



Codex Committee on Nutrition and Foods for Special Dietary Uses

*November 26-30, 2018
Berlin, Germany*

The 40th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses ([CCNFSDU](#)) convened on November 26-30, 2018 in Berlin, Germany. The session was chaired by Germany and attended by delegates from 73 Member countries, 1 Member Organization, and 41 observer organizations.

Representing the United States were the Head of the U.S. Delegation, Dr. Douglas Balentine (U.S. Food and Drug Administration), Alternate Delegate Dr. Pamela Pehrsson (USDA Agricultural Research Service), ten government advisors and eight non-government advisors.

The Committee had an ambitious agenda and achieved progress on many of the agenda items.

Highlights of the 40th Session:

- The Committee agreed to retain the essential requirements for follow up formula for older infants and the product for young children at Step 7
- Agreed to advance Section A of the follow up formula for older infants for adoption by the Codex Alimentarius Commission 42 (2019) at Step 5; and send the labelling provisions for follow up formula for older infants for endorsement by the Codex Committee on Food Labeling (CCFL45)
- Re-establish the electronic working group (EWG) on the Review of Follow Up Formula to work on dextrose equivalence (DE) under carbohydrates and complete the remaining sections of the follow up formula standard.
- Retain the standard of Ready to Use Therapeutic Foods at Step 4 and establish an electronic working group, chaired by South Africa and co -chaired by Senegal and Uganda to work on the remaining sections on food additives (Section 5.22) and proteins (Section 6.2)
- Forward the Proposed Draft Definition on Biofortification at Step 4 to the CCFL45 to consider the use and placement in Codex text
- Consider a discussion paper that will be prepared by Canada on the different risk management approaches within the mandate of Codex for the reduction of trans fatty acids (TFAs)
- Refer updated methods of analyses for infant formulas submitted by the United States for Vitamin K, folic acid and nine mineral and trace elements for review,

typing, endorsement and retyping or removal of existing methods to the Codex Committee on Methods and Analyses (CCMAS)

- Establish an EWG chaired by Ireland and co-chaired by the United States and Costa Rica to consider the remaining recommendations numbers 3-6 in the Discussion Paper (CX/NFSDU 18/40/10), prioritize the vitamins and minerals to review, and consider protein for NRV-R for older infants and young children for inclusion in Codex texts, and determine which ones were to be applied to which Codex texts.
- Discontinue work on the Proposed Draft NRV-NCD for EPA and DHA Long Chain Omega-3 Fatty Acids but recognizing that this work can be reinitiated when new evidence becomes available.
- Establish a physical working group (PWG) to further consider the framework mechanism for evaluating the technological justification of food additives covered by CCNFSDU, in particular, xanthan gum, pectin, and gellan gum.

The Committee advanced to the 42nd CAC Session for adoption at Step 7:

- Essential composition requirements for follow up formula for older infants and young children (Appendix II, REP19/NFSDU).
- Section A: follow up formula for older infants to Step 5 (Appendix III, REP19/NFSDU) and the labelling provisions for follow up formula for older infants for endorsement by CCFL and CAC.

The following paragraphs provide highlights on the conclusions of the committee in more detail. The full official report of the session will be available on the Codex Alimentarius website: www.fao.org/fao-who-codexalimentarius/meetings/detail/en/?meeting=CCNFSDU&session=40.

Matters of Interest Arising from FAO and WHO (Agenda Item 3)

The representatives of FAO and WHO provided an update of their various activities of relevance and interest to CCNFSDU. FAO reported that the Joint FAO/WHO Expert Meetings on Nutrition (JEMNU) will provide scientific advice for the establishment of nitrogen to protein conversion factors for soy-based and milk-based ingredients used in infant formula and follow up formula. The systematic review is slated to be completed by mid-year 2019 and the call for data had been already been issued with a due date of December 15th, 2018. The FAO notified the Committee that outcomes from the report of the FAO Expert Working Group on protein quality assessment in follow up formula for young children and Ready to Use Therapeutic Foods (RUTF) were published and presented to the Committee on November 24, 2018. In addition, the WHO representative remarked on the new Information Note on the *Classification of Follow up*



Formulas for Children 6-36 Months as Breastmilk Substitutes and Draft Guidelines on Saturated and Trans Fatty Acids Intake in Adults and Children released in May /June 2018.

Review of the Standard for Follow-Up Formula (CODEX STAN 156-1987) at Step 6 (Agenda Item 4a)

The 2018 electronic working group (EWG) led by New Zealand and co- chaired by Indonesia and France held two rounds of consultations.

The Committee focused on the remaining areas for discussion for the product for young children which included carbohydrates (footnote 4), Vitamin D requirements, and the provision for protein (footnote 2), given the recent publication the FAO Expert Working Group Report on Protein Quality Assessment in Follow up Formula for Young Children and Ready to use Therapeutic Foods.

With respect to carbohydrates (footnote 4), the Committee discussed the need for carbohydrates other than lactose for plant-based products. The Committee discussed the appropriate method for measuring sweetness while not compromising palatability. The Committee discussed the proposals to refer carbohydrates with a dextrose equivalence (DE) of 15 to measure sweetness; however, some delegations did not support this proposal, arguing that the dextrose equivalence measures the sugar level and not necessarily sweetness. The Committee also considered the intervention made by the European Union to note the types of non-carbohydrates ingredients that should be added to impart or enhance sweet tastes in flavorings in the food additives section or in the section on optional ingredients.

The Committee was unable to reach a conclusion on this discussion and consequently placed these proposals in brackets for further discussion at the next meeting.

Regarding Vitamin D, some delegates noted that Vitamin D3 is more efficacious and preferred than Vitamin D2 yet both are found in the Advisory List. After some the discussion, the Committee reached consensus to adopt the form Vitamin D because the term covered both forms of Vitamin D3 and D2. The Committee agreed that the requirement would be for Vitamin D and to set minimum and maximum values as well as the footnotes 9 and 10 as proposed. The Committee concluded to retain the essential requirements for follow up formula for older infants for product for young children at Step 7 (Appendix II) and have the EWG consider recommendations on the proposal for DE for products not based on milk protein.

With respect to protein (footnote 2), the Committee agreed to indicate that PDCAAS (Protein Digestibility Corrected Amino Acid Score) and PER (Protein Efficiency Ratio)

methods could both be used to determine protein quality for the product for young children. The Committee also agree to further indicate PDCAAS, as the preferred method recommended by the FAO Expert Working Group and to note that the DIAAS (Digestible Indispensable Amino Acid Score) method could be another alternative method, pending future recommendation from FAO.

Review of Standard for Follow up Formula (Codex Stan 15-1987) (Agenda Item 4b)

The Committee considered the recommendations of the EWG on the following sections of the Standard: Section A: follow up formula for older infants: scope, product definition and labelling; and Section B [Product] for young children, scope, product definition and labelling; and options for the structure of the Standard and preamble.

Regarding the scope, the Committee agreed to include sampling as one of the requirements under the scope section. The Committee addressed questions on whether that World Health Assembly (WHA) resolutions could be addressed in the scope and concluded that they could be considered as well in the labelling section and the preamble.

Regarding the Product definition (Section 2.1), after some consideration on the precise description for the product, the Committee agreed to define the product for follow up formula for older infants as a "breastmilk substitute as a liquid part of a diet for older infants when progressively diversified complementary feeding is introduced."

Regarding Labeling (Section 9), the Committee agreed to reinsert text relating to the prohibition on the use of nutrition and health claims to give further emphasis of this principle. Regarding Additional Labeling Requirements (Section 9.6), the Committee noted that this section was largely based on Article 9 of the WHO International Code of Marketing of Breastmilk Substitutes and Recommendation 4 of the *WHO Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children* (specifically provision 9.6.2) and the Committee largely accepted the draft labeling provisions recommended by the EWG with some amendments. The Committee discussed removing the statement under 9.6.2, the use of this product should not replace breast milk. There were polarized views expressed on this deletion, but ultimately the Committee concluded to delete this phrase because it could contradict with the definition section and would make it more stringent that the Codex infant formula standard. The Committee considered a new amendment to include "cross promotion between product categories is not permitted on the label/[labelling] of the product" in Section 9.6.4. The United States made an intervention seeking clarification on whether cross promotion included advertising and marketing and whether this went beyond the mandate of this Committee. In response and after conference with the

Codex Secretariat, the Chair confirmed that any reference to cross-promotion should be related to the label of the product. The Delegations of Argentina, New Zealand, and United States did not support the term 'labelling' as it could ambiguously extend to marketing and advertising; Chile, Nepal, and Senegal supported retaining the term labeling to cover promotion more broadly; however, due to time constraints and divergence in views, the Committee placed the term 'labelling' in brackets for consideration at the next session.

When discussing product definition, the Committee discussed whether the product could be considered as a breastmilk substitute. The views expressed were deeply polarized. Those who support that the product was a breastmilk substitute, specifically, Norway, Nepal, Nigeria, Senegal, Philippines, Sri Lanka, Niger, South Africa, Egypt gave the following arguments: that the product should be defined by its function; WHA Resolution 69.9 considered this product as a breastmilk substitute; the *WHO Information Note on Clarification of the classification of follow up formula for children 6-36 months* indicated that there was scientific evidence that these products could be considered as a breastmilk substitute; several countries regulated them as breastmilk substitutes; and evidence was pointed out that these products have contributed to the decline in breastfeeding.

Those who did not support defining these products as a breastmilk substitutes included the European Union, New Zealand, Thailand, Cuba, Australia and United States. Some of the reasons were, while they noted that while breastfeeding should be promoted, the role and purpose of the product was different than those of breastmilk substitutes; the product was used as an alternative to cow's milk rather than breastmilk; when developing the composition (essential composition requirements), there was previous agreement to base the composition on nutritional needs of young children that should be contributed where consumption of the nutrient is widely inadequate; and there may be inadequate intake of protein, energy and micronutrients among young children as they are weaned onto complementary foods. The Chair, noting this divergence of views, raised the option of remaining silent on classifying product for young children as a breast milk substitute.

Since there was no consensus on this matter, the Committee decided to continue discussion at the next year's session. The Committee also concluded with deferring discussion on Section B: [product] for young children, the structure of the Standard and preamble for discussion at CCNFSDU41; and re-establishing the EWG chaired by New Zealand and co-chaired by France and Indonesia to address the issue of DE and to complete the remaining sections including sections on purity requirements, vitamin compounds and mineral salts, consistency and particle size, specific prohibitions, food



additives, contaminants, hygiene, packaging, fill of container and methods of analysis and sampling.

Proposed Draft Guideline for Ready-to-use Therapeutic Foods (RUTF) (Agenda Item 5)

The chair of the EWG, South Africa highlighted the recommendations of the PWG, as described in CRD 28. The Committee confirmed and adjusted section 5.1.2 on Legumes and Seeds, Section 5.15 (vitamins and Minerals), Section 5.2.1 (Available carbohydrates); Section 5 (Suitable Basic Raw Materials and Ingredients), Section 2.1 (Energy), Section 5.2.2 (Food additives and Flavors). The Committee had extensive discussion on the available carbohydrates provision where there was debate on whether to set added levels for free sugars of 20 percent or 15 percent of total energy. Some believed that 20 percent of total energy was too high; however, it was explained that there was limited data available on products containing free sugars at less than 20 percent of total energy. The Committee also had extensive discussion on Section 5.2.2 on food additives and flavors and reached consensus to address to take a step wise approach in evaluating food additives, the steps being to first identify the additives that were currently in use, second, review if such additives were already permitted for use in existing Codex standards, and then develop a text that would make reference to the food additive provisions standards.

In conclusion, the Committee agreed to re-establish an EWG, chaired by South Africa and co-chaired by Senegal and Uganda to continue working on 5.2.2 (food additives) and Section 6.2. (proteins) and hold the remaining text at Step 4.

Proposed Draft Definition for Biofortification (Agenda Item 6)

Co-chairs Zimbabwe and South Africa discussed the outcome of the electronic working group which resulted in five recommendations on the revised draft definition with six footnotes, including recommendations on alternative terms to biofortification, placement of the definition and its intended use. Several delegations, supported the current draft definition, including Brazil, Philippines, Cuba, Ghana, Mali, Senegal, Nigeria, Burkina Faso. Some delegations, such as United States and Malaysia, supported the definition but still had concerns that the definition did not give guidance on what constituted a meaningful increase of nutrient content, which is necessary for compliance and labeling purposes.

Several delegations, including the European Union, Thailand and Chile, expressed fundamental concerns with the definition, for which the intended use still seemed unclear, as well as how the definition will be used, and where it will be placed in Codex

text. Without clarity, these delegations noted, it would be problematic for use the definition for labeling claims and compliance.

The Committee concluded that these remaining questions would be more appropriately handled by the Codex Committee on Food Labeling. Therefore, the Committee decided to place the definition to Step 4 and send forth the definition to the Codex Committee on Food labeling to assess if the definition met its intended needs and the intended use of the definition and where the definition could be best placed in Codex text.

Proposed Draft NRV-NCD for EPA and DHA long chain omega-3 fatty acids (Agenda Item 7)

The EWG Chairs, Delegation of the Russian Federation and co-Chair Chile reported their findings on the proposal for an NRV-NCD of 250 mg/day. The Committee considered that the WHO NUGAG (Nutrition Guidance Expert Advisory Group) recently conducted a substantial study which concluded that there was not enough evidence on the effect of the EPA and DHA on CHRD (Chronic Heart Disease) mortality. The Committee agreed to discontinue this work but recognized that this work could be revisited when new evidence becomes available. In addition, the Committee agreed not to undertake new work on revision of the *General Principles for Establishing Nutrient Reference Values for the General Population* to the *Guidelines on Nutrition Labelling* (CXG 2-1985).

Discussion Paper on Claim for “free” of Trans Fatty Acids (TFA) (Agenda Item 8)

Canada presented two options for Committee to either set the condition for the claim as Conditions (not more than): 1 g of TFA per 100 g of fat and must meet the conditions for “low” in saturated fats or not set conditions for a claim. The Committee weighed the pros and cons of setting a claim; some delegations, including the United States, expressed that it would not be possible to accurately measure TFAs in all foods, making it difficult to implement and enforce and lead to a claim that could be misleading as some foods which might not have TFAs could also be labelled as ‘free’ of TFAs. In response to concerns with linking the condition to ‘low’ in saturated fatty acids, the WHO representation noted that the recommendation of the updated WHO guideline on *trans*-fatty acids (TFA) intake being less than 1% of total energy intake is for total TFA but given the large part of TFA consumption is related to industrially-produced TFA, the REPLACE action package released to guide country actions focuses on developing and implementing the measures for eliminating industrially-produced TFA. Several countries, such as the European Union and Thailand, noted that they follow risk management approaches that have been successful in regulating TFAs. Also, those

delegations in favor of continuing work, China, noted that it could provide incentive to industry to reduce TFAs.

The Committee, agreeing that reducing TFAs in foods was an important public health goal, decided not to take the proposed draft condition for a claim for “free” form TFAs and requested Canada prepare a discussion paper on the different risk management possibilities for the reduction of TFAs within the mandate of Code for the next session.

NRV-Rs for Older Infants and Young Children (Agenda Item 9):

Ireland, as chair of the electronic working group, explained the results of EWG which was tasked to 1) assess the need and value of establishing Nutrient Reference Values-Requirements (NRV-R's) for older infants and young children in Codex texts in relation to their purpose in the Guidelines for Nutrition Labeling and Codex texts for special dietary use for older infants and young children; 2) identify the specific age groups to which these NRV-R would apply; and 3) based on findings from 1) and 2), analyze labeling provisions in Codex texts and where appropriate, develop a request to CCFL to provide advice on the potential for amendments to provide further clarity.

The Committee completed progress on Recommendation 1-3 from the Discussion Paper, by determining that actual values of the nutrient requirements would influence whether to combine the two sets of NRVs-R for older infants and young children. The Committee agreed with recommendation to standardize the age ranges through the codex texts (i.e. 6 to less than 12 months and 12 to less than 36 months) as proposed and to continue working to develop NRV-s-R for use in Codex texts and deciding to disregard the Guidelines for Vitamin and Mineral Food Supplements (CXG 55-2015) to establish labeling of nutrient declaration and reference criteria for vitamin and mineral composition for NRVs-Rs. The Committee agreed to reestablish an EWG chaired by Ireland and co-chaired by Costa Rica and the United States to address the remaining recommendations of 3-6 from the discussion paper.

Food additives – Framework for considering technological justification for use of food additives in the Standards developed by CCNFSDU (Agenda Item 10)

The European Union, chair of the EWG, chaired two in-session working groups in which Committee gave feedback on the proposed process and draft framework for CCNFSDU to appraise the technological justification of food additives.



The Committee agreed the framework should apply to all foods covered by CCNFSDU. The United States and Canada supported by Australia, and New Zealand, questioned whether the proposed framework was overly complex and went beyond technological justification to include issues on food safety, which is exclusively within the remit of Codex Committee on Food Additives. As a result, some questions in the framework were simplified and merged; however, due to time constraints, not all the questions under the framework were not reviewed and therefore bracketed for future discussion. The Committee agreed to do further work on the framework questions and to appraise the technological need for the food additives of xanthum gum, pectin and gellum gum, The Committee agreed to hold a PWG to be chaired by the European Union and Russia and tasked the EWG to further refine on a framework and to appraise the technological need for the use of xanthan gum, pectin, and gellum gum, using the information received in VX/NFDU 18/40/11 Annex D

Other Matters

- **Alignment of Food Additives in CCNFSDU Standards with the GSFA**
The Chair encouraged members to consider leading this work. The Committee also agreed to discuss how to approach the exercise of the alignment of food additives in CCNFSDU standards with the General Standard of Food Additives (GSFA) at the next session.
- **Harmonized Probiotic Guidelines for Use in Foods and Dietary Supplements**
The Committee decided not to take up the new work proposal on the development of guidelines with a harmonized framework for probiotics for use in foods in and dietary supplements due to workload constraints and need for more clarity on the scope of the work. It was noted also that it may premature to embark this work, as collection of information and data needed to be first conducted before identifying a globally applicable definition of probiotics.

Other Business and Future Work (Agenda Item 11)

- **Methods of Analysis in the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72-1981)**
The United States presented a conference room document and conducted an in-session working group on Methods of Analysis for Infant Formula. The Committee agreed to refer the proposed methods for vitamin K, folic acid and nine minerals and trace elements to CCMAS for review, typing, and endorsement and request retyping of related existing method.



- **General guidelines to establish nutritional profiles**
Costa Rica, speaking also on behalf of Paraguay, presented a discussion paper and project document on guidelines to establish nutritional profiles that would complement the work on Front of Pack Labeling (FOPL) ongoing in CCFL. The Committee agree to request Costa Rica and Paraguay and noted the offer of support from the United States to take a stock take of the different nutrient profile model building on the work of WHO and other publications.
- **Proposal for new work on the general requirements for protein supplements intended for bodybuilding submitted by Egypt**
This Committee, due to time constraints, was unable to discuss this proposal.

Date and Place of the Next Session

The 41st session of the CCNFSDU is tentatively set for November 25-29, 2019 in Dusseldorf, Germany.