWG, led by Australia and co-chaired by the United States. (REP 17/FA, para. 55(ii)) to:
 - a) Prepare proposals for the alignment of the 14 standards for fish and fish products under food categories 9.2.1 and 9.2.2: Standards for Canned Salmon (CODEX STAN 3-1981), Canned Shrimp or Prawns (CODEX STAN 37-1991), Canned Tuna and Bonito (CODEX STAN 70-1981), Canned Crab Meat (CODEX STAN 90-1981), Canned Sardines and Sardine-Type Products (CODEX STAN 94-1981), Canned Finfish (CODEX STAN 119-1981), Salted Fish and Dried Salted Fish of the Gadidae Family of Fishes (CODEX STAN 189-1993), Dried Shark Fins (CODEX STAN 189-1993), Crackers from Marine and Freshwater Fish, Crustacean and Molluscan Shellfish (CODEX STAN 222-2001), Boiled Dried Salted Anchovies (CODEX STAN 236-2003), Salted Atlantic Herring and Salted Sprat (CODEX STAN 244-2004), Sturgeon Caviar (CODEX STAN 291-2010), Fish Sauce (CODEX STAN 302-2001), and Smoked Fish, Smoke-Flavoured Fish and Smoke-Dried Fish (CODEX STAN 311-2013);
 - b) Consider a revised approach to listing corresponding commodity standards in Table 3 of the GSFA;
 - c) Finalize the alignment of the Standard for Certain Canned Fruits (CODEX STAN 319-2015) (annexes on canned pears and canned pineapples); and
 - d) Finalize guidance for commodity committees on the alignment of food additive provisions of commodity standards with the GSFA.
- The 50th CCFA (2018) considered the report of the eWG on Alignment, and agreed to forward to the 41st CAC (2018) for adoption:
 - The revised food additive sections of provisions in the commodity standards for Standards for Canned Salmon (CODEX STAN 3-1981), Canned Shrimp or Prawns (CODEX STAN 37-1991), Canned Tuna and Bonito (CODEX STAN 70-1981), Canned Crab Meat (CODEX STAN 90-1981), Canned Sardines and Sardine-Type Products (CODEX STAN 94-1981), Canned Finfish (CODEX STAN 119-1981), Salted Fish and Dried Salted Fish of the Gadidae Family of Fishes (CODEX STAN 189-1993), Dried Shark Fins (CODEX STAN 189-1993), Crackers from Marine and Freshwater Fish, Crustacean and

- Molluscan Shellfish (CODEX STAN 222-2001), Boiled Dried Salted Anchovies (CODEX STAN 236-2003), Salted Atlantic Herring and Salted Sprat (CODEX STAN 244-2004), Sturgeon Caviar (CODEX STAN 291-2010), Fish Sauce (CODEX STAN 302-2001), Smoked Fish, Smoke-Flavoured Fish and Smoke-Dried Fish (CODEX STAN 311-2013), and Certain Canned Fruits (CODEX STAN 319-2015) (REP 18/FA, Para. 48(i) point a and b, 30(ii) and Appendix IV); and
- the relevant GSFA provisions for the fish and fish product commodity standards and the *Standard for Certain Canned Fruits* (CODEX STAN 319-2015) (REP 18/FA, para. 48(i) points c, and d and Appendix V Part B).

U.S. Position:

- The United States supports adoption of the revisions to the food additive provisions in the commodity standards and the relevant provisions in the GSFA (REP 18/FA, Appendix IV and Appendix V).

CCPR: Codex Committee on Pesticide Residues

- **MRLs for different combinations of pesticide/commodity(ies) proposed by adoption by CCPR50 (proposed draft and draft) (REP18/PR-Appendix II)**

Background:

- The accelerated procedure and criteria for decision-making were again successfully used to advanced most MRLs using the accelerated 5/8 procedure.
- CCPR agreed to forward 386 MRLs (at Step 5/8) to the Codex Alimentarius Commission (CAC) for final adoption at its next session.
- These MRLs are associated with 39 pesticides; 248 of the MRLs are for plant commodities, while 138 are for animal commodities.
- Five of the nine new compounds reviewed by JMPR in 2017 were nominated by the United States.
- Crop Group and Subgroup MRLs accounted for 44 of the 386 MRLs forwarded for adoption.
- Draft Maximum Residue Limits at Step 5/8
 - 015 Chlormequat (23 MRLs)
 - 126 Oxamyl (16 MRLs)
 - 188 Fenpropimorph (24 MRLs)
 - 189 Tebuconazole (1 MRL)
 - 193 Fenpyroximate (27 MRLs)
 - 207 Cyprodinil (7 MRLs)
 - 213 Trifloxystrobin (4 MRLs)
 - 224 Difenconazole (18 MRLs)
 - 229 Azoxystrobin (3 MRLs)
 - 232 Prothioconazole (9 MRLs)

- 233 Spinetoram (33 MRLs)
- 243 Fluopyram (55 MRLs)
- 249 Isopyrazam (25 MRLs)
- 251 Saflufenacil (2 MRLs)
- 258 Picoxystrobin (30 MRLs)
- 267 Imazapyr (2 MRLs)
- 276 Imazamox (2 MRLs)
- 282 Flonicamid (6 MRLs)
- 285 Flupyradifurone (4 MRLs)
- 287 Quinclorac (13 MRLs)
- 295 Bicyclopyrone (20 MRLs)
- 297 Fenazaquin (2 MRLs)
- 298 Fenpyrazamine (21 MRLs)
- 299 Isoprothiolane (6 MRLs)
- 302 Fosetyl-AI (20 MRLs)
- 303 Triflumezopyrim (13 MRLs)

U.S. Position

- The United States supports adoption of these MRLs
- **[Revision of the Codex Classification of Foods and Animal Feeds \(REP18/PR-Appendix VII\)](#)**

Background

- Revision of the Codex Classification of Foods and Animal Feeds is part of an ongoing effort to revise all of the crop groups.
- The United States has chaired/co-chaired this working group since the beginning of the effort and provided much of the documentation for the proposed crop groups.
- The Committee considered proposed amendments for the following crop groups and subgroups: Type 04 Nuts, seeds and saps and Type 05 Herbs and Spices. Description of the Committees recommendations for each crop group/subgroup is provided below.

Recommendations for Type 04 Nuts, seeds and saps:

- The Committee agreed to forward all groups in Type 04 (Groups 022, 023, 024 and 025) to CAC41 for adoption at Steps 8 and 5/8 (Appendix VII). The Committee recommended:
 - Including Chilean hazelnut in Group 022 Tree nuts.
 - maintaining perilla seed in Group 023 Oilseeds and not to transfer it to Group 028 Spices;
 - including coconut, inflorescence sap and Palmyra palm, inflorescence sap in Group 025 Tree saps, without the creation of separate subgroups and modify the commodity descriptor to indicate that sap can also be collected from the inflorescence of the trees;
 - removing specific provisions for chestnuts in the portion of the commodity to which the MRLs applies (and which is analyzed) in Group 022 Tree nuts as the general provision for tree nuts is also applicable to this commodity;

- excluding soya bean and cupuacu (*Theobroma grandiflorum*);
 - maintaining Subgroup 023D “Other Oilseeds in Group 023 Oilseeds and oilfruits; and
 - excluding additional synonym scientific names for shea nut.
- Recommendations for Type 05 Herbs and Spices:
 - The Committee agreed to forward all groups in Type 05 (Groups 027 and 028) to CAC41 for adoption at Step 8 (Appendix VIII). The Committee recommended:
 - maintaining the subgroups of 028I Dried chili peppers and 028H Citrus peel in Class A Primary commodities of plant origin;
 - maintaining milk thistle in Group 028 Spices;
 - including caraway in Subgroup 028A Spices, seeds; and
 - changing the entries for oregano and marjoram to consolidate the entries for marjoram and to cross reference oregano to marjoram.

U.S. Position

- The United States supports the adoption of these crop group/subgroup recommendations.
- ***Tables on Examples of Representative Commodities for Commodity Groups in Type 04 and Type 05 (For Inclusions in the Principles and Guidance for the Selection of Representative Commodities for the Extrapolation of Maximum Residue Limits for Pesticides for Commodity Groups (CXG 84-2012) (Step 5/8)***

Background

- The revision of commodity groups are retained until final completion of the related commodity groups and the corresponding tables on examples of representative commodities for inclusion in the Classification of Food and Feed and the Principles and Guidance on the Selection of Representative Commodities for the Extrapolation of Maximum Residue Limits for Pesticides to Commodity Groups (CXG 84-2012) respectively.
- CCPR Member Countries were requested to provide comments on Table 4 and 5 in Appendices I and II of CX/PR 18/50/10, which contain examples of representative commodities for Type 04 (Nuts, seeds and saps) and Type 05 (Herbs and Spices) at both the group and subgroup level. Based on comments submitted, CCPR made the following recommendations.
- Table 4 (examples of representative commodities for Type 04 Nuts, seeds and saps) (REP18/PR-Appendix VII)
- CCPR agreed to forward Table 4 (examples of representative commodities for Type 04) to CAC41 for adoption at Step 5/8 and inclusion in the Principles and Guidance for the selection of representative commodities for the extrapolation of maximum residue limits for pesticides for commodity groups (CXG 84-2012) (Appendices VII and VIII). Recommendations included:

- Changing the representative commodities for tree nuts to provide more guidance by adding specific examples for almonds, chestnuts, pecan, pistachios and walnuts (coconut is excluded as a representative commodity for this group).
 - Adding new commodities in groups 022 to 025 based on written comments submitted to this session.
 - Bringing the crops in Table 4 in line with the crops of the groups 022 to 025.
 - Agree that it is not possible to set a Group CXL for the whole Group 023 as crops in Subgroup 023D Other oilseeds vary broadly and it is not possible to identify representative commodities.
- Table 5 (examples of representative commodities for Type 05 Herbs and Spices) (REP18/PR–Appendix VIII)
 - CCPR agreed to forward Table 5 (examples of representative commodities for Type 05) to CAC41 for adoption at Step 5/8 and inclusion in the Principles and Guidance for the selection of representative commodities for the extrapolation of maximum residue limits for pesticides for commodity groups (CXG 84-2012) (Appendices VII and VIII). Recommendations included:
 - Subgroup 027A Herbs (herbaceous plants): Replace the conjunction “and” with “or” to allow for flexibility when selecting commodities within the subgroup.
 - Subgroup 028D Spices, roots or rhizomes: To apply the appropriate concentration factors when considering residue data from representative commodities from roots and tuber vegetables identified for this subgroup.

U.S. Position

- The United States supports the advancement of Tables 4 and 5 for final adoption.

CCRVDF: Codex Committee on Residues of Veterinary Drugs in Food

- **[Draft Risk Management Recommendation \(RMR\) for gentian violet \(REP18/RVDF, paras. 37-39, App. II\) at Step 8](#)**

Background:

- Canada nominated gentian violet to the Priority List at CCRVDF19 (2010) specifically requesting JECFA to consider whether an ADI could be established.
- The 78th JECFA (2013) evaluated gentian violet and determined that it could not establish an Acceptable Daily Intake (ADI) or recommend Maximum Residue Limits (MRLs) due to specific human health concerns.
- CCRVDF22 (2015) agreed to establish an RMR for gentian violet in light of the JECFA conclusions, but could not reach consensus on the RMR language and circulated two options at Step 3 for further consideration at the next session.
- CCRVDF23 (2016) discussed both options and agreed to forward RMR language to CAC 40 (2017) for adoption at Step 5, noting that this would allow more time for

discussion. The forwarded language read:

- “In view of the JECFA conclusions on the available scientific information, there is no safe level of residues of gentian violet or its metabolites in food that represents an acceptable risk to consumers. For this reason, competent authorities should prevent residues of gentian violet in food. This can be accomplished by not using gentian violet in food producing animals.”
- The United States placed a reservation on the advancement of language including the sentence “This can be accomplished by not using gentian violet in food producing animals.” This could be interpreted as overly prescriptive and beyond the scope of Codex in intruding upon the prerogatives of national to choose appropriate means or preventing residues in foods.
- CCRVDF24 (2018) discussed the RMR text at Step 6. Many countries supported adoption of the text, while others, including the United States, suggested deletion or modification of the last sentence of the RMR. Changes to the RMR were not broadly supported, but the Committee agreed to note in the report *“that the current RMR text would allow member countries to choose appropriate risk management approaches to prevent residues of Gentian Violet in food.”*
- CCRVDF24 (2018) agreed to forward the RMR text to CAC 41 (2018) for final adoption at Step 8, with the reservations from several countries out of concerns that the text could be interpreted as prescriptive when read independently of the CCRVDF24 report.

U.S. Position

- The United States supports providing risk management recommendation language to Codex Members to prevent gentian violet residues in food. However, the United States believes the sentence “This can be accomplished by not using gentian violet in food producing animals,” can be interpreted as prescriptive and is beyond the scope of Codex and the Committee, when read independently of the CCRVDF24 report.
- ***Proposed draft MRLs for amoxicillin (finfish fillet and muscle) (85th JECFA); ampicillin (finfish fillet and muscle) (85th JECFA); lufenuron (salmon and trout fillet) (85th JECFA); monepantel (cattle fat, kidney, liver, muscle) (85th JECFA) (REP18/RVDF, paras. 60, 64, 77, 79, App. IV) at Step 5/8***

Background:

- Amoxicillin
 - CCRVDF24 (2018) considered the proposed draft MRLs for amoxicillin in finfish recommended by the 85th JECFA (2017) and agreed to forward them for final adoption at Step 5/8.
- Ampicillin
 - CCRVDF24 (2018) considered the proposed draft MRLs for ampicillin in finfish recommended by the 85th JECFA (2017) and agreed to forward them for final adoption at Step 5/8.

- Lufenuron
 - CCRVDF24 (2018) considered the proposed draft MRLs for lufenuron in salmon and trout recommended by the 85th JECFA (2017) and agreed to forward them for final adoption at Step 5/8.
- Monepantel
 - CCRVDF24 (2018) considered the proposed draft MRLs for monepantel in cattle fat, kidney, liver, and muscle recommended by the 85th JECFA (2017) and agreed to forward them for final adoption at Step 5/8.

U.S. Position:

- The United States supports adoption of the proposed draft MRLs at Step 5/8.

CCMAS: Codex Committee on Methods of Analysis and Sampling

- **Endorsement of Methods of Analysis and Sampling Plans for Provisions in CODEX Standards (REP18/MAS) paras 10-34 and Appendix II**

Background:

- The physical working group (pWG) on the endorsement of methods, which was led by United States and Australia, reviewed the methods and sampling plans referred to CCMAS by Codex Committees. The pWG recommendations were subsequently considered by CCMAS for final endorsement.
- The methods and sampling plans referred to CCMAS for final endorsement were:
 - Methods of analysis in the Standards for Infant Formula and Formulas for Special Medical Purposes Intended for Infants – except for Vitamin D.
 - (CXS 72-1981) (Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU)
 - Methods of analysis for dairy permeate powders Codex Committee on Milk and Milk Products (CCMMP)
 - Methods of analysis for quinoa except for saponins Codex Committee for Cereals, Pulses and Legumes (CCCPL)
 - Sampling plan for MLs for methylmercury in fish (CXSS 193-1995) Codex Committee on Contaminants in Food (CCCF)
 - Numeric criteria for methods of analysis for mercury and methylmercury except for the sampling plan (CCCF).
- CCMAS returned the sampling for MLs for methylmercury to CCCF for additional information; requested clarification from CCNFSDU on the provisions for Vitamin D in infant formula, informed CCCPL that no method for saponins was identified, for quinoa, and did not endorse a method for lactose in dairy permeate powders.

U.S. Position:

- The United States supports the adoption of all the methods and the numeric criteria that were endorsed by CCMAS39 (2018) (See Appendix II of REP18/MAS)
 - Methods of analysis in the Standards for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CXS 72-1981.CCNFSDU)
 - Methods of analysis for dairy permeate powders, except for lactose (CCMMP)
 - Methods of analysis for quinoa (CCCPL)
 - Numeric criteria for methods of analysis for mercury and methylmercury in fish (CCCF)

Part 2 – Standards and related texts held at Step 8 by the Commission

CCRVDF: Codex Committee on Residues of Veterinary Drugs in Food

- **Proposed draft MRLs for recombinant bovine somatotropin (rBST) (cattle) (ALINORM 95/3, Appendix II) Held at Step 8 by CAC23, (ALINORM 03/41, para. 34)**

Background:

- The CAC32 (2009) had an extensive discussion regarding the standards for rBST, currently held at Step 8, short of final adoption.
- The CAC35 (2012) requested the Joint FAO/WHO Expert Committee on Food Additives (JECFA) to address specific questions regarding rBST and any potential new information available since the last evaluation. The CAC further asked CCRVDF to provide a recommendation following receipt of the JECFA evaluation.
- The CAC36 (2013) noted that rBST would be considered at the next Commission meeting following completion of the JECFA evaluation.
- The 78th JECFA (2013) evaluated rBST and the specific questions posed to it by CAC35 (2012). The JECFA reaffirmed its previous evaluation and the recommendation of MRL “not specified” for residues of the somatotropins in food. (Because of the wide margin of safety, it was not necessary to establish a numerical limit as an MRL.)
- CCRVDF22 (2015) could not reach consensus on a recommendation for the Commission, but agreed that JECFA had addressed all of the questions posed to it by the CAC. There were different opinions regarding the JECFA replies. As no agreement had been reached, a synopsis of the Committee discussion would be forwarded to the CAC38 (2015), but no recommendation would be made.
- There was extensive discussion at the CAC38 (2015), but, despite the clear conclusions of the independent expert review by JECFA and overwhelming scientific evidence, The CAC was unable to come to a conclusion and agreed to continue to hold the standard at Step 8.

U.S. Position:

- The United States supports the evaluation of the 78th JECFA and the final adoption of the MRLs for rBST, currently held at Step 8, at CAC41.

Agenda Item 5: Adoption of Codex Texts at Step 5 CX/CAC 18/41/5

CCFFV: Codex Committee of Fresh Fruits and Vegetables

- **[Standard for Ware Potatoes \(Proposed Draft\) REP 18/FFV, Para. 60 \(ii\), Appendix IV](#)**

Background:

- The 17th CCFFV (2012) considered the Delegation of India's request for the development of a Standard for Ware Potatoes.
- The 18th CCFFV (2014) considered a revised project document for the Ware Potatoes Standard and decided to establish an electronic working group led by India and co-chaired by France to develop a standard.
- At the 19th CCFFV (2015), the Committee discussed the Draft Standard at Step 3.
- At the 20th CCFFV (2017), the Committee recommended the Draft Standard for Ware Potatoes for adoption by the CAC 41 (2018) at Step 5, which will allow for another round of comments and consideration at the next CCFFV session.
- Currently both United Nations Economic Council for Europe and the U.S. standard for potatoes are predominantly used in international trade. Both are more liberal than the proposed Codex draft standard.
- Sections of the draft standard that are unresolved are:
 - U.S. Position Requirements for green coloration and length of sprouts
 - Tolerances for soft rot, decay and internal breakdown in Extra Class; and for soil and extraneous matter.

U.S. Position:

- The United States supports approval of the standard at Step 5.

CCNFSDU: Codex Committee of Nutrition and Foods for Special Dietary Uses

- **[Essential Composition requirements for older infants and young children \(Proposed Draft\) P REP 18/NFSDU Para 71, Appendix II](#)**

Background:

- At CCNFSDU34 (2012), New Zealand proposed to review and update this Standard to reflect technological advances and diversification of follow-up formula in several countries. Several countries and the WHO opposed the work because they viewed the product as not nutritionally necessary for young children. An electronic Working Group (eWG) chaired by New Zealand and co-chaired by France and Indonesia was established. After much discussion at CCNFSDU35 (2013) and CCNFSDU 36 (2014), the Committee agreed the review should proceed, as these products were on the market and should be safe and nutritionally appropriate. The eWG chaired by New Zealand and co-chaired by France and Indonesia has led the work to date.
- At CCNFSDU39 (2017), the Committee discussed the proposed draft revised Standard for Follow-up Formula. CCNFSDU recommended adoption of the

essential composition and quality factors for Follow-up formula for Older Infants and Young children for the following nutrients and associated text and footnotes (REP18/NFSDU App II):

Section A: For Older Infants (6-12 months)	Section B: For Young Children (12-36 months)
Protein	Protein
Lipids (total fat, linoleic acid, α -linolenic acid, ratio of linoleic acid: α -linolenic acid)	Lipids (total fat, linoleic acid, α -linolenic acid)
Carbohydrates (available carbohydrates)	Carbohydrates (available carbohydrates)
Vitamins	Vitamins
vitamins A, D, E, K	Vitamin A and D3
Thiamin, Riboflavin, niacin, Vitamin B-6, Vitamin B-12, pantothenic acid, folic acid	Riboflavin, Vitamin B-12,
Vitamin C	Vitamin C
Biotin	
Minerals and trace elements	Minerals and trace elements
Iron, Zinc, Selenium, Copper	Iron, Zinc,
Calcium, Phosphorus, ratio of Calcium/Phosphorus	Calcium
Magnesium	
Sodium	
Chloride	
Potassium	
Manganese	
Iodine	
Optional ingredients	Optional ingredients
Taurine, Docosahexanoic acid, Choline, Myo-inositol, L-carnitine, L(+) lactic producing cultures	

U.S. Position:

- The United States supports adoption of the proposed draft essential composition requirements at Step 5, which will allow for another round of discussion in CCNFSDU

CCCF: Codex Committee on Contaminants in Foods

- **[Proposed draft Code of Practice 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 \(REP 18/CF para 102, Appendix VI\)](#)**

Background:

- In 2016, at the request of CCCF10, JECFA evaluated the toxicity of 3-MCPDE and

GE and dietary exposure to these compounds. JECFA recommended that efforts to reduce 3-MCPDE and 3-MCPD in infant formula be implemented and that measures to reduce GE and glycidol in fats and oils continue, particularly when used in infant formula.

- At CCCF11 (2017), the Committee agreed to establish an eWG, chaired by the United States and co-chaired by the EU and Malaysia, to prepare a draft *Code of Practice for the Reduction of 3-Monochloropropane-1,2-diol Esters and Glycidyl Esters in Refined Oils and Products Made with Refined Oils, Especially Infant Formula*. CAC40 approved the new work.
- At CCCF12 (2018), the United States introduced the item and highlighted 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 solvents, degumming, agricultural practices, and bleaching clay deodorization. The Committee agreed to forward the proposed draft Code of Practice to CAC41 (2018) for adoption at Step 5.

U.S. Position:

- The United States supports adoption of the proposed draft COP at Step 5.
- ***Proposed draft Guidelines for Risk Analysis of Instances of Contaminants in Food Where There is no Regulatory Level or Risk Management Framework Established (REP 18/CF para 124, Appendix IX)***

Background:

- At CCCF11 (2017), following a pre-plenary workshop, New Zealand presented a project document for new work on detection of chemicals of very low public health concern. The Committee agreed to:
 - endorse new work on the development of risk analysis guidelines to address chemicals inadvertently present in food at low levels;
 - forward the project document to CAC40 (2017) for approval; and
 - establish an eWG chaired by New Zealand, and co-chaired by the Netherlands, to advance this work.
- At CCCF12 (2018), New Zealand introduced the new work and noted that an informal meeting took place prior to the plenary session to address some key questions on the scope, definitions, and availability of rapid risk assessment methodologies. The Committee agreed to advance the guidelines document as revised at the pre-session meeting to CAC41 for adoption at Step 5.

U.S. Position:

- The United States does not object to adoption of the revised guidelines document at Step 5.

CCRVDF: Codex Committee on Residues of Veterinary Drugs in Food

- **Proposed draft MRL for flumethrin (honey) at Step 5 (85th JECFA) REP 18/RVDF, para.73, Appendix IV**

Background:

- The 85th JECFA (2017) evaluated flumethrin and recommended an MRL for honey.
- At CCRVDF24 (2018), some Member Countries expressed concern that the proposed draft MRL, based on the limit of quantification, could lead to trade problems as developing countries may not have laboratory capacity to measure such low levels.
- One Member Country instead proposed an MRL listed as “unnecessary” as residues resulting from the use of this substance with Good Veterinary Practices (GVP) would be expected to be very low and would be unlikely to pose a hazard to human health.
- CCRVDF24 (2018) agreed to advance the proposal that an MRL was “unnecessary” for adoption by the CAC at Step 5 to allow for further consideration at the next CCRVDF session (2020).

U.S. Position:

- The United States supports adoption of the proposed MRL for flumethrin in honey as “unnecessary” at Step 5.

- **Proposed draft MRLs for zilpaterol (cattle kidney, liver, muscle) (78th JECFA) (REP18/RVDF, paras. 52-55, App. III) at Step 4**

Background:

- The United States nominated zilpaterol hydrochloride for evaluation by the JECFA at CCRVDF20 (2012). The Committee was unable to reach consensus on its inclusion on the Priority List and requested guidance from CAC regarding the appropriate steps to take when a compound has met the criteria for inclusion, but delegations object to inclusion for other reasons.
- CAC35 (2012) discussed the request for guidance from CCRVDF20 (2012). The Representative of the Legal Counsel of FAO noted the need for predictable procedures in Codex and that the consistent practice in CCRVDF had been to include compounds which met the criteria for inclusion in the Priority List. On that basis, the Legal Council considered that zilpaterol should be included for JECFA evaluation, and the Chairperson of CAC35 (2012) concluded that risk management decisions should follow the risk assessment.
- The 78th JECFA (2013), established an ADI for zilpaterol hydrochloride, but requested additional data to recommend MRLs.
- The pharmaceutical sponsor developed and submitted the requested data which was evaluated by the 81st JECFA (2015). The 81st JECFA proposed draft MRLs for cattle kidney, liver, and muscle.
- CCRVDF23 (2016) agreed to hold the proposed draft MRLs for cattle tissues at Step 4 to allow the sponsor to develop and provide additional data on the bioavailability of

incurred residues for re-evaluation by JECFA.

- The new data developed by the sponsor was submitted and evaluated by the 85th JECFA (2017). The 85th JECFA (2017) reconfirmed the 81st JECFA's recommended proposed draft MRLs.
- CCRVDF24 (2018) reached consensus that JECFA had conducted a robust scientific evaluation and that there were no scientific or public health concerns regarding the proposed draft MRLs for zilpaterol hydrochloride. The Committee could not reach consensus to advance the proposed draft MRLs in the Step procedure due to concerns outside the scope of Codex and the draft MRLs remained at Step 4. Twenty-eight Member Countries placed reservations objecting to the decision not to advance the MRLs, because no relevant or legitimate factors consistent with the Procedural Manual had been raised and the procedures adopted by Codex were not being followed.
- The Codex Secretariat noted that the CCEXEC and the CAC would need to take action and discuss this issue as CCRVDF24 (2018) was prevented from acting on the standards for zilpaterol hydrochloride due to factors beyond science.

U.S. Position:

- The United States supports adoption of the proposed draft MRLs for zilpaterol hydrochloride at Step 5 in light of the consensus reached by CCRVDF24 (2018) on the robust JECFA evaluation and the lack of objections consistent with the *Statements of Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to Which Other Factors are Taken into Account in the Procedural Manual*.

Committees Working by Correspondence

CCCPL: Codex Committee on Cereals, Pulses and Legumes

- **[Proposed Draft Standard for Quinoa \(CL 2018/25-CPL, April 2018\)](#)**

Background:

- The 38th Session of the Codex Alimentarius Commission (CAC) (July 2015) approved new work on a standard for quinoa and agreed to reactivate the Codex Committee on Cereals, Pulses and Legumes (CCCPL) to work by correspondence on the development of the standard. CAC38 also agreed to establish an electronic working group (eWG), chaired by Bolivia and co-chaired by the United States, in order to prepare an initial draft standard for quinoa for distribution for comments at Step 3. The eWG would work in English and Spanish.
- The CAC40 (July 2017) adopted the proposed draft Standard for Quinoa at Step 5 and also agreed to re-establish an eWG, chaired by Plurinational State of Bolivia and co-chaired by the United States, to continue the work and address the outstanding issues. The eWG worked in English and Spanish.
- In an April 2018 Circular Letter (CL 2018/25-CPL), a revised eWG draft Standard for Quinoa was circulated for comments at Step 8, with a deadline of May 31, 2018.
- The April 2018 Circular Letter also made the following request for comments:
 - Codex members and observers are invited to send their comments at Step 8 on the draft Standard for Quinoa. Specifically, please comment on whether the proposed the draft Standard for Quinoa 0.12% maximum limit for saponin content in Section 3.2.6 can be supported for adoption at Step 8.

U.S. Position:

- The United States supports:
 - adoption of the draft standard for quinoa at Step 8 with the proposed 0.12% maximum limit for saponin content in Section 3.2.6.
 - the proposed ISO 712 method for determining moisture content in quinoa.
- The United States does not support
 - ISO 1871 method for determining protein content in quinoa as the United States considers ISO 1871 method (Kjeldahl method) to be a general method for determining nitrogen in food and feed products.
 - ISO 20483 method, applicable to cereals and pulses, to be more appropriate for determining protein content in quinoa, and recommends referring this method to the Codex Committee on Methods of Analysis and Sampling (CCMAS) for endorsement.
- Regarding a method for determining saponin content in quinoa, the 39th Session of CCMAS (May 2018) was not in a position to recommend a suitable method and noted the interest by an observer organization for undertaking collaborative studies using an appropriate method. The United States supports such collaborative studies.

CCS: Codex Committee on Sugars

- **Standard for Non-centrifuged dehydrated sugar cane juice**

Background:

- CCS was reactivated by CAC34 (2011) to start work by correspondence. The work was limited to the development of a Standard for Dehydrated Non-Centrifuged Sugar Cane Juice. When work on this standard is completed, CCS should be adjourned sine die.
- CAC36 (2013) adopted the standard at Step 5 only in view of the extensive comments received.
- The Chair, CCS, proposed adoption at Step 8 in both CAC37 (2014) and CAC38 (2015), but instead, the standard was returned to Step 6 both times in view of unresolved issues related to the identity (product name/scope) and quality (chemical characteristics, etc.) of the product.
- CAC38 instructed CCS that if no consensus could be reached on final adoption by CAC39 (2016), consideration should be given either to convening a physical meeting of CCS or to discontinuing work. CAC 39 requested CCS to clarify the scope of the standard only and to provide evidence of the international support for the defined scope. CAC 40 (2017) granted another year of extension for the work.
- With the understanding that the aspects of scope and product definition are mutually dependent in the draft standard, Colombia, the Host Country of CCS, prepared a new proposal for scope and product definition, which was circulated for comments under circular letter CL 2017/45-CS.
- Based on the comments in response to the Circular Letter (CL), Colombia further revised the scope and product definition and concluded that "The comments received by Codex member countries and observers on the scope demonstrate broad international support."
- The summary analysis of the comments submitted in reply to CL 2017/45-CS, explanatory notes, and proposal are presented in CL 2017/84-CS for consideration by CAC41. Colombia reiterated that the option of holding a face-to-face meeting of CCS should not be ruled out as a way of expediting the steps in the draft standard.

U.S. Position:

- The United States believes that even though this draft standard is at Step 6 in the Codex process, there are still a number of outstanding issues that prevent it from being advanced for final adoption at this session of the CAC. Those issues are the very same issues that have previously impeded advancement of the standard.
- The United States submitted comments in response to CL 2017/84-CS indicating:
 - Disappointment to see the name of the product remains "non-centrifuged dehydrated sugar cane juice," despite our previous comments on CL2015/19-CS, CL 2016/15-CS, and 2017/45-CS that strongly opposed this name. The United States strongly believes that the draft standard being developed is for a type of non-centrifugal sugar, not a sugar cane juice. Naming this product "sugar cane juice" with qualifying terms related to its processing is misleading to consumers, because it suggests that the product is "juice" or is made from

“juice,” without revealing that its major component (maximum saccharose at 91% and minimum reducing sugar at 4.5% as proposed in the draft standard) is sugar.

- Confusion that our comment about the adoption of FAO terminology "non-centrifugal" was not addressed in CL2017/84-CS or in CL2017/45-CS, especially when it was recommended by several of the member countries during previous discussions of the working group. The United States strongly believes that it is more appropriate to name the product "Non-Centrifugal Cane Sugar" than "Non-Centrifuged Dehydrated Sugar Cane Juice."
- Concern regarding the summary listed in para. 8 of CL2017/84-CS (Section 1. Scope) with respect to the comments received for the scope of the product. The concerns received from member countries do not necessarily demonstrate broad international support for the current proposal. In fact, several countries have expressed concerns that the proposed standard may turn into a standard for panela only; Japan suggested turning the proposed standard into a regional standard instead of an international standard if its own product is not included in the proposal.
- The United States does not disagree that other chemical characteristics of the product, such as ash and protein content, may differentiate this product from centrifugal sugars. However, it does not change the fact that this product is a non-centrifugal sugar (i.e., the distinction is mainly caused by not undergoing purification and centrifugation processes). We recall that at least two other member countries have commented about this product being a type of non-centrifugal sugar in their comments to several previous CLs.
- Since progress has not been made on these issues through several rounds of discussion by CL, a physical meeting cannot guarantee the consensus can be reached. Instead of a physical meeting, the United States recommends that Colombia revise the proposed standard based on the comments received in response to the CL. In particular, we strongly recommend that the term “Non-Centrifuged Dehydrated Sugar Cane Juice” be replaced by “Non-Centrifugal Cane Sugar” in the scope, product definition, and the remaining of the standard.

Agenda Item 6: Revocation of Codex texts CX/CAC 18/41/7

CCFA: Codex Committee on Food Additives

- [Food Additive Provisions in the GSFA \(REP 18/FA paras. 111\(ii\) and Appendix VI\)](#)

Background:

- The 50th CCFA (2018) forwarded for revocation one adopted provision in the GSFA – Sucroglycerides (INS 474) in food category 12.6 (Sauces and like products). This revocation was recommended to address an inconsistency with adopted provisions in the sub-categories of food category 12.6. (FA/18 CRD2 addendum, Rep 18/FA para 111(ii) & Appendix VI).

U.S. Position:

- The United States can remain silent on the revocation of the provisions in REP 18/FA Appendix VI.

- [Relevant Food Additive Provisions from the Standards for Various Cheeses](#)

- [Mozzarella \(CODEX STAN 262-2006\), Cottage Cheese \(CODEX STAN 273-1968\), Cream Cheese \(CODEX STAN 275-1973\), Fermented Milks \(CODEX STAN 243-2003\), Dairy Fat Spreads \(CODEX STAN 253-2006\), and Cream Cheese \(CODEX STAN 75-1973\). \(REP 18/FA para 47, 48\(ii\)\)](#)

Background:

- The 50th CCFA (2018) noted that there are no JECFA specifications for specific malates and tartrates. It is the normal practice in CCFA to revoke provisions for additives that do not have JECFA specifications. Due to the lack of JECFA specifications for the additives under discussion, 50th CCFA (2018) forwarded for revocation the food additives in the Commodity Standards as listed in REP 18/FA para. 48(ii).

U.S. Position:

- The United States can remain silent on the revocation of the provisions presented in REP 18/FA para 48(ii).

- [Food-additive provision in commodity standards for sodium sorbate \(INS 201\)](#)

From the *Standards for Instant Noodles* (CODEX STAN 249-2006), *Fermented Milks* (CODEX STAN 243-2003), *Dairy Fat Spreads* (CODEX STAN 253-2006), *Mozzarella* (CODEX STAN 262-2006), *Cheddar* (CODEX STAN 263-196), *Danbo* (CODEX STAN 264-1966), *Edam* (CODEX STAN 265-1966), *Gouda* (CODEX STAN 266-1966), *Havarti* (CODEX STAN 267-1966), *Samsø* (CODEX STAN 268-1966), *Emmental* (CODEX STAN 269-1967), *ilsiter* (CODEX STAN 270-1968), *Saint-Paulin* (CODEX STAN 271-1968), *Provolone* (CODEX STAN 272-1968), *Cottage Cheese* (CODEX STAN 273-

1968), *Cream Cheese* (CODEX STAN 275-1973) and *Cheese* (CODEX STAN 283-197) (REP 18/FA para 132 and 134(iv))

Background:

- Sorbates share a group ADI and group listing for which there are approximately 90 existing adopted provisions. The 50th CCFA (2018) noted that there were no JECFA specifications for sodium sorbate (INS 201) and that none had been provided in response to a call for data. Therefore the 50th CCFA agreed to remove sodium sorbate from the group listing for sorbates in the GSFA and forward for revocation all provisions for sodium sorbate in all commodity standards (REP 18/FA para 134(iv)). The revocation is limited to sodium sorbate only and will not impact the other sorbates listed under the group heading in the GSFA.

U.S. Position:

- The United States can remain silent on the revocation of the provisions in the GSFA and commodity standards listed in REP 18/FA para 134(iv).

CCCF: Codex Committee on Contaminants in Foods

- **Revocation of Revised MLs for lead and for tomato concentrates**

Background:

- At CCCF12 (2018), the Committee agreed to request revocation by CAC41 of the following current MLs for lead in the GSCTFF (CODEX STAN 193-1995): mango chutney, salt, fat spreads and blended spreads, and edible fats and oils in view of the adoption of revised MLs, and the ML for processed tomato concentrates categories in view of the decision that the ML for fruiting vegetables could be used to derive appropriate levels for tomato concentrates.

U.S. Position:

- The United States supports revocation of the listed current MLs by CAC41 (2018).

CCPR: Codex Committee on Pesticide Residues

- **Codex MRLs (CXLs) for different combinations of pesticide/commodity(ies) proposed for revocation by CCPR50 (REP18/PR-Appendix III)**

Background

- CCPR recommended revocation for 135 previously adopted CXLs (Codex MRLs) associated with 11 pesticides. Of these, 92 of the MRLs proposed for revocation were for plant commodities and 43 are for animal commodities.
- These are typically CXLs being replaced based on review of additional data; uses no longer supported; or CXLs deemed by JMPR to have potential dietary intake

concerns with no alternative good agricultural practice.

- Proposed Maximum Residue Limits Recommended for Revocation
 - 015 Chloromequat(24 MRLs)
 - 126 Oxamyl (17 MRLs)
 - 188 Fenpropimorph (19 MRLs)
 - 193 Fenpyroximate (15 MRLs)
 - 207 Cyprodinil (2 MRLs)
 - 213 Trifloxystrobin (1 MRLs)
 - 224 Difenconazole (4 MRLs)
 - 232 Prothioconazole (3 MRLs)
 - 233 Spinetoram (8 MRLs)
 - 243 Fluopyram (20 MRLs)
 - 249 Isopyrazam (13 MRLs)

CCMAS: Codex Committee on Methods of Analysis and Sampling

- **Revocation of Methods of Analysis**

Background:

- At CCMAS2018, the Committee agreed to request revocation by CAC41 of the following methods:
 - Methyl mercury for fish, AOAC 988.11
 - Vitamin D in Infant Formula, AOAC 992.26

U.S. Position:

- The U.S. supports revocation of the listed methods by CAC41.

CCFFV: Codex Committeeon Fresh Fruits and Vegetables

- **Project document for new work on a standard for yams REP 18/FFV Para. 60. Appendix V of the report**
- **Project document for new work on a standard for onions and shallots REP 18/FFV, Para 60. Annex I of the reprot**
- **Project document for new work on a standard for berry fruits REP 18/FFV, Para 48, Annex II of the report**

Background:

- The 19th CCFFV Session (2015) agreed that two proposals, for shallots (proposed by Indonesia) and yams (proposed by Costa Rica), should be revised and resubmitted in reply to the CL 2015/29-FFV. The Committee agreed that these two proposals would be considered as already prioritized by the 20th CCFFV Session (2017).
- In addition, to the previously prioritized new work proposals for shallots and yams, three new proposals were submitted for consideration by the 20th CCFFV session:
 - Curry leaves (India)
 - Onion (Iran)
 - Blackberry (Mexico)
- The CCFFV Priorities working group recommended, and the Committee agreed:
- to combine the new work proposals for onions and shallots into one new work proposal, and
- to develop a general standard for “berry fruits” rather than a standard for blackberries only. The Committee further agreed that provisions concerning sizing may be either optional, or per existing trade practices (diameter or volume per litre or pint). The berry fruits standard would include the following berries:
 - raspberries (*Rubus idaeus* L.)
 - blackberries (*Rubus* sect. *Rubus*)
 - loganberries (*Rubus loganobaccus* L. H. Bailey)
 - currants (*Ribes rubrum* L., *Ribes nigrum* L.)
 - gooseberries (*Ribes uva-crispa* L.)
 - bilberries (*Vaccinium myrtillus* L.)
 - blueberries (*Vaccinium corymbosum* L., *Vaccinium formosum* Andrews,
 - *Vaccinium angustifolium* Aiton, *Vaccinium virgatum* Aiton)
 - cowberries, lingonberries (*Vaccinium vitis-idaea* L.)
 - cranberries (*Vaccinium macrocarpon* Aiton)
 - wild cranberries (*Vaccinium oxycoccos* L.)

- cloudberrries (*Rubus chamaemorus* L.)
 - hybrids of these species such as boysenberries (*Rubus ursinus* Cham. et Schltl. X *Rubus idaeus* L.), tayberries (*Rubus* sect. *Rubus* x *Rubus idaeus* L.), jostaberries (*Ribes nigrum* L. x *Ribes uva-crispa* .).
- The Committee agreed to establish eWGs to develop the following standards, subject to the approval of the Codex Alimentarius Commission and with the goal of circulating draft standards at Step 3 for consideration at the next session of CCFFV (21):
 - Yams, with an eWG chaired by Costa Rica and co-chaired by Ghana, working in English and Spanish;
 - Onions and shallots, with an eWG chaired by Iran and co-chaired by India and Indonesia, working in English only; and
 - Berry fruits, with an eWG chaired by Mexico and co-chaired by Argentina, working in English and Spanish.

U.S. Position:

- The United States supports the development/commencement of work on new CCFFV standards for yams, berry fruits and for onions and shallots.
- The CCFFV and Codex must explore methods to expedite the standard development process to meet the needs of its member countries and international trade.

CCFL: Codex Committee on Food Labelling

- **Project document for new work on the development of guidance on use of simplified nutrition information on the front of pack REP 18/FL Para. 48, Appendix III**

Background:

- Front of pack labeling (FOPL) was proposed as a potential topic for new work at CCFL43 (2016) by Costa Rica and New Zealand. An electronic working group (eWG) was established following the plenary to gather information about current practices and the need for work on FOPL in CCFL. The information gathered in the eWG was compiled and a project document was prepared and presented at CCFL44 (2017).
- At CCFL44 (2017), the committee made minor changes to the project document and discussed whether to take up new work on FOPL.
- CCFL44 agreed to start new work (after submission of the project document for approval by CAC41 (2018) which would involve developing guidelines on the use of simplified nutrition information on the front of pack, consistent with the text on simplified nutrition information in the *Guidelines for Nutrition Labeling* (CXG 2-1985).
- The committee agreed to establish an eWG, chaired by Costa Rica and co-chaired by New Zealand to begin the work before CCFL45 (2019).
- There are four aspects which will be covered by text developed by CCFL: (1) purpose and scope, (2) definition of FOPL, (3) general principles for FOPL, and (4)

aspects to consider in the development of FOPL systems.

- Most countries, including the United States, stated that the guidelines which CCFL develops should be voluntary, and very general. They indicated that the guidelines should not be prescriptive and that there should be no “one size fits all” approach to the development of the Guidelines.

U.S. Position:

- The United States supports new work on front-of-pack-labeling, consistent with the project document agreed upon at CCFL44. The intention of this work is to develop voluntary guidelines that provide clear and transparent scientific guidance to governments, industry or others wishing to develop and implement nutrition labeling on the front of packaging and not to establish a specific global scheme of front-of-pack nutrition labelling.
- The United States believes that care should be taken to ensure that the work is done in a manner that is consistent with Codex scope and principles and in areas where consensus is likely to be reached.

CCFH: Codex Committee on Food Hygiene

- **[Project document for new work on a Code of Practice for food allergen management for food business operators REP 18/FH para. 48, Annex III of the report](#)**

Background:

- During an in-session working group on new work priorities at CCFH49 (November 2017), Australia introduced a project document prepared by Australia and the United States to develop a Code of Practice (CoP) on food allergen management for food business operators. The CoP would address allergen management throughout the supply chain and it would complement the revised *General Principles of Food Hygiene*, which will include information on the importance of controlling food allergens.
- In the plenary session, the Committee further clarified that the purpose of the CoP is to provide guidance to food business operators and governments to manage allergens in food production and retail/food service, including controls to prevent cross-contact. Food allergen management also involves allergen labelling, which is addressed by the *General Standard for the Labelling of Prepackaged Foods* (CODEX STAN 1-1985). (Note: the Codex Committee on Food Labeling (CCFL) is considering new work in allergen labeling and a discussion paper is being developed by the U.K., Australia and the United States for consideration in that committee.)
- CCFH49 (2017) supported this as new work and an EWG was established with Australia as chair and the United Kingdom and United States as co-chairs. Australia worked with the United States and the U.K. to submit a revised project document to the Codex Alimentarius Commission (through the Secretariat) for approval as new work.

U.S. Position:

- The United States supports this new work proposal.
- ***Project document for new work on a Code of Practice on guidance for the management of (micro)biological foodborne crises/outbreaks REP 18/FH, Para. 54. Annex IV of the report***

Background:

- During an in-session working group on new work priorities at CCFH49 (November, 2017), the EU presented the project document they had prepared, noting that the scope of the new work was to provide guidance to competent authorities on the management of foodborne outbreaks/crises in order to limit the extent of such events by enhancing preparedness and improving management.
- This project resulted in much discussion, since many non-EU country delegations in the working group were not clear on purpose of this new work and felt that a discussion paper was necessary to allow for better understanding of the gaps in existing guidance/documents and further evaluation by their countries' agencies involved in outbreak management; and to expand the scope to include the role of food business operators in a foodborne crisis. European delegations believed there was sufficient information in the project document to start this as new work.
- In the plenary session, the EU clarified that the work was intended to supplement FAO/WHO guidance and Codex texts, and that the guidance would also be addressed to food business operators. They argued that developing a discussion paper would unnecessarily delay this urgently needed work and proposed that the Committee agree to start new work.
- The Committee clarified the purpose and scope of the new work to:
 - provide guidance to competent authorities on the management of foodborne outbreaks/crises, including communication between national programs and INFOSAN;
 - address preparedness, detection, response and recovery, with the intent of limiting the extent of such events;
 - limit the scope to biological hazards;
 - provide a supplement and a link to documents developed by FAO/WHO and Codex texts, as appropriate.
- The document will define the role of competent authorities and collaboration with food business operators and other stakeholders during foodborne outbreaks/crises.
- CCFH49 (2017) supported this as new work and an eWG was established, with Denmark as chair and Chile and the EU as co-chairs. The EU and Denmark were to submit a revised project document to the Codex Alimentarius Commission (through the Secretariat) for approval as new work.

U.S. Position:

- Although we would have preferred to see a discussion paper to identify existing information and gaps, the United States supports this new work proposal.

CCFA: Codex Committee on Food Additives

- **Priority List of Substances Proposed for Evaluation by JECFA (REP 18/FA para. 130-133, 134(i) and Appendix X)**

Background:

- A large list of substances was included on the JECFA Priority List for consideration for evaluation by JECFA.
- The Committee agreed to remove gold (INS 175) and silver (INS 174) from the Priority List as no confirmation of data availability had been provided.
- The Committee agreed to remove sodium sorbate (INS 201) from the JECFA Priority List.
- The United States proposed that the following be added to the JECFA Priority List:
 - black carrot extract for safety evaluation and specifications,
 - 8 flavouring substances for a revision of specifications, and
 - Steviol glycosides (Steviol Glycosides, Rebaudioside A, Rebaudioside D, Rebaudioside M, Enzyme Modified Stevia Leaf Extract) for re-evaluation and establishment of specifications.

U.S. Position:

- The United States can support the JECFA Priority List as published in Appendix X of REP 18/FA.

- **New proposed draft food additive provisions of the GSFA at Steps 3 and 2 (REP 18/FA para. 111(iii) and Appendix VII)**

Background:

- CCFA issues a general request for proposals for new and or/revisions of food additive provisions on an annual basis through circular letter (CL 2017/47-FA).
- The United States did not submit any proposals in response to CL 2017/47-FA.

U.S. Position:

- The United States can remain silent on the new proposed draft food additive provisions of the GSFA.

CCRVDVDF: Codex Committee on Residues of Veterinary Drugs in Food

- **Draft Priority List of Veterinary Drugs (REP18/RVDF, para. 116, App. VI) for approval of new work**

Background:

- CCRVDVDF24 (2018) agreed to include the following compounds for evaluation or re-evaluation by JECFA on the Priority List of Veterinary Drugs:
 - Flumethrin in cattle
 - Fosfomycin in chicken and swine

- Ivermectin in pigs and sheep/goats
- CCRVDF24 (2018) also agreed to include the following compounds to consider extrapolation to additional species on the Priority List of Veterinary Drugs:
 - Amoxicillin in ruminants
 - Benzylpenicillin in ruminants
 - Tetracyclines in ruminants
 - Cyhalothrin in ruminants
 - Cypermethrin in ruminants
 - Deltamethrin in ruminants
 - Moxidectin in ruminants
 - Spectinomycin in ruminants
 - Levamisole in ruminants
 - Tilimicosin in ruminants
 - Deltamethrin in fish
 - Flumequine in fish
 - Teflubenzuron in fish
- The compounds for extrapolation have existing Codex MRLs in one or more species and will be considered by an Electronic Working Group (eWG) chaired by the EU. If the eWG determines extrapolations to additional species is appropriate, proposed draft MRLs for new species will be circulated for comment prior to CCRVDF25 (2020).

U.S. Position:

- The United States supports approval of new work on the Priority List of Veterinary Drugs.

CCMAS: Codex Committee on Methods of Analysis and Sampling

- **[Proposal for New Work to Amend the Guidelines on Measurement Uncertainty \(CXG 54-2004\) \(REP18/MAS\) paras 55-61](#)**

Background:

- At its 35th Session (2015), CCMAS agreed to develop procedures for determining uncertainty of measurement results including sub-sampling, sample processing and analysis (REP14/MAS, paragraph 86). This work was initially undertaken as a part of the development of the Principles on Sampling and Testing in International Trade, but has led to further discussion of addressing more practical problems in determining measurement uncertainty (MU).
- At the 37th Session of CCMAS in 2016, the Delegation of Germany, as chair of the eWG on determining uncertainty of measurement results, introduced this agenda item and indicated that the document included procedures to estimate measurement uncertainty without being prescriptive. The procedures should be regarded as

practical examples, which were applicable in many routine situations. The list of the examples was not intended to be exhaustive, and the Committee noted that other procedures might be used in special situations.

- At the most recent session (CCMAS39, 2018), the Committee made adjustments to the new work proposal to address the role of uncertainty in sampling. The Committee agreed to propose new work on the revision of the Guidelines on Measurement Uncertainty (CXG 54-2004) and to submit the revised project document to CAC 41 for approval.

U.S. Position:

- The United States supports approval of the new work.

• **[Proposal to Amend the Guidelines on Sampling \(CXG 50-2004\) \(REP18/MAS\) paras 62-71](#)**

Background:

- At the 37th Session of CCMAS in 2016, there was discussion on the usefulness of the General Guidelines on Sampling (CAC/GL 50-2004). Some members considered the current guidelines difficult to understand. Following these discussions, CCMAS agreed to establish an electronic working group (eWG) chaired by New Zealand and working in English to develop a discussion paper for consideration by the next session.
- At the 38th Session of CCMAS in 2017, the Delegation of New Zealand, chair of the eWG, introduced the paper (CX/MAS 17/38/9) and explained that there was wide support in the eWG to undertake new work on simplifying and updating CAC/GL 50-2004. Along with support for the work, delegations also noted that the current *General Guidelines on Sampling* (CAC/GL50-2004) was very theoretical and that the revision should avoid inclusion of additional theoretical information. The Committee also noted that the revision would require extensive work and may be premature. The Committee concluded that a clear outline of what the work would entail should be included in a project document that would be prepared for consideration by CCMAS39.
- At the most recent session, (CCMAS39, 2018), New Zealand presented the work of the eWG, including a new spreadsheet tool that could assist users with determining appropriate sampling plans. The proposed outline and priorities were presented, along with the new work proposal.

U.S. Position:

- The United States supports the approval of new work as outlined in the project document considered by CCMAS39.

Agenda Item 8: Discontinuation of Work CX/CAC 18/41/9

CCPR: Codex Committee on Pesticide Residues

- [Proposed Draft Maximum Residue Limits Withdrawn by CCPR \(REP18/PR-Appendix VI\)](#)

Background

- CCPR recommended withdrawal from further consideration of 11 draft MRLs for 6 pesticides.
- These are typically CXLs being replaced based on review of additional data; uses no longer supported; or CXLs deemed by JMPR to have potential dietary intake concerns with no alternative good agricultural practice.
- Proposed Maximum Residue Limits Recommended for Withdrawal
 - 126 Oxamyl (4 MRLs)
 - 177 Abamectin (1 MRL)
 - 189 Tebuconazole (1 MRL)
 - 243 Fluopyram (2 MRLs)
 - 246 Acetamiprid (1 MRL)
 - 264 Fenamidone (2 MRL)

U.S. Position:

- The United States supports withdrawal of these MRLs.

Agenda Item 9: Amendments to Codex Standards and Related Texts CX/CAC 18/41/10

- There have been no documents issued for this Agenda Item

Agenda Item 10: Matters referred from Codex Meetings CX/CAC 18/41/

CCFA: Codex Committee on Food Additives

- **Management of CCFA Work**

Background:

- The adoption of food additive provisions for colors and sweeteners has been blocked for more than 7 years in the CCFA due to the widespread use of Note 161, “Subject to national legislation of importing country,” for these provisions. The CCFA has advised the Executive Committee of the progress the Committee has made in terms of finding a path forward for adopting additive provisions for colors and sweeteners.
- The Committee will begin work on colors in certain confectionary categories and an electronic working group, co-chaired by the United States and the European Union, was established to find an alternative to Note 161.

U.S. Position

- The United States strongly supports work on colors in the confectionary categories and is committed to working to find an alternative to Note 161 that is in conformance with the *Procedural Manual*.

Agenda Item 11: Committees Working by Correspondence and Pilot for a Committee on Standards Advancement CX/CAC 18/41/12

CCSA: Codex Committee for Standards Advancement

• Pilot for a Committee on Standards Advancement Background:

Background:

- For several years now, work in Codex commodity committees that have adjourned, (e.g., Codex Committee on Milk and Milk Products; Codex Committee on Cereals, Pulses and Legumes; and Codex Committee on Sugars), has been conducted via correspondence. Those who have participated in drafting standards by correspondence believe that there are unique problems inherent in working by this method. Frequently cited is the lack of uniform procedures, and lack of an impartial, inclusive and transparent way to reach consensus on contentious issues. In some cases, the Chair has determined that consensus has been reached and unilaterally moved the document forward when a large number of committee members did not agree with this, but had no way to voice their concerns effectively. In other cases, when there are serious disagreements on an issue, there is no clear mechanism, such as an in-session working group, for committee members to come together and to achieve consensus.

Timeline

- The issue of committees working by correspondence was discussed thoroughly at CCEXEC72 (July – August 2016). CCEXEC72 established a CCEXEC subcommittee to identify options available to the Codex Alimentarius Commission (CAC) when new work falls within the TOR of an adjourned committee, or does not fall within the TOR of an existing committee.
- The subcommittee established by CCEXEC72 presented the following four options for work by adjourned committees to the CCEXEC73 (July 2017) for discussion:
- Reactivation of a relevant committee adjourned *sine die* to work by correspondence or to meet, as required
- Establishment by the Commission of an EWG to conduct the new work, reporting directly to the Commission
- Assignment of the new work to an active Codex committee that is convening physical meetings or assignment of the new work to a FAO/WHO Regional Coordinating committee
- Establishment of a “super committee”, which could meet one week prior to the CCEXEC meeting or in conjunction with a meeting of another committee.
- The CCEXEC73:
- requested the Codex Secretariat to prepare a document for CCEXEC75 which would analyze the advantages and disadvantages of the options presented in the subcommittee’s paper, and
- recommended the CAC40 consider, as a pilot, the establishment of a Committee on Standards Advancement (CCSA) as envisaged under Rule XI.1(a) of the Codex

Rules of Procedure.

- The CAC40 (2017) agreed with the CCEXEC73 recommendation to have the Secretariat prepare a detailed proposal regarding the CCSA committee and analyze the advantages and disadvantages of the different options.

U.S. Position

- The United States believes that the CCSA is a tool that should be available to the CAC when a situation occurs for which it could be used efficiently.
- The United States does not believe there is any work that is currently being done by correspondence that would be “ripe” for a CCSA pilot.
- While the United States is supportive of establishing a CCSA for future use, we do think that clarification is needed for Section 2.4.3 and chairing of a CCSA and looks forward to the discussion in CCEXEC and CAC.

Agenda Item 12: Regular review of Codex work management report 2017 – 2018 CX/CAC 18/41/13

- No U.S. Position is required for this agenda item.

Agenda Item 13.1: Codex budgetary and financial matters: report 2017 – 2017 and progress 2018 -2019 CX/CAC 18/41/14

- No U.S. Position is required for this agenda item.

Agenda Item 13.2 Codex budgetary and financial matters: proposal 2020 – 2021 CX/CAC 18/31/15

- No U.S. Position is required for this agenda item.

Agenda Item 14: FAO/WHO Scientific Support to Codex activities, budgetary and financial matters

Background:

- The Codex subsidiary bodies receive scientific advice primarily from the expert bodies, notably the Joint FAO/WHO Expert Committee on Food Additives (JECFA), the Joint FAO/WHO Expert Meetings on Pesticide Residues (JMPR), and the Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment (JEMRA).
- The newly created Joint FAO/WHO Expert Meeting on Nutrition (JEMNU) will meet for the first time in 2019.
- These expert meetings are independent of the Codex Alimentarius Commission (CAC) and the subsidiary bodies, although their output contributes significantly to the scientific credibility of Codex's work.
- The experts selected to participate in the expert meeting must be pre-eminent in their field, have the respect of their scientific peers, and be impartial and objective their judgment. They are appointed in their own person right – not as representatives for any government or organization.
- There is increasing recognition that the resources available for scientific advice are inadequate to meet the workload of requests from the Codex subsidiary bodies, and the current financial situation no longer allows response to all requests for scientific advice by Codex.
- The Secretariat for expert bodies has made pleas to the Codex Member Countries for contributions for many years, but the number of contributors remains very limited. There is general recognition that this funding is not sustainable.
- The recent paper submitted (CX/CAC 18/41/16) found at: http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-701-41%252FWD%252FWD%252Fcac41_16e.pdf, which will be discussed at the upcoming CAC 41 (July 2018), underscores the need for increased funds.
- In fact, approximately USD \$12 million per biennium (2018-2019) is projected for the overall contribution of FAO and WHO to the scientific advice program. According to the paper, the scientific advice program cost approximately USD \$11,196,773 in the previous biennium (2016-2017). The paper does not outline any new initiative or proposals to help increase the funding needed.
- On a separate note, the 170th Session of the FAO Finance Committee met May 21-25, 2018 and we hope to receive a readout in the coming days. In advance of the meeting, we learned that the 2016-17 unspent FAP balance was lower than expected and would not be available for supporting Codex.
- In the Finance Committee background paper (FC 170/16) entitled: "Implementing a Sustainable Funding Solution to the FAO's Work and Activities relating to Food Safety Scientific Advice for Codex Alimentarius" (http://www.fao.org/fileadmin/user_upload/bodies/Fin_Comm/FC_170-Documents/FC170-16/FC170-16.pdf) there is mention of potential funding from the

unspent balances remaining from the other Monitoring and Analyzing Food and Agricultural Policies (MAFAP) project and the Multi-partner Program Support Mechanism (FMM) Trust Funds, as discussed during the November 2017 Joint Meeting negotiations.

- Of note in the paper cited above is a proposal to establish a multi donor Trust Fund to support the functioning of the Committee for Scientific Advice. It would cover expenses for expert travel costs, contracts and consultants for technical prep work and operating expenses for holding meetings. Private entities could provide un-earmarked financial contributions to the Trust Fund.
- The document is a follow-up from the FAO Open Ended Working group, which met two times in 2017. Based on previous discussions, the United States agreed that engagement with and funding of FAO (and WHO) is critical, but there were fundamental concerns whether the proposed Trust Fund will provide us the possibility to discuss and achieve the necessary Codex process improvements.

U.S. Position:

- The United States is a long-standing contributor to the support of independent expert scientific advice to inform Codex standard development work, in terms of both human and financial resources.
- We also have a long-standing interest in the issue of providing sustainable support for the expert scientific advice activities of FAO and WHO, notably JECFA, JEMRA, and JMPR. We also have supported the creation of JEMNU, which is now scheduled to meet for the first time in 2019.
- The advice provided by these expert bodies is critical to the scientific basis of Codex standards and related texts.
- The United States considers ensuring that they are adequately supported to be vital to the timely and relevant development of Codex texts.
- The United States encourages the Codex Alimentarius Commission and the FAO Secretariat and Members of the Finance Committee to find thoughtful and innovative solutions.
- In addition to setting up a Blind Trust Fund, we encourage the FAO Secretariat to consider allocation of funds from the regular budget through upcoming budget transfers.

Agenda Item 15: Matters arising from FAO and WHO CX/CAC 18/41/17

- The United States is carefully reviewing this paper with a view toward the WHO influence in Codex Work.

Agenda Item 16: Report of the side event on FAO and WHO capacity development activities CX/CAC 18/41/18

- No U.S. Position is required for this agenda item.

Agenda 17: Report of the side event on Codex Trust Fund (CTF2) CX/CAC 18/41/19

- No U.S. position is required for this agenda item.

Agenda 18: Report of the discussion panels with IGOs and NOGs CX/CAC 18/41/20

Background:

- The Commission will be asked to discuss the recommendations provided by the Codex Secretariat regarding a thematic approach in terms of the interaction between the Commission (CAC) and intergovernmental organizations (IGO) and non-governmental organizations NGOs (e.g., IAEA, IPPC, ISO, and UNECE).
- The Secretariat has recommended that the Codex committees could interact with the IGOs and NGOs on cross cutting issues.
- As an example, the Secretariat has suggested the theme of “Food Integrity and Food Authenticity” as an area of future collaboration between the CAC and these international organizations. The Codex Committee on Import and Export Inspection and Certification Systems is currently working on this issue.
- The Codex Secretariat will create a dedicated web page on the Codex website for organization liaising with Codex, on which international organizations can provide information and a contact point.

U.S. Position:

- The United States is interested in discussing how the CAC could interact with the IGOs and NGOs on cross cutting issues, and would take an active role in ensuring that all organizations would respect the mandate of each of the organizations.

Agenda Item 19: Election of the chairperson and vice-chairpersons CX/CAC 18/41/21

Background:

- Elections of the Codex Alimentarius Chairperson and Vice Chairpersons will only be held if there is a challenge to the current office holders. The United States is not aware of any challenges and therefore do not expect elections to be held.

Agenda Item 20: Designation of countries responsible for appointing the chairpersons of Codex subsidiary bodies CX/CAC 18/41/22

Background

- This agenda concerns the host countries for the Codex Subsidiary bodies, i.e., committees and task forces. The United States plans to continue to be the Host Secretariat for the Codex Committee on Food Hygiene, the Codex Committee on Residues of Veterinary Drugs in Food, the Codex Committee on Processed Fruits and Vegetables and the Codex Committee on Cereals, Pulses and Legumes.
- The United States is not aware of any proposals to change the current host secretariats.

Agenda Item 21: Any Other Business

- There is no U.S. position at this time.

Agenda Item 22: Adoption of the report