U.S. Delegate's Report

42nd Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU42)

(Virtual)

November 19–25 and December 1, 2021

INTRODUCTION

The 42nd Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU42) convened virtually November 19-25 and December 1, 2021. The session was Chaired and Co-Chaired by Ms. Hilke Thordsen-Böhm and Dr. Anja Brönstrup, both from the Federal Ministry of Food and Agriculture of Germany. The session was attended by delegates from 99 Member countries, one Member Organization (the European Union/EU), and 35 observer organizations.

Dr. Douglas Balentine (U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition) led the U.S. Delegation, assisted by Alternate Delegate Dr. Pamela Pehrsson (U.S. Department of Agriculture, Agricultural Research Service), nine government advisors, and three non-government advisors. Due to the virtual nature of the session, the Committee had a reduced agenda, and the United States was generally successful in achieving its key objectives on the major agenda items.

HIGHLIGHTS

For the Follow-Up Formula (FUF) Standard:

- The Committee completed discussion of all four agenda items.
- For <u>Agenda Item 4a</u>, the Committee reached agreement on the remaining provisions which included purity requirements, particle size, additives, flavorings, etc., and agreed to the revised text. However, the revised text will not be sent forward to the Commission Alimentarius Commission at its next session (CAC45, November 2022) for adoption but will be held until completion of the remainder of the FUF Standard.
- For <u>Agenda Item 4b</u>, in the spirit of compromise, the Committee agreed to remove the text in square brackets for the Product Definition (Section 2.1.1) provisions in Section B (Drink/Product for Young Children) and to retain the definition agreed at CCNFSDU41 (2019). We note that the name formats agreed to as part of Agenda Item 4c are to be carried to the Definitions section in Agenda Item 4b, as shown below:

2.1.1 Drink for young children with added nutrients, Product for young children with added nutrients, Drink for young children, and Product for young children means a product manufactured for use as a liquid part of the diversified diet of young children.

• For <u>Agenda Item 4c</u>, the Committee agreed to amend Section 9.1.2 by listing the four name options for the products covered by Section B of the FUF Standard.

- For <u>Agenda Item 4d</u>, the Committee concluded:
 - For Sections A and B, that a nitrogen to protein conversion factor of 6.25 be retained in the FUF Standard; and
 - For Section B only, that the text on sweetness / sweet taste in Footnote 5 in the Available Carbohydrate provisions be retained and rediscussed at CCNFSDU43.
- The remaining issues to be discussed by the Committee are: (1) the availability of internationally validated methods for determining sweet taste, (2) the structure of the standard, and (3) the preamble text. Once all the FUF Standard provisions are completed by the Committee, the entire standard will be sent to the Commission for consideration and adoption.

For the <u>Ready to Use Therapeutic Foods (RUTF) Guideline</u>:

- The Committee completed the preamble text of the guideline and discussion regarding essential fatty acids and essential composition for magnesium and iron.
- The Committee recommended the draft Guidelines advance to the Commission for final adoption at Step 8.

For the General Principles for the Establishment of <u>Nutrient Reference Values – Requirement (NRVs-R)</u> for Persons Aged 6-36 Months:

- The Committee had extensive discussions about the General Principles and the recommendations of the intersessional Electronic Working Group (EWG).
- The Committee did not progress the work of the General Principles and, instead, sent it back to the EWG for continued discussion and a pilot program. The EWG Chair and Co-Chairs may also consider convening a Physical Working Group (PWG) prior to the next session (CCNFSDU43, anticipated to convene in 2023).

MEETING SUMMARY

The following paragraphs summarize issues of interest to the United States in more detail, by Agenda Item. The official CCNFSDU42 meeting report and related documents from the session are posted on the Codex Alimentarius website at:

https://www.fao.org/fao-who-codexalimentarius/meetings/detail/en/?meeting=CCNFSDU&session=42

Agenda item 2: Matters Referred to the Committee by the Codex Alimentarius Commission and/or Other Subsidiary Bodies

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

This item involved matters for information, not action by CCNFSDU42. Due to the limited amount of time for the virtual meeting, the Codex Secretariat, the representative from the Food and Agriculture Organization (FAO), and the representative from the World Health Organization (WHO) highlighted the major points as outlined in the CCNFSDU42 meeting documents for these two agenda items. There was very little discussion about the points made.

Agenda item 4: Review of the Standard for Follow-Up Formula (CXS 156-1987)

Agenda item 4a: Proposed Draft Revised Standard for Follow-Up Formula (FUF) for Older Infants and Drink/Product for Young Children with Added Nutrients or Drink for Young Children: Remaining Sections

Agenda item 4a considered Recommendations 3-15 from the relevant meeting documents (including <u>CX/NFSDU 19/41/5</u>) which dealt with other provisions in the FUF Standard that are not included as part of Essential Composition or the labeling provisions.

Recommendations 3 (Purity Requirements), 4 (Vitamin Compounds and Mineral Salts), 5 (Consistency and Particle Size) were discussed with minimal debate and endorsed by the Committee.

Recommendation 6 (Specific Prohibitions) was discussed, and the Committee agreed to retain the current provisions for both Section A (Follow-Up Formula (FUF) for Older Infants) and Section B (Drink/Product for Young Children). Of note was an intervention from Ecuador to prohibit use of genetically modified derived ingredients, but the Committee did not agree to consider that proposal. This is an issue that may need attention in the Committee at some point in the future since it is consistently brought up at plenary, primarily by observers, but also on occasion by a few members.

Recommendations 7 (Permissions for Food Additives) and 8 (Administrative Changes) were not discussed during plenary because the Codex Secretariat informed the Committee that food additives would be addressed as part of the alignment work by the Codex Committee on Food Additives (CCFA). The CCFA's alignment work is expected to result in replacing the list of food additives in the Follow-Up Formula (FUF) Standard with a reference to the corresponding sections of the *General Standard for Food Additives* (GSFA) (<u>CXS 192-1995</u>). The Committee agreed to align the FUF Standard's table for food additives (in both Sections A and B) with the text in <u>CX/NFSDU 19/41/5</u>, Part D, and inform CCFA that a footnote be included in Section 3.1 of the FUF Standard regarding sodium ascorbate (INS 301). This footnote will indicate that for Section A (FUF for Older Infants), the use of sodium ascorbate should be limited by the sodium threshold established for this section of the standard. However, this footnote will not be used in the FUF Standard's Section B (Drink/Product for Young Children) because a sodium limit was not established for the products within the scope of Section A and Section B of the FUF Standard.

With little discussion, the Committee agreed to adopt the text of Recommendation 9 (Carry-over of Food Additives and Nutrient Carriers) from the Codex *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CXS 72-1981) and the Codex *Standard for Processed Cereal-Based Foods for Infants and Young Children* (CXS 74-1981) for both Sections A and B of the FUF Standard. The Committee noted that CCFA would review the carry-over principles as part of its work to align the food additive sections of the Codex commodity standards to the GSFA.

Recommendation 10 (Flavorings) was the subject of substantial debate and discussion. There were divergent views among CCNFSDU delegations regarding the use of flavorings in products covered by the standard, particularly, the products covered by Section B (Drink/Product for Young Children). There was general agreement to delete the provisions for flavorings from Section A (FUF for Older Infants), which

would align with the Codex *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CXS 72-1981) as these products are considered breast milk substitutes.

However, there were divergent views on the suitability and appropriateness of the use of flavors for products covered by Section B (Drink/Product for Young Children). The EU was particularly vocal regarding their view that the use of flavors in products covered by Section B should not be permitted because in their view, the use of flavors may expose young children to new flavors early in life and may contribute to young children developing a taste/liking for flavored sweet tasting foods rather than more natural foods. Several Observer organizations (e.g., Specialised Nutrition Europe (SNE) and the Institute of Food Technologists (IFT)) noted that current EU regulations permitted the use of flavorings for these types of products in the EU, a comment that was not acknowledged or rebutted by the EU delegation at plenary. The EU proposed that rather than permitting the use of flavorings, the Committee might consider simply indicating that the use of flavors be determined at the regional or national level. Other members (including the United States, Canada, New Zealand, and Australia) expressed their position that the use of flavors in products for young children was appropriate and suitable and would not expose young children to flavors they would not already be tasting in many other foods typically consumed by young children as they move to consuming family foods. These members also noted that the use of flavors was already permitted in their national legislation for these types of products. Ultimately, the Committee could not reach agreement. The Codex Secretariat suggested that a footnote stating: "National and/or Regional authorities may restrict or prohibit the use of the listed flavorings" in Section B. An Observer, the International Special Dietary Foods Industries (ISDI), expressed the view that a footnote was not necessary as National or Regional Authorities already have the ability to restrict use of flavors in their regulation and the proposed footnote was similar to Note 161 which CCFA was working to avoid. In the spirit of compromise, the Committee agreed to add the suggested footnote to Section B. However, this resolution was not acceptable to Mexico as they were opposed to permitting the use of flavorings in the FUF Standard and they registered a reservation to signal their disagreement.

Recommendations 11 (Contaminants), 12 (Hygiene), 13 (Packaging), 14 (Fill of Container), and 15 (Method of Analysis and Sampling) were reviewed and agreement was reached with minimal debate. For Recommendation 12 (Hygiene), the Committee agreed to include two additional Codex codes of practice as references for both Sections A and B because products produced from the standard are available in liquid form and commercially sterilized (i.e., the Codex *Code of Hygienic Practice for Aseptically Processed and Packaged Low Acid Foods* (CXC 40-1993) and the Codex *Code of Hygienic Practice for Practice for Low and Acidified Low Acid Canned Foods* (CXC 23-1979)). For Recommendation 13 (Packaging), the Committee agreed to remove the section on packaging, concluding that the section was not necessary as it covered the use of packaging gases and CCFA would cover the use of packaging gases as food additives as part of its alignment work.

CCNFSDU42 reached agreement on the provisions covered under Agenda Item 4a. However, the revised text will not be sent forward to the Commission because it will be held pending completion of the remainder of the FUF Standard. Once all the FUF Standard provisions are completed by the Committee, the entire standard will be sent to the Commission for endorsement.

Further, the Committee agreed to inform CCFA that the FUF Standard was currently split into two Sections, Section A (FUF for Older Infants, aged 6-12 months) and Section B (now with the four name options: Drink for Young Children with Added Nutrients; Product for Young Children with Added Nutrients; Drink for Young Children; and Product for Young Children, aged 12-36 months), as discussed below in Agenda Item 4c). CCNFSDU42 also agreed to inform CCFA and provide an accompanying note stating "within the limits for sodium in Section 3.1" associated with sodium ascorbate (INS 301) should be included in the table for Section A. The accompanying note would not be included in the table of food additives for Section B as there were no maximum levels for sodium for the drink/product for young children.

Finally, CCNFSDU42 agreed to inform CCFA of the decision to reference permissible food additives in the GSFA, the need to address carry over principles, and the decisions on use of flavorings.

Agenda item 4b: Draft Scope, Description and Labelling for Drink/Product for Young Children with Added Nutrients or Drink for Young Children (at Step 7) and EWG-Report on draft product definition of drink/product for young children with added nutrients or drink for young children; and Nitrogen to protein conversion factors

The Product Definition (Section 2.1.1) provisions in Section B (Drink/Product for Young Children) were debated during CCNFSDU41 (2019) and most of the text of the product definition was agreed to in the spirit of compromise during that session. However, some text within the definition remained in square brackets: "[which may contribute to the nutritional needs of young children]" because the Committee could not reach consensus on that text at CCNFSDU41.

During the intersessional period between CCNFSDU41 and CCNFSDU42, the FUF EWG considered the text in square brackets. Responses to the EWG discussion paper highlighted the divergent views of the EWG. Prior to CCNFSDU42, responses to two Circular Letters (CL 2021/03/OCS-NFSDU and CL 2021/54/OCS-NFSDU) also indicated divergent views on the text in square brackets. The CL responses are compiled in two meeting documents (CX/NFSDU 21/42/5 Add.1 and CX/NFSDU 21/42/5 Add.2). Delegations generally retained their positions expressed in the CL responses during plenary discussion and the Committee remained divided regarding the text in square brackets. The United States expressed its position supporting including the text in square brackets as part of the definition as the text was factual statement about the nutritional contribution of the product to the diet of young children.

The CCNFSDU Chair noted the lack of agreement and suggested that the definition section be considered in context with the rest of the FUF Standard, which contained additional text which helps define the product, and that a simple definition might be sufficient. The United States specifically noted that a simple definition might be acceptable considering the text in Section 3.1.1 at the start of the Essential Composition section. In the spirit of compromise, the Committee agreed to remove the text in square brackets and to retain the simple definition.

Agenda item 4c: Draft Scope, Description and Labelling for Follow-Up Formula for Older Infants

CCNFSDU41 had agreed to the labeling section of the standard and sent it to the 46th Session of the Codex Committee on Food Labelling (CCFL46, 2021) for endorsement. CCFL46 endorsed the labeling section, however raised a question regarding the product names. CCFL46 asked CCNFSDU if it had intentionally omitted the word "Product" in the name option: "Drink for Young Children". CCFL46 noted that the word "Product" was included in the other name option: "Drink/Product with Added Nutrients". In essence, CCFL46 flagged this issue for CCNFSDU to consider whether it was an intentional or an unintentional omission.

During the plenary discussion, there was general agreement that leaving out the word "Product" from one of the naming options was, indeed, an unintentional omission, since the product was often not in liquid form. It was clear that the naming options were creating confusion among Committee members – especially with regards to the use of the forward slash "/". Therefore, the Chair suggested listing the four (4) name options in the text of the FUF Standard for clarity:

- Drink for Young Children with Added Nutrients,
- Product for Young Children with Added Nutrients,
- Drink for Young Children, and
- Product for Young Children.

The Committee agreed to the listing of the four (4) name options in Section B of the FUF Standard for clarity.

Several Observer organizations – including the International Baby Food Action Network (IBFAN) and the European Network of Childbirth Associations (ENCA) – voiced a view that the name "Drink for Young Children" was their preferred option and that it should be listed first and the names referencing "Added Nutrients" be listed last as those two name options were not preferred by them. The Chair did not accept that suggestion and clarified that the listing order of the name options did not imply priority. The Committee agreed to amend Section 9.1.2 by listing the name options and the agreed text is presented in Appendix III of the CCNFSDU42 meeting report.

With that, the discussion of the scope, description, and labeling provisions of Section B of the FUF Standard was completed and will be held until all other provisions of the standard are completed. At that time, the entire standard will be sent to the Commission for consideration and final adoption.

Agenda item 4d: Essential Composition Requirements for Follow-Up Formula for Older Infants and Drink/Product for Young Children with Added Nutrients or Drink for Young Children (held at Step 7)

CCNFSDU42 noted that the majority of Essential Composition provisions in both Sections A and B of the FUF Standard had been discussed and agreed, with the exception of two outstanding issues: (1) the nitrogen to protein conversion factor and (2) the availability of methods to measure sweetness (or sweet taste) in Section B, which CCNFSDU41 referred to CCMAS.

The Committee began its discussion with the issue of nitrogen to protein conversion factors for both Sections A and B of the FUF Standard. The Chair recalled that the Joint FAO/WHO Expert Meetings on Nutrition (JEMNU) had reviewed the data on nitrogen to protein conversion factors and concluded that the evidence was not robust enough to determine a nitrogen to protein conversion factor for the various protein ingredients used in both infant formula and follow up formula. JEMNU also noted that using a single nitrogen to protein conversion factor (NCF) of 6.25 for a wide variety of diverse protein sources was also not appropriate because there are a variety of protein sources used in infant formula and follow up formula and the science suggested that the NCF was not the same for the range of ingredients. The topic was also considered by the intersessional FUF EWG. The EWG concluded that due to lack of sound scientific data, an alternative NCF could not be established, and continued review and consideration of this issue was not possible without new scientific data. Therefore, the FUF EWG recommended retaining the current NCF of 6.25 for the standard and not to pursue further work at this time. The Committee agreed to the FUF EWG's recommendation and concluded that a NCF of 6.25 would be retained in the FUF Standard and no further work would be taken up at this time.

Regarding the issue of measuring sweetness (or sweet taste) in Section B, the Committee considered Footnote 5 in Section B under the "Available Carbohydrates" provisions. The Chair recalled that during CCNFSDU41, the Committee had agreed to the following footnote text in the spirit of compromise: "for products based on non-milk protein, carbohydrate sources that have no contribution to sweet taste should be preferred and in no case be sweeter than lactose". The Chair also noted that since the text was agreed to by CCNFSDU41, square brackets were not included in the text and that further editing was not possible. Finally, the Chair recalled that CCNFSDU41 agreed to ask CCMAS if there were any internationally validated methods to measure sweetness of carbohydrates for these products.

CCMAS considered the issue and responded to the Committee's request indicating that no internationally validated methods were available and that therefore the provision should be removed as compliance measures were not available. New Zealand, as chair of the CCNFSDU FUF EWG, provided a summary of the issue, also noting that the Committee already agreed to the text, that it was important to limit sweetness, and that provisions had already been included in the standard to meet the objective of limiting sweetness. These provisions include limiting available carbohydrates, limiting the amounts of mono and disaccharides, and a provision that sucrose and fructose not be added to the products covered by Section B of the FUF Standard.

The CCNFSDU Chair offered the Committee two options for consideration:

- 1) deleting the Footnote 5, or
- 2) retaining Footnote 5 but note that there were no validated methods to determine compliance to the provision.

There was robust debate about the footnote and the two options offered. Chile, Cuba, Uruguay, and Mexico all expressed the view that limiting sweetness in these products was important, that the footnote should be retained, and that a valid method was not necessary to include it. Malaysia had a similar view.

The United States made a strong intervention advocating that the limit of 2.5 g/100 kcal of mono and disaccharides was already sufficient to limit sweetness to not more than that provided by lactose in milk and the provision was unnecessary to accomplish the objective of the Committee. Further, the United States noted that 2.5 g/100 kcal sucrose (which cannot be added to the product, but sucrose is the sweetness reference sugar and is sweeter than all permitted mono and disaccharides) would provide a sweetness only 80% of that provided by 12 g/100 kcal of lactose and, therefore, products could not be sweeter than milk. Canada, Morocco, and Indonesia supported the United States. The exchange of views continued with Australia, New Zealand, the Philippines, Costa Rica, and Columbia supporting Option 1.

The EU was particularly vocal about the need to retain the provision and insisted that sensory methods were available to compare sweetness of carbohydrate sources. An observer organization, the International Organization for Standardization (ISO), was asked to comment and first responded that there were no appropriate validated methods but when challenged noted that the <u>ISO 5495 sensory</u> <u>analysis method</u> could be a method to determine compliance with the provision.

Belgium, Switzerland, and Norway continued to voice support for Option 2. Some Observers supported Option 1 (e.g., the Association of Official Analytical Collaboration (AOAC International), IFT, and ISDI) while other Observers supported Option 2 (e.g., National Health Federation (NHF) and ENCA). The WHO representative also indicated support for Option 2. While it was clear the Committee remained divided, the Chair concluded that the text would be retained as it was agreed at CCNFSDU41 and the discussion of methods would be taken up again during CCNFSDU43.

The Chair summarized the status of the draft FUF Standard, noting that all sections were now completed and the two remaining issues for the Committee to address at the next session (CCNFSDU43) were the structure of the FUF Standard and the preamble section.

The Committee concluded Agenda Item 4 and noted that all matters related to the FUF Standard in the CCNFSDU42 meeting agenda had been addressed. The Chair stated that the question of appropriate methods for determining sweetness of carbohydrate sources in the footnote in the Available Carbohydrates provisions in Section B of the FUF Standard would be further considered during CCNFSDU43. New Zealand agreed to continue as the FUF EWG Chair and agreed to prepare a Discussion Paper and transmit it through a Circular Letter (CL) to members to solicit comments on the structure of the FUF Standard and the preamble section. New Zealand also agreed to compile the CL responses and provide a summary to CCNFSDU43 as input to the discussions during CCNFSDU43.

Agenda item 5: Draft Guidelines for Ready-To-Use Therapeutic Foods (RUTF) (at Step 7)

CCNFSDU42 discussed the following provisions of the draft RUTF guidelines: (1) the preamble text, (2) the compositional requirement for essential fatty acids, and (3) the levels of magnesium and iron.

Regarding the preamble text, the RUTF EWG Chair and Co-Chair (South Africa and Uganda), the Codex Secretariat, the WHO, and the FAO collaborated on a conference room document (CRD) which proposed a more simplified preamble text for the guideline. The proposal, contained in <u>CRDO3</u>, also considered the guidance from CCEXEC75 and CCEXEC78 regarding references to other documents in Codex texts (e.g., see <u>REP18/EXEC2-Rev1</u>). The proposal was based on a previous decision by CCNFSDU41 to keep the preamble text "simple" but also to use the preamble text to highlight the RUTF's basic composition, target age group, general programmatic guidelines, and RUTF's use as a tool for the management of severe acute malnutrition (SAM) in children without medical complications.

There were lengthy discussions during the plenary sessions debating the need to include references to other documents in the preamble text and/or using footnotes as part of the preamble text. The main points of controversy during these discussions were aimed mainly at preventing promotion or advertising of RUTF. Some observers (e.g., ENCA and IBFAN) were concerned that without prohibitions on marketing, RUTF would be promoted and sold in a retail setting, and this could potentially lead to its use as a breast milk substitute or competing with local foods.

India was particularly vocal about the need to include the WHO's International Code of Marketing of Breast Milk Substitutes and other related World Health Assembly (WHA) resolutions in the preamble text, even though the Committee had already agreed that RUTFs were <u>not</u> breast milk substitutes. The Committee did not support adding additional references to the simplified preamble in <u>CRD03</u>; the preamble text continues to refer only to the 2007 <u>WHO Joint Statement on the community-based</u>

management of severe acute malnutrition. The 2007 WHO Joint Statement served as the basis for the provisions of the guideline.

The Committee agreed to categorize RUTF as a "food for special medical purposes" (as defined in the Codex *Standard for Labelling of and Claims for Foods for Special Medical Purposes* (CXS 180-1991)) and agreed that this provision would limit its promotion and advertising. An observer organization (ENCA) continued to express the view that marketing of these products needed to be restricted and the guideline should have specific provisions for this. The Codex Secretariat reaffirmed that the guideline was intended only for RUTFs used for public health initiatives in facilitating critical food aid to manage SAM in children, and that the products covered by the RUTF guidelines were not intended for retail sale.

A number of members (e.g., Colombia, Brazil, Philippines, Ecuador) and observer organizations (e.g., IBFAN, ENCA, and the United Nations Children's Fund (UNICEF)) continued to express their concerns that the preamble text of the RUTF guidelines should explicitly support breastfeeding, including behavioral support for nursing mothers. With minor editing, the preamble text was modified to include this concept. The Committee then agreed to the simplified preamble text.

During CCNFSDU41, an observer organization, UNICEF, proposed to increase the minimum amount of omega n-3 fatty acids to 110 mg/100 kcal and to reduce the maximum level of omega n-6 fatty acids to 780 mg/100cal. The proposal was made to facilitate conversion of short chain omega n-3 fatty acids to long chain omega n-3 fatty acids which was thought to be important for supporting the neurological development and catch-up growth in children recovering from SAM.

Intersessional discussions showed divergent views on the scientific basis for the changes proposed by UNICEF at CCNFSDU41. In 2021, the Codex Secretariat requested that the WHO conduct a systematic review to assess whether RUTF with fatty acid profiles that are different from specifications in the 2007 WHO Joint Statement improve outcomes such as neurodevelopment in children aged 6 months or older recovering from severe wasting. The WHO representative at CCNFSDU42 shared the outcomes of the review which indicated that:

a) adding Docosahexaenoic acid (DHA) or using oleic acid to increase Alpha-linolenic acid (ALA) and reduce Linoleic acid (LA) content may confer some benefits to neurodevelopment, but the evidence was not sufficiently robust to allow for a conclusion that changing the fatty acid range would benefit, be neutral or harm SAM children; and

b) the evidence did not allow for determination of amounts of ALA and LA in RUTF different from those already set in the 2007 WHO Joint Statement.

The United States' draft position going into the CCNFSDU42 plenary was to maintain the current essential fatty acid ranges, which would be consistent with the 2007 WHO Joint Statement. The draft U.S. position was also consistent with the findings of the WHO's 2021 systematic review. However, in the spirit of compromise to advance the discussion and bring the RUTF guideline to completion, the United States supported an alternative proposal provided by UNICEF to revise the essential fatty acids range to both provide the necessary absolute amounts of essential omega n-3 and omega n-6 fatty acids but in amounts believed necessary to enable conversion of short chain omega n-3 fatty acids to long chain omega n-3 fatty acids. The United States supported this proposal because most RUTF products currently produced are already within the newly proposed range of essential fatty acids and

the text was a Codex guideline (and not a Codex standard). The Committee agreed to the proposal by UNICEF to adjust the amounts on omega n-3 and omega n-6 fatty acids with a goal of supporting conversion of omega n-3 short chain fatty acids to long chain fatty acids and agreed to a maximum value for omega n-6 fatty acids of 780 mg/100 kcal and a minimum value for omega n-3 fatty acids of 110 mg/100 kcal.

CCNFSDU42 also considered the range for magnesium set in the Essential Composition section. At CCNFSDU41, the United States had supported a proposal by an observer organization, NHF, to increase the magnesium range to support bone growth and balance the higher levels of calcium and phosphorus. The proposal was raised at CCNFSDU41 but not fully discussed until CCNFSDU42. At CCNFSDU42, the Committee did not support the proposed change and agreed to maintain the original magnesium range of 15 mg/100kcal – 45 mg/100kcal, as supported by the 2007 WHO Joint Statement.

The final provision discussed at CCNFSDU42 was the range of iron in the Essential Composition section. The issue was raised during the intersessional informal small working group due to a concern that the iron levels in the draft guideline were too low, particularly for products formulated with cereal-based proteins containing phytates (as noted by International Council on Amino Acid Science (ICAAS)), although the iron range was consistent with the 2007 WHO Joint Statement. At the request of the Codex Secretariat, the WHO conducted a systematic review in 2021 of scientific studies on iron levels in RUTFs used for management of SAM in children. The WHO did not find sufficient evidence to support changing the levels of iron from those in the 2007 WHO Joint Statement due to a limited number of studies and lack of dose response data. During CCNFSDU42, the United States did not support changing the iron levels, given remaining knowledge gaps in terms of understanding the ability of children with SAM to metabolize iron based on trials that would support the establishment of evidence-based values.

The Committee completed final revisions of the text in square brackets and agreed to forward the RUTF Guideline to the Commission for final adoption at Step 8.

Agenda item 6: General Principles for the Establishment of Nutrient Reference Values – Requirement (NRVs-R) for Persons Aged 6-36 Months

During the intersessional period, the CCNFSDU NRVs-R EWG developed draft general principles for establishing NRVs-R for persons aged 6-36 months (CX/NFSDU 21/42/7) using the commissioned FAO scientific report "Review of Derivation Methods of Dietary Intake Reference Values (DIRVs) for Older Infants and Young Children". Unfortunately, the Committee had little time in advance of the session to review the draft general principles (as set forth in CRD12) and the FAO scientific report. Therefore, the Committee Chair noted that the discussion during plenary of the draft general principles would be general in nature and that specific text edits would not be considered.

The EU commented extensively that the preamble, definitions, and basis for establishing NRVs-R sections of the draft general principles for this age group should mirror those for the general population and be tailored to 6-36 months only when needed. The EU, New Zealand, and the WHO representative expressed concern with the inclusion of a ranking system to select and prioritize NRVs-R and stated that further discussion is necessary. Ireland, as the NRVs-R EWG chair, noted that due to the scarcity of data for NRVs for this age group, the ranking system was needed to explain and guide how values would be selected. As the establishment of DIRVs by WHO will take several years, the United States intervened

that including rigorous scientific principles is critical for the evaluation of many sources of data and that the proposed ranking approach would be applied on a case-by-case basis.

During CCNFSD41, the Committee had agreed to add potassium to the list of nutrients for establishing NRVs-R (see Para. 147 of the <u>CCNFSDU41 meeting report</u>). During the intersessional period, the EWG chairs recognized that sodium was not on the list of nutrients for establishing NRVs-R. Because of the inter-related nutritional functions of potassium and sodium and the importance of sodium in labeling, the EWG chairs added sodium to the list of nutrients to be a part of the FAO commissioned scientific advice. A number of Recognized Authoritative Scientific Bodies (RASBs) had established NRVs for both potassium and sodium not based on physiological or nutritional requirements but based on their role in reducing risks of non-communicable diseases (NCDs). Therefore, during the intersessional period, the NRVs-R EWG considered and explored the need for having general principles that enable establishing an NRV based on either requirements (R) or NCD risk reduction. This concept was presented to the Codex membership through <u>CL 2021/56</u>/OCS-NFSDU prior to CCNFSDU42. Member comments supported limiting the scope of the current general principles to NRVs-R and not developing general principles for NRVs-NCDs at this time (see <u>CX/NFSDU 21/42/7 Add.1</u>). The Committee Chair noted that consideration of NRVs-NCDs could be taken up by the Committee in the future.

The main purpose of establishing NRVs-R was for use in labeling of products for persons aged 6-36 months. The meeting documents (<u>CX/NFSDU 21/42/7</u> and <u>CX/NFSDU 21/42/7 Add.1</u>) recommended that CCNFSDU seek input from CCFL on the specific uses of NRVs-R for labeling purposes and the need for specific NRVs-R for persons aged 6-12 months, 12-36 months, or a combined set of NRVs-R for persons aged 6-36 months. The EU commented that developing a combined set of NRVs-R for persons aged 6-36 months would not be prevented by the proposed general principles. Plenary discussion indicated that there was a lack of clarity among Committee members regarding how NRVs-R might be used in labeling. The Committee Chair noted that discussion of purpose and application of NRVs-R was premature and a request to CCFL regarding this could be considered in the future.

The Committee expressed general support that the location for the General Principles for establishing NRVs-R for Older infants and Young Children should be in Part B of Annex 1 of the Codex *Guidelines on Nutrition Labeling* (CXG 2-1985). The Committee also agreed to re-establish the NRVs-R EWG with the objectives of finalizing recommendations for general principles to guide the establishment of NRVs-R for persons aged 6-36 months and piloting the general principles on a sub-set of nutrients (i.e., vitamin B12, iodine, vitamin B6, and riboflavin). Finally, the Committee agreed to consider holding a PWG to further progress this work prior to CCNFSDU43.

Agenda item 7: Other Business

Prioritization mechanism to better manage the work of CCNFSDU

The Committee Chair and the Host Country Secretariat presented this agenda item and the Committee agreed to establish an EWG with the following terms of reference:

 revise the draft guideline for the preliminary assessment and identification of work priorities for CCNFSDU (<u>REP20/NFSDU</u> Appendix IX) as well as the proposed criteria taking into account the written comments received by the CCNFSDU Secretariat (Germany) as well as the comments and decision made at CCNFSDU41 for the development of a long term work prioritization mechanism; and

• prepare a revised proposed prioritization mechanism for use on a trial basis for consideration by CCNFSDU43.

Canada offered to co-chair the EWG and the offer was accepted by the German CCNFSDU Secretariat.

In conclusion, the Committee agreed to:

- request the Codex Secretariat to extend the deadline of the Circular Letter, <u>CL 2020/30</u>-NFSDU, requesting proposals for new work and emerging issues. New work proposals that have already been received would not need to be re-submitted.
- reserve the possibility of holding a PWG chaired by Germany and co-chaired by Canada, to meet immediately prior to CCNFSDU43 and conduct a case-by-case review of the emerging issues and proposals for new work submitted by members in response to the Circular Letter.

Agenda item 8: Date and Place of the Next Session

The Committee was informed that CCNFSDU43 was tentatively scheduled to take place within the next 12-18 months, with the location to be confirmed and the final arrangements being subject to confirmation by the Host Country (Germany) in consultation with the Codex Secretariat.