# Report of the U.S. Delegate 53rd Session of the Codex Committee on Food Additives (CCFA53) Hong Kong, China March 27-31, 2023

#### INTRODUCTION

The 53<sup>rd</sup> Session of the Codex Committee on Food Additives (CCFA53) met in Hong Kong, People's Republic of China, from March 27-31, 2023. The meeting was chaired by Dr. Yongxiang Fan of the Chinese National Center for Food Safety Risk Assessment and attended by 35 member countries; one member organization (the European Union, EU); representatives of 21 international observer organizations; the UN Food and Agriculture Organization (FAO); and the World Health Organization (WHO).

The United States Delegation was led by Dr. Paul Honigfort (Head of Delegation), Dr. Daniel Folmer (Alternate Delegate), and Dr. LaShonda T. Cureton from the U.S. Food and Drug Administration (FDA); Ms. Mary Frances Lowe (U.S. Codex Office, U.S. Department of Agriculture/USDA); and Mr. Chih-Yung Wu (Foreign Agricultural Service, USDA).

The 53<sup>rd</sup> Session of CCFA was a highly productive session, with the United States continuing to play a leading role in the discussion of the *General Standard for Food Additives* (GSFA, CXS 192-1995) and CCFA53 advancing hundreds of provisions for the safe use of food additives that will protect consumer health and promote fair trade practices. CCFA53 was the first in person meeting of the Committee in four years, which facilitated sidebar discussions and real-time negotiations that helped the Committee to reach, agreement on several complex issues it had been unable to resolve in the past.

#### HIGHLIGHTS

<u>GSFA</u>: As the result of working groups chaired or co-chaired by the United States, the Committee took action on 781 provisions: 418 provisions forwarded for final adoption by the 46<sup>th</sup> Session of the Codex Alimentarius Commission (CAC46, November 2023); 34 sent for revocation; and 329 provisions to be discontinued.

<u>Continued removal of Note 161 and related notes:</u> CCFA53 continued the work to eliminate Note 161 (which references national legislation) from the GSFA, in accordance with the Committee's previous conclusion that such a note was not appropriate in Codex as it undermines harmonization goals. This note has historically been attached to provisions in the GSFA for food additives with "color" or "sweetener" functions.

<u>Sweeteners:</u> CCFA53 progressed all remaining provisions for sweeteners in the GSFA through the step process, except for six provisions for the use of sweeteners in bread that will be addressed at CCFA54 (2024). The Committee forwarded 122 provisions for sweeteners to CAC46 for final adoption without Note 161 and recommended removal of Note 161 from the final seven adopted provisions for sweeteners with Note 161 that remained after CCFA52 (2022). <u>Colors:</u> For the first time, CCFA53 advanced a significant number of provisions for color additive provisions for the use of colors in dairy foods, fats and oils, and edible ices, forwarding 81 provisions to CAC46 for final adoption without Note 161 and recommending removal of Note 161 from 19 previously adopted provisions

<u>Stabilizers in fruit and vegetable juices and nectars</u>: CCFA historically used Note 122 (which also references national legislation) to reach consensus on the use of certain additives in fruit and vegetable juices and nectars due to the perceived "natural" aspects of these products by certain Codex Members. After discussing this issue for several sessions, CCFA53 finally progressed provisions for the use of stabilizers in these products, advancing four provisions for final adoption by CAC46.

<u>Additives in Grape Wine:</u> After discussing this issue for several sessions over the past decade, CCFA53 reached consensus and advanced provisions for the use of additives in grape wines based on good manufacturing practice (GMP), forwarding 10 provisions for final adoption by CAC46 with a note indicating that some Members specify the use as consistent with the International Organisation of Vine and Wine (OIV) code of practice.

A more detailed summary of the meeting is presented below. The official report of the 53rd Session of CCFA can be found at: <u>http://www.fao.org/fao-who-</u>codexalimentarius/meetings/detail/en/?meeting=CCFA&session=53.

#### **MEETING SUMMARY**

## Agenda Item 2: Matters Referred by Other Codex Subsidiary Bodies

<u>Fats and Oils</u>: The Codex Committee on Fats and Oils (CCFO) replied to a request for guidance from CCFA on the technological justification for the use of mono- and diglycerides of fatty acids (International Numbering System/INS 471) in products conforming to commodity standards that correspond to Food Category 02.1.2, "Vegetable oils and fats," in the GSFA. Based on this response, CCFA53 forwarded the draft provision for INS 471 in FC 02.1.2 of the GSFA to CAC46 for final adoption.

<u>Endorsement of Maximum Levels for Food Additives and Processing Aids in Codex Standards</u>: The Committee endorsed the food additive sections of eleven draft and proposed draft standards forwarded by the Codex Committee on Fresh Fruits and Vegetables (CCFFV), the Codex Committee on Spices and Culinary Herbs (CCSCH), the FAO/WHO Coordinating Committee for Africa (CCAFRICA), FAO/WHO Coordinating Committee for Asia (CCASIA), and FAO/WHO Coordinating Committee for Latin America and the Caribbean (CCLAC).

# Agenda Item 3: Matters Arising from the 92<sup>nd</sup> and 95<sup>th</sup> Meetings of the Food and Agriculture Organization (FAO)/World Health Organization (WHO) Joint Expert Committee on Food Additives (JECFA)

The provision for <u>benzoates</u> in Food Category (FC) 14.1.4, "Water-based flavored drinks, including 'sport,' 'energy,' or 'electrolyte' drinks and particulated drinks," had been discussed in CCFA for several years due to exposure concerns. CCFA48 (2016) requested JECFA to re-evaluate this additive and attached Note 301 ("Interim maximum level until CCFA53") to the provision in FC 14.1.4 pending JECFA's

reevaluation. The 92<sup>nd</sup> JECFA (2021) reevaluated the safety of benzoic acid, its salts and derivates and established a new group Acceptable Daily Intake (ADI) of 0-20 milligrams/kilogram body weight (bw) which was 4 times higher than the previous ADI. CCFA53 deleted Note 301 from the provision for benzoates in FC 14.1.4 and maintained the existing use level.

The 92<sup>nd</sup> JECFA withdrew the previous numeric group ADI for <u>Riboflavin</u>, synthetic (INS 101(i)), Riboflavin 5'-phosphate sodium (INS 101(ii)), and Riboflavin from Bacillus subtilis (INS 101(iii)) and established a new group ADI of "not specified" applicable to these three additives and Riboflavin from Ashbya gossypii (INS 101(iv)). Based on an analysis by the United States submitted in a conference room document (CRD 13), CCFA53 included INS 101(iv) in the existing group header for RIBOFLAVINS and recommended final adoption of provisions for all four food additives.

The 95<sup>th</sup> JECFA (2022) completed specifications for <u>spirulina extract</u> (INS 134) and, consequently, the temporary status was removed from the corresponding ADI determined at the 86<sup>th</sup> JECFA meeting (2018). As spirulina extract now has a full JECFA evaluation, specifications, and an ADI of "not specified," CCFA53 agreed to include a provision for INS 134 in Table 3 of the GSFA.

As a result of the 92<sup>nd</sup> and 95<sup>th</sup> JECFA meetings the Committee forwarded full <u>specifications</u> for nine food additives to CAC46 for adoption.

# Agenda Item 4: Alignment of the General Standard for Food Additives (GFSA) and Commodity Standards

Based on the work of the electronic working group (EWG) on Alignment (co-chaired by Australia, the United States, and Japan) CCFA53 completed the alignment of the GSFA and 16 commodity and regional standards and an accompanying guideline and forwarded them to CAC46 for adoption.

During the meeting, Australia indicated they will step down from their role as chair of the Alignment EWG. Replacing Australia, Canada will serve as the new chair of the Alignment EWG, with continued cochairing by Japan and the United States.

# Agenda Item 5: General Standard for Food Additives (GFSA)

The physical working group (PWG) on the GSFA, chaired by the United States, considered the report of the EWG on the GSFA (also chaired by the United States) and made recommendations on over 750 GSFA provisions either in the step process or already adopted.

This work included the progression of all remaining provisions for sweeteners through the step process (with the exception of 6 provisions for the use of sweeteners in bread); the completion of provisions for the use of colors in dairy foods, fats and oils, and edible ices; and addressing the withdrawal of the established group ADI for carotenoids by JECFA87 (2019), the use of additives in fruit and vegetable juices and nectars, the use of notes for additives in seven different group headers in the GSFA, a draft provision for propylene glycol alginate (INS 405) in fluid milks, and proposals to revise two existing adopted provisions in the GSFA to expand use.

The PWG on the GSFA also recommended the inclusion of 53 new provisions in the GSFA at Step 2 (for further review and comment) based on proposals submitted in response to the annual circular letter soliciting proposals for new provisions or revision of adopted provisions in the GSFA.

#### Commodity standards and use of food additives in fruit juices and nectars

The PWG on the GSFA discussed the use of pectins (INS 440), xanthan gum (INS 415), and tamarind seed polysaccharide (INS 437) as emulsifiers/stabilizers in fruit and vegetable juices and nectars (FCs 14.1.2 and 14.1.3). It was noted that, while the use of emulsifiers/stabilizers is technologically justified in these products, some countries only allow the use of pectins for this purpose due to the perceived "natural" aspects of fruit and vegetable juices.

Brazil, Canada, and Chile questioned whether FCs 14.1.2 and 14.1.3 included standardized and nonstandardized foods, or if there were non-standardized fruit juices and nectars. Historically, CCFA has considered that all fruit juices and nectars conform to the corresponding commodity standard, and those countries that did not agree with the use of INS 415 and INS 437 in these products require those products to be standardized. To reach consensus, CCFA53 discussed the attachment of Note XS247 ("Excluding products conforming to the standard for Fruit Juices and Nectars (CODEX STAN 247-2005)") to the provisions for INS 440 and INS 415.

The European Union, the United States, Australia, and other delegations, including the International Fruit and Vegetable Juice Association (IFU) and International Council of Beverage Associations (ICBA), stated they could agree to the use of the XS note. After further discussion, CCFA53 agreed to forward the provisions for xanthan gum (INS 415) and tamarind seed polysaccharide (INS 437) to CAC46 for adoption with Note XS247 attached.

<u>Carotenoids</u>: As a result of the 87<sup>th</sup> JECFA's review (2019), CCFA53 recommended the following changes be adopted by CAC46: (1) revise the list of additives under the related group header (now "Beta-Carotenes"), (2) revise 145 adopted provisions to reduce their use level, (3) revoke 26 adopted provisions, (4) discontinue 71 provisions in the step process due to their incorporation into the revised group header, and (5) adopt 28 provisions for a related food additive (Beta-apo-8'-Carotenal (INS 160e)).

<u>New Provisions</u>: CCFA53 added 53 new provisions into the GSFA at Step 2 to be circulated for comment by the electronic working group (EWG) on the GSFA, chaired by the United States, and considered at the next session (CCFA54, 2024).

Discrepancies between use levels proposed in the GSFA and JECFA exposure assessments During discussion in the PWG on the GSFA on provisions for carotenoids related to 87<sup>th</sup> JECFA's withdrawal of the established group ADI due to effects seen only in heavy smokers as opposed to the general population, the EU noted the significant discrepancy between the uses and use levels that were reported to JECFA for the exposure assessment of these additives, compared to those reported to CCFA for inclusion as maximum use levels in the GSFA. They expressed the view that, as a general matter, such discrepancies raise questions as to the applicability of JECFA's assessment to the uses and use levels in the GSFA. The FAO JECFA Secretariat noted that such discrepancies may raise concerns when setting maximum use levels if such discrepancies cannot be reconciled, indicating such maximum use levels may not be compatible with applicable health-based guidance levels.

Australia and the United States noted that the two different sets of data serve different purposes; typical use levels are provided to JECFA to allow a dietary exposure assessment, while maximum use levels are the maximum use in any product in a particular food category and, as such, do not necessarily

correlate to any individual's actual exposure. Exposure information provided to JECFA is often regionally specific, and different regions may utilize higher levels in some foods and lower levels in others. To progress the discussion on the provisions for carotenoids, CCFA53 agreed to include a note in the Committee's report informing CAC46 of the importance of encouraging stakeholders to provide JECFA data that are precise and reliable.

The JECFA Secretariat also requested that CCFA53 consider including an update of the exposure assessment for carotenoids, in particular beta-apo-8'-carotenal (INS 160e) which has an ADI, to the priority list of substances for evaluation by JECFA. During the discussion on adding these substances to the JECFA priority list, the EU expressed concern that the time indicated for data availability (up to December 2025) was too long and should be shorter. Several Observers noted they needed sufficient time for collection of robust data, and the United States and Canada supported this view. As a result, CCFA53 maintained the date of December 2025.

## Agenda Item 6: International Numbering System (INS)

The Committee endorsed the recommendation to modify the functional classes and technological purpose(s) in Sections 3 of the INS for gum ghatti (INS 419), cassia gum (INS 427), methacrylate copolymer, and anionic (INS 1207), and to delete Rebaudioside A from multiple gene donors expressed in Yarrowia lipolytica (INS 960b(i)) from *Class Names and the International Numbering System for Food Additives* (CXG 36-1989).

## Agenda Item 7: JECFA Priority List

The JECFA priority list of additives for scientific review was updated to include a total of 27 entries for food additives and 24 entries for processing aids (primarily enzymes). The United States supported the inclusion of silicon dioxide, amorphous (INS 551), glycolipids, and steviol glycosides, as well as additional flavorings for review. The United States, as the chair of the electronic and physical working groups on the GSFA, also requested adding adipic acid (INS 355) to help progress provisions for the group header Adipates through the step process (see CRD 08). The Committee also agreed to advise the Codex Committee on Nutrition and Special Dietary Uses (CCNFSDU) that its request to add gellan gum, low acyl clarified to the JECFA Priority List had been revised to a request to establish specifications for this form of gellan gum, as JECFA had already established the safety of this product for its consumption by infants under 12 weeks of age.

During the session, Canada announced that they would step down as Chair of the in-session working group on JECFA Priorities due to their new responsibility for chairing the Alignment EWG. It is expected that a new Chair of the in-session working group on JECFA Priorities will be announced at CCFA54 (2024).

# Agenda Item 8: Mapping of FOODEX2 Database to GSFA Food Categories

Canada, along with co-authors Japan and Australia, presented a discussion paper on the mapping of the GSFA food category system to the FOODEX2 classification system, which is a primarily European-based food classification system used frequently by JECFA for exposure estimates. JECFA noted that, following an initial mapping evaluation, they would post a document mapping FOODEX2 classifications to the GSFA food category system. CCFA53 agreed that initial mapping would be undertaken by Japan and be

available by the end of 2023. Australia offered to peer review the mapping and the EU noted their willingness to provide support given their experience with FoodEX2.

## Agenda Item 9: Use of Trisodium Citrate in Fluid Milk

Because of concerns raised by African countries on the technological justification for the use of trisodium citrate in bovine milk, CAC42 (2019) returned for further consideration the provision for the use of trisodium citrate (INS 331(iii)) in fluid milks that CCFA51 (2019) had recommended for final adoption. At CCFA53 the United States met with CCAFRICA members and explained that an additive may be technologically justified even if not used by certain countries. CCAFRICA Members in attendance (Kenya and Senegal) agreed to allow the provision to progress while expressing a reservation. CCFA53 forwarded the provision to CAC46 for final adoption, noting in the Committee report that all technical issues had been thoroughly discussed and that the decision should not be re-opened at CAC46 (2023).

#### Agenda Item 10: Food Additives in Wine and References to Organizations Outside of Codex

Since there is no safety-based reason to utilize a numerical use limit which may restrict trade, the United States supports a maximum use level (ML) of GMP ("Good Manufacturing Practice") for provisions in the GSFA for additives which JECFA has determined to be of low toxicological concern. However, other delegations, including the EU, have historically opposed MLs of GMP for the use of additives in grape wines due to the perceived "natural" aspects of these products, and instead have supported numeric use limits aligned with those set by the OIV, an intergovernmental organization with wine making expertise. The United States was successful in bringing the Committee to consensus in previous sessions that these provisions should be listed at GMP rather than numerical limits, but several members continued to insist that a note be attached to these provisions defining GMP in a manner that would require GMP to be consistent with levels set by OIV. The United States opposed a direct link to the levels set by OIV on the basis that Codex should not defer competence to outside organizations. At CCFA52 (2022) Chile, the EU and the United States agreed to co-author a discussion paper on the use of additives in wine to present at CCFA53.

At CCFA53, Chile, the EU, and the United States proposed a compromise text for the note that indicated that GMP applies and only some Members further specify the use of additives in wine to be consistent with the OIV Code of Practice. Brazil, Canada, and Japan expressed concern with the note, considering that any mention of an outside organization went against Codex principles of independently establishing worldwide standards and could set precedent. The Russian Federation stated their opposition to the use of food additives in wine. However, Australia, Chile, the European Union, the United States, and New Zealand supported the note as a means to reach consensus. The Codex Secretariat confirmed that the note as drafted did not violate Codex procedures. CCFA53 agreed to advise the Codex Executive Committee (CCEXEC) and CAC that this approach represented an exception, rather than a precedent, as these circumstances are unlikely to occur again since there were no other instances where an external organization was cited in the descriptor of a food category in the GSFA. CCFA53 agreed to forward the provisions at GMP with this note.

#### Agenda Item 11: Other Business and Future Work

#### Other Business

<u>Discussion paper on the development of a standard for yeast:</u> As advised by CAC44 (2022), China presented their proposal to develop a Codex standard for yeast to CCFA53 (see CRD 06). After some discussion, CCFA53 agreed to have China, France, and other interested Members prepare a new discussion paper for CCFA54 defining a scope for the proposed standard, which would exclude edible yeast.

#### Future Work

## <u>GSFA</u>

- The Committee agreed to establish an EWG (chaired by the United States) to consider:
  - i. all remaining draft and proposed draft provisions for sweeteners in the GSFA as well as adopted provisions for sweeteners with Note 161 in the GSFA;
  - ii. draft and proposed draft provisions for colors as well as adopted provisions for colors with Note 161 in FCs 07.0, 12.0, 13.0 and 15.0 and their subcategories;
  - iii. draft and proposed draft provisions in FCs 14.2 and its subcategories;
  - iv. provisions entered at Step 2 of the GSFA at CCFA53; and
  - v. all remaining draft and proposed draft provisions in the GSFA except for: colors not addressed in parts ii and iii, and provisions for which CCFA is awaiting guidance from other Codex Alimentarius committees and JECFA.
- The Committee also agreed to establish a related physical working group, chaired by the United States and working in English only, to meet immediately prior to CCFA54 (1.5 days) to consider and prepare recommendations on:
  - i. the report of the EWG on the GSFA to CCFA54; and
  - ii. responses to the circular letter (CL) on proposals for new and/or revised provisions on the GSFA

## <u>Alignment</u>

- The Committee agreed to establish an EWG, chaired by Canada and co-chaired by the United States and Japan to consider the following:
  - i. re-circulate the alignment of the following milk and milk products commodity standards: CXS 243-2003; CXS 288-1976;
  - ii. initiate development and maintenance of Table 3 notes in the GSFA, in consultation with the Codex Secretariat;
  - iii. verify if the Standard for Processed Tomato Concentrates (CXS 57-1981) has been aligned, and if so, to verify that the provisions in the corresponding food categories in Tables 1 & 2 accurately reflect the alignment;
  - iv. recommend alignment of the following commodity standards developed by the Codex Committee on Processed Fruits and Vegetables: CXS 66-1981, CXS 260-2007, CXS 320-2015; and
  - v. recommend alignment for the following regional standards: CXS 308R-2011, CXS 313R-2013, CXS 314R-2013, CXS 323R-2017, CXS 324R-2017;
  - vi. update the alignment future work plan contained in the Information Document titled Guidance to Commodity Committees on the Alignment of Food Additive Provisions;

- The Committee also agreed to establish a physical working group, chaired by Canada, to meet immediately prior to CCFA54 to consider and prepare recommendations for the plenary on:
  - i. the report of the Alignment EWG; and
  - ii. the endorsement of food-additive provisions referred by commodity committees
- The Committee agreed to request China, Canada, and the EU as co-authors, to prepare a discussion paper to identify the outstanding issues on avoiding future divergence between the GSFA, commodity standards and other texts.

# <u>INS</u>

- The Committee agreed to establish an EWG, chaired by Belgium, to consider:
  - replies to a CL requesting proposals for changes and/or additions to Section 3 of the *Class* Names and the International Numbering System for Food Additives (CXG 36-1989); and to prepare a proposal for circulation for comments;
  - proposals for the addition of the new additive glycolipids (INS 246) as a preservative, oat lecithin (INS 322a) as an emulsifier and carbomer (INS 1210) as a bulking agent, stabilizer, and thickener in the CXG 36-1989) (as mentioned in CX/FA 23/53/13 Add.1);
  - the addition of the functional classes of "stabilizer" and "thickener" for sodium sesquicarbonate (INS 500(iii)) (see CX/FA 23/53/6);
  - the appropriateness of including the functional class of "preservative" for sodium thiosulfate (INS 539) (see CX/FA 23/53/6);
  - the appropriateness of including the functional class of "carrier" and the technological purpose of "nutrient carrier" for INS 421, 1450, and 301 (see CX/FA 23/53/6); and
  - o assigning an INS number to low acyl clarified gellan gum (see CX/FA 23/FA 23/53/2 Add.2).

# <u>Yeast</u>

• The Committee agreed to consider a discussion paper on a standard for yeast to be prepared by China, France, and other interested Members.

## DATE AND PLACE OF NEXT SESSION

The next session of the CCFA is tentatively scheduled to take place April 22-26, 2024, with final arrangements subject to confirmation by the host Government with the Codex Secretariat.