

CODEX ALIMENTARIUS COMMISSION

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Food and Agriculture
Organization of the
United Nations



World Health
Organization

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REP22/NFSDU

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Forty-fifth Session

TBC

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

Virtual

19 – 25 November and 1 December 2021

TABLE OF CONTENTS

Summary and Status of Work	page ii
List of Abbreviations.....	page iii
List of CRDs	page iv
Report of the Forty-second Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses	page 1
	<u>Paragraphs</u>
Introduction	1
Opening of the Session	2 - 4
Adoption of the Agenda (Agenda item 1)	5
Matters Referred to the Committee by the Codex Alimentarius Commission and/or Other Subsidiary Bodies (Agenda item 2)	6
Matters of Interest Arising from FAO and WHO (Agenda item 3)	7 - 11
Review of the <i>Standard for Follow-up Formula</i> (Agenda item 4)	12 – 99
Proposed Draft Revised Standard for Follow-up Formula for Older Infants and Drink/Product for Young Children with Added Nutrients or Drink for Young Children: Remaining Sections (Agenda item 4a)	13 - 53
Draft Scope, Description and Labelling for Drink/Product for Young Children with Added Nutrients or Drink for Young Children (Agenda item 4b)	54 - 70
Draft Scope, Description and Labelling for Follow-up Formula for Older Infants (Agenda item 4c).....	71 - 72
Essential Composition Requirements for Follow-up Formula for Older Infants and Drink/Product for Young Children with Added Nutrients or Drink for Young Children (Agenda item 4d)	73 99
Draft Guideline for Ready-to-Use Therapeutic Foods (Agenda item 5).....	100 - 126
General Principles for the Establishment of NRVs-R for Persons Aged 6 – 36 Months (Agenda item 6)	127 - 171
Other business (Agenda item 7) Prioritization Mechanism to Better Manage the Work of CCFNSDU.....	172 -175
Date and place of next session (Agenda item 8)	176
Appendices	page
Appendix I - List of Participants	22
Appendix II – Guidelines for Ready-to-Use Therapeutic Foods (RUTF)	45
Appendix III – Review of the Standard for follow-up Formula: scope, description, essential composition and quality factors, and labelling: Sections A and B.....	53
Appendix IV – Review of the Standard for follow-up Formula: remaining sections: Sections A and B.....	66

SUMMARY AND STATUS OF WORK

Responsible Party	Purpose	Text/Topic	Code	Step	Para.
CCEXEC 81/82 CAC45	Adoption	Guidelines for Ready-to-Use Therapeutic Foods (RUTF)	-	8	126
CCNFSDU43	Hold	Review of the <i>Standard for Follow-up Formula</i> : Section A: scope, description, essential composition and labelling; and remaining sections and Section B: scope, description, essential composition and labelling; and remaining sections	CXS 156-1987	7 / 4	53 (i), 70 (i), 72, and 73
		Methods for measuring sweetness of carbohydrate sources		4	99 (i)
NZ / CCNFSDU43	Discussion	Review of the <i>Standard for Follow-up Formula</i> : preamble and structure			99 (ii)
CCNFSDU43		Reply from CCFL46: nutrient profiles	-	-	6(ii)
		Request from CCMAS: methods for fructans, beta-carotene and lycopene in infant formula	CXS 72-1981 / CXS 234-1999	-	6 (ii)
CCFL47	Information	Review of the Standard for Follow-up Formula: Section B – Section 9.1.2 labelling	CXS 156 - 1987	7	70 (ii)
		Guidelines for RUTF: Section 12: labelling	-	8	126 (ii)
CCFA53	Information	Review of the Standard for Follow-up Formula	CXS 156 - 1987	-	53 (ii)
EWG / PWG (Ireland, Costa Rica and United States of America) CCNFSDU43	Redrafting	General Principles for the establishment of NRVs-R for persons aged 6 – 36 months / pilot NRVs-R	CXG 2-1985	2/3	170 - 171
EWG / PWG (Germany and Canada) CCNFSDU43	Redrafting / reviewing	Prioritization mechanism / emerging issues or new work proposals	-	-	175

LIST OF ABBREVIATIONS

AI	Adequate intake
ALA	Alpha Linolenic Acid
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
CCFL	Codex Committee on Food Labelling
CCFO	Codex Committee on Fats and Oils
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
DHA	Docosahexaenoic acid
DIRV	Dietary Intake Reference Values
EFA	Essential Fatty Acids
EWG	Electronic Working Group
FAO	Food and Agriculture Organization of the United Nations
FSMP	Foods for Special Medical Purposes
GSFA	General Standard for Food Additives
IDF	International Dairy Federation
ISO	International Organization for Standardization
JECFA	Joint FAO/WHO Expert Committee on Food Additives
JEMNU	Joint FAO/WHO Expert Meetings on Nutrition
LA	Linoleic acid
MHLW	Ministry of Health, Labour and Welfare of Japan
NCF	Nitrogen to protein conversion factor
NUGAG	WHO Nutrition Guidance Expert Advisory Group
NRV-NCD	Nutrient reference values – non-communicable disease
NRV-R	Nutrient reference values-requirements
PDCAAS	Protein digestibility-corrected amino acid score
PWG	Physical Working Group
RASB	Recognized Authoritative Scientific Body
RUTF	Ready-to-use therapeutic foods
SAM	Severe acute malnutrition
TFA	Trans fatty acid
UNICEF	The United Nations Children Fund
UNSCN	United Nations System Standing Committee on Nutrition
WFP	World Food Programme
WHA	World Health Assembly
WHO	World Health Organization

LIST OF CONFERENCE ROOM DOCUMENTS (CRDS)

CRD No.	Agenda Item	Submitted by
1	Division of Competence between EU and its Member States	EU
2	4 (Review of the Standard for Follow-Up Formula: Consideration of relevant concepts and technical guidance in WHO/WHA documents for the labelling and other provisions in the draft standard for follow-up formula)	New Zealand
3	5 (Proposal for a revised preamble of the proposed draft guidelines for ready to use therapeutic foods (RUTF))	South Africa, Uganda, Codex secretariat, WHO and FAO
4	4a	EU, Kenya and Rwanda
5	4b	Kenya, Rwanda and Uruguay
6	4d	Australia, AOAC/ISO/IDF and IFT
7	5	Rwanda, GOE and NHF
8	6	Rwanda
9	4a, 4b and 5	Morocco
10	2, 4a, 4b, 4c, 4d and 6	HKI
11	4a, 4b, 4c, 4d, 5 and 6	South Africa
12	6 (Updated draft general principles for the establishment of NRVs-R for persons aged 6 - 36 months)	Ireland, the USA and Costa Rica
13	4b and 6	Uganda
14	4a, 4b, 4c, 4d and 5	India
15	4a and 4b	EU
16	5	UNCEF
17	4a, 4b and 6	Ghana
18	5	IBFAN
19	4a, 4b, 5 and 6	Nigeria
20	1, 2, 3, 4, 4a, 4b, 5 and 6	Senegal
21	5	NHF
22	4d	Switzerland
23	4a and 6	Republic of Korea

INTRODUCTION

1. The Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) held its forty-second session virtually from 19 – 25 November and 1 December 2021 at the kind invitation of the Federal Government of Germany. Ms Hilke Thordsen-Böhm and Dr Anja Brönstrup, both from the Federal Ministry of Food and Agriculture of Germany, served as Chair and Co-Chair of the Session, respectively. The Session was attended by 99 Member countries, one Member Organisation and 35 Observer Organisations. A list of participants is given in Appendix I.

OPENING OF THE SESSION

2. Ms Julia Klöckner, Federal Minister of Food and Agriculture, Germany, welcomed delegates and opened the meeting. She mentioned that it was important to resume the work of CCNFSDU virtually due to the need to promote healthy diets, and stressed that deliberations within CCNFSDU contribute immensely to consumer protection worldwide and in the fight against hunger and malnutrition. She called for mutual exchange, understanding and compromise during the deliberations with a view to advance and complete pertinent work.
3. Mr Steve Wearne, speaking as the newly elected Chairperson and on behalf of the three newly elected vice Chairpersons of the Codex Alimentarius Commission (CAC) and Mr Tom Heilandt, Codex Secretary, also addressed the meeting. Both speakers stressed the need for compromise in order to progress work and hoped that the same spirit of compromise demonstrated at other sessions of the Committee would prevail also at this Session.

Division of competence¹

4. CCNFSDU noted the division of competence between the European Union and its Member States, according to paragraph 5, Rule II of the Rules of Procedure of CAC.

ADOPTION OF THE AGENDA (Agenda Item 1)²

5. CCNFSDU adopted the Provisional Agenda as the Agenda for the session with the addition of discussion on the prioritization mechanism for emerging issues or new work proposals under Agenda Item 7 – other business and future work.

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

6. CCNFSDU:
 - i. noted that some matters were for information only, and that certain matters as outlined in paragraph 28 of CX/NFSDU 21/42/2 would be considered under the relevant agenda items as follows:
 - Reply from CCMAS41 on methods to measure sweetness of carbohydrate sources (Agenda item 4d); and
 - Endorsements by CCFA52 and CCFL46 and related comments (Agenda items 4b, 4c and 5)
 - ii. agreed to consider at CCNFSDU43 the following:
 - The reply from CCLF46 relating to nutrient profiles; and
 - The request from CCMAS41 relating to the methods for fructans, beta-carotene and lycopene in infant formula.
 - iii. noted that the Codex Secretariat would continue working closely with the Chairpersons of CCNFSDU, Chairs of electronic working groups (EWGs) and the host country Secretariat on ways to improve work management of the Committee to ensure continued timeliness of working

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

² CX/NFSDU 21/42/1

³ CX/NFSDU 21/42/2

documents.

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

7. The Representative of FAO drew the attention of the Committee to the following issues to be considered under relevant Agenda items: (i) The Joint FAO/WHO scientific advice provided by JEMNU in 2019 for establishing nitrogen to protein conversion factors for soy-based and milk-based ingredients used in infant and follow-up formula; (ii) the Supplementary guidance provided by FAO on computing PDCAAS for follow-up formula for young children that has been made available on the CCNFSDU42 meeting webpage; (iii) the report that was commissioned by FAO providing scientific advice to develop general principles for the establishment of NRVs-R for older infants and young children; and (iv) ongoing work by FAO/WHO to update nutrient requirements for infants and young children, 0 to 4 years of age.
8. The Representative further noted other activities in the report that could be of interest to the Committee including the updated FAO Nutrition Strategy, the UN Food Systems Summit and subsequent collaborative coalitions led by UN agencies and member countries and the upcoming Nutrition for Growth Summit to be hosted by the Government of Japan in December 2021.
9. With reference to the document CX/FNFSDU 21/42/3, in addition to the joint FAO/WHO activities reported by FAO on behalf of FAO and WHO, the Representative of WHO highlighted the WHO activities of interest to the on-going work of the Committee and various other Codex Committees. These included the WHO guideline development process to review the efficacy, safety, and effectiveness of ready-to-use therapeutic foods (RUTF) and also the recently undertaken systematic evidence reviews regarding the contents of essential fatty acids and iron which would contribute to the discussions on Agenda Item 5; the accelerated actions to eliminate industrially produced trans fatty acids (TFAs) and planned high-level launching of the 3rd annual progress report on 7 December 2021 as the need for relevant risk management actions by Codex to support Member States' efforts to eliminate TFAs is being discussed at CCFL and CCFO; and the launching of the WHO Global Sodium Benchmarks for different food categories in May 2021 as this work and increasing country actions might have implications for various existing Codex standards and guidelines possibly requiring reviews and updates to promote the health of consumers.
10. The Representative also informed the Committee of two additional activities which were not reported in the document CX/FNFSDU 21/42/3. These were the planned joint WHO/MHLW Japan Nutrition for Growth Summit (N4G) side event on sodium reduction on 8 December 2021, and the reconvening of the Global Network of Institutions for Scientific Advice on Nutrition. This network was created to strengthen the collaboration, harmonization of methods and sharing of information and experiences among institutions which are developing national and/or regional guidelines on diet and nutrition. These institutions include some of the Codex's Recognized Authoritative Scientific Bodies (RASBs).
11. CCNFSDU thanked FAO and WHO for the information provided and noted that certain parts of the information provided would be considered under the relevant Agenda Items. One Observer thanked WHO for their important role in providing timely updated science-based recommendations for breastfeeding during the pandemic.

REVIEW OF THE STANDARD FOR FOLLOW-UP FORMULA (CXS 156 – 1987) (Agenda Item 4)

12. The Chairperson recalled that the work on the review of the *Standard for Follow-up Formula* was being undertaken in stages and that there were various parts that would be addressed under Agenda items 4a – 4d, and provided an overview of the issues to be discussed under each of the items. She reminded the Committee that the structure of the Standard and the preamble would be considered after completion of all other parts of the Standard as previously agreed by CCNFSDU.

⁴ CX/FNFSDU 21/42/3

PROPOSED DRAFT REVISED STANDARD FOR FOLLOW-UP FORMULA FOR OLDER INFANTS AND DRINK/PRODUCT FOR YOUNG CHILDREN WITH ADDED NUTRIENTS OR DRINK FOR YOUNG CHILDREN REMAINING SECTIONS (Agenda Item 4a)⁵

13. The Chairperson recalled that at CCNFSDU41, recommendations 1 and 2 contained in CX/NFSDU 19/41/5 had already been addressed. Due to time constraints, recommendations 3 – 15 contained in CX/NFSDU 19/41/5 had to be deferred for discussion at this session.
14. New Zealand, as Chair of the EWG, speaking also on behalf of the Co-Chairs France and Indonesia, introduced the item. The EWG Chair explained that the EWG had made reference to four standards (i.e. *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CXS 72-1981), *Canned Baby Foods* (CXS 73-1981), *Processed Cereal-Based Foods for Infants and Young Children* (CXS 74-1981) and the current *Standard for Follow-up Formula* (CXS 156-1987)) and considered whether applicable provisions in these Standards were suitable for adoption or should be modified for the revised Standard. It was further explained that there were some minor amendments that needed to be made in order to ensure that the provisions contained the most up-to-date references and to accommodate advancements in the Food Additive section.
15. CCNFSDU considered the recommendations 3 - 15 of the EWG for both Sections A and B and made the following comments and decisions in addition to editorial corrections.

Recommendation 3 (Purity requirements)

16. One delegation proposed to include the requirements on extraneous and foreign matters in the provision. However, CCNFSDU did not agree to this proposal. CCNFSDU endorsed the recommendations for both Sections A and B.

Recommendation 4 (Vitamin Compounds and Mineral Salts)

17. CCNFSDU endorsed the recommendation to retain the current provisions in CXS 156-1987 for Section A, noting that (i) the correct sections in the recommendation should be sections 3.1.3 (d) and (e) and 3.2.1 instead of sections 3.3.1 and 3.3.2; and (ii) the title of CXG 10-1979 should be precisely quoted (i.e. *Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses intended for Infants and Young Children* (CXG 10-1979)).
18. Regarding the corresponding provision in Section B, in addition to the amendments as described above, CCNFSDU endorsed the recommendation to retain only provision 3.4.2.1 in CXS 156-1987, and deleted the provision 3.4.2.2 as a maximum level for sodium had not been set for this product.

Recommendation 5 (Consistency and Particle Size)

19. One delegation proposed to insert the wording “and suitable for adequate feeding of older infants” at the end of the provision in Section A; and “and suitable for adequate feeding of young children” at the end of Section B in order to be consistent with the provision in CXS 72-1981 which had been recently revised.
20. Other delegations were not in favour of the proposed changes to the provision reiterating that the provision was an existing requirement in the current Standard and the proposed amendment could lead to different interpretations.
21. In response to the suggestions to include: (i) the word “label” before “directions of use” for consistency with the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CXS 72-1981); and (ii) other quality specifications e.g. “insolubility index”, “scorched particles” and “dispersibility and wettability”, noting there were corresponding testing methods available; the EWG Chair explained that (i) the word “label” might limit future development in terms of communicating directions of use; and (ii) the proposal to include other quality specifications had not been considered by the EWG and it was inappropriate to include them at the current stage.
22. CCNFSDU agreed with the recommendation i.e. to retain the current provision in CXS 156-1987 for both Sections A and B.

⁵ CX/NFSDU 19/41/5; CX/NFSDU 19/41/5 Add.1; CX/NFSDU 19/41/5 Add.2; CX/NFSDU 21/42/4

Recommendation 6 (Specific prohibitions)

23. A proposal was made to prohibit GMO-derived ingredients or components but CCNFSDU did not consider this proposal.
24. CCNFSDU endorsed the recommendation to retain the current provision for both Sections A and B.

Recommendation 7 (Food additives – permissions for food additives)**Recommendation 8 (Food additives-administrative changes)**

25. CCNFSDU42 recalled that CCNFSDU41 had agreed to forward the alignment document (CX/NFSDU 19/41/9) to CCFA and that CCFA was conducting the alignment exercises for all CCNFSDU standards, including CXS156-1987. It was further noted that the two packaging gases (i.e. carbon dioxide and nitrogen) were included in the table for food additives forwarded to CCFA for alignment, and that once the alignment exercise is completed the list of food additives in CCNFSDU standards would be replaced by a reference to the corresponding sections of the *General Standard for Food Additives* (GSFA, CXS 192-1995).
26. CCNFSDU42 agreed to:
 - align the table of food additives for Sections A and B with the text in CX/NFSDU 19/41/5 part D; and
 - inform CCFA that an accompanying note stating "within the limits for sodium in Section 3.1" associated with sodium ascorbate (INS 301) should be included in the table for Section A and the accompanying note should not be included in the table of food additives for Section B as there were no maximum levels for sodium for that product.

Recommendation 9 (Carry-over principle)

27. CCNFSDU42 endorsed Option 2 of the recommendation, i.e. to adopt the text from the *Standard for Infant Formula and Formulas for Special Medical Purposes* (CXS 72-1981), and the *Standard for Processed Cereal-Based Foods for Infants and Young Children* (CXS 74-1981) for the carry-over of food additives and nutrient carriers, for both Sections A and B. This option was consistent with the text in both standards and would provide clarity.
28. CCNFSDU noted that CCFA would examine the food additive sections including the carry-over principle when aligning the food additive provisions between the GSFA and the commodity standards.

Recommendation 10 (Flavourings)

29. CCNFSDU noted divergent views expressed by delegations on the provision for flavourings.
30. Those delegations objecting to the addition of flavourings to the products covered by both Sections A and B indicated that:
 - these products are considered as breastmilk substitutes in their countries and by WHO; therefore, the provision on flavourings should be aligned to that in CXS 72-1981;
 - flavourings could cause infants to develop a preference for sweet-tasting foods, which could have a negative effect on food choices and could cause negative consequences throughout a child's life and into adulthood;
 - WHA resolution 69.9 provided guidance on ending the inappropriate promotion of foods for infants and young children. The addition of flavorings would increase the sweetness of the product, which would increase children's demand for these products and encourage care-givers to use these products; and
 - there is no technological justification for the use of flavourings in these products targeted at the vulnerable group.
31. Delegations supporting permitting the use of flavourings in products described under Section B only were of the view that:
 - the product in Section B is not considered as a breastmilk substitute;

- the product in Section B was consumed by children who were being exposed to many different flavourings and tastes as they are moving to family foods and therefore there was no need to limit the use of flavourings for that age group;
 - the currently permitted flavourings are not sweeteners and do not add sweet taste and are used for reasons of palatability; and
 - there was no scientific evidence to support the restriction of the use of flavourings.
32. One delegation suggested that the provision for flavourings in both Sections A and B should be determined by national or regional authorities.
33. The Representative of WHO highlighted their concern on inclusion of the provision for flavouring in both Sections A and B as WHO considered these products as breastmilk substitutes and there was no technological justification for their addition.
34. Safety concerns were raised for the listed category of natural fruit extracts. Questions on whether vanilla was a natural or synthetic flavouring, whether natural fruit extracts were too broad to be included and whether all the listed flavourings had been evaluated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) were raised.
35. The Codex Secretariat clarified that the listed flavourings were currently included in CXS 156-1987 which indicated that these flavourings had been endorsed by CCFA. When endorsing these provisions, CCFA would have taken JECFA's evaluation into account and there should be no safety concerns.
36. CCNFSDU agreed with the Chairperson's proposal to concentrate on the discussion of flavourings in Section A followed by Section B.

Discussion on Recommendation 10a (Flavourings in Section A)

37. The Codex secretariat clarified that normally commodity standards are elaborated to provide what is allowed in a standard. In the case of the *Standard for Infant formula and formulas for special medical purposes* (CXS 72-1981), there was no provision for flavourings which could be interpreted that flavourings are prohibited.
38. In view of the wide support on prohibiting the use of flavourings in Section A since the products covered by this Section function as breastmilk substitutes, the Chairperson proposed to follow the approach in CXS 72-1981 i.e. not including the flavouring provision in the Standard.
39. Some delegations supported the Chairperson's proposal as it was a normal practice in Codex standards while others were of the view that a prohibition statement should be included under the provision for flavourings in order to avoid confusion and furthermore, the same statement should consequently also be inserted in CXS 72-1981.

Conclusion on recommendation 10a (Flavourings in Section A)

40. CCNFSDU agreed to delete the provisions for flavourings and to indicate that no flavourings are permitted in this product.
41. CCNFSDU noted that the consequential amendments to CXS 72-1981 could be considered in future.

Discussion on Recommendation 10b (Flavourings in Section B)

42. Taking into account the divergent views on this provision, a proposal was made to add a footnote to explain whether flavourings were allowed or not should be determined at national or regional level as this would allow the relevant authorities who considered the product a breastmilk substitute or who had other concerns, to prohibit or restrict the use of flavourings.
43. There continued to be opposing views on the use of flavourings with delegations reiterating their objection on the use of flavourings in the product and stressing that they were not in agreement with the proposal and while other delegations stating that they could accept the footnote in the spirit of compromise, noting that similar footnotes had been utilized in other parts of the Standard.

44. One Observer highlighted that it was not necessary to insert the footnote, and indicated that CCFA had been making efforts to remove a similar note (i.e. Note 161) in the GSFA and these provisions should be considered by CCFA.

Conclusion on Recommendation 10b (Flavourings in Section B)

45. CCNFSDU endorsed the recommendation proposed by the EWG with the insertion of a footnote as follows:

“National and/or regional authorities may restrict or prohibit the use of the listed flavourings.”

46. CCNFSDU noted the reservation of Mexico and the concern of some observers on permitting the use of flavourings in the product.

Recommendation 11 (Contaminants)

47. CCNFSDU endorsed the recommendation as proposed for both Sections A and B.

Recommendation 12 (Hygiene)

48. CCNFSDU agreed to:

- the recommendation as proposed for both Sections A and B; and
- the inclusion of the two additional Codex codes of practice (i.e. 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)) in both Sections A and B since there were products available in liquid form and commercially sterilized.

Recommendation 13 (Packaging)

49. CCNFSDU agreed to remove the section on packaging from the Standard noting that (i) the provision on packaging was not necessary as per the Format for Codex Commodity Standards in the Codex Procedural Manual; (ii) the two packaging gases (i.e. carbon dioxide and nitrogen) had been covered under the food additive sections; and (iii) the *General Principles of Food Hygiene* (CXC 1- 1969) and other relevant Codes of Hygienic Practice sufficiently addressed requirements for packaging.

Recommendation 14 (Fill of containers)

50. CCNFSDU endorsed the recommendation for both Sections A and B.

Recommendation 15 (Method of analysis and sampling)

51. In response to some questions raised by delegations, the Codex Secretariat clarified that: (i) the provision was the standard wording in accordance with the Codex Procedural Manual; (ii) CCNFSDU could submit testing methods for consideration by CCMAS; and (iii) CCMAS was in the process of reviewing all methods of analysis in CXS 234 and if needed, CCMAS might make recommendations on methods of analysis to CCNFSDU.

52. CCNFSDU agreed with the recommendation for both Sections A and B.

Conclusion

53. CCNFSDU agreed:

- i. that the provisions were ready for adoption at Step 5/8 but in order to advance the entire Standard to CAC for adoption, the provisions would be held at Step 4 on the understanding that all issues on the remaining sections of Sections A and B had been addressed and no further discussion was needed (Appendix IV);
- ii. to inform CCFA:
 - that the *Standard for Follow-up Formula* was currently split into two Sections i.e. Section A follow-up formula for older infants and Section B: drink for young children with added nutrients or products for young children with added nutrients or drink for young children or product for young children;
 - of the accompanying note relating to limits to sodium (see para. 26); and

- of the changes of the provisions for carry-over principle and flavourings respectively (see paras 27)

DRAFT SCOPE, DESCRIPTION AND LABELLING FOR DRINK/PRODUCT FOR YOUNG CHILDREN WITH ADDED NUTRIENTS OR DRINK FOR YOUNG CHILDREN (Agenda Item 4b)⁶

54. The Chairperson introduced the item and recalled that CCNFSDU41 had advanced the scope, description and labelling for drink/product for young children with added nutrients or drink for young children to CAC43 for adoption at Step 5; that CAC43 had adopted the text and advanced it to Step 6 for comments and further consideration at Step 7 by CCNFSDU42. The Chairperson further recalled that the aforementioned text was a result of constructive discussion at CCNFSDU41 and that the only part that remained for further discussion was Section 2.1.1. CCNFSDU41 had agreed that an EWG chaired by New Zealand and co-chaired by France and Indonesia would finalise the definition of drink/product for young children with added nutrients or drink for young children and provide proposals for consideration by this session. She also noted that CCFL had endorsed the labelling provisions and had requested CCNFSDU to consider whether exclusion of the term “product” in the name for “drink for young children” was an omission (see CX/NFSDU 21/42/2).

55. In addition to editorial corrections, the following comments and decisions were made.

Product Definition: Section 2.1.1

56. New Zealand, as Chair of the EWG, introduced the report of the EWG and its recommendations for the definition. She recalled that there had been considerable discussion on the definition over several rounds in the course of the discussions in the various EWGs and that numerous options had been considered over the years. She reported that the EWG had not agreed upon a single option but had proposed 2 options for consideration by the session. She further reminded the Committee that while there might be several name options for countries to choose from, there would only be one definition for the Standard.

57. The Chairperson noted that there were diverse views on the definition as reflected by the comments received to CL 2021/54-NFSDU and in order to progress, one option would need to be decided upon. She proposed that the Committee consider whether the text in square brackets provided any meaningful addition to defining the product. She further reminded the Committee that the definition was to describe the product covered by the Standard and was not to be confused with the information on the label or information to be provided in any other way to consumers.

Discussion

58. There was general support for option 2 (deletion of the following text in square brackets “*which may contribute to the nutritional needs of young children*”).

59. Those delegations in favour of this option expressed the view that:

- the additional text was not a meaningful addition and that the purpose and target population was already covered in the text of the definition;
- option 2 could be supported because when taken in context with the introduction to the section on composition (i.e. Section 3.1.1) more clarity about the nature of the product is provided.

60. A proposal to further amend Section 2.1.1 to distinguish the product in question from other products used as drinks by this age group by the addition of a phrase “*which has been produced according to the compositional requirements laid down in this Standard*” was not agreed to. The Chairperson noted that it was self-evident that all requirements within the Standard, including the compositional requirements should be complied with.

61. Those delegations in favour of option 1 (acceptance of the text in square brackets “*which may contribute to the nutritional needs of young children*”), expressed the following views:

- dietary guidelines recommend the consumption of milk by children of all age groups; and therefore, nutritious milk should be made available. A clear definition was important to serve as information

⁶ REP20/NFSDU, Appendix IV, CX/NFSDU 21/42/ 5; CX/NFSDU 21/42/5 Add.1; CX/NFSDU 21/42/5 Add.2

to consumers as well as to emphasize to manufacturers that nutritious milk products should be made available;

- the product can contribute to the nutritional needs of young children when they make the transition to the family diet. A clear definition would help to clarify the meaning of the Standard.

62. Two Observers further noted that while their preference was for option 2, they were of the view that these products were not necessary and this should be reflected in the definition. Furthermore, in their view, the addition of nutrients was often used for the promotion of these products.

Conclusion

63. Noting the general support for option 2 and the willingness of those who originally supported option 1 to go along with option 2, CCNFSDU42 agreed to delete the text in square brackets.

Labelling: Section 9.1.2⁷

64. CCNFSDU recalled that CCNFSDU41 had agreed on the names as presented in Section 9.1.2 and the only matter for consideration was the question from CCFL on whether the term “product” was an omission.

65. The Chairperson noted that, in addition, a question had come up on the interpretation of the slash (/) in the name option i.e. Drink/Product for young children with added nutrients

66. The Codex Secretariat clarified that normally the use of a slash (/) between terms means “or” and that such terms could be used interchangeably thus giving different options. In order to avoid ambiguity, the Codex Secretariat proposed to remove the slash (/) and to refer to “*Drink for young children with added nutrients*” and “*Product for young children with added nutrients*”.

67. CCNFSDU42 therefore agreed to write out all the name options for purposes of clarity and to avoid ambiguity and in addition, agreed to include also an additional name option: “*product for young children*”, for consistency with the other name option “*product for young children with added nutrients*”. CCNFSDU also noted that if the name options provided were not deemed satisfactory by a country or region, any other more appropriate designation indicating the true nature of the product could be used as described in this provision.

68. In response to a proposal to include a statement that countries and regions can allow only one of the names to be used on their territory, it was clarified that the Standard should be read in conjunction with the *General Standard for the Labelling of Prepackaged Foods* (CXS 1-1985) and that Section 4.1.1.1 of CXS 1-1985 addressed this issue. CCNFSDU therefore did not take up this proposal.

Conclusion

69. CCNFSDU42 agreed to amend Section 9.1.2 as stated in para. 67, and as presented in Appendix III.

General Conclusion

70. CCNFSDU42 agreed:

- i. that all outstanding points had been addressed, and to hold the scope, description and labelling of Section B at Step 7 (Appendix III) until all other sections of the Standard were completed in order to advance the entire Standard to CAC for adoption; and
- ii. to inform CCFL of the decision on Section 9.1.2.

DRAFT SCOPE, DESCRIPTION AND LABELLING FOR FOLLOW-UP FORMULA FOR OLDER INFANTS (Agenda Item 4c)⁸

71. CCNSDU recalled that CCNFSDU41 had agreed on the text for the scope, description and labelling for follow-up formula for older infants and to hold it at Step 7, and to send the labelling provision in Section 9.6.5 to CCFL46 for endorsement. Noting that CCFL46 had endorsed the provision, and an editorial change

⁷ Labelling section has been renumbered as Section 8 (see Appendix III)

⁸ REP20/NFSDU, Appendix II

to Section 9.1.2 made in session, all issues related to this item were addressed and no further discussion was necessary.

Conclusion

72. CCNFSDU agreed to hold the scope, description and labelling provisions of Section A as amended at Step 7 (Appendix III) until all other sections of the Standard were complete in order to advance the entire Standard to CAC for adoption.

ESSENTIAL COMPOSITION REQUIREMENTS FOR FOLLOW-UP FORMULA FOR OLDER INFANTS AND DRINK/PRODUCT FOR YOUNG CHILDREN WITH ADDED NUTRIENTS OR DRINK FOR YOUNG CHILDREN (Agenda Item 4d)⁹

73. CCNFSDU recalled that the essential composition requirements for both Sections A and B had been agreed and were held at Step 7, but that two outstanding issues remained, namely, the nitrogen to protein conversion factor (NCF) that was addressed by the EWG led by New Zealand and co-chaired by France and Indonesia, and the reply from CCMAS on the availability of methods to measure sweetness of carbohydrate sources.

Nitrogen to protein conversion factors (Protein: Footnote 2): Sections A and B

74. New Zealand, as chair of the EWG, introduced the discussions in the EWG and its recommendations. She recalled that the EWG had been tasked to take into account the work and recommendations of The Joint FAO/WHO Expert Meetings on Nutrition (JEMNU): Nitrogen to protein conversion factors for soy-based and milk-based ingredients used in infant formula and follow-up formula (Report of the meeting of the expert panel, Geneva, Switzerland, 16 – 17 July 2019).
75. She informed CCNFSDU that the EWG had noted that the NCF for these products could not be considered in isolation from infant formula and that a change in NCF would have implications for the minimum and maximum protein levels and other composition requirements for the products covered by the Standard. Also prior to any consideration to change the NCF, a decision was needed on the primary aim of determining protein content, i.e. delivery of amino acid or of total protein. The recommendation of the EWG was to maintain the current NCF of 6.25.
76. The Chairperson noted that JEMNU had judged that the application of an NCF of 6.25 to a wide variety of proteins was inappropriate, but that it was important to note that a potential change of the NCF could have a major impact on the evaluation of the products in question as well as on product formulation and product labelling. Further questions needed to be addressed first, such as whether the recommended ranges of protein provided in the relevant Codex standards intended to ensure adequate deliver of amino acids or of total protein as raised by JEMNU. In addition, there were different degrees of certainty associated with the NCF for soy-based and milk-based ingredients proposed by JEMNU and as a risk management body, it was important for the Committee to consider what degree of certainty was needed for accepting a certain NCF.
77. She proposed that CCNFSDU consider endorsing the recommendation of the EWG.

Conclusion

78. Noting the recommendation of the EWG and implications as mentioned above in para. 75, CCNFSDU42:
- agreed to maintain the NCF of 6.25; and
 - noted that there was no immediate need to pursue the matter further and to try to find answers to some of the questions raised in relation to the most appropriate NCF.

Section B: Footnote 5 (Available Carbohydrates)

79. CCNFSDU recalled that at CCNFSDU41, the following compromise text was agreed *“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.”*

⁹ REP20/NFSDU, Appendix III (Parts A and B); CX/NFSDU 21/42/5

80. CCNFSDU41 had also agreed to ask CCMAS whether there were internationally validated methods to measure sweetness of carbohydrate sources for these products.
81. CCMAS41 had considered this question and had replied that there were no known validated methods to measure sweetness of carbohydrate sources and therefore no way to determine compliance for such a provision.
82. CCNFSDU was therefore requested to consider the implications of this reply from CCMAS.
83. New Zealand, as chair of the EWG, informed CCNFSDU that the need to limit the sweetness of products for young children had been discussed since CCNFSDU38 and there was clear agreement that it was important to limit the sweetness of these products. As a result, CCNFSDU had agreed to several provisions for carbohydrates: a maximum limit for available carbohydrates; that lactose should be the preferred carbohydrate for products based on milk protein; that a maximum limit of total mono- and disaccharides other than lactose was provided; and that sucrose and fructose should not be added.
84. She further explained that in previous discussions of the EWG, consideration was given to numerous options as to how and whether it was necessary to further limit the sweetness of products not based on milk protein and the enforceability of such a requirement.
85. She further noted that CCNFSDU41 had agreed to include the statement as mentioned in para. 79 above, and following the reply from CCMAS41, consideration should be given whether to retain the statement in footnote 5¹⁰ noting that there were other provisions already in place to limit the sweetness of products based on non-milk protein.
86. CCNFSDU42 was requested to consider the option of either: i) deleting the provision from footnote 5 or ii) retaining the provision in footnote 5, but to note in the report that there were currently no validated methods to measure sweetness of carbohydrate sources. CCNFSDU was reminded that the content of the provision itself was not for discussion.

Discussion

87. The following views were expressed in favour of retaining the footnote:
- it was important to limit additional sweet tasting ingredients in the product as taste preferences were strongly influenced during the life stage of the targeted age group and might lead to overweight, obesity and non-communicable diseases later in life. Even though there were no current validated methods, this could change in future;
 - CCMAS could be asked again on a validated method to assess relative sweetness of carbohydrate sources as compared to lactose in order to enforce the provision, as this provision concerns an ingredient; such methods are already available; Provisions on ingredients are also contained in Section 3.2.1.
 - the paired-comparison sensory test, ISO 5495, could be applied and would allow manufacturers to exclude carbohydrate sources (ingredients) that are sweeter than lactose;
 - that each country could decide to use their own method(s) for enforcement of the provision until an internationally validated method became available. This decision did not lie with CCMAS, but with CCNFSDU;
88. The following views were expressed in favour of deletion of the provision:
- there were already sufficient safeguards to limit the sweetness since the footnote limited mono- and disaccharides other than lactose to no more than 2.5g/100kcal and addition of fructose and sucrose was not allowed;
 - there were no validated methods and it would be difficult to apply the standard and adopt it into national standards or national legislation;

¹⁰ Renumbered as footnote 6 in Section B of Appendix III

- even if methods were available, they were not internationally validated and would not produce any reliability or reproducibility which was a requirement for methods of analysis in Codex and therefore from an enforceability point of view, it was not feasible to retain the provision;
- there were no known validated methods for evaluation of sweetness of finished products or ingredients that would apply to enforcement of the provision. Sensory methods were highly variable and subjective and would not meet the specific requirements for validating methods. Standards development organisations had already invested a great deal of research in this area.

89. The Observer from ISO, referring to CRD 6 (written jointly by AOAC, IDF and ISO), noted that there were no known validated methods to measure sweetness of carbohydrate sources in the product in question and to compare it to the sweetness of a product with lactose only and therefore there was no way to determine compliance for such a provision.
90. As there was no direct method, the idea proposed in CRD 22 by Switzerland would be to make a comparison of the sweetness between 2 ingredients (lactose and other carbohydrate sources), however the question to CCMAS was not raised like that.
91. The Observer also noted that there were some ISO methods to do a comparison (although the quoted method ISO 5495 may not be the most appropriate).
92. The Observer further clarified that it was possible to compare the sweetness of lactose with the sweetness of another carbohydrate source, but only if this carbohydrate source is alone, diluted in water. If this carbohydrate source is in a finished product (e.g. follow-up formula), the sweetness would be modified by the other ingredients and it would not be possible to measure it anymore nor to compare it to the sweetness of lactose.
93. Noting the reply from ISO that on an ingredient level there might be methods that could be used to measure sweetness of a given ingredient, the Chairperson proposed that the provision be retained and that at the next session, further consideration should be given to identifying appropriate methods for possible submission to CCMAS. She further noted that it was preferable, but not a requirement, that a method(s) should be endorsed by CCMAS and included in CXS 234-1999 so that a common method can be used to enforce the provision.
94. Those delegations in favour of the removal of the provision continued to support its deletion and questioned whether the proposal of the Chairperson would affect the advancement of the Standard.
95. The Codex Secretariat clarified that as also mentioned at CCNFSDU41 generally questions on methods of analysis should not prevent the progress of a Standard nor its adoption. The Codex Secretariat also clarified that although methods recommended by Codex normally refer to the finished product, they could also refer to ingredients.

Conclusion

96. CCNFSDU agreed to retain the provision and to consider appropriate methods for assessing conformity to the provision and possible endorsement by CCMAS at its next session.

Other matters

97. CCNFSDU noted that the structure and preamble were the other outstanding issues for consideration by the Committee and considered a proposal by New Zealand to prepare a discussion paper based on previous discussions and recommendations in the earlier EWG (2018) and the background information to support discussions on a preamble presented in CRD5 (2019) and CRD2 (2021) for consideration by CCNFSDU43.

Conclusion

98. CCNFSDU agreed to the offer by New Zealand to prepare a discussion paper on structure and preamble and to circulate the paper for comments through a CL well in advance of the next session. CCNFSDU also accepted New Zealand's offer to analyse the responses to the CL and provide a CRD to CCNFSDU43.

Conclusion

99. CCNFSDU agreed that:
- i. All matters related to this item had been addressed; and that the question of appropriate methods for assessing sweetness of carbohydrate sources in the footnote of the respective section associated with available carbohydrates of Section B would be considered by CCNFSDU43; and
 - ii. CCNFSDU43 would consider the preamble and structure of the Standard based on a discussion paper to be prepared by New Zealand.

DRAFT GUIDELINES FOR READY-TO-USE THERAPEUTIC FOODS (Agenda Item 5)¹¹

100. The Chairperson recalled that CCNFSDU41 agreed to forward the Guidelines for Ready-to-Use Therapeutic Foods (RUTF) to Step 5 for adoption by CAC43, and that the following issues remained unresolved i.e. the preamble, and the compositional requirements for the essential fatty acids and magnesium. Besides these issues, CCFL had also requested CCNFSDU to consider whether the *Guidelines for Use of Nutrition and Health Claims* (CXG 23-1997) were relevant to the labelling of RUTF as pointed out under Agenda item 2. She invited the Committee to consider the aforementioned issues with a view to submit the Guidelines to CAC for adoption at Step 8.
101. CCNFSDU noted that at its previous session, there was no electronic working group (EWG) established to do further work on guidelines for RUTF. Following the rescheduling of CCNFSDU42 in 2020, the previous EWG Chair and Co-Chair (South Africa and Uganda, respectively) undertook informal consultations with members and observers on outstanding issues as well as the comments submitted at Step 6.

Preamble

102. South Africa, speaking as the former EWG Chair, introduced CRD3 and explained that the Chair and Co-Chair of the EWG together with FAO, WHO and the Codex Secretariat had revised the preamble taking into account the previous decision of CCNFSDU41 to keep it simple, yet understandable and to cover the following important aspects: the basic composition of the product; target age group; that RUTF is a recommended option for dietary management of children aged 6 – 59 months with severe acute malnutrition (SAM) without medical complications; the latter concept recognizes that RUTF is one of the dietary management options thus allowing for the use of RUTF in conjunction with other local family foods.
103. In addition, the advice of CCEXEC75 on referencing WHO/WHA documents; and CCEXEC78 on references to other standards setting organisations was taken into account, it was therefore proposed to omit the footnote and refer to the actual text of the Joint Statement of WHO, WFP UNSCN¹² and UNICEF as this sets the framework for the guidelines on RUTF. This would ensure a minimum number of references that would require life-long monitoring.
104. Furthermore, CRD3 also recognized the inclusion of provisions related to the promotion of breastfeeding in Section 12.4 (labelling) of the draft guidelines on RUTF. It was also explained that RUTF is quoted as a food for special medical purposes (FSMP) in the general part of the guidelines and as such, the product is prohibited from being advertised.
105. The Chairperson clarified that the preamble sets the scene by providing the overall context of the Guidelines and does not specify any product requirements, which are found within the main body of the Guidelines.
106. The Codex Secretariat further clarified that the preamble should not address matters outside the scope of Codex and the Guidelines, and that discussion on the preamble should be guided by the *General Principles of the Codex Alimentarius* and in particular, drew the attention of the Committee to Section 3 of the Principles: *Nature of Codex Standards*: that stated that Codex standards and related texts were not a substitute for, or alternative to national legislation and as such, every country's laws and administrative procedures contain provisions with which it is essential to comply. Thus issues not addressed in the Guidelines were still subject to countries' laws and requirements.

¹¹ REP20/NFSDU, Appendix VI; CX/CCNFSDU 21/42/6.

¹² In 2020, the United Nations System Standing Committee on Nutrition (UNSCN) and the UN Network for SUN (UNN) merged to form a new entity, called UN Nutrition.

Discussion

107. CCNFSDU held a brief discussion and noted the following proposals/issues put forward by delegations that the preamble should clearly cover:
- RUTF is one of the options for the dietary management of children with uncomplicated SAM from 6-59 months without medical complications; and these are therapeutic products that should be used for a short period, before transitioning back to local foods. The efficacy of RUTF should be demonstrated by scientific evidence.
 - Use of local foods to address SAM should be promoted and should be the preferred option over the use of commercially manufactured RUTF. The use of RUTF should be in specific situations of food insecurity when local food production is insufficient or under emergency situations. If water supply is inadequate or inaccessible, water should also be provided to SAM children.
 - The use of RUTF should not undermine national nutrition programmes, for example continuation of breastfeeding; psychosocial support for recovery among others. As such, the product should neither be advertised/promoted nor be for direct retail sale.
 - The footnote referencing the WHO International Code of Marketing of Breast-milk Substitutes (1981) and the relevant WHA resolutions' especially on ending the inappropriate promotion of food for infants and young children should be retained. Similarly, reference to national nutritional policies should be included in the preamble.
 - Support for re-lactation.
108. CCNFSDU supported the revised and simplified preamble and agreed:
- To its further revision to clearly take into account concepts such as: the promotion of continuation of breastfeeding, transition to nutritious family food; psycho-social support for recovery; the use of locally based foods; RUTF is not for general retail sale.
 - To the proposal to omit the footnote and instead make direct reference to the actual text in the 2007 Joint Statement of WHO, WFP, UNSCN, and UNICEF which essentially sets the framework for the Guidelines on RUTF. This approach was considered consistent with the advice of CCEXEC75 and CCEXEC78.
 - That the concepts and technical information in other reference documents, previously stated in the footnote had already been incorporated into the text of the Guidelines and there was a need to keep the references to a minimum as advised by CCEXEC.

Conclusion

109. CCNFSDU agreed with a revised preamble as presented in Appendix II to this report.

Section 6.3 Lipids

110. CCNFSDU agreed to delete the sentences in square brackets noting that this information was already contained in the annex of the Guidelines.

Essential fatty acids (EFA)

111. The former EWG Chair informed the Committee that informal consultations that were undertaken to progress the discussions on the values for the draft provisions for essential fatty acids (i.e. n-3 and n-6 fatty acids), were not conclusive due to a limited number of responses received. However, from the consultations, a number of concerns were raised including: limited available scientific data on quality of raw materials; the need for product stability shelf-life tests due to change in formulation; and cost implications due to changes in the formulation. She mentioned that an analysis of the comments in reply to the Circular Letter (CL 2019/78-NFSDU) had also been undertaken, and the majority of the responses were in favour of retaining the values stated in the 2007 Joint Statement of WHO, WFP, UNSCN, and UNICEF. There was also a proposal that favoured the maximum value for n-6 fatty acids being set at 780 mg/100kcal, with the minimum value for n-3 fatty acids being set at 110 mg/100 kcal.

112. The Representative of WHO stated that WHO had commissioned a systematic review to assess if the provision of RUTF with fatty acid profiles that are different from specifications in the Joint Statement improve outcomes such as neurodevelopment in children aged 6 months or older recovering from severe wasting with a view to contribute to progressing the discussions on the EFA values, and highlighted the outcomes which indicated that: 1) adding DHA or using oleic acid to increase ALA and reduce LA content may confer some benefits to neurodevelopment, but the evidence is not strong enough to suggest that this change will have substantial benefits or harms, and 2) the evidence also does not allow for determination of definite amounts of ALA and LA in RUTF was based on.
113. The Representative further noted that the systematic review outcomes were those of the evidence review conducted based on the most recently available evidence to date, and not WHO recommendations as such. WHO was aware of some concerns expressed regarding the specifications of RUTF which are based on the 2007 Joint Statement and therefore, WHO was discussing about possibly undertaking WHO's internal guideline development process to review further the specifications of RUTF including EFA content, also taking into consideration of on-going WHO guideline development on PUFA intake. The Representative stated that WHO would inform the Committee when and as WHO recommendations became available so that the Committee could consider the updating of the values of the Guidelines as required.
114. An Observer highlighted the importance of n-6 and n-3 polyunsaturated fatty acids in cognitive recovery, and rapid growth that ensues during and after treatment in infants and children have been affected by severe wasting. The proposed maximum values of 1111 mg/100 kcal for n-6 fatty acids and the minimum values of 33 mg/100 kcal for n-3 fatty acids derived from the 2007 Joint Statement were not based on scientific evidence but rather on an expert review. Since 2007, there had been advances in science on RUTF and the most recent findings of a trial conducted in Malawi that demonstrated developmental improvement and cognitive benefits in children with SAM six months after treatment with an adjusted formula RUTF containing lower n-6 fatty acids, higher n-3 fatty acids and added DHA, when compared to children who received standard RUTF. Based on the outcome of this trial, the Observer recommended that CCNFSDU consider reducing the maximum values for n-6 fatty acids to 780 mg/100kcal or 800 mg/100kcal and increasing the minimum values of n-3 fatty acids to 110 mg /100 kcal to enable endogenous production of n-3- fatty acids which are important for the brain and the eye.
115. CCNFSDU noted the general support for the levels proposed by the Observer.
- Conclusion
116. CCNFSDU agreed to decrease the maximum value for n-6 fatty acids to 780 mg/100 kcal and increase the minimum value for n-3 fatty acids to 110 mg/100 kcal.
- Magnesium
117. The former EWG Chair, reported that in the informal discussions there was no consensus on both the minimum and maximum values for magnesium; however, from an analysis of the comments in reply to CL 2019/78-NFSDU, there seemed to be majority support for the retention of the current minimum and maximum values of 15 mg/100 kcal and 45 mg/100 kcal, respectively.
118. A delegation supported an increase of both the minimum and maximum values for magnesium to 30 mg/100 kcal and 90 mg/100 kcal respectively, noting that this corresponding increase would allow for a favourable ratio between calcium, phosphorous and magnesium and lead to better absorption of both calcium and phosphorous to support catch-up bone growth.
119. An Observer reiterated their concern expressed at CCNFSDU41 over the high ratio of calcium to magnesium as well as over the generally low minimum and maximum levels being set for magnesium, noting that extensive science supporting higher levels exists and had been previously submitted to the Committee.
- Conclusion
120. CCNFSDU42 agreed to maintain the proposed values of the minimum and maximum values for magnesium of 15 mg/100 kcal and 45 mg/100 kcal respectively.

Section 12- Labelling reference to Claims

121. CCNFSDU considered the recommendation from CCFL and agreed to include a statement in Section 12 to indicate that nutrition and health claims shall not be permitted for RUTF, rather than a reference to the *Guidelines for Use of Nutrition and Health Claims* (CXG 23-1997) to avoid any misinterpretation about the application of the provision. This prohibition would re-enforce that nutrition and health claims for foods for RUTF should not be allowed.

Others

122. The Representative of WHO stated that WHO had commissioned a systematic review to assess if the provision of RUTF with higher iron content compared with standard RUTF improves outcomes such as blood haemoglobin, and iron deficiency, and highlighted the outcomes which indicated that: 1) there is rationale to increase the content of iron in RUTF to prevent iron deficiency; and 2) the available evidence is not adequate to determine the optimal content of iron in RUTF.
123. An Observer expressed concern about increasing the content of iron in RUTF noting that the absorption and utilization of added iron in food products was rather low. The impact of the high content of iron are unclear especially on the microbiome of older infants and young children in regard to the immunological development and immunological capacity.
124. The Representative of WHO explained that when setting up the systematic reviews, one of the focus areas was to assess adverse effects of high iron levels in RUTF on children, but the studies used in the systematic review did not report on any of these outcomes. Future studies should look into adverse effects of iron dosages in RUTF.
125. CCNFSDU noted that all the remaining issues had been addressed and that there were no further comments on other parts of the Guidelines, CCNFSDU agreed to the entire text and noted that the Guidelines were therefore ready to be advanced to Step 8.

General Conclusion

126. CCNFSDU agreed to:
- i. forward the Guidelines for Ready-to-Use Therapeutic Foods to CAC45 for adoption at Step 8 (Appendix II); and
 - ii. inform CCFL on the proposed change to Section 12 Labelling in relation to the inclusion of a statement to indicate that nutrition and health claims shall not be permitted for RUTF.

GENERAL PRINCIPLES FOR THE ESTABLISHMENT OF NRVs-R FOR PERSONS AGED 6-36 MONTHS (Agenda Item 6)¹³

127. Ireland, as Chair of the EWG, and speaking also on behalf of the Co-Chairs, USA and Costa Rica, introduced the item and provided a summary of the work of the EWG as presented in CX/NFSDU 21/42/7.
128. The EWG Chair recalled that the development of the General Principles for the establishment of NRVs-R required the assessment of the most appropriate approach to derive NRVs-R for the age group of 6 to 36 months. This involved the analysis of dietary intake reference values (DIRVs) from FAO, WHO and the 6 RASBs for which the EWG had sought scientific advice to assist with this particular task as agreed to by CCNFSDU. To assist in this regard, FAO commissioned a review of derivation methods for DIRVS for older infants and young children. The EWG Chair briefly introduced the FAO final draft scientific report on the *Review of derivation methods for dietary intake reference values for older infants and young children* as available on the CCNFSDU42 meeting webpage and indicated that this would greatly assist the EWG in the further development of the General Principles and in particular the establishment of NRVs-R. She further noted that the report identified 25 nutrients for this age group, including sodium, and that the addition of this particular nutrient would need further consideration by CCNFSDU. As the report became available in July 2021, the EWG could not consider its findings, but the findings were considered by the Chairs of the EWG to develop the proposal for the General Principles in CX/NFSDU 21/42/7. The EWG Chair drew the

¹³ CX/NFSDU 21/42/7; CL 2021/56-NFSDU, CX/NFSDU 21/42/7-Add.1

attention of CCNFSDU to CRD12 which assessed comments submitted in reply to CL 2021/56-NFSDU and proposed revised General Principles for consideration by CCNFSDU.

129. The Chairperson, supported by the EWG Chair, advised to take CRD12 as the basis for discussion to aid progress in the EWG. CCNFSDU agreed with this recommendation and proceeded with the consideration of the General Principles as laid down in Appendix I to CRD12. The Chairperson clarified that comments submitted would be forwarded to the EWG for further consideration in reviewing the General Principles for this age group and that no specific changes would be made to the text at the Session.

General comments

130. A delegation noted that the Annex on *General Principles for the Establishment of NRVs for the General Population* in the *Guidelines on Nutrition Labelling* (CXG 2-1985) should be retained to the extent possible and only, when necessary, be adjusted to include specific requirements for other population groups such as persons aged 6-36 months.
131. This delegation supported the approach that NRVs-R should be based on DIRVs derived using the most rigorous scientific method available, however, the ranking of such methods should not only be based on scientific rigour but should consider other relevant factors such as data quality, strength of evidence as well as the most recent and independent review of the scientific evidence when deciding on the most suitable method for the derivation of NRVs-R. The current text seemed to place more weight on the scientific rigour as opposed to a combined consideration of this and other relevant factors that might determine the final selection of the most suitable DIRVs for the derivation of NRVs-R for this age group.
132. The delegation further noted that such ranking should not apply to FAO and WHO DIRVs, as FAO/WHO were the primary source of scientific advice to CCNFSDU and their values should be taken without comment. Only when there were no values or no recent values available from FAO and WHO, data and information from RASBs should be considered for the establishment of NRVs-R. This should be reflected in the General Principles.

Specific comments

Section 1 - Preamble

133. The Chairperson noted that the deletion of point 3 was proposed based on feedback received in reply to CL 2021/56-NFSDU as the purpose of the General Principles was to establish NRVs-R for nutrient declaration for labelling purposes only and not guiding the composition of certain Codex commodities for infants and young children.
134. As to the proposed text that “*governments may also consider whether to establish separate NRVs-R for labelling for specific segments of the age group from 6 to 36 months*”, a Delegation reiterated its previous comments on the need to keep consistency with the General Principles for the general population (see paragraph 130) where a similar provision provided flexibility for governments to derive values for sub-populations, in addition to a combined value for the whole age group, according to their needs and regulatory frameworks. The proposed text would thus allow such flexibility while keeping the title inclusive to the broader age group covered by these Principles (see also Section 3.2.1.2).
135. A delegation recalled that CCNFSDU had not yet decided on whether the NRVs-R would be derived for the entire age group only or whether a further breakdown of this category would be needed and that the statement might not be necessary. It was noted that this was already a specific group as opposed to the broader category of the general population where such breakdown might be needed (i.e. products targeted to specific population groups such as pregnant women) and thus the need to provide flexibility for government to identify segments within the general population group.
136. CCNFSDU noted that the proposal could be further considered by the EWG.

Section 2 - Definitions

137. The Chairperson noted that this section was drafted in such a way to complement the corresponding section in the General Principles for the general population and, in this regard, consideration could be given to include the definition for Adequate Intake (AI) in the General Principles for the general population as it could be relevant for both population groups.

138. A delegation noted it would be advisable to keep the General Principles for the general population unchanged since the General Principles for the general population and the values derived according to these principles for this population group were interrelated and had been already agreed. If any future review were undertaken, there would be scope to look into the General Principles and its values and at that point to adapt and revise them.
139. Another delegation noted that the definition for AI was only used in the table with the ranking of the derivation methods and questioned whether there was a need to have this level of detail in the General Principles. It was further noted that if provisions in Section 3 were simplified, this definition might not be required.

Section 3 – General Principles for the Establishment of NRVs-R

140. CCNFSDU noted the proposal to delete the chapeau and that this would be further considered by the EWG.

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

141. The Chairperson noted that the first two paragraphs had been aligned with the corresponding provisions in the General Principles for the general population and that a reference was added to “*persons aged 6 to 36 months*” in the last paragraph to improve clarity.

Section 3.2 – Appropriate Basis for the Establishment of NRVs-R

Sections 3.2.1 – Selection and Priority of Derivation of Methods for the Establishment of NRVs-R

142. The Chairperson invited the EWG Chair to provide background and rationale for the table in this Section.
143. The EWG Chair introduced Section 3.2.1 and confirmed that the proposed table provided a ranking of derivation methods to establish NRVs-R which were applicable to all values that might be available, i.e. FAO, WHO and the 6 RASBs, with the primary source being FAO and WHO followed by the RASBs.
144. The EWG Chair further explained that, based on the feedback in reply to CL 2021/56-NFSDU, there was general support for the proposed 3 ranking categories, and this was also consistent with the FAO scientific report. However, following concerns were expressed by respondents to the CL:
- The limited available time to consider the findings of the FAO Scientific Report taking into account how such findings related to the different nutrients. The EWG chair indicated that, when choosing the values for NRVs-R, each nutrient would be examined on a case-by-case basis, and this approach would provide time to consider the issues in the scientific report relevant to each nutrient.
 - The inclusion of the ranking of methods which were not included in the General Principles for the general population although the same methods were used to derive the NRVs-R for this population group. The EWG noted that such inclusion was necessary to establish NRVs-R for the population aged from 6 to 36 months in view of the limited scientific evidence available for this age group. There was more diversity and evidence in approaches used to establish DIRVs for this age group which required a more detailed categorization and ranking of derivation methods as described in the FAO scientific report.

145. The EWG Chair also indicated that the EWG Co-Chairs would work closely with FAO and WHO to avoid duplication of efforts in establishing NRVs-R for the population aged from 6 to 36 months considering the ongoing FAO/WHO review of nutrients requirements for this age group.
146. In addition, the EWG Chair noted that NRVs-R for many nutrients for this age group would be extrapolated down from older age groups (general population). She stressed the need to ensure that the values reflected relative differences in nutrient requirements to keep consistency between the two population group (i.e. general population and persons aged from 6 to 36 months) and that the FAO scientific report would assist in this endeavour.
147. The EWG Chair therefore supported the inclusion of the table at this stage as providing relevant guidance for the establishment the NRVs-R for persons aged from 6 to 36 months; that the basis for the selection of NRVs-R should be scientific rigour with the aim to identify the most suitable method from the ranked methods; and that the concerns expressed above could be further addressed in the EWG in the further development of the General Principles.

148. CCNFSDU noted the following comments with regard to this Section:
149. A delegation reiterated its view that the relevant DIRVs provided by FAO/WHO that were based on a recent review of the science should be taken into account as primary sources to establish NRVs-R. She further stated that relevant DIRVs reflecting independent recent review of the science from RASBs could also be taken into account but only when such data were not available from the parent organizations as the body providing global DIRVs that should not be ranked against national or regional values which was consistent with the Section 3.1 and the principles for the general population. This delegation further noted that CCNFSDU should not decide whether FAO or WHO DIRVs had less scientific rigour than those from national or regional RASBs and Section 3.2 should be amended accordingly to reflect that the selection and priority of derivation methods for the establishment of NRVs-R should only apply to values available from RASBs. This view was supported by an Observer who further proposed that wording should also be inserted in Section 3.2.1.1 regarding ensuring no conflict of interest.
150. Following on this intervention, the EWG Co-Chair indicated that the FAO/WHO values might not be the most recent ones to establish NRVs-R for the population group aged from 6 to 36 months and that FAO/WHO was undertaking an evidence-based review of their DIRVs to update them which would take some time to complete. He further noted that there were DIRVs based on a more recent assessment of the scientific evidence available from the RASBs and therefore, it might be necessary to apply the same scientific rigour to both FAO/WHO and RASBs datasets to determine the most suitable values that could be taken by CCNFSDU to derive the NRVs-R for this age group. Having this set of principles would thus allow CCNFSDU to set science-based reference values until updated DIRVs become available from FAO/WHO which was critical for CCNFSDU to provide timely guidance to Codex members.
151. Based on the explanation provided by the EWG Co-chair, other delegations indicated that Section 3.2.1 should be clarified to match the concept in Section 3.1 i.e. that the ranking method was based on scientific rigour and was used only where there was no recent DIRVs from the WHO/FAO so that CCNFSDU could default to the recommendation in Section 3.2.1 when considering the establishment of NRVs-R for the population aged from 6 to 36 months. It was further noted that to this aim, the word “recent” was instrumental in delivering this concept.
152. The Representative of WHO noted that the ranking could be misleading as it might be difficult to determine in practice whether the DIRVs had been derived according to one of the 3 ranking categories defined in the tables. Moreover, in some cases, they might have been derived through combined methods currently ranked in different order of defined proposed scientific rigour. Although the intended aim of the proposed ranking was understood, it would be better not to be described as ranking as the selection of the most appropriate data would vary depending on various elements and conditions of the nature of each nutrient of concern..
153. The EWG Chairs confirmed that the situation varied for the different nutrients and that there would be instances where more than one method could apply to the DIRVs available for these nutrients. However, guidance on methods as shown in the table were needed in order to proceed with work on establishing NRVs-R for persons aged from 6 to 36 months. They further drew the attention of CCNFSDU to Section 3.2.1.1 where additional elements were included to complement the selection of the most suitable method besides the scientific rigour. They emphasized that the ranking of the methods was an attempt to ranking the quality of the data and total science in terms of evidence that would be considered stronger vs evidence that would be considered less strong and stressed the need to work collaboratively with FAO/WHO when addressing nutrients and DIRVs to establish NRVs-R for this age group.

Section 3.2.1.1

154. A delegation while supporting the assessment of the scientific rigour as outlined in Section 3.2.1, noted that other elements such as data quality, strength of the evidence and recent independent review of the science should also be considered on a case-by-case basis when deciding on the most suitable DIRVs for the establishment of NRVs-R by CCNFSDU. This proposal received support from members and observers including FAO and WHO.
155. Based on the above support another paragraph was proposed to for inclusion to this section for further consideration by the EWG:

“The NRVs-R should be reviewed on a case-by-case basis. They should be based on evidence derived using Rank 1, 2, or 3 methods, preferably in that order. Equally important as the ranking are the underlying data quality, strength of evidence and being based on a more recent independent review of science which may be taken into account when deriving NRVs-R.”

156. The Chairperson noted that Section 3.2.1 should be revised to clarify that in the absence of recent FAO/WHO DIRVs the selection and prioritization of derivation methods to establish NRVs-R only applies to values available from RASBs. For selecting the most rigorous scientific method that support DIRVs for the setting of NRVs, it might be useful to keep the ranking approach of such methods and to also consider with the additional elements identified in Section 3.2.1.1.

Section 3.2.1.2

157. The Chairperson noted support for the deletion of this section.
158. A delegation re-emphasized the need to consider NRVs for age subgroups on top of the whole age group, and therefore the principles should allow the establishment of NRVs to address either or both situations in recognition of the different policies and regulations in Codex member countries. A statement should be included to clarify that NRVs-R for persons aged 6 – 36 months can be derived by combining data from different sources, differently ranked methods, different underlying data quality, from different strength of evidence and based on various recent independent reviews of the science.
159. The Chairperson noted that the approach for the establishment of NRVs-R for the age group of 6 to 36 months, e.g. either to establish three sets of values or a single set of combined values, could be further discussed in the EWG to enable CCFSDU to make a decision on this at a later stage.

Section 3.2.2 – Selection and Priority of Derivation Methods for the Establishment of NRVs-NCD

160. The Chairperson noted support for the deletion of this section consistent with the project document and the terms of reference for this work.

Section 3.3 – Consideration of Upper Levels of Intake

161. A delegation noted that the provision still needed alignment with the General Principles for the general population and that in order to be consistent with Section 3.1 under which FAO and WHO are the primary sources for the establishment of NRVs-R by CCFSDU, the word “other” be deleted so that the parent organizations clearly stood apart from RASBs.

Other matters

Structure of the General Principles for establishing nutrient reference values for persons aged 6 to 36 months

162. The Chairperson drew the attention of CCFSDU to the proposal in CRD12 which tried to find compromise between those Codex members supporting the approach to integrate the General Principles into the principles for the general population and those supporting a separate annex in the *Guidelines on Nutrition Labelling*.
163. The Chairperson noted general support for this proposal.
164. A delegation proposed that Section B should be followed by a title “draft general principles for establishing nutrient reference values for persons aged 6 to 36 months”.

List of nutrients - inclusion of sodium in the list of nutrients for the establishments of NRVs and the type of NRV for sodium

165. The Chairperson recalled that CCFSDU had already agreed the list of nutrients including 13 vitamins (Vitamins A, D, C, K and E, thiamine, riboflavin, niacin, vitamins B6 and B12, folate, pantothenic acid and biotin); 10 minerals (calcium, magnesium, iron, zinc, iodine, copper, selenium, manganese, phosphorus and potassium, and protein (but with low priority). She noted a proposal by the EWG Chair to include sodium in the list of nutrients to be covered in the ongoing work.
166. The EWG Chair informed CCFSDU that sodium was included in the FAO scientific review report as part of the scientific advice on DIRVs as an important mineral for nutrient declaration especially for processed

foods and that limiting the sodium intake for the age group of 6-36 months was important . She however recognized that based on the list of nutrients agreed by CCFNSDU, sodium was not part of the mandate of the EWG.

167. The Chairperson advised that the scope of the project document agreed by the Commission was on the derivation of NRV-R for persons aged 6-36 months and that sodium could be addressed at a later stage and this could envisage considerations for the establishment of NRVs-NCD that were excluded from the current work on the General Principles for this age group. This proposal received support from the Committee.

Development of NRVs-R

168. CCFNSDU considered whether the EWG should already consider development of NRVs-R for certain vitamins and minerals. CCFNSDU noted concerns with proceeding with NRVs-R prior to agreement on the General Principles, however, the EWG chair explained that working on NRVs-R in tandem with the finalization of the Principles would help to understand the usefulness of the principles and guide its further elaboration.
169. CCFNSDU therefore agreed that the draft General Principles could be piloted for NRVs-R for certain nutrients.

Conclusion

170. CCFNSDU agreed to continue its work on NRVs-R for persons aged 6 – 36 months and to re-establish the EWG, chaired by Ireland, and co-chaired by Costa Rica and the United States of America, working in English and Spanish to:
- i. finalize the General Principles for establishing NRVs-R for persons aged 6 to 36 months including presenting the new structure for Annex 1 in CXG 2-1985, taking account of discussion at the session and any written comments submitted, for circulation for comments and consideration by CCFNSDU43; and
 - ii. pilot the draft General Principles on the following nutrients: vitamin B12, iodine, vitamin B6, riboflavin and, if time permits, thiamine, niacin and vitamin C.
171. CCFNSDU agreed to keep open the possibility of a Physical Working Group (PWG), chaired by Ireland and co-chaired by Costa Rica and the United States of America to meet prior to the next session to consider written comments submitted and prepare a revised proposal for consideration by CCFNSDU43.

OTHER BUSINESS AND FUTURE WORK (Agenda item 7)

Prioritization mechanism to better manage the work of CCFNSDU

172. The Chairperson recalled that the Host Secretariat had prepared an approach for a prioritization mechanism including possible criteria which had been discussed at CCFNSDU41. CCFNSDU41 agreed to the prioritization mechanism, to start using it on a pilot basis as well as to adjust the framework for the prioritization system as necessary and to conduct a case-by-case review of the proposals submitted by Members in response to CL 2020/30-NFSDU.
173. CCFNSDU considered the proposal to establish an EWG to continue developing a framework for the prioritization mechanism and its application to the proposals for new work.

Conclusion

174. CCFNSDU agreed to establish an EWG chaired by Germany and co-chaired by Canada, working in English, with the following terms of reference:
- revise the draft guideline for the preliminary assessment and identification of work priorities for CCFNSDU (REP20/NFSDU Appendix IX) as well as the proposed criteria taking into account the written comments received by the CCFNSDU Secretariat (Germany) as well as the comments and decision made at CCFNSDU41 for the development of a long term work prioritization mechanism; and
 - prepare a revised proposed prioritization mechanism for use on a trial basis for consideration by

CCNFSDU43.

175. CCNFSDU42 further agreed to:

- request the Codex Secretariat to extend the deadline of the Circular Letter, CL 2020/30-NFSDU, requesting proposals for new work and emerging issues. All new work proposals already received would remain valid and would not need to be re-submitted.
- reserve the possibility of holding a PWG chaired by Germany and co-chaired by Canada, to meet immediately prior to CCNFSDU43 and conduct a case-by-case review of the emerging issues and proposals for new work submitted by members in response to the Circular Letter.

DATE AND PLACE OF THE NEXT SESSION (Agenda item 8)

176. CCNFSDU42 was informed that its 43rd Session was tentatively scheduled to take place within the next 12-18 months, with the location to be confirmed and the final arrangements being subject to confirmation by the Host Country in consultation with the Codex Secretariat.

APPENDIX I

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APPENDIX II

DRAFT GUIDELINES FOR READY TO USE THERAPEUTIC FOODS (RUTF)

(For adoption at Step 8)

1. PREAMBLE

Children affected by severe acute malnutrition (SAM) need efficacious and timely intervention including safe, palatable foods with a high energy content and adequate amounts of vitamins, minerals and other nutrients within an appropriately designed programme that promotes continuation of breastfeeding, appropriate transition to nutritious family food and psycho-social support for recovery. In accordance with the Joint Statement by the World Health Organization (WHO), the World Food Programme (WFP), the United Nations System Standing Committee on Nutrition (UNSCN) and the United Nations Children's Fund (UNICEF) (2007) and taking note of other relevant documents by WHO and FAO, Ready-to-Use Therapeutic Food (RUTF) is a WHO recommended option for the dietary management of children aged 6 to 59 months with SAM without medical complications. However, this does not preclude other dietary options including the use of locally based foods. RUTF is not for general retail sale.

2. PURPOSE OF THE GUIDELINES

To provide guidance on technical and nutritional aspects of the production of RUTF for children from the age of 6 to 59 months with severe acute malnutrition, including

- i. Nutritional Composition
- ii. Raw Materials and Ingredients
- iii. Good Manufacturing Practices
- iv. Microbiological and Chemical Contaminant Criteria
- v. Methods of Analysis and Sampling
- vi. Provisions for Packaging and Labelling

3. SCOPE

The provisions of these guidelines apply to RUTF for children aged 6 to 59 months with severe acute malnutrition. Ready-to-Use Supplementary Foods (RUSF), micronutrient supplements², processed cereal based foods³, formulated complementary foods for older infants and young children⁴, canned baby foods⁵ are not covered by these guidelines.

²*Guidelines for Vitamin and Mineral Food Supplements (CXG 55-2005)*

³*Standard for Processed Cereal-Based Foods for Infants and Young Children (CXS 74-1981)*

⁴*Guidelines on Formulated Complementary Foods for Older Infants and Young Children (CXG 8-1991)*

⁵*Standard for Canned Baby Foods (CXS 73-1981)*

4. DESCRIPTION

4.1 Ready-to-Use Therapeutic Foods (RUTF) are foods for special medical purposes and are high-energy and contain adequate protein and other essential nutrients for the dietary management of children from 6 to 59 months with severe acute malnutrition without medical complications with appetite. These foods should be soft or crushable and should be easy for children to eat without any prior preparation.

4.2 Severe Acute Malnutrition is defined by weight for height (or length) less than -3 Z-score of the median WHO growth standards, or by mid upper arm circumference (MUAC) <11.5 cm, or by the presence of bilateral oedema.

5. SUITABLE RAW MATERIALS AND INGREDIENTS

RUTF are made of ingredients embedded in a lipid-rich matrix e.g. paste or biscuit, resulting in an energy and nutrient-dense food. The following raw materials, many of which can be sourced locally, are suitable ingredients for the production of RUTF under the specified conditions given below. Any formulation of RUTF shall comply with Section 3 of the *Standard for the Labelling of and Claims for Foods for Special Medical Purposes* (CXS 180-1991) including the specification that their use should have been demonstrated, by scientific evidence, to be safe and beneficial in meeting the nutritional requirements of the persons for whom they are intended.

5.1 Basic Raw Materials and Ingredients

5.1.1 Milk and other Dairy Products

Milk and other dairy products used in the manufacturing of RUTF must comply with the *Standard for Milk Powders and Cream Powder* (CXS 207-1999) and the *Standard for Whey Powders* (CXS 289-1995), and other Codex milk and milk product standards as well as other guidelines and Codes of Practice recommended by Codex Alimentarius Commission, which are relevant to these products. Relevant codes of practice include the *Code of Hygienic Practice for Milk and Milk Products* (CXC 57-2004) and the *Code of Hygienic Practices for Low-Moisture Foods* (CXC 75-2015).

5.1.2 Legumes and Seeds

Legumes and seeds such as soybeans, lentils, chickpeas, cowpeas, beans, peanut, sesame and other types of legumes and seeds must comply with the relevant Codex Alimentarius texts when used in the manufacturing of RUTF.

Legumes and seeds must be appropriately processed to reduce, as much as possible, the anti-nutritional factors normally present, such as phytate, lectins (haemagglutinins), trypsin, chymotrypsin inhibitors and phytoestrogens.

Field beans or Faba beans (*Vicia faba* L) should not be used in the formulation of RUTF because of the danger of favism.

5.1.3 Fats and Oils

Fats and oils used in the manufacturing of RUTF must comply with the relevant Codex Alimentarius texts. Fats and oils are incorporated as technologically feasible for the purpose of achieving the energy density and providing essential fatty acids. Care must be taken to avoid oxidized fat which will adversely affect nutrition, flavour and shelf life.

Partially hydrogenated fats and oils should not be used in RUTF.

5.1.4 Cereals, Roots and Tubers and their derived Products

All milled cereals, roots and tubers and their derived products suitable for human consumption may be used provided that they are processed in such a way that the fibre content is reduced, when necessary, and that the effects of anti-nutritional factors such as phytates, tannins or other phenolic materials, lectins, trypsin, and chymotrypsin inhibitors which can lower the protein quality and digestibility, amino acid bioavailability and mineral absorption are removed or reduced, whilst retaining maximum nutrient value.

5.1.5 Vitamins and Minerals

Vitamin and mineral forms used must be soluble and easily absorbed by patients with SAM. Children with SAM have low or absent gastric acid which means that they should not be given inorganic salts of minerals that are insoluble or requiring an acid gastric environment for absorption, in order to avoid metabolic acidosis. It is important that RUTF should have a mineral composition that leads to a moderate excess of non-metabolizable buffer base. The non-metabolizable buffer base can be approximated by the formula: estimated absorbed millimoles (sodium + potassium + calcium + magnesium) - (phosphorus + chloride).

All added vitamins and minerals must be in accordance with the *Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children* (CXG 10-1979). Examples of mineral forms for RUTF formulation can be found in the *WHO Management of severe malnutrition: A manual for physicians and other senior health workers* (1999). The amount of vitamins and minerals added to achieve the target level must be adjusted based on the chemical form, interaction, and impaired absorption with other nutrients and non-nutrients and scientific evidence showing adequate stability and bioavailability in the finished product.

5.2 Other Ingredients

5.2.1 Carbohydrates

Carbohydrates are used to achieve energy requirements in balance with proteins and lipids. Plant starch, lactose, maltodextrin and sucrose are the preferred carbohydrates in RUTF. Free sugars should be limited and should not exceed 20% of total energy. Only precooked and/or gelatinized starches may be added. Glucose and fructose should not be used. Carbohydrates must adhere to the relevant Codex Alimentarius texts.

Honey should not be used in RUTF due to the risk of infant botulism from *Clostridium botulinum*.

5.2.2 Food Additives

Only the food additives listed in this Section (Table A: Food Additives in RUTF Formulation) 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 4.1 of these Guidelines. Other than by direct addition, an additive may be present in RUTF 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 additive is acceptable for use in the raw materials or other ingredients (including food additives) according to the *General Standard for Food Additives* (CXS 192-1995);
- The amount of the additive in the raw materials or other ingredients (including food additives) does not exceed the maximum use level specified in the *General Standard for Food Additives* (CXS 192-1995); and
- The food into which the additive is carried over does not contain the additive in greater quantity than would be introduced by the use of the raw materials or ingredients under proper technological conditions or good manufacturing practice, consistent with the provisions on carry-over in the Preamble of the *General Standard for Food Additives* (CXS 192-1995).

Table A: Food Additives in RUTF Formulation

Functional Class	Food Additive	International Numbering System (INS)	Maximum Use Level
Emulsifier	Mono- and di-glycerides of fatty acids	471	4000 mg/kg
	Citric and fatty acid esters of glycerol	472c	9000 mg/kg
	Lecithin	322(i)	5000 mg/kg
Antioxidant	Ascorbyl palmitate	304	10 mg/kg
	Tocopherol concentrate, mixed	307b	10 mg/kg
	Ascorbic acid, L-	300	GMP
Acidity regulator	Citric acid	330	GMP
Packaging gas	Nitrogen	941	GMP
	Carbon dioxide	290	GMP
Carrier	Silicon dioxide, amorphous	551	10 mg/kg

6. NUTRITIONAL COMPOSITION AND QUALITY FACTORS

The nutritional composition of RUTF shall comply with the requirements set out in the table in the Annex. Furthermore, the following requirements shall be complied with.

6.1 Energy

The energy density of the formulated RUTF should be between 5.2 - 5.5 kcal per gram. The energy density of RUTF can be achieved during manufacturing by the addition of energy containing ingredients (i.e. fats and oils and/or digestible carbohydrates) and/or processing the basic raw materials and ingredients as indicated in Section 8.

6.2 Proteins

Protein should provide 10% to 12% of the total energy.

Protein quality should be determined using Protein Digestibility Corrected Amino Acid Score (PDCAAS), calculated according to the reference amino acid requirement and scoring patterns related to catch-up growth of 10 g/kg per day in the target population for RUTF which is children with SAM aged 6 to 59 months.

For all RUTF formulations, the PDCAAS shall not be less than 0.9. The PDCAAS shall be calculated using appropriate digestibility values and the reference amino acid pattern as stipulated in the *Report of the FAO Expert Working Group: Protein quality assessment in follow-up formula for young children and ready to use therapeutic foods (2018)*.

High quality protein will be achieved with RUTF formulations containing a minimum of 50% of protein from milk products.

In formulations with lower PDCAAS scores, the quality and/or quantity of protein should be adjusted to achieve the desired value. The addition of limiting amino acids, solely in the L-form, shall be permitted only in amounts necessary to improve the protein quality of the RUTF.

6.3 Lipids

Lipids should provide 45% to 60% of the total energy.

6.4 Vitamins and Minerals

RUTF should contain the vitamins and minerals presented in the Annex: Nutritional Composition of RUTF. RUTF should comply with the minimum and maximum or guidance upper levels in the Annex.

6.5 Water Activity

RUTF is a low-moisture food with a water activity of 0.6 or below.

7. CONTAMINANTS

It is recommended that the products covered by the provisions of these guidelines and the ingredients used in such products comply with the *General Standard for Contaminants and Toxins in Food and Feed* (CXS 193-1995), Maximum Residue Limits (MRLs) and Risk Management Recommendations (RMRs) for Residues of Veterinary Drugs in Foods (CXM 2-2015) and Codex Maximum Residue Limits for Pesticides.

Further guidance is given by Codex Codes of practice and should be adhered to.

The product should not contain contaminants or other undesirable substances (e.g. biologically active substances, metal fragments) in amounts which may represent a risk to the health of children.

8. PROCESSING TECHNOLOGIES

Processing technologies used for RUTF and their ingredients shall be validated to prove that they do not alter the nutritional value of RUTF and that they allow the reduction of anti-nutritive factors. Milling or grinding, roasting, toasting are examples of processing technologies that can be used on ingredients.

Any technologies used should take into consideration the target group and any impact on the integrity of the nutrient content of the products. In addition to the practices described above, Good Hygiene Practices should be implemented for manufacturing of RUTF, according to the *General Principles of Food Hygiene* (CXC 1-1969) and *Code of Hygienic Practices for Low Moisture Foods* (CXC 75-2015) to avoid cross contamination during the storage of raw materials and the manufacturing process.

RUTF and/or their raw materials should be treated with a validated microbial reduction treatment in order to inactivate pathogens such as *Salmonella*, noting that some pathogens have increased heat resistance characteristics at reduced water activities in food matrices. Commonly used microbial reduction treatments that could be applied to RUTF and/or their raw materials include both thermal and non-thermal control measures.

For additional information on validation of control measures, refer to the *Guidelines for the Validation of Food Safety Control Measures* (CXG 69-2008). Additionally, refer to the *Principles and Guidelines for the Conduct of Microbiological Risk Management* (MRM) (CXG 63-2007).

9. GOOD MANUFACTURING PRACTICES AND GOOD HYGIENE PRACTICES

It is recommended that the products covered by the provisions of these guidelines be prepared and handled in accordance with the appropriate sections of the *General Principles of Food Hygiene* (CXC 1-1969), and *Code of Hygienic Practice for Low-Moisture Foods* (CXC 75-2015), and other relevant Codex texts.

The product 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).

The ingredients and final product should be prepared, packed and held under sanitary conditions and should comply with relevant Codex texts.

10. METHODS OF ANALYSIS AND SAMPLING

It is recommended that methods of analysis and sampling of RUTF be in accordance with the *Recommended Methods of Analysis and Sampling* (CXS 234-1999).

11. PACKAGING

It is recommended that RUTF be packaged in such a way to safeguard the hygienic and other qualities including nutritional properties of the food for the duration of its defined shelf-life.

The packaging materials shall be made only of substances which are safe and suitable for their intended uses. Where the Codex Alimentarius Commission has established a standard for any such substance used as packaging materials, that standard shall apply.

12. LABELLING

It is recommended that the labelling of RUTF for children from 6 to 59 months with SAM be in accordance with the *Standard for the Labelling of and Claims for Foods for Special Medical Purposes* (CXS 180-1991), the *General Standard for the Labelling of and Claims for Pre-packaged Foods for Special Dietary Uses* (CXS 146-1985), and the *Guidelines on Nutrition Labelling* (CXG 2-1985). Nutrition and health claims shall not be permitted for RUTF.

12.1 The Name of the Food

The name of the food to be declared on the label shall indicate that the food is a Ready-To-Use Therapeutic Food for Children from 6 to 59 months with SAM. The appropriate designation indicating the true nature of the food should be in accordance with national legislation. The age from which the product is recommended for use shall appear in close proximity to the name of the food.

12.2 List of Ingredients

The list of ingredients shall be declared in accordance with Section 4.2 of the *General Standard for the Labelling of Prepackaged Foods* (CXS 1-1985).

12.3 Additional Mandatory Labelling Requirements

Provisions of Section 4.4 and 4.5 of the *Standard for the Labelling of and Claims for Food for Special Medical Purposes* (CXS 180-1991) shall apply.

12.4 The following additional statements shall appear on the label of RUTF:

- The product is not to be used for Nasogastric Tube (NG tube) administration.
- The product should be used in conjunction with breastfeeding.
- Exclusive breastfeeding is recommended for the first 6 months of life, and continued breastfeeding is recommended for up to two years or beyond.

12.5 Instructions for use

- The label should indicate clearly from which age the product is recommended for use. This age shall not be less than six months for any product.
- Feeding instructions shall be given; preferably accompanied by graphical presentations.
- The time within which the product should be consumed after opening should be clearly indicated.

Table: Nutritional Composition of RUTF

Energy			
Unit	Minimum	Maximum	GUL
kcal/100 g	520	550	-
Protein			
Unit	Minimum	Maximum	GUL
g/100 kcal	2.5	3.0	-
Lipids			
Unit	Minimum	Maximum	GUL
g/100 kcal	5	7	-
n-6 Fatty acids			
Unit	Minimum	Maximum	GUL
mg/100 kcal	330	780	-
n-3 Fatty acids			
Unit	Minimum	Maximum	GUL
mg/100 kcal	110	280	-
Vitamin A			
Unit	Minimum	Maximum	GUL
² µg RE/100 kcal	145	308	-
² 1µg RE = 3.33 IU Vitamin A = 1 µg 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
³ µg/100 kcal	2.7	4.2	-
³ 1 µg calciferol = 40 IU vitamin D.			
Two forms of Vitamin D allowed in RUTF formulation are cholecalciferol (D3) and ergocalciferol (D2).			
Vitamin E			
Unit	Minimum	Maximum	GUL
⁴ mg α-TE /100 kcal	3.6	-	-
⁴ 1 mg α-tocopherol = 1 mg RRR-α-tocopherol (d-α-tocopherol)			
⁴ 1 mg RRR-α-tocopherol = 2.00 mg <i>all-rac</i> -α-tocopherol (dl- α-tocopherol)			
Vitamin K			
Unit	Minimum	Maximum	GUL
µg/100 kcal	2.7	6	-
Vitamin B1			
Unit	Minimum	Maximum	GUL
mg/100 kcal	0.09	-	-

Vitamin B2

Unit	Minimum	Maximum	GUL
mg/100 kcal	0.29	-	-

Vitamin C

Unit	Minimum	Maximum	GUL
mg/100 kcal	9	-	-

Vitamin B6

Unit	Minimum	Maximum	GUL
mg/100 kcal	0.11	-	-

Vitamin B12

Unit	Minimum	Maximum	GUL
µg/100 kcal	0.29	-	-

Folic Acid

Unit	Minimum	Maximum	GUL
⁵ µg/100 kcal	36	-	-

⁵ 1 µg of folic acid = 1.7 µg of Dietary Folate Equivalents (DFE)

Niacin

Unit	Minimum	Maximum	GUL
mg/100 kcal	0.91	-	-

Pantothenic Acid

Unit	Minimum	Maximum	GUL
mg/100 kcal	0.55	-	-

Biotin

Unit	Minimum	Maximum	GUL
µg/100 kcal	11	-	-

Minerals**Sodium**

Unit	Minimum	Maximum	GUL
mg/100 kcal	-	56	-

Potassium

Unit	Minimum	Maximum	GUL
mg/100 kcal	200	308	-

Calcium

Unit	Minimum	Maximum	GUL
mg/100 kcal	55	151	-

Phosphorus

Unit	Minimum	Maximum	GUL
mg/100 kcal	55	151	-

Magnesium

Unit	Minimum	Maximum	GUL
mg/100 kcal	15	45	-

Iron

Unit	Minimum	Maximum	GUL
mg/100 kcal	1.8	2.7	-

Zinc

Unit	Minimum	Maximum	GUL
mg/100 kcal	2	2.7	-

Copper

Unit	Minimum	Maximum	GUL
mg/100 kcal	0.25	0.35	-

Selenium

Unit	Minimum	Maximum	GUL
µg/100 kcal	3.6	8	-

Iodine

Unit	Minimum	Maximum	GUL
µg/100 kcal	13	27	-

APPENDIX III

REVIEW OF THE STANDARD FOR FOLLOW-UP FORMULA
(scope, description, essential composition and quality factors and labelling)

(Held at Step 7)

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) ¹⁾ 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	-

¹⁾ 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.

- 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

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 Section A, 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.

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.
- 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'.
 - 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'.
 - 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.

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 children¹.
- 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)², 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	-	-

¹ In some countries these products are regulated as breastmilk substitutes

² 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 μ g RE = 3.33 IU Vitamin A = 1 μ g 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
μ g ¹¹⁾ /100 kcal	1.5	4.5	-
μ g 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 Section B, 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.

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.

APPENDIX IV

REVIEW OF THE STANDARD FOR FOLLOW-UP FORMULA

(REMAINING SECTIONS HELD AT STEP 4 FOR ADVANCEMENT TO STEP 5/8 AS PART OF THE ENTIRE STANDARD)

SECTION A: FOLLOW-UP FORMULA FOR OLDER INFANTS

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 permitted¹⁾:

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		

¹⁾ 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.”

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	Limited by GMP
526	Calcium hydroxide	
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

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.

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

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:¹⁾

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

4.6 Flavourings ²⁾

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).

²⁾ 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.

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