



## 48th Session of the Codex Committee on Food Additives

March 14-18, 2016

Xi'an, Peoples Republic of China

The 48th Codex Committee on Food Additives (CCFA) met in Xi'an, Peoples Republic of China, March 14-18, 2016. The meeting was chaired by Dr. Junshi Chen and attended by 48 member countries, one member organization (EU), and 31 observers from international organizations, and FAO and WHO.

The U.S. Government participation in the meeting included: Dr. Paul Honigfort (Head of Delegation), Dr. Daniel Folmer (technical expert), Dr. LaShonada Cureton (FDA), Ms. Mari Kirrane (TTB), and Mr. Chih-Yung Wu (USDA FAS).

The highlights of the decisions made by the Committee are outlined below.

### *Matters Referred by the Codex Alimentarius Commission (CAC) and Other Codex Subsidiary Bodies*

The Executive Committee (CCEXEC) had recommended that all Committees consider the need to develop an approach for the management of their work. In response to the request from the CCEXEC the Committee agreed to a proposal from the Chair that a discussion paper on this topic be prepared by China and the United States for consideration by the Committee at its next session. This discussion paper would also consider aspects related to the prioritization of substances for JECFA evaluation.

The Committee considered the proposal by the Committee on Fish and Fishery Products (CCFFP) to align the use level for phosphates in Note 229 of the General Standard for Food Additives (GSFA) to that listed in CODEX STAN 166-1989. It was noted that Note 229 is a direct reference to the level for phosphates specified in CODEX STAN 166-1989. The Committee agreed that Note 229 should be revised to reflect the correct use level.

### *Matters of Interest from the 80th Meeting of JECFA*

The Committee was informed of the recommendations of the 80th JECFA regarding the food additives that were evaluated. The Committee considered JECFA's recommendation that the maximum use level (ML) for benzoates in food category (FC) 14.1.4 (Water-based flavoured drinks, including "sport," "energy," or "electrolyte" drinks and particulated drinks) be decreased in light of JECFA's recent exposure assessment which demonstrated that in some countries overall dietary exposure may exceed the acceptable dietary intake (ADI) for some populations such as toddlers, children, and adolescents. Some delegations were in favour of revoking the provision for benzoates in 14.1.4 due to safety concerns and that the provision had been adopted with Note 123 "on an interim basis". However, the Committee decided to reduce the use level from 600 mg/kg to 250 mg/kg and remove a note allowing a higher use level in drinks with a specific pH. The Committee also agreed to request further information on actual use levels and technical justification on benzoates for consideration by the electronic Working Group (eWG) on the GSFA, and add a note "interim maximum level until CCFA 49" to reflect that this provision will be further amended at the next session of the Committee.

The Committee noted that two enzymes (Lipase from *Fusarium heterosporum* expressed in *Ogataea polymorpha*, and Maltotetrahydrolase from *Pseudomonas stutzeri* expressed in *Bacillus licheniformis*) had been given ADIs of "not specified" and that they should be included in the database on processing aids.

JECFA also requested that information be provided to complete tentative specifications for several food additives to be provided by December 2016 (*i.e.*, Mixed  $\beta$ -glucanase, cellulase and xylanase from *Rasamsonia emersonii*, Mixed  $\beta$ -glucanase and xylanase from *Disporotrichum dimorphosporum*, Silicon dioxide, amorphous (INS 551), and Sodium Aluminium Silicate (INS 554)).

The Committee noted JECFA's withdrawal of specifications for three food additives (aluminium silicate (INS 559), calcium aluminium silicate (INS 556), and glycerol ester of gum rosin (INS 445(ii))). As a result the Committee is recommending that provisions for these additives in the GSFA and commodity standards be revoked.



## *Endorsement and/or Revision of Maximum Levels for Food Additives and Processing Aids in Codex Standards*

The Committee endorsed the food additive provisions forwarded by the Codex Committee on Spices and Culinary Herbs (CCSCH) for inclusion in the proposed draft *Standard for Thyme*. However, the Committee also noted that CCSCCH had not provided the justification required by the Procedural Manual as to why provisions for specific anticaking agents were necessary as opposed to a general reference to the GSFA. Therefore, the Committee agreed to request that CCSCCH provide justification for limiting the use of food additives in the proposed draft *Standard for Thyme* to only three anticaking agents.

## *Alignment of the Food Additive Provisions of Commodity Standards and Relevant Provisions of the GSFA*

The document prepared by the eWG, led by Australia and co-chaired by the United States, was considered by the in-session working group on alignment. The recommendations of the in-session working group, as recorded in Conference Room Document (CRD) 3, were considered by the Committee.

The Committee agreed to forward to the CAC for adoption:

- Revised food additive section of the *Standard for Cocoa Butter* (CODEX STAN 86-1981), *Standard for Cocoa (Cacao) Mass (Cocoa/Chocolate Liquor)* and *Cocoa Cake* (CODEX STAN 141-1983), and *Standard for Cocoa Powders (Cocoas) and Dry Mixtures of Cocoa and Sugars* (CODEX STAN 105-1981);
- Revised food additive provisions of the GSFA in FC 05.0 (Confectionery) and its sub-categories, as well as to Table 3 of the GSFA, that correspond to CODEX STANs 86-1981, 141-1983, and 105-1981; and
- Revised specific food additive provisions of the GSFA in FC 09.2 (Processed fish and fish products, including mollusks, crustaceans and echinoderms) and its subcategory 09.2.5 (smoked, dried, fermented and/or salted fish and fish products, including mollusks, crustaceans and echinoderms) to align those provisions with the *Standard for Smoked Fish, Smoked-flavoured Fish, and Smoke-dried Fish* (CODEX STAN 311-2013).

The Committee noted that the physical working group (pWG) on the GSFA had not considered provisions for the use of additives in FC 05.0 or 5.1 (Cocoa products and chocolate products including imitations and chocolate substitutes) due to the ongoing work on alignment with CODEX STANs 86-1981, 141-1983, and 105-1981, which correspond to subcategories of these two FCs. As the Committee had finished the alignment work with these standards the Committee agreed that these provisions would be considered by the eWG on the GSFA.

The Committee noted that several provisions in FC 09.2.5 had note 22 “for use in smoked fish products only” associated with them, however these food additives were not allowed in CODEX STAN 311-2013. As CODEX STAN 311-2013 specifies non-standardized products, and it was unclear if these food additives were used in non-standardized products, the Committee agreed to revise Note 22 to specify use in non-standardized products only, and these provisions would be considered by the eWG on the GSFA to determine if they are used in non-standardized products.

The Committee also agreed to re-establish an eWG on Alignment, led by Australia and co-chaired by the United States, to:

- Address the request of the 34th CCFFP concerning alignment of provisions for ethylene diamine tetra acetates (INS 385, 386) in FC 9.4 “Fully preserved, including canned or fermented fish and fish products, including mollusks, crustaceans, and echinoderms” of the GSFA (340 mg/kg with Note 21 “As anhydrous calcium disodium ethylene diamine tetra acetate.” – adopted in 2001) with that of the Standard for Canned Shrimps or Prawn (CODEX STAN 37-1991) (250mg/kg).
- Develop an alignment proposal for FC 09.2.1 (Frozen fish, fish fillets, and fish products, including molluscs, crustaceans and echinoderms) and FC 09.2.2 (Frozen fish, fish fillets, and fish products, including molluscs, crustaceans and echinoderms) with their 10 corresponding commodity standards;
- Develop guidelines for active commodity committees to undertake work on alignment;
- Consider the work, conducted by the eWG on Alignment to the 48th CCFA that could not be addressed by the 48th CCFA due to time constraints, on food additive provisions in the GSFA that, according to the Codex Committee on Processed Fruits and Vegetables (CCPFV) are not technologically justified in products corresponding to the *Standard*



for *Certain Canned Citrus Fruits* (CODEX STAN 254-2007), the *Standard for Preserved Tomatoes* (CODEX STAN 13-1981), or the *Standard for Table Olives* (CODEX STAN 66-1981).

## GSFA

The pWG on the GSFA, chaired by the United States, met for two days prior to the Plenary meeting of the Committee to reach consensus recommendations on the following:

- a. Food additive provisions in Table 1 and 2 in FCs 01.2 through 08.4, with the exception of FCs 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 pending from the 47th CCFA (CX/FA 16/48/7)
  - b. Use of nisin (INS 243) in FC 08.3.2 in general, and specifically in products conforming to the corresponding commodity standards (CX/FA 16/48/8)
  - c. Proposed draft provisions for quillaia extracts (INS 99 (i-ii) in FC 14.1.4 and related comments in response to CL 2015/9-FA Part B, point 7 (CX/FA 16/48/9)
  - d. Use and use levels of paprika extract (INS 160c(ii)) provided in response to a request for information in CL 2015/9-FA Part C, point 8 (CX/FA 16/48/10)
  - e. Proposals for new and/or revision of food additive provisions (replies to CL 2015/12-FA (CX/FA 16/48/11)
- The Committee considered the recommendations of the pWG on the above issues. The Committee agreed to forward 274 food additive provisions for adoption at Step 8 or 5/8 by the CAC, discontinued work on 77 draft and proposed draft provisions, circulated 41 provisions for further comment, and entered 70 new provisions at Step 2. This will result in approximately 4000 adopted (Step 8) provisions and 1800 provisions in the step process in the GSFA.

During discussion of the provisions for Adipates, the Committee noted concerns for exposure and the lack of a JECFA exposure assessment for Adipates. The Committee agreed to issue a circular letter requesting use level information for adipic acid (INS 355) be provided to the JECFA Secretariat by November 2016 for the purposes of exposure assessment and that the 49th CCFA discontinue those provisions for which no information is provided.

During discussion of the provisions for Nitrates (INS 251, 252) and Nitrites (INS 249, 250) concerns were raised as to the expression of the MLs for these additives as well as the balance between the benefits and risk of the use of these additives. The Committee agreed that the Netherlands, with input from the JECFA Secretariat, would prepare a discussion paper to address issues related to:

- i. The expression of MLs as ingoing amount and/or residual amount taking into account feasibility of controls, preserving effect (in particular the inhibitory activity against *C. botulinum*) and possible formation of nitrosamines;
- ii. The technological need seeking a balance between the benefits (microbiological safety, desired effect on colour and flavour) and risks (formation of nitrosamines) taking into account existence of effective alternatives;
- iii. Appropriate levels taking into account the ADIs for nitrites and nitrates and the discussion on points (i) and (ii) above.

The Committee endorsed the recommendations of the pWG regarding requests to seek advice from Codex commodity committees regarding:

- Technological justification on the use of emulsifiers and acidity regulators in FC 02.1.2 (vegetable fats and oils) in general, and the use of polyglycerol esters of fatty acids (INS 475), polyglycerol esters of interesterified ricinoleic acid (INS 476), propylene glycol alginate (INS 405), sorbitan esters of fatty acids (INS 491-495), stearyl lactylates (INS 481(i), 482(i)), and tartrates (INS 334, 335(ii), 337) specifically (Codex Committee on Fats and Oils (CCFO))
- Technological justification on the use of emulsifiers and acidity regulators in FC 02.1.3 (Lard, tallow, fish oil, and other animal fats) in general, and the use of polyglycerol esters of fatty acids (INS 475), polyglycerol esters of interesterified ricinoleic acid (INS 476), propylene glycol alginate (INS 405), and tartrates (INS 334, 335(ii), 337) specifically (CCFO)
- The use of acidity regulators in general, and the use of tartrates specifically, in products conforming to CODEX STANs 177-1991, 260-2011, and 160-1987 (CCPFV)
- The general use of antioxidants in FC 04.1.2 (processed fruit) and the use of tocopherols (INS 307 a, b, c) (CCPFV) specifically, in standardized and non-standardized foods for all subcategories
- The use of propylene glycol alginate (INS 405) as a thickener in products conforming to CODEX STAN 296-2009. The Committee also agreed that, in addition to the 41 provisions recommended to be circulated for comment by the eWG on the GSFA, the provisions for polydimethyl siloxane (INS 900a), propylene glycol esters of fatty acids (INS 477), and sucrose esters of fatty acids (INS 473) in the subcategories of FC 06.8 (Soybean products) corresponding to the *Regional Standard for Non-fermented Soybean Products* would also be circulated for comment by the eWG on the GSFA.



The Committee agreed to discard the proposed new provisions for Paprika extract (INS 160c(ii)) provided in response to CL 2015/9-FA Part C, point 8, as well as the proposed new provisions provided in response to CL 2015/12-FA for magnesium stearate (INS 470(iii)) in FCs 05.2, 05.3, 07.0, 13.6, and for polyvinyl alcohol (PVA)-polyethylene glycol (PEG) graft copolymer (INS 1209) in FC 13.6 for use as a binder and stabilizer.

### *Proposed Draft Revision of FC 01.1 “Milk and Dairy Based Drinks” and Its Sub-Categories*

The Committee considered CRD 17, which contained proposals based on the report of the eWG on this issue (CX/FA 16/48/12) as well as comments on this report contained in CX/FA 16/48/12 Add.1, 2, and CRD 18. The Committee agreed to forward revisions to food categories 01.1, 01.1.1, 01.1.3, and 01.1.4, as well as a new FC 01.1.2 “other fluid milks (plain)” and consequential changes to CAC 39 for adoption at step 5/8. The Committee also noted that the scope of FCs 01.1, 01.1.1, 01.1.3, and 01.1.4 had not substantially changed and therefore it was not necessary to revoke or discontinue the provisions currently included in those FCs, but only to verify their appropriateness. These provisions would be circulated for comment by the eWG on the GSFA. However, the Committee noted that the new FC 01.1.2 would need to be populated with food additive provisions. Proposed new provisions for this FC could be provided in response to the CL for proposed new or revision of adopted provisions in the GSFA.

### *eWG and pWG on the GSFA*

The Committee agreed to establish an eWG, led by the United States, to consider:

- i. actual use levels and technical justification on the use of benzoates in FC 14.1.4
  - ii. provisions for the use of additives in FC 05.0 or 05.1 and related subcategories
  - iii. provisions in FC 09.2.5 with note 22 and specifically their use in non-standardized products
  - iv. provisions recommended by the pWG on the GSFA to the 48th CCFA to be circulated for comment, and the provisions for polydimethyl siloxane (INS 900a), propylene glycol esters of fatty acids (INS 477), and sucrose esters of fatty acids (INS 473) in the subcategories of FC 06.8 (Soybean products) corresponding to the *Regional Standard for Non-fermented Soybean Products*
  - v. the appropriateness of current provisions in the renamed FCs 01.1, 01.1.1, 01.1.3, and 01.1.4
- The Committee also agreed to establish a pWG on the GSFA that would meet immediately prior to the 49th Session, chaired by the United States, to consider and prepare recommendations for the plenary on:

- i. the report of the eWG on the GSFA;
- ii. Comments submitted in responses to the CL requesting information on the use and use levels of adipic acid
- iii. new proposals for entry or revision of food additive provisions (replies to CL).

### *Discussion Paper on the Use of Specific Food Additives in the Production of Wine*

The Committee considered the report of the eWG, chaired by France and Australia. The majority of the discussion focused on GMP and the status of guidance on GMP from internationally recognized bodies. The Committee agreed to re-establish an eWG, Chaired by the European Union and Australia, to:

- i. Develop and analyze recommendations for the amendment of the GSFA with respect to food additives in wine;
- ii. Consider provisions for food additives belonging to the following functional classes: acidity regulators, stabilizers and antioxidants.

### *Discussion Paper on the Use of Secondary Additives*

The Committee considered the discussion paper, prepared by the eWG led by the EU, on secondary additives. The paper provided several recommendations on how to account for the use of secondary additives, either in the GSFA (through the formation of either a new food category for preparations, or through the use of notes in existing food categories) or through the use of Guidelines separate from the GSFA. The Committee could not reach consensus on any of the recommendations. Therefore, the Chairperson noted that no new work would be proposed to account for secondary additives, and the Committee would continue to address secondary additives within the GSFA through the use of notes associated with provisions within existing food categories.



## *Proposed Draft Revision of Section 4.1c and 5.1c of the General Standard for the Labelling of Food Additives When Sold as Such (CODEX STAN 107-1981)*

The Committee endorsed all recommendations contained in the report of the eWG led by the United States (CX/FA 16/48/18) and to forward them to the 39th CAC for adoption. The Committee also considered subsequent recommendations from the discussion paper on the inconsistent terminology related to flavourings in other Codex Texts (CX/FA 15/47/20) presented at the 47th session of the CCFA. The Committee agreed to:

- i. Recommend to the Codex Committee on Food Labeling (CCFL) to consider revising Section 4.2.3.4 of the *General Standard for the Labeling of Prepackaged Foods* (CODEX STAN 1-1985) taking into account the work of CCFA on CODEX STAN 107-1981;
- ii. Recommend that other active Committees revise standards within their mandate for consistency with the terms utilized in the *Guidelines for the Use of Flavourings* (CAC/GL 66-2008).
- iii. Revise the *Standard for Dairy Fat Spreads* (CODEX STAN 253-2006) to delete the term “flavour” and forward this revision to the 39th CAC for adoption
- iv. At a future date, consider revision of the descriptors in the GSFA for consistency with the terms utilized in CAC/GL 66-2008.

### *Other Agenda Items*

The Committee also considered amendments to the International Numbering System (INS) for food additives; the priority list of additives for JECFA review, and information on the commercial use of potassium hydrogen sulfate (INS 515(ii)), sodium sorbates (INS 201), and calcium hydrogen sulfite (INS 227).

The Committee determined that before an additive can be included on the JECFA Priority List for consideration of the safety of its use in infant formula, CCNFSDU must first confirm the technological need for the use of the additive in infant formula. For the current meeting, CCFA would send a request to CCNFSDU to confirm the technological need for Gellan gum (INS 418) in infant formula. However, for future requests, it will be the responsibility of the sponsor to obtain CCNFSDU confirmation before requesting that an additive for use in infant formula be included on the JECFA Priority List.

It was decided that provisions for those food additives without specifications should be removed from the GSFA and recommended for removal from commodity standards. The Committee also noted that the 46th session of CCFA had noted several additional food additives without JECFA specifications but had not recommended removing provisions for those food additives from commodity standards. The discussion resulted in recommendations that provisions for potassium bisulfite (INS 228), potassium hydrogen sulfate (INS 515(ii)), and calcium hydrogen sulfite (INS 227) be recommended for removal from several commodity standards with active commodity committees, and that provisions for potassium bisulfite, sodium sorbates, calcium hydrogen sulfite, ammonium lactate (INS 328), chlorine dioxide (INS 926) and potassium hydrogen malate (INS 351(i)) in the GSFA and/or commodity standards for which there is no longer an active commodity committee, be forwarded to the 39th session of CAC for revocation.

The next session of the CCFA is tentatively scheduled for March 20 – 24, 2017 in the Peoples Republic of China.