**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 and Alignment 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 16/48/1, as the Agenda for the Session.

### Agenda

<table>
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<tr>
<th>Agenda Item</th>
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<tbody>
<tr>
<td>1</td>
<td>Adoption of the Agenda</td>
<td>CX/FA 16/48/1</td>
</tr>
</tbody>
</table>

### Matters Referred by the Codex Alimentarius Commission and Other Subsidiary Bodies

**Standards and Related Texts Adopted by the Commission**

No action required by CCFA

**Proposals for New Work**

Are addressed in Agenda Items 5(f) and 9.

**Revocation of Existing Codex Standards and Related Texts**

No action required by CCFA

**Discontinuation of Work**

No action required by CCFA

### Matters Arising from the 38th Session of the Codex Alimentarius Commission - Matters For Information

**Executive Committee of the Codex Alimentarius Commission (CCEXEC)**

CCEX recommends all Committees consider the need to develop an approach for the management of their work similar to that used by CCFH.

**U.S. Position:**

**Background:**
The CCFH utilizes a process to prioritize new work where:
- The Secretariat issues a circular letter requesting proposals for new work.
- Replies to the circular letter are considered by a physical working group (pWG) on CCFH work priorities, which meets the day before the plenary. This pWG scores the requests for new work based on criteria outlined in REP14/FH Appendix IX (Process by Which CCFH Will Undertake Its Work).
- Requests for new work are ranked on the CCFH Forward Workplan based on scoring as per the criteria. The Forward Workplan lists all current and future work of CCFH.

**Codex Committee on Spices and Culinary Herbs (CCSCH)**

**MATTERS FOR INFORMATION**

Technological justification for the use of food additives in herbs

CCSCH is currently elaborating two standards on culinary herbs (thyme and oregano). Neither include provisions for antioxidants. The Standard for Thyme includes proposals for the use of microcrystalline cellulose (INS 460(i)), powdered cellulose (INS 460(ii)) and silicon dioxide, amorphous (INS 551) as anticaking agent in ground/powdered thyme.

**U.S. POSITION**

**Background:**

The 47th CCFA requested clarification from CCSCH (para 64, Rep 15/FA) as to:

- Are antioxidants used in herbs and specifically the use of ascorbic acid, L- (INS 300) and sodium ascorbate (INS 301) in herbs as antioxidants. There are provisions in the GSFA step process for the use of these additives in the GSFA in FC 12.2.1
- Are anticaking agents are used in herbs, and specifically the use of silicon dioxide amorphous (INS 551) and sodium carbonate (INS 500(i)) in herbs as anticaking agents. There are provisions in the GSFA step process for the use of these additives in the GSFA in FC 12.2.1

**Codex Committee on Fish and Fishery Products (CCFFP)**

**MATTERS FOR INFORMATION**

No action required by CCFA

Revision of standards for fish and fishery products

CCFA forwarded revisions of food additive provisions in existing commodity standards to the Commission for adoption.

**Functional class associated with phosphates in CODEX STAN 315-2014:**

CCFFP is revising CODEX STAN 315-2014 to associate the functional classes of acidity regulator and stabilizer with INS 342(i),(ii) and INS 343(i)-(iii).

**Background:**

The 46th CCFA noted that the draft CODEX STAN 315-2014 listed the functional classes of humectant or sequestrant with INS 342(i),(ii) and INS 343(i)-(iii) and that these technological functions were not associated with these additives in CAC/GL 36-1989 (see Rep14/FA, para 29).

*(From CODEX STAN 315-2014):*

**4.2 Quick Frozen Scallop Meat and Quick Frozen Roe-on Scallop Meat Processed With Phosphates**

Humectant / Sequestrant / Acidity Regulator/Stabilizer (bolded and underlined reflect changes listed in REP16/FFP Appendix VI)
<table>
<thead>
<tr>
<th>INS</th>
<th>Additive Name</th>
<th>Maximum Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>338; 339(i)-(iii); 340(i)-(iii); 341(i)-(iii); 342(i),(ii); 343(i)-(iii); 450(i)-(iii), (v)-(vii); 451(i),(ii); 452(i)-(v); 542</td>
<td>Phosphates</td>
<td>2200 mg/kg as phosphorus</td>
</tr>
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</table>

**MATTERS FOR ACTION**

Standards for Atlantic Herring and Salted Sprat (CODEX STAN 244-2004) and Salted Fish and Dried Salted Fish of the Gadidae Family of Fishes (CODEX STAN 167-1989) – **TO BE DISCUSSED UNDER AGENDA ITEM 7(B)**

CCFFP is requesting CCFA’s advice on retention of provisions for sodium sorbate (INS 201) in these commodity standards as there are no corresponding JECFA specifications for this additive.

**US Position:**

Follow general recommendation for INS 201 from Agenda Item 7(b). The US also **notes** that these two standards may not be the only commodity standards that have provisions for sodium sorbate.

**Background:**

- CODEX STANs 167-2009 (revised in REP16/FFP Appendix VI) and 244-2004 do not have specific provisions for INS 201, rather it is included under a general provision for sorbates:

  **Antioxidants**
  
  INS 200-203 Sorbates 200 mg/kg (expressed as sorbic acid)

- The general topic of lack of JECFA specifications for sodium sorbate is discussed in Agenda Item 7(b).

Standard for Canned Shrimps or Prawn (CODEX STAN 37-1981)

CCFFP is requesting CCFA to align the provision 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 ethylenediaminetetraacetate.” – adopted in 2001) with that of the Standard for Canned Shrimps or Prawn (CODEX STAN 37-1991) (250mg/kg).

**US Position:**

Propose to add the following notes to the provision for INS 385, 386 in FC 09.4 of the GSFA:

“Except for use in products conforming to the Standard for Canned Shrimps or Prawns (CODEX STAN 37-1991) or the Standard for Canned Crab Meat (CODEX STAN 90-1981) at 250 mg/kg.”

and


**Background:**

- CODEX STANs 37-1991 and 90-1981 (Revised in REP16/FFP Appendix VI) have the following provision for INS 385 and 386:

  **Sequestrants**
  
  INS 385-386 Ethylene diamine tetra acetates 250 mg/kg (as anhydrous calcium disodium ethylenediaminetetraacetate)
• The remaining commodity standards that correspond to FC 09.4 (CODEX STANs 3, 70, 94, 119) do not have provisions for INS 385 or 386.
• This FC contains both standardized and non-standardized foods. This FC includes both canned and fermented foods. The corresponding commodity standards only apply to canned foods.

Note 299 of the GSFA
CCFFP is requesting CCFA to align the use level in Note 299 of the GSFA with that listed in CODEX STAN 166-1989 (i.e., 440 mg/kg).

**US Position:**
The US can support this proposal

**Background:**
• Note 229 “For use at 400 mg/kg as phosphorous singly or in combination in breaded or batter coating in accordance with Standard for Quick Frozen Fish Sticks (Fish Fingers), Fish Portions and Fish Fillets – Breaded or in Batter (CODEX STAN 166-1989).” is only associated with one provision in the GSFA for the use of phosphates in FC 09.2.2.
• CODEX STAN 166-1989 only corresponds to FC 09.2.2 and has the following use level for phosphates “440 mg/kg as phosphorus, singly or in combination”

**Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU)**
**MATTERS FOR INFORMATION**

Use of Gum Arabic (Acacia gum) (INS 414) in FC 13.1 and corresponding commodity standards
CCNSFDU informs CCFA that there is no technological need for INS 414 in FC 13.1 (Infant formula, follow-up formula and formula for special medical purpose for Infants) or products conforming to the commodity standards which correspond to that FC, although INS 414 is used as a nutrient carrier.

**Background:**
The 47th CCFA requested clarification from CCNFSDU (para 73, Rep 15/FA) on the use of (INS 414) in food category 13.1. There is a provision in the GSFA step process for the use of this additive in FC 13.1

Use of Carrageenan (INS 407) in FC 13.2 (Complementary foods for infants and young children) and corresponding commodity standards
CCNSFDU informs CCFA that INS 407 is approved for use in some countries as a stabilizer and emulsifier in canned baby foods FC 13.1 (Complementary foods for infants and young children) while in others it was not permitted because in those countries the technological need was not demonstrated.

**Background:**
The 47th CCFA requested clarification from CCNFSDU (para 73, Rep 15/FA) on the use of (INS 407) in food category 13.2. There is a provision in the GSFA step process for the use of this additive in FC 13.2

**Codex Committee on Sugars (CCS)**
**MATTERS FOR INFORMATION**
No action required by CCFA

**Background**
Document CX/FA 16/48/2, prepared by the Codex Secretariat, includes matters referred to the Committee by the Codex Alimentarius Commission and other Codex Committees and Task Forces.
Informational Items

- Currently, only the Summary and Conclusions of the 80th JECFA are available (http://www.who.int/foodsafety/publications/Summary80.pdf?ua=1). The full report and toxicological monographs will be made available at a later date. Updated specifications from the 80th JECFA are also available (http://www.fao.org/documents/card/en/c/001c43bb-c473-4a65-a511-d876831f41a0/).
- The 80th JECFA recommended that short amino acid sequence comparisons between genetically modified enzymes and known allergens be increased from six to eight amino acid sequences.
- The 80th JECFA is in the process of revising guidance documents for WHO monographers and reviewers of food additives and contaminants. A request was also made for the preparation of a guidance document on enzymes.
- The JECFA Secretariat has begun a project to modernize the FAO JECFA databases for food additives, flavouring agents and residues of veterinary drugs. The first database to be modernized will be the flavouring agents database. An update was also provided on several WHO databases including FOSCOLLAB and the FAO/WHO Chronic Individual Food Consumption Database – Summary Statistics (CIFOCOss).
- The JECFA Secretariat reiterated that requests for scientific advice from CCFA, CCCF, and CCRVDF are increasing, and that JECFA will not be able to address all requests made at the JECFA meeting following the request from the Codex committee.

Matters for Action from 80th JECFA

- CX/FA 16/48/3 put forward a list of recommended actions for the CCFA based on information put forward by the 80th JECFA.

<table>
<thead>
<tr>
<th>INS Num</th>
<th>Food Additive Name</th>
<th>ADI or Other Tox Recommendation</th>
<th>Recommended Action by CCFA</th>
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<tr>
<td></td>
<td>Benzoates: dietary exposure assessment</td>
<td>JECFA had previously established an ADI of 0-5 mg/kg bw for benzoates, and was asked now to update the exposure assessment based on actual use levels. Based on the available data set, the 80th JECFA noted that there is consistency in the average typical range of concentration levels for benzoates reported to be used or analysed in non-alcoholic (“soft”) beverages (General Standard for Food Additives [GSFA] food category 14.1). For example, typical reported concentration levels from industries ranged from 83 to 209 mg/L, and analytically quantified measurements ranged from 63 to 259 mg/L in GSFA food category 14.1; these levels are lower than national maximum limits (150–400 mg/L) or limits for GSFA food category 14.1.4 (600 mg/L). The 80th JECFA also noted that most of the reported estimates for mean and high percentile benzoate exposure were below the ADI of 0–5 mg/kg body weight (bw), expressed as benzoic acid, despite different methodologies and assumptions applied in the preparation of the exposure estimates.</td>
<td>Note the JECFA conclusion on the current estimated dietary exposures for benzoates. In light of JECFA conclusion on actual use levels, consider: - The feasibility to reduce the ML for benzoates in GSFA food category 14.1.4 Water-based flavoured drinks, including “sport,” “energy,” or “electrolyte” drinks and particulated drinks. <strong>U.S. Position:</strong> The U.S. is seeking input from industry on appropriate use levels.</td>
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<td>INS Num</td>
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<td>Note the JECFA conclusion on an ADI “not specified” for lipase from F. heterosporum expressed in O. polymorpha when used in the applications specified and in accordance with GMP. Consider to: - Recommend inclusion in the database on processing aids. <strong>U.S. Position:</strong> The U.S. can <strong>support</strong> the recommendation</td>
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<tr>
<td>1104</td>
<td>Lipase from <em>Fusarium heterosporum</em> expressed in <em>Ogataea polymorpha</em></td>
<td>No treatment-related adverse effects were seen at the highest dose tested (669 mg total organic solids [TOS]/kg bw per day) in a 13-week study of oral toxicity in rats. A comparison of the dietary exposure estimate of 0.5 mg TOS/kg bw per day (for a 60 kg individual) with the highest dose tested of 669 mg TOS/kg bw per day results in a margin of exposure (MOE) of at least 1300. The 80th JECFA established an ADI “not specified” for lipase from F. heterosporum expressed in O. polymorpha when used in the applications specified and in accordance with good manufacturing practice.</td>
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<td>470(iii)</td>
<td>Magnesium stearate</td>
<td>The 80th JECFA estimated the potential total dietary exposure to magnesium stearate based on the proposed maximum use levels: 44 mg/kg bw per day for children and 83 mg/kg bw per day for adults, corresponding to 2 and 4 mg/kg bw per day, expressed as magnesium, respectively. These dietary exposures would contribute up to an additional 250 mg/day to the background exposure to magnesium from food of 180–480 mg/day. The 80th JECFA noted that the consumption of the food additive may lead to an additional dietary exposure to stearic and palmitic acids in the order of 5 g/day. An ADI “not specified” has previously been established for a number of magnesium salts used as food additives. JECFA concluded that there are no differences in the evaluation of the toxicity of magnesium stearate compared with other magnesium salts, and therefore confirmed the ADI “not specified” for magnesium salts of stearic and palmitic acids. However, the 80th JECFA was concerned that the use of magnesium salts in many food additives may result in combined exposure that could lead to a laxative effect. Therefore, the JECFA reiterated its previous recommendation to undertake an exposure assessment for magnesium from use of food additives. Note the JECFA conclusion on the ADI “not specified” for magnesium salts of stearic and palmitic acids and consider to: - Include magnesium stearate (INS 470(iii)) in Table 3 of GSFA and circulate for comments at Step 3; and - Request comments/proposals on uses and use levels of magnesium stearate (INS 470(iii)) for the food categories listed in the Annex to Table 3. Note the JECFA recommendation on exposure assessment for magnesium from use of food additives and consider to: - Recommend countries to submit information to JECFA on actual use level for</td>
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<td>INS Num</td>
<td>Food Additive Name</td>
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<td>Recommended Action by CCFA</td>
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<td>magnesium-containing food additives.</td>
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<td><strong>U.S. Position:</strong> The U.S. can <strong>support</strong> the recommendation</td>
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<td>Maltotetra-ohydrolase from <em>Pseudomonas stutzeri</em> expressed in <em>Bacillus licheniformis</em></td>
<td>No treatment-related adverse effects were seen at the highest dose tested (93 mg TOS/kg bw per day) in a 13-week study of oral toxicity in rats. A comparison of the dietary exposure estimate of 0.1 mg TOS/kg bw per day (for a 60 kg individual) with the highest dose tested of 93 mg TOS/kg bw per day results in an MOE of at least 900. The 80th JECFA established an ADI “not specified” for maltotetraohydrolase from <em>P. stutzeri</em> expressed in <em>B. licheniformis</em> when used in the applications specified and in accordance with good manufacturing practice.</td>
<td>Note the JECFA conclusion on an ADI “not specified” for maltotetraohydrolase from <em>P. stutzeri</em> expressed in <em>B. licheniformis</em> when used in the applications specified and in accordance with GMP. Consider to: - Recommend inclusion in the database on processing aids <strong>U.S. Position:</strong> The U.S. can <strong>support</strong> the recommendation</td>
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<td>Mixed β-glucanase, cellulase and xylanase from <em>Rasamsonia emersonii</em></td>
<td>No treatment-related adverse effects were seen at the highest dose tested (84.8 mg TOS/kg bw per day) in a 13-week study of oral toxicity in rats. A comparison of the dietary exposure estimate of 0.08 mg TOS/kg bw per day (for a 60 kg individual) with the highest dose tested of 84.8 mg TOS/kg bw per day results in an MOE of at least 1000. The 80th JECFA established an ADI “not specified” for the mixed β-glucanase, cellulase and xylanase enzyme preparation from <em>R. emersonii</em> when used in the applications specified and in accordance with good manufacturing practice. New tentative specifications were prepared, with a request for the following information: - a method to determine the identity for β-glucanase, including data from a minimum of five batches using the method described; - a method to determine the identity for cellulase, including data from a minimum of five batches using the method described; - a non-proprietary method to determine the identity and activity for xylanase that can be used by control laboratories, and data from a minimum of five batches using the method described. The above-requested information should be submitted by December 2016 in order for the tentative specifications to be revised; failure to provide this information may lead to a withdrawal of the specifications, with a possible impact on the ADI.</td>
<td>Note the JECFA conclusion on an ADI “not specified” for the mixed β-glucanase, cellulase and xylanase enzyme preparation from <em>R. emersonii</em> when used in the applications specified and in accordance with GMP. <strong>No action required</strong> as the new specifications is tentative. Note the JECFA request for information to complete to revise the tentative specifications</td>
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<td>Mixed β-glucanase and xylanase from <em>Disporotrichum dimorphosporum</em></td>
<td>No treatment-related adverse effects were seen at the highest dose tested (199 mg TOS/kg bw per day) in a 13-week study of oral toxicity in rats. A comparison of the dietary exposure estimate of 0.7 mg TOS/kg bw per day (for a 60 kg individual) with the highest dose tested of 199 mg TOS/kg bw per day gives an MOE of at least 280.</td>
<td>Note the JECFA conclusion on an ADI “not specified” for the mixed β-glucanase and xylanase enzyme preparation from <em>D. dimorphosporum</em> when used in the applications specified and in accordance with GMP. <strong>No action required</strong> as the new specifications is tentative. Note the JECFA request for information to complete to revise the tentative specifications</td>
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<tr>
<td>INS Num</td>
<td>Food Additive Name</td>
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<td>Recommended Action by CCFA</td>
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<td>The 80th JECFA established an ADI “not specified” for the mixed β-glucanase and xylanase enzyme preparation from D. dimorphosphorum when used in the applications specified and in accordance with good manufacturing practice.</td>
<td>with GMP.</td>
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<td>New tentative specifications were prepared, with a request for the following information:</td>
<td>No action required as the new specifications is tentative.</td>
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<td>- a method to determine the identity for β-glucanase, including data from a minimum of five batches using the method described;</td>
<td>Note the JECFA request for information to complete to revise the tentative specifications.</td>
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<td>- a non-proprietary method to determine the identity and activity for xylanase that can be used by control laboratories, and data from a minimum of five batches using the method described.</td>
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<td>The above-requested information should be submitted by December 2016 in order for the tentative specifications to be revised; failure to provide this information may lead to a withdrawal of the specifications, with a possible impact on the ADI.</td>
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<td>1209</td>
<td>Polyvinyl alcohol (PVA) – polyethylene glycol (PEG) graft copolymer</td>
<td>On the basis of the available studies, in which no treatment-related effects were seen at the highest doses tested, the 80th JECFA considered PVA-PEG graft copolymer to be a substance of low oral toxicity in rats, rabbits and dogs.</td>
<td>Note the JECFA conclusion on the use of PVA-PEG graft co-polymer that complies with the specifications established at the current meeting is not of safety concern when the food additive is used as a glazing agent (aqueous film coating), stabilizer and binder for tablets in the preparation and formulation of food supplements and consider to:</td>
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<td>The bioavailability of PVA-PEG graft copolymer in rats is negligible, and PVA-PEG graft copolymer is unlikely to be genotoxic and is not associated with reproductive or developmental toxicity.</td>
<td>- Request comments and proposals on the use level of Polyvinyl alcohol (PVA) – polyethylene glycol (PEG) graft copolymers (INS 1209) for use as a glazing agent (aqueous film coating), stabilizer and binder only in food category for tablets in the preparation and formulation of food supplements and in accordance with good manufacturing practice in food category 13.6 Food supplement of GSFA.</td>
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<td>Therefore, the 80th JECFA concluded that calculation of an MOE for PVAPEG graft copolymer would not be meaningful. Based on these data, the Committee would normally establish an ADI “not specified”.</td>
<td><strong>U.S. Position:</strong> INS 1209 is currently only listed in the INS list under the Functional Class of Glazing agent. See U.S. position under Agenda Item 7(a). Requests for new provisions for INS 1209 should be called for as part of the circular letter</td>
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<td>However, the 80th JECFA decided not to establish an ADI “not specified” for PVAPEG graft copolymer in view of the impurities present, some of which may also be impurities in other food additives.</td>
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<td>The 80th JECFA had concerns that establishing an ADI “not specified” could lead to additional uses beyond those considered at the current meeting and consequently could increase exposure to the impurities.</td>
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<td>The use of PVA-PEG graft co-polymer that complies with the proposed specifications could lead to a dietary exposure to ethylene glycol and diethylene glycol from both food supplements and pharmaceutical products up to 0.016 mg/kg bw per day for children (high consumers).</td>
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<td>This is 3% of the tolerable daily intake (TDI) of 0.5 mg/kg bw per day derived by the Scientific Committee on Food of the European Union, and therefore the exposure to ethylene glycol and diethylene glycol from the use of PVAPEG graft co-polymer that complies with the specifications established at the current meeting is not of safety concern when the food additive is used in the applications specified. The use of PVA-PEG graft co-polymer</td>
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</tbody>
</table>

**Note:** The Table above provides a summary of the food additive and its specifications as discussed in the 80th JECFA meeting. The recommendations and actions are based on the scientific evaluations and considerations at that meeting. Further updates or clarifications may be needed as part of the regulatory processes.
that complies with the proposed specifications could lead to a
dietary exposure to vinyl acetate from both food supplements and
pharmaceutical products up to 0.0008 mg/kg bw per day for
children. This dietary exposure estimate is at least 62,500 times
lower than the dose levels at which increases in tumour incidence
are observed in oral studies of long term toxicity and
carcinogenicity in rats and mice. Therefore, the dietary exposure
to vinyl acetate from the use of PVA-PEG graft co-polymer that
complies with the specifications established at the current
meeting is not of safety concern when the food additive is used in
the applications specified.

The 80th JECFA concluded that the use of PVA-PEG graft co-
polymer that complies with the specifications established at the
current meeting is not of safety concern when the food additive is
used as a glazing agent (aqueous film coating), stabilizer and
binder for tablets in the preparation and formulation of food
supplements and in accordance with good manufacturing
practice.

The above-requested information should be submitted by
December 2016 in order for the tentative specifications to be
revised; failure to provide this information may lead to a
withdrawal of the specifications, with a possible impact on the

<table>
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<tr>
<th>INS Num</th>
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</thead>
</table>
| 551     | Silicon dioxide, amorphous | Prepared at the 80th JECFA and published in FAO JECFA Monographs 17 (2015), superseding tentative specifications prepared at the 77th JECFA (2013) and published in FAO JECFA Monographs 14 (2013). An ADI ‘not specified’ for silicon dioxide and certain silicates was established at the 29th JECFA (1985). Revised tentative specifications were prepared, with a request for the following information:
- Raw materials used and methods of manufacture for different forms of silicon dioxide (pyrogenic silica, precipitated silica, hydrated silica, silica aerogel and colloidal silica)
- Identification methods allowing the differentiation between the above forms of silicon dioxide - Functional uses of different forms, and information on the types of products in which it is used and the use levels in these products
- Data on solubility using the procedure documented in “Compendium of Food Additives Specifications, Vol.4, Analytical methods”
- Data on the impurities soluble in 0.5 M hydrochloric acid for all forms of silicon dioxide used as food additives, from a minimum of five batches. If a different extraction and determination method is used, provide data along with details of method and QC data.
- Suitability of the analytical method for the determination of aluminium, silicon and sodium using the proposed “Method of assay” along with data, from a minimum of five batches. If a different method is used, provide data along with details of the method and QC data.
- In addition to the above information, data on pH, loss on drying and loss on ignition for hydrated silica, silica aerogel and colloidal silica.

The above-requested information should be submitted by December 2016 in order for the tentative specifications to be revised; failure to provide this information may lead to a withdrawal of the specifications, with a possible impact on the new specifications is tentative.

No action required as the new specifications is tentative.
Note the JECFA request for information to complete to revise the tentative specifications.
### Background


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<tr>
<th>Agenda Item</th>
<th>Subject Matter</th>
<th>Document Reference</th>
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<tbody>
<tr>
<td>3(b)</td>
<td>Proposed Draft Specifications for the Identity and Purity of Food Additives Arising from the 80th JECFA Meeting</td>
<td>CX/FA 16/48/4</td>
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<tr>
<td></td>
<td>Comments at Step 3</td>
<td>CX/FA 16/48/4 Add. 1</td>
</tr>
</tbody>
</table>

### Information

The U.S. did not provide comments to CX/FA 16/48/14

Food additive specifications designated as “Full” for adoption by Codex
A total of 8 specifications were designated as “Full” by the 80th JECFA for adoption by Codex
• Advantame (Revised spec) (INS 969)
• Annatto extracts (solvent-extracted bixin) (Revised spec) (INS 160b(i))
• Annatto extracts (solvent-extracted norbixin) (Revises spec) (INS 160b(ii))
• Calcium silicate (Revised spec) (INS 552)
• Lipase from *Fusarium heterosporum* expressed in *Ogataea polymorpha* (New spec) (INS 1104)
• Magnesium stearate (New spec) (INS 470(iii))
• Maltotetraohydrolase from *Pseudomonas stutzeri* expressed in *Bacillus licheniformis* (New spec)
• Polyvinyl alcohol (PVA)-polyethylene glycol (PEG) graft co-polymer (New spec) (INS 1209)

**U.S. POSITION**
The U.S. can **support** the adoption of these specifications by Codex.

**Food additive specifications that were withdrawn at the 80th JECFA**

- Recommended for revocation of Codex specifications
  - Aluminium silicate (INS 559)
  - Calcium aluminium silicate (INS 556)
- Removed from JECFA database (were never adopted by Codex)
  - Glycerol ester of gum rosin (INS 445(ii))

**U.S. POSITION**
The U.S. can **support** the revocation of the two adopted Codex specifications.

In addition, four specifications were identified as “Tentative” until additional information is provided to JECFA

- Mixed β-glucanase and xylanase from *Disporotrichum dimorphosphorum* (N)
- Mixed β-glucanase, cellulase and xylanase from *Rasamsonia emersonii* (N)
- Silicon dioxide, amorphous (R) (INS 551)
- Sodium aluminium silicate (R) (INS 554)

**Background**


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<tr>
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<th>Subject Matter</th>
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<tr>
<td>4(a)</td>
<td>Endorsement and/or Revision of Maximum Levels for Food Additives and Processing Aids in Codex Standards</td>
<td>CX/FA 16/48/5</td>
</tr>
</tbody>
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**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.


**U.S. POSITION - SPECIFIC COMMODITY STANDARDS**

**CODEX COMMODITY COMMITTEE ON SPICES AND CULINARY HERBS (CCSCH)**

**Proposed Draft Standard for Thyme (REP 16/SCH, Appendix IV)**

- The Scope of the draft standard indicates that thyme is for use as a condiment (REP 16/SCH, Appendix IV, Section 1: (“This Standard applies to dried leaves/flowers of thyme (Thymus spp.) of the Lamiaceae family offered for industrial food production as a condiment and for direct human consumption or for repackaging if required. [It does not apply to the product when indicated as being intended for further processing.]”)
- Although described for use as a “condiment” in the commodity standard, the description fits the definition of an “herb” in the GSFA (“Herbs and spices are usually derived from botanical sources, and may be dehydrated, and either ground or whole. Examples of herbs include basil, oregano and thyme. . . .”) Herbs and spices are included in food category 12.2.1.
- Food category 12.2.1 is listed in the Annex to Table 3 of the GSFA, and excludes spices. Therefore, any uses of food additives in herbs must be specifically listed in Tables 1 and 2 of the GSFA.
- CCSCH did not provide justification for restricting the use of anticaking agents in ground/powdered thyme to those listed (REP16/SCH para. 34(g))
- Microcrystalline cellulose (INS 460(i)) and powdered cellulose (INS 460(ii)) are listed in Table 3 of the GSFA. However, they are not currently listed in Tables 1 and 2 of the GSFA in food category 12.2.1.
- Silicon dioxide, amorphous (INS 551) is included in Table 3 of the GSFA, and currently has a proposed draft provision (Step 4) listed in Tables 1 and 2 of the GSFA in food category 12.2.1 for use at GMP with Note 51 (“For use in herbs only.”).
- The U.S. notes that a technological justification for limiting the use of anticaking agents in ground/powdered thyme to those three additives proposed was not provided by CCSCH.
  - The GSFA is intended to be the single Codex reference for food additives. The Procedural Manual is clear that 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. (see General Comment, above)
  - Therefore, **CCSCH should be requested to provide a technological justification for limiting the anticaking agents to those in the proposed draft standard.**
- However, the U.S. **would not object** to the endorsement of the additives in the proposed draft standard.

**Background**

Document CX/FA 16/48/5 compiles food additive and processing aid provisions in draft and proposed draft commodity standards submitted by various Codex Committees to the CCFA for endorsement.

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<td>4(b)</td>
<td>Alignment of the Food Additive Provisions of Commodity Standards and Relevant Provisions of the GSFA</td>
<td>CX/FA 16/48/6</td>
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The U.S. participated in the eWG.

**U.S. POSITION**

**Appendix 1 – Decision Tree**
For information only. No action required.

**Appendix 2 – Explanatory Document on Chocolate and Cocoa Standards**

**A. Key Individual Issues**

1. **Proposed Amendments to the GSFA for Polysorbates in Food Category 05.1.4**

*Chair’s Proposal*

- The U.S. **supports** the proposals to:
  - Maintain the current level in the GSFA (5000 mg/kg)
  - Amend Note 101 (see **Outstanding Issue #1**)
  - Not refer to the commodity standard because there is a 1-to-1 correspondence between the commodity standard and food category 05.1.4

*Outstanding Issue #1*

- The U.S. **supports** the proposal to expand New Note 101 to include all polysorbates in the group. This is consistent with the approach for other group additives that perform the same functional effect.
- The U.S. **supports** the proposed wording for New Note 101 as presented in Appendix 2 (“When used in combination as emulsifiers: ammonium salts of phosphatidic acid (INS 442), polyglycerol esters of interesterified ricinoleic acid (INS 476), sorbitan monostearate (INS 491), sorbitan tristearate (INS 492), and polysorbates (polyoxyethylene (20) sorbitan monolaurate (INS 432), polyoxyethylene (20) sorbitan monooleate (INS 433), polyoxyethylene (2) sorbitan monostearate (INS 435) and polyoxyethylene (20) sorbitan tristearate (INS 436)), the total combined use level shall not exceed 15,000 mg/kg.”)
- The U.S. **notes** that the text of New Note 101 in Appendix 4 for food category 05.1.4 would need to be revised to reflect the text presented in Appendix 2, Part A, Point 1.

2. **Inclusion of a Section on Carry-Over in CXS 87-1981**

- The U.S. **supports** the Chair’s proposal. The carry-over principle is adequately addressed in the Preamble to the GSFA.

3. **Amendments Relating to Food Category 05.1.1**

- The U.S. **supports** the Chair’s proposal that:
  - There is a 1-to-1 correspondence between food category 05.1.1 and CXS 105-1981 and 141-1983
  - Consequently, there is no need to include New Note 97 (“On the final cocoa and chocolate basis in products conforming to the *Standard for Cocoa Powders (Cocoss) and Dry Mixtures of Cocoa and Sugars* (CODEX STAN 105-1981).”) and Note 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).”) [New Note 97 and Note MM appear in CX/FA 17/47/6, Appendix 5, Part 2C]
  - The current Note 97 (“On the final cocoa and chocolate product basis.”) should be retained because there is no need to specifically refer to the commodity standards (as in New Note 97 and Note MM) when there is a 1-to-1 correspondence between the food category and the commodity standards

4. **Inclusion of Provisions for Group Additives Compared to Single Additives**

- The U.S. **supports** the Chair’s proposal that:
  - The listing of the group “Tartrates” instead of the individual L(+)-Tartaric acid in food categories 05.1.1 and 05.1.4, with the consequence that Note EE (“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 Powders (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).” and Note FF (“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.”) are not necessary since they refer only to L(+)-tartaric acid. [Notes EE and FF were contained in the 2nd circular of the eWG for the 48th CCFA]

- This approach is consistent with the group permissions for other additives (including for polysorbates in food category 05.1.4; see Appendix 2, Part A1, above; and phosphates in food categories 05.1.1 and 05.1.4)

5. Amendments Relating to Food Category 05.1.4
- The U.S. supports the Chair’s proposal, since there is a 1-to-1 correspondence between food category 05.1.4 and CXS 87-1981

6. GMP Food Additives in Commodity Standards and Entries in Table 3 of the GSFA

- The U.S. supports the Chair’s proposal:
  - CXS 105-1981 should be added to Table 3 for the 3 silicates (silicon dioxide, amorphous (INS 551), calcium silicate (INS 552), and magnesium silicate, synthetic (INS 553(i))
  - Beeswax (INS 901), candelilla wax (INS 903), and shellac, bleached (INS 904) should not be included in Table 3 because they do not meet the criteria:
    - These 3 additives have been assigned JECFA ADIs that are acceptable for specific uses only
    - Additives in Table 3 have been assigned JECFA ADIs of “not specified” or “not limited” for general use in food at *quantum satis* levels and in accordance with GMP

Outstanding Issue #2
- The U.S. does NOT support including beeswax (INS 901), candelilla wax (INS 903), and shellac, bleached (INS 904) in Table 3 (even with the qualifier “for use as a glazing agent in surface treatment only”), since these additives do not meet the criteria for inclusion in Table 3
  - Additives with JECFA ADIs that are acceptable for specific uses only are not the same as those that have been assigned JECFA ADIs of “not specified” or “not limited”
  - The latter are intended for use in food generally, while the former have uses in specific foods, and as such, have more in common with additives that have been assigned numerical JECFA ADIs (i.e., they have uses in specific foods). Therefore, additives with JECFA ADIs that are acceptable for specific uses only should continue to be listed only in Tables 1 and 2 of the GSFA, and not listed in Table 3.

- The U.S. supports the Chair’s proposal regarding the proposed wording

8. Amendments to New Note AA (Food Category 05.0)
- The U.S. supports the Chair’s proposal to amend Note AA to New Note AA (“Excluding products conforming to the *Standard for Chocolate and Chocolate Products* (CODEX STAN 87-1981) except for white chocolate, where ascorbyl palmitate (INS 304) may be used only as an antioxidant at 200 mg/kg calculated on a fat content basis.”) to incorporate the editorial changes

9. Amendments to CXS 87-1981 Regarding Vanillin and Ethyl Vanillin
- The U.S. supports the Chair’s proposal that there is no need to consider the amendments, as they have been addressed in Appendix 2, Part A, Point 7, above.

B. Explanation of Amendments that Have Not Been Incorporated
The U.S. supports the explanation. No action is required.

Appendix 3 – Proposed Amendments to the Food Additive Provisions of the Chocolate and Cocoa Standards

A. Standard for Cocoa Butter (CXS 86-1981)
The U.S. supports the proposed amendments

B. Standard for Chocolate and Chocolate Products (CXS 87-1981)
The U.S. supports the proposed amendments

C. Standard for Cocoa (Cacao) Mass (Cocoa/Chocolate Liquor) and Cocoa Cake (CXS 141-1983)
The U.S. supports the proposed amendments

D. Standard for Cocoa Powders (Cocoas) and Dry Mixtures of Cocoa and Sugars (CXS 105-1981)
The U.S. supports the proposed amendments

Appendix 4 – Proposed Amendments to Tables 1, 2 and 3 of the GSFA Regarding the Chocolate and Cocoa Standards

A. Food Category 05.0
The U.S. supports the proposed amendments

B. Food Category 05.1
The U.S. supports the proposed amendments

C. Food Category 05.1.1 (CXS 105-1981 and 141-1983)
The U.S. supports the proposed amendments

D. Food Category 05.1.3 (CXS 86-1981)
The U.S. supports the proposed amendments

E. Food Category 05.1.4 (CXS 87-1981)
The U.S. supports the proposed amendments

Appendix 5 – Background Document on the Alignment of the Commodity Standards Identified by CCFFP and CCPFV

The U.S. supports the explanation. No action is required.

Appendix 6 – Proposed Amendments to Tables 1, 2, and 3 of the GSFA Regarding the Commodity Standards Identified by CCFFP and CCPFV

I. CCFFP
The U.S. supports the proposed amendments and New Note 22 (“For use in non-standardized smoked fish products only.”)

II. CCPFV

A. Standard for Canned Citrus Fruits (CXS 254-2007)
The U.S. supports the proposed amendments
B. Standards for Preserved Tomatoes (CXS 13-1981) and for Processed Tomato Concentrates (CXS 57-1981)

- The U.S. supports the proposed amendments
- Section 2 of the Annex to Table 3: Although not within the scope of the eWG, the U.S. supports the proposed additions to ensure complete alignment between the commodity standards and the GSFA
- Consequential Changes to Table 3: The U.S. supports the proposed changes
- Food Additive Section of Commodity Standards: The U.S. supports the proposed replacement of the list of specific additives in the commodity standards with a reference to the GSFA, with the concurrence of CCPFV

C. Standard for Table Olives (CXS 66-1981)

The U.S. supports the proposed amendments

**Background**

Document CX/FA 16/48/6 presents the report of the eWG (led by Australia and co-chaired by the USA) that was tasked to: (i) further develop the alignment of the Standards for Cocoa Butter (CODEX STAN 86-1981); Chocolate and Chocolate Products (CODEX STAN 87-1981); Cocoa Powders (Cocoas) and Dry Mixtures of Cocoa and Sugars (CODEX STAN 105-1981); and Cocoa (Cacao) Mass (Cocoa/Chocolate Liquor) and Cocoa Cake (CODEX STAN 141-1983); (ii) consider the food additive provision in the GSFA, that according the CCFFP, are not technologically justified in the products covered by the Standard for Smoked Fish, Smoked-Flavoured Fish and Smoke-Dried Fish (CODEX STAN 311-2013); and (iii) consider the food additive provisions in the GSFA that, according to the CCPFV, are not technologically justified in specific food categories covered by the Standards for Certain Canned Citrus Fruits (CODEX STAN 254-2003), for Preserved Tomatoes (CODEX STAN 13-1981), for Processed Tomato Concentrates (CODEX STAN 57-1981), and for Table Olives (CODEX STAN 66-1981). (REP 15/FA, para. 58(ii))

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<td>Codex General Standard on Food Additives (GSFA)</td>
<td>CX/FA 16/48/8</td>
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<td>5(a)</td>
<td>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 (Outstanding from CCFA47)</td>
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**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 U.S. (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).

<table>
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<tr>
<th>Additive</th>
<th>INS No.</th>
<th>U.S. Technical Function</th>
<th>U.S. Max use level</th>
<th>U.S. Food Category</th>
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<tr>
<td>ADIPATES</td>
<td>355, 356, 357, 359</td>
<td>Acidity Regulator, Leavening Agent</td>
<td>200 mg/kg</td>
<td>Foods in General</td>
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<tr>
<td>CALCIUM ASCORBATE</td>
<td>302</td>
<td>Preservative</td>
<td>GMP</td>
<td>Foods in General</td>
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<tr>
<td>ERYTHORBIC ACID (ISOASCORBIC ACID)</td>
<td>315</td>
<td>Preservative</td>
<td>GMP</td>
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<td>637</td>
<td>Flavour Enhancer</td>
<td>GMP</td>
<td>Foods in General</td>
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<td>GLYCEROL</td>
<td>422</td>
<td>Multipurpose</td>
<td>GMP</td>
<td>Foods in General</td>
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<td>MALTOL</td>
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<td>GMP</td>
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<td>POLYDIMETHYLXANES</td>
<td>900a</td>
<td>Defoaming Agent</td>
<td>10 mg/kg</td>
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<td>POLYGLYCEROL</td>
<td>475</td>
<td>Emulsifier</td>
<td>GMP</td>
<td>Foods in General</td>
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</table>
The following additives are not regulated for use in the U.S. The U.S. will remain silent for any provisions specific to these food additives.

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

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

### Background

Document CX/FA 16/48/7 reproduces the report of the eWG (led by the U.S.) from the 47th CCFA 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 (REP 14/FA, paras. 103 and 104) that were not discussed at the 47th Session. (REP 15/FA para. 75)
**U.S. POSITION**
The US can support the use of nisin in FC 08.3.2 at levels up to 5.5 mg/kg in ready-to-eat products that require refrigeration.

**Background**
Document CX/FA 16/48/8 presents the report of the eWG (led by the U.S.) that was tasked with requesting information on the use of nisin in food category 08.3.2 in general, and specifically in products conforming to the corresponding commodity standards, and to prepare proposals based on the information received. (REP 15/FA, paras. 84 and 116)

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<td>5(c)</td>
<td>Proposed Draft Provision for Quillaia Extracts (INS 999(i), (ii)) in Food Category 14.1.4</td>
<td>CX/FA 16/48/9</td>
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<td>Comments at Step 3 (Replies to CL 2015/9-FA, Part B, Point 7)</td>
<td>CX/FA 16/48/9 Add. 1</td>
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**U.S. POSITION**
Several countries submitted comments in support of Chile’s request to remove Note 168 (“Quillaia extract Type 1 (INS 999(i)) only”) from the currently adopted provision for Quillaia Extracts (Types I and II) in FC 14.1.4 of the GSFA.

The U.S. does not oppose the removal of Note 168 (which would allow the use of Quillaia Extracts (Type II) in FC 14.1.4). However, only Quillaia extracts Type I have regulatory status in the U.S. (GRN 165). Thus, the U.S. should remain silent on this issue.

**Background**
Document CX/FA 16/48/9 agreed to the proposal of the Delegation of Chile to circulate for comments at Step 3 and consideration at the 48th Session the revision of the provision for quillaia extracts (INS 999(i), (ii)) in food category 14.1.4 (Water-based flavoured drinks, including “sport,” “energy,” or “electrolyte” drinks and particulated drinks). The proposal aimed at allowing the use of both quillaia extract Type 1 and Type 2 by deleting Note 168 (“Quillaia extract Type 1 (INS 999(i)) only.”). (REP 15/FA, para. 103)

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<td>5(d)</td>
<td>Uses and Use Levels of Paprika Extract (INS 160c(ii)) (Replies to CL 2015/9-FA, Part C, Point 8)</td>
<td>CX/FA 16/48/10</td>
</tr>
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</table>

**U.S. POSITION**
• The U.S. supports the Uses and Use Levels of Paprika Extract INS 160c(ii).

**U.S. POSITION – SPECIFIC COMMENTS**
• Paprika extract is known in the U.S. as *Paprika oleoresin* and is defined in 21 CFR §73.345 for use as a color additive.

• Two proposals (use and use level of Paprika extract) were submitted in response to CL 2015/12-FA and are included in CX/FA 16/48/10 from the International Association of Color Manufacturers (IACM) and from the Natural Food Colours Association (NATCOL).

• The two proposals indicate a variation in the use levels. The U.S. **recommends** the maximum use levels as determined from a comparison between IACM and NATCOL to be used to define the use of Paprika extract as a color additive.

**Background**

Document CX/FA 16/48/10 presents comments and proposals on the uses and use levels of paprika extracts (INS 160c(ii)), which was assigned an ADI of 1.5 mg/kg bw, expressed as total carotenoids, for use as a food color, by the 79th JECFA. (REP 15/FA, para. 29)

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<td>5(e)</td>
<td>Proposals for New and/or Revision of Food Additive Provisions (Replies to CL 2015/12-FA)</td>
<td>CX/FA 16/48/11</td>
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</table>

**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 2015/12-FA.

**U.S. POSITION – SPECIFIC COMMENTS**

• IADSA (International Alliance of Dietary/Food Supplements Associations) for Polyvinyl alcohol (PVA)-polyethylene glycol (PEG) graft co-polymer (INS 1209) for use as a binder and stabilizer. The U.S. notes that the technological purpose of binder and stabilizer is not associated with INS 1209 in CAC/GL 36-1989.

**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. The 47th CCFA discussed improvements to the form, which is for internal use by CCFA (REP 15/FA, paras. 108-112). Proposals submitted in response to CL 2015/12-FA are included in CX/FA 16/48/11.

• The following comments were submitted:
  o Japan for *Advantame* (INS 969).
  o Russian Federation provided comments on the food additive Nisin (INS 234) for use as a preservative. The proposal for removing existing provisions for Nision from the GSFA.
  o Cefic (European Chemical Industry Council) for *Magnesium Stearate* (INS 470(iii)).
  o IADSA (International Alliance of Dietary/Food Supplements Associations) for Polyvinyl alcohol (PVA)-polyethylene glycol (PEG) graft co-polymer (INS 1209).
  o International Special Dietary Foods Industries (ISDI) for Carrageenan (INS 407)
  o ISDI (International Special Dietary Foods Industries) for *Citric and fatty acid esters of glycerol* (INS 472c)
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-o ISDI for Starch sodium octenyl succinate (INS 1450)

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<td>5(f)</td>
<td>Proposed Draft Revision of Food Category 01.1 (Milk and dairy-based drinks) and Its Sub-Categories</td>
<td>CX/FA 16/48/12</td>
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<tr>
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<td>Comments at Step 3</td>
<td>CX/FA 16/48/12 Add. 1</td>
</tr>
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</table>

The U.S. participated in the eWG.

U.S. POSITION

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

U.S. POSITION – SPECIFIC COMMENTS

- **Proposed Revisions to the Food Category System (FCS)**
  - Food Category 01.0
    - The U.S. supports the proposed revised title and descriptor for FC 01.0.
  - Food Category 01.1
    - The U.S. supports the proposed revised title for FC 01.1.
    - However, the U.S. recommends an additional edit (strikethrough text) to the descriptor as follows:
      
      *Includes all plain and flavoured fluid milks that are based on skim, part-skim, low-fat and whole milk, excluding plain fermented products and plain renneted milk products of FC 01.2. Plain Fluid milks are “milk products” as defined in CODEX STAN 206-1999, are obtained by the processing of milk, and may contain food additives and other ingredients functionally necessary for processing. Raw milk (“milk” as defined in CODEX STAN 206-1999) shall not contain any food additives.*

      ➢ The reasoning for this edit is that the subcategories of FC 01.1 include both plain and flavored fluid milks. Furthermore, the Codex General Standard for the Use of Dairy Terms (CODEX STAN 206-1999) discusses both plain and flavoured products as milk products (see Section 4.5)).

  - Food Category 01.1.1
    - The U.S. supports the proposed revised title and descriptor for FC 01.1.1.
    - The U.S. supports maintaining the phrase “includes skim, part-skim, low-fat and whole milk.” in the descriptor for FC 01.1.1
      - The U.S. notes that skim, part-skim, low-fat, and whole milk are commonly used internationally and are recognized by consumers; thus, they should be included in the descriptor.

  - Food Category 01.1.2
    - The U.S. supports the proposed revised title in FC 01.1.2.
    - However, the U.S. recommends an additional edit (underlined text) to the descriptor for FC 01.1.2 as follows:
Includes all plain fluid milk, excluding products of food categories 01.1.1 (Fluid milk (plain)), 01.1.3 (Buttermilk (plain)), and 01.2 (Fermented and renneted milk products (plain)). Includes plain recombined fluid milks, plain reconstituted fluid milks, plain composite fluid milks, non-flavoured vitamin and mineral fortified fluid milks, lactose reduced milk products, plain milk product with modified organoleptic properties, and plain milk-based beverages.

- It is the understanding of the U.S. that this FC is intended to include all plain fluid milks that are not included in food categories 01.1.1, 01.1.3, and 01.2. It is the opinion of the U.S. that the examples in the descriptor should include not only “plain reconstituted fluid milks” and “plain recombined fluid milks,” but also include “plain composite fluid milk” so as to include all of the milk product terms from CODEX STAN 206-1999.

- **Food Category 01.1.3**
  - The U.S. supports the title and descriptor for FC 01.1.3.

- **Food Category 01.1.4**
  - The U.S. supports the title for FC 01.1.4.
  - The U.S. supports the majority of the proposed revised descriptor. However, we note that the proposed descriptor removes mixes from the scope of this FC. It is the opinion of the U.S. that FC 01.1.4 should include both mixes and ready-to-drink products.
  - The U.S. proposes that if there is any technological need to limit the use of a food additive to mixes only this can be done by attaching the Note “for use in mixes only” to the provision for that additive.
  - For the reasons given above, the U.S. recommends that mixes be added back to the descriptor for FC 01.1.4. The edit is presented below as underlined text:

  Includes all mixes and ready-to-drink fermented or not fermented flavoured and aromatized milk-based fluid beverages with flavourings and food ingredients that impart flavour, excluding mixes for cocoa (cocoa-sugar mixtures, category 05.1.1). Examples include hot chocolate, chocolate malt drinks, strawberry-flavoured yoghurt drink, lactic acid bacteria drinks, and lassi (liquid obtained by whipping curd from the lactic acid fermentation of milk, and mixing with sugar or synthetic sweetener).

  - The reasoning for this edit is that the subcategory of FC 01.1.4 is intended to replace the current FC 01.1.2 in the FCS. The descriptor for the current FC 01.1.2 includes both mixes and ready-to-drink products. If mixes are removed from the scope of FC 01.1.4, these mixes will not be included within the FCS.

- **Consequential Changes to the Titles and/or Descriptors of Certain Food Categories Based on the Above Revised Proposal**

- **Food Category 01.2**
  - It is the concern of the U.S. that the revisions proposed in CX/FA 16/48/12 do not account for plain drinks based on fermented milk. It is the opinion of the US that plain drinks based on fermented milk are included in the subcategories of FC 01.2. The U.S. proposes that text for plain drinks based on fermented milk be included in the descriptors for subcategories of FC 01.2. The proposed edits to the descriptors of these subcategories is presented below as underlined text:

    Food Category 01.2.1 (Fermented milks (plain))

1 Flavoured drinks based on fermented milk are included in the new FC 01.1.4.
Includes all plain products, including fluid fermented milk, acidified milk and cultured milk. Plain yoghurt and plain drinks based on fermented milk, 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 Category 01.2.1.1 (*Fermented milks (plain), not heat treated after fermentation*)

 Includes fluid and non-fluid plain products, such as yoghurt and plain drinks based on fermented milk.

- The above recommendations would be in agreement with Section 4 of CODEX STAN 243-2003, which specifies that “plain drinks based on fermented milk” and “plain fermented milks” share the same set of food additives while “plain drinks based on fermented milk (heat treated) and “plain fermented milks (heat treated)” also share the same set of additives. As such, plain drinks based on fermented milks can be included in the subcategories of FC 01.2 without any change to the existing food additive provisions in those food categories.

- **Consequential Revisions to the Annex to Table Three of the GSFA**

  - The U.S. supports the consequential changes to the Annex to Table Three of the GSFA as a result of the proposed revisions to FC 01.0.

- **Consequential Changes to the GSFA Annex C**

  - The U.S. does not support the revision to Annex C of the GSFA as proposed in CX/FA 16/48/2. The proposed revision would imply that plain drinks based on fermented milk are included in FC 01.1.4. It is not appropriate to include plain products in a FC intended to include flavoured products. The United States recommends further revision to Annex C of the GSFA with proposed edits in underlined text:

<table>
<thead>
<tr>
<th>Standard No</th>
<th>Codex Standard Title</th>
<th>Food Cat. No</th>
</tr>
</thead>
<tbody>
<tr>
<td>243-2003</td>
<td>Fermented milks (drinks based on fermented milk, plain or flavoured, heat treated or not heat treated)</td>
<td>01.1.2 01.1.4</td>
</tr>
</tbody>
</table>

**Background**

Document CX/FA 15/47/12 presents the report of the eWG (led by New Zealand) that was tasked with preparing a proposed draft revision of the food category 01.1 (Milk and dairy-based drinks) and its sub-categories, for circulation for comments at Step 3 and consideration at the 48th Session. (REP 15/FA, para. 92)

<table>
<thead>
<tr>
<th>Agenda Item</th>
<th>Subject Matter</th>
<th>Document Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>5(g)</td>
<td>Codex General Standard on Food Additives (GSFA)</td>
<td>CX/FA 16/48/13</td>
</tr>
<tr>
<td>5(g)</td>
<td>Discussion Paper on the Use of Specific Food Additives in the Production of Wine</td>
<td>CX/FA 16/48/13</td>
</tr>
</tbody>
</table>

The U.S. participated in the eWG.

**U.S. POSITION**

Recommendation 1:
• The US notes that the discussion in Recommendation 1 deals with additives for which JECFA recommends no numerical Acceptable Daily Intake (ADI).
• The US notes that the wording for the footnote provided in Recommendation 1 may be interpreted by some readers to imply that JECFA has expertise in wine-making practices. The US can support the note if it is revised to clarify that JECFA’s expertise are in the area of risk assessment. The U.S. proposes the following revision to the note (bold text):

“The maximum level of the additive in grape wine set as good manufacturing practice must prevent (i) the modification of the natural and essential characteristics of the wine and (ii) a substantial change in the composition of the wine. Countries may seek guidance on GMP from internationally recognized bodies with expertise in oenological practices or risk assessment, such as the International Organization of Vine and Wine (OIV, which recommends conditions for use for additives in wines) and the Joint FAO/WHO Expert Committee on Food Additives (JECFA, which assess food additives for their safety and recommends specification for those additives).”

Recommendation 2:
• The U.S. supports recommendation 2 (a) through (g).
• The US requests that fumaric acid (INS 297) also be included under Recommendation 2 for adoption in FC 14.2.3 with the technological function “acidity regulator” at GMP with the footnote proposed in Recommendation 1.
  o Fumaric acid is a Table 3 additive (i.e., has a non-numerical JECFA ADI) with the functional effect of acidity regulator. Fumaric acid currently has a provision at step 7 for use in FC 14.2.3. This provision has been discussed by the eWG on wine for the past several CCFA meetings. All arguments presented in CX/FA 16/48/13 in support of Recommendation 2 (a) through (g) also apply to fumaric acid.
• Fumaric acid is naturally occurring in grapes, yeast, bacteria, etc. as it is part of the Krebs cycle.
• It is used as an acidity regulator in the U.S. and wines treated with fumaric acid are imported into Argentina, Australia, Canada, Chile, Georgia, EU, New Zealand, and South Africa, and other countries.
• Its use in wines is covered by the 2006 U.S./EU Wine Agreement.
• The U.S. notes that calcium sulfate (INS 516) is not included under Recommendation 2.
  o Calcium sulfate is a Table 3 additive (i.e., has a non-numerical JECFA ADI) with functional effects that include acidity regulator and stabilizer. Calcium sulfate currently has a provision at step 7 for use in FC 14.2.3.3 (Fortified grape wine, grape liquor wine, and sweet grape wine).

Background
Document CX/FA 16/48/14 presents the report of the eWG (led by France and co-chaired by Australia) that was established with the following terms of reference: In the context of the general use of emulsifiers, stabilizers, thickeners, acidity regulators, and antioxidants in the production of wine to: (a) provide clarity and specificity on the general concerns of wine identity, wine stability, global applicability of limitation for the use of food additives in wine, and innovation in wine production; and (b) based on the outcome of point (a), perform an examination of the effect of expressing a maximum use level of additives in wine on a numerical basis and as GMP. The eWG was not to examine specific provisions (REP 15/FA, para. 78)
The U.S. participated in the INS eWG and submitted comments to CX/FA 16/48/14.

**U.S. POSITION**

Table 1: Modification of an existing INS name or new INS number purpose

**Colours**

Three colors were put forward in Table 1 of CX/FA 16/48/14 for inclusion in the INS

- Spirulina extract (INS 134)
- Purple sweet potato colour (INS 163(vii))
- Red radish colour (INS 163(viii))

The U.S. **supports** the inclusion in the INS of the three colours and their proposed INS numbers.

**Proteases**

- The request to consider revisions to Protease (INS 1101(i)) first appeared in CX/FA 15/47/2 (paras. 23–24) based on the following text: “It is noted that INS 1101(i) Protease, includes a number of specific proteases for which no corresponding INS has been set and in particular proteases from *Aspergillus oryzae*, var., and from *Streptomyces fradiae*, which are included in the General Standard for Food Additives (GSFA). The Committee is invited to consider assigning INS numbers to these compounds.”
- There are currently four entries in the INS listed under the “parent” heading Proteases (INS 1101):

<table>
<thead>
<tr>
<th>INS No.</th>
<th>Name of Food Additive</th>
<th>Functional Class</th>
<th>Technological Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>1101</td>
<td>Proteases</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1101(i)</td>
<td>Proteases</td>
<td>Flavour enhancer</td>
<td>Flavour enhancer</td>
</tr>
<tr>
<td>1101(ii)</td>
<td>Papain</td>
<td>Flour treatment agent</td>
<td>Flour treatment agent</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Flavour enhancer Stabilizer</td>
<td>Flavour enhancer Stabilizer</td>
</tr>
<tr>
<td>1101(iii)</td>
<td>Bromelain</td>
<td>Flour treatment agent</td>
<td>Flour treatment agent</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Flavour enhancer Stabilizer</td>
<td>Flavour enhancer Stabilizer</td>
</tr>
<tr>
<td>1101(iv)</td>
<td>Ficin</td>
<td>Flour treatment agent, Flavour enhancer, Stabilizer</td>
<td>Flour treatment agent</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Flavour enhancer Stabilizer</td>
<td>Flavour enhancer Stabilizer</td>
</tr>
</tbody>
</table>

- The additive Protease (INS 1101(i)) is currently adopted in Table 3 of the GSFA, and also has an adopted provision in Tables 1 and 2 of the GSFA (food category 06.2.1 (Flours)). Only the non-specific additive name Protease (INS 1101(i)) is listed in the GSFA, and therefore it is not completely clear which specific proteases were intended to be included in the GSFA.
- JECFA has reviewed several proteases, two of which have INS 1101(i) included in the specifications monograph as a synonym:
  - Protease from *Aspergillus oryzae*, var.
    - Has a JECFA ADI of Not Specified (31st JECFA 1987, TRS 759)
    - JECFA specs monograph only lists functional effect as Enzyme Preparation.
Streptomyces fradiae

- ADI withdrawn by JECFA (28th JECFA 1984, TRS 710).
- JECFA specs monograph only lists functional effect as Enzyme Preparation.

- The only commodity standard that corresponds to food category 06.2.1 and contains provisions for food additives is the Standard for Wheat Flour (CODEX STAN 152-1985). CODEX STAN 152-1985 permits the use of the proteases “Proteolytic enzyme from Bacillus subtilis” and “Proteolytic enzyme from Aspergillus oryzae” under the functional effect of Enzyme.

- It is important to note that because the INS is the source of additive names used in the GSFA, any change to the name of Protease (INS 1101(i)) would result in a consequential change to the Tables 1 and 2 adopted GSFA provision for Protease (INS 1101(i)) in food category 06.2.1 (Flours), as well as to its general listing in Table 3 of the GSFA. These changes may have the effect of limiting the scope of proteases that could be used in the GSFA in association with the adopted provision in food category 06.2.1 (Flours) and in Table 3.

U.S. POSITION

- The U.S. can support the assignment of INS numbers to proteases that have been reviewed by JECFA and for which INS functional classes can be assigned.
  - The current proposal does not suggest food additive functional classes and technological purposes for Protease from Aspergillus oryzae, var., Protease from Streptomyces fradiae, or Protease from Bacillus subtilis.
  - The U.S. can support the assignment of INS 1101(i) to 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 2, and in Table 3.
  - The U.S. can support the assignment of INS 1101(v) to Protease from Streptomyces fradiae, and INS 1101(vi) to Protease from Bacillus subtilis.

- The U.S. does not have information on the appropriate functional classes and technological purposes to assign to Protease from Aspergillus oryzae, var., Protease from Streptomyces fradiae, or Protease from Bacillus subtilis. However, the United States welcomes any information in this regard offered by other Codex Members and Observers.

Table 2: Proposal for additional technological purposes

Polyvinyl alcohol (PVA)-polyethylene glycol (PEG) graft co-polymer (INS 1209)

- There appear to be typographical errors in the listing of “Technological Purposes” for Polyvinyl alcohol (PVA)-polyethylene glycol (PEG) graft co-polymer (INS 1209). Table 2 of CX/FA 16/48/14 indicates that INS 1209 currently has associated with it in the INS (CAC/GL 36-1989) the Technological Purposes of “Anticaking agent,” “Glazing agent,” and “Carrier.” However, the 2015 revision of the INS (CAC/GL 36-1989) only lists the functional class and technological purpose of “Glazing agent” for INS 1209. Thus, “Anticaking agent” and “Carrier” should not be associated with INS 1209 in Table 2 of CX/FA 16/48/14.
- Table 2 of CX/FA 16/48/14 presents a proposal to add the technological purposes of “Binder” and “Stabilizer” to Polyvinyl alcohol (PVA)-polyethylene glycol (PEG) graft co-polymer (INS 1209) based on the recent review of INS 1209 at the 80th JECFA (2015). In conjunction with the review at the 80th JECFA, JECFA recently published a specifications monograph for INS 1209 in FAO JECFA Monographs 17 (2015), which associates the functional uses of “Glazing agent,” “Binder for tablets,” and “Stabilizer” with INS 1209.
- The U.S. supports the inclusion of the functional class and technological purpose of “Stabilizer” with INS 1209 based on the JECFA review.
- The U.S. does not support the association of “Binder” with INS 1209 in the INS based on the JECFA functional use of “Binder for tablets,” as these two terms do not necessarily represent the same function.
  - “Binder” is a technological purpose in the INS, and if it were listed with INS 1209 in the INS, the
associated functional class of “Thickener” would also need to be added for INS 1209. Thickener is not an appropriate functional class for INS 1209.

The U.S. can support the following changes for INS 1209 in the INS list:

<table>
<thead>
<tr>
<th>INS No.</th>
<th>Name of Food Additive</th>
<th>Functional Class</th>
<th>Technological Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>1209</td>
<td>Polyvinyl alcohol (PVA)-polyethylene glycol (PEG) graft co-polymer</td>
<td>Glazing agent, Stabilizer</td>
<td>Glazing agent, Stabilizer</td>
</tr>
</tbody>
</table>

**Background**

Document CX/FA 16/48/14 is the report of the eWG on the INS (led by Iran) that was tasked with considering the replies to CL 2015/10-FA, which requested proposals for changes and addition to the INS list. Comments at Step 3 are compiled in CX/FA 16/48/14 Add.1.

<table>
<thead>
<tr>
<th>Agenda Item</th>
<th>Subject Matter</th>
<th>Document Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>7(a)</td>
<td>Proposals for Additions and Changes to the Priority List of Food Additives Proposed for Evaluation by JECFA (Replies to CL 2015/11-FA)</td>
<td>CX/FA 16/48/15</td>
</tr>
</tbody>
</table>

**U.S. POSITION**

The U.S. submitted 83 flavors for inclusion on the JECFA Priority List at the 48th CCFA in response to CL 2015/11-FA. The list includes 8 new flavors, 20 flavors that were included on the JECFA Priority List at previous CCFA meetings, and 55 flavors for which JECFA had requested additional safety information in order to complete its review.

The U.S. currently has four entries on the JECFA Priority list from the 47th CCFA:

<table>
<thead>
<tr>
<th>Substance</th>
<th>Questions to be Answered</th>
<th>Data availability (as of 47th CCFA)</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flavouring substances (3 new + 21 from previous Priority Lists + 39 for which JECFA requested additional info = 63 total)</td>
<td>Safety assessment and establishment of specifications</td>
<td>December 2015</td>
<td>This entry should be updated to incorporate the list of 83 flavors submitted by the U.S. to the 48th CCFA (taking into account any flavours included in 82nd JECFA call for data). Data availability should be updated based on information from sponsor.</td>
</tr>
<tr>
<td>Flavourings (JECFA no. 973, 1114, 1122, 1203, 1238, 2031, and 2123)</td>
<td>Revision of specifications and safety assessment as appropriate</td>
<td>Immediately</td>
<td>All flavours (except JECFA no. 973) included in the 82nd JECFA call for data.</td>
</tr>
<tr>
<td>Gum ghatti</td>
<td>Safety assessment and establishment of specifications</td>
<td>December 2015</td>
<td>Data availability should be updated based on information from sponsor.</td>
</tr>
<tr>
<td>Xanthan gum (INS 415)</td>
<td>Safety assessment for use in infant formula and formulae for special medical purposes intended for infants</td>
<td>December 2015</td>
<td>Included in 82nd JECFA call for data, and should be removed from list.</td>
</tr>
</tbody>
</table>
The U.S. should **ensure that** flavourings and Gum ghatti **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.

**Background**

Document CX/FA 16/48/15 when released will compile proposals for addition and changes to the Priority List of Food Additive proposed for evaluation by JECFA, submitted in response to CL 2015/11-FA.

<table>
<thead>
<tr>
<th>Agenda Item</th>
<th>Subject Matter</th>
<th>Document Reference</th>
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</thead>
<tbody>
<tr>
<td>7(b)</td>
<td>Information on Commercial Use of Potassium Hydrogen sulfate (INS 515(ii)), Sodium Sorbate (INS 201), and Calcium Hydrogen Sulfite (INS 227) (Replies to CL 2015/9-FA, Part C, Point 9)</td>
<td>CX/FA 16/48/16</td>
</tr>
</tbody>
</table>

The decision on this Agenda Item will impact the discussion in Agenda Item 2 on the listing of sodium sorbate in CODEX STANs 244-2004 and 167-1989

**U.S. POSITION**

- The U.S. did not respond to CL 2015/19-FA, Part C, Point 9. However, the U.S. **notes** that if the decision is to remove food additives from the GSFA, this may also impact commodity standards that list provisions for affected additives.

**Background**

During discussion on the topic of food additives in the GSFA without corresponding specifications (Agenda Item 2) at the 47th CCFA, it was noted that potassium hydrogen sulfate (INS 515(ii)), sodium sorbate (INS 201), and calcium hydrogen sulfite (INS 227) do not have corresponding JEFCA specifications. The Committee agreed that the Codex Secretariat would request, through a Circular Letter (CL 2015/9-FA, Part C, point 9), information on commercial use of these additives in food. Specific to each additive, if no information on commercial use is provided in response to the CL the 48th Session of the CCFA will recommend to remove the food additive from the GSFA. If information on commercial use is provided that food additive will be included in the JECFA Priority List with the understanding that interested countries will provide data for drafting specifications to JECFA by CCFA 49. If information for drafting specifications are not provided to JECFA by CCFA 49 the additive will be removed from the GSFA. (REP 15/FA, para. 18).

The USA **supported** this approach.

- Potassium hydrogen sulfate (INS 515(ii)) is a GSFA Table 3 acidity regulator and does not have any provisions in Tables 1 and 2.
- Sodium sorbate (INS 201) is a Table 1 & 2 additive (Functional Class: Preservative). INS 201 is a sorbate and is one of the food additives listed under the general heading for “sorbates” in Table 1. There are numerous provisions for “sorbates” in Tables 1 and 2. There are no specific provisions for INC 201 as an individual additive.
- Calcium hydrogen sulfite (INS 227) is a Table 1 & 2 additive (Functional Class: Antioxidant, Preservative). INS 227 is a sulfite and is one of the food additives listed under the general heading for “sulfites” in Table 1. There are numerous provisions for “sulfites” in Tables 1 and 2. There are no specific provisions for INC 227 as an individual additive.

If removed from the GSFA, INS 201 and INS 227 would only be removed from their respective general headers in Table 1, *i.e.* Sorbates and Sulfites.

**In response to CL 2015/9-FA, Part C, Point** only Columbia provided comments (documented in CX/FA 16/48/16). Columbia states that sodium sorbate is used as a preservative with a maximum use level of 1000 ppm,
and that there is no evidence of unacceptable risks from its use. Columbia did not state what foods sodium sorbate is used in. Columbia does not support removal of sodium sorbate from CODEX STAN 192-1995. With regard to potassium sulfate and calcium hydrogen sulfide, Columbia supports their removal from CODEX STAN 192-1995, since they are not used in that country’s food industry.

<table>
<thead>
<tr>
<th>Agenda Item</th>
<th>Subject Matter</th>
<th>Document Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>8</td>
<td>Discussion Paper on Secondary Additives</td>
<td>CX/FA 16/48/17</td>
</tr>
</tbody>
</table>

The U.S. participated in the eWG.

**U.S. POSITION**

**Recommendation 1:** If the Committee decides to address the use of secondary additives in Food Categories 13.1 and 13.2 within the GSFA, the U.S. notes that there is a one-to-one correspondence between these food categories and corresponding commodity standards. Therefore, the U.S. recommends consultation with the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) to ascertain whether they have considered the use of secondary additives in these foods, if so how, and if not why not.

Recommendations 2 and 3: In general, the U.S. supports the development of Guidelines, separate from the GSFA, to address the use of secondary additives (Option C discussed in Recommendation 2 of CX/FA 16/48/7). In general, the US does not support proposals to address the use of secondary additives within the GSFA, either through the addition of a new food category for “Preparations” (Options A) or through the use of notes within the existing food category system (Option B).

**Background**

Document CX/FA 16/48/17 is the report of the eWG (led by the EU) that was tasked with comparing the working definition of secondary additives (REP 15/FA, para. 147) with Section 4 of the Preamble to the GSFA, and if this analysis establishes that Section 4 does not appropriately cover all aspects of the definition, then analyze the impact of the definition on the GSFA. (REP 15/FA, para. 148-149). The document contains three recommendations:

Recommendation 1: deals specifically with the use of secondary additives in FCs 13.1 and 13.2. This recommendation is that the use of secondary additives in these FCs should be addressed in through the use of notes attached to provisions contained within the FC. CX/FA 16/48/17 notes that these FCs are specifically discussed in Section 4.3 of the Pre-amble of the GSFA:

**4.3 Foods for Which the Carry-over of Food Additives is Unacceptable**

Carry-over of a food additive from a raw material or ingredient is unacceptable for foods belonging to the following food categories, unless a food additive provision in the specified category is listed in Tables 1 and 2 of this standard.

a) 13.1 - Infant formulae, follow-up formulae, and formulae for special medical purposes for infants.

b) 13.2 - Complementary foods for infants and young children.

Also, there is a one-to-one correspondence between FCs 13.1 and 13.2 and corresponding commodity standards i.e. CODEX STANs 72-1981, 74-1981, and 72-1981. These commodity standards each contain statements regarding food additives and carry-over.

Recommendation 2: Deals with the general approach to address the use of secondary additives: within the GSFA or outside the GSFA. The Committee is asked to consider two options: Options A or C.
**Option A**: Establishment of a new category in the GSFA food category system to address the use of secondary additives.

**Option C**: Development of separate Guidelines for the use of secondary additives following the approach of CAC/GL 66-2008.

Recommendation 3: Proposes that the Committee continue with its current approach if consensus cannot be reached on Options A or C. “If no consensus can be reached on Recommendation 2, secondary additives will be addressed by use of notes within the current GSFA food category system (**Option B**).”

- Four provisions for the use of secondary additives are currently adopted into the GSFA, one with Note 12 “As a result of carryover from flavouring substances” and three with Note 131 “For use as a flavour carrier only”. Options A and C would result in these provisions being discontinued.

<table>
<thead>
<tr>
<th>Agenda Item</th>
<th>Subject Matter</th>
<th>Document Reference</th>
</tr>
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<tbody>
<tr>
<td>9</td>
<td>Proposed Draft Revision of Sections 4.1(c) and 5.1(c) of the General Standard for the Labelling of Food Additives When Sold as Such (CODEX STAN 107-1981)</td>
<td>CX/FA 16/48/18</td>
</tr>
<tr>
<td></td>
<td>Comments at Step 3</td>
<td>CX/FA 16/48/18 Add. 1</td>
</tr>
</tbody>
</table>

**U.S. POSITION**

**Recommendation 1**  
The U.S. supports maintaining the current wording of the first sentence in Sections 4.1(c) and 5.1(c).

**Recommendation 2**  
The U.S. supports the revision of the current wording of the second sentence in Sections 4.1(c) and 5.1(c).

Taking into account our comments on Recommendation 3, below, the United States is of the view that the term “flavour” should be removed from the revised second sentence, as follows:  
“The generic expression “flavour” or “flavouring” may be used, together with an indication of the organoleptic properties (e.g. “apple flavouring”) and/or the origin or source of the product.”

**Recommendation 3**  
The U.S. supports the revision of the current wording of the third sentence in Sections 4.1(c) and 5.1(c), as presented in Recommendation 3.

As a consequence, the term “flavour” should be removed from the second sentence in Sections 4.1(c) and 5.1(c).

**Recommendation 4**  
The U.S. supports the deletion of the current fourth sentence in Sections 4.1(c) and 5.1(c).

However, the U.S. is of the view that, although herbs and spices are food, they may be used in flavouring preparations and food additive preparations. As such, the labelling of herbs and spices should be included, specifically or generally, as food ingredients in an appropriate sub-section of Sections 4.1 and 5.1 (see Recommendation 5).

**Recommendation 5**  
The U.S. supports the inclusion of a new sub-section in Sections 4.1 and 5.1 to allow for the general listing of food ingredients to include, but not be limited to, herbs and spices.
The U.S. supports the proposal for CCFA to consult with the Codex Committee on Food Labelling (CCFL) as to whether it is appropriate to include text regarding the labelling of allergens in CODEX STAN 107-1981.

The U.S. supports the proposed text for the new sub-section, as presented in Recommendation 5. However, depending upon the outcome of the discussion with CCFL regarding the appropriateness of including text regarding the labelling of allergens, the proposed text “. . . except for those ingredients that are identified in Section 4.2.1.4 of the General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985) as foods or ingredients that are known to cause hypersensitivity.” may need to be revised or deleted.

Annex 1: Proposed Draft Revision of Sections 4.1(c) and 5.1(c) of the General Standard for the Labelling of Food Additives When Sold as Such (CODEX STAN 107-1981)
The text in Annex 1 represents the revision of Sections 4.1(c) and 5.1(c) as per Recommendations 1 to 5, above.

The U.S. supports the revision of Sections 4.1(c) and 5.1(c) as presented in Annex 1, noting that the proposed inclusion of the text regarding the labelling of allergens in the last sentence may need to be revised or deleted (see Recommendation 5).

Background
Document CX/FA 16/48/18 is the report of the eWG (led by the U.S.) that was tasked with preparing a proposed draft revision of the General Standard for the Labelling of Food Additives When Sold as Such (CODEX STAN 107-1981), for circulation for comments at Step 3 and consideration at the 48th Session (REP 15/FA, para. 164).