

CODEX ALIMENTARIUS COMMISSION

E



Food and Agriculture
Organization of the
United Nations



World Health
Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: codex@fao.org - www.codexalimentarius.org

REP23/NFSDU

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Forty-Sixth Session

27 November – 2 December 2023

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

Düsseldorf, Germany
07 – 10 March and 15 March 2023

TABLE OF CONTENTS

Summary and Status of Work.....	page ii – iii
List of Abbreviations	page iv
Report of the Forty-third Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses	page 1

Paragraphs

Introduction	1
Opening of the Session	2 - 4
Adoption of the Agenda (Agenda item 1)	5 - 7
Matters Referred to the Committee by the Codex Alimentarius Commission and/or Other Subsidiary Bodies (Agenda item 2)	8 - 9
Matters of Interest Arising from FAO and WHO (Agenda item 3)	10 - 17
Review of the <i>Standard for Follow-up Formula</i> (Preamble and structure) (Agenda item 4)	18 – 51
General principles for the establishment of NRVs-R for persons aged 6-36 months (Agenda item 5)	52 - 73
Technological justification for several food additives (Agenda item 6).....	74 - 86
Prioritization mechanism / emerging issues or new work proposals (Agenda item 7)	87 - 118
Other business (Agenda item 8)	
Methods of analysis	119 -128
Date and place of next session (Agenda item 9)	129

Appendices

page

Appendix I - List of Participants	16
Appendix II – Standard for follow-up Formula for older infants and product for young children	30
Appendix III – Proposed draft general principles for establishing nutrient reference values for persons aged 6 to 36 months	49
Appendix IV – Proposed amendment to the <i>Standard for Canned Baby Foods</i> (CXS 73-1981).....	51
Appendix V – Proposed amendment to the <i>Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children</i> (CXG 10-1979)	52
Appendix VI – Proposed methods of analysis for endorsement and inclusion in CXS 234-1999.....	53

SUMMARY AND STATUS OF WORK

Responsible Party	Purpose	Text/Topic	Code	Step	Para.
CCEXEC84/85 CAC46	Adoption	Revised <i>Standard for Follow-up Formula</i> (renamed as the <i>Standard for Follow-up Formula for Older Infants and Product for Young Children</i>) (CXS156-1987)	N07-2013	5/8 and 8	50, and App II
		Amendments to the <i>Standard for Canned Baby Foods</i> (CXS 73-1981) and the <i>Advisory list of nutrient compounds for use in foods for special dietary uses intended for infants and young children</i> (CXG 10-1979)	-	-	100 and 101
		General Principles for establishing Nutrient Reference Values (NRVs-R) for persons aged 6 to 36 months (CXG 2-1985)	N06-2008	5	72 (i) App. III
CCMAS	Endorsement, and Action	i. Amend CXS 234-1999 to include new entry "product for young children" with the "follow-up formula" ii. Methods for vitamin B12; total amino acids (excluding taurine and tryptophan), and tryptophan in CXS 72-1981)	-	-	51; 122-123
		Note: a) the technological justification and use levels for: i) of low-acyl clarified gellan gum (INS 418); and to be include in the GSFA under the food category 13.1.3 "Formulae for special medical purposes for infants"; ii) ascorbyl palmitate (INS 304) and tocopherol concentrate, mixed (INS 307b); and iv) phosphates (INS 339(i), 339(ii) and 339(iii) and INS 340(i), 340(ii) and 340(iii)) b) include them on JECFA priority list	-	-	78; 80; 82; and 86 (i)
EWG / PWG (Ireland, Costa Rica and United States of America) CCNFSDU44	Redrafting	Address outstanding issues on General Principles for the establishment of NRVs-R for persons aged 6 – 36 months; revise the draft Stepwise Process; apply the stepwise process to propose NRVs-R for persons aged 6-36 months	-	5	72
EWG / PWG (European Union) CCNFSDU44	Action	Collection and review of information on the use, and use levels for 5 identified additives; and their technological justification	-	-	86 (ii)
EWG / PWG (Canada and Germany) CCNFSDU44	Redrafting / reviewing	Prioritization mechanism / emerging issues or new work proposals	-	-	97
EWG (Argentina, China and Malaysia) PWG on prioritization / emerging issues or new work proposals CCNFSDU44	Redrafting	Harmonised probiotic guidelines	-	-	106

Responsible Party	Purpose	Text/Topic	Code	Step	Para.
Codex Secretariat CCNFSDU44	Review	Approaches to review all the texts under the purview of CCNFSDU	-	-	118
EWG (United States of America) CCNFSDU44	Review	Use of fructans, beta-carotene, lycopene in CXS 72-1981			125
EWG (European Union; Switzerland) CCNFSDU44	Review	Methods for assessing the sweetness of carbohydrate sources			128

LIST OF ABBREVIATIONS

AOAC	AOAC International (formerly the Association of Official Agricultural Chemists)
CAC	Codex Alimentarius Commission
CCEXEC	Executive Committee of the Codex Alimentarius Commission
CCFA	Codex Committee on Food Additives
CCFH	Codex Committee on Food Hygiene
CCFL	Codex Committee on Food Labelling
CFS	Committee on World Food Security
CCMAS	Codex Committee on Methods of Analysis and Sampling
CCNFSDU	Codex Committee on Nutrition and Foods for Special Dietary Uses
CRD	Conference Room Document
CL	Circular Letter
CXS	Codex Standard
CXG	Codex Guideline
DIRV	Dietary Intake Reference Values
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
IDF	International Dairy Federation
IAEA	International Atomic Energy Agency
INL98	Individual Nutrient Level 98
ISO	International Organization for Standardization
JECFA	Joint FAO/WHO Expert Committee on Food Additives
JEMNU	Joint FAO/WHO Expert Meetings on Nutrition
NUGAG	WHO Nutrition Guidance Expert Advisory Group
NCD	Noncommunicable diseases
NRV-NCD	Nutrient reference values – non-communicable disease
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
UNICEF	The United Nations Children’s Fund
WHA	World Health Assembly
WHO	World Health Organization

INTRODUCTION

1. The forty-third Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) was held in Düsseldorf, Germany, from 7 to 10 March 2023, with virtual report adoption on 15 March 2023, at the kind invitation of the Federal Government of Germany. Dr Anja Brönstrup from the Federal Ministry of Food and Agriculture, Germany, and Ms Martine Püster from the Federal Office of Consumer Protection and Food Safety, Germany, served as Chairperson and Co-Chairperson of the Session respectively. The Session was attended by 60 Member Countries, one Member Organisation and 29 Observer organisations. A list of participants is given in Appendix I.

OPENING OF THE SESSION

2. The Parliamentary State Secretary to the Federal Minister of Food and Agriculture, Dr Ophelia Nick, Germany, welcomed delegates via a video message. Dr Doris Heberle from the Federal Ministry of Food and Agriculture, Germany, gave the opening address. She underlined the unique mandate of the Codex Alimentarius Commission, to protect consumer health and ensure fair practices in the food trade at a time when health protection and the elimination of trade barriers were more important than ever in a globalised world.
3. The Chairperson of the Codex Alimentarius Commission (CAC), Steve Wearne (United Kingdom), Francesco Branca, World Health Organization (WHO), Fatima Hachem, Food and Agriculture Organization of the United Nations (FAO) and Tom Heilandt, Codex Secretary also addressed the meeting.

Division of competence¹

4. CCNFSDU43 noted the division of competence between the European Union (EU) and its Member States, according to paragraph 5, Rule II of the Rules of Procedure of the Codex Alimentarius Commission as presented in CRD1.

ADOPTION OF THE AGENDA (Agenda Item 1)²

5. CCNFSDU43 adopted the Provisional Agenda as the Agenda for the session and agreed to establish the following in-session working groups:
6. Agenda Item 6 – Technological justification for several food additives, chaired by the EU, working in English, French and Spanish with the following terms of reference:

To discuss:

- a) The technological justification of the following additives for use in the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CXS 72-1981):
 - i. low acyl clarified gellan gum (INS 418)
 - ii. ascorbyl palmitate (INS 304)
 - iii. mixed tocopherol concentrates (INS 307b)
 - iv. phosphates (INS 339(i), 339(ii) and 339(iii) and INS 340(i), 340(ii), and 340(iii))
- b) The plan/programme for the consideration of the remaining food additives in Annex 2 to Circular Letter (CL) 2022/80/OCS-NFSDU

7. Agenda Item 8a – Methods of analysis, co-chaired by the United States of America (USA) and the EU, working in English, French and Spanish with the following terms of reference:

To consider:

- a) Analytical methods for provisions in the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CXS 72-1981) (CRD4);
- b) The request from CCMAS41 relating to the methods for fructans, beta-carotene and lycopene in CXS 72-181 (CX/NFSDU 23/43/2 Rev, para. 18 and CRDs 10, 20, 23, 25), and
- c) The appropriate methods for assessing sweetness of carbohydrate sources in "Drink for young children with added nutrients or Product for young children with added nutrients or Drink for young children or Product for young children" (CRDs 11, 16, 18).

¹ CRD1 (Annotated Agenda – Division of competence between the EU and its Member States)

² CX/NFSDU 23/43/1

MATTERS REFERRED TO THE COMMITTEE BY THE CODEX ALIMENTARIUS COMMISSION AND/OR OTHER SUBSIDIARY BODIES (Agenda Item 2)³

8. CCNFSDU43 noted that some matters were for information only, and that the following matters as outlined in paragraph 18 of document CX/NFSDU 23/43/2 Rev would be considered under the relevant agenda items:
- reply from CCFL46 relating to nutrient profiles (Agenda Item 7);
 - request from CCMAS41 relating to the methods for fructans, beta-carotene and lycopene in CXS 72-1981 (Agenda Item 8a).
9. CCNFSDU43 agreed that the request from CCEXEC83 in paragraph 19 of CX/NFSDU 23/43/2 Rev; i.e. to give due regard to ongoing global efforts to achieve health and nutrition related goals through reducing noncommunicable diseases (NCD) risk factors such as sodium intake when considering new standards or during the review of standards relating to composition of foods.

MATTERS OF INTEREST ARISING FROM FAO AND WHO (Agenda Item 3)⁴

10. The Representative of FAO reported on the joint FAO/WHO scientific advice activities, in particular the work related to the update of nutrient intake values (NIVs) for infants and young children from birth through three years of age. She informed the Committee of the progress to date in the work related to the NIVs of calcium, vitamin D and zinc, noting that the draft NIVs for the three nutrients are expected to be available no later than September 2023.
11. The Representative also reported on the FAO commissioned report to assess, categorize and rank the methods used to derive Dietary Intake Reference Values (DIRVs) for protein and 24 micronutrients for older infants (6-12 months) and young children (12-36 months). She informed the Committee that the report had been shared with the Electronic Working Group (EWG) on the establishment of NRVs-R for persons aged 6-36 months.
12. The Representative presented other joint activities with WHO highlighted in CX/NFSDU 23/43/3 including an update on the UN Decade of Action on Nutrition 2016-2025, the State of Food Security and Nutrition in the World 2022, and the Committee on World Food Security (CFS) Voluntary Guidelines on Food Systems and Nutrition.
13. The Representative further informed the Committee of the outcomes of a Joint IAEA/FAO meeting on the Way Forward for the Assessment of Protein Requirements and Protein Quality and for the Development of a Protein Digestibility and Quality Database (October 2022), the new FAO methodology to develop and implement Food Systems-Based Dietary Guidelines, the launch of the School Food Global Hub in support of the Peer-to-Peer Initiative under the School Meals Coalition, and the joint FAO/UNICEF global capacity development initiative for education officials and curriculum developers.
14. The Representative of WHO highlighted relevant WHO activities including the activities related to: Ready-to-Use Therapeutic Foods (RUTF) - development of the 2021 WHO guideline on the dairy protein content in RUTF for treatment of uncomplicated severe acute malnutrition; a 2021 technical workshop to improve availability of RUTF; a soon-to-be published guideline on wasting management, which includes updated recommendations on the quantity and duration of RUTF usage; and a joint application of WHO and UNICEF to add RUTF to the WHO Model List of Essential Medicines (EML). The Representative noted that the complementary feeding guidelines were expected to be released shortly and further referred to 2022 studies on the Code of Marketing of Breast-milk Substitutes, and a global congress on the Code to be held in June 2023.
15. The Representative further drew the attention of the Committee to the forthcoming Nutrition Guidance Expert Advisory Group (NUGAG) guidelines on diet and health: total fat; saturated fatty acids and trans-fatty acids; carbohydrates; non-sugar sweeteners; polyunsaturated fatty acids; and low-sodium salt substitutes. The forthcoming NUGAG guidelines on policy actions were also highlighted: food marketing; fiscal policies; school food and nutrition policies; and nutrition labelling policies.
16. The Representative also informed the Committee on activities related to the global elimination of industrially-produced trans-fatty acids (TFA) by 2023 as well as the first Global Report on Sodium Reduction; past and ongoing work on nutrient profile models; and the call for experts for the Joint FAO/WHO Expert Consultation on the Risks and Benefits of Fish Consumption scheduled in October 2023.

³ CX/NFSDU 23/43/2 Rev; CRD10 (Mali, Niger and Nigeria); CRD20 (Kenya); CRD23 (African Union); CRD25 (Senegal)

⁴ CX/NFSDU 23/43/3

Conclusion

17. CCNFSDU43 noted the information provided by FAO and WHO and expressed its thanks for their work in commissioning and providing scientific advice.

REVIEW OF THE STANDARD FOR FOLLOW-UP FORMULA (CXS 156-1987): PREAMBLE AND STRUCTURE (AT STEP4) (Agenda Item 4)⁵

18. The Chairperson of the EWG, New Zealand, speaking on behalf of the Co-chairpersons France and Indonesia, provided an overview of the history and status of the work on the revision of the *Follow-Up Formula Standard* (CXS 156-1987) highlighting:
- the extensive global scientific data gathered on nutrient requirements and the role of these products in the diet to underpin the composition of the products for the two age ranges;
 - the key compositional improvements made in the draft revised standard compared to the 1987 version;
 - the establishment of provisions for optimized protein levels and enhanced protein quality to meet the needs of older infants and young children; that there is now a ban on the use of partially hydrogenated fats and oils for both product categories and the establishment of carbohydrate provisions for both product categories that includes maximum levels and guidance on carbohydrate sources, and;
 - that whilst the Committee acknowledges that follow-up formula for older infants and product for young children are not considered nutritionally necessary in the diets of older infants and young children, there is agreement that as these products are commonly consumed and traded it is considered essential that they are adequately regulated.
19. The EWG Chairperson highlighted further how the Committee had used the WHO/World Health Assembly (WHA) documents to inform the labelling provisions as illustrated within CRD3 providing for a significant level of regulation over the labelling of these products that will result in greater restriction and control than in the current standard.
20. The EWG Chairperson reminded the Committee that the draft revised standard has been in development for over 10 years and has included eight EWGs and two physical working groups (PWG), 19 consultation papers, eight agenda papers, two scientific reports from FAO and one from JEMNU on protein quality and nitrogen conversion factors.
21. The CCNFSDU Chairperson recalled that CCNFSDU42 had agreed to keep the remaining sections of the text at Step 4 on the understanding that all issues in Sections A and B had been addressed and no further discussions were required. CCNFSDU42 had further agreed to hold the scope, description and labelling and essential composition of Sections A and B at Step 7 to advance the entire standard to the Commission for adoption once all outstanding points had been addressed.
22. In March 2022, a CL was circulated seeking comments on the last two remaining aspects of the draft revised standard, the Structure and the Preamble. Comments received in response to this CL informed the recommendations put forward to CCNFSDU43 in CRD2.

Structure of the standard

23. Based on the clear majority of the respondents to the CL, CRD2 recommended one standard in two parts as the structure of the standard; part A covering Follow-up Formula for Older Infants and part B covering Product for Young Children or Drink for Young Children with Added Nutrients or Product for Young Children with Added Nutrients or Drink for Young Children (hereafter referred to as “Product for Young Children”).
24. The EWG Chairperson explained that the common justification provided in support of this approach was that this is in line with how the Committee has approached and conducted the review of the standard, and that while the two products had different compositions and were intended for two distinct age groups, they were based on a similar concept as being a liquid part of the diversified diet of either older infants or young children.
25. One standard with two parts was seen as an adequate approach to distinguish the two products, as had been done with the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CXS 72-1981) covering two compositionally distinct but conceptually similar product categories.

⁵ CX/NFSDU 23/43/4; CL2022/24/OCS-NFSDU; CRD2 (New Zealand); CRD3 (New Zealand); CRD11 (Costa Rica, Malaysia, Mali, Nepal, Niger, Nigeria, Norway, Republic of Korea, Rwanda, South Africa, Uganda, Vietnam, Helen Keller International, ILCA, ISDI, UNICEF); CRD17 (Argentina); CRD19 (Indonesia); CRD 20 (Kenya); CRD23 (African Union); CRD24 (IBFAN); CRD25 (Senegal); CRD27 (Panama); CRD29 (Mexico); CRD30 (Thailand); CRD31 (Russian Federation); CRD34 (Ghana); CRD38 (Ecuador)

Discussion

26. Views expressed by delegations in favour of a single standard with two parts included: that some countries regulate products for the entire age range of 6-36 months; the need for harmonizing and simplifying the standard at the international level; that a single standard was a more simple and adequate approach to distinguish the two product categories; it provided consistency with CXS 72-1981, and the need to provide a safeguard as both products are regulated as breastmilk substitutes in some countries.
27. There were also views expressed for either two separate standards which was deemed more logical due to the differences in composition; or a single standard that covered four different products, which included the products covered by CXS 72-1981.
28. The CCNFSDU Chairperson summarized the discussion noting overwhelming support for establishing one standard with two parts: Part A covering Follow-up Formula for Older Infants and Part B covering Product for Young Children. The Chairperson noted that delegations had underlined their preference for a pragmatic approach that would enable the timely completion of the revision of the standard.

Conclusion on the structure

29. CCNFSDU43 agreed to progress with one standard with two parts.

Name of the standard

30. In response to a question posed by the Chairperson on rules and approaches for renaming the revised standard, the Codex Secretary confirmed that the name of the standard, in accordance with the Procedural Manual (PM), should be as clear and concise as possible. In this case, that would mean establishing a new name indicating both follow-up formula for older infants and product for young children in a new title, and that if a fully informative title was inordinately long, a footnote could be included on the first page of the Standard to capture all naming conventions.
31. The Codex Secretary proposed that the title of the revised standard be the *Standard for Follow-up Formula for Older Infants and Product for Young Children* with a footnote stating: 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*.

Conclusion on the name of the standard

32. CCNFSDU43 agreed to rename the draft revised standard as proposed.

Preamble

33. The Chairperson recalled that Circular Letter (CL) 2022/24/OCS-NFSDU asked delegations whether they considered a preamble necessary and if so, what detail it should contain. The CL had recalled that any preamble texts should not be in conflict with the provisions of the standard or be more stringent than the composition and labelling aspects of the standard, as these had already been agreed to by the Committee. The preamble should set the scene by providing the overall context, without specifying any product requirements which are found within the main body of the standard.
34. The EWG Chairperson summarized that CL respondents were almost equally split between those who preferred a simple statement to say that the standard is divided into two parts versus those who supported a more detailed text that referenced WHO documents and/or WHA resolutions.
35. CL responses supporting a more detailed preamble identified policy coherence as the premise for this approach, as the Preamble could act as a prompt to countries that in addition to the standard itself other guidance material and international instruments exist.
36. Those supporting a simple preamble or no preamble at all were primarily of the view that the Committee had followed the advice of the 75th session of the Executive Committee (CCEXEC75) and incorporated the applicable concepts and guidance from WHO documents and WHA resolutions into the text of the Standard itself, making reference to these within the preamble unnecessary.
37. The Chairperson of the Committee reminded the Committee that the PM did not require a standard to have a preamble, nor did it provide guidance on the purpose of a preamble and what it should include. She however cited several texts that did contain a preamble including the *General Standard for Food Additives* (GSFA, CXS 192-1995), the *General Standard for Contaminants and Toxins in Food and Feed* (CXS 193-1995), the recent *Guidelines for Ready-to-use Therapeutic Foods* (CXG 95-2022), and the example most often mentioned in relation to this discussion, the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CXS 72-1981).

38. The Chairperson further recalled that the Codex Secretariat had previously clarified that the preamble should not address matters outside the scope of Codex, and that discussion on the preamble should be guided by the general principles of the Codex Alimentarius. By means of an example, she cited the PM and Section three of the General Principles of The Codex Alimentarius, "*Nature of Codex standards*", which states "Codex standards and related texts are not a substitute for or alternative to national legislation".

Discussion

39. The Chairperson opened discussions asking delegations to comment on the need for, purpose, and content of a preamble.
40. The rationale provided by those who intervened for including a preamble included the following:
- To set the scene and assist countries in contextualizing the standard.
 - To guide countries in the application and implementation of the standard.
 - The need to include WHO references and WHA resolutions for the protection of breastfeeding.
 - To ensure policy coherence with WHO texts and WHA resolutions.
 - The need to include a statement on the importance of breastfeeding.
41. Some delegations felt that no preamble was necessary in the light of the changed title of the standard which made it clear that the standard had two parts.
42. Some delegations supported including a short preamble, which should be a factual statement similar to that in the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CXS 72-1981) and reads: "This Standard is divided into two sections. Section A refers to Infant Formula, and Section B deals with Formulas for Special Medical Purposes Intended for Infants." They noted that all relevant information was contained in the body of the draft revised standard and there was no need to repeat information. Reopening discussion on a preamble could put at risk the consensus reached on the main text of the standard.
43. The Chairperson concluded that in principle there was agreement on including a preamble. She invited the Committee to comment on the different paragraphs proposed in CRD2 as follows:
- Paragraph 1 This Standard is divided into two sections. Section A refers to Follow-up Formula for Older Infants, and Section B deals with Drink for Young Children with Added Nutrients, or Product for Young Children with Added Nutrients, or Drink for Young Children, or Product for Young Children.
- Paragraph 2 The application of this Standard should be consistent with national health and nutrition policies and relevant national/regional legislation and take into account the recommendations made in the International Code of Marketing of Breast-milk Substitutes, as per the national context.
- Paragraph 3 Relevant World Health Organization (WHO) guidelines and policies and World Health Assembly (WHA) resolutions were considered in the development of this Standard and may provide further guidance to countries.
44. In the discussion consensus emerged on Paragraph one which was considered short, concise and factual.
45. Regarding paragraphs 2 and 3, although most delegations could accept the text as drafted, some delegations did not support either or both of paragraphs two and three.
46. One member commented that paragraph two would reopen discussions that had already taken place and was contrary to the consensus reached by the Committee and inconsistent with international trade obligations and the guidance provided by CCEXEC.
47. The Chairperson invited the Committee to consider the three proposed Preamble paragraphs as a whole and not attempt to dissect them. Whilst it was self-evident that paragraphs two and three provided context on content that was already covered in the text of the draft revised standard, it was important for some delegations to stress this information again in a prominent position in the Preamble as a starting point for the standard.
48. The Chairperson therefore proposed that the Committee agree to accept all three paragraphs (with the editorial addition of the word "/regional" after the word "national" in paragraph two).

Conclusion on the Preamble

49. The Committee agreed to adopt all three paragraphs as the Preamble to the draft revised standard and noted reservations from the following countries on specific paragraphs of the proposed text:

- Argentina - Reservation to paragraphs two and three
- Colombia – Reservation to paragraph two
- Costa Rica – Reservation to paragraphs two and three
- Cuba - Reservation to paragraphs two and three
- Guatemala - Reservation to paragraphs two and three
- Panama - Reservation to paragraph two
- Morocco – Reservation to paragraph two
- United States of America – Reservation to paragraph two
- Vietnam - Reservation to paragraphs two and three

Overall Conclusion

50. Noting that agreement had been reached on the title, the structure and the Preamble and recalling that CCNFSDU42 had already reached agreement on all other issues in the remainder of the text which were currently at Steps 4 and 7, CCNFSDU43 agreed to forward the:
- a) proposed draft revised standard with the title as shown in Appendix II; the Structure and the Preamble together with the remaining sections of Part A and B, agreed to at CCNFSDU42, to CAC46 for adoption at Step 5/8;
 - b) parts of the text at Step 7 of the draft Revised Standard for Follow-up Formula (*Standard for Follow-up Formula for Older Infants and Product for Young Children*) to CAC46 for adoption at Step 8 (Appendix II).
51. CCNFSDU43 further agreed to inform the Codex Committee on Methods of Analysis and Sampling (CCMAS) to include a new entry titled "product for young children" within the "follow-up formula" section of the Recommended Methods of Analysis and Sampling (CXS 234-1999).

GENERAL PRINCIPLES FOR THE ESTABLISHMENT OF NRVS-R FOR PERSONS AGED 6 – 36 MONTHS (Agenda Item 5)⁶

52. Ireland, as EWG/PWG Chairperson, speaking also on behalf of the Co-chairpersons 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; a stepwise process to apply the draft general principles for establishing NRVs-R, and piloting the draft general principles on the agreed-upon nutrients. She highlighted that the draft Stepwise Process needed revision following the changes made to the draft General Principles during the PWG (see CRD05).
53. CCNFSDU43 agreed to the proposal of the Chairperson to use CRD05 as the basis for discussion on the draft General Principles for establishing NRVs-R for persons aged 6 - 36 months.

Recommendation 1 - Preamble

54. Ireland (PWG Chairperson) explained that the working group had broadly supported the proposed draft preamble, in particular the application of the NRVs-R for persons aged 6 – 36 months to be limited to those foods for special dietary uses (FSDU) targeting this age group. It was agreed not to list the relevant FSDU texts in the Preamble as these would be outlined in the main body of CXG 2-1985 with the list of NRVs-R clarifying which foods they applied to. It was also noted that the PWG had recommended not to refer to population weighted values as these were not relevant to this limited age group.
55. CCNFSDU43 agreed to the editorial changes, and endorsed the recommendation noting that the preamble was consistent to that of Annex 1 to the *General Principles for Establishing Nutrient Reference Values for the General Population* (CXG 2-1985).

Recommendation 2 – Definition of Recognized Authoritative Scientific Body (RASB)

56. CCNFSDU43 endorsed the recommendation to adopt the original wording of the definition for the RASB from Annex 1 in CXG 2-1985.

⁶ CX/NFSDU 23/43/5; CX/NFSDU 23/43/5 Add.1; CRD5 (Report of the PWG); CRD8 (Summary of comments by EWG Co-Chairpersons); CRD12 (European Union, Mali, Morocco, Niger, Nigeria, Rwanda, South Africa, Uganda); CRD19 (Indonesia); CRD20 (Kenya); CRD23 (African Union); CRD25 (Senegal); CRD27 (Panama); CRD29 (Mexico); CRD31 (Russian Federation); CRD32 (El Salvador); CRD34 (Ghana); CRD 35 (Costa Rica)

Recommendation 3

a) Definition for Adequate Intake

57. CCNFSDU43 considered the recommendation of the PWG to use the WHO definition for Average Intake which is the same as Adequate Intake and exchanged the following views:
- Adopting the definition from WHO would ensure a consistent approach with the work WHO is completing on nutrient intake values for infants and young children.
 - Adequate Intake is a recommended intake based on observed or experimentally determined approximations or estimates of nutrient intake by a group (or groups) of apparently healthy people that are assumed to be adequate. This definition covers the derivation of DIRVs for persons aged 6 to 36 months, which often involves scaling.
 - If the definition for Adequate Intake was adopted, the footnote on growth and development could be removed.
 - The proposed definition was unclear as it included a circular definition.
 - Reference to health promotion should not be included in the definition.
 - As the age range for the draft general principles is 6 to 36 months as stated in the preamble, there is no need to include this information in the definition.
 - Annex 1 to CXG 2-1985 did not contain such a definition and there was no need to include it in the proposed draft general principles.
58. Regarding the definition, the Representative of WHO noted that the WHO definition indicated by one delegation in the PWG came from the 2007 WHO document *Guidelines on food fortification with micronutrients*⁷. In this document, a definition is provided for “average intake” which created some confusion with “estimated average intake”, but the Representative clarified that this definition is in fact for “adequate intake” (a separate definition is provided in the same document, same glossary, for estimated average intake). This definition for adequate intake has subsequently been used by others with or without slight modifications since the publication of the 2007 document and is a concise and accurate description of what an adequate intake is.
59. The Representative of WHO further noted that to aid users of the forthcoming FAO/WHO guidance on calcium, vitamin D and zinc intake values and facilitate the work of the EWG and CCNFSDU on the General Principles for establishing NRVs-R for persons aged 6 to 36 months, the FAO/WHO expert group that is updating the nutrient intake values for infants and young children will be tasked with reviewing and updating the definition for adequate intake (along with other relevant terms) as needed. This definition will be available for use by the EWG and CCNFSDU once the guidance for calcium, vitamin D and zinc have been finalized, which is estimated for no later than September 2023.
60. CCNFSDU43 agreed to rename the title “Definitions” to “Definitions as used in these Principles” and to delete “as used in these Principles” elsewhere in section 2.
61. CCNFSDU43 also agreed to put the definition for the Adequate Intake in square brackets until the WHO report on the first set of intake values for nutrients is published later in 2023.

b) Editorial re-arrangement of the definitions

62. The Committee endorsed the recommendation for the editorial change to move the definition of Adequate Intake (currently in square brackets) before the definition for Upper Level of Intake (UL).

Recommendation 4 – 3.1 Selection of suitable data sources to establish NRVs-R

63. The PWG Chairperson explained that there had been broad support both within the EWG and PWG for FAO/WHO being the primary source of the daily intake reference values required for establishing NRVs; and that the proposed text in section 3.1 was aligned with the *Guidelines on Nutrition Labelling* (CXG 2-1985), Annex 1: General Principles for establishing Nutrient Reference Values for the General Population.
64. CCNFSDU43 endorsed the recommendation.

⁷ https://apps.who.int/iris/bitstream/handle/10665/43412/9241594012_eng.pdf

Recommendation 5 – 3.2 Appropriate basis for establishing NRVs-R

65. CCNFSDU43 considered the proposed draft text and agreed to:
- i. retain the reference to Individual Nutrient Level 98 (INL98) adding the word 'Ideally' at the beginning of the sentence; and
 - ii. to delete the reference "(2021 FAO report)"; and with these changes, endorsed the recommendation.

Recommendation 6 – NRVs-R for the 6-36 months age group

66. The PWG Chairperson informed the Committee that the EWG had recognised that there were many foods on the market covering the entire age range of 6-36 months and that it was timely to consider approaches for establishing NRVs-R for the entire age group. She explained that it would be feasible to select the higher value of the proposed NRVs-R for older infants and young children for the combined age range if it did not exceed the UL for older infants and young children, where available. Such an approach would be developed and piloted as the stepwise process was being developed as outlined in CRD08.
67. It was also proposed to explore the possibility of including the selection of the lower value or of the mean value of the two age groups when developing the NRVs-R for the combined age group of 6-36 months.
68. CCNFSDU43 agreed to insert the following text in square brackets for further consideration under section 3.2 to consider the combined NRVs-R values for persons aged 6-36 months:

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

OR

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

OR

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

Recommendation 7 – 3.3 Upper levels of Intake

69. CCNFSDU43 endorsed the recommendation noting that the proposed text of section 3.3 is in line with the corresponding section in CXG 2-1985, Annex I.

Recommendation 8 – Revision to the Stepwise process

70. CCNFSDU43 endorsed the recommendation to revise the proposed draft Stepwise Process considering the changes made to the text of the proposed draft General Principles.
71. The Chairperson of the PWG highlighted that the Stepwise Process could be contained in a standalone document and would not be included in the General Principles to ensure these were overarching and had the flexibility to ensure their future use.

Conclusion

72. CCNFSDU43 agreed to:
- i. Forward the proposed draft General Principles for establishing Nutrient Reference Values (NRVs-R) for persons aged 6 to 36 months to CAC46 for adoption at Step 5 (Appendix III); and
 - ii. Re-establish the EWG open to all Members and Observers, chaired by Ireland, and co-chaired by Costa Rica and the USA, working in English and Spanish to:
 - a. Revise the draft Stepwise Process taking into account the revisions to the draft General Principles and to develop an approach to propose NRVs-R for the combined age range of 6-36 months.
 - b. Apply the revised draft Stepwise Process to propose NRVs-R for persons aged 6-12 months, 12-36 months and 6-36 months for the following nutrients:
 - vitamins A, D, C, K and E, thiamine, riboflavin, niacin, vitamins B6 and B12, folate, pantothenic acid and biotin;
 - calcium, magnesium, iron, zinc, iodine, copper, selenium, manganese, phosphorus and potassium.
73. The possibility of holding a PWG prior to the next session of the Committee was kept open.

TECHNOLOGICAL JUSTIFICATION FOR SEVERAL FOOD ADDITIVES (Agenda Item 6)⁸

74. The Chairperson recalled that at CCNFSDU41, the "CCNFSDU framework for appraising the technological need for food additives" (hereafter referred to as the Framework) had been completed. Additionally, the appraisal of the technological need for xanthan gum (INS 415) and pectins (INS 440) had been carried out, and it was decided to continue with the appraisal of low-acyl clarified gellan gum (INS 418) and three other food additives, including a group food additive, in CCFA49/CRD15Rev. The Chairperson informed the participants that (i) the Framework had been published on the Codex website as an information document, and (ii) CL 2022/80/OCS-NFSDU had been circulated to collect comments from Members and Observers, as the EWG had not completed its work.
75. The EU, Chairperson of the in-session WG, explained that CCFA49/CRD15Rev provided an overview of food additives permitted for use in infant formula or formulas for special medical purposes intended for infants; noting that several food additives had no adequate risk assessment by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) for infants under the age of 12 weeks. The Chairperson further emphasized that the in-session WG had made recommendations for the four food additives as well as the Plan/Programme for the remaining food additives.
76. CCNFSDU43 considered the recommendations (as outlined in CRD40), took decisions and made comments as follows:

Recommendation 1: low acyl clarified gellan gum (INS 418)

77. In response to a question on the necessity of using low-acyl clarified gellan gum (INS 418), it was explained that this food additive was used in liquid formulas for special medical purposes that were based on hydrolysed protein and/or amino acids (e.g. for infants with milk allergy) and the reason for using this additive was to efficiently maintain the homogeneity of these products.
78. CCNFSDU43 agreed:
- i. that the proposed use of low-acyl clarified gellan gum (INS 418) as a thickener and stabilizer in formulas for special medical purposes intended for infants at 5 mg/100 ml limited to hydrolysed protein and/or amino acid-based liquid formula was technologically justified; and
 - ii. to request that CCFA consider including the food additive in the GSFA food category 13.1.3 "Formulae for special medical purposes for infants" once the specifications for the food additive had been assigned as "full", noting the on-going CCFA work on alignment of the food additive provisions in CXS 72-1981 with the GSFA as well as the "tentative" specification status for this food additive.

Recommendations 2 and 3: Ascorbyl palmitate (INS 304) and tocopherol concentrate, mixed (INS 307b)

79. The in-session WG Chairperson explained that: (i) for ascorbyl palmitate the proposal to change the maximum use level to GMP had not been agreed on since this additive had a numerical ADI and such change would not be in line with the principle for the use of additives in foods intended for infants and young children; and (ii) the reference to "singly or in combination" for ascorbyl palmitate (INS 304) and tocopherol concentrate, mixed (INS 307b) was irrelevant and therefore should be deleted.
80. CCNFSDU43 agreed that:
- i. the use of ascorbyl palmitate (INS 304) as an antioxidant at 1 mg/100 ml in all types of formula covered by CXS 72-1981 was technologically justified; and
 - ii. the use of tocopherol concentrate, mixed (INS 307b) as an antioxidant at 1 mg/100 ml in all types of infant formula covered by CXS 72-1981 was technologically justified.

Recommendation 4: Phosphates (INS 339(i), 339(ii) and 339(iii) and INS 340(i), 340(ii) and 340(iii))

81. An Observer pointed out that according to available epidemiological studies, there was a link between sodium intake and chronic diseases. As a result, allowing food additives containing sodium to be used in infant formula would be inappropriate.
82. CCNFSDU43 agreed that the use of phosphates (INS 339(i), 339(ii) and 339(iii) and INS 340(i), 340(ii) and 340(iii)) as acidity regulators at 45 mg/100 ml as phosphorus singly or in combination and within the limits for sodium, potassium and phosphorus in section 3.1.3 (e) of CXS 72-1981 in all types of formula was technologically justified.

⁸ CX/NFSDU 23/43/6; CRD13 (Mali, Niger, Nigeria, Republic of Korea, Rwanda, and South Africa); CRD19 (Indonesia); CRD20 (Kenya); CRD21 (Syrian Arab Republic); CRD23 (African Union); CRD24 (IBFAN); CRD25 (Senegal); CRD27(Panama); CRD30 (Thailand); CRD31 (Russian Federation); CRD40 (Report of the in-session WG on the technological justification for several food additives)

Recommendation 5: Plan/programme for the consideration of the remaining food additives in CCFA49/CRD15Rev

83. CCNFSDU43 agreed with the recommendation to establish an EWG to continue the work related to batch 2, as listed in CL 2022/80/OCS-NFSDU Annex 2.

Others

84. Some delegations reaffirmed the JECFA principle that "Baby foods should be prepared without food additives whenever possible" and expressed their view that food additives in infant formula should be reduced.
85. CCNFSDU43 noted that the following editorial corrections to CL 2022/80/OCS-NFSDU Annex 2, including:
- in batch 3, "L(+) lactic acid" should be replaced with "lactic acid, L-, D-, and DL- (INS 270) (only L(+)-form of lactic acid is permitted for use in products in compliance with CXS 72-1981)"; citric acid and citrates (INS 330, 331, 331iii, 332, 332ii) should be revised as citric acid and citrates (INS 330, 331(i), 331(iii), 332(i), 332(ii)); and
 - in batch 4, carbonates (INS 500, 501) should be revised as carbonates (INS 500(i), 500(ii), 501(i), 501(ii)).

Conclusion

86. CCNFSDU43 agreed to:
- i. inform CCFA of the aforementioned decisions regarding the technological justifications for the four food additives and request that CCFA include them in the priority list of substances proposed for evaluation by JECFA for use in foods intended for infants below 12 weeks of age;
 - ii. establish an EWG open to all Members and Observers, chaired by the EU, working in English with the following terms of reference:
 - a. to collect information from the applicants on the use and use levels and confirmation to provide data on the safety assessment for infants below 12 weeks of age on the following additives: guar gum (INS 412), distarch phosphate (INS 1412), phosphated distarch phosphate (INS 1413), acetylated distarch phosphate (INS 1414), hydroxypropyl starch (INS 1440);
 - b. to collect information from the applicants with the framework for considering technological justification for use in CXS 72-1981 on food additives for which the use, use levels and commitment to provide the data is confirmed; and
 - c. to review the information provided and provide recommendations to CCNFSDU44 on the technological justification of each additive.

PRIORITIZATION MECHANISM / EMERGING ISSUES OR NEW WORK PROPOSALS (Agenda item 7)⁹

87. The Chairperson recalled that the work on a prioritization mechanism had begun following a request from CCEXEC75 (2018).
88. At CCNFSDU41, the German Host Secretariat had proposed a draft guideline for the preliminary assessment and identification of work priorities for CCNFSDU (REP20/NFSDU Rev Appendix IX) including a process and criteria for prioritizing the work of CCNFSDU. CCNFSDU41 had agreed to implement these on a pilot basis to assess their usefulness. CCNFSDU41 had also agreed to set up a PWG chaired by Germany and co-chaired by Canada to meet prior to CCNFSDU42 to review all new work proposals and to simplify the draft guideline.
89. Due to the COVID-19 pandemic, CCNFSDU42 took place virtually in 2021 with an abridged agenda. The review of new work proposals was postponed to CCNFSDU43 while in the interim work on the prioritization mechanism continued in an EWG chaired by Germany and co-chaired by Canada. The results of this working group were published in CX/NFSDU 23/43/8.
90. A Circular Letter, (CL) 2020/30-NFSDU had been issued requesting proposals for new work. The Chairperson confirmed that all new work proposals received in reply to this CL had been kept for consideration by CCNFSDU43. Six new work proposals had been submitted in response to the CL and were published in CX/NFSDU 23/43/7.

⁹ CX/NFSDU 23/43/7, CX/NFSDU 23/43/8; CRD6 (Report of the PWG), CRD7 (Switzerland), CRD9 (Argentina and Malaysia), CRD14 (European Union, Malaysia, Mali, Niger, Nigeria, Republic of Korea, Vietnam, EUVEPRO, ENSA and IMACE, Fediol, Helen Keller International, IDF, IMACE, IPA, ISO); CRD19 (Indonesia); CRD20 (Kenya); CRD22 (Dominican Republic and Malaysia); CRD23 (African Union); CRD25 (Senegal); CRD26 (PWG on the prioritization mechanism, emerging issues: proposed addition to criteria); CRD27 (Panama); CRD28 (Paraguay); CRD29 (Mexico); CRD30 (Thailand); CRD31 (Russian Federation); CRD33 (Good Food Institute); CRD34 (Ghana); CRD35 (Costa Rica); CRD37 (WHO); CRD39 (Argentina and Malaysia)

91. The PWG that had met prior to CCNFSDU43 had reviewed all new work proposals using the revised prioritization mechanism on a pilot basis and had also reviewed the mechanism itself.

Draft guideline and prioritization mechanism

92. The Chairperson of the PWG described the aim of the guideline to pre-filter proposals for new work and ensure that only proposals which fulfil all procedural requirements would be forwarded to the Committee.
93. The Chairperson of the Committee proposed to discuss the different sections of the draft guideline: the process for considering and prioritizing proposals for new work; the decision tree for the preliminary assessment of new work proposals, and the criteria for the prioritization of new work proposals.

Process for considering and prioritizing proposals for new work

94. The Committee agreed to the stepwise process for submitting new work proposals outlined under points 7-16 in the draft guideline for the preliminary assessment to identify and prioritize new work for CCNFSDU (CX/NFSDU 23/43/8, Appendix I).

Decision tree

95. CCNFSDU43 agreed that the decision tree required further development after the revision of the prioritization criteria. The Chairperson clarified that the wording in step 1 should be revised based on the fact that proposals by observers needed a member leading the work, ideally endorsing an observer proposal and submitting it in reply to the CL.

Prioritization criteria

96. A number of suggestions, comments and questions were raised during the consideration of the draft guideline:
- Should the word “positive” before “impact” in the self-assessment criteria as well as in the decision tree be maintained or deleted; should possible negative impacts also be captured?
 - Should further criteria be added e.g. “impact on consumer interests”?
 - Should “global impact” be deleted or clarified as to create a common understanding including the impact on food security and whether One Health should be given consideration?
 - More guidance was needed on how to apply, interpret, limit or widen the Scale-System (high, medium, low), and/or the colours used in the decision tree.
 - Is a self-assessment the most appropriate way for evaluating proposals or would it be more useful to ask the submitter to provide more information on the criteria and let the PWG carry out the assessment?
 - An additional step in the process could ensure the scope of the new work proposal and the rationale are clear, and the Committee wishes to proceed with the new work.
 - An additional step in the process could determine whether there is a need to prioritize proposals e.g. when an insufficient number of acceptable new work proposals have been submitted to warrant prioritization, also considering the overall workload of the Committee.
 - More guidance to submitters was needed on how to be clear about the scope of their proposals.

Conclusion

97. The Committee agreed to:
- i. establish an EWG open to all Members and Observers, chaired by Canada and co-chaired by Germany, working in English and French with the following terms of reference:
 - ii. to prepare a revised draft guideline for the preliminary assessment and identification of work priorities for CCNFSDU, including prioritization criteria and the decision tree, taking into account the comments made in the PWG held prior to CCNFSDU43 as well as the comments and decisions made at CCNFSDU43; request that the Codex Secretariat issue a CL requesting for proposals for new work using the revised draft guideline, which would be implemented on a trial basis; and
 - iii. It was noted that a PWG, chaired by Canada and co-chaired by Germany, working in English, French and Spanish may be established and held in conjunction with CCNFSDU44 to consider the revised draft guideline on a trial basis and assess any new work proposals received in response to the CL.

Proposals for Amendments

Proposal 1.1: Proposed amendment/revision: *Standard for Canned Baby Foods (CXS 73-1981)* (submitted by the Dominican Republic)

98. The Representative of WHO noted the scientific literature has documented an increased risk of methaemoglobinaemia related to high nitrate intake among infants and young children. However, the risk appears to be rather low and linked primarily to consumption of contaminated well water. Consumption of root vegetables and other green leafy vegetables have also been linked to high nitrate intake when these are grown in soil with high nitrate content. However, the risk of methaemoglobinaemia is likely limited to infants who consume very large quantities of such vegetables. Several authors have suggested that the overall health and nutritional benefits of vegetables would outweigh the potential risk of methaemoglobinaemia except in very specific circumstances.
99. The Representative further noted that while the sentence in CXS 73-1981 paragraph 9.5.2 refers only to canned beetroot and spinach, other root vegetables (e.g. carrots) and other green leafy vegetables (e.g. chard, kale) may also contain high nitrate levels when the soil in which these were grown is contaminated. The risk of methaemoglobinaemia declines with age, but there does not appear to be a specific cutoff age at which the risk is particularly high. There is little justification for a cutoff of either 12 weeks (as currently specified in CXS 73-1981) or 12 months (as suggested in the proposed amendment). As such, in the view of WHO the current statement in 9.5.2 is not adequately evidence-based and should be deleted.
100. CCNFSDU43 agreed to the recommendation of the PWG to delete paragraph 9.5.2 from Standard CXS 73-1981 and submit the amendment directly to CAC46 for adoption (Appendix IV).

Proposal 1.2: Proposal to align the permitted uses of the folic acid source Calcium-L-Methyl-Folate with those of N-Pteroyl-L-Glutamic acid in the *Advisory list of nutrient compounds for use in foods for special dietary uses intended for infants and young children (CXG 10-1979)* (submitted by Switzerland)

101. CCNFSDU43 agreed to the recommendation of the PWG to revise the *Advisory list of nutrient compounds* in CXG 10-1979, part B, row 10.2 Calcium-L-methyl-folate by adding four additional checkmarks in the columns Sec. A of IF, FUF, PCBF and CBF as well as adding the reference USP to the column International and/or national bodies and submit the revision directly to CAC46 for adoption (Appendix V).

Proposals for new work

102. The Chairperson recalled that the reason for introducing a draft guideline for the preliminary assessment to identify and prioritize new work proposals was to screen proposals both for their completeness and for their precision regarding the scope and expected result of the new work.

Proposal 2.1: Harmonized probiotic guidelines for use in foods and food supplements (submitted by Argentina and Malaysia)

103. Argentina and Malaysia introduced the proposal and provided a response to concerns raised in the PWG (see CRD39).

Discussion

104. Delegations in favour of the new work proposal expressed the following views:
- The topic was of considerable relevance in many countries and tackled current challenges resulting from lack of national regulations on probiotics.
 - Although the work may be challenging, this was not a reason to not proceed.
 - Probiotic substances are in use as food ingredients in many countries and guidance was required.
 - It would be appropriate to consider developing a harmonized guideline for the age group above two years.
 - A Codex text would help ensure consumers have access to safe and effective probiotics, facilitate trade, and ensure that consumers are protected from unsafe and fraudulent probiotic products.
 - Harmonized probiotic guidelines for use in food and food supplements were necessary to ensure the quality of probiotic products on a global scale.
 - Guidance would help countries to regulate the proliferation of probiotic use in conventional foods and as food supplements.
 - The proposed guidelines are within the mandate of CCNFSDU and include several aspects not covered by existing Codex texts.

105. Delegations not in favour of proceeding with the new work expressed the following views:
- Probiotics represented a health concern rather than a food safety concern.
 - The term “probiotics” constituted a health claim since it was defined as live microorganisms which confer beneficial effects on health; for the establishment of minimum requirements, the strain specific health effect needs to be established, intellectual property rights need to be considered here, scientific assessment of effects would not be for this Committee, but for scientific risk assessment bodies such as JEMNU.
 - There were concerns on how the products were labelled and what kind of claims were being made for products for infants and young children.
 - Foods for persons below 3 years of age should be excluded from the scope.
 - The scope of the work, including considerations of a scientific or microbiological nature were beyond the mandate and resources of CCNFSDU.
 - The scope would need to be clarified regarding definition, minimum safety requirements and labelling parameters.
 - The work could go to CCFH or CCFL if the proposal were refined.
 - If the work is to support countries who do not have the resources to evaluate probiotics and rule out microbial microorganisms that are not probiotics, would the work of CCNFSDU include the evaluation of individual strains and how would this work be kept updated?

Conclusion

106. CCNFSDU43 agreed to establish an EWG open to all Members and Observers chaired by Argentina and co-chaired by China and Malaysia, working in English and Spanish, with the following terms of reference:
- i. Further refine and clarify Proposal 2.1 Discussion Paper on Harmonized Probiotic Guidelines for Use in Foods and Food Supplements in document CX/NFSDU 23/43/7, especially with regards to the scope, impact on food safety and need for scientific advice; and
 - ii. Develop a revised discussion paper and project document, taking into account comments at CCNFSDU43 and with the aim to consider it at CCNFSDU44 as part of the discussions of new work proposals.

Proposal 2.2: Guidelines including General Principles for the Nutritional Composition of Foods and Beverages made from Plant-based and other Alternative Protein Sources (submitted by Canada and USA)

107. The USA presented the proposal and outlined how a Codex text could give general guidance on what nutrients replacement foods (such as plant or other alternative protein sources) might need to contain to assure that when consumers replace animal-based variants with an alternate protein-based variant, nutrient adequacy would not be compromised. They asked for input from the Committee on aspects of this scope and stated that for fully developing/refining the scope of this work scientific advice from FAO and WHO would be helpful.
108. The Representative of the International Organization for Standardization (ISO) clarified that their own work on this topic seeks to identify what could be defined as plant-based food and what type of ingredients could be used. They further clarified that the nutritional composition of such products was currently out of their scope. They informed that the draft ISO standard would be available at the end of 2023 and expected to be finalized in 2024.
109. One Member Organization recommended limiting the scope, where essential nutrients, adequacy or equivalency were required, to voluntary initiatives. As there were different attitudes in the world with regards to adding nutrients to foods any guidance on mandatory addition of nutrients might be difficult to accept on worldwide.
110. One Member suggested that these products fall under the scope of new food sources and production systems (NFPS) which has been discussed at CAC44 and CAC45.
111. It was proposed that the *General Principles for the Addition of Essential Nutrients to Foods* (CXG 9-1987) could be amended to address the concerns mentioned by the proponents of the new work.
112. Other delegations expressed concern regarding the ultra-processed nature of plant-based and other alternative protein sources, including specific concerns about parasites and human allergic reactions to insect consumption. It was also suggested the global food-wastage problem be addressed first.

Conclusion

113. CCNFSDU43 agreed that Canada and USA would refine the scope of the new work proposal.

Proposal 2.3: General Guidelines to establish nutrient profiles for front-of-pack nutrition labelling (FOPNL)(submitted by Costa Rica, EU, Paraguay and USA)

Conclusion

114. CCNFSDU43 agreed that past and ongoing work in this area by WHO (CRD37) may be sufficient to meet the Committee's needs. CCNFSDU43 also agreed that due to the lack of support, the proposal should not be pursued at this time.

Proposal 2.4: Nutrient reference value (NRV-NCD) for trans-fatty acids (submitted by IMACE)

Conclusion

115. CCNFSDU43 agreed to not take up the new proposal in the absence of Member support.

Review of all CCNFSDU standards

116. The Chairperson recalled that the EWG had recommended the Committee consider conducting a review of its standards to ensure they remain relevant, consistent with other Codex texts and up to date. Following such a general review each revision proposed would need to be considered as new work and follow the draft guideline for the preliminary assessment to identify and prioritize new work for CCNFSDU.
117. The Codex Secretary proposed that the Codex Secretariat could initiate such a process in collaboration with FAO and WHO and calling upon advice from Members as needed and report back to CCNFSDU44.

Conclusion

118. CCNFSDU43 agreed that the Codex Secretariat would consider approaches to review all texts under the purview of CCNFSDU to assess if they were still fit for purpose and noted the willingness of FAO and WHO to assist in this task.

OTHER BUSINESS AND FUTURE WORK (Agenda Item 8)¹⁰**a) Methods of analysis¹¹**

119. The Chairperson of the In-session Working Group (USA) highlighted the three recommendations as contained in its report (CRD41).
120. CCNFSDU43 considered the recommendations and took the following decisions:

Methods of analysis for the provisions in the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CXS 72-1981)*

Recommendation 1 – Vitamin B12, Total Amino Acids and Tryptophan

121. One Member Organization clarified that the testing methods for total amino acids (excluding taurine and tryptophan) and tryptophan should be used for assessing compliance with Section 3.1.3a, footnotes 3 and 4 of CXS 72-1981 and not with "Section 3.2 Optional ingredients", and these requirements should be clearly stated in the *Recommended Methods of Analysis and Sampling (CXS 234-1999)*.
122. CCNFSDU43 agreed to forward the methods of analysis for vitamin B12; total amino acids (excluding taurine and tryptophan), and tryptophan to CCMAS for endorsement and inclusion in CXS 234-1999.
123. CCNFSDU43 also agreed that a note should be inserted in CXS 234-1999 to clarify that the provisions are methods for testing total amino acids (excluding taurine and tryptophan) and tryptophan, i.e. for use according to Section 3.1.3a footnotes 3 and 4 of CXS 72-1981 (see Appendix VI).

Recommendation 2 – Fructans, beta-carotene and lycopene

124. One Member Organization stated that the proposed work is an amendment of CXS 72 1981, section 3.2 on optional ingredients. Amounts may need to be established for these optional ingredients.
125. CCNFSDU43 endorsed the recommendation and agreed to establish an EWG open to all Members and Observer, chaired by USA, and working in English, with the following terms of reference:

¹⁰ REP22/NFSDU, paras 6(ii); CRD15 (CCC)

¹¹ CRD4 (ISDI); CRD16 (EU, Switzerland, AOAC International, IDF and ISO); CRD20 (Kenya); CRD27 (Panama); CRD30 (Thailand); CRD36 (USA); CRD41 (Report of the in-session WG on methods of analysis)

- i. to review the use of fructans, beta-carotene, lycopene in the context of optional ingredients in CXS 72-1981;
- ii. to develop recommendations to CCNFSDU44 regarding the safety and suitability of these ingredients as optional ingredients in CXS 72-1981; and
- iii. to submit a report for discussion at CCNFSDU44.

Methods of analysis for the provisions in the *Standard for Follow-up formula (CXS 156-1987)*

Recommendation 3 – Assessing the sweetness of carbohydrate sources

126. One delegation questioned the need for an EWG noting the narrow application of the request for a method related to a subset of product for young children, those based on non-milk protein.
127. CCNFSDU43 noted support for the recommendation along with the following views:
 - The EWG should collect scientifically available methods for use in sensory evaluation in the target age group (i.e. 12-36 months).
 - The preferred methods would be those based on comparison with lactose.
 - The ratio between lactose and glucose polymers in terms of how sweetness will be measured could be explored.
 - Concern was expressed about the use of flavourings and potential impact on sweetness.
128. CCNFSDU43 endorsed the recommendation and agreed to establish an EWG, open to all Members and Observers, chaired by the EU and co-chaired by Switzerland, , working in English, with the following terms of reference:
 - i. To review, identify and, if appropriate, recommend methods for referral to CCMAS for endorsement, in particular ISO 5495, for assessing the sweetness of carbohydrate sources in comparison to lactose in “Product for Young Children” in line with the revised CXS 156-1987, Section B, point 3.1.3c footnote 6 for those products based on non-milk protein.
 - ii. The approach described in CRD16 by the EU and Switzerland should be taken as a starting point.
 - iii. To submit a report for discussion at CCNFSDU44.

DATE AND PLACE OF THE NEXT SESSION (Agenda Item 9)

129. CCNFSDU43 was informed that its 44th Session was tentatively scheduled to take place within the next 18 months, the final arrangements being subject to confirmation by the Host Country in consultation with the Codex Secretariat.

LIST OF PARTICIPANTS

LISTE DES PARTICIPANTS

LISTA DE PARTICIPANTES

CHAIRPERSONS – PRÉSIDENTES - PRESIDENTAS

Dr Anja Broenstrup
Chairperson
Federal Ministry of Food and Agriculture
Bonn

Ms Martine Puester
Co-Chairperson
Federal Office of Consumer Protection and Food Safety
Berlin

CHAIRS'S ASSISTANT – ASSISTANTE DES PRÉSIDENTES – ASISTENTA DE LAS PRESIDENTAS

Dr Britta Nagl
Assistant to the Chair
Federal Institute for Risk Assessment

MEMBERS NATIONS AND MEMBER ORGANIZATIONS**ÉTATS MEMBRES ET ORGANISATIONS MEMBRES****ESTADOS MIEMBROS Y ORGANIZACIONES MIEMBROS****ALGERIA - ALGÉRIE - ARGELIA**

Mr Kolli Sami
 Directeur Général de la Régulation et de l'Organisation
 des Activités
 Ministère du Commerce et de la Promotions des
 Exportations
 Alger

ANGOLA

Dr Carlos Alberto De Sousa
 State Secretary
 Ministry of Health

Dr Jose Alberto Sofia
 Presidente Do Codex Angola
 Comite Nacional para o Codigo Alimentar em Angola
 Luanda

Mr Leopoldo Baio
 Press Officer
 Embassy of Angola in Germany

Ms Analgisa De Oliveira
 Protocol Officer
 Embassy of Angola in Germany

Ms Natália Maria Ferreira Conceição Rodrigues
 Coordinator of National Nutrition Program
 Ministry of Health

Ms Balbina M. Da Silva
 Ambassador
 Embassy of Angola in Germany

Eng Vítor Manuel
 Chefe de Departamento de Investigacao Cientifica
 Monitoramento e Supervisao da Qualidade
 Comite Nacional para o Codigo Alimentar em Angola
 Luanda

Mr Július Nierere De Campos Almeida
 Director of the Office of the State Secretary
 Ministry of Health

ARGENTINA - ARGENTINE

Ms Andrea Virginia Moser
 Jefa del Servicio de Alimentos Especiales

Instituto Nacional de Alimentos (INAL) - Administración
 Nacional de Medicamentos, Alimentos y Tecnología
 Médica (ANMAT)
 Buenos Aires

Ms Maria Soledad Echarri
 Asistente Profesional
 Instituto Nacional de Alimentos (INAL) -Administración
 Nacional de Medicamentos, Alimentos
 y Tecnología Médica (ANMAT)
 Buenos Aires

Eng María Alejandra Larre
 Asesora
 Secretaría de Agricultura, Ganadería y Pesca
 Ciudad Autónoma de Buenos Aires

AUSTRALIA - AUSTRALIE

Ms Jenny Hazelton
 Director - Labelling and Information Standards
 Food Standards Australia New Zealand, Australian
 Government
 Canberra

Ms Jane Broughton
 Regulatory Affairs Manager Infant Nutrition
 Nestle Nutrition Oceania
 Sydney

BELGIUM - BELGIQUE - BÉLGICA

Ms Isabelle Laquière
 Regulatory Expert Foods for specific groups, Nutrition
 and health claims, Novel foods, Allergens
 Federal Public Service Health, Food chain safety and
 Environment
 Brussels

BOTSWANA

Ms Onalenna Ntshebe
 Chief Health Officer
 Ministry of Health
 Gaborone

Ms Maemo Lesiapeto
 CHIEF DIETICIAN
 PRINCESS MARINA HOSPITAL - MINISTRY OF
 HEALTH
 GABORONE

Dr Tiyapo Carnio Mongwaketse
 Research Scientist
 National Food Technology Research Center
 Kanye

BRAZIL - BRÉSIL - BRASIL

Mrs Ana Claudia Marquim Firmo De Araújo
 Health Regulation Expert
 Brazilian Health Surveillance Agency - ANVISA
 Brasília-DF

Mrs Ana Paula De Rezende Peretti Giometti
Health Regulation Expert
Brazilian Health Surveillance Agency – Anvisa
Brasilia

Mr Rodrigo De Toledo Vianna
IBFAN/Brazil member
IBFAN/Brazil
São Paulo

Mr Henrique Moreira
Regulatory Affairs Manager
Brazilian National Confederation of Industry

CAMBODIA - CAMBODGE - CAMBOYA

Mr Dim Theng
Deputy Director General
Ministry of Commerce
Phnom Penh

Mr Kroeun Hou
Country Director
Helen Keller International Cambodia Office
Phnom Penh

CANADA - CANADÁ

Ms Maya Villeneuve
Associate Director
Health Canada
Ottawa

Mrs Chantal Martineau
Manager, Regulatory Projects
Health Canada
Ottawa

Mrs Misu Paul
Policy and Programs Leader
Canadian Food Inspection Agency (CFIA)
Ottawa

Ms Simmer Randhawa
A/National Manager,
Canadian Food Inspection Agency
Calgary

CHILE - CHILI

Mr Cristian Cofre
Asesor Técnico
Ministerio de Salud
Santiago

Mr Diego Orellana
Regulatory Affairs Manager Chile-Paraguay-Uruguay
Abbott Laboratories
Santiago

CHINA - CHINE

Mrs Dong Liang
Associate Professor
China National Center for Food Safety Risk
Assessment
Beijing

Ms Hoi Lam Alam Ng
Scientific Officer (Health and Nutrition Claims)
Centre for Food Safety, Food and Environmental
Hygiene Department, HKSAR Government
Hong Kong

COLOMBIA - COLOMBIE

Mrs Alba Rocio Jimenez Tovar
Profesional Especializado
Instituto Nacional de Vigilancia de Alimentos y
Medicamentos INVIMA
Bogota D.C.

COSTA RICA

Mrs Alejandra Chaverri Esquivel
Nutricionista
Ministerio de Salud
San Jose

Mrs Mónica Elizondo Andrade
Directora Asuntos Científicos y Regulatorios
Cámara Costarricense de la Industria Alimentaria
(CACIA)
San José

CROATIA - CROATIE - CROACIA

Ms Marija Pašalić
Senior Expert Advisor
Ministry of Health
Zagreb

CUBA

Mrs Yarisa Domínguez Ayllón
Jefa Departamento de Nutrición Comunitaria
Instituto de Higiene Epidemiología y Microbiología
INHEM
La Habana

DENMARK - DANEMARK - DINAMARCA

Ms Sandra Fisker Tomczyk
Academic Officer
Danish Veterinary and Food Administration
Glostrup

Ms Louise Myhre Utzen
Industry Observer
SEDAN
Copenhagen

ECUADOR - ÉQUATEUR

Ms Daniela Vivero
Secretaría del Comité Coordinador FAO/OMS para
América Latina y El Caribe CCLAC
Agencia de Regulación y Control Fito y Zoonosanitario -
AGROCALIDAD
Quito

EGYPT - ÉGYPTE - EGIPTO

Eng Mohamed Naser
 Technical Secretariat for Foods for Special Dietary
 Uses Committee
 Egyptian Organization for Standardization and Quality
 (EOS)
 Cairo

Dr Haidy Mohyeldin Hamdy Abdelkarim
 Scientific Regulatory Affairs Manager (Egypt, North
 Africa and Levant)
 PEPSICO
 Cairo

Dr Rasha Salaheldin Kamel Galal
 Head of the Department
 Egyptian National Food Safety Authority
 Cairo

Dr Adel Ismail
 Research and Development Director
 Hero Middle East & Africa
 New Cairo

Prof Mervat Ahmed Fouad Nasr
 Consultant of Special Food and Pharmacognosy
 National Nutrition Institute (NNI)
 Giza

Dr Shaymaa Sarhan
 Regulatory and Scientific Affairs Manager
 Nestle-Egypt
 Cairo

ESTONIA - ESTONIE

Ms Evelin Kivima
 Chief Specialist
 Ministry of Rural Affairs
 Tallinn

EUROPEAN UNION - UNION EUROPÉENNE - UNIÓN EUROPEA

Ms Judit Krommer
 Administrator
 European Commission
 BRUSSELS

Ms Carolin Bendadani
 Policy Officer
 European Commission
 Brussels

Ms Stephanie Bodenbach
 Administrator
 European Commission
 Brussels

Mr Jiri Sochor
 Head of Sector
 European Commission
 Brussels

FINLAND - FINLANDE - FINLANDIA

Ms Anna Lemström
 Senior Officer, Food Policy
 Ministry of Agriculture and Forestry

FRANCE - FRANCIA

Ms Alice Stengel
 Rédactrice
 Ministère de l'Économie et des Finances
 Paris

Mr Lucas Proust
 Point de contact national Codex
 SGAE
 Paris

GERMANY - ALLEMAGNE - ALEMANIA

Mrs Hilke Thordsen-Böhm
 Delegate
 Federal Ministry of Food and Agriculture
 Berlin

Ms Juliane Bauch
 Scientific Officer
 Federal Office of Consumer Protection and Food Safety
 Berlin

Ms Vanessa Beier
 Officer
 Federal Ministry of Food and Agriculture
 Berlin

Ms Anne Beutling
 Officer
 Federal Ministry of Food and Agriculture
 Berlin

Dr Evelyn Breitweg-Lehmann
 Head of General Affairs and Food Unit
 Federal Office of Consumer Protection and Food Safety
 (BVL)
 Berlin

Mrs Tatjana Drewitz
 Scientific Officer
 Federal Office of Consumer Protection and Food Safety
 Berlin

Dr Gerd Fricke
 Vice-President
 Federal Office of Consumer Protection and Food Safety
 Berlin

Mrs Anke Weissenborn
 Scientific Officer
 German Federal Institute for Risk Assessment
 Berlin

GHANA

Mrs Maria Aba Lovelace-Johnson
 Chief Regulatory Officer
 Food and Drugs Authority
 Accra

GUATEMALA

Mrs Pamela Castillo
 Coordinadora Comité Técnico
 GREMAB
 Guatemala

INDIA - INDE

Dr Kavitha Ramasamy
 Joint Director
 Food Safety and Standards Authority of India
 New Delhi

Ms Veenu Taneja
 Assistant Director (T)
 Food Safety and Standards Authority of India
 New Delhi

INDONESIA - INDONÉSIE

Mrs Sofhiani Dewi
 Coordinator for Standardization of Certain Food
 Product (Food for Special Dietary Uses, Claims,
 Nutrition Labelling, and Certain Processed Food)
 Indonesian Food and Drug Authority
 Jakarta

Mrs Desti Dwiputri
 Junior Policy Analyst
 Indonesian Food and Drug Authority
 Jakarta

Mrs Laily Fajariah
 Regulatory Affairs
 APPNIA
 Jakarta

Mrs Yanni Parmawati
 Coordinator for Multilateral Cooperation
 Indonesian Food and Drug Authority
 Jakarta

IRELAND - IRLANDE - IRLANDA

Dr Mary Flynn
 Chief Specialist Public Health Nutrition
 Food Safety Authority of Ireland
 Dublin

Ms Katie Little
 Nutrition Placement Student
 Food Safety Authority of Ireland
 Dublin

Ms Oonagh Lyons
 Technical Executive
 Food Safety Authority of Ireland
 Dublin

Ms Emily Martin
 Nutrition Placement Student
 Food Safety Authority of Ireland
 Dublin

ITALY - ITALIE - ITALIA

Mr Giulio Cardini
 Officer
 Ministry of Agriculture, Food Sovereignty and Forests
 Rome

JAPAN - JAPON - JAPÓN

Dr Masafumi Saito
 Deputy Director
 Consumer Affairs Agency
 Tokyo

Mr Manato Ebina
 Technical Officer, Office of International Food Safety
 Ministry of Health, Labour and Welfare
 Tokyo

Ms Ai Hoshikawa
 Assistant Manager
 Consumer Affairs Agency
 Tokyo

Dr Yoshiko Ishimi
 Professor
 Tokyo University of Agriculture
 Tokyo

Ms Kanako Sasaki
 Deputy Director, Office of International Food Safety
 Ministry of Health, Labour and Welfare
 Tokyo

KENYA

Ms Maryann Kindiki
 Manager, National Codex Contact Point
 Kenya Bureau of Standards
 Nairobi

LITHUANIA - LITUANIE - LITUANIA

Mrs Ieva Gudaviciene
 Chief expert of Health Promotion Division
 Ministry of Health of Lithuania
 Vilnius

MALAYSIA - MALAISIE - MALASIA

Ms Faridah Malik Shari
 Deputy Director
 Food Safety and Quality Division
 Ministry of Health Malaysia

W.P Putrajaya
 Ms Munirah Mohd Nasir
 Senior Assistant Director
 Nutrition Division
 Ministry of Health Malaysia

W.P Putrajaya
 Dr Kanga Rani Selvaduray
 Head of Nutrition Unit
 Malaysian Palm Oil Board
 Selangor

Dr Phooi Tee Voon
Research Officer
Malaysian Palm Oil Board
Selangor

Dr E-Siong Tee
President
Nutrition Society of Malaysia
Selangor

Ms Mazlyn Mena Mustapha
Associate Director
Yakult (M) Sdn Bhd
Selangor

Mr Hiroki Yanase
Managing Director
Yakult (M) Sdn Bhd
Selangor

Mr Ali Muzammil Abdullah
Regulatory Affairs and Policy Director
Mead Johnson Nutrition (Malaysia) SDN BHD
Kuala Lumpur

MALI - MALÍ

Mr Mahmoud Abdoul Camara
Chargé du Service Central de Liaison du Codex pour le
Mali
Institut National de Santé Publique
Bamako

MOROCCO - MAROC - MARRUECOS

Prof Nezha Mouane
Professeur en Pédiatrie surspécialité Gastroentérologie
Nutrition
Hôpital d'enfants Rabat – CH Ibn Sina
Rabat

Eng Med El Mehdi Karom
Cadre à la division des produits végétaux et d'origine
végétale
ONSSA
Rabat

Mr Mohamed Tannaoui
Chef de la Section Agricole
Laboratoire Officiel d'Analyses et de Recherches
Chimiques
Casablanca

NEPAL - NÉPAL

Dr Matina Joshi Vaidya
Director General
Department of Food Technology and Quality Control,
Ministry of Agriculture and Livestock Development
Kathmandu

Mr Surendra Manandhar
President Food, Ayurvedic, Nutraceutical and
Cosmeceutical Association of Nepal (FANCAN)
Kathmandu

Dr Atul Upadhyay
Chief Executive officer
Baliyo Nepal Nutrition Initiative
Kathmandu

NETHERLANDS - PAYS-BAS - PAÍSES BAJOS

Mrs Claudia Van Houte
Senior Policy Officer
Ministry of Health, Welfare and Sport
The Hague

Mrs Annemieke Hoogeveen
Senior Policy Officer
Ministry of Health, Welfare and Sport
The Hague

NEW ZEALAND - NOUVELLE-ZÉLANDE – NUEVA ZELANDIA

Mrs Charlotte Channer
Market Access Counsellor
Ministry for Primary Industries
Wellington

Ms Michelle Gibbs
Senior Adviser
Ministry for Primary Industries
Wellington

Ms Jenny Reid
Agriculture Counsellor
MFAT
Wellington

Ms Cathy Zhang
Regulatory Manager
Fonterra Co-operative Group Ltd
Auckland

NIGER - NÍGER

Mr Salou Dioffo Alahouynouma
Nutritionniste et PCC
MSP
Niamey

NIGERIA - NIGÉRIA

Mrs Olubunmi Stella Aribeara
Director
Federal Ministry of Health
Abuja

Mr Olugbemiga John Atanda
Director/National Coordinator Food Safety and Quality
Program
Federal Ministry of Health
Abuja

NORWAY - NORVÈGE - NORUEGA

Mrs Svanhild Vaskinn
Senior Adviser
Norwegian Food Safety Authority
Oslo

Mrs Gry Hay
Senior Adviser, Dr.Philos
Norwegian Directorate of Health
Oslo

OMAN - OMÁN

Mr Hiatham Alhashmi
Conformity specialist
Food Safety & Quality Center

PANAMA - PANAMÁ

Eng Joseph Gallardo
Ingeniero de Alimentos / Punto de Contacto Codex
Ministerio de Comercio e Industrias
Panama

PHILIPPINES - FILIPINAS

Ms Helena Alcaraz
Food and Drug Regulation Officer V
Food and Drug Administration
Muntinlupa City

Mr Philip Martin Palo
Member, SCNSFDU
SCNFSDU
Makati

POLAND - POLOGNE - POLONIA

Dr Katarzyna Stos
Head of Unit
National Institute of Public Health NIH - National
Research Institute
Warsaw

Mrs Anna Janasik
Expert
Agricultural and Food Quality Inspection
Warsaw

**REPUBLIC OF KOREA - RÉPUBLIQUE DE CORÉE -
REPÚBLICA DE COREA**

Dr Chan Soo Lee
Officer
Ministry of Food and Drug Safety
ChungCheongBuk-Do

Ms Yeon Ju Kim
Researcher
Ministry of Food and Drug Safety

Prof Yoo Kyoung Park
Professor
Kyung Hee University
Yong-in

**SAUDI ARABIA - ARABIE SAOUDITE - ARABIA
SAUDITA**

Ms Hind Alajaji
Standard and Regulation Specialist
Saudi Food and Drug Authority
Riyadh

Mr Abdulaziz Alangaree
Risk Assessment Expert
Saudi Food and Drug Authority
Riyadh

Mr Fahad Albadr
Senior scientific evaluation Specialist II
Saudi Food and Drug Authority
Riyadh

Mrs Tagreed Alfuraih
Senior specifications and regulations Specialist II
Saudi Food and Drug Authority
Riyadh

SENEGAL - SÉNÉGAL

Dr Maty Diagne Camara
Chef de Division
Direction de la Sante de la Mère et de l'enfant
Dakar

Prof Mohamadou Guelaye Sall
Expert SSA
UCAD
Dakar

Mrs Ndeye Yaga Sy
Chargée De Projet
Hellen Keller International
Dakar

SINGAPORE - SINGAPOUR - SINGAPUR

Ms Peik Ching Seah
Deputy Director
Singapore Food Agency
Singapore

Mr Mohamad Na'im Mohamad Ayob
Manager
Singapore Food Agency
Singapore

SOUTH AFRICA - AFRIQUE DU SUD - SUDÁFRICA

Ms Nolene Naicker
Assistant Director: Nutrition
Department of Health
Pretoria

Mrs ZaOndile Kubeka
Assistant Director: Nutrition
Department of Health
Pretoria

SPAIN - ESPAGNE - ESPAÑA

Dr Álvaro Rol Rúa
Jefe de Servicio de residuos de productos fitosanitarios
y medicamentos veterinarios en alimentos
Agencia Española de Seguridad Alimentaria y Nutrición
(AESAN)-Ministerio de Consumo
Madrid

**STATE OF LIBYA - L'ÉTAT DE LIBYE –
ESTADO DE LIBIA**

Dr Moufida Ben Hamed
Head of Nutrition department
National Center of Diseases Control
Tripoli

Eng Hadi Elalem
Head of technical support office
Libyan National Centre for Standardization and
Metrology
Tripoli

SUDAN - SOUDAN - SUDÁN

Mr Abayazid Fadl Almola
Manager of Madani Branch
Sudanese Standards and Metrology Organisation
Madni

Dr Thoria Elnageeb Akasha
Chemist of Food
Sudanese Standard & Metrology
Khartoum

Mrs Maha Ibrahim
Executive Office Manager
Sudanese Standard & Metrology Organization
Khartoum

SWEDEN - SUÈDE - SUECIA

Mrs Kristina Lagestrand Sjölin
Principal Regulatory Officer
Swedish Food Agency
Uppsala

Dr Adrienn Barna
Policy Administrator
Council of the European Union
Brussel

Ms Svanhild Foldal
Senior Administrative Officer
Ministry of Enterprise and Innovation
Stockholm

Ms Martina Görnebrand
Principal Regulatory Officer
Swedish Food Agency
Uppsala

Mrs Sanna Wallje Pettersson
Principal Regulatory Officer
Swedish Food Agency
Uppsala

SWITZERLAND - SUISSE - SUIZA

Mr Didier Lusuardi
Scientific Officer
Federal Food Safety and Veterinary Office FSVO
Bern

THAILAND - THAÏLANDE - TAILANDIA

Mr Paisarn Dunkum
Secretary General, Food and Drug Administration
Food and Drug Administration, Ministry of Public Health
Nonthaburi

Dr Pichet Itkor
Secretary General, Food and Beverage Industry Club
The Federation of Thai Industries
Bangkok

Mr Lertchai Lertvut
Director of Food Division
Food and Drug Administration, Ministry of Public Health
Nonthaburi

Mrs Sitanun Poonpolsub
Director of International Affairs Division
Food and Drug Administration, Ministry of Public Health
Nonthaburi

Ms Sirirat Preecha
Food and Drug Technical Officer, Practitioner Level
Food and Drug Administration, Ministry of Public Health
Nonthaburi

Ms Panadda Tungsawas
Food and Drug Technical Officer, Practitioner Level
Food and Drug Administration, Ministry of Public Health
Nonthaburi

UGANDA - OUGANDA

Ms Rehema Meeme
Standards Officer
Uganda National Bureau of Standards
Kampala

Ms Diana Kabuzire
Head Legal Services
National Drug Authority
Kampala

Mr Ramathan Mutungirehi
Principal Quality Management Systems Officer
National Drug Authority
Kampala

Mrs Irene Wanyenya Mwigwa
Principal Food Safety Officer
National Drug Authority
Kampala

**UNITED ARAB EMIRATES –
ÉMIRATS ARABES UNIS – EMIRATOS ARABES
UNIDOS**

Mr Eyad Attari
Head of Regulatory and Scientific Affairs
Fonterra

**UNITED KINGDOM - ROYAUME-UNI –
REINO UNIDO**

Mr Steve Wearne
Chairperson
Codex Alimentarius Commission

Mrs Debby Webb
Head of Nutrition Legislation
Department of Health and Social Care

Ms Bethany Knowles
Policy Advisor
Department of Health and Social Care

**UNITED STATES OF AMERICA –
ÉTATS-UNIS D'AMÉRIQUE –
ESTADOSUNIDOS DE AMÉRICA**

Dr Douglas Balentine
Senior Science Advisor, International Nutrition Policy
U.S. Food and Drug Administration
College Park, MD

Dr Carolyn Chung
Nutritionist
U.S. Food and Drug Administration
College Park, MD

Ms Audrae Erickson
Vice President Global External & Public Affairs
Mead Johnson Nutrition/Reckitt
Washington, DC

Ms Alexandra Ferraro
Agriculture Science Advisor
Foreign Agricultural Service, U.S. Department of
Agriculture
Washington, DC

Mr Nicholas Gardner
Vice President, Codex and International Regulatory
Affairs
U.S. Dairy Export Council
Arlington, VA

Ms Franciel Ikeji
International Program Analyst,
Center for Food Safety and Applied Nutrition, FDA
College Park, MD

Ms Marie Maratos Bhat
International Issues Analyst
U.S. Department of Agriculture
Washington, DC

Dr Pamela Pehrsson
Research Leader
ARS-Nutrient Data Laboratory
Beltsville

Mr Richard White
Consultant
Corn Refiners Association
Bradenton, FL

VIET NAM

Mrs Thi Thuy Lan Do
Regulatory Affair Manager
Abbott Laboratories S.A
Hanoi

Mr Thanh Van Hoang
R&D Manager
Vietnam Dairy products J.C.CO
Ho Chi Minh

Mr Nguyen Hong Uy
Head of Regulatory and External Affairs
Abbott Laboratories S.A
Hanoi

Mr Hung Nguyen Le
Deputy Chief Executive Officer
Yakult VietNam Co. Ltd
Binh Duong

Mr Thanh Nhan Ngo
R&D Manager
Vietnam Dairy products J.C.CO
Ho Chi Minh

Mr Hung Long Nguyen
deputy general director
Ministry of Health
Hanoi

Mrs Thi Ngoc Pham
Deputy Secretary Genera
Viet Nam Dairy Association

Mr Tran Quang Trung
Chair
Vietnam Dairy Association
Hanoi

Mr Hiroshi Ueno
Director
Yakult VietNam Co. Ltd
Binh Duong

Mrs Thi Thuy Van
PR & Science Manager
Yakult VietNam Co. Ltd
Binh Duong

OBSERVERS - OBSERVATEURS – OBSERVADORES**INTERNATIONAL GOVERNMENTAL ORGANIZATIONS
–ORGANISATIONS GOUVERNEMENTALES
INTERNATIONALES –
ORGANIZACIONES GUBERNAMENTALES
INTERNACIONALES****AFRICAN UNION (AU)**

Mr John Opong
AU

**NON-GOVERNMENTAL ORGANIZATIONS –
ORGANISATIONS NON GOUVERNEMENTALES –
ORGANIZACIONES NO GUBERNAMENTALES****ASSOCIATION INTERNATIONALE POUR LE
DÉVELOPPEMENT DES GOMMES NATURELLES
(AIDGUM)**

Mr Olivier Bove
President
AIDGUM

AOAC INTERNATIONAL (AOAC)

Mr Darryl Sullivan
Liaison
AOAC INTERNATIONAL
Rockville

Mr Erik Konings
Past President
AOAC INTERNATIONAL

AMERICAN OIL CHEMISTS' SOCIETY (AOCS)

Dr Scott Bloomer
Director
American Oil Chemists' Society
Urbana

COUNCIL FOR RESPONSIBLE NUTRITION (CRN)

Dr James Griffiths
SVP, International & Scientific Affairs
Council for Responsible Nutrition
Washington

**EUROPEAN NETWORK OF CHILDBIRTH
ASSOCIATIONS (ENCA)**

Mrs Patti Rundall
Global Advocacy Spokesperson
Babymilk Action UK IBFAN

Mr Manuel Abebe
adviser
Public Eye

**FEDERATION OF EUROPEAN SPECIALTY FOOD
INGREDIENTS INDUSTRIES (EU SPECIALTY FOOD
INGREDIENTS)**

Mrs Catherine Mignot
Member
EU Specialty Food Ingredients

Ms Nicola Leinwetter
Member
EU Specialty Food Ingredients

Mr Petr Mensik
Secretariat
EU Specialty Food Ingredients

**EUROPEAN VEGETABLE PROTEIN ASSOCIATION
(EUVEPRO)**

Ms Nuria Moreno Odero
Secretary General
EUVEPRO
Brussels

Dr Huub Scheres
Scientific & Regulatory Advocacy, Director
IFF

FOODDRINKEUROPE

Ms Sara Lamonaca
Director
FoodDrinkEurope
Bruxelles

Mrs Angelika Mrohs
Managing Director
Lebensmittelverband Deutschland
Berlin

HELEN KELLER INTERNATIONAL (HKI)

Ms Jane Badham
Consultant
Helen Keller International
Johannesburg

Dr Alissa Pries
Senior Research Advisor
Helen Keller International
Washington DC

Mrs Elizabeth Zehner
Project Director
Helen Keller International
Washington DC

**INTERNATIONAL ALLIANCE OF DIETARY/FOOD
SUPPLEMENT ASSOCIATIONS (IADSA)**

Mr Simon Pettman
Executive Director
IADSA
LONDON

Ms Antje Preussker
member
IADSA
LONDON

Ms Cynthia Rousselot
Dir Regulatory & Technical Affairs
IADSA
LONDON

Ms Michelle Stout
Member
IADSA

**INTERNATIONAL BABY FOOD ACTION NETWORK
(IBFAN)**

Ms Elisabeth Sterken
Global Council
International Baby Food Action Network (IBFAN)
Rockport

Ms Ellie Mulpeter
Director
International Baby Food Action Network (IBFAN)
South Dennis, MA

INTERNATIONAL CO-OPERATIVE ALLIANCE (ICA)

Mr Kazuo Onitake
Senior Scientist, Department of Quality Assurance
International Co-operative Alliance (ICA)
Tokyo

Mr Yuji Gejo
Officer
International Co-operative Alliance
Tokyo

**INTERNATIONAL COUNCIL ON AMINO ACID
SCIENCE (ICAAS)**

Mr Takasu Masaharu
General Manager
Meiji Co., Ltd

Dr Keiji Takahashi
R&D Div
Meiji Co., Ltd
Tokyo

**INTERNATIONAL COUNCIL OF BEVERAGES
ASSOCIATIONS (ICBA)**

Ms Joanna Skinner
Senior Manager, Regulatory Advocacy
The Coca-Cola Company
Atlanta

Ms Jacqueline Dillon
Senior Manager
PepsiCo
Chicago, IL

Dr Tatsuya Ehara
Senior Research Scientist
Morinaga Milk Industry Co.,LTD
Zama city

Dr Maia Jack
VP, Science & Regulatory Affairs
American Beverage Association
Washington, DC

Ms Elizabeth Roark
Nutrition Science, Policy, Engagement and
Sustainability
PepsiCo
Plano, TX

**INTERNATIONAL CHEWING GUM ASSOCIATION
(ICGA) (ICGA)**

Mr Christophe Leprêtre
Executive Director
ICGA
Brussels

Mrs Kirstie Canene-Adams
Senior Principal Scientist
Mars Wrigley
Chicago, IL

INTERNATIONAL DAIRY FEDERATION (IDF/FIL)

Mrs Laurence Rycken
Science and Standards Program Manager
International Dairy Federation
Schaerbeek

Mr Jacco Gerritsen
Regulatory Affairs Manager
Dutch Dairy organization (NZO)

Mrs Melanie Grivier
Regulatory affairs officer
ATLA

INSTITUTE OF FOOD TECHNOLOGISTS (IFT)

Prof Rosemary Walzem, Rd, Phd
Professor of Nutritional Biochemistry
Institute of Food Technologists
Texas A&M University

**INTERNATIONAL LACTATION CONSULTANT
ASSOCIATION (ILCA)**

Ms Maryse Arendt
ILCA Codex Liaison
International Lactation Consultant Association (ILCA)
Luxemburg

**THE EUROPEAN MARGARINE ASSOCIATION
(IMACE)**

Mr Carlo Bulkman
Expert
IMACE

**INTERNATIONAL ORGANIZATION OF THE FLAVOR
INDUSTRY (IOFI)**

Ms Jing Yi
Director Advocacy and Regulatory Affairs
IOFI
Brussels

INTERNATIONAL PROBIOTICS ASSOCIATION (IPA)

Mr George Paraskevacos
Executive Director
International Probiotics Association
Marina Del Rey

Mrs Audrey Bru
Regulatory affairs manager
Lallemand Health Solutions

Mrs Kristine Koppelhus
Director Scientific & Public Affairs
Bioagaia
Lund

Mrs Mariella Kuilman
Global Regulatory Affairs Manager
DSM

Mr Svend Laulund
Global External Affairs Manager
Chr. Hansen

Mrs Rosanna Pecere
Executive Director
IPA EUROPE
Brussels

Mr David Pineda Ereno
Associate
International Probiotics Association

INTERNATIONAL SPECIAL DIETARY FOODS INDUSTRIES (ISDI)

Mr Jean-Christophe Kremer
Secretary-General
International Special Dietary Foods Industries (ISDI)
Brussels

Ms Wioleta Dzieszuk-Brzozowska
ELN Regulatory Director Specialized Nutrition - Danone
ISDI
Brussels

Mrs Shefa Alhalah
Senior Regional Manager-Regulatory, Government &
Public Affairs - Danone
International Special Dietary Foods Industries (ISDI)
Brussels

Mrs Jan Carey
CEO - Infant Nutrition Council (INC)
International Special Dietary Foods Industries (ISDI)
Brussels

Mr Dirk Cremer
Senior Regulatory Affairs Manager (DSM)
International Special Dietary Foods Industries (ISDI)
Brussels

Ms Patricia Garcia De Mendoza
Secretariat
International Special Dietary Foods Industries (ISDI)
Brussels

Dr Paul Hanlon
Director of Regulatory Affairs - Abbott
International Special Dietary Foods Industries (ISDI)
Brussels

Ms Duygu Lisa Korucu
Secretariat
International Special Dietary Foods Industries (ISDI)
Brussels

Mr Xavier Lavigne
Director, Regulatory Policy & Intelligence - Abbott
Nutrition
International Special Dietary Foods Industries (ISDI)
Brussels

Mrs Fanny Lebouc
Regulatory Affairs & Category Compliance Manager -
Danone
International Special Dietary Foods Industries (ISDI)
Brussels

Ms Xiaowei Li
Head of Regulatory Policy, Mead Hohnson Nutritionals
International Special Dietary Foods Industries (ISDI)
Brussels

Ms Lucia Martinez
Regulatory Affairs EMEA
International Special Dietary Foods Industries (ISDI)
Brussels

Ms Julie Mcmanus
Head of Global Regulatory Affairs (Reckitt)
International Special Dietary Foods Industries (ISDI)
Brussels

Ms Michelle Mendador
Regulatory Affairs Strategist with strong Pharma,
Medical Device and Nutrition experience
International Special Dietary Foods Industries (ISDI)
Brussels

Ms Ran Qin
Government Affairs Desk Manager, European Chamber
of Commerce in China
International Special Dietary Foods Industries (ISDI)
Brussels

Mr Karl Wallen
Secretariat
International Special Dietary Foods Industries (ISDI)
Brussels

Ms Mary Weiler
Nutrition Scientist at Abbott
International Special Dietary Foods Industries (ISDI)
Brussels

Ms Qingxin Ye
RA manager, Mead Hohnson Nutritionals
International Special Dietary Foods Industries (ISDI)
Brussels

Ms Ziting Zhang
 Head of Government Affairs, European Chamber of
 Commerce in China
 International Special Dietary Foods Industries (ISDI)
 Brussels

**INTERNATIONAL ORGANIZATION FOR
 STANDARDIZATION (ISO)**

Mr Paul Whitehouse
 Conveyor of the ISO working group on plant-based
 foods
 ISO

NATIONAL HEALTH FEDERATION (NHF)

Mr Scott Tips
 President
 National Health Federation
 Mossyrock WA

Mr Yunes-Louis Amadid
 advisor
 National Health Federation
 MOSSYROCK

SPECIALISED NUTRITION EUROPE (SNE)

Mr Beat Spaeth
 Secretary General
 Specialised Nutrition Europe

Ms Laure De Hauteclocque
 Senior Regulatory & Scientific Manager
 Specialised Nutrition Europe

Ms Annette Lau
 Global Regulatory Affairs Manager
 Specialised Nutrition Europe

Ms Evangelia Mavromichali
 Senior Regulatory Affairs Specialist
 Specialised Nutrition Europe

Ms Sarah Methner
 Scientific Advisor
 Specialised Nutrition Europe

Mr Declan O'brien
 Director General
 Specialised Nutrition Europe

Ms Marie-france Pagerey
 Global Senior Regulatory and Scientific Affairs Manager
 Specialised Nutrition Europe

Ms Norbert Pahne
 Director
 Specialised Nutrition Europe
 Brussels

Ms Miriam Ryan
 Head of Specialised Nutrition & Food Policy
 Specialised Nutrition Europe

Ms Petra Wendorf-ams
 Principle Scientist Nutritional Needs through Life &
 Healthspan
 Specialised Nutrition Europe

**WORLD PUBLIC HEALTH NUTRITION
 ASSOCIATION (WPHNA)**

Dr Sara Garduno-Diaz
 Secretary
 World Public Health Nutrition Association

**ASSOCIATION OF YOGHURTS & LIVE FERMENTED
 MILKS (YLFA)**

Dr Bart Degeest
 Managing Director, President YLFA
 YLFA International
 Brussels

Dr Sonja Heinritz
 Expert
 YLFA International
 Neuss

Mr Toshimitsu Morita
 Expert
 YLFA International

Mr Atsushi Nose
 Expert
 YLFA International

**UNITED NATIONS CHILDREN'S FUND (UNICEF)
 (UNICEF)**

Ms Katherine Shats
 Legal Specialist
 UNICEF

Ms Linda Shaker
 Nutrition Specialist
 UNICEF

FAO PERSONNEL

Mrs Fatima Hachem
 Senior Nutrition Officer
 Food and Agriculture Organization of the U.N. (FAO)
 Rome

WHO PERSONNEL

Dr Francesco Branca
 Director
 Department of Nutrition and Food Safety
 World Health Organization (WHO)
 Geneva

Dr Laurence Grummer-Strawn
 Unit Head
 Food and Nutrition Action in Health Systems
 Department of Nutrition and Food Safety
 World Health Organization (WHO)
 Geneva

Dr Jason Montez
 Scientist
 Standards and Scientific Advice on Food and Nutrition
 Department of Nutrition and Food Safety
 World Health Organization (WHO)
 Geneva

Dr Rain Yamamoto
Scientist
Standards and Scientific Advice on Food and Nutrition
Department of Nutrition and Food Safety
World Health Organization (WHO)
Geneva

Dr Fabio Da Silva Gomes
Advisor
Nutrition and Physical Activity, Risk Factors and
Nutrition Unit
Pan American Health Organization / WHO Regional
Office for the Americas
Washington, DC

CCNFSDU SECRETARIAT

Mrs Alina Steinert
CCNFSDU Secretariat
Federal Ministry of Food and Agriculture
Bonn

Ms Emily Krueger
CCNFSDU Secretariat
Federal Office of Consumer Protection and Food Safety
Berlin

Mr Christoph Gebauer
CCNFSDU Secretariat
Federal Office of Consumer Protection and Food Safety
Berlin

Mr Niklas Arnold
German CCNFSDU Secretariat
Federal ministry of food and agriculture

CODEX SECRETARIAT

Mr Tom Heilandt
Secretary, Codex Alimentarius Commission,
Joint FAO/WHO Food Standards Programme
Food and Agriculture Organization of the U.N. (FAO)
Rome

Mr Patrick Sekitoleko
Food Standards Officer
Joint FAO/WHO Food Standards Programme
Food and Agriculture Organization of the U.N. (FAO)
Rome

Ms Lingping Zhang
Food Standards Officer
Joint FAO/WHO Food Standards Programme
Food and Agriculture Organization of the U.N. (FAO)
Rome

Mr David Massey
Special Advisor, Codex Partnership Programme
Joint FAO/WHO Food Standards Programme
Food and Agriculture Organization of the U.N. (FAO)
Rome

APPENDIX II

STANDARD FOR FOLLOW-UP FORMULA FOR OLDER INFANTS AND PRODUCT FOR YOUNG CHILDREN***(For adoption at Step 5/8 and 8)**

*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.

PREAMBLE

This Standard is divided into two sections. Section A refers to Follow-up Formula for Older Infants, and Section B deals with Drink for Young Children with Added Nutrients, or Product for Young Children with Added Nutrients, or Drink for Young Children, or Product for Young Children.

The application of this Standard should be consistent with national/regional health and nutrition policies and relevant national/regional legislation and take into account the recommendations made in the International Code of Marketing of Breast-milk Substitutes, as per the national/regional context.

Relevant World Health Organization (WHO) guidelines and policies and World Health Assembly (WHA) resolutions were considered in the development of this Standard and may provide further guidance to countries.

SECTION A: FOLLOW-UP FORMULA FOR OLDER INFANTS**1 SCOPE**

- 1.1 This section of the Standard applies to Follow-up formula for older infants, as defined in Section 2.1, in liquid or powdered form.
- 1.2 This section of the Standard contains compositional, quality, safety, labelling, analytical and sampling requirements for Follow-up formula for older infants.
- 1.3 Only products that comply with the criteria laid down in the provisions of this Section of this Standard shall be presented as Follow-up formula for older infants.

2 DESCRIPTION**2.1 Product Definition**

- 2.1.1 **Follow-up formula for older infants** means a product, manufactured for use as a breastmilk-substitute, as a liquid part of a diet for older infants when progressively diversified complementary feeding is introduced.
- 2.1.2 Follow-up formula for older infants is so processed by physical means only and so packaged as to prevent spoilage and contamination under all normal conditions of handling, storage and distribution in the country where the product is sold.

2.2 Other Definitions

- 2.2.1 The term **infant** means a person of not more than 12 months of age.
- 2.2.2 The term **older infant** means a person from the age of 6 months and not more than 12 months of age

3 ESSENTIAL COMPOSITION AND QUALITY FACTORS**3.1 Essential Composition**

- 3.1.1 Follow-up formula for older infants is a product based on milk of cows or other animals or a mixture thereof and/or other ingredients which have been proven to be safe and suitable for the feeding of older infants. The nutritional safety and adequacy of follow-up formula for older infants shall be scientifically demonstrated to support growth and development of older infants.
- 3.1.2 When prepared ready for consumption in accordance with the instructions of the manufacturer, the products shall contain per 100 ml not less than 60 kcal (251 kJ) and not more than 70 kcal (293 kJ) of energy.

3.1.3 Follow-up formula for older infants prepared ready for consumption shall contain per 100 kcal (100 kJ) the following nutrients with the following minimum and maximum or guidance upper levels (GUL) ¹²⁾ as appropriate.

a) Protein ^{2), 3), 4)}

Unit	Minimum	Maximum	GUL
g/100 kcal	1.8 ^{5), 6)}	3.0	-
g/100 kJ	0.43 ^{5), 6)}	0.72	-

²⁾ For the purpose of this standard 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.

³⁾ For an equal energy value the formula must contain an available quantity of each essential and semi-essential amino acid at least equal to that contained in the reference protein (breastmilk as defined in Annex I of the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CXS 72-1981)); nevertheless for calculation purposes the concentrations of tyrosine and phenylalanine may be added together and the concentrations of methionine and cysteine may be added together.

⁴⁾ Isolated amino acids may be added to follow-up formula for older infants only to improve its nutritional value for infants. Essential and semi-essential amino acids may be added to improve protein quality, only in amounts necessary for that purpose. Only L-forms of amino acids shall be used.

⁵⁾ The minimum value applies to cows' and goats' milk protein. For follow-up formula for older infants based on non-cows' or non-goats' milk protein, other minimum values may need to be applied. For follow-up formula for older infants based on soy protein isolate, a minimum value of 2.25 g/100 kcal (0.54 g/100 kJ) applies.

⁶⁾ A lower minimum protein level between 1.6 and 1.8 g/100 kcal (0.38 and 0.43 g/100 kJ) in follow-up formula for older infants based on non-hydrolysed milk protein can be accepted. Such follow-up formula and follow-up formula for older infants based on hydrolysed protein should be evaluated for their safety and suitability and assessed by a competent national and/or regional authority based on clinical evidence.

b) Lipids

Total Fat ^{7), 8)}

Unit	Minimum	Maximum	GUL
g/100 kcal	4.4	6.0	-
g/100 kJ	1.1	1.4	-

⁷⁾ Partially hydrogenated oils and fats shall not be used in follow-up formula for older infants.

⁸⁾ Lauric acid and myristic acid are constituents of fats, but combined shall not exceed 20% of total fatty acids. The content of trans fatty acids shall not exceed 3% of total fatty acids. Trans fatty acids are endogenous components of milk fat. The acceptance of up to 3% of trans fatty acids is intended to allow for the use of milk fat in follow-up formula for older infants. The erucic acid content shall not exceed 1% of total fatty acids. The total content of phospholipids should not exceed 300 mg/100 kcal (72 mg/100 kJ).

Linoleic acid

Unit	Minimum	Maximum	GUL
mg/100 kcal	300	-	1400
mg/100 kJ	72	-	335

¹²⁾ Guidance upper levels (GULs) are for nutrients without sufficient information for a science-based risk assessment. These levels are values derived on the basis of meeting nutritional requirements of older infants and an established history of apparent safe use. They may be adjusted based on relevant scientific or technological progress. The purpose of the GULs is to provide guidance to manufacturers and they should not be interpreted as goal values. Nutrient contents in follow-up formula for older infants should usually not exceed the GULs unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of follow-up formula for older infants or due to technological reasons. When a product type or form has ordinarily contained lower levels than the GULs, manufacturers should not increase levels of nutrients to approach the GULs.

α-Linolenic acid

Unit	Minimum	Maximum	GUL
mg/100 kcal	50	N.S.*	-
mg/100 kJ	12	N.S.	-

*N.S. = not specified

Ratio Linoleic acid/ α-Linolenic acid

Min	Max
5:1	15:1

c) Carbohydrates**Available carbohydrates ⁹⁾**

Unit	Minimum	Maximum	GUL
g/100 kcal	9.0	14.0	-
g/100 kJ	2.2	3.3	-

⁹⁾ Lactose and glucose polymers should be the preferred carbohydrates in follow-up formula for older infants based on milk protein and hydrolysed protein. Only precooked and/or gelatinised starches gluten-free by nature may be added. Sucrose and/or fructose should not be added, unless needed as a carbohydrate source, and provided the sum of these does not exceed 20% of available carbohydrates.

d) Vitamins**Vitamin A**

Unit	Minimum	Maximum	GUL
µg RE ¹⁰⁾ /100 kcal	75	180	-
µg RE ¹⁰⁾ /100 kJ	18	43	-

¹⁰⁾ expressed as retinol equivalents (RE)

1 µg RE = 3.33 IU Vitamin A = 1 µg all-trans retinol. Retinol contents shall be provided by preformed retinol, while any contents of carotenoids should not be included in the calculation and declaration of vitamin A activity.

Vitamin D

Unit	Minimum	Maximum	GUL
µg ¹¹⁾ /100 kcal	1.0	3.0	-
µg ¹¹⁾ /100 kJ	0.24	0.72	-

¹¹⁾ Calciferol. 1 µg calciferol = 40 IU Vitamin D.

Vitamin E

Unit	Minimum	Maximum	GUL
mg α-TE ¹²⁾ /100 kcal	0.5 ¹³⁾	-	5
mg α-TE ¹²⁾ /100 kJ	0.12 ¹³⁾	-	1.2

¹²⁾ 1 mg α-TE (alpha-tocopherol equivalents) = 1 mg d-α-tocopherol

¹³⁾ Vitamin E shall be at least 0.5 mg α-TE per g PUFA, using the following factors of equivalence to adapt the minimal vitamin E content to the number of fatty acid double bonds in the formula: 0.5 mg α-TE/g linoleic acid (18:2 n-6); 0.75 α-TE/g α-linolenic acid (18:3 n-3); 1.0 mg α-TE/g arachidonic acid (20:4 n-6); 1.25 mg α-TE/g eicosapentaenoic acid (20:5 n-3); 1.5 mg α-TE/g docosahexaenoic acid (22:6 n-3).

Vitamin K

Unit	Minimum	Maximum	GUL
µg /100 kcal	4	-	27
µg /100 kJ	0.96	-	6

Thiamin

Unit	Minimum	Maximum	GUL
µg /100 kcal	60	-	300
µg /100 kJ	14	-	72

Riboflavin

Unit	Minimum	Maximum	GUL
µg /100 kcal	80	-	500
µg /100 kJ	19	-	120

Niacin¹⁴⁾

Unit	Minimum	Maximum	GUL
µg /100 kcal	300	-	1500
µg /100 kJ	72	-	359

¹⁴⁾ Niacin refers to preformed niacin

Vitamin B₆

Unit	Minimum	Maximum	GUL
µg /100 kcal	35	-	175
µg /100 kJ	8	-	42

Vitamin B₁₂

Unit	Minimum	Maximum	GUL
µg /100 kcal	0.1	-	1.5
µg /100 kJ	0.02	-	0.36

Pantothenic acid

Unit	Minimum	Maximum	GUL
µg /100 kcal	400	-	2000
µg /100 kJ	96	-	478

Folic acid

Unit	Minimum	Maximum	GUL
µg /100 kcal	10	-	50
µg /100 kJ	2.4	-	12

Vitamin C¹⁵⁾

Unit	Minimum	Maximum	GUL
mg /100 kcal	10	-	70 ¹⁶⁾
mg /100 kJ	2.4	-	17 ¹⁶⁾

¹⁵⁾ expressed as L-ascorbic acid

¹⁶⁾ This GUL has been set to account for possible high losses over shelf-life in liquid products; for powdered products lower upper levels should be aimed for.

Biotin

Unit	Minimum	Maximum	GUL
µg /100 kcal	1.5	-	10
µg /100 kJ	0.36	-	2.4

e) Minerals and Trace Elements**Iron¹⁷⁾**

Unit	Minimum	Maximum	GUL
mg /100 kcal	1.0	2.0	-
mg /100 kJ	0.24	0.48	-

¹⁷⁾ For follow-up formula for older infants based on soy protein isolate a minimum value of 1.5 mg/100 kcal (0.36/100 kJ) and maximum of 2.5 mg/100 kcal (0.6 mg/100 kJ) applies.

Calcium

Unit	Minimum	Maximum	GUL
mg /100 kcal	50	-	180
mg /100 kJ	12	-	43

Phosphorus

Unit	Minimum	Maximum	GUL
mg /100 kcal	25	-	100 ¹⁸⁾
mg /100 kJ	6	-	24 ¹⁸⁾

¹⁸⁾ This GUL should accommodate higher needs with follow-up formula for older infants based on soy protein isolate.

Ratio Calcium/Phosphorus

Min	Max
1:1	2:1

Magnesium

Unit	Minimum	Maximum	GUL
mg /100 kcal	5	-	15
mg /100 kJ	1.2	-	3.6

Sodium

Unit	Minimum	Maximum	GUL
mg /100 kcal	20	60	-
mg /100 kJ	4.8	14	-

Chloride

Unit	Minimum	Maximum	GUL
mg /100 kcal	50	160	-
mg /100 kJ	12	38	-

Potassium

Unit	Minimum	Maximum	GUL
mg /100 kcal	60	180	-
mg /100 kJ	14	43	-

Manganese

Unit	Minimum	Maximum	GUL
µg /100 kcal	1.0	-	100
µg /100 kJ	0.24	-	24

Iodine

Unit	Minimum	Maximum	GUL
µg /100 kcal	10	-	60
µg /100 kJ	2.4	-	14

Selenium

Unit	Minimum	Maximum	GUL
µg /100 kcal	2	-	9
µg /100 kJ	0.48	-	2.2

Copper¹⁹⁾

Unit	Minimum	Maximum	GUL
µg /100 kcal	35	-	120
µg /100 kJ	8	-	29

¹⁹⁾ Adjustment may be needed in these levels for follow-up formula for older infants made in regions with a high content of copper in the water supply.

Zinc²⁰⁾

Unit	Minimum	Maximum	GUL
mg /100 kcal	0.5	-	1.5
mg /100 kJ	0.12	-	0.36

²⁰⁾ For follow-up formula for older infants based on soy protein isolate a minimum value of 0.75 mg/100 kcal (0.18 mg/100kJ) applies.

3.2 Optional Ingredients

- 3.2.1** In addition to the compositional requirements listed under 3.1.3, other ingredients or substances may be added to follow-up formula for older infants where the safety and suitability of the optional ingredient for particular nutritional purposes, at the level of use, is evaluated and demonstrated by generally accepted scientific evidence.
- 3.2.2** When any of these ingredients or substances is added the formula shall contain sufficient amounts to achieve the intended effect, taking into account levels in human milk.
- 3.2.3** The following substances may be added in conformity with national legislation, in which case their content per 100 kcal (100kJ) in the follow-up formula for older infants ready for consumption shall not exceed the levels listed below. This is not intended to be an exhaustive list, but provides a guide for competent national and/or regional authorities as to appropriate levels when these substances are added.

Taurine

Unit	Minimum	Maximum	GUL
mg /100 kcal	-	12	-
mg /100 kJ	-	2.9	-

Total nucleotides

Levels may need to be determined by national authorities.

Docosahexaenoic acid²¹⁾

Unit	Minimum	Maximum	GUL
mg /100 kcal	-	-	30
mg /100 kJ	-	-	7

²¹⁾ If docosahexaenoic acid (22:6 n-3) is added to follow-up formula for older infants, a minimum level of 20 mg/100 kcal (4.8 mg/100 kJ) should be reached, and arachidonic acid (20:4 n-6) contents should reach at least the same concentration as DHA. The content of eicosapentaenoic acid (20:5 n-3), which can occur in sources of LC-PUFA, should not exceed the content of docosahexaenoic acid. Competent national and/or regional authorities may deviate from the above conditions, as appropriate for the nutritional needs of their population.

Choline

Unit	Minimum	Maximum	GUL
mg /100 kcal	-	-	50
mg /100 kJ	-	-	12

Myo-inositol

Unit	Minimum	Maximum	GUL
mg /100 kcal	-	-	40
mg /100 kJ	-	-	10

L-carnitine

Levels may need to be determined by national authorities.

L (+) lactic acid-producing cultures

Only L (+) lactic acid-producing cultures may be used for the purpose of producing acidified follow-up formula for older infants. The acidified final product should not contain significant amounts of viable L (+) lactic acid-producing cultures, and residual amounts should not represent any health risk.

The safety and suitability of the addition of specific strains of L (+) lactic acid-producing cultures for particular beneficial physiological effects, at the level of use, must be demonstrated by clinical evaluation and generally accepted scientific evidence. When added for this purpose, the final product ready for consumption shall contain sufficient amounts of viable cultures to achieve the intended effect.

3.3 Purity Requirements

3.3.1 General

All ingredients shall be clean, of good quality, safe and suitable for ingestion by older infants. They shall conform with their normal quality requirements, such as colour, flavour and odour.

3.3.2 Vitamin Compounds and Mineral Salts

3.3.2.1 Vitamin compounds and mineral salts used in accordance with Sections 3.1.3 (d) and (e) and 3.2.1 should be selected from the *Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses intended for Infants and Young Children* (CXG 10-1979).

3.3.2.2 The amounts of sodium derived from vitamin and mineral ingredients shall be within the limit for sodium in Section 3.1.3 (e).

3.4 Consistency and Particle Size

When prepared according to the directions of use, the product shall be free of lumps and of large, coarse particles.

3.5 Specific Prohibitions

The product and its components shall not have been treated by ionizing radiation.

4. Food Additives

The following additives are permitted²²⁾:

INS	Additive	Maximum level in 100 mL of the product ready for consumption
4.1 Thickeners		
412	Guar gum	0.1 g
410	Carob bean gum	0.1 g
1412	Distarch phosphate	0.5 g singly or in combination in soy-based products only; 2.5 g singly or in combination in hydrolyzed protein and/or amino acid-based products only
1414	Acetylated distarch phosphate	
1413	Phosphated distarch phosphate	
1422	Acetylated distarch adipate	
407	Carrageenan	0.03 g singly or in combination in milk and soy-based products only; 0.1 g singly or in combination in hydrolyzed protein and/or amino acid-based liquid products only
440	Pectins	1 g
4.2 Emulsifiers		
322(i)	Lecithin	0.5 g
471	Mono- and diglycerides of fatty acids	0.4 g

4.3 Acidity Regulators		
500(ii)	Sodium hydrogen carbonate	Limited by GMP
500(i)	Sodium carbonate	
331(i)	Sodium dihydrogen citrate	
331(iii)	Trisodium citrate	
524	Sodium hydroxide	Within the limits for sodium in Section 3.1
501(ii)	Potassium hydrogen carbonate	Limited by GMP
501(i)	Potassium carbonate	
332(i)	Potassium dihydrogen citrate	
332(ii)	Tripotassium citrate	
525	Potassium hydroxide	
526	Calcium hydroxide	Limited by GMP
270	Lactic acid, L-, D-, and DL-	Limited by GMP
330	Citric acid	Limited by GMP
4.4 Antioxidants		
307b	Tocopherols concentrate, mixed	3 mg singly or in combination
307a	Tocopherol, d-alpha	
307c	Tocopherol, dl-alpha	
304	Ascorbyl palmitate	5 mg singly or in combination, expressed as ascorbic acid (INS 300, 301,302,304) Within the limits for sodium in Section 3.1
300	Ascorbic acid, L-	
301	Sodium ascorbate	
302	Calcium ascorbate	
4.5 Packaging Gases		
290	Carbon dioxide	GMP
941	Nitrogen	GMP

²²⁾ The table of food additive provisions is for information only. Following the completion of the alignment work for CXS 156-1987, the table will be replaced by a general reference to the GSFA as below:

“Acidity regulators, antioxidants, emulsifiers, thickeners, packaging gases used in accordance with Tables 1 and 2 of the *General Standard for Food Additives* (CXS 192-1995) in food category 13.1.2 (Follow-up formulae) are acceptable for use in foods conforming to this Standard.”

4.6 Flavourings

No flavourings are permitted in this product.

4.7 Carry-Over Principle

Only the food additives listed in this Section or in the *Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses intended for Infants and Young Children* (CXG 10-1979) may be present in the foods described in Section 2.1 of this Standard, as a result of carry-over from a raw material or other ingredient (including food additive) used to produce the food, subject to the following conditions:

- The amount of the food additive in the raw materials or other ingredients (including food additives) does not exceed the maximum level specified; and
- The food into which the food additive is carried over does not contain the food additive in greater quantity than would be introduced by the use of the raw materials or ingredients under good manufacturing practice, consistent with the provisions on carry-over in the Preamble of the *General Standard for Food Additives* (CXS 192-1995).

5. Contaminants

The products covered by this Standard shall comply with the Maximum levels of the *General Standard for Contaminants and Toxins in Food and Feed* (CXS 193-1995).

The products covered by this Standard shall comply with the maximum residue limits for pesticides established by the Codex Alimentarius Commission.

6. Hygiene

6.1 It is recommended that the product covered by the provisions of this standard be prepared and handled in accordance with the appropriate sections of the *General Principles of Food Hygiene* (CXC 1-1969), and other relevant Codex texts such as the *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children* (CXC 66-2008), and in the case of liquid formula that has been commercially sterilised should also consider the appropriate sections of the *Code of Hygienic Practice for Aseptically Processed and Packaged Low-acid Foods* (CXC 40-1993) and the *Code of Hygienic Practice for Low and Acidified Low-acid Canned Foods* (CXC 23-1979), as applicable.

6.2 The products should comply with any microbiological criteria established in accordance with the *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* (CXG 21-1997).

7. Fill of Containers

In the case of products in ready-to-eat form, the fill of container shall be:

- (i) not less than 80% v/v for products weighing less than 150 g (5 oz.);
- (ii) not less than 85% v/v for products in the weight range 150-250 g (5 - 9 oz.); and
- (iii) not less than 90% v/v for products weighing more than 250 g (9 oz.) of the water capacity of the container. The water capacity of the container is the volume of distilled water at 20°C which the sealed container will hold when completely filled.

8. LABELLING

The requirements of the *General Standard for the Labelling of Prepackaged Foods* (CXS 1-1985), the *Guidelines on Nutrition Labelling* (CXG 2-1985) and the *Guidelines for Use of Nutrition and Health Claims* (CXG 23-1997) apply to Follow-up formula for older infants. These requirements include a prohibition on the use of nutrition and health claims for foods for infants except where specifically provided for in relevant Codex Standards or national legislation.

8.1 The Name of the Product

8.1.1 The text of the label and all other information accompanying the product shall be written in the appropriate language(s).

8.1.2 The name of the product as defined in Section 2.1 shall be Follow-up formula for older infants, or any appropriate designation indicating the true nature of the product, in accordance with national or regional usage.

8.1.3 The sources of protein in the product shall be clearly shown on the label.

- a) If [name of animal] milk is the only source of protein*, the product may be labelled 'Follow-up formula for older infants based on [name of animal] milk protein.'
- b) If [name of plant] is the only source of protein*, the product may be labelled 'Follow-up formula for older infants based on [name of plant] protein.'
- c) If [name of animal] milk and [name of plant] are the sources of protein*, the product may be labelled 'Follow-up formula for older infants based on [name of animal] milk protein and [name of plant] protein' or 'Follow-up formula for older infants based on [name of plant] protein and [name of animal] milk protein'.

* For clarity, addition of individual amino acids where needed to improve protein quality does not preclude use of the above labelling options.

8.1.4 A product which contains neither milk nor any milk derivative shall be labelled "contains no milk or milk products" or an equivalent phrase.

8.2 List of Ingredients

8.2.1 A complete list of ingredients shall be declared on the label in descending order of proportion except that in the case of added vitamins and minerals, these ingredients may be arranged as separate groups for vitamins and minerals. Within these groups the vitamins and minerals need not be listed in descending order of proportion.

8.2.2 The specific name shall be declared for ingredients of animal or plant origin and for food additives. In addition, appropriate functional classes for food additives shall be included on the label. The food additives INS number may also be optionally declared.

8.3 Declaration of Nutritive Value

The declaration of nutrition information for Follow-up formula for older infants shall contain the following information which should be in the following order:

- a) the amount of energy, expressed in kilocalories (kcal) and/or kilojoules (kJ), and the number of grams of protein, carbohydrate and fat per 100 g or per 100 ml of the food as sold as well as per 100 ml of the food ready for use, when prepared according to the instructions on the label.
- b) the total quantity of each vitamin and mineral as listed in paragraph 3.1.3 of Section A and any other ingredient as listed in paragraph 3.2 of Section A per 100 g or per 100 ml of the food as sold as well as per 100 ml of the food ready for use, when prepared according to the instructions on the label.
- c) In addition, the declaration of nutrients in a) and b) per 100 kilocalories (kcal) or per 100 kilojoules (kJ) is permitted.

8.4 Date Marking and Storage Instructions

8.4.1 The date marking and storage instructions shall be in accordance with Section 4.7 of the *General Standard for the Labelling of Prepackaged Foods* (CXS 1-1985).

8.4.2 Where practicable, storage instructions shall be in close proximity to the date marking.

8.5 Information for Use

8.5.1 Ready to use products in liquid form should be used directly. Concentrated liquid products and powdered products must be prepared with potable water that is safe or has been rendered safe by previous boiling before feeding, according to directions for use. Adequate directions for the appropriate preparation and handling should be in accordance with Good Hygienic Practice.

8.5.2 Adequate directions for the appropriate preparation and use of the product, including its storage and disposal after preparation, i.e. that product remaining after feeding should be discarded, shall appear on the label.

8.5.3 The label shall carry clear graphic instructions illustrating the method of preparation of the product.

8.5.4 The directions should be accompanied by a warning about the health hazards of inappropriate preparation, storage and use.

8.5.5 Adequate directions regarding the storage of the product after the container has been opened, shall appear on the label.

8.5.6 The label of Follow-up formula for older infants shall include a statement that the product shall not be introduced before 6 months of age, is not to be used as a sole source of nutrition and that older infants should receive complementary foods in addition to the product.

8.6 Additional Labelling Requirements

8.6.1 Labels should not discourage breastfeeding. Each container label shall have a clear, conspicuous and easily readable message which includes the following points:

- a) the words "important notice" or their equivalent;
- b) the statement "Breastmilk is the best food for your baby" or a similar statement as to the superiority of breastfeeding or breastmilk;
- c) a statement that the product should only be used on advice of a health worker as to the need for its use and the proper method of use.
- d) the statement; 'The use of this product should not lead to cessation of continued breastfeeding'.

8.6.2 The label shall have no pictures of infants, young children and women nor any other picture, text, or representation that might:

- 8.6.2.1 idealize the use of Follow-up formula for older infants;
- 8.6.2.2 suggest use for infants under the age of 6 months (including references to milestones and stages);
- 8.6.2.3 recommend or promote bottle feeding;
- 8.6.2.4 undermine or discourage breastfeeding; or that makes a comparison to breastmilk, or suggests that the product is similar, equivalent to or superior to breastmilk;
- 8.6.2.5 convey an endorsement or anything that may be construed as an endorsement by a professional or any other body, unless this has been specifically approved by relevant national or regional regulatory authorities.

8.6.3 The terms "humanized", "maternalized" or other similar terms shall not be used.

8.6.4 Follow-up formula for older infants shall be distinctly labelled in such a way as to avoid any risk of confusion with Infant formula, Drink for young children with added nutrients or Product for young children with added nutrients or Drink for young children or Product for young children, and Formula for special medical purposes intended for infants, in particular as to the text, images and colours used, to enable consumers to make a clear distinction between them.

8.6.5 The labelling of follow-up formula for older infants shall not refer to Infant formula, Drink for young children with added nutrients or Product for young children with added nutrients or Drink for young children or Product for young children, or Formula for special medical purposes intended for infants, including numbers, text, statements, or images of these products.

9. Methods of Analysis and Sampling

For checking the compliance with this Standard, the methods of analysis contained in the *Recommended Methods of Analysis and Sampling* (CXS 234-1999) relevant to the provisions in this standard, shall be used.

SECTION B: DRINK FOR YOUNG CHILDREN WITH ADDED NUTRIENTS OR PRODUCT FOR YOUNG CHILDREN WITH ADDED NUTRIENTS OR DRINK FOR YOUNG CHILDREN OR PRODUCT FOR YOUNG CHILDREN

1 SCOPE

- 1.1 This section of the Standard applies to the product as defined in Section 2.1, in liquid or powdered form.
- 1.2 This section of the Standard contains compositional, quality, safety, labelling, analytical and sampling requirements for the product as defined in Section 2.1.
- 1.3 Only products that comply with the criteria laid down in the provisions of this section of this Standard shall be presented as the product defined in Section 2.1.

2 DESCRIPTION

2.1 Product Definition

- 2.1.1 **Drink for young children with added nutrients or Product for young children with added nutrients or Drink for young children or Product for young children** means a product manufactured for use as a liquid part of the diversified diet of young children¹³⁾.
- 2.1.2 Drink for young children with added nutrients or Product for young children with added nutrients or Drink for young children or Product for young children is so processed by physical means only and so packaged as to prevent spoilage and contamination under all normal conditions of handling, storage and distribution in the country where the product is sold.

2.2 Other Definitions

- 2.2.1 The term **young child** means a person from the age of more than 12 months up to the age of three years (36 months).

3 ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Essential composition

- 3.1.1 The product as defined in Section 2.1 is a product based on milk of cows or other animals or a mixture thereof and/or other ingredients which have been proven to be safe and suitable for the feeding of young children. The nutritional safety and adequacy of the product as defined in Section 2.1 shall be scientifically demonstrated to support growth and development of young children.
- 3.1.2 When prepared ready for consumption in accordance with the instructions of the manufacturer, the products shall contain per 100 ml not less than 60 kcal (251 kJ) and not more than 70 kcal (293 kJ) of energy. National and/or regional authorities can deviate from the minimum energy content in line with national/regional dietary guidelines taking into account the nutritional needs of the local population.
- 3.1.3 The product as defined in Section 2.1 prepared ready for consumption shall contain per 100 kcal (100 kJ) the following nutrients with the following minimum and maximum or guidance upper levels (GUL)¹⁴⁾, as appropriate. The general principles for establishing these levels are identified in Annex I of this Standard.

a) **Protein**^{3), 4)}

Unit	Minimum	Maximum	GUL
g/100 kcal	1.8	-	-
g/100 kJ	0.43	-	-

¹³⁾ In some countries these products are regulated as breastmilk substitutes

¹⁴⁾ Guidance upper levels are for nutrients without sufficient information for a science-based risk assessment. These levels are values derived on the basis of meeting nutritional requirements of young children and an established history of apparent safe use. They may be adjusted based on relevant scientific or technological progress. The purpose of the GULs is to provide guidance to manufacturers and they should not be interpreted as goal values. Nutrient contents in the product as defined in Section 2.1 should usually not exceed the GULs unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of the product as defined in Section 2.1 or due to technological reasons. When a product type or form has ordinarily contained lower levels than the GULs, manufacturers should not increase levels of nutrients to approach the GULs.

3) For the purpose of this Standard 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.

4) PDCAAS is the preferred method to determine protein quality. However, PER can continue to be used. DIAAS could also be considered should it be recognized by FAO in the future. When determined using PDCAAS methodology, appropriate Digestibility values and the reference amino acid pattern (see Table 5 of the [Report of the FAO Expert Working Group: Protein quality assessment in follow-up formula for young children and ready to use therapeutic food](#)), the PDCAAS shall be not less than 0.9. In formulations with lower scores the quality and/or quantity of protein should be adjusted to achieve the desired value. Detail on how to calculate the PDCAAS is listed in the [Report of the FAO Expert Working Group: Protein quality assessment in follow-up formula for young children and ready to use therapeutic food](#).

When determined by PER methodology the protein quality shall not be less than 85% of that of casein.

b) Lipids ⁵⁾

Total fat

Unit	Minimum	Maximum	GUL
g /100 kcal	3.5	-	-
g /100 kJ	0.84	-	-

⁵⁾ Partially hydrogenated oils and fats shall not be used in the product as defined in Section 2.1.

α -Linolenic acid

Unit	Minimum	Maximum	GUL
mg /100 kcal	50	-	-
mg /100 kJ	12	-	-

Linoleic acid

Unit	Minimum	Maximum	GUL
mg /100 kcal	300	-	-
mg /100 kJ	72	-	-

c) Carbohydrates

Available carbohydrates^{6), 7)}

Unit	Minimum	Maximum ⁸⁾	GUL
g /100 kcal	-	12.5	-
g /100 kJ	-	3.0	-

⁶⁾ Lactose should be the preferred carbohydrate in the product as defined in Section 2.1 based on milk protein. 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.

⁷⁾ Mono- and disaccharides, other than lactose, should not exceed 2.5 g/100kcal (0.60 g/100kJ). National and/or regional authorities may limit this level to 1.25 g/100 kcal (0.30 g/100 kJ). Sucrose and/or fructose should not be added.

⁸⁾ For the product as defined in Section 2.1 with a protein level below 3.0 g/100 kcal a maximum level of available carbohydrates up to 14 g/100 kcal (3.3 g/100 kJ) may be permitted by competent national and/or regional authorities.

d) Vitamins

Vitamin A

Unit	Minimum	Maximum	GUL
μ g RE ⁹⁾ /100 kcal	60	180	-
μ g RE ⁹⁾ /100 kJ	14	43	-

⁹⁾ expressed as retinol equivalents (RE)

1 µg RE = 3.33 IU Vitamin A = 1 µg all-trans retinol. Retinol contents shall be provided by preformed retinol, while any contents of carotenoids should not be included in the calculation and declaration of Vitamin A activity.

Vitamin D ¹⁰⁾

Unit	Minimum	Maximum	GUL
µg ¹¹⁾ /100 kcal	1.5	4.5	-
µg ¹¹⁾ /100 kJ	0.36	1.1	-

¹⁰⁾ Competent national and/or regional authorities may deviate from the conditions as appropriate for the nutritional needs of their population.

¹¹⁾ Calciferol. 1 µg calciferol = 40 IU Vitamin D.

Riboflavin

Unit	Minimum	Maximum	GUL
µg /100 kcal	80	-	650
µg /100 kJ	19	-	155

Vitamin B₁₂

Unit	Minimum	Maximum	GUL
µg /100 kcal	0.1	-	2.0
µg /100 kJ	0.02	-	0.48

Vitamin C¹²⁾

Unit	Minimum	Maximum	GUL
mg /100 kcal	10	-	70
mg /100 kJ	2.4	-	17

¹²⁾ expressed as L-ascorbic acid

e) Minerals and Trace Elements

Iron¹³⁾

Unit	Minimum	Maximum	GUL
mg /100 kcal	1.0	3.0	-
mg /100 kJ	0.24	0.72	-

¹³⁾ For the product as defined in Section 2.1 based on soy protein isolate a minimum value of 1.5 mg/100 kcal (0.36 mg/100 kJ) applies.

Calcium

Unit	Minimum	Maximum	GUL
mg /100 kcal	90	-	280
mg /100 kJ	22	-	67

Zinc

Unit	Minimum	Maximum	GUL
mg /100 kcal	0.5	-	1.5
mg /100 kJ	0.12	-	0.36

Sodium chloride should not be added to the product as defined in Section 2.1.

3.1.4 National and/or regional authorities may add mandatory requirements for essential nutrients listed under 3.1.3, Section B. Any additional mandatory nutrients should be chosen from the essential composition of Follow-up formula for older infants under 3.1.3 Section A. If additional mandatory nutrients are added, the nutrient levels must be based on the nutrient composition of follow-up formula for older infants (3.1.3 Section A) which is informed by the composition of breastmilk, and take into account the inherent levels of nutrients in cows' milk.

All nutrient levels may be amended if the nutritional needs of the local population and scientific justification warrants such deviation.

3.2 Optional Ingredients

- 3.2.1 In addition to the compositional requirements listed under 3.1.3, other ingredients or substances may be added to the product as defined in Section 2.1 where the safety and suitability of the optional ingredient for particular nutritional purposes, at the level of use, is evaluated by national and/or regional authorities and demonstrated by generally accepted scientific evidence. Optional ingredients listed in 3.2.3 Section A are also permitted.
- 3.2.2 When any of these ingredients or substances is added the product as defined in Section 2.1 shall contain sufficient amounts to achieve the intended effect.
- 3.2.3 Additional nutrients may also be added to the product as defined in Section 2.1 provided these nutrients are chosen from the essential composition of Follow-up formula for older infants and levels are as per the minimum, maximum, GULs stipulated for follow-up formula for older infants (3.1.3 Section A) and take into account the inherent levels of nutrients in cows' milk; or amended by national and/or regional authorities if the nutritional needs of the local population and scientific justification warrants such deviation.
- 3.2.4 Ingredients shall not be added with the purpose of imparting or enhancing a sweet taste of the product as defined in Section 2.1.

3.3 Purity Requirements

3.3.1 General

All ingredients shall be clean, of good quality, safe and suitable for ingestion by young children. They shall conform with their normal quality requirements, such as colour, flavour and odour.

3.3.2 Vitamin Compounds and Mineral Salts

Vitamin compounds and mineral salts used in accordance with Sections 3.1.3 (d) and (e) and 3.2.1 should be selected from the *Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses intended for Infants and Young Children (CXG 10-1979)*.

3.4 Consistency and Particle Size

When prepared according to the directions of use, the product shall be free of lumps and of large, coarse particles.

3.5 Specific Prohibitions

The product and its components shall not have been treated by ionizing radiation.

4. Food Additives

The following additives are permitted:¹⁴⁾

INS	Additive	Maximum level in 100 mL of the product ready for consumption
4.1 Thickeners		
412	Guar gum	0.1 g
410	Carob bean gum	0.1 g
1412	Distarch phosphate	0.5 g singly or in combination in soy-based products only; 2.5 g singly or in combination in hydrolyzed protein and/or amino acid-based products only
1414	Acetylated distarch phosphate	
1413	Phosphated distarch phosphate	
1422	Acetylated distarch adipate	
407	Carrageenan	0.03 g singly or in combination in milk and soy-based products only; 0.1 g singly or in combination in hydrolyzed protein and/or amino acid-based liquid products only
440	Pectins	1 g

4.2 Emulsifiers		
322(i)	Lecithin	0.5 g
471	Mono- and diglycerides of fatty acids	0.4 g
4.3 Acidity Regulators		
500(ii)	Sodium hydrogen carbonate	Limited by GMP
500(i)	Sodium carbonate	
331(i)	Sodium dihydrogen citrate	
331(iii)	Trisodium citrate	
524	Sodium hydroxide	
501(ii)	Potassium hydrogen carbonate	Limited by GMP
501(i)	Potassium carbonate	
332(i)	Potassium dihydrogen citrate	
332(ii)	Tripotassium citrate	
525	Potassium hydroxide	
526	Calcium hydroxide	Limited by GMP
270	Lactic acid, L-, D-, and DL-	Limited by GMP
330	Citric acid	Limited by GMP
4.4 Antioxidants		
307b	Tocopherols concentrate, mixed	3 mg singly or in combination
307a	Tocopherol, d-alpha	
307c	Tocopherol, dl-alpha	
304	Ascorbyl palmitate	5 mg singly or in combination, expressed as ascorbic acid (INS 300, 301,302,304)
300	Ascorbic acid, L-	
301	Sodium ascorbate	
302	Calcium ascorbate	
4.5 Packaging Gases		
290	Carbon dioxide	GMP
941	Nitrogen	GMP

¹⁴⁾ The table of food additive provisions is for information only. Following the completion of the alignment work for CXS 156-1987, the table will be replaced by a general reference to the GSFA as below:

“Acidity regulators, antioxidants, emulsifiers, thickeners, packaging gases used in accordance with Tables 1 and 2 of the *General Standard for Food Additives* (CXS 192-1995) in food category 13.1.2 (Follow-up formulae) are acceptable for use in foods conforming to this Standard.”

4.6 Flavourings ¹⁵⁾

Natural Fruit Extracts: GMP

Vanilla extract: GMP

Ethyl vanillin (JECFA no. 893): 5 mg/100 ml

Vanillin (JECFA no. 889): 5 mg/ 100 ml

The flavourings used in products covered by this Standard should comply with the *Guidelines for the Use of Flavourings* (CXG 66-2008).

¹⁵⁾ National and/or regional authorities may restrict or prohibit the use of the listed flavourings.

4.7 Carry-Over Principle

Only the food additives listed in this Section or in the *Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses intended for Infants and Young Children* (CXG 10-1979) may be present in the foods described in Section 2.1 of this Standard, as a result of carry-over from a raw material or other ingredient (including food additive) used to produce the food, subject to the following conditions:

- a) The amount of the food additive in the raw materials or other ingredients (including food additives) does not exceed the maximum level specified; and

- b) The food into which the food additive is carried over does not contain the food additive in greater quantity than would be introduced by the use of the raw materials or ingredients under good manufacturing practice, consistent with the provisions on carry-over in the Preamble of the *General Standard for Food Additives* (CXS 192-1995).

5. Contaminants

The products covered by this Standard shall comply with the Maximum levels of the *General Standard for Contaminants and Toxins in Food and Feed* (CXS 193-1995).

The products covered by this Standard shall comply with the maximum residue limits for pesticides established by the Codex Alimentarius Commission.

6. Hygiene

6.1 It is recommended that the product covered by the provisions of this Standard be prepared and handled in accordance with the appropriate sections of the *General Principles of Food Hygiene* (CXC 1-1969), and other relevant Codex texts such as the *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children* (CXC 66-2008), and in the case of liquid formula that has been commercially sterilised should also consider the appropriate sections of the *Code of Hygienic Practice for Aseptically Processed and Packaged Low-acid Foods* (CXC 40-1993) and the *Code of Hygienic Practice for Low and Acidified Low-acid Canned Foods* (CXC 23-1979), as applicable.

6.2 The products should comply with any microbiological criteria established in accordance with the *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* (CXG 21-1997).

7. Fill of Containers

In the case of products in ready-to-eat form, the fill of container shall be:

- (i) not less than 80% v/v for products weighing less than 150 g (5 oz.);
- (ii) not less than 85% v/v for products in the weight range 150-250 g (5 - 9 oz.); and
- (iii) not less than 90% v/v for products weighing more than 250 g (9 oz.) of the water capacity of the container. The water capacity of the container is the volume of distilled water at 20°C which the sealed container will hold when completely filled.

8. LABELLING

The requirements of the *General Standard for the Labelling of Prepackaged Foods* (CXS 1-1985), the *Guidelines on Nutrition Labelling* (CXG 2-1985) and the *Guidelines for Use of Nutrition and Health Claims* (CXG 23-1997) apply to the product as defined in Section 2.1. These requirements include a prohibition on the use of nutrition and health claims for foods for infants and young children except where specifically provided for in relevant Codex Standards or national legislation.

8.1 The Name of the Product

- 8.1.1 The text of the label and all other information accompanying the product shall be written in the appropriate language(s).
- 8.1.2 The name of the product as defined in Section 2.1 shall be “Drink for young children with added nutrients” or “Product for young children with added nutrients” or “Drink for young children” or “Product for young children”, or any appropriate designation indicating the true nature of the product, in accordance with national or regional usage.
- 8.1.3 The sources of protein in the product shall be clearly shown on the label.
 - a) If [name of animal] milk is the only source of protein*, the product may be labelled “Drink for young children with added nutrients based on [name of animal] milk protein” or “Product for young children with added nutrients based on [name of animal] milk protein” or “Drink for young children based on [name of animal] milk protein” or “Product for young children based on [name of animal] milk protein”.
 - b) If [name of plant] is the only source of protein*, the product may be labelled “Drink for young children with added nutrients based on [name of plant] protein” or “Product for young children with added nutrients based on [name of plant] protein” or “Drink for young children based on [name of plant] protein” or “Product for young children based on [name of plant] protein”.

- c) if [name of animal] milk and [name of plant] are the sources of proteins*, the product may be labelled "Drink for young children with added nutrient based on [name of animal] milk protein and [name of plant] protein" or "Product for young children with added nutrients based on [name of animal] milk protein and [name of plant] protein" or "Drink for young children based on [name of animal] milk protein and [name of plant] protein" or "Product for young children based on [name of animal] milk protein and [name of plant] protein".

* For clarity, addition of individual amino acids where needed to improve protein quality does not preclude use of the above labelling options.

- 8.1.4 A product which contains neither milk nor any milk derivative shall be labelled "contains no milk or milk products" or an equivalent phrase.

8.2 List of Ingredients

- 8.2.1 A complete list of ingredients shall be declared on the label in descending order of proportion except that in the case of added vitamins and minerals, these ingredients may be arranged as separate groups for vitamins and minerals. Within these groups the vitamins and minerals need not be listed in descending order of proportion.

- 8.2.2 The specific name shall be declared for ingredients of animal or plant origin and for food additives. In addition, appropriate functional classes for food additives shall be included on the label. The food additives' INS number may also be optionally declared.

8.3 Declaration of Nutritive Value

The declaration of nutrition information for the product as defined in Section 2.1 shall contain the following information which should be in the following order:

- a) the amount of energy, expressed in kilocalories (kcal) and/or kilojoules (kJ), and the number of grams of protein, carbohydrate and fat per 100 g or per 100 ml of the food as sold as well as per 100 ml of the food ready for use, when prepared according to the instructions on the label.
- b) the total quantity of each vitamin and mineral as listed in paragraph 3.1.3 of Section B and any other ingredient as listed in paragraph 3.2 of Section B per 100 g or per 100 ml of the food as sold as well as per 100 ml of the food ready for use, when prepared according to the instructions on the label.
- c) In addition, the declaration of nutrients in a) and b) per 100 kilocalories (kcal) or per 100 kilojoules (kJ) and/or per serving size, provided that the serving size is quantified on the label, is permitted.

8.4 Date Marking and Storage Instructions

- 8.4.1 The date marking and storage instructions shall be in accordance with Section 4.7 of the *General Standard for the Labelling of Prepackaged Foods*.

- 8.4.2 Where practicable, storage instructions shall be in close proximity to the date marking.

8.5 Information for use

- 8.5.1 Ready to use products in liquid form should be used directly. Concentrated liquid products and powdered products must be prepared with potable water that is safe or has been rendered safe by previous boiling before feeding, according to directions for use. Adequate directions for the appropriate preparation and handling should be in accordance with Good Hygienic Practice.

- 8.5.2 Adequate directions for the appropriate preparation and use of the product, including its storage and disposal after preparation, i.e. that product remaining after feeding should be discarded, shall appear on the label.

- 8.5.3 The label shall carry clear graphic instructions illustrating the method of preparation of the product.

- 8.5.4 The directions should be accompanied by a warning about the health hazards of inappropriate preparation, storage and use.

- 8.5.5 Adequate directions regarding the storage of the product after the container has been opened, shall appear on the label.

8.5.6 The label of the product as defined in Section 2.1 shall include a statement that the product shall not be introduced to infants 12 months of age or less, and is not to be used as a sole source of nutrition.

8.6 Additional Labelling Requirements

8.6.1 The label of the product as defined in Section 2.1 shall have no image, text or representation, including pictures of feeding bottles, that could undermine or discourage breastfeeding or which idealises the use of the product as defined in Section 2.1. The terms 'humanized', 'maternalized' or other similar terms must not be used on the label.

8.6.2 Labels should not discourage breastfeeding. Each container label shall have a clear, conspicuous and easily readable message which includes the following points:

a) the statement "Breastfeeding is recommended up to two years and beyond."

b) a statement that the mother/caregiver should seek advice of a health worker on proper feeding of the young child.

8.6.3 The label shall have no pictures of infants, older infants, young children and women or any other picture, text, or representation that:

8.6.3.1 undermines or discourages breastfeeding; or that makes a comparison to breastmilk, or suggests that the product is similar, equivalent to or superior to breastmilk;

8.6.3.2 might convey an endorsement or anything that may be construed as an endorsement by a professional or any other body, unless this has been specifically approved by relevant national or regional regulatory authorities.

8.6.4 The product as defined in Section 2.1 shall be distinctly labelled in such a way as to avoid any risk of confusion with infant formula, follow-up formula for older infants, and formula for special medical purposes intended for infants, in particular as to the text, images and colours used, to enable consumers to make a clear distinction between them.

8.6.5 The labelling of the product as defined in Section 2.1 shall not refer to infant formula, follow-up formula for older infants, or formula for special medical purposes intended for infants, including numbers, text, statements, or images of these products.

9. Methods of Analysis and Sampling

For checking the compliance with this Standard, the methods of analysis contained in the *Recommended Methods of Analysis and Sampling* (CXS 234-1999) relevant to the provisions in this standard, shall be used.

APPENDIX III

PROPOSED DRAFT GENERAL PRINCIPLES FOR ESTABLISHING NUTRIENT REFERENCE VALUES FOR PERSONS AGED 6 TO 36 MONTHS**(For adoption at Step 5)****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)¹⁵ 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 recommended intake based on observed or experimentally determined approximations or estimates of nutrient intake by a group (or groups) of apparently healthy people that are assumed to be adequate for persons aged 6-36 months].

Upper Level of Intake (UL)¹⁶ 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.

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.

¹⁵ 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).

¹⁶ Different countries may use other terms for this concept, for example, Tolerable Upper Nutrient Intake Level (UL) or upper end of safe intake range.

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 rigor 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.

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

OR

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

OR

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

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.

**PROPOSED AMENDMENT TO THE STANDARD FOR
CANNED BABY FOODS (CXS 73-1981)**

(For adoption)

Text to be deleted is indicated in **bold/strikethrough**

9.5 Information for Utilization

9.5.1 Directions as to the preparation and use of the food and its storage and keeping before and after the container has been opened, shall appear on the label or on the accompanying leaflet.

9.5.2 ~~For canned beets (beetroot) and spinach, the following statement shall appear on the label "use after the age of 12 weeks".~~

APPENDIX V

PROPOSED AMENDMENT TO THE ADVISORY LISTS OF NUTRIENT COMPOUNDS FOR USE IN FOODS FOR SPECIAL DIETARY USES INTENDED FOR INFANTS AND YOUNG CHILDREN (CXG 10-1979)

(For adoption)

SECTION B: ADVISORY LIST OF VITAMIN COMPOUNDS FOR USE IN FOODS FOR SPECIAL DIETARY USES INTENDED FOR INFANTS AND YOUNG CHILDREN

All additions are shown in **bold underlined** font.

Nutrient Source	Purity Requirements by		Use in Codex Food Standards Applicable to Infants and Young Children					
	CAC ¹	International and/or national bodies	IF		FUF ⁴	PCBF ⁵	CBF ⁶	FSMP ⁷ for infants and young children
			Sec. A ²	Sec. B ³				
10. Folic acid								
10.1 N-Pteroyl-L-glutamic acid		Ph Int, FCC, USP, Ph Eur, Jap Food Stan	√	√	√	√	√	√
10.2 Calcium-L-methyl-folate		JECFA (2005); <u>USP</u>	<u>√</u>	√	<u>√</u>	<u>√</u>	<u>√</u>	√

¹ CAC = Codex Alimentarius Commission

² IF Sect. A = Section A of the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants

³ IF Sect. B = Section B of the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants

⁴ FUF = Follow-up Formula

⁵ PCBF = Processed Cereal Based Foods for Infants and Young Children

⁶ CBF = Canned Baby Food

⁷ FSMP = Food for Special Medical Purposes other than Infant Formula

APPENDIX VI

PROPOSED METHODS OF ANALYSIS FOR ENDORSEMENT AND INCLUSION IN CXS 234-1999

(For endorsement by CCMAS)

All additions are shown in **bold underlined** font.

<i>Commodity</i>	<i>Provision</i>	<i>Method</i>	<i>Principle</i>	<i>Type</i>
Infant Formula	<u>Vitamin B12</u>	<u>AOAC 2014.02</u>	<u>LC-UV</u>	<u>III</u>
	<u>Total amino acids (excluding taurine and tryptophan)</u> <u>For use according to Section 3.1.3 (a) footnotes 3 and 4 of CXS 72-1981</u>	<u>AOAC 2018.06 / ISO 4214 IDF 254 /AACC 07-50.01</u>	<u>UHPLC-UV</u>	<u>II</u>
	<u>Tryptophan</u> <u>For use according to Section 3.1.3 (a) footnotes 3 and 4 of CXS 72-1981</u>	<u>AOAC 2017.03</u>	<u>HPLC</u>	<u>II</u>