Report of the U.S. Delegate, 39th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses

December 4-8, 2017
Berlin, Germany

The 39th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) convened on December 4-8th, 2017 in Berlin, Germany. The session was chaired by Dr. Pia Noble of Germany and attended by delegates from 66 Member Countries, one Member Organization (the European Union), and 39 observer organizations, including representatives of the UN Food and Agriculture Organization (FAO) and the World Health Organization (WHO).

The 39th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CNNFSDU)

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), nine government advisors and six non-government advisors.

The Committee had an ambitious agenda and achieved progress on many of the agenda items. The United States' objectives for the session were generally accomplished.

HIGHLIGHTS

The Committee

- Advanced the essential composition requirements for follow up formula for older infants and young children to the 41st Session of the Codex Alimentarius Commission (CAC 41, July 2018) for adoption at Step 5 (subject to another round of review by CCNFSDU), but reached no conclusion on issues related to the preamble of the standard and references to WHO documents.
- Activated and assigned scientific review work to the Joint Expert Meeting on Nutrition (JEMNU). The United States and Canada refined the project described in Conference Room Document (CRD) 6 in conjunction with FAO and WHO representatives and developed questions using the PICO evidence based framework on establishing a nitrogen to protein conversion factor for dairy and soy proteins in infant and follow-up formula.
- Agreed to refer updated methods of analysis for infant formula for biotin, Vitamin D and chloride, as presented by the United States, to the Codex Committee on Methods of Analysis and Sampling (CCMAS) for review, typing, endorsement and retyping or removal of existing methods.
- Agreed to undertake new work and (subject to approval by CAC 41) created an Electronic Working Group (eWG), chaired by Ireland and co-chaired by the

United States and Mexico, to assess the need and values for the establishment of Nutrient Reference Values- Requirements (NRVs-R) for older infants and young children.

- Noted the CCMAS request on the methods for chromium, molybdenum, and selenium in infant formula and encouraged members to submit validation data to CCMAS.
- Deferred discussion of the matter referred from CCMAS on criteria for endorsement of biological methods used to detect chemicals of concern.
- Agreed to revisit discussion of a Claim for "Free" of Trans Fatty Acids at its next session, following a round of comments.
- Continued work in several areas:
    i. Revision of the Standard for Follow-Up Formula (CODEX STAN 156-1987)
    ii. Proposed Draft Definition for Biofortification
    iii. Proposed Draft Nutrient Reference Values- Non-Communicable Diseases (NRV-NCD) for EPA and DHA long chain omega-3 fatty acids
    iv. Proposed Guideline for Ready-to-Use Therapeutic Foods
    v. Alignment of Food Additives in the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72-1981) with the General Standard for Food Additives (GSFA).

The Chair of the Committee, Dr. Pia Noble, announced that this was her last session as Chair and the Committee welcomed her replacement, Marie Louisa Trebes, as the incoming Chair.

The following paragraphs provide more 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/detail/en/?meeting=CCNFSDU&session=39

MEETING SUMMARY

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

The representatives of FAO and WHO provided an update on their various activities of interest to CCNFSDU. In her report on WHO activities, the WHO Representative indicated that World Health Assembly (WHA) Resolution 69.9, a resolution which some members have proposed be referenced in the Revised Standard on Follow up Formula, was approved.

The Delegation of France asked the WHO Representative to clarify whether Resolution WHA69.9 on the Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children was "approved" since this resolution was officially denoted as "welcomed with appreciation." France, supported by the European Union and the United States, indicated the view that this was an error. The WHO Representative responded that resolutions that use the phrase "welcomed with appreciation" or other similar terms

indicated an absence of rejection, and therefore can be construed as “approved,” so there was no error in the document. The WHO Representative indicated that she had consulted the WHO legal office on this point. The Delegation of the European Union, supported by the United States, noted that the WHO Representative’s interpretation of approval did not accurately reflect the context of certain WHA Resolutions, which may have recorded disassociations from countries. The United States noted that the United States filed a disassociation from WHA Resolution 70.11 on “best buys” and other recommended interventions to address non-communicable diseases (NCDs) due to insufficient evidence supporting certain recommendations. NOTE: Subsequent inquiries to the WHO legal office have indicated that the views expressed by the WHO Representative at CCNFSDU did not accurately reflect the WHO view, and that the words in WHA resolutions do carry meaning. The Committee report will require correction on this point.

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

The 2017 electronic working group (eWG) led by New Zealand and co-chaired by Indonesia and France held two rounds of consultations and provided a report with recommendations to the Committee.

The Committee agreed to focus on the essential composition of follow up formula (FUF) and postpone discussion of the preamble until after completing the discussion on the essential composition for both products (FUF for older infants aged 6-12 months and products for young children aged 12-36 months).

For follow up formula for the older infant (6-12 months), the Committee agreed on a minimum protein value of 1.8 g/100 kcals, with a footnote (Footnote 6) providing that a lower minimum protein level between 1.6 and 1.8 g/100 kcals for hydrolysed protein based FUF can be accepted if a safety and suitability and assessment is evaluated by a competent national and/or regional authority. The Committee agreed with the Guidance Upper level (GUL) of 30 mg/ 100 kcals and a minimum of 20 mg/ 100 kcals for Docosahexanoic acid (DHA) levels.

In a related matter on protein, the Committee agreed to make the following requests to the Joint Expert Meeting on Nutrition (JEMNU) for scientific advice:

1. When determining the protein content of soy-based ingredients used in infant formula and follow-up formula, what is the appropriate science-based nitrogen to protein conversion factor to use when comparing protein content derived from nitrogen based methods to amino acid based methods?
2. When determining the protein content of milk-based ingredients2 used in infant formula and follow-up formula, what is the appropriate science-based nitrogen to protein conversion factor to use when comparing protein content derived from nitrogen based methods to amino acid based methods?

Regarding the essential composition discussion on follow up formula for the young child (12-36 months), the Committee agreed not to include a calcium to phosphorus ratio for calcium recommendations. (Phosphorus is an optional ingredient.)

The Committee agreed to establish a minimum level for fat of 3.5 g / 100kcal and a maximum level for available carbohydrates of 12.5 g / 100kcal, and to add, in brackets, a footnote (Footnote 4) to indicate that for a product with a protein level below 3 g/ 100kcal, a maximum level of available carbohydrate up to 14 g / 100kcal may be permitted by national and/or regional competent authorities. The Committee confirmed its earlier decision that Vitamin D should be mandatory. Noting the diversity of views on the appropriate levels for Vitamin D and the need to clarify that the form of Vitamin D was Vitamin D3, the Committee agreed to retain in brackets the proposal to allow competent authorities to deviate from provisions as appropriate for the nutritional needs of their local populations. Data on Vitamin D status from sun exposure and from fortification in tropical regions may be helpful in finalizing the decisions for this nutrient.

Regarding the labeling section for the Follow Up Formula Product for Older Infants, the Committee reached agreement on the sections on (a) list of ingredients, which was amended to delete the reference to ”optional ingredients,” (b) declaration of nutritive value; and (c) date marking and storage instructions, which was aligned with the work on date marking finalized by Codex Committee on Food Labeling (CCFL). The remaining components of labeling were left for discussion at the next CCNFSDU session.

For the name of the product, the Committee agreed to clarify that the name of the food should also contain a reference to the source of protein. It was also agreed that for mixed source products, the name of the product should indicate the source of both the animal and plant proteins and the main source should be mentioned first.

For information for use, the Committee agreed to insert reference to potable water and delete “products in powdered form should be reconstituted with water that is safe or has been rendered safe by previous boiling for preparation.” The discussion on additional labeling requirements for the follow up formula for older infants and for the product for young children was postponed to the next CCNFSDU session.

In concluding this agenda item, the Committee agreed to the following:

- To advance the essential composition requirements for older infants and young children agreed at this and previous sessions for adoption by CAC41 at Step 5 (this will allow for another round of comments and resolution of bracketed text);
- To discuss the preamble further at the next session; and
- To re-establish the eWG chaired by New Zealand, and co-chaired by France and Indonesia and working in English with the following terms of reference:

    i. finalize the labelling requirements for follow up formula for older infants;
    ii. finalize the labelling requirements for [name of product] for young children;

iii. consider options for the structure of the standard/standards (e. g., whether one standard or two separate standards for the products for the two age groups);
iv. develop a proposal for the scope sections for both follow up formula for older infants and [name of product] for young children consistent with discussions at CCNFSDU39;
v. finalize the product definitions contained within Section 2.1 for both follow up formula for older infants and [name of product] for young children and finalize the name of the product for young children.

Although the chair initially concluded on this agenda item before the lunch break, it was re-opened at the request of delegations who apparently wished to express views on references to WHO documents in the preamble. A number of members (including India, Nepal, Sri Lanka, the Philippines, South Africa, Senegal, Burkina Faso, Nigeria, Kenya, Sudan, Chile, Brazil, Ecuador, and Mexico), the UNICEF Representative and six nongovernmental observer groups supported WHO references, while others expressed concerns. The United States, the EU, Russia, and the International Special Dietary Foods Industries observer re-iterated the view that it was preferable to finalize the content of the standard first. The United States and the European Food Law Association observer further noted significant concerns about referencing WHO resolutions and documents that go beyond the scope of the standard.

The Committee confirmed its decision to include a preamble, however, the Chair noted that the Committee needs to address: whether to include specific references to WHA resolutions and WHO Guidelines or to have more general references; that some WHA resolutions go beyond the mandate of Codex and therefore are inappropriate to reference; and whether guidance from the CCEXEC or CAC might be needed before the wording of the preamble could be finalized. The United States and the European Food Law Association (AEDA) stated that inclusion of WHO policy documents that are outside the scope and mandate of Codex could undermine the credibility of Codex Standards. The United States, supported by Argentina, Russia and the European Union, noted that discussing the preamble was premature and should be considered after the content of the standard and other outstanding technical questions were resolved. United States and Argentina also noted that the legal implications of inclusion of WHA resolutions should also be evaluated before drafting the preamble. Several countries, including India, the Philippines, Nepal, Sri Lanka, Kenya, South Africa, Senegal, Burkina Faso, Nigeria, Sudan, Chile, Brazil, Mexico and Ecuador, supported including references to the WHA resolutions in the preamble. The Committee also briefly discussed the definition and name of the product for older infants and young children. Brazil, Nepal, and the Philippines noted that the definition of the product for older infants should state that FUF is a breastmilk substitute. South Africa, Nepal, Philippines, Sri Lanka, India and Zimbabwe also thought that the definition of the product for young children should state it is a breastmilk substitute. Canada, the United States, Switzerland, and Thailand noted that it was problematic to call FUF for young children a breastmilk substitute as the product does not completely meet the nutritional needs of young children. The Committee noted the diverging views on the preamble,

definition and name of the products and did not take any decision. The Committee further noted that it was premature to request advice from CCEXEC or CAC and that work should continue on the preamble, scope, product name, and definitions in order to assess whether further guidance is needed.

Proposed Draft Definition for Biofortification at Step 4 (Agenda Item 5)

Co-chairs Zimbabwe and South Africa discussed the outcome of the electronic working group and the round of consultations which resulted in criteria for developing a draft definition.

The Delegation of the European Union expressed concern about how to proceed with developing a definition when it is still undecided how the definition will be used and where it will be placed in Codex text, which was part of the original charge from the CAC when it approved this as new work in 2015. The Committee concluded that these issues would be more appropriately addressed by the Codex Committee on Food Labeling. The European Union also stated that the prefix 'bio' and its use in labeling could be misleading since "bio" has a specific meaning associated with organic foods for European consumers. The International Food Policy Research Institute (IFPRI), an observer group, proposed for the Committee to consider alternative terms for biofortification. The Delegation of India questioned whether methods of production should be part of the definition and the Delegation of Costa Rica supported that the definition covers all methods of production.

The Committee took note of points raised in the discussion and re-established the eWG, which will be chaired by Zimbabwe and co-chaired by South Africa. The eWG was tasked with refining the draft definition and accompanying footnotes; exploring other alternative terms to biofortification; and considering the request from CAC38 (2015) on how the definition would be used and where it would be best placed.

Proposed Draft NRV-NCD for EPA and DHA long chain omega-3 fatty acids at Step 4 (Agenda Item 6)

The Russian Federation, as chair of the eWG on this issue, and co-chair Chile reported the eWG's recommendations and proposed an NRV-NCD of 250 mg/day, based on information and data from Joint FAO/WHO expert consultations and several recognized authoritative scientific bodies (RASBs). The Committee decided to defer discussion of this agenda item to allow for a complete assessment of current scientific evidence presented in the WHO Nutrition Guidance Expert Advisory Group (NUGAG) systematic reviews and consider further advice from FAO/WHO. The WHO sponsored a presentation on the NUGAG systematic reviews at a lunch break that answered questions raised in the report of the eWG. The conclusions from the WHO presentation were the following: that there is little evidence that LCn3 fats, including EPA and DHA, has any important effect on all-cause mortality, cardiovascular outcomes (including deaths) or risk factors; there are no data suggesting dose effects with which to establish thresholds; and LCn3 fats reduce serum triglycerides and raise HDL but these effects

are not strong enough risk factors to support establishment of guidance or thresholds. The presentation on the systematic review of prospective cohort studies restated the information provided in the report provided to the Committee.

The Russian Federation and Chile agreed to continue chairing the eWG with the following terms of reference:

i. Complete assessment of the NUGAG systematic reviews and further advice from FAO/WHO;
ii. Clarify if the conclusions of RASBs that did not set NRVs-NCD could be considered when establishing Codex NRVs;
iii. Discuss and clarify what level of evidence in the GRADE (Grading of Recommendations Assessment, Development and Evaluation) classification constitutes "relevant convincing/generally accepted scientific evidence;"
iv. Discuss if the definition of convincing evidence in the 2002 Joint FAO/WHO expert consultation, "Diet, Nutrition and Prevention of Chronic Disease," is applicable for the purpose of setting a NRV-NCD;
v. Make proposals to CCFNSDU40.

Proposed Draft Guideline for Ready-to-use Therapeutic Foods (RUTF) (Agenda Item 7)

As chair of the eWG, South Africa introduced the item and noted that a revised proposal had been submitted in CRD15. The Committee agreed to certain revisions to the sections on the description, raw materials and ingredients, fats and oils, and cereals. Due to time constraints, the Committee agreed to continue discussing the sections on vitamins and minerals, available carbohydrates and contaminants at the next session.

The Committee agreed to re-establish the eWG, chaired by South Africa and co-chaired by Senegal and Uganda, to continue drafting the proposed guideline for RUTF. There will be a physical working group meeting immediately prior to the next session.

NRV-Rs for Older Infants and Young Children (Agenda Item 8)

The Chair introduced this item and noted that the Committee for the past two sessions was unable to find a chair for work to set NRV-Rs for Older Infants and Young Children. At this session, Ireland volunteered to chair with Mexico and the United States as co-chair an eWG to conduct this preparation. This eWG will use the following terms of reference, as proposed by Australia : (1) assess the need and value of establishing NRV-R's for older infants and young children in Codex texts in relation to their purpose in the Guidelines for Nutrition Labeling (CXG 2-1985) and Codex texts for special dietary use for older infants and young children, and the specific age groups to which these NRV-R would apply; and (2) where a need is established, 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.

Food Additives – Framework for Considering Technological Justification for Use of Food Additives in the Standards developed by CCNFSDU (Agenda Item 9)

The European Union, chair of the eWG, presented three recommendations: (1) to broaden the scope of the framework to apply to all foods covered by CCNFSDU and not just to foods intended for infants and young children, (2) to establish criteria for application of the framework, and (3) to apply the framework to food additives listed in CRD 15 rev from the 49th Session of the Codex Committee on Food Additives (CCFA49, 2017).

The Committee agreed the framework should apply to all foods covered by CCNFSDU. The United States and Canada, supported by Australia, New Zealand, Mexico, and Viet Nam, supported a simple framework for technological justification and noted their view that the proposed framework went beyond technological justification to include food safety issues, which are exclusively within the remit of Codex Committee on Food Additives. The European Union supported including the evaluation of food additives listed in CRD15 rev under the framework, noting that the CCFA specifically referred this information to CCNFSDU. The United States and Switzerland noted that inclusion of all additives listed in CRD 15 rev from CCFA49 was not a priority and the request for technological justifications for the food additives xanthum gum, pectin and gellum gum should be completed first, before examining the food additives listed in CRD 15 rev.

The United States and the International Special Dietary Foods Industries (ISDI) noted that xanthan gum (INS 415), and pectin (INS 440) had already been evaluated for safety by the Joint Expert Committee on Food Additives, the technological justifications for these additives had already been provided, and the request for technological justification for gellum gum was submitted last session. However, the Committee decided that more time was necessary to confirm the technological justification for these additives.

The Committee agreed to re-establish the eWG to continue working on the framework and to test the framework with xanthan gum, pectin, and gellan gum.

Discussion Paper on Claim for “free” of *Trans* Fatty Acids (TFA) (Agenda Item 10)

Canada presented a revised discussion paper and informed the Committee that CCMAS had replied that three analytical methods could detect the level that Canada proposed for a claim of “free” of *trans* fat: to carry a claim for “free” of *trans* fat, a food should contain no more than 1 g of TFA per 100 g of fat and should also be “low” in saturated fat. While there was general agreement on the value of 1g of TFA per 100 g of fat, several delegations, namely Malaysia, the Philippines, Sri Lanka and Viet Nam, did not support the accompanying requirement that the food also be “low” in saturated fat.

The Committee agreed to send the proposal for comment and further consideration at its next session.

Other Business and Future Work (Agenda Item 11)

- **Harmonized Probiotic Guidelines for Use in Foods and Dietary Supplements**

The observer from the International Probiotic Association presented a discussion paper on development of guidelines to ensure and sustain the quality of probiotic products worldwide. Argentina agreed to prepare a discussion paper and project document for consideration at the next session.

- **General Guidelines for Establishing 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. Costa Rica proposed either to establish a eWG to further elaborate the scope of the work and refine the project document, or to issue a circular letter to collect information and assess models of nutritional profiles used globally. Ecuador volunteered to chair an eWG. The WHO Representative, the United States, and several other Delegations noted that establishing an eWG at this point would be premature and that the Committee already has a full agenda.
The Committee agreed to postpone the discussion on this item to next session.

NEXT SESSION

The 40th session of the CCNFSDU is tentatively set for November 26-30, 2018 in Berlin, Germany.