REPORT OF THE UNITED STATES DELEGATE
ON THE 44th SESSION OF THE
CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

October 2-6, 2024
Dresden, Germany

BACKGROUND SUMMARY

The 44th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU44) met in Dresden, Germany from October 2 – October 6, 2024. The session was co-chaired by Ms. Martine Püster and Dr. Carolin Bendadani, both of the German Federal Office of Consumer Protection and Food Safety. There were participants from 51 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, Human Foods Program; Alternate Delegate, Dr. Anna Waller of the U.S. Department of Agriculture, Agricultural Research Service, Beltsville Human Nutrition Research Center; four government advisors; and one non-government advisor.

CCNFSDU44 was a successful meeting, including two physical working groups (PWG) prior to the session and one in-session working group:

- PWG on the Guideline on the prioritization mechanism and emerging or new work proposals, co-chaired by Canada and Germany (September 30, 2024)
- PWG on Nutrient Reference Values-Requirement (NRVs-R) for persons aged 6-36 months, chaired by Ireland and co-chaired by Costa Rica and the United States (October 1, 2024)
- In-session working group on methods of analysis, chaired by the United States (October 2, 2024)

The following report summarizes significant agenda items discussed at CCNFSDU44. The official report of the session along with all documents considered at the meeting are available on the Codex website at: https://www.fao.org/fao-who-codexalimentarius/meetings/detail/en/?meeting=CCNFSDU&session=44.

HIGHLIGHTS

The 44th Session of Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU44) agreed to advance the following texts to the 47th Session of the Codex Alimentarius Commission (CAC47, 2024):

NRVs-R

- Advanced the General Principles for establishing nutrient reference values for persons aged 6-36 months to Step 8 for adoption for inclusion in CXG 2-1985 as Annex 1, Part B.
- Advanced the NRVs-R for Vitamins A, B6, D, and E, thiamin, riboflavin, niacin, pantothenic acid, calcium, copper, iodine, potassium, zinc and protein to Step 8 for adoption by CAC47 and inclusion in CXG 2-1985 (section 3.4.4.2).

Infant formula amendments

- Forwarded amendments to the CXS 72-1981 resolving a few rounding inconsistencies in converting kilocalories to kilojoules.

New work

- Forwarded the new work proposal submitted by the United States to develop a standard for foods for older infants and young children, to CAC47 for approval as new work.

Nitrogen to protein conversion factor

- Forwarded the nitrogen conversion factor for follow-up formula for older infants and products for young children to CAC47 for inclusion in the Annex listing nitrogen conversion in CXS 234-1999.

NEXT SESSION OF CCNFSDU

The 45th Session of CCNFSDU (CCNFSDU45) is tentatively scheduled to take place approximately 2 years from CCNFSDU44 (i.e., fall 2026), in a location yet to be determined.

MEETING SUMMARY

TECHNOLOGICAL JUSTIFICATION FOR SEVERAL FOOD ADDITIVES
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? No**
United States Objective The United States supported the conclusion of the EWG on Technological Justification for Several Food Additives to inform CCFA there is no technological need for the use of guar gum, distarch phosphate, phosphate distarch phosphate, acetylated distarch phosphate, and hydroxypropyl starch in infant formula and formulas for special medical purposes intended for infants, associated with the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CXS 72-1981).
Outcome/ Conclusion The Committee agreed to: • Inform CCFA that there was no technological need for the use of guar gum (INS 412), distarch phosphate (INS 1412), phosphated distarch phosphate (INS 1413), acetylated distarch phosphate (INS 1414) and hydroxypropyl starch (INS 1440) in foods conforming to *the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CXS 72-1981) and request that CCFA take appropriate actions. • Inform CCFA that *the Standard for Canned Baby Foods* (CXS 73-1981) permitted the use of the food additives listed in CXG 10-1979 Part D as nutrient carriers. • Establish an EWG, chaired by the EU, on Batch 3 of additives, and add methacrylate copolymer, basis (BMC) to the terms of reference for the EWG.
Other Comments The 54th Session of the Codex Committee on Food Additives (CCFA54) requested CCNFSDU to appraise the technological need/justification of BMC for use in CXS 72-1981, *the Standard for Follow-up formula for Older Infants and Product for Young Children* (CXS 156-1987); CXS 73-1981; *the Standard for Processed Cereal-Based Foods for Infants and Young Children* (CXS 74-1981); and *the Guidelines for ready-to-use therapeutic foods (RUTF)* (CXG 95-2022). The Committee considered adding the technological justification of BMC for use in these standards to the Terms of Reference for the EWG. Senegal noted the high levels of vitamin A deficiency in developing countries and that since Vitamin A content is variable due to humidity and heat, BMC can provide vitamin A protection, improving bioavailability. They noted the importance of BMC for their region and noted no known toxicity concerns. The United States supported Senegal's proposal to add BMC to the Terms of Reference, noting USAID's role in addressing micronutrient deficiencies around the world.

DISCUSSION PAPER ON USE OF FRUCTANS, BETA-CAROTENE, LYCOPENE IN CXS-72-1981
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? No**
United States Objective The objective for the United States as a chair of the EWG was to present the outcomes of the EWG consultations and to reach a final decision on responding to the request from CCMAS.
Outcome/ Conclusion The Committee agreed that in future only methods for which there are clear provisions in standards under the purview of CCNFSDU will be considered. CCNFSDU44 agreed to inform CCMAS that there is no longer a need for CCMAS to endorse the methods for beta-carotene, lycopene, and fructans as there were no provisions for them in the relevant standard.
Other Comments Prior to the CCMAS procedures for the submission, consideration, and endorsement of methods coming to the Committee's attention, the EWG had recommended that CCNFSDU request CCMAS endorse AOAC 2016.13/ISO 23443 for use with beta-carotene in the CXS 72-1981 as a Type II method. The European Union did not agree that beta-carotene had been determined to be safe and suitable for use as a vitamin A compound in infant formula. Rather than proceed with a discussion on the safety and suitability of each optional ingredient, the Chair and the United States clarified that the request from CCMAS was whether or not CCNFSDU would forward methods for optional ingredients for endorsement. Although there was some support for forwarding the method for beta-carotene, CCNFSDU agreed that methods for optional ingredients are not needed, as countries can still use available methods even if they are not listed in CXS 234, and that the work it would take to list out separate provisions for each optional ingredient is not warranted just to have methods of analysis listed in CXS 234.

DISCUSSION PAPER ON METHODS OF ASSESSING THE SWEETNESS OF CARBOHYDRATE-SOURCES IN CXS 156-1987
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? No**
United States Objective The United States objective was to oppose sending the ISO 5495 method to CCMAS for endorsement, as provisions limiting sweetness are already established in the CXS 156-1987, the method is burdensome, and the method is not suitable for CCNFSDU's needs.
Outcome/ Conclusion The Committee agreed to discontinue consideration of the method of analysis for assessment of sweetness of carbohydrate sources.
Other Comments The European Union presented the findings of the EWG. An in-session working group on methods was convened which further discussed this issue, and the in-session working group concluded that the Committee should consider referring the method ISO 5495 to CCMAS for endorsement in CXS 234-1999. Those in favor of the proposal, including the EU, Chile, and several observers, mentioned that the method is widely used and fit for purpose. Those in favor also suggested the provision title to change to "sweetness of carbohydrates." Those opposed, including Canada, New Zealand, India, and Australia, strongly supported or were aligned with the intervention of the United States, stating that the method is not validated for this purpose, that the use of carbohydrates is already limited by the standard, that the method proposed was burdensome, and data on relative sweetness are already published and publicly available. It was also noted that the ISO method was more of a guideline for establishing a validated method but not a validated method itself. CCNFSDU44 did not uphold the conclusion of the in-session working group, deciding instead to discontinue consideration of ISO 5495 for the assessment of sweetness of carbohydrate sources.

METHODS OF ANALYSIS
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? No**
United States Objective The United States' objective was to request CCMAS to endorse, retype, or revoke several type I, II, and III methods in the Follow-up formula standard; request CCMAS to endorse AOAC 2022.01/ICC Standard 191/AACC 32-61.01 as type I for the determination of insoluble and soluble dietary fibres of higher and lower molecular weight in food that may or may not contain resistant starches. The United States served as Chair of the in-session working group that discussed these methods.
Outcome/ Conclusion To allow fuller consideration of methods of analysis prior to the next session, the Committee agreed to establish an EWG chaired by the United States to consider existing methods of analysis in CXS 234-1999 for standards falling under its remit to check their fitness for purpose and to make proposals for additional methods/replacement methods, and other corrections/revocations. The EWG will consider proposals for analytical methods and provide recommendations to CCNFSDU44 regarding their suitability for submission to CCMAS. The Committee agreed to: • Request CCMAS to endorse AOAC 2022.01/ICC Standard 191/AACC 32-61.01 as Type I for the determination of insoluble and soluble dietary fibers of higher and lower molecular weight in food that may or may not contain resistant starches. A footnote as follows is to be inserted: *Isolated, purified, and/or synthetic fibres captured by AOAC 2022.01/ICC Standard 191/AACC 32-61.01 that do not meet the Codex definition of dietary fibre in the Guidelines on nutrition labelling (CXG 2-1985) should be subtracted from the final measurement, where deemed appropriate by competent authorities.* • Revoke AOAC 2011.25/AACC 32-50.01 for use with the same provision. • Request CCMAS to endorse the methods listed in Table 1 for review, (re)typing, revocation and endorsement as Type II/Type III methods for the determination of nutrients in infant formula (CXS 72-1981, Section A) and follow-up formula (CXS 156-1987, Section A). • Request CCMAS to consider revoking/retyping of methods for follow-up formula currently listed in CXS 234-1999 as follows: retype/revoke AOAC 992.24 for iodine; retype/revoke AOAC 974.29, AOAC 992.04, AOAC 992.06 for vitamin A; and retype AOAC 992.07 for pantothenic acid. • Request CCMAS to endorse the method for crude protein in follow-up formula as Type I method. • Establish an EWG, chaired by the United States, to consider existing methods of analysis in CXS 234-1999 for standards falling under its remit to check their fitness for purpose and to make proposals for additional methods/replacement methods, other corrections/revocations. • Forward the nitrogen conversion factor for follow-up formula for older infants and products for young children to CAC47 for inclusion in the Annex listing nitrogen

conversion in CXS 234-1999.
Other Comments There was discussion regarding the types of fibers that would be captured by the new method of analysis for dietary fiber. The EU, Belgium, and Switzerland expressed concern that the new method would overestimate fiber analysis and capture fibres not within the Codex definition of dietary fibre. To alleviate these concerns, the Committee agreed to insert a footnote for dietary fiber method as follows: *Isolated, purified, and/or synthetic fibres captured by AOAC 2022.01/ICC Standard 191/AACC 32-61.01 that do not meet the Codex definition of dietary fibre in the Guidelines on Nutrition Labeling (CXG 2-1985) should be subtracted from the final measurement, where deemed appropriate by competent authorities*.

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? No**
United States Objective The United States objective was to continue the significant progress made on NRVs-R for persons aged 6-36 months, including advancing the General Principles to the CAC47 for final adoption and agreeing to a Stepwise Process as an information document.
Outcome/ Conclusion The Committee agreed to: • Advance the General Principles for establishing nutrient reference values for persons aged 6-36 months to Step 8 for adoption for inclusion in CXG 2-1985 as Annex 1, Part B. • Advance the NRVs-R for Vitamins A, B6, D, and E, thiamin, riboflavin, niacin, pantothenic acid, calcium, copper, iodine, potassium, zinc and protein to Step 8 for adoption by CAC47 and inclusion in CXG 2-1985 (section 3.4.4.2). • Request the Codex Secretariat to publish the Stepwise Process as an information document on the Codex website for internal use by CCNFSDU • Return to Step 2/3 the remaining NRVs-R for Vitamins C, B12, and K, folate, biotin, selenium, manganese, magnesium, phosphorous and iron for development using the stepwise process through an EWG chaired by Ireland and co-chaired by the United States and Costa Rica.
Other Comments *Discussion on General Principles:* Regarding the definition of Adequate Intake, the Committee agreed to adopt the definition of Adequate Intake provided by the WHO and FAO. There was significant discussion regarding the method to determining the combined NRVs-R (6-36 months) from the two NRVs-R (6-12 and 12-36 months). The EU and Norway preferred to take the lower value, expressing concerns with safety given that most products on the market in this category are formulated for persons 6-12 months. Other members, including the United States and China, preferred the higher value for a population coverage approach, noting that breast milk is a large source of nutrients for this population and children in the older age group were more dependent nutritionally on these products. China's position closely aligned with the initial U.S. position taken in the PWG. Other members supported taking the mean value and noted it would be a suitable compromise. An additional proposal was suggested by Chile as the following: "if there is UL determined by RASB for an age group outside of 6-36 months. If there is no UL available for persons aged 6-36 months, but it exists for another age range, the combined value will be determined by the mean of the two age groups. If no UL exists for any age range, the highest value would be selected." During plenary, in order to advance the work in the spirit of compromise, the U.S. view was to use a consistent approach across all nutrients. The United States therefore supported the compromise of using the mean value, and the Committee eventually agreed to use the mean

value for the combined NRVs-R. China maintained their opposition to the mean value and took a reservation as such.

Discussion on Stepwise Process:
The Chair and Co-chairs of the PWG presented a flowchart diagram, developed by the United States, to illustrate the Stepwise Process. The flowchart diagram reflected the discussions and conclusions of the PWG. There was general agreement amongst the members to the flowchart diagram as proposed. Some members expressed that the text within the flowchart diagram should be written in text form. The U.S. view was that the Committee should focus on the text within the flowchart diagram in order to progress the work. The Committee and Chairs agreed that the re-established EWG will pull the text from the flowchart diagram into a narrative form as a complementary text format for the flowchart diagram.

Discussion on NRVs-R for 6-36 months:
The FAO/WHO presented new DIRVs for calcium, vitamin D, and zinc. There was agreement amongst the Committee to finalize the FAO/WHO values as the NRVs-R for these three nutrients as this was consistent with the stepwise process the Committee established. There was significant discussion on establishing the NRVs-R for vitamin B12 and magnesium. The EU expressed that the values for vitamin B12 were too low. The United States was of the view that the values for vitamin B12 proposed by the PWG chair took into account all recent global data and should be finalized. New Zealand expressed that these values were consistent with the general principles and stepwise process for deriving NRVs-R. The Committee agreed to transfer vitamin B12 and magnesium to the list of nutrients requiring further consideration by the EWG.

NEW WORK

GUIDELINE FOR THE PRELIMINARY ASSESSMENT TO IDENTIFY AND PRIORITIZE NEW WORK FOR CCNFSDU
To Be Presented for Adoption at Next CAC? N/A **Have the United States' Objectives Been Met? Yes** **Is it anticipated that this item will or should be raised at the CAC? No**
United States Objective The United States objective was to support the guideline for the preliminary assessment to identify and prioritize new work for CCNFSDU.
Discussion in Relation to United States' Objectives The United States noted that the initial rating of the new work proposal should not be done by the submitter, as this would introduce bias to the prioritization mechanism, and that the submitter should recuse themselves from the ranking. The United States intervened to suggest that the ranking system could be accomplished by a smaller working group rather than the large PWG. The Committee agreed to continue with the prioritization mechanism with the caveat that the initial rating would be completed by the Chair of the working group, rather than the original submitter. The Committee discussed the four new work proposals in relation to the prioritization mechanism and ranked the two that the physical working group proposed to move forward: proposal to develop a standard for foods for older infants and young children and proposal to develop general guidelines and principles for the nutritional composition of foods formulated with protein from plant-based sources.
Outcome/ Conclusion The Committee agreed to request the Codex Secretariat to publish the Guideline for the preliminary assessment to identify and prioritize new work for CCNFSDU as an information document on the Codex website and to inform CCEXEC87 accordingly.

DEFINITION OF DIETARY FIBER
To Be Presented for Adoption at Next CAC? No **Have the United States' Objectives Been Met? No** **Is it anticipated that this item will or should be raised at the CAC? No**
United States Objective The United States objective was to support CCNFSDU to amend the 2009 definition of dietary fiber to three or more monomeric units as this would align with the U.S. definition.
Discussion in Relation to United States' Objectives An observer, the Calorie Control Council, proposed to amend the definition of dietary fiber to three or more monomeric units. Some members noted that the 2009 Codex definition of dietary fiber was developed with a compromise footnote after lengthy discussions. The representative of WHO made an intervention during the PWG that the current definition is satisfactory as it stands and should not be changed and emphasized WHO's recommendation is to increase

dietary fiber intake as to those naturally occurring in food. Following this intervention, the PWG decided not to forward the new work proposal.

Outcome/ Conclusion
The Committee agreed not to forward the proposal.

GENERAL GUIDELINES AND PRINCIPLES FOR THE NUTRITIONAL COMPOSITION OF FOODS FORMULATED WITH PROTEIN FROM NON-ANIMAL SOURCES

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

United States Objective
The United States objective was to support CCNFSDU establishing principles and guidelines concerning the nutritional composition of foods formulated with proteins from non-animal sources intended to imitate similar foods based on animal proteins.

Discussion in Relation to United States' Objectives
Based on discussions during the PWG, Canada and the United States agreed to revise the new work proposal with an amended scope to limit it to plant-based sources and remove insects, fungi, and bacteria from the scope, and to remove labeling provisions from the new work proposal. Several members expressed concern that the FAO report has not yet been made public. Some members were concerned that the proposal presumed foods made from non-animal protein contained more nutrients of concern than foods made from animal protein, other members were concerned that the new work would encourage the consumption of these foods. Therefore, the Committee agreed not to forward the new work proposal at this session and noted it could be re-submitted after members have the opportunity to review the FAO report on alternative protein sources that is expected to be published by the end of 2024.

Outcome/ Conclusion
The Committee agreed not to forward the proposal at this session and noted that a revised proposal could be submitted at the next CCNFSDU, emphasizing the need to consider the forthcoming FAO publication on alternative proteins.

DEVELOPMENT OF A CODEX STANDARD FOR FOODS FOR OLDER INFANTS AND YOUNG CHILDREN

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? No

United States Objective
The United States objective was to advance new work on guidelines for nutritional composition of formulated complementary foods for older infants and young children.

Discussion in Relation to United States' Objectives

During the PWG on prioritizing new work, this new work proposal was ranked by the PWG as having the top priority. There was large support and consensus to advance this new work proposal. The Committee agreed to move forward the new work proposal with an amended scope to limit the texts to be updated and replaced to the *Standard for canned baby foods* (CXS 73-1981) and *Standard for processed cereal based foods for infants and young children* (CXS 74-1981)— and remove the *Guidelines on formulated complementary foods for older infants and young children (CXG 8-1991)*. The Committee agreed to establish an EWG chaired by the United States. There was interest from several member countries to co-chair. The United States expressed appreciation for all the members' interest to co-chair and noted that Kenya's interest was welcome as the African region's inputs are valuable for this topic. It was agreed that the EWG would be co-chaired by Kenya, Panama, and EU. The terms of reference of the new work will be to develop the draft standard for circulation for comments at step 3 and consideration by CCNFSDU45 subject to approval by CAC47. CCNFSDU will keep open the possibility to convene a PWG prior to CCNFSDU45.

Outcome/ Conclusion

The Committee agreed to forward the project document submitted by the United States, a new work proposal to develop a standard for foods for older infants and young children, to CAC47 for approval as new work.