

## INTRODUCTION

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

## OPENING OF THE SESSION

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

## Division of competence<sup>1</sup>

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

## ADOPTION OF THE AGENDA (Agenda Item 1)<sup>2</sup>

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

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

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

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

<sup>2</sup> CX/NFSDU 21/42/1

<sup>3</sup> CX/NFSDU 21/42/2

to improve work management of the Committee to ensure continued timeliness of working documents.

#### **MATTERS OF INTEREST ARISING FROM FAO AND WHO (Agenda Item 3)<sup>4</sup>**

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

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

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

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<sup>4</sup> CX/FNFSDU 21/42/3

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

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

**Recommendation 3 (Purity requirements)**

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

**Recommendation 4 (Vitamin Compounds and Mineral Salts)**

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

**Recommendation 5 (Consistency and Particle Size)**

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

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

**Recommendation 6 (Specific prohibitions)**

23. CCNFSDU endorsed the recommendation to retain the current provision for both Sections A and B.

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

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

**Recommendation 9 (Carry-over principle)**

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

**Recommendation 10 (Flavourings)**

28. CCNFSDU noted divergent views expressed by delegations on the provision for flavourings.
29. Those Delegations objecting to the addition of flavourings to the products covered by Sections A and B indicated that:
- these products replaced the liquid part of a diet and were considered as breastmilk substitutes in some countries; therefore, the provision on flavourings should be aligned to that in CXS 72-1981;
  - flavourings could cause infants to develop a preference for sweet-tasting foods, which could have a negative effect on food choices and could cause negative consequences throughout a child's life and into adulthood;
  - WHA resolution 69.9 provided guidance on ending the inappropriate promotion of foods for infants and young children. The addition of flavorings would increase the sweetness of the product, which would encourage care-givers to use these products; and
  - there was no technological justification for the use of flavourings in these products targeted at the vulnerable group.
30. Delegations supporting the use of flavourings in products described under Section B only were of the view that:
- the product in Section B should not be considered as a breastmilk substitute;
  - the product in Section B was consumed by children who were being exposed to many different flavourings as they began to eat family foods and therefore there was no need to limit the use of flavourings for that age group;

- flavourings are not sweeteners and they were not supposed to add sweet taste; and
- there was no scientific evidence to support the restriction of the use of flavourings.; Allowing flavourings to be used could be of benefit by way of having the better foods accepted by young children.

31. One Delegation suggested that the provision for flavourings in both Sections A and B should be determined by national or regional authorities.
32. The Representative of WHO highlighted their concern on inclusion of the provision for flavouring in both Sections A and B as WHO considered these products as breastmilk substitutes and there was no technological justification for their addition.
33. Questions on whether vanilla was a natural or synthetic flavouring, whether natural fruit extracts were too broad to be included and whether all the listed flavourings had been evaluated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) were raised.
34. The Codex Secretariat clarified that the listed flavourings were currently included in CXS 156-1987 which implied that these flavourings had been endorsed by CCFA. When endorsing these provisions, CCFA would have taken JECFA's evaluation into account and there should be no safety concerns.
35. CCNFSDU agreed with the Chairperson's proposal to concentrate on the discussion of flavourings in Section A followed by Section B.

#### Discussion on Recommendation 10a (Flavourings in Section A)

36. In view of the wide support on prohibiting the use of flavourings in Section A since the products covered by this section function as breastmilk substitutes, the Chairperson proposed to follow the approach in CXS 72-1981 i.e. not including the flavouring provision in the standard.
37. Some Delegations supported the Chairperson's proposal as it was a normal practice in Codex standards while others were of the view that a prohibition statement should be included under the provision for flavourings in order to avoid confusion and furthermore, the same statement should consequently also be inserted in CXS 72-1981.

#### **Conclusion on recommendation 10a (Flavourings in Section A)**

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

#### Discussion on Recommendation 10b (Flavourings in Section B)

40. Taking into account the divergent views on this provision, a proposal was made to add a footnote to explain whether flavourings were allowed or not should be determined at national or regional level as this would allow the relevant authorities who considered the product a breastmilk substitute or who had other concerns, to prohibit or restrict the use of flavourings.
41. There continued to be opposing views on the use of flavourings with delegations reiterating their objection on the use of flavourings in the product and stressing that they were not in agreement with the proposal and while other delegations stating that they could accept the footnote in the spirit of compromise, noting that similar footnotes had been utilized in other parts of the standard.
42. One Observer highlighted that it was not necessary to insert the footnote, and indicated that CCFA had been making efforts to remove a similar note (i.e. Note 161) in the GSFA and these provisions should be considered by CCFA.

#### **Conclusion on Recommendation 10b (Flavourings in Section B)**

43. CCNFSDU endorsed the recommendation proposed by the EWG with the insertion of a footnote as follows:  
*"National and/or regional authorities may restrict or prohibit the use of the listed flavourings."*
44. CCNFSDU noted the reservation of Mexico on permitting the use of flavourings in the product.

**Recommendation 11 (Contaminants)**

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

**Recommendation 12 (Hygiene)**

46. CCNFSDU agreed to:
- the recommendation as proposed for both Sections A and B; and
  - the inclusion of the two additional Codex codes of practice (i.e. the *Code of Hygienic Practice for Aseptically Processed and Packaged Low-acid Foods* (CXC 40-1993) and the *Code of Hygienic Practice for Low and Acidified Low-acid Canned Foods* (CXC 23-1979)) in both Sections A and B since there were products available in liquid form and commercially sterilized.

**Recommendation 13 (Packaging)**

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

**Recommendation 14 (Fill of containers)**

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

**Recommendation 15 (Method of analysis and sampling)**

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

**Conclusion**

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

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

52. The Chairperson introduced the item and recalled that CCNFSDU<sup>41</sup> had advanced the scope, description and labelling for drink/product for young children with added nutrients or drink for young children to CAC43 for adoption at Step 5; that CAC43 had adopted the text and advanced it to Step 6 for comments and further consideration at Step 7 by CCNFSDU<sup>42</sup>. The Chairperson further recalled that the aforementioned text

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

was a result of constructive discussion at CCNFSDU41 and that the only part that remained for further discussion was Section 2.1.1. CCNFSDU41 had agreed that an EWG chaired by New Zealand and co-chaired by France and Indonesia would finalise the definition of drink/product for young children with added nutrients or drink for young children and provide proposals for consideration by this session. She also noted that CCFL had endorsed the labelling provisions and had requested CCNFSDU to consider whether exclusion of the term “product” in the name for “drink for young children” was an omission (see CX/NFSDU 21/42 /2).

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

**Product Definition: Section 2.1.1**

54. New Zealand, as Chair of the EWG, introduced the report of the EWG and its recommendations for the definition. She recalled that there had been considerable discussion on the definition over several rounds in the course of the discussions in the various EWGs and that numerous options had been considered over the years. She reported that the EWG had not agreed upon a single option but had proposed 2 options for consideration by the session. She further reminded the Committee that while there might be several name options for countries to choose from, there would only be one definition for the Standard.
55. The Chairperson noted that there were diverse views on the definition as reflected by the comments received to CL 2021/54-NFSDU and in order to progress, one option would need to be decided upon. She proposed that the Committee consider whether the text in square brackets provided any meaningful addition to defining the product. She further reminded the Committee that the definition was to describe the product covered by the standard and was not to be confused with the information on the label or information to be provided in any other way to consumers.

Discussion

56. There was general support for option 2 (deletion of the following text in square brackets “*which may contribute to the nutritional needs of young children*”).
57. Those delegations in favour of this option expressed the view that:
- the additional text was not a meaningful addition and that the purpose and target population was already covered in the text of the definition;
  - option 2 could be supported because when taken in context with the introduction to the section on composition (i.e. section 3.1.1 more clarity about the nature of the product is provided).
58. A proposal to further amend section 2.1.1 to distinguish the product in question from other products used as drinks by this age group by the addition of a phrase “*which has been produced according to the compositional requirements laid down in this Standard*” was not agreed to. The Chairperson noted that it was self-evident that all requirements within the standard, including the compositional requirements should be complied with.
59. Those delegations in favour of option 1 (acceptance of the text in square brackets “*which may contribute to the nutritional needs of young children*”), expressed the following views:
- Dietary guidelines recommend the consumption of milk by children of all age groups; and therefore, nutritious milk should be made available. A clear definition was important to serve as information to consumers as well as to emphasize to manufacturers that nutritious milk products should be made available.
  - The product can contribute to the nutritional needs of young children when they make the transition to the family diet. A clear definition would help to clarify the meaning of the standard.
60. Two observers further noted that while their preference was for option 2, they were of the view that these products were not necessary and this should be reflected in the definition. Furthermore, in their view, the addition of nutrients was often used for the promotion of these products.

### Conclusion

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

### **Labelling: Section 9.1.2**

62. CCNFSDU recalled that CCNFSDU41 had agreed on the names as presented in Section 9.1.2 and the only matter for consideration was the question from CCFL on whether the term “product” was an omission.
63. The Chairperson noted that, in addition, a question had come up on the interpretation of the slash (/) in the name option i.e. Drink/Product for young children with added nutrients
64. The Codex Secretariat clarified that normally the use of a slash (/) between terms means “or” and that such terms could be used interchangeably thus giving different options. In order to avoid ambiguity, the Codex Secretariat proposed to remove the slash (/) and to refer to “Drink for young children with added nutrients” and “Product for young children with added nutrients”.
65. CCNFSDU42 therefore agreed to write out all the name options for purposes of clarity and to avoid ambiguity and in addition, agreed to include also an additional name option: “*product for young children*”, for consistency with the other name option “product for young children with added nutrients”. CCNFSDU also noted that if the name options provided were not deemed satisfactory by a country or region, any other more appropriate designation indicating the true nature of the product could be used as described in this provision.
66. In response to a proposal to include a statement that countries and regions can allow only one of the names to be used on their territory, it was clarified that the standard should be read in conjunction with the *General Standard for the Labelling of Prepackaged Foods* (CXS1-1985) and that Section 4.1.1.1 of CXS 1-1985 addressed this issue. CCNFSDU therefore did not take up this proposal.

### Conclusion

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

### **General Conclusion**

68. CCNFSDU42 agreed:
- i. that all outstanding points had been addressed, and to hold the scope, description and labelling of Section B at Step 7 (Appendix III) until all other sections of the Standard were completed in order to advance the entire Standard to CAC for adoption; and
  - ii. to inform CCFL of the decision on Section 9.1.2.

### **DRAFT SCOPE, DESCRIPTION AND LABELLING FOR FOLLOW-UP FORMULA FOR OLDER INFANTS (Agenda Item 4c)<sup>7</sup>**

69. CCNSDU recalled that CCNFSDU41 had agreed on the text for the scope, description and labelling for follow-up formula for older infants and to hold it at Step 7, and to send the labelling provision in Section 9.6.5 to CCFL46 for endorsement. Noting that CCFL46 had endorsed the provision, and an editorial change to Section 9.1.2 made in session, all issues related to this item were addressed and no further discussion was necessary.

### **Conclusion**

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

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<sup>7</sup> REP20/NFSDU, Appendix II



**ESSENTIAL COMPOSITION REQUIREMENTS FOR FOLLOW-UP FORMULA FOR OLDER INFANTS AND DRINK/PRODUCT FOR YOUNG CHILDREN WITH ADDED NUTRIENTS OR DRINK FOR YOUNG CHILDREN (Agenda Item 4d)<sup>8</sup>**

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

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

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

Conclusion

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

**Section B: Footnote 5 (Available Carbohydrates)**

77. CCNFSDU recalled that at CCNFSDU41, the following compromise text was agreed *“for products based on non-milk protein, carbohydrate sources that have no contribution to sweet taste should be preferred and in no case be sweeter than lactose.”*
78. CCNFSDU41 had also agreed to ask CCMAS whether there were internationally validated methods to measure sweetness of carbohydrate sources for these products.
79. CCMAS41 had considered this question and had replied that there were no known validated methods to measure sweetness of carbohydrate sources and therefore there was no method to determine compliance with the proposed provision currently contained in the essential composition requirements of Section B.
80. CCNFSDU was therefore requested to consider the implications of this reply from CCMAS.

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<sup>8</sup> REP20/NFSDU, Appendix III (Parts A and B); CX/NFSDU 21/42/5

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

#### Discussion

85. The following views were expressed in favour of retaining the footnote:
- it was important to limit additional sweet tasting ingredients in the product as taste preferences were strongly influenced during the life stage of the targeted age group and might lead to overweight, obesity and non-communicable diseases later in life. Even though there were no current validated methods, this could change in future;
  - the paired-comparison sensory test, ISO 5495, could be applied and would allow manufacturers to exclude carbohydrate sources (ingredients) that are sweeter than lactose;
  - that each country could decide to use their own method(s) for enforcement of the provision until an internationally validated method became available. This decision did not lie with CCMAS, but with CCNFSDU.
86. The following views were expressed in favour of deletion of the provision:
- there were already sufficient safeguards to limit the sweetness since the footnote limited mono- and disaccharides other than lactose to no more than 2.5g/100kcal and addition of fructose and sucrose was not allowed;
  - there were no validated methods it would be difficult to apply the standard and adopt it into national standards or national legislation;
  - even if methods were available, they were not internationally validated and would not produce any reliability or reproducibility which was a requirement for methods of analysis in Codex and therefore from an enforceability point of view, it was not feasible to retain the provision;
  - there were no known validated methods for evaluation of sweetness of finished products or ingredients that would apply to enforcement of the provision. Sensory methods were highly variable and subjective and would not meet the specific requirements for validating methods. Standards development organisations had already invested a great deal of research in this area.
87. The Observer from ISO, referring to CRD 6 (written jointly by AOAC, IDF and ISO), noted that there were no known validated methods to measure sweetness of carbohydrate sources in the product in question and to compare it to the sweetness of a product with lactose only and therefore there was no way to determine compliance for such a provision.
88. As there was no direct method, the idea proposed in CRD 22 by Switzerland would be to make a comparison of the sweetness between 2 ingredients (lactose and other carbohydrate sources), however the question to CCMAS was not raised like that.

89. The Observer from ISO noted that there were some ISO methods to do a comparison (although the quoted method ISO 5495 may not be the most appropriate).
90. The Observer further clarified that it was possible to compare the sweetness of lactose with the sweetness of another carbohydrate source, but only if this carbohydrate source is alone, diluted in water. If this carbohydrate source is in a finished product (e.g. follow-up formula), the sweetness would be modified by the other ingredients and it would not be possible to measure it anymore nor to compare it to the sweetness of lactose.
91. Noting the reply from the Observer from ISO that on an ingredient level there might be methods that could be used to measure sweetness of a given ingredient, the Chairperson proposed that the provision be retained and that at the next session, further consideration should be given to identifying appropriate methods for possible submission to CCMAS. She further noted that it was preferable, but not a requirement, that a method(s) should be endorsed by CCMAS and included in CXS 234-1999 so that a common method can be used to enforce the provision.
92. Those Delegations in favour of the removal of the provision continued to support its deletion and questioned whether the proposal of the Chairperson would affect the advancement of the Standard.
93. The Codex Secretariat clarified that as also mentioned at CCNFSDU41 generally questions on methods of analysis should not prevent the progress of a Standard nor its adoption. The Codex Secretariat also clarified that although methods recommended by Codex normally refer to the finished product, they could also refer to ingredients.

#### Conclusion

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

#### **Other matters**

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

#### Conclusion

96. CCNFSDU agreed to the offer by New Zealand to prepare a discussion paper on structure and preamble and to circulate the paper for comments through a CL well in advance of the next session.

#### **Conclusion**

97. CCNFSDU agreed that:
- i. All matters related to this item had been addressed; and that the question of appropriate methods of analysis for measuring sweetness of carbohydrate sources in footnote 5 associated with available carbohydrates of Section B would be considered by CCNFSDU43; and
  - ii. CCNFSDU43 would consider the preamble and structure of the Standard based on a discussion paper to be prepared by New Zealand.

#### **DRAFT GUIDELINES FOR READY-TO-USE THERAPEUTIC FOODS (Agenda Item 5)<sup>9</sup>**

98. The Chairperson recalled that CCNFSDU41 agreed to forward the Guidelines for Ready-to-Use Therapeutic Foods (RUTF) to Step 5 for adoption by CAC43, and that the following issues remained unresolved i.e. the preamble, and the compositional requirement for the essential fatty acids and magnesium. Besides these issues, CCFL had also requested CCNFSDU to consider whether the *Guidelines for Use of Nutrition and Health Claims* (CXG 23-1997) were relevant to the labelling of RUTF as

<sup>9</sup> REP20/NFSDU, Appendix VI; CX/CCNFSDU 21/42/6.

pointed out under Agenda Item 2. She invited the Committee to consider the aforementioned issues with a view to submit the Guidelines to CAC for adoption at Step 8.

99. CCNFSDU noted that at its previous session, there was no electronic working group (EWG) established to do further work on guidelines for RUTF. Following the rescheduling of CCNFSDU42 in 2020, the previous EWG Chair and Co-Chair (South Africa and Uganda, respectively) undertook informal consultations with members and observers on outstanding issues as well as the comments submitted at Step 6.

#### Preamble

100. South Africa, speaking as the former EWG Chair, introduced CRD3 and explained that the Chair and Co-Chair of the EWG together with FAO, WHO and the Codex Secretariat had revised the preamble taking into account the previous decision of CCNFSDU41 to keep it simple, yet understandable and to cover the following important aspects: the basic composition of the product; target age group; that RUTF is a recommended option of dietary management of children aged 6 – 59 months with severe acute malnutrition (SAM) without medical complications; the latter concept recognizes that RUTF is one of the dietary management options thus allowing for the use of RUTF in conjunction with other local family foods.
101. In addition, the advice of CCEXEC75 on referencing WHO/WHA documents; and CCEXEC78 on references to other standards setting organisations was taken into account, it was therefore proposed to omit the footnote and refer to the actual text of the Joint Statement of WHO, WFP UNSCN<sup>10</sup> and UNICEF as this sets the framework for the guidelines on RUTF. This would ensure a minimum number of references that would require life-long monitoring.
102. Furthermore, CRD 3 also recognized the inclusion of provisions related to the promotion of breastfeeding in Section 12.4 (labelling) of the draft guidelines on RUTF. It was also explained that RUTF is quoted as a food for special medical purposes (FSMP) in the general part of the guidelines and as such, the product is prohibited from being advertised.
103. The Chairperson clarified that the preamble sets the scene by providing the overall context of the Guidelines and does not specify any product requirements, which are found within the main body of the Guidelines.
104. The Codex Secretariat further clarified that the preamble should not address matters outside the scope of Codex and the Guidelines, and that discussion on the preamble should be guided by the *General Principles of the Codex Alimentarius* and in particular, drew the attention of the Committee to Section 3 of the Principles: *Nature of Codex Standards*: that stated that Codex standards and related texts were not a substitute for, or alternative to national legislation and as such, every country's laws and administrative procedures contain provision with which it is essential to comply. Thus issues not addressed in the Guidelines were still subject to countries' laws and requirements.

#### **Discussion**

105. CCNFSDU held a brief discussion and noted the following proposals/issues put forward by delegations that the preamble should clearly cover:
- RUTF is one of the options for the dietary management of children with uncomplicated SAM from 6-59 months without medical complications; and these are therapeutic products that should be used for a short period, before transitioning back to local foods. The efficacy of RUTF should be demonstrated by scientific evidence.
  - Use of local foods to address SAM should be promoted and should be the preferred option over the use of commercially manufactured RUTF. The use of RUTF should be in specific situations of food insecurity when local food production is insufficient, water supply is inadequate or inaccessible or under emergency situations.
  - The use of RUTF should not undermine national nutrition programmes, for example continuation of breastfeeding; psychosocial support for recovery among others. As such, the product should neither be advertised/promoted nor be for direct retail sale.

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<sup>10</sup> In 2020, the United Nations System Standing Committee on Nutrition (UNSCN) and the UN Network for SUN (UNN) merged to form a new entity, called UN Nutrition

- The footnote referencing the WHO International Code of Marketing of Breast-milk Substitutes (1981) and the relevant WHA resolutions' especially on ending the inappropriate marketing of food for infants and young children should be retained. Similarly, reference to national nutritional policies should be included in the preamble.

106. CCNFSDU supported the revised and simplified preamble and agreed:

- a) To its further revision to clearly take into account concepts such as: the promotion of continuation of breastfeeding, transition to nutritious family food; psycho-social support for recovery; the use of locally based foods; RUTF is not for general retail sale.
- b) To the proposal to omit the footnote and instead make direct reference to the actual text in the 2007 Joint Statement of WHO, WFP, UNSCN, and UNICEF which essentially sets the framework for the Guidelines on RUTF. This approach was considered consistent with the advice of CCEXEC75 and CCEXEC78.
- c) That the concepts and technical information in other reference documents, previously stated in the footnote had already been incorporated into the text of the Guidelines and there was a need to keep the references to a minimum as advised by CCEXEC.

## **Conclusion**

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

### Section 6.3 Lipids

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

### Essential fatty acids (EFA)

109. The former EWG Chair informed the Committee that informal consultations that were undertaken to progress the discussions on the values for the draft provisions for essential fatty acids (i.e. n-3 and n-6 fatty acids), were not conclusive due to a limited number of responses received. However, from the consultations, a number of concerns were raised including: limited available scientific data on quality of raw materials; the need for product stability shelf-life tests due to change in formulation; and cost implications due to changes in the formulation. She mentioned that an analysis of the comments in reply to the Circular Letter (CL 2019/78-NFSDU) had also been undertaken, and the majority of the responses were in favour of retaining the values stated in the 2007 joint statement of WHO, WFP, UNSCN, and UNICEF. There was also a proposal that favoured the maximum value for n-6 fatty acids being set at 780 mg/100kcal, with the minimum value for n-3 fatty acids being set at 110 mg/100 kcal.
110. The Representative of WHO stated that WHO had commissioned a systematic review to assess if the provision of RUTF with fatty acid profiles that are different from specifications in the Joint Statement improve outcomes such as neurodevelopment in children aged 6 months or older recovering from severe wasting with a view to contribute to progressing the discussions on the EFA values, and highlighted the outcomes which indicated that: 1) adding DHA or using oleic acid to increase ALA and reduce LA content may confer some benefits to neurodevelopment, but the evidence is not strong enough to suggest that this change will have substantial benefits or harms, and 2) the evidence also does not allow for determination of definite amounts of ALA and LA in RUTF was based on.
111. The Representative further noted that the systematic review outcomes were those of the evidence review conducted based on the most recently available evidence to date, and not WHO recommendations as such. WHO was aware of some concerns expressed regarding the specifications of RUTF which are based on the 2007 Joint Statement and therefore, WHO was discussing about possibly undertaking WHO's internal guideline development process to review further the specifications of RUTF including EFA content, also taking into consideration of on-going WHO guideline development on PUFA intake. The Representative stated that WHO would inform the Committee when and as WHO recommendations become available so that the Committee could consider the updating of the values of the guideline as required.
112. An Observer highlighted the importance of n-6 and n-3 polyunsaturated fatty acids in cognitive recovery, and rapid growth that ensues during and after treatment in infants and children have been affected by

severe wasting. The proposed maximum values of 1111 mg/100 kcal for n-6 fatty acids and the minimum values of 33 mg/100 kcal for n-3 fatty acids derived from the 2007 Joint Statement were not based on scientific evidence but rather on an expert review. Since 2007, there had been advances in science on RUTF and the most recent findings of a trial conducted in Malawi that demonstrated developmental improvement and cognitive benefits in children with SAM six months after treatment with an adjusted formula RUTF containing lower n-6 fatty acids, higher n-3 fatty acids and added DHA, when compared to children who received standard RUTF.. Based on the outcome of this trial, the Observer recommended that CCNFSDU consider reducing the maximum values for n-6 fatty acids to 780 mg/100kcal or 800 mg/100kcal and increasing the minimum values of n-3 fatty acids to 110 mg /100 kcal to enable endogenous production of n-3- fatty acids which are important for the brain and the eye.

113. CCNFSDU noted the general support for the levels proposed by the Observer. .

### **Conclusion**

114. CCNFSDU agreed to decrease the maximum value for n-6 fatty acids to 780 mg/100 kcal and increase the minimum value for n-3 fatty acids to 110 mg/100 kcal.

### Magnesium

115. The former EWG Chair, reported that in the informal discussions there was no consensus on both the minimum and maximum values for magnesium; however, from an analysis of the comments in reply to CL 2019/78-NFSDU, there seemed to be majority support for the retention of the current minimum and maximum values of 15 mg/100 kcal and 45 mg/100 kcal respectively as laid down in the 2007 Joint Statement.
116. A Delegation supported an increase of both the minimum and maximum values for magnesium to 30mg/100 kcal and 90mg/100kcal respectively, noting that this corresponding increase will allow for a favourable ratio between calcium, phosphorous and magnesium and lead to better absorption of both calcium and phosphorous to support catch-up bone growth.
117. An Observer reiterated their concern expressed at CCNFSDU41 over the high ratio of calcium to magnesium as well as over the generally low minimum and maximum levels being set for magnesium, noting that extensive science supporting higher levels exists and had been previously submitted to the Committee.

### **Conclusion**

118. CCNFSDU42 agreed to maintain the proposed values of the minimum and maximum values for magnesium of 15mg/100kcal and 45mg/100kcal respectively in line with the 2007 Joint Statement.

### Section 12- Labelling reference to Claims

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

### Others

120. The Representative of WHO stated that WHO had commissioned a systematic review to assess if the provision of RUTF with higher iron content compared with standard RUTF improves outcomes such as blood haemoglobin, and iron deficiency, and highlighted the outcomes which indicated that: 1) there is rationale to increase the content of iron in RUTF to prevent iron deficiency; and 2) the available evidence is not adequate to determine the optimal content of iron in RUTF.
121. An Observer expressed concern about increasing the content of iron in RUTF noting that the absorption and utilization of added iron in food products was rather low. The impact of the high content of iron are unclear especially on the microbiome of older infants and young children in regard to the immunological development and immunological capacity.

122. The Representative of WHO explained that when setting up the systematic reviews, one of the focus areas was to assess adverse effects of high iron levels in RUTF on children, but the studies used in the systematic review did not report on any of these outcomes. Future studies should look into adverse effects of iron dosages are increased in RUTF.
123. CCNFSDU noted that all the remaining issues had been addressed and that there were no further comments on other parts of the Guidelines, CCNFSDU agreed to the entire text and noted that the Guidelines were therefore ready to be advanced to Step 8.

### **General Conclusion**

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

### **GENERAL PRINCIPLES FOR THE ESTABLISHMENT OF NRVs-R FOR PERSONS AGED 6-36 MONTHS (Agenda Item 6)<sup>11</sup>**

125. Ireland, as Chair of the EWG, and speaking also on behalf of the Co-Chairs, USA and Costa Rica, introduced the item and provided a summary of the work of the EWG as presented in CX/NFSDU 21/42/7.
126. The EWG Chair recalled that the development of the General Principles for the establishment of NRVs-R required the assessment of the most appropriate approach to derive NRVs-R for the age group of 6 to 36 months. This involved the analysis of dietary intake reference values (DIRVs) from FAO, WHO and the 6 RASBs for which the EWG had sought scientific advice to assist with this particular task as agreed to by CCNFSDU. To assist in this regard, FAO commissioned a review of derivation methods for DIRVs for older infants and young children. The EWG Chair briefly introduced the FAO final draft scientific report on the *Review of derivation methods for dietary intake reference values for older infants and young children* as available on the CCNFSDU42meeting webpage and indicated that this would greatly assist the EWG in the further development of the General Principles and in particular the establishment of NRVs-R. She further noted that the report identified 25 nutrients for this age group, including sodium, and that the addition of this particular nutrient would need further consideration by CCNFSDU. As the report became available in July 2021, the EWG could not consider its findings, but the findings were considered by the Chairs of the EWG to develop the proposal for the General Principles in CX/NFSDU 21/42/7. The EWG Chair drew the attention of CCNFSDU to CRD12 which assessed comments submitted in reply to CL 2021/56-NFSDU and proposed revised General Principles for consideration by CCNFSDU.
127. The Chairperson, supported by the EWG Chair, advised to take CRD12 as the basis for discussion to aid progress in the EWG. CCNFSDU agreed with this recommendation and proceeded with the consideration of the General Principles as laid down in Appendix I to CRD12. The Chairperson clarified that comments submitted would be forwarded to the EWG for further consideration in reviewing the General Principles for this age group and that no specific changes would be made to the text at the Session.

### General comments

128. A Delegation noted that the Annex on *General Principles for the Establishment of NRVs for the General Population* in the *Guidelines on Nutrition Labelling* (CXG 2-1985) should be retained to the extent possible and, when necessary, be adjusted to include specific requirements for other population groups such as persons aged 6-36 months.
129. This Delegation supported the approach that NRVs-R should be based on DIRVs derived using the most rigorous scientific method available, however, the ranking of such methods should not only be based on scientific rigour but should consider other relevant factors such as data quality, strength of evidence as well as more recent and independent review of the scientific evidence when deciding on the most suitable method for the derivation of NRVs-R. The current text seemed to place more weight on the scientific rigour

<sup>11</sup> CX/NFSDU 21/42/7; CL 2021/56-NFSDU, CX/NFSDU 21/42/7-Add.1

as opposed to a combined consideration of this and other relevant factors that might determine the final selection of the most suitable DIRVs for the derivation of NRVs-R for this age group.

130. The Delegation further noted that such ranking should not apply to FAO and WHO DIRVs, as FAO/WHO were the primary source of scientific advice to CCNFSDU and their values should be taken without comment. Only when there were no values available from them, data and information from RASBs should be considered for the establishment of NRVs-R. This should be reflected in the General Principles.

#### Specific comments

##### Section 1 - Preamble

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

##### Section 2 - Definitions

135. The Chairperson noted that this section was drafted in such a way to complement the corresponding section in the General Principles for the general population and, in this regard, consideration could be given to include the definition for Adequate intake (AI) in the General Principles for the general population as it could be relevant for both population groups.
136. A Delegation noted it would be advisable to keep the General Principles for the general population unchanged since the General Principles for the general population and the values derived according to these principles for this population group were interrelated and had been already agreed. If any future review were undertaken, there would be scope to look into the General Principles and its values and at that point to adapt and revise them.
137. Another Delegation noted that the definition for AI was only used in the table with the ranking of the derivation methods and questioned whether there was a need to have this level of detail in the General Principles. It was further noted that if provisions in Section 3 were simplified, this definition might not be required.

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

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

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

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



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

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

140. The Chairperson invited the EWG Chair to provide background and rationale for the table in this Section.
141. The EWG Chair introduced section 3.2.1 and confirmed that the proposed table provided a ranking of derivation methods to establish NRVs-R which were applicable to all values that might be available, i.e. FAO, WHO and the 6 RASBs, with the primary source being FAO and WHO followed by the RASBs.
142. The EWG Chair further explained that, based on the feedback in reply to CL 2021/56-NFSDU, there was general support for the proposed 3 ranking categories, and this was also consistent with the FAO scientific report. However, following concerns were expressed by respondents to the CL:
- a) The limited available time to consider the findings of the FAO Scientific Report taking into account how such findings related to the different nutrients. The EWG chair indicated that, when choosing the values for NRVs-R, each nutrients would be examined on a case-by-case basis, and this approach would provide time to consider the issues in the scientific report relevant to each nutrient.
  - b) the inclusion of the ranking of methods which were not included in the General Principles for the general population although the same methods were used to derive the NRVs-R for this population group. The EWG noted that such inclusion was necessary to establish NRVs-R for the population aged from 6 to 36 months in view of the limited scientific evidence available for this age group. There was more diversity and evidence in approaches used to establish DIRVs for this age group which required a more detailed categorization and ranking of derivation methods as described in the FAO scientific report.
143. The EWG Chair also indicated that the EWG Co-Chairs would work closely with FAO and WHO to avoid duplication of efforts in establishing NRVs-R for the population aged from 6 to 36 months considering the ongoing FAO/WHO review of nutrients requirements for this age group.
144. In addition, the EWG Chair noted that NRVs-R for many nutrients for this age group would be extrapolated down from older age groups (general population). She stressed the need to ensure that the values reflected relative differences in nutrient requirements to keep consistency between the two population group (i.e. general population and persons aged from 6 to 36 months) and that the FAO scientific report would assist in this endeavour.
145. The EWG Chair therefore supported the inclusion of the table at this stage as providing relevant guidance for the establishment the NRVs-R for persons aged from 6 to 36 months; that the basis for the selection of NRVs-R should be scientific rigour with the aim to identify the most suitable method from the ranked methods; and that the concerns expressed above could be further addressed in the EWG in the further development of the General Principles.
146. CCNFSDU noted the following comments with regard to this Section:
147. A Delegation reiterated its view that the relevant DIRVs provided by FAO/WHO that were based on a recent review of the science should be taken into account as primary sources to establish NRVs-R. She further stated that relevant DIRVs reflecting independent recent review of the science from RASBs could also be taken into account but only when such data were not available from the parent organizations as the body providing global DIRVs that should not be ranked against national or regional values which was consistent with the Section 3.1 and the principles for the general population. This delegation further noted that CCNFSDU should not decide whether FAO or WHO DIRVs had less scientific rigour than those from national or regional RASBs and Section 3.2 should be amended accordingly to reflect that the selection and priority of derivation methods for the establishment of NRVs-R should only apply to values available from RASBs. This view was supported by an Observer who further proposed that wording should also be inserted in section 3.2.1.1 regarding ensuring no conflict of interest.
148. Following on this intervention, the EWG Co-Chair indicated that the FAO/WHO values might not be the most recent ones to establish NRVs-R for the population group aged from 6 to 36 months and that FAO/WHO was undertaking an evidence-based review of their DIRVs to update them which would take some time to complete. He further noted that there were DIRVs based on a more recent assessment of the scientific evidence available from the RASBs and therefore, it might be necessary to apply the same

scientific rigour to both FAO/WHO and RASBs datasets to determine the most suitable values that could be taken by CCNFSDU to derive the NRVs-R for this age group. Having this set of principles would thus allow CCNFSDU to set science-based reference values until updated DIRVs become available from FAO/WHO which was critical for CCNFSDU to provide timely guidance to Codex members.

149. Based on the explanation provided by the EWG Co-chair, other delegations indicated that Section 3.2.1 should be clarified to match the concept in Section 3.1 i.e. that the ranking method was based on scientific rigour and was used only where there was no recent DIRVs from the WHO/FAO so that CCNFSDU could default to the recommendation in Section 3.2.1 when considering the establishment of NRVs-R for the population aged from 6 to 36 months. It was further noted that to this aim, the word “recent” was instrumental in delivering this concept.
150. The Representative of WHO noted that the ranking could be misleading as it might be difficult to determine in practice whether the DIRVs had been derived according to one of the 3 ranking categories defined in the tables. Moreover, in some cases, they might have been derived through combined methods currently ranked in different order of defined proposed scientific rigour. Although the intended aim of the proposed ranking was understood, it would be better not to be described as ranking as the selection of the most appropriate data would vary depending on various elements and conditions of the nature of each nutrient of concern..
151. The EWG Chairs confirmed that the situation varied for the different nutrients and that there would be instances where more than one method could apply to the DIRVs available for these nutrients. However, guidance on methods as shown in the table were needed in order to proceed with work on establishing NRVs-R for persons aged from 6 to 36 months. They further drew the attention of CCNFSDU to Section 3.2.1.1 where additional elements were included to complement the selection of the most suitable method besides the scientific rigour. They emphasized that the ranking of the methods was an attempt to ranking the quality of the data and total science in terms of evidence that would be considered stronger vs evidence that would be considered less strong and stressed the need to work collaboratively with FAO/WHO when addressing nutrients and DIRVs to establish NRVs-R for this age group.

#### Section 3.2.1.1

152. A Delegation while supporting the assessment of the scientific rigour as outlined in Section 3.2.1, noted that other elements such as data quality, strength of the evidence and recent independent review of the science should also be considered on a case-by-case basis when deciding on the most suitable DIRVs for the establishment of NRVs-R by CCNFSDU. This proposal received support from members and observers including FAO and WHO.
153. Based on the above support another paragraph was proposed to for inclusion to this section for further consideration by the EWG:  
*“The NRVs-R should be reviewed on a case-by-case basis. They should be based on evidence derived using Rank 1, 2, or 3 methods, preferably in that order. Equally important as the ranking are the underlying data quality, strength of evidence and being based on a more recent independent review of science which may be taken into account when deriving NRVs-R.”*

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

#### Section 3.2.1.2

155. The Chairperson noted support for the deletion of this section.
156. A Delegation re-emphasized the need to consider NRVs for age subgroups on top of the whole age group, and therefore the principles should allow the establishment of NRVs to address either or both situations in recognition of the different policies and regulations in Codex member countries. A statement should be included to clarify that NRVs-R for persons aged 6 – 36 months can be derived by combining data from

different sources, different ranked methods, different underlying data quality, from different strength of evidence and based on various recent independent reviews of the science.

157. The Chairperson noted that the approach for the establishment of NRVs-R for the age group of 6 to 36 months, e.g. either to establish three sets of values or a single set of combined values, could be further discussed in the EWG to enable CCNFSDU to make a decision on this at a later stage.

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

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

Section 3.3 – Consideration of Upper Levels of Intake

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

Other matters

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

160. The Chairperson drew the attention of CCNFSDU to the proposal in CRD12 which tried to find compromise between those Codex members supporting the approach to integrate the General Principles into the principles for the general population and those supporting a separate annex in the *Guidelines on Nutrition Labelling*.

161. The Chairperson noted general support for this proposal.

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

162. The Chairperson recalled that CCNFSDU had already agreed the list of nutrients including 13 vitamins (Vitamins A, D, C, K and E, thiamine, riboflavin, niacin, vitamins B6 and B12, folate, pantothenic acid and biotin); 10 minerals (calcium, magnesium, iron, zinc, iodine, copper, selenium, manganese, phosphorus and potassium, and protein (but with low priority)). She noted a proposal by the EWG Chair to include sodium in the list of nutrients to be covered in the ongoing work.

163. The EWG Chair informed CCNFSDU that sodium was included in the FAO scientific review report as part of the scientific advice on DIRVs as an important mineral for nutrient declaration especially for processed foods and that limiting the sodium intake for the age group of 6-36 months was important. She however recognized that based on the list of nutrients agreed by CCNFSDU, sodium was not part of the mandate of the EWG.

164. The Chairperson advised that sodium could be addressed at a later stage and this could envisage considerations for the establishment of NRVs-NCD that were excluded from the current work on the General Principles for this age group. This proposal received support from the Committee.

Development of NRVs-R

165. CCNFSDU considered whether the EWG should already consider development of NRVs-R for certain vitamins and minerals. CCNFSDU noted concerns with proceeding with NRVs-R prior to agreement on the General Principles, however, the EWG chair explained that working on NRVs-R in tandem with the finalization of the Principles would help to understand the usefulness of the principles and guide its further elaboration.

166. CCNFSDU therefore agreed that the draft General Principles could be piloted for NRVs-R for certain nutrients.

**Conclusion**

167. CCNFSDU agreed to continue its work on NRVs-R for persons aged 6 – 36 months and to re-establish the EWG, chaired by Ireland, and co-chaired by Costa Rica and the United States of America, working in English and Spanish to:
- a) finalize the General Principles for establishing NRVs-R for persons aged 6 to 36 months including presenting the new structure for Annex 1 in CXG 2-1985, taking account of discussion at the session and any written comments submitted, for circulation for comments and consideration by CCNFSDU43
  - b) To pilot the draft General Principles on the following nutrients: vitamin B12, iodine, vitamin B6, riboflavin and, if time permits, thiamine, niacin and vitamin C.
168. CCNFSDU agreed to keep open the possibility of a Physical Working Group, chaired by Ireland and co-chaired by Costa Rica and the United States of America to meet prior to the next session to consider written comments submitted and prepare a revised proposal for consideration by CCNFSDU43.

**OTHER BUSINESS (Agenda item 7)****Prioritization mechanism to better manage the work of CCNFSDU**

169. The Chairperson recalled that the Host Secretariat had prepared an approach for a prioritization mechanism including possible criteria which had been discussed at CCNFSDU41. CCNFSDU41 agreed to the prioritization mechanism, to start using it on a pilot basis as well as to adjust the framework for the prioritization system as necessary and to conduct a case-by-case review of the proposals submitted by Members in response to CL 2020/30-NFSDU.
170. CCNFSDU42 considered the proposal to establish an EWG to continue developing a framework for the prioritization mechanism and its application to the proposals for new work.
171. CCNFSDU42 agreed to establish an EWG chaired by Germany and co-chaired by Canada, working in English, with the following terms of reference:
- a) Revise the draft guideline for the preliminary assessment and identification of work priorities for CCNFSDU (REP20/NFSDU Appendix IX) as well as the proposed criteria taking into account the written comments received by the CCNFSDU Secretariat (Germany) as well as the comments and decision made at CCNFSDU41 for the development of a long term work prioritization mechanism; and
  - a) Prepare a revised proposed prioritization mechanism for use on a trial basis for consideration by CCNFSDU43.
172. CCNFSDU42 further agreed to:
- a) Request the Codex Secretariat to extend the deadline of the Circular Letter, CL 2020/30-NFSDU, requesting proposals for new work and emerging issues. All new work proposals already received would remain valid and would not need to be re-submitted.
  - b) To reserve the possibility of holding a Physical Working Group (PWG) chaired by Germany and co-chaired by Canada, to meet immediately prior to CCNFSDU43 and conduct a case-by-case review of the emerging issues and proposals for new work submitted by members in response to the Circular Letter.

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

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