Report of the U.S. Delegate to the 51st Session of the Codex Committee on Food Additives (CCFA)

March 25-29, 2019
Jinan, People’s Republic of China

The 51st Session of the Codex Committee on Food Additives (CCFA) met in Jinan, People’s Republic of China, from March 25-29, 2019. The meeting was chaired by Dr. Yongxiang Fan of the Chinese National Center for Food Safety Risk Assessment and attended by 48 member countries, one member organization (the European Union, EU), representatives of 33 international observer organizations, the UN Food and Agriculture Organization (FAO), and the World Health Organization (WHO).

U.S. Government participation in the meeting included: Dr. Paul Honigfort (Head of Delegation), Dr. Daniel Folmer (Alternate Delegate), Dr. LaShonda Cureton, and Dr. Annette McCarthy from the U.S. Food and Drug Administration (FDA); Mr. Ken Lowery (U.S. Codex Office, U.S. Department of Agriculture/USDA); Ms. Marie Kirrane (Alcohol and Tobacco Tax and Trade Bureau/TTB) and Mr. Chih-Yung Wu (Foreign Agricultural Service, USDA).

The 51st Session of CCFA was a productive session, with the United States continuing its leadership role in populating the General Standard for Food Additives (GSFA) with provisions for the safe use of food additives in a manner that protects consumers and facilitates fair trade practices.

HIGHLIGHTS:

- **GSFA**: The Committee completed work on 106 draft and proposed draft provisions, with 76 being forwarded for final adoption by the 42nd Session of the Codex Alimentarius Commission (CAC42, July 2019) and 30 provisions being discontinued. A total of 95 new provisions were also added to the GSFA at Step 2 or 3 (to be reviewed further by CCFA at a future session).

- **Alternatives to Footnote 161 Relating to the Use of Sweeteners**: The Committee made significant progress in resolving the longstanding impasse over the use of Footnote 161 (“subject to the national legislation of the importing country”), reaching consensus on two replacement notes for sweeteners that do not refer to national legislation. This allowed the Committee to agree to remove Note 161 from 111 adopted provisions. For the first time in 10 years, CCFA also agreed to advance a
number of color additive provisions without attaching Note 161. This progress represents a major achievement and was a key U.S. goal for the session.

- **86th Joint Expert Committee on Food Additives (JECFA) Meeting**: The 86th JECFA (2018) established an acceptable daily intake (ADI) of “not specified” for basic methacrylate copolymer (INS 1205), lutein from *Tagetes erecta* (INS 161b(i)), and zeaxanthin (synthetic) (INS 161(h)). The three additives were included in Table 3 of the GSFA at Step 3 and will be discussed at the next CCFA for potential adoption. (Table 3 additives are permitted for use in food in general at levels consistent with good manufacturing practices (GMP) in non-standardized foods unless a food is part of a food category included in the Annex to Table 3, whereby the use of the additive would require a separate provision in Tables 1 and 2 of the GSFA.) The Committee also forwarded specifications for 6 food additives (5 revised and 1 new) and 24 flavorings evaluated at the 86th JECFA meeting to CAC42 for final adoption.

- **Alignment of the GSFA and commodity standards**: The Committee completed work on the alignment of 23 commodity standards with the GSFA, 6 of which were prepared by the United States as one of the co-chairs of the Electronic Working Group (EWG). This resulted in over 70 provisions being forwarded to CAC42 for adoption.

- **International Numbering System (INS)**: The Committee endorsed the listing of basic methacrylate copolymer (INS 1205) with the functional class of carrier and agreed to change the name of INS 160a(iv) to β-carotene-rich extract from *Dunaliella salina*. The additives distarch glycerol (INS 1411) and Red 2G (INS 128) were removed from the INS list.

- **JECFA Priority List**: The JECFA priority list was updated to contain 21 entries for food additives, and 29 entries for processing aids (enzymes). The United States supported the entry of additional flavorings for review by JECFA.

**FUTURE WORK:**

- The Committee agreed to establish an EWG on the GSFA (chaired by the United States) to:
  - Consider all remaining or new draft and proposed draft provisions in Tables 1 and 2 of the GSFA in Food Categories (FCs) 01.0 through 16.0\(^1\) (with the exception of those additives with technological functions of colors or sweetener (excluding those provisions in specific FCs described in the mandate),

\(^1\) A complete listing of the GSFA food category system (including food category descriptors) can be found in Annex B of the GSFA (CODEX STAN 192-1995).
adipates, benzoates, the provisions in food category 14.2.3 and its subcategories, and provisions awaiting a reply from the Codex Committee on Processed Fruits and Vegetables (CCPFV) and all new draft or proposed draft provisions in Table 3 of the GSFA;

- Consider the draft and proposed draft provisions for sweeteners in FCs in lists T, U, and Y of CX/FA 15/47/13 with the exception of those in FCs 07.1 and its subcategories, and 12.2.2 and 12.3;
- Consider the actual use and use level for the adopted provisions for the sweeteners [?] Alitame (INS 956), and the use levels for acesulfame potassium (INS 950) in FCs 14.1.4 and its subcategories and 14.1.5 and saccharin (INS 954(i)-(iv)) in FCs 14.1.4.1, 14.1.4.2, and 14.1.4.3;
- Consider draft, proposed draft and adopted provisions with the technological function of color with Note 161 in FCs 05.0 (excluding provisions in FC 05.3), 13.6 and 14.0 (excluding FCs 14.1.2, 14.1.3 and 14.2.3 and its subcategories) and the adopted provisions with 05.2 and 05.3;
- Consider the draft, proposed draft and adopted provisions for sucrose esters of fatty acids (INS 473), sucrose oligoesters, type I and type II (INS 473a), and sucroglycerides (INS 474) as a result of the group Acceptable Daily Intake (ADI) and create a group heading accordingly; and
- Consider the in-going use levels and residual levels for the draft, proposed draft and adopted provisions for nitrates (INS 251, 252) and nitrites (INS 249, 250).

- The Committee agreed to establish an EWG (co-chaired by the United States and the EU) to:
  - Discuss provisions with Note 161 attached to them and provide recommendations for either the use of the approved replacement note(s) or whether the provisions should be revoked/discontinued in select food categories;
  - Discuss and provide recommendations on the additional FCs with adopted provisions or provisions in the step process which may not have been previously considered by the EWG; and
  - Discuss if sweeteners or flavor enhancers are justified in FCs 07.1 and its subcategories, and 12.2.2 and 12.3.

- The Committee also agreed to establish EWGs on (1) Alignment of the GSFA and commodity standards (chaired by Australia and co-chaired by the United States and Japan); (2) the International Numbering System (INS) (chaired by Belgium); and (3) the JECFA Priority List (chaired by Canada).

- The Committee requested the Codex Secretariat to report the progress on resolving issues with the online database that prevent the implementation of decisions aimed at modernizing the database to make it functional. The Committee also agreed to bring the issue to the attention of the Codex Executive Committee (CCEXEC).
MEETING SUMMARY:

The following paragraphs discuss the key decisions made by the Committee in more detail. The full official report of the session is available on the Codex Alimentarius website at: [www.fao.org/fao-who-codexalimentarius/committees/committee/en/?committee=CCFA](http://www.fao.org/fao-who-codexalimentarius/committees/committee/en/?committee=CCFA).

General Standard for Food Additives

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 155 GSFA provisions either in the step process or already adopted). The Committee endorsed these recommendations in large part, with the exception of the recommendation contained in Conference Room Document (CRD) 2, Annex 1 Part D, pertaining to provision for the use of propylene glycol alginate in food category 01.1.2 (Other fluid milk (plain)) which was held for further discussion on the numeric use level.

For the first time in 10 years, CCFA advanced for adoption provisions for colors without Note 161, for use in confectionery, candy and chewing gum. Additionally, the Committee agreed to put on the agenda for next year’s session work to start the removal of Note 161 from adopted color provisions in these food categories and the remaining confectionery subcategories, food supplements and beverages with the exception of fruit and vegetable juices, nectars and grape wine. The Committee tasked the EWG on the GSFA to consider the draft and proposed draft provisions for colors in the remaining confectionery subcategories, food supplements and beverages with the exception of fruit and vegetable juices, nectars and grape wine for discussion at the next CCFA.

This session of CCFA also endorsed the use of emulsifiers and stabilizers in milk-based drinks and the use of specific additives in coatings of fresh fruits and vegetables to preserve the freshness of these agricultural products.

Discussion Paper on Wording for an Alternative to Note 161 Relating to the Use of Sweeteners

This discussion paper was the result of an EWG co-chaired by the United States and the EU. This discussion paper explored wording for an alternative note to Footnote 161 (“subject to national legislation of the importing country”) for sweeteners that would be consistent with Section 3.2 of the GSFA Preamble and the Statements of Principle in
the Codex Procedural Manual. The co-chairs noted the draft alternative notes were developed in a cooperative manner and provided a good compromise solution to longstanding difficulties in reaching consensus on approaches to address Footnote 161, which has been attached to numerous provisions for colors and sweeteners and has resulted in a halt to the adoption of new color and sweetener provisions into the GSFA. The Committee agreed to endorse the recommendations in the discussion paper for two alternative replacement notes and to forward to CAC42 for adoption the revised provisions for sweeteners in various food categories, accounting for approximately 25% of all adopted provisions which contain Note 161.

In addition, the Committee agreed to establish an EWG co-chaired by the United States and the EU to continue the work on replacing Note 161 by considering recommendations for replacement notes for additional food categories, to discuss whether sweeteners or flavor enhancers are technologically justified in select food categories, and to discuss alternative notes or the revocation/discontinuation of provisions in those food categories.

Discussion Paper on the Use of Nitrates (INS 251, 252) and Nitrites (INS 249, 250)

This discussion paper was the result of an EWG (in which the United States participated) co-chaired by the EU and the Netherlands. The EWG compiled and presented information on existing risk management approaches used by regulatory agencies; available approaches to expressing the basis of use levels (ingoing or residual)\(^2\); use of alternative food additives in lieu of nitrates and nitrites; use and use levels of nitrates (INS 251, 252) and nitrites (INS 249, 250); information on natural occurrence of nitrates and nitrites, e.g., in vegetables; and need for risk assessment and further scientific advice.

The Committee recognized that the previous call for data had a narrow scope and that there was a need to take a more comprehensive approach to obtain data that could be used to inform CCFA’s recommendation on the next steps. The Committee agreed to request the Codex Secretariat, in consultation with the JECFA Secretariat, to issue a Circular Letter (CL) to collect general information on the availability of occurrence data

\(^2\) Nitrate and nitrite levels may change over time as a result of chemical transformation between when the food product is manufactured and when the product is made available for consumption. Ingoing levels refer to the maximum level of nitrate or nitrite added to food at the time of manufacture. Residual levels refer to the maximum level of nitrate or nitrite present during post-market sampling of the finished product.
and/or dietary exposure to nitrates and nitrites and surveys of natural occurrence levels and exposure from use as food additives.

The Committee, recognizing the lack of consensus within the EWG, supported the proposal by the Chair to take a risk management approach that would include both ingoing amounts and residual amounts when addressing the uses and use levels for nitrates and nitrites in the GSFA. The Committee tasked the EWG on the GSFA to circulate all provisions (draft, proposed draft and adopted), taking into account information provided in the discussion paper.

Discussion Paper on the Use of the Terms “Unprocessed” and “Plain” in the GSFA

This discussion paper was drafted by the Russian Federation. The paper asserted that the terms “fresh” and “plain” are too general to be included as definitions in Codex Alimentarius and suggested developing the terms “unprocessed” and/or “untreated” to avoid misleading the consumer and unfair trade practices.

The EU and the Russian Federation expressed the view that there was some uncertainty in determining the categories of food products in which food additives should not be used and that the definition of the term “unprocessed” could help to address the issue. Many other delegations, including the United States, did not favor undertaking work in this area, noting that the proposed terms were used in a few food category descriptors in the GSFA and that most of the food categories where such terms were used fell under the purview of either active or previously active commodity committees. These delegations observed that it is the practice of CCFA to defer to commodity committees to determine the technological justification for the use of food additives in standardized foods, and therefore further work on developing definitions would not be helpful.

Regarding the question of technological justification, it was recognized that multiple sources were available to the Committee for consultation, i.e., Section 3.2 of the Preamble of the GSFA and the existing practice of consultation with the responsible commodity committees on standardized foods. In the context where concerns arose on the use of any food additive provision under consideration, such a provision would be held in the step process and guidance on the use would be sought from the respective commodity committee. Therefore, procedures to facilitate comprehensive and transparent conversations were already in place.
The Committee agreed to discontinue further discussion due to lack of consensus.

NEXT SESSION:

The next session of the CCFA is tentatively scheduled for March 2–6, 2019 in the People’s Republic of China.