

# CODEX ALIMENTARIUS COMMISSION



**Food and Agriculture  
Organization of  
the United Nations**



**World Health  
Organization**

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**REP 11/NFSDU**

## **JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

### **CODEX ALIMENTARIUS COMMISSION**

*Thirty fourth Session*

*Geneva, Switzerland, 4-9 July 2011*

### **REPORT OF THE THIRTY SECOND SESSION OF THE CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES**

*Santiago, Chile  
1 - 5 November 2010*

**Note:** This report includes Circular Letter CL 2010/53-NFSDU

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CX 5/20.2

CL 2010/53-NFSDU  
November 2010

**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 32<sup>nd</sup> Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (REP11/NFSDU)

## A. MATTERS FOR ADOPTION BY THE 33<sup>rd</sup> SESSION OF THE COMMISSION:

### Draft Guidelines Step 8 of the Procedure

1. Draft Annex to the Guidelines on Nutrition Labelling: General Principles for Establishing Nutrient Reference Values of Vitamins and Minerals for General Population (para. 37, Appendix II).

Governments and interested international organizations wishing to comment on the above document, should do so in writing, in conformity with the *Procedure for the Elaboration of Codex Standards and Related Texts* (Procedural Manual of the Codex Alimentarius Commission), to the above address, before **15 March 2011**.

## B. REQUEST FOR COMMENTS AND INFORMATION

### Proposed Draft Guidelines at Step 3 of the Procedure

2. Proposed Draft Annex to the Codex Guidelines on Nutrition Labelling: General Principles for Establishing Nutrient Reference Values for Nutrients Associated with Risk of Noncommunicable Diseases for the General Population (para. 111, Appendix IV)

Governments and interested international organizations wishing to submit comments on the above document, should do so by writing preferably by email to Dr Barbara O. Schneeman, Director, Office of Nutrition Labeling and Dietary Supplements, Center for Food Safety & Applied Nutrition, U.S. Food and Drug Administration (HFS-800), 5100 Paint Branch Parkway, College Park, MD 20740, United States of America, E-Mail: [barbara.schneeman@fda.hhs.gov](mailto:barbara.schneeman@fda.hhs.gov), with a copy to the Secretariat at the address above before **15 February 2011**.

## SUMMARY AND CONCLUSIONS

The summary and conclusions of the 31<sup>st</sup> Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses are as follows:

### **Matters for adoption by the 33<sup>rd</sup> Session of the Commission:**

The Committee:

- advanced to Step 8 the Draft Annex to the Guidelines on Nutrition Labelling: General Principles for Establishing Nutrient Reference Values of Vitamins and Minerals for General Population (para. 37, Appendix II);
- agreed to propose 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) (para.123, Appendix V)

### **Other Matters of Interest to the Commission**

The Committee agreed:

- to request scientific information to WHO/FAO in regard to potential NRVs and to retain the proposed draft additional or revised nutrient reference values for labelling purposes in the *Codex Guidelines on nutrition labelling* at Step 4 for further consideration taking into account the information to be provided at the next session (para. 50 and Appendix III);
- to return to Step 3 the Proposed Draft Annex to the Codex Guidelines on Nutrition Labelling: General Principles for Establishing Nutrient Reference Values for Nutrients Associated with Risk of Noncommunicable Diseases for the General Population for comment, redrafting and consideration at the next session (para. 111 and Appendix IV);
- to return the proposed draft revision of *the Codex General Principles for the Addition of Essential Nutrients to Foods* (para. 74, Appendix VII) and proposed draft revision of *the Guidelines on Formulated Supplementary Foods for Older Infants and Young Children* for redrafting, comments at Step 3 and consideration at the next session (para. 90);
- that the current Nutritional Risk Analysis Principles and the current definition of “hazard” should not be revised (para. 12-13);
- to consider the revision of the Standard for Follow-up Formula at its next session (para. 125).

### **Matters referred to other Codex Committees**

The Committee agreed

- To forward to Codex Committee on Methods of Analysis and Sampling the revised list of methods analysis for dietary fibre (para. 15) and Appendix VI.

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**REP 11/NFSDU****INTRODUCTION**

1. The Thirty-second Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) was held in Santiago, Chile from 1 to 5 November 2010 at the kind invitation of the Government of Chile in cooperation with 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, and co-chaired by Dr. Lorena Rodriguez, Ministry of Health, Chile. The Committee was attended by 227 delegates representing 46 Member Countries, one Member Organization and 20 International Organizations.

**OPENING OF THE SESSION**

2. Dr Jaime Mañalich, Ministry of Health of Chile, welcomed participants and highlighted the importance for Chile of hosting the Committee for the first time. He stressed the various challenges relating to non-communicable diseases faced by Chile and many countries and the relevance of the standards developed by the Committee in order to address public health issues, and also recalled the need for international standards in order to provide clear rules in international trade.

3. Mr Rodrigo Contreras, Representative of the Ministry of Foreign Affairs, recalled that Chile had been participating very actively in Codex work for many years. He stressed the relevance of the standards developed by the Committee in order to protect consumers' health and to ensure fair trade practices at the international level, and wished the Committee success to address the complex issues on its agenda.

4. Mrs Ines Montalva, Director of the Chilean Food Safety Agency, outlined the work of the food control authorities in Chile in order to ensure food safety, food quality and consumer protection, following an integrated approach throughout the food chain, in order to meet the expectations of consumers for safe and nutritious food.

5. Mr Jose Graziano da Silva, FAO Regional Representative for Latin America and the Caribbean, highlighted the action of FAO in order to achieve food security in the framework of the Millenium Development Goals, its capacity building work to improve food safety and quality, and its support to the Codex programme in cooperation with WHO. He noted that the Committee had an important role to play in relation to the reduction of malnutrition and non communicable diseases. Recalling the concerns relating to the proliferation of private standards, he stressed the need for increased participation of developing countries in Codex in order to ensure the relevance of Codex standards.

6. Mr Bernhard Kühnle, Director General for Nutrition, Food Safety and Animal Health, Federal Ministry of Food, Agriculture and Consumer Protection of Germany, addressed the Committee on behalf of the German Federal Minister, Ms Ilse Aigner and recalled the strong support of Germany for the Codex programme as host of the Committee and through active participation in Codex work. He recalled that Germany regularly co-hosted the Committee and had found this experience very useful. He noted that the Committee had an important responsibility in relation to nutrition issues, malnutrition and deficiencies as well as obesity, that several critical issues were scheduled on its agenda, and wished delegates all success in their work.

**Division of competence**

7. 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)<sup>1</sup>**

8. The Committee agreed to discuss Agenda Item 7 after Agenda item 3 as both items addressed the principles applicable to NRVs.

9. The Committee agreed to consider the proposal of the Delegation of New Zealand to discuss the need for the revision of the Standard for Follow-up Formula (CODEX STAN 156-87) under Agenda Item 9. Other business and Future Work.

**MATTERS REFERRED TO THE COMMITTEE BY THE CODEX ALIMENTARIUS COMMISSION AND/OR OTHER CODEX COMMITTEES (Agenda Item 2(i))<sup>2</sup>**

10. The Committee noted that the matters referred by the 33<sup>rd</sup> session of the Commission and presented in Parts A and B of the CX/NFSDU 10/32/2 were for information purposes. The Committee considered matters arising from other Codex Committees as follows:

**Codex Committee on General Principles****Nutritional Risk Analysis Principles**

11. The Committee recalled that the 26<sup>th</sup> Session of the Committee on General Principles (CCGP) had reviewed the *Nutritional Risk Analysis Principles* and had concluded that the Principles generally followed the structure of the *Working Principles for Risk Analysis*. The CCGP also noted several points, including that they did not include specific provisions regarding risk communication. The order of some sections might be reviewed and the Committee might further develop the Principles if needed.

12. The Committee agreed that it was not necessary to revise the Principles as they had been adopted by the Commission in 2009 and it was too early to revise them for the time being.

**Definition of “hazard”**

13. As regards the question from the 26<sup>th</sup> Session of the CCGP whether the definition of hazard in the Procedural Manual should be revised, the Committee agreed that it was not necessary to revise the definition.

**Codex Committee on Methods of Analysis and Sampling****Method of analysis of dietary fibre**

14. The Committee recalled that the 31<sup>st</sup> Session of CCMAS had indicated that most of the methods of analysis for dietary fibre were empirical and some of them might be overlapping, and therefore had agreed that they could be endorsed as Type IV in order to make them available as Codex methods and asked the CCNFSDU to define their scope more precisely.

15. The Committee agreed to change the provisions for six general methods of analysis to describe them more precisely and proposed them as Type I methods. Regarding eight methods that measure individual specific components, the Committee agreed to propose them as Type I methods. Regarding the three “other methods”, the Committee agreed to propose that they should be maintained as Type IV methods (See Appendix VI). Some delegations indicated that they were unable to comment at this stage and would make their comments to the CCMAS.

16. In reply to the proposal of CCMAS to delete the AOAC 2001.03 method, the Committee agreed to keep it because it was applicable when resistant starches are not present and AOAC 2009.01 was applicable to food that may, or may not, contain resistant starches.

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<sup>1</sup> CX/NFSDU 10/32/1

<sup>2</sup> CX/NFSDU 10/32/2; CRD 4 (Comments of Japan); CRD 23 (Comments of the United States of America); CRD 25 (Comments of the European Union); CRD 32 (Comments of the United States of America and European Union)

**MATTERS OF INTEREST ARISING FROM FAO AND WHO (Agenda Item 2(ii))<sup>3</sup>**

17. The Representative of WHO, while referring to the document CX/NFSDU 10/32/2-Add.1, highlighted some on-going work of relevance to the work of the Committee including salt/sodium reduction work, nutrition guidelines development, set of recommendations on the marketing of foods and non-alcoholic beverages to children and global network of institutions for scientific advice on nutrition.

18. As part of the implementation of the Global Strategy on Diet, Physical Activity and Health (DPAS) and the Noncommunicable Diseases Action Plan, WHO has convened three Population Salt Reduction Strategy Platforms, as described in the document. The review and analysis of evidence on the most appropriate levels of iodine for salt fortification is currently being undertaken. In addition, a number of on-going regional efforts and initiatives are being implemented by the WHO Regional Offices. The Regional Office for the Americas (PAHO/AMRO) established a Regional Expert Group which recommends that the declaration of the sodium content of foods be mandatory on food and nutrition labels and that the sodium intake should be the internationally recommended target of less than 2000 mg sodium/day/person, or lower.

19. The Representative of WHO further updated the Committee about the WHO Nutrition Guidance Expert Advisory Group (NUGAG) which consists of four subgroups: 1) micronutrients, 2) diet and health, 3) nutrition in the life course and undernutrition and 4) monitoring and evaluation. Some relevant work which may be of interest to the work of the Committee relates to the NUGAG Subgroup on diet and health which is currently reviewing the effects of the level of total fat intake on obesity and other related noncommunicable diseases (NCDs) as well as on the effects of the level of sugars intake on obesity and other NCDs and will be starting a review on the current salt/sodium recommendations in view of the on-going global and regional salt reduction work.

20. The Representative of WHO also informed the Committee of another relevant on-going work related to the nutrient profiling which was initiated responding to an increasing request for guidance from Member States. Development of nutrient profiling was also recognized as being an urgent priority in the effort to implement Objective 3 of the NCD Action Plan endorsed by the 61<sup>st</sup> World Health Assembly. Furthermore, nutrient profiling is one mechanism which may be utilized by Member States in implementing a set of recommendations on the marketing of foods and non-alcoholic beverages to children which was endorsed by the 63<sup>rd</sup> World Health Assembly. The Representative of WHO highlighted the outcome of the technical meeting in October 2010, jointly with the International Association for the Study of Obesity (IASO), in order to set in motion a process for validating the revised proposed guiding principles and methodological framework and define the process for validation in various countries. Some next steps agreed upon by the meeting include identification of other tools needed to implement the methodological procedures outlined in the guiding principle document; identification of countries participating in testing of the guiding principles focusing on the following 4 applications (i.e. labelling, food marketing to children, public procurement of foods and health claims), implementation of the country process and validation and technical review meeting in October/November 2011 which the Government of Brazil has kindly offered to host. The Committee noted that the report of the above meeting would be available on the WHO website at the end of the year.

21. Furthermore, the Representative of WHO drew the attention of the Committee to the establishment of a global network of institutions for scientific advice on nutrition as part of WHO's effort in strengthening its role in providing scientific advice and developing evidence-informed policy and programme guidance. The first meeting was held in March 2010 and the final report is currently being printed and should be posted on the WHO website shortly.

22. A delegation asked to clarify the role of the WHO Nutrition Guidance Expert Advisory Group (NUGAG) and the Joint FAO/WHO Expert Meetings on Nutrition (JEMNU) and whether their work overlapped and how it would relate to the work of the Committee. The Representative of WHO explained that NUGAG is a required development process of the WHO Guidelines Review Committee

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<sup>3</sup> CX/NFSDU 10/32/2 Add.1; CRD 5 (Comments of European Union)

(GRC) for developing WHO guidelines and recommendations, while JEMNU is a new procedural arrangement proposed by FAO and WHO to replace the previous *ad hoc* expert consultation arrangement for provision of scientific advice to the Codex and Member States.

23. The Representative of FAO informed the Committee about their work. In November 2008, FAO and WHO held an expert consultation on fats and fatty acids and the report would be published in November 2010. The interim summary and conclusions were posted on the FAO and WHO websites last spring and these recommendations and conclusions were the same in the final report. The expert consultation on the risk and benefits of fish consumption was held in January 2010. The executive summary was published on the FAO website and the report was expected to be published in 2011.

24. The Representative also informed the Committee that FAO would host a meeting on protein quality in March 2011 in New Zealand and confirmed that it would consider conversion factors. Regarding complementary foods, FAO was carrying out research in collaboration with the German Ministry of Food, Agriculture and Consumer Protection to improve recipes for nutrient-rich local foods. FAO was carrying out two technical cooperation projects on food composition in South America and Central America. FAO was hosting a meeting this week on sustainable diets as there was a need to ensure the sustainability of the food supply and improve diets.

#### **DRAFT ANNEX TO THE GUIDELINES ON NUTRITION LABELLING : GENERAL PRINCIPLES FOR ESTABLISHING NUTRIENT REFERENCE VALUES OF VITAMINS AND MINERALS FOR THE GENERAL POPULATION AT STEP 7 (Agenda Item 3)<sup>4</sup>**

25. The Committee recalled that the 33<sup>rd</sup> Session of the Commission had adopted the Draft Annex at Step 5 and that it had been circulated at Step 6 in CL 2010/28-NFSDU. The Committee considered the text section by section and made the following amendments and comments, in addition to editorial changes.

26. The Committee noted that there were many similarities between the Draft Annex under consideration and the Proposed Draft Annex on NRVs for Nutrients Associated with Risk of Diet-Related Non-communicable Diseases (NRV-NCDs) to be discussed under Agenda Item 7. The Committee agreed to ensure as much consistency as possible between these two documents.

#### **Preamble**

27. In the second paragraph, the Committee discussed a proposal to indicate in the first sentence that governments should be encouraged to choose NRV, in the interest of harmonisation. The Committee noted that harmonisation at the international level was one of the objectives of the Codex programme, and this did not need to be specified in individual Codex texts. After some discussion, it was agreed to amend the text to read that “governments are encouraged to use NRVs”.

28. The Committee noted a proposal to delete the second sentence providing an example of how values may be established at the national level, in order to retain the general character of the preamble. However the Committee recognised that this sentence provided useful guidance to governments and it was retained.

29. Some observers indicated that it was not sufficient to mention country or region specific factors that affect nutrient absorption or utilisation, as other factors may also be relevant when establishing NRVs. After some discussion, the Committee agreed to refer to “nutrient absorption, utilisation, or requirements” in order to provide an additional example.

#### **Definitions**

30. The Committee noted a proposal to amend the definition of Upper Level of Intake (UL) but noted that it was the same definition as in the *Nutritional Risk Analysis Principles*, except that there was no reference to “related substance” as the present text covered only nutrients. For the definitions

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<sup>4</sup> CL 2010/28-NFSDU, CX/NFSDU 10/27/3 (comments of Argentina, Australia, Costa Rica, Mexico, New Zealand, Paraguay, United States, IDF and IFT), CX/NFSDU 10/27/3-Add.1 (comments of ICBA), CRD 6 (comments of European Union and South Africa), CRD 15 (comments of Malaysia), CRD 19 (comments of CIAA), CRD 22 (comments of IADSA)

in Section 2.2 of Appendix III, the Observer from NHF raised its concern about the ambiguity of the term “judged by” and proposed adding the word “serious” in front of the term “adverse health effects in humans.” The Committee however retained the current text as this was a standard definition.

### **General Principles for Establishing Vitamin and Mineral NRVs**

#### ***Selection of suitable data sources to establish NRVs (renumbered section 3.1)***

31. The Committee agreed that when considering values from authoritative scientific bodies other than FAO/WHO, higher priority should be given, as appropriate, to values in which the evidence has been evaluated through a systematic review and the second paragraph (3.1.2) was amended accordingly.

#### ***Selection of the appropriate basis (renumbered section 3.2)***

32. The Committee discussed several proposals to amend the description of the age ranges for adults, as the current text included references to specific ages for adult males and females.

33. Some delegations supported a general reference to adults without specifying the age range, while other delegations proposed to retain a general statement but to specify age groups when establishing individual values for NRVs in a note or an Annex. After some discussion, it was agreed to refer to the widest applicable range for each of adult males and adult females, in order to cover all possible cases.

#### ***Consideration of upper levels of intake (section 3.3)***

34. The Delegation of Australia expressed the view that the consideration of upper level of intake was not adequate as a risk management strategy and was not applicable to the establishment of suitable NRVs as it was not targeted to specific population, and did not distinguish between adults and young children. The Delegation suggested that FAO/WHO should establish upper levels of intake. The Representative of WHO indicated that this could be considered in the future but was not feasible at this stage.

### **General discussion**

35. The Committee recognised that all issues had been solved and that the text was ready for adoption. However, some delegations expressed the view that, as the other Annex under Agenda Item 7 (NRVs-NCDs) was at a different step, it would be preferable to wait until both Annexes were finalised in order to integrate them into a single document. These delegations expressed some concerns that if the Annex on vitamins and minerals was adopted by the Commission, it may not be possible later to merge it with the other Annex on NRVs-NCDs or to modify the annex in the light of proposed NRVs for vitamins and minerals.

36. The Secretariat recalled that both Annexes were intended to be part of the same document, the Guidelines on Nutrition Labelling. Following the adoption of the present Annex on vitamins and minerals, work would proceed on the Annex on NRVs-NCDs, and it would be possible, if the Committee agreed, to merge it with the adopted Annex or to propose other consequential changes to the text of the Guidelines, as required. The Committee noted that the main text of the Guidelines may also need to be amended by the Committee on Food Labelling (see Agenda Item 7).

### **Status of the Draft Annex to the Guidelines on Nutrition Labelling: General Principles for Establishing Nutrient Reference Values of Vitamins and Minerals for the General Population**

37. The Committee agreed to advance the Draft Annex to Step 8 for adoption by the 34<sup>th</sup> Session of the Codex Alimentarius Commission (see Appendix II).

## **PROPOSED DRAFT ADDITIONAL OR REVISED NUTRIENT REFERENCE VALUES FOR LABELLING PURPOSES IN THE CODEX GUIDELINES ON NUTRITION LABELLING AT STEP 4 (Agenda Item 4)<sup>5</sup>**

38. The Committee recalled that its last session had agreed to establish the physical working group (pWG), chaired by Republic of Korea and co-chaired by Australia, which was held prior to this session to prepare a document for potential NRVs (pNRV) for vitamins and minerals.
39. The Delegation of Australia, on behalf of the working group, informed the Committee that the working group agreed to proceed and derive the pNRVs according to amended or new draft General Principles for vitamins and minerals and to note the substance of those draft principles in the pWG report. The working group considered whether the pNRVs calculated from WHO/FAO RNIs are suitable with respect to their scientific basis but could not reach a consensus because of lack of data.
40. After extensive discussion, the pWG agreed to propose that the Committee request WHO and WHO/FAO to provide information on relevant and recent values that reflect an independent review of the science, from recognized authoritative scientific bodies. The Committee supported the view of the working group and considered how to formulate the request.
41. The Committee expressed its appreciation to the Delegation of the Republic of Korea and Australia and the working group for their work and considered the options proposed by the working group.
42. The Committee noted that the information to be provided by WHO/FAO should be available by its next session. Some delegations proposed to prioritize vitamins and minerals in order to limit the scope of work and to receive the result in time. However it was agreed to consider all the nutrients listed in CRD 1.
43. The Observer from NHF raised specific concerns about the assumption underlying the “physiological end points” in Table 1 and suggested that FAO/WHO review and revise them. The Committee however noted that Table 1 was not referred for consideration as such and that FAO and WHO would only consider the requests included in Appendix III.
44. The Delegation of Malaysia drew the attention of the Committee to the fact that several constituents of vitamin E, in particular gamma- and delta-tocotrienol were not reflected using the units currently used for vitamin E.
45. The Representative of WHO reminded the Committee of the existence of the Global Initiative for Food Related Scientific Advice (GIFSA) to support the scientific work requested to FAO/WHO by the Committee, as without financial support, it will be difficult to undertake the requested work to the extent which was requested in a timely manner. Governments were encouraged to provide necessary funds, through GIFSA if appropriate or directly to FAO or WHO, to support the scientific work of FAO and WHO which the Committee had requested.
46. The Committee considered the draft request on CRD 1 and made the following amendments and comments, in addition to editorial changes (See Appendix III).

### **Request to WHO/FAO**

47. In regard to the first request, the Committee agreed to add a sentence “The report, through the presentation of information in tables, should provide a comparison of nutrient recommendations from recognized authoritative scientific bodies and from WHO/FAO.” after the first sentence to clarify the purpose of the report. The Committee also agreed to delete the second paragraph.

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<sup>5</sup> CX/NFSDU 10/32/4 (Comments of Argentina, Costa Rica, Egypt and the United States of America); CX/NFSDU 10/32/4 Add.1 (Comments of Mexico, Thailand and IADSA); CX/NFSDU 10/32/4 Add.2 (Comments of Brazil, Canada, Chile, Colombia and Republic of Korea); CX/NFSDU 10/32/4 Add.3 (Comments of European Union and NHF); CRD 1 (Report of the physical working group); CRD 7 (Comments of China and South Africa); CRD 8 (Comments of Japan); CRD 16 (Comments of Malaysia); CRD 30 (Comments of ISDI)

48. The Committee agreed to add sodium and potassium to the table of minerals submitted for advice to WHO/FAO.

### **Request to WHO**

49. For the second request concerning potassium, the Committee noted that WHO was currently working on salt and sodium and amended the text to reflect that it may wish “to consider daily potassium intake values in this framework”.

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

50. The Committee agreed to retain the Proposed Draft Additional or Revised Nutrient Reference Values for Labelling Purposes in the Codex Guidelines on Nutrition Labelling at Step 4, pending consideration of the report from WHO and FAO on the request presented in Appendix III.

### **PROPOSED DRAFT REVISION OF THE CODEX GENERAL PRINCIPLES FOR THE ADDITION OF ESSENTIAL NUTRIENTS TO FOODS (CAC/GL 9-1987) (Agenda Item 5)<sup>6</sup>**

51. The Committee recalled that its last session had established an electronic working group (eWG) chaired by Canada and co-chaired by Chile and New Zealand to prepare draft revised General Principles for consideration by its next session, following approval as new work by the Commission.

52. The Delegation of Canada informed the Committee that the eWG had held two rounds of consultations and had considered all main aspects outlined in the project document, addressing the need to ensure that the Principles continue to protect consumers against excesses, deficits and imbalance; the extension of the Principles to include voluntary addition of essential nutrients; their application to voluntary as well as mandatory fortification; scientific advances in nutrient risk assessment; and the need to ensure that the consumer should not be misled.

53. The Committee expressed its thanks to Canada and to the working group for this comprehensive work and had a general discussion on the revised document.

54. The Committee recalled that, while the project document referred to the “amendment” of the General Principles, not to its ‘revision’, the project document indicated that the review of the general principles would evaluate the totality of the current document, and therefore the extent of the changes would depend on how this review would proceed. Some delegations expressed the view that the principles had been developed a long time ago and should be comprehensively revised while other delegations considered that relevant sections should be updated but that the basic structure should be retained and new principles and revisions to the text could be considered.

55. The Committee agreed to concentrate on the main general issues identified by the working group and the sections which were in square brackets for further consideration.

### **Title**

56. The Committee discussed whether the current title “principles” should be retained or if it should be amended to “guidelines”. The Committee noted that it was possible to use any of these titles, and that it might also refer to “principles and guidelines” if required. The Committee did not come to a conclusion and agreed that the title would be reconsidered after the entire document had been discussed.

### **Introduction**

57. The Delegation of the United States pointed out that the introduction should focus on the purpose of the document and therefore several provisions which provided principles on addition of nutrients should preferably be transferred to the section on principles.

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<sup>6</sup> CX/NFSDU 10/32/5; CX/NFSDU 10/32/5-Add.1 (comments of Brazil, Chile, Thailand), CRD 9 (comments of Bolivia, Japan, South Africa, Thailand), CRD 10 (comments of USA), CRD 14 (comments of Argentina), CRD 17 (comments of Malaysia), CRD 19 (comments of CIAA), CRD 21 (comments of IADSA) CRD 31 (comments of IDF), CRD 27 (comment of Philippines)

58. Some delegations supported the deletion of the phrase “to allow a wider choice for fortified foods” as it stated an outcome, not a principle. However, no final conclusion was made. After some discussion, the Committee agreed to combine the first and second indents of the current text, with a few amendments, in order to describe the purpose of the document and to transfer the rest of the section, except the last paragraph, to Section 3. Principles. It was also confirmed that the addition of nutrients to food should not only be safe but also “rational”, as this term was well understood and was already included in the current *Principles*.

59. In the last paragraph, it was noted that the *Nutritional Risk Analysis Principles* apply in the framework of Codex while the *Principles for the Addition of Essential Nutrients to Foods* are intended for governments and the text was revised to clarify that the relevant provisions would be taken into consideration where applicable.

## 2. Definitions

### 2.2 Essential nutrients

60. Some delegations pointed out that the text in square brackets concerning vitamin and mineral nutrients was redundant and should be deleted, as nutrients were already defined. Other delegations recalled that it had been included to avoid confusion, and it was retained in square brackets.

### 2.3 Nutritional Equivalence

61. The Committee agreed to include the WHO definition of nutritional equivalence as an alternative to the current definition in square brackets for further consideration.

### 2.5 Fortification

62. The Committee considered the WHO definition of fortification. Several delegations pointed out that it was preferable to use the current Codex terminology, which was more consistent with the *Nutritional Risk Analysis Principles* and that the WHO definition includes the concept of biofortification which the Committee had specifically agreed to exclude from consideration in the discussions of the General Principles. It was also noted that the Task Force on Foods Derived from Biotechnology had developed specific guidance in this area and had acknowledged the applicability of CAC/GL 9-1987 in Annex 2 of their Guidelines.<sup>7</sup>

63. The Committee agreed to insert in square brackets at the end of the paragraph the proposal from the European Union concerning contribution to the improvement of health and/or nutritional status and the wording from the WHO definition to the effect that fortification should be “with minimal risk to health”.

64. The Committee also considered an alternative proposal to limit the text to the definition only and to delete any reference to the purpose of the fortification in the definition. The Committee could not come to a conclusion and agreed that the definition should be considered further at the next session.

## Principles

65. The Committee agreed to include a new introductory paragraph that would apply to all principles under the section. Some delegations pointed out that some of the proposed introductory text regarding mandatory and voluntary addition was similar to definitions and could be transferred to section 2. The introductory text was placed in square brackets for further consideration.

66. The Committee noted the proposal from one observer to indicate that “food manufacturers are permitted to add specified nutrients” to reflect the importance of regulatory infrastructures and to avoid introducing fortified foods into unregulated markets. The Committee however noted that the principles provided guidance to governments when developing regulations as already indicated in the introduction.

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<sup>7</sup> Guideline for the Conduct of Food Safety Assessment of Foods Derived From Recombinant-DNA Plants (CAC/GL 45-2003) - Annex 2: Food Safety Assessment of Foods Derived From Recombinant-DNA Plants Modified for Nutritional or Health Benefits

67. The Committee agreed that the section should be divided into two parts, one on fundamental principles that would include mainly the sections transferred from the original Introduction, and the other on basic principles applicable to all types of addition of nutrients to foods.

68. The Committee had an extensive discussion on the application of the principles to mandatory and voluntary fortification. Several delegations expressed the view that the majority of principles for mandatory and voluntary fortification apply to both and where differences exist, they could be identified within the relevant sections. Other delegations pointed out that, while some common principles existed, there were significant differences and two separate sets of principles should be developed.

69. The Delegation of the European Union expressed the view that scientific evidence, dietary habits and socio-economic conditions had evolved since the adoption of the current Principles in 1987 and that voluntary fortification was now very widespread and more frequent than mandatory fortification in some regions. Some delegations indicated that they used mandatory fortification at the national level and needed guidance in this respect.

70. The Committee could not come to a conclusion and agreed to consider further the development of principles, their application to mandatory and/or voluntary fortification, and how these principles should be presented and organized.

71. The Committee agreed that work should proceed in the electronic working group with the following mandate:

In keeping with the purpose and scope of the proposed new work to amend the Codex General Principles for the Addition of Essential Nutrients to Foods (Appendix V, ALINORM 10/33/26) the EWG that will work between the 32<sup>nd</sup> and 33<sup>rd</sup> session of the Committee will consider the principles and which of these in sections 3, 4, 5 and 6 of the current draft revised document (CX/NFSDU 10/32/5) are applicable to mandatory and/or voluntary addition of essential nutrients, taking also into account the discussion at the present session of the CCNFSDU, and the amendments to the text (presented in Appendix VII for ease of reference). The EWG would make proposals for the structure of the document based on this review of the principles.

The EWG would also consider the options for definitions discussed by the Committee.

The EWG would propose options, items, and a revised text to be circulated for additional comments at Step 3. The revised text and the related comments will be addressed by the physical working group that would work immediately before the 33<sup>rd</sup> Session of the Committee.

72. It was agreed that the EWG would be chaired by Canada and co-chaired by Mexico and New Zealand and would work in English, French and Spanish, as required.

73. The Committee further agreed to establish a physical working group chaired by Canada, co-chaired by Mexico and New Zealand, which will work immediately before the 33<sup>rd</sup> Session of the Committee. The physical working group will work in English, French and Spanish.

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

74. The Committee agreed to return the Proposed Draft Revised General Principles for redrafting by a working group, as indicated above, circulation for comments at Step 3, and consideration at the next session.

**PROPOSED DRAFT REVISION OF THE GUIDELINES ON FORMULATED SUPPLEMENTARY FOODS FOR OLDER INFANTS AND YOUNG CHILDREN (Agenda Item 6)<sup>8</sup>**

75. The Committee recalled that its last session had agreed to undertake new work, subsequently approved by the Commission, on the revision of the Guidelines and had established for this purpose an electronic working group chaired by Ghana.

76. The Delegation of Ghana highlighted the rationale for the revision and main aspects covered: extensive comments had been made in the working group and a number of issues had not been solved, in particular the title, the scope of the document, the use of terminology, such as “complementary” and “supplementary”, several specific provisions on nutrient content or use of ingredients, and the need for a section or Table on vitamins and minerals.

77. The Committee expressed its thanks to Ghana and to the working group for their extensive work to address complex issues and had a general discussion on the revised document, as it was not possible at this stage to consider the full document in detail.

78. The Committee considered the title of the document and the related terminology, especially how to address “complementary” and “supplementary” foods.

79. Several delegations expressed the view that reference should be made only to “complementary” foods, as defined by WHO, and as initially agreed in the project document. Other delegations pointed out that the Guidelines should also cover the foods which were added to “complementary foods” in order to improve nutrition and prevent malnutrition.

80. Some delegations pointed out that “supplementary foods” were intended for malnourished children and should not be mentioned in the Guidelines.

81. Some delegations and observers indicated that supplementary foods intended for children suffering from malnutrition should be administered under medical prescription and should be considered separately if they were included in the Guidelines.

82. Some observers expressed the view that some important issues had not been addressed, especially as regards marketing and regulations, and suggested that the Committee revise the Standard for Processed Cereal-Based Foods rather than the Guidelines.

83. The Committee noted several proposals for the title and description of these products, such as “supplements to complementary foods” or “complementary formulated foods”, and proposals to reorder the document according to the type of products covered. Some delegations expressed concerns with the use of the term “food supplements” in the context of complementary feeding as it might create confusion with products that were specifically excluded from the Guidelines.

84. After an extensive discussion, the Committee agreed that the title should refer to “formulated complementary foods”.

85. As regards the Description, some delegations and observers pointed out that the text was not clear as it covered a number of products that were intended for different purposes.

86. Some delegations noted that some of the ready-to-eat foods or home based fortificants were currently used to improve nutritional quality of the local diet. It was also proposed to refer to the use of formulated or supplemented foods for the prevention of malnutrition. The Observer from IACFO made the point that there is no consensus and some concern about the proposal to market to the general public products for the prevention of malnutrition.

87. After some discussion, the Committee considered a simplified text proposed by the Delegation of EU modified by the Delegation of Thailand and agreed on the following Description:

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<sup>8</sup> CX/NFSDU 10/32/6; CX/NFSDU 10/32/6-Add.1 (Comments of Argentina, Botswana, Brazil, Canada, Chile, China, European Union, Indonesia, Malaysia, Philippines, South Africa, United States of America, WFP, IBFAN and ISDI), CRD 11 (comments of Thailand), CRD 18 (comments of Mexico), CRD 19 (comments of CIAA), CRD 20 (comments of Kenya), CRD 26 (comments of Nigeria)

**Description**

*“Formulated complementary foods” means foods suitable for use during the complementary feeding period. These foods are specifically formulated foods with improved nutritional quality. They can be used as a supplement to local diet to provide those nutrients which either are lacking or are present in insufficient quantities.*

88. The Committee could not consider the document further due to time constraints and agreed that the electronic working group chaired by Ghana, working in English, would redraft the Proposed Draft Guidelines, taking into account written comments and the discussion at the current session, for consideration at the next session.

89. The Committee also agreed to establish a physical working group, chaired by Ghana and co-chaired by the United States of America, and working in English, French and Spanish, which would meet immediately prior to the 33<sup>rd</sup> Session to consider the revised document and comments at Step 3.

**Status of the Proposed Draft Revision of the Guidelines on Formulated Supplementary Foods for Older Infants and Young Children**

90. The Committee agreed to return the Proposed Draft Guidelines for redrafting by a working group, as indicated above, circulation as Step 3 and consideration at the next session.

**PRINCIPLES AND CRITERIA FOR THE DEVELOPMENT OF NRVS FOR LABELLING PURPOSES FOR NUTRIENTS ASSOCIATED WITH RISK OF DIET-RELATED NONCOMMUNICABLE DISEASES (Agenda Item 7)<sup>9</sup>**

91. The Committee recalled that its last session had agreed to establish an electronic working group and a physical working group, chaired by the United States of America and co-chaired by Thailand and Chile, to prepare a document on principles and criteria for the development of Nutrient Reference Values for nutrients associated with risk of diet-related noncommunicable disease for the general population.

92. The Delegation of the United States of America, introduced the document (CRD 2) on behalf of the co-chairs (Thailand and Chile) and the physical working group which was held prior to this session and explained in detail the discussions and recommendations from the working group which were put forward for consideration by the Plenary.

93. The Committee expressed its appreciation to the Delegations of the United States of America, Thailand and Chile and to the members of the electronic and physical working groups for their considerable efforts and excellent work which had allowed the Committee to progress on the discussion of complex issues.

94. In addition to minor editorial changes, the Committee made the following observations and conclusions.

**Preamble**

95. The Committee considered replacing “a government may choose to use the NRVs-NCD” with “Governments are encouraged to use the NRVs-NCD” in line with the documents discussed in Agenda Item 3. The Committee agreed to retain the current text, as there was no labelling provision on NRV-NCDs.

96. The Committee also agreed to add the same sentence as in the Annex on NRVs for vitamins and minerals concerning the establishment of NRVs at the national level.

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<sup>9</sup> CX/NFSDU 10/32/7; CX/NFSDU 10/32/7 Add.1 (Comments of Argentina, Canada, Chile, European Union, Japan, Malaysia, Norway, United States of America and IFT); CRD 2 (Report of the physical working group); CRD 12 (Comments of South Africa); CRD 18 (Comments of Mexico); CRD 19 (Comments of CIAA); CRD 26 (Comments of WHO); CRD 27 (Comments of Philippines); CRD 29 (Comments of ISDI)

## Definitions

97. The Delegation of Malaysia expressed the view that the discussion on the definition section was still premature and should be deferred until the Committee on Food Labelling complete the work of the definition of NRV.

98. The Committee retained the definition of Upper Level of Intake (UL) in square brackets as it could not come to a conclusion on the consideration of daily intake values for upper levels (see section 3.4 below).

## General Principles for Establishing NRVs-NCD

### Criteria for Selection of Nutrients (Section 3.1)

99. The Committee agreed that the evidence should be “Convincing/Generally Accepted” and that these terms were synonymous. The Committee also considered whether “Probable” scientific evidence for nutrient-noncommunicable disease risk relationship should also be included in the criteria in the selection of nutrients for the establishment of NRVs-NCD. (+US)

100. The Representative of WHO clarified that “probable” evidence was strong enough to support a judgement of a causal relationship. The Representative stated that the definition used in the report of the 2002 joint WHO/FAO Expert Consultation on Diet, Nutrition and the Prevention of Chronic Diseases was based on the criteria used by the World Cancer Research Fund (WCRF) in 1997, but had been modified by the 2002 Expert Consultation to include the results of controlled trials where relevant and available. The WCRF criteria have since been further clarified for their 2007 expert report. The description of “probable” in the 2007 WCRF report is consistent with the way in which the criteria were applied in the 2002 Expert Consultation for Probable evidence. The Representative of WHO stated that when comparing the categories of “convincing” and “probable”, a major difference is that “probable” requires “evidence of biological plausibility” whereas “convincing” requires the presence of a “biological gradient” and “strong and plausible experimental evidence”; if “probable” evidence was excluded from the criteria, NRVs-NCD for sugars and dietary fibre could not be established because they had “probable”, not “convincing” association with NCDs. The Representative of WHO was ready to contribute to further work of the Committee on this question.

101. Several delegations supported the inclusion of “probable” evidence because if only “convincing” criteria were considered, it would not be possible to establish NRVs-NCD for several important nutrients, such as dietary fibre and sugars. These delegations also drew the attention of the Committee to the consequences of admitting only convincing evidence in relation to regulations. Other delegations supported only the reference to “convincing” evidence for the following reasons: the criteria for “probable” was not strong enough; the highest level of evidence should be required in the framework of Codex, with the understanding that “probable” evidence could be used at the national level; the use of “probable” evidence was not sufficient for regulatory purposes and may also result in misleading claims. The Delegation of the United States clarified that the criteria used in the 2003 Technical Report on Diet, Nutrition and Prevention of Chronic Diseases (WHO TRS 916) for “convincing” and “probable” were provided in the report of the eWG, and that the 916 report criteria were also used by the 2008 FAO/WHO Joint Expert Consultation on Fats and Fatty Acids in Human Nutrition. Shortcomings of the criteria for “probable” for the work of the CCNFSDU were identified by the U. S. Delegation. In addition, it was pointed out that many factors can be considered to determine what nutrients should be declared on the label.

102. After extensive discussion, the Committee could not reach a consensus and agreed to retain the word “probable” in square brackets for further consideration.

103. The Committee agreed to move the third bullet on peer-reviewed scientific evidence to the first paragraph of Section 3.3 with an amendment.

### Selection of Suitable Data Sources to Establish NRVs-NCD (Section 3.2)

104. The Committee added a sentence at the end of 3.2.2 to clarify how priority should be established in order to be in line with the Draft Annex to the Guidelines on Nutrition Labelling: General Principles for Establishing Nutrient Reference Values of Vitamins and Minerals for General

Population, and in general to follow the same structure as in the Draft Annex in order to ensure consistency.

### **Selection of Appropriate Basis for Determining and Expressing NRVs-NCD (Section 3.3)**

105. The section was reordered for clarification purposes. The Committee agreed to delete the square brackets in paragraph 3.3.4 because it would be useful when establishing NRV-NCDs for males and females separately. The Committee further agreed to move the paragraph to a more logically appropriate place, right after 3.3.2 (renumbered 3.3.3). Paragraph 3.3.3 (renumbered 3.3.5) on how governments may determine NRVs-NCD was retained without square brackets as the information was useful.

### **Consideration of Daily Intake Values for Upper Levels (Section 3.4)**

106. The Committee considered whether the section would be included in the document. Some delegations proposed to delete square brackets and retain the text as in some cases, such as sodium and saturated fat, when establishing NRV-NCDs consideration of ULs and other daily intake values for the upper levels was essential. Other delegations and one observer proposed to delete the reference to the UL as they considered that there was not enough scientific basis to take them into account in the establishment of NRVs-NCD. It was also proposed to amend the text in 3.4 to read that the establishment of NRVs-NCD “may” (instead of “should”) take into account daily intake values for ULs.

107. Some delegations pointed out that ULs were used differently for vitamins and minerals and for the establishment of NRVs-NCD, and that there were some difficulties in their interpretation. The Delegation of the United States explained how they are considering the UL at the national level for the purposes of updating sodium food labelling values.

108. The Committee considered a proposal from the Delegation of Canada to refer to Acceptable Macronutrient Distribution Range (AMDR) as defined by the United States Institute of Medicine (IOM) an alternative to the UL, or in addition to the UL.

*An Acceptable Macronutrient Distribution Range (AMDR) is defined as a range of intakes for a particular energy source or macronutrient that is associated with reduced risk of chronic disease while providing adequate intakes of essential nutrients.*

109. It was however noted that AMDR were more generally used in relation to energy balance, while Upper Macronutrient Ranges (UMDR) were used for risk associated with fat. The Committee noted that a similar definition for reference intake ranges for macronutrients existed in the European Union, as follows:

*A range of intakes that are adequate for maintaining health and are associated with a low risk of selected chronic diseases*

110. The Committee could not reach a consensus on these proposals and agreed to retain section 3.4 on daily intake values for upper levels in square brackets and to consider further the above proposals at the next session.

### **Status of the Proposed Draft Annex to the Codex Guidelines on Nutrition Labelling: General Principles for Establishing Nutrient Reference Values for Nutrients Associated with Risk of Noncommunicable Diseases for the General Population**

111. The Committee noted that although significant progress had been made on the document, there were still major issues to be solved and it was premature to forward it to the Commission. Therefore, the Committee agreed to return the document, as amended at the session, to Step 3 (See Appendix IV). The Secretariat indicated that the CL would have a short time frame for comments to allow their consideration by the eWG.

112. The Committee further agreed to establish an electronic working group chaired by the United States of America and co-chaired by Chile and Thailand, working in English and Spanish, to prepare a revised document for its next session on the basis of the comments at Step 3, focusing on the issues

that had not been addressed (sections 3.1 and 3.4), for further comments if time allowed and consideration at the next session.

### **Review of NRVs-NCD**

113. The Committee recalled that its work on NRVs-NCD also included consideration of specific NRVs and that priority should be given to the review of the nutrients referred by the Committee on Food Labelling. The Delegation of Malaysia expressed the view that specific nutrients should not be considered as long as the principles were not finalised. Other delegations pointed out that considering specific nutrients would be useful to see how the principles applied in practice, and it was also noted that consideration of NRVs-NCD referred by CCFL was scheduled in the project document. The Committee therefore agreed that in conjunction with ongoing work on the principles, the working group would also make proposals on NRVs for sodium and saturated fatty acids for consideration at the next session.

### **Referral to CCFL**

114. As a result of developing NRVs for nutrients associated with risk of noncommunicable diseases, the Committee recalled that section 3.4.4 in the Guidelines on Nutrition Labelling (CAC/GL 2-1985) should be revised. The Committee therefore agreed to send following referral to CCFL.

CCNFSDU would like to inform the CCFL that as a part of the work to update the NRVs for vitamins and minerals and develop NRVs for nutrients associated with risk of noncommunicable diseases, the text of section 3.4.4 and perhaps other sections of the Guidelines on Nutrition Labelling needs to be revised to reflect the ongoing work of the CCNFSDU relating to the NRVs for vitamins and minerals and NRVs-NCD. It would be useful to know if CCFL has any comments with regard to the revision of the Guidelines for use by CCNFSDU in developing proposed text.

### **DISCUSSION PAPER ON THE INCLUSION OF NEW PART B FOR UNDERWEIGHT CHILDREN IN THE STANDARD FOR PROCESSED CEREAL-BASED FOODS FOR INFANTS AND YOUNG CHILDREN (CODEX STAN 74-1981) (Agenda Item 8)<sup>10</sup>**

115. The Committee recalled that its last session had agreed to establish an electronic working group chaired by India to prepare the revised discussion paper on the inclusion of a new Part B for underweight children in the Standard for Processed Cereal-Based Foods.

116. The Delegation of India, on behalf of the electronic working group, recalled that children's undernutrition is a serious global problem, especially in developing countries, and for preventing and addressing the nutritional needs of underweight infants and young children, a new Part B of the Standard should provide specific provisions especially for enhancing the cereal content, minimum protein contents and energy density.

117. The Committee expressed its appreciation to the Delegation of India and the electronic Working Group for their work and many members agreed with the concept of improving nutrition of underweight children.

118. A delegation expressed the view that a standard for some kinds of specific food for underweight children would be more appropriate than an addition to the cereal-based foods standard. An observer supported the revision of the current standard to address this issue since they were concerned about the way the products would be presented.

119. Several delegations were of the view that Part B should be clearly distinguished from the current Standard for Processed Cereal-Based Foods which, in itself, should not reopen for discussion. The Delegation of Mexico and the Observer from ESPGHAN drew the attention of the Committee to the fact that the Standard for Processed Cereal-Based Foods already covered the proposed provisions of protein and cereal content and energy density.

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<sup>10</sup> CX/NFSDU 10/32/8; CX/NFSDU 10/32/8 Add.1 (Comments of Botswana, Canada, Chile, European Union, Thailand and IBFAN); CRD 18 (Comments of Mexico); CRD 20 (Comments of Kenya); CRD 28 (Comments of ISDI)

120. The Representative of WHO raised various concerns with the discussion paper, in particular, the focus on underweight children, as children who are underweight are also often stunted and therefore, simply to address underweight will not solve the global problem of child undernutrition. In addition, the work carried out by the WHO/UNICEF/WFP/UNHCR Consultation on the Management of Moderate Malnutrition in Children under 5 Year of Age clearly indicated that cereal and pulses alone are not adequate to address undernutrition. The Representative of WHO, therefore, requested that if this work were to move forward, careful review of the concept and approach be undertaken.

121. The Delegation of India indicated that at the national level, they followed the WHO New Growth Standard, which referred to underweight children and that they also worked with UNICEF on the WHO New Growth Standard. The Delegation also noted that protein and micronutrient would be considered during the process of elaboration of the standard. India also clarified that the target population and labelling provisions would be considered if necessary.

122. After some general discussion, the Committee considered the proposed project document attached to CX/NFSDU 10/32/8. Besides several editorial amendments, the Committee agreed to clarify that children were “at risk of becoming underweight” in the third paragraph of section 2. Numerical values of minimum cereal and protein content and energy density were deleted as they should be considered by the Committee. The Committee agreed to include that the Committee should consider if specific labelling is required to distinguish a specific target population and directions for use.

123. The Committee agreed to ask the 34<sup>th</sup> Session of the Commission to approve 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). The Project Document for this work is attached to this report as Appendix V.

124. The Committee agreed to establish an electronic Working Group chaired by India, working in English, to prepare a draft New Part B of the Standard for circulation at Step 3 and consideration by the next Session of the Committee, subject to approval by the Commission.

#### **OTHER BUSINESS AND FUTURE WORK (Agenda Item 9)**

##### **Standard for Follow-up formula**

125. The Delegation of New Zealand proposed to prepare a discussion document for the Committee to consider the revision of part or all of the Standard for Follow-up Formula (CODEX STAN 156-1987). The Committee agreed with this proposal.

#### **DATE AND PLACE OF THE NEXT SESSION (Agenda Item 10)<sup>11</sup>**

126. The Committee was informed that its 33<sup>rd</sup> Session would take place in Bad Soden am Taunus, Germany, from 14 to 18 November 2011.

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<sup>11</sup> CRD 13

## SUMMARY STATUS OF WORK

SUBJECT MATTER	STEP	ACTION BY:	DOCUMENT REFERENCE (REP11/NFSDU)
Draft Annex to the Guidelines on Nutrition Labelling: General Principles for Establishing Nutrient Reference Values of Vitamins and Minerals for General Population	8	Governments 34 <sup>th</sup> CAC	para. 37 Appendix II
Proposed Draft Additional or Revised Nutrient Reference Values for Labelling Purposes in the Codex Guidelines on Nutrition Labelling	4	WHO, FAO (Reply to request of the Committee) 33 <sup>rd</sup> CCNFSDU	para. 50 Appendix III
Proposed Draft Revision of the Codex General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 9-1987)	2/3	Working group Governments 33 <sup>rd</sup> CCNFSDU	para. 74 Appendix VII
Proposed Draft Revision of the Guidelines on Formulated Supplementary Foods for Older Infants and Young Children (CAC/GL 8-1991)	2/3	Working group Governments 33 <sup>rd</sup> CCNFSDU	para. 90
Proposed Draft Nutrient Reference Values (NRVs) for Nutrients Associated with Risk of Diet-Related Noncommunicable Diseases for General Population	2/3	Working group Governments 33 <sup>rd</sup> CCNFSDU	para. 111 Appendix IV
New work on a New Part B for Underweight Children in the Standard for Processed Cereal-Based Foods for Infants and Young Children (CODEX STAN 74-1981)	1/2/3	65 <sup>th</sup> CCEXEC 34 <sup>th</sup> CAC Working group 33 <sup>rd</sup> CCNFSDU	para. 123 Appendix V
Discussion Paper for consideration of the revision of the Standard for Follow-up Formula (CODEX STAN 156-1987)	-	New Zealand 33 <sup>rd</sup> CCNFSDU	para. 125

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**REP11/NFSDU  
APPENDIX II**

**DRAFT ANNEX TO THE CODEX GUIDELINES ON NUTRITION LABELLING: GENERAL PRINCIPLES FOR ESTABLISHING NUTRIENT REFERENCE VALUES OF VITAMINS AND MINERALS FOR THE GENERAL POPULATION**

(at Step 8)

## 1. PREAMBLE

These principles apply to the establishment of Codex Nutrient Reference Values for labelling purposes (NRVs) for vitamins and minerals for the general population identified as individuals older than 36 months. These values may be used for helping consumers 1) estimate the relative contribution of individual products to overall healthful dietary intake and 2) as one way to compare the nutrient content between products.

Governments are encouraged to use the NRVs, or alternatively, consider the suitability of the general principles below and additional factors specific to a country or region in establishing their own nutrient reference values for labelling purposes. For example, at the national level, population-weighted values for the general population may be established by weighting science-based reference values for daily intakes for age-sex groups using census data for a country and proportions of each age-sex group. In addition, governments may establish nutrient reference values for food labelling that take into account country or region specific factors that affect nutrient absorption, ~~or~~ utilization, or requirements. Governments may also consider whether to establish separate food labelling reference values for specific segments of the general population such as pregnant and lactating women.

## 2. DEFINITIONS

2.1. *Individual Nutrient Level 98 (INL<sub>98</sub>)*<sup>1</sup> is the daily nutrient intake value that is estimated to meet the nutrient requirement of 98 percent of the apparently healthy individuals in a specific life stage and sex group.

2.2. *Upper level of intake (UL)*<sup>2</sup> is the maximum level of habitual intake from all sources of a nutrient judged to be unlikely to lead to adverse health effects in humans.

## 3. GENERAL PRINCIPLES FOR ESTABLISHING VITAMIN AND MINERAL NRVs

### 3.1 Selection of suitable data sources to establish NRVs

3.1.1 Relevant and recent daily nutrient intake values provided by FAO/WHO should be taken into consideration as primary sources in establishing NRVs.

3.1.2 Relevant and recent values that reflect independent review of the science, from recognized authoritative scientific bodies other than FAO/WHO could also be taken into consideration. Higher priority should be given, as appropriate, to values in which the evidence has been evaluated through a systematic review.

### 3.2 Selection of the appropriate basis

3.2.1 The NRVs should be based on Individual Nutrient Level 98 (INL<sub>98</sub>). In cases where there is an absence of an established INL<sub>98</sub> for a nutrient for a specific sub-group(s), it may be appropriate to consider the use of other reference values or ranges that have been established by recognized authoritative scientific bodies. The derivation of these values should be reviewed on a case-by-case basis.

3.2.2 The general population NRVs should be determined by calculating the mean values for a chosen reference population group older than 36 months. Nutrient Reference Values derived by the CCFNSDU are based on the widest applicable age range for each of adult males and adult females.

3.2.3 For the purpose of establishing these NRVs, the values for pregnant and lactating women should be excluded.

### 3.3 Consideration of upper level of intake

The establishment of general population NRVs should also take into account upper level of intake established by recognized authoritative scientific bodies.

<sup>1)</sup> Different countries may use other terms for this concept, for example, Recommended Dietary Allowance (RDA), Recommended Daily Allowance (RDA), Reference Nutrient Intake (RNI), or Population Reference Intake (PRI).

<sup>2)</sup> Different countries may use other terms for this concept, for example, Tolerable Upper Nutrient Intake Level (UL), or upper end of safe intake range.

**REP11/NFSDU  
APPENDIX III****PROPOSED DRAFT ADDITIONAL OR REVISED NUTRIENT REFERENCE VALUES FOR  
LABELLING PURPOSES IN THE CODEX GUIDELINES ON NUTRITION LABELLING****REQUEST to WHO/FAO**

1 WHO/FAO are requested to provide a report to 33<sup>rd</sup> session of CCNFSDU, 2011 that details the results of a review of existing daily vitamin and mineral intake reference values and their basis as outlined below for an apparently healthy population of adult males (preferably aged 19-65 years) and adult females (preferably aged 19- 50 years) The report, through the presentation of information in tables, should provide a comparison of nutrient recommendations from recognized authoritative scientific bodies and from WHO/FAO. This information should be taken from data sources published after 1998 that reflect the Committee's second draft General Principle for selection of data sources *Relevant and recent values that reflect independent review of the science, from recognized authoritative scientific bodies other than FAO/WHO*. The 28 vitamins and minerals are listed in the Table below.

The details should include, where relevant and available:

- The values themselves
- Applicable age ranges
- Physiological endpoints used to establish the INL50 or similar, or other measures such as AI and the reason for the choice
- Method of calculation of INL98 or similar from INL50 or similar including coefficients of variation
- Reference body weights and basis for extrapolation methods if used
- Determination of or assumptions about dietary bioavailabilities of the vitamin or mineral
- Conversion factors applied to provitamins, isomers or other relevant nutrients to units of equivalents such as niacin equivalents.
- Year that scientific evaluation was conducted
- Basis for the value i.e., primary evaluation or derivation from other countries' values

2 WHO/FAO are also requested to provide an estimate to 33<sup>rd</sup> session of CCNFSDU, 2011 of the extent of the change in the scientific evidence base since 1998 for the vitamins and minerals listed in the Table below. It is anticipated that an estimate could be done by a literature search on relevant scientific data bases using appropriate inclusion and exclusion criteria and counting the number of papers published since 1998. The report would document, for each vitamin and mineral, the number of papers found and the search strategy employed.

**REQUEST to WHO**

3 WHO may wish to consider the establishment of daily potassium intake values for the general population on the basis of dietary adequacy and/or reduction of chronic, noncommunicable disease risk as a part of its work on salt and sodium.

This work is anticipated to be included in the forthcoming review of salt and sodium recommendations by the WHO Nutrition Guidance Expert Advisory Group (NUGAG).

**Vitamins and minerals requested to WHO/FAO**

<b>Vitamins</b>	<b>Minerals</b>
Vitamin A	Calcium
Vitamin D	Magnesium
Vitamin E	Iodine
Vitamin K	Iron
Vitamin C	Zinc
Thiamin	Selenium
Riboflavin	Copper
Niacin	Chloride
Vitamin B6	Chromium (3+)
Folate	<del>Copper</del> <u>Sodium</u>
Vitamin B12	Fluoride
Pantothenate	Manganese
Biotin	Molybdenum
	Phosphorus
	<u>Potassium</u>

**PROPOSED DRAFT ANNEX TO THE CODEX GUIDELINES ON NUTRITION LABELLING:  
GENERAL PRINCIPLES FOR ESTABLISHING NUTRIENT REFERENCE VALUES FOR  
NUTRIENTS ASSOCIATED WITH RISK OF NONCOMMUNICABLE DISEASES FOR THE  
GENERAL POPULATION**

**(at Step 3)**

## **1. PREAMBLE**

These principles apply to the establishment of Codex Nutrient Reference Values for labelling purposes for nutrients associated with risk of diet-related noncommunicable diseases (NRVs-NCD) for the general population identified as individuals older than 36 months. These values may be used for helping consumers 1) estimate the relative contribution of individual products to overall healthful dietary intake, and 2) as one way to compare the nutrient content between products. A government may choose to use the NRVs-NCD, or alternatively, consider the suitability of the general principles below and additional factors specific to a country or region in establishing their own reference values for labelling purposes, for nutrients associated with noncommunicable diseases.

For example, at the national level, population-weighted values for the general population may be established by weighting science-based reference values for daily intakes for age-sex groups using census data for a country and proportions of each age-sex group. Governments may also consider whether to establish separate food label reference values for specific segments of the general population.

## **2. DEFINITION(S)**

**2.1 Nutrient Reference Values - Noncommunicable Diseases (NRVs-NCD)** refer to Codex nutrient reference values for food labelling purposes for nutrients that are associated with risk of diet-related chronic non-communicable diseases not including nutrient deficiency diseases or disorders.

2.2 Daily Intake Reference Values as used in these principles refer to reference nutrient intake values provided by FAO/WHO or other recognized authoritative scientific bodies that may be considered in establishing an NRV-NCD based on the principles and criteria in Section 3. These values may be expressed in different ways (e.g., as a single value or a range), and are applicable to the total population or to a segment of the population (e.g., recommendations for a specified age range). For macronutrients, they are generally expressed as a percentage of energy intake).

[2.3 Upper Level of Intake (UL) is the maximum level of habitual intake from all sources of a nutrient or related substance judged to be unlikely to lead to adverse health effects in humans.]

## **3. GENERAL PRINCIPLES FOR ESTABLISHING NRVs-NCD**

### **3.1 Criteria for Selection of Nutrients**

The following criteria should be considered in the selection of nutrients for the establishment of NRVs-NCD:

- Convincing/Generally Accepted<sup>3</sup> [or Probable] and relevant scientific evidence for the nutrient-noncommunicable disease risk relationship.
- Public health importance of the nutrient-noncommunicable disease risk relationship among Codex member countries

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<sup>3</sup> For these General Principles these terms are considered synonymous.

### **3.2 Selection of Suitable Data Sources to Establish NRVs-NCD**

3.2.1 Relevant and recent daily intake reference values provided by FAO/WHO should be taken into consideration as primary sources in establishing NRVs-NCD.

3.2.2 Relevant and recent values that reflect independent review of the science, from recognized authoritative scientific bodies other than FAO/WHO could also be taken into consideration. Higher priority should be given, as appropriate, to values in which the evidence has been evaluated through a systematic review.

3.2.3 These values should be based on intake recommendations for healthy populations.

#### **3.3. Selection of Appropriate Basis for Determining and Expressing NRVs-NCD**

3.3.1 Relevant peer-reviewed scientific evidence for a quantitative reference value for daily intake should be available in order to determine an NRV-NCD that is applicable to the general population.

3.3.2 Daily intake reference values from recognized authoritative scientific bodies that may be considered for NRVs-NCD include values expressed in absolute amounts or as a percentage of energy intake.

3.3.3 For practical application in nutrition labelling, a single NRV-NCD for the general population should be established for each nutrient that meets the principles and criteria in this Annex.

3.3.4 An NRV-NCD for the general population should be determined from the daily intake reference value for the general population or adults, or if given by gender, the mean of adult males and adult females.

3.3.5 Where a daily intake reference value is based on a percentage energy intake, the single NRV-NCD should be expressed in grams or milligrams based on a reference intake for the general population of 2000 kilocalories/8370 kilojoules.

Governments may use a Codex NRV-NCD based on the reference energy intake of 2000 kilocalories/8370 kilojoules, or may derive their own reference values for nutrition labelling based on another reference energy intake that considers factors specific to their country or region.

#### **[3.4 Consideration of Daily Intake Values for Upper Levels**

The establishment of general population NRVs-NCDs should take into account daily intake reference values for upper levels established by recognized authoritative scientific bodies where applicable (e.g., Upper Level of Intake).]

REP11/NFSDU  
APPENDIX V**PROPOSAL FOR INCLUSION OF NEW “PART B” FOR UNDERWEIGHT CHILDREN IN THE  
STANDARD FOR PROCESSED CEREAL-BASED FOODS FOR INFANTS AND YOUNG  
CHILDREN (CODEX STAN 74-1981 Rev. 1-2006)****PROJECT DOCUMENT****1. The purposes and the scope of the standard:**

The main purpose of this document is to establish a new ‘Part B’ concerning cereal based foods for underweight infants and young children in the Codex Standard for Processed Cereal Based Foods for Infants and Young Children (CODEX STAN 74-1981, Rev. 1-2006) that would include specific provisions for considering the minimum cereal content, energy density and prescribing minimum protein contents.

**2. Its relevance and timeliness:**

Globally it is estimated that undernutrition is responsible, directly or indirectly, for at least 35% of deaths in children less than five years of age. Undernutrition is also a major cause of disability preventing children who survive from reaching their full development potential. An estimated 32% or 186 million, children below five years of age in developing countries are stunted and about 10% or 55 million are wasted<sup>4</sup>. Millions of children in the developing world are at border line of normal and underweight and may slip into the category of underweight at any time due to one or another cause of malnutrition unless timely and appropriate interventions are made.

According to State of Worlds Children, 2009 by UNICEF, 148 million children under the age of five years in the developing world were underweight for their age in 2007 and two thirds of these children live in Asia alone. Together Asia and Africa accounted for 93% of all underweight children under the age of five years in the developing world.

Considering the magnitude of the problem of undernutrition it is necessary that all the efforts are focused towards reducing undernutrition which also includes setting up of suitable Codex Standards for processed cereal based complementary foods.

The new ‘Part B’ is intended for all the underweight Infants and young children’ as well as children at risk of becoming underweight due to inadequate complementary feeding practices for preventing undernutrition later. It would also support progress towards achieving Goal 1 and 4 of the Millennium Development Goals (MDGs) that sets out to reduce hunger as well as to reduce the mortality rate by two thirds among children under five, by the year 2015.

The relevance of the new work was well supported by several delegations and observers and volunteered to join India to develop the revised version of the discussion paper.

**3. The main aspects to be covered:**

The proposed work focuses on the following three key issues concerning underweight infants and young children including those at risk:

**3.1 Cereal content:** The processed foods for underweight infants and young children are based primarily on cereals, as they are not only an important source of carbohydrates but also provide a good amount of protein and other nutrients like minerals and vitamins. The Committee would consider to establish a minimum cereal content for these foods.

**3.2 Minimum protein content:** The Committee would consider establishing the minimum protein content and quality in the processed cereal based foods for underweight infants and young children.

**3.3 Energy Density:** The Committee would consider establishing the minimum energy density of processed cereal based foods for underweight infants and young children and if fats and oils may be added to increase the energy density.

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<sup>4</sup> Indicators for assessing infant and young child feeding practices, Part 3, Country profiles, World Health Organization, 2010

The Committee should then consider if specific labelling is required to distinguish specific target population and directions for use.

#### **4. An assessment against the Criteria for the establishment of work priorities:**

The proposed addition as 'Part B' to the Codex Standard for Processed Cereal Based Foods for Infants and Young Children (CODEX STAN 74-1981 Rev. 1-2006) will ensure protection of consumer health and ensuring fair practices in the food trade addressing the needs of underweight infants and young children and those at risk of becoming underweight.

#### **5. Relevance to the Codex strategic objectives:**

The proposed new work is in line with the Codex Alimentarius Commission Strategic Plan 2008–2013

**Goal 1** – Promoting Sound Regulatory Framework- (specifically **1.1** Review and develop Codex standards and related texts for food safety and **1.2** Review and develop Codex standards and related texts for food quality)

**Goal 2:** Promoting widest and consistent application of scientific principles and risk analysis point no 11.

**Goal 5:** Promoting Maximum and Effective Participation of Members especially from developing countries

#### **6. Information on the relation between the proposal and other existing Codex documents:**

The draft Guidelines on Formulated Complementary Foods for Older Infants and Young Children is at step 3. These draft Guidelines are considering changes to serving sizes, fortification levels, ingredients which also includes cereals and legumes, processing methods.

This proposal focuses mainly on changes in cereal content and energy density and protein content in Processed Cereal-Based Foods for Infants and Young Children. It is proposed that the Committee would consider that a part B may be added to the existing "CODEX STAN 74-1981, Rev. 1-2006", in order to consider the points highlighted in section 3.

#### **7. Identification of any requirement for and availability of expert scientific advice;**

None foreseen

#### **8. Identification of any need for technical input to the standard from external bodies so that this can be planned for;**

None foreseen

#### **9. The proposed time-line for completion of the new work, including the start date. The proposed date for adoption at Step 5, and the proposed date for adoption by the Commission; the time frame for developing a Standard should not normally exceed five years:**

<b>ACTIVITY</b>	<b>Step / date</b>
The 32 <sup>nd</sup> CCFNSDU agrees the work to be undertaken	November 2010
34th Session of the Commission approves New Work	July 2011
Draft standard for new 'Part B' of Codex Stan 074-1981, Rev. 1 - 2006 is circulated for comments for consideration by 33rd Session of the CCFNSDU, 2011	Step 3/ Nov. 2011
Provisional adoption by the 35th Session of the Commission	Step 5/ July 2012
Final adoption by the 36th Session of the Commission	Step 8/ July 2013

**REP11/NFSDU  
APPENDIX VI**

**LIST OF METHODS OF ANALYSIS FOR DIETARY FIBRE**

Standard	Provisions	Method	Principle	Type
<b>General methods that do not measure the lower molecular weight fraction (i.e. monomeric units<math>\leq</math>9)<sup>(2)</sup></b>				
All foods (1)	<del>Dietary fibre based on precipitation in 4 parts alcohol and 1 part water. Resistant insoluble and soluble polysaccharides, lignin, and plant cell wall. (4)</del> (Total dietary fibre) <u>Method applicable for determining dietary fibres that do not include the lower molecular weight fraction. (4)</u>	AOAC 985.29 AACC Intl 32-05.01 (1991,1999)	Enzymatic gravimetric	<del>IV</del>
All foods (1)	<del>Dietary fibre based on precipitation in 80% ethanol. Resistant insoluble and soluble polysaccharides, lignin, and plant cell wall (4).</del> (Can determine total, but also determines soluble a insoluble dietary fibre) <u>Method applicable for determining dietary fibres that do not include the lower molecular weight fraction and also includes determination for soluble and insoluble dietary fibres (4)</u>	AOAC 991.43 AACC Intl 32-07.01 (1999, 1991) NMKL 129, 2003	Enzymatic gravimetric	<del>IV</del>
All foods (1)	<u>Method applicable for determining dietary fibres that do not include the lower molecular weight fraction, in foods and food products containing more than 10% dietary fibres and less than 2% starch (e.g. fruits) (<del>Foods with &gt;10% TDF and &lt; 2% starch (fruits)</del>) (4)</u>	AOAC 993.21	Non-enzymatic gravimetric	<del>IV</del>
All foods (1)	<del>Dietary fibre based on precipitation in 4 parts alcohol and 1 part water, quantitated as component neutral sugars, uronic acids, plus Klason lignin. (4)</del> (Determine sugars, useful for commodity where fibre a sugar are both necessary) <u>Method applicable for determining dietary fibres that do not include the lower molecular weight fraction. Provides sugar residue composition of dietary fibre polysaccharides, as well as content of Klason lignin (4).</u>	AOAC 994.13 AACC Intl 32- 25.01 (1999, 1994) NMKL 162, 1998	Enzymatic chemical	<del>IV</del>

<b>General methods that measure both the higher (monomeric units &gt; 9) and the lower molecular weight fraction (monomeric units ≤9)<sup>(2)</sup></b>				
All foods (1)	<del>Dietary fibre based on precipitation in 4 parts alcohol and 1 part water. Resistant insoluble and soluble polysaccharides, resistant maltodextrins, lignin, and plant cell wall. (3)</del> Method applicable for determining the content of dietary fibres of higher and lower molecular weight, in food where resistant starches are not present	AOAC 2001.03 AACC Intl 32-41.01 (2002)	Enzymatic gravimetric and Liquid chromatography	<del>IV</del>
All foods (1)	<del>Dietary fibre (Soluble + insoluble polysaccharides + lignin + resistant starch + oligosaccharides)</del> Method applicable for determining the content of dietary fibres of higher and lower molecular weight. The method is applicable in food that may, or may not, contain resistant starches.	AOAC 2009.01 AACC Intl 32-45.01 (2009)	Enzymatic-Gravimetric-High Pressure Liquid Chromatography Method	<del>IV</del>
<b>Methods that measure individual specific components (monomeric units: the whole range for each type of components is covered)<sup>(2)</sup></b>				
All foods (1)	Insoluble dietary fibres in food and food products	AACC Intl 32-20.01 (1999, 1982) AOAC 991.42 (Specific for insoluble fibre)	Enzymatic gravimetric	<del>IV</del>
All foods (1)	Soluble dietary fibres in food and food products	AOAC 993.19 (Specific for soluble fibre)	Enzymatic gravimetric	<del>IV</del>
All foods (1)	(1→3)(1→4) <i>Beta</i> -D-Glucans	AOAC 995.16 AACC Intl 32-23.01 (1999, 1995)	Enzymatic	<del>IV</del>
All foods (1)	Fructans (oligofructoses, inulin, hydrolyzed inulin, polyfructoses, fructooligosaccharides) (applicable to added fructans)	AOAC 997.08 AACC Intl 32-31.01 (2001)	Enzymatic & HPAEC-PAD	<del>IV</del>
All foods (1)	Fructans (oligofructoses, inulin, hydrolyzed inulin, polyfructoses, fructooligosaccharides) (not applicable highly depolymerised fructans)	AOAC 999.03 AACC Intl 32-32.01 (2001)	Enzymatic & colorimetric	<del>IV</del>
All foods (1)	Polydextrose	AOAC 2000.11 AACC Intl 32-28.01 (2001)	HPAEC-PAD	<del>IV</del>
All foods (1)	Trans-galacto-oligo saccharides	AOAC 2001.02 AACC Intl 32-33.01 (2001)	HPAEC-PAD	<del>IV</del>
All foods (1)	Resistant starch (Recommended for RS3)	AOAC 2002.02 AACC Intl 32-40.01 (2002)	Enzymatic	<del>IV</del>

<b>Other methods<sup>(2)</sup> that have not been subjected to interlaboratory evaluation under AOAC international guidelines</b>				
All foods	Insoluble glucans and mannans of yeast cell wall (for yeast cell wall only)	Eurasyp (European association for specialty yeast product) – LM Bonanno. Biospringer- 2004 – online version : <a href="http://www.eurasyp.org/public.technique.home.screen">http://www.eurasyp.org/public.technique.home.screen</a> .	Chemical & HPAEC-PAD	IV
All foods	Fructo-oligosaccharides (monomeric units<5)	Ouarne et al. 1999 in <i>Complex Carbohydrates in Foods</i> . Edited by S. Sungsoo, L. Prosky & M. Dreher. Marcel Dekker Inc, New York	HPAEC-PAD	IV
All foods	Non-starch polysaccharides (NSP) (3)	Englyst H.N, Quigley M.E., Hudson G. (1994) Determination of dietary fibre as non-starch polysaccharides with gas-liquid chromatographic high performance liquid chromatographic or spectrophotometric measurement of constituent sugars – Analyst 119, 1497-1509	Gas-Liquid Chromatography	IV

<sup>(1)</sup> Users should consult the description of each method for the food matrices that were the subject of interlaboratory study in the Official methods of Analysis of AOAC International.

<sup>(2)</sup> Two issues are left for national authorities: to include monomeric units 3-9 and which isolated or synthetic compounds have physiological benefit. (Refer to the Guidelines for Nutrition Labelling (CAC/GL 2-1985), as revised in 2009.

<sup>(3)</sup> Quantitation lost for resistant starch. Refer to specific methods.

<sup>(4)</sup> Quantitation lost for inulin, resistant starch, polydextrose and resistant maltodextrins. Refer to specific methods.

**REP11/NFSDU  
APPENDIX VII**

**PROPOSED DRAFT REVISION OF *THE CODEX GENERAL PRINCIPLES FOR THE  
ADDITION OF ESSENTIAL NUTRIENTS TO FOODS***

**[GENERAL PRINCIPLES] [GUIDELINES] FOR THE ADDITION OF ESSENTIAL  
NUTRIENTS TO FOODS**

**(CAC/GL 09-1987)**

**INTRODUCTION**

The *[General Principles] [Guidelines] for the Addition of Essential Nutrients to Foods* provide a framework for the addition of essential nutrients to food and are intended to provide guidance to those 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 ~~pertaining to the addition of essential nutrients to foods~~ through the establishment of a set of principles.

- ~~• [Establish a uniform set of principles for the rational addition of essential nutrients to foods.]~~
- ~~• Facilitate acceptance in international trade of foods which contain added essential nutrients.~~
- ~~• [To allow a wider choice of fortified foods] [to contribute to the improvement of health and/or the nutritional status of the population or specific population groups.]~~

~~[The *General Principles for the Addition of Essential Nutrients to Foods* aim at providing a framework for the addition of essential nutrients to foods for the purpose of:~~

- ~~• correcting a demonstrated deficiency of one or more essential nutrients in the population or specific population groups;~~
- ~~• contributing to meeting requirements of one or more essential nutrients and reducing the risk of their deficiency;~~
- ~~• contributing to the improvement of health and/or nutritional status of the population or specific population groups.]~~

~~[The *[General Principles] [Guidelines] for the Addition of Essential Nutrients to Foods* take into consideration] provisions in ~~[are consistent and used in conjunction with]~~ 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.~~

**1. SCOPE**

These [principles] [guidelines] are intended to apply to all foods to which essential nutrients are added, not including vitamin and mineral food supplements<sup>5</sup>.

**2. DESCRIPTION [DEFINITIONS]**

~~[Definitions]~~

For the purpose of these [principles] [guidelines]:

**2.1 Nutrient** means any substance normally consumed as a constituent of food:

- (a) which provides energy; or
- (b) which is needed for growth and development and maintenance of healthy life; or

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<sup>5</sup> Codex Guidelines for Vitamin and Mineral Food Supplements (CAC/GL 55-2005)

(c) a deficit of which will cause characteristic bio-chemical or physiological changes to occur.

**2.2 Essential nutrient** means any substance normally consumed as a constituent of food which is needed for growth and development and the maintenance of healthy life and which cannot be synthesized in adequate amounts by the body. [Essential nutrient includes but is not limited to vitamins and mineral nutrients.]

**2.3 Nutritional equivalence** means being of similar nutritive value in terms of quantity and quality of protein and in terms of kinds, quantity and bioavailability of essential nutrients. ~~For this purpose, nutritional equivalence means that essential nutrients provided by the food being substituted, that are present in a serving or portion or 100 kcal of the food at a level of 5% or more of the recommended intake of the nutrient(s) are present in the substitute or partially substituted food (extender) in comparable amounts.~~

[proposal WHO: 2.3 Nutritional equivalence is achieved when an essential nutrient is added to a product that is designed to resemble a common food in appearance, texture, flavour and odour in amounts such that the substitute product has a similar nutritive value, in terms of the amount and bioavailability of the added essential nutrient.]

**2.4 Substitute food** is a food which is designed to resemble a common food in appearance, texture, ~~flavour and odour~~, and is intended to be used as a complete or partial replacement for the food it resembles, e.g., plant protein-based beverages as a replacement for milk.

**2.5 Fortification ~~for enrichment~~** ~~[which may be called enrichment]~~ means the addition, of one or more essential nutrients to a food, whether or not it is normally contained in the food ~~[, [for the purpose of reducing risk of inadequate intakes], including preventing or correcting a demonstrated deficiency [or a potential deficiency] of one or more nutrients in the population or specific population group(s) or for the purpose of contribution to the improvement of health and/or nutritional status of the population or specific population groups [with minimal risk to health].]~~

[to be moved to “principles” Fortification may be mandatory or voluntary.]

**2.6 Restoration** means the addition to a food of essential nutrient(s) which are lost during the course of good manufacturing practice, or during normal storage and handling procedures, in amounts which will result in the presence in the food of the levels of the nutrient(s) present in the edible portion of the food before processing, storage or handling.

**2.7 Special purpose foods** are foods that have been designed to perform a specific function, such as to replace a meal which necessitates a content of essential nutrients which cannot be achieved except by addition, direct or indirect, of one or more of these nutrients. These foods include but are not limited to foods for special dietary use, [and also include foods intended for infants and young children].

**2.8 Nutrient density** means the amount of nutrients (in metric units) per stated unit of energy (MJ or kcal).

[2.9 Standardization means the addition of nutrients to a food in order to compensate for natural variations in nutrient level, [e.g., seasonal variation in nutrient content.]

### 3. ~~BASIC PRINCIPLES~~

[The following principles are applicable, as appropriate, to mandatory and/or voluntary addition.]

[Following text to be moved to definition section?

Mandatory nutrient addition occurs when governments require food manufacturers to add specified essential nutrients to particular foods or categories of food for a specific purpose. Voluntary nutrient addition is when a food manufacturer chooses to add specified nutrients to particular foods or food categories for a specific purpose [the benefit of the consumer of the food].]

#### 3.1 Fundamental Principles

> The Following bullets are moved from Introduction section – to be reconsidered by EWG

- Maintain or improve the overall nutritional quality of foods.

- contributing to the improvement of health and/or nutritional status of the population or specific population groups.
- correcting a demonstrated deficiency of one or more essential nutrients in the population or specific population groups;
- contributing to meeting requirements of one or more essential nutrients and reducing the risk of their deficiency; ]
- Prevent the indiscriminate addition of essential nutrients to foods thereby decreasing the risk of health hazard due to essential nutrient excesses, deficits or imbalances. This will also help to prevent practices which may mislead or deceive the consumer.

### **3.2 Basic Principles**

to be reconsidered/completed by EWG

~~[3.1 Essential nutrients may be added, to foods for the purpose of:~~

~~3.1.1 restoration;~~

~~3.1.2 nutritional equivalence of substitute foods;~~

~~3.1.3 fortification [or enrichment];~~

~~3.1.4 ensuring the appropriate nutrient composition of a special purpose food;.~~

~~[3.1.5 to allow a wider choice of fortified foods]~~

[3.1 Essential nutrients may be added to foods for the purpose of restoration, nutritional equivalence of substitute foods, fortification and ensuring the appropriate nutrient composition of a special purpose food. The following basic principles are generally applicable to both mandatory and voluntary fortification.]

**3.2 (modified 6.1) ~~Fortification~~** The mandatory and voluntary addition of essential nutrients to foods should be the responsibility of in accordance with food law and other policies established by national authorities since and take into account the kinds and amounts of essential nutrients to be added, and foods to be fortified, will depend upon the particular nutritional problems to be corrected, the characteristics of the target populations, and the food consumption patterns of the area.

**3.2.1 (New)** [Mandatory nutrient addition occurs when governments require food manufacturers to add specified essential nutrients to particular foods or categories of foods.]

**3.2.2 (New)** [Voluntary nutrient addition is when a food manufacturer chooses to add specified nutrients to particular foods or food categories.]

**3.3 (Former 3.2)** The [addition of an] essential nutrient should be [scientifically and nutritionally justified and be] present at a level which will not result in either an excessive or an insignificant intake of the added essential nutrient, considering amounts from other sources in the diet. [Upper levels of intake based on scientific risk assessment may be used to identify the need for any restrictions on the types of foods to be fortified.]

**3.4 (Former 3.3)** The addition, of an essential nutrient to a food should not result in an adverse effect on the metabolism of any other nutrient.

**3.5 (new)** [The sources of the essential nutrient may be either natural or synthetic and their selection should be based on considerations such as safety and bioavailability. In addition, purity criteria should take into account FAO/WHO standards, or if FAO/WHO standards are not available, international Pharmacopoeias or recognized international standards. In the absence of criteria from these sources, national legislation may be used.]

**3.6 (Former 3.4)** The essential nutrient should be sufficiently stable in the food under customary conditions of packaging, storage, distribution and use.

**3.7 (Former 3.5)** The essential nutrient should be biologically available from the food.

**3.8** (Former 3.6) The essential nutrient should not impart undesirable characteristics to the food (e.g. colour, taste, flavour, texture, cooking properties) and should not unduly shorten shelf-life.

**3.9** (Former 3.7) Technology and processing facilities should be available to permit the addition of the essential nutrient to a food in a satisfactory manner.

**3.10** (Former 3.8) Addition of essential nutrients to foods should not be used to mislead or deceive the consumer, [including by presentation or labelling practices], as to the nutritional merit [or the health benefit] of the food.

~~[3.9 The additional cost of addition [of essential nutrients to foods] should be reasonable for the intended consumer.]~~ applicable to mandatory fortification; moved to section 6.2 as 6.2.7

**3.11** Methods of measuring, controlling and/or enforcing the levels of added essential nutrients in foods should be available.

**3.12** When provision is made in food standards, regulations or guidelines for the addition of essential nutrients to foods, specific provisions should be included identifying the essential nutrients to be considered or to be required and the levels at which they should be present in the food to achieve their intended purpose.

[3.13 Monitoring total intakes of the added nutrients in population(s) by national authorities is essential particularly to assess the extent to which public health needs are being addressed and to ensure that a risk of excessive intakes is absent.]

OR

[3.13 National authorities should give highest priority to monitoring total nutrient intakes and the relative contributions from all dietary sources for those nutrients that are most likely to pose a risk of inadequate or excessive intakes for the population(s).]

#### **4. [NUTRIENT] ADDITION [OF ESSENTIAL NUTRIENTS] FOR PURPOSES OF RESTORATION**

**4.1** Where the food has been identified as a significant [contributor to intake ~~source~~] of energy and/or essential nutrients in the [population group(s) ~~food supply~~], and particularly where there is demonstrated evidence of public health need, restoration of the essential nutrients of concern lost during processing, storage or handling should be strongly recommended.

**4.2** A food should be considered a significant [contributor to intake ~~source~~] of an essential nutrient if the edible portion of the food prior to processing, storage or handling contains the essential nutrient in amounts equal to or greater than 10% of the recommended nutrient intake [or INL<sub>98</sub>] in a reasonable daily intake [of the food] (or in the case of an essential nutrient for which there is no recommended intake, 10% of the average daily intake [of the nutrient]).

#### **5. [NUTRIENT] ADDITION [OF ESSENTIAL NUTRIENTS] FOR PURPOSES OF NUTRITIONAL EQUIVALENCE**

**5.1** Where a substitute food is intended to replace a food which has been identified as a significant [contributor to intake ~~source~~] of energy and/or essential nutrients in the [population group(s) ~~food supply~~], and particularly where there is demonstrated evidence of public health need, nutritional equivalence in terms of the essential nutrients of concern should be strongly recommended.

**5.2** A food being substituted or partially substituted should be considered a significant [contributor ~~source~~] of an essential nutrient if a serving or portion or 100 kcal of the food contains the essential nutrient in amounts equal to or greater than 5% [or INL<sub>98</sub>] of the recommended nutrient intake.

**5.3** 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.

#### **6. NUTRIENT ADDITION FOR PURPOSES OF FORTIFICATION**

**[6.1 [move to section 3.2] Mandatory fortification should be the responsibility of national authorities since the kinds and amounts of essential nutrients to be added, and foods to be fortified, will depend upon the particular nutritional problems to be corrected, the characteristics of the target populations,**

and the food consumption patterns of the area.]

**6.1** (*former 6.2*) The following conditions should be fulfilled [when fortifying foods]~~[for any fortification programme]~~:

~~[6.2.1 There should be a demonstrated need for increasing the intake of an essential nutrient in one or more population groups. This may be in the form of actual clinical or subclinical evidence of deficiency, estimates indicating low levels of intake of nutrients or possible deficiencies likely to develop because of changes taking place in food habits.~~

6.1.1 (*former 6.2.1*) There should be a demonstrated [public health] need for increasing the intake of an essential nutrient in one or more population groups [through fortification]. This need may be demonstrated by ~~may be in the form of~~ actual clinical or subclinical evidence of deficiency, estimates indicating ~~low~~ inadequate or potentially inadequate levels of intake of nutrients or possible deficiencies likely to develop because of changes taking place in food habits. Mandatory fortification is appropriate in addressing serious public health needs such as clinical deficiency whereas voluntary fortification may be appropriate in addressing lower order risk of inadequate nutrient intakes.

6.1.2 (*former 6.2.2*) The food selected as a vehicle for the essential nutrient(s) should be consumed by the population at risk.

6.1.3 (*former 6.2.3*) The intake of the food selected as a vehicle should be stable and uniform and the lower and upper levels of intake should be known.

6.1.4 (*former 6.2.4*) The amount of the essential nutrient added to the food, should be sufficient to [address the public health need] [correct or prevent the deficiency] when the food is consumed in normal amounts by the population at risk.

6.1.5 (*former 6.2.5*) The amount of the essential nutrient added to a food, should not result in excessive [total] intakes [of the nutrient from the fortified food when combined with other dietary sources] [by individuals with a high intake of a fortified food].

[6.1.6 (*former 3.7*) Technology and processing facilities should be available to permit the addition of the essential nutrient [to a food] in a satisfactory manner.]

[6.1.7 (*former 3.9*) The additional cost [of mandatory addition of essential nutrients to foods] should be reasonable for the intended consumer.]

**[6.2** (*6.3 in previous draft; this entire section is renumbered consequently*) The following conditions should be fulfilled in the case of fortification programs that are voluntary:

6.2.1 Foods which may be fortified:

6.2.1.1 The intake of the food (s) which may be fortified should be stable and the lower and upper levels of intake should be known.

6.2.1.2 Certain foods should be excluded from voluntary fortification because of their ubiquity in the food supply and thus the potential for exposure to high intakes associated with a risk of adverse health effects.

**OR**

[6.2.1.2 Certain foods may not be appropriate for voluntary fortification, e.g., foods with the potential to result in exposure to high intakes associated with a risk of adverse health effects.]

[6.2.1.3 Consideration should be given to the nutrient profile of the food before fortification to ensure that nutritionally appropriate foods are selected for fortification.]

[6.2.1.4 Foods with nutrient profiles associated with a risk of adverse health effects as a consequence of a high content of risk-increasing nutrients, as demonstrated by scientific evidence, should be excluded from fortification.]

[6.2.1.5 Essential nutrients should not be added to unprocessed foods, including, but not limited to, fruit, vegetables, meat, poultry and fish.]

[6.2.1.6 Essential nutrients should not be added to beverages containing more than 1.2% by volume of alcohol.]

6.2.2 Selection of essential nutrients that may be added:

6.2.2.1 The severity of the adverse effect on which the Upper Intake Level (UL) is based should be reviewed by national authorities and should inform restrictions on essential nutrients permitted to be added to foods on a voluntary basis.

6.2.3 Determination of amounts of essential nutrients that may be added:

6.2.3.1 Minimum and/or maximum limits on the addition of essential nutrients to foods may be established by national authorities based on information on the level to achieve a health benefit without the risk of resulting in an adverse effect on health or on the metabolism of any nutrient.

6.2.3.2 The amount of the essential nutrient added to the food, should be sufficient for the purpose of contributing to meeting requirements of one or more essential nutrients and reducing the risk of their deficiency when the food is consumed in normal amounts by the population.

6.2.3.3 The amount of the essential nutrient added to a food, should not result in excessive intakes by individuals with a potentially high intake of a fortified food.

6.2.3.4 Intake data and a careful modelling approach by national authorities should be used to provide evidence to ensure that the exposure to the essential nutrient in question is within the Upper Level of Intake where this is available.

6.2.3.5 The Upper Level of Intake should be used to assess exposure to excessive intakes and to estimate safe limits of addition for essential nutrients.

6.2.3.6 Where an Upper Level of Intake is not available, the scientific evidence to support the safe addition of an essential nutrient should include:

a) demonstration of an upper level or a range of intake that is unlikely to result in adverse health effects, and

b) intake data and a careful modelling approach adopted by national authorities should be used to provide evidence to ensure that aggregate exposure to the essential nutrient in question is within acceptable limits.]

## **7. NUTRIENT ADDITION TO SPECIAL PURPOSE FOODS**

**7.1** Nutrients may be added to special purpose foods, including foods for special dietary uses, to ensure an appropriate and adequate nutrient content [based on the principles in this guidance wherever applicable]. Where appropriate, such addition should be made with due regard to the nutrient density of such foods.