CODEX ALIMENTARIUS COMMISSION

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Food and Agriculture Organization of the United Nations

World Health Organization

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REP18/NFSDU

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

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I. Report of the Thirty-Ninth Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses

II. Addendum to the Report of the Thirty-Ninth Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses

TABLE OF CONTENTS

Summary and Status of Work....page ii

List of Abbreviations ....page iii

Report of the Thirty-ninth Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses ....page 1

Paragraphs

Introduction 1

Opening of the Session ....2 - 3

Adoption of the Agenda (Agenda item 1) 4

Matters referred to the Committee by the Codex Alimentarius Commission and/or Other Subsidiary Bodies (Agenda item 2) ....5 - 7

Matters of interest arising from FAO and WHO (Agenda item 3)....8 - 15

Review of the *Standard for Follow-up Formula* (Agenda item 4) ....16 - 71

Proposed draft definition for biofortification (Agenda item 5) ....72 – 93

Proposed draft NRV-NCD for EPA and DHA (Agenda item 6) ....94 – 104

Proposed draft guideline for ready-to-use therapeutic foods (Agenda item 7) ....105 – 129

NRV-R for older infants and young children (Agenda item 8)....130 – 132

Food additives – mechanism / framework for considering technological justification and other matters (Agenda item 9)....133 – 144

Discussion paper on claim for “free” of trans fatty acids (Agenda item 10)....145 - 150

Other business and future work (Agenda item 11) ....151 - 161

Date and place of next session (Agenda item 12) 162

Addendum ***page***

Addendum to the Report 20

Appendices

Appendix I - List of Participants 21

Appendix II – Proposed draft revised Standard for Follow-up Formula (CXS 156-1987) (essential composition)....51

Appendix III – Proposed draft revised Standard for Follow-up Formula (CXS 156-1987) (other sections)....59

Appendix IV – Proposed draft definition for biofortification 65

Appendix V – Proposed draft guidelines for ready-to-use therapeutic foods (RUTF)....66

Appendix VI – Proposed draft conditions for a “free” of trans fatty acids (TFA) claim 68

Appendix VII – Methods of analysis for provisions in the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CXS 72-1981)....69

SUMMARY AND STATUS OF WORK

Responsible Party	Purpose	Text/Topic	Code	Step	Para.
Members CCEXEC75 CAC41	Adoption	Review of the *Standard for Follow-up Formula*: Proposed draft Essential composition requirements for older infants and young children	CXS 156-1987	5	71 and App.II
Members CCNFSDU40	Comments	Proposed draft Claim for “free” of trans fatty acids	CXG 23 - 1997	3	150 and App. VI
CCMAS	Endorsement	Methods for biotin, vitamin D and chloride: infant formula	CXS 234 – 1999	-	152 and App. VII
Members CCNFSDU40	Discussion	Biological methods	CXS 234 – 1999	-	7
EWG (New Zealand, France, Indonesia) CCNFSDU40	Drafting	Review of the Standard for Follow up Formula: scope, product definition, labelling	CXS 156-1987	2/3	Para 71 and App. III
EWG (Zimbabwe and South Africa) CCNFSDU40	Redrafting	Proposed draft definition for biofortification	-	2/3	93 and App. IV
EWG (Russian Federation and Chile) CCNFSDU40	Redrafting	Proposed draft NRV-NCD for EPA and DHA	CXG 2 - 1985	2/3	104
EWG (South Africa, Senegal and Uganda) CCNFSDU40	Redrafting	Proposed draft guideline for ready-to-use therapeutic foods	-	2/3	129 and App. V
EWG (Ireland, Mexico, and United States of America) CCNFSDU40	Discussion	NRV-R for older infants and young children	-	-	132
EWG (European Union and the Russian Federation) CCNFSDU40	Redrafting	Mechanism / framework for considering the technological justification of food additives	-	-	144
Argentina CCNFSDU40	Discussion	Discussion paper on harmonized probiotic guidelines for use in foods and dietary supplements	-	-	156
CCNFSDU40	Discussion	General guidelines to establish nutritional profiles			161

LIST OF ABBREVIATIONS

ARA	Arachidonic acid
CAC	Codex Alimentarius Commission
CCEXEC	Executive Committee of the Codex Alimentarius Commission
CCFA	Codex Committee on Food Additives
CCFL	Codex Committee on Food Labelling
CCMAS	Codex Committee on Methods of Analysis and Sampling
CCNFSDU	Codex Committee on Nutrition and Foods for Special Dietary Uses
CRD	Conference Room Document
DHA	Docosahexaenoic acid
EFSA	European Food Safety Authority
Elena	WHO e-Library of Evidence for Nutrition Actions
EPA	Eicosapentaenoic acid
EU	European Union
EWG	Electronic Working Group
FAO	Food and Agriculture Organization of the United Nations
FOPL	Front of pack nutrition labelling
FUF	Follow-up formula
GIFT	FAO/WHO Global Individual Food Consumption Data Tool
GINA	WHO Global Database on the Implementation of Nutrition Action
GUL	Guidance upper level
GRADE	The Grading of recommendations assessment, development and evaluation
GSCTFF	General Standard for Contaminants and Toxins in Food and Feed
GSFA	General Standard for Food Additives
ISO	International Organization for Standardization
JECFA	Joint FAO/WHO Expert Committee on Food Additives
JEMNU	Joint FAO/WHO Expert Meetings on Nutrition
NUGAG	WHO Nutrition Guidance Expert Advisory Group
NCD	Non-communicable disease
NRV	Nutrient reference value
NRV-R	Nutrient reference values-requirements
PICO	Population, intervention/indicator, comparator, and outcomes
PUFA	Polyunsaturated fatty acids
PWG	Physical Working Group
RUTF	Ready-to-use therapeutic foods
SAM	Severe acute malnutrition
TFA	Trans fatty acid
UNICEF	The United Nations Children Fund
WHA	World Health Assembly
WHO	World Health Organization
WTO	World Trade Organization

INTRODUCTION

1. The thirty-ninth Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) was held in Berlin, Germany, from 4 to 8 December 2017 at the kind invitation of the Federal Government of Germany. Dr Pia Noble and Ms Marie-Luise Trebes, Former Head and Head of Division of Special Foods, Food Supplements, Food Additives, Federal Ministry of Food and Agriculture of Germany, served as Chair and vice-Chair of the Session, respectively. The Committee was attended by 66 member countries, one member organisation and 39 observer organisations. A list of participants is given in Appendix I.

OPENING OF THE SESSION

2. Dr Maria Flachsbarth, Parliamentary State Secretary, Federal Ministry of Food and Agriculture, speaking on behalf of Mr Christian Schmidt, Federal Minister of Food and Agriculture, opened the Session and welcomed delegates. She indicated that the large number of participants to the meeting demonstrated both the interest in the work in contributing towards realisation of the UN Decade of Action on Nutrition (2016-2025) and further stressed the importance of science-based Codex standards in consumer protection and food trade. Ms Mariam Eid, Vice-Chairperson of the Codex Alimentarius Commission, also addressed the meeting and emphasised the importance of consensus in decision making for several crucial agenda items at this meeting.

Division of competence[1]

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

ADOPTION OF THE AGENDA (Agenda item 1)[2]

4. The Committee adopted the Agenda with the following additions under agenda item 11 - Other business:

   i. General guidelines to establish nutritional profiles (Costa Rica and Paraguay);

   ii. Methods of analysis in the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CXS 72-1981) (the United States of America); and

   iii. Harmonised probiotic guidelines for use in foods and dietary supplements (International Probiotics Association).

Matters Referred to the Committee by the Codex Alimentarius Commission and/or Other Subsidiary Bodies (Agenda item 2)[3]

5. The Committee noted that some matters were for information only, and that several matters would be considered under other relevant agenda items, and took the following decisions:

Method for Chromium, molybdenum and selenium: Infant formula

6. The Committee; noted the request of the Committee on Methods of Analysis and Sampling (CCMAS) concerning the possible retyping of the method for chromium, molybdenum and selenium provided validation data is submitted; and encouraged members to submit such validation data to CCMAS.

Criteria for endorsement of biological methods used to detect chemicals of concern

7. The Committee agreed to defer the discussion on this matter to its next session.

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

[2] CX/NFSDU 17/39/1; CRD3 (Comments of IPA); CRD4 (Costa Rica, Paraguay); CRD14 (the United States of America); CRD21 (ISDI)

[3] CX/NFSDU 17/39/2, CRD4 (Costa Rica, Paraguay)

MATTERS OF INTEREST ARISING FROM FAO AND WHO (Agenda item 3)[4]

8. The Representative of FAO called the attention of the Committee to various activities of FAO of interest to CCNFSDU: (1) FAO Expert Working Group on protein quality assessment in follow-up formula for young children and Ready to Use Therapeutic Foods, that was held in Rome from 6 to 9 November 2017; (2) FAO/WHO Global Individual Food Consumption Data Tool (GIFT), which provides simple and accurate food-based indicators, derived from sex and age disaggregated data on individual food consumption; (3) UN Decade of Action on Nutrition 2016 – 2025, under which the Milan Global Nutrition Summit has taken place on 4 November 2017; and (4) the International Symposium on Sustainable Food Systems for Healthy Diets and Improved Nutrition organised jointly by FAO and WHO in December 2016 and the Regional Symposia on the same theme organised in 2017 to further anchor the discussion around the actual challenges of each region.

9. The Representative of WHO highlighted some of the activities of relevance to the ongoing work of the Committee. With reference to the UN Decade of Action on Nutrition, the Representative provided additional information which included: launching of Member States' SMART commitment repository linked to WHO Global Database on the Implementation of Nutrition Action (GINA), establishment of Action Networks such as Global Action Network on Sustainable Food from the Ocean for Food Security and Nutrition led by Norway, Global Action Network on Nutrition Labelling led by France, Regional Action Network on enabling food environment led by Chile, Regional Action Network on childhood obesity led by the Pacific countries and Regional Action Network on school food procurement led by Thailand. She also called the attention of the Committee to the new World Health Assembly (WHA) resolution and decision – one being WHA70.11[5] on updated Appendix 3 (which lists "best buys" and other recommended interventions to address Non-communicable diseases (NCDs)) of the NCD Action Plan 2013 – 2020 and the WHA70 (19)[6] on the implementation plan of the report of the Commission on Ending Childhood Obesity.

10. The Representative also provided updates: (i) on the work of the NUGAG Subgroup on Diet and Health, including planned launching of draft guidelines on saturated fatty acids and trans-fatty acids for public consultation; preparation of draft guidelines on non-sugar sweeteners, polyunsaturated fatty acids (including n-3, n-6 and total PUFA) and carbohydrates (starch and fibre); and ongoing evidence reviews on dietary patterns, as well as starting of the work of the NUGAG Subgroup on Policy Actions, including nutrition labelling policies, fiscal policies, trade and investment policies which affect diet and nutrition; and (ii) on WHO's work on nutrient profiling, including the adaptations of nutrient profile models for different applications such as regulating food and beverages in schools and nutrition labelling, and the planned development of a regional nutrient profile model for the African Region.

11. The Representative of WHO further informed the Committee of three additional activities which were not included in the document CX/NFSDU 17/39/3. They were: (i) preparation of the 13th General Programme of Work which contains 5 nutrition-related targets (reduction in stunting, reduction in wasting, no increase of overweight/obesity in children and adolescents, elimination of industrially produced trans fatty acids (TFA) and reduction in salt/sodium intake) and will guide WHO's work in 2019 – 2023; (ii) taking part in the implementation of the RESOLVE initiative which is a new global health initiative, aiming to save millions of lives by reducing preventable deaths from cardiovascular diseases (CVDs) through accelerating progress in improving treatments of high blood pressure, sodium reduction and elimination of industrially produced TFA; and (iii) updating of nutrient requirements for infants and young children (0 – 24 months) jointly with FAO.

12. The Delegation of France, supported by the United States of America and the EU, stated that the WHA "welcomed with appreciation", but did not approve or endorse the WHA resolution on the WHO Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children (WHA69.9) and therefore it was an error to state in CX/NFSDU 17/39/3 that WHA69.9 was approved by WHA. The Delegation of the United States of America further informed the Committee that it had dissociated from WHA Resolution 70.11 because the evidence underlying certain recommendations was not sufficient to support them.

[4] CX/NFSDU 17/39/3
[5] http://apps.who.int/gb/ebwha/pdf_files/WHA70/A70_R11-en.pdf
[6] http://apps.who.int/gb/ebwha/pdf_files/WHA70/A70(19)-en.pdf

13. In response, the Representative of WHO stated that there was no error as WHA69.9 was in fact approved by WHA. The Representative stated that resolutions and decisions of the WHO Governing Bodies (i.e. Executive Board, WHA) use various operative phrases to express their views regarding the substantive content contained in or annexed to the resolutions or decisions. After reviewing resolutions and decisions approved by WHA during the last 10 years, it was clearly noted that they do use various operative phrases and commonly used phrases are: *adopts, approves, endorses, welcomes*, *noted with appreciation and notes*. The Representative of the WHO reported that according to the WHO Department of Governing Bodies and External Relations, and Office of the Legal Counsel, it is possible to see these various phrases as lying on a spectrum expressing approval – with greater or somewhat less strength – on one side, and general recognition on the other and the terms "*welcomes*", "*welcomes with appreciation*" (which was the term used in WHA69.9) and "*notes with appreciation*" express approval as well, although somewhat less strongly. She highlighted that regardless of different operative phrases used by various resolutions and decisions, there is one thing which is common to all these resolutions and decisions and that is they are the resolutions and decisions of the WHA which is the highest Governing Body of WHO. The Representative noted that at WHA in May 2017, there were 2 Member States which had disassociated themselves from WHA70.11 on Appendix 3 of the NCD Action Plan (2013 – 2020) which lists "best buys" and other recommended interventions to address NCDs, but no Member State had disassociated from WHA69.9.

14. One Observer commented that conflict of interest safeguards are embedded in all WHO policies and recommendations, and are highly relevant for the standard-setting procedures of Codex.

15. Delegations noted that the document had been distributed late and requested that, in future, FAO and WHO should make available the document well in advance of the meeting to allow sufficient time to undertake thorough review and carry out consultations with their experts. A delegation, while noting the usefulness of the information, requested that the document should focus on joint work of FAO and WHO that can benefit the work of the Committee.

REVIEW OF THE STANDARD FOR FOLLOW-UP FORMULA (CXS 156-1987) (Agenda item 4)[7]

16. The Chair of the electronic working group (EWG) New Zealand, introduced the item and briefly outlined the work undertaken.

17. The Committee agreed to focus discussion first on the essential composition of follow-up formula for older infants and for the "product" for young children before discussing the labelling, the name of the product, product definition, scope and preamble, noting the proposal of one observer that the preamble should be considered before other sections due to its importance.

General

18. An observer expressed the view that since the market growth of these products is strongest in developing countries, it is essential for these countries to assess the risks, safety and appropriateness of these products as a whole, in the local context, before allowing imports.

Essential Composition of Follow-up Formula for older infants (6-12 months)

19. The Chair of the EWG recalled that for follow-up formula for older infants aged 6-12 months the essential compositional requirements for protein and Docosahexaenoic acid (DHA) needed to be finalised.

20. The Committee considered the recommendations of the EWG, and made the following decisions and comments.

Protein

21. The chair of the EWG recalled that CCNFSDU38 had agreed to postpone decision on a minimum protein level in order to take into account the European Food Safety Authority (EFSA) opinion. She noted that while EFSA proposed a minimum protein level of 1.6 g / 100kcal, it was recognised that this was not a global value.

[7] CX/NFSDU 17/39/4 Rev1; CX/NFSDU 17/39/4-Add.1 (Comments of Argentina, Brazil, Colombia, Ecuador, India, Japan, Nepal, New Zealand, Russia, Senegal, Switzerland, USA, EU speciality food ingredients, GOED, HKI, IACFO, IBFAN, IDF, IFT, ISDI, UNICEF); CX/FH 17/39/5-Add.2 (Australia, Canada, Kenya, Malaysia, Norway, Philippines, Tanzania, Thailand, EFLA, ICGMA, ISDI); CRD5 (Discussion paper by USA and Canada); CRD7 (Costa Rica, El Salvador, EU, Kyrgyzstan, Morocco, Nigeria, Sierra Leone, Sri Lanka, African Union, EU Specialty Food Ingredients); CRD17 (Indonesia); CRD19 (Republic of Korea); CRD24 (EUVEPRO); CRD25 (Mali); CRD26 (Mexico); CRD28 (El Salvador)

Discussion

22. Delegations, in particular those from developing countries, expressed a preference for a higher value (of protein level) of 1.8 g / 100 kcal, noting that the high incidence of protein and energy malnutrition occurred during the weaning period and that intake of high quality protein was necessary; and other complementary foods in their region were often from sources with low protein content or quality and would therefore not provide sufficient levels of protein. These delegations were also of the view this would avoid countries having to carry out or to assess clinical trials in order to establish a higher protein level as stated in the associated footnote 6; this would be of particular difficulty for many countries. It was noted that 1.6 g/100 kcal was not a global recommendation as it had been evaluated for the European infant population only.

23. Those in favour of the protein level of 1.6 g / 100 kcal noted that the associated footnote would state that below protein level of 1.8 g / 100 kcal, the follow-up formula needed to be evaluated. It was further noted that competent authorities were not responsible for clinical trials, but the assessment or evaluation thereof.

24. Many delegations further noted that:

    a) all follow-up formula based on hydrolysed protein should be evaluated, and not only those containing less than 2.25 g of protein / 100 kcal; and

    b) those products with protein levels falling between 1.6 g / 100 kcal and 1.8 g / 100 kcal should be evaluated for their safety and suitability and assessed based on clinical evidence.

Conclusion

25. The Committee agreed with a minimum protein value (level) of 1.8 g/ 100 kcal and an amended associated footnote 6.

Docosahexaenoic acid (DHA)

26. The chair of the EWG noted that DHA was agreed as an optional ingredient, but that some EWG members were of the view that it was necessary to ensure that when DHA is added, the levels should be effective. She further noted that there was a reference to arachidonic acid (ARA) in the associated footnote, and that although matching levels are critical for younger infants this may not be the case for older infants and young children due to the diversified diet of these age groups. The associated footnote was consistent with the footnote in the infant formula standard, but could be modified to suit the purpose of the product for older infants.

Discussion

27. A delegation expressed a preference for DHA to be mandatory, while another delegation was of the opinion that DHA was not needed at all as there was no substantial scientific basis for this optional ingredient. An observer noted that the voluntary addition of DHA could open up the possibility of claims which could create the impression that follow-up formula is needed to provide DHA, and noted that in her view there had been problems of acceptability of some infants and that all ingredients should be safe.

28. There was support for the Guidance Upper Limit (GUL) of 30 mg / 100 kcal, but proposals were made to raise the minimum level covered in the associated footnote to 20 mg /100 kcal, noting that follow-up formula was part of an increasingly diversified diet, with most complementary foods providing no or only very little DHA, and a minimum of 20 mg / 100 kcal would get close to the intake considered adequate by WHO (10 – 12 mg / kg body weight for the age group 6 – 24 months).

29. An observer expressed concern with the minimum level as the range between the GUL and minimum level was narrow and this would be difficult for manufacturers to achieve; and further questioned the link between DHA and ARA as there was no sufficient evidence to support this.

Conclusion

30. The Committee agreed with the GUL of 30 mg / 100 kcal and a minimum of 20 mg / 100 kcal and noted the reservation of Colombia to the decision on the minimum DHA level as in their view, there was sufficient evidence that 16 mg / 100 kcal was sufficient to achieve health benefits.

Other matters

JEMNU request for the establishment of nitrogen to protein conversion factors for soy and milk proteins

31. The Committee considered the proposal for scientific advice from JEMNU, prepared by Canada and the United States of America (CRD5), noting its previous discussion at CCNFSDU37 on the appropriateness of 5.71 as the nitrogen to protein conversion factor for soy protein and the recommendation of CCMAS that FAO and WHO could convene an expert panel to assess the scientific basis for nitrogen to protein conversion factors.

32. An observer proposed to not limit the work to soy-based and milk-based ingredients, however the Committee agreed to the proposal as presented.

Conclusion

33. The Committee agreed to the following request to JEMNU:

1. When determining the protein content of soy-based ingredients[1] used in infant formula and follow-up formula, what is the appropriate science-based nitrogen to protein conversion factor to use when comparing protein content derived from nitrogen based methods to amino acid based methods?
2. When determining the protein content of milk-based ingredients[1] used in infant formula and follow-up formula, what is the appropriate science-based nitrogen to protein conversion factor to use when comparing protein content derived from nitrogen based methods to amino acid based methods?

P – Soy-based or milk-based ingredients for infant formula and follow-up formula

I – Determining the protein content from nitrogen content using a conversion factor (of milk-based and soy-based ingredients)

C – Nitrogen based methods for deriving protein content compared to amino acid based methods

O – Determination of science-based nitrogen to protein conversion factor(s) for soy-based and milk-based ingredients.

1. A list of ingredients is being compiled which will be included with the PICO questions.

The essential composition of [name of the product] for young children (12-36 months)

34. The Chair of the EWG recalled that outstanding requirements for the essential composition of product for young children (12-36 months) included: i) minimum total fat level; ii) maximum available carbohydrates and associated sugar specifications in footnote 4; iii) whether a calcium-to-phosphorous ratio should be established; and iv) vitamin D minimum and maximum levels.

35. The Committee agreed that no calcium to phosphorous ratio was needed, and took the following decisions on minimum total fat, maximum available carbohydrates and vitamin D minimum and maximum levels.

Minimum total fat

36. Those in favour of a higher minimum total fat level of 4 g / 100 kcal expressed the opinion that this level would contribute to about 30% of energy from fat; and fat was an important contributor to child growth and development in the first three years of age.

37. Those in favour of a minimum total fat of 3.5 g / 100 kcal were of the opinion that:

- this level was in line with public health advice to lower fat intake by young children
- the level was consistent with low fat milk recommended as part of a diet for this age group; and
- there was a problem with overweight, therefore the need for the lowest minimum level of fat.

38. An observer pointed out that a minimum total fat of 4 g / 100 kcal would result in a 36% of energy intake from fat. Another observer clarified that 28 – 29% of energy should come from fat and the product was part of a diversified diet.

39. It was also pointed out that all macronutrient options should be considered together and add up to 100% of needed kcal, i.e. the ranges of total fat, protein and maximum carbohydrates.

Maximum level for available carbohydrates

40. Those in favour of 12.5 g / 100 kcal (of available carbohydrates) expressed the following views:

- that this level was closer to that of breastmilk and cow's milk;
- that the level was within the recommended range for available carbohydrates and would contribute to about 50% of energy which was aligned with the recommendations on energy; and
- there was a need to limit the addition of sugars in order to avoid that young children consume products with too high sugar levels.

41. Those in favour of a higher maximum level of 14 g / 100 kcal (of available carbohydrates) expressed the following views:

    - that this was based on nutrient modelling;
    - was in line with international recommendations for nutrient range for young children; and
    - if taken with the agreed protein level, the proposed minimum total fat level, 14 g / 100 kcal, was appropriate to achieve 100kcal.

42. A delegation clarified that a product with 14 g / 100 kcal of available carbohydrate could result in a product with little protein and fat. Breastmilk had a high carbohydrate content, and this was the sole food for infants, whereas the product in question was part of a diversified diet with carbohydrates from other sources in the diet. Several observers noted that the carbohydrate content in breastmilk was different from that in these products.

43. In view of the discussion on the total available carbohydrate and fats, it was agreed to convene an in-session working group led by New Zealand to prepare further proposals for consideration.

44. The in-session working group proposed a minimum level of fat of 3.5 g / 100 kcal of fat (equivalent to 31.5% of energy), but could not conclude on the maximum level of available carbohydrate. It was noted that the product was considered a substitute for cow's milk, the level of 14 g /100 kcal of available carbohydrate was too high, but would provide greater flexibility.

45. In view of this, consideration was given to the lower level available carbohydrates of 12.5 g / 100 kcal with the addition of a footnote to clarify that a maximum level of available carbohydrate up to 14 g / 100 kcal may be permitted by competent national and/or regional authorities for a product with a protein level below 3 g / 100 kcal.

Footnote 4

46. The Committee; agreed that lactose should be the preferred carbohydrate in the product and the need to limit the amount of mono- and disaccharides to reduce sweet taste; but could not agree on a proposal that for products not based on milk protein, carbohydrate sources that have no contribution to the sweet taste should be preferred. The Committee also noted that no non-carbohydrate sweeteners were permitted in this products.

47. There was agreement that the percentage limit for sugars is converted to an absolute amount based on energy density.

48. Further proposals considered were to include: (i) a text to clarify that the content of mono- and disaccharides, other than lactose, should not exceed 2.5 g /100 kcal amounting to 20% of available carbohydrate; and (ii) that competent authorities may limit this level to 1.25 g / 100 kcal. The major discussion was on ensuring that when carbohydrates were added they were not added for the purpose of sweetening the product; and that the text should avoid making comparisons on sweetness as this would be difficult to implement and control due to a lack of internationally validated methods and it would be difficult to objectively measure sweetness. A delegation stated that the sensory profile could be measured in an objective way by ISO methods 3972 and 13299 and that in this context the sweetness level could be compared. Several observers expressed concern about the impact that sweet products have on the development of a child's taste palate.

Conclusion

49. The Committee agreed with a minimum level for fat of 3.5 g / 100 kcal and for a maximum level for available carbohydrates of 12.5 g / 100 kcal with the addition of a new footnote to indicate that for a product with a protein level below 3 g/ 100 kcal, a maximum level of available carbohydrate up to 14 g / 100 kcal may be permitted by national and/or regional competent authorities; and agreed to retain the amended footnote 4 in square brackets for further consideration.

Vitamin D

50. Some delegations supported the view for vitamin D to be an optional ingredient as increased levels of vitamin D could have toxic effects, especially in countries with high sunlight. However, some other delegations were of the opinion that vitamin D should be a mandatory ingredient.

51. Other delegations expressed support for the levels recommended by the EWG and noted that even in countries with high sunlight, vitamin D deficiency remained a problem. It was further noted that it was necessary to clarify which form of Vitamin D was referred to, either vitamin D2 or vitamin D3. While other delegations reiterated their position for lower levels of vitamin D, i.e. minimum of 1 µg / 100 kcal and maximum of 3 µg /100 kcal, noting that levels up to 4.5 µg /100kcal could result in unsafe levels of vitamin D being consumed; that the lower levels would safeguard breast feeding. A delegation pointed out that there was a wide margin of safety between the maximum level and the upper level of 62.5 µg per day of vitamin D for this age group set by the US Institute of Medicine.

52. Noting the different requirements for vitamin D in different parts of the world, a proposal was made to allow competent authorities to deviate from the conditions appropriate for the nutritional needs of their local population.

Conclusion

53. The Committee noted the diverse views on the appropriate levels for vitamin D and the need to clarify in the text that the form of vitamin D was vitamin D3, the Committee agreed to retain the proposal in square brackets for further consideration at CCNFSDU40.

Labelling section: older infants

54. The Committee agreed with the sections: list of ingredients which was amended by deletion of reference to "optional ingredients", declaration of nutritive value; and date marking and storage instructions which was aligned with the work on date marking finalised by Codex Committee on Food Labelling (CCFL); and made the following additional decisions or comments.

55. The Committee noted the diverse views on whether to include in the introductory text, explaining that the requirements included a prohibition on the use of nutrition and health claims, from the *Guidelines for use of nutrition and health claims* (CXG 23-1997). Those in favour of retaining the text noted that the proposed wording was consistent with the infant formula standard; and that it was necessary to reiterate and clarify that nutrition and health claims were not appropriate for older infants.

Conclusion

56. The Committee agreed to retain the last sentence of the introductory paragraph in square brackets for further consideration.

Section 9.1 name of product

57. The Committee agreed to sections 9.1.1, 9.1.2 and 9.1.3. Regarding 9.1.4, the Committee agreed to option 1, i.e. to split the provision 9.1.4 into two parts in order to clearly explain that the name of the food may also contain the reference to the source of protein. The proposal was further amended to indicate that in case of mixed source products, the source of both the animal and plant proteins should be indicated in the name of the product, with the main source being mentioned first. In addition, the Committee agreed to use the term "shall" in section 9.1.5 instead of "may".

Section 9.5 – Information for use

58. The Committee noted and discussed the following views on section 9.5.1:

- that the product should be prepared with potable water; and that potable was a broader term to ensure both chemical and microbiological safety;
- whether to maintain the current wording as it was aligned with the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CXS 72 – 1981); or to refer to clean water for which a definition existed; and
-
- to maintain the current wording stating that water could be rendered safe by previous boiling and to include guidance that the water should be not less than 70 °C before reconstitution in line with WHO/FAO guidelines on the preparation, storage and handling of powdered infant formula and the guidance in the *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (CXC 66-2008)*. This was especially important taking into account that the product was not sterile and could contain *Enterobacter* and *Salmonella*, amongst others.

59. It was agreed to retain the text "it is not to be used as a sole source of nutrition" in section 9.5.6.

Conclusion

60. The Committee agreed to insert reference to potable water and to maintain the text as proposed by the EWG.

Section 9.6 – Additional labelling requirements

61. The Committee considered the following points and views expressed:

- a proposal to insert in 9.6.1 c) an exception to introduce the product to infants under 6 months as there might be situations where the product could be introduced earlier under medical supervision. Delegations questioned this proposal noting that it would imply that the follow-up formula was meant to deal with special dietary needs for which it was not intended for. The Representative of WHO expressed concern over the ambiguity of the proposed wording, as it failed to qualify why and when exceptions are justified, thereby creating opportunities for inappropriate promotion of the product for use below 6 months of age. For infants below 6 months of age, who do not receive breastmilk for legitimate reasons, infant formula should be available up to, and where needed beyond, 6 months. Therefore WHO did not agree with the proposed wording.
- a question was also raised on why it was needed to refer to independent health workers, as all health workers were professionals and independent;
- the need to reference the International Code of Marketing of Breastmilk Substitutes and subsequent WHA resolutions, especially WHA69.9, in this section; and
- the need to finalise the preamble first, before the labelling provisions can be finalised.

Conclusion

62. The Committee agreed to retain the section in square brackets for further consideration.

Labelling for product for young children

63. Due to time constraints, the Committee did not discuss the proposals for the labelling of product for young children.

Preamble, scope, name of product and product definitions and structure: older infants and young children

64. The Committee did not take a decision on the definition for these two products, but agreed not to refer to the products as "*specially*" manufactured; and in the case of the definition for the product for young children to delete the last two sets of text in square brackets; and noted the following opinions:

- the name of the product should clearly state that the product for both older infants and young children was a breastmilk substitute;
- the product for young children should not be considered breastmilk substitutes as it was not intended to replace breastmilk and was not nutritionally adequate;
- the preference for other terms such as "formula for older infants" which would help to better define the product for older infants; and that consideration should be given to combining the standard for infant formula with that for older infants, and to have a separate standard for the product for young children;
- the term "follow-up" implied that one does follow up, which was not the case and consideration should therefore be given to naming the product "drink for older infants"; and
- the product for young children was meant to be used as part of a diversified diet, but the product for older infants could be part of the overall foods to meet nutritional requirements for this age group.

65. The Committee noted that consideration could be given to the structure of the standard as discussed at CCNFSDU38.

66. The Committee noted that it was premature to discuss the name of the product for young children and the scope, and agreed to hold a general exchange of views on the preamble to inform the ongoing work.

67. The Committee confirmed its decision to have a preamble to the standard. However, the chair noted that several fundamental questions needed to be answered first on whether to have specific references to WHA resolutions and WHO guidelines or whether to have a more general reference; that some of the WHA resolutions went beyond the mandate of Codex and therefore was inappropriate to reference them; and whether guidance from the CCEXEC or CAC might be needed before the wording of the preamble could be refined.

68. The Committee noted the following views made by delegations but did not take any decisions:

- That relevant WHA resolutions, such as WHA69.9, 55.25 and 39.28, and the International Code of Marketing of Breastmilk Substitutes, the Global Strategy for Infant and Young Child Feeding and the Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children should be explicitly mentioned either in the preamble or the scope and such references would give credibility to Codex standards;
- That inclusion of references to WHA resolutions could have implications under the World Trade Organization (WTO) and that decision on the preamble was premature in view of ongoing discussions in CAC on WHO and FAO policies in relation to Codex work;
- It was not the role of Codex to include references to WHO policies and some WHA resolutions that may go beyond the scope of the standard and the mandate of Codex, and such inclusion could set a risky precedent and could undermine the credibility of Codex standards;
- There was precedent in Codex to include WHA resolutions and WHO guidelines and it should be borne in mind that the preamble was an introductory part to the standard to set the context for the standard;
- Governments that had adopted the 1981 Code of Marketing of Breastmilk Substitutes were under obligation to promote breast feeding beyond 6 months and beyond, and reference to relevant WHO policies in this regard could serve as reminder to governments;
- Resolutions of WHA state that Codex should give full consideration to WHA resolutions; and
- It was premature to discuss the preamble and that such a discussion would be informed once there was more clarity on the structure of the standard.

69. The Secretariat clarified that CCEXEC73 had concluded its discussion on relations between FAO and WHO policies, strategies and guidelines and Codex work[8] and that the discussion at CAC was not on policy coherence, but was on matters arising from FAO and WHO: policy and related matters[9]. The aim was to inform members of the WHO and FAO policies and other related matters so that the work of FAO and WHO could be taken into account at national and other levels, including Codex.

70. The Committee further noted that it was premature to request advice from CCEXEC and that work should continue on the preamble, scope, product name and definitions in order to assess whether any further guidance was needed. The Committee also recalled that CCNFSDU38[10] had agreed that the reference to relevant WHO guidelines and WHA resolutions could either be included in a preamble to the standard or in the scope.

Conclusion

71. The Committee agreed to:

- forward the essential composition requirements for older infants and young children agreed at this and previous sessions to Step 5 for adoption by CAC41 (Appendix II);
- to keep in bracket the preamble for further discussion at the next session of the CCNFSDU; and
- re-establish the EWG chaired by New Zealand, and co-chaired by France and Indonesia and working in English with the following terms of reference:

  i. finalise the labelling requirements for follow up formula for older infants (see Appendix III);
  ii. finalise the labelling requirements for [name of product] for young children (see Appendix III);
  iii. consider options for the structure of the standard/standards (e. g. whether one standard or two separate standards for the products for the two age groups);
  iv. develop a proposal for the scope sections for both follow-up formula for older infants and [name of product] for young children consistent with discussions at CCNFSDU39; and
  v. finalise the product definitions contained within section 2.1 for both follow-up formula for older infants and [name of product] for young children and finalise the name of the product for young children.

[8] REP17/EXEC2, paras 161 - 170
[9] REP17/CAC, paras 168 - 184
[10] REP17/NFSDU, para. 113 ii

PROPOSED DRAFT DEFINITION FOR BIOFORTIFICATION (Agenda item 5)[11]

72. Zimbabwe, as the co-chair of the EWG, introduced the item and noted that the EWG had focused on further development of the five criteria to assist in guiding the drafting of the definition. Accordingly the EWG had made six recommendations (five related to the draft criteria and one on the draft definition) for consideration by the Committee.

73. The Chair of the Committee reminded the Committee of the other outstanding issues from CCNFSDU38, i.e. how the definition would be used and where it would be placed, and that these would also need consideration. She proposed that the Committee first consider the draft definition (recommendation 6) since the criteria had been discussed several times and that these were tools developed to assist the EWG in coming up with the draft definition. She further noted that not all the specific wording in the five criteria would necessarily form part of the definition.

74. The Committee agreed with the proposal of the Chair to first consider the definition (recommendation 6) and noted the following general and specific comments made by delegations:

General Comments

75. The EU and its Member States, supported by two delegations, observed that before embarking on the elaboration of the definition, it would be important to first clarify how the definition would be used; the purpose of the work and where the definition would be best placed as requested by CAC38 following the CCEXEC recommendations. Answers to these questions were a pre-requisite to enable substantial progress on the definition. These delegations further observed that in the EU there were legally binding regulations on the use of the term "bio" where it is reserved for organic production. Therefore, a claim for biofortification on a food label of any foods not produced through organic farming could not be supported. It was not necessary for Committee resources to be spent on developing a definition for biofortification as a definition already existed in the WHO website under the glossary of terms.

76. Some observers, expressed support for the views of the EU. In addition, it was noted that there was no Codex definition for the term "conventional fortification". Some observers and one delegation noted that such a definition would open avenues for use of technologies including genetic modification (GM), that they consider harmful. These observers proposed that the work be discontinued and further expressed the view that the definition would also promote a single nutrient approach rather than a biodiverse diet.

77. The observer from NHF objected to the inclusion with definition of the words "any potential sources," and "any method of production", and the associated footnote 5 – "the methods of production may be determined by national authorities" -, in their view, this would allow use of techniques used in genetic modification to be employed for biofortification thereby misleading consumers who could view "biofortification" as a natural processes for enhancing the nutrient content of food. NHF further objected to the term itself as "bio" is already a term of art meaning "organic" and consumers would be confused by the two terms' similarity.

78. The observer from IFPRI reiterated their view expressed at previous committee sessions that the focus of biofortification was the breeding of conventional crops as one of the strategies to combat micronutrient deficiencies in the population. She explained that alternative, but equivalent terminologies to biofortification existed, e.g. agro-fortification, agri-fortification, nutri-fortification, and these could be used in different countries. To bring clarity around the definition, the observer proposed that the Committee could consider inserting a footnote: "*Some member governments may prefer to use the equivalent terms agri-fortification, agro-fortification, nutri-fortification*" to this effect.

79. A delegation expressed the view that the definition of biofortification was important for countries in developing their legislation and policies, particularly since biofortification is currently used to increase the vitamin A content of cassava, for example.

80. Noting the potential limitation to the use of the term biofortification in some regions/countries where it was associated with organic agriculture, the Committee therefore agreed that the use of alternative term(s) to "biofortification" be explored.

[11] CX/NFSDU 17/39/5; CX/NFSDU 17/39/5 Add.1 (Comments of Albania, Australia, Brazil, Canada, Colombia, Costa Rica, Egypt, India, New Zealand, Paraguay, Philippines, Switzerland, Thailand, USA, IBFAN, ICBA, ICGMA, IFU, FAO); CX/NFSDU 17/39/5 Add.2 (Kenya, Malaysia, Tanzania and IACFO); CRD8 (EU, Nicaragua, Nigeria, African Union); CRD16 (Sierra Leone); CRD22 (NHF); CRD 25 (Mali); CRD26 (Mexico).

81. In response to the question about the definition of biofortification noted in the WHO e-Library of Evidence for Nutrition Actions (eLENA), the Representative of WHO clarified that there is in fact a title page on biofortification of staple foods where some information on biofortification can be found in eLENA. But it states clearly that currently there is no WHO guideline on biofortification and although the 2016 WHO/FAO technical consultation reviewed the definition of biofortification of staple crops among various other issues, it was not a guideline-development expert meeting and therefore did not develop any definitive recommendations.

82. The Chair of the Committee explained that the request for undertaking new work originated from CCFL, that CCFL was the right committee to make a recommendation on how the definition would be used and where it would be best placed, but that CCNFSDU could make proposals to CCFL. It was further clarified that the definition would exclude feed.

Specific comments

83. The Committee considered the proposed draft definition and exchanged views on the following elements:

- *"Potential Source organisms"*

84. Agreed that the definition should be simple, clear and concise, and that examples of potential source organisms, i.e. animal, plant, fungi, yeasts, bacteria should be included in a footnote.

- *"Nutrient"*

85. Noted that the term "nutrients" as defined in the *Guidelines on Nutrition Labelling* (CXG 2-1985) was more appropriate for use in the definition. The Committee noted that the term "nutrient", instead of essential nutrient (as defined in the *General Principles for the Addition of Essential Nutrients to Foods* (CXG 9-1985)), should be used both in the definition and the associated footnote 1.

- *"Related substances"*

86. It was explained that the inclusion of the term "related substances" was intended to accommodate other substances such as phytochemicals and anti-nutritional factors that may not fall within the definition of nutrients. However, a concern was raised that including "related substances" in the definition would make the scope broader and thus complicate the situation, and that such substances needed to be clearly defined.

87. The Representative of FAO noted that there would be a need to clarify explicitly which substances fall within the category of related substances; how the health outcomes associated with these would be evaluated and proposed that this parameter be reconsidered.

88. It was thus proposed that these should be excluded from the definition.

- *Increase of nutrient by measurable levels and nutrient bioavailability*

89. It was mentioned that the intended positive health outcomes could be achieved either, through a quantitative increase in the desired nutrients, or through reduction of target anti-nutrients (e.g. phytate) and thus make the nutrients more bioavailable. However, from an enforcement point of view, it would be easier to measure the nutrient increase rather than nutrient bioavailability. Therefore the definition should focus on the expected outcome, i.e. measurable levels but also take into account nutrient bioavailability.

- *Footnote 4 – Intended purpose*

90. The Committee considered the suitability of the principles listed in section 3.1.1 of CXG 9-1987, and reaffirmed that the purpose of biofortification is to improve nutritional quality and confirmed that the principles as listed were applicable and suitable for use in the definition. To ensure clarity and precision of the definition, it was proposed the principles should be listed in a footnote as follows:

a) preventing/reducing the risk of, or correcting, a demonstrated deficiency of one or more essential nutrients in the population;

b) reducing the risk of, or correcting, inadequate nutritional status or intakes of one or more essential nutrients in the population;

c) meeting requirements and/or recommended intakes of one or more essential nutrients;

d) maintaining or improving health; and/or

e) maintaining or improving the nutritional quality of foods.

- *Method of production*

91. Some delegations expressed the view that production methods should not be part of the definition and that their inclusion would create potential trade barriers as competent authorities would seek verification of production methods. Other delegations noted that the definition should apply only to conventional plant breeding and should exclude GM techniques.

Other considerations

- *Allergenicity*

92. Concerns were also expressed on the potential increase in allergens in foods; and that there would be a need to specify the target population the products obtained from biofortification are intended for. It was clarified the allergenicity should be dealt with through labelling.

Conclusion

93. The Committee noted that a number of aspects in the definition needed further consideration, as well as the questions on where the definition would be placed and how it should be used, and agreed to re-establish the eWG, chaired by Zimbabwe and co-chaired by South Africa and working in English and French to:

a) refine the draft definition and its accompanying footnotes' texts on the basis of the comments received and CCNFSDU39 recommendations (Appendix IV);

b) explore other alternative terms to biofortification; and

c) consider the request from CAC38 on how the definition would be used and where it would be best placed.

PROPOSED DRAFT NRV-NCD for EPA and DHA LONG CHAIN OMEGA-3 FATTY ACIDS (Agenda item 6)[12]

94. The Russian Federation, as Co-Chair of the EWG, introduced the item and presented the results of the EWG.

95. The Co-Chair of the EWG reported that:

- the EWG proposal of 250 mg/day for EPA/DHA was based on two Joint FAO/WHO expert consultations and one FAO expert consultation in accordance with the general principles, in a similar way for establishing NRV-NCD for sodium and potassium;
- ten RASBs whose opinion was recommended to be taken into account when discussing NRV-NCD for EPA and DHA had been identified; and
- there were conflicting views on the RASB selection, i.e. whether opinions of RASBs which did not find convincing evidence for setting a daily intake reference value (DIRV) should also be considered or not.

96. The Committee was further informed that the two NUGAG documents (abridged versions) were also considered in the work of the EWG.

97. The Representative of WHO further clarified that with reference to NRV-NCD for sodium and potassium, the Committee established initially the values based on the outcome of the 2002 Joint WHO/FAO Expert Consultation on Diet, Nutrition and the Prevention of Chronic Diseases (TRS 916), but when the updated WHO guideline on sodium intake for adults and children (2012) became available, the Committee updated it to follow the 2012 WHO guideline as indicated in the reference to the NRV-NCD for sodium. In the same manner, NRV-NCD for potassium was developed based on the WHO guideline on potassium intake for adults and children (2012) as the 2002 Joint WHO/FAO expert consultation did not provide any specific value for potassium.

98. The Committee welcomed the side-event on evidence reviews on n-3 polyunsaturated fatty acids (PUFA): background reviews conducted for the work of NUGAG, considered the six recommendations of the EWG and made the following decisions and comments.

Recommendations 1 - 3

99. Delegations were of the view that: i) the systematic reviews conducted for the PUFA guideline development by the NUGAG Subgroup on Diet and Health (NUGAG documents) were: very comprehensive, but had been presented late to the EWG and more time would be needed to consider them; ii) risk assessors should consider the systematic NUGAG reviews rather than the Committee who were risk managers.

[12] CX/NFSDU 17/39/6; CRD9 (Comments of European Union, Thailand, GOED); CRD23 (Canada); CRD29 (Peru)

100. In response to the question on the publication process and status of the NUGAG documents, the Representative of WHO stated that it is planned that the n-3, n-6 and total PUFA randomised clinical trial (RCT) reviews on CVD related outcomes would be published as Cochrane reviews while RCT reviews on all other health outcomes and the reviews on cohort studies would be published in peer-reviewed journals in 2018.

101. The Committee agreed with recommendations 1, 2 and 3.

Recommendation 4 - 6

102. The Committee noted the explanation from WHO that the term "convincing" was included in the text of section 3.2.2 on NRV-NCD under general principles after the discussion took place at CCNFSDU32 (2010) based on the criteria used by the 2002 Joint WHO/FAO Expert Consultation on Diet, Nutrition and the Prevention of Chronic Diseases (TRS 916). The criteria for evaluating the strength of evidence using "*critical, probably, possible* and *insufficient*" was developed based on the criteria used by the World Cancer Research Fund, but with some modifications made by the 2002 Expert Consultation in an effort to evaluate the quality of evidence in a more systematic manner. But these criteria were used only at the 2002 Expert Consultation and again at the 2008 Joint FAO/WHO Expert Consultation on Fats and Fatty Acids in Human Nutrition. But since the implementation of the organisation-wide change in the guideline development process in WHO in 2010, WHO no longer uses such criteria as the evaluation of the quality of evidence is now required to be done through Grading of Recommendations Assessment, Development and Evaluation (GRADE). The Representative therefore suggested that the Committee might wish to consider whether it was still necessary to keep the term "convincing".

103. The Committee agreed to recommendations 5 and 6 and that recommendation 4 should be further considered. The Committee also agreed that the clarification of sections 3.1 and 3.2 of the Annex: General Principles for Establishing Nutrient Reference Values for the General Population to the *Guidelines on Nutrition Labelling* (CXG 2-1985) would first focus on resolving the work on establishing NRV-NCD for EPA and DHA noting the interpretation of the principles might be applicable for other NRV-NCD in future.

Conclusion

104. The Committee agreed to establish an EWG, co-chaired by the Russian Federation and Chile, working in English with the following terms of reference:

(i) to complete the assessment of the most current scientific evidence as presented in the NUGAG systematic reviews taking into consideration further advice from FAO/WHO;

(ii) to clarify under Section 3.1 of the Annex: General Principles for Establishing Nutrient Reference Values for the General Population to the *Guidelines on Nutrition Labelling* (CXG 2-1985) if opinions from RASBs that did not set DIRVs could also be taken into account when establishing NRVs;

(iii) to discuss the first bullet of Section 3.2.2 of the Annex: General Principles for Establishing Nutrient Reference Values for the *General Population to the Guidelines on Nutrition Labelling* (CXG 2-1985) and clarify what level of evidence quality under the GRADE classification shall be considered as the "relevant convincing/generally accepted scientific evidence";

(iv) to discuss if the definition of convincing evidence given in "Diet, Nutrition and the Prevention of Chronic Diseases: Report of a Joint FAO/WHO Expert Consultation, 2002" is applicable for the purpose of establishing an NRV-NCD; and

(v) to make proposals to CCNFSDU40.

PROPOSED DRAFT GUIDELINE FOR READY-TO-USE THERAPEUTIC FOODS (Agenda item 7)[13]

105. South Africa as chair of the EWG, introduced the item and noted that based on written comments the chairs had prepared a revised proposal (CRD15).

[13] CX/NFSDU 17/39/7; CX/NFSDU 17/39/7 Add 1 (Albania, Brazil, Canada, Colombia, Costa Rica, Egypt, India, Paraguay, Philippines, USA, EU Specialty Food Ingredients, HKI, IBFAN, ICAAS, IDF, IOFI, ISDI, MSF, UNICEF);CX/NFSDU 17/39/7 Add.2 (Kenya, Malaysia, Tanzania, Thailand and IACFO); CRD10 (European Union, Nigeria, African Union); CRD15 (Proposal of EWG Chairs); CRD16 (Sierra Leone); CRD25 (Mali)

106. The Committee considered the recommendations, made proposals, amendments and took the following decisions:

Recommendation 1

107. The Committee briefly discussed the preamble, and agreed that it would be considered after discussing the technical part of the guideline. The Committee noted the clarification from the Secretariat that the first paragraph should be deleted as the current wording was not appropriate and reference to the *Code of Ethics for International Trade in Food including Concessional and Food Aid Transactions* (CXC 20 – 1979) could be inserted at an appropriate point at the end of the preamble. Similar points were also raised by other delegations.

108. Concerns were raised that the guideline could result in increased marketing and sale of ready-to-use therapeutic food (RUTF) products, the Secretariat clarified that the project document clearly explained that the guideline for RUTF will provide a reference for industry, consumers and government regulatory authorities to follow and provide the needed framework for the supply of consistently safe and nutritionally appropriate emergency food aid products across borders and was therefore not for general sale. One delegation did not support the use of RUTF as enough evidence was not available for the use of commercially manufactured RUTF for the management of severe acute malnutrition (SAM) and strongly supported the use of local foods to manage the condition in accordance with national policy. Another delegation noted that RUTF should not be prioritised and noted that children with SAM needed adequate treatment and care.

Recommendation 2 - Description

4.1 Ready-to-Use Therapeutic Foods (RUTF)

109. The definition was amended to clearly indicate that RUTF should contain adequate protein and other essential nutrients. It was clarified that the term high energy was associated with high fats and high sugars and there was no need to specifically mention these two nutrients in the definition. The Committee generally supported this recommendation.

5. Raw materials and ingredients

110. Agreed to:

- delete the words “powdered or ground ingredients” and instead refer to ingredients in general as this would provide for other ingredients that may exist in liquid form, and allow for innovative products and use of emerging technologies; and
- support the recommendation

5.1.1 Milk and other Dairy Products

111. Agreed to:

- amend section 5.1.1 (Milk and other Dairy Products) to include “other animal source products” to cater for other ingredients that could be sourced locally;
- make reference to relevant Codex Standards on milk and milk products; and
- support the recommendation.

5.1.2 Legumes and Seeds

112. Agreed to:

- replace the term “pulses” with “seeds” as the raw materials were broadly classified into either legumes or seeds (e.g. sesame); and
- include soybeans among the raw materials as soybeans were widely used as a source of protein.

113. An Observer noted there were a number of advisories on feeding children between 6 to 59 months on soy based products and such information should be taken into account.

5.1.3 Fats and oils and 5.1.4 Cereals

114. Agreed with the proposed changes detailed in CRD 15.

5.1.5 Vitamins and Minerals

115. Noted that the list for nutrients compounds should:

- be an open list to allow for its updating based on emerging science;

- include clearly those vitamins and minerals that are recommended and those that should be avoided; and
- make reference to the WHO Publication of 1999.

116. Agreed that minerals in general would require further consideration.

5.2.1 Available Carbohydrates

117. The Committee considered the footnote associated to available carbohydrates and noted the following issues for further consideration:

- the quantity of free sugar in the product should be restricted and should be in accordance with WHO guidelines and WHA recommendations;
- the value of 20% was too high and should be indicated on the label;
- a statement to read "*Any carbohydrate added for sweetness should be used sparingly*" should be included in the footnote; and
- glucose syrup and corn syrup should be grouped together, as their reported negative health implications were similar.

118. The Representative of WHO mentioned that there were clear recommendations to reduce the consumption of sugars and understanding that it may be possible to further reduce the content of sugars with future technological advances, clearer relevant language could be included in the guideline to address this issue.

119. The Representative of UNICEF explained that sugar was normally added to RUTF to enhance palatability of the product, and for technological reasons to act as a filler and a binder and extend the shelf-life. It was currently only possible to reduce sugar by 5%, but in future, with technological advances, sugar might be further reduced.

120. One observer said that countries should not be pressurised to accept globally traded RUTF, as locally made foods could be more nutritious and might not need the addition of such high levels of sugar.

121. The Committee agreed that available carbohydrates would require further consideration.

Contaminants

122. The EWG Chair noted that the section would cover all types of contaminants to be controlled in RUTF; however there were no set maximum levels for contaminants in the *General Standard for Contaminants in Food and Feed* (CXS 193-1995) (GSCTFF) for RUTF; and that the stepwise approach proposed to deal with contaminants.

123. The Representative of WHO expressed support for the proposals by the EWG to manage contaminants in products such as RUTF, and noted that one way would be to make a cross reference to the relevant standards where the ML could be found (such as CXS 193-1995). However to better help and guide producers of RUTF to comply with the ML for contaminants (stated in CXS 193-1995) consideration could be given to listing the relevant ML for contaminants for RUTF products in the guideline. He also stressed the importance of having proper risk management measures in place for contaminants, like aflatoxins, focusing more on the raw material, rather than in the finished product.

124. The Representative of FAO emphasised the important need to having safe RUTF. Yet, a ML might not always be the most suitable risk management measure, he encouraged the Committee to carefully consider the best measures to minimise the amount of contaminants present in RUTF. FAO reminded the Committee that the Committee on Contaminants in Food (CCCF) is the committee under the Codex system that focused on all aspects of contaminants in foods and CCNFSDU might consider to ask CCCF for advice on this critical question. FAO reminded the Committee further that contaminants are best controlled through a careful management of the ingredients and the supply chains in general, and pointed out that suitable provisions from various codes of practice, GAP, GMP and a close control of the ingredients used for the production of RUTF already existed. The Committee was encouraged to consider the suitability of these provisions in addition of or in place of a maximum level for contaminants in the final product.

125. The Secretariat clarified that while a reference to the GSCTFF was the preferred option as outlined in the *Format for Codex Commodity Standards* in the Procedural Manual, exceptions to this rule were allowed. However, any MLs would still require endorsement by CCCF and clear justification should be provided on why a general reference to the GSCTFF was not appropriate. She further explained that any MLs sent to CCCF should also be accompanied by an explanation on the scientific basis of the ML.

126. A delegation proposed that consideration be given to a ML for aflatoxin of 5 ppb as prescribed in the Joint Statement by the World Health Organization, the World Food Programme, the United Nations System Standing Committee on Nutrition and the United Nations' Children's Fund: Community-based Management of Severe Acute Malnutrition.

127. The Committee agreed with the proposed stepwise approach by the EWG, and that it would be the starting point for further work in this area.

Other sections

128. Due to time constraints, other sections could not be considered.

Conclusion

129. The Committee agreed to establish:

a) an EWG, Chaired by South Africa and co-chaired by Senegal and Uganda and working in English and French (with the support of France) to continue drafting the guidelines for RUTF taking into account the decisions and comments made at the session (Appendix V) and written comments submitted to CCNFSDU39, for comments and further discussion at the next session.

b) a PWG, to meet immediately prior to the next session, chaired by South Africa, and co-chaired by Senegal and Uganda, working in English, French and Spanish, to further elaborate the proposed draft guidelines for RUTF taking into account the conclusions and recommendations of the EWG and the comments received prior to CCNFSDU40.

NRV-R FOR OLDER INFANTS AND YOUNG CHILDREN (Agenda item 8)[14]

130. The Chair introduced the item and recalled that while there was interest to continue this work, the Committee had been unable to find countries ready to lead the work in the previous two sessions. The Delegation of Australia urged the Committee to continue the work and proposed how it could be taken forward through an EWG as presented in CRD 2.

131. The Committee agreed to continue this work and considered the terms of reference of the EWG presented by Australia. The Committee made amendments to the terms of reference for clarity and feasibility.

Conclusion

132. The Committee agreed to establish an EWG chaired by Ireland, and co-chaired by Mexico and the United States of America, working in English and Spanish, with the following terms of reference:

A. Assess the need and value for the establishment of NRV-R for older infants and young children in Codex texts in relation to:

i. the purpose of such NRVs-R in the *Guidelines for Nutrition Labelling* (CXG 2-1985) and Codex texts for special dietary use for older infants and young children; and

ii. the specific age groups to which these NRV-R may apply.

Where a need is established under TOR A:

B. Analyse nutrition labelling provisions in Codex texts under TOR A (i) and, where appropriate, develop a request to CCFL to provide advice on the potential for amendments to provide further clarity.

FOOD ADDITIVES – MECHANISM / FRAMEWORK FOR CONSIDERING TECHNOLOGICAL JUSTIFICATION AND OTHER MATTERS (Agenda item 9)[15]

133. The EU as chair of the EWG, reviewed the process followed by the EWG, and presented their results.

134. The Committee considered the three recommendations of the EWG and made the following decisions and comments.

Recommendation 1 – Scope

135. One observer was of the view that the scope should be limited to standards with foods intended for infants and young children.

[14] REP17/NFSDU, para.40; CRD2 (Discussion paper by Australia); CRD11 (Comments of Tanzania, Thailand, African Union, ISDI); CRD17 (Indonesia); CRD25 (Mali)

[15] CX/NFSDU 17/39/8; CRD6 (ISDI); CRD12 (Canada, European Union, USA); CRD17 (Indonesia)

136. The Committee agreed that all foods within its mandate should be covered by the framework.

Recommendation 2 – criteria (Annex A)

137. The Committee noted the views that: i) the questions included in Annex A were overly complex and difficult to understand; ii) some questions went beyond technological justification, and should be considered by the Committee on Food Additives (CCFA); and iii) the three sub-titles were unnecessary.

138. After explaining the rationale for the three sections in Annex A, i.e. section I was to check the eligibility and intended use, Section II was to verify the compliance with the approach on the use of additives in foods intended for infants and young children, and section III was to verify the compliance with section 3.2 of the preamble to the General Standard for Food Additives (GSFA), the EU indicated that the order of sections II and III could be changed in view of the decision on the scope.

139. The Committee agreed to use Annex A, comments received at the meeting, and comments reflected in the CRDs as a basis for further consideration.

Recommendation 3 - continuation of the framework

140. In response to the concern on whether the framework could have an impact on special dietary foods such as gluten-free foods, it was clarified that the purpose of the development of the framework was to appraise the technological justification for food additives intended for JECFA evaluation rather than to prevent use of food additives.

141. The Committee agreed to continue the work on the framework.

142. On the proposed list of food additives for testing the framework, the Committee noted the explanation and views that:

- there had been concerns that several adopted food additive provisions for foods intended for infants below 12 weeks of age had no appropriate safety assessment (see CRD15 of CCFA49), and that the Committee was requested to consider this matter in its ongoing work on technological justification; depending on the outcome of technological justification, these food additives could be either deleted from the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CXS 72-1981) or included in the JECFA priority list;
- testing of the framework should be focused first on xanthum gum (INS 415), pectin (INS 440) and gellan gum (INS 418); and that the food additives in CRD15 of CCFA49 should only be considered after the framework had been tested on the aforementioned three food additives; and
- the framework should be applicable to new food additive requests and not delay decision on pectin and xanthan gum for which JECFA has already undertaken safety assessments, and for which sufficient technological justification had already been provided.

143. In the spirit of compromise, the Committee agreed to evaluate the relevant food additives in CRD15 of CCFA49 as a next step.

Conclusion

144. The Committee agreed to establish an EWG, chaired by the EU, and co-chaired by the Russian Federation working in English with the following terms of reference:

(i) continue working on a mechanism or framework for considering the technological justification on the basis of CX/NFSDU 17/39/8 and taking into account the comments in the CRDs and the discussion at CCNFSDU39; and

(ii) test the agreed framework with the proposed use of xanthan gum (INS 415), pectin (INS 440) and gellan gum (INS 418).

DISCUSSION PAPER ON CLAIM FOR "FREE" OF TRANS FATTY ACIDS (Agenda item 10)[16]

145. Canada introduced the item and recalled that CCNFSDU38 had been presented with a value for a free of TFAs claim of 1 g per 100 g of fat, and that three analytical methods for determining TFAs, had been referred to CCMAS for consideration. Canada further informed the Committee that CCMAS38 had replied that the three analytical methods could detect the levels of the proposed claim.

[16] CX/NFSDU 17/39/9; CRD13 (Comments of Philippines, Tanzania, Thailand, USA, African Union); CRD17 (Indonesia); CRD18 (Malaysia); CRD19 (Republic of Korea); CRD20 (IFMA); CRD25 (Mali)

146. Based on the discussions of CCNFSDU38 and feedback from CCMAS38, the discussion paper had been revised. The Committee considered an updated proposal of Canada that in order to carry a claim for "free of trans-fat" the food should contain no more than 1 g per 100 g of fat and must meet the conditions set for "low" in saturated fats.

Discussion

147. There was a general agreement on the value of 1 g per 100 g of fat. Several delegations and an observer, while in support of the level of 1 g per 100 g of fat, did not support the accompanying conditions for "low" in saturated fats based on a number of recent studies including a prospective cohort study in 18 countries (PURE study) in five continents that saturated fat consumption showed no association with CVD and mortality, hence the approach to limit the choice of TFA-free products to only those low in saturated fats would deprive consumers of the right choice of food.

148. The Representative of WHO supported the proposal made by Canada to include the conditions for low saturated fats in order to avoid increasing replacement of TFA with saturated fats. She also stated that the PURE study cited by some member countries as new scientific evidence had in fact been criticised by many experts and that WHO had also reviewed it carefully. It could be considered that an important strength of the PURE study might be the large sample size and inclusion of populations from various countries and regions throughout the world. But the pooling together of such diverse populations with diverse dietary patterns and other factors would pose challenges and concerns with respect to interpretation of the results presented in the study. WHO further found various concerns about their conclusion indicating that a higher intake of fats (including saturated fats) was associated with lower NCD events and mortality. Among others, a key limitation of the study was a lack of a clear definition of carbohydrates, whose consumption was compared with that of fats in the paper. It was not clear which carbohydrates were included in the analyses and they did not seem to distinguish carbohydrates with detrimental health effects (e.g. free sugars, refined grains) and those with health benefits (e.g. fibre rich wholegrains, legumes, vegetables and fruits). She stated, therefore, it should not be used as the evidence to promote the consumption of saturated fats.

149. The Committee further noted the following additional views expressed by delegations and observers:

- the condition for nutrient content claims for saturated fats requires that TFA should be taken into account, and therefore the same should be applied to the claim free of TFA for consistency;
- the two large-scale prospective cohort studies, the Nurses' Health Study and the Health Professional Follow-up Study, found that increase in TFA by 1% was associated with 10% increase in total mortality whereas increase in saturated fats by 5% was associated with the same outcome: therefore, the ratio between TFA (1 g) and saturated fats (1.5 g) seemed to be an underestimation;
- the ingredient of concern was industrial trans fats; and that the methods should be sent back to CCMAS to obtain validation data per 100 g of fat; and
- the issue of trans fats was better addressed through warnings, rather than through health claims.

Conclusion

150. The Committee agreed to send the proposal for comments at Step 3 and further consideration at its next session (Appendix VI).

OTHER BUSINESS AND FUTURE WORK (Agenda item 11)[17]

Methods of analysis for provisions in the *Standard for infant formula and formulas for special medical purposes intended for infants* (CXS 72-1981)

151. The United States of America introduced this item.

152. The Committee agreed to:

(i) submit the methods for biotin, vitamin D, and chloride to CCMAS for typing, endorsement and inclusion in the *Recommended Methods of Analysis and Sampling* (CXS 234-1999) as these methods reflected the most recent scientific methods of analysis for these nutrients in infant formula and had been validated in this product (Appendix VII); and

(ii) request CCMAS to re-type the related existing methods for biotin, vitamin D and chloride in CXS 234-1999.

[17] CRD3 (Comments of IPA); CRD4 (Costa Rica, Paraguay); CRD14 (USA); CRD21 (ISDI); CRD27 (Argentina).

Harmonised probiotic guidelines for use in foods and dietary supplements

153. The observer of IPA introduced this item and proposed to develop guidelines with a harmonised framework for probiotics to ensure and sustain the quality of probiotic products on a global scale.

154. Argentina expressed their support to the proposal and their willingness to lead this work.

155. In view of the late receipt of the document, delegations were not in a position to fully discuss the proposal in order to make an informed decision on starting new work.

156. The Committee agreed that Argentina would prepare a discussion paper together with a project document for consideration at its next session.

General guidelines to establish nutritional profiles

157. Costa Rica, speaking also on behalf of Paraguay, introduced the item and explained that the guidelines to establish nutritional profiles would be used to complement the work on front of pack nutrition labelling (FOPL) in CCFL. Costa Rica proposed to establish an EWG to further scope the new work and refine the project document; or to issue a circular letter to collect information on models of nutritional profiles from members in order to have a global stock take.

158. Ecuador stated that they had lots of experience on this matter and would be willing to chair the EWG, if agreed.

159. In response to the question on the difference between FOPL and nutrition profiles, the Representative of WHO clarified that a nutrient profile model is a tool to classify or rank foods and are used to implement various applications including FOPL. The Representative also expressed their willingness to share the catalogue on models of nutrient profiles for different application compiled by WHO which needed to be updated.

160. While recognizing the importance of this work, delegations expressed their views that: i) the document was made available very late and more time for consultation and consideration would be needed; ii) it might be premature to discuss this item as CCFL had not reached decision on whether nutrient profiles were necessary; iii) there were already a number of agenda items and pending issues to be considered by this Committee; iv) a circular letter would be of assistance to analyse different nutritional profile systems and facilitate better understanding of this work.

161. The Committee agreed that:

(i) the discussion on this item be postponed to its next session; and

(ii) Costa Rica could look into the possible specific questions for the circular letter, if such a CL to be sent out after CCNFSDU40.

DATE AND PLACE OF THE NEXT SESSION (Agenda item 12)

162. The Committee was informed that the 40th Session was scheduled to be held in Berlin, Germany from 26 to 30 November 2018, the final arrangements being subject to confirmation by the host government in consultation with the Codex Secretariat.

Addendum

CORRECTION BY THE WHO OFFICE OF THE LEGAL COUNSEL

With reference to the response provided by the WHO Representative, as reflected in paragraph 13 of the report, concerning the meaning of certain operative verbs in resolutions and decisions adopted by the WHO governing bodies, the following correction is provided:

- It is WHO Member States that give meaning to the language they use.
- Furthermore, in WHO practice, operative terms such as "welcomes," "welcomes with appreciation", “notes,” and "notes with appreciation" have different meanings and are not used synonymously with the term “approves.” In this regard, the WHO Technical Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children was not approved or endorsed but was welcomed with appreciation (see operative paragraph 1 of resolution WHA69.9). Resolution WHA69.9 itself (i.e., the resolution as a whole) was adopted by consensus on 28 May 2016 at the eighth plenary meeting of the Sixty-ninth World Health Assembly.

Appendix I

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Appendix II

PROPOSED DRAFT REVISED *STANDARD FOR FOLLOW-UP FORMULA* (CXS 156-1987)

- ESSENTIAL COMPOSITION -
(for adoption at Step 5)

SECTION A: FOLLOW-UP FORMULA FOR OLDER INFANTS

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 (250 kJ) and not more than 70 kcal (295 kJ) of energy

3.1.3 Follow-up Formula 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	-

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 (breast-milk 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 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 based on non-cows' or non-goats' milk protein other minimum values may need to be applied. For follow-up formula 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 based on non-hydrolysed milk protein can be accepted. Such follow-up formula and follow-up formula 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 acids 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 infant formulae. 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 formula based on cow's 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 carbohydrate.

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 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 αTE /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 eicosapentanoic 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	1.0	-	6.5

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	-	119

Niacin [14)]

Unit	Minimum	Maximum	GUL
µg /100 kcal	300	-	1500
µg /100 kJ	72	-	360

[14)] Niacin refers to preformed niacin

Vitamin B_6

Unit	Minimum	Maximum	GUL
µg /100 kcal	35	-	175
µg /100 kJ	8.4	-	41.8

Vitamin B_{12}

Unit	Minimum	Maximum	GUL
µg /100 kcal	0.1	-	1.5
µg /100 kJ	0.024	-	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 C [15)]

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 formulas; for powdered products lower upper levels should be aimed for.

Biotin

Unit	Minimum	Maximum	GUL
µg /100 kcal	1.5	-	10
µg /100 kJ	0.4	-	2.4

e) Minerals and Trace Elements

Iron [17)]

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

[17)] For Follow-up formula 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 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	5	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	-	14.3

Selenium

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

Copper [19)]

Unit	Minimum	Maximum	GUL
µg /100 kcal	35	-	120
µg /100 kJ	8.4	-	29

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

Zinc [20)]

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

[20)] For Follow-up formula based on soy protein isolate a minimum value of 0.75 mg/100 kcal (0.18 mg/100 kJ).

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 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	-	3	-

Total nucleotides

Levels may need to be determined by national authorities.

Docosahexaenoic acid [21)]

Unit	Minimum	Maximum	GUL
mg /100 kcal	-	-	30
mg /100 kJ	-	-	7.2

[21)] If docosahexaenoic acid (22:6 n-3) is added to follow-up formula, 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.

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	-	-	9.6

L-carnitine

Levels may need to be determined by national authorities.

L (+) lactic producing cultures

Only L (+) lactic producing cultures may be used for the purpose of producing acidified follow-up formula for older infants. The acidified final formula 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.

SECTION B: [NAME OF PRODUCT] FOR YOUNG CHILDREN

3 ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Essential composition

3.1.1 **[Name of product] for young children** 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 [Name of Product] for young children 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 (250 kJ) and not more than 70 kcal (295 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 (Name of product) for young children 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)*, as appropriate. The general principles for establishing these levels are identified in Annex I of this standard.

a) Protein [1), 2)]

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

1) 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.

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

The protein quality shall be determined provisionally using the PER or PDCAAS and other methods that come available in the future.

b) Lipids [3)]

Total fat

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

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	-	-

3) Partially hydrogenated oils and fats shall not be used in [name of product] for young children.

c) Carbohydrates

Available carbohydrates [4)]

Unit	Minimum	Maximum[5)]	GUL
g /100 kcal	-	12.5	-
g /100 kJ	-	3.0	-

* 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 [name of product] for young children should usually not exceed the GULs unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of [name of product] for young children 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.

[4] [Lactose should be the preferred carbohydrates in [name of product] based on milk protein. For products not based on milk protein, carbohydrate sources (like starch) that have no contribution to the sweet taste should be preferred.

Mono- and disaccharides, other than lactose, either added as ingredients, or constituents of ingredients and/or increased above the amount contributed by the ingredients by some other means, should not exceed 2.5 g/100kcal (0.60 g/100kJ) of available carbohydrate. National and/or regional authorities may limit this level to 1.25 g/100 kcal (0.30 g/100 kJ). Sucrose and/or fructose or other carbohydrates contributing to the sweet taste of [name of product] should not be added, unless needed as a carbohydrate source. Other non-carbohydrate ingredients should not be added with the purpose of imparting or enhancing a sweet taste.]

[5] For [Name of the product] for young children 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 and Minerals

Iron [6]

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

[6] For [name of product] based on soy protein isolate a minimum value of 1.5 mg/100 kcal (0.36 mg/100 kJ) applies.

Vitamin C [7]

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

[7] expressed as L-ascorbic acid

Calcium

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

Riboflavin

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

Vitamin B_{12}

Unit	Minimum	Maximum	GUL
µg /100 kcal	0.1	-	2.0
µg /100 kJ	0.024	-	0.48

Zinc

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

Vitamin A

Unit	Minimum	Maximum	GUL
µg RE[8] /100 kcal	60	180	-
µg RE[8] /100 kJ	14	43	-

[8] 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_3[9)]]

Unit	Minimum	Maximum	GUL
µg[10)] /100 kcal	[1.5]	[4.5]	-
µg[10)] /100 kJ	[0.36]	[1.08]	-

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

10) Calciferol. 1 µg calciferol = 40 IU vitamin D.

Sodium chloride should not be added to [name of the product] for young children.

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 breast milk, 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 essential compositional requirements listed under 3.1.3 Section B, other ingredients, substances or nutrients may be added to [name of the product] for young children 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, substances or nutrients is added the formula shall contain sufficient amounts to achieve the intended effect.

3.2.3 Additional nutrients may also be added to [name of the product] for young children 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.

Appendix III

PROPOSED DRAFT REVISED *STANDARD FOR FOLLOW-UP FORMULA* (CXS 156-1987)

- OTHER SECTIONS -

(for further consideration by EWG)

PREAMBLE

[The Codex Alimentarius Commission acknowledges the need to [**protect and support** / **recognize**] breast-feeding as an unequalled way of providing ideal food for the healthy growth and development of infants. At the same time Codex acknowledges that numerous formulae have been produced, intended for use, where [**necessary** / **appropriate**], as a substitute for human milk in meeting the normal nutritional requirements of infants provided they are prepared under hygienic conditions and given in adequate amounts. In addition, various products have also been produced intended specifically for young children as they progress to a more diversified diet of family foods and these products should not discourage breastfeeding.

The production, distribution, sale and use of follow-up formula for older infants and [name of product] for young children should be consistent with national health and nutrition policies and relevant national/regional legislation, and take into account, [**as appropriate**,] the recommendations made in the International Code of Marketing of Breast-milk Substitute (1981) and the Global Strategy for Infant and Young Child Feeding. Relevant WHO guidelines and policies as well as relevant World Health Assembly (WHA) resolutions that have been [**endorsed** / **supported**] by member states [**may also**] provide guidance to countries in this context.

This Standard is divided into two sections. Section A refers to Follow-up Formula for Older Infants (6 to 12 months of age), and Section B deals with [Name of Product] for Young Children (12 to 36 months of age). It does not apply to products covered by the ~~Codex~~ Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (~~CODEX STAN 72 – 1981~~ CXS 72-1981).]

SECTION A: FOLLOW-UP FORMULA FOR OLDER INFANTS

2 [SCOPE

2.1 This section of the Standard applies to Follow-up Formula for Older Infants, as defined in Section 2.1, in liquid or powdered form.

2.2 This section of the Standard contains compositional, quality, safety, ~~[~~labelling and analytical~~]~~ requirements for Follow-up Formula for Older Infants.

2.3 Only products that comply with the criteria laid down in the provisions of this section of this Standard **[should / shall]** be presented as Follow-up Formula for Older Infants.]

3 DESCRIPTION

3.1 Product Definition

3.1.1 [Follow-up formula for older infants means a product, ~~**specially**~~ manufactured for use **as a substitute for breastmilk,** as a liquid part of a progressively diversified diet for older infants when complementary feeding is introduced.**]**

3.1.2 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.

3.2 Other Definitions

3.2.1 The term **infant** means a person of not more than 12 months of age.

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

9. ~~[~~LABELLING~~]~~

The requirements of the ~~Codex~~ General Standard for the Labelling of Pre-packaged 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 and young children except where specifically provided for in relevant Codex Standards or national legislation.]

9.1 The Name of the Product

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

9.1.2 The name of the product shall be Follow-up Formula for Older Infants as defined in Section 2.1, or any appropriate designation indicating the true nature of the product, in accordance with national ~~[~~or regional~~]~~ usage.

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

a) If [name of animal] milk is the only source of protein~~[*]~~, the product may be labelled 'Follow-up Formula for Older Infants Based on [name of animal] milk ~~[~~protein~~]~~.

b) If [name of plant] is the only source of protein~~[*]~~, the product may be labelled 'Follow-up Formula for Older Infants Based on [name of plant] ~~[~~protein~~]~~.

c) if [name of animal] milk and [name of plant] are the sources of proteins*, 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.~~]~~

9.1.5 A product which contains neither milk nor any milk derivative **[**shall**] ~~[may]~~** be labelled "contains no milk or milk products" or an equivalent phrase.

9.2 List of Ingredients

9.2.1 A complete list of ingredients ~~[including optional 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.

9.2.2 The specific name shall be declared for ingredients of animal or plant origin and for food additives. **In addition, appropriate functional classes for these ingredients and additives may be included on the label.** ~~[~~**The f**ood additive~~s~~ **INS number** may also **be** optionally declare**d ~~the INS number].~~**

9.3 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 grams or per 100 millilitres of the food as sold ~~[~~as well as] ~~[or]~~ per 100 millilitres 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 grams or per 100 millilitres of the food as sold ~~[~~as well as~~]~~ ~~[or]~~ per 100 millilitres 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 (or per 100 kilojoules) is permitted.

9.4 Date Marking and Storage Instructions

9.4.1 **(i)** The ***"Best Before Date" or "Best Quality Before Date"*** shall be declared by the day, month and year except that for products with a shelf-life of more than three months, [at least] the month and year [shall be declared]. [The day and year shall be declared by uncoded numbers with the year to be denoted by 2 or 4 digits, and the month shall be declared by letters or characters or numbers. Where only numbers are used to declare the date or where the year is expressed as only two digits, the competent authority should determine whether to require the sequence of the day, month, year, be given by appropriate abbreviations accompanying the date mark (e.g. DD/MM/YYYY or YYYY/DD/MM).]

(ii) In the case of products requiring a declaration of month and year only, the [date shall be introduced by the words "Best before end <insert date>; or "Best Quality Before end <insert date>].

9.4.2 In addition to the date, any special conditions for the storage of the food shall be indicated ~~if~~ [where they are required to support the integrity of the food and, where] the validity of the date depends thereon.

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

9.5 Information for Use

9.5.1 ~~[~~Ready to use~~]~~ products in liquid form **should** ~~may~~ be used ~~[either]~~ directly.~~or in the case of c~~**C**oncentrated 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. ~~[Products in powder form should be reconstituted with water that is safe or has been rendered safe by previous boiling for preparation.]~~ Adequate directions for the appropriate preparation and handling should be in accordance with Good Hygienic Practice.

9.5.2 Adequate directions for the appropriate preparations 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.

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

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

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

~~[~~9.5.6 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.~~]~~

[9.6 Additional Labelling Requirements

9.6.1 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 "Breast milk is the best food for your baby" or a similar statement as to the superiority of breastfeeding or breast milk;

~~[~~c) a statement that the product should only be used on advice of an [independent] health worker as to the need for its use **[including any exception to the age of introduction of 6 months]** and the proper method of use.~~]~~

[d) the statement; 'The use of this product must not replace breastmilk and lead to cessation of continued breastfeeding'.]

~~[~~9.6.2 The label shall have no pictures of infants and women nor any other picture[,] ~~or~~ text[,] ~~which idealizes the use of follow up formula. The label shall have no pictures images, text~~ or ~~other~~ representation that might:
9.6.2.1 idealize the used of follow-up formula for older infants;
9.6.2.2 suggest use for infants under the age of 6 months (including references to milestones and stages);
9.6.2.3 recommend or promote bottle feeding;
9.6.2.4 undermine or discourage breastfeeding, ~~that makes a comparison to breast-milk,~~ or suggest~~s~~ that the product is ~~nearly~~ equivalent to or superior to breast-milk;
9.6.2.5 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, regional or international regulatory authorities.~~]~~

9.6.3 The terms "humanized", "maternalized" or other similar terms shall not be used. **~~[~~**~~In addition, the product should not be compared to breast-milk].~~

~~[~~9.6.4~~]~~ Products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula for older infants, (name of product) for young children, and formula for special medical purposes**[,** and to enable consumers to make a clear distinction between them, in particular as to the text, images and colours used.]**]**

SECTION B: [NAME OF PRODUCT] FOR YOUNG CHILDREN

1 [SCOPE

1.1 This section of the Standard applies to [name of product] for young children, as defined in Section 2.1, in liquid or powdered form.

1.2 This section of the Standard contains compositional, quality, safety, ~~[~~labelling and analytical~~]~~ requirements for [name of product] for young children.

1.3 Only products that comply with the criteria laid down in the provisions of this section of this Standard [**should / shall]** be presented as~~]~~ [name of product] for young children.]

2 DESCRIPTION

2.1 Product Definition

2.1.1 **[[Name of product] for young children** means a product ~~specially[formulated and]~~ manufactured for use **[as a breastmilk substitute],** as a liquid part of the ~~[progressively] [~~diversified~~]~~ diet of young children ~~[in order to contribute to the nutritional needs of young children] [when nutrient intakes may not be adequate to meet nutritional requirements~~.]

2.1.2 **[Name of 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).

9. [LABELLING

The requirements of the ~~Codex~~ General Standard for the Labelling of Pre-packaged 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 [Name of Product] for young children. 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.

9.1 The Name of the Product

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

9.1.2 The name of the product shall be [Name of Product] for Young Children as defined in Section 2.1, or any appropriate designation indicating the true nature of the product, in accordance with national ~~[~~or regional~~]~~ usage.

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

9.1.4 OPTION 1: Split provision 9.1.4 into two:

9.1.4(a) If [name of animal] milk is the only source of protein[*], the product may be

labelled '[Name of Product] for Young Children based on [name of animal] milk [protein]'.

9.1.4(b) If [name of plant] is the only source of protein[*], the product may be labelled '[Name of Product] for Young Children based on [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.]

OR

OPTION 2: Delete provision 9.1.4 as it is covered by 9.1.3

9.1.5 A product which contains neither milk nor any milk derivative **[**shall**] [**~~may~~**]** be labelled "contains no milk or milk products" or an equivalent phrase.

9.2 List of Ingredients

9.2.1 A complete list of ingredients ~~[including optional 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.

9.2.2 The specific name shall be declared for ingredients of animal or plant origin and for food additives. [Food additives may also optionally declare the INS number].

9.3 Declaration of Nutritive Value

The declaration of nutrition information [for [name of product] for young children] 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 grams or per 100 millilitres of the food as sold [as well as] [or] per 100 millilitres 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 grams or per 100 millilitres of the food as sold [as well as] [or] per 100 millilitres 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 [serving size and/or per] 100 kilocalories (or per 100 kilojoules) is permitted.

9.4 Date Marking and Storage Instructions

9.4.1 The **"Best Before Date" or "Best Quality Before Date"** date of minimum durability (preceded by the words "best before") shall be declared by the day, month and year in uncoded numerical sequence except that for products with a shelf-life of more than three months, [at least] the month and year [shall be declared] will suffice. The month may be indicated by letters in those countries where such use will not confuse the consumer. [The day and year shall be declared by uncoded numbers with the year to be denoted by 2 or 4 digits, and the month shall be declared by letters or characters or numbers. Where only numbers are used to declare the date or where the year is expressed as only two digits, the competent authority should determine whether to require the sequence of the day, month, year, be given by appropriate abbreviations accompanying the date mark (e.g. DD/MM/YYYY or YYYY/DD/MM).]

In the case of products requiring a declaration of month and year only, and the shelf-life of the product is valid to the end of a given year, the expression "end (stated year)" may be used as an alternative.

9.4.2 In addition to the date, any special conditions for the storage of the food shall be indicated if [where they are required to support the integrity of the food and, where] the validity of the date depends thereon.

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

9.5 Information for use

9.5.1 [Ready to use] products in liquid form may be used [either] directly or in the case of concentrated liquid products [and powdered products], must be prepared with water that is safe or has been rendered safe by previous boiling before feeding, according to directions for use. [Products in powder form should be reconstituted with water that is safe or has been rendered safe by previous boiling for preparation.] Adequate directions for the appropriate preparation and handling should be in accordance with Good Hygienic Practice.

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

9.5.3 The label shall carry clear graphic instructions illustrating the method of preparation of the product. [Pictures of feeding bottles are not permitted on labels of (name of product) for young children.]

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

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

[9.5.6 The label of [name of product] for young children shall include a statement that the product shall not be introduced before 12 months of age and should be used as part of a [**diversified**] [balanced] diet.]

9.6 Additional Labelling Requirements

~~[~~9.6.1 The label of [name of product] for young children shall have no image, text or representation, **[including pictures of feeding bottles,]** that could undermine or discourage breastfeeding or which idealises the use of [name of product] for young children. The terms 'humanized', 'maternalized' or other similar terms must not be used on the label**.~~]~~**

~~[~~9.6.2~~]~~ Products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula for older infants, [name of product] for young children, and formula for special medical purposes**[, and to enable consumers to make a clear distinction between them, in particular as to the text, images and colours used]**. **]**

Appendix IV

PROPOSED DRAFT DEFINITION FOR BIOFORTIFICATION

(for further consideration by EWG)

Definition:

[Biofortification* is the process whereby ~~any~~ nutrients[1)] **are increased [by a measurable level] or become more bioavailable in**~~of~~ all potential source organisms[2)] [for] **OR** [of] **OR** [and] foods ~~are increased by a measurable level~~for the intended **nutritional** purposes[3)].The process applies to any method of production[4)] [and excludes conventional addition of nutrients to food[5)]].

***) Some Member governments may prefer to use the equivalent term of agro-fortification, agri-fortification or nutri-fortification.**

[1)] **Nutrient** is defined by Guidelines on Nutrition Labelling (CAC/GL 2-1985) to mean: any substance normally consumed as a constituent of food: a) which provides energy; or b) which is needed for growth and development and maintenance of life; c) or a deficit of which will cause characteristic biochemical or physiological changes to occur.

[2)] e.g. animal, plant, fungi, yeasts, bacteria.

[3)] **Intended purposes:**

- preventing/reducing the risk of, or correcting, a demonstrated deficiency in the population;
- reducing the risk of, or correcting, inadequate nutritional status or intakes in the population;
- meeting requirements and/or recommended intakes of one or more nutrients;
- maintaining or improving health; and/or
- maintaining or improving the nutritional quality of food.

[4)] **Method of production** should be determined by the competent National/Regional authority.

[5)] Biofortification does not include conventional fortification covered by CAC/GL 9/1987**.]**

Appendix V

PROPOSED DRAFT GUIDELINES FOR READY TO USE THERAPEUTIC FOODS (RUTF)

(for further consideration by EWG)

1. PREAMBLE

~~[The major objectives of the work of the Codex Alimentarius Commission are to protect the health of the consumer and ensure fair practices in the trade in food through the elaboration and harmonization of definitions and requirements for food. In order to realize this objective CAC developed a *Code of Ethics for International Trade in Food including Concessional and Food Aid Transactions* (CAC/RCP 20-1979) embodying the principles of sound consumer protection. The objective of this code is to establish standards of ethical conduct for all those engaged in international trade in food or for those responsible for regulating food and thereby protecting the health of the consumers and promoting fair trade practices. It is within this context that all those engaging in the international trade in food with specific reference to Ready-to-Use Therapeutic Foods (RUTF) commit themselves to the provisions of the code].~~

Children affected by severe acute malnutrition (SAM) need **[adequate treatment and care] OR [**safe, palatable foods with a high energy content and adequate amounts of vitamins, minerals and other critical nutrients. Children with SAM need timely treatment and RUTF is a critical part of the treatment~~]~~. ~~[RUTF are high energy, fortified, ready-to-eat foods for special medical purposes suitable for the dietary management of children with SAM].~~ RUTF are primarily intended for children with uncomplicated SAM from 6-59 months. Although RUTF are given to other age groups with various forms of malnutrition at the implementation level, the primary focus for these guidelines is children with SAM from 6-59 months. Since RUTF are prescribed according to weight, National Authorities may decide to include the provision of RUTF in their national protocols for use by other age groups.

[1] Joint Statement on Community-Based Management of Severe Acute Malnutrition by the World Health Organization, the World Food Programme, the United Nations System Standing Committee on Nutrition and the United Nations Children's Fund, 2007

[2] WHO. Child growth standards and the identification of severe acute malnutrition in infants and children, 2006
A Joint Statement by the World Health Organization and the United Nations Children's Fund; Geneva: World Health Organization; 2009

[3] WHO. Guideline: *Updates on the management of severe acute malnutrition in infants and children*. Geneva: World Health Organization; 2013.

[4] WHO. Global Strategy for Infant and Young Child Feeding. Geneva: World Health Organization; 2003.

[5] WHO. *International code of marketing of breast-milk substitutes.* Geneva: World Health Organization; 1981.

4. DESCRIPTION

4.1 Ready-to-Use Therapeutic Foods (RUTF) are **foods for special medical purposes that are** high-energy, ~~fortified, ready-to-eat foods for special medical purposes~~ **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 **and 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[10].

5. RAW MATERIALS AND INGREDIENTS

RUTF are made ~~of powdered or ground~~ ingredients embedded in a lipid-rich matrix, ~~[~~e.g. paste **or** ~~and~~ 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. The 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).

5.1 Basic Raw Materials and Ingredients

5.1.1 Milk and other Dairy Products OR "Animal source products"

Milk and other dairy products used in the manufacturing of RUTF must comply with the *Standard for Milk Powders and Cream Powder* (Codex STAN 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 [~~Pulses~~] Seeds

Legumes and ~~pulses~~ **seeds**, such as **soybeans**, lentils, chickpeas, cowpeas, beans, peanut, sesame and other types of legumes and ~~pulses~~**seeds** must comply with the~~*Standard for Peanuts* (CODEX STAN 200-1995), *Code of Hygienic Practice for Groundnuts (Peanuts)* (CAC/RCP 22- 1979) and the *Code of Hygienic Practices for Low-Moisture Foods* (CAC/RCP 75-2015), and other~~ relevant Codex Alimentarius texts when used in the manufacturing of RUTF.

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

[6]Guidelines for Vitamin and Mineral Food Supplements (CXG 55-2005)
[7]Standard for Processed Cereal-Based Foods for Infants and Young Children (CXS 74-1981)
[8]Guidelines on Formulated Complementary Foods for Older Infants and Young Children (CXG 8-1991)
[9]Standard for Canned Baby Foods (CXS 73-1981)
[10] WHO child growth standards and the identification of severe acute malnutrition in infants and children. A joint statement by the World Health Organization and the United Nations Children's Fund. Geneva: World Health Organization; 2009]

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~~]. [~~[~~The composition of fats and oils should allow for a product that flows during processing to have desirable consistency and ensures physical and chemical stability throughout the supply chain~~]~~].

Partially Hydrogenated fats and oils [~~[~~, the major dietary source of industrially-produced trans fat in processed food,~~]~~ should not be used in RUTF.

5.1.4 Cereals

All milled cereals suitable for human consumption may be used provided that [~~[~~their processing reduces~~]~~ ~~they are processed in such a way that the~~ fibre ~~content is reduced~~, when necessary. ~~, and that The effects of a~~**A**nti-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 should be ~~are~~ removed or reduced, whilst retaining maximum nutrient value.

5.1.5 Vitamins and Minerals

All added vitamins ~~and minerals~~ must be in accordance with the [~~[~~principles of~~]~~ *Advisory Lists of Nutrient Compounds for use in Foods for Special Dietary Uses Intended for Infants and Young Children* (CXG 10-1979). **Examples of minerals for RUTF can be found in WHO Management of severe Malnutrition: a manual for physicians and other senior health workers (1999).**

5.2 Other Ingredients

5.2.1 [Available] Carbohydrates[1]

The palatability of the RUTF can be increased by the addition of [~~appropriate~~] available carbohydrates.

[Available] 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.*

[1][Sucrose, plant ~~vegetable~~ starch, [~~[~~maltodextrin~~]~~, glucose, glucose syrup] should be the preferred carbohydrates in RUTF. **[**Fructose and corn syrup as ingredients should **[not be used] OR [**be avoided**]** in RUTF, because of potential adverse effects in SAM children.**]** Only precooked and/or gelatinised starches [gluten-free] by nature may be added]. **[Any carbohydrate added for sweetness should be used sparingly.]**

Appendix VI

PROPOSED DRAFT CONDITIONS FOR A "FREE" OF TRANS FATTY ACIDS (TFAs) CLAIM IN THE *GUIDELINES FOR USE OF NUTRITION AND HEALTH CLAIMS* (CXG 23-1997)[1]

(for comments at Step 3)

Component	Claim	Conditions (not more than)
Trans fatty acids	Free	1 g per 100 g of fat And must meet the conditions for "low" in saturated fats[2]

[1] To be inserted between Saturated Fat and Cholesterol within the Table of conditions for nutrient content claims in the *Guidelines for Use of Nutrition and Health Claims* (CXG 23-1997)

[2] As per the Table conditions for nutrient content claims in the *Guidelines for Use of Nutrition and Health Claims*, the conditions for "low" in saturated fats are as follows: 1.5 g saturated fat per 100 g (solids), 0.75 g saturated fat per 100 mL (liquids) and 10% of energy of saturated fat.

Appendix VII

METHODS OF ANALYSIS FOR PROVISIONS IN THE *STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS*

(CXS 72-1981)

(for endorsement by CCMAS)

Commodity	**Provision**	**Method**	**Principle**	**Proposed Type**
Infant Formula	Biotin	EN 15607	HPLC	**II III**
		AOAC 2016.02	**HPLC**	**II**
	Vitamin D	AOAC 992.26	HPLC	III
		EN 12821	HPLC	**II III**
		AOAC 995.05	HPLC	III
		AOAC 2016.05 | ISO DIS 20636	**LC-MS**	**II**
	Chloride	AOAC 986.26	Potentiometry	III
		AOAC 2016.03 | ISO DIS 21422 | IDF 242	**Potentiometry**	**II**