CODEX ALIMENTARIUS COMMISSION

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Food and Agriculture Organization of the United Nations

World Health Organization

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REP24/NFSDU

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Forty-Seventh Session

CICG, Geneva, Switzerland

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REPORT OF THE FORTY- FOURTH SESSION OF THE CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Dresden, Germany
02 – 10 October 2024

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SUMMARY AND STATUS OF WORK

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CCEXEC87 CAC47	Critical Review Adoption	General Principles for establishing Nutrient Reference Values (NRVs-R) for persons aged 6 to 36 months	CXG 2-1985	8	38 and App. II, Part A
		NRVs for older infants and product for young children	CXG 2-1985	5/8	67i and App. II, Part B
		Proposed amendments to the Standard for infant formula and formulas for special medical purposes intended for infants	CXS 72-1981	-	141iv and App. VI
		Proposal to include the nitrogen to protein conversion factors for follow-up formula for older infants and product for young children in the annex in CXS 234-1999	CXS 234-1999	-	190i and App. VII, Part C
CCEXEC87 CAC47 EWG/PWG (USA and co-chaired by EU, Kenya and Panama) CCNFSDU45	Critical Review Approval Drafting Consideration	New work on a standard for foods for older infants and young children	-	1,2,3	128i and App. V
CCEXEC87 / Codex Secretariat	Information / Publication	Guideline for the preliminary assessment to identify and prioritize new work for CCNFSDU	-	-	99i and App. IV
Codex Secretariat	Publication	Stepwise process for establishing NRVs-R for persons aged 6 – 36 months	-	-	67ii and App. III
CCMAS	Endorsement / Action	• Methods of analysis for endorsement and inclusion in CXS 234-1999 • Methods of analysis included in CXS 234-1999 for revocation or retyping	CXS 234-1999	-	177, 181 and App. VII, Parts A and B
CCFA	Information / Action	• 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 and request that CCFA take appropriate actions; • CXS 73-1981 permits the use of the food additives listed in CXG 10-1979 Part D as nutrient carriers; and • Gum arabic (Acacia gum) (INS 414), silicon dioxide, amorphous (INS 551), mannitol (INS 421), and	CXS 192-1995	-	84 and 85

Responsible Party	Purpose	Text/Topic	Code	Step	Para.
		sodium ascorbate (INS 301) will be included as batch 6 in the CCNFSDU work plan for future technological justification appraisal.			
EWG / PWG (Ireland, Costa Rica and USA) CCNFSDU45	Redrafting	NRVs-R for Vitamins C, B12, and K, folate, biotin, selenium, manganese, magnesium, phosphorous and iron	CXG 2-1985	2/3	67iii
EWG (EU) CCNFSDU45	Review	Collection and review of information on the use, and use levels for 5 identified additives; and their technological justification	CXS 192-1995	-	86
PWG (Germany and Canada) CCNFSDU45	Review	To review and prioritize new work proposals and develop recommendations for consideration by CCNFSDU45	-	-	128ii
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LIST OF ABBREVIATIONS

AOAC	AOAC International (formerly the Association of Official Agricultural Chemists)
BMC	methacrylate copolymer, basic
CAC	Codex Alimentarius Commission
CCEXEC	Executive Committee of the Codex Alimentarius Commission
CCEURO	FAO/WHO Regional Coordinating Committee for Europe
CCFA	Codex Committee on Food Additives
CCFH	Codex Committee on Food Hygiene
CCFL	Codex Committee on Food Labelling
CCMAS	Codex Committee on Methods of Analysis and Sampling
CCNFSDU	Codex Committee on Nutrition and Foods for Special Dietary Uses
CL	Circular Letter
CRD	Conference Room Document
CXG	Codex Guideline
CXS	Codex Standard
DIRV	Dietary Intake Reference Values
EFSA	The European Food Safety Authority
EU	The European Union (EU)
EWG	Electronic Working Group
FAO	Food and Agriculture Organization of the United Nations
FSDU	Food for Special Dietary Uses
GSFA	General Standard for Food Additives
HBGV	Health Based Guidance Values
IAEA	International Atomic Energy Agency
IDF	International Dairy Federation
INL98	Individual Nutrient Level 98
ISO	International Organization for Standardization
IWG	In session Working Group
JECFA	Joint FAO/WHO Expert Committee on Food Additives
JEMNU	Joint FAO/WHO Expert Meetings on Nutrition
NCM	Nordic Council of Ministers
NIHN	National Institute of Health and Nutrition
NRV-R	Nutrient reference values - requirements
PM	Codex Procedural Manual
PWG	Physical Working Group
RASB	Recognized Authoritative Scientific Body
RUTF	Read-to-use Therapeutic Foods
ToR	Terms of Reference
USA	The United States of America
WHO	World Health Organization

LIST OF CONFERENCE ROOM DOCUMENTS

(CRDs)

CRD No.	Agenda Item	Submitted by
1	Division of Competence	European Union
2 Rev	Item 6	Chair of the Physical Working Group (Canada, Germany)
3	Item 4	Chair of the Physical Working Group (Ireland, USA, Costa Rica)
4 Rev	Item 2	Codex Secretariat
5 Rev	Item 10	AOAC INTERNATIONAL, C&G, ICC, IDF, ISDI and ISO
6	Item 4	Chairs of the EWG/PWG (Ireland, USA and Costa Rica)
7	Item 7	New Zealand
8	Item 2	Burundi, Panama, Senegal, Thailand
9	Item 3	Panama, Thailand
10	Item 4.1	Burundi, Morocco, Panama, Thailand
11	Item 4.2	Burundi, Morocco, Panama, Thailand
12	Item 5	Burundi, Morocco, Panama, Thailand
13	Item 6.1	Burundi, Panama, Thailand
14	Item 6.2	Burundi, Panama, Thailand
15	Item 6.21	Burundi, Morocco, Panama, Senegal, Thailand, IPA
16	Item 7	Burundi, Panama, Senegal, Thailand
17	Item 8	Burundi, Panama, Thailand
18	Item 9	Morocco, Panama, Thailand
19	Item 10	Thailand
20	Item 11	Panama
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23	Item 8	USA
24	Item 6.21	Malaysia
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26	Item 4	Republic of Korea
27	Items 6.21, 8, 9	Viet Nam
28	Items 4.1, 6.1, 8, 9	European Union
29	Items 2, 4.1, 4.2, 5, 9	India
30	Items 6.2, 6.21, 8	IBFAN
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32	Items 4.1, 4.2, 5, 6.1, 6.21, 7, 8	Egypt
33	Item 6.2	GFI
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35	Items 2, 9	ISDI

CRD No.	Agenda Item	Submitted by
36 Rev2	Item 6.2	Chair of the Physical Working Group (Canada, USA)
37	Item 6.2	EUVEPRO, ENSA and IMACE
38	Item 3	IFT
39	Items 2, 4.1, 4.2, 5, 6.2, 6.21, 7, 8	Nigeria
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41	Items 4.1, 5, 6.2, 6.21, 9	Indonesia
42	Item 9	IBFAN and ENCA
43	Item 6.21	Argentina
44	Item 4.1	Chile
45	Items 4.1, 5, 6.2, 6.21, 8, 11	China
46	Item 6.21	IPA
47	Item 10	Chair of the In-Session WG (USA and the European Union)

INTRODUCTION

1. The forty-fourth Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU44) was held in Dresden, Germany, from 2 to 6 October 2024, at the kind invitation of the Federal Government of Germany. Ms Martine Püster and Dr Carolin Bendadani, both from the Federal Office of Consumer Protection and Food Safety of Germany, served as Chairperson and co-Chairperson of the Session respectively. CCNFSDU44 was attended by 51 Member countries, one Member Organisation and 29 Observer Organisations. A list of participants is given in Appendix I.

OPENING OF THE SESSION

2. Mr Cem Özdemir, Federal Minister of Food and Agriculture of Germany, welcomed delegates via a video message. He underlined safe food was an important precondition for food and nutrition security and the importance of good cooperation at the global level. Ms Petra Köpping, Minister of Saxon State Ministry for Social Affairs and Cohesion, offered CCNFSDU her congratulations on the successful conclusion last year of the *Standard for follow-up formula for older infants and product for young children* (CXS 156-1987). Dr Monika Mertens, Deputy Director General of the Consumer Health Protection, Federal Ministry of Food and Agriculture of Germany, underlined the importance of this Codex work particularly in relation to child food poverty and highlighted new topics such as the proposed revision of the Codex texts on complementary foods for older infants and young children and the proposed new work on alternative protein sources.

3. Dr Fatima Hachem and Dr Rain Yamamoto welcomed the attendees on behalf of FAO and WHO, respectively. Mr Steve Wearne, Chairperson of the Codex Alimentarius Commission (CAC) and Dr Sarah Cahill, Codex Secretary, also addressed the meeting.

Division of competence

4. CCNFSDU44 noted the division of competence between the European Union and its Member States, according to paragraph 5, Rule II of the Rules of Procedure of the Codex Alimentarius Commission as presented in CRD01.

ADOPTION OF THE AGENDA (Agenda Item 1)[1]

5. CCNFSDU44 adopted the Provisional Agenda with the addition of the proposals for analytical methods for provisions in the *Standard for infant formula and formulas for special medical purposes intended for infants* (CXS 72-1981), CXS 156-1987, and the *Guidelines for Use of Nutrition and Health Claims* (CXG 23-1997) for inclusion in the *Recommended Methods of Analysis and Sampling* (CXS 234-1999) (CRD05 Rev, proposed by AOAC INTERNATIONAL, C&G, ICC, IDF, ISDI and ISO) under Agenda Item 10 – other business:

6. CCNFSDU44 also agreed to establish an in-session working group (IWG), chaired by the United States of America (USA) open to all Members and Observers and working in English, French and Spanish to:

- consider proposals for analytical methods published in CRD05 Rev for provisions in CXS 72-1981, CXS 156-1987, and CXG 23-1997 for inclusion in CXS 234-1999; and
- to provide recommendations to CCNFSDU44 regarding the suitability of the methods for submission to CCMAS for review.

MATTERS REFERRED TO THE COMMITTEE BY THE CODEX ALIMENTARIUS COMMISSION AND/OR OTHER SUBSIDIARY BODIES (Agenda Item 2)[2]

7. CCNFSDU44 noted the information presented in CX/NFSDU 24/44/2 Rev.1.

8. The Codex Secretariat presented additional information from the two surveys conducted in 2022 and 2023 on the use and impact of Codex texts. The *General principles for the addition of essential nutrients to foods* (CXG9-1987) was one of the four Codex texts evaluated in the 2022 survey. However, only 48 Member countries out of 98 responded regarding its usage, and it was indicated that CXG 9-1987 was the least familiar and least utilized text of the texts surveyed. The Codex Secretariat emphasized the importance of participation in future surveys to improve understanding of these texts' relevance and effectiveness.

[1] CX/NFSDU 24/44/1
[2] CX/NFSDU 24/44/2

9. Regarding matters from CCEURO33 related to the development of dietary guidelines, the CCEURO Regional Coordinator announced that the registration deadline for the electronic working group (EWG) would be extended. The Coordinator encouraged Observer Members from outside the CCEURO region, as well as other Observers, to participate and contribute to the discussions.

10. Regarding matters for action, the Codex Secretariat reminded CCNFSDU that CRD04 Rev had been prepared to facilitate discussions on the request from CCMAS concerning nitrogen-to-protein conversion factors (Nx values).

11. CCNFSDU44 noted that the following matters would be addressed under relevant agenda items:

- Matters from CCFA53 concerning whether the *Standard for canned baby foods* (CXS 73-1981) permits the use of food additives 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) Part D as nutrient carriers (agenda item 5);
- Matters from CCFA54 regarding the technological need/justification of methacrylate copolymer, basic (BMC), in several CCNFSDU Standards (agenda item 5); and
- Matters from CCMAS43 relating to the consideration of revocation of Nx values in CCNFSDU standards (agenda item 10).

12. CCNFSDU44 encouraged Members and Observers to actively engage in discussions on the Codex Strategic Plan 2026-2031 by responding to CL 2024/82-CAC, requesting comments on a proposal on the draft goals and outcome statements for the Codex Strategic Plan 2026-2031.

MATTERS OF INTEREST ARISING FROM FAO AND WHO (Agenda Item 3)[3]

13. The Representative of FAO called the attention of CCNFSDU44 to the following issues included in CX/NFSDU 24/44/3 to be considered under relevant agenda items: 1) The FAO recently completed a literature review to assess the nutritional composition of foods made from plant-based protein sources, which are intended to replace animal-based products, and compared the nutritional composition of these products to their animal-based counterparts. The Representative noted that the report was expected to be released by the end of 2024 and will provide evidence to inform the new proposed work on “Guidelines including General Principles for the Nutritional Composition of Foods and Beverages made from Plant-based and other Alternative Protein Sources". 2) The FAO has also commissioned a series of background reviews of the evidence on the benefits and risks of Alternative Animal Source Foods (A-ASFs) looking into aspects including nutrition, environment, socio-economic considerations, and food safety. 3) The launch of a new “Food and Diet” domain on FAOSTAT, which is the corporate statistical database for food and agriculture. 4) Finally, in collaboration with the International Atomic Energy Agency (IAEA), a series of meetings have been held in the past two years to inform the development of a Joint FAO/IAEA database on ileal digestibility of protein and individual amino acids in foods.

14. The Representative of WHO reported on the joint FAO/WHO scientific advice activities. The Representative informed the Committee that the work to update nutrient intake values (NIVs) for infants and young children from birth through three years of age was now complete for calcium, vitamin D and zinc, and the Representative presented the NIVs for these three nutrients. A guidance document covering the three nutrients will be launched for public consultation in early 2025, with the final publication scheduled later in 2025. As for other nutrients, while FAO and WHO completed scoping reviews for iron, vitamin A, folate and magnesium, the Representative noted that a mechanism and resources were still to be explored for evaluating remaining nutrients.

15. The Representative presented other joint activities highlighted in CX/NFSDU 24/44/3 including the forthcoming Joint FAO/WHO Statement on the Principles of a Healthy Diet, the Joint IAEA/FAO/WHO meeting to review Human Energy Requirements held in June 2024, and the Joint FAO/UNICEF/WHO Healthy Diets Monitoring Initiative, which released its guidance in June 2024.

[3] CX/NFSDU 24/44/3

16. The Representative highlighted relevant WHO activities including: 1) four WHO guidelines on diet and health published since the last CCNFSDU meeting (total fat intake, saturated fatty acids and *trans*-fatty acids intake, carbohydrate intake, and use of non-sugar sweeteners); 2) three WHO guidelines under development (use of lower-sodium salt substitutes, polyunsaturated fat intake, and tropical oil consumption); and 3) two new WHO guidelines in the early stages (optimal intake of animal source foods, and consumption of "Ultra-processed" foods). The Representative further drew the attention of the Committee to the two guidelines on nutrition policies that were recently published (food marketing, and fiscal policies) and two more that were forthcoming (nutrition labelling policies (currently under public consultation), and school food nutrition policies).

17. The Representative also informed CCNFSDU that the WHO guideline for complementary feeding of infants and young children 6-23 months of age had been published in October 2023 and highlighted its key recommendations. The Representative also presented WHO's technical support on the International Code of Marketing of Breast-milk Substitutes including the Global Congress on Implementation of the International Code co-organized by WHO and UNICEF in June 2023, and the 2024 Code Status Report. Finally, the Representative shared with the Committee that the WHO guideline on the prevention and management of wasting and nutritional oedema (acute malnutrition) in infants and children under 5 years had been published in December 2023 and that the Ready-to-Use Therapeutic Foods (RUTF) was now included in the WHO Model List of Essential Medicines for the treatment of severe wasting and/or nutritional oedema in children older than 6 months.

18. Delegations expressed their appreciation to FAO and WHO for their work and further made the following points, amongst others:

- support should be provided to assist with the application of their guidelines as well as provision of FAO and WHO documents in languages other than English;
- the work of CCNFSDU should be supported through the provision of joint FAO/WHO scientific advice;
- the joint work of FAO and WHO is important to inform the difficult work that Codex has in transforming food systems; and
- expressed appreciation for WHO plans to better define ultra-processed foods.

Conclusion

19. CCNFSDU44 noted:

i. the information provided by FAO and WHO and expressed its thanks for their work; and

ii. some information would be considered under agenda items 4 and 6.

NRVS-R FOR PERSONS AGED 6 – 36 MONTHS (Agenda Item 4)

20. The Chairperson introduced the item and reminded CCNSFDU of the purpose of NRVs-R as defined in the preamble of the General principles for the establishment and use of NRVs-R for persons aged 6-36 months. The Chairperson explained that NRVs-R for consideration under this item may be used in the labelling of pre-packaged foods for special dietary uses (FSDU) intended for persons aged 6 – 36 months. The four relevant Codex texts for this age group are the *Standard for processed cereal-based foods for infants and young children* (CXS 74-1981), CXS 73-1981, and CXS 156-1987 and the *Guidelines on formulated complementary foods for older infants and young children* (CXG 8-1991). The Chairperson further reminded CCNFSDU that in the preamble, it was also stated that governments may:

- establish NRVs-R for food labelling that take into account country and region-specific factors; and
- consider whether to establish separate or combined food label NRVs-R.

21. The Chairperson also recalled that the General principles for the establishment of NRVs-R for persons aged 6 – 36 months and the values themselves would be included in the *Guidelines on nutrition labelling* (CXG 2-1985) and that a proposal of the Codex Secretariat would be considered.

22. Ireland, as EWG/PWG Chair, speaking also on behalf of the Co-Chairs Costa Rica and the United States of America, introduced the work of both the EWG and PWG noting that there had been significant progress on all three assigned tasks i.e. consideration of the draft general principles for establishing NRVs-R; a stepwise process to apply the draft general principles, and piloting the draft general principles on the agreed-upon nutrients. The EWG/PWG Chair reiterated the purpose of NRVs-R and explained the process followed for the derivation of the NRVs-R under consideration, noted that according to the Principles FAO/WHO was the primary source of information and in the absence of recent data from FAO/WHO, the general principles indicated that data from recognized authoritative scientific bodies (RASBs) could be considered.

23. The EWG/PWG Chair explained the different approaches for the derivation of the NRVs-R and the basis for values presented; and that the PWG had agreed on:

- the outstanding issues in the general principles,
- the schematic outline of the stepwise process for establishing NRVs-R for persons aged 6 – 36 months; and
- several NRVs-R (‘green list’) for advancing in the step process,

24. The EWG/PWG Chair further explained that the NRVs-R for magnesium and vitamin B12 required further consideration at the session; the NRVs-R in the “amber list” would require more consideration by the EWG; and due to time constraints the PWG could not discuss the text for the updated stepwise process and that it would need to be considered by CCNFSDU at the session.

25. The EWG/PWG Chair proposed that CCNFSDU consider the recommendations of the PWG in CRD03 as the basis for discussion.

26. CCNFSDU44 agreed to this proposal.

Location and presentation of the General principles for the establishment of NRVs-R for persons aged 6 – 36 months and the NRVs-R for persons aged 6 – 36 months

27. CCNFSDU44 agreed with the proposal of the Secretariat to include the:

- General principles as Part B in Annex 1 of CXG 2-1985; and
- the NRVs-R as section 3.4.4.2 with a note to clarify that the NRVs-R applied to the commodities covered by the four Codex texts, as follows: *“These NRVs-R can be used for the labelling of foods for special dietary uses for older infants and young children (6 - 36 months) for which there are existing Codex texts”.*

28. CCNFSDU44 noted that other consequential changes would be needed for sections 3.4.4, 3.4.4.1, 3.4.4.2 and Annex 1 to reflect the addition of Principles and NRVs-R for persons aged 6 – 36 months.

GENERAL PRINCIPLES FOR THE ESTABLISHMENT OF NRVS-R FOR PERSONS AGED 6 – 36 MONTHS (AT STEP 7) (Agenda Item 4.1)[4]

29. CCNFSDU44 noted that the only outstanding issues for discussion were in squared bracketed text in section 2 the definition for adequate intake (AI) and in section 3.2 the basis for establishing combined NRVs-R for persons aged 6 – 36 months.

Discussion

Definition for Adequate Intake (AI)

30. CCNFSDU44 agreed with the recommendation of the PWG to adopt the definition of AI provided by FAO/WHO and to remove the square brackets from the definition for AI.

Basis for establishing combined NRVs-R for persons aged 6-36 months

31. CCNFDSU44 considered the recommendation of the PWG for a revised option 3: “*NRVs-R should be derived for persons aged 6 – 12 months and 12 – 36 months from suitable data sources according to 3.1 and the appropriate basis described above. The combined NRV-R value for persons from 6-36 months should be determined by calculating the mean value of the two age groups 6 – 12 months and 12 – 36 months*.”

[4] CX/NFSDU 24/44/4 (Part A); CX/NFSDU 24/44/4 Add.1

32. Delegations expressed diverse views as follows.

- selecting the higher value as long as it doesn't exceed the upper limit (UL) for the older infants and/or young children (option 1) noting that for older infants their main source of nutrition could still come from breastfeeding whereas for young children, the main source of nutrition tends to come from a diverse variety of complementary foods. Therefore, the selection of complementary foods during this age stage was important and food labelling played an important role for young children. The other options could lead to inadequate nutrient intake for young children, which potentially could have negative impacts on their health.
- selecting the lower value (option 2) noting that such a combined value would likely be used for labelling of processed cereal-based foods and canned baby foods. The majority of products sold and consumed lies at the beginning of the age range and not at the end. Therefore, a value derived from option 2 would be more appropriate for this situation. After 12 months of age in many countries, it is recommended that there is a move towards a family adapted diet, meaning that there are no specific foods for children in this age group. Therefore, having NRVs-R for foods which do not cover this age group (12 – 36 months) did not make sense. Older infants were the most vulnerable and should be protected from higher intakes than necessary.

33. China explained that if CCNFSDU44 did not agree with selecting the higher value, then they would express their reservation.

34. A Member also proposed that CCNFSDU consider a new proposal that ""If there is no UL available for older infants or young children, but a UL exists for another age range, the combined value will be calculated by averaging the NRVs-R for the two age groups (6-12 months and 12-36 months). If no UL exists for any age range, the highest NRVs-R value for older infants and young children will be selected". Some Members expressed a preference for a consistent approach to be taken for all nutrients.

35. Delegations supporting option 2 however explained that they understood there was wide support to use the mean value (option 3) and in the spirit of compromise could accept the recommendation of the PWG.

36. Reasons for supporting option 3, selecting the mean value of the proposed NRVs-R (recommendation of the PWG) were that using the mean value made it easier to give consistent nutritional advice and made sure that products made for this age group are safe to eat for older infants. This would avoid the risks of choosing the highest or lowest values which could lead to an overconsumption or insufficient supply of nutrients.

37. CCNFSDU44 agreed to use the mean value for the combined NRVs-R for persons aged 6 – 36 months (option 3) and to remove the square brackets.

Conclusion

38. CCNFSDU44 agreed to advance the General principles for establishing nutrient reference values for persons aged 6 to 36 months to Step 8 for adoption by CAC47 (Appendix II, Part A) and inclusion in CXG 2-1985 as Annex 1, Part B.

NRVS-R FOR PERSONS AGED 6 – 36 MONTHS (AT STEP 4) (Agenda item 4.2) [5]

Stepwise process for establishing NRVs-R for persons aged 6 – 36 months

39. The Chairperson clarified that the stepwise process should mirror the General Principles. The PWG visualized the stepwise process in the form of a schematic outline with the following changes: In Step 1 the PWG proposed to add "clarify DIRVs with FAO/WHO, if needed, and select for establishing NRVs-R". A Member Organisation clarified that the PWG had agreed that this should not be understood as a possibility of scrutinizing the FAO/WHO values. In Step 3A the PWG agreed that not only data provided by FAO/WHO should be taken into account when physiological data are available. The PWG drew attention to the new step 4 added to the stepwise process to review the resulting NRVs-R on a case-by-case basis. This check shall consider scientific rigour of the methods, underlying data and data quality and all available evidence. The PWG chair clarified that the term 'all available evidence' also includes available Health Based Guidance Values (HBGV).

40. CCNFSDU44 considered the revised schematic outline of the updated revised stepwise process and agreed with the schematic outline making editorial amendments for purposes of clarity.

[5] CX/NFSDU 24/44/4 (Part B Rev); CX/NFSDU 24/44/4 Add.1

41. CCNFSDU44 then considered whether it was necessary to also have the stepwise process explanatory text.

42. Views were expressed that the schematic outline was sufficient for the purpose of the description of the derivation process of the NRVs-R and it was unnecessary to duplicate it, while other views were expressed to retain the stepwise process text that was provided in Table 1 Appendix II of CRD03 to provide more explanation, but to revise it to mirror the agreed schematic outline.

43. CCNFSDU44 considered a proposal from the EWG/PWG Chair for a more simplified version of the descriptive stepwise process text which had been aligned with the schematic outline and made some editorial amendments for clarity and consistency with the schematic outline.

Conclusion

44. CCNFSDU44 agreed to retain the amended text to describe the stepwise process together with the schematic outline presented in Appendix II figure from CRD03.

NRVs-R (Appendix III of CRD03)

45. The EWG/PWG Chair drew attention to recommendation 1 in CRD03 that the tables in the 2021 FAO Report would be updated further with the new NIHN data (updated in 2020) and that the PWG had agreed that CCNFSDU would reconsider any NRVs-R that changed based on new information on the derivation of the NIHN values. PWG Chair reported that the derivation of the updated NIHN values remain identical which was confirmed by Japan. Consequently, the NRVs-R as proposed didn´t change. CCNFSDU44 agreed with recommendation 1.

46. The Chairperson pointed out that under item 3 FAO/WHO presented updated DIRVs for calcium, vitamin D and zinc. According to step 1 of the stepwise process the values are selected as NRVs-R. The Committee agreed to the respective NRVs-R.

47. The EWG/PWG Chair proposed to categorize the NRVs-R in two groups:

- the 'green light' NRVs-R, listed in Table 1, 2 and 3 of Appendix III, CRD03 that were recommended to be adopted; and
- the 'amber light' NRVs -R, listed in Table 4 of Appendix III which the PWG did not discuss values and a deeper review by an EWG would be needed.

48. CCNFSDU44 noted that the units for the expression of nutrients would be aligned with the NRVs-R for the general population as illustrated in CXG 2 – 1985 and would include the unit of expression for copper (µg). It was clarified that the conversion factors for vitamins A, E and niacin were already listed in CXG 2-1985.

49. The EWG/PWG Chair also recalled that the PWG had not addressed the rounding of the values and that this should be addressed by plenary.

50. A Member recalled that CCNFSDU had agreed on a more systematic approach to rounding of values during the discussion on the review of the CXS 156-1987 (see also agenda item 7). CCNFSDU agreed to use the rounding rules as listed in by hyperlink in CX/NFSDU 24/44/7 and consideration of the specificity of the values used by the RASBsThe PWG Chair presented the rounded NRVs-R.

51. CCNFSDU44 agreed to the rounded nutrients listed in Appendix II.

52. The PWG could not reach consensus on the NRVs-R proposed for vitamin B12 and magnesium and agreed to discuss these nutrients at plenary.

53. In the course of applying step 4 the plenary expressed diverse views on whether to use Approach 1 or 2 and the mean or median values to derive the NRVs-R for magnesium and vitamin B12 (Table 3, Appendix III of CRD03).

Vitamin B12

54. A Member Organisation supported by other Members indicated that the NRV-R for vitamin B12 for older infants and young children was too low and did not take into account the EFSA value. The Member Organisation explained that for Vitamin B12 EFSA and Nordic Council of Ministers (NCM) DIRVs are considered as "outliers" and thus the mean of all DIRVs is recommended. However, rather than treating them as outliers, it would be more appropriate and consistent with the general principles to consider EFSA and NCM DIRVs as reflecting an evolution of the scientific data on the vitamin (biomarkers data) and of the interpretation of these data. The Member Organisation further noted that the newer EFSA value is downgraded twice due to the use of the median and all data available (approach 2).

55. However, other Members noted that all global data were considered, including that from National Institute of Health and Nutrition (NIHN) which was conducted in 2020, more recently than EFSA, and that the stepwise process had been followed. It was further noted that EFSA also noted uncertainties with respect to cut-off values for the serum B12 biomarkers. The application of step 4 reflected the best available evidence with respect to establishing the value and thus aligned with the agreed process, which accounted for significant differences in dietary intakes and was necessarily relevant when setting global values.

56. The EWG/PWG Chair pointed out that the DIRVs were based on intake data from RASBs and vitamin B12 requirement is heavily based on the intake of animal products. As a response a Member Organisation clarified that EFSA values took into account the biomarker data, which were not influenced by dietary intake but the function of vitamin B12 itself.

57. The EWG/PWG Chair clarified the RASBs were looking at their own region and their requirements. The EWG/PWG Chair further explained that for the establishment of the NRVs-R, the PWG had used the median, which had the advantage of excluding outliers. The EWG/PWG Chair indicated that at step 4, all data were considered. As a compromise the EWG/PWG chair proposed that CCNFSDU consider the mean value.

58. There was no consensus on this proposal, and it was noted that this was not consistent with the approach taken for the other NRVs-R agreed at the session.

59. There was no consensus on the NRVs-R for vitamin B12 and CCNFSDU44 agreed to transfer NRVs-R for vitamin B12 to the “amber list” for further consideration by the EWG.

Magnesium

60. There were diverse views on the NRVs-R for magnesium and no consensus could be reached on the proposals. Most of the arguments related to the use of some of the more recent data, in particular from EFSA and NCM.

61. A Member Organisation mentioned that the value for young children for magnesium, EFSA and NCM DIRVs were, in their view, wrongly classified as category 3 and thus not considered in the calculation of the proposed NRVs-Rs. This overlooked the scientific considerations made in the derivation of these DIRVs, which were motivated by the high uncertainty in the data underpinning existing INL98.

62. It was clarified by the EWG/PWG Chair and other Members once again that all requirements had been met for step 4 of the process. The EWG/PWG chair highlighted that when using category 3 data on nutrient intakes, it needed to be looked at globally and all regions need to be taken into account.

63. An Observer did not support the proposed NRVs-R noting that it was important to take into account the magnesium to calcium ratio.

64. The Chairperson, noting that there was no consensus, proposed to transfer the NRVs-R for vitamin B12 and magnesium to the ‘amber list’. CCNFSDU44 agreed with the Chairperson’s proposal.

“Amber light” NRVs-R

65. CCNFSDU44 agreed to re-establish the EWG with the following terms of reference:

- Apply the Stepwise Process to propose NRVs-R for persons aged 6-12 months, 12-36 months and 6-36 months for the following nutrients in the “amber list”:

  vitamins C, K, and B12, folate, biotin, selenium, manganese, phosphorus, iron, magnesium;

66. CCNFSDU44 agreed to keep open the option of a PWG prior to the next session to consider comments and prepare revised proposal for CCNFSDU45.

Conclusion

67. CCNFSDU44 agreed to:

i. advance the NRVs-R for Vitamins A, B6, D and E, thiamin, riboflavin, niacin, pantothenic acid, calcium, copper, iodine, potassium, zinc and protein to Step 8 for adoption by CAC47 and inclusion in CXG 2-1985 (section 3.4.4.2) (Appendix II, Part B);

ii. request the Codex Secretariat to publish the Stepwise Process as an information document on the Codex website for internal use by CCNFSDU (Appendix III);

iii. return to Step 2/3 the remaining NRVs-R for Vitamins C, B12, and K, folate, biotin, selenium, manganese, magnesium, phosphorous and iron for development using the stepwise process through an EWG chaired by Ireland and co-chaired by the United States of America and Costa Rica, working in English and Spanish; and request the EWG to update the tables that are presented in Appendix II of CX/NFSDU 24/44/4 (Part B Rev) with NIHN data;

iv. inform CCEXEC of the deadline for completing the work should be extended to 2026 (since CCNFSDU will not be meeting in 2025); and

v. keep open the possibility to convene a PWG prior to the next session to review comments and prepare a revised proposal for CCNFSDU45.

TECHNOLOGICAL JUSTIFICATION FOR SEVERAL FOOD ADDITIVES (Agenda Item 5)

Technological justification for five food additives (guar gum (INS 412), distarch phosphate (INS 1412), phosphated distarch phosphate (INS 1413), acetylated distarch phosphate (INS 1414) and hydroxypropyl starch (INS 1440))[6]

68. The European Union (EU), as chair of the EWG, introduced the item, noting that CCNFSDU is responsible for evaluating the technological justification for using food additives in products covered by its standards. CCFA48 confirmed that CCNFSDU should assess the need for additives in infant formula before they were included in the JECFA priority list. CCNFSDU38 began developing a framework for this assessment, which was completed and published by CCNFSDU41. JECFA's review (CCFA49/CRD15Rev) identified that some additives in infant formulas lacked risk assessment for infants under 12 weeks. At CCNFSDU43, work on these additives was split into five batches, with decisions made on batch 1 and work to continue on batch 2. The outcomes of CCNFSDU43 were considered by CCFA53, resulting in the inclusion of several additives in JECFA's priority list for re-evaluation of safety to address consumption by infants under 12 weeks of age.

69. The EWG Chair further explained that following CCNFSDU43's request, the EWG had conducted two consultations on additives in batch 2, including guar gum (INS 412), distarch phosphate (INS 1412), phosphated distarch phosphate (INS 1413), acetylated distarch phosphate (INS 1414), and hydroxypropyl starch (INS 1440). It was confirmed that these additives were not used in current products and there was no commitment to generate data for safety assessments. The EWG concluded that there was no technological need for these additives in products conforming to CXS 72-1981.

70. An Observer supported the EWG's conclusion, noting that their internal survey found no current use of the additives in question, although this might not be expected in future batches. They highlighted the industry's efforts to minimize the use of food additives in infant formula, aligning with the principles outlined in the *General standard for food additives* (GSFA, CXS 192-1995).

Conclusion

71. CCNFSDU44 agreed with the EWG's recommendation.

Matter from CCFA53 on whether CXS 73-1981 permits the use of the food additives listed in CXG 10-1979 Part D as nutrient carriers[7]

72. The Chairperson recalled that this was a matter referred by CCFA53 and provided some background information. It was explained that CXG 10-1979 Part D contains five food additives which may be used in ready-to-use foods for infants and young children, without differentiating between canned baby foods and cereal-based foods. The Chairperson noted that in the GSFA, Note XS73 stating "excluding products conforming to the *Standard for canned baby foods* (CXS 73-1981)" had been associated with several food additives in Food Category 13.2, "Complementary Foods for Infants and Young Children".

73. To address CCFA53's request regarding these food additives, the Chairperson proposed the following three options for consideration:

- Option 1: inform CCFA that CXS 73-1981 permits the use of food additives listed in CXG 10-1979 Part D as nutrient carriers.
- Option 2: inform CCFA that CXS 73-1981 does not permit the use of food additives listed in CXG 10-1979 Part D as nutrient carriers.

[6] CX/NFSDU 24/44/5
[7] CX/NFSDU 24/44/2 Rev. 1

- Option 3: Add the request from CCFA53 to the ToRs of the EWG if options 1 or 2 cannot be agreed upon.

74. A Member Organisation emphasized that, according to Section 3.1.2 of CXS 73-1981, vitamins and minerals may only be added in accordance with the legislation of the country in which the food is sold. Therefore, if these nutrients were allowed in foods conforming to CXS 73-1981, the use of nutrient carriers listed in CXG 10-1979 Part D in foods conforming to CXS 73-1981 should also be technologically justified.

75. This Member Organisation further noted that four out of the five additives listed in CXG 10-1979 Part D (i.e. gum arabic (Acacia gum) (INS 414), silicon dioxide, amorphous (INS 551), mannitol (INS 421), and sodium ascorbate (INS 301)), were not included in CCFA49/CRD15 Rev and had not been evaluated by JECFA for use in foods intended for infants under 12 weeks. This was further confirmed by the Codex Secretariat with the JECFA Secretariat. The Member Organisation proposed adding these four additives to the work plan as batch 6 for further evaluation.

76. In response to a query on the mechanism for handling food additives listed in CXG 10-1979 Part D, the Codex Secretariat clarified that, since the food additive provisions in CXS 73-1981 had been aligned with those in the GSFA, once CCNFSDU confirmed their permission, CCFA would take necessary actions, such as removing Note XS 73 from the pertinent provisions in the GSFA. For the four additives lacking JECFA evaluation, they would undergo the technological justification assessment within CCNFSDU. After this process, CCFA would proceed with the appropriate actions.

77. In response to the suggestion to revoke CXS 73-1981 as it was not fit for purpose, the Codex Secretariat clarified that the review of CCNFSDU standards and any new work proposals would be addressed under the relevant agenda items.

Conclusion

78. CCNFSDU44 endorsed option 1 as proposed by the Chairperson.

79. CCNFSDU44 also agreed to include the four food additives as indicated above (paragraph. 72) as batch 6 in the work plan.

Matter from CCFA54 on the technological need/justification for methacrylate copolymer, basic (BMC) (INS 1205) [8]

80. The Chairperson recalled that this issue was from agenda item 2 and proposed referring it to the EWG, to be established by CCNFSDU44 under this agenda item.

81. A Member supported the proposal that BMC should be considered by the EWG and underscored the urgent need to address BMC in light of high child mortality rates in developing countries, particularly in Africa and Asia. Vitamin A deficiency was identified as a significant contributor to child mortality. The Member emphasized the necessity of fortifying foods with vitamin A, noting that environmental factors such as light, heat, and humidity could reduce its effectiveness and BMC was considered as an important means to protect vitamin A from degradation, enhance its bioavailability, and improve immune responses. The Member urged CCNFSDU to support CCFA's request for a technological justification for the use of BMC in specific products, aiming to improve vitamin A supply and reduce child mortality.

82. Another Member pointed out initiatives to combat global micronutrient deficiencies through supplements and food fortification. It was reiterated that vitamin A deficiency, along with other micronutrient deficiencies, remained a pressing challenge. It was acknowledged that BMC, as a critical tool, could significantly enhance the fortification and availability of these essential nutrients for young children. The Member expressed support for advancing this issue through the established processes to assess the technical justification for this food additive and facilitate necessary future approvals.

Conclusion

83. CCNFSDU44 agreed with the Chairperson's proposal.

Overall Conclusion on Food Additives

84. CCNFSDU44 noted that gum arabic (Acacia gum) (INS 414), silicon dioxide, amorphous (INS 551), mannitol (INS 421), and sodium ascorbate (INS 301) would be included as batch 6 in the work plan for future technological justification appraisal.

[8] CX/NFSDU 24/44/2 Rev. 1

85. CCNFSDU44 agreed to inform CCFA that:

i. there was 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 and request that CCFA take appropriate actions; and

ii. CXS 73-1981 permitted the use of the food additives listed in CXG 10-1979 Part D as nutrient carriers.

86. CCNFSDU44 also agreed to establish an EWG open to all Members and Observers, chaired by the EU, working in English with the following ToRs:

i. to collect information from the applicants:

a. on the use and use levels in foods conforming to CXS 72-1981 and confirmation to provide data on the safety assessment for infants below 12 weeks of age on the following additives: lactic acid, L-, D-, and DL- (INS 270), lecithins (INS 322i), citric acid and citrates (INS 330, 331(i), 331(iii), 332(i), 332(ii)), mono- and diglycerides of fatty acids (INS 471) and methacrylate copolymer, basic (BMC) (INS 1205);

b. using the framework for considering technological justification:

- on use in CXS 72-1981 for additives for which the use, use levels and commitment to provide the data is confirmed in point a;
- for use of methacrylate copolymer, basic (BMC) (INS 1205) in CXS 156-1987; CXS 73-1981; CXS 74- 1981; and *Guidelines for ready-to-use therapeutic foods* (RUTF) (CXG 95-2022); and

ii. to review the information provided and provide recommendations to CCNFSDU45 on the technological justification of each food additive use.

PRIORITIZATION MECHANISM / EMERGING ISSUES OR NEW WORK PROPOSALS (Agenda Item 6)

87. The Chairperson recalled the history of developing the prioritization mechanism for emerging issues or new work proposals. In response to requests from CCEXEC70 and CCEXEC75, CCNFSDU41 considered the draft *Guideline for the preliminary assessment to identify and prioritize new work for CCNFSDU* (hereafter referred to as "the Guideline"), developed by the host secretariat, and agreed to be piloted. CCNFSDU42 postponed reviewing new work proposals and continued revising the Guideline. At CCNFSDU43, the Guideline was piloted, and an EWG was established for further revisions. Before this plenary session, a PWG revised the Guideline and used it to rank new work proposals. The Chairperson also noted that the Codex Secretariat was preparing practical guidance for new work proposals which will also include an overview of existing new work procedures and prioritization mechanisms, expected to be available in 2025. The Chairperson emphasized that the Guideline was intended as internal tool for CCNFSDU to provide practical guidance for assessing and prioritizing new work.

88. Canada, as Chair of the EWG/PWG, speaking also on behalf of the Co-Chair Germany, introduced the work carried out by both the EWG and PWG. Two rounds of consultations were held within the EWG, resulting in revised guidelines that clarified how the prioritization mechanism complements the criteria for work priorities in the Procedural Manual. The EWG recommended that "One Health" and "consumer interests" be excluded and incorporated a numerical rating system to assess impacts. During the PWG meeting, the Guideline was further revised, two out of the four new work proposals received passed the review as to scope and rationale for clarity, and were rated and ranked, and recommendations were made to improve the rating process, including pre-rating by the Chairs or a small committee. The PWG report was published as CRD02 Rev.

89. CCNFSDU44 agreed to use CRD02 Rev as the basis for discussion.

GUIDELINE FOR THE PRELIMINARY ASSESSMENT TO IDENTIFY AND PRIORITIZE NEW WORK FOR CCNFSDU (Agenda Item 6.1)[9]

90. CCNFSDU44 considered the recommendations from the PWG.

[9] CL 2024/52-NFSDU, Appendix I

91. In response to requests for clarification regarding the new text in the decision tree at Step 5, "No" option (CRD02 Rev Appendix I) the EWG/PWG Chair explained that the alternatives (i.e. rejecting the new work proposal or requesting further information) were indicated when additional work was required due to an unclear scope or existing gaps. In these cases, the proposal should be resubmitted in response to a Circular Letter calling for new work. In response to a request to clarify if the EWG/PWG Chair or small committee would pre-rate proposals, the Chairperson explained that it is reflected in the PWG report but that the Guideline was not amended as it doesn’t go into this level of detail.

92. Regarding the suggestion to include specific paragraphs from the Codex Procedural Manual (PM), such as paragraph 42, in the Guideline, it was clarified that the Guideline serves as a complement to the PM. A general reference to the relevant section of the PM was included, making it unnecessary to repeat all relevant paragraphs.

93. A Member emphasized the crucial importance of assessing both public health impact and global consequences of standards. They highlighted the need for evaluations to consider the supply value chain of food production and processing, particularly in relation to Sustainable Development Goals (SDGs), for example, SDG13 climate action. The Member asserted that Codex should actively contribute to achieving these goals.

94. In response to the Member's suggestion, the Codex Secretary noted that while the topic was not currently addressed in the PM, the Codex Strategic Plan for 2026-2031 was in development, with future directions for Codex being identified. Members and Observers were encouraged to engage in strategic discussions linking these global issues, as outlined in CL 2024/82-CAC.

95. A Member emphasized the necessity for a more objective approach to minimize subjective bias within the ad hoc working group. It was suggested that employing clear methodologies, such as checklists, could enhance the decision-making process and ensure a fair and transparent assessment. This was noted for future consideration if updating the Guideline.

96. Another Member recommended that the submitter of a new work proposal should recuse themselves from the rating process.

97. CCNFSDU44 noted that the Guideline document was a living document and could be amended in the future as experience was gained in its use for evaluating and prioritizing new work proposals.

Conclusion

98. CCNFSDU44 agreed:

i. to revise paragraph 13 of the Guideline to align it with the review process as piloted in the PWG (CRD02 Rev, paragraph 48);

ii. to the decision tree for the preliminary assessment of new work proposals for CCNFSDU as amended in the PWG (CRD02 Rev Appendix I).

99. CCNFSDU44 further agreed to:

i. request the Codex Secretariat to publish the Guideline as an information document on the Codex website (Appendix IV);

ii. continue using the Guidelines to evaluate and prioritize new work proposals, as necessary; and

iii. inform CCEXEC87 accordingly.

PROPOSALS FOR NEW WORK/EMERGING ISSUES (REPLIES TO CL 2024/52-NFSDU) (Agenda item 6.2) [10]

DISCUSSION PAPER ON HARMONIZED PROBIOTIC GUIDELINES FOR USE IN FOODS AND FOOD SUPPLEMENTS (Agenda item 6.21) [11]

100. The three new work proposals outlined in agenda item 6.2 and the new work proposal in agenda item 6.21 were considered by the PWG.

[10] CX/NFSDU 24/44/6 Rev
[11] CX/NFSDU 24/44/6 Add.1

Proposal 1.3 Proposal to open and amend the 2009 Codex definition of dietary fibre included under paragraph. 2 in the *Guidelines on nutrition labelling* (CXG 2-1985): Submitted by the Calorie Control Council

101. The EWG/PWG Chair summarized the discussions from the PWG. It was noted that: (i) there was no justification for changing the definition of dietary fibre based on current evidence; (ii) the existing definition represented a satisfactory compromise reached after extensive discussions; and (iii) the definition provides flexibility, and many authorities recommend increasing the consumption of fruits, vegetables, pulses, and whole grains to enhance fibre intake. The PWG concluded that there was no need to amend the definition of dietary fibre in the *Guidelines on nutrition labelling* (CXG 2-1985).

102. The Chairperson informed the Committee that during the PWG, the Representative of WHO had stated that the current definition is satisfactory as it stands and should not be changed. WHO's recommendation is to increase dietary fibre intake as to those naturally occurring in food.

103. CCNFSDU44 endorsed the PWG's recommendation to reject the proposal.

Proposal 2.1 Harmonized probiotic guidelines for use in foods and food supplements: Submitted by Argentina, Malaysia and China

104. The EWG/PWG Chair summarized the discussions in the PWG, highlighting the lack of consensus on the proposal's scope and the divergent views regarding its progression. Therefore, the PWG recommended to reject the proposal.

105. Malaysia, as co-Chair of the EWG on this subject and speaking on behalf of Argentina (the EWG Chair, who was unable to attend) and Co-Chair China, emphasized four key points to address the concerns raised by Members during the PWG meeting:

- regarding expectations from the proposal: Members sought harmonized guidance on definitions, minimum characterization, safety requirements, and labelling parameters specific to probiotic microorganisms. There was no expectation that CCNFSDU would evaluate the safety and efficacy of specific strains or create positive or negative lists of approved strains;
- regarding the rationale for the guidelines: Members from various regions emphasized that numerous probiotic products were available in their markets, backed by scientific support for health benefits. However, concerns about dubious products that did not meet established definitions and might contain harmful organisms had been raised;
- regarding the development process: the guidelines would utilize the two FAO and WHO reports (i.e. "Health and Nutrition Properties of Probiotics in Food including Powder Milk with Live Lactic Acid Bacteria" (2001) and "Guidelines for the Evaluation of Probiotics in Food" (2002) [12,13] as a scientific basis. Given the recognition of the validity of these reports, they would be officially incorporated into Codex as guidelines to ensure harmonized use among Members; and
- regarding the utilization of the guidelines: the guidelines would be voluntary in nature and would assist many countries in developing national legislation, ensuring that probiotic products met safety criteria and were appropriately labelled so that consumers could make informed choices.

106. China, as co-Chair of the EWG, added that the guidelines would be developed in line with FAO and WHO recommendations. It aimed to assist Members in effectively integrating these recommendations into their national regulations, thereby enhancing human health, food safety, consumer protection, and global trade in a cooperative and consistent manner.

107. Delegations supporting the new work proposal expressed the following views:

- The absence of internationally harmonized guidelines created trade barriers, especially for developing countries that relied on Codex for regulatory guidance.

[12] Probiotics in Food, Health and Nutritional properties and guidelines for evaluation, https://openknowledge.fao.org/server/api/core/bitstreams/382476b3-4d54-4175-803f-2f26f3526256/content

[13] Guidelines for the Evaluation of Probiotics in Food, Report of a Joint FAO/WHO Working Group on Drafting Guidelines for the Evaluation of Probiotics in Food, published in 2002, https://isappscience.org/wp-content/uploads/2019/04/probiotic_guidelines.pdf

- Establishing guidelines would ensure beneficial microorganism levels and clear labelling, facilitating informed consumer choices and assisting national authorities in creating local standards.
- Intestinal microorganisms were vital for immune health and linked to metabolic diseases, underscoring the need for guidelines that protect consumers from improper probiotic absorption.
- With the increasing industrial value and global consumption of probiotics, establishing a universally recognized Codex framework was crucial, particularly for Members lacking resources for independent studies.
- Probiotics were prevalent in food and food supplements, necessitating harmonized guidelines that set specifications to ensure their quality and safety in the global market.
- As the use of probiotic-containing products grew, localizing specific strains to regions or countries was essential. Establishing national gene banks for probiotic bacteria and validating the physiological effects of these strains might be needed.
- The guidelines would assist national and regional authorities in legislative processes and recommend *in vitro* and *in vivo* methods for evaluating probiotic functionality and safety.

108. One Member, while not objecting to the proposal, expressed concerns regarding its scope. They noted that the term "probiotic" was considered a health claim and would conflict with their national legislation, where no health claims had been approved. The Member also highlighted that the current definition suggested a general health benefit for probiotics, which could mislead consumers. They stressed the importance of ensuring that a harmonized definition of probiotics did not imply health benefits without sufficient scientific evidence.

109. Another Member mentioned that they had established their own regulations on probiotics based on FAO/WHO guidelines and other scientific references. In the view of several Members, this work should not be a priority for CCNFSDU.

110. Delegations not in support of the new work proposal expressed the following views:

- The proposal's scope remained unclear, with many Members seeking guidance on the efficacy and safety of specific probiotic strains.
- Existing FAO/WHO guidelines were considered sufficient, and the proposal did not address the expressed needs.
- The term probiotics was classified as health claims, requiring strain-specific studies for substantiation; thus, CCNFSDU might not be the appropriate forum for this issue.
- The proposal was viewed as premature and not a priority, as it did not provide added value given that these topics had already been covered in the FAO/WHO guidelines.
- The work required to assess benefits and safety of probiotic strains would require an independent systematic review of available scientific evidence, necessitating adequate resources.. Both benefits and safety assessments should be conducted by the relevant joint scientific bodies of FAO and WHO, such as JEMNU, or from other internationally recognised expert bodies, as approved by the Commission; and
- Current studies could not provide high-quality evidence supporting the benefits of probiotics, and labelling them could pose risks, particularly to vulnerable populations, such as premature and low-birth-weight infants.

111. The Representative of FAO invited Members to reflect if their needs would be met with updated guidelines of FAO/WHO and agreed to update them. The Representative noted that Members could seek technical support from FAO and WHO to strengthen their capacities in establishing national standards.

112. The Representative of WHO explained that if CCNFSDU chose to heavily rely on or transpose the FAO/WHO documents into Codex text, the FAO/WHO documents should be reviewed due to their age and the need to align them with current data and evidence.

113. In view of the challenges in achieving consensus on the matter, the Chairperson proposed requesting FAO and WHO to review the document titled “Guidelines for the Evaluation of Probiotics in Food.” Once the Guidelines from FAO and WHO have been reviewed and a literature review of additional scientific evidence on probiotics have been completed, CCNFSDU could decide to consider a piece of new work as to probiotics.

114. CCNFSDU44 noted the widespread support for the Chairperson's proposal.

Conclusion

115. CCNFSDU44:

i. agreed to request FAO and WHO to conduct a review of the documents "Health and Nutrition Properties of Probiotics in Food including Powder Milk with Live Lactic Acid Bacteria" (2001)and "Guidelines for the Evaluation of Probiotics in Food" (2002), incorporating a literature review of scientific evidence on probiotics;

ii. noted the willingness of FAO and WHO to take over this task and encouraged Members to provide resources to support FAO and WHO to conduct this review; and

iii. noted that once the review of the two documents were completed, a new work proposal on probiotics could be submitted in response to the CL and could be reconsidered by CCNFSDU

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 USA

116. The EWG/PWG Chair summarized the discussions in the PWG, highlighting that the proposal received a rating of 7 points, making it the second priority out of the two rated proposals. The EWG/PWG Chair highlighted the voluntary nature of the proposal and recommended forwarding the proposal for approval by the Committee. It was noted that FAO had conducted a review on the matter, with the report expected by the end of 2024. Based on recommendations from the PWG meeting, the submitters revised the project document to exclude bacteria, insects, fungi, and labelling considerations, and refined the title to "protein from plant sources". The revised project document was presented in CRD36 Rev2.

117. Diverse views were expressed on the proposal. For delegations not opposing the proposal, certain questions or concerns remained on certain aspects of the proposal, while other delegations, not supporting the proposal, questioned its feasibility, usefulness and the added value of developing guidelines at this time.

118. CCNFSDU44 noted the following views:

- The proposal focused exclusively on plant-based foods, responding to consumer interest and dietary trends, but lacked sufficient scientific evidence to justify establishing Codex guidelines.
- Both plant and animal-based foods offered nutritional benefits, but over- or under consumption of either could pose health risks, and consumer education was suggested as a solution rather than relying solely on plant-based options. Establishing nutrient profiles for plant-based products was challenging due to significant variations in nutrient composition and regional dietary differences.
- Setting strict nutrient composition standards might reduce consumer choice and innovation, while existing guidelines provided flexibility for national authorities in managing nutrient intake.
- This proposal could lead to increased consumption of ultra-processed foods
- Developing specific nutritional guidelines for plant-based foods was considered premature and redundant.
- The existing General principles for the addition of essential nutrients to foods (CXG 9-1987) provides broad recommendations for the addition of essential nutrients to substitute foods and allows national and regional competent authorities to address adequately the issues highlighted in the project document
- The FAO report needs to be reviewed, once published, to get a better understanding of the issue.

119. In response to the EWG/PWG Chair's suggestion to forward the new work for approval at CAC47 and initiate the EWG work following the publication of the FAO report, a Member questioned if this work might need refinement after publication and review of the FAO report. The submitter suggested that the work could move forward and analysis of the FAO report be included in the ToR of the EWG.

120. The Codex Secretariat emphasized the importance of having clear work objectives. It was noted that ambiguity could hinder progress and lead to inefficiencies. Using the time before the next session to refine the proposal based on the forthcoming FAO report could help avoid repeated discussions or potential rejection by CCEXEC and CAC. This approach would ultimately save time and improve overall effectiveness.

121. The Chairperson proposed two options: submit the proposal for approval at CAC47, which may encounter delays at CCEXEC and CAC, or return it to the submitters for further development while awaiting the FAO's publication to refine the proposal.

122. CCNFSDU44 noted widespread support for the second option.

Conclusion

123. CCNFSDU44:

i. agreed to return the proposal to the submitters for further development, emphasizing the need to consider the forthcoming FAO publication; and

ii. noted the revised proposal could be submitted in response to the Circular Letter for new work proposals.

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

124. The EWG/PWG Chair summarized the discussions in the PWG, noting that the proposal received 14 points, ranking it as the top priority. Based on recommendations from the PWG meeting, the submitters revised the project document, excluding the *Guidelines on formulated complementary foods for older infants and young children* (CXG 8-1991) from the scope, removing "formulated complementary" from the title of the standard, and making related adjustments to clarify the scope of the work. The updated project document was presented in CRD36 Rev2.

125. One Member expressed support for advancing the proposal but emphasized the need to carefully consider the title of the standard to ensure its objectives were clear. They referred to previous discussions on supplementary and complementary foods, suggesting the focus should include foods for infants during the weaning period, specifically targeting those up to 24 or 36 months of age.

126. Another Member also requested clarification regarding the title of the standard.

127. There was general support to submit this new work proposal as contained in CRD36 Rev2 for approval by CAC47 and establish an EWG to work on it.

Conclusion

128. CCNFSDU44 agreed to:

i. forward the project document to CAC47 for approval as new work (Appendix V);

ii. establish an EWG, chaired by the USA and co-chaired by EU, Kenya and Panama, working in English and Spanish, and subject to approval of CAC47, to prepare the proposed draft standard for circulation for comments at Step 3 and consideration at CCNFSDU45; and

iii. keep open the possibility of a PWG to meet prior to CCNFSDU45.

129. CCNFSDU44 noted that the title of the standard could be further discussed and determined within the EWG.

OTHER CONCLUSIONS FOR AGENDA ITEM 6

130. CCNFSDU44 agreed:

i. to request the Codex Secretariat to issue a Circular Letter requesting for proposals for new work and emerging issues for consideration at CCNFSDU45; and

ii. that an ad-hoc PWG, chaired by Germany and co-chaired by Canada, with the ToR as set in paragraph 13 of the Guideline for the Preliminary Assessment to Identify and Prioritize New Work for CCNFSDU (see Appendix IV), working in English, French and Spanish, might be established and meet prior to CCNFSDU45 or in-between sessions, to develop recommendations for consideration by CCNFSDU45.

REVIEW OF TEXTS UNDER THE PURVIEW OF CCNFSDU (Agenda Item 7) [14]

131. The Chairperson recalled the decision of CCNFSDU43 to request the Codex Secretariat to consider approaches to review all texts under the purview of CCNFSDU to assess if they were still fit for purpose. This request followed a recommendation by the EWG which had developed the draft Guideline for the preliminary assessment to identify and prioritize new work for CCNFSDU to regularly review its standards and other texts to ensure they remain relevant, up to date and consistent with other Codex texts.

132. The Codex Secretariat briefly introduced the paper and explained the approach taken, its conclusions and recommendations. The Secretariat also drew attention to the screening exercises to support possible future work.

133. The Chairperson emphasized that the screening exercises presented in the paper were to stimulate thinking on possible future work for CCNFSDU. The Chairperson thanked Australia, Canada, Finland, Germany and Ghana, FAO and WHO for having undertaken these screening exercises. The Chairperson further noted that already a proposal had been submitted considering some of the screening exercises, which had identified the need to review CXS 73-1981 and CXS 74-1981 (agenda item 6).

134. The Chairperson proposed that CCNSFDU endorse the recommendations with regard to using existing procedures to review standards under the purview of CCNFSDU. The Chairperson further drew attention to maintaining an “inventory list” for the purpose of keeping track of all ideas for new work and that this list includes a subsection for current standards under the purview of CCNFSDU to keep within view these standards that might need updating in the future. Any ideas on how to present the inventory list were welcome.

135. The Chairperson further noted that consequential amendments to CXS 72-1981 had been identified and proposed by New Zealand during the finalization of work on the revision of the *Standard for follow-up formula* (CXS 156-1987) renamed *Standard for follow-up formula for older infants and product for young children* and requested CCNFSDU to consider these amendments.

136. New Zealand, drawing attention to the proposal for consequential amendments provided through hyperlink in CX/NFSDU 24/44/7 and their CRD07, explained that discussion on essential composition is normally based on 100 kcal. In the development of CXS 72-1981 and the review of CXS 156-1987, the values per 100 kcal were agreed to and subsequently converted to a value per 100 kJ. During the review of CXS 156-1987, it was identified that there were inconsistencies in the conversion of essential compositional requirements from kcal to kJ, partly due to rounding inconsistencies in the development of CXS 72-1981. A level of specificity is required to ensure that the same minimum and maximum levels are listed per 100 kJ as for those presented per 100 kcal, which was particularly important for compliance purposes in jurisdictions where only use of kJ are used in regulations.

137. New Zealand explained that CCNFSDU40 had agreed to a systematic approach to determine the essential composition per 100 kcal to ensure that the converted values per 100 kcal to per 100 kJ are nutritionally equivalent to a reasonable level of specificity.

138. Since the revised CXS 156-1987 has been adopted, it was timely to consider the consequential amendments to CXS 72-1981 (CRD07, Table 1) to ensure that the two standards were aligned.

139. In addition, New Zealand was also proposing three editorial amendments (CRD07, Table 2).

140. CCNFSDU44 considered and agreed to the proposal for the consequential and editorial amendments proposed.

Conclusion

141. CCNFSDU44 agreed to:

    i. use the existing procedures to review standards under the purview of CCNSFDU;

    ii. encourage Members (and Observers) to propose revisions / amendments to existing standards, and to flag emerging issues in response to CL requesting new work proposals;

    iii. request the 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” of the *Guideline for the preliminary assessment to identify and prioritize new work for CCNFSDU*; and

    iv. request the Codex Secretariat to submit the consequential and editorial amendments identified for CXS 72-1981 for adoption by CAC47 (Appendix VI).

[14] CX/NFSDU 24/44/7

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) (Agenda item 8) [15]

142. The USA, the Chair of the EWG, introduced this item recalling the background to this work, explained the consultations in the EWG, its conclusions and recommendations as follows:

- Beta-carotene is a suitable optional ingredient as defined in CXS 72-1981 and listed in CXG 10-1979 and to request CCMAS to endorse the methods as listed in CX/NFSDU 24/44/8; and
- Fructo-oligosaccharides (FOS), oligofructose (OF) and oligofructan are suitable optional ingredients as defined in CXS 72-1981 and to request CCMAS to endorse the methods as listed in CX/NFSDU 24/44/8; and
- To inform CCMAS that CCNFSDU could not determine a rationale to endorse the method of analysis as listed in CX/NFSDU 24/44/8 for use with lycopene at this time.

143. The EWG Chair, drawing attention to CRD23, informed CCNFSDU that in accordance with *Comprehensive guidance for the process of submission, consideration and endorsement of methods for inclusion in CXS 234-1999* they had prepared information on the ranges of Human Milk Oligosaccharides (HMOs) and beta-carotene found in human milk and proposed levels for referral to CCMAS for fructans and beta-carotene in commercial infant formula based on regulatory limits.

Discussion

144. CCNFSDU44 considered the recommendations of the EWG and started its discussion first on whether beta-carotene could be considered a suitable optional ingredient.

145. CCNSDU44 noted that there was no support for this nutrient as a suitable optional ingredient for the following reasons:

- the suitability and safety of beta-carotene had not been demonstrated by the EWG and the presence of beta -carotene together with lycopene in human milk was not sufficient cause for β-carotene to be used in infant formula. The listing of beta-carotene as provitamin A in CXG 10-1979 might be a mistake and should be reviewed; noted that carotenoids have so far not been considered as sources of vitamin A in infants as reflected in the footnotes to the provisions for vitamin A in CXS 72-1981 and CXS 156-1987; and that further clarification could be provided for CCNFSDU45 or beta-carotene should be removed from CXG 10-1979.
- Beta-carotene was a source of vitamin A but there was not enough scientific evidence that it was needed for development and health of infants. It was however used as a colourant.
- beta-carotene is typically added not as a source of vitamin A but rather as an antioxidant. Having a method to measure the amount of beta-carotene in infant formula would be useful, but more for its antioxidant properties.
- If an ingredient is permitted then it must be demonstrated to be safe and suitable by rigorous independent science and in case where such ingredients demonstrate a well-defined benefit, it should be a mandatory ingredient rather than an optional ingredient.

146. Noting that there was no support at this time for the recommendation, the chairperson recalled the reason for CCNSDU having started the work was to add methods of analysis to CXS 234-1999. The Chairperson noted that even if methods were not listed in CXS 234-1999, they could still be used by countries and that countries can decide at national level on what optional ingredients could be allowed in infant formula. The Chairperson noted that CCNFSDU should carefully consider how to proceed taking into account the workload of the committee and to first consider if methods of analysis were actually needed before proceeding to consider whether the nutrients were suitable as optional ingredients.

[15] CX/NFSDU 24/44/8

147. The Codex Secretariat emphasized that CCNFSDU should carefully consider whether all the work on optional ingredients was warranted just to have methods of analysis listed in CXS 234-1999. CCNFSDU was under no obligation to list methods of analysis for optional ingredients and countries can use available methods even if they are not listed in CXS 234-1999. The Secretariat further noted that it was never the intent of the Committee to open any standards to address the issue of optional ingredients. To avoid a similar situation in future, the Secretariat proposed that CCNFSDU discontinue discussion on this item and to take a decision to only consider methods for essential composition requirements in standards under the purview of the CCNSDU. The Secretariat furthermore noted that additional optional ingredients for infant formula could be considered within the broader context of review/revision of standards (agenda item 7).

148. There was general support for the proposal of the Codex Secretariat, noting that methods of analysis should not be limited to essential composition only since CXS 72-1981 for example also list some optional ingredients and that it should rather be for clear provisions in standards under the purview of CCNFSDU.

149. A Member, while not opposed to the proposal, noted that it would have been useful to consider the issue of optional ingredients, as not all countries were able to assess their safety and suitability, and that this matter could be considered further under other relevant agenda items.

150. An Observer while supporting the proposal expressed the view that countries should ensure that products in their markets are safe, and that legislation is implemented in line WHO advice.

151. In view of the above discussion, CCNFSDU44 did not consider the rest of the recommendations of the EWG.

Conclusion

152. CCNFSDU44 agreed:

i. discontinue discussion on this item;

ii. to inform CCMAS that it was withdrawing its request to endorse methods of analysis for beta-carotene, fructans and lycopene; and

iii. to only consider proposals for methods of analysis for which there are clear provisions in standards under the purview of the Committee.

DISCUSSION PAPER ON METHODS OF ASSESSING THE SWEETNESS OF CARBOHYDRATE SOURCES IN THE *STANDARD FOR FOLLOW-UP FORMULA* (CXS 156-1987) (Agenda item 9)[16]

153. The Chairperson introduced the item and recalled that CCNFSDU43 had completed work on updating CXS 156-1987 which was adopted at CAC46. The Chairperson explained that CXS 156-1987 requires that for products based on non-milk protein, carbohydrate sources that have no contribution to sweet taste should be preferred and in no case be sweeter than lactose (footnote 4 of Section B, point 3.1.3 c). CCNFSDU43 agreed to establish an EWG to continue work in order to identify appropriate methods for assessing sweetness of carbohydrate sources (sweet taste) in Section B.

154. The EU, as Chair of the EWG, introduced the work of the EWG and explained that the ISO 5495 – Sensory analysis – Methodology – Paired comparison test for the comparative assessment (to assess the sweetness of carbohydrate sources used as an ingredient against lactose as a reference material) was proposed. The Chair of the EWG explained that the EWG had one round of consultation on the proposed method. Specific defined questions were put to the EWG on the preparation protocol, reference values or whether other methods could be identified. There was wide agreement in the EWG for the method and EWG Chair proposed that CCNFSDU consider submitting the method as presented in paragraph 22 of CX/NFSDU 24/44/9 to CCMAS for endorsement and inclusion in CXS 234-1999.

Discussion

155. There were diverse views on the appropriateness of the method and whether to send it to CCMAS for endorsement.

156. Those delegations supporting the method expressed the following views:

- The method should be submitted to CCMAS for consideration and endorsement, but the text under provision of the proposed method should be amended to better describe what was being measured, i.e. sweetness of the carbohydrate.

[16] CX/NFSDU 24/44/9

- CCMAS was the appropriate committee to determine the method's suitability for testing compliance with the provision and that the footnote was not in question as it had already been agreed by CCNFSDU.
- The method was well suited for the use, was widely used in the field and had a high sensitivity to detect small differences in sweetness.
- The method was suitable, but clarification on the reason for the concentration being doubled (17.5 g of lactose in water) in the protocol from the original proposal was asked.

157. Those not supporting the method expressed the following views:

- The method was not scientifically validated and as such would be difficult to use in national legislation, and therefore more expert advice was needed before the method could be supported;
- CCMAS has previously informed CCNFSDU that there are no known validated methods for determining compliance with footnote 4;
- The practicality of enforcing the sensory methods at an ingredient level was questioned as was the need for a method at all. The rationale for the latter is that the applicability clause as whole restricted the use of mono- and disaccharides, regardless of the protein source, and there was already a limit for total carbohydrates. The restrictions for the use of mono- and disaccharides were already more stringent than those for infant formula and follow up formula for older infants as is the limit for total available carbohydrates, and as such a method was not required.
- The method had not been validated for assessment of relative sweetness of a carbohydrate against lactose as the reference (paragraph 15 of CX/NFSDU 24/44/9) and was in conflict with footnote 4 (CXS 156-1987, Part Section B, point 3.1.3. c). It was not appropriate to submit an unvalidated method to CCMAS for endorsement.
- The method was burdensome requiring a large number of trained sensory panelists and that setting the panels up would be expensive.
- Carbohydrates already have very prescriptive requirements which control not only the source, but also the amount, and in turn the sweetness of formula. Sweetness is also largely affected by other components in the total formula, including things such as the amino acid contribution. Any method should be assessing the sweetness of the total finished product. It was noted that the meeting paper itself, paragraph 15 specifically says that the proposed method has not been validated for assessment of relative sweetness of a carbohydrate against lactose as the reference.
- Questions were raised on the relevance of testing carbohydrates at 17.50 g per 100 mL of water when according to a Member the limit of mono- and disaccharides that can be added to the product in question is at 2.5 g/100 kcal. Noting that there would only be a 50% perceived difference at this level, it was questioned whether this would be effective in giving a real view of how these carbohydrate sources would influence the sweet taste of products at the limits of the standard. Literature has already been published on the relative sweetness of most of the mono- and disaccharides using sensory methods, and this information is generally available for use in assessing whether or not a carbohydrate source is appropriate against the standard.

158. In response to the points raised, the EU, as the EWG Chair, clarified that:

- ISO 5495 was a validated, scientifically accepted method, but while it has not been specifically validated for the assessment of relative sweetness of a carbohydrate ingredient against lactose as a reference, this kind of sensory testing is widely applied in the food industry and has found general acceptance as a sensory test to choose the sample that is perceived higher in the specified sensory attribute. Therefore, the proposal was to submit the method for endorsement as a Type IV method.
- measuring the sweetness of the entire formula was not for discussion, but rather on the compliance with footnote 4.

159. The EWG Chair proposed to establish an IWG to further consider the method and address some of the concerns raised.

160. CCNFSDU44 agreed to this proposal and to include the consideration of the method in the IWG established under agenda item 1. The ToRs were therefore extended to consider the method of assessing the sweetness of carbohydrate sources in CXS 156-1987 and to provide recommendations to the Committee to refer the method for submission to CCMAS for review, if appropriate. The EU was requested to chair discussion on this specific point in the in-session WG.

161. Following discussion in the IWG, CCNFSDU44 considered the recommendation of the IWG as presented in CRD47. The EU, Chair of IWG explained that there was overall support to submit the method to CCMAS for endorsement and inclusion in CXS 234-1999. The IWG Chair informed CCNFSDU that 4 countries and 2 observers continued to raise concerns with the validity of the method, that it would not allow to test for compliance and that considerable resources would be needed to implement the method. The IWG Chair recommended that CCNFSDU consider the proposal as revised for submission to CCMAS for endorsement.

162. Delegations continued to reiterate points made earlier in the discussion and during the IWG.

163. Those delegations not supporting the method emphasized that they were not looking at reopening footnote 4, but rather questioned the suitability of the method since the proposed method had not been validated for this specific measurement of sweetness of carbohydrate sources against lactose. Therefore, doubts remained about the use of the method for enforcement purposes. It was questioned whether "perception" is a suitable criterion for enforcement purposes.

164. Those delegations in support of the method, maintained that CCMAS was the appropriate body to assess the appropriateness of the methods, that the proposed method was the only validated method available and the need for a globally harmonized method to be included in CXS 234-1999 to enforce footnote 4. As regards practicability of the method, only 18 panelists are needed, if done in replicates, a number available in most professional panels.

165. Two Observers expressed their view on the importance of footnote 4 to protect public health, that sweetness is an addictive quality, which influences taste preferences at young age and therefore needs to be controlled.

166. The Chair of the IWG again clarified that the proposed ISO method itself is validated, that validation is not a requirement for methods to be included in CXS 234-1999 as Type IV, and that footnote 4 is a requirement on ingredient level, which the Codex Secretariat had confirmed as being possible. Upon request, the IWG Chair further clarified that the reduction from 17.5 g to 8.75 g of test substance was made to ensure that the test concentration was in line with the maximum amount of the carbohydrate source allowed, as well as providing more precise result according to scientific literature. The IWG Chair also clarified that footnote 4 refers to sweetness as the element to be measured for enforcement, which is only possible with sensory methods. A Member Organisation expressed their view that sensory methods are scientifically as valid as chemical methods, while being less commonly used.

167. The Chairperson, noting that there was no consensus on the method, proposed to discontinue discussion at this time and if a new method was proposed in future this could be considered by CCNFSDU. The Chairperson noted, that even if there was no internationally harmonized method this did not preclude the use of ISO 5495 as presented in CRD47 or any other available method.

Conclusion

168. CCNFSDU44 noted the Chairperson's proposal in paragraph 164 regarding the availability of ISO 5495 and not to submit the method to CCMAS and agreed to discontinue consideration of the method of analysis for assessment of sweetness of carbohydrate sources.

OTHER BUSINESS (Agenda Item 10)

169. The Chairperson recalled that, as discussed under agenda items 1 and 2, issues related to methods of analysis and nitrogen to protein conversion factors would be addressed under this agenda item.

Methods of analysis

170. The United States of America, as the Chair of the IWG, introduced this item. It was noted that the IWG had considered the three proposals contained in CRD05 Rev and provided recommendations on them. The report of the IWG was presented in CRD47.

171. CCNFSDU44 considered the recommendations contained in CRD47 and took the following decisions:

Method for dietary fibre

172. The IWG Chair informed CCNFSDU that the new AOAC method was more accurate and alleviates inaccuracies with the older method. The IWG chair clarified that the purpose of the new method was not to evaluate physiological benefits but to facilitate the separation of fibres by molecular weight into soluble and insoluble categories. In light of concerns regarding the potential for the new method to capture fibres that did not conform to national definitions of dietary fibre or established criteria, the IWG recommended adding a footnote for clarification.

173. One Member Organisation pointed out that the footnote references isolated, purified, and/or synthetic fibres, corresponding to the second and third categories of fibres defined in paragraph 2 of the *Guidelines on nutrition labelling* (CXG 2-1985). These categories included: (i) carbohydrate polymers which have been obtained from food raw materials by physical, enzymatic, or chemical means and which have been shown to have a physiological effect of benefit to health, as demonstrated by generally accepted scientific evidence to competent authorities; and (ii) synthetic carbohydrate polymers which have a physiological effect of benefit to health as demonstrated by generally accepted scientific evidence to competent authorities. Due to the complexity of these definitions, a simplified reference was suggested.

174. Another Member noted that technological limitations might occasionally make the subtraction of certain fibres impossible, resulting in a small amount being inadvertently captured outside the dietary fibre definition. To avoid creating trade barriers, it was suggested to introduce flexibility in the footnote.

175. In this context, it was noted that the dietary fibre definition already acknowledged that competent authorities were responsible for determining which items (specifically isolated, purified, and/or synthetic fibres) aligned with the definition. These authorities had the discretion to make such determinations within the existing framework, making further explanation in the footnote potentially unnecessary.

176. In the spirit of compromise, CCNFSDU44 agreed to include the phrase "where deemed appropriate by competent authorities" at the end of the footnote.

<u>Conclusion</u>

177. CCNFSDU44 agreed to request CCMAS to:

- Endorse AOAC 2022.01/ICC Standard 191/AACC 32-61.01 as Type I for the determination of insoluble and soluble dietary fibres of higher and lower molecular weight in food that may or may not contain resistant starches. A footnote as follows should be inserted (see Appendix VII, Part A.1):

  > I*solated, purified, and/or synthetic fibres captured by AOAC 2022.01/ICC Standard 191/AACC 32-61.01 that do not meet the Codex definition of dietary fibre in the Guidelines on nutrition labelling (CXG 2-1985) should be subtracted from the final measurement, where deemed appropriate by competent authorities.*

- Revoke AOAC 2011.25/AACC 32-50.01 for use with the same provision.

Methods of analysis in the CXS 72-1981, Section A and CXS 156-1987, Section A

178. One Member expressed the view that the methods for measuring iodine and vitamin A listed in Table 1 of CRD47, proposed for revocation, were still in use by many Members and recommended that these methods be retained and retyped.

179. AOAC clarified that AOAC 992.24 measured iodate was therefore not suitable for measuring iodine. CCMAS had already confirmed this.

180. In response to a query regarding whether AOAC 992.24 should be revoked or retyped, the Codex Secretariat noted that both options were presented to provide flexibility. CCMAS had the authority to revoke the method if it was deemed unfit for purpose.

<u>Conclusion</u>

181. CCNFSDU44 agreed to request CCMAS to:

- endorse the methods listed in Table 1 for review, (re)typing, revocation and endorsement as Type II/Type III methods for the determination of nutrients in infant formula (CXS 72-1981, Section A) and follow-up formula (CXS 156-1987, Section A) (see Appendix VII, Part A.2).

- consider revoking/retyping of methods for follow-up formula currently listed in CXS 234-1999 as follows (see Appendix VII, Part B):
    - retype/revoke AOAC 992.24 for iodine;
    - retype/revoke AOAC 974.29, AOAC 992.04, AOAC 992.06 for vitamin A; and
    - retype AOAC 992.07 for pantothenic acid.

Measurement of Crude Protein

182. CCNFSDU44 agreed to request CCMAS to endorse the method for crude protein in follow-up formula as Type I method (see Appendix VII).

Other matters related to methods of analysis

183. The Chairperson noted that CCNFSDU had frequently received proposals for new methods of analysis related to its standards, particularly for infant formula. Currently, there was no specific mechanism for considering these proposals, leading to their publication in CRDs immediately before sessions, which gave delegates limited time to prepare for discussion. The Chair proposed that CCNFSDU follow a more systematic approach to addressing methods of analysis by having for the foreseeable future a standing agenda item dedicated to methods of analysis and establish an EWG to review the methods for food for special dietary uses in CXS 234-1999.

184. CCNFSDU44 agreed with the Chairperson's proposal.

Conclusion

185. CCNFSDU44 agrees to establish an EWG, chaired by the United States of America, working in English, to consider existing methods of analysis in CXS 234-1999 for standards falling under its remit to check their fitness for purpose and to make proposals for additional methods/ replacement methods, other corrections/ revocations.

NITROGEN TO PROTEIN CONVERSION FACTORS

186. The Chairperson recalled this matter was a matter referred by CCMAS and provided background information. It was explained that CRD04 Rev presented two options: Option 1, to retain the conversion factors in the standards; and Option 2, to remove them and instead reference CXS 234-1999.

187. One Member expressed a preference for Option 2, recognizing that establishing the nitrogen conversion factors were the responsibility of the technical committee (i.e. CCNFSDU), that nitrogen conversion factors be maintained by CCMAS within CXS 234-1999, along with the associated analytical methods. This would centralize all relevant information, simplifying access for analysts.

188. However, no other Members intervened in this discussion and the Chair proposed to consider this matter at CCNFSDU45 based on the proposals in CRD04 Rev.

189. CCNFSDU44 noted that the nitrogen conversion factor for follow-up formula for older infants and products for young children had been omitted from the list of nitrogen conversion factors prepared by CCMAS and agreed to propose its inclusion as outlined in CRD04 Rev Annex II.

Conclusion

190. CCNFSDU44 agreed to:

    i. forward the nitrogen conversion factor for follow-up formula for older infants and products for young children to CAC47 for inclusion in the Annex listing nitrogen conversion in CXS 234-1999 (Appendix VII, Part C);

    ii. consider whether to retain the conversion factors in the *Standard for infant formula and formulas for special medical purposes intended for infants* (CXS 72-1981) and the *Standard for follow-up formula for older infants and products for young children* (CXS 156-1987) at CCNFSDU45; and

    iii. inform CCMAS accordingly.

DATE AND PLACE OF THE NEXT SESSION (Agenda Item 11)

191. CCNFSDU44 was informed that the 45th session was scheduled to be held in approximately 24 months' time, the final arrangements being subject to confirmation by the host government in consultation with the Codex Secretariat.

APPENDIX I

LIST OF PARTICIPANTS
LISTE DES PARTICIPANTS
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APPENDIX II

REVISIONS TO THE *GUIDELINES ON NUTRITION LABELLING* (CXG 2-1985)

Part A:

General principles for establishing nutrient reference values for older infants and young children (6-36 months)

(For adoption at Step 8)

1. PREAMBLE

These Principles apply to the establishment of Codex Nutrient Reference Values-Requirement (NRVs-R) for persons aged 6–36 months. These values may be used in the labelling of pre-packaged foods for special dietary uses (FSDU) intended for persons aged 6–36 months to help consumers 1) estimate the relative contribution of individual products to overall healthful dietary intake, and 2) as one way to compare the nutrient content between products.

Governments are encouraged to use the NRVs-R, or alternatively, consider the suitability of the general principles below including the level of evidence required, and additional factors specific to a country or region in establishing their own NRVs-R. In addition, governments may establish NRVs-R for food labelling that take into account country or region-specific factors that affect nutrient absorption, utilization, or requirements. Governments may also consider whether to establish separate or combined food label NRVs-R for specific segments of persons aged 6–36 months.

2. DEFINITIONS AS USED IN THESE PRINCIPLES

Daily Intake Reference Values (DIRV) refer to reference nutrient intake values provided by FAO/WHO or recognized authoritative scientific bodies that may be considered in establishing an NRV for persons aged 6–36 months based on the principles and criteria in Section 3. These values may be expressed in different ways (e.g. as single values or a range), and are applicable to persons aged 6–36 months or to a segment of this age group (e.g. recommendations for a specified age range).

Individual Nutrient Level 98 (INL98)[1] is the daily intake reference value that is estimated to meet the nutrient requirement of 98 percent of the apparently healthy individuals in the population aged from 6 to 36 months.

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.

Upper Level of Intake (UL)[2] is the maximum level of habitual intake from all sources of a nutrient judged to be unlikely to lead to adverse health effects in persons aged 6 to 36 months.

Other than FAO and/or WHO (FAO/WHO), a Recognized Authoritative Scientific Body (RASB) refers to an organization supported by a competent national and/or regional authority(ies) that provides independent, transparent*, scientific and authoritative advice on daily intake reference values through primary evaluation** of the scientific evidence upon request and for which such advice is recognized through its use in the development of policies in one or more countries.

*In providing transparent scientific advice, the Committee would have access to what was considered by a RASB in establishing a daily intake reference value in order to understand the derivation of the value.

**Primary evaluation involves a review and interpretation of the scientific evidence to develop daily intake reference values, rather than the adoption of advice from another RASB.

3. GENERAL PRINCIPLES FOR ESTABLISHING NRVs-R

3.1 Selection of suitable data sources to establish NRVs-R

Relevant daily intake reference values provided by FAO/WHO that are based on a recent review of the science should be taken into consideration as primary sources in establishing NRVs-R.

[1] Different countries may use other terms for this concept, for example, Recommended Dietary Allowance (RDA), Recommended Daily Allowance (RDA), Reference Nutrient Intake (RNI), or Population Reference Intake (PRI).

[2] Different countries may use other terms for this concept, for example, Tolerable Upper Nutrient Intake Level (UL) or upper end of safe intake range

Relevant daily intake reference values that reflect recent independent review of the science, from recognized authoritative scientific bodies could also be taken into consideration. Higher priority should be given to values in which the evidence has been evaluated through a systematic review.

The daily intake reference values should reflect intake recommendations for persons aged 6 to 36 months.

3.2 Appropriate Basis for Establishing NRVs-R

Ideally, the NRVs-R should be based on Individual Nutrient Level 98 (INL98). In certain cases, where there is an absence of, or an older, established FAO/WHO DIRV for a nutrient, it may be more appropriate to consider the use of other daily intake reference values or ranges that have been more recently established by recognized authoritative scientific bodies. The derivation of these values should be reviewed on a case-by-case basis.

Nevertheless, the derivation of these values from recognized authoritative scientific bodies, shall take into account the following elements: the rigour of scientific methods, the underlying data quality, the strength of evidence used to establish these values and the most recent independent review of the science.

NRV-Rs should be derived for persons aged 6-12 months and 12-36 months from suitable data sources according to 3.1 and the appropriate basis described above. 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.

3.3 Consideration of Upper Levels of Intake

The establishment of NRVs-R for persons aged 6 to 36 months should also take into account upper levels of intake (UL) established by FAO/WHO or recognized authoritative scientific bodies where/if available.

Part B:

NRVs-R for older infants and young children (6-36 months)

(For adoption at Step 5/8)

Nutrient	Older Infants (6-12months)	Young Children (12-36 months)	6–36-months age group
Vitamin A (µg RAE or RE)*	250	300	275
Thiamin (mg)	0.3	0.5	0.4
Riboflavin (mg)	0.4	0.6	0.5
Vitamin B_6 (mg)	0.3	0.6	0.5
Protein (g)	11	13	12
Vitamin E(mg)*	5	7	6
Niacin (mg NE)*	4	6	5
Pantothenic acid (mg)	3	3	3
Copper (µg)	220	300	260
Iodine (µg)	80	95	90
Potassium (mg)	725	850	790
Calcium (mg)**	390	590	490
Vitamin D (µg)**	10	10	10
Zinc (mg)**	3.6	4.8	4.2

* Conversion factors for niacin, vitamins A and E are presented in CXG 2-1985.

** FAO/WHO age brackets are 7-12 months, and 1-3 years inclusive, in line with reporting of age brackets in the 2004 documents, *Vitamin and mineral requirements in human nutrition, 2nd edition* (https://www.who.int/publications/i/item/9241546123 (for information only.

Part C:

Consequential amendments to CXG 2-1985

(For adoption)

Bolded and underlined red texts are the those for which the consequential amendments are required.

3.4.4.1 *NRVs-R* ***for general population***

3.4.4.2 *NRVs-R for older infants and young children (6-36 months)**

****These can be used for the labelling of foods for special dietary uses for older infants and young children (6-36 months) for which there are existing Codex texts***

3.4.4 […] The following NRVs **in Sections 3.4.4.1 and 3.4.4.3** are for the general population identified as individuals older than 36 months. They should be used for labelling purposes to help consumers make choices that contribute to an overall healthful dietary intake. […]

The NRVs-R in Section 3.4.4.2 are for older infants and young children (6-36 months).

In addition, consequential changes be made to certain sections (i.e. Sections 3.4.4, 3.4.4.1, 3.4.4.2 of the main body), Annex 1 be changed to Annex I: Part A and sections to be renumbered accordingly.

APPENDIX III

STEPWISE PROCESS FOR ESTABLISHING NRVS-R FOR PERSONS AGED 6 - 36 MONTHS

(For publication as an information document)

Step 1: Identify new or updated DIRVs from FAO/WHO for older infants and young children, if available. Clarify DIRVs with FAO/WHO if needed and select for establishing NRVs-R. Go to step 5.

Step 2: In the absence of new or updated DIRVs from FAO/WHO, consider relevant DIRVs that reflect recent independent review of the science from RASBs (higher priority to values evaluated by systematic review).

DIRVs based on relevant physiological evidence, if available

Step 3.A: Select FAO/WHO if same as median of DIRVs from RASBs based on physiological evidence. If not - select the median of available RASBs data based on physiological evidence (with or without FAO/WHO) as the NRVs-R for each nutrient for persons 6 – 12 months and 12 – 36 months. Go to step 4.

DIRVs informed by relevant extrapolation from other age groups, if available

Step 3.B: Select FAO/WHO if same as median of DIRVs from RASBs based on extrapolation from other age groups. *If not*, select median of available RASBs data (with or without FAO/WHO) as the NRVs-R for each nutrient for persons 6 – 12 months and 12 – 36 months. Go to step 4.

No available data informed by physiological evidence or extrapolation from other age groups

Step 3.C: Select FAO/WHO if same as median of DIRVs from RASBs based on estimates of nutrient intake from the target group or interpolation. *If not*, select median of available RASBs data (with or without FAO/WHO) as the NRVs-R for each nutrient for persons 6 –12 months and 12 –36 months. Go to step 4.

Step 4: All proposed NRV-Rs established in Step 3, are reviewed on a case-by-case basis. Proposed NRVs-R for all nutrients for persons 6 -12 months and 12 - 36 months are checked considering scientific rigor of the methods, underlying data and data quality, and all available evidence. If necessary, proposed NRVs-R are amended/adjusted. Go to step 5.

Step 5: Estimate the NRVs-R for the combined 6 – 36 months age group by calculating the mean value of the two age groups 6–12 months and 12–36 months. Go to step 6.

Step 6: Consider ULs (where available) to ensure that proposed NRVs-R do not exceed the lowest of the UL values available.

Stepwise Process for establishing NRVs-R for persons aged 6-36 months

Step 1: Identify new or updated DIRVs from FAO/WHO for Older Infants and Young Children, if available. Clarify DIRVs with FAO/WHO if needed and select for establishing NRVs-R.

OR

Step 2: In the absence of new or updated DIRVs from FAO/WHO, consider relevant DIRVs that reflect recent independent review of the science from RASBs (higher priority to values evaluated by systematic review).

DIRVs based on relevant physiological evidence

Step 3.A: Select FAO/WHO if same as median of DIRVs from RASBs based on physiological evidence.
If not, select the median of available RASBs data based on physiological evidence (with or without FAO/WHO) as the NRVs-R for each nutrient for persons 6-12 months and 12-36 months.

DIRVs informed by relevant extrapolation from other age groups

Step 3.B: Select FAO/WHO if same as median of DIRVs from RASBs based on extrapolation from other age groups.
If not, select median of available RASBs data (with or without FAO/WHO) as the NRVs-R for each nutrient for persons 6-12 months and 12-36 months.

No available data informed by physiological evidence or extrapolation from other age groups

Step 3.C: Select FAO/WHO if same as median of DIRVs from RASBs based on estimates of nutrient intake from the target group or interpolation.
If not, select median of available RASBs data (with or without FAO/WHO) as the NRVs-R for each nutrient for persons 6-12 months and 12-36 months.

Step 4: All proposed NRV-Rs established in Step 3, are reviewed on a case-by-case basis. Proposed NRVs-R for all nutrients for persons 6-12 months and 12-36 months are checked considering scientific rigor of the methods, underlying data and data quality, and all available evidence. If necessary, proposed NRVs-R are amended/adjusted.

Step 5: Estimate the NRVs-R for the combined 6-36 months age group by calculating the mean value of the two age groups 6-12 months and 12-36 months.

Step 6: Consider ULs (where available) to ensure thatproposed NRVs-R do not exceed the lowest of the UL values available.

APPENDIX IV

GUIDELINE FOR THE PRELIMINARY ASSESSMENT TO IDENTIFY AND PRIORITIZE NEW WORK FOR CCNFSDU

(For publication as an information document)

Purpose

1. The following guideline is intended to assist the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) to identify and prioritize new work.

Scope

2. Proposals for new work should fall within the terms of reference of CCNFSDU and typically address issues associated with nutritional aspects of all foods and/or issues concerning foods for special dietary uses. Proposals may regard the development of new Codex texts or the revision of existing Codex texts.

Process for Submitting Proposals for New Work

3. Proposals for new work (including revision of an existing text) should be submitted in a determined timeframe in response to a Codex Circular Letter (CL) before each session of CCNFSDU. This ensures that all proposals will be submitted within a deadline and all members have adequate time to consider them.

4. New work proposals must be submitted or supported by a Member and must contain three elements: (1) a discussion paper, (2) a project document (as per paragraph 5 of the guidelines), and (3) an assessment against the prioritization criteria, as defined in para. 6 and 7.

5. Proposals for new work should follow the process and provisions outlined in Section 2 Part 2, paragraph 12, of the *Procedural Manual* for proposals to undertake new work or revise a Standard.[1]

6. Proposals need to be assessed using the criteria for the establishment of new work priorities outlined in Section 2 Part 7 (Criteria for the establishment of work priorities for general subjects) of the *Procedural Manual*, and their explanatory description below.

7. The explanatory descriptions in the table below have been developed to complement the new work criteria of the *Procedural Manual* for the specific purposes of CCNFSDU. They shall assist in classifying the scope of the work and the extent to which the proposed work impacts (positively and/or negatively), Codex Members in terms of public health, food safety, trade practices and global impact, and should be accompanied by a detailed rationale and supported by available scientific evidence and other validated data. In this framework, the criteria are also intended to assist the ad hoc Working Group in their reviewing process on a case-by-case basis (para. 13).

8. The submitter should provide an assessment based on the explanatory description of the prioritization criteria that contains all necessary information to support the ad hoc Working Group's rating process (para. 14). The submitter shall not perform a rating.

Prioritization Criterion	Explanatory Description	Rating (see para.14)
Impact on public health	Describe the target group(s) (e.g. infants, the elderly, patients, whole population) that would be affected by the proposed new work and describe the intended and unintended health impact on the target group(s), and on other groups, if applicable. For example, what is the potential of the proposed work to resolve, prevent, or significantly reduce a public health risk? The impact should be justified and supported by examples and available data, when possible or helpful.	High: (+/-) 6 points Medium: (+/-) 4 points Low: (+/-) 2 points Neutral: 0 points
Impact on food safety	Describe how the proposed new work would impact food safety (i.e. biological, chemical, or physical risks). The impact should be justified and supported by examples and available data, when possible or helpful.	High: (+/-) 6 points Medium: (+/-) 4 points Low: (+/-) 2 points

[1] Codex Alimentarius Commission Procedural Manual, Section 2 (Elaboration of Codex standards and related texts), Part 2 (Critical Review, Proposals to undertake new work or to revise a standard). The current version of the Procedural Manual applies.

Prioritization Criterion	Explanatory Description	Rating (see para.14)
		Neutral: 0 points
Impact on trade practices	Describe how the proposed new work would impact global food trade and how this work might harmonize international standards and reduce barriers to fair trade. Potential impacts on product consumption should also be considered. The impact should be justified and supported by examples and available data, when possible or helpful.	High: (+/-) 3 points Medium: (+/-) 2 points Low: (+/-) 1 point Neutral: 0 points
Global Impact	Describe how the proposed new work would be suitable for addressing a worldwide nutrition problem, as per the Codex mandate. The impact should be justified and supported by examples and available data, when possible or helpful.	High: (+/-) 3 points Medium: (+/-) 2 points Low: (+/-) 1 point Neutral: 0 points

Process for Compiling New Work Proposals

9. Proposals for new work received in response to the CL will be transmitted to the CCNFSDU host country Secretariat which will undertake an administrative check on whether the proposals received meet the basic requirements (step one to four of the decision tree).

10. The CCNFSDU host country Secretariat will prepare a summary document presenting the proposals for new work including all three elements as per para. 4. It will be distributed by the Codex Secretariat to Codex Members and Observers for their consideration.

11. The summary document will contain an "Inventory of CCNFSDU Proposals and Potential Future Areas of Work (all-time list)", comprising of two sections. Section "A. Proposals" will include: "Part 1: Amendments / Revisions", and "Part 2: New Work", while Section "B. Potential future areas of work" will include "Part 3: Review of existing standards" and "Part 4: Emerging issues". This document will include a comprehensive overview of all new topics that have been proposed to CCNFSDU and such topics that have been considered in the preceding years by the Committee including:

- requests from CAC or other Committees,
- identified needs for revision of existing texts under purview of the Committee,
- topics that were considered as priorities but postponed for various reasons (medium/long-term planning),
- topics that have not been supported.

Process for Prioritizing New Work Proposals

12. An ad hoc Working Group for the Establishment of CCNFSDU Work Priorities will meet prior to the first plenary session of CCNFSDU or in-between sessions, to develop recommendations for consideration by the Committee. The ad hoc Working Group will be co-chaired by the host country and another delegation.

13. The following Terms of Reference (ToRs) 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)

14. In order to facilitate the ranking of the new work proposals, a rating system of high/medium/low/neutral shall be employed for each criterion, supported by the use of a (+/-) point system. Positive points shall be assigned for positive impacts, while negative points shall be assigned for negative impacts. A neutral rating (0 points) shall be assigned when a new work proposal is not expected to have any impact according to a particular criterion. The criteria related to health and food safety shall be assigned double the value to the

criteria related to trade practices and global impact to reflect their higher degree of importance (see table para. 8).

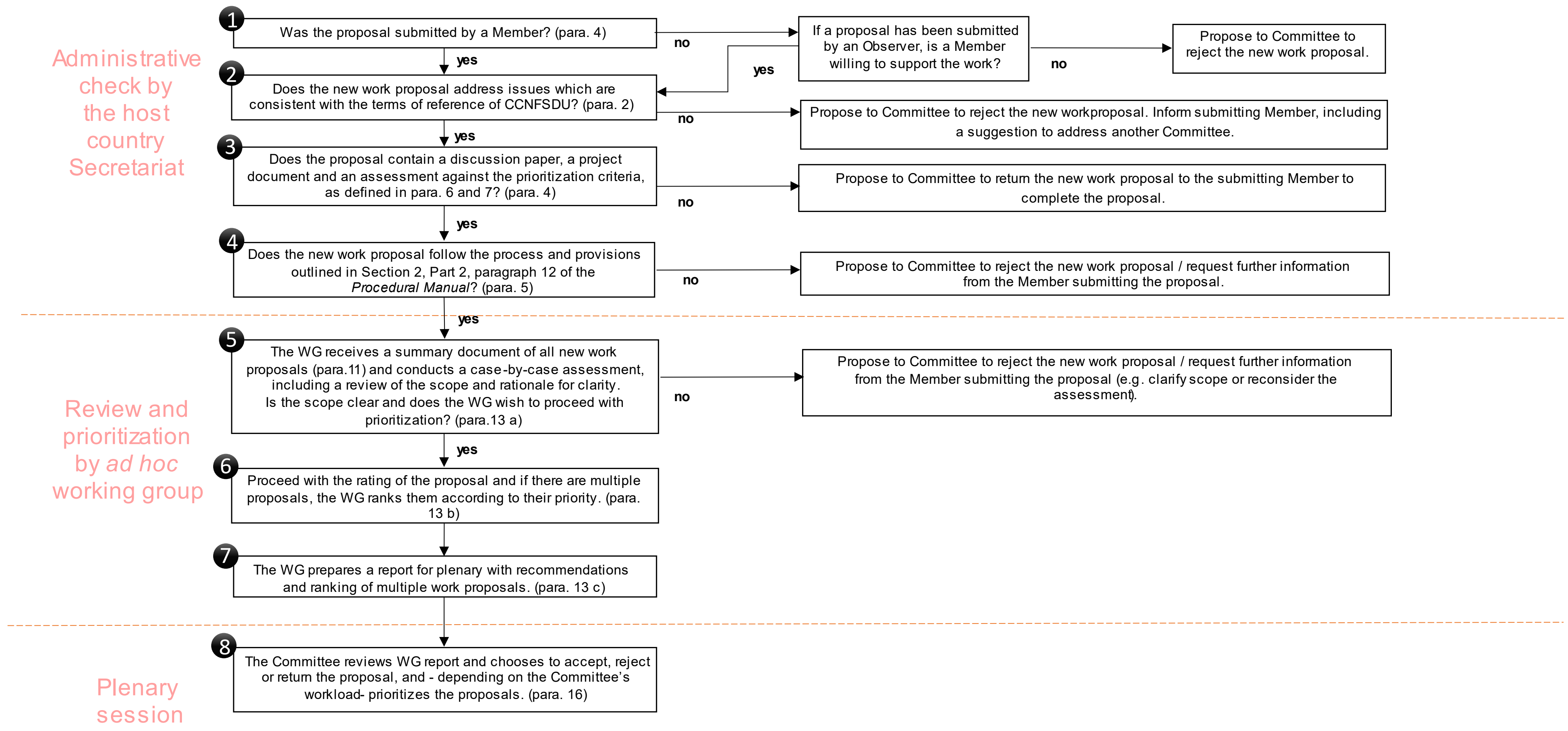
15. For each of the four criteria, a net impact will be calculated once the respective negative and positive impacts have been considered. A final score shall be calculated from the points awarded across all four criteria and will be used by the ad hoc Working Group to rank the new work proposals (per para. 13).

16. During the CCNFSDU plenary session, the ad hoc Working Group Chair shall introduce the recommendations for consideration of new work proposals to the Committee. The Committee will then accept or reject a proposal for new work or return it to the proposing party for additional information. Depending on the workload of CCNFSDU, the Committee may decide not to accept any new work proposals at a session. At the same time, the Committee should retain the option to bypass the prioritization process for immediate action, where circumstances and/or exceptional global situations so require.

17. The recommendation of the ad hoc Working Group will be considered by the Committee for progression through the Codex process in the usual manner.

Decision Tree: 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 OF NEW WORK PROPOSALS FOR CCNFSDU



APPENDIX V

PROJECT DOCUMENT

Proposal for the development of standard for foods for older infants and young children

I. Purpose and Scope of the New Work

The purpose of this project is to develop a Standard for baby foods, and processed cereal-based foods, which include complementary foods, for older infants and young children (persons aged 6 months to 36 months).

The Guidelines on formulated complementary foods for older infants and young children (CXG 8-1991) defines Formulated Complementary Foods as foods that are suitable for use during the complementary feeding period. These foods should be specifically formulated with appropriate nutritional quality to provide additional energy and nutrients to complement family foods derived from the local diet and should provide nutrients which are either lacking or are present in insufficient quantities.

CXG 8-1991 defines the Complementary Feeding Period as the period when older infants and young children transition from exclusive feeding of breastmilk and/or breast milk substitutes to eating the family diet.

The scope of the proposed new standard would be:

- The standard applies to baby foods, and processed cereal-based foods, which includes complementary foods, for older Infants and young children, including but not limited to meat, vegetable, fruit or pulses-based products, and foods for older infants and young children. This standard does not apply to beverages (follow-up formula and product/drink) for older infants and young children. The foods in this standard can be provided in the form of baby foods, cereal based foods.

Breastmilk substitutes are a separate category of products from complementary foods and will not be considered in the proposed standard. In accordance with the Codex definition of complementary foods, complementary foods are intended to complement the feeding of breastmilk as older infants and young children make the transition from sole source nutrition from breastmilk or infant formula to dietary patterns composed of solid foods. Therefore, the products covered by the proposed standard are not breastmilk substitutes and should not be formulated or presented as such.

II. Relevance and Timeliness

Complementary feeding of children between the ages of 6 and 36 months is necessary for healthy growth and development at this critical period. In 2023 the WHO issued an update of the WHO Guideline for complementary feeding of infants and young children 6-23 months of age.[1] These guidelines use a food-based approach and recommend a diet diverse in daily animal-source foods, daily fruits and vegetables, and adequate pulses, nuts, and seeds. The Guideline also recommends limiting foods high in sugar, salt, and trans-fat.

In December of 2023 an expert consultation was held to consider the recommendations of the updated WHO Guideline and approaches to making food systems work for complementary feeding in low and middle-income countries, including through support from international assistance programs, such as USAID. This consultation concluded that food systems are not meeting the needs of children in low- and middle-income counties and that two in three children are not able to be fed diverse diets needed for healthy growth and development during this critical period of development. This same conclusion was reached in a 2021 report published by UNICEF.[2] When possible, food systems should be improved to provide affordable, locally grown, nutrient-dense foods needed for the nutritional needs of older infants and young children. When this is not possible, formulated complementary foods can play an important role in meeting dietary and nutritional needs of this age group.

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[1] World Health Organization. "Guideline for complementary feeding of infants and young children 623 months of age." (2023): 96-96.

[2] United Nations Children's Fund (UNICEF). Fed to Fail? The Crisis of Children's Diets in Early Life. 2021 Child Nutrition Report. UNICEF, New York, 2021.

Market research has shown that complementary foods have increased in volume and diversity in the global trade.[3] However, international standards to guide composition and labelling for complementary foods are lacking, outdated, or not followed. A recent report found that most commercially available fortified complementary foods are not nutritionally adequate.[4]

The Codex Secretariat's recent review of CCNFSDU standards (CX/NFSDU 24/4/7) identified both the *Standard for canned baby-foods* (CXS 73-1981) and the *Standard for processed cereal based foods for infants and young children* (CXS 74-1981) as standards in need of revision and/or update. The proposed new standard would replace these standards and establish science-based nutrition, quality, and safety provisions for the foods currently covered by these outdated standards and for complementary foods for which there are no current Codex standards.

It is therefore both relevant and timely that Codex develop a Standard on Foods for Older Infants and Young Children.

III. Main Aspects to be Considered

The proposed standard would incorporate the foods from the two existing standards related to foods (CXS 73-1981 and CXS 74-1981). The main aspects that this proposed standard would consider are as follows:

- Relevant updates in light of current scientific findings and recommendations for complementary feeding for persons aged 6-36 months
- foods for older infants and young children comprised of basic food groups including animal-source foods, fruits and vegetables, cereals and grains, pulses, nuts, and seeds as individual foods or in food group combinations
- Essential compositional and safety factors, including food group requirements and nutritional composition
- Additional food safety, quality, packaging, labelling, and analytical methods and sampling provisions, as appropriate
- Name and structure of the standard

IV. Assessment Against the Criteria for the Establishment of New Work Priorities General Criteria:

A standard on foods for older infants and young children will provide:

- Scientifically supported, evidence-based direction and guidance to Codex Members, policymakers, and non-governmental organizations who wish to establish and use up-to-date, science-based guidelines for the formulation of foods for older infants and young children and implement associated policies.
- Food business operators with a clear and consistent direction on nutritional criteria for product formulation; and
- Consumers with more consistent and nutritionally balanced products to reduce their risk of potentially inadequate or excess nutrient intakes.

Criteria applicable to general subjects:

a. Diversification of national legislation and apparent resulting or potential impediments to international trade

The lack of a science-based standard to guide the nutritional composition, safety, quality, and labelling for such foods as the market size of and consumption of these products grow[5] has led to divergence and/or variability in approaches to managing the nutritional composition of these products. The absence of Codex guidance to promote more harmonized approaches can result in impediments to trade.

[3] https://agriculture.canada.ca/en/international-trade/market-intelligence/reports/customized-report-service-baby-foodtrends-canada-united-states-mexico-cusma#a

[4] Masters WA, Nene MD, Bell W. Nutrient composition of premixed and packaged complementary foods for sale in low- and middle-income countries: Lack of standards threatens infant growth. *Matern Child Nutr*. 2017; 13:e12421. https://doi.org/10.1111/mcn.12421

[5] https://agriculture.canada.ca/en/international-trade/market-intelligence/reports/customized-report-service-baby-foodtrends-canada-united-states-mexico-cusma#a

A 2017 report found that most commercially available fortified complementary foods are not nutritionally adequate, and a 2021 UNICEF report states that few affordable products are appropriately formulated in low-income countries.[6,7] There is currently no international, science-based standard to ensure that the foods that are being traded meet the nutritional needs of the target population, resulting in health risks and impediments to international trade. Developing a Codex standard would help address issues of availability, affordability, and accessibility of appropriately formulated products. It is necessary to take action to develop a science-based, international standard to reduce existing and potential impediments to trade.

b. Scope and establishment of priorities between the various sections of the work

The proposed standard would include a food-based approach including animal-source foods, fruits and vegetables, cereals and grains, pulses, nuts, and seeds as individual foods or in food group combinations to provide nutritional composition guidance that is aligned with international, science-based dietary guidance for the target age group. Essential compositional and safety factors, including mandatory and optional nutrient addition and guidance on quality, packaging, labelling, analytical methods and sampling considerations would also be addressed with the aim of providing an international standard with which countries could harmonize their regulations for foods for older infants and young children.

All sections of the proposed standard are of high priority for the text to be maximally useful, but first priorities will be to develop a scope that covers all such foods and to update nutritional composition provisions to reflect current science.

c. Work that has already been undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body(ies).

The WHO recently updated its guidelines on complementary infant feeding.[8]

d. Amenability of the subject of the proposal to standardization

Codex has developed standards for specific categories of foods for older infants and young children in the past—the *Standard for canned baby-foods* (CXS 73-1981) and *Standard for processed cereal based foods for infants and young children* (CXS 74-1981)—so it is clear that this category of foods is amenable to standardization. As established in the introduction and paragraph on relevance/timeliness, foods for older infants and young children have expanded to encompass more food groups and product varieties and an international standard that covers all these products is needed. Based on the success of past work to develop standards for such foods, there is no reason to question the amenability of the subject of this proposal to standardization.

e. *Consideration of the global magnitude of the problem*

The recently updated WHO guideline demonstrated through its dietary modelling work that nutrient gaps exist even in best-case food patterns. A further consultation supported by USAID found that food systems are not meeting the nutritional needs of children in low- and middle-income counties and that two in three children in the target group (aged 6-36 months) are not able to be fed diverse diets needed for healthy growth and development during this critical period. Recent UNICEF findings confirm this is a global public health challenge and other studies have found that most commercially available fortified complementary foods are not nutritionally adequate.[9] Developing a Codex standard for complementary foods to ensure they are nutritionally adequate and safe can help address these global issues in a timely manner.

V. Relevance to the Codex Strategic Plan's[10] Goals and Objectives

The proposed work is consistent with the Commission's mandate to develop standards, guidelines and other international recommendations to protect consumer health and to ensure fair practices in the food trade. The new standard will contribute to the achievement of Strategic Goals 1, 2, 3, and 4.

[6] Masters WA, Nene MD, Bell W. Nutrient composition of premixed and packaged complementary foods for sale in low- and middle-income countries: Lack of standards threatens infant growth. *Matern Child Nutr*. 2017; 13:e12421. https://doi.org/10.1111/mcn.12421

[7] United Nations Children's Fund (UNICEF). Fed to Fail? The Crisis of Children's Diets in Early Life. 2021 Child Nutrition Report. UNICEF, New York, 2021.

[8] https://cdn.who.int/media/docs/default-source/nutrition-and-food-safety/complementary-feeding/cf-guidelines/dietarymodelling.pdf?sfvrsn=8e2abbff_3

[9] United Nations Children's Fund (UNICEF). Fed to Fail? The Crisis of Children's Diets in Early Life. 2021 Child Nutrition Report. UNICEF, New York, 2021.

[10] For more information, please see the Codex Strategic Plan 2021-2025

- **Goal 1: Address current, emerging and critical issues in a timely manner**

Recent research has found that food systems are not meeting the complementary feeding needs of children, especially in low- and middle-income counties. Two in three children in the target group are not able to be fed diverse diets needed for healthy growth and development during this critical period.[11] Complementary foods have increased in volume and diversity in the global trade,[12] but most commercially available fortified complementary foods are not nutritionally adequate[13] and not all foods currently marketed are covered by existing Codex standards. While food systems should be improved to provide affordable, locally grown, nutrient-dense foods, this proposal recognizes that critical issues have emerged in older infant and young child nutrition and that developing a Codex standard for such foods to ensure they are nutritionally adequate and safe can help address these issues in a timely manner.

- **Goal 2: Develop standards based on science and Codex risk-analysis principles**

The proposed standard would be based on recent science and Codex risk analysis principles. This project may seek scientific advice if needed to set composition requirements for individual foods or food groups for the target population. The standard will seek and rely on globally representative nutrition data and input from all Codex Members and may request additional scientific advice from the Joint Expert Meeting on Nutrition (JEMNU) as required to complete the work.

- **Goal 3: Increase impact through the recognition and use of Codex standards**

This proposed new work would need to incorporate and update the relevant information from the existing related Codex standards and would be complementary to the work CCNFSDU has completed in the development of the *Standard on infant formula and formulas for special medical purposes intended for infants* (CXS 72-1981) and the *Standard on follow-up formula for older infants and product for young children* (CXS 156-1987) providing guidance to governments to ensure that foods for infants and young children are safe and nutritionally appropriate. This will fill important gaps and thereby increase the impact and use of Codex standards.

- **Goal 4: Facilitate the participation of all Codex Members through the standard setting process**

Foods for older infants and young children are relevant to all Codex Members and regions. In particular, the proposed standard would provide a food-based approach, either as individual foods or food group combinations, applicable globally. The participation of all Codex Members is necessary to set a standard that serves all Codex regions and the development of a proposed standard that is relevant to all Members encourages and facilitates participation in the standard setting process. The proposed new work would seek to use all available means, electronic, virtual, and physical, to reduce barriers to active participation in this standard setting process**.**

VI. Relationship Between This Proposal and Other Existing Codex Documents

CCNFSDU has three texts related to complementary feeding of older infants and young children: *Guidelines on formulated complementary foods for older infants and young children* (CXG 8-1991), *Standard for canned baby-foods* (CXS 73-1981), and *Standard for processed cereal based foods for infants and young children* (CXS 74-1981).

CXG 8-1991 provide nutrient targets for complementary foods that are based on WHO/FAO data that are two decades old.[14] The Codex Secretariat's recent review of CCNFSDU standards (CX/NFSDU 24/4/7) identified both the CXS 73-1981 and the CXS 74-1981 as standards in need of revision and/or update. CXS 73-1981 and CXS 74-1981 provide requirements for composition of canned baby foods and cereal-based foods; they only cover canned baby foods without a designated age range and cereal-based foods for infants and young children. Codex standards are lacking for other complementary foods, such as meat, vegetable, fruit or pulses-based products. Other related texts are the *Advisory list of nutrient compounds for use in foods for special dietary uses intended for infants and young children (*CXG 10-1979*), General principles for the addition of nutrients to foods* (CXG 9-1987), and the Committee's ongoing work to establish General Principles and Nutrient Reference Values-Requirements (NRVs-R) for persons aged 6-36 months.

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[11] Choudhury, Samira, Derek D. Headey, and William A. Masters. "First foods: Diet quality among infants aged 6–23 months in 42 countries." *Food Policy* 88 (2019): 101762.

[12] https://agriculture.canada.ca/en/international-trade/market-intelligence/reports/customized-report-service-baby-foodtrends-canada-united-states-mexico-cusma#a

[13] Masters WA, Nene MD, Bell W. Nutrient composition of premixed and packaged complementary foods for sale in low- and middle-income countries: Lack of standards threatens infant growth. *Matern Child Nutr.* 2017; 13:e12421. https://doi.org/10.1111/mcn.12421

[14] World Health Organization. *Vitamin and mineral requirements in human nutrition*. World Health Organization, 2004.

The new work will take into consideration all the existing Codex texts in developing a single new standard for foods for older infants and young children. It will incorporate and update the relevant aspects of existing texts and replace two Codex texts: CXS 73-1981 and CXS 74-1981.

VII. Requirement for and Availability of Expert Scientific Advice

CCNFSDU may need scientific advice from the Joint Expert Meeting on Nutrition (JEMNU).

VIII. Need for Technical Input to the Standard from External Bodies

None anticipated.

IX. Proposed Timeline

The work can be completed in four (4) sessions, with final adoption at Step 8 by 2029.

APPENDIX VI

Proposed amendments to the *Standard for infant formula and formulas for special medical purposes intended for infants* (CXS 72-1981)

(For adoption by CAC47)

Bolded values/texts are those for which the amendment is required to CXS 72-1981.

Part A: Consequential amendments to CXS 72-1981 to align with the corrections made in the *Standard for follow-up formula for older infants and product for young children* (CXS 156-1987)

Compositional requirement	**Per 100 kcal/ 100 kJ**	**CXS 72-1981**	**Amendment to CXS 72-1981**
Energy (/100mL)	kcal	60-70	60-70
	kJ	250 - 295	**251-293**
Protein cow's milk (g)	kcal	1.8-3.0	1.8-3.0
	kJ	0.45-0.7	**0.43-0.72**
Protein Soy protein (minimum) (g)	kcal	2.25	2.25
	kJ	0.5	0.5**4**
Fat (g)	kcal	4.4-6.0	4.4-6.0
	kJ	1.05-1.4	**1.1**-1.4
Linoleic acid (mg)	kcal	300-1400	300-1400
	kJ	70-330	**72-335**
Vitamin D (µg)	kcal	1-2.5	**1.0**-2.5
	kJ	0.25-0.6	**0.24**-0.6
Vitamin K (µg)	kcal	4-27	4-27
	kJ	1-6.5	**0.96-6**
Riboflavin (µg)	kcal	80-500	80-500
	kJ	19-119	19-**120**
Niacin (µg)	kcal	300-1500	300-1500
	kJ	70-360	**72-359**
Vitamin B6 (µg)	kcal	35-175	35-175
	kJ	8.5-45	**8-42**
Vitamin B12 (µg)	kcal	0.1-1.5	0.1-1.5
	kJ	0.025–0.36	**0.02**-0.36
Folic acid (µg)	kcal	10-50	10-50
	kJ	2.5-12	**2.4**-12
Vitamin C (mg)	kcal	10-70	10-70
	kJ	2.5-17	**2.4**-17
Biotin (µg)	kcal	1.5-10	1.5-10
	kJ	0.4-2.4	**0.36-**2.4
Sodium (mg)	kcal	20-60	20-60
	kJ	5-14	**4.8**-14
Manganese (µg)	kcal	1-100	1**.0**-100
	kJ	0.25-24	**0.24**-24
Iodine (µg)	kcal	10-60	10-60
	kJ	2.5-14	**2.4**-14
Copper (µg)	kcal	35-120	35-120
	kJ	8.5-29	**8**-29
Taurine (mg)	kcal	N.S.-12	N.S.-12
	kJ	N.S-3	N.S.-**2.9**
Myo-inositol (mg)	kcal	4-40	4-40
	kJ	1-9.5	1-**10**

Part B: Editorial amendments to CXS 72-1981 to align with the corrections made in the *Standard for follow-up formula for older infants and product for young children (CXS 156-1987)*

CXS 72-1981	**Amendment to CXS 72-1981**
Total carbohydrates	**Available** carbohydrates
Vitamin C[14)] [14)] Expressed as ascorbic acid	Vitamin C[14)] [14)] Expressed as **L-**ascorbic acid
Phosphorous[17)] [17)] This GUL should accommodate higher needs with soy formula	Phosphorous[17)] [17)] This GUL should accommodate higher needs for **infant formula based on soy protein isolate**

APPENDIX VII

MATTERS RELATED TO METHODS OF ANALYSIS

Part A: Methods of analysis for endorsement and inclusion in CXS 234-1999

A.1 Method for dietary fibre

Table 4. Methods of analysis for dietary fibre: *Guidelines for use of nutrition and health claims* (CXG 23-1997): Table of conditions for claims

General methods that measure both the higher (monomeric units > 9) and the lower molecular weight fraction (monomeric units <=9)				
Standard	**Provisions**	**Method**	**Principle**	**Type**
All foods	Method applicable for determining the content of insoluble and soluble dietary fibres of higher and lower molecular weight. The method is applicable in food that may, or may not, contain resistant starches.	AOAC 2022.01/ AACC 32-61.01/ ICC Standard No. 191*	Enzymatic-Gravimetry High Pressure Liquid Chromatography	I

*Isolated, purified, and/or synthetic fibres captured by AOAC 2022.01/ICC Standard 191/AACC 32-61.01 that do not meet the Codex definition of dietary fibre in the *Guidelines on nutrition labelling* (CXG 2-1985) should be subtracted from the final measurement, where deemed appropriate by competent authorities.

A.2 Methods for provisions in follow-up formula and infant formula

Commodity	Provision	Method	Principle	Type
Follow-up formula	Vitamin A	AOAC 2012.10 / ISO 20633	HPLC-UV	II
	Vitamin E	AOAC 2012.10 / ISO 20633	HPLC	II
	Vitamin D	AOAC 2016.05 / ISO 20636	LC-MS	II
	Thiamine	AOAC 2015.14 / ISO 21470	Enzymatic digestion and UHPLC-MS/MS	II
	Riboflavin	AOAC 2015.14 / ISO 21470	Enzymatic digestion and UHPLC-MS/MS	II
	Niacin	AOAC 2015.14 / ISO 21470	Enzymatic digestion and UHPLC-MS/MS	II
	Vitamin B_6	AOAC 2015.14 / ISO 21470	Enzymatic digestion and UHPLC-MS/MS	II
	Vitamin B_{12}	AOAC 2011.10 / ISO 20634	HPLC	II
		AOAC 2014.02	LC-UV	III
	Pantothenic acid	AOAC 2012.16 / ISO 20639	UHPLC-MS/MS	II
	Folic Acid	AOAC 2011.06 / ISO 20631	LC-MS/MS	II
	Vitamin C	AOAC 2012.22 / ISO 20635	HPLC-UV	II
	Biotin	AOAC 2016.02 / ISO 23305	HPLC-UV	II
	Iron	AOAC 2015.06 / ISO 21424 | IDF 243	ICP-MS	II
		AOAC 2011.14 / ISO 15151 | IDF 229	ICP emission spectroscopy	III

Commodity	Provision	Method	Principle	Type
	Calcium	AOAC 2015.06 / ISO 21424 | IDF 243	ICP-MS	II
		AOAC 2011.14 / ISO 15151 | IDF 229	ICP emission spectroscopy	III
	Phosphorus	AOAC 2015.06 / ISO 21424 | IDF 243	ICP-MS	II
		AOAC 2011.14 / ISO 15151 | IDF 229	ICP emission spectroscopy	III
	Magnesium	AOAC 2015.06 / ISO 21424 | IDF 243	ICP-MS	II
		AOAC 2011.14 / ISO 15151 | IDF 229	ICP emission spectroscopy	III
	Sodium	AOAC 2015.06 / ISO 21424 | IDF 243	ICP-MS	II
		AOAC 2011.14 / ISO 15151 | IDF 229	ICP emission spectroscopy	III
	Chloride	AOAC 2016.03 / ISO 21422 | IDF 242	Potentiometry	II
	Potassium	AOAC 2015.06 / ISO 21424 | IDF 243	ICP-MS	II
		AOAC 2011.14 / ISO 15151 | IDF 229	ICP emission spectroscopy	III
	Manganese	AOAC 2015.06 / ISO 21424 | IDF 243	ICP-MS	II
		AOAC 2011.14 / ISO 15151 | IDF 229	ICP emission spectroscopy	III
	Iodine	AOAC 2012.15 / ISO 20647 | IDF 234	ICP-MS	II
	Selenium	AOAC 2011.19 / ISO 20649 | IDF 235	ICP-MS	II
	Copper	AOAC 2015.06 / ISO 21424 | IDF 243	ICP-MS	II
		AOAC 2011.14 / ISO 15151 | IDF 229	ICP emission spectroscopy	III
	Zinc	AOAC 2015.06 / ISO 21424 | IDF 243	ICP-MS	II
		AOAC 2011.14 / ISO 15151 | IDF 229	ICP emission spectroscopy	III
	Total nucleotides	AOAC 2011.20 / ISO 20638	LC	II
	Choline	AOAC 2015.10 / ISO 21468	UHPLC-MS/MS	II
	Myo-inositol	AOAC 2011.18 / ISO 20637	LC-pulsed amperometry	II
	L-carnitine	AOAC 2015.10 / ISO 21468	UHPLC-MS/MS	II
	Total amino acids (excluding taurine and tryptophan) for use according to section 3.1.3 (a) notes 2) and 3) of CXS 156-1987	AOAC 2018.06 / ISO 4214 | IDF 254 /AACC 07-50.01	UHPLC-UV	II
	Tryptophan	AOAC 2017.03	HPLC	II
	Total fatty acids	AOAC 2012.13 / ISO 16958 | IDF 231	Gas chromatography	II
	Crude protein	ISO 8968-1 | IDF 20-1	Titrimetry (Kjedahl)	I
Infant formula	Folic acid	AOAC 2011.06/ISO 20631	LC-MS/MS	II

Part B: Methods of Analysis i~~I~~ncluded in CXS 234-1999 for revocation or retyping

B.1 Methods for provisions in follow-up formula for revocation or retyping

Commodity	Provision	Method	Principle	Type	Note
Follow-up formula	Vitamin A	AOAC 992.04	HPLC	II	Retype or revoke
		AOAC 992.06	HPLC	III	Retype or revoke
		AOAC 974.29	Colorimetry	IV	Retype or revoke
	Pantothenic acid	AOAC 992.07	Microbioassay	~~II~~ III	Retype
	Iodine	AOAC 992.24	Ion-selective potentiometry	~~II~~III	Retype or revoke

B.2: Methods for dietary fibre for revocation

General methods that measure both the higher (monomeric units > 9) and the lower molecular weight fraction (monomeric units <=9)				
Standard	**Provisions**	**Method**	**Principle**	**Type**
All foods	Method applicable for determining the content of insoluble and soluble dietary fibres of higher and lower molecular weight. The method is applicable in food that may, or may not, contain resistant starches.	AACC Intl 32-50.01 AOAC 2011.25	Enzymatic-Gravimetry High Pressure Liquid Chromatography	I

Part C: proposal to include the nitrogen to protein conversion factors for follow-up formula for older infants and product for young children in the annex in CXS 234-1999 (for information by CCMAS)

Follow-up formula for older infants and product for young children[1]: The calculation of the protein content of the final product ready for consumption should be based on N x 6.25, unless a scientific justification is provided for the use of a different conversion factor for a particular product. The protein levels set in this standard are based on a nitrogen conversion factor of 6.25. For information the value of 6.38 is used as a specific factor appropriate for conversion of nitrogen to protein in other Codex standards for milk products.

[1] *Other equivalent names for this product are “Drink for young children with added nutrients”, or “Product for young children with added nutrients”, or “Drink for young children”