



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

Forty-fourth Session

Dresden, Germany

REPORT OF THE PHYSICAL WORKING GROUP ON THE PRIORITIZATION MECHANISM / EMERGING ISSUES OR NEW WORK PROPOSALS

30 September 2024

(Prepared by the Physical Working Group Chaired by Canada and co-Chaired by Germany)

1. At CCNFSDU43, the Committee agreed to establish a physical working group (PWG) chaired by Canada and co-chaired by Germany, working in English, French and Spanish. The PWG was tasked with meeting immediately prior to CCNFSDU44 to review the revised draft guideline and prioritization criteria outlined in the draft Guideline for the Preliminary Assessment to Identify and Prioritize New Work for CCNFSDU (see CL 2024/52-NFSDU, Appendix I). This draft guideline would be tested on a trial basis and used for case-by-case review of new work proposals submitted by Members in response to CL 2024/52-NFSDU.

2. The aim of the PWG was to provide clear recommendations to the Committee during the plenary session on whether to accept the new work proposals, identify the need for further development of the discussion paper, or reject the new work proposal at this time, with the potential for future reconsideration.

3. At the end of the PWG Members had the opportunity to provide feedback on the draft guideline and decision tree, in response to the changes made within this year's EWG.

DISCUSSION OF THE PWG ON THE PRIORITIZATION MECHANISM

4. The Chairs opened the meeting with a presentation summarizing the progress of the EWG on the prioritization mechanism. The presentation reviewed changes made to the draft guideline concerning processes for submitting, compiling, and prioritizing new work proposals, reflecting the EWG discussions (see CL 2024/52-NFSDU Appendix II for the EWG report). An explanation was also provided for the numerical rating system.

DISCUSSION OF THE PWG ON THE NEW WORK PROPOSALS

5. The PWG reviewed three proposals submitted in response to CL 2024/52-NFSDU, including one amendment to an existing CCNFSDU text and two new work proposals, located in CX/NFSDU 24/44/6 Rev and CX/NFSDU 24/44/6 Add.1. The revised new work proposal to develop a harmonized framework for probiotics informed by the EWG was also included for discussion at the PWG.

6. The Chairs utilized the Decision Tree (Annex 1, CL 2024/52-NFSDU Appendix I) to guide the review and test the draft guidelines. The Chairs presented the findings of the administrative check, performed by the host country Secretariat, in accordance with Steps 1-4 of the decision tree. Attention was drawn to Proposal 1.3, which seeks to amend the 2009 Codex definition of dietary fibre in the *Guidelines on Nutrition Labelling* (CXG 2-1985). As this proposal was submitted by a Codex Observer, support from a Member is required for the work to proceed.

PROPOSAL FOR AMENDMENTS TO EXISTING CCNFSDU TEXTS

Proposal 1.3 Proposal to open and amend the 2009 Codex definition of dietary fibre included under para.2 in the *Guidelines on nutrition labelling* (CXG 2-1985)

Submitted by the Calorie Control Council

7. This proposal (CX/NFSDU 24/44/6 Rev Annex II) requests that CCNFSDU amend the 2009 Codex definition of dietary fibre, currently included under para. 2 in the *Guidelines on Nutrition Labelling* (CXG 2-1985), to lower the minimum monomeric units from ten to three. The footnote in the current definition, which leaves the decision on including carbohydrates with 3 to 9 monomeric units to national authorities, would also

be removed. As populations globally fail to meet the recommended daily intake of dietary fibre, the proposed amendments to the definition of dietary fibre would ensure more products with dietary fibre are available, which could result in a key public health benefit. The Chair asked the physical working group if a Member would support the proposal to amend the dietary fibre definition. The United States of America intervened to confirm their support.

8. The Chair opened the floor to the physical working group to discuss whether the Members support or do not support this work. The WHO expressed its view that the definition is a satisfactory definition as it stands, and it should not be changed. Based on current evidence, there is no justification due to physiological effects for revisiting this definition. Regarding synthetic and extracted polymers such as oligosaccharides which are 3-9 monomeric units, evidence is limited. In contrast, for naturally occurring fibre we have a large body of evidence to demonstrate health benefits. The WHO concluded that they believe the current definition is a good compromise that has achieved in 2008 after many years of discussion. There were interventions by several Members that agreed with the WHO that the definition provides flexibility and does not require revisions. Furthermore, the Member organization pointed out that many national and/or regional competent authorities recommend to increase consumption of fruits, vegetables, pulses and whole grains as a means to increase fibre intake. The PWG Chairs concluded that there wasn't support by the physical working group to proceed with this proposed amendment to the 2009 Codex definition of dietary fibre.

9. The recommendation of the PWG to the Committee is as follows:

There is no support in the PWG to go ahead with this proposed amendment to the 2009 Codex definition of dietary fibre. It is recommended to reject the proposal.

PROPOSALS FOR NEW WORK

Proposal 2.1 Harmonized probiotic guidelines for use in foods and food supplements

Submitted by Argentina, Malaysia and China

10. This is the second time this proposal has been brought to the PWG, as there was no consensus in the PWG held before CCNFSDU43 to recommend that the Committee proceed with this new work proposal. It was recommended that the submitters further develop their discussion paper on the new work proposal.

11. This revised proposal (CX/NFSDU 24/44/6 Add.1.) requests that the Committee agrees to the development of harmonized probiotic guidelines for use in foods and food supplements. The submitters indicated that the proposed guidelines would establish a harmonized definition and minimum safety and characterization requirements for the consistent interpretation and application of the definition of probiotics and guidelines in the 2001 FAO/WHO consultation and labelling parameters for probiotics.

12. Malaysia, speaking on behalf of the submitters, brought attention to the PWG that a CRD (CRD24) had been published before the meeting to provide additional information on their proposal and references to key scientific evidence that can be used to inform the development of the framework.

13. The Chairs reminded the PWG Members that this proposal had been presented at CCNFSDU43, and it was recommended to the submitters to further develop their proposal, especially in regards to the scope. Therefore, the Chairs asked the committee if the scope was clearer and if there was support for the revised proposal.

14. Several Members were supportive of developing a definition and a harmonized framework for probiotics as these products are currently in their markets. In the absence of a Codex text on probiotics, harmonization is a challenge. Information on their benefits, safety, efficacy, amounts and duration of use, and labelling is required. Furthermore, some Members also identified a need for more detailed information on nomenclature.

15. The FAO raised concerns that the proposal scoped out health claims. However, the proposal contains several mentions related to health claims. The FAO also pointed out that scientific evidence needs to be assessed independently. Furthermore, they asked the submitters to clarify what was missing from the existing Guidelines for the Evaluation of Probiotics in Food developed by the expert group in 2002 that would be addressed through this proposed work.

16. The submitters raised that the 2002 document was an expert report that is over 20 years old. There is a lot of new evidence on probiotics and a Codex definition is needed. There are systematic reviews which can be shared.

17. Other Members and the Member organization raised concerns with the scope of the proposal, as it still references benefits to health. Furthermore, some of these Members indicated that the FAO/WHO Guidelines for the Evaluation of Probiotics in Food provides sufficient information.

18. The Chairs requested clarification from Members who supported the proposal on whether they are looking for general guidelines such as those in the FAO/WHO Guidelines for the Evaluation of Probiotics in Food, or more specific information on probiotic strains in regards to benefits and safety. The PWG Members in support of the proposal had mixed views regarding what would be in scope of the guideline.

19. The Member organization raised that when looking at aspects such as safety, information from risk assessors such as JEMNU would be needed and requires important resources.

20. Due to divergent views, the PWG Chairs concluded that there was no consensus on the scope of the new work proposal.

21. The recommendation of the PWG to the Committee is as follows:

There is no consensus in the PWG on the scope of this proposal, and there are divergent views on whether it should proceed or not. It is therefore recommended to reject the proposal.

Proposal 2.2 General guidelines and principles for the nutritional composition of foods formulated with protein from non-animal sources

Submitted by Canada and the United States of America (USA)

22. This is the second time this proposal has been brought forward, as there was no consensus in the PWG held before CCFSDU43 to recommend that the Committee proceed with this new work proposal. At that time, it was recommended that the submitters refine the scope of the proposal.

23. This revised proposal (CX/NFSDU 24/44/6 Rev Annex II) requests that the Committee agrees to the development of general guidelines for the nutritional composition of foods formulated with non-animal protein sources, including those from plant, fungi, fermentation, and insects. The submitters indicated that markets for these products are rapidly expanding but variations in nutrient composition across products from one country to the next could pose a trade barrier, and difference in nutrient composition between non-animal and their animal-based counterpart may pose health risks.

24. Canada, speaking on behalf of the submitters, clarified that the composition aspects would be voluntary in nature.

25. The PWG Chairs asked the Committee if there was support for the proposal with the revised scope. Some Members questioned the inclusion of insects and some of the non-animal sources being within the scope of the proposal. The submitters acknowledged that the inclusion of insects in the proposal may not be necessary, and instead the proposal could be revised to focus on plant-based products as those currently have the most data available.

26. A PWG Member asked about the availability of the FAO work cited in the proposal. The FAO indicated that the report is being finalized and is expected to be published before the end of the year. They further clarified that the work did not only focus on protein, but also looked at other nutrients. They also indicated the limited availability of information on insects. They shared with the PWG that they have commissioned additional work to review the impact of non-animal foods on safety and other aspects. This work will hopefully be published by the end of the year.

27. Some Members pointed out that these products are not within scope of dietary guidelines, which instead focuses minimally processed plant-based foods.

28. The Member organization raised that there is already the Codex General Principles for the Addition of Essential Nutrients to Foods that provides principles for nutritional equivalency. National authorities can determine approaches to address nutrient deficiencies for public health purposes. They raised that the existing Codex General Principles for the Addition of Essential Nutrients could be open to further elaborate on these gaps rather than a new text created. They also proposed that compositional aspects for guidelines should be considered first, and not labelling aspects.

29. The PWG Chairs indicated that there seemed to be support for the proposal, however, narrowing the scope of the work may be beneficial as there is limited data on some of the non-animal protein sources and addressing the compositional aspects but not labelling.

30. Some Members questioned the need for this work. The submitter clarified that even though there are limited countries with regulations for these products at this time, several countries are looking at developing policies and regulations. International guidance would help with alignment of policies and facilitate trade.

31. The PWG Chairs concluded that this proposal could move to the rating with the narrowed scope of work. The Chairs also requested that the submitters modify the project document to reflect these changes.

32. The PWG Members agreed on the following ratings in the assessment against the prioritization criteria, based on the information provided in the submission:

Prioritization Criteria	Rating
Impact on public health	Medium: +4 points
Impact on Food Safety	Neutral: 0 points
Impact on trade practices	Medium: +2 points
Global impact	Low: +1 point

33. The recommendation of the PWG to the Committee is as follows:

The PWG supported the proposal to move forward with the revised scope to focus on plant-based foods only and compositional aspects, and provided a total rating of 7.

Proposal 2.5 New work proposal to develop a standard for formulated complementary foods for older infants and young children

Submitted by the United States of America

34. This proposal (CX/NFSDU 24/44/6 Rev Annex II) requests that the Committee agrees to the development of a comprehensive Codex standard for formulated complementary foods for older infants and young children. This proposal would address the gap in current standards, which are outdated and do not align with recent scientific recommendations from the World Health Organization on complementary feeding. Given the inadequate nutritional adequacy of many commercially available complementary foods, especially in low- and middle-income countries, a single science-based standard would replace the existing Codex texts and encompass all formulated complementary food groups.

35. The United States raised to the PWG that some Members indicated the existing Guideline may not need to be updated. Therefore they are open to consider narrowing the scope of the proposed work to exclude the Guideline.

36. The Member organization supported the exclusion of the Guideline in the proposed work, but indicated challenges with not retaining separation of the product categories currently covered by the two standards. If one standard is developed, they recommended that the two product categories be maintained in a distinct manner in the new standard.

37. Other Members supported the exclusion of the Guidelines from the scope of the work, and no Members opposed this exclusion.

38. One Member supported the work, but asked for clarification on if the standards would be revised or if a new standard would be developed from scratch. The submitter indicated they initially thought this would be a new standard. However, this can be decided if the work moves forward.

39. The WHO asked for confirmation on the age range of the proposed work to ensure that these products would not be recommended to infants younger than six months. They also asked if the scope of the proposed work would not cover what is already included in the standard for the product for older infants and for young children. The submitter confirmed this understanding, and further added that the age range for up to 36 months could also be looked at to consider lowering it to 24 months.

40. The PWG Chairs concluded that this proposal could move to the rating with the narrowed scope of work. The Chairs also requested that the submitters modify the project document to reflect these changes.

41. The PWG Members agreed on the following ratings in the assessment against the prioritization criteria, based on the information provided in the submission:

Prioritization Criteria	Rating
Impact on public health	High: +6 points
Impact on Food Safety	Medium: +4 points
Impact on trade practices	Medium: +2 points
Global impact	Medium: +2 points

42. The recommendation of the PWG to the Committee is as follows:

The PWG supported the proposal to move forward with the revised scope to exclude the Guideline, and provided a total rating of 14.

RANKING OF PROPOSALS

43. In conclusion, the new work proposals that were rated against the CCNFSDU prioritization assessment criteria were ranked according to their total rating.

Proposal	Rating Against Prioritization Criteria					Ranking
	Public Health	Food Safety	Trade Practices	Global Impact	Total Rating	
Proposal 1.3 Dietary fibre						
Proposal 2.1 Probiotics						
Proposal 2.2 Non-animal source protein foods	Medium (4)	Neutral (0)	Medium (2)	Low (1)	7	2
Proposal 2.5 Complementary foods for older infants and young children	High (6)	Medium (4)	Medium (2)	Medium (2)	14	1

DRAFT GUIDELINE

44. Based on earlier feedback and questions raised during the PWG, the Chairs propose amendments to the decision tree to account for feedback received from the Codex Secretariat related to Step 2 about not being required to inform the CAC of a rejection. The Chairs also proposed to clarify Step 5 of the decision tree to account for a proposal not moving forward to the rating and the ranking. In addition, it was recommended that the rating of the proposal should be added to Step 6. See Appendix 1.

45. In addition, the PWG recommended that the rating be conducted by the Chairs of the PWG or ad hoc working group, or a small committee, for consideration of the PWG.

46. The Chair also asked the submitters of proposals if they had feedback to provide on their use of the Guideline. One submitter indicated that in their experience there was some duplication with the global magnitude of the problem from the procedural manual and the CCNFSDU prioritization mechanism global impact criteria.

CONCLUSION OF THE PWG

47. Recommendations to the Committee for each of the three new work proposals received in response to CL2024/52-NFSDU and the proposed probiotic guidelines for use in foods and food supplements were made.

PROPOSAL BY THE CHAIRS

48. After reflection on the discussions during the PWG, and taking into account the amendments made during the PWG to the decision tree (para. 44), the Chair and Co-Chair of the PWG propose to align Step 13 of the Guideline as follows:

13. The following Terms of Reference (ToR) of the ad hoc Working Group are proposed:

- a. Conduct a case-by-case review of every proposal for new work, including a review of the scope and rationale for clarity and the assessments submitted by the petitioning Member(s). **Determine if the Working Group recommends that the proposal for new work be taken up by the Committee.**
- b. **Rate the new work proposal(s).** Rank the new work proposals according to their priority, when there are multiple new work proposals to consider.
- c. Prepare a report containing the new work proposal(s) for presentation to the plenary to support CCNFSDU in evaluating and accepting of new work proposal(s).

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

