REPORT OF THE UNITED STATES DELEGATE
ON THE 43rd SESSION OF THE
CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

March 7 - 10, 2023
Düsseldorf, Germany
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The 43rd Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU43) met in Dusseldorf, Germany from March 7-10, 2023. The session was chaired by Dr. Anja Brönstrup of the Federal Ministry of Food and Agriculture, Germany, and co-chaired by Ms. Martine Püster of the Federal Office of Consumer Protection and Food Safety, Germany. There were participants from 60 Member countries, one Member Organization (the European Union), and 29 Observer Organizations. The United States was represented by the Delegate, Dr. Douglas Balentine of the U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition; Alternate Delegate, Dr. Pamela Pehrsson of the U.S. Department of Agriculture, Agricultural Research Service; four government advisors; and three non-governmental advisors.

Overall, the United States was satisfied with the outcomes from CCNFSDU43. Most agenda items were resolved consistent with U.S. objectives for the meeting. Although efforts to achieve the most-preferred option for preamble language in the updated revised *Standard for Follow-Up Formula* were ultimately not successful, the final version is acceptable and represents significant progress over options considered by the Committee at previous sessions.

HIGHLIGHTS

The 43rd Session of CCNFSDU made significant progress on several work items:

Revised *Standard for Follow-Up Formula* (**CXS 156 -1987):** CCNFSDU43 completed the work on updating this standard, which has occupied much of the Committee's attention over several sessions. CCNFSDU43 agreed to forward the revised Name (*Standard for Follow-up Formula for Older Infants and Product for Young Children*), Structure, and Preamble, together with the remaining sections of Parts A and B that were agreed to at CCNFSDU42 (2021), to the 46th Session of the CAC (CAC46, currently scheduled for November 2023) for final adoption at Step 5/8. Other parts of the text that were held at Step 7, short of final adoption, were forwarded to CAC46 for final adoption at Step 8.

Nutrient Reference Values: CCNFSDU43 agreed to forward the draft *General Principles for Establishing Nutrient Reference Values – Requirements for Older Infants and Young Children* (proposed Annex B in the *Guidelines on Nutrition Labeling* (CXG 2-1985) to CAC46 for interim adoption at Step 5. Work on establishing nutrient reference values (NRVs-R) for older infants and young children will continue.

New Work Prioritization: CCNFSDU43 agreed to establish an Electronic Working Group (EWG) to revise the proposed guidance on identification and prioritization of new work proposals, which will be used on a trial basis at the next session (CCNFSDU44, late 2024).

Methods of Analysis: CCNFSDU43 agreed to forward methods of analysis for total amino acids (minus tryptophan and taurine), tryptophan, and Vitamin B12 in the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CXS 72-1981) to the Codex Committee on Methods of Analysis and Sampling (CCMAS) for endorsement.

A summary of the 43rd Session of the CCNFSDU is given below. All working documents (including conference room documents (CRDs)), remarks, presentations, and the official final report of CCNFSDU43 may be found on the Codex website at the following link: https://www.fao.org/fao-who-codexalimentarius/meetings/detail/en/?meeting=CCNFSDU&session=43.

NEXT SESSION OF CCNFSDU

The 44th Session of CCNFSDU is tentatively scheduled to take place approximately 18 months from CCNFSDU43 (i.e., late 2024), at a location still to be determined.

MEETING SUMMARY

REVIEW OF THE *STANDARD FOR FOLLOW-UP FORMULA* (CXS 156-1987): PREAMBLE AND STRUCTURE
To Be Presented for Adoption at Next CAC? Yes **Have the United States' Objectives Been Met?** Yes, for the most part. **Is it anticipated that this item will or should be raised at the CAC because it is contentious?** Possibly; however, Codex Members are expected to support final adoption consistent with CCNFSDU43 recommendations. Nine Member countries, including the United States, raised reservations on inclusion of the preamble as approved by the Committee. Concerns also remain about the use of footnotes to resolve an impasse—in particular, the footnotes in Part B of the Standard for the definition of flavors and carbohydrates (sweet taste), which was not on the agenda for CCNFSDU43, but which was discussed at earlier CCNFSDU sessions. Additionally, the footnote referring to how the products for young children may be regulated as breastmilk substitutes in some countries, which would more appropriately be reflected in committee reports rather than as footnotes to the standard. (The United States does not consider the product for young children to be a breastmilk substitute, based on the compositional requirements in the draft revised standard and the intended use of the product as part of the increasingly diversified diet of young children.)
United States Objective The United States objective was to finalize the outstanding issues regarding the preamble and structure in order to advance the revised standard to CAC46 for final adoption.

Discussion in Relation to United States' Objectives
In plenary session, the EWG Chair (New Zealand) provided background on the work prior to CCNFSDU43 of analyzing responses to the Circular Letter (CL 2022/24/OCS-NFSDU) and developing the recommendations outlined in CRD02. The Committee Chair then set-up the discussion to decide the structure, title, and then the preamble.

Structure
The United States supported maintaining the current structure as a pragmatic approach to facilitating the Committee's work. This was identified as Option A—one standard with two parts. Several delegations also supported this view while a few favored two separate standards. The Committee agreed to progress with Option A—one standard with two parts, Part A for follow-up formula for older infants (6-12 months) and Part B for products for young children (12-36 months).

Standard Name
Given the decision to structure the document as one standard with two parts, the name of the standard needed to be updated to accommodate the two products under the standard: "Follow-Up Formula for Older Infants" and "Product/Drink for Young Children." The Codex Secretary proposed that the title of the revised standard be "Standard for Follow-up Formula for Older Infants and Product for Young Children" with a footnote stating that other equivalent names for this product are "Drink for Young Children with Added Nutrients," "Product for Young Children with Added Nutrients," or "Drink for Young Children." There were no objections and the Committee agreed to rename the draft revised standard as proposed.

Preamble
There was considerable discussion around the need for a preamble, with some Members and Observers expressing no need for this section and several delegations' wanting a preamble to set the stage for the standard.

The proposed preamble paragraphs were:

- Paragraph One – stating that the standard is divided into two parts.
- Paragraph Two – stating that the application of the standard should be consistent with national policies and take into account recommendations in the WHO International Code of Marketing of Breast-milk Substitutes.
- Paragraph Three – stating that relevant World Health Organization (WHO) guidelines and policies and World Health Assembly (WHA) resolutions were considered in the development of the revised/updated standard.

The United States intervened to state that preambles are not generally necessary for Codex standards and that, in this case, the revised name made it clear that the standard included two separate products. In the end, the Chair ruled that there was agreement on including a preamble.

Once the Committee agreed that a preamble would be included, the United States intervened to support a simple and factual preamble with only the first paragraph. 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). The United States noted further that all critical aspects had been thoroughly discussed, agreed to, and incorporated into the text.

There was extensive discussion on the content of the preamble and whether only the first paragraph, a combination, or all three paragraphs should be included. Clear consensus was reached on the inclusion of paragraph one.

Several delegations did not support the second and third paragraphs, either alone or together. Other delegations wanted to include all three paragraphs to help guide countries in the application and implementation of the standard with reference to WHO texts and World Health Assembly (WHA) resolutions.

The United States intervened and did not support the inclusion of the second paragraph, stating that all the issues related to the Code that the Committee could agree to (i.e., those related to the naming and the labeling sections, including promotion of the importance of breastfeeding) had been addressed. This paragraph was not in line with the guidance from the Codex Executive Committee (CCEXEC) on minimizing references to external texts and could be interpreted as inconsistent with other international obligations. As a compromise, the United States indicated support for including the third paragraph as a factual statement that the relevant texts had been taken into account in the development of the revised standard.

Although several concerns remained, the Committee agreed to adopt all three paragraphs in CRD02 as the Preamble to the draft revised standard and noted reservations from the following countries on specific paragraphs of the proposed text:

- Argentina - Reservation to paragraphs two and three
- Colombia – Reservation to paragraph two
- Costa Rica – Reservation to paragraphs two and three
- Cuba - Reservation to paragraphs two and three
- Guatemala - Reservation to paragraphs two and three
- Panama - Reservation to paragraph two
- Morocco – Reservation to paragraph two
- United States of America – Reservation to paragraph two
- Vietnam - Reservation to paragraphs two and three

In filing its reservation, the United States indicated that the second sentence was not acceptable, since it was unnecessary and may be interpreted as inconsistent with international trade obligations.

Outcome/ Conclusion

The Committee agreed to forward:

- the proposed draft revised Name (*Standard for Follow-up Formula for Older Infants and Product for Young Children* (CXS 156-1987)) and the Preamble, together with the remaining sections of Part A and B, to CAC46 for final adoption at Step 5/8.
- the parts of the text that had been held at Step 7 to CAC46 for final adoption at Step 8.

PROPOSED DRAFT GENERAL PRINCIPLES FOR ESTABLISHING NUTRIENT REFERENCE VALUES (NRVS-R) FOR PERSONS AGED 6 – 36 MONTHS

To Be Presented for Adoption at Next CAC? Yes
Have the United States' Objectives Been Met? Yes
Is it anticipated that this item will or should be raised at the CAC because it is contentious? No

United States Objective
The United States objective was to advance the draft *General Principles for Establishing Nutrient Reference Values (NRVs-R) for Persons Aged 6 – 36 Months* at CCNFSDU43 and forward to CAC46 for interim adoption at Step 5.

Discussion in Relation to United States' Objectives
The plenary session discussed recommendations in CRD05, made by the Physical Working Group (PWG) held prior to CCNFSDU43. The PWG resolved a number of key issues, however, some issues remained for discussion in plenary.

Preamble
The United States supported keeping the Preamble overarching, clear, and aligned with that of Annex A in the *Guidelines on Nutrition Labeling* (CXG 2-1985). Several delegations supported this view. In addition to existing text stating that governments could establish NRVs-R for specific segments of the population aged 6 to 36 months, the EU requested insertion of text specifying that separate or combined NRVs could be established for this age group.

Definitions
The Committee agreed to use the definition of Recognized Authoritative Scientific Body (RASB) used in Annex A to indicate the WHO as a primary source of Dietary Intake Reference Values (DIRVs). After a thorough discussion on whether sustaining health included the concept of growth and development, the Committee agreed to keep the proposed definition of Adequate Intake (AI) in brackets to align with the WHO report on the requirements for calcium, Vitamin D, and zinc, expected to be published in the fall of 2023.

General Principles for Establishing NRVs-R
The Committee quickly agreed on the text for the Suitable Data Sources. With respect to Section 3.2, Appropriate Basis for Establishing NRVs, the United States intervened to include the concept that NRVs should be established on an Individual Nutrient Level 98 (INL98) to indicate that the strongest scientific data (i.e., a value derived from physiological evidence) should be used to establish an NRV-R. In some cases, an AI derived from physiological data has been set for this age group. To address these cases, the Committee agreed on a clarifying edit to indicate that the INL98 should ideally be used.

There was extensive discussion on whether text on combining values for older infants and young children belonged in the general principles. The United States reminded the Committee that the Preamble provides flexibility for governments to set NRVs-R for specific segments of persons aged 6-36 months, and a method for combining values had not yet been developed.

Canada proposed additional text for using the mean value for older infants and young children. Ireland, the EWG Chair, reminded the Committee that the agenda paper included a proposed rationale for how to derive a higher value, and suggested amending the proposed text to include use of a higher value—provided it doesn't exceed the Upper Level (UL)--to cover the needs of both groups. The EU proposed adding in the lower value. The Chair suggested keeping the proposed text in brackets until the EWG develops a method for combining the NRV-R value for older infants and young children.

Consideration of Upper Levels of Intake
The Committee agreed on the proposed text on the Consideration of Upper Levels of Intake.

Outcome/ Conclusion
The Committee agreed to forward the draft *General Principles for Establishing Nutrient Reference Values – Requirements for Older Infants and Young Children* (proposed Annex B in the *Guidelines on Nutrition Labeling* (CXG 2-1985)) to the Commission for interim adoption at Step 5.

Other Comments
The draft *General Principles* are viewed as working principles that may be amended based on the outcomes of the EWG chaired by Ireland, and co-chaired by Costa Rica and the United States. The EWG will revise the stepwise process for establishing NRVs-R for vitamins and minerals for older infants, young children, and both groups combined. A PWG may be convened prior to CCNFSDU44 .

PRIORITIZATION MECHANISM / EMERGING ISSUES OR NEW WORK PROPOSALS

To Be Presented for Adoption at Next CAC? No
Have the United States' Objectives Been Met? Yes
Is it anticipated that this item will or should be raised at the CAC because it is contentious? No

United States Objective
The United States believes the prioritization mechanism will be a helpful tool for the Committee and offered guidance and input to help improve the pilot mechanism.

Discussion in Relation to United States' Objectives
The plenary session discussed the recommendations in CRD06 made by the PWG held prior to CCNFSDU43. The PWG reviewed all new work proposals using the revised prioritization mechanism on a pilot basis and made recommendations to the Committee regarding each new work proposal. The PWG also developed recommendations on the prioritization mechanism itself, which the plenary reviewed.

Decision Tree
The Committee had significant discussion during the consideration of the draft prioritization criteria. As the revision of these criteria would likely impact the decision tree, the Committee agreed that the decision tree would require further revision, and this was included in the terms of reference for the EWG.

Prioritization Criteria
Delegations made several suggestions to change, delete, or add content to the draft prioritization criteria. The EU proposed removing the word "positive" from "positive impact" in all of the proposed criteria such that they would read "Impact on…". The United States had no objections to this edit, several delegations supported it, and Canada and New Zealand recommended "net impact" instead.

The EU also wanted to add a criterion concerning consumer interest; however, New Zealand and the United States did not agree.

Several delegations supported the elaboration and/or expansion of the global impact criterion.

There was discussion on how the criteria would help prioritize new work and whether the criteria should be used by the Committee in addition to the submitters in their self-assessment.

The United States questioned whether there would be a need to prioritize work if the Committee did not have enough new work proposals to warrant prioritization.

New Work Proposals
Proposal 1.1: Proposed amendment/revision: *Standard for Canned Baby Foods* (CXS 73-1981) (submitted by the Dominican Republic):
In response to the proposal to amend the provision regarding the introduction of beetroot and spinach at twelve weeks of age, the WHO provided scientific advice on the diminishing risks of methemoglobinemia with age associated consumption of root vegetables and leafy greens. The United States supported the recommendation to delete this provision given the WHO's advice that there is no clear cutoff for the introduction of beetroot and spinach.

Proposal 1.2: Proposal to align the permitted uses of the folic acid source Calcium-L-Methyl-Folate with those of N-Pteroyl-L-Glutamic acid in the *Advisory List of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children* (CXG 10-1979)(submitted by Switzerland):
There were no objections to this proposed amendment, which will not require the initiation of new work and will be handled by the Codex Secretariat.

Proposal 2.1: Harmonized probiotic guidelines for use in foods and food supplements (submitted by Argentina and Malaysia):
The Committee had a lively discussion on this proposal. The delegations supporting it cited a need for harmonized guidelines to help countries regulate probiotic products, facilitate trade, and protect consumers from unsafe probiotic products. The United States expressed concerns about lack of clarity in the proposal, especially regarding the use of the term "health," and that in general the framing of the scope of work was too broad. Canada expressed the view that this work falls within the mandates of CCFL and the Codex Committee on Food Hygiene (CCFH). The EU highlighted their concerns with the scope and questioned whether these issues were within the mandate of CCNFSDU. China supported the new work proposal, citing the wide use of probiotic products in China.

Proposal 2.2: Guidelines including General Principles for the Nutritional Composition of Foods and Beverages made from Plant-based and other Alternative Protein Sources (submitted by Canada and the United States):
The United States presented this proposal highlighting the need for guidelines on the nutritional composition of such products to ensure that nutritional adequacy is not compromised when these products are used a replacement for animal-based foods. The International Organization for Standardization (ISO) confirmed that nutritional composition of alternative protein products was outside the scope of their current work in the area. The United States highlighted the need to seek scientific advice from FAO and WHO to better inform the scope of this work.

Proposal 2.3: General Guidelines to establish nutrient profiles for front-of-pack nutrition labelling (FOPNL) (submitted by Costa Rica, the European Union, Paraguay and the United States):
The Committee discussed past and ongoing work by the WHO to develop guidance on nutrient profile models for different policy applications. The WHO confirmed that the first tranche of these documents would be available in the first half of 2023, and the second in the latter half of 2023. In light of this, the Committee generally agreed that this proposal should not move forward at this time. The United States proposed waiting until the WHO guidance is published, as that may inform how CCNFSDU proceeds. The United States and Costa Rica emphasized that work by WHO and Codex on Nutrient Profile Models (NPMs) is not mutually exclusive and that Codex has a unique mandate to develop standards and guidelines to address both public health and trade.

Proposal 2.4: Nutrient reference value (NRV-NCD) for trans-fatty acids (submitted by IMACE):
This proposal was not endorsed by a Codex Member and thus could not move forward according to the prioritization mechanism.

Conclusions
The Committee agreed to establish an EWG that would revise the draft prioritization guidance, including the prioritization criteria and the decision tree, taking into account the comments of the PWG and CCNFSDU43. This revised draft will be used on a trial basis for consideration by CCNFSDU44.

Proposal 1.1: CCNFSDU43 agreed to the recommendation of the PWG to delete paragraph 9.5.2 from CXS 73-1981 and submit the amendment directly to CAC46 for adoption.

Proposal 1.2: CCNFSDU43 agreed to the recommendation of the PWG to revise the *Advisory List of nutrient compounds* in CXG 10-1979 and submit the revision directly to CAC46 for adoption.

Proposal 2.1: CCNFSDU43 agreed to establish an EWG open to all Members and Observers chaired by Argentina and co-chaired by China and Malaysia to further refine and the Discussion Paper on Harmonized Probiotic Guidelines for Use in Foods and Food Supplements, especially with regards to the scope, impact on food safety and need for scientific advice; and develop a revised discussion paper and project document, taking into account comments at CCNFSDU43 for consideration at CCNFSDU44 as part of the discussions of new work proposals.

Proposal 2.2: CCNFSDU43 agreed that Canada and the United States would refine the scope of the new work proposal.

Proposal 2.3: CCNFSDU43 agreed that due to ongoing work in this area by WHO and the lack of support in the PWG, the proposal should not be pursued at this time.

Proposal 2.4: CCNFSDU43 agreed to not take up the new proposal in the absence of Member support.

Other Comments
A PWG may be held prior to CCNFSDU44 to revise the draft guidance.

METHODS OF ANALYSIS
To Be Presented for Adoption at Next CAC? No **Have the United States' Objectives Been Met?** Yes (Mostly) **Is it anticipated that this item will or should be raised at the CAC because it is contentious?** No
United States Objective To refer updated methods of analysis for total amino acids (AA) (minus tryptophan and taurine), tryptophan, and Vitamin B12 to CCMAS for endorsement; to inform CCMAS that fructans, beta-carotene, and lycopene are valid optional ingredients for use in infant formula; and to review suitability of sensory methods of assessing sweetness of carbohydrate sources.
Discussion in Relation to United States' Objectives *Methods of analysis for the provisions in the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CXS 72-1981) The plenary discussed the outcomes of the in-session working group (WG) (CRD 41) on this topic. The in-session WG heard technical experts present the methods for consideration and recommended to the Committee that the three updated methods be referred to CCMAS for endorsement. *Fructans, beta-carotene, and lycopene as optional ingredients* The United States provided background to the plenary on CCMAS41's request that CCNFSDU provide a reference to the standard to which the referred methods of analysis for fructans, beta-carotene, and lycopene are pertinent. The in-session WG had heard an expert presentation on these methods, however, technical issues prevented adequate review of the issues. The Committee endorsed the in-session WG's recommendation to establish an EWG to further deliberate these ingredients' suitability as optional ingredients in the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CXS 72-1981). The EU commented that the safety of the ingredients should be scientifically demonstrated. *Methods for assessing sweetness of carbohydrates sources in Product for Young Children* The United States presented background to the plenary regarding CCMAS' response to CCNFSDU41. CCMAS replied that there are no validated international methods for assessing sweetness in non-milk-based products for young children. The United States highlighted that

the in-session WG had serious questions about the suitability of sensory methods for assessing the sweetness of carbohydrates used in formulating non-milk-based products for young children. The Committee decided there was a need to review the scientific literature and available data to determine if sensory methods would be fit for purpose. The in-session WG recommended establishing an EWG to review the issue further and CCNFSDU43 agreed. New Zealand questioned whether this work warranted an EWG, noting resource limitations and that these methods related to only a small subset of non-milk based products for young children. The EU and Switzerland strongly supported this work.
Outcome/ Conclusion *Total amino acids (minus tryptophan and taurine), tryptophan, and Vitamin B12:* CCNFSDU43 agreed to forward the methods of analysis for Vitamin B12; total amino acids (excluding taurine and tryptophan), and tryptophan to CCMAS for endorsement and inclusion in the *Recommended Methods of Analysis and Sampling* (CXS 234-1999). *Fructans, beta-carotene, and lycopene*: CCNFSDU43 agreed to establish an EWG, chaired by the United States, to review the use of fructans, beta-carotene, and lycopene in the context of optional ingredients in *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CXS 72-1981); to develop recommendations to CCNFSDU44 regarding the safety and suitability of these ingredients as optional ingredients in CXS 72-1981; and to submit a report for discussion at CCNFSDU44. *Methods for Assessing the sweetness of carbohydrate sources:* CCNFSDU43 agreed to establish an EWG, chaired by the EU and co-chaired by Switzerland, to review, identify and, if appropriate, recommend methods for referral to CCMAS for endorsement.