Codex Alimentarius Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) Outcome

Last week of November, the Codex Alimentarius Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) reviewed most of the draft standards and guidelines on its agenda. However, only in part and to be further worked out (e.g. follow-up formulas; RUTFs), or sent back for further elaboration (e.g. NRV-R for older infants and young children; nutrient profiles; probiotics), or with a changed focus (i.e. “Free of TFA claim” conditions turned into a risk management options for reducing - if not phasing out - the presence of neo-formed TFA during edible oils and fats partial hydrogenation manufacturing process). Other proposals did not get through and the work was either stopped (e.g. NRV-NCD for EPA/DHA) or sent back to other Codex Committees (e.g. biofortification) or added to a priority list for possible new work (e.g. prebiotics; food supplements for bodybuilders).

Mr Christophe Leprêtre Mrs Katia Merten-Lentz

Over 400 delegates from 73 countries, the European Union, and 41 NGOs attended the 40th session of the Codex Alimentarius Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU40, Berlin, Germany; 26-30 November 2018). CCNFSDU40 covered all its agenda - and a bit more - this year. This specialised Codex Committee is one of the horizontal committees of the Codex Alimentarius Commission, dealing with nutrition, but not nutrition policies. It also elaborates Codex vertical/commodity standards and guidelines on specific foods, such as “baby foods” (e.g. infant formulas and follow up formulas for older infants and young children) and “food for special dietary uses” (e.g. gluten free foods, foods for special medical purposes (FSMPs) and food supplements). The Committee oversees nutrition labelling and nutrition claims together with the Codex Committee on Labelling (CCFL).

Revised Follow Up Formula Standard - progress made on composition, still a long way to go on labelling, the preamble and the structure of the standard

CCNFSDU40 went through the various parts of the revised follow up formula texts (i.e. composition requirements for both age groups, scope for both age groups, labelling requirements and definitions for older infants only) but, due to time constraints, it did not discuss the controversial preamble. In short, CCNFSDU40 agreed to:

(i) retain the essential requirements for follow-up formula for older infants and for products for young children at Step 7, and to request the EWG on follow-up formula (see (v) below) to consider the proposal on dextrose equivalent for products not based on milk protein and to provide further recommendations for comments and consideration at the next session; (ii) advance Section A: follow up formula for older infants to Step 5 for interim adoption by CAC42 (in Appendix III of CCNFSDU40 report) and a request for comments at Step 6; (iii) send the labelling provisions for FUF for older infants to CCFL45 for endorsement; (iv) defer the discussion on product definition and labelling of [product] for young children, the structure of the Standard (s) and preamble (s) for discussion at CCNFSDU41; and, (v) re-establish the EWG chaired by New Zealand and co-chaired by France and Indonesia, to address the issue of Dextrose Equivalent and the sentence in square bracket in section 3.2.1 on non-sugar substances conferring sweet taste (i.e. foods like honey), with the understanding stated in the report that this concept does not relate to intense sweeteners, regulated as food additives, given that such use is prohibited both by the FUF standard and the GSFA. CCFFSDU also agreed to complete the remaining sections as
follows (a) purity requirements, (b) vitamin compounds and mineral salts, (c) consistency and particle size, (d) specific prohibitions, (e) food additives, (f) contaminants, (g) hygiene, (h) packaging, (i) fill of container, and (j) methods of analysis and sampling.

One aspect requires some additional attention. During the discussion on composition requirements, it appears that many references to national and/or regional competent authorities have been retained or even added, in order (i) to help advance the provisions or (ii) provide flexibility to address local nutritional needs when countries are to implement the future revised standard or (iii) both. This is raising a fundamental question about Codex Alimentarius Commodity Standards. In the 20th century Codex's and WTO/SPS and TBT agreements’ assumptions, Codex Alimentarius standards and related texts should provide precise enough standards to promote the reduction of non-tariff barriers to trade. As such, the fact that CCNFSDU introduces a range of values for a nutrient and its requirements, or references to different national/regional competent authorities de facto allowing national deviations from the international norm is of particular concern. Indeed, international Codex standards aim at serving as a non-ambiguous reference, i.e. set one value per criterion. But because consensus must be reached at all costs, these permitted deviations made their way even into commodity standards, which is clearly equivalent to a Note 161 added across the board.

Arguably, the purpose of internationally “standardized” foods is precisely to be... standardized. And in such a manner that it reduces to the maximum the margin of flexibility - such margin shall ideally be equal to zero, i.e. the international standard sets one value for one given nutrient. The overall purpose of the Codex Alimentarius since its creation in 1963, well before WTO was created, has been and is to promote harmonization of rules through non-ambiguous standards, and thus facilitate trade and fair practices in trade. If that trend continues, it would be hard to consider any longer Codex standards and related texts as core reference for judging non-tariff related trade disputes (especially in times where leading voices are announcing a reform of the WTO).

We can think of two out-of-the-box ideas to resolve this issue in the context of CCNFSDU work on this standard revision, regardless on whether the “norm” discussed falls under WTO/SPS or WTO/TBT.

In the first place, in order to address different nutritional needs of different target groups of consumers, several singled-out values could be set for those nutrients where certain composition formula should be labeled as intended for certain population groups.

After such acknowledgment, once the standard (e.g. the FUF standard) is advanced at Step 8 by the Committee (i.e. CCNFSDU), it could be referred to the six Codex Regional Coordinating Committees which could discuss regional differences and address those regional different nutritional needs. It would lead to the creation of six (or less) regional Codex standards on e.g. FUF, allowing at least some level of intra-regional harmonization and free trade based on one standard. The international level Codex standard on FUF would then cover only those areas and composition requirements where a full consensus about their relevance for all populations and regions would be reached out in the Committee, i.e. CCNFSDU. In doing so, it would then limit the number of deviations and still permit, at least on a regional basis, the relative stability of the standardization. And thus, references to national/regional competent authorities could be completely deleted from any Codex standards (both in international and regional ones)”. Maybe the two above ideas could be explored also by other Codex Committees. It may help to reach consensus in a more expeditious manner on core international pieces of the standards while increasing the role of regional standards to define their own level of flexibility where it is not feasible.
in the Committee in charge, and still minimize the risks of a multiplication of even more national standards with the current trend.

To be continued... Nutrient Reference Values Recommended (NRV-R) for labelling purposes on foods to older infants and young children - new work approved

CCNFSDU40 reviewed the recommendations included in the discussion paper prepared by Ireland for the plenary. The committee followed the recommendations to:

(i) develop three sets for the future NRVs-R, one for older infants, one for young children and one combined for both age groups, depending on the actual values of nutrient requirements for those age groups; (ii) harmonize all the age ranges referred to in existing relevant Codex standards and related text under the purview of the CCNFSDU (i.e. 6-12 months old and 12-36 months old), since WHO is aligning its own age groups with the Codex age ranges for nutritional requirements; and, (iii) continue the development of NRVs-R for the 4 Codex Standards for the age groups identified above while excluding the Guidelines for Vitamin and Mineral Food Supplements (CXG 55-2015) from the list of Codex texts for which NRVs-R would be established for labelling of nutrient declaration as well as for which NRVs-R would be applied as reference criteria for vitamin and mineral composition.

As a next step, Ireland, with the help of Costa Rica and the USA, will chair and co-chair an inter-session electronic working group (EWG) tasked (i) to advance the work described above and to further discuss unresolved issues such as the place where the NRV-R for older infant and young children is to be added in the Codex texts, and (ii) to develop a prioritized list of NRV-R for vitamins and minerals adequate to these age groups, as well as for protein requirements.

To be continued...

Draft guidelines on ready-to-use ("therapeutic") foods (so-called RUTFs) for nutritionally deprived people - progress made but still a long ride ahead

A pre-session Physical Working Group (PWG) reviewed the outcome of an inter-session electronic working group. The hope was that this doubled effort could help the CCNFSDU40 to make faster progress on these guidelines for RUTFs by simply adopting an advanced revised text through a reduced set of recommendations from the PWG. Unfortunately, this was not exactly the case, and the plenary went through technical amendments to the text and left a large part uncovered due to the time constraints.

CCNFSDU40 established again an inter-session EWG, chaired by South Africa and co-chaired by Senegal and Uganda, to continue developing the section 5.2.2 on Food additives and Section 6.2 on Proteins, for circulation for comments and consideration at next year’s CCNFSDU plenary. CCNFSDU40 also agreed to keep on hold the rest of the text at Step 4, and to consider the remaining recommendations of this year’s PWG at next year’s Plenary session. Yes, it is a bit confusing: it simply means a lot remains to be addressed before the text can be moved to the next steps; either piece by piece or as a whole, starting at next year’s session.

To be continued...
Nutrition Profiles Guidelines - no new work, but existing systems compilation

The suspense was short. The Committee considered the discussion paper and decided to task again Costa Rica and Paraguay to revise the discussion paper and produce a stock-take of all existing nutrient profiles primarily used in the context of FOPNL systems, but also for other purposes, and further develop the discussion paper for consideration by the next session.

Particularly interesting was the statement of the representative of WHO that WHO is willing to share a similar catalogue of existing nutrient profile models developed for different applications already compiled at WHO level. The WHO representative reminded that WHO Regional Offices have also developed their own regional nutrient profile models for restricting marketing of foods and non-alcoholic beverages to children, and for multiple policy tools and in several regions, while countries are adapting or using those regionally-based nutrient profile models for multiple applications - such as regulating promotion and sales of food and beverages in and around schools and nutrition labelling. The WHO Representative suggested to add those nutrient profiles to the Codex process.

But WHO made clear that, in its view, it would be premature to develop Codex guidelines on nutrient profiling models for front-of-pack nutrition labelling (FOPNL) as proposed in this year’s discussion paper, since the CCFL had not yet determined how they would modify the section of supplementary information in the Guidelines on Nutrition Labelling to incorporate the guidance on FOPL. This issue is still under consideration by a CCFL inter-session EWG and its report, due early January, will be considered at the forthcoming CCFL (to be held early May 2019). As WHO is also working on policy documents to countries on FOPNL, the WHO representative expressed WHO’s interest in contributing to the stock-take exercise.

No electronic working group was formed. Note however that the USA offered its assistance to Costa Rica and Paraguay in their compiling work and the refinement of the scope of the future possible new work on specific Codex guidelines. What about the other countries? They will have to wait until the next CCNFSDU.

To be continued...

Technological Need and Food Additive: Mechanism and related alignment issue (CCNFDU texts and CCFA GSFA) - almost approved, but...

As reported in last month’s WFRR issue, the purpose of this work is to optimize the review of food additives used in the texts elaborated by CCNFDU both from a technical need and from a safety perspective due to the target populations exposed to those foods (e.g. early life formulas and other baby foods, sometimes intended for children with diseases, i.e. foods for special medical purposes).

Although the relationship between Codex Committees elaborating food/commodity “standards” and the Codex Committee on food additives (CCFA) is laid down fairly clearly in the Codex Alimentarius Commission’s Procedural Manual, there was a need from a CCNFDU point of view to develop a dedicated framework to make sure that CCNFDU can confirm first and foremost that the technological needs, justifications and purpose(s) of a given additive in a given food for those vulnerable subsets of the population are duly provided by the applicants and duly checked and cleared by the CCNFDU.
Two in-session working group sessions, chaired by the EU, were called upon by the CCNFSDU Chair to continue advancing the discussion on (i) the process by which technological needs are appraised and (ii) the list of questions to be answered on such technological needs for being counterchecked by CCNFSDU. They were included in two one-page documents, which came out from the intersession EWG which elaborated them since last year, also under the EU chairmanship.

The process itself describes the various action steps to be taken by the CCNFSDU to collect information on technological needs (e.g. by a Circular Letter (CL) issued by the Codex Secretariat) when JECFA assessment would be required or via an EWG when a new standard is under development by CCNFSDU. If CCNFSDU concludes that the needs are sufficiently substantiated, then there are two possibilities:

(a) If a JECFA assessment is necessary, then the applicant must follow the CCFA process to seek inclusion of the substance for JECFA priority list (to be agreed at subsequent CCFA meeting), after which JECFA evaluates and return its conclusions to CCFA, which in return sends it back to CCNFSDU. Then GSFA and applicable standards (if this is in a standardized food) are amended based on use levels justified. (b) If a JECFA assessment is not necessary, then the normal endorsement procedure is followed with CCNFSDU sending the projected additive use level(s) in a given CCNFSDU food standard to CCFA for endorsement and inclusion in the GSFA, and if the food standard is not aligned with GSFA, for inclusion in that food standard.

The justification of the technological needs itself consists of a list of three main questions for the applicant to answer and for CCNFSDU to check the answers.

(1) Identification and Intended use: the applicant must provide detailed info on the International Numbering System (INS) (or in absence of INS its chemical registered name), foods and forms of that food, where additive is used, and – this is a real novelty - the range of the proposed use level of the food additive needed to accomplish the desired technological effect at the lowest possible use level.

(2) Compliance with section 3.2 of the GSFA preamble, while indicating also the functional class and the expected technological purpose(s) the food additive will exert in the targeted food(s). Under (2), two additional criteria would apply as foreseen by the preamble of GSFA (and therefore should normally also apply to GSFA provision discussions): (a) Can the objectives be achieved by other economically and technologically practicable means? and (b) Would any characteristic of the food be modified in a way that might mislead the consumer?

(3) Compliance with the approach on use of food additives intended for infants (both new born and older) and young children: the objective is to determine whether other food additives with the same/similar technological purpose and level of performance are already authorized in the target food. If this is the case, further justification must be provided on the advantage that additive brings. If this is not the case, the need(s) for this additive with new functional class or other technological purpose must be made clear.

The plenary of CCNFSDU was very close to endorsing Question (3) after having discussed Question (1) and (2) and amended the outcome of the two successive in-session working groups. As the CCNFSDU Chair was fairly under time pressure to review other items on the agenda, the text of Question (3) remained unapproved.

In summary, CCNFSDU agreed to include the process and the framework in Annex 2 of its plenary report and to
organize a physical working group immediately before next year’s CCNFSDU to (i) address the remaining parts still unapproved (such as question (3)) and (ii) test the future revised protocol and framework to appraise the technological needs for the proposed uses of xanthan gum (INS 415), pectin (INS 440) and gellan gum (INS 418) in infant formulas, as already submitted this year by manufacturers (International Special Dietary Food Industries; ISDI).

In addition, during the plenary the Chair tried to address the issue of alignment of food additive provisions between Codex texts (standards) already elaborated by CCNFSDU and the Codex GSFA. However, no-country-for-old-men on this topic, since delegates were a bit taken by surprise. Thus, the issue was postponed to next year. CCNFSDU40 official report refers to an information document prepared by CCFA to the attention of all Codex Commodity Committees on how such an alignment work has been conceived by CCFA (and drafted by Australia) and should be carried out by them.

See www.fao.org/fileadmin/user_upload/codexalimentarius/committee/docs/INF_CCFA_e.pdf. That document also includes a tentative workplan and priorities must be given by CCS, CCFO, CCPFV, and CCNFSDU to this important alignment task.

Next year, ISDI may use that opportunity to suggest a pilot review of the possible alignment e.g. on infant formula, in the same manner that IDF demonstrated their ability to help CCFA to perform such an alignment work on one dairy standard, as a test-case (see WFRR June 2018 feature article on the outcome of CCFA).

All delegates who attended the two in-session working groups and the follow up discussions during the CCNFSDU plenary highlighted and commended the fair and excellent chairmanship of the European Commission official in charge, Jiri Sochor, leading up to this unexpectedly good and consensual interim result by CCNFSDU. Well done J.S.!

To be continued...

Conditions of Use of claim on “Free of Trans Fatty Acids (TFAs)” - nope, again and new (expanded) focus on industrially neo-formed TFAs in PHOs

CCNFSDU40 was supposed to reach a conclusion on the conditions for making the claim “free of TFAs”. However, opinions diverged on those conditions, given the uncertainty about the accuracy of the methods of analysis in different food matrices. In addition, not all TFAs are necessarily bad for health (IDF says dairy product contain good TFAs), so “free of TFA’s” claim could mislead the consumer and the focus on TFA alone as a nutrient of concern may not be the adequate message to help consumers to make healthier food choices. Also, technical relationship with other saturated fats was not necessarily well spelled out in the current suggested conditions of use of the claim.

The WHO representative also indicated that the NUGAG was finalising its guidance on saturated fats and TFAs, to be published during the first quarter of 2019. The WHO representative made clear that the WHO policy objective is to completely phase out “industrially” neo-formed TFAs during partial hydrogenation of vegetable oils and animal fats from the food chain supply, given the fact that these types of TFAs were clearly correlating with noncommunicable diseases (NCDs) due to dietary intake. WHO pointed out that their policy approach is to limit all
TFAdaily intake to less than 1% of total energy in the daily diet while simultaneously limit saturated fatty acids (fats) to less than 10% of total energy in the daily diet.

CCNFSDU40 debated whether other risk management options could be considered, ranging from a ban of all partially hydrogenated oils (PHOs) to FOPlabelling warnings against the presence of such PHOs full of industrially neo-formed TFAs. CCNFSDU40 also discussed whether it could alternatively or in parallel refer the issue to the Codex Committee on Contaminants in Foods (CCCF) to develop (i) a maximum limit of industrially neo-formed TFAs in food ingredients or in foods where PHOs are used, or (ii) a Code of practice for their reduction in PHOs or (iii) both. The JECFA/FAO representative indicated that JECFA was totally capable to perform a risk assessment of the toxicological safety of industrially neo-formed TFAs from PHOs, should CCCF would require such a scientific advice. But that route was considered premature.

CCNFSDU40 therefore decided (i) to keep on hold the discussion on the current conditions for the claim “Free of TFA”; (ii) agreed that Canada will prepare a discussion paper for next CCNFSDU consideration to explore various risk management possibilities for reducing TFAs in the food supply chain; and, (iii) to inform the Codex Committees on fats and oils (CCFO meeting end of February 2019) and the CCCF (meeting end of April 2019) about this discussion.

To be continued...

Definition and associated criteria of “Biofortification” - sent back to CCFL

CCNFSDU40 discussed a further elaborated definition of “biofortification”, coming from a consensus outcome of an inter-session electronic working group. One NGO stated that, despite the overall consensus found in the EWG, the CCNFSDU has the power to override such a consensus. That statement created a large perplexity in the meeting room, as the purpose of Codex inter-session EWG is precisely to help building consensus in advance to Codex Committee plenary meeting and are generally recognized to achieve that goal.

The Committee slightly amended the definition as follows:


Arguments put forward last year were reiterated. Most of the African, Asian and Latin American countries, where new genetic breeding technics plant (but not with GMO techniques) are already cultivated, were overwhelmingly in favor of the final adoption at Step 8 of such a definition. Other countries were unclear as to where such a definition should be used in the Codex system or added to existing Codex texts also expressed their opposition to proceed. These countries, including the EU and its member countries, reiterated the need to take the time to assess the impact on claims, labelling, classical food composition, and possible confusion caused by the prefix “BIO”, which is generally devoted to the organic farming products (e.g. issued from the “agriculture biologique” in French). The definition was found too broad as new genetic modification techniques could ultimately fall under a “GMO” definition. Also, the decision left to national authorities could result in a lack of necessary harmonization on such a WTO/SPS-related matter.
Countries in favor were Nigeria, Burkina Faso, Senegal, Mali, Ghana, Cuba, the Philippines, Costa Rica (requesting a cross-reference to the Codex Procedural Manual existing definition of bioavailability to be added), Uganda, and to some extent Malaysia, Chile, Brazil; and the USA which suggested to add a reference to an increase insufficient amount of conventional nutrients, compared to the counterpart crop. Countries which expressed a fresh welcome to this work were the EU (including Belgium), Norway, Argentina, the Russian Federation, Nepal, and the observer of NHF.

In conclusion, without really coming up with a consensus over the proposed definition, the Chair concluded that the CCNFSDU40 decided to send the text as amended during this session back to the CCFL, to get further guidance from the Codex labelling experts, in a very apparent relief in passing on the very “hot” (e.g. beta-carotene-enriched-orange-flesh-sweet-) potato to Canada as CCFL’s host country.

Next CCFL meets in May 2019 and it is unclear what they may do, given that the initial request to CCNFSDU to work on a biofortification definition - and to indicate what to do with it in the Codex system - came originally from the CCFL.

To be continued...

Probiotics in foods or as food supplements - not quite yet, so play it again

Based on the discussion paper prepared by Argentina, CCNFSDU40 discussed the proposal to develop guidelines to define probiotics and lay out guidance and main common grounds on how countries could regulate their use and their labelling and assess their claimed health benefits at national and/or regional level.

Many country delegations who spoke out expressed some reservations about the scope of the document and the expected final output for the guidelines. They were in principle supportive of the idea to further discuss the probiotics topic, while noticing that this topic may be considered as a lower priority for the Committee to embark on. Those countries were Canada, USA, Malaysia, Vietnam, Norway, Russian Federation, and the European Union. The EU delegation had the strongest doubt about even the need to develop such guidelines at all. Just a few countries supported the proposal as presented, such as Iran, requesting an electronic working group to work on the document (with the Codex Regional Standard on Doogh where “probiotics” is mentioned), China (indicating its nationally regulated positive list of approved bacteria strains), Nepal, Nigeria, Egypt, Sudan (using this opportunity to promote prebiotics as well - see down below) and obviously the IPA (representing the probiotics manufacturers in Codex).

The CCNFSDU40 requested Argentina to revise the discussion paper for the second time in two years, especially to revisit the scope for the proposed future guidelines, to discuss it again at next year CCNFSDU plenary meeting as a plain agenda item.

To be continued...

NRV-NCD on EPA/DHA - Discontinued, ouch
CCNFSDU40 did not find a consensus on the way to make any further progresses for establishing a NRV-NCD for EPA/DHA. According to WHO NUGAG, there aren’t enough positive correlations between consumptions of EPA/DHA and reduction of NCDs (e.g. CVD, Heart attacks) or reduction of risk factors favoring the appearance of NCDs (LDL-cholesterol vs HDL-cholesterol in blood), at consumption levels compatible with food supplements.

CCNFSDU40 agreed to discontinue discussing the matter (i.e. to drop it off its agenda and work program), until new scientific evidences are reviewed again systematically by WHO NUGAG or eventually by JEMNU in the future, as recommended by EPA/DHA food supplements manufacturers. Future new work will have to follow the procedure and may also be considered within the broader context of priority setting announced by the German chair of CCNFSDU40.

Proposal for new work on Codex G

Based on late proposal tabled by Sudan as CRD, CCNFSDU40 did not discuss this matter at all due to lack of time. Sudan’s discussion paper is interesting as it lays out the growing trend of prebiotics as a source of nutrients for the symbiotic bacteria living in human intestines and bowel. Obviously, the primary focus of Sudan is on Gum Arabic / Acacia Gum (also known as food additive INS/E 414, e.g. as an emulsifier or a carrier,), as clearly stated in their written comments to be found in CRD30. Such new work would also be of high interest of other prebiotic manufacturers (e.g. GOS, inulin, fructo-oligosaccharides, resistant starches, etc.).

Therefore, it is to be seen next year where this proposal may go. To know more about Sudan’s proposal, go to CRD4 at www.fao.org/faowho-codexalimentarius/meetings/detail/en/?meeting=CCNFSDU&session=40.

To be continued...

Proposal for new work on General Requirements For Protein Supplements Intended for “Bodybuilding” – sent to waiting list

Due to lack of time, this proposed new work submitted by Egypt was not discussed at all.

However, both proposals on (a) prebiotics and (b) bodybuilding foods will be retained and listed as part of the broader discussion paper on prioritization of the work of the Committee - to be prepared by Germany as the host country of CCNFSDU - and will be considered under a plain agenda item at the next year session (CCNFSDU41), to be held in Düsseldorf (Germany) from 25 to 29 November 2019.

To be continued...

To access CCNFSDU40 official report, go to www.fao.org/faowho-codexalimentarius/meetings/en/. To access to all CRDs and latest documents go to www.fao.org/faowho-codexalimentarius/meetings/detail/en/?meeting=CCNFSDU&session=40

[1] Some Member governments may prefer to use the equivalent term.

[2] Process to be determined by the competent national/regional authority.
**Conventional addition to food** is covered by the General principles for the addition of essential nutrients to foods (CXG 9-1987).

**e.g. animal, plant, fungi, yeasts, bacteria.**

**Nutritional purpose:** - preventing/reducing the risk of, or correcting, a demonstrated deficiency in the population;

- reducing the risk of, or correcting, inadequate nutritional status or intakes in the population;

- meeting requirements and/or recommended intakes of one or more nutrients;

- maintaining or improving health; and/or

- maintaining or improving the nutritional quality of food.