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## Report of the United States Delegate to the 50th Session of the Codex Committee on Food Additives

March 26-30, 2018

Xiamen, Peoples Republic of China

The 50th Codex Committee on Food Additives (CCFA) met in Xiamen, Peoples Republic of China, March 26-30, 2018. The meeting was chaired by Dr. Yongxiang Fan and attended by 53 member countries, one member organization (the European Union), 32 observers from international organizations, and representatives from the Food and Agriculture Organization and the World Health Organization.

The U.S. Government participation in the meeting included: Dr. Paul Honigfort, Head of Delegation, U.S. Food and Drug Administration (FDA); Dr. Daniel Folmer, Alternate Delegate, FDA; Dr. LaShonda Cureton, FDA; Dr. Annette McCarthy, FDA; Dr. Dennis Keefe, FDA; Ms. Barbara McNiff, U.S. Department of Agriculture (USDA); Dr. Julie Callahan, Office of the U.S. Trade Representative; Ms. Marie Kirrane, Alcohol and Tobacco Tax and Trade Bureau, and Mr. Chih-Yung Wu, USDA.

The 50th Session of the Codex Committee on Food Additives (CCFA) was a highly 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 ensures fair practices in the food trade. Particularly noteworthy at this CCFA session was the success of U.S. led efforts to forge a breakthrough on the close-to-10-year impasse the Committee experienced in trying to resolve the problem of Note 161, which is a footnote to the GSFA associated primarily with colors and sweeteners. The Note states that the additive provision is subject to the national legislation of the importing country, and has long been opposed by the United States. Additionally, the United States was pleased with the Committee's acceptance of a recommendation by the U.S. Chair of GSFA, that CCFA begin work on colors in certain confectionary categories. Work on colors had been stopped for more than 7 years due to Note 161.

### HIGHLIGHTS:

- GSFA: The Committee completed work on 305 draft and proposed draft provisions, with 183 provisions forwarded for adoption by 41st Codex Alimentarius Commission (CAC41, July 2018), 122 discontinued and 1 provision recommended for revocation. Additionally, the Committee completed work on the alignment of 15 commodity standards with the GSFA, 9 of which were prepared by the United States as co-chair of the electronic working group (eWG). This resulted in over 200 provisions being forwarded to the CAC for revision. Altogether more than 383 provisions were forwarded by the CCFA to CAC41 for adoption.
- 84th Joint Expert Committee on Food Additives (JECFA) Meeting: The Committee forwarded specifications for 10 food additives completed at the 84th JECFA Meeting to CAC41 for adoption..
- Regional Committees: The Committee did not endorse the food-additive provisions in the draft Regional Standard for Dough and returned the standard to the Codex Committee on the Near East (CCNEA) to consider whether a general reference to the GSFA was possible in place of specific food-additive provisions, and to reconsider the reference to national legislation in footnote (a) in the Table of Section 4.1 of the draft standard.
- International Numbering System (INS): The Committee endorsed the listing of Steviol glycosides (INS 960) as a food additive grouping containing Steviol glycosides from *Stevia rebaudiana* Bertoni (Steviol glycosides from *Stevia*) (INS 960a) and Rebaudioside A from multiple gene donors expressed in *Yarrowia lipolytica* (INS 960b(i)). The Committee also agreed to make consequential amendments to the GSFA and to the List of Codex specifications of food additives (CAC/MISC 6-2017).
- JECFA Priority List: Twelve food additives were added to the JECFA priority list, three of which were nominated by the United States.
- Future Work – the Committee agreed to:
  - o Establish an electronic Working Group (eWG) on the GSFA (chaired by the United States) to consider all remaining draft and proposed draft provisions in Tables 1 and 2 of the GSFA in food categories 01.0 through 16.0, with the exception of those additives with technological functions of color or sweetener, adipates, nitrites and nitrates, the use of additives in grape wines, and provisions awaiting guidance from certain commodity committees.
  - o Mandate the eWG on the GSFA to consider draft and proposed draft provisions for the use of colors in confectionaries, chewing gum, and decorations.
  - o Establish a separate eWG (co-chaired by the United States and the European Union (EU)) to develop working for an alternative to Note 161 "Subject to National Legislation of the importing country aimed, in particular, at consistency



with Section 3.2 of the Preamble.” Subject to an agreement on the wording of an alternative, the eWG will review pending and adopted GSFA provisions for sweeteners in the context of recommendations from a previous EWG report (CX.FA 15/47/13).

- o Establish eWGs on alignment of the GSFA and commodity standards (co-chaired by the United States and Australia) and the INS (co-chaired by Belgium and Iran).
- o Task the Codex Secretariat to seek comment on the proposed amendments to the descriptors of food categories 14.1.4.2 and 14.1.5 to differentiate cold versus hot ready-to-drink coffee and tea beverages.
- o Establish an eWG (co-chaired by the EU and The Netherlands) to develop an inventory of data available on nitrates and nitrites to further consider feasibility and the need for risk assessment as outlined in CX/FA 18/50/9.
- o Task the Russian Federation to develop a discussion paper on how the terms “fresh,” “plain,” “unprocessed” and “untreated” are used in existing Codex texts to determine whether definitions could be developed for the purposes of allocating food additive provisions in those foods.

## **MEETING SUMMARY**

The following paragraphs discuss the key decisions made by the Committee in more detail. The full official report of the session and related documents are available on the Codex Alimentarius website at [http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-711-50%252FReport%252FREP18\\_FAe.pdf](http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-711-50%252FReport%252FREP18_FAe.pdf).

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

The Committee considered the document prepared by the eWG, led by Australia and co-chaired by the United States. The Committee endorsed the forward workplan on alignment, contained in CRD 3 Annex 6. The Committee agreed to utilize preparatory work undertaken by Codex observers; invited Japan to participate as an additional co-chair; and endorsed a partnership approach between CCFA and commodity committees. The Committee completed work on the alignment of 15 commodity standards with the GSFA, 9 of which were prepared by the United States as co-chair of the eWG.

### **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 over 320 additive provisions either in the step process and/or already adopted. The Committee endorsed these recommendations in large part, with the exception of the recommendations contained in CRD 2 Annex 3 Part D, pertaining to provisions for the use of certain food additives in food categories 14.1.4 (*Water-based flavoured drink, including “sport”, “energy”, or “electrolyte” drinks and particulated drinks*) and 14.1.5 (*Coffee, coffee substitutes, tea, herbal infusions, and other hot cereal and grain beverages, excluding cocoa*).

Regarding the recommendations of the pWG pertaining to food categories 14.1.4 and 14.1.5, the EU asserted that the use of certain food additives in products of these food categories at the proposed maximum levels (ML) may exceed their acceptable daily intakes (ADIs) if even limited amount of the products was consumed by a 20 kg child. After discussion, the pWG recommended that these provisions be held pending data provided to JECFA and reception by CCFA of the resultant JECFA evaluation. During a subsequent discussion of this recommendation by the Committee, several delegations, including the United States, Australia and Canada, noted that such a calculation did not demonstrate that the proposed ML of a specific food additive was unsafe and that the dietary exposure calculation utilized by the EU was a simplistic method used for preliminary screening. Those delegations expressed concern that the dietary exposure calculation utilized by the EU was not sufficient to require referral of food-additive provisions to JECFA for review. These delegations further noted that, for tocopherol, the European Food Safety Agency had completed a safety assessment in 2015, concluding that “tocopherols [were] not of safety concern at the levels used in food.” In conclusion, the Committee recommended that the draft provision for tocopherols be adopted, that certain provisions be discontinued due to lack of information provided on use, and that the remaining pending provisions in food categories 14.1.4 and 14.1.5 be forwarded to the eWG on the GSFA to CCFA51 to request information on available relevant dietary exposure and technological justification for the proposed use levels for those additives for consideration by the 2019 session of CCFA. The United States as well as several countries from Africa and Latin America and the Caribbean supported this decision as it follows normal procedure for CCFA consideration of pending provisions in the GSFA.



### Discussion Paper on 'Future Strategies for CCFA – Note 161

This discussion paper was co-authored by the CCFA host country (Peoples Republic of China) and the Chairs of the standing WGs in CCFA (GSFA – United States; Alignment – Australia; INS – Iran; and JECFA Priority List – Canada) in consultation with the JECFA and Codex Secretariats. This discussion paper explored strategies to address the major issues affecting the key topics under the purview of CCFA. Pertaining to the GSFA, the Committee noted the difficulties in reaching consensus on approaches to address Note 161, which refers to national legislation and has been attached to over 400 provisions for colors and sweeteners in the GSFA. The use of Note 161 has essentially stopped all work in CCFA on these two types of additives for more than 7 years. The discussion paper provided three different options for resolving the issue, none of which received strong support from the Committee. Recognizing this, the United States worked closely with other countries prior to the discussion, and was able to put forth a proposal to convene an eWG, co-chaired by the EU and the United States, to develop wording for an alternative to Note 161 relating to the use of sweeteners consistent with Section 3.2 of the Preamble to the GSFA and the Statement of Principles in the Codex *Procedural Manual*. Subject to an agreement on the wording of an alternative, the eWG will review applying the alternative to pending and adopted GSFA provisions for sweeteners in the context of recommendations from a previous eWG report (CX.FA 15/47/13). There was wide support from all regions for the U.S. proposal, as it was the first breakthrough in attempting to resolve the stalemate on considering additive provisions in these categories in close to 10 years.

### 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 with additional comment from the JECFA Secretariat. This paper discussed issues associated with risk management and risk assessment for the additives use of nitrates (INS 251, 252) and nitrites (INS 249, 250). In addition to exposure to nitrates and nitrites, the paper notes the formation of and exposure to nitrosamines as a result of the use of these additives.

The Committee noted that additional data were needed to make an informed decision on effective risk-management options to address resultant safety concerns from the use of these additives and to identify for which issues it may be appropriate to request further scientific advice from JECFA. The Committee expressed broad support for establishing an eWG to collect data enabling CCFA to take a decision at its next session (CCFA51, in 2019). However, some members questioned if the information pertaining more to risk assessment than risk management should be collected by JECFA through a call for data rather than by CCFA. The JECFA Secretariat suggested that an efficient approach might be for CCFA to collect risk assessment data concurrently with risk management data, as is done in other Codex Committees. The Committee agreed to establish an eWG, chaired by the EU and co-chaired by The Netherlands, to develop an inventory of risk assessment and risk management information that is currently available. It was noted that this mandate is very broad and that it might not be feasible to address all points by CCFA51.

### 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 definitions for the terms “unprocessed” and “plain” were required in order to differentiate what food additives, if any, should be allowed in these types of foods. Some European delegations in favor of developing definitions expressed the opinion that doing so would reduce any risk of misleading consumers and ensure that the use of food additives was guided by the principles laid out in Section 3 of the Preamble to the GSFA. The United States, Canada, Australia, New Zealand and a number of countries from the Asian, African, and Latin American regions were not in favor of the work and stressed that unilaterally developing horizontal definitions in the context of the GSFA would undermine the work of commodity committees which are responsible for determining which types of food additives are technologically justified in standardized products. They noted that the development of these definitions by CCFA would contravene the relationships between the commodity committees and the CCFA as outlined in the *Procedural Manual*. These delegations further observed that the work may result in significant consequences for many existing Codex texts, with implications for trade, and that the GSFA Preamble sufficiently addresses the concerns raised and provides adequate explanation on the use of additives. These delegations questioned the competence of CCFA to undertake the task and suggested that the matter be referred to the CAC. Despite these views, to study the issue further, CCFA agreed to request the Russian Federation to prepare a discussion paper on how the terms “fresh,” “plain,” “unprocessed” and “untreated” are used in Codex texts.

## Next Session



United States Department of Agriculture

The next session of the CCFA is tentatively scheduled for March 25 – 29, 2019 in the Peoples Republic of China.