ANALYSIS OF AGENDA ITEMS IN PREPARATION FOR THE 44th SESSION OF THE CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES (CCNFSDU44)

Prepared to Support the Participation Codex Communities of Practice Supported by GFoRSS

Dresden, Germany, 2 – 6 October 2024

Disclaimer and Disclosure of Interest

It is important to note that the proposed analysis and associated conclusions and recommendations are stemming from the work of independent food regulatory experts. The analysis and associated recommendations or positions are presented as mere suggestions and should not be considered as a direction or final recommendation to the competent authority empowered to develop and endorse Codex positions

Disclosure of Interest: *Experts involved in the development of this analysis contribute to various food safety and nutrition regulatory capacity building initiatives funded by other Governments, aid agencies, industry and international organizations.*

SUMMARY OF AGENDA ITEMS AND PROPOSED POSITIONS

AGENDA ITEM 2: Matters arising from the Codex Alimentarius Commission and its subsidiary bodies

- Document Number: CX/NFSDU 24/44/2
- Status in Codex Step Process: N/A

POSITION: The matters for information provided are to be noted

AGENDA ITEM 3: Matters of interest arising from FAO and WHO

- Document Number: CX/NFSDU 24/44/3
- Status in Codex Step Process: N/A

POSITION: The matters for information provided are to be noted

AGENDA ITEM 4.1: General principles for the establishment of NRVs-R for persons aged 6-36 months (Comments at Step 7)

- Document Numbers: CX/NFSDU 24/44/4 (Part A), CX/NFSDU 24/44/4 Add.1

AGENDA ITEM 4.2: NRVs-R for persons aged 6 – 36 months (Comments at Step 4)

- Document Number: CX/NFSDU 24/44/4 (Part B), CX/NFSDU 24/44/4 Add.1

AGENDA ITEM 5: Technological justification for several food additives

- Document Number: CX/NFSDU 24/44/5

AGENDA ITEM 6.1: Guideline for the preliminary assessment to identify and prioritize new work for CCNFSDU

- Document Number: CL 2024/52-NFSDU

AGENDA ITEM 6.2: Proposals for new work/emerging issues (replies to CL 2024/52-NFSDU)

- Document Number: CX/NFSDU 24/44/6

AGENDA ITEM 6.2.1: Discussion paper on harmonized probiotic guidelines for use in foods and food supplements

- Document Number: CX/NFSDU 24/44/6 Add.1

Agenda Item 7: Review of texts under the purview of CCNFSDU

- Document Number: CX/NFSDU 24/44/7

POSITION: CCNFSDU is invited to consider the following recommendations:

❶ **To** use the existing procedures to review standards **under the purview of CCNSFDU;**

❷ Encourage Members **(and Observers)** to propose revisions / amendments to existing standards**,**

❸ **Request the Codex Secretariat to** submit the consequential amendments

❹ **Request the CCNFSDU host country Secretariat to** include the existing standards **developed by CCNFSDU** in the inventory of proposals and potential areas of work

AGENDA ITEM 8: Discussion paper on use of fructans, beta-carotene, lycopene in Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CXS 72-1981)

- Document Number: CX/NFSDU 24/44/8
- Status in Codex Step Process: N/A

POSITION: The proposal of recommendations issued by the EWG is worthy of consideration

AGENDA ITEM 9: Discussion paper on methods of assessing the sweetness of carbohydrate sources in the Standard for Follow-up Formula (CXS 156-1987)

- Document Number: CX/NFSDU 24/44/9

OBJECTIVES

This document offers a review and analysis of the agenda items planned for discussion at the 44th session of the Codex Committee on Nutrition and Foods for Special Dietary Uses, scheduled to take place physically in Dresden, Germany from 2 October 2024 – 6 October 2024.

The document is intended for possible use by the Codex communities of practice promoted by the Global Food Regulatory Science Society (GFoRSS) as part of their contribution to enhancing awareness and supporting effective participation in international standard setting meetings (Codex meetings) by representatives from members and observers.

The analysis provided in this document offers a factual review of key agenda items of CCNFSDU44, pertaining to:

A. **Agenda Item 2: Matters arising from the Codex Alimentarius Commission and its subsidiary bodies**

B. **Agenda Item 3: Matters of interest arising from FAO and WHO**

C. **Agenda Item 4.1: General principles for the establishment of NRVs-R for persons aged 6 – 36 months (Comments at Step 7)**

D. **Agenda Item 4.2: NRVs-R for persons aged 6 – 36 months (Comments at Step 4)**

E. **Agenda Item 5: Technological justification for several food additives**

F. **Agenda Item 6.1: Guideline for the preliminary assessment to identify and prioritize new work for CCNFSDU**

G. **Agenda Item 6.2: Proposals for new work/emerging issues (replies to CL 2024/52-NFSDU)**

H. **Agenda Item 6.2.1: Discussion paper on harmonized probiotic guidelines for use in foods and food supplements**

I. **Agenda Item 7: Review of texts under the purview of CCNFSDU**

J. **Agenda Item 8: Discussion paper on use of fructans, beta-carotene, lycopene in *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CXS 72-1981)**

K. **Agenda Item 9: Discussion paper on methods of assessing the sweetness of carbohydrate sources in the *Standard for Follow-up Formula* (CXS 156-1987)**

This document will offer an analysis of select key agenda items to support the development of positions at the national and regional level.

This analysis is indicative in nature and does not represent an official position of the organization, its membership or its management.

A. Agenda Item 2: Matters arising from the Codex Alimentarius Commission and its subsidiary bodies

Document Number: CX/NFSDU 24/44/2

Status in Codex Step Process: N/A

Recap of CCNFSDU 43 – Year 2023

Follow-up Formula

- Forward proposed draft revised standard, the Structure and the Preamble together with the remaining sections of Part A and B to CAC46 for adoption at Step 5/8
- Forward parts of the text at Step 7 of the draft to CAC46 for adoption at Step 8

NRVs –R for 6-36 months

- Forward the proposed draft to CAC46 for adoption at Step 5
- Revise the draft Stepwise Process and apply it to propose NRVs-R for persons aged 6-12 months, 12-36 months and 6-36 months

Food additives

- Inform CCFA of the decisions regarding the technological justifications for four food additives (low acyl clarified gellan gum, ascorbyl palmitate, tocopherol concentrate and phosphates) and include them in the priority list of substances proposed for evaluation by JECFA for use in foods intended for infants below 12 weeks.

Prioritization mechanism

- Prepare a revised draft guideline for the preliminary assessment and identification of work priorities for CCNFSDU
- Request that the Codex Secretariat issue a CL requesting for proposals for new work using the revised draft guideline, implemented on a trial basis

Probiotic guidelines

- Further refine and clarify Discussion Paper, especially with regards to the scope, impact on food safety and need for scientific advice
- Develop a revised discussion paper and project document, with the aim to consider it at CCNFSDU44 as part of the discussions of new work proposals

Methods of analysis

- To review, identify and recommend methods for referral to CCMAS for endorsement, in particular ISO 5495, for assessing the sweetness of carbohydrate sources in comparison to lactose in “Product for Young Children” in line with the revised CXS 156-1987, Section B, point 3.1.3c footnote 6 for those products based on non-milk protein.

Key Considerations

CAC46(2023) adopted the:

- **Revised Standard for follow-up formula** (CXS 156-1987) (renamed: Standard for follow-up formula for older infants and product for young children) **at Steps 5/8 and 8**, the list of food additives would be replaced by the texts recommended by CCFA53 and adopted by CAC46.
- **Revisions were adopted for food additives sections in five CCNFSDU Standards** to align with the General standard for food additives (GSFA, CXS 192-1995):

a. Amendments to the **Standard for canned baby foods** (CXS 73-1981).

b. Amendments to the **Advisory list of nutrient compounds** for use in foods for special dietary uses intended for infants and young children (CXG 10-1979).

c. **General principles for establishing nutrient reference values** for persons aged 6 – 36 months, at Step 5.

d. **Maximum Level (ML) for lead in ready-to-eat meals** for infants and young children for inclusion in General standard for contaminants and toxins in food and feed (CXS 193-1995), at Step 8.

e. the **sampling plans for total aflatoxins** in certain cereals and cereal-based products including foods for infants and young children for inclusion in CXS 193-1995.

Proposed Position

The matters for information provided were noted

B. Agenda Item 3: Matters of interest arising from FAO and WHO

Document Number: CX/NFSDU 24/44/3

Status in Codex Step Process: N/A

Background

- FAO and WHO conducted the update of the nutrient intake values (e.g. average nutrient requirement [ANR], adequate intake [AI], individual nutrient level [INLx]) and safe upper levels of intake (ULs) for infants and young children from birth through 3 years of age, focusing on calcium, vitamin D and zinc as the first three priority nutrients to be updated. Guidance documents are being drafted and will be ready for public consultation in Q4 2024.
- In response to a request from the 43rd CCNFSDU session, FAO prepared a literature review to guide the future development of “Guidelines including General Principles for the Nutritional Composition of Foods and Beverages made from Plant-based and other Alternative Protein Sources". A narrative review is set for publication in Q4 2024.
- In September 2024, FAO and WHO will publish a Joint Statement on the Principles of a Healthy diet. The statement will lay out four core principles of what makes diets healthy for humans.
- FAO in collaboration with world-renowned experts have elaborated a new methodology for the development and implementation of second-generation dietary guidelines that are food systems based. An overview of the new methodology is available and can be accessed at: https://openknowledge.fao.org/handle/20.500.14283/cc9394en. The methodology will be released in a modular format, starting from later this year (2024).

Position

The matters for information provided were noted

C. Agenda Item 4.1: General principles for the establishment of NRVs-R for persons aged 6 – 36 months (Comments at Step 7)

Document Numbers: CX/NFSDU 24/44/4 (Part A), CX/NFSDU 24/44/4 Add.1

Status in the Codex Step Process: Step 7

Background

EWG Chair: Ireland; co-chairs: Costa Rica & United States

Objective: To develop general principles to guide the establishment of NRVs-R for persons aged 6 to 36 months that describe:

A) the most appropriate approach to derive NRVs-R, based on an analysis of Dietary Intake Reference Values (DIRVs) from FAO/WHO and the 6 recognized, authoritative scientific bodies (RASBs);

B) the purpose(s) of these NRVs-R for labelling and, if appropriate, for composition for Guidelines on Formulated Complementary Foods for Older Infants and Young Children

In 2017: CNFSDU agreed to establish an EWG and the Initial objective to assess the need and value for the establishment of NRV-R for older infants and young children in Codex texts and analyze nutrition labelling provisions in Codex texts as appropriate

In 2019: EWG members supported establishing two separate sets of NRVs-R for older infants and your children based on the different nutritional needs. Members agreed to list and prioritize vitamins and minerals, and, potentially protein for NRVs-R for older infants and young children required based on existing Codex texts and determine which ones were to be allocated/applied to which Codex texts.

In 2021: The committee agreed to: **Finalize the General Principles** for establishing NRVs-R for persons aged 6 to 36 months and; to **pilot the draft General Principles** on the following nutrients: vitamin B12, iodine, vitamin B6, riboflavin and, if time permits, thiamine, niacin and vitamin C.

Conclusion at CCNFSDU 43, the Committee agreed to:

- Forward the proposed draft General Principles for establishing NRVs-R for persons aged 6 to 36 months to CAC46 for adoption at Step 5. CAC46 adopted the General Principles at Step 5 and advanced it to Step 6.
- Re-establish the EWG open to all Members and Observers, chaired by Ireland, and co-chaired by Costa Rica and the USA, to complete work under the Terms of Reference (ToR) below:
    - Revise the draft Stepwise Process taking into account the revisions to the draft General Principles and to develop an approach to propose NRVs-R for the combined age range of 6 to 36 months.
    - Apply the revised draft Stepwise Process to propose NRVs-R for persons aged 6 – 12 months, 12-36 months and 6 – 36 months, for the following nutrients:
        - Vitamins A, D, C, K and E, thiamine, riboflavin, niacin, vitamins B6 and b12, folate, pantothenic acid and biotin;
        - Calcium, magnesium, iron, zinc, iodine, copper, selenium, manganese, phosphorus and potassium.

Key Considerations

Areas in the draft General Principles remained in square brackets [ ]:

1. Definition of Adequate Intake:

During the second Consultation held by the EWG, FAO/WHO made the following definition of Adequate

Intake available for use by the EWG and, ultimately, by the Committee:

[Adequate intake (AI) is a reference value for a specified population based on observed or experimentally determined approximations or estimates of nutrient intakes by a group (or groups) of presumably healthy people with no known evidence of deficiency.]

This definition is presented in square brackets [ ] in section 2. DEFINITIONS AS USED IN THESE PRINCIPLES.

The EWG Chair and Co-Chairs concluded that the **FAO/WHO definition of Adequate Intake is the most appropriate definition** and the [ ] can be removed, and **recommend the Committee agree** with the definition of Adequate Intake currently in square brackets

2. The combined NRV-R value for persons aged 6–36 months:

Three options (HIGHEST, LOWEST and MEAN) to identify the most appropriate choice for the establishment of a combined NRV-R value for persons aged 6–36 months, all three have been applied to each nutrient on a case-by-case basis.

[The combined NRV-R value for persons aged 6-36 months should be determined by selecting the higher value of the proposed NRVs-R for older infants and young children if it does not exceed the UL for older infants and/or young children, where available. (Highest - Option 1)

OR

The combined NRV-R value for persons aged 6-36 months should be determined by selecting the lower value of the proposed NRVs-R for older infants and young children. (Lowest - Option 2)

OR

The combined NRV-R value for persons aged 6-36 months should be determined by calculating the mean value of the two age groups 6-12 months and 12-36 months. (Mean - Option 3)]

The combined NRV-R value for persons aged 6–36 months - Feedback in CP1 & CP2

Option 1 (Highest)	▪ Supported by a sizable proportion of CMs ▪ Select the higher value of the proposed NRVs-R for older infants and young children if it does not exceed the UL for older infants and/or young children, where available. ▪ Concerns o May be inappropriate if the food for the combined age rage (6-36 months) is targeted more at the younger age group (6-12 months Older Infants) as the requirements specified will be higher than necessary. o Unknown potential risk for this vulnerable age group due to excessive intake of nutrients where no UL has been set.

Option 2 (Lowest)	▪ The combined NRV-R value for persons aged 6-36 months would be determined by calculating the lower value of the two age groups 6-12 months and 12-36 months. ▪ Concerns - this will not reflect the INL98 of the older age group (Young Children) and will, therefore, not align with the draft General Principles under 3.2 where 'Ideally, the NRVs-R should be based on Individual Nutrient Level 98 (INL98)'.
Option 3 (Mean)	▪ A compromise where agreement may be achieved

The combined NRV-R value for persons aged 6–36 months - EWG Chair and Co-Chairs's conclusion and recommendation:
Conclusion from feedback in CP1 and CP2:

- None of the three Options can establish NRVs-R that align with the INL98 for aged 6-36 months
- Choosing Option 1 over Option 2 (or vice versa) result in a 'seesaw situation' where risks associated with higher or lower NRVs-R are exchanged between those persons at the younger or older ends of the age range 6 – 36 months;
- Option 3 addresses concerns about this vulnerable age group getting 'too much' or too little' and so represents the most appropriate option.
- Clarification on how these combined NRV-R value for persons aged 6–36 months should be used will be addressed as part of the next steps of this project, where text in relevant Codex documents is amended to clarify use of the NRVs-R for persons aged 6-36 months.

The EWG Chair and Co-Chairs recommend option 3 whereby the combined NRV-R value for persons aged 6-36 months is determined by selecting the mean value of the proposed NRVs-R for older infants and young children.

Position

The proposal of the EWG and Co-chairs is sensible and well-supported

D. Agenda Item 4.2: NRVs-R for persons aged 6 – 36 months (Comments at Step 4)

Document Number: CX/NFSDU 24/44/4 (Part B), CX/NFSDU 24/44/4 Add.1

Status in Codex Step Process: Step 4

Background

1. Draft Stepwise Process

The draft Stepwise Process was revised to take account of revisions to the draft General Principles at CCNFSDU43 and applied in a pilot. This pilot included proposing draft NRVs-R for persons aged 6–12 months, 12–36 months and 6–36 months for seven nutrients previously examined.

Feedback in the CP 1:

- Positive feedback on Stepwise Process providing consistency and clarity in implementing Section 3 of the draft General Principles for deriving NRVs-R

- FAO/WHO data was strongly supported as the primary source of data for establishing NRVs-R wherever possible.
- There was broad support for using FAO/WHO DIRVs when no physiological data is available and when the FAO/WHO DIRV is the same as the median DIRV from suitable RASBs at the same level of evidence.
- There was widespread support for the replacement of data from RASBs outlined in the 2021 FAO report when necessary.

Feedback in CP 2:

- The draft Stepwise Process needed to equally consider all the elements outlined in the draft General Principles under 3.2 and not to prioritise any element. In particular this feedback identified as a major issue the failure of the approach used in to address 'recent'

2. Two approaches for application of the draft Stepwise Process

Approach 1:

The Stepwise Process is applied using data from FAO/WHO and data published by RASBs over the past 10 years. The choice of 10 years was selected as a threshold amount of time to allow for the generation of new evidence. This interpretation of 'more recent' limited RASB data to four sources publishing data within the past 10 years – NCM (2023), NASEM (2019), NIHN (2015) and EFSA (2014-2017)

Approach 2:

The Stepwise Process is applied using data from FAO/WHO and ALL data published by RASBs. This includes consideration of data from all RASBs regardless of date of publication.

3. Comparison of the resulting NRVs-R from using two approaches:

The NRVs-R for Older Infants and Young Children using Approach 1 and Approach 2 shows:

- very similar NRVs-R values are established for the majority of nutrients provided by the two Approaches examined;
- restricting consideration of RASB data to more recently available publications makes very little difference to the NRVs-R established using the Stepwise Process;
- a strong validation of the Stepwise Process as it verifies the scientific reality that nutrient requirement data does not change much over time, with exception to: Vitamin B12 for Older Infants and biotin, magnesium and phosphorus for young Children

4. Finalizing the Draft Stepwise Process

The EWG concludes that:

- the work undertaken validates the decision to adopt Approach 1 and restrict use of RASB data to more recently available publications;
- although 'recent' and 'more recent' was defined as a 10-year period, a specific definition of these terms should not be included in the Stepwise Process to allow for flexibility in the future so the most appropriate DIRV data from RASBs can be used.

It is recommended that the draft Stepwise Process is adopted for use to establish NRVs-R for R for persons aged 6–12 months, 12–36 months and 6–36 months.

Key Considerations

The EWG concluded that:

- more recent data from the primary source (FAO/WHO) and from the RASBs is preferable
- Using Approach 1 (more recent data only) performs well as an update to the inclusion of older data (Approach 2), with NRVs-R being very similar

The EWG recommended:

- Using approach 1 for draft Stepwise Process so that more recent data from RASBs is used
- Adopting NRVs-R for all nutrients established using Approach 1 to be recommended as the established NRVs-R for Older Infants and Young Children (summary Table 1, appendix 1)
- Adopting NRVs-R for all nutrients established using Approach 1 and in Option 3 for the combined age range 6-36 months (summary tables 2 and 3b, appendix 1)
- Rounding NRVs-R values to avoid giving the impression that the NRVs-R are very precise in final recommendations for 6-12 months, 12-36 months and 6-36 months

Position

The recommendations of the EWG are sound and well founded.

E. Agenda Item 5: Technological justification for several food additives

Document Number: CX/NFSDU 24/44/5

Status in Codex Step Process: **N/A**

Background

The objective was to develop a framework to address technological justification of food additives. The EWG was chaired by the EU.

In 2019, The committee finalized the "CCNFSDU framework for appraising the technological need" and forwarded to CAC43 for adoption of the provisions for xanthan gum (INS 415) and pectin (INS 440) as thickeners in the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants.

In 2021, The CAC adopted the inclusion of xanthan gum (INS 415) and pectin (INS 440) in FC 13.1.3 "Formulae for special medical purposes for infants" of the GSFA (CXS 192-1995).

In 2023, CCFA49/CRD15Rev highlighted that several food additives had no adequate risk assessment by the JECFA for infants under the age of 12 weeks.

The output from the First EWG consultation was:

- 4 out of 7 feedback received replied positively as regards the use of the food additives under consideration and provided information on the use levels; 2 out of those 4 EWG members committed to provide the data necessary for the safety assessment for infants below 12 weeks of age.

- 3 EWG members reported no use in infant formulas. The Codex Observer commonly acting as a data provider for JECFA assessments, noted that its members do not use any of these additives due to the availability of more advanced alternatives, though those additives may have remained authorised per national or regional authorities.
- **Inconsistent feedback was received in reply to the first circular. It was not clear whether the information from the EWG Members confirming the use and use levels was based on the respective regulatory provisions permitting the use of the additives in question or on real uses**

The output from the Second EWG consultation was:

Second circular requested:

- EWG members to confirm that their reported use is based on the existing products available on the market and to commit to providing data for safety assessment of the food additives when used in foods for infants below 12 weeks of age in products conforming to CXS 72-1981.
- Information necessary for appraising the technological need should be submitted only if the EWG members confirm the use and commit to provide the data

The second circular clarified **that without confirmation of use or commitment to provide the, no further work of the current EWG would be conducted** and the EWG consultation would imply (i) no technological need for the food additives under consideration in infant formulas and (ii) revocation of the respective food additive provisions.

Six EWG members provided feedback, reporting no use of the products currently available on the market and no commitment to generate the data necessary for the safety assessment was made. The EWG concludes that there is no technological need for the use of guar gum (INS 412), distarch phosphate (INS 1412), phosphated distarch phosphate (INS 1413), acetylated distarch phosphate (INS 1414) and hydroxypropyl starch (INS 1440) in foods conforming to CXS 72-1981.

Key Considerations

At CCNFSDU43, decision were made on the technological justifications for four additives in and it was requested that CCFA prioritise them for JECFA evaluation.

CCNFSDU43 also reviewed and agreed to continue work on the remaining food additives in CCFA49/CRD15Rev, as listed in CL 2022/80/OCS-NFSDU Annex 2

The committee at **CCNFSDU 43 concluded :**

- that the proposed use of low-acyl clarified gellan gum (INS 418) as a thickener and stabilizer in formulas for special medical purposes intended for infants was technologically justified; and CCFA is requested to consider including it in GSFA food category 13.1.3 “Formulae for special medical purposes for infants” once its specifications are finalized.
- that the use of ascorbyl palmitate (INS 304) and tocopherol concentrate, mixed (INS 307b) as an antioxidant and phosphates (INS 339(i), 339(ii) and 339(iii) and INS 340(i), 340(ii) and 340(iii)) as acidity regulators in all types of infant formula was technologically justified
- to inform CCFA of the technological justifications for the four food additives and request their inclusion in JECFA’s priority evaluation list for infants under 12 weeks

- to establish an EWG, chaired by the EU, with the following ToR:
  - collect safety and usage data on guar gum (INS 412), distarch phosphate (INS 1412), phosphated distarch phosphate (INS 1413), acetylated distarch phosphate (INS 1414), and hydroxypropyl starch (INS 1440) for infants below 12 weeks
  - to collect information from the applicants with the framework for considering technological justification for use in CXS 72-1981 on food additives
  - review the information provided and provide recommendations to CCNFSDU44 on the technological justification of each additive.

Position

The approach to create the EWG and proceed with the tasks identified is well justified

F. Agenda Item 6.1: Guideline for the preliminary assessment to identify and prioritize new work for CCNFSDU

Document Number: CL 2024/52-NFSDU

Status in Codex Step Process: N/A

Background

- CCEXEC75 specifically requested that the CCNFSDU consider a prioritization mechanism to better manage its work
- CCNFSDU41 in 2019, the Committee's host country Secretariat introduced a discussion paper on a prioritization mechanism to better manage the work of CCNFSDU. Included a uniform approach on submission of work proposals; additional prioritization criteria besides what is set out in the Procedural Manual; use of a circular letter to collect new work proposals; and establishing an ad hoc working group to review submitted work proposals.
- Committee agreed to the draft prioritization mechanism and to start it on a pilot basis to assess its usefulness through a PWG:
  - Adjust the draft framework as necessary of the prioritization mechanism with regard to simplification of the criteria and the process
  - Conduct a case-by-case review of the proposal submitted by members

Key Considerations

The proposed prioritization approach is quite comprehensive and underpinned by a sound approach.

The application of such approach needs to follow a heavy agenda of items being put forward for consideration by CCNFSDU, to support such prioritization exercise.

G. Agenda Item 6.2: Proposals for new work/emerging issues (replies to CL 2024/52-NFSDU)

Document Number: CX/NFSDU 24/44/6

Status in Codex Step Process: N/A

Background

1. The 43rd Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU43) agreed to **establish an electronic working group (EWG)** open to all Members and Observers, chaired by Canada and co-chaired by Germany, working in English and French with the following terms of reference:

- to **prepare a revised draft guideline for the preliminary assessment and identification of work priorities for CCNFSDU**, including the prioritization criteria and the decision tree, taking into account the comments made in the PWG held prior to CCNFSDU43 as well as the comments and decisions made at CCNFSDU43.

2. CCNFSDU43 also agreed to **request that the Codex Secretariat issue a CL requesting for proposals for new work** using the revised draft guideline, which would be **implemented on a trial basis**.

3. A **physical working group (PWG)**, chaired by Canada and co-chaired by Germany, working in English, French and Spanish will be established and held in conjunction with CCNFSDU44 to consider the revised draft guideline on a trial basis and assess any new work proposals received in response to the aforementioned CL.

4. **CL 2024/52-NFSDU** was sent out to all Members and Observers in May 2024. Members and Observers were invited to provide proposals for new work relevant to CCNFSDU. In identifying emerging issues and/or proposals for new work / emerging issues, **Members and Observers should provide information in line with the proposed Draft Guideline for the Preliminary Assessment to Identify and Prioritize New Work for CCNFSDU.**

5. Until 31 July 2024, **one proposed amendment and two new work proposals** were received in response to CL 2024/52-NFSDU.

6. A **PWG will meet prior to CCNFSDU44** in order to consider and assess the new work proposals submitted in reply to the CL using the guidelines and criteria as outlined in the Draft Guideline for the preliminary assessment to identify and prioritize new work for CCNFSDU (see CL 2024/52-NFSDU, Appendix I).

Key Considerations

CCNFSDU44 is invited to consider the report of the PWG and the new work proposals in light of the prioritization mechanism (see CL 2024/52-NFSDU, Appendix I).

H. Agenda Item 6.2.1: Discussion paper on harmonized probiotic guidelines for use in foods and food supplements

Document Number: CX/NFSDU 24/44/6 Add.1

Status in Codex Step Process: N/A

Background

Objective: To develop harmonized probiotic guidelines for use in Foods and Food Supplements
Chair: Argentina, Malaysia and China
In 2017, Proposal raised by International Probiotics Association (IPA) at CCNFSDU39.
Argentina expressed their support for the proposal and their willingness to lead this work. **The Committee agreed that Argentina would prepare a discussion paper** together with a project document for consideration at its next session

In 2018, Argentina introduced the discussion paper at CCNFSDU40. It was not discussed in great detail due to time constraints. Argentina was requested to **redraft the discussion paper, elaborating further on the sections on scope, definition as well as health and trade concerns** in particular, further addressing problematic issues related to health and trade.

In 2019, Argentina introduced the revised discussion paper at CCNFSDU41.

The Committee agreed that the proposal could be **submitted in accordance with the Prioritization Mechanism to Better Manage the CCNFSDU**, for consideration by the working group on prioritization. The Committee noted the offer of **Argentina and Malaysia to prepare a revised proposal**.

Note: CCNFSDU42 in 2021, held virtually, did not include this agenda item

CCNFSDU43 agreed to establish an Electronic Working Group (EWG), open to all Members and Observers, chaired by Argentina and co-chaired by China and Malaysia, working in English and Spanish, with the following terms of reference:

I. **Further refine and clarify** Proposal 2.1 Discussion Paper on Harmonized Probiotic Guidelines for Use in Foods and Food Supplements in document CX/NFSDU 23/43/7**, especially with regards to the scope, impact on food safety and need for scientific advice**; and
II. Develop a **revised discussion paper and project document**, taking into account comments at CCNFSDU43 and with the aim to **consider it at CCNFSDU44** as part of the discussions of new work proposals.

EWG consultations – summary of positions:

- The status of support by members of the EWG for the new work proposal to develop a Harmonised Probiotic Guidelines is rather similar during both rounds of the consultation.
- A majority of the EWG members supported the new work proposal. Some indicated either they did not have a pressing need for this work or did not consider it to be high priority, but recognised that there could be a significant benefit for many countries. Several members made suggestions to provide further clarity to the scope and to address certain aspects of the new work proposal.
- The EU indicated not supporting the proposal, pointing out that providing comments on the discussion paper does not mean that possible future work on probiotics will be supported. Several concerns raised by the EU were addressed in the revised documents.

- Two observers expressed a neutral position in relation to this proposal.

Key Considerations

- After three sessions of the CCNFSDU and two rounds of consultation among EWG members, the chair and co-chairs are of the opinion that there is general support from many countries of different regions of the world for the proposal to initiate new work to develop a harmonized probiotic guideline by CCNFSDU.
    - Countries have stated very clearly that the products are in their markets and that they require harmonized regulatory guidance for foods and food supplements containing probiotics.
- It would be adequate for CCNFSDU44 to approve this proposal for new work for a harmonized guideline on probiotics as attached in Annex 1, with highest priority
    - and to forward it to the 47th Session of the Codex Alimentarius Commission (CAC47) for endorsing the adoption as new work.

Proposed time-line for new work:

- Agreement to undertake new work by the CCNFSDU44. Approval by CAC48.
- Finalization of work by CCNFSDU46 in 2026 for adoption by CAC50 in 2027

I. Agenda Item 7: Review of texts under the purview of CCNFSDU

Document Number: CX/NFSDU 24/44/7

Status in Codex Step Process: N/A

Background

- The **revision of Codex standards aims** to ensure that they are consistent with and reflect current scientific knowledge and other relevant information.
- At **CCNFSDU43**, the Committee agreed that the Codex Secretariat would consider approaches to **review all texts under the purview of CCNFSDU** to assess **if they were still fit for purpose**
- This item explores **approaches to review texts under CCNFSDU**, provides **review background** since standards' adoption, **mechanisms for review**, and **possible updates** that could be undertaken as part of the amendments (editorial / alignment) or revision
- In preparation for this paper, the Codex Secretariat together with the chairs of CCNFSDU and the host Secretariat with the assistance of Australia, Canada, Finland, Germany Ghana, WHO and FAO undertook **SCREENING EXERCICES** of certain standards as examples **to facilitate further discussion** on the need to review existing standards.
- The **screening exercises** was undertaken on **12 standards** to set the ball rolling for discussions on:
    - (**i**) **possible new work to revise/amend existing standards**, or
    - (**ii**) **further in-depth reviews to determine whether there is a need to update certain standards**.
- A **summary of the screening exercises** on each of the standards/guidelines is compiled in Appendix I of **CX/NFSDU 24/44/7**.

Key Considerations

The Outcome and recommendations from the screening exercises are as following:

Group 1: Possible revision/amendment

- *Standard for foods for special dietary use for persons intolerant to gluten (CXS 118-1979)*
- *Standard for canned baby foods (CXS 73-1981)*
- *Standard for processed cereal-based foods for infants and young children (CXS 74-1981)*
- *Standard for formula foods for use in weight control diets (CXS 181-1991)*
- *Guidelines for vitamin and mineral food supplements (CXG 55-2005)*

Group 2: Further review / possible revision/amendment in future

- *Standard for infant formula and formulas for special medical purposes intended for infants (CXS 72-1981)*
- *Standard for labelling of and claims for foods for special medical purposes (CXS 180-1991)*

Group 3: No immediate need for revision/amendment

- *Guidelines on formulated complementary foods for older infants and young children (CXG 8-1991)*
- *General principles for the addition of essential nutrients to food (CXG 9-1987)*
- *Standard for special dietary foods with low-sodium content (including salt substitutes) (CXS 53-1981)*
  Standard for formula foods for use in very low energy diets for weight reduction (CXS 203-1995).

Following the general procedures of Codex, **updating standards can be requested** because:

- **New information** (scientific or other) has become available, or
- Of **editorial nature**, or
- to **align with the Format for codex commodity standards** as per Section 2 of the Procedural Manual for which no new work proposal is required

Such updates can be undertaken by the Codex Secretariat for submission to and approval by the CAC. Submission **can be made directly to CAC** or through the Committee.

There are **general procedures for the development and revision of Codex standards** prescribed in the Procedural Manual.

Some committees have **developed internal procedures** to either identify existing standards that require review or have prescribed formal procedures for periodic review, eg CCCF, CCPR, CCFA

In the **case of CCNFSDU**, the need for **additional procedures might not be warranted** due to the **nature of nutrition science and developments** in this field.

As conclusion:

The **screening summaries** in Appendix I of CX/NFSDU 24/44/7 provide **a starting point** for further consideration by CCNFSDU

- A **specific mechanism to review standards under CCNSFDU** is **not necessary** since:
  - **There are existing procedures and guidance** in the Procedural Manual for **proposals for new work** (including **revision** / **amendment** of standards)

- **CCNFSDU** has embarked on a **process of prioritization of new work** / emerging issues including the revision / **amendment of existing standards** and the issuance of a **regular circular letter calling for proposals** for new work **since 2020**
- **Limited number of existing CCNFSDU standards**

- **Maintaining an inventory list** as introduced with the draft Guideline for the preliminary assessment to identify and prioritize new work for CCNFSDU **could be sufficient**

Recommendations

CCNFSDU is invited to consider the following recommendations:

❶ To **use the existing procedures to review standards** under the purview of CCNSFDU;

❷ **Encourage Members** (and Observers) **to propose revisions / amendments to existing standards**, where needed, in response to the regular circular letter requesting new work proposals. In doing so, the initial screening exercises could be considered to guide new work proposals;

❸ Request the Codex Secretariat to **submit the consequential amendments** identified for CXS 72-1981 (*Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants*) and/or any other editorial amendments for consideration and approval by CAC47; and

❹ Request the CCNFSDU host country Secretariat to **include the existing standards** developed by CCNFSDU **in the inventory of proposals and potential areas of work** as proposed in the "Process for compiling new work proposals" (see CL 2024/52-NFSDU) (*Agenda item 6*).

J. Agenda Item 8: Discussion paper on use of fructans, beta-carotene, lycopene in *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CXS 72-1981)

Document Number: CX/NFSDU 24/44/8

Status in Codex Step Process: N/A

Background

Conclusion at CCNFSDU 43:

The Committee agreed to establish an EWG chaired by the United States of America with the following Terms of References (TORs):

- Review the use of fructans (fructo-oligosaccharides and other relevant fructans in human milk), beta-carotene, lycopene in the context of optional ingredients in the Standard for infant formula and formulas for special medical purposes intended for infants (CXS 72- 1981);
- Develop recommendations to CCNFSDU44 regarding the safety and suitability of these ingredients as optional ingredients in CXS 72-1981; and
- Submit a report for discussion at CCNFSDU44.

The EWG was established in July 2023 and has 24 Members and Observers (20 Codex Members, one Codex Member Organization, and 3 Codex Observers)

The EWG completed two rounds of consultation seeking to develop recommendations to CCNFSDU44 regarding the rationale to recommend that CCMAS endorse the methods of analysis for beta-carotene, lycopene, fructo-oligosaccharides (FOS), oligofructose (OF), and oligofructan.

The methods of analysis referred from CCMAS41 back to CCNFSDU were as follows:

- Beta-carotene: AOAC 2016.13 / ISO DIS 23443
- Lycopene: AOAC 2016.13 / ISO DIS 23443
- Fructo-oligosaccharides, oligofructose, oligofructan: AOAC 2016.14 / ISO DIS 22579 |IDF 241

Key Considerations

Based on the First consultation, requested responses from EWG members regarding the safe use, and suitability of FOS, OF, & oligofructan included:

Beta-carotene	▪ 11/13 responded in support of recommending to CCNFSDU that CCMAS be informed that beta-carotene is a safe and suitable ingredient and is listed in CXG 10-1979 for use as a vitamin compound, and request CCMAS to endorse the method. ▪ There was broad agreement on this recommendation due to beta-carotene's existing listing CXG 10-1979. ▪ Opposing responses cited a need for additional scientific evidence to substantiate the benefits of beta-carotene for infants and questioned whether it met criteria for use as an optional ingredient
Fructo-oligosaccharides (FOS), oligofructose (OF), & oligofrutan	▪ Widespread agreement (11/13 responses received) to develop a recommendation to CCNFSDU44 regarding the use, safety, and suitability of beta-carotene and fructo-oligosaccharides, oligofructose, and oligofructan and a recommendation to CCMAS to endorse methods related to these
Lycopene	▪ Of the 13 responses received, 10 either chose to wait for more information on lycopene's use and benefits for infants or did not support recommending to CCNFSDU that it inform CCMAS that lycopene is a nutrient compound consistent with the provisions established in CXG 10-1979 or a suitable optional ingredient as defined in CXS 72-1981, and further did not support recommending to CCNFSDU that it request CCMAS endorse the associated method. ▪ Two Observers supported recommending to CCNFSDU that CCMAS recognise lycopene as a nutrient compound consistent with the provisions established in CXG 10-1979 and a suitable optional ingredient as defined in CXS 72-1981, but did not support recommending to CCNFSDU that the Codex Secretariat update either text, recalling that optional ingredients do not need to be included in a specific list to be used. ▪ One Member supported the proposals, but suggested CCNFSDU seek more data on lycopene in infant formulas.

A Second consultation to seek additional **input from EWG members on lycopene in infant formulas** for a recommendation to CCNFSDU on its suitability as an optional ingredient in infant formulas, concluded:

All 11 respondents (10 Codex Members and 1 Member Organisation) indicated that their countries either do not have provisions in their regulations for the use of lycopene in infant formulas or currently do not allow its use. Those members who responded that their national regulations require premarket assessments to be conducted prior to lycopene's approval and use indicated that they have not received any requests regarding lycopene.

Position

The proposal of recommendations issued by the EWG is worthy of consideration, it considers informing CCMAS that:

- **beta-carotene is a suitable optional ingredient** as defined in CXS 72-1981 and is listed in the Advisory lists of nutrient compounds for use in foods for special dietary uses intended for infants and young children (CXG 10-1979), and requesting **CCMAS to endorse AOAC 2016.13 / ISO DIS 23443** (beta-carotene and lycopene) for use with beta-carotene in the CXS 72-1981 as a Type II method;
- **FOS, OF, and oligofructan are nutrient compounds** consistent with the provisions established in the CXG 10-1979 and **suitable optional ingredients** as defined in CXS 72-1981, and requesting **CCMAS to endorse AOAC 2016.14/ISO DIS 22579 | IDF 241 (Fructans)** for use with CXS 72-1981 as a Type II method; and
- CCNFSDU **could not determine a rationale to endorse** the method of analysis AOAC 2016.13 / ISO DIS 23443 (beta-carotene and lycopene) **for use with lycopene** at this time.

K. Agenda Item 9: Discussion paper on methods of assessing the sweetness of carbohydrate sources in the *Standard for Follow-up Formula* (CXS 156-1987)

Document Number: CX/NFSDU 24/44/9

Status in Codex Step Process: N/A

Background

Discussion at CCNFSDU43:

1. CCNFSDU43 completed the work on updating the Standard for follow-up formula for older infants and product for young children (CXS 156 -1987) (hereafter referred to as the Standard for follow-up formula), which was adopted at CAC46.

2. During CCNFSDU43, an in-session WG discussed the issue and recommended that the Committee:

- Establish an EWG to review and identify and, if appropriate, recommend methods for referral to CCMAS for endorsement and typing, in particular ISO 5495, for assessing the sweetness of carbohydrate sources in comparison to lactose in "Product for Young Children" [in line with section B footnote 6 (1) for those products with non-milk protein, point 3.1 of the new Standard].
- The approach described in CRD16 regarding assessment of sweetness by the EU and Switzerland should be taken as a starting point.

3. CCNFSDU43 noted support for the recommendation along with the following views:

- The EWG should collect scientifically available methods for use in sensory evaluation in the target age group (i.e.12-36 months).
- The preferred methods would be those based on comparison with lactose.
- The ratio between lactose and glucose polymers in terms of how sweetness will be measured could be explored.
- Concern was expressed about the use of flavourings and potential impact on sweetness.

4. CCNFSDU43 endorsed the recommendation of the in-session WG and agreed to establish an EWG, chaired by the EU and co-chaired by Switzerland, with the following terms of reference (para 128):

- To review, identify and, if appropriate, recommend methods for referral to CCMAS for endorsement, in particular ISO 5495, for assessing the sweetness of carbohydrate sources in comparison to lactose in "Product for Young Children" in line with the revised CXS 156-1987, Section B, point 3.1.3 c) footnote 6 (2) , for those products based on non-milk protein.
- The approach described in CRD16 of CCNFSDU43 by the EU and Switzerland should be taken as a starting point.
- To submit a report for discussion at CCNFSDU44.

Conclusion of the EWG

There was general support from many countries of different regions of the world for the proposed method, preparation protocol and reference values for assessing the sweetness of carbohydrate sources in comparison to lactose in "Product for Young Children" in line with CXS 156-1987, Section B, point 3.1.3 c) footnote 4, for those products based on non-milk protein, general support to refer the method to CCMAS. Observer Organisations expressed disagreement on the proposed method. It is worth to note that disagreement of Observer Organisations relates generally not to the method itself, but object to footnote 4 of CXS 156 -1987, although CXS 156-1987 has been adopted with footnote 4. The Chair and co-Chair of the EWG propose to submit the method to CCNSFDU44 for discussion and consultation of CCMAS.

Key Considerations

CCNFSDU44 is invited to consider referring the method below to CCMAS for endorsement and inclusion in the Recommended Methods of Analysis and Sampling (CXS 234-1999):

Commodity	Provision	Method	Principle	Type
Foods for special dietary uses				
Follow-up formula, Section B: Drink for young children with added nutrients or Product for young children with added nutrients or Drink for young children or Product for young children	Carbohydrates (based on non-milk protein)	ISO 5495 The relative sweetness of a carbohydrate ingredient shall be measured by comparing a sample solution prepared with 17.50 g carbohydrate in 100 ml water[4] with a reference solution of 17.50 g lactose in 100 ml water[5] at 20 to 22°C. When the carbohydrate ingredient solution is rated sweeter than the lactose solution by a trained sensory panel[5], the carbohydrate source does not comply with the provision.	Sensory test	IV