CODEX ALIMENTARIUS COMMISSION







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Agenda Item 10 CX/NFSDU 19/41/10

JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Forty-first Session

Dusseldorf, Germany 24 - 29 November 2019

DISCUSSION PAPER ON A PRIORITIZATION MECHANISM TO BETTER MANAGE THE WORK OF CCNFSDU

Prepared by the host country Secretariat

Purpose

- 1. The aim of this discussion paper is to aid in the development of a prioritization mechanism that takes account of the particular needs of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU), and to establish an ongoing procedure to consider and prioritize new work proposals.
- 2. This discussion paper includes draft guidelines intended to act as a starting point for consideration by CCNFSDU on a prioritization mechanism to better manage the committee's work going forward.

Introduction

- 3. The Codex Alimentarius Commission (CAC), in establishing CCNFSDU, recognized the importance of elaborating general guidelines, principles and standards for nutrition and foods for special dietary uses in protecting the health of consumers and ensuring fair practices in food trade. To date, CCNFSDU has developed a considerable number of standards and guidelines (see para 14).
- 4. The 75th Session of the Executive Committee of the Codex Alimentarius Commission (CCEXEC) requested CCNFSDU to consider a prioritization mechanism to better manage its work.¹
- 5. CCNFSDU40 discussed the request of CCEXEC75 and noted that there was a need to investigate the future working strategy of CCNFSDU. It was agreed to:
 - Develop a forward work plan to prioritize and manage the work of CCNFSDU on a longer-term basis.
 - b. Prepare a discussion paper that summarizes
 - i. the work completed so far,
 - ii. previously proposed work that had not gone forward in the Committee,
 - iii. the currently ongoing work, and
 - iv. how to deal with emerging issues.
 - c. Consider a prioritization approach for the future work of the Committee.

Background

- 6. CCNFSDU's commitment to consider its strategic direction is consistent with the Codex Alimentarius Strategic Plan 2020-2025, in particular with the following Strategic Goals and Objectives:
 - . Goal 1: Address current, emerging and critical issues in a timely manner.
 - Objective 1.1: Identify needs and emerging issues.
 - o Objective 1.2: Prioritize needs and emerging issues.
 - Goal 5: Enhance work management systems and practices that support the efficient and effective achievement of all strategic plan goals.

¹ REP18/EXEC2-Rev.1, para. 19

 Objective 5.1: Develop and maintain efficient and effective work management practices and systems.

7. Several other Codex Committees (inter alia CCFH, CCFICS, CCFL and CCFO) have already discussed and initiated similar strategic and prioritization approaches.

Work of CCNFSDU

- 8. The Committee was established in 1965 as the Codex Committee on Dietetic Foods. It was tasked with the elaboration of general guidelines, principles and standards for dietetic foods, for some explicitly mentioned categories of dietetic foods. The particularly highest priority was given to foods for nursing mothers, infants and the aged. The first session of the Committee was held in May 1966. At its 2nd session, the Committee changed its name and replaced "dietetic foods" with the wider term "foods for special dietary uses". In the early 1980s nutritional issues in conjunction with Codex Work were also assigned to the Committee. The Terms of References (ToRs) were amended accordingly and the name was changed to "Nutrition and Foods for Special Dietary Uses" (CCNFSDU).
- 9. The current ToRs of CCNFSDU are:
 - a. to study specific nutritional problems assigned to it by the Commission and advise the Commission on general nutrition issues;
 - to draft general provisions, as appropriate, concerning the nutritional aspects of all foods;
 - c. to develop standards, guidelines or related texts for foods for special dietary uses, in cooperation with other committees where necessary;
 - d. to consider, amend if necessary, and endorse provisions on nutritional aspects proposed for inclusion in Codex standards, guidelines and related texts.
- 10. Since the Committee's inception, its work has been varied and challenging. At several sessions the agenda was so heavy that the Committee decided not to start work on any new topics until the items in progress had been finalized (first time at the 3rd session, last time at the 40th session).
- 11. There is a high likelihood that CCNFSDU's heavy workload will continue. Nutritional topics and issues related to the diet of vulnerable population groups remain centre-stage, are high on political agendas and under increasing public scrutiny. Furthermore, new scientific research findings may lead to the need to update or revise adopted standards/guidelines. The revision of existing standards and guidelines with the aim to align them with new scientific findings and developments in the marketing of foods for special dietary uses will form a large part of CCNFSDU's future work program.
- 12. The elaboration of standards is often very challenging. Discussions and consensus-building often take several years. An example for this is the Codex *Standard for Follow-Up Formula* (CXS 156-1987). Since 2011 CCNFSDU has been working on a complete revision of the Standard in order to take account of new scientific knowledge and developments in infant and young child nutrition.
- 13. CCNFSDU is one of the Codex Committees with the highest number of participants. The strong rise in recent years to more than 400 delegates from over 70 members and 40 observers shows the high level of interest in the topics under discussion. This leads to an increase in the spectrum of opinions and in the time needed for individual agenda items.

Existing adopted CCNFSDU texts²

14. The following is a compilation of existing CCNFSDU texts with the date of their last modification:

Document reference	Document title	Last modification*
CXA 2-1976	Statement on Infant Feeding	1976
CXS 53-1981	Standard for Special Dietary Foods with Low- Sodium Content (Including Salt Substitutes)	1983
CXS 180-1991	Standard for the Labelling of and Claims for Foods for Special Medical Purposes	1991

² CCNFSDU also contributes significantly to the revision/amendment of the *Guidelines on nutrition labelling* (CXG 2-1985) and other texts under the purview of CCFL.

Document reference	Document title	Last modification*
CXS 181-1991	Standard for Formula Foods for Use in Weight Control Diets	1991
CXS 203-1995	Standard for Formula Foods for Use in Very Low Energy Diets for Weight Reduction	1995
CXG 55-2005	Guidelines for Vitamin and Mineral Food Supplements	2005
CXG 9-1987	General Principles for the Addition of Essential Nutrients to Foods	2015
CXG 10-1979	Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses intended for Infants and Young Children	2015
CXS 118-1979	Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten	2015
CXS-1981	Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants	2016
CXG 8-1991	Guidelines on Formulated Complementary Foods for Older Infants and Young Children	2017
CXS 73-1981	Standard for Canned Baby Foods	2017
CXS 74-1981	Standard for Processed Cereal-Based Foods for Infants and Young Children	2017
CXS 156-1987	Standard for Follow-up Formula	2017

^{*} not meant to be a full revision or similar work

Previously Proposed Work that had not gone forward in the Committee

15. The following is a compilation of work that CCNFSDU first considered but thereafter agreed to discontinue:

Proposal	Period of time	Source
Amendment to the Codex Standard for Processed Cereal-Based Foods for Infants and Young Children (CXS 74-1981) - Maximum level of the flavouring "vanillin"	1987-1988	ALINORM 89/26, paras 160-161
Amendment to the Codex Standard for Infant Formula (CXS 72-1981) - Maximum level of vitamin D	1988	ALINORM 89/26, para 159
Proposed Draft Guidelines on the Inclusion of Nutrition Provisions on Nutritional Quality in Food Standards	1992- 1996	ALINORNI 97/26, para 102
Provisions for Fortification of Iodine, Iron and Vitamin A in the Guidelines for Use of Nutrition Claims	1998-2000	ALINORM 01/26, paras 126-127
Discussion Paper on the Production and Processing Standards Regarding the Nutritional Quality and Safety of Foods	2007	ALINORM 08/31/26, paras 34-140
Development of principles for countries to evaluate criterion 1 "the ability of nutrition labelling to address public health issues" when addressing balancing national and global health issues	2009	ALINORM 10/33/26, paras 23-24
Amendment to the Standard for Processed Cereal-based Foods for Infants and Young Children (CXS 74-1981) to include a New Part B for Underweight Children	2008-2014	REP15/NFSDU, para 89

Proposed draft NRV-NCD for EPA and DHA long chain	2015-2018	REP19/NFSDU,	para
omega-3 fatty acids		94	

Current or Envisaged Work

16. The following is a compilation of the current work of CCNFSDU:

Topic	At Step	In progress since
Review of the Standard for Follow-up Formula (CXS 156-1987):		2011
Proposed draft Scope, Description and Labelling for follow-up formula for older infants (Section A)	6	
Proposed draft product definition and labelling for [product] for young children (Section B)	4	
Essential composition requirements for follow-up formula for older infants and [product] for young children, except for	7	
footnote 4 (Carbohydrate proposal for DE for product not based on milk protein and for section 3.2.1 (optional ingredients) for [product] for young children)	2/3	
Remaining sections of the Standard (e.g. food additives, contaminants)	2/3	
Proposed Draft Guideline for Ready-to-Use Therapeutic Foods	4	2015
Proposed Draft Definition for Biofortification	4 (Hold)	2013
Proposed draft Claim for "free" of trans fatty acids	4 (Hold)	2014
Discussion Paper on NRV-R for older infants and young children	-	2016
Discussion paper on Mechanism/framework for considering the technological justification of food additives	-	2012
Mechanism/framework for considering technological justification of food additives and alignment of food additive provisions in CCNFSDU standards with the General Standard for Food Additives (CXS 192-1995)	To be addressed at 41st session	

Potential New Work of CCNFSDU

Discussion Paper on Harmonized Probiotic Guidelines for Use in Foods and Dietary Supplements

17. The proposal was raised by the International Probiotics Association (IPA) at the CCNFSDU39 in 2017. Argentina prepared a first discussion paper for CCNFSDU40. Only a short time was available for discussion due to time constraints, the high workload of the Committee and the need for a prioritization mechanism to better manage its work on a longer-term basis. Argentina has been asked to redraft the discussion paper elaborating further on the sections on scope, definition as well as health and trade concerns.

Discussion Paper on General Guidelines to establish Nutrient Profiles

18. Following a request from CCFL this item was brought to CCNFSDU's attention at its 40th session in 2018. Only a short time was available for discussion due to time constraints, the high workload of the Committee and the need for a prioritization mechanism to better manage its work on a longer-term basis. Costa Rica and Paraguay have agreed to undertake a stock-take of nutrient profiles and to develop the discussion paper further.

Proposal for new work on the General Requirements for Protein Supplements intended for Bodybuilding

19. The topic was proposed by Egypt at CCNFSDU40 in 2018. The proposal has not been discussed due to time constraints, the high workload of the Committee and the need for a prioritization mechanism to better manage the work of the Committee.

Proposal for new work on International Prebiotic Guidelines for Use in Foods and Dietary Supplements

20. The topic was proposed by Sudan at CCNFSDU40 in 2018. The proposal has not been discussed for the same reason as given in para 19.

Prioritization Approach and Process

- 21. The current workload and continuing volume of new work proposals illustrate the need for a mechanism to decide on the future work for CCNFSDU. This includes a mechanism to prioritize potential new work. The Codex Alimentarius Strategic Plan 2014-2019 identifies the need for Committees to be able to prioritize new work (Goal 1, Objective 1.2, Activity 1.2.1 and 1.2.2). The Codex Alimentarius Strategic Plan 2020-2025 reinforces this goal (Goal 1, Objective 1.2).
- 22. Several Codex Committees (inter alia CCFH, CCFICS, CCFL and CCFO) have started to discuss or have already installed future work strategies and prioritization mechanisms. The host country Secretariat has reviewed the related documents and has identified approaches that may be of potential use to CCNFSDU.
- 23. The aim of this paper is to develop a prioritization mechanism regarding the particular needs of CCNFSDU and to establish an ongoing procedure to consider and prioritize new work proposals.
- 24. To consider a mechanism for decisions on future work, the following steps are necessary:
 - a. identify criteria (weighing/rating)
 - b. determine a process for considering and prioritizing proposals for new work.
- 25. The Procedural Manual contains criteria for the elaboration of new Codex texts and some procedural instructions (form and content of the proposal). The Criteria are the following:

a. General criterion

 Consumer protection from the point of view of health, food safety, ensuring fair practices in the food trade and taking into account the identified needs of developing countries.

b. Criteria applicable to general subjects

- Diversification of national legislations and apparent resultant or potential impediments to international trade.
- Scope of work and establishment of priorities between the various sections of the work.
- Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body(ies).
- Amenability of the subject of the proposal to standardization.
- Consideration of the global magnitude of the problem or issue.
- 26. For the prioritization of new work proposals further specific criteria for CCNFSDU are needed. The host country Secretariat suggests the following criteria (not in order of importance):
 - Revision of existing texts necessary due to new scientific findings and/or other developments
 - Request from CAC
 - Request from other Codex committees
 - Target group(s)
 - · Impact on public health
 - · Impact on food safety
 - Impact on fair trade practices
- 27. It is proposed that a detailed rationale including pertinent references be attached to the proposal and that the criteria be addressed via a self-assessment by the proposing member.

28. Furthermore, it is proposed that the rationale of the criteria "impact on public health", "impact on food safety" and "impact on fair trade practices" include a rating whether the appropriate impact is high, medium or low. The rating has to be justified.

- 29. It is suggested that a request for proposals for new work and/or revision of an existing standard be issued in the form of a Circular Letter by the Codex Secretariat before each session. The Circular Letter would contain a deadline for submitting proposals. It is proposed that new work Proposals be provided as a discussion paper and address the additional criteria outlined above and include a project document (in accordance with the Procedural Manual).
- 30. It is suggested that a standing *ad hoc Working Group for the Establishment of CCNFSDU Work Priorities* be established to consider any new work proposals or requests for revisions prior to each session of the Committee. The following ToRs are proposed for the *ad hoc Working Group*:
 - a. To conduct a case-by-case review of every proposal on the basis of a decision tree and the detailed rationale including the rating (high/medium/low impact) as presented in the discussion paper and to propose a list of work proposals ranked according to their priority.
 - b. To prepare a report to be presented to the plenary to enable CCNFSDU to evaluate and decide on the new work proposals.
- 31. The decision to submit a new work proposal to CAC is made by the Committee. Depending on the workload of CCNFSDU, the Committee may also decide to not accept any new work proposals at a session.
- 32. To assist the Committee to give effect to the above elements, a draft prioritization guideline has been prepared (Appendix A). The guideline was developed in recognition of the criteria for new work as laid down in the Procedural Manual, as well as the above-suggested criteria specific to CCNFSDU.
- 33. The Committee may overturn the guideline in cases of consensus, especially to respond quickly to emerging issues perhaps not foreseen in the normal round of CL's.

Conclusion

- 34. This discussion paper including guideline is proposed as a starting point for discussion by CCNFSDU on a prioritization mechanism to better manage its work on a longer term basis.
- 35. Members and Observers are encouraged to critically consider the draft, especially the suggested guideline. It is proposed that CCNFSDU take a broad view of its charge, reflecting on:
 - a. the work it has done to support health and fair practices in food trade;
 - b. the need for updating and further developing existing standards and guidelines; and
 - c. new areas for which guidance may be needed.
- 36. The outcome of this discussion should inform the long-term planning and work management of CCNFSDU.

Appendix A

DRAFT GUIDELINE FOR THE PRELIMINARY ASSESSMENT AND IDENTIFICATION OF WORK PRIORITIES FOR CCNFSDU

- 1. The following guideline is intended to assist the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) to identify and prioritize its work.
- 2. Proposals for new work should follow the process and criteria outlined in the Procedural Manual for *Proposals to Undertake New Work or Revise a Standard*, in addition to the following criteria specific to CCNFSDU.

Criteria for Prioritization of New Work Proposals

Criteria	Further information	
Revision of existing texts	Describe the rationale for the proposed revision of an existing CCNFSDU text. Is it necessary due to new scientific findings and/or other developments? Can these new findings or developments cause a safety concern to a special group of people?	
Request from CAC	Has the CAC requested CCNFSDU to work on a CCNFSDU text or to start new work?	
Request from other Codex committees	Has another Codex Committee asked to consider a revision of an existing CCNFSDU text or to consider new work?	
Availability of scientific advice	Is scientific advice available or will be provided soon?	
Target group	Describe the target group of the proposal. Does the proposal refer to a vulnerable target group (infants, the aged, patients, etc.) or is the target group large (e.g. whole population)?	
Impact on public health	Describe the impact on public health (high/medium/low?).	
Impact on food safety	Describe the impact on food safety (high/medium/low?).	
Impact on fair trade practices	Describe the impact on fair trade practices (high/medium/low?).	

Process for Considering and Prioritizing Proposals for New Work

- 3. Proposals for new work and/or revision of an existing text should be submitted following a Codex Circular Letter (CL) before each session. This ensures that all proposals will be submitted within a deadline and all members have adequate time to consider them.
- 4. New work proposals should be submitted as a discussion paper together with a project document according to the Procedural Manual and address also the additional criteria outlined above.
- 5. The criteria should be addressed in a self-assessment and should include a detailed rationale. Pertinent references should accompany the assessment.
- 6. The rationale of the criteria "impact on public health", "impact on food safety" and "impact on fair trade practices" includes a rating, whether the appropriate impact is high, medium or low. The choice of the respective impact level has to be justified.
- 7. Proposals for new work received in response to the CL will be transmitted to the CCNFSDU host country Secretariat. The CCNFSDU host country Secretariat will prepare a summary document presenting the proposals for new work and the associated self-assignment against the above criteria. The document will be distributed by the Codex Secretariat to Codex members and observers for review.
- 8. Revisions of existing texts necessary due to new scientific findings and/or other developments and requests from CAC or other Codex Committees on CCNFSDU texts will be prioritized.

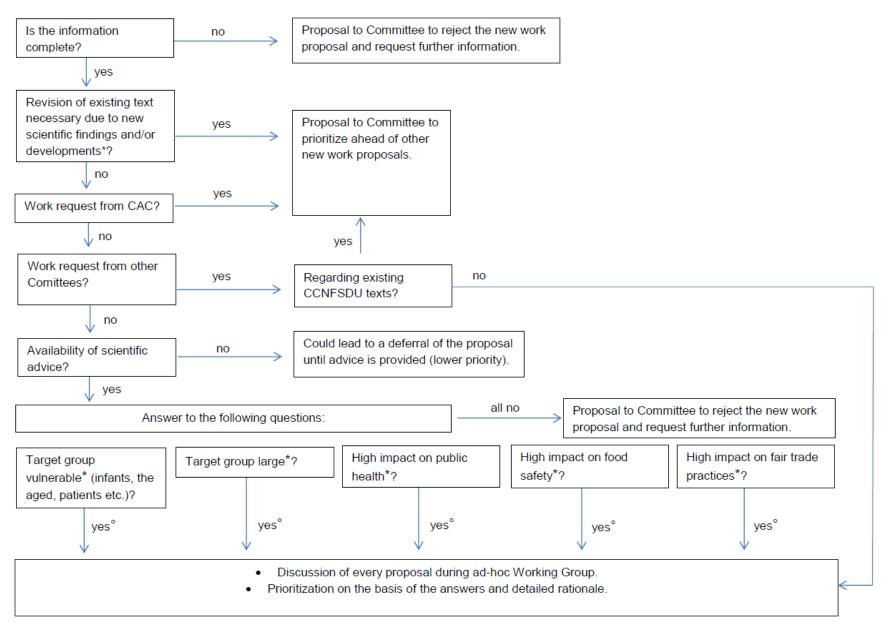
9. The *ad hoc* Working Group for the Establishment of CCNFSDU Work Priorities will meet as decided by the Committee, e.g. on the day prior to the plenary session of CCNFSDU or intra-session, to develop recommendations for consideration by the Committee during the CCNFSDU session. The *ad hoc* Working Group will be co-chaired by the host country and a voluntary delegation. The following Terms of Reference (ToR) of the *ad hoc* Working Group are proposed:

- a. To conduct a case-by-case review of every proposal on the basis of a decision tree and the detailed rationale including the rating (high/medium/low impact) as presented in the discussion paper and to propose a list of work proposals ranked according to their priority.
- b. To prepare a report to be presented to the plenary to enable CCNFSDU to evaluate and decide on the new work proposals.
- 10. It is proposed that, at the CCNFSDU session, the *ad hoc* Working Group Chair introduces the recommendations to the Committee. The Committee will then accept or reject a proposal for new work and/or revision of an existing text, or return it to the proposing party for additional information. Depending on the workload of CCNFSDU, the Committee may decide to not accept any new work proposal at a session.
- 11. If accepted by the Committee, a proposal will be submitted to CAC with a request for approval as new work.

Decision Tree

12. The following decision tree serves as a tool for the *ad hoc* Working Group to classify new work proposals:

DECISION TREE FOR THE PRELIMINARY ASSESSMENT AND PRIORITIZATION OF NEW WORK PROPOSALS FOR CCNFSDU



^{*} Detailed rationale including pertinent references is essential. One "yes" answer would suffice to be taken into account.