



Report of the U.S. Delegate, 38th Session of the Activities of the Codex Committee on Nutrition and Foods for Special Dietary Uses

December 5-9, 2016

Hamburg, Germany

The 38th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses ([CCNFSDU](#)) convened December 5-9th, 2016 in Hamburg-Bergedorf, Germany. The session was chaired by Germany and attended by delegates from 56 Member countries, one Member Organization (the European Union), and 38 observer organizations. The formal committee session was preceded by a one day physical working group on the Review of the Follow-Up Formula Standard.

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), seven government advisors and four nongovernment advisors.

Overall, the session was completed successfully, and the United States achieved its principal objectives for the meeting. The Committee had an ambitious agenda and made progress on many of the agenda items. Several documents were advanced to the Codex Alimentarius Commission (CAC) for final adoption at Step 5/8 or Step 8, and new work was recommended.

Highlights of the 38th Session

The Committee celebrated its fiftieth anniversary and noted the progress and contributions towards improving nutrition throughout the world.

The U.S. Delegate, Dr. Douglas Balentine, presented at a side event session on the evidence-based review processes used by U.S. federal agencies.

The United States led an in-session working group to provide responses to the Codex Committee on Methods and Analyses (CCMAS) questions on the methods of analysis in the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72-1981). The U.S. Delegate presented the results of this working group to the Committee and prepared responses to CCMAS for endorsement.

The Committee advanced to the 40th CAC Session (2017) for adoption:

- Proposed draft amendments to Section 6, Paragraph 33 of the CCNFSDU Risk Analysis Principles to identify the Joint FAO/WHO Expert Meetings on Nutrition (JEMNU) as a primary source of scientific advice (as recommended by the Codex Committee on General Principles and the CAC);
- Methods of analysis in the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72-1981);
- Editorial amendments proposed by the Codex Committee on Food Additives (CCFA) which related to the appropriate use of the term flavorings in CODEX STANs 73-1981; 74-1981; 156-1987; and CAC/GL8-1191;
- Proposed Nutrient Reference Values- Requirements (NRV-R's) for Vitamin E and its dietary equivalents and Vitamin D.

The Committee continued work in several areas:

- The Standard for Follow-Up Formula (CODEX STAN 156-1987), for continued work on definitions, essential composition requirements, and optional ingredients;
 - The proposed Draft Definition for Biofortification;
 - The proposed Draft NRV-NCD for EPA and DHA long chain omega-3 fatty acids, which will consider the upcoming publication of the World Health Organization (WHO) Nutrition Guidance Expert Advisory Group (NUGAG) report;
 - The proposed Guideline for Ready-to-Use Therapeutic Foods.
- The Committee also agreed to revisit the discussion of work on a Claim for "Free" of Trans Fatty Acids after receiving advice from CCMAS on the analytical methods for trans fatty acids.



The Committee agreed to undertake new work on:

- The alignment of Food Additives in the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72-1981). Technical justifications for the food additives xanthan gum and pectin will be reviewed, although they have already received WHO/FAO Joint Expert Committee on Food Additives (JEFCA) approval. An electronic working group (eWG) will also consider the technological justification of gellan gum and determine if a request for its inclusion in CODEX STAN 72-81 is needed. The following paragraphs provide greater detail on the conclusions of the committee. The full official report of the session is available on the Codex Alimentarius website at <http://www.fao.org/fao-who-codexalimentarius/meetings-reports/detail/en/?meeting=CCNFSDU&session=38>

Consistency of the Risk Analysis Texts across Relevant Committees (Agenda item 2)

The Committee agreed:

- i. To forward the proposed draft amendments to Section 6, Paragraph 33 that identify the Joint FAO/WHO Expert Meetings on Nutrition (JEMNU) as a primary source of scientific advice for the Committee, for adoption by the Codex Alimentarius Commission (CAC);
- ii. To forward the amendments to Section 3.1 and 3.2 of *Guidelines on Nutrition Labelling* (GL 2 -1985) to reflect the current definition of Recognized Authoritative Bodies (RASBs), for adoption by the CAC.

Methods of Analysis (Agenda Item 2)

- The Committee considered the recommendations from the in-session working group, chaired by the United States, on responses to matters referred by the Codex Committee on Methods and Sampling (CCMAS) on the appropriate methods of analyses in infant formula.
- The Committee agreed to exclude the ELISA G12 method in the standard for Foods for Special Dietary Use for Persons Intolerant to Gluten (CODEX STAN 118-1979), noting that there were no comparability results with the R5 method, but would reconsider the method at a future date when the results from the ongoing comparability studies become available.

Editorial amendment to texts on flavorings (Agenda Item 2)

The Committee agreed to editorial amendments proposed by the Codex Committee on Food Additives (CCFA) related to the appropriate use of the term flavorings in the CODEX STANs 73-1981; 74-1981; 156-1987; and CAC/GL8-1191.

NRV-R for Vitamin E and Dietary equivalents for Vitamin E (Agenda Item 4a)

The delegate from Australia, who last chaired the e-WG on NRV-R's in 2015, reported that the outcome of the 2015 European Food Safety Assessment (EFSA) was now available and that many of daily values from FAO/WHO and Recognized Authoritative Scientific Bodies (RASBs) were based on dietary intakes that were considered sufficient for adequate nutritional status. The Committee recommended a value of 9.0 milligrams (mg) per day, which is the average of values from EFSA, WHO/FAO, and the National Institute of Health and Nutrition (NIHN). CCFSDU agreed to identify alpha-tocopherol as the active form of Vitamin E at a NRV-R of 9 mg/day and to submit this determination to the CAC for final adoption at Step 8, noting the reservation from China who preferred a value of 14 mg per day.

The Committee discussed the conversion factor for Vitamin E dietary equivalents, a topic that had been discussed for several committee sessions. As in previous meetings, divergent views were expressed by Indonesia and Malaysia, who noted that there were various naturally occurring forms of Vitamin E as tocopherols and tocotrienols that could be Vitamin E equivalents. Others, including the United States, noted that alpha-tocopherol is the only form of the vitamin that is biologically active in humans; other forms have either not demonstrated biological activity or the alpha-tocopherol measurement of such activity has been inconsistent. At this session, the Committee achieved consensus, agreeing to recommend a conversion factor of 1.0 mg alpha-tocopherol equaling 1 mg RRR-alpha-tocopherol for final adoption by the CAC at Step 5/8, noting reservations from Malaysia and Indonesia.

NRV-R for Vitamin D (Agenda Item 4b)



The Committee received the awaited result from EFSA and was informed by the former chair of the working group on NRV-R's, Australia, that some recognized authoritative scientific bodies (RASBs) used the serum level of 25(OH)D as the biomarker of Vitamin D status at 50 nmol/L in setting a NRV-R of 15 micrograms, as this level is associated with maintenance of musculoskeletal/bone health. Several delegations supported various values, ranging from 5 to 15 micrograms per day, because of the differences in seasonality and exposure to sunlight across the world. To aid the Committee in reaching agreement on the appropriate value, the United States made an intervention to explain that the NRV-R is used for labeling purposes and is not independent from fortification levels; when foods are fortified with Vitamin D, the basis for fortification is the NRV-R, so that a lower NRV-R would result in lower values of fortification. In the spirit of consensus, the Committee decided to recommend adoption of a range from 5-15 micrograms/day, with a footnote associated with the 15 mcg level: "(based on minimal sunlight exposure throughout the year)."

NRV-Rs for Older Infants and Young Children (Agenda Item 4c)

The Committee was unable to nominate a chair for the proposed working group on NRV-R's for older infants and young children. Therefore, the Committee agreed to postpone establishment of the eWG and to reconsider this matter at the next session.

Review of the Standard for Follow-Up Formula (CODEX STAN 156-1987) at Step 4 (Agenda Item 5)

The electronic working group (eWG), led by New Zealand and co-chaired by Indonesia and France, reported that there had been two rounds of consultations, leading to 21 recommendations. A physical working group (pWG) on this standard met the day before the formal Committee plenary session. As chair of the pWG, New Zealand focused the discussion only on the recommendations for the nutrient composition of the product that would be consumed by young children 12- 36 months of age. The recommendations included consideration of the nutrient profiles of: the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72-1981), the existing Follow-Up Formula Standard (CODEX STAN156-1987, the composition of cows' milk, and nutrients of global concern.

The Committee reviewed the findings of the pWG and agreed to recommend nutrients for older infants (6-12 months), including protein levels, Vitamin K, Vitamin C, zinc, docosahexaenoic acid (DHA) and L(+) lactic acid producing cultures.

The Committee agreed to continue discussion of a minimum protein level value of 1.8 g/100 kcal to await the outcome of the EFSA report on the safety of a 1.6 level in clinical trials. The Committee also agreed to provide information on the amino acid pattern of human milk in a footnote.

The Committee also agreed on the conversion factor for soy products: "for the purposes of this standard, the calculation of the protein content of the final product ready for consumption should be based on nitrogen (Nx 6.25), unless a scientific justification is provided for the use of a different conversion factor for a particular product."

The Committee agreed on the importance of providing information on the minimum levels for DHA, even though designated as an optional ingredient. The amount of DHA added, the DHA minimal level, and whether DHA should be expressed as a percent of total fatty acids or in milligrams per 100 kcal will be considered by the Committee at the next session.

The Committee entered into discussions on the nutritional composition of the follow-up formula product for the 12-36 month old young child and reached agreement on the following: a framework for essential composition of product for young children which explains the distinction between mandatory and optional ingredients; to establish values setting maximum levels for carbohydrates and minimum levels for protein and fat; to indicate that the quality of protein should be no less than 85 percent of that of casein; not to allow partially hydrogenated oils and fats; to set proposed levels for iron and Vitamin C but allow for adjustment by national and regional authorities to consider their specific nutritional needs; to set a guidance upper limit (GUL) for zinc and values for vitamin A; to continue discussing values for Vitamin D and the allowable types of carbohydrates; and to forego setting a value for sodium. The Committee agreed to continue work on a format similar to that of the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants CODEX STAN 72-1981 for the moment as it continues working out the nutritional composition of the Follow-Up Formula Standard with a point of differentiation at 12months.

The Committee discussed whether the scope and labelling sections should consider the 69th World Health Assembly resolutions that provided guidance on ending inappropriate promotion of foods for infants and young



children. Several delegations, such as Mexico, Nigeria, Philippines, Nepal, and China, expressed support for referencing the resolutions in the standard or preamble. The Committee decided to explore the issue further in the eWG.

The Committee agreed to continue the eWG chaired by New Zealand and co-chaired by Indonesia and France to review remaining issues. The eWG was charged with: a) finalizing the minimum protein requirements and levels for the optional addition of DHA in the essential composition provisions for follow-up formula for older infants (6-12 months); b) finalizing the outstanding requirements for the essential composition of product for young children (12-36 months), c) finalizing the product definitions contained in Section 2.1, including the name of the product for young children of 12-36 months, and d) reviewing the scope and labelling sections with a point of differentiation at 12 months for section A and Section B of the Draft Standard based on the discussion at CCNFSDU38 (2016) and proposing draft text for discussion at the next session.

Proposed Draft Definition for Biofortification at Step 4 (Agenda Item 6)

Electronic working group co-chairs Zimbabwe and South Africa discussed the outcome of the eWG and their round of consultations, which resulted in six criteria for elements to include in the definition and a proposed draft definition based on the criteria. The co-chairs requested guidance from the Committee regarding each of the six criteria so that they could continue to refine the definition. The Committee agreed that further discussion was needed, particularly on the criterion related to methods of production, which the Committee previously confirmed should cover all methods of production. The delegation of the European Union and other delegations expressed concern about the use of the proposed definition for labeling claims, which they believed could be misleading given its inclusion of all methods of production, and supported developing a concept definition to enhance countries' understanding of biofortification but not for labeling purposes. The Committee took note of the concerns and suggestions expressed by delegations and re-established the eWG, which will again be chaired by Zimbabwe and co-chaired by South Africa, to refine the criteria and further develop the definition of biofortification for consideration at CCNFSDU in 2017 and completion by 2019.

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

As chair and co-chair of the eWG, the Russian Federation and Chile reported their findings on the proposal for an NRV-NCD of 250 mg/day, which they reported is based on information and data from several recognized authoritative scientific bodies (RASBs). The Committee decided that it would be best to defer decision on this agenda item until the WHO Nutrition Guidance Expert Advisory Group (NUGAG) review on fatty acids and their relationship to chronic disease is made available in April 2017. The Russian Federation and Chile agreed to continue chairing the eWG and to consider the NUGAG report in their review, for discussion at CCNFSDU in 2017.

Discussion Paper on a Standard for Ready-to-use Foods (RUTF) (Agenda Item 8)

The chair of the eWG, South Africa, presented a series of recommendations on purpose, scope, food additives, and quality of protein. The Committee agreed to have the eWG, chaired by Senegal, South Africa, and Uganda, continue development of the proposed guideline for circulation for comments at Step 3 and discussion at the next session.

Discussion Paper on Claim for “free” of Trans Fatty Acids (TFA) (Agenda Item 9)

Canada presented a revised discussion paper on findings from two WHO systematic reviews on saturated fat and trans fatty acids. In the presentation, Canada noted the comments made at CCNFSDU36 (2014) and CCMAS36 (2015) that “the methods of analysis for determining TFAs should be practical and internationally accepted as well as being reliable and consistently reproducible.” In light of this, the Committee agreed to request advice from CCMAS on the three methods that could be applied to determine TFA as defined in the *Guidelines on Nutrition Labelling* (CAC/GL 2-1985) and the WHO definition, which specifies that at least one double bond in the trans configuration at the level of 1 g per 100 g of fat. Based on the reply from CCMAS, the Committee will further consider the proposed claim.

Alignment of Food Additive Provisions in the Standards developed by CCNFSDU (Agenda Item 10)

In light of the decision in CCNFSDU 37 (2015) to begin work on aligning CCNFSDU commodity standards with food additive standards of CCFA, the Committee established an electronic working group to be led by the European Union and the Russian Federation to develop a framework for confirming the technological justification for food additives.



An observer organization, International Special Dietary Food Industries, noted that the food additives in Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72-1981), xanthan gum (INS 415), and pectin (INS 440) had been already evaluated by JECFA and the technical justifications for these additives were provided to CCNFSDU in their Conference Room Document submission (CRD 11) and previously at the 2014 CCNFSDU session. However, the Committee decided that it needed more time to confirm the technical justification for these additives and receive the final guidance document from CCFA on the alignment of food additives standards among Codex committees.

Other Business and Future Work (Agenda Item 11)

a) 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 led an in-session working group to provide responses to the matters referred to by CCMAS and presented the working group's recommendations at the plenary session. The Committee agreed to the following working group recommendations: to refer the proposed methods for chromium, selenium, and molybdenum and Vitamin C to CCMAS for review and typing as Type II; to request reclassification of existing methods, if needed; to inform CCMAS that existing methods for Vitamin B12 and total fatty acid profile were fit for purpose and to request CCMAS to endorse the proposed new methods and forward them to the CAC for adoption; and, to inform CCMAS that the definition and scope of methods for myo-inositol and Vitamin E coincide and should be sent to CAC for adoption. The Committee also agreed to inform CCMAS that it did not recommend a conversion of units in CODEX STAN 72-1981.

Next Session

The 39th session of the CCNFSDU is tentatively set for December 4 –9, 2017 in Berlin, Germany.