



JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Thirty seventh Session

Geneva, Switzerland, 14-18 July 2014

REPORT OF THE THIRTY FIFTH SESSION OF THE CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Bad Soden am Taunus, Germany

4 – 8 November 2013



CL 2013/28-NFSDU
November 2013

TO: Codex Contact Points
Interested International Organizations

FROM: Secretariat, Codex Alimentarius Commission
Joint FAO/WHO Food Standards Programme

SUBJECT: Distribution of the Report of the 35th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (REP14/NFSDU)

The report of the 35th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses will be considered by the 37th Session of the Codex Alimentarius Commission (Geneva, Switzerland, 14-18 July 2014).

MATTERS FOR ADOPTION BY THE 37th SESSION OF THE COMMISSION:

Proposed Draft Standards at Step 5 of the Procedure and for adoption by the Commission

1. Proposed Draft Revision of the Codex General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 9-1987) (para. 79, Appendix II)
2. Proposed Draft Additional or Revised Nutrient Reference Value for Labelling Purposes in the Codex Guidelines on Nutrition Labelling: NRV-R for Protein (para. 35)

Governments and interested international organizations wishing to comment on the above documents should do so in writing, *preferably by e-mail*, to the Secretariat, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Viale delle Terme di Caracalla, 00153 Rome, Italy (e-mail: codex@fao.org; Fax +39 06 570 54593), before **31 March 2014**.

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SUMMARY AND CONCLUSIONS

The 35th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses reached the following conclusions:

Matters for adoption by the 37th Session of the Codex Alimentarius Commission

The Committee:

- advanced to Step 5 the Proposed Draft Revision of the Codex General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 9-1987) (para. 79, Appendix II)
- forwarded the NRV-R for protein to be included in the Codex Guidelines on Nutrition Labelling for adoption (para. 35)

Proposal for New Work

The Committee agreed to submit to the Commission, through the Executive Committee a proposal for new work on:

- Potential NRV for Potassium in Relation to the Risk of NCD (paras 120-121, Appendix III)

Other Matters of Interest to the Commission

The Committee agreed:

- to retain at Step 4 the Review of the Codex Standard for Follow-up Formula (CODEX STAN 156-1987) (para. 109)
- to return to Step 2/3 for redrafting, comments and further discussion at the next session the Proposed Draft Additional or Revised Nutrient Reference Values for Labelling Purposes in the Codex Guidelines on Nutrition Labelling (para. 36); and the Proposed Draft Amendment of the Standard for Processed Cereal-Based Foods for Infants and Young Children (CODEX STAN 74-1981) to include a New Part B for Underweight Children (para. 92)

Matters of Interest to Other Committees and Task Forces

Committee on Food Additives (CCFA)

Note 55 “Singly or in combination, within the limits for sodium, calcium, and potassium specified in the commodity standard” should apply to all relevant provisions, both with numerical levels and at GMP, in the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CODEX STAN 72-1981). (para. 7)

The limits of sodium that applies to certain food additive provisions in the Standard for Canned Baby Foods (CODEX STAN 73-1981) should also apply to the relevant provisions of the *Standard for Processed Cereal-Based Foods for Infants and Young Children* (CODEX STAN 74-1981). (para. 8)

INTRODUCTION

1. The thirty-fifth Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) was held in Bad Soden am Taunus, Germany from 4 to 8 November 2013 at the kind invitation of the Government of Germany. The Session was chaired by Dr Pia Noble, Head of Division of Specific Foods, Food Supplements and Food Additives, Federal Ministry of Food, Agriculture and Consumer Protection. The Committee was attended by 264 delegates representing 67 Member Countries, one Member Organization and 33 International Organizations.

OPENING OF THE SESSION

2. Mr Bernhard Kühnle, Director General of Food Safety, Animal Health of the Federal Ministry of Food, Agriculture and Consumer Protection, Germany opened the Session and welcomed participants. He commended the contribution of CCNFSDU towards the success of Codex work in the last 50 years, especially in supporting the global efforts to address the challenge of underweight and malnutrition in children; hidden hunger as related to chronic undersupply of nutrients; and diet related noncommunicable diseases among others. The Director General finally commended the spirit of compromise existing within the Committee that has enabled timely completion of work and wished delegates fruitful deliberations.

3. In her statement, Mrs Awilo Ochieng Pernet, Vice-Chairperson of Commission, expressed gratitude and appreciation to the Government of Germany for hosting the Committee since 1966. She pointed out that despite the successes scored in the last years 50 years, Codex continue to face the challenge of lack of sufficient funding for scientific advice. Mrs Ochieng thanked FAO, WHO, the Codex Secretariat, Codex Coordinating Committees, National Codex Contact Points, and Host Countries for organizing various events to mark the 50th Anniversary of Codex.

Division of competence¹

4. Following Rule II.5 of the Rules of Procedure of the Codex Alimentarius Commission, the Committee was informed about CRD 3 on the division of competence between the European Union (EU) and its Member States.

ADOPTION OF THE AGENDA (Agenda Item 1)²

5. Under Agenda Item 10 “Other Business”, the Committee agreed to discuss the proposal from the Delegation of Belgium to replace the term “kamut” with “khorasan wheat” in the *Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten*, as “kamut” was registered as a commercial name in several countries. The Committee adopted the Provisional Agenda as its Agenda for the Session.

¹ CRD 3

² CX/NFSDU 13/35/1

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

6. The Committee noted that some matters were only for information and that several matters would be considered under other agenda items.

Recommendations for Provisions in Tables 1 and 2 for Food Additives Listed in Table 3 with “Acidity Regulator” Function and Horizontal Approach for Provisions in Table 1 and 2 for Food Additives Listed in Table 3 with “Emulsifier, Stabilizer and Thickener” Function

7. In response to the request from CCFA in this regard, the Committee clarified that Note 55 “Singly or in combination, within the limits for sodium, calcium, and potassium specified in the commodity standard” should apply to all relevant provisions, both with numerical levels and at GMP, in the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CODEX STAN 72-1981).

8. The Committee further clarified that the limits of sodium that applies to certain food additive provisions in the *Standard for Canned Baby Foods* (CODEX STAN 73-1981) should also apply to the relevant provisions of the *Standard for Processed Cereal-Based Foods for Infants and Young Children* (CODEX STAN 74-1981).

Claim for “free” of Trans Fatty Acids (TFAs)

9. The Committee recalled that CCFL at its last session had agreed to request the Committee to establish conditions for free of TFAs claims. The Committee noted that the outcome of NUGAG was preferable to consider the conditions.

10. The Committee agreed that the Delegation of Canada would draft a proposal for consideration at the next CCNFSDU, taking into consideration the outcome of the next session of NUGAG.

11. The Committee recalled that this work was covered by the project document of the proposal for the establishment of claims for sugars, salt/sodium and trans-fatty acids⁴, which had been approved by the Commission, and thus noted that there was no need to ask for approval to start this work to the Commission.

³ CX/NFSDU 13/35/2; CRD 2 (Comments of European Union); CRD 10 (Comments of African Union); CRD 12 (comments of IDF); CRD 14 (comments of Malaysia)

⁴ ALINORM 10/33/22, Appendix V

MATTERS OF INTEREST ARISING FROM FAO AND WHO (Agenda Item 2b)⁵

12. The Representative of FAO introduced the document CX/NFSDU 13/35/3 and drew the attention of the Committee to several current activities and new publications. The Representative informed the Committee that the report 2011 Dietary Protein Quality Evaluation in Human Nutrition: Report of FAO Expert Consultation as well as two sub-committee reports had been published and were available on the FAO website. As follow up to the consultation FAO was organizing two additional technical working group meetings and the first call for experts was issued in August 2013. These working groups would address the need to improve data on protein quality and the implications of changing from PDCAAS (protein digestibility-corrected amino acid score) to DIAAS (digestible indispensable corrected amino acid score).

13. The Representative also noted that the 2010 Expert Report on Fats and Fatty Acids in Human Nutrition, which had already been available in English and Spanish, would be published in French.

14. The Representative said that at the CCFL in May 2013, FAO and WHO had organized an information session about Front of Pack nutrition labelling, the presentations of which were posted on the FAO and WHO websites⁶.

15. In the context of possible need for scientific advice for the on-going work of the Committee, information was requested about the process and modalities of JEMNU. The Representatives of FAO and WHO reminded the Committee that the detailed process of JEMNU had been explained last year. JEMNU will convene with a request from a Codex or Member States. FAO and WHO will form a joint secretariat to carry out the requested work. The specific scoping of the requested work will be provided by the concerned Codex Committee and based on the identified scope, evidence review through systematic review will be conducted. An expert meeting will then be convened through call for experts and will evaluate the strength of evidence.

16. The Representatives of FAO and WHO highlighted the need for the funds required to carry out the work of JEMNU, as this had been explained to the Committee last year.

⁵ CX/NFSDU 13/35/3

⁶ <http://www.fao.org/ag/humannutrition/foodlabel@185302/en/>;
http://www.who.int/nutrition/events/2013_FAO_WHO_workshop_frontofpack_nutritionlabelling/en/index.html

17. Referring to the document CX/NFSDU 13/35/3, the Representative of WHO highlighted some of the activities which might be of relevance to the on-going work of the Committee. These included the work of the NUGAG Subgroup on Diet and Health (i.e. updating of the guidelines on sugars and fatty acids, in particular saturated fatty acids and trans-fatty acids), completion of the nutrient profiling guiding principle manual and its accompanying catalogue, publishing of nutrition interventions to address obesity and diet-related noncommunicable diseases (NCDs) in WHO e-Library of Evidence for Nutrition Actions (eLENA), inclusion of Code monitoring information in WHO Global Database on the Implementation of Nutrition Action (GINA) as well as the publication of 3 major documents (i.e. Global Nutrition Policy Review, Essential Nutrition Actions and Country Implementation of the Code⁷). The Representative of WHO informed the Committee that the WHO statement on follow-up formula which was issued in July 2013 will be discussed at Agenda 6.

18. The Representative of WHO further highlighted to the Committee some major meetings which had taken place and those that would be taking place in 2013. These include, Informal consultation with Member States on a proposed set of indicators for the global monitoring framework for maternal, infants and young child nutrition (30 September – 1 October 2013), Formal Meeting with Member States to complete the work on a draft terms of reference for a global coordination mechanism for NCDs (11 – 12 November 2013), Formal Meeting with Member States to complete the work on the terms of reference for the UN Interagency Task Force on NCDs and division of tasks and responsibilities for UN organizations (13 November 2013) and Consultation with Member States to complete the work on a draft limited set of NCD Action Plan indicators (14 – 15 November 2013).

PROPOSED DRAFT ADDITIONAL OR REVISED NUTRIENT REFERENCE VALUES FOR LABELLING PURPOSES IN THE CODEX GUIDELINES ON NUTRITION LABELLING (Agenda Item 3)⁸

19. The Committee recalled that at its last session it had agreed to advance to Step 5/8 the Proposed Draft NRVs for Vitamin K, Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenate, Biotin, Calcium and Iodine and to return the other values for further consideration at the next session.

20. The Committee noted that the working document had not been circulated for comments at Step 3 because no additional or revised NRVs had been proposed and that considering the Codex procedure, the Committee should not forward any NRVs to the Commission for adoption before circulation at Step 3.

21. The Delegation of Australia, as the chair of the eWG for NRVs, introduced the working document and proposed that the following recommendations among 13 recommendations made by the eWG should be considered by the session: 2, 3-1, 4, 5, 11 and 13 and that other recommendations should be considered at the future sessions. The Committee thanked Australia and the eWG for their work and agreed with the proposal to consider the recommendations.

⁷ International Code of Marketing of Breast- milk substitutes

⁸ CX/NFSDU 13/35/4; CRD 4 (comments of European Union, Kenya, United States of America, NHF); CRD 12 (comments of Japan, IDF); CRD 14 (comments of Malaysia)

Recommendation 2

22. The Committee agreed to use the term “absorption” in place of “bioavailability” when the evidence referred to dietary absorption only and not to utilization in metabolism. It was noted that some individual nutrients might need further consideration.

Recommendation 3-1

23. The Committee considered whether DIRVs of one or more than one RASB should constitute the basis of a NRV-R and how to calculate a NRV-R if using DIRVs of more than one RASB.

24. Several delegations and one Observer said that the most appropriate value from one RASB should be used although selection of the most appropriate value might be difficult. The Committee, however, agreed that NRV-R should be calculated on a case-by-case basis: if values from RASBs resulted from the same physiological endpoint and thus the values were similar, NRV-R could be the average of these values; and if this was not the case, the most appropriate value should be chosen.

25. It was noted that the General Principles stated that NRV-R should be based on the average of male and female DIRVs. One Observer noted that the male and female DIRVs for Iron could not be averaged however because doing so would leave either males with too high an iron intake or women with too low an intake.

Recommendations 4 and 5

26. The Committee agreed that the WHO/FAO DIRV of 0.83 g/kg bw/day was suitable and that 50 g per day was suitable for the NRV-R for protein. It was noted that the reference mean adult body weight proposed by FAO/WHO, 60 kg, was suitable for this calculation. One delegation proposed a higher reference mean adult body weight of 68 kg, which was not acceptable to the Committee.

27. The Committee considered whether protein quality, which had been considered by FAO and WHO⁹, should be taken into account (See also Agenda Item 2b). It was concluded that there was no need to take into account protein quality for calculation of the NRV-R for protein because information was not sufficient for consideration and protein quality was not critical to the issue. With regard to a proposal to include a footnote for protein quality in the final document, the Committee did not agree because it was difficult to implement, considering that the NRV-R was intended for labelling purposes.

Recommendation 11

28. The Committee considered the working definition in the working document and made the following changes in addition to editorial changes.

⁹ Protein and Amino Acid Requirements in Human Nutrition: Report of a Joint WHO/FAO/UNU Expert Consultation, WHO Technical Report Series, No 935. 2007.

29. The Committee discussed about the terminology referring to the governmental authorities in the working definition. Several delegations preferred “Competent Authorities” as it was simple and used in several Codex documents. Other several delegations preferred “Competent National and/or Regional Authorities” as this term clearly covered both national and regional authorities. After some discussion, the Committee agreed to use “Competent National and/or Regional Authorities”.

30. The Committee noted that there was no need to include FAO and WHO in the definition as Section 3.1.1 of the *General Principles for Establishing Nutrient Reference Values for the General Population*¹⁰ indicated that nutrient intake values provided by FAO and WHO should be taken into consideration as primary sources in establishing NRVs. In addition, section 3.1.2 provided for RASB other than FAO/WHO to be taken into consideration. The Committee therefore agreed that the definition did not need to include FAO and WHO.

31. The Committee agreed to include “through primary evaluation of the scientific evidence” after “daily intake reference values”.

The Committee agreed with the following working definition for RASBs. For the purposes of establishing Codex Nutrient Reference Values, a recognized, authoritative, scientific body other than FAO and/or WHO is an organization supported by a competent national and/or regional authority(ies) that provides independent, transparent*, authoritative and scientific advice on daily intake reference values through primary evaluation of the scientific evidence upon request and for which such advice is recognised through its use in the development of policies in one or more countries.

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

Given that recommendation 1 was not discussed it was agreed that the revised agreed definition for RASBs will be used for the further work on this item.

Future work and timeframe

32. For further work, the Committee agreed to establish an eWG, chaired by Australia and working in English, with the following terms of reference:

- 1) Recommend revised or additional NRVs-R for vitamin C, Zinc, Iron, Selenium, Manganese, Molybdenum, and Fluoride, in accordance with the revised definition of RASB and the General Principles for establishing NRVs for the General Population.
- 2) Recommend relevant supporting information for the vitamins and minerals in Terms of Reference 1.
- 3) As appropriate, recommend amendments to the General Principles arising from consideration of Terms of Reference 1.

¹⁰ Annex to the *Guidelines on Nutrition Labelling* (CAC/GL 2-1985)

33. The Committee also agreed with the following timeframes:

	CCNFSDU	Commission
I. General Population		
NRVs-R from batch 2 (vitamin C, Zinc, Iron, Selenium, Manganese, Molybdenum, and Fluoride); supporting information; amended General Principles	2014	2015
NRVs-R from batch 2; NRVs-R from batch 3 (vitamin A, D, E, Phosphorus, Chromium, Magnesium, Copper, Chloride (=) and supporting information	2015	2016
NRVs-R from batch 3; supporting information	2016	2017
II. 6–36 months		
General Principles; NRVs-R (unspecified)	2017	2018
NRVs-R (unspecified)	2018	2019

34. The Committee discussed whether NRVs-R for 6-36 months might be considered in parallel with, rather than after, NRVs-R for the general population but the decision was deferred to the next session.

Status of the Proposed Draft Additional or Revised Nutrient Reference Values for Labelling Purposes in the Codex Guidelines on Nutrition Labelling

35. The Committee agreed to recommend the Commission that the current NRV-R for protein (50 g per day based on 8.3 g/kg bw/day) should be retained.

36. The Committee agreed to return the other NRVs for further consideration in the eWG as described above, circulation for comments at Step 3 and consideration at the next session.

PROPOSED DRAFT REVISION OF THE CODEX GENERAL PRINCIPLES FOR THE ADDITION OF ESSENTIAL NUTRIENTS TO FOODS (CAC/GL 9-1987) (Agenda Item 4)¹¹

37. The Committee recalled that its last session had agreed to return the Proposed Draft Revision for redrafting by an electronic working group chaired by Canada and New Zealand, comments at Step 3 and consideration in a physical working group to be held prior to the 35th Session.

38. The Delegation of Canada presented the process followed by the electronic working group to identify the questions to be addressed, and indicated that the physical working group had considered the Introduction, Scope, and Principles in detail and had solved several contentious issues (CRD 1). The definitions were left for consideration after all principles had been reviewed and sections 3.4, 3.5 and 4 were not considered due to time constraints. Throughout the following paragraphs “working group” refers only to the physical working group.

39. The Committee considered the text proposed by the working group as presented in Appendix B of CRD 1 and made the amendments and comments presented below, in addition to editorial changes.

¹¹ CX/NFSDU 13/35/5, CX/NFSDU 13/35/5-Add.1 (comments of Canada, Costa Rica, Kenya, Norway, United States of America, ICBA, ICGA, IDF), CRD 1 (Report of the physical working group held prior to the session), CRD 5 (comments of Brazil, Philippines), CRD 11 (comments of India), CRD 12 (comments of Ghana, Peru), CRD 17 (ICGMA, ICBA)

Introduction

40. The Committee agreed with the conclusion of the working group not to include the text “to prevent the indiscriminate addition of essential nutrients to foods” in the introduction but instead to refer rational and safe nutrition addition more generally.

41. The Committee agreed to adopt the decision made during Item 3 to refer to “competent national and/or regional authorities” in place of “national authorities” throughout the text (See Agenda Item 3).

Scope

42. In reply to a question on the addition of nutrient through feed consumed by animals, the Committee recalled that the principles applied only to the direct addition of nutrient to foods, as reflected in the title.

Definitions

43. The Committee agreed to include a footnote referring to the *Guidelines on Nutrition Labelling* which include the definition of “nutrient” rather than repeating the definition.

2.1 Essential nutrient

44. It was agreed to refer to “growth and development and/or the maintenance of life”, deleting the word “healthy” for consistency with the definition of “nutrient”. One delegation supported the term “healthy life” to ensure optimal quality of life.

2.2 Substitute Food

45. The Committee agreed to delete the example of plant protein beverages as a replacement for milk in view of some comments that the name used for such beverages was an issue currently under discussion in other committees, and that the definition should not include examples. One Observer indicated that the General Standard for Use of Dairy Terms should be taken into account. It was also agreed to delete the reference to “flavour and odour” as some concern was expressed that this would encourage the addition of flavourings to food. It was also clarified that nutritional aspects of equivalence were covered in section 4.3, not in the definition.

2.3 Nutritional Equivalence

46. The Committee agreed that the meaning of nutritional equivalence is “a substitute food is of similar nutritional value to its counterpart” and therefore deleted the additional explanations as the definition should be short and the principles for conditions for nutritional equivalence were specified under section 4.3.

Fortification

47. The Committee agreed to delete the definition of fortification as it was no longer used in the text of the Principles. However, the Delegation of the Philippines, supported by other delegations, pointed out that “fortification” was still commonly used in several countries for mandatory addition of nutrients and was used in the *WHO/FAO Guidelines on Food Fortification with Micronutrients* and proposed to retain the definition. Some delegations pointed out that even if fortification was not defined in the Principles, this did not prevent countries from using this term at the national level.

48. After some discussion the committee agreed to insert a footnote to the title of section 2 indicating that the term fortification was used in certain member countries.

2.4 Restoration

49. The Committee agreed to simplify the text and not to include the requirements related to compensating natural variations as was proposed for addition to the definition as these are difficult to achieve.

2.5 Mandatory nutrient addition

2.6 Voluntary nutrient addition

50. Several delegations proposed to retain the definition of mandatory and delete the definition of voluntary as voluntary nutrient addition was clarified in the explanatory notes in section 3.1.2.

51. Other delegations supported retaining both definitions to provide a clear understanding of the different types of fortification and as the explanatory notes were not definitions. The Committee agreed to retain both definitions in square brackets for further consideration. The Committee also agreed to delete the definition of special purpose foods as this was covered by other texts.

General Principles

52. The Committee agreed that the titles of sections 3 and 3.1 should be respectively “General Principles” and “Fundamental Principles”.

53. In section 3.1.1, the Committee agreed with the revised list of purposes proposed by the working group to reflect the progressive nature of the concepts and clarify what was being prevented/ reduced risk, corrected, maintained or improved. It was agreed to retain the term “preventing” jointly with the term “reducing the risk” to indicate the alternative use of these terms in different jurisdictions in the world. One Delegation proposed to refer to “correcting a demonstrated deficiency and intervening promptly to prevent new deficiencies.

54. The Committee discussed whether to use “requirements” or “recommended intakes” in the third indent and noted a proposal to use “reference nutrient intake values” as in the document on NRVs. As it was recognized that these terms were used with different meanings in different countries, it was agreed to retain both terms.

55. Some delegations expressed the view that the last sentence of section 3.1.1 was not consistent with the regulatory framework applied in some countries and was not needed as it referred to compliance issues. Several delegations expressed the view that competent authorities should have the possibility of requesting scientific rationale and evidence to demonstrate that the purpose(s) described in the list were fulfilled and the text was retained with some editorial amendments.

56. In section 3.1.2, the Committee discussed how to reflect that the authorities would decide if addition should be mandatory or voluntary. The Delegation of the European Union expressed concern about the use of the term “voluntary” which could be interpreted differently in various countries, and proposed that authorities should determine if addition “should be mandatory or not”. The Committee considered an explanatory text proposed by the Delegation of Canada in order to clarify the different regulatory approaches to voluntary addition, including the “conditional voluntary” approach and agreed to include this text, with some amendments at the end of the section. In view of the clarification provided in this text, the Committee could reach an agreement on the use of term “mandatory or voluntary”. In section 3.1.2, an Observer urged the deletion of “generally accepted” before the phrase “scientific evidence” as all evidence should be considered so that innovation is not restricted.

57. In section 3.1.4, many delegations and one observer supported the reference to advertising in addition to labelling in order not to deceive consumers. Some delegations proposed to insert the same text as in the Guidelines for Use of Nutrition and Health Claims relating to advertising. One Observer proposed to make only a reference to these Guidelines. The Committee agreed to refer to “labelling and advertising”. It was noted that the definition in the above Guidelines is specific to nutrition and health claims and it was agreed not to include this definition in the present text.

3.2 Selection of Nutrients and Determination of Amounts

58. In section 3.2.1, it was agreed that the addition of “essential nutrient” should be in line with the purposes identified in 3.1.1 and the references to “risk based” or “scientific and nutritional justification” were deleted as these were covered in 3.1.1 and other principles. The Committee noted a proposal to delete the reference to food supplements, but the reference was retained in order to take into account all relevant sources of nutrients.

59. In section 3.2.4 the Committee considered the proposed text “the severity of the adverse effect on which the UL is based “should” or “may” be reviewed to inform restrictions on the addition...” and agreed to use “may” as this would depend on the severity of the adverse effect. The Delegation of the EU expressed its reservation about maintaining this section.

3.3 Selection of Foods

60. In section 3.3.2 concerning foods to which essential nutrients may not be added, the Delegation of Norway, supported by other delegations, expressed the view that the first sentence was too general, and that nutrient addition to energy-dense and nutrient-poor foods should be avoided. Unhealthy diets are one of the main causes of major non-communicable diseases. Many foods with added nutrients have a high content of fat, sugar and salt, and from a public health perspective, addition of nutrients to food groups that may contribute to unhealthy dietary patterns should be avoided. The Delegation noted that fortification programmes with salt, sugar and margarine as vehicles had been very effective in reducing deficiencies or risk of deficiencies, and therefore it was important that national governments use food vehicles they deem effective, and proposed to add the following text:

Nutrient addition to energy-dense and nutrient-poor foods should be avoided unless such addition is nutritionally justified to meet national public health goals.

Some delegations were in favour of retaining the text taking into account the nutritional value in the food in section 3.2.2.

61. Other delegations expressed the view that this restriction would prevent the addition of nutrients to foods which are widely consumed by the population and which have been used successfully to reduce deficiencies, and that the notion of «energy dense and nutrient poor» could be interpreted differently in various countries, and therefore the decision on the foods to be avoided should be left to the authorities. Some observers expressed the view that this provision would restrict innovation and unduly limit the possibilities for using the adequate food vehicle for addition of nutrients.

62. After some discussion, the Committee agreed that the decision should be left to the competent national and/or regional authorities and amended the text accordingly.

63. Many delegations supported the inclusion of section 3.3.5 as essential nutrients should not be added to alcoholic beverages, taking into account the risks of alcoholism and the protection of public health, and it was retained. One Observer expressed the view that this restriction would not prevent alcoholism and that nutrients could be added to alcoholic beverages as to other foods and therefore this sentence should be deleted. The Delegation of the European Union, while supporting the substance of this section, pointed out that its inclusion in a Codex standard would be problematic as alcoholic beverages were not clearly defined. The Committee noted that a description of various types of alcoholic beverages was included in the General Standard for Food Additives (food category 14.2).

3.4 Technological aspects

64. The Committee made some amendments for clarification purposes to section 3.4.1 and agreed to delete sections 3.4.3 and 3.4.4 as they were outdated in view of current technological practices.

3.5 Monitoring

65. Some delegations proposed to delete section 3.5.2 as monitoring can involve purposes and approaches different from those used to gather evidence to decide on nutrient addition, such as the use of biomarkers. Other delegations supported the use of an equivalent methodology for the purpose of monitoring as was used in deciding on the addition of nutrients.

66. The Committee considered an alternative text referring to the use of equivalent methodology, unless otherwise necessary for the specific nutrient concerned but could not come to a conclusion and agreed to retain both proposals for section 3.5.2 in square brackets for further consideration.

Principles for Specific Types of Addition of Essential Nutrients

67. The Delegation of Canada indicated that there had been significant divergence of views in the working group on the title of the section and whether the principles apply only to mandatory addition or could apply to voluntary addition, and on how to include the principles for restoration and nutrition equivalence in the section. The Committee considered a new text proposed by the co-chairs of the working group for this section.

68. The Committee agreed that the title should read: Principles for Specific Types of Addition of Essential Nutrients. It was also agreed to use the term “addition of essential nutrients” instead of “nutrient addition” throughout the text.

4.1 Principles for Specific Types of Addition of Essential Nutrients

69. In section 4.1.1 it was agreed to include the evidence from biochemical indicators and to add at the end of the second sentence a reference to “another health outcome” to cover all situations.

70. In section 4.1.2, some delegations supported the use of target population while other delegations considered that “at risk” population was more specific. After some discussion it was agreed to retain “target population”. In 4.1.3 it was agreed to refer only to “public health need” in general as the purposes of addition of nutrients were described in other sections.

71. It was agreed that section 4.1.4 should address both the distribution of the population intake of the food and the lower and upper percentiles and the text was amended accordingly.

72. In section 4.1.5 some delegations supported a general statement on the consideration of cost effectiveness while other delegations pointed out that reference should be made to the intended consumer as the cost of adding nutrients would be ultimately borne by the consumer. The Committee could not come to a conclusion and agreed to retain the reference to the intended consumer in square brackets for further consideration.

4.2 Nutrient Addition for the Purposes of Restoration

73. The Committee rearranged the paragraph 4.2.1 to make it clear which criteria were applied and agreed to retain the reference to public health need. It was also agreed to simplify the text in 4.2.2 regarding the basis for considering a food as a significant contributor to intake of an essential nutrient.

4.3 Nutrient Addition for Purposes of Nutritional Equivalence

74. The Committee agreed to reorder the text using a similar structure as in section 4.2.

75. Some delegations pointed out that nutritional equivalence was not related to loss of nutrients but to improvement of nutritional quality. It was agreed to delete the text providing details on the level of consumption which should be applied to selection of the food being substituted.

76. The Committee considered a proposal to delete section 4.3.3 “where there is a clear public health reason to moderate the intake of a specific nutrient, the level of this nutrient need not be equivalent” and a proposal to retain this text as it would apply to nutrients such as saturated fat and sodium for which NRV-NCD existed. It was not possible to reach a conclusion and the text was retained in square brackets for further consideration.

77. The Committee agreed to delete section 4.4 on nutrient addition to special purpose foods as it was covered in the relevant standards.

78. The Committee recognised that significant progress had been made on the text and that only a few questions remained to be addressed and therefore it could be forwarded to Step 5. The Committee expressed its thanks to the delegations of Canada and New Zealand and to the electronic and physical working groups for their excellent work in the development of this revision.

Status of the Proposed Draft Revised Principles for the Addition of Essential Nutrients to Foods

79. The Committee agreed to forward the Proposed Draft Revised Principles to Step 5 for adoption by the 37th Session of the Codex Alimentarius Commission (see Appendix II).

PROPOSED DRAFT AMENDMENT TO THE STANDARD FOR PROCESSED CEREAL-BASED FOODS FOR INFANTS AND YOUNG CHILDREN (CODEX STAN 74-1981), TO INCLUDE A NEW PART B FOR UNDERWEIGHT OLDER INFANTS AND YOUNG CHILDREN (Agenda Item 5)¹²

80. The Committee recalled that the 34th Session of the Commission in 2011 had approved new work on the inclusion of a New Part B for Underweight Children in the Standard for *Processed Cereal-Based Foods for Infants and young Children* (CODEX STAN 74-1981) and that at its last session it had agreed to return the Proposed Draft Amendment to Step 3.

81. The Delegation of India, as the chair of the eWG introduced the working document and explained that underweight was defined in the document as having weight-for-age up to -2 standard deviations.

¹² CX/NFSDU 13/35/6; CX/NFSDU 13/35/6-Add.1 (comments of Canada, Cuba, European Union, Kenya, Mexico, New Zealand, Nicaragua, Philippines, ENA, IFT); CRD 6 (comments of Brazil, Malaysia, South Africa); CRD 10 (comments of African Union); CRD 12 (comments of Ghana, Peru); CRD 13 (comments of ISDI); CRD 14 (comments of Malaysia)

82. The Representative of WHO reiterated the concern on the scope of the proposed standard, especially since the definition of underweight seemed to be misunderstood and misused to describe the target population for which these foods were intended. The Representative explained that underweight, wasting and stunting are not different levels of severity and successions to describe undernutrition, but they are separate indicators which measure different kinds of undernutrition and -1 SD, -2 SD or -3 SD simply indicates the severity of each indicator such as underweight, wasting or stunting. The Representative also explained that underweight is a combination of stunting and wasting and that stunted children and wasted children have different dietary needs.

83. The Representative informed the Committee that there were globally agreed principles underlying the dietary management of children with moderate acute malnutrition (defined as weight-for-height between -3 and -2 SD of the median of the WHO Child Growth Standards) with a proposed nutrient composition profile for supplementary foods relevant to situations in which their use might be warranted and that these were provided in the WHO Technical Note published in 2012 which was presented at the 34th Session of CCNFSDU in November 2012. The Representative, however, said that there was no global agreement on dietary management of stunted children at present. The Representative therefore explained that simply introducing increased energy-dense processed cereal-based foods to underweight children most of whom were stunted would not improve their nutrition status, but it might even create yet another nutrition problems among those children, such as overweight and obesity.

84. The Representative requested reconsideration, further review and clarification of the scope of the proposed work.

85. Many delegations and observers supported the view of the Representative of WHO. Several delegations and some observers said that the scope of Part B should be clearly defined. Several other delegations and some observers were of the view that the work should be discontinued.

86. Several delegations identified that most of the parts in the current draft, except for some specifications, i.e. cereal content, energy density and minimum protein content, were the same as Part A and proposed to amend Part A of the Standard, rather than to establish Part B, to address the issue.

87. Several other delegations and one Observer did not agree with the proposal because amending the protein content and cereals content would not solve the problem; Part A is intended for healthy infants and children whereas the targets of Part B were underweight children who are not considered as healthy so that it would be difficult to accommodate in Part A; and there had been a lengthy discussion to finalise Part A, when the Standard was revised. One Observer clarified that the intention was not that Part B should be for unhealthy children.

88. One delegation suggested that the issue of malnutrition could be addressed at national level.

89. One Observer recalled that labelling and marketing was critically important, especially if terms such as “underweight” are used. Such terms could mislead parents, suggesting that the products are superior to local home prepared family foods.

90. The Committee recalled that the project document approved by the Commission stated that the work was to include new Part B in the Standard and noted that to start the work to amend Part A of the Standard, the Committee had to revise the project document and submit it to the Commission for approval.

91. After some discussion, the Committee agreed to establish an eWG, chaired by India and working in English, with the following terms of reference:

- Considering the scope to address categories of older infants and young children taking into account WHO guidance documents
- Considering all comments of the committee in its 35th session to resolve issues emerging in the current draft
- Considering all comments received by the members of eWG to draft a new part B of the standard or consider a different approach, if appropriate

Status of the Proposed Draft Amendment to the Standard for Processed Cereal-Based Foods for Infants and Young Children (CODEX STAN 74-1981), to Include a New Part B For Underweight Older Infants And Young Children

92. The Committee agreed to return the proposed draft amendment to Step 2/3 for redrafting by the above-mentioned working group, circulation for comments at Step 3 and consideration at the next session.

93. It was also agreed that if eWG failed to establish the scope in line with WHO guidance documents, the Committee at its next session would recommend the discontinuation of work.

REVIEW OF THE CODEX STANDARD FOR FOLLOW-UP FORMULA (CODEX STAN 156-1987) (Agenda Item 6)¹³

94. The Committee recalled that at its 34th session, it had agreed to propose new work to review the Standard for Follow-up Formula, subject to approval by the Commission and had also agreed to establish an eWG chaired by New Zealand and co-chaired by France and Indonesia. It was noted that the Commission approved the proposal and the eWG undertook its work.

95. In introducing the document, New Zealand as the Chair of the eWG reported that the scope of work included five terms of reference, and that labelling and advertising as well as the necessity of follow-up formula were excluded from this scope. Technical advice was still needed to inform the essential composition along with clarifying some areas to avoid overlaps. The Committee noted that no comments were requested and that document CX/NFSDU 13/35/7-Add.1 was not prepared.

¹³ CX/NFSDU 13/35/7;CRD 07 (Comments of European Union); CRD 10 (Comments of African Union); CRD 12 (Comments of Ghana); CRD 18 (Comments of NHF)

96. On request from a member country, WHO provided a description of the process undertaken to revise the statement on follow-up formula. The Representative of WHO stated that the 2013 statement entitled “*information concerning the use and marketing of follow-up formula*”(FUF), replaced an earlier version from 2001, which focused mainly on follow-up formula in the context of the International Code of Marketing of Breast-milk Substitutes. The Representative informed the Committee that the 2013 statement addressed the non-necessity and current unsuitability of FUF, and the growing concern as to the impact of FUF marketing strategies on exclusive breastfeeding up to 6 months of age, and continued breastfeeding up to two years and beyond.

97. The Representative noted that the statement was issued following careful review of background documents which were noted in the document, and a number of internal meetings, both with technical departments and the WHO Legal Counsel.

98. The statement contains two aspects:

- WHO recommends exclusive breastfeeding for the first six months of an infant's life. Thereafter, local, nutritious foods should be introduced, while breastfeeding continues for up to two years or beyond. *Follow-up formula is therefore unnecessary.* In addition, follow-up formula is not a suitable substitute for breast milk, due to its composition.
- If follow-up formula is marketed or otherwise represented to be suitable, with or without modification, for use as a partial or total replacement for breast milk, it is covered by the Code. In addition, where follow-up formula is otherwise represented in a manner which results in such product being perceived or used as a partial or total replacement for breast milk, such product also falls within the scope of the Code.

99. With regard to the non-necessity of FUF, this position was taken by the World Health Assembly in 1986, as reflected in WHA resolution 39.28, which states that “*the practice being introduced in some countries of providing infants with specially formulated milks (so-called ‘follow-up milks’) is not necessary*”. Nutrient needs of infants and young children between 6 and 23 months can be covered with a diet that includes breast milk and locally available, safe and nutritious foods following the guiding principles for complementary feeding of the breastfed child, or the guiding principles for feeding non-breastfed children 6-24 months of age, in those cases where breastfeeding is not possible.

100. The Representative of WHO informed the Committee that in principle WHO considers that there is no need of a Codex Standard for products which are not necessary in general. The Representative emphasised that even if the composition would be modified based on a thorough scientific review of the nutritional needs of older infants and young children, and thereby ensure better quality of the product, this would not validate its necessity. The Representative however noted that as the products were currently on the market, regulation of its composition and marketing was needed.

101. The Committee agreed that breast milk was the best for feeding to infants and young children and that the replacement product, which existed on the market and was traded internationally, must be safe and meet their nutritional needs if it had to be replaced.

102. Several delegations and observers supported the position of WHO and were of the view that the standard for infant formula was adequate as it covered infants up to 12 months and that infants more than the age of 6 months should continue breast feeding and be fed on a diversified family diet rather than on the follow-up formula which was unsuitable and unnecessary.

103. Several delegations and some observers pointed out that follow-up formula which existed on the market required the establishment of a regulatory framework to ensure product safety and quality and the review and establishment of an appropriate Codex Standard was necessary as this product was traded internationally.

104. Several delegations also proposed that the review of the standard should take into account available scientific data, nutrient requirements among the different age groups and careful consideration in deciding the cut off point for the age. They supported a distinction for products for different age groups: 6-12 months and 12-36 months and this could be done by either dividing the standard into two parts, or retaining the current scope but with separate composition requirements (Options 2 and 3 of the working document). In that context the Delegation of the EU informed the Committee that the European Food Safety Authority issued a scientific opinion published on 25 October 2013 about the nutrient requirements and dietary intakes of infants and young children in the EU¹⁴ and is expected to publish a second one on the compositional requirements of formulas in 2014. One delegation supported considering the infant formula standard as the starting basis for a separate FUF Standard for infants 6 to 12 months.

105. Some delegations indicated that, while they did not agree to develop provisions for follow-up formula, if the Committee decided to proceed, such provisions should be included in the Standard for Infant Formula, with amendments to accommodate the compositional requirements for older infants (6-12 months), and no standard for FUF should be developed (Option 5). One delegation supported retaining the Standard for Infant Formula as is, or modified to accommodate compositional requirements for older infants (6-12 months) and the standard for FUF to include product for young children (12 to 36 months) only (Option 4). The Delegation of the European Union asked whether WHO had followed the deliberation within CCNFSDU on infant formula, and said that follow-up formula was considered as part of the liquid part of the diversified diet.

106. Some observers were of the view that the standard would simply legitimise a product that was not needed. They also called for both labelling and marketing of these products to be considered in order to ensure consistency with the Code of Marketing of Breast-milk Substitutes to protect breastfeeding

¹⁴ <http://www.efsa.europa.eu/en/efsajournal/doc/3408.pdf>

107. Some delegations and one Observer emphasized the need for scientific rationale which is critical in underpinning standards and therefore recommended that an electronic working group should continue to collect data which would enable CCNSFDU to make an informed decision.

108. The Committee agreed to establish an electronic working group led by New Zealand and co-chaired by Indonesia and France, working in English and with the following Terms of Reference:

- 1) Continue to review the nutritional requirements of the older infants and young children taking into account recent scientific developments and global data;
- 2) Compare the requirements identified under the Terms of Reference (1) above with current compositional requirements of the existing infant formula and follow-up formula standards, taking into account dietary intakes and the role of the follow-up formula products as covered by the existing standard in the diet of the older infants and young children
- 3) Develop a discussion document outlining the findings of the eWG.

Status of the Review of the Codex Standard for Follow-up Formula

109. The Committee agreed to retain the Proposed Draft Review at Step 4 pending consideration of the discussion paper mentioned above.

PROPOSED DRAFT REVISION OF THE LIST OF FOOD ADDITIVES (Agenda Item 7)¹⁵

110. The Committee recalled that, following consideration of food additives provisions in infant formula in earlier sessions, the last session had agreed that Switzerland would prepare a revised list of additives for comments and consideration at the next session.

111. The Delegation of Switzerland introduced the paper and informed the Committee that consultations were held with the industry through ISDI, to establish which additives are necessary for use, after which a list was compiled and circulated for comments. The Delegation further reported that according to the analysis of the comments, divergent views on additives were received and therefore the list of additives would need further consideration through an electronic working group.

112. Several delegations supported the establishment of an electronic working group. The Committee noted the following comments: baby food should be prepared without food additives whenever possible; the level of additives in foods for infants should be as low as possible; scientific evidence was lacking for some additives; some of the additives proposed for deletion were still used in several countries; and the basis for inclusion of additives should take into consideration comments provided by the eWG as currently they were based only on ISDI proposals.

¹⁵ CX/NFSDU 13/35/8, CX/NFSDU 13/35/8-Add.1 (comments of Brazil, Costa Rica, Mexico, New Zealand, Peru, United States of America, AIDGUM, ELC, IFAC, ISDI) CX/NFSDU 13/35/8-Add.2 (comments of Canada, Colombia, European Union, Kenya, Nicaragua, Norway, Philippines, Thailand), CRD 10 (comments of African Union), CRD 12 (comments of Russian Federation), CRD 15 (comments of Republic of Korea)

113. One Observer noted that there was no data for infants less than 12 weeks, who are highly vulnerable and therefore JECFA should look into this. Another Observer also pointed out that the conduct of studies on infants raised ethical issues that need to be addressed.

114. The Secretariat recalled that this question had been already considered in CCFA and forwarded to the 68th JECFA for advice and that the reply had been provided to the CCNFSDU in 2008 (ALINORM 07/30/12, paras.25-29, and ALINORM 08/31/12, paras. 23-26).

115. The Committee agreed to establish an electronic Working Group chaired by Switzerland working in English with the following Terms of Reference:

- 1) The use of additives in foods for infants and young children should satisfy a technological need and their addition should be limited to the lowest level possible to achieve the required technological effect, in line with the principles contained in the GSFA Preamble CODEX STAN 192-1995.
- 2) It is necessary to address in depth the comments received on the document CX/NFSDU 13/35/8 regarding the Proposed Draft Revision of the List of Food Additives in CODEX STAN 72-1981.
- 3) It is important that the electronic working group evaluate the technological need of the food additives in foods for infants and young children (including the use of approved additives at different levels or in different products). This evaluation should take into account additives that have been authorised for use by competent authorities; the process by which JECFA evaluates additives in these products; and technical information from industry and other relevant stakeholders.
- 4) Following this evaluation, the electronic working group will provide recommendations for the Committee on the actions and next steps and a revised list.

DISCUSSION PAPER ON A POTENTIAL NRV FOR POTASSIUM IN RELATION TO THE RISK OF NCD (Agenda item 8)¹⁶

116. The Committee recalled that at its 34th Session, it had agreed to consider at its next session a discussion paper prepared by the United States of America on a potential Nutrient Reference Value (NRV) for Potassium in relation to Noncommunicable Disease (NCD).

117. The Delegation of the United States introduced the discussion paper and pointed out that the work to establish NRV-NCD for Potassium by CCNFSDU is in line with the implementation of WHO Global Strategy on Diet, Physical Activity and Health. The Delegation further noted that CCNFSDU had already elaborated General Principles for Establishing NRV-NCDs and also established the NRV-NCD for Sodium and saturated fatty acids; therefore the NRV-NCD for Potassium would complement the NRV-NCD for Sodium in providing additional means for Codex member governments to reduce the global burden of diet-related NCDs.

¹⁶ CX/NFSDU 13/35/9; CRD 08 (Comments of European Union, Philippines, FoodDrinkEurope); CRD 10 (Comments of African Union); CRD 11 (Comments of India); CRD 12 (Comments of Nicaragua); CRD 19 (Comments of Uruguay)

118. The Committee expressed gratitude to the United States of America for preparing the discussion paper and supported the proposal to establish the NRV-NCD for Potassium.

119. One Observer pointed out that this work should be undertaken in line with the general principles for establishing NRVs-NCD and that in future, related nutrients should be considered together.

Conclusion

120. The Committee agreed to submit the project document on the establishment of a NRV-NCD for Potassium to the 37th Session of the Commission for approval as new work (Appendix III).

121. Subject to the approval of the Commission, the Committee agreed to establish an eWG, chaired by the United State of America and co-chaired by Chile and working in English and Spanish, to recommend a proposed draft NRV-NCD for potassium and consequent amendments to the listing of NRVs-NCD in Section 3.4.4.2 of the *Guidelines on Nutrition Labelling*.

DISCUSSION PAPER ON BIOFORTIFICATION (Agenda Item 9)¹⁷

122. The Committee recalled that at its last session it had agreed with the proposal of Canada to collaborate with IFPRI to clarify the purpose of the discussion paper on the biofortification of the staple crops with essential vitamins and minerals through conventional breeding. The Committee also noted that CCFL had requested it to consider establishing a definition for biofortified foods.

123. The Observer from IFPRI explained that there was a rapid expansion of the production of biofortified food crops containing high levels of nutrients such as Vitamin A, Iron, and Zinc especially in developing countries. She explained that biofortified crops could be produced through a number of ways including agronomic practices, genetic modification or conventional breeding and these production methods may be subject to regulation by governments or competent authorities. She also noted that there are multiplicity of definitions for the term biofortification and mentioned importance of having a consensus definition.

124. Many delegations supported the proposal for CCNFSDU to develop a definition for biofortification due to increasing evidence that this could be one of the sustainable methods to fight hidden hunger among the rural communities in developing countries.

125. Some delegations acknowledged the complexities involved in undertaking this work and said that the scope should be carefully defined taking into consideration the following factors: the need for scientific evidence; bioavailability of nutrients; quality of food; how the distinction between bio-fortified and non-bio fortified crops would be made; how crops already on the market should be considered; consumer perception of new crops. One delegation expressed the view that the definition should focus on the nutritional aspects and should not refer to the method of production.

¹⁷ CX/NFSDU 13/35/10; CRD 09 (Comments from European Union, Kenya, Philippines, BIO, FoodDrinkEurope); CRD 10 (Comments from African Union); CRD 11 (Comments from India); CRD 12 (Comments of Nicaragua); CRD 16 (Comments from Uruguay); CRD 20 (Comments of Panama)

126. Other delegations noted that the work should not lead to impediment to trade, harm human health and discouragement of farmers from embracing optimal production practices. One Observer also pointed out that biofortification should not undermine traditional farming systems and affect small farmers.

127. Some delegations proposed to develop criteria for labelling of biofortified foods. However, one delegation noted that this should be the responsibility of CCFL.

128. The Delegations of Zimbabwe and South Africa offered to develop a discussion paper for submission to the next session of the CCNFSDU.

Conclusion

129. The Committee welcomed the offer by Zimbabwe and South Africa to develop a discussion paper and project document on the development of a definition for consideration at its next session.

OTHER BUSINESS AND FUTURE WORK (Agenda Item 10)

Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten

130. The Delegation of Belgium raised a concern as to the fact that the term “kamut” is a registered trade mark for a type of cereal, yet it had been used in the *Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten* (CODEX STAN 118-1981), and proposed that this name be replaced with the common name “khorasan wheat”.

131. The Secretariat clarified that during the review of the standard, member states agreed to include the term “kamut” as the common name of a cereal and there were no objections at the time. The Committee noted that the final decision to change the name rests with members, who can always propose an amendment or addition to the name used in the Standard.

132. One Observer reported that “kamut” was a widely used name well known to consumers, food producers and all codex Member states and advised against removing this name from the list of gluten containing cereals as it would be understood that kamut does not contain gluten and this would cause very severe and adverse consequences for the health of the gluten intolerant population world-wide.

Guidelines for Formulated Complementary Foods for Older Infants and Young Children

133. In section 4.1.3 Oil Seed Flours and Oil Seed Protein Products, the Committee agreed to correct an error, by deleting Footnote 7 on the *Standard for Wheat Protein* (CODEX STAN 163-1987) which was not related to this section.

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

134. The Committee was informed that the 36th Session was scheduled to be held in Bali, Indonesia from 24 to 28 November 2014, the final arrangements being subject to confirmation by the Host Country and the Codex Secretariat.

SUMMARY STATUS OF WORK

SUBJECT MATTER	STEP	ACTION BY:	DOCUMENT REFERENCE (REP14/NFSDU)
Proposed Draft Additional or Revised Nutrient Reference Values for Labelling Purposes in the Codex Guidelines on Nutrition Labelling (Protein)	Adoption	Government 37 th CAC	para. 35
Proposed Draft Revision of the Codex General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 9-1987)	5	Government 37 th CAC	para. 79 Appendix II
Proposal to Review the Codex Standard for Follow-up Formula (CODEX STAN 156-1987)	4	eWG chaired by New Zealand, co-chaired by France and Indonesia 36 th CCNFSDU	para. 109
Proposed Draft Additional or Revised Nutrient Reference Values for Labelling Purposes in the Codex Guidelines on Nutrition Labelling (Other values than protein)	2/3	eWG chaired by Australia Government 36 th CCNFSDU	para. 36
Proposed Draft Amendment to the Standard for Processed Cereal-Based Foods for Infants and Young Children to Include a New Part B for Underweight Older Infants and Young Children	2/3	eWG chaired by India Government 36 th CCNFSDU	para. 92
Potential NRV for Potassium in relation to the risk of NCD	1/2/3	37 th CAC eWG chaired by the United States, co-chaired by Chile Government 36 th CCNFSDU	paras 120 -121 Appendix III
Proposed Draft Revision of the List of Food Additives	-	Switzerland 36 th CCNFSDU	para. 115
Discussion Paper on Biofortification	-	Zimbabwe and South Africa 36 th CCNFSDU	para. 129

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APPENDIX II

**PROPOSED DRAFT PRINCIPLES FOR THE ADDITION OF
ESSENTIAL NUTRIENTS TO FOODS****(Step 5)****INTRODUCTION**

The *Principles for the Addition of Essential Nutrients to Foods (the Principles)* are intended to provide guidance to competent national and/or regional authorities responsible for developing guidelines and legal texts through the establishment of a set of principles that serve as a basis for the rational and safe addition of essential nutrients to foods.

The *Principles* take into consideration provisions in the Codex Nutritional Risk Analysis Principles and Guidelines for Application to the Work of the Committee on Nutrition and Foods for Special Dietary Uses (CAC Procedural Manual), where applicable.

Competent national and/or regional authorities may also consult FAO/WHO publications for further guidance on the addition of essential nutrients.

1. SCOPE

These Principles are intended to apply to all foods to which essential nutrients are added, not including vitamin and mineral food supplements¹, without prejudice to the provisions in Codex standards and guidelines for foods for special dietary uses.

The *Principles* are applicable, as appropriate, to both mandatory and voluntary addition of essential nutrients.

2. DEFINITIONS²

For the purpose of these Principles:

2.1 Essential nutrient³ means any substance normally consumed as a constituent of food which is needed for growth and development and/or the maintenance of life and which cannot be synthesized in adequate amounts by the body.

2.2 Substitute food is a food which resembles a common food in appearance and texture and is intended to be used as a complete or partial replacement for the food it resembles.

2.3 Nutritional equivalence means that a substitute food is of similar nutritional value to its counterpart.

2.4 Restoration means the addition of essential nutrient(s) to a food in amounts to replace those lost during the course of good manufacturing practice, or during normal storage and handling procedures.

[**2.5 Mandatory nutrient addition** is when National Authorities require food manufacturers to add specified essential nutrients to particular foods or food categories.]

[**2.6 Voluntary nutrient addition** is when National Authorities permit food manufacturers to add specified essential nutrients to particular foods or food categories.]

2.7 Population refers to a national population or specific population group(s) as appropriate.

3. GENERAL PRINCIPLES**3.1 Fundamental Principles**

3.1.1 Essential nutrients may be appropriately added to foods for the purpose of contributing to:

- preventing/reducing the risk of, or correcting, a demonstrated deficiency of one or more essential nutrients in the population;
- reducing the risk of, or correcting, inadequate nutritional status or intakes of one or more essential nutrients in the population;

¹ See the Codex *Guidelines for Vitamin and Mineral Food Supplements* (CAC/GL-55-2005)

² Different types of addition of essential nutrients for the purposes described in these Principles may be described by the term 'fortification' in certain Member Countries.

³ 'Nutrient' definition: See section 2.5 of the Codex *Guidelines on Nutrition Labelling* (CAC/GL 2-1985)

- meeting requirements and/or recommended intakes of one or more essential nutrients;
- maintaining or improving health ; and/or
- maintaining or improving the nutritional quality of foods.

Competent national and/or regional authorities may request scientific rationale and evidence demonstrating that one or more of the purposes listed above are fulfilled.

3.1.2 Competent national and/or regional authorities should determine whether addition of essential nutrients should be mandatory or voluntary⁴. This decision may be based on severity and extent of public health need as demonstrated by generally accepted scientific evidence.

3.1.3 Specific provision may be made in food standards, regulations or guidelines that identify the food(s) and essential nutrients for addition and, where appropriate, the minimum and /or maximum amounts within which the essential nutrients should be present.

3.1.4 The labelling and advertising of food products to which essential nutrients have been added should not mislead or deceive the consumer as to the nutritional merit of the food.

3.2 Selection of Nutrients and Determination of amounts

3.2.1 The addition of an essential nutrient, including the amount added, should be in line with one or more of the purposes identified in 3.1.1. The amount added should not result in either an excessive intake or an insignificant intake of the added essential nutrient(s), considering total daily intakes from all relevant sources including food supplements.. .

3.2.2 When an essential nutrient is added to foods, including addition for technological reasons, the total amount of the essential nutrient in the food should not exceed maximum amounts that may be set by competent national and/or regional authorities.

The maximum amounts mentioned above may be set taking into account

- a) upper levels of intake of essential nutrients established by scientific risk assessment based on generally accepted scientific data;
- b) the daily intake of essential nutrients from all sources.

When the maximum levels are set, due account may be taken of the reference intake values of essential nutrients for the population.

3.2.3 Where an Upper Level of Intake is not available, the scientific evidence to support the safe addition of an essential nutrient should be considered including evidence for intakes that are unlikely to result in adverse health effects-including consideration of the Highest Observed Intake⁵.

3.2.4 The severity of the adverse effect on which the upper level of intake (UL) is based may be reviewed to inform restrictions on the addition of essential nutrients to foods.

3.2.5 When competent national and/or regional authorities establish minimum-amounts for the addition of essential nutrients to foods-they should ensure that these amounts are significant and in line with the intended purpose as identified in 3.1.1. In determining significant amounts, they may also consider conditions of use for a 'source' claim in the Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997).

⁴ Internationally, there are different regulatory approaches to how voluntary addition of essential nutrients is legally framed and/or managed by competent national and/or regional authorities. In all these approaches, some form of regulatory oversight is required. There are approaches whereby addition of essential nutrients is generally permitted within a regulatory framework that can restrict foods or categories of foods to which nutrients may be added and set specific limits for those nutrients. There are other approaches that may be described as conditional voluntary. In one example, the framework in place describes all the foods or categories of foods to which manufacturers may choose to add nutrients, along with the nutrients and levels of nutrients. In another of these examples, if a manufacturer chooses to make a statement on the label indicating that a nutrient has been added, then certain nutrients are required to be added at specified levels. Also, in another example, if a manufacturer chooses to add an essential nutrient to certain foods, they must do so in accordance with policies on addition of nutrients and/or meet requirements in place in relation to the nutrients and amounts for addition.

⁵ Highest-Observed Intake – the highest level of intake observed or administered as reported within a study(ies) of acceptable quality. It is derived only when no adverse health effects have been identified (Source: Codex *Nutritional Risk Analysis Principles*).

3.3 Selection of Foods

3.3.1 The selection of foods to which essential nutrients may be added should [be in line with the intended purposes of nutrient addition as identified in 3.1.1, dietary patterns, socioeconomic situations and the need to avoid any risks to health.

3.3.2 Foods to which essential nutrients may not be added may be determined by competent national and/or regional authorities.

3.3.3 Essential nutrients should not be added to alcoholic beverages.

3.4 Technological aspects

3.4.1 The sources of the added essential nutrient may be either natural or synthetic and their selection should be based on considerations such as safety and bioavailability of the nutrient. In addition, purity criteria should take into account FAO/WHO standards, international Pharmacopoeias or other recognized international standards.

3.4.2 The added essential nutrient should be sufficiently stable in the food under customary conditions of processing, packaging, storage, distribution and use.

3.5 Monitoring

3.5.1 It is important that competent national and/or regional authorities monitor population intakes from all sources including the essential nutrients added to foods to assess the extent to which the purposes identified in 3.1.1 are addressed and to ensure that any risk of excessive intakes is minimised.

[**3.5.2** The assessment of the impact of the addition of essential nutrients should use an equivalent methodology.

OR

Monitoring of total nutrient intakes should in principle use the same ~~method~~[approach] as used in deciding the addition of essential nutrients unless otherwise necessary for the specific nutrient concerned].

4.0 Principles for Specific Types of Addition of Essential Nutrients

4.1 Mandatory Addition of Essential Nutrients to Address a Demonstrated Public Health Need

4.1.1 Where there is a demonstrated public health need for increasing the intake of an essential nutrient in the population, competent national and/or regional authorities may decide that this may be accomplished by mandatory addition of essential nutrients. This need may be demonstrated by evidence of clinical or subclinical deficiency, suboptimal or inadequate nutritional status using biochemical indicators, estimates indicating inadequate or potentially inadequate intake of nutrients, or evidence related to another health outcome. While most addition to address a serious public health need is through mandatory addition of essential nutrients, there may be some situations where a conditional voluntary approach may be used.

4.1.2 The food(s) selected as a vehicle for the added essential nutrient(s) should be habitually consumed in sufficient amount by the target population.

4.1.3 The amount of the essential nutrient added to the food should aim to be sufficient to meet the public health need. ~~when the food is consumed in habitual amounts by the population at risk.~~

4.1.4. The intake of the food selected as a vehicle should be stable and uniform and the ~~[lower and upper levels of intake]~~ distribution of the population intake of the food including the lower and upper percentiles should be known.

4.1.5 The cost effectiveness of the addition of essential nutrients to foods [for the intended consumer] should be considered.

4.2 Addition of Essential Nutrients for Restoration

4.2.1 Where restoration is to serve as a justification for the maintenance or improvement of the nutritional quality of a food, especially in relation to a public health need, the following criteria should be considered:

- the food should be a significant contributor to the intake of essential nutrients in the population
- the food prior to restoration would be subject to loss of the essential nutrients it contains during processing, storage or handling.

4.2.2 A food may be considered a significant contributor to intake of an essential nutrient based on its nutrient content and/or frequency of consumption.

4.3 Addition of Essential Nutrients for Nutritional Equivalence

4.3.1 Where nutritional equivalence is to serve as a justification for the improvement of the nutritional quality of a substitute food, especially in relation to a public health need, the counterpart food should be a significant contributor to the intake of essential nutrients in the population.

4.3.2 A food being substituted or partially substituted may be considered a significant contributor to intake of an essential nutrient based on its nutrient content and/or frequency of consumption.

[**4.3.3** Where there is a clear public health reason to moderate the intake of a specific nutrient, the level of this nutrient need not be equivalent.]

APPENDIX III

PROJECT DOCUMENT

PROPOSAL FOR NEW WORK ON A POTENTIAL NRV FOR POTASSIUM IN RELATION TO REDUCING RISK OF NONCOMMUNICABLE DISEASE FOR INCLUSION IN THE CODEX GUIDELINES ON NUTRITION LABELLING**1. PURPOSE AND SCOPE OF THE PROPOSED WORK**

WHA Resolution 57.17 endorsed the Global Strategy on Diet, Physical Activity and Health (hereafter referred to as the “Global Strategy”), and requested that the Codex Alimentarius Commission (CAC) give full consideration to evidence-based action to improve the health standards of foods, consistent with the Commission’s operational mandate and the aims and objectives of the Global Strategy.¹ It noted that public health efforts may be strengthened by the use of international norms and standards, particularly those by Codex, and identified labelling as an area for further development to allow consumers to be better informed about the content of foods.

The main purpose of this proposed work is to consider the establishment of a Nutrient Reference Value for potassium based on levels of this nutrient that reduce the risk of diet-related noncommunicable disease (NRV-NCD).

A potassium NRV associated with levels that reduce NCD risk (and that would also meet requirements) is deemed to have more global public health relevance than a potential NRV based only on minimum requirements. For example, whereas FAO/WHO has not established a daily intake reference value for potassium based on requirements, recent WHO guidelines on recommended potassium intakes are based on NCD risk. Nonetheless, this proposed new work does not preclude future consideration of a potential potassium NRV based only on requirements if sufficient interest and justification is expressed among Codex member governments.

2. RELEVANCE AND TIMELINESS

The work is relevant and timely with respect to the implementation of the Global Strategy as a means to address the global burden of noncommunicable diseases.

The work is in line with the terms of reference for the CCNFSDU including:

- (a) to study specific nutritional problems assigned to it by the Commission and advise the Commission on general nutrition issues; and
- (b) to draft general provisions, as appropriate, concerning the nutritional aspects of all foods.

In its draft action plan to implement the Global Strategy, the WHO and FAO proposed that CCNFSDU and CCFL consider the development of NRVs for labelling purposes for nutrients associated with increased and decreased risk of noncommunicable diseases (CL 2006/44-CAC). In response, the Commission approved new work for the CCNFSDU to develop general principles for establishing NRVs-NCD and to establish values for selected nutrients, with the first priority consideration of NRVs-NCD for sodium and saturated fatty acids. At the 2013 36th CAC Session, the Commission adopted amendments to the Guidelines on Nutrition Labelling (CAC/GL 2-1985) that include NRVs-NCD for sodium and saturated fatty acids, and general principles for establishing NRVs in an Annex to these guidelines (REP 13/CAC).

¹ WHO. 2004. *Global Strategy on Diet, Physical Activity and Health*. WHA 57.17. Geneva, World Health Organization (WHO). Web reference (accessed July 11, 2013): <http://www.who.int/dietphysicalactivity/strategy/eb11344/en/>

As part of WHO's work to review the scientific evidence of sodium in relation to NCD risk, CCNFSDU asked WHO at its 2010 32nd Session to consider the establishment of daily potassium intake values for the general population on the basis of dietary adequacy and/or reduction of NCD risk (REP11/NFSDU paragraph 49, Appendix III). In 2012, the WHO issued a guideline that recommended that potassium intake from food be increased and sodium intake decreased to reduce blood pressure and risk of cardiovascular disease, stroke and coronary heart disease in adults.² The establishment of an NRV-NCD for potassium will complement the sodium NRV-NCD in providing an additional means for Codex member governments to reduce the global burden of diet-related NCDs.

3. THE MAIN ASPECTS TO BE COVERED

The work would consider a potential NRV-NCD for potassium in accordance with the General Principles for Establishing Nutrient Reference Values for the General Population in the Annex to the Guidelines on Nutrition Labelling (CAC/GL 2-1985). If the CCNFSDU agrees to establish a potassium NRV-NCD, the Committee would then propose consequent amendments to section 3.4.4 of these guidelines.

4. ASSESSMENT AGAINST THE CRITERIA FOR THE ESTABLISHMENT OF WORK PRIORITIES

This work meets Codex criteria for the establishment of work priorities and would enhance protection of consumer health, help ensure fair practices in food trade, and take into account the identified needs of developing countries.

5. RELEVANCE TO THE CODEX STRATEGIC OBJECTIVES

This work would contribute to the following objectives in the Strategic Plan of the Codex Alimentarius Commission 2014-2019 (REP13/CAC, Appendix IX)

- Objective 1.1: Establish new and review existing Codex standards, based on priorities of the CAC.
- Objective 2.1: Ensure consistent use of risk analysis principles and scientific advice.
- Objective 3.1: Increase the effective participation of developing countries in Codex.
- Objective 4.1: Strive for an effective, efficient, transparent, and consensus based standard setting process.

6. INFORMATION ON THE RELATION BETWEEN THE PROPOSAL AND OTHER EXISTING CODEX DOCUMENTS

As noted in 3 above, the recommendation for a potassium NRV-NCD would be derived in accordance with the general principles for establishing NRVs, and a recommendation made to amend 3.4.4 of the Guidelines on Nutrition Labelling to add this value to the listing of NRVs-NCD.

² WHO. 2012. *Guideline: Potassium intake for adults and children*. Geneva, World Health Organization (WHO), Web reference (Accessed July 11, 2013); http://www.who.int/nutrition/publications/guidelines/potassium_intake/en/index.html

7. IDENTIFICATION OF ANY REQUIREMENT FOR AND AVAILABILITY OF EXPERT SCIENTIFIC ADVICE

Expert scientific advice on potassium in relation to reducing risk of diet-related NCDs is available from recent scientific reviews by WHO and other recognized authoritative scientific bodies.

8. IDENTIFICATION OF ANY NEED FOR TECHNICAL INPUT TO THE STANDARD FROM EXTERNAL BODIES SO THAT THIS CAN BE PLANNED FOR

Given recent scientific reviews by WHO and other recognized authoritative bodies on potassium in relation to reducing risk of diet-related NCDs, it is not anticipated that there will be a need to request joint FAO/WHO advice from the Joint Expert Meetings on Nutrition (JEMNU).

9. PROPOSED TIME-LINE FOR COMPLETION OF THE NEW WORK SUBJECT TO APPROVAL³

Activity	Date
35 th CCNFSDU Session agrees to undertake the new work and to establish an electronic working group to make recommendations	November 2013
37 th CAC Session approves new work	July 2014
36 th CCNFSDU Session considers the electronic working group recommendations and agrees on a proposed draft value and consequent proposed amendments to the Guidelines on Nutrition Labelling. The CCNFSDU advances the provisions to Step 5/8	November 2014
38 th CAC Session adopts the provisions at Step 5 or 5/8	July 2015

³ The timeline includes the start date, the proposed date for adoption at step 5, and the proposed date for adoption by the Commission.