47th CODEX COMMITTEE ON FOOD ADDITIVES
Jianguo Hotel
Xi'an, China, 23-27 March 2015

Working Group on the Codex General Standard for Food Additives (GSFA)	Friday & Saturday, 20-21 March 2015 from 09:00 to 18:00 hours

Agenda Item	Subject Matter	Document Reference
1	**Adoption of the Agenda**	**CX/FA 15/47/1**

U.S. POSITION
Anticipate the establishment of informal working groups to meet in the morning prior to the plenary (INS (Tuesday)), or over lunch (Endorsement of Food Additive Provisions in Commodity Standards (Monday), and JECFA Priorities (Tuesday)).

Background
The Committee will be invited to adopt the Provisional Agenda, as contained in document CX/FA 15/47/1, as the Agenda for the Session.

Agenda Item	Subject Matter	Document Reference
2	**Matters Referred by the Codex Alimentarius Commission and Other Codex Committees and Task Forces**	**CX/FA 15/47/2**

MATTERS ARISING FROM THE 37TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION

A. MATTERS FOR INFORMATION

Standards and Related Texts Adopted by the Commission
No action required by CCFA

Revocation of Existing Codex Standards and Related Texts
No action required by CCFA

Discontinuation of Work
No action required by CCFA

Guidance on Information Documents (Appendix I of CX/FA 15/47/2)
No action required by CCFA

B. MATTERS FOR ACTION

Codex Strategic Plan 2014 - 2019
The 37th CAC endorsed the establishment of a monitoring framework for the implementation of the Strategic Plan, including mechanisms for systematic data collection (templates). CCFA is invited to provide replies to the activities of relevance as indicated in the provisional template (Appendix II).

U.S. POSITION

The U.S. is aware that the Codex Secretariat is preparing responses to the questions included in the provisional template for discussion by CCFA.

MATTERS ARISING FROM OTHER COMMITTEES

Codex Committee on Processed Fruits and Vegetables (CCPFV)

Standard for Canned Chestnuts and Canned Chestnut Puree (CODEX STAN 145-1985)

- CCPFV agreed to revoke the provision for aluminium potassium sulfate (INS 522), so that no firming agents were listed. CCPFV could not take a decision as to whether consideration should be given to a general reference to the GSFA or to identify specific firming agents.

  U.S. POSITON
  No action is needed
  Endorsement of food additive provisions considered under Agenda Item 4(a)

Standard for Canned Bamboo Shoots (CODEX STAN 241-2003)

- CCPFV agreed to the use of all tartrates (as tartaric acid) listed in the GSFA for food category 04.2.2.4.

  U.S. POSITON
  No action is needed
  Endorsement of food additive provisions considered under Agenda Item 4(a)

Standard for Certain Canned Vegetables – Annex on Mushrooms

- CCPFV agreed to a general reference to the GSFA for flavor enhancers and to extend the list of colors to all caramels listed in the GSFA for food category 04.2.2.4 as technologically justified for use in canned mushrooms.

  U.S. POSITON
  No action is needed

Standard for Pickled Fruits and Vegetables (CODEX STAN 241-2003)

- CCPFV agreed to a general reference to the GSFA that would limit the food additives in the agreed functional classes to the food categories corresponding to pickled fruits and vegetables.

  U.S. POSITON
  No action is needed

FAO/WHO Coordinating Committee of Asia (CCASIA)

Regional Standard for Tempe (CODEX STAN 313R-2013)

- CCASIA agreed to include a reference to the Guidelines on Substances Used as Processing Aids (CAC/GL 75-2010) in the standard as recommended by the 45th CCFA.

  U.S. POSITON
  No action is needed

Codex Committee on Nutrition and Foods for Special Dietary Use (CCNFSDU)

- CCNFSDU agreed to ask CCFA to examine if the following criteria could be included in the Preamble to the GSFA:

"Additives for use in CODEX STAN 72-1981 shall require also an assessment from JECFA that explicitly states that the substance is safe to be used in infants below twelve weeks of age."

U.S. POSITON

- The U.S. **does not support** the inclusion of this text in the Preamble to the GSFA.
- The U.S. **has the following concerns** regarding this text:
  - This text represents a new requirement for inclusion in the GSFA.
  - JECFA has only very recently assessed safety for infants younger than 12 weeks of age. Therefore, JECFA would not have data already in its files to the assess safety of other food additives. Consequently, JECFA would need to reevaluate the additives listed in CODEX STAN 72 for this age group. Given concerns regarding JECFA's resources, such a reevaluation would need to be prioritized. Priority could be given to those additives with numerical ADIs.
  - Any reevaluation by JECFA would have consequences:
    - Work on alignment of the food additive provisions in CODEX STAN 72 and the GSFA (see bullet, below) would need to be postponed until JECFA completed the reevaluations. Otherwise, there will be 2 "classes" of additives in GSFA food categories 13.1.1 and 13.1.3 and in CODEX STAN 72, depending on whether or not they have been reevaluated by JECFA under the new requirement.
    - The use of the additives as listed in GSFA food categories 13.3.1 and 13.1.3 and in CODEX STAN 72 could be called into question until JECFA completed the reevaluations.
  - This requirement is specific to a particular commodity standard. Therefore, the Preamble is not the appropriate place for such text. It may be more appropriate to associate this text with the descriptors for food categories 13.1.1 (Infant formulae) and 13.1.3 (Formulae for special medical purposes for infants), which have a 1-to-1 correspondence with CODEX STAN 72.

- CCNFSDU agreed to ask CCFA if work on alignment of the food additive provisions in Sections A and B of the Codex Standard for Infant Formula and Formula for Special Medical Purposes Intended for Infants (CODEX STAN 72-1981) and the corresponding GSFA food categories 13.1.1 (Infant formulae) and 13.1.3 (Formulae for special medical purposes for infants) could be prioritized.

U.S. POSITON

- The U.S. notes that CCNFSDU is an active committee. Therefore, the U.S. **recommends** that CCFA remind CCNFSDU that they are responsible for aligning the food additive provisions in their commodity standards with the GSFA.
- The U.S. **recommends** that the following advice could be provided to CCNFSDU:
  - There is a 1-to-1 correspondence between CODEX STAN 72 and GSFA food categories 13.1.1 and 13.1.3.
  - CCNFSDU should compare the food additive provisions in CODEX STAN 72 and in GSFA food categories 13.1.1 and 13.1.3, and inform CCFA of any inconsistencies so that the GSFA provisions can be aligned with those currently in CODEX STAN 72.
  - CCNFDSU should then remove the specific list of food additives from CODEX STAN 72 and replace it with the general reference to the GSFA (GSFA provisions now reflect those in CODEX STAN 72).
  - CCNFSDU should then forward the revised food additive section of CODEX STAN 72 (with the general reference to the GSFA) to CCFA for endorsement.
- The U.S. notes that, depending on the outcome of the discussion regarding the proposed text for the Preamble (above), it may be necessary for JECFA to reevaluate additives currently in CODEX STAN 72. If this is the case, the work on alignment of CODEX STAN 72 with the GSFA should be postponed until the JECFA reevaluations are completed.

- **Provisions for carrageenan:** There currently is no provision, adopted or in the step process, for carrageenan, in food categories 13.1.1 (Infant formulae) or 13.1.3 (Formulae for special medical purposes for infants), even though there is a 1-to-1 correspondence between those food categories and CODEX STAN 72. CODEX STAN 72 lists carrageenan for use in food category 13.1.1 at 300 mg/kg with restriction "in regular milk and soy-based liquid infant formula only," and in food category 13.1.3 at 1,000 mg/kg with restriction "in hydrolysed protein- and/or amino acid based liquid infant formula only." The provision for carrageenan in CODEX STAN 721 has the note "Not endorsed by the 39t^{h} Session of the CCFA. JECFA evaluation is pending national authorities may restrict its use until JECFA evaluation has been completed."

  U.S. POSITON
  - The U.S. would **support** any proposal to include provisions for carrageenan in the step process in the GSFA in FCs 13.1.1 and 13.1.3, although such provision may need to be proposed in reply to the CL
  - The U.S. would **support** any proposal that CCFA recommend to CCFSNDU that the note concerning endorsement by CCFA and JECFA evaluation be deleted from the provision for carrageenan in CODEX STAN 72-1981 as JECFA has completed its evaluation of the use of carrageenan in infant formula.

OTHERS

Food Additives Included in the GSFA Without Corresponding Specifications

- Potassium hydrogen sulfate (INS 515(ii)), Sodium sorbate (INS 201) and Calcium hydrogen sulfite (INS 227) that do not have specifications have been included in the GSFA. It is proposed to apply the same approach used by the 45th CCFA, namely: (i) to request, via CL, information on the commercial use of these additives; and (ii) based on the information provided, the 48th CCFA will recommend either to remove these food additives from the GSFA for those commercial uses for which information was not provided, or to include them in the JECFA priority list with a commitment for draft specifications to JECFA by the 49th CCFA.The CCFA is invited to consider this approach.

  U.S. POSITION
  The U.S. **supports** this approach.

Protease (INS 1101(i)

- INS 1101(i) includes a number of specific proteases for which a corresponding INS has not been assigned, as well as proteases from *Aspergillus oryzae, var.* and from *Streptomyces fradiae*, which are included in the GSFA. The CCFA is invited to consider assigning INS numbers to these substances.
- Protease (INS 1101(i)) is adopted in Table 3 of the GSFA, and has provisions in Table 1 (1 adopted, 4 in step process). Two other proteases (Papain (INS 1101(ii)) and Bromelain (INS 1101(iii))) are also listed in Tables 1 and 3 of the GSFA. Another protease (Ficin (INS 1101(iv))) is listed in the INS, but is not listed in the GSFA.
- It is not completely clear what proteases are covered under the GSFA Table 1 and Table 3 provisions for "Protease." While JECFA has reviewed other proteases, there are two JECFA specification monographs for proteases that are associated with INS 1101(i): Protease from Aspergillus oryzae, var., and Protease from Streptomyces fradiae. Of these two, only Protease from Aspergillus oryzae, var. has a JECFA ADI (not specified, 31st JECFA 1987, TRS 759). The ADI for Protease from Streptomyces fradiae was withdrawn by JECFA (28th JECFA 1984, TRS 710).

  U.S. POSITON
  - The U.S. can **support** the assignment of INS numbers to proteases that have been reviewed by JECFA

- The U.S. **recommends** seeking clarification from JECFA regarding which JECFA-reviewed proteases should be considered to fall under the existing GSFA entry for "Protease," as this has practical considerations for the application of the GSFA.
- The U.S. **recommends** that INS 1101(i) be associated with Protease from Aspergillus oryzae, var., as this protease has a JECFA ADI, and is listed as INS 1101(i) in the JECFA specifications monograph. This INS assignment would result in the revision of the entry for Protease in GSFA Tables 1 and 3.
- The U.S. **recommends** that an INS number other than INS 1101(i) be assigned to Protease from Streptomyces fradiae, as this protease does not have a JECFA ADI, and its association with INS 1101(i) (as currently listed in the JECFA specifications monograph for Protease from Streptomyces fradiae) could be misconstrued to indicate that it is permitted for use in the GSFA.
- The U.S. would **support** the assignment of INS numbers to any additional proteases that JECFA recommends.

Discuss under Agenda Item 6

Corrections to the GSFA Provisions Related to the Five Meat Commodity Standards

- The 46th CCFA inadvertently omitted several Table 3 additives from the list of revised food additive provisions of the GSFA related to the five meat commodity standards (REP 14/FA, Appendix IX, Part D):
  - Ascorbic acid, L- (INS 300) – acceptable in foods conforming to CS 88-1981, 89-1981, 96-1981, 97-1981, 98-1981
  - Erythorbic acid (Isoascorbic acid) (INS 315) – acceptable in foods conforming to CS 88-1981, 89-1981, 96-1981, 97-1981, 98-1981
  - Sodium ascorbate (INS 301) – acceptable in foods conforming to CS 88-1981, 89-1981, 96-1981, 97-1981, 98-1981
  - Sodium erythorbate (Sodium isoascorbate) (INS 316) – acceptable in foods conforming to CS 88-1981, 89-1981, 96-1981, 97-1981, 98-1981
  - Potassium alginate (INS 402) – acceptable in foods conforming to CS 96-1981, 97-1981
  - Sodium alginate (INS 401) – acceptable in foods conforming to CS 96-1981, 97-1981
  - Glucono delta-lactone (INS 575) – acceptable in foods conforming to CS 89-1981, 98-1981

- The 46th CCFA also omitted the listing of CX 98-1981 for Sodium dihydrogen citrate (INS 331(i)) and Trisodium citrate (INS 331(iii)).

- The Committee is invited to forward the proposed changes to Table 3 of the GSFA (as above, summarized in Appendix III) to the 38th CAC for adoption.

U.S. POSITION

The U.S. **supports** forwarding these provisions, as in Appendix II of CX/FA 15/47/2, to the 38th CAC for adoption.

Background

Document CX/FA 15/47/2, prepared by the Codex Secretariat, includes matters referred to the Committee by the Codex Alimentarius Commission and other Codex Committees and Task Forces.

Agenda Item	Subject Matter	Document Reference
3(a)	**Matters of Interest Arising from FAO/WHO and from the 79th Meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA)**	**CX/FA 15/47/3**

Agenda Item	Subject Matter	Document Reference
	Specifications Monograph of the Modified Starches	**CX/FA 15/47/Add. 1**

Informational Items

- The meeting report, toxicological monographs, and specifications monographs from the 79th JECFA are available on the FAO and WHO websites.
- FAO/WHO have finalized a handbook on Risk Communication in food safety which provides guidance on good risk communication principles and practices. The document will soon be available online.
- The WHO and EFSA organized a stakeholder and expert meeting to review the science underlying the Threshold of Toxicological Concern (TTC) concept. A revised decision tree developed at the meeting will be discussed at the next JECFA meeting dealing with flavors.
- FAO and WHO have commenced new work to collate available disaggregated food consumption data collected at the individual level and to tie these data to existing global databases (e.g., FAOSTAT, GEMS Cluster Diets). When completed, the data should be of use to various Codex Committees (e.g., CCFA, CCCF, CCFFP).

Limits for Lead in Specifications of Food Additives for Use in Infant Formula

- The 8th CCCF set an ML of 0.01 mg/kg lead in infant formula (as consumed). The 79th JECFA reviewed four additives (carrageenan, CITREM, pectin and OSA-modified starch) for use in infant formula. JECFA determined that infant formula containing CITREM, pectin or OSA-modified starch at the maximum use levels considered by JECFA could result in the exceedance of the lead ML set by CCCF in infant formula if the additives contained lead at the maximum level set in the specifications (2 mg/kg for CITREM and OSA-modified starch and 5 mg/kg for pectin). Due to this concern, the 79th JECFA considered lowering the lead specifications for the three additives. Information provided by the infant formula sponsors indicated that actual lead levels in CITREM, OSA-modified starch and pectin used in infant formula were below the current JECFA lead specification levels. However, information was not available to JECFA during the meeting to indicate that CITREM, OSA-modified starch and pectin used in foods other than infant formula would be able to meet lower lead specifications.
- JECFA is asking for feedback from the CCFA on whether specific purity criteria for additives for use in infant formulas should be considered (i.e., lead), and appropriate ways to present these criteria (e.g., establishing specifications for additives for use in infant formulas only or establishing different purity limits for additives for use in infant formulas in existing specifications).

U.S. POSITION

The U.S. **supports** the lowering of lead specification limits in JECFA monographs for additives used in infant formula. The U.S. would prefer the inclusion of lead limits pertaining to additives for use in infant formula within the existing specifications monographs.

Matters for Action from 79th JECFA

- CX/FA 15/47/3 put forward a list of recommended actions for the CCFA based on information put forward by the 79th JECFA.

INS Num	Food Additive Name	ADI or Other Tox Recommendation	Recommended Action by CCFA
	Benzoe tonkinensis	The Committee confirmed the conclusion from the seventy-fourth meeting that Benzoe tonkinensis would not be of safety concern at current estimated dietary exposures, provided that it complies with the specifications prepared at the 79th meeting, when used as	Note the JECFA conclusion on the safety of Benzoe tonkinensis at current estimated dietary exposures **U.S. Position:**

INS Num	Food Additive Name	ADI or Other Tox Recommendation	Recommended Action by CCFA
		a flavouring agent and in accordance with good manufacturing practice.	Use is indicated as a flavoring agent. No action necessary.
407	Carrageenan (for use in infant formula and formula for special medical purposes intended for infants)	The margins of exposure (MOEs) between the NOAEL of 430 mg/kg bw per day (2250 mg/kg formula), the highest dose tested, from a neonatal pig study and human infant exposures at 2–4 weeks of age range from 2 to 12 on a body weight basis and from 2 to 8 on a concentration basis. The 79th JECFA noted that although the MOEs are small in magnitude, they are derived from a neonatal pig study in which the highest dose tested was without adverse effects on the gut or on immune parameters, supported by a neonatal minipig study. These new studies allay the earlier concerns that carrageenan, which is unlikely to be absorbed, may have a direct effect on the immature gut. The Committee also took account of the previous toxicological database on carrageenan, which did not indicate other toxicological concerns. It also noted that at carrageenan concentrations higher than 2500 mg/kg, formula becomes highly viscous, which adversely affects palatability and growth. The 79th JECFA concluded that the use of carrageenan in infant formula or formula for special medical purposes at concentrations up to 1000 mg/L is not of concern. The Committee recognized that there is variability in medical conditions among infants requiring formulas for special medical purposes that contain the higher levels of carrageenan, and the Committee noted that these infants would normally be under medical supervision.	Note the JECFA conclusion on the safety of carrageenan in infant formula or formula for special medical purposes at concentrations up to 1000 mg/L. **U.S. Position:** See Agenda Item 2. The U.S. would **support** any proposal to include provisions for carrageenan in the step process in the GSFA in food categories 13.1.1 and 13.1.3, although such provision may need to be proposed in reply to the CL for new/revised GSFA provisions. The U.S. would **support** any proposal that CCFA recommend to CCFSNDU that the note concerning endorsement by CCFA and JECFA evaluation be deleted from the provision for carrageenan in CODEX STAN 72-1981, as JECFA has completed its evaluation of the use of carrageenan in infant formula.
472c	Citric and fatty acid esters of glycerol (CITREM) (for use in infant formula and formula for special medical purposes intended for infants)	The 79th JECFA considered it unlikely that consumption of formulas containing typical levels of CITREM used in powdered formulas (up to 2.7 g/L as reconstituted), which is equivalent to an exposure to citrate of 440 mg/kg bw per day for the very young infant at the 95th percentile energy intake, would cause diarrhoea. At the high end of the requested range for use (up to 9 g/L), which is equivalent to an exposure to citrate of 1140 mg/kg bw per day for the very young infant at the 95th percentile energy intake, diarrhoea might occur in some infants. The 79th JECFA concluded that there are no toxicological concerns about the use of CITREM in infant formula and formula for special medical purposes at concentrations up to 9 g/L. At the higher use levels, there is a possibility of diarrhoea from free citric acid released from formula containing CITREM. Given the paucity of clinical data and the fact that exposure assumptions for citric acid have been maximized, it is difficult to estimate the risk of diarrhoea, but it is considered to be low.	Note the JECFA conclusion on the safety of CITREM in infant formula and formula for special medical purposes at concentrations up to 9 g/L. **U.S. Position:** CITREM is permitted for use in infant formula in the US
	Gardenia yellow	Given the deficiencies in the toxicological and specifications databases, including incomplete data on the manufacturing process and composition of the material, missing toxicological studies (e.g. long-term toxicity, carcinogenicity, reproductive toxicity and developmental toxicity), the inadequate characterization of the test	No action required **U.S. Position:** No action required

INS Num	Food Additive Name	ADI or Other Tox Recommendation	Recommended Action by CCFA
		material in the available toxicological studies and limited reporting of the available studies, the 79th JECFA was unable to evaluate gardenia yellow proposed for use as a food colour.	
	Lutein esters from *Tagetes erecta*	The 79th JECFA concluded that there was no need to establish a numerical ADI. This decision was based on a number of factors, including the absence of any observed toxicity of lutein or lutein esters in any of the available toxicological studies in animals; the absence of any adverse effects in humans consuming lutein or lutein esters; the large MOE (>1500) between the NOAEL for lutein in a new 13-week study in rats and the estimated dietary exposure of 0.32 mg/kg bw per day (from additive and natural sources); a 2-fold increase in the NOAEL for lutein as a result of the new 13-week study; and the fact that lutein esters from Tagetes erecta are considered to be substitutional for other lutein extracts. The 79th JECFA established a temporary ADI "not specified" 1 for lutein esters from Tagetes erecta. The ADI was made temporary because the specifications for lutein esters from Tagetes erecta were tentative. The 79th JECFA considered establishing a group ADI "not specified"a for lutein esters from Tagetes erecta that would include lutein from Tagetes erecta (INS 161b) and synthetic zeaxanthin (INS 161h) and related xanthophylls, but this would be possible only when the specifications for lutein esters from Tagetes erecta are finalized.	In view of the tentative specifications - Wait for further evaluation by JECFA. - Consider assigning an INS Number **U.S. Position:** U.S. supports recommendations
423	Octenyl succinic acid (OSA)–modified gum arabic	The tentative status of the specifications was maintained pending the submission of additional data. The 79th JECFA noted that additional safety data may also be needed to complete the evaluation of OSA-modified gum arabic. The 79th JECFA decided that the temporary ADI "not specified" will be withdrawn unless adequate data to complete the safety evaluation are submitted by the end of 2015.	In view of the temporary ADI "not specified" and tentative specifications - Wait for further evaluation by JECFA - Encourage submission of the relevant data to JECFA to complete the safety evaluation. **U.S. Position:** U.S. supports recommendations
1450	Octenyl succinic acid (OSA)–modified starch (starch sodium octenyl succinate) (for use in infant formula and formula for special medical purposes intended for infants)	Taking into account the overall low toxicity of OSA-modified starch, the conservatism in the NOAEL, which was the highest dose tested in a study in neonatal animals, and in the exposure assessments, as well as the supporting evidence from clinical trials and postmarketing surveillance, the 79th JECFA concluded that the consumption of OSA-modified starch in infant formula or formula for special medical purposes intended for infants is not of concern at use levels up to 20 g/L. New data available since the 26th meeting of JECFA confirm the very low toxicity of OSAmodified starch, and the 79th JECFA confirmed the ADI "not specified" established at that meeting for its use as a food additive for the general population.	Note the JECFA conclusion on the safety of OSA-modified starch in infant formula and formula for special medical purposes at use levels up to 20 g/L. **U.S. Position:** OSA-modified starch is permitted for use in infant formula in the US
160c(ii)	Paprika extract	The 79th JECFA established an ADI for paprika extract used as a food colour of 0–1.5 mg/kg bw, expressed as total carotenoids, with the application of an uncertainty factor of 100 to the NOAEL of 153 mg/kg bw per day	In view of the numerical ADI established and the maintained full specifications, consider whether to recommend its inclusion in the GSFA

INS Num	Food Additive Name	ADI or Other Tox Recommendation	Recommended Action by CCFA
		from a 2-year toxicity and carcinogenicity study in rats. The 79th JECFA concluded that dietary exposure to paprika extract used as a food colour does not present a health concern.	**U.S. Position:** U.S. supports recommendation
440	Pectin (for use in infant formula and formula for special medical purposes intended for infants)	In a 3-week study in neonatal pigs fed pectin-containing milk replacer, the NOAEL was 847 mg/kg bw per day, with decreased feed intake and body weight gain observed at 3013 mg/kg bw per day. Using the NOAEL from this study, the MOEs were estimated to be 0.9 for infants with median energy intake and 0.8 for infants with high (95th percentile) energy intake. The 79th JECFA concluded that estimated exposure to pectin from its use in infant formula is in the region of the NOAEL derived from the neonatal pig study and close to the LOAEL based on decreased feed intake and body weight gain. While no overt toxicological effects were observed in the neonatal pigs, decreased food intake and body weight gain would be considered an undesirable effect in human infants. The available clinical studies were mainly conducted with pectin or pectin-derived oligosaccharides at concentrations of 0.2% or less and therefore do not provide support for tolerance and normal growth at the proposed use level. Therefore, the 79th JECFA concluded that the use of pectin in infant formulas at the maximum proposed use level (0.5%) is of concern.	Note the JECFA conclusion that the use of pectin in infant formulas at the maximum proposed use level (0.5%) is of concern. **U.S. Position:** U.S. supports waiting for further review by JECFA

Safety Evaluation of Flavors

- Safety evaluations were performed for 28 flavors in 8 different structural groups. As noted in Table 2 of CX/FA 15/47/3, a determination of no safety concern was made for 25 of the flavors.

  U.S. Position
  The U.S. **supports** the flavor evaluations performed by JECFA.

- The document also indicates that specifications for two additives (Lutein esters from Tagetes erecta and Octenyl succinic acid modified gum Arabic (INS 423)) were made tentative awaiting additional information as outlined in Table 3 of CX/FA 15/47/3.

CX/FA 15/47/3 Add. 1

- At the 79th JECFA a recommendation was made to split the current single monograph for Modified starches (which contains specifications for 16 different modified starches with unique INS numbers) into 16 separate specifications monographs. JECFA has determined that additional information is required on many of the substances in order to prepare full separate specification monographs. JECFA is asking interested parties to submit comments and data in support of this effort by the 82nd JECFA in June 2016.

Background

Document CX/FA 15/47/3, prepared by FAO and WHO, includes matters from FAO and WHO and from the 79th JECFA Meeting (Geneva, Switzerland, 17-26 June 2014) referred to the Committee for information and action. The summary report is available at:
http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/summary-reports/en/ (FAO JECFA website) and at: http://www.who.int/foodsafety/chem/jecfa/summaries/en/index.html (WHO JECFA website)
The full report is available at: http://apps.who.int/iris/bitstream/10665/150883/1/9789241209908_eng.pdf?ua=1

Agenda Item	Subject Matter	Document Reference
3(b)	**Proposed Draft Specifications for the Identity and Purity of Food Additives Arising from the 79th JECFA Meeting**	**CX/FA 15/47/4**
	Comments at Step 3	**CX/FA 15/47/4 Add. 1**

U.S. POSITION

The U.S. did not provide comments to CX/FA 15/47/4.

A total of 10 food additive specifications and 26 flavor specifications were designated as "Full" by the 79th JECFA for adoption by Codex:

Food additive specifications designated as "Full" for adoption by Codex
Benzoe tonkinensis (Revised specs)
Carrageenan (INS 407) (Revised specs)
Citric acid (INS 330) (Revised specs)
Citric and fatty acid esters of glycerol (INS 472c) ((Revised specs)
Gellan gum (INS 418) (Revised specs)
Modified starches (INS 1400-1405, 1410, 1412-1414, 1420, 1422, 1440, 1442, 1450, 1451) (Revised specs)
Paprika extract (INS 160c(ii)) (Maintained specs)
Polyoxyethylene (20) sorbitan monostearate (INS 435) (Revised specs)
Potassium aluminium silicate (INS 555) (Revised specs)
Quillaia extract (Type 2) (INS 999 (ii)) (Revised specs)

- Of the 26 flavour specifications designated as "Full" by the 79th JECFA, one flavor, trans-α-Damascone (JECFA 2188) still had additional data requirements by JECFA, and therefore its safety review was not finished. Based on previous CCFA meetings, the CCFA is likely to recommend postponing adoption of the specification for JECFA 2188 until the safety review is completed.
- Specifications for the flavor JECFA 1051 (2,5-dimethyl-3-acetylthiophene) were withdrawn at the 79th JECFA as a result of safety concerns (potential mutagenicity) brought to the attention of JECFA.
- As also indicated in CX/FA 15/47/3, specifications for two additives (Lutein esters from Tagetes erecta and Octenyl succinic acid modified gum Arabic (INS 423)) were made tentative pending receipt of additional data.

U.S. POSITON

The U.S. **supports** the adoption by Codex of the specifications designated as "Full" by the 79th JECFA and the withdrawal of specifications for the flavor 2,5-dimethyl-3-acetylthiophene (JECFA 1051).

Background

Document CX/FA 15/47/4 references specifications arising from the 79th JECFA Meeting (Genava, Switzerland, 17-26 June 2014) referred to the Committee for information and action. The summary report of the 77th JECFA is available at:
http://www.fao.org/fileadmin/user_upload/agns/news_events/JECFA%2077%20Summary%20Report%20Final.pdf (FAO JECFA website) and at:
http://www.fao.org/fileadmin/templates/agns/pdf/jecfa/JECFA_77_Summary_Report_Final.pdf
(WHO JECFA website). The specifications are available on the on-line edition of the Combined Compendium of Food Additive Specifications at: http://www.fao.org/ag/agn/jecfa-additives/search.html. Comments at Step 3 are compiled in document CX/FA 15/47/4 Add.1.

Agenda Item	Subject Matter	Document Reference

Agenda Item	Subject Matter	Document Reference
4(a)	**Endorsement and/or Revision of Maximum Levels for Food Additives and Processing Aids in Codex Standards**	**CX/FA 15/47/5**

U.S. POSITION - GENERAL POINTS

- CAC has expressed several times that GSFA is intended to be the single Codex reference for food additives.
- Procedural Manual has standardized text for the food additive section of commodity standards *"[Food Additive functional class] used in accordance with Tables 1 and 2 of the Codex General Standard of Food Additives in food category x.x.x.x [food category name] or listed in Table 3 of the General Standard for Food Additives are acceptable for use in foods conforming to this standard."*
- The Procedural Manual is clear on the responsibilities of commodity committees and food additives. Any deviations from the standard reference text to the GSFA in commodity standards proposed by commodity committees should be fully justified when they are referred to the CCFA for endorsement.
- Ref: Procedural Manual, 22th Ed., Section II: Elaboration of Codex Texts, Relations Between Commodity Committees and General Subject Committees, Food Additives, pp. 50-51.

U.S. POSITION - SPECIFIC COMMODITY STANDARDS

CODEX COMMODITY COMMITTEE ON PROCESSED FRUITS AND VEGETABLES (CCPFV)

Standard for Certain Canned Vegetables – Annex on Mushrooms (CODEX STAN 297-2009)

- The U.S. **supports** endorsement of the provisions for Caramel I – plain caramel (INS 150a) and Caramel III – ammonia caramel (INS 150c). However, the U.S. **notes** that REP 15/PFV, Appendix V states that Caramel I – plain caramel (INS 150a; GMP), Caramel III – ammonia caramel (INS 150c; 50,000 mg/kg) and Caramel IV – sulfite ammonia caramel (INS 150d; 50,000 mg/kg) are permitted for use in canned mushrooms in sauce. The limitation "for use in canned mushrooms in sauce" has been deleted from the provisions for endorsement in CX/FA 15/47/5, Annex I. The U.S**. requests that the text "Only for use in canned mushrooms in sauce" be included with the provisions for Caramel I and Caramel III for endorsement**.
- The U.S. **supports** endorsement of the general reference to the GSFA for flavor enhancers listed in Table 3 of the GSFA.

Amendments to the Standard for Pickled Fruits and Vegetables (CODEX STAN 260-2007)

- The U.S. **supports** endorsement of the general reference to the GSFA for acidity regulators, antifoaming agents, antioxidants, colors, firming agents, flavor enhancers, preservatives, sequestrants, and sweeteners.

Draft Standard for Quick Frozen Vegetables (At Step 8)

- The U.S. **supports** endorsement of the reference to the general food additive section of the standard and to the food additive section of the appropriate Annexes.
- The U.S. **supports** endorsement of the general reference to the *Guidelines on Substances Used as Processing Aids* (CAC/GL 75-2010).

Annexes to the Draft Standard for Quick Frozen Vegetables – Annex on Carrots (at Step 5/8)

- For information only. No food additives are permitted.

Annexes to the Draft Standard for Quick Frozen Vegetables – Annex on Corn-on-the-Cob (at Step 5/8)

- For information only. No food additives are permitted.

Annexes to the Draft Standard for Quick Frozen Vegetables – Annex on Leek (at Step 5/8)

- For information only. No food additives are permitted.

Annexes to the Draft Standard for Quick Frozen Vegetables – Annex on Whole Kernel Corn (at Step 5/8)

- For information only. No food additives are permitted.

Draft Standard for Certain Canned Fruits (At Step 8)

- The U.S. **supports** endorsement of the reference to the general food additive section of the standard and to the food additive section of the appropriate Annexes.
- The U.S. **supports** the general reference to the GSFA for acidity regulators for general use in foods conforming to the standard.

Annexes to the Draft Standard for Certain Canned Fruits – Annex on Mangoes (at Step 5/8)

- The U.S. **supports** endorsement of the general reference to the GSFA for antioxidants and firming agents.
- The U.S. **supports** endorsement of the provisions for the specific colors. However, the USA **notes** the provision specifies "Only the colours listed below are permitted for use in canned mushrooms in sauce**."** This text is not appropriate for this standard. The U.S. **requests that the text "Only the colours listed below are permitted for use in canned mushrooms in sauce" be deleted for endorsement.**

Annexes to the Draft Standard for Certain Canned Fruits – Annex on Pears (at Step 5/8)

- The U.S. **supports** endorsement of the general reference to the GSFA for colors (used in specialty holiday packs only).
- The U.S. **supports** the general reference to the *Guidelines for the Use of Flavourings* (CAC/GL 66-2008).

Proposed Draft Standard for Ginseng Products (At Step 5/8)

- For information only. No food additives are permitted.

FAO/WHO COORDINATING COMMITTEE FOR ASIA (CCASIA)

Draft Regional Standard for Non-Fermented Soybean Products (at Step 8)

General Requirements

- The U.S. **supports** endorsement of the General Requirements.

Specific Food Additive Provisions

Plain Soybean Beverage

- For information only. No food additives are permitted.

Composite/Flavoured Soybean Beverages and Soybean-based Beverages

- The U.S. **supports** endorsement of the general reference to the GSFA for acidity regulators, antioxidants, colors, emulsifiers, flavor enhancers, stabilizers, and sweeteners. [N.B.: This refers to the *current* provisions for these functional classes in the GSFA.]
- The U.S. **supports** endorsement of the specific colors, emulsifiers, stabilizers, and sweeteners.
- The U.S. **supports** the endorsement of the provision for Tocopherols (INS 307a, b, c; antioxidant).
- The U.S. **does not support** the endorsement of the provision for **Ascorbyl palmitate** (INS 304; antioxidant). The U.S. **asks for the technological justification for limiting use to this additive**. Both Ascorbyl palmitate (INS 304) and Ascorbyl stearate (INS 305) are assigned a JECFA ADI of 1.25 mg/kg by JECFA, and are listed as the "group" additive "Ascorbyl Esters (INS 304, 305)" in the GSFA.
- The U.S. **does not support** the endorsement of the provision for Potassium chloride (INS 508; flavor enhancer) at 1000 mg/kg. Potassium chloride has been assigned a JECFA ADI of "not limited," and is therefore included in Table 3 of the GSFA. A maximum level of GMP is appropriate. The U.S. **supports the endorsement of Potassium chloride at GMP**.
- The specific additives are the same functional classes as those included in the general reference to the GSFA. Therefore, the U.S. does not believe that technological justification for these specific additives is needed. The U.S. notes that, when the provisions for the specific additives are included in the GSFA, the specific provisions will be deleted from the commodity standard, since they will then be covered by the general reference to the GSFA.

Soybean Curd

- The U.S. **supports** endorsement of the general reference to the GSFA for acidity regulators, firming agents, and stabilizers.

Compressed Soybean Curd

- The U.S. **supports** endorsement of the general reference to the GSFA for acidity regulators, firming agents, and preservatives listed in Table 3 of the GSFA.
- The U.S. **supports** endorsement of the provision for Sodium diacetate (INS 262(ii); preservative).

Dehydrated Soybean Curd Film

- The U.S. **supports** endorsement of the general reference to the GSFA for preservatives listed in Table 3 of the GSFA.
- The U.S. **supports** endorsement of the provision for Sulfites (INS 220-225, 227, 228, 539; preservatives).
- The U.S. **supports** endorsement of the general reference to the *Guidelines for the Use of Flavourings* (CAC/GL 66-2008).
- The U.S. **supports** endorsement of the reference to the general reference to the *Guidelines on Substances Used as Processing Aids* (CAC/GL 75-2010).

CODEX COMMITTEE FOR NUTRITION AND FOOD FOR SPECIAL DIETARY USES (CCNFSDU)

Amendments to the Standard for Infant Formula and Formula for Special Medical Purposes Intended for Infants (CODEX STAN 72-1981)

- The U.S. **supports** endorsement of the provisions for Starch sodium octenyl succinate (INS 1450; thickener) and Citric and fatty acid esters of glycerol (INS 472c; emulsifier). Although both additives have been assigned a non-numerical ADI, JECFA concluded that consumption at the maximum level in the commodity standard is of no toxicological concern.

Background

Document CX/FA 15/47/5 compiles food additive and processing aid provisions in draft and proposed draft commodity standards submitted by various Codex Committees to the CCFA for endorsement.

Agenda Item	Subject Matter	Document Reference
4(b)	**Alignment of the Food Additive Provisions of Commodity Standards and Relevant Provisions of the GSFA**	**CX/FA 15/47/6**

U.S. POSITION

Recommendations (paras. 13 – 20)

- The U.S. **supports** the **proposed revision of the "Principles"** regarding the decision tree that is presented in **Appendix 1** of the document (para. 13).
- The U.S. **notes** the explanation of issues arising from the eWG discussion that is presented in Appendix 2 of the document (para. 14).
- The U.S. **notes** the comments provided regarding the development of a draft list of commodity standards to guide future alignment work in Appendix 3 of the document (para. 15). The U.S. provided comments, which are included in the Appendix. The U.S. **supports the eWG Chair's proposed prioritization criteria**:
  - Proposal (i), in which priority should be given to an inactive commodity committee.
  - Proposal (ii), in which priority is given to older commodity standards.
  - Proposal (iii), which considers the number of adopted food additive provisions in the food category. Presumably, those food categories with the greater number of adopted provisions in the GSFA would be given priority.

- Proposal (iv), which considers the level of support from a "peak body/trade association" to assist by addressing technical issues. Presumably those commodities that can be supported by trade associations' expertise would be given priority.
- Proposal (v), which considers the extent of international trade in the commodity. Presumably evidence of more trade (either in quantity or global reach) would be given priority.

- The U.S. has **specific comments, below**, on the proposals contained in Appendices 4 and 5 for the revision of the relevant food categories of the GSFA and the food additive sections of the standards for bouillons and consommés, and for the standards related to chocolate and cocoa products (para. 16).
- The U.S. **remains silent** regarding the inclusion of the functional class "emulsifier" for glycerol (INS 422) and inclusion of the functional class "glazing agent" for pectins (INS 440) (para. 17). The U.S. **notes** that this **recommendation should be made to the in-session WG on the INS**.
- The U.S. **supports** the general reference to the *Guidelines for the Use of Flavourings* (CAC/GL 66-2008) in the commodity standards that include provisions for flavourings (para. 18).
- The U.S. **supports** the proposal to establish an eWG with the terms of reference as indicated (para. 19).
- The U.S. **supports** the development of a draft list of commodity standards, prioritized according to the criteria outlined in para. 15 (para. 20).

Proposed Amendments to the Food Additive Provisions in the Codex Commodity Standards (Appendix 4)

- The U.S. **supports** the proposed amendments, as presented in Appendix 4, for the:
  - Standard for Bouillons and Consommés (CODEX STAN 117-1981)
  - Standard for Cocoa Butter (CODEX STAN 86-1981)
  - Standard for Chocolate and Chocolate Products (CODEX STAN 87-1981)
  - Standard for Cocoa (Cacao) Mass (Cocoa/Chocolate Liquor) and Cocoa Cake (CODEX STAN 141-1983)
  - Standard for Cocoa Powders (Cocoas) and Dry Mixtures for Cocoa and Sugars (CODEX STAN 105-1981)

Proposed Amendments to Tables 1, 2, and 3 of the GSFA (Appendix 5)

Working Principles

- The U.S. **supports** the Working Principles.
- *Comment: Adopted and Draft GSFA Provisions*
  - The U.S. had proposed to the eWG that, for complete alignment of the commodity standard and the GSFA, it is necessary to consider all the additives listed in the commodity standard – whether they have adopted or draft provisions in the GSFA.
  - The eWG Chair noted that the 46th CCFA agreed that only adopted GSFA food additive provisions would be considered for alignment, stating that this approach simplifies the current work, while acknowledging that future amendments would be required when the draft GSFA provisions were adopted. Therefore, the Chair proposed that the **proposals should focus only on adopted food additive provisions** (Appendix 2, Part A, Point 1). The U.S. **supports** this proposal. However, the U.S. **has concerns regarding this approach**:
    - **The status of those additive provisions in the commodity standard that correspond to a draft provision in the GSFA is unclear**. A summary of these provisions was provided in Appendix 2, Part C. These commodity standard provisions will become "lost" once the general reference to the GSFA is included in the commodity standard, as proposed in Appendix 4, because there will be no action to actually align them with the GSFA. The U.S. believes the **best approach is to propose that the draft GSFA provisions for these additives be aligned with the commodity standard**. This approach is consistent with what was done previously for the provisions for nitrites and phosphates in the meat commodity standards in food category 08.2.2 (see FA 46/CRD 3).
    - The U.S. observes that, if CCFA decides to consider only adopted GSFA provisions for alignment, the **application of the working principle to only consider alignment of adopted GSFA provisions has NOT been uniformly applied** in the lists of provisions for endorsement in Tables 1 and 2. Some of these lists contain proposals for endorsement of draft provisions. The U.S. has **noted these draft**

provisions, which should not be considered for endorsement, in the comments for the specific commodity standards, below.

Standard for Bouillons and Consommés (CODEX STAN 117-1981)

Tables 1 and 2

- The U.S. **supports** the proposal, **except** as noted below:
  - Draft GSFA provisions: The GSFA provisions for the following additives are **draft provisions**, and therefore should **NOT be endorsed based on the working principles** to consider only adopted GSFA provisions:
    - Azorubine (INS 122)
    - Curcumin (INS 10(i))
    - Quinoline yellow (INS 104)
    - Sucrose esters of fatty acids (INS 473)
    - Tartrazine (INS 102)
    - Tocopherols (INS 307 a, b, c)

    The provisions for these additives are already listed in Appendix 2, Part C as draft provisions.

    However, if CCFA decides to align these draft GSFA provisions with the commodity standards, the proposals for alignment are as follows (Table 2 format only):

Food category 12.5 Soups and Broths			
Food additive	**INS**	**Maximum Level**	**Notes**
Azorubine	122	~~300~~ **50** mg/kg	**AA**
Curcumin	100i	~~300~~ **50** mg/kg	**AA**
Quinoline yellow	104	~~300~~ **50** mg/kg	**AA**
Sucrose esters of fatty acids	473	~~5000~~ **2000** mg/kg	**II**
Tartrazine	102	~~300~~ **50** mg/kg	**AA**
Tocopherols	307a, b, c	~~200~~ **50** mg/kg	**JJ**

    AA: For use in products conforming to the *Standard for Bouillons and Consommés* (CODEX STAN 117-1981) at 50 mg/kg.

    II: For use in products conforming to the *Standard for Bouillons and Consommés* (CODEX STAN 117-1981): sucrose esters of fatty acids (INS 473) and sucroglycerides (INS 474) singly or in combination at 2000 mg/kg.

    JJ: For use in products conforming to the Codex Standard for Bouillons and Consommés (CODEX STAN 117-1981), singly or in combination: d-alpha-tocopherol (INS 307a) and dl-alpha-tocopherol (INS 307c) at 50 mg/kg.

  - Phosphates: The U.S. **does not agree** with the addition of the **sentence in Note GG for the calculation** on the "as phosphorus basis":
    - The sentence is not necessary because the "as P_2O_5 basis" that is currently specified in the commodity standard will no longer be relevant once the provision is aligned in the GSFA on the "as phosphorus" basis
    - Almost all of the GSFA provisions for Phosphates require a calculation to the "as phosphorus" basis. It would be very complicated to specify all of the calculations, and as such, they have not been included in the notes to the GSFA. The U.S. does not see the need to include the calculation for this one provision.

- Lauric arginate ethyl ester: The U.S. observes that the proposed provisions in the sub-categories 12.5.1 and 12.5.2 are the same (with the proposed deletion of Note 127 in 12.5.2). The "parent" food category (12.5) contains only the sub-categories 12.5.1 and12.5.2. Therefore, the U.S. **proposes** that the provisions for the sub-categories 12.5.1 and 12.5.2 be removed and combined into the **provision for the "parent" food category (12.5)** as follows:

  12.5 (Soups and broths) – 200 mg/kg – **XS117** - Endorse

Table 3 – Section 2

- The U.S. **supports** the proposal.

Standards Related to Chocolate and Cocoa Products (CODEX STAN 86-1981, 87-1981, 105-1981, and 141-1983)

Amendments to Food Category 05.0

Tables 1 and 2

- The U.S. **supports** the proposal. **However, if CCFA decides to align these draft GSFA provisions with the commodity standards, the proposals for alignment are as follows (Table 2 format only):**

Food category 05.0 Confectionery			
Food additive	**INS**	**Maximum Level**	**Notes**
Caramel II – sulfite caramel	150b	50000 mg/kg	~~183~~, **New Note 183, XS86, XS87, XS105, XS141**
Propylene glycol	1520	240000 mg/kg	**XS86, XS87, XS105, XS141**

New Note 183: For use in surface decoration only.

XS86: Excluding products conforming to the *Standard for Cocoa Butter* (CODEX STAN 86-1981).

XS87: Excluding products conforming to the *Standard for Chocolate and Chocolate Products* (CODEX STAN 87-1981).

XS105: Excluding products conforming to the *Standard for Cocoa Powders (Cocoas) and Dry Mixtures of Cocoas and Sugars* (CODEX STAN 105-1981).

XS141: Excluding products conforming to the *Standard for Cocoa (Cacao) Mass (Cocoa/chocolate liquor) and Cocoa Cake* (CODEX STAN 141-1983).

NOTE: **Sorbitan esters of fatty acids (INS 491-495)** has a draft provision in food category 05.0. However, as per the Chair's proposal (Appendix 2, Part A, Point 9), the alignment has been made directly with the relevant subcategories 05.1.1 and 05.1.4 only. Therefore, **no action is required for the draft provision in food category 05.0**.

Amendments to Food Category 05.1

Tables 1 and 2

- The U.S. **supports** the proposal, **except** as noted below.
- The U.S. **requests clarification regarding Note LL**, which is associated with the provision for Propyl gallate (INS 310).
  - According to the information in Appendix 2, Part A, Point18, Note LL was intended to address a concern in the eWG that the New Note 141 that was proposed in the eWG draft ("For use in white chocolate

conforming to the *Standard for Chocolate and Chocolate Products* (CODEX STAN 87-1981).") did not allow use in other standardized chocolate products besides white chocolate.
  - The proposed Note LL ("Excluding products (other than white chocolate) conforming to the *Standard for Chocolate and Chocolate Products* (CODEX STAN 87-1981).") does not appear to address the concern. Note LL also appears to exclude all standardized chocolate products *except* for white chocolate. Therefore, Note LL is the same as the New Note 141, just with different text.
  - The U.S. asks for **clarification as to whether Note LL actually addresses the concern raised in the eWG**.
- **If CCFA decides to align these draft GSFA provisions with the commodity standards, the proposals for alignment are as follows (Table 2 format only):**

Food category 05.1 Cocoa products and chocolate products including imitations and chocolate substitutes			
Food additive	**INS**	**Maximum Level**	**Notes**
Curcumin	100(i)	300 mg/kg	~~183~~, **New Note 183, XS86, XS87, XS105, XS141**
Quinoline yellow	104	300 mg/kg	~~183~~, **New Note 183, XS86, XS87, XS105, XS141**
Sucrose esters of fatty acids	473	10000 mg/kg	**New Note 97, XS86, XS87. XS141**
Tartrazine	102	300 mg/kg	~~183~~, **New Note 183, XS86, XS87, XS105, XS141**

New Note 97: On the final cocoa and chocolate basis in products conforming to the *Standard for Cocoa Powder (Cocoas) and Dry Mixtures of Cocoa and Sugars* (CODEX STAN 105-1981).

New Note 183: For use in surface decoration only.

XS86: Excluding products conforming to the *Standard for Cocoa Butter* (CODEX STAN 86-1981).

XS87: Excluding products conforming to the *Standard for Chocolate and Chocolate Products* (CODEX STAN 87-1981).

XS105: Excluding products conforming to the *Standard for Cocoa Powders (Cocoas) and Dry Mixtures of Cocoas and Sugars* (CODEX STAN 105-1981).

XS141: Excluding products conforming to the *Standard for Cocoa (Cacao) Mass (Cocoa/chocolate liquor) and Cocoa Cake* (CODEX STAN 141-1983).

Amendments to Food Category 05.1.1

Tables 1 and 2

- The U.S. **supports** the proposal, **except** as noted below:
  - The provisions for the following additives are **draft provisions**, and therefore should **NOT be endorsed based on the working principles** to consider only adopted GSFA provisions:
    - Polyglycerol esters of fatty acids (INS 475)
    - Polyglycerol esters of interesterified ricinoleic acid (INS 476)
    - Tartrates (INS 334; 335(i), (ii); 336(i), (ii); 337)
      - The provisions for Polyglycerol esters of fatty acids and for Tartrates are already listed in Appendix 2, Part C as draft provisions. The provision for Polyglycerol esters of interesterified ricinoleic acid is not listed.

However, if CCFA decides to align these draft GSFA provisions with the commodity standards, the proposals for alignment are as follows (Table 2 format only):

Food category 05.1.1 Cocoa mixes (powders) and cocoa mass/cake			
Food additive	**INS**	**Maximum Level**	**Notes**
Polyglycerol esters of fatty acids	475	~~9000~~ **5000** mg/kg	**New Note 97, XS 141**
Polyglycerol esters interesterified ricinoleic acid	476	5000 mg/kg	**New Note 97, MM**
Tartrates	334; 335(i), (ii); 336(i), (ii); 337	5000 mg/kg	45, **PP**

Note 45: As tartaric acid.

New Note 97: On the final cocoa and chocolate basis in products conforming to the *Standard for Cocoa Powder (Cocoas) and Dry Mixtures of Cocoa and Sugars* (CODEX STAN 105-1981).

MM: On the final cocoa and chocolate basis in products conforming to the *Standard for Cocoa (Cacao) Mass (Cocoa/chocolate liquor) and Cocoa Cake* (CODEX STAN 141-1983).

PP: For use of L(+)-tartaric acid (INS 334) only as an acidity regulator on the cocoa fraction of products conforming to the *Standard for Cocoa Powder (Cocoas) and Dry Mixtures of Cocoa and Sugars* (CODEX STAN 105-1981), and as an acidity regulator on the final cocoa and chocolate basis in products conforming to the *Standard for Cocoa (Cacao) Mass (Cocoa/chocolate liquor) and Cocoa Cake* (CODEX STAN 141-1983).

XS141: Excluding products conforming to the Codex Standard for Cocoa (Cacao) Mass (Cocoa/chocolate liquor) and Cocoa Cake (CODEX STAN 141-1983).

Table 3 – Section 2

- The U.S. **supports** the proposal.

Amendments to Food Category 05.1.3

Tables 1 and 2

- The U.S. **supports** the proposal. **However, if CCFA decides to align these draft GSFA provisions with the commodity standards, the proposals for alignment are as follows (Table 2 format only):**

Food category 05.1.3 Cocoa-based spreads, including fillings			
Food additive	**INS**	**Maximum Level**	**Notes**
Tartrates	334; 335(i),(ii); 336(i),(ii); 337	5000 mg/kg	45, **XS 86**
Tocopherols	307a, b, c	500 mg/kg	15, **XS 86**

Note 15: On the fat or oil basis.

Note 45: As tartaric acid.

XS86: Excluding products conforming to the Codex Standard for Cocoa Butter (CODEX STAN 86-1981).

Table 3 – Section 2

- The U.S. **supports** the proposal.
- The U.S. **notes** that the reference to the *Guidelines on Substances Used as Processing Aids* (CAC/GL 75-2010) is listed as Appendix 2 of the CX. This reference should be to Appendix 4, Part B (p. 14 of the CX), which discusses the food additive provisions in the commodity standards.

Amendments to Food Category 05.1.4

Tables 1 and 2

- The U.S. **supports** the proposal, **except** as noted below:
  - The provision for Tartrates (INS 334; 335(i), (ii); 336(i), (ii); 337) is a **draft provision**, and therefore should **NOT be endorsed based on the working principles** to consider only adopted GSFA provisions.
    - The provisions for L-Tartaric acid (INS 334) and for Tartrates are already listed in Appendix 2, Part C as draft provisions.

    If CCFA decides to align these draft GSFA provisions with the commodity standards, the proposals for alignment are as follows (Table 2 format only):

Food category 05.1.4 Cocoa and chocolate products			
Food additive	**INS**	**Maximum Level**	**Notes**
Annatto extracts, bixin-based	160b(i)	25 mg/kg	8, ~~183~~, **New Note 183, XS87**
Brilliant black (Black PN)	151	300 mg/kg	~~183~~, **New Note 183, XS87**
Brown HT	155	80 mg/kg	~~183~~, **New Note 183, XS87**
Tartrates	334; 335(i),(ii); 336(i),(ii); 337	~~10000~~ **5000** mg/kg	45, **SS**

Note 8: As bixin.

Note 45: As tartaric acid.

New Note 183: For use in surface decoration only.

SS: For use of L(+)-tartaric acid (INS 334) only as an acidity regulator in products conforming to the *Standard for Chocolate and Chocolate Products* (CODEX STAN 87-1981) at 5000 mg/kg.

XS87: Excluding products conforming to the Codex Standard for Chocolate and Chocolate Products (CODEX STAN 87-1981).

Table 3 – Section 2

- The U.S. **supports** the proposal.

Amendments to Table 3

The U.S. **supports** the proposal.

Background

Document CX/FA 15/47/5 presents the report of the eWG (led by Australia) that was tasked to: (i) consider the application of the decision tree (REP 14/FA, Appendix VI) the *Standard for Bouillons and Consommés* (CODEX STAN 117-1981), and the 4 commodity standards related to cocoa and chocolate products (CODEX STAN 86-1981, 87-1981, 105-1981, and 141-1983); (ii) consider the food additive provisions of the GSFA that, according to the Committee on Processed Fruits and Vegetables (CCPFV) are not technologically justified in specific food categories covered by the standards for *Certain Canned Citrus* (CODEX STAN 254-2007), for *Preserved Tomatoes* (CODEX STAN 13-1981), and for *Processed Tomato Concentrates* (CODEX STAN 57-1981); and (iii) develop a draft list of prioritized commodity standards for application of the decision tree approach to guide future work on alignment. (REP 14/FA, para. 44)

Agenda Item	Subject Matter	Document Reference
	Codex General Standard on Food Additives (GSFA)	
5(a)	**Provisions in Tables 1 and 2 of Table 3 Food Additives Food Additives with: (i) "Acidity Regulator" Function for Other Uses Than Acidity Regulators; and (ii) for Other Table 3 Food Additives with Functions Other Than "Emulsifier, Stabilizer and Thickener," "Color," and "Sweetener" – Pending from the 46th CCFA**	**CX/FA 15/47/7**

U.S. POSITION

Appendix 1- Table 3 additives for use other than "acidity regulator", "colour", and "sweetener"

Many of the food additives under consideration in this Appendix are GRAS for use in all foods at GMP levels in the US (i.e. regulations are for general use and do not correspond to use in any specific FC). A such the U.S. can **remain silent** on provisions for those additives or choose to **support proposals if the use of these additives appears justified** (for example, if there is technical justification for the use of other additives of that functional class in that food category). The USA will **remain silent** for any provisions for food additives which the below table indicates there is no US regulation for its use.

Regulatory status in the U.S. for specific additives under discussion

INS	Name	Status	Use type	Level
260	Acetic Acid (Glacial)	Foods in General	Curing and Pickling Agent, flavor Enhancer, Flavoring Agent and Adjuvant, pH Control Agent, Solvent, Boiler Water Additive	0.15%
510	Ammonium Chloride	Foods in General	Dough Strengthener, Flavor Enhancer, Leavening Agent, Processing Aid	GMP
300	Ascorbic Acid (L)	Foods in General	Preservative	GMP
1100	Alpha-Amylase (Bacillus stearothermophilis)	Foods in General	Enzyme	GMP
1101(iii)	Bromelain	Foods in General	Enzyme	GMP
302	Calcium Ascorbate	Foods in General	Preservative	GMP
578	Calcium Gluconate	Foods in General	Nutrient supplement	GMP
623	Calcium Glutamate (D,L-)	No Regulation		
629	Calcium 5'-Guanylate	No Regulation		
526	Calcium Hydroxide	Foods in General	Multipurpose	GMP
633	Calcium 5'-Inosinate	No Regulation		
327	Calcium Lactate	Foods in General excluding infant formulae	Firming Agent, Flavor Enhancer, Flavor and Adjuvant, Leavening Agent, Nutrient, Stabilizer, Thickener	GMP
529	Calcium Oxide	Foods in General	Multipurpose	GMP
282	Calcium Propionate	Baked Goods, frostings, cheese, puddings, etc.	Antimicrobial	GMP
634	Calcium 5'-Ribonucleotides			

INS	Name	Status	Use type	Level
552	Calcium Silicate	Foods in General	Anticaking Agent	2%
290	Carbon Dioxide	Foods in General	Leavening Agent, Processing Aid, Propellant, Aerating Agent, Gas	GMP
330	Citric Acid	Foods in General	Multipurpose	GMP
628	Dipotassium Guanylate, 5'	No Regulation		
632	Dipotassium Inosinate, 5'	No Regulation		
627	Disodium 5'-Guanylate	Foods in General	Flavor Enhancer	GMP
631	Disodium 5'-Inosinate	Foods in General	Flavoring Adjuvant	GMP
635	Disodium 5'-Ribonucleotides	No Regulation		
315	Erythorbic Acid	Foods in General	Preservative	GMP
575	Glucono delta-Lactone	Foods in General	Curing and Pickling Agent, Leavening Agent, pH Control Agent, Sequesterant	GMP
1102	Glucose oxidase enzyme preparation from Aspergillus niger	Foods in General	Enzyme	GMP
620	Glutamic Acid, L-/+	Foods in General	Multipurpose	GMP
422	Glycerol	Foods in General	Multipurpose	GMP
626	Guanylic Acid, 5'-	No Regulation		
630	Inosinic Acid, 5' (INS 630)	No Regulation		
270	Lactic Acid (L-, D-, and DL-)	Foods in General except infant foods	Antimicrobial, Curing and Pickling Agent, Flavor Enhancer, Flavor and Adjuvant, pH Control Agent, Solvent and Vehicle	GMP
504(i)	Magnesium Carbonate	Foods in General	Anticaking Agent, Flour treating Agent, Lubricant, Release Agent, Nutrient, pH Control Agent, Processing Aid, Synergist	GMP
504(ii)	Magnesium Hydrogen Carbonate	No Regulation		
528	Magnesium Hydroxide	Foods in General	Nutrient, pH Control Agent, Processing Aid	GMP
625	Magnesium Glutamate	No Regulation		
518	Magnesium Sulphate	Foods in General	Flavor Enhancer, Nutrient, Processing Aid	GMP
624	Monoammonium Glutamate	Foods in General	Multipurpose	GMP
622	Monopotassium Glutamate	Foods in General	Multipurpose	GMP
621	Monosodium Glutamate	Foods in General	Multipurpose	GMP
941	Nitrogen	Foods in General	Propellant, aerating agent, gas	GMP
1101(ii)	Papain	Foods in General	Enzyme	GMP
261(i)	Potassium Acetate	Foods in General	Flavor (Artificial) or flavor adjuvant	GMP

INS	Name	Status	Use type	Level
303	Potassium Ascorbate	Foods in General	Multipurpose	
326	Potassium Lactate	Foods in General excluding infant formulae/foods	Flavor Enhancer, Flavor and Adjuvant, Humectant, pH Control Agent	GMP
1204	Pullulan	Foods in General	Multipurpose	GMP
551	Silicon dioxide, Amorphous	foods in general	Anticaking Agent	2%
551	Silica (aerogel)	foods in general	antifoamer	GMP
301	Sodium Ascorbate	Foods in General	Preservative	GMP
500(i)	Sodium Carbonate	Foods in General	Antioxidant, Curing and Pickling Agent, Flavor and Adjuvant, pH Control Agent, Processing Aid	GMP
500(ii)	Sodium Hydrogen Carbonate	Foods in General	Multipurpose	GMP
325	Sodium Lactate	Foods in General except infant foods	Emulsifier, Flavor Enhancer, Flavor and Adjuvant, Humectant, pH Control Agent	GMP
350(ii)	Sodium Malate	No Regulation		

It is expected that the "additives in additives" issue will be raised for proposals in FC 9.2.2, 9.2.3.

- It is the opinion of the USA that the food category describes the product as marketed. Therefore, the food is the glazed fish. The use of an additive in the batter or glaze is best captured through the use of a note in the existing food category for the products as marketed (i.e. battered fish). This is the approach in the current GSFA:
    - The descriptor for FC 09.0 states that these subcategories include " Fish products may be treated with coatings, such as glazes and spice rubs, prior to marketing to the consumer (e.g. glazed frozen fish fillets). In the Food Category System, this is indicated with a notation for "use as a glaze or coating (surface treatment)."
    - Many adopted provisions are listed in FC 09.2.2 with Note 41 "For use in breading or batter coatings only.", and in FC 9.2.3 with Note 16 "For use in glaze, coatings or decorations for fruit, vegetables, meat or fish only." As such, the CCFA has already considered it appropriate to list additives for use in batter or glazes in these FCs with these notes.

It is the opinion of the USA that the use of these **additives in FC 09.2.2 and 09.2.3 should be discussed in Appendix 2** as acidity regulators.

Appendix 2 – Table 3 food additives for use as "acidity regulator"

This appendix deals specifically with the use of acidity regulators in FC 09.2 (Processed fish and fish products, including mollusks, crustaceans, and echinoderms) that were not considered by the 45th CCFA. The U.S. can **support** all eWG proposals as being in-line with the approach used by the 45th CCFA.

It is expected that the "additives in additives" issue will be raised for proposals in FC 9.2.2, 9.2.3.

- The pWG of the 45th CCFA agreed that the use of acidity regulators is horizontally justified in FCs 09.2.2, 09.2.3, 09.2.4, and 09.2.5. Although that session of the GSFA raised the issue of additives in additives in other Food categories, it did not raise that issue for the subcategories for FC 09.2.2 and 09.2.3. The 45th CCFA adopted provisions for acidity regulators in FC 09.2.2 with Note 41 "For use in breading or batter coatings only.", and in FC 9.2.3 with Note 16 "For use in glaze, coatings or decorations for fruit, vegetables, meat or fish only."

- It is the opinion of the USA that the food category describes the product as marketed. Therefore, the food is the glazed fish. The use of an additive in the batter or glaze is best captured through the use of a note in the existing food category for the products as marketed (i.e. battered fish). This is the approach in the current GSFA:
    - The descriptor for FC 09.0 states that these subcategories include " Fish products may be treated with coatings, such as glazes and spice rubs, prior to marketing to the consumer (e.g. glazed frozen fish fillets). In the Food Category System, this is indicated with a notation for "use as a glaze or coating (surface treatment)."

Many adopted provisions are listed in FC 09.2.2 with Note 41 "For use in breading or batter coatings only.", and in FC 9.2.3 with Note 16 "For use in glaze, coatings or decorations for fruit, vegetables, meat or fish only." As such, the CCFA has already considered it appropriate to list additives for use in batter or glazes in these FCs with these notes

Background

Document CX/FA 15/47/7 contains the remaining recommendations on the horizontal approach for the GSFA provisions contained in CX/FA 14/46/9 for food additives with technological function "acidity regulator" for other uses than as acidity regulators, and for other Table 3 food additives with functions other than "emulsifier, stabilizer, thickener," "color," and "sweetener" that were not discussed at the 46th Session. (REP 14/FA, paras. 58, 60, 64-66, 103, and 104)

Agenda Item	Subject Matter	Document Reference
	Codex General Standard on Food Additives (GSFA)	
5(b)	**Provisions in Tables 1 and 2 of Table 3 Food Additives with "Emulsifier, Stabilizer, Thickener" Function for Their Use for Technological Functions Other Than as "Emulsifier, Stabilizer, Thickener"**	**CX/FA 15/47/8**

The U.S. participated in the eWG.

U.S. POSITION

Appendix 1- Table 3 additives for use other than "emulsifier, stabilizer, thickener"

Many of the food additives under consideration in this Appendix are GRAS for use in all foods at GMP levels in the US (i.e. regulations are for general use and do not correspond to use in any specific FC). AS such the U.S. can **remain silent** on provisions for those additives or choose to **support proposals if the use of these additives appears justified** (for example, if there is technical justification for the use of other additives of that functional class in that food category).

Additive	INS No.	USA technical function	USA Max use level	USA food Category
ACETIC AND FATTY ACID ESTERS OF GLYCEROL	472a	Multipurpose	GMP	Foods in General
ACETYLATED DISTARCH PHOSPHATE	1414	Emulsifier, Stabilizer, Thickener , Bulking agent	GMP	Foods in General
AGAR	406	Humectant, Stabilizer, Thickener	2500 mg/kg	Foods in General
CALCIUM ALGINATE	404	Stabilizer, Thickener	3000	Foods in General

Additive	INS No.	USA technical function	USA Max use level	USA food Category
			mg/kg	
CALCIUM SULFATE	516	Anticaking Agent, Dough Strengthener, Drying Agent, Firming Agent, Flour Treatment Agent, , Leavening Agent, Nutrient, Acidity Regulator, , Stabilizer, Thickener, Texturizer	700 mg/kg	Foods in General
CAROB BEAN GUM	410	Stabilizer, Thickener	1000 mg/kg	Foods in General
CARRAGEENAN	407	Emulsifier, Stabilizer, Thickener	GMP	Foods in General
GELLAN GUM	418	Stabilizer, Thickener	GMP	Foods in General
GUAR GUM	412	Stabilizer , Thickener	5000 mg/kg	Foods in General
GUM ARABIC (ACACIA GUM)	414	Emulsifier, Stabilizer, Thickener, Texturizer	10,000 mg/kg	Foods in General
HYDROXYPROPYL CELLULOSE	463	Emulsifier, Stabilizer, Thickener	GMP	Foods in General
HYDROXYPROPYL METHYL CELLULOSE	464	Emulsifier, Stabilizer, Thickener	GMP	Foods in General
HYDROXYPROPYL STARCH	1440	Emulsifier, Stabilizer, Thickener	GMP	Foods in General
KARAYA GUM	416	Stabilizer, Thickener	20 mg/kg	Foods in General
LACTIC AND FATTY ACID ESTERS OF GLYCEROL	472b	Emulsifier	GMP	Foods in General
LECITHIN	322(i)	Multipurpose	GMP	Foods in General
MAGNESIUM CHLORIDE	511	Flavour, Nutrient	GMP	Foods in General
METHYL CELLULOSE	461	Multipurpose	GMP	Foods in General
METHYL ETHYL CELLULOSE	465	Aerating Agent, Emulsifier, Foaming Agent	GMP	Foods in General
MONO- AND DI-GLYCERIDES OF FATTY ACIDS	471	Emulsifier, Stabilizer, Thickener	GMP	Foods in General
OXIDIZED STARCH	1404	Emulsifier, Stabilizer, Thickener	GMP	Foods in General
PECTINS	440	Emulsifier, Stabilizer, Thickener	GMP	Foods in General
POLYDEXTROSES	1200	Humectant	GMP	Foods in General
POTASSIUM ALGINATE	402	Stabilizer, Thickener	100 mg/kg	Foods in General
PROCESSED EUCHEUMA SEAWEED (PES)	407a	Emulsifier, Stabilizer, Thickener	GMP	Foods in General
SALTS OF MYRISTIC, PALMITIC AND STEARIC ACIDS WITH AMMONIA, CALCIUM, POTASSIUM AND SODIUM	470(i)	Binder, Emulsifier, Anticaking Agent	GMP	Foods in General
SALTS OF OLEIC ACID WITH CALCIUM, POTASSIUM AND SODIUM	470(ii)	Binder, Emulsifier, Anticaking Agent	GMP	Foods in General
SODIUM ALGINATE	401	Emulsifier, Firming agent	1000 mg/kg	Foods in General
SODIUM CARBOXYMETHYL CELLULOSE (CELLULOSE GUM)	466	Multipurpose	GMP	Foods in General
TRAGACANTH GUM	413	Emulsifier, Stabilizer, Thickener	1000 mg/kg	Foods in General

Additive	INS No.	USA technical function	USA Max use level	USA food Category
TRISODIUM CITRATE	331(iii)	Multipurpose	GMP	Foods in General
XANTHAN GUM	415	Emulsifier, Stabilizer, Thickener, Foaming Agent	GMP	Foods in General

The following additives are not regulated for use in the USA. The USA will **remain silent** for any provisions specific to these food additives.

- Konjac Flour (INS 425)
- Tara Gum (INS 417)
- Powdered Cellulose (INS 460(ii))

Appendix 2 – Table 3 food additives for use as "emulsifier, stabilizer, thickener"

This appendix deals with the use of emulsifiers, stabilizers, thickeners or acidity regulators in subcategories of parent categories where emulsifiers, stabilizers, thickeners, or acidity regulators are not justified on a general basis. The U.S. can **support** all eWG proposals as being in-line with the approach used by the 45th and 46th CCFA.

- It is expected that some objections may be raised concerning adoption of the provision for Carrageenan in FC 13.1.2 (Follow-up formulae). The USA notes that JECFA's recent evaluation states that carrageenan in infant formulae at up to 1000 mg/L is not of concern, and this evaluation considered infants less than 12 weeks of age.
    - The USA **supports adoption** of the provision for carrageenan in FC 13.1.2 at 300 mg/kg with Notes 72 and 151 as this puts the provision in alignment with CODEX STAN 156-1987.
    - The USA **supports forwarding** the provision for the use of carrageenan in FC 13.2 for consideration of inclusion in corresponding CODEX STANs 73-1981 and 74-1981, both of which allow emulsifiers and thickeners.

Background

Document CX/FA 15/47/8 presents the report of the eWG (led by the U.S.) that was tasked with preparing proposals for provisions in Tables 1 and 2 of the GSFA of Table 3 food additives with provisions in Tables 1 and 2 of Table 3 food additives with "emulsifier, stabilizer, thickener" function for their use for technological functions other than as "emulsifier, stabilizer, thickener" for discussion at the 47th Session. (REP 14/FA, paras. 103 and 104)

Agenda Item	Subject Matter	Document Reference
	Codex General Standard on Food Additives (GSFA)	
5(c)	**Food Additive Provisions in Tables 1 and 2 in Food Categories 01.2 through 08.4, with the Exclusion of Food Categories 04.1.2.4, 04.2.2.4, 04.2.2.5, 04.2.2.6, 05.1.1, 05.1.3, and 05.1.4**	**CX/FA 15/47/9 CX/FA 15/47/9 Add. 1**

The U.S. participated in the eWG.

U.S. POSITION

Many of the food additives under consideration in Appendix 1 are GRAS for use in all foods at GMP levels in the US (i.e. regulations are for general use and do not correspond to use in any specific FC). AS such the U.S. can **remain silent** on provisions for those additives or choose to **support proposals if the use of these additives appears justified** (for example, if there is technical justification for the use of other additives of that functional class in that food category).

Additive	INS No.	USA technical function	USA Max use level	USA food Category
ADIPATES	355, 356, 357, 359	Acidity Regulator, Leavening Agent	200 mg/kg	Foods in General
CALCIUM ASCORBATE	302	Preservative	GMP	Foods in General
ERYTHORBIC ACID (ISOASCORBIC ACID)	315	Preservative	GMP	Foods in General
ETHYL MALTOL	637	Flavour Enhancer	GMP	Foods in General
GLYCEROL	422	Multipurpose	GMP	Foods in General
MALTOL	636	Flavour Enhancer	GMP	Foods in General
POLYDIMETHYLSILOXANE	900a	Defoaming Agent	10 mg/kg	Foods in General
POLYGLYCEROL ESTERS OF FATTY ACIDS	475	Emulsifier	GMP	Foods in General
POLYOXYETHYLENE STEARATES	430, 431	(INS 431) Defoaming Agent (INS 430) No Regulation	GMP	Foods in General
POTASSIUM LACTATE	326	Acidity Regulator	GMP	Foods in General
PROPYLENE GLYCOL ALGINATE	405	Defoaming Agent	GMP	Foods in General
PROPYLENE GLYCOL ALGINATE	405	Emulsifier, Flavoring Adjuvant, Formulation Aid, Stabilizer, Thickener, Surface-Active Agent	3,000 mg/kg	Foods in General
PROPYLENE GLYCOL	1520	Anticaking Agent, Antioxidant, Dough Strengthener, Emulsifier, Humectant, Stabilizer, Thickener, Texturizer	20,000 mg/kg	Foods in General
PROTEASE	1101(i)	Enzyme	GMP	Foods in General
PULLULAN	1204		GMP	Foods in General
SODIUM CARBONATE	500(i)	Antioxidant, Acidity Regulator	GMP	Foods in General
SODIUM HYDROGEN CARBONATE	500(ii)		GMP	Foods in General
SORBATES	200-203	Preservative	GMP	Foods in General
SORBITAN ESTERS OF FATTY ACIDS	493, 494, 495, 491, 492	Flavour or flavour adjuvant (491 only – 492, 493, and 495: no regulation)	GMP (491 only)	Foods in General
TARTRATES	334, 335(i),(ii), 336(i),(ii), 337	Humectant, Acidity Regulator	GMP	Foods in General
TOCOPHEROLS	307a, b, c	Preservative, Nutrient	GMP	Foods in General

The following additives are not regulated for use in the USA. The USA will **remain silent** for any provisions specific to these food additives.

- Diphenyl (INS 230)
- Hydrogenated Poly-1-Decenes (INS 907)

The USA submitted comments on specific provisions for those food additives which US regulations list specific use in foods that correspond to the Food Categories under discussion. The USA's comments are captured in Appendix 1of the working document for each specific provision. The USA **will support adoption of provisions in line with the specific "USA" comments listed in Appendix 1 of the working document**.

Background

Document CX/FA 15/47/9 presents the report of the eWG (led by the U.S.) that was tasked with preparing proposals for provisions in Tables 1 and 2 of the GSFA in food categories 01.2 through 08.4, with the exclusion of

food categories 04.1.2.4, 04.2.2.4, 04.2.2.5, 04.2.2.6, 05.1.1, 05.1.3, and 05.1.4 for discussion at the 47th Session. (REP 14/FA, paras. 103 and 104)

Agenda Item	Subject Matter	Document Reference
	Codex General Standard on Food Additives (GSFA)	
5(d)	**Food Additive Provisions of Food Category 14.2.3 (Grape wines) and Its Sub-Categories (Information on Actual Use Levels and Recommendations)**	**CX/FA 15/47/10**

The U.S. participated in the eWG.

U.S. POSITION

- The U.S. **does NOT support** the recommendations and proposals set forth in the document. As a member of the eWG, the U.S. strongly expressed its concerns regarding the procedures and principles used in developing the document.
- The U.S.' main concerns are:
  - **There is a fundamental issue with proposals that defer a risk management decision to a non-Codex body**.
    - The proposals (with the exception of that for carbon dioxide (INS 290)) defer the decision regarding the provision to an international organization outside Codex Alimentarius. While international technical organizations can advise Codex in a particular area of expertise, the decision regarding the specific additive provisions in the GSFA is CCFA's responsibility.
    - While the proposals and justifications refer to "international technical organizations," there is an **apparent bias to the views of the OIV** over other Codex-recognized organizations (e.g., FIVS). In particular, Recommendation 7 (para. 49) specifically mentions "close cooperation . . . between CCFA and . . . OIV." This appears to exclude the advice from other technical organizations, such as FIVS.
  - With regard to the appropriateness of setting a numeric maximum level (ML) or GMP, the U.S. maintains its position that **additives with non-numerical ADIs** (Table 3 additives) **should be listed for use in wine at GMP**:
    - GMP is an acceptable ML for provisions for other foods in the GSFA, and for Table 3 additives in particular. **There does not appear to be a justification as to the need for a numerical ML for a Table 3 additive**. Without information demonstrating that the proposed numerical MLs are applicable on a global basis (i.e., regardless of region, climate, and vintage), establishing a numerical ML could arbitrarily apply the limits from one region to all winegrowing regions in the world.
    - Under the principles of GMP, an additive is used at the minimum level appropriate to achieve the intended technical function in the food (Section 3.3 of the Preamble to the GSFA). The use of additives at levels greater than that necessary to achieve the intended technical function is not reasonable from an economic perspective, and it risks the production of an unpalatable product.
    - GMP allows for natural variances (e.g., growing conditions, which is affected by global region and year-to-year variance with a region) and for consumer taste preferences, which can vary regionally and nationally. Neither of these factors affect the safety of the wine.
    - A numerical ML for an additive that is naturally-occurring in grapes is particularly problematic for compliance:
      - A numerical ML for the amount of a substance *added* to wine could be enforced in some markets as the *actual* limit for the total level of that substance in the finished wine.
      - It is uncertain how a regulator could differentiate between the naturally-occurring level of an acid in grapes and a level that has been added during winemaking. While recordkeeping may be able to distinguish between these scenarios, it places an unreasonable burden on wine producers and on regulators, particularly since there is no public health concern.
    - A ML of GMP does not need to be revised due to manufacturing changes, anticipated climate changes, or other unforeseen factors. If a numerical ML is established for an additive provision in the

GSFA, and later needs to be revised, it will be several years before CCFA would be able to consider revising it. This may result in barriers to trade.

- The proposals, in general, **defer the decision of a numerical ML or GMP to pending technological justification by internationally-recognized technical organizations, even though there is a clear indication that the additive is in use.** The eWG members provided information that clearly indicated that the additives are in use in wine in at least 2 countries, demonstrating that the wine is in international trade. As such, further technological justification should not be needed. If technological justification is needed in a particular case, information should be provided by all Codex-recognized bodies.

Background

Document CX/FA 15/47/10 presents the report of the eWG (led by France) that was tasked with collecting information on the actual levels of use in provisions listed in Appendix 6 of FA/46 CRD 2, including sodium carboxymethyl cellulose (INS 466) and preparing recommendations on a case-by-case basis for discussion at the 47th Session. (REP 14/FA, paras. 67-72 and 104)

Agenda Item	Subject Matter	Document Reference
	Codex General Standard on Food Additives (GSFA)	
5(e)	**Provisions for Cyclotetraglucose (INS 1504(i)), Cyclotetraglucose Syrup (INS 1504(ii)), and Nisin (INS 234) (Comments in response to CL 2014/8-FA)**	**REP 14/FA. Appendix XI, Part 1** **CX/FA 15/47/11** **CX/FA 15/47/11 Add. 1**

Cyclotetraglucose (INS 1504(i)) and Cyclotetraglucose Syrup (INS 1504(ii)

U.S. POSITION

- These two additives were assigned an ADI "not specified" by the 71st JECFA, and should have been included in Table 3 of the GSFA at Step 3 and circulated for comment at the 43rd CCFA.
- The U.S. did not submit comments to CL 2014/8-FA.
- The U.S. **supports** inclusion of Cyclotetraglucose (INS 1504(i)) and Cyclotetraglucose syrup (INS 1504(ii)) in Table 3 of the GSFA and forwarding these provisions for **adoption at Step 8** by the 38th CAC.

Nisin (INS 234)

U.S. POSITION

- The U.S. did not submit comments to CL 2014/8-FA. The U.S. submitted comments in response CL 2012/5-FA, Part B, Point 8 for the 46th CCFA.
- Nisin is used in the U.S.as follows:

Food Cat. No.	Food Category	Max Level
08.2.2	Heat-treated processed meat, poultry, and game products in whole pieces or cuts	5.5 mg/kg as nisin
08.3.2	Heat-treated processed comminuted meat, poultry, and game products	5.5 mg/kg as nisin
08.4	Edible casings (e.g., sausage casings)	7 mg/kg as nisin

Nisin is safe and suitable for use as an antimicrobial preservative, and is effective primarily against Gram positive bacteria, such as *Clostridium botulinum*, *Bacillus cereus*, and *Listeria monocytogenes*. Nisin is typically applied to the outside of the meat product immediately prior to packaging. Nisin has limited effectiveness vs. *L. monocytogenes* when added to meat before thermal processing. It appears that undenatured meat proteins bind

nisin, and thus inhibit its activity. Nisin is not particularly effective by itself against Gram negative bacteria, such as *Salmonella* spp. and *Escherichia coli*. Because different pathogens are associated with different meats products, nisin is used in ready-to-eat meat products where growth inhibition is critical. Nisin is applied to meat products in commercial preparations that usually consist of 2.5% nisin. The use level is typically 5 – 25 mg/kg as nisin.

The U.S. **supports** the proposed use levels of nisin in FCs 08.2.2 and 08.3.2 (25 mg/kg) and 08.4 (7 mg/kg), reported "as nisin" (Note 233), in REP 14/FA, Appendix XI, Part 1(b). These maximum levels are consistent with the typical use level range (5 – 25 mg/kg as nisin).

Background

The 46th CCFA agreed to include the provisions in Table 3 of the GSFA for cyclotetraglucose (INS 1504(i)) and cyclotetraglucose syrup (INS 1504(ii)) for circulation at Step 3 and consideration at the 47th Session (REP 14, Appendix XI, Part 1(a)). The request for comments was made in CL 2014/8-FA, Part B. (REP 14/FA, paras. 16 and 104)

The U.S. Delegation was charged by the 44th CCFA to compile the proposals submitted for the use of nisin (INS 234) in food category 08.0 (Meat and meat products, including poultry and game) and its sub-categories. The 45th CCFA noted that nisin was scheduled for re-evaluation by the 77th JECFA (June 2013), and agreed to postpone consideration of new proposals until the 46th Session to take into account the outcome of the JECFA evaluation. The 46th CCFA considered the proposals in CX/FA 14/46/15, which compiled the information in the document and comments submitted to the 45th CCFA, and agreed: (i) not to include the provision for nisin in food category 08.0, noting it had been discontinued at the 44th Session; and (ii) to include into the GSFA at Step 3 the provisions for nisin in food categories 08.3.2 (Heat treated processed meat, poultry, and game products in whole pieces or cuts), 08.3.2 (Heat treated processed comminuted meat, poultry, and game products); and 08.4 (Edible casings (e.g., sausage casings)) to be circulated for comments at Step 3 (REP 14/FA, Appendix XI, Part 1(b)). The request for comments was made in CL 2014/8-FA, Part B. (REP 14/FA, paras. 89-90 and 104)

Document CX/FA 15/47/11 presents the comments submitted in response to CL 2014/8-FA for discussion at the 47th Session.

Agenda Item	Subject Matter	Document Reference
	Codex General Standard on Food Additives (GSFA)	
5(f)	**Proposal for Revision of Food Category 01.1 (Milk and dairy-based drinks) and Its Sub-Categories**	**CX/FA 15/47/12**

The U.S. participated in the eWG.

U.S. POSITION – GENERAL COMMENTS

- The U.S. **supports** the revision of food category 01.1 (Milk and dairy-based drinks) and its sub-categories.

U.S. POSITION – SPECIFIC COMMENTS

- ***"Milk products" vs. "Milk"*** (para. 12)
  - In the eWG, the U.S. proposed that the term "milk products" be used in the title and descriptors. The Codex definition of "milk" refers only to raw milk. Therefore, it seems clear that "milk," as it is typically consumed, would actually be considered to be "milk products" under the Codex definition. As a result, the USA believes that it is appropriate to use the term "milk products" in the titles and descriptors of food categories 01.1, 01.1.1, and 01.1.2 so that it is clear that these categories do not include "milk" as defined in CODEX STAN 206-1999. This is also for consistency with the use of the term "milk products" in food category 01.1.4.

- The document states that the term "milk" or "milks" could be used is based on the statement in Section 5(b) of the Preamble to the GSFA that states that the "food category system is based on product descriptors of foodstuffs as marketed unless otherwise stated" and the fact that fluid milk is marketed internationally as "milk" and not a "milk product."
- The U.S. **prefers the use of the term "milk products."**

- ***Proposed Revisions to the Food Category System*** (para. 14)
  - Food Category 01.1.1
    - Revise the descriptor:
      - The words "**fat and/or protein adjusted milk**" should be in **bold font**, since this is new text.
      - Add clarification for **protein adjusted milk: "(only the total protein amount can be adjusted, without altering the casein-to-whey ratio)"** (see para. 9).
    - The revised descriptor would read as:

      01.1.1 Fluid milk [**products]** (plain) **[currently 01.1.1.1]**
      Plain fluid milk [**products]** obtained from milking animals (e.g., cows, sheep, goats, buffalo) **that have been heat treated or separated. Includes** pasteurized, ultra-high temperature (UHT) treated, **or** sterilized, **fat and /or protein adjusted milk (only the total protein amount can be adjusted, without altering the casein-to-whey ratio)**. ~~plain milk, plain skim milk, plain part-skim, and plain low-fat **milk.**~~

  - Food Category 01.1.2 (also Figure B and para. 13)
    - The proposed title ("Other fluid milk [products] (plain)") excludes the text "excluding products of food category 01.2," which is included in the title of the broader category (01.1 (Fluid milk [products] (plain), other fluid milk [products] (plain) excluding products of food category 01.2, buttermilk (plain), and fluid milk products with added flavouring))
    - The document notes that this text is unnecessary in the title of 01.1.2 since it is covered in the parent category (para. 14, "Explanation" under 01.1.2)
    - The U.S. **supports** the **inclusion** of the text **"excluding products of food category 01.2" in the title** of food category 01.1.2:
      - This text is included in the title for the broader category (01.1) as a descriptor applied to "other fluid milk products," which corresponds to subcategory 01.1.2.
      - Therefore, for clarity, this text should also be included in the title for the subcategory 01.1.2, so that there is no misinterpretation as to the scope of 01.1.2, if it is read separately from the broader category
      - The U.S. notes that the exclusion of food category 01.2 is included in the descriptor of 01.1.2, but is of the view that this text should also appear in the title.
      - The inclusion of such text in the title is consistent with the titles for other food categories (i.e., 02.4, 04.1.2.6, 04.2.2.7, 05.2, 06.0, 06.8, 06.8.4.3, 09.3.4, 11.2, 11.3, 12.7, 13.3, and 13.5).

  - Food Category 01.1.4
    - The U.S. **supports** the **inclusion** of the text **"fermented or non-fermented"** in the **title and descriptor**, and **proposes** the following **revision of the descriptor**:
      "Includes all ready-to-drink ~~flavoured and aromatized~~ **fermented and or non-fermented** milk-based fluid beverages . . ."
    - The U.S. notes that if the text **"that are fermented or non-fermented"** is included in the title of food category 01.1.4, this text **should also be included in the title of the broader category (01.1)** for clarity:
      "Fluid milk [products] (plain), other fluid milk [products] (plain) excluding products of food category 01.2, buttermilk (plain), and fluid milk products with added flavouring **that are fermented or non-fermented**"
    - This is consistent with the approach for food category 01.1.2, and other food categories, as discussed above.

- ***Consequential Changes to the Food Category System*** (para. 14)
  - Food Category 01.2
    - The title states "Fermented and renneted milk products (plain) ~~excluding food category 01.1.2 (Dairy-based drinks)~~ **01.1.4 (Fluid milk products with added flavouring [that are fermented or non-fermented])**
    - The newly-proposed text ("**01.1.4 (Fluid milk products with added flavouring [that are fermented or non-fermented])**") is **not necessary** because:
      - Food category 01.2 includes plain products only, so that the flavoured products (included in food category 01.1.4) are excluded by definition.
      - The descriptor for food category 01.2 clearly states that flavoured beverages are included under 01.1.4.

  - Food Category 01.2.1 (**NEW PROPOSAL**)
    - The descriptor for food category 01.1.3 (Buttermilk) includes buttermilk "produced by fermentation of fluid skim milk . . ."
    - The descriptor for food category 01.2.1 (Fermented milks (plain)) includes "all plain milk products, including fluid fermented milk, acidified milk, and cultured milk . . ."
    - There is **potential overlap between food categories 01.1.3 and 01.2.1**:
      - Both descriptors mention fermentation of fluid milk (fermented milk).
      - The U.S. cultured milk standard (21 CFR 131.112) covers cultured buttermilk, which while a "buttermilk" under 01.1.3 is also a "cultured milk" under 01.2.1. The description of 01.1.3
    - The U.S. proposes that the descriptor of food category 01.2.1 be revised to specifically exclude buttermilk:

      "Includes all plain products, including fluid fermented milk, acidified milk, and cultured milk, **but excludes buttermilk (01.1.3)**. Plain yoghurt, which does not contain flavours or colours, may be found in one of the sub-categories of 01.2.1, depending on whether it is heat-treated after fermentation or not."

- ***Food Additive Revisions Using the Proposed Revised Food Categories*** (para. 18)
  - Food Category 01.1.1
    - The U.S. asks for **clarification** regarding the statement that "no additives other than phosphates and sodium citrate are proposed for use in sterilised and UHT milk based on information from the 46th CCFA."
    - The document that is the basis for this statement should be identified and provided as a reference in a future discussion document.

- ***Recommendations***
  - The U.S. **supports** starting new work to revise food category 01.1 (Milk and dairy-based drinks) (para. 20)
  - The U.S**. supports** delaying the discussion of individual food additive provisions until the revision of food category 01.1 is completed (para. 21)
  - The U.S. **supports** forwarding the project document (Attachment 1) to the Commission for endorsement as new work (para. 22)

Background

Document CX/FA 15/47/12 presents the report of the eWG (led by New Zealand) that was tasked with: (i) further revising the structure of food category 01.1 (Milk and dairy-based drinks) and its sub-categories to resolve the issues identified regarding the correct placement of certain dairy products in the food category system; and (ii) preparing a project document for new work that would also include an analysis of the implications of the proposed revision on the current provisions of the GSFA for discussion at the 47th Session (REP 14/FA, paras. 73-77)

Agenda Item	Subject Matter	Document Reference
	Codex General Standard on Food Additives (GSFA)	
5(g)	**Note 161 – Application of Alternative Note to Provisions for Sweeteners**	**CX/FA 15/47/13**

The U.S. participated in the eWG.

U.S. POSITION

It is the general position of the USA that Note 161 should be **removed from the GSFA** and, if necessary, replaced with a technologically based note that does not refer to national legislation. It is also the general position of the USA that such a replacement note should not tie the use of sweeteners to any specific energy reduction value.

- The technological function of these additives is "sweetener", not calorie reduction.
- These additives have been evaluated by JECFA and exposure from their use has been demonstrated to fall below JECFA's ADI.

Recommendations 1 and 2:
The USA **would not support** maintaining Note 161 in the food categories discussed in lists T and U.

Recommendation 3 and 4:
The USA **would not support** replacing Note 161 with the proposed note, which ties the use of sweeteners to energy reduction, for lists V or W. In general, the USA **would not support** the discontinuation of provisions listed in list W.

Recommendations 5 and 6:
In general, the USA **can support** replacing Note 161 with the specific notes proposed in lists X and Y.

Recommendation 7:
The USA may **remain silent** on the proposal to revoke the provisions in list in Z.

Recommendation 8:
The USA **can support** ensuring consistency between the use levels for aspartame-acesulfame salt and corresponding provisions for aspartame and acesulfame in the same food category. The USA would **not support** the addition of Note 161 to any provisions which do not currently have Note 161 attached to them.

Recommendation 9:
Although in general the USA could support the horizontal application of a consensus replacement note, it is the opinion of the USA that the issue of replacement notes has not been sufficiently decided for recommendation 9 to be implemented at this time.

Background

The pWG on the GSFA at the 46th CCFA discussed the report of the eWG (led by the UK) that was contained in CX/FA 14/46/14. There appeared to be a strong consensus to remove Note 161 from the GSFA and that the use of sweeteners was justified in energy-reduced food and foods with no added sugar. However, the pWG could not reach consensus on the use of sweeteners in food that do not meet the definition of "energy reduced" or "no added sugar." There was general support by the Committee to advance work on Note 161 and re-establish the eWG. However, there was no consensus on Recommendation 3 of the GSFA pWG (FA/46 CRD 2) and whether the eWG should base its work on Option 3 or both Options 1 and 3 as stated in CX/FA 14/46/14, para. 11. After an

extensive debate, the 46th CCFA agreed to establish an eWG, led by the UK and with the assistance of the U.S.., to request information on the effect of the following note: "For use only in energy-reduced food or food with no added sugars as defined in CAC/GL 23-1997." to the provisions for sweeteners contained in Appendix 8 of FA/45 CRD 2. The eWG will use this information to determine if this replacement note is applicable on a general basis or if alternative notes can be developed for those food categories where the replacement note is not appropriate. (REP 14/FA, paras. 91-97, and 104)

Agenda Item	Subject Matter	Document Reference
	Codex General Standard on Food Additives (GSFA)	
5(h)	**Proposals for New and/or Revision of Food Additive Provisions (Replies to CL 2014/15-FA)**	**CX/FA 15/47/14**

U.S. POSITION

- Industry did not ask the U.S. for support of any new or revised provisions. Therefore, the U.S. did not respond to CL 2013/15-FA.

Background

The 46th CCFA agreed that the CL requesting information on new and/or revised food additive provisions in the GSFA would include a form on which the proposals were to be submitted. The submitted information would be compiled by the Secretariat in a working document for consideration by the pWG on the GSFA, which will make recommendations as to their inclusion in the GSFA at Step 2. As such, the CCFA agreed not to consider the proposals submitted in reply to CL 2013/8-FA, Part B, Point 5, and to request Members and Observers to resubmit their proposals in response to CL 2014/15-FA. (REP 14/FA, paras. 98-99 and 104)

Agenda Item	Subject Matter	Document Reference
6	**International Numbering System (INS) for Food Additives**	
	Proposals for Changes and/or Addition to the International Numbering System for Food Additives	**CX/FA 15/47/15**
	Comments at Step 3	**CX/FA 15/47/15 Add. 1**

The U.S. participated in the INS eWG. The U.S. did not provide comments to CL 2014/12-FA and CX/FA 15/47/15.

- A proposal was made to add Manganese ammonium pyrophosphate to the INS list as a colorant for all polymers intended for use in contact with food. There was not support from members of the eWG for the addition of this substance to the INS list as the proposed use as a colorant in food contact polymers would not be considered a food additive use under Codex.

U.S. POSITION

In general, the US can support the proposed revisions to the INS list put forward in CX/FA 15/47/15. However, the US does not support the addition of Manganese ammonium pyrophosphate to the list as the proposed use is for a non food additive use.

Background

Document CX/FA 15/47/15 is the report of the eWG on the INS (led by Iran) that was tasked with considering the replies to CL 2014/12-FA, which requested proposals for changes and addition to the INS list. Comments at Step 3 are compiled in CX/FA 15/47/15 Add.1.

Agenda Item	Subject Matter	Document Reference
	Priority List of Food Additive Proposed for Evaluation by JECFA	
7(a)	**Proposals for Additions and Changes to the Priority List of Food Additives Proposed for Evaluation by JECFA (Replies to CL 2014/13-FA)**	**CX/FA 15/47/16**

U.S. POSITION

The U.S. submitted 63 flavors for inclusion on the JECFA Priority List at the 47th CCFA in response to CL 2014/13-FA. The list includes 3 new flavors, 21 flavors that were included on the JECFA Priority List at previous CCFA meetings, and 39 flavors for which JECFA had requested additional safety information in order to complete its review. The complete list of proposed flavors is included on pp. 22-24 of CX/FA 15/47/16.

The U.S. currently has four entries on the JECFA Priority list from the 46th CCFA:

Substance	Questions to be Answered	Data availability (as of 46th CCFA)	Comment
Flavouring substances (continued from the priority list recommended by the 43rd CCFA)	Safety assessment and establishment of specifications	December 2014	This entry should be updated to incorporate the list of 63 flavors submitted by the US to the 47th CCFA. Data availability should be updated to December 2015.
Flavourings (JECFA no. 973, 1114, 1122, 1203, 1238, 2031, and 2123)	Revision of specifications and safety assessment as appropriate	December 2014	Request has not changed. Data availability should be updated to December 2015.
Monk fruit extract/Lo han guo (LHG); *Siraitia grosvenorii* Swingle	Safety assessment and establishment of specifications	December 2014	Data availability should be updated based on information from sponsor.
Steviol glycosides	Safety assessment and revision of specifications ((1) To include rebaudioside M and rebaudioside E; (2) delete the requirement for stevioside and/or rebaudioside A as the primary steviol glycosides in stevia preparations)	December 2014	Data availability should be updated based on information from sponsor.

The U.S. should **ensure that** all four entries above **remain on the JECFA Priority List**.

Several requests have been made asking that the U.S. support inclusion of additives on the JECFA Priority List:

- Gum ghatti (INS 419) – Submitted in response to CL by the International Association of Color Manufacturers (IACM) for use as an emulsifier in food.
  - U.S. Position: The U.S. **supports** the request. Gum ghatti is generally recognized as safe (GRAS) in the US for use as an emulsifier and emulsifier salt at levels of 2,000 mg/kg in nonalcoholic beverages and beverage bases, and at levels of 1,000 mg/kg in all other food categories (21 CFR 184.1333).
- Xanthan gum (INS 415) – Submitted in response to CL by the International Special Dietary Foods Industries (ISDI) for consideration by JECFA for use in infant formula and formulae for special medical purposes intended for infants.
  - U.S. Position: The U.S. **supports** the request. Xanthan gum is permitted for use in infant formula in the US.
- Gellan gum (INS 418) – Submitted in response to CL by ISDI for consideration by JECFA for use in infant formula and formulae for special medical purposes intended for infants.
  - U.S. Position: The U.S. **supports** the request. Gellan gum is permitted for use in infant formula in the US.

Background

Document CX/FA 15/47/16 compiles proposals for addition and changes to the Priority List of Food Additive proposed for evaluation by JECFA, submitted in response to CL 2014/13-FA.

Agenda Item	Subject Matter	Document Reference
	Priority List of Food Additive Proposed for Evaluation by JECFA	
7(b)	**Information on the Availability of Data for the Re-Evaluation of Six Priority Colours (Replies to CL 2014/14-FA)**	**CX/FA 15/47/17**

- JECFA requested information on the availability of data to re-evaluate the following six colors:

  Allura red (INS 129)
  Tartrazine (INS 102
  Brillian blue (INS 133)
  Erythrosine (INS 127)
  Fast green FCF (INS 143)
  Indigotine (INS 132)

- Select summary data and an indication of the availability of more complete data were submitted separately by Japan and IACM for all six colors identified by JECFA.

U.S. POSITION

- The U.S. did not respond to CL 2014/14-FA.

Background

The 46th CCFA discussed the options for the re-evaluation of food additives by JECFA presented in the discussion paper (CX/FA 14/46/20). The JECFA Secretariat proposed to allocate a limited portion of JECFA meetings on food additives to the re-evaluation of compounds, ad prioritized by CCFA, and emphasized that confirmation of the availability of the data was a key criterion for re-evaluation. The CCFA supported this proposal and agreed to start the process using the colours listed as priority in Group 1 and Group 2, as amended by the 45th CCFA, as a working example (CX/FA 13/45/17 and REP 13/FA, para. 133). CCFA agreed that information on the availability of data for the re-evaluation of the 6 colors will be requested by CL and that, based on responses, the Working Group (WG) on JECFA Priorities at the 47th CCFA will provide JECFA with a final prioritized list. The CCFA agreed that the JECFA Priorities WG report would contain two separate tables: one addressing new evaluation requests, and the other the re-evaluation of colors. (REP 14/FA, paras. 137-144)

Agenda Item	Subject Matter	Document Reference
	Priority List of Food Additive Proposed for Evaluation by JECFA	
7(c)	**Information on Commercial Use of Potassium Diacetate (INS 261(ii)) in Food (Replies to CL 2014/24-FA)**	**CX/FA 15/47/18**

- Comments by the European Union and Norway indicated that potassium diacetate was recently authorized for use as a replacement for sodium diacetate in the European Union and Norway to help in the reduction of dietary sodium intake, and therefore potassium diacetate is in commercial use.

U.S. POSITION

- The U.S. did not respond to CL 2014/24-FA. There are no food additive regulations permitting the use of potassium diacetate in the US, nor is it the subject of a successful GRAS notification. The US does not have a concern with the addition of potassium diacetate to the JECFA Priority List.

Background

The 46th CCFA agreed to request JECFA to revise the specification monograph for potassium acetate to list only INS 261(i), and to clarify whether the group ADI for potassium acetates also includes potassium diacetate. The CCFA noted that JECFA would require data and information to reply to this request. The request for data was communicated in CL 2014/24-FA. (REP 14/FA, paras. 22-23).

Agenda Item	Subject Matter	Document Reference
8	**Discussion Paper on Secondary Additives**	**CX/FA 14/47/19**

U.S. POSITION

- USP has indicated that they will not likely comment on this issue until a path has been chosen by Codex (e.g., a guidance document) as they don't feel comfortable talking about this issue from a safety standpoint, as FCC does not focus on safety *per se*. [from 46th CCFA]

Definition

- *Recommendation 1:* The U.S. **supports** the definition of a secondary food additive (para. 15):

  ***"Secondary food additive** means any food additive that: (i) is used in preparations of food additives, enzymes, flavourings or nutrients (including substances with physiological effect) that are formulated particularly for commercial use; (ii) exerts a technological function in those preparations; and (iii) does not have a technological function in the food in which those preparations have a function. Secondary food additives are incorporated in the preparations to fulfil a technological function in that preparation (e.g. to facilitate their storage, standardisation, dispersion, dilution or dissolution). The term does not include processing aids which do not have any technological function in the preparations or in the food in which the preparations have a function."*

Possible Ways to Address the Use of Secondary Additives

- *Recommendation 2:* Whether the use of secondary additives should be addressed in the GSFA, and options to address their use in the GSFA.

  The U.S. **observes** that secondary additives **are already addressed** in the GSFA through notes (Option 2, below). The U.S. prefers this approach.

  Option 1: Establish a new GSFA food category (i.e., "Preparations of food additives, enzymes, flavourings and nutrients").

  The U.S. **does not support** this option.
  - The use of secondary additives can already be accounted for in the food category system because they can be accommodated under the carry-over and reverse carry-over principles (Sections 4.1 and 4.2 of the Preamble to the GSFA).
  - A review of the carry-over principle in the Preamble may be needed to ensure that secondary additives are appropriately accounted for in a transparent manner (see Recommendation 3, below).

- The food category system represents foods as marketed (i.e., sold to the consumer). Most preparations are used commercially, and are not sold to the consumer, and are therefore outside the current scope of the food category system. Therefore, implementing Option 1 would result in changing the scope of the food category system.
- If CCFA was to agree that the food category system should be expanded to include commercial preparations, this revision would require initiation of new work and an assessment of its effect on the GSFA. This would need to be considered alongside the CCFA's other priorities.
- Listing provisions for the use of secondary additives in a food category for preparations unnecessarily complicates exposure assessments. It would be difficult to equate use levels in a "preparations" food category to actual consumer exposure. However, if the use level is instead listed in the food category for the consumed food (e.g., with appropriate notes, as in Option 2) and the use levels are reported on the level in that food, exposure evaluation would be simplified.

Option 2: Use notes within the current GSFA food category system.

The U.S. **supports** this option.

- The use of notes is consistent with the application of the "reverse carry-over" principle (Section 4.2 of the Preamble to the GSFA). A provision for a secondary additive in the GSFA food category that covers the food would provide an overview of the use of that secondary additive in preparations used to produce that food. In fact, this concept has already been applied to the existing provisions in the GSFA with Notes 12, 65, or 131 associated with them.[1]
- General notes (e.g., "For use in food additive preparations"; "For use in color preparations") could be developed wherever possible and applied to the GSFA provisions in the appropriate food category where the preparations are used.
- Specific notes (e.g., specifying maximum levels or specific preparations (e.g., for a specific enzyme)) should be used only where a general note is not justified.
- The information regarding the notes could be obtained from comments in response to the Circular Letter requesting new or revised provisions to the GSFA.
- This option would cause little disruption on the work of the GSFA, as CCFA could request the information as a matter of course as it continues working through the GSFA.
- This option would facilitate exposure assessment for the purposes of risk management.

- *Recommendation 3:* If Recommendation 2 is supported, consider if changes to the Preamble to the GSFA would be needed.

  The U.S. **supports** discussion as to whether changes to the Preamble are needed.
  - The U.S. is of the view that the use of secondary additives can be accommodated under the carry-over and reverse carry-over principles in the Preamble (Sections 4.1 and 4.2). However, a review of these Sections may be needed to ensure that secondary additives are appropriately accounted for in a transparent manner.

- *Recommendation 4:* Consider whether developing a separate *Guideline for the Use of Secondary Food Additives* would be useful to explain the use of secondary additives in various preparations and its relationship to the relevant provisions in the GSFA.

  The U.S. preferred option is to address secondary additives through notes associated with specific GSFA provisions (Recommendation 2, Option 2). However, if there is no consensus for this option, the U.S**. would not object** to developing separate *Guidelines*, **provided** that, in doing so, **secondary additives would not be directly addressed in the GSFA, including the Preamble** (Recommendation 2).

[1] Note 12 ("As a result of carryover from flavouring substances."); Note 65 ("As a result of carryover from nutrient preparations."); and Note 131 ("For use as a flavour carrier only.")

- There is no need to duplicate work by listing secondary additives in the GSFA and developing *Guidelines* to address the same issue.
- If *Guidelines* were developed, they could:
  - Be constructed along the *Guidelines for the Use of Flavourings* (CAC/GL 66-2008).
  - Address the use of secondary additives in various preparations (food additives, enzymes, flavorings, nutrients) and clearly explain the relationship of these uses to the relevant provisions in the GSFA.
  - Clarify how the carry-over and "reverse carry-over" principles in the Preamble to the GSFA (Sections 4.1 and 4.2) cover the use of secondary additives.
- Developing the *Guidelines* would require approval as new work. However, it would have less impact on CCFA's work on GSFA provisions.

Other U.S. Comments – Secondary Additives Covered by "Reverse Carry-over"

The U.S. notes that, for a given food, the exposure from the use as a secondary additives is negligible (similar to that of a processing aid) compared to the exposure from the direct addition of additives to food for a technical effect on the food. Listing a provision for a secondary additive in the food category for the food that contains the preparation (i.e., application of the "reverse carry-over" principle, which is provided in Section 4.2 of the Preamble to the GSFA) allows the Committee to easily evaluate the exposure and provides the tool necessary to take risk management measures (i.e., to set a limit for use) in the unlikely event that any limits are necessary for the use of secondary additives.

Under Section 4.2 of the Preamble (the "reverse carry-over" principle), if an additive is permitted for use in a food, the additive can be used in ingredients used to manufacture that food without a provision for the use of the additive in the ingredient itself, provided that the amount of the additive in the ingredient will not result in an exceedance of the level allowed in the food. This same concept can be applied to preparations. If reverse carry-over was applied to secondary additives, a provision for a secondary additive in the GSFA food category that covers the food would provide an overview of the use of that secondary additive in preparations used to produce that food. In fact, this concept has already been applied to the existing provisions in the GSFA with Notes 12, 65, or 131 associated with them.

Background

At the 45th Session, the JECFA Secretariat proposed that CCFA develop guidance on how to address the use of secondary additives, and to prepare a discussion paper for the 46th Session. The Delegation of the EU prepared a discussion paper, which was contained in CX/FA 14/46/18. The 47th CCFA considered the discussion paper and recognized that secondary additives are an important topic; however, there were differing views on how to proceed. The Chairperson noted that there was a need to have a common understanding of this issue, and that, as a starting point, a definition for secondary additives should be developed, and the implication of undertaking new work on this topic analyzed. The CCFA supported this proposal and agreed to establish an eWG, led by the EU, to further develop the discussion paper. (REP 14/FA, paras. 124-128)

Agenda Item	Subject Matter	Document Reference
9	**Discussion Paper on Inconsistent Terminology Related to Flavourings in Codex Texts**	**CX/FA 14/47/20**

U.S. POSITION

Recommendation I:

- The U.S. **supports** the recommendation to revise the *Codex General Standard for the Labelling of Food Additives When Sold as Such* (CODEX STAN 107-1981) as stated in para. 48.
- The U.S. **prefers** limiting the scope of the revision to that outlined in para. 48 and in the Draft Project Document (Appendix III). While revision of other sections of CODEX STAN 107-1981 may be needed to

update the standard, those sections are beyond the scope of the current discussion paper, and may not be the best use of CCFA's agenda and resources at this time.

Recommendation II:

- The U.S. **supports** CCFA's recommendation that CCFL consider the revision of the *Codex General Standard for the Labelling of Prepackaged Foods* (CODEX STAN 1-1985) taking into account the discussion paper and the proposed revision to CODEX STAN 107-1981.

Recommendation III:

- The U.S. **supports** the Codex Secretariat's informing active commodity committees of this work, and that a general reference to the *Guidelines for the Use of Flavourings* (CODEX STAN 66-2008) should be included in the commodity standards as much as possible; however, if a specific list of flavourings is technologically justified, the text regarding flavourings be revised to use the terms indicated in para. 50.

Recommendation IV:

- The U.S. **supports** the revision of the texts identified in Appendix I that are not the responsibility of an active commodity committee, in accordance with the discussion.

Recommendation V:

- The U.S. **supports** the revision of the food category descriptors identified in Appendix II, in order to harmonize the terms regarding flavourings. The U.S. considers these editorial amendments, not subject to initiation of new work.

Background

At the 46th Session, the Observer from IOFI presented FA/46 CRD 13 on the inconsistencies in terminology related to flavorings in various standards on labelling and the *Guidelines for the Use of Flavourings* (CAC/GL 66-2008). The CCFA supported further work to address this issue and agreed to request the U.S. to prepare a discussion paper to analyze and make recommendations to address the issue of inconsistent terminology related to flavourings between the *Guidelines* and other Codex standards (REP 14/FA, paras. 145-146)

Agenda Item	Subject Matter	Document Reference
10	**Other Business and Future Work**	

U.S. POSITION

The U.S. has no proposals for new work.

Background

The Committee will discuss issues, raised under Item 1, as other business and/or proposals for future work.