THE UNITED STATES DELEGATION

TO THE 43rd SESSION OF THE

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

(CCNFSDU43)

Plenary: March 7-10, 2023
Dusseldorf, Germany

Report Adoption: March 15, 2023
Virtual

U.S. Draft Positions
For the February 8, 2023, Public Meeting

Agenda Item 1: Adoption of the Agenda

Meeting Document: CX/NFSDU 23/43/1 – Provisional Agenda

Note from the CCNFSDU43 Provisional Agenda:

Two physical working groups, on general principles for the establishment of nutrient reference values-required (NRVs-R) for persons aged 6 – 36 months and on prioritization mechanism / emerging issues or new work proposals, will meet at the same venue on Monday, 6 March 2023.

Draft U.S. Position:

The United States supports the proposed agenda and hopes the Committee can make significant progress. As part of Agenda Item 8a, Methods of Analysis, there will be consideration of responding to the Codex Committee on Methods of Analysis and Sampling (CCMAS) regarding methods of analysis for optional nutrients in infant formulas and updated methods for total amino acids (minus tryptophan), tryptophan and vitamin B12.

Agenda Item 2: Matters referred to the Committee by the Codex Alimentarius Commission (CAC) and/or Other Subsidiary Bodies

Meeting Document: CX/NFSDU 23/43/2 Rev

Draft U.S. Position:

The United States welcomes the information provided as Matters for Information from CAC44 (2021) and CAC45 (2022) and from other subsidiary bodies and has no comments at this time.

Regarding Matters for Action:

- The United States agrees that the reply from the Codex Committee on Food Labelling (CCFL) regarding nutrient profile models should be considered in discussing potential work to establish guidelines for nutrient profile models.
- The United States will lead an in-session working group to consider the request from CCMAS related to proposed methods for fructans, beta-carotene, and lycopene in infant formula.
- The United States supports the World Health Organization (WHO) request that Codex committees in the course of their work consider how Codex standards can help reduce diet-related risk factors for noncommunicable diseases (NCDs), such as sodium intake.

Agenda Item 3: Matters of Interest Arising from FAO and WHO

Meeting Document: CX/NFSDU 23/43/3 – *not yet available*

Draft U.S. Position:

The meeting document has not yet been posted to the CCNFSDU43 website.

Agenda Item 4: Review of the *Standard for Follow-up Formula* (CXS 156-1987)

Meeting Documents: CX/NFSDU 23/43/4
CL 2022/24/OCS-NFSDU
NFSDU/43 CRD 2

Note from the CCNFSDU43 Provisional Agenda:

The review of the *Standard for Follow-Up Formula* has been undertaken in stages with completion first of the essential composition and quality factors for both Sections A (follow-up formula) and B (Drink for young children with added nutrients or Product for young children with added nutrients or Drink for young children or Product for young children), followed by other remaining provisions.

As parts of the draft revised standard were completed, they were held at Step 7 (not transmitted to the CAC for final adoption at Step 8) to allow discussion and agreement on further parts of the draft revised standard. The Committee agreed that the structure of the standard and the proposed preamble would be considered after completion of the other provisions. CCNFSDU42 (2021) confirmed this agreement and agreed that CCNFSDU43 would consider the preamble and structure of the standard. Thereafter, it is intended to submit the complete revised standard for final adoption at Step 8 by the 46th Session of the Commission (CAC46, 2023).

Draft U.S. Position:

The United States supports the previous decisions of the Committee on organizing the work and hopes that the standard can be completed at this session and transmitted to CAC46 for final adoption at Step 8. To complete the standard a simple and pragmatic approach to both the structure and preamble is necessary.

Structure:
The United States supports maintaining the current structure as a pragmatic approach to facilitating the Committee's work. There is no real value in separating the standard into two independent standards and, therefore, the United States supports Option A – one standard with two parts. We note that the name of the standard will need to be updated to accommodate the two products under the standard, Follow Up Formula for Older Infants and Product/Drink for Young Children.

Preamble:
The United States notes that a preamble is not necessary for Codex standards. However, the United States could support a simple preamble which states that the standard consists of two parts, Part A (FUF for Older Infants) and Part B (Drink/Product for Young Children). This would be consistent with the preamble of the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CXS 72-1981). Additional text and/or references are not necessary for the preamble as all critical aspects important to the standard have been thoroughly discussed, agreed to, and incorporated into the text of the standard by the Committee – in particular, in the definitions and labeling sections. This is also consistent with the guidance provided by the Codex Executive Committee at its 75th Session (CCEXEC75, 2018) and reaffirmed by CCEXEC77 (2019). (See REP18/EXEC2-Rev.1, paras 12-18 and REP19/EXEC2, para. 11).

A draft preamble for consideration has been provided in NSFDU/43 Conference Room Document #2 (CRD2) which follows:

> *This Standard is divided into two sections. Section A refers to Follow-up Formula for Older Infants, and Section B deals with Drink for Young Children with Added Nutrients, or Product for Young Children with Added Nutrients, or Drink for Young Children, or Product for Young Children. [The application of this Standard should be consistent with national health and nutrition policies and relevant national/regional legislation and take into account the recommendations made in the International Code of Marketing of Breast-milk Substitutes, as per the national context]. [Relevant World Health Organization (WHO) guidelines and policies and World Health Assembly (WHA) resolutions were considered in the development of this Standard and may provide further guidance to countries]*

The United States could support the first sentence of the proposed Draft Preamble as it is consistent with the position outlined above and makes clear the two sections of the standard. The United States views the text in the square brackets of the proposed preamble as unnecessary and has the position that the text should not be included.

Agenda Item 5: General Principles for the establishment of Nutrient Reference Values-Required (NRVs-R) for persons aged 6–36 months (at Step 4)

Meeting Documents: CX/NFSDU 23/43/5
CX/NFSDU 23/43/5 Add.1 – *not yet available*

Note from the CCNFSDU43 Provisional Agenda:

At CCNFSDU42 (2021) the Committee agreed to continue work chaired by Ireland and co-chaired by Costa Rica and the United States to (a) finalize General Principles for establishing NRVs-R for persons aged 6 to 36 months and (b) pilot the draft General Principles for the following nutrients: vitamin B-12, iodine, vitamin B6, riboflavin and if time permitted, thiamine, niacin, and vitamin C. The Committee also agreed to consider holding a physical working group (PWG) prior to the next session to help progress the work.

A PWG will meet prior to the session to consider written comments submitted and prepare a revised proposal for consideration by CCNFSDU43. The PWG report will be considered under this item and will be made available as a CRD prior to the session.

Draft U.S. Position:

The United States thanks Ireland for its leadership in progressing the work and generally supports the draft General Principles. The United States welcomes further discussions during the PWG session, in particular, the areas of appropriate data and review of the data to determine strength and quality of evidence need more consideration. The work of WHO and/or the Joint Expert Meeting on Nutrition (JEMNU) should be one of the main sources of data for consideration but should not be taken to the exclusion of data from the Recognized Authoritative Scientific Bodies (RASBs).

The table providing an overview of the types of data and relative strength of evidence has been removed and the United States suggests that it be added back as it provides an important reference for the General Principles. The paper for this agenda item (CX/NFSDU 23/43/5), in Appendix II Part B, outlines a stepwise approach to considering data sources and determining NRVs-R for persons 6-36 months. The United States suggests that Step 4 needs further discussion and refinement during the PWG with respect to selection of data sources. The United States suggests that all suitable data sources be included without rounding, and that all suitable data sources be used to set a value using the median of the values from all data sources.

Agenda Item 6: Technological justification for several food additives

Meeting Document: CX/NFSDU 23/43/6

Draft U.S. Position:

- With regard to (i) in the agenda document, the United States has the view that low acyl clarified gellan gum, ascorbyl palmitate, mixed tocopherol concentrates, and phosphates are technically justified for use as additives in infant formula based on the information provided.
- With regard to (ii), the United States questions the need for the proposed program for the consideration of the remaining food additives. The United States does not believe there is a need to spend resources to reaffirm the technical justification of additives already permitted as part of the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CXS 72-1981). These additives were included in the *Standard* and Codex already has agreed there was a basis/justification for their use. The United States suggests that the list be reviewed to determine if all the additives are still being used and the typical levels of use in commercial infant formula products to be sure that use levels are consistent with those already listed in CXS 72-1981. Those in use would be considered technically justified and remain listed in CXS 72-1981 and would be submitted for safety assessment. Those not in use would be removed from CXS 72-1981 and not be submitted for safety clearance. The United States believes this work could be completed in one Electronic Working Group (EWG) period and that this approach would be a pragmatic way to progress this work. Finally, the United States believes that detailed technical justification should be reserved for new additives not currently listed as part of CXS 72-1981.

Agenda Item 7: Prioritization mechanism / emerging issues or new work proposals

Meeting Documents: CX/FNSDU 23/43/7
CX/NFSDU 23/43/8

Note from the CCNFSDU43 Provisional Agenda:

A PWG will consider the report of the EWG on the prioritization mechanism to better manage the work of CCNFSDU and do a case-by-case review of all new work proposals submitted in response to CL 2020/30-NFSDU as well as the discussion paper on general guidelines on nutrient profiles. The report of the PWG will be considered under this item and will be made available as a CRD prior to the session.

Draft U.S. Position:

The United States supports the prioritization mechanism presented in Appendix 1 of CX/NFSDU 23/43/8 as it will aid the committee in reviewing proposals for new work and setting priorities. The mechanism can be amended, if necessary, after the committee has experience with its application.

Part 1: Requests for Amendments/Revisions of Existing CCNFSDU Texts.

- Proposal 1.1: *Standard for Canned Baby Foods* (CXS 73-1981). The United States notes that recommendations regarding timing of appropriate introduction of beets and spinach to an infant's diet vary internationally. The American Association of Pediatrics, while recommending exclusive breast feeding for the first 6 months of life, notes that some children are developmentally ready to begin solid foods as early as 4 months of age. As risk managers, the Committee should have a science-based recommendation regarding timing of both introduction of solid foods and appropriate age for introduction of beets and spinach before amendment of the text can be considered.

- Proposal 1.2: Align the permitted uses of folic acid source calcium-L-methyl-folate with those of N-pteroyl-L-glutamic acid in the advisory list of nutrients for use in the *Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children* (CXG 10-1979). The United States supports amending the following standards: Section A of the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CXS 72-1981); *Standard for Follow-up Formula* (CXS 156-1987) (noting that this should be reflected in the current update by the Committee); *Standard for Processed and Cereal-Based Foods for Infants and Young Children* (CXS 74-1981); and *Standard for Canned Baby Foods* (CXS 73-1981). If the Committee generally agrees, the United States questions the need for a formal new work proposal and would propose that the amendments be handled as technical amendments by the Codex Secretariat.

Part 2: Requests for New Work

- Proposal 2.1: Discussion Paper on Harmonized Probiotic Guidelines for use in Foods and Food Supplements. The United States is generally supportive of the proposal in that a harmonized definition and labelling provisions can support trade. The priority of this work should be determined via the prioritization mechanism and based on timing of workflow.

- Proposal 2.2: Guidelines including General Principles for the Nutritional Composition of foods and beverages made from plant-based and other alternative protein sources. Alternative protein-based foods that replace animal-based foods are a focus of innovation, market growth and international trade. Science-based guidelines for the nutritional composition of these products would be important to ensure dietary patterns containing these replacement foods meet nutrient adequacy and are not excessively high in nutrients associated with noncommunicable disease (NCD) risk such as sodium, saturated fats, and added/free sugars. The United States supports starting this project with a first step of seeking scientific advice to guide the scope and frame of the project. As obtaining scientific advice will take at least one year, work on other projects can be progressed in the interim.

- Proposal 2.3: Discussion Paper on General Guidelines to Establish Nutrient Profiles for Front of Package Nutrition Labelling (FOPNL). The United States is supportive of the proposal to establish general principles for nutrient profile models as a complement to the General Principles for FOPNL established by CCFL. The United States is of the view that if the General Principles for FOPNL established by CCFL is used as a framework that work on General Principles for Nutrient Profiles and be completed in 1-2 sessions of CCNFSDU or by 2025.

- Proposal 2.4: Discussion Paper on Establishing a Nutrient Reference Value (NRV-NCD) for Trans-Fatty Acids. The United States notes that WHO Nutrition Guidance Expert Advisory Group (NUGAG) is due to publish is updated guidelines on dietary fats which will include guidelines on trans fatty acids. If the current recommendation of less than 1% energy or 2 grams per day trans fatty acids is retained, then based on the General Principles for establishing NRVs for the General Population the recommendation of the WHO would be adopted, and there would be little work needed by the Committee. The United States suggests that this work be reconsidered once the WHO NUGAG report is published as it would form the basis for setting the NRV.

Agenda Item 8: Other Business and Future Work
Agenda Item 8a: Methods of Analysis

Meeting Documents: CX/NFSDU 23/43/9 -*not yet available*
REP22/NFSDU, paras 6(ii) and 99

Note from the CCNFSDU43 Provisional Agenda:

This item will consider the request from CCMAS relating to the methods for fructans, beta-carotene and lycopene in infant formula as well as appropriate methods for assessing sweetness of carbohydrate sources in "Drink for young children with added nutrients or Product for young children with added nutrients or Drink for young children or Product for young children". This item will also consider referral to CCMAS of updated Type II methods for total amino acids (minus tryptophan) and tryptophan and a Type III method for vitamin B12.

Draft U.S. Position:

The United States will lead an in-session working group to consider the response to CCMAS related to methods for fructans, beta-carotene, and lycopene as optional ingredients in infant formula and referral of the new methods.

The United States supports informing CCMAS that fructans, beta-carotene and lycopene are valid optional ingredients based on the definition found in the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CXS 72-1981)* and that the methods can be endorsed. The United States would support referring the updated methods for total amino acids (minus tryptophan), tryptophan and vitamin B12 to CCMAS for typing and endorsement.

Agenda Item 9: Date and Place of the Next Session

The date and place of the next session will be determined based on consultations between the host country and the Codex Secretariat.

Agenda Item 10: Adoption of the Report

Report adoption is scheduled to take place virtually on March 15, 2023.