codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE: Viale delle Terme di Caracalla 00153 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

ALINORM 08/31/26

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION
Thirty first Session
Geneva, Switzerland, 30 June - 5 July 2008

REPORT OF THE 29th SESSION OF THE CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Bad Neuenahr-Ahrweiler, Germany
12 - 16 November 2007

Note: This report includes Circular Letter CL 2007/43-NFSDU

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CX 5/20.2 **CL 2007/43-NFSDU**
November 2007

TO: Codex Contact Points
Interested International Organizations

FROM: Secretary,
Codex Alimentarius Commission,
Joint FAO/WHO Food Standards Programme, FAO,
Viale delle Terme di Caracalla,
00153 Rome, Italy

SUBJECT: **Distribution of the Report of the 29th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (ALINORM 08/31/26)**

A. REQUEST FOR COMMENTS AND INFORMATION AT STEP 8 OF THE PROCEDURE:

1. Draft Revised Codex Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten (ALINORM 08/31/26 para. 64 and Appendix III)

Governments and international organizations wishing to comment on the above text should do so in writing, preferably by email to: the Secretary, Codex Alimentarius Commission, Viale delle Terme di Caracalla, 00153 Rome, Italy (fax: +39 06 5705 4593, e-mail: codex@fao.org) **before 1 April 2008**.

2. Draft Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children (ALINORM 08/31/26, para. 78 and Appendix IV)

Governments and international organizations wishing to comment on the above text should do so in writing, preferably by email to: the Secretary, Codex Alimentarius Commission, Viale delle Terme di Caracalla, 00153 Rome, Italy (fax: +39 06 5705 4593, e-mail: codex@fao.org) **before 1 April 2008**.

B. REQUEST FOR COMMENTS AND INFORMATION AT STEP 5 OF THE PROCEDURE:

Establishment and Application of Risk Analysis Principles by the Codex Committee on Nutrition and Foods for Special Dietary Uses (ALINORM 08/31/26 para. 121 and Appendix VI)

Governments and international organizations are invited to comment on the above text and should do so in writing, preferably by email to the Secretary, Codex Alimentarius Commission, Viale delle Terme di Caracalla, 00153 Rome, Italy (fax: +39 06 5705 4593, e-mail: codex@fao.org), with a copy to: Dr Rolf Grossklaus, Director and Professor, Federal Institute for Risk Assessment, P.O. Box 33 00 13, 14191 Berlin, Germany, Fax: +49 1888 529 – 49 65, e-mail: ccnfsdu@bmelv.bund.de **before 1 April 2007**;

C. REQUEST FOR COMMENTS AND INFORMATION AT STEP 6 OF THE PROCEDURE:

1. Guidelines for Use of Nutrition Claims: Draft Table of Contents for Nutrient Contents (Part B Containing Provisions on Dietary Fibre) (ALINORM 08/31/6, para. 41 and Appendix II)

While considering this matter, the Committee agreed that it was not possible to progress further on the document at this stage, as it was preferable to allow more time for consultations at the national level, as the scientific papers had only been available shortly before the meeting. The Committee also agreed to ask comments as to how the FAO/WHO scientific update applied to the definition proposed for dietary fibre and its applicability for conditions for claims (for details of consideration see paras 22-41).

Governments and international organizations are invited to comment on the above text and should do so in writing, preferably by email to: Dr Rolf Grossklaus, Director and Professor, Federal Institute for Risk Assessment, P.O. Box 33 00 13, 14191 Berlin, Germany, Fax: +49 1888 5 29 – 49 65, e-mail: ccnfsdu@bmelv.bund.de with a copy to the Secretary, Codex Alimentarius Commission, Viale delle Terme di Caracalla, 00153 Rome, Italy (fax: +39 06 5705 4593, e-mail: codex@fao.org) **before 1 April 2008**;

2. Draft Advisory List of Nutrient Compounds for Use in Foods for Special Dietary Uses Intende for Infants and Young Children: Part D Advisory List of Food Additives for Special Nutrient Forms: Provisions on gum arabic (gum acacia) (ALINORM 08/31/26, paras 75-78 and Appendix V)

While considering the level of gum arabic that should be included in the list as there had been no consensus at the last session on the levels of 10 or 100 mg/kg, the Committee could not come to a conclusion and agreed to retain the two levels of 10 and 100 mg/kg in square brackets (for details of consideration see paras 75-78).

Governments and international organizations are invited to comment on the above text and should do so in writing, preferably by email to: Dr Rolf Grossklaus, Director and Professor, Federal Institute for Risk Assessment, P.O. Box 33 00 13, 14191 Berlin, Germany, Fax: +49 1888 5 29 – 49 65, e-mail: ccnfsdu@bmelv.bund.de with a copy to the Secretary, Codex Alimentarius Commission, Viale delle Terme di Caracalla, 00153 Rome, Italy (fax: +39 06 5705 4593, e-mail: codex@fao.org) **before 1 April 2008**.

SUMMARY AND CONCLUSIONS

The 29th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses reached the following conclusions:

MATTERS FOR FINAL ADOPTION BY THE 31ST SESSION OF THE CODEX ALIMENTARIUS COMMISSION:

The Committee:

- agreed to forward to the Commission the Draft Revised Codex Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten for final adoption at Step 8 (ALINORM 08/31/26 para. 64 and Appendix III);

- agreed to forward to the Commission the Draft Advisory List of Nutrient Compounds for Use in Foods for Special Dietary Uses Intende for Infants and Young Children for final adoption at Step 8 (ALINORM 08/31/26, para. 78 and Appendix IV)

MATTERS FOR PROVISIONAL ADOPTION BY THE 31ST SESSION OF THE CODEX ALIMENTARIUS COMMISSION:

The Committee:

- agreed to forward to the Commission the Establishment and Application of Risk Analysis Principles by the Codex Committee on Nutrition and Foods for Special Dietary Uses for adoption at Step 5 (ALINORM 08/31/26 para. 121 and Appendix VI).

MATTERS FOR ACTION BY THE 31ST SESSION OF THE COMMISSION

NEW WORK

The Committee:

- Agreed to ask, through the 61st Session of the Executive Committee, the 31st Session of the Commission to approve new work on the Revision of Nutrient Reference Values for Labelling Purposes. The Project Document is attached as Appendix VII (paras 122-133).

MATTERS OF INTEREST TO THE 31ST SESSION OF THE COMMISSION

The Committee:

- agreed to return the draft Table of Conditions for Nutrient Content (Part B containing provisions on dietary fibre) to Step 6 and to ask comments in the Circular Letter as to how the FAO/WHO scientific update applied to the definition proposed for dietary fibre and its applicability for conditions for claims (paras 22-41);

- agreed to cease the consideration of the Discussion Paper on the Production and Processing Standards Regarding the Nutritional Quality and Safety of Foods as these matters were already covered by the General Principles for the Addition of Essential Nutrients to Foods and the Proposed Draft Risk Analysis Principles Applied by the Committee on Nutrition and Foods for Special Dietary Uses being elaborated by the Committee (paras 134-140).

Intergovernmental Task Force on Foods Derived from Biotechnology (CTFBT)

- following the established Procedures between General Committees and Commodity Committees, the Committee noted that the proposed Annex on *Food safety assessment of foods derived from*

recombinant-DNA plants modified for nutritional or health benefits was considerably debated by the Itergovernmental Task Force on Foods derived from Biotechnology and after some discussion agreed to endorse the text as proposed by the Task Force (paras 16-21).

MATTERS REFERRED TO OTHER COMMITTEES

Codex Committee on Food Additives (CCFA)

The Committee noted the clarification of the Secretariat of JECFA regarding the applicability of ADI concept for infants below 12 weeks of age as presented in CRD 12 and agreed that there was no need to consider the food additives provisions at the Committee before JECFA and CCFA conclude their work on remaining food additive issues posed by the 28th Session of the Committee (para.15).

Codex Committee on Methods of Analysis and Sampling (CCMAS)

Following the established Procedures between Commodity Committees and General Committees, the CCNFSDU refers some responses to the questions on several methods in the standard for Infant Formula and Formulass for Special Medical Purposes Intended for Infants (paras 149-159).

Codex Committee on Food Labelling (CCFL)

Following the established Procedures between Commodity Committees and General Committees, the CCNFSDU refers the Section of Food Labelling of the Draft Revised Codex Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten for endorsement by the CCFL (see paras 59-60 and Appendix III).

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INTRODUCTION

1. The Twenty-ninth Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) was held in Bad-Neuenahr-Ahrweiler, Germany from 12 to 19 November 2007 at the kind invitation of the Government of Germany. Dr Rolf Grossklaus, Director and Professor of the Federal Institute for Risk Assessment, Berlin chaired the Session. The Committee was attended by 278 delegates, observers and advisors representing 71 member countries, one member organization and 26 international organizations.

OPENING OF THE SESSION

2. Mr Gert Lindemann, State Secretary of the Federal Ministry of Food, Agriculture and Consumer Protection, Germany welcomed the participants and noted the importance of the work of the Committee in ensuring the highest standards worldwide to protect the health of consumers, especially infants and children while ensuring fair practices of food trade. Mr Lindemann pointed out the importance of the Committee's work in implementing the WHO Global Strategy on Diet Physical Activity and Health and in such diverse areas as reducing malnutrition and obesity in countries around the world. While referring to the Provisional Agenda for this session of the Committee, Mr Lindemann encouraged the delegates to finalize the Draft Revised Standard for Gluten Free Foods and the Advisory List of Nutrient Compounds for the Use in Foods for Special Dietary Uses Intended for Infants and Young Children in order to ensure the protection of such vulnerable populations. Mr Lindemann indicated that it was very important to progress with the work on Substantiation of Health Claims and on the Application of Risk Analysis Principles by the Committee on Nutrition and Foods for Special Dietary Uses and decide on the work for Nutrient Reference Values for Food Labelling Purposes as these items were very important for the protection of consumers from deceptive and misleading claims and for choosing products on the basis of appropriate information. In conclusion, Mr Lindemann pointed out the importance of arriving at consensus with the work and wished all success to the delegates in their important work.

3. Following Rule II.5 of the Rules of Procedure of the Codex Alimentarius Commission the Committee was informed about CRD 2 on the division of competence between the European Community (EC) and its Member States and noted that 19 Member States of the EC were present at the current session.

ADOPTION OF THE AGENDA (Agenda Item 1)[1]

4. The Committee noted the proposal of the delegation of Canada that the delegates might benefit from the presence of the Chairperson of the Codex Committee on Food Labelling and agreed to consider information from the Committee on Food Labelling on the consideration of the WHO Global Strategy on Diet, Physical Activity and Health under Agenda Item 11 "Other Business and Future Work".

5. The Committee also noted that the Delegation of India had prepared a document (CRD 9) containing the proposal for new work on the elaboration of a standard for "Processed Cereal Based Foods for Underweight Infants and Young Children" and agreed to discuss this matter on Agenda Item 11 "Other Business and Future Work".

6. The Delegation of Republic of Korea drew the attention of the Committee to the fact that sufficient time should be allocated to discuss Item 8 in order to have a clear guidance from the Committee regarding further work on this issue.

7. With these modifications the Committee adopted the Provisional Agenda as the Agenda for the 29th Session of the Committee.

[1] CX/NFSDU 07/26/1; CRD 2 (Annotated Provisional Agenda on the Division of Competence between the European community and its Member States according to Rule II paragraph 5 of the Codex Alimentarius Commission; CRD 15 (comments of India).

MATTERS REFERRED BY THE CODEX ALIMENTARIUS COMMISSION AND/OR OTHER CODEX COMMITTEES (Agenda Item 2)[2]

8. The Committee noted that most of the matters referred by the 30th session of the Commission were for information purposes while others would be discussed in more detail under relevant Agenda items. The Committee also noted that assignments given by the Commission in relation to the implementation of the Strategic Plan 2008-2013 of the Codex Alimentarius Commission such as the review and development of Codex standards and related texts for food safety was ongoing work and that Activity 2.2 Review of risk analysis principles would be taken on Item 7 while considering the elaboration of application of risk analysis principles by the Committee on Nutrition and Foods for Special Dietary Uses. In addition, the Committee noted matters referred as follows:

Trans fatty acids

9. The Representative of WHO informed the Committee about the Scientific Update on trans fatty acids (TFA) which was led by WHO. The Representative indicated that the Scientific Update reviewed the health effects of TFA from both epidemiological and experimental perspectives, as well as the feasibility of alternative replacements and pointed out that the expert group reviewed scientific background papers prepared and further agreed to prepare six scientific review papers. These include: 1) General historical background of the work related to TFA and the Global Strategy; 2) Risk assessment on TFA: epidemiological/experimental; 3) Quantification of consequences/model to assess alternatives to TFA; 4) Feasibility for replacement of TFA; 5) Assessing approaches to removing TFA in the food supply in industrialized countries and in developing countries; and 6) Summary and conclusions of the scientific update. The Representative indicated that the final papers would be published most likely in the European Journal of Clinical Nutrition in early 2008.

Prioritization of work

10. The Committee noted that the General Criteria for Prioritization of Work presented in the Codex Procedural Manual sufficiently covered needs of the Committee and therefore there was no need to develop additional criteria for the prioritization of work by the Committee.

Project documents

11. With regard to project documents for new work, the Committee noted that the 30th Session of the CAC was of the view that some project documents were not of sufficient quality, not addressing all criteria with sufficient explanation/justification and that the CAC had requested that in future all documents should be prepared in accordance with provisions set forth in the Codex Procedural Manual.

Methods of Analysis in the Codex Standard for Infant Formula

12. The Committee recalled that the 30th Session of the Commission had adopted the draft Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants with the understanding that the Section on Methods of Analysis would be reviewed by the CCNFSDU with a view to its submission to CCMAS for endorsement. The Committee noted that some proposals relevant to questions posed by the 28th session of the Codex Committee on Methods of Analysis and Sampling were contained in CRD 10 prepared by the United States and agreed to establish an inter-session working group to review issues related to methods of analysis and sampling in the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants and Young Children.

13. Some delegations drew the attention of the Committee to the fact that CRD 10 contained some provisions which were not acceptable to all members and expressed their view that more work on methods of analysis and sampling for all foods for special dietary uses was necessary. CRD 15 prepared by the EC was also made available. It was proposed that the work on this matter be extended between the current and subsequent sessions and that an electronic working group could do it (see also Item 11).

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[2] CX/NFSDU 07/26/2; CX/NFSDU 07/29/2-Add.1 (matters referred from the Intergovernmental Task Force on Biotechnology); CRD 3 (information from WHO); CRD 15 (comments of India).

Review of Codex Committee structure and mandates of Codex Committees and Task Forces

14. The Delegation of Australia drew the attention of the delegates to the fact that the last session of the Commission due to time constraints was not able to finalize discussions and provide conclusions on Proposal No 10 regarding the work of the Committee and encouraged the Executive Committee and the Commission to finalize this discussion which would provide clear direction for future work to be undertaken by the CCNFSDU.

Food additives in infant formula

15. The Committee noted the clarification of the Secretariat of JECFA regarding the applicability of ADI concept for infants below 12 weeks of age as presented in CRD 12 and agreed that there was no need to consider the food additives provisions at the Committee before JECFA and CCFA conclude their work on remaining food additive issues posed by the 28th Session of the Committee.

Food safety assessment of foods derived from recombinant-DNA plants modified for nutritional or health benefits[3]

16. The Committee recalled that the 7th session of the Codex *ad hoc* Intergovernmental Task Force invited the 29th Session of the Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) to review the annex on Food safety assessment of foods derived from recombinant DNA plants modified for nutritional or health benefits and provide comments if necessary as an annex contained references to certain concepts related to nutrition.

17. The Chairperson of the Task Force Dr H. Yoshikura briefly introduced this Annex and explained that while developing it, the Task Force tried to ensure its consistency with other Codex texts developed by the Committees on Nutrition and Food Labelling by making references to appropriate texts elaborated by the above Committees and indicated that the wording contained in annex was reached after a careful consideration.

18. The Delegation of Norway while agreeing in principle with the content of the document proposed to amend last sentences of paragraphs 14 and 17 for clarification purposes.

19. The Delegation of Thailand drew the attention of the Committee to the fact that in document in the definition section only the definition of "nutrient" was included, however in the text the "upper level of intake" and "bioavailability" was used, therefore was of the view that these terms should be also defined. The Delegation also indicated that "bioavailability" in humans was required for both nutrients and undesirable substances in the document and was of the view that it would be inappropriate to allow an evaluation of undesirable substances in humans therefore in vitro or animal studies for them should be allowed.

20. Some delegations pointed out that this annex contained relevant references to the texts elaborated by the CCNFSDU, therefore proposed to endorse the document without additional changes.

21. The Committee noted that the proposed Annex was considerably debated by the Task Force and after some discussion agreed to endorse the text as proposed by the Task Force.

GUIDELINES FOR THE USE OF NUTRITION CLAIMS: DRAFT TABLE OF CONDITIONS FOR NUTRIENT CONTENTS (PART B CONTAINING PROVISIONS ON DIETARY FIBRE) AT STEP 7 (Agenda Item 3)[4]

22. The Committee recalled that its last session had agreed to return the Draft Table of Conditions for Claims (dietary fibre) to Step 6 with a Circular Letter asking comments and additional input on the definition and other provisions for dietary fibre in the light of the results of the FAO/WHO scientific update of

[3] ALINORM 08/31/34, Appendix III.

[4] CL 2007/3-NFSDU, CX/NFSDU 07/29/3 (comments of Argentina, Australia, Costa Rica, Dominican Republic, Guatemala, Japan, Mexico, New Zealand, Philippines, United States of America, INFOODS, AAC, AIDGUM, EDA, IACST, IADSA, ICBA, ICGMA, IDF, IFAC, IFT, ILSI, IUNS), CX/NFSDU 07/29/3- Add.1 (comments of Brazil), CRD 1 (Report of the Working Group on the Revision of the Standard for Gluten Free Foods), CRD 3 (comments of India, Indonesia, Philippines), CRD 13 (comments of CIAA)

carbohydrates in human nutrition, including the definition of dietary fibre, which had been presented at the last session of the Committee.

23. The Representative of WHO informed the Committee that FAO and WHO had agreed to undertake a scientific update on some of the key issues related to carbohydrates in human nutrition in 2005. This Scientific Update of existing knowledge and evidence relating to the current recommendations was viewed as essential in the process leading up to an eventual expert consultation on carbohydrates in human nutrition. A meeting of the authors of the scientific background papers, together with several other expert peer-reviewers, was held in July 2006. At this meeting, the experts also reviewed issues related to dietary fibre, among various other issues, and proposed a definition of dietary fibre.

24. The Representative also informed the Committee about the availability of all the papers prepared for the Joint FAO/WHO Scientific Update on Carbohydrates in Human Nutrition as a supplement of the European Journal of Clinical Nutrition (Volume 61, Supplement 1, December 2007), which was also distributed to Codex Contact Points.

25. The brief rationale used by the experts for defining dietary fibre as "intrinsic plant cell wall polysaccharides" was provided by the Representative of WHO at the 28th Session of CCNFSDU. However, the Committee requested additional information regarding the work of the expert group and the issues and approaches employed by the expert group in reaching the conclusions. Therefore, WHO requested Professor J. Cummings, as a member of the expert group which undertook the scientific update for FAO and WHO, to participate and further inform the Committee. This information is presented in paragraphs 27 to 35.

26. Professor Cummings highlighted that the Joint FAO/WHO Scientific Update concerned the whole of carbohydrates, not just fibre. New evidence of the importance to health regarding glycaemic index and glycaemic load, sugars in relation to obesity, resistant starch, the concept of whole grains and of prebiotic oligosaccharides was considered. Most of these encroach upon the traditional area of fibre, and therefore, it is necessary in considering any definition of fibre to place it in the context of carbohydrates as a whole.

27. The expert group reviewed the classification of carbohydrates, based on their chemistry and dividing them into sugars, oligosaccharides and polysaccharides. The classification of the 1997 Joint FAO/WHO Expert Consultation was endorsed by the expert group. For all food components, it was agreed that they should be defined first by their chemistry. This was felt to be essential for good methods of measurement, labelling, health claims and enforcement.

28. In this context the definition of fibre was discussed. The importance of fibre to general health was accepted, in that a high fibre diet based on whole grain foods, fruits and vegetables was well established as being protective against various chronic diseases, such as diabetes, coronary heart disease and some cancers. The question of how to characterise fibre continues to present some difficulty. Existing definitions were considered, including that being proposed by the CCNFSDU. After considerable discussion, the expert group decided to define fibre as “intrinsic plant cell wall polysaccharides”.

29. A physiological basis for the definition, such as “non digestibility”, was considered inappropriate. Inclusion of “non digestibility” poses many problems as there is no agreement on the definition of digestibility and no method to measure nor validate it, without extensive difficult studies in humans. Digestion of food components in the gut is affected by many factors, such as gut transit time, the nature of the microflora, history of antibiotic use, other components of the diet and the amount consumed. Food processing, storage conditions, cooking and physical treatments such as grinding, also affect digestibility.

30. The expert group agreed that a food component should be defined in the first instance by its chemistry, not its function. The expert group was also unconvinced that the definition should include “properties” of fibre, such as effects on transit time, fermentation and lipid metabolism. These were not consistent effects of fibre and were felt to be the province of health claims. Many factors contributed to their control other than fibre.

31. The inclusion of carbohydrates, such as resistant starch and the prebiotic oligosaccharides in the definition of fibre was considered to be potentially misleading for the consumer. These carbohydrates, while having important properties in their own right, cannot be said to confer the benefits of fibre as originally

proposed. “There is no good evidence of protection against cardiovascular disease and diabetes when various oligosaccharides or isolated components of whole-grains, fruits, vegetables and legumes are added to functional and manufactured foods.”

32. Professor Cummings further provided responses to some of the written comments made on the new proposed definition as the outcome of the Joint FAO/WHO Scientific Update. One was the issue related to "intrinsic". There are two reasons for the inclusion of the term “intrinsic” in the proposed new definition. Firstly the Institute of Medicine of the USA makes the distinction between intrinsic and other types of fibre, which the expert group found to be a reasonable concept. Secondly, as stated already, there is no evidence that diets high in resistant starch, isolated and purified cell wall material, plant gums and oligosaccharides confer the health benefits traditionally ascribed to fibre.

33. To the question regarding the exclusion of lignin, Prof Cummings clarified that lignin was not included in the proposed definition because true lignin is very difficult to measure. What is normally reported as lignin in the fibre method is Klasson lignin, which is an impure mixture of often unidentified substances. If true lignin is found to be important to health, it should be measured separately.

34. Finally, the Committee was urged to take a broader view of carbohydrates, into which a definition of fibre can be fitted. The newly discovered properties of the carbohydrate components of the diet can only be exploited by the food industry with benefit to the consumer if these are defined and measured separately. Fibre represents a unique component that does not encroach on the other clearly defined classes of carbohydrates.

35. The Chair invited the Committee to provide general comments or questions on the scientific update and to consider whether the discussion on the Draft Table should be deferred until the next session in order to allow delegates to consider carefully the provisions for dietary fibre in the light of the scientific update.

36. The Committee had an opportunity to ask questions regarding the scientific update and considered in particular the following questions: the difference between intrinsic and other fibre; the substances which were not included in the definition of fibre, such as resistant starch; and analytical issues.

37. As regards the non-inclusion of resistant starch in the definition of fibre, Prof Cummings noted that there was always a possibility of declaring the presence of resistant starch as a health claim if adequate scientific justification existed. Other added nutrients could also be declared in the list of ingredients or as part of nutrition labelling.

38. The Delegation of the EC pointed out that the purpose of the Table of Conditions was to define nutritional claims. Therefore, some clarification was needed as to how the scientific update could affect the definition of fibre in this context.

39. The Observer from IUNS drew the attention of the Committee to the problems related to methodology and indicated that IUNS was currently working with IUPAC on the analytical methodology for the determination of fibre and that this work would be completed in 2008.

40. Several delegations expressed the view that they would need more time to consider the results of the scientific update. The Committee agreed that it was not possible at this stage to progress further on the document, as it was preferable to allow more time for consultations at the national level, as the scientific papers had only been available shortly before the meeting. It was noted that if the document was retained at Step 7 no comments would be requested and several delegations indicated that they would prefer to submit comments. After some discussion, the Committee agreed to return the current document to Step 6 and to ask comments in the Circular Letter as to how the FAO/WHO scientific update applied to the definition proposed for dietary fibre and its applicability for conditions for claims.

Status of the Guidelines for the Use of Nutrition Claims: Draft Table of Conditions for Nutrient Contents (Part B Containing Provisions on Dietary Fibre)

41. The Committee agreed to return the Draft Table (Provisions on Dietary Fibre) to Step 6 for further comments and consideration at the next session (see Appendix II).

DRAFT REVISED STANDARD FOR GLUTEN-FREE FOODS AT STEP 7 (Agenda Item 4)[5]

42. The Committee recalled that at its 28th session it had agreed to return the Draft Revised Standard for Gluten-Free Foods to Step 6 for further comments and that a physical working group chaired by Sweden and co-chaired by Canada would meet before the current Session of the Committee to review the comments received and to prepare proposals in order to assist the Plenary in finalizing the Standard.

43. The Co-chairs from Sweden and Canada introduced CRD 1 and explained all changes that were proposed in the title and other sections of the Standard, which was presented in Appendix to the CRD 1.

44. The Committee expressed its appreciation to the Working Group for their excellent work and decided to consider the Standard based on the document prepared by the Working Group and presented in the Appendix to CRD 1. The Committee agreed to concentrate discussion only on those sections comments were received and square brackets existed. In addition to editorial and formatting corrections the Committee made the following changes and recommendations on the following sections.

Title

45. The Committee agreed to rename the title to Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten.

Scope

46. After some discussion, the Committee accepted the second option for the scope proposed by the Working Group. It also clarified in the second paragraph that foods were for "general" rather than "normal" consumption and that foods that by their nature were "gluten-free" could also be represented for use by persons intolerant to gluten.

Section 2.1.1 Gluten-free foods and Section 2.1.2 Foods specially processed to reduce gluten content to levels above 20 up to 100 mg/kg

47. The Committee had a lengthy discussion regarding the definition for gluten-free foods described in this section and how to address labelling issues related to gluten-free foods and foods specially processed to reduce gluten.

48. A number of delegations were of the view that the term "gluten-free" sho uld be reserved only for products that contain not more than 20 mg gluten per kg as sold or distributed to consumers or products gluten-free by nature containing no more than 20 mg gluten per kg and preferred to have only this group of products in the standard and pointed out that the Committee should help celiac patients to reduce the amount of gluten in their diet as low as possible.

49. A number of other delegations preferred to have two groups of foods: one for gluten free foods with a level not exceeding 20 mg/kg and another for products such as specially processed wheat starch based products with reduced gluten content above 20 to at a level of 100 mg/kg. They drew the attention of the Committee to the fact that products containing those levels of gluten were on the market and had been used as gluten free foods for a long time without any negative consequence and that the removal of these products would limit consumers' choice for their diets.

50. Some delegations indicated that there was significant variation in the sensitivity to gluten among celiac patients and not all countries have those products on their markets. However, it was important to convey a message to consumers about the true nature of the products.

51. The Committee noted that this matter was also discussed at length at the Working Group which, as a compromise solution, inserted a footnote that starch at levels above 20mg gluten per kg could not be labelled as "gluten free" but can be as ingredient in a gluten-free product provided that the final product contained

[5]ALINORM 07/30/26, Appendix IV; CX/NFSDU 07/29/4 (comments from Argentina, Australia, Canada, Costa Rica, Guatemala, Mexico, United States of America, AAC, ISDI, IWGA, WGPAT); CX/NFSDU 07/29/4-Add.1 (comments from Brazil, AOECS); CX/NFSDU 07/29/4-Add.2 (comments from Cuba, Ghana); CRD 1 (Report of the Working Group); CRD 4 (comments from India, Philippines); CRD 11 (comments from AAC); CRD 16 (comments from South Africa).

lesson more than 20 mg gluten per kg. The Committee inserted Section 2.1.2 for foods with gluten content above 20 mg/km to 100 mg/kg.

52. After some discussion, the Committee agreed that matters presented in the Description Section regarding gluten free foods and other foods with reduced gluten content should be addressed in conjunction with Section 4 on Labelling.

53. The Committee made some amendments to sections 2.1.1 a) and b) and 2.1.2 for clarification purposes and clarified a footnote regarding the tolerance to oats. The Committee agreed to specify that the allowance of oats that are not contaminated with wheat, rye or barley in foods covered by the standard may be determined at national level.

54. The Committee noted that the terms "very low gluten foods" or "low gluten foods' or 'gluten-reduced foods" presented in the title and text of Section 2.1.2 might create confusion among consumers in different countries and after some discussion decided to rename this section to Foods Specially Processed to Reduce Gluten Content to level above 20 up to 100 mg/kg with consequential amendments in the text to that effect. The Committee also made some editorial amendments to the first paragraph of this section and deleted the square brackets around the level of 100 mg/kg.

55. The Committee agreed to insert the provision that decisions on marketing of products described in this section may be determined at national level.

56. The Delegation of Spain expressed their reservation on the decision to include Section 2.1.2 defining products from 20 to 100 mg gluten per kg.

57. In view of these changes, the Committee agreed to delete a footnote 2 from section 2.1.1 b) containing provisions for starch at levels above 20 to 100 mg gluten per kg as this was already covered by Section 2.1.2.

Section 3 Essential composition and quality factors

58. The Committee agreed to delete the square brackets around 100mg/kg in section 3.2 in view of its decision on section 2.1.2.

Section 4 Labelling

59. In section 4.1, the Committee clarified that the use of term "gluten-free" was for products described in Section 2.1.1.

60. Different proposals were put forward for section 4.2 in order to describe how foods processed to reduce gluten content to a level above 20 up to 100 mg/kg should be labelled. After some discussion the Committee agreed to use the second option of section 4.2 proposed by the working group with the addition of clarification that labeling of products described in Section 2.1.2 may be determined at the national level and that these products must not be called "gluten-free" and that labelling terms for such products should indicate the true nature of the food.

Section 5 Methods of analysis and sampling

61. The Committee agreed to the proposal of the Observer from WGPAT to rearrange section 5.1 for clarity and in order to provide more logic for the text and clarified that for qualitative analysis the presence of gluten shall be based on relevant methods e.g. ELISA or DNA.

62. The Committee agreed to emphasize that methods should be validated against a certified reference material and clarified that the detection limit should be at 10 mg gluten per kg or below. The Committee also deleted the reference to "traceability" and "internationally accepted standards" in the second paragraph.

63. To the concern expressed by the Delegation of Canada that the ELISA R5 Mendez method does not meet the definition of a Type I method and the request to ask the Committee on Methods of Analysis and Sampling to reconsider the status of this method, the Secretariat clarified that this matter had been substantively considered by the CCMAS at its 26th and 27th sessions and that the Committee came to a conclusion that a Type I should be allocated to this method. The Secretariat also recalled that new methods

could be proposed as they are available and meet criteria presented in Codex Procedural Manual, considered by the Committee and forwarded to the CCMAS for endorsement.

Status of the draft revised Standard for Gluten-Free Foods

64. The Committee agreed to forward the renamed draft revised Standard for Foods for Special Dietary Uses for Persons Intolerant to Gluten to the 31st Session of the Commission for final adoption at Step 8 (see Appendix III).

DRAFT ADVISORY LIST OF NUTRIENTS COMPOUNDS FOR USE IN FOODS FOR SPECIAL DIETARY USES INTENDED FOR INFANTS AND YOUNG CHILDREN AT STEP 7 (Agenda Item 5)[6]

65. The Committee recalled that the Draft Advisory List had been adopted at Step 5 by the 29th Session of the Commission and circulated for comments at Step 6. The Committee considered the text section by section and made the following amendments and comments.

66. The Committee agreed with the proposal of the Delegation of the United States to add a new section on optional ingredients, as Codex standards on foods for infants and young children do not identify all optional ingredients. It was agreed that optional ingredients should met the criteria specified in section 2.1, and the provisions in relevant Codex standards.

67. The Delegation of Mexico expressed the view that Hydrogen reduced iron had a low bioavailabilty and therefore should not be included in the advisory list. The Committee however retained this substance, noting that it was of an advisory nature and that countries could select the nutrient source that was most suitable at the national level.

68. The Delegation of India, referring to its written comments, proposed to include Sodium Iron EDTA as a source of iron. The Committee agreed that in order to consider the inclusion of additional substances, relevant data should be provided in accordance with the criteria set out in section 2.1.

69. Some editorial corrections were made throughout the text, including the references to the use of some substances in Codex standards and to the relevant Pharmacopoeia.

70. It was clarified in footnote 7 that the last column referred to foods for special medical purposes other than infant formula, as infant formula for special medical purposes intended for infants were included in a specific column.

71. In section 4. Sources of Sodium, the references to the use of sodium sulphate in Codex Standards were corrected. The Committee agreed with the proposal of the Delegation of the EC to delete Sodium Tartrate due to the possibility of exceeding the ADI and the contribution to sodium intake resulting from its use.

72. Following some discussion, the Committee clarified that in section 10. Folic Acid, Calcium-L-methyl-folate was suitable only in foods for special medical purposes and section B of the Standard for Infant Formula.

73. In Part C, the Committee agreed to include Calcium-L-methyl pholate in Part B on the basis of available purity requirements and to delete 4.6 Lecithin as it is an additive. In section 6. Nucleotides, the square brackets were deleted and all substances listed were retained.

74. The Committee agreed to delete the entire section listing the substances that lack official purity requirements as no additional information had been provided on these substances.

75. In Part D. Advisory List of the Committee recalled that the Committee on Food Additives had endorsed the additives in Part B with some amendments. The Committee discussed the level of gum arabic that should be included in the list as there had been no consensus at the last session on the levels of 10 or 100 mg/kg.

[6] ALINORM 07/29/26, Appendix V, CL CX/NFSDU 07/29/05 (comments of Brazil, Costa Rica, Cuba, Dominican Republic, Ghana. Guatemala, United States), CRD 5 (comments of European Community, India, Indonesia, Philippines)

76. The Delegation of the European Community expressed the view that the level of gum arabic should be 10 mg/kg as there was no justification for a higher level. The Delegation of the United States pointed out that the level in the current Advisory List was 100 mg/kg and that it should be retained as no new information had been provided to justify a lower level. The Observer from AIDGUM supported this position and proposed to provide additional information on technological justification why higher levels should be used.

77. The Committee could not come to a conclusion and agreed to retain the two levels of 10 and 100 mg/kg in square brackets for further consideration. However, it was agreed that this should not delay the progress of the Draft Revised Advisory List as all other issues had been addressed, including the other additives in part D.

Status of the Draft Advisory List of Nutrients Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children

78. The Committee agreed to advance the Draft Advisory List to Step 8 for adoption by the 31st Session of the Codex Alimentarius Commission (See Appendix IV), with the exception of the level of gum Arabic in Part D, which was returned to Step 6 for further comments and consideration at the next session (see Appendix V).

PROPOSED DRAFT RECOMMENDATIONS ON THE SCIENTIFIC BASIS OF HEALTH CLAIMS AT STEP 4 (Agenda Item 6)[7]

79. The Committee recalled that its 28th session had not been able to consider this item in detail due to time constraints and had agreed to retain the Proposed Draft Recommendations at Step 4 for consideration at its next session.

80. The Delegation of France recalled the background of the development of the recommendations and noted that the text had been redrafted for the last session in the light of the comments received and the guidance provided by the Committee at previous sessions. The Delegation stressed the importance of the nature of scientific evidence as addressed in section 4 and noted that special cases were addressed separately. Some issues remained to be clarified, such as the scope, since the Committee had taken different views at different sessions as to whether claims should refer to total diets. The question of reevaluation of health claims also required further consideration as two approaches were possible: reevaluation on a regular basis or only when new substantial scientific evidence became available.

81. The Committee expressed its thanks to the Delegation of France and the drafting group for their excellent work on complex issues and had a general discussion on the main sections in the document.

Preamble

82. The Committee agreed that the Proposed Draft Recommendations, when finalized would be included as an Annex in the Guidelines for Use of Nutrition and Health Claims. The Committee therefore agreed to delete the Preamble as no additional reference to other Codex texts would be required as the recommendations would be part of the Guidelines.

Scope

83. The Delegation of India, referring to its written comments, proposed to add new provisions concerning the application of health claims under various circumstances. The Committee however agreed that the purpose of the Recommendations was to define the scientific basis of health claims and that other issues concerning health claims were addressed in the adopted Guidelines, which were not under consideration.

84. The Committee discussed the need to include additional food safety considerations. After some discussion, it was agreed to retain the current paragraph on food safety with an editorial amendment for clarification purposes.

[7] CX/NFSDU 07/29/6 (previously CX/NFSDU 06/28/7) CX/NFSDU 27/29/6-Add.1 (comments of Argentina, Australia, Bolivia, Brazil, Guatemala, Kenya, New Zealand, United States, CIAA, IASDA, ISDI, WSRO), CRD 6 (comments of Australia, Cuba, European Community, India, Indonesia, Malaysia, Philippines, United States)

Definition

85. It was proposed to delete this section as the Guidelines for Use of Nutrition and Health Claims did not refer to properties in the definition of health claims and this would ensure consistency of the Annex with the Guidelines.

86. Some delegations pointed out that biologically active substances were not defined and should not be included in the definition. The Committee agreed that this term should be replaced by "related substances or components".

87. It was also agreed to replace "whole diets" with "categories of foods" as claims on whole diets were excluded.

88. The Delegation of France pointed out that this definition has been inserted in order to cope with the inclusion of whole diet in the Scope of the Recommendations and this might no longer be required.

89. The Delegation of the United States suggested that the phrase "properties of food" be replaced by the language of the Guidelines for Use of Nutrition and Health Claims "food or food constituent" throughout the text.

Evaluation of Scientific Evidence

90. The Delegation of the United States expressed the view that there should be a more detailed description of the clinical studies used as a basis for the substantiation of health claims, and proposed additional text to this effect The Delegation therefore proposed to add new text in section 4.1 in order to describe the requirements for these studies more precisely. The Delegation of Malaysia proposed to include a reference to epidemiological studies in paragraph 4.1.

91. Some observers expressed the view that it was not always possible to substantiate health claims on the basis of well designed clinical trials. They were concerned that it might not be feasible and practical to base all health claims on evidence from human studies, especially as many original health claims were based on observational studies and epidemiological research. Some observers also pointed out that some common claims, for example for groups of foods such as vegetables, would be excluded by such provisions.

92. After some discussion, the Committee recognized that it was not possible to complete the review of the text section by section in view of the issues raised in the discussion and considered how to proceed further.

93. The Delegation of the United States proposed to reorganize the document in order to follow the steps for the substantiation of health claims, and to include the following in Section 4. Evaluation of Scientific Evidence: 4.1 Nature, quality and scope of the evidence; 4.2 Evaluation of the total body of relevant evidence; and 4.3 Special cases.

94. The Delegation of France recalled that the current structure was the outcome of responses to a circular letter and that a specific section was necessary to define the level of scientific evidence, while expressing some concern that this might be lost if the document was reorganized. The Delegation pointed out that while further development of the Section "Step-by-Step Process" might provide more useful information, the main issue to be addressed was the standard of evidence required to substantiate claims and sought the guidance of the Committee in order to proceed with the document.

95. The Delegation of Australia expressed the view that the structure of the document should correspond to the different types of health claims described in the Guidelines for Use of Nutrition and Health Claims and that the presentation of scientific evidence for substantiation could be also significantly different according to the type of claim concerned.

96. The Committee could not come to a conclusion on the provisions for scientific evidence or the reorganization of the text at this stage and agreed that an electronic working group led by France with the assistance of interested delegations working in English only would revise the document in the light of the comments received.

Status of the Proposed Draft Recommendations on the Scientific Basis of Health Claims

97. The Committee agreed to return the Proposed Draft Recommendations to Step 2/3 for redrafting by the electronic working group led by France, comments and consideration at the next session.

PROPOSED DRAFT NUTRITIONAL RISK ANALYSIS PRINCIPLES AND GUIDELINES FOR APPLICATION TO THE WORK OF THE COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES AT STEP 4 (Agenda Item 7)[8]

98. The Committee recalled that a new work proposal on the Establishment and Application of Nutritional Risk Analysis Principles was approved by the 30th Session of the Commission.

99. The Delegation of Australia introduced the document and explained the structure and the content of the document. The Delegation indicated that the main definitions were taken from the Codex Procedural Manual and that two options for the title were proposed. The Delegation pointed out that the purpose of the document was intended for the application in the framework of the Codex rather than by governments.

100. The Committee expressed appreciation to the Delegation of Australia for the very high quality of their document.

General Comments

101. The Delegation of Malaysia drew the attention of the Committee to the need for a use of consistent language in various examples and pointed out that not all saturated fatty acids have the same physiological effect.

102. The Representative of FAO indicated that WHO/FAO should be the primary if not only source of scientific advice to CCNFSDU, and that international expert groups might not provide independent and unbiased scientific advice. FAO and WHO are committed, if requested by CCNFSDU, to hold expert meetings and consultations on the topics requested and to publish reports in a timely manner. For global risk assessment only international nutritional reference standards, but not regional or national ones should be used. For international nutritional risk assessment international databases on food consumption and food composition will have to be developed. For food safety, e.g. JECFA, the GEMS/food 13 cluster diets are used for exposure assessment, which might not be appropriate for nutritional risk assessment.

103. In response to the clarification requested by the Delegation of the United States of America regarding the need for a FAO/WHO expert consultation, the Representative of WHO indicated that the suggestion was made as the purpose of the draft principles was not clear, whether they were being developed for internal Codex use or for governments. However, following the explanation by the Delegation of Australia while introducing the document, it was clear that these principles are being developed for internal Codex use, but not for the use of the governments. The Representative of WHO explained that for developing guidance to governments, such as to develop recommendations for an approach to nutritional risk assessment, it is a standard practice for WHO to have an expert consultation involving external international experts. The Representative of WHO further noted that WHO is very much aware that Codex Member States are increasingly expressing the need for strengthening the role of FAO and WHO in providing timely scientific advice. WHO is ready to ensure timely provision of scientific advice with timely support from governments. A good example of this was the 2005 Technical Workshop on Nutrient Risk Assessment. With support from governments, FAO and WHO were able to deliver scientific advice in time. This issue should also be seen in the light of the development of the Global Initiative for Food related Scientific Advice (GIFSA) which will support the scientific work of FAO/WHO expert bodies, including various expert consultations and meetings related to nutrition.

104. The Committee considered the document section by section and in addition to editorial corrections made the following comments and changes.

[8] CX/NFSDU 07/29/7; CX/NFSDU 07/29/7 - Add.1 (comments from the United States, WSRO); CX/NFSDU 07/29/7-Add.2 (comments from Mexico); CRD 7(comments from the European Community, Indonesia and Philippines)

Title

105. The Committee agreed to clarify the title to read "Nutritional Risk Analysis Principles and Guidelines for Application to the Work of the Committee on Nutrition and Foods for Special Dietary Uses" as it better addressed the content of the document, and it was consistent with titles of documents elaborated by other Codex Committees on this matter.

Section 1. Background

106. The Representative of WHO requested a clarification or adding some wording in the second paragraph of the text to ensure that the joint FAO/WHO expert consultations referred to in the document are those requested by the CCNFSDU, but not all FAO/WHO expert consultations, as many of the joint FAO/WHO expert consultations are not only for Codex, but for developing guidelines and recommendations for the governments, including those on human nutrient requirements, fortification guidelines, supplementation guidelines.

Section 2. Introduction

107. The Committee noted that it was not clear what the term "attendant" meant in relation to risk, therefore agreed to delete "attendant" in paragraph 3.

108. The Committee agreed to change "nutritional principles" to "nutritional risk analysis principles" in paragraph 4 and throughout the document.

109. The Committee agreed that the "favorable impact on health" should be changed to "nutritional or physiological effect" and placed it in square brackets in footnote 2 to better describe the potential impact of a related substance.

Section 3. Scope and Application

110. The Committed agreed to combine paragraphs 9 and 10 by deleting the reference to examples in the first and second bullet of paragraph 9 and combined the first and second bullets of paragraph 10 and moved it as the third bullet in paragraph 9, and put this bullet in square brackets for further comments and consideration.

111. The second bullet of old paragraph 12 was amended by deleting "potentially eligible " and clarifying that formulating general principles for assessing and managing risk related to food not only to health claims but also to nutrition claims.

112. Paragraph 13 was deleted as it covered issues that were not related to nutritional risk analysis.

Section IV Definitions

113. The Delegation of the European Community requested clarification regarding the status of the definitions as presented, indicating that some of these may need to be revised by the Committee to reflect more clearly nutritional risk assessment.

Section 5. Principles for Nutritional Risk Analysis

114. The Committee deleted the paragraph 16 because Section 1 already covered it.

115. The Committee agreed to combine paragraph 31 and 32 by deleting the first sentence of paragraph 31 and move the second sentence to the end of paragraph 32 and put this sentence into square brackets. The Delegation of Mexico proposed to add "stability" after "availability" in paragraph 31.

116. The Committee agreed to delete paragraph 33 as nutritional risk analysis was not in the terms of reference of JECFA.

117. The Committee agreed to consider a new paragraph as proposed by the Delegation of European Community in CRD 7 clarifying that nutritional risk management decisions should take into account food habits of different consumers and put this paragraph in square brackets for further comments and consideration.

Section 6. Selection of Risk Assessor by CCNFSDU

118. The Committee noted a proposal that in some cases national expertise might be required, therefore agreed to amend last sentence of paragraph 38 and put new wording into square brackets.

119. The Delegation of Malaysia expressed its concern with the inclusion of other sources of scientific advice in addition to FAO/WHO, and indicated that it should be clarified whether "national expertise" was provided by governments or by other sources.

120. In view of the deletion of some paragraphs, the text was renumbered accordingly.

Status of the Proposed Draft Nutritional Risk Analysis Principles and Guidelines for Application to the Work of the Committee on Nutrition and Foods for the Special Dietary Uses

121. The Committee recognized that significant progress had been made on the revision of the document and, despite the fact that a number of paragraphs were left in square brackets, it agreed to advance the Proposed Draft Nutritional Risk Analysis Principles and Guidelines for Application to the Work of the Committee on Nutrition and Foods for the Special Dietary Uses to Step 5 for adoption by the 31st Session of the Codex Alimentarius Commission (see Appendix VI).

DISCUSSION PAPER ON THE PROPOSALS FOR ADDITIONAL OR REVISED NUTRIENT REFERENCE VALUES FOR LABELLING PURPOSES (Agenda Item 8)[9]

122. The Committee recalled that an electronic working group coordinated by the Delegation of Republic of Korea was requested to revise the discussion paper on Nutrient Reference Values (NRVs) for labelling purposes by addressing the following issues: to set up principles for the establishment of NRVs, and the need to establish NRVs for different population groups.

123. The Delegation Republic of Korea introduced the revised document, which overviewed the existing situation and current practices in member countries; criteria for establishing NRVs for food labeling purposes and use of NRVs by national authorities and the basis for NRVs in different countries. The Delegation drew the attention of the Committee to the fact that it was very important to reach a firm agreement on the scope of nutrients and population group(s) to be covered and the use of NRVs before proceeding with further work. The Delegation also indicated that draft principles for establishing NRVs for general population were presented in the Appendix to the document and that the Project Document for new work (CRD 14) was prepared, if the Committee decided to proceed with it.

124. The Committee expressed its appreciation to the Delegation of Republic of Korea for their excellent work and had a lengthy discussion on the scope of the document and the way to proceed further.

125. The Delegation of the United States, while acknowledging the importance of the elaboration of NRVs for infants and young children, pointed out that the main priority for the Committee should progress on the work for NRVs for general population limited only for labeling purposes since the elaboration of NRVs for infants and young children would require additional preparatory work. This view was supported by several delegations.

126. The Delegation of the European Community proposed that the revision of NRVs was a very important work and should be continued in order to establish NRVs for the adult population and also for infants and young children from 6 to 36 months and was of the view that this work could progress in parallel. This view was supported by several delegations.

127. Some delegations pointed out that the establishment of principles and NRVs for infants and young children required the elaboration of a separate set of principles and additional data therefore proposed to start working on NRVs for adult population and to address infants and young children at a later stage.

[9] CX/NFSDU 07/29/8; CRD 8 (comments from European Community, Indonesia, Philippines, IADSA); CRD 14 (Project Document for New Work to Revise Nutrient Reference Values for Vitamins and Minerals prepared by Republic of Korea); CRD 16 (comments from South Africa).

128. The Committee agreed that the scope of the document should be limited to vitamins and minerals and that the use of NRVs should be limited to food labeling purposes.

129. The Committee noted that it would be very difficult to progress on the elaboration of two sets of principles and NRVs for adult population and for infants young children at the same time and agreed that this work would involve a process to develop the general principles for the establishment of NRVs for the general population as a first step. The Committee agreed that the next step would be a process to review all available reference values and their scientific basis by the principles agreed upon and, if appropriate, update and extend the current list of vitamin and mineral NRVs in the Guidelines for Nutrition Labelling. Once the above was completed, the Committee would establish vitamin and mineral NRVs for labeling for individuals 6 months to 36 months of age. The Committee then begin to work to establish principles that would apply to NRVs for this age group, using as a basis the principles identified for NRVs for the general population and modifying them as appropriate. Once those principles were developed, the NRVs for this age group would be established. The Committee also agreed to amend the Section 3 on Main Aspects to be covered in the Project Document presented in CRD 14 to that effect.

130. The Committee considered the need for scientific advice for the development of NRVs for infants and children and after some discussion agreed to amend Section 7 dealing with the identification of scientific advice in Project Document that the necessity for FAO/WHO scientific advice would be identified at a later stage during the elaboration of the document.

131. The Observer of NHF proposed to establish an additional NRV for each nutrient, to represent the population group with the greatest need for it, however the Committee did not support this proposal.

132. The Committee agreed to request the 31st Session of the Commission to approve new work on the revision of Nutrient Reference Values of Vitamins and Minerals for Food Labeling Purposes. Project Document for this work is attached to this report as Appendix

133. The Committee agreed that the Delegation of Republic of Korea with assistance of other interested parties would prepare a revised document, taking into account decisions taken by this session of the Committee, which would be sent for comments and subsequent consideration by the next session of the Committee.

DISCUSSION PAPER ON THE PRODUCTION AND PROCESSING STANDARDS REGARDING THE NUTRITIONAL QUALITY AND SAFETY OF FOODS (Agenda Item 9)[10]

134. The Committee recalled that at its last session it had agreed that the delegation of Canada would prepare a document providing more explanations on the development of such guidelines, for consideration at the current session.

135. The Delegation of Canada introduced the document and recalled that the WHO/FAO Draft Action Plan for the Implementation of the Global Strategy on Diet, Physical Activity and Health in Action 5, para. 43 addressed to the CCNFSDU stated that the CCNFSDU was to "Review the need for guidelines intended for governments on the use of sound nutrition principles in the production, processing and formulation of foods based on population nutrient intake goals of the 2002 Expert Consultation, taking into account advances in nutrition sciences during the past decade and the General principles for the Addition of Essential Nutrients to Foods". The Draft Action Plan stated that such guidelines could assist in the development of foods suitable for inclusion in diets aimed at reducing risk of chronic diseases e.g. when reducing or eliminating trans fats in foods, such guidelines could provide advice on more healthful alternatives.

136. The Delegation recalled that the Guidelines for Use by Codex Committees on the Inclusion of provisions on Nutritional Quality in Food Standards and other Codex Texts developed by the Committee were adopted by the Commission in 1987 and were included in the CAC Procedural Manual. The major focus of the Guidelines was on addition of essential nutrients and restoration of nutrient losses in foods. The Committee started a revision of these guidelines in 1992 in order to address concerns over excessive intakes of fat, sugars and sodium and inadequate intakes of fibre. Canada had lead on the revision at that time,

[10] CX/NFSDU 07/29/9.

however the work on the revision was discontinued and the guidelines were withdrawn from the Procedural Manual in 1997 after the Committee on General Principles and the Executive Committee of the Codex Alimentarius Commission recognized that many definitions and objectives of the Guidelines were already covered by the General Principles for the Addition of Essential Nutrients to Foods and that advice on nutrition policy was outside the mandate of the Committee.

137. The Delegation emphasized that food standards should promote and not impede the development of foods that are consistent with the Global Strategy. Food standards can clearly address several of the recommendations for diet in the Global Strategy such as limit energy intake from total fats and shift fat consumption away from saturated fats to unsaturated fats and towards elimination of trans-fatty acids, limit intake of free sugars and limit salt (sodium) consumption from all sources and ensure that salt is iodized. The Delegation therefore was of the view that guidance in the production, processing and formulation of foods that would address the above recommendations would be useful for consideration both by Codex Committees and national authorities. Canada pointed out however, that the Committee in deciding how to proceed on this item, should also consider current and proposed work such as the Draft Nutritional Risk Analysis Principles and Guidelines for Application by the Committee on Nutrition and the proposed work on to revise the General Principles for the Addition of Essential Nutrients to Foods and the work of the Codex Committee on Food Labelling on Modified Standardized Common Names.

138. The Delegation of the European Community while complimenting Canada for their work on the Discussion Paper indicated that advice on nutrition policy was outside the mandate of the Committee and that many definitions and objectives of the guidelines were already covered by the General Principles for the Addition of Essential Nutrients to Foods and that the revision of the general principles for the addition of essential nutrients to foods is currently under consideration for new work. The Delegation was of the opinion that the recently adopted guidelines on nutrition and health claims already took into account specific recommendations on nutritional quality and safety developed in the context of the WHO Global Strategy on Diet, Physical Activity and Health and that a draft on the establishment and application of principles for nutritional risk analysis and a discussion paper on the proposals for additional revised nutrient reference values for labelling purpose were currently under discussion by the Committee, therefore some of the specific recommendations of the WHO strategy could be taken into account in the above documents that are currently under discussion.

139. The Delegation of the United States was of the view that many issues in the Guidelines for Use by Codex Committees on the Inclusion of provisions on Nutritional Quality in Food Standards were already covered by the General Principles for Addition of Essential Nutrients to Food and that the Committee would consider its revision on the following agenda item and that several key issues would be addressed during the elaboration of the Proposed Draft Nutritional Risk Analysis Principles and Guidelines for Application to the Work of the CNFSDU.

140. In view of these proposals, the Committee agreed to cease the consideration of the discussion paper and concluded that the revision of the Guidelines for Use by Codex Committees on the Inclusion of provisions on Nutritional Quality in Food Standards and other Codex Texts was not necessary.

DISCUSSION PAPER ON THE PROPOSAL FOR NEW WORK TO AMEND THE CODEX GENERAL PRINCIPLES FOR THE ADDITION OF ESSENTIAL NUTRIENTS TO FOODS (CAC/GL 09-1987) (Agenda Item 10)[11]

141. The Delegation of Canada introduced the document and indicated that the General Principles were adopted in 1987 and since then there were changed approaches or philosophies related to controlling the addition of vitamin and minerals for foods, changes in technologies employed for achieving addition or enhancement of vitamin and mineral levels in foods and an increased interest in the addition to foods of non-nutrient bioactive substances. The Delegation proposed new work to revise the General Principles that would address three separate issues within the Principles: addition or enhancement of the levels of essential nutrients to foods by indirect methods, including biofortification; discretionary addition of vitamins and minerals to food to provide consumers with a greater variety of foods with added vitamin and mineral

[11] CX/NFSDU 07/29/10.

nutrients, including the need for setting maximum and minimum levels of addition and addition of bioactive substances that are non essential constituents to foods. The Delegation indicated that the project document for new work was prepared and presented in CX/NFSDU 07/29/10-Add.1 in line with the terms of reference and Strategic Objectives of the Commission.

142. The Committee expressed its appreciation to the Delegation of Canada for their work and agreed to concentrate on general comments.

143. The Delegation of the European Community was of the view that the evolving dietary habits of the population and technological progress accomplished by industry would justify the update of the General Principles. However it was of the opinion that at a first stage this update should continue to concentrate on the issues that are obviously within the scope of the current General Principles, namely the direct addition of nutrient to foods. The Delegation acknowledged the importance of taking into account issues arising from biofortification in the overall vitamin intake, but was sceptical about the capability of the CCNFSDU to tackle all the issues that would be relevant to biofortification in the framework of these general principles. The Delegation was in favour of the suggestion to introduce the concept of discretional fortification, allowing the addition of essential nutrients for reasons other than those listed in the current General Principles.

144. Concerning the addition of bioactive substances, the Delegation considered that, at this stage, the General Principles should continue to consider as a priority the addition of essential nutrients and that the inclusion of bioactive substances would render difficult to elaborate common principles.

145. As regards discretional fortification, the Delegation considered that restrictions for discretional fortification should only be justified on the basis of safety and on the possibility to mislead consumers and that discretionary fortification should be allowed only with sources evaluated for their safety and bioavailability. The risk of excessive intake of nutrients could be tackled with the establishments of maximum amounts for nutrients that could be added to foods and these maximum amounts should be established taking into consideration in particular the tolerable upper intake levels established by scientific risk assessment and the intakes from the diet. Periodic nutritional surveys should be envisaged in order to monitor shifts in dietary habits and/or industrial practices, which would need a revision of such levels.

146. Some other delegations noted the availability of new technologies and were in favour for further development of the document and emphasize importance of these issues for public health.

147. The Delegation of the United States supporting the concerns expressed by the Delegation of the European Community, indicated that the document described how principles could be applied to new technologies and pointed out that the last session of Task Force on Foods Derived from Biotechnology had noted that the General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 9-1987) elaborated by this Committee were applicable to foods elaborated by these new technologies. The Delegation also pointed out that the revision of the General Principles might open many controversial areas on which it would be very difficult to reach an agreement as there was no common understanding on these issues.

148. The Committee noted that the work on the revision might proceed in areas where it could be possible to get an agreement and requested the Delegation of Canada to prepare a revised document, narrowing its scope in the light of the comments provided at the current session. The revised document would then be considered by the next session of the Committee.

OTHER BUSINESS AND FUTURE WORK (Agenda Item 11):

Methods of Analysis in the revised infant formula Standard[12]

149. The Committee recalled that the Committee on Methods of Analysis and Sampling had not endorsed the methods proposed for inclusion in the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants and had addressed some specific questions on several methods (see Agenda Item 2).

[12] CRD 10 (comment of the United States), CRD 15 (comments of the EC), CRD 17 (proposals from the Working Group held during the session), CRD 18 (proposed mandate of the electronic working group)

150. The Delegation of the United States introduced the report of the working group that had met during the session and included proposals for reply to the questions from the CCMAS. The Delegation indicated that it had not been possible to come to a conclusion on all issues and to establish a list of methods as this required careful review of existing methods and delegations would need to consult with their experts at the national level. It was therefore proposed to establish an electronic working group to consider all remaining issues.

151. The Delegation of the European Community, recalling the recommendation of CCMAS to replace microbiological assays with more modern methods, proposed to forward several methods developed by CEN for the determination of vitamins for endorsement to CCMAS. The Delegation of the United States indicated that it had also proposed specific methods for nutrients listed in Section 3.1 in the revised Standard for Infant Formula . However as there was no consensus on these proposals, the Committee agreed that no specific methods could be sent for endorsement at this stage.

152. The Committee discussed the terms of reference of the working group proposed in CRD 18, and especially the possibility of revising other methods for special foods and the need for additional information in addition to the Principles for the Establishment of Codex Methods of Analysis. The Committee however agreed that the working group should concentrate on the finalisation of the methods applicable to infant formula, with the understanding that other methods could be considered at a later stage, and agreed on the following terms of reference.

153. The electronic working group (EWG) should prepare a list of methods of analysis for infant formulae to be considered at the 30th Session of the CCNFSDU in 2008. In preparing this list, the EWG should:

- Review methods of analysis for provisions listed in Section 3.1 of the Codex Revised Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants;
- Follow the Principles for the Establishment of Codex Methods of Analysis in the Codex Procedural Manual, including the General Criteria for the Selection of Methods of Analysis;
- The electronic working group, chaired by New Zealand, would be open to all members and observers, and would work in English.

154. The Committee agreed with the proposal of the Delegation of France to provide some responses to the questions from CCMAS specified in paragraphs 82-88 of ALINORM 07/30/23, as general agreement existed on some proposals from the working group listed in CRD 17. After some discussion, the Committee agreed on the following position.

155. The Delegation of the United States indicated that other responses in CRD 17 contained information relevant to the CCMAS inquiries and CRD 17 indicates issues have been referred to the electronic working group.

Paragraphs 82 and 83 (methods for dietary fibre and PER)

156. As Dietary Fibre and PER were not listed in section 3.1 Essential Composition, the Committee did not recommend including a method for any substance or provision that was not included in section 3.1.

Paragraph 85 (Method for sodium and potassium)

157. The Committee agreed that both the current AOAC method and the ISO 8070| IDF 119.2007 method should be listed.

Paragraph 86 (crude protein)

158. The Committee noted that the AOAC method 991.20 Nitrogen (total) in milk, identical to ISO 8968-1/2| IDF 20-1/2: 2001, specifies a nitrogen conversion factor of 6.38. This method can also be used for analysis of nitrogen in soy infant formulas with the use on an appropriate conversion factor. The Revised Standard includes a footnote for use of nitrogen conversion factors for calculation of the protein content of infant formulas. Consistent with that footnote, the Committee proposed the following wording for the use of nitrogen conversion factor for insertion in the Description column or footnote to the method.

"The calculation of the protein content of infant formulas prepared ready for consumption may be based on N x 6.25, unless a scientific justification is provided for the use of a different conversion factor for a particular product. The value of 6.38 is generally established as a specific factor appropriate for conversion of nitrogen to protein in other milk products, and the value of 5.71 as a specific factor for conversion of nitrogen to protein in other soy products.

159. The Committee agreed that the other questions from the CCMAS would be considered further at the next session on the basis of the recommendations of the electronic working group.

Proposal for new work to establish a standard for processed cereal-based foods for underweight infant and young children[13]

160. The Delegation of India recalled that the 29th session of the Commission had adopted the Revised Standard for Processed Cereal-Based Foods for Infants and Young Children. India's comments related to minimum cereal content, energy density and protein content in the revised Standard. The delegations of India and Thailand had reserved their position on the decision of the Commission to adopt a revised Standard. The Commission agreed to request the Committee on Nutrition and Foods for Special Dietary Uses to evaluate the need for revising sections 3.2, 3.3 and 3.4 of the adopted standard.

161. The Delegation drew the attention of the Committee to the adverse effects of malnutrition especially in developing countries of the world, causing a high infant, child and maternal mortality. Further consequences of malnutrition could lead to high level of anemia, low weight gain during pregnancy, acute infections and chronic diseases. It also significantly affects cognitive development and learning achievements of children and this puts additional stress on health care expenditures.

162. A vicious intergenerational cycle of malnutrition commences when a child is born with low birth weight. While malnutrition is caused by multiple problems including poverty, lack of health care and low consumption of protective foods such as milk, cereals, fruits and vegetables, the delayed and inadequate complementary feeding is found to be an important reason for the onset of malnutrition among children of 6 months to 2 years.

163. The Delegation indicated that in India about 46% of children in 0 to 3 years of age group are underweight and about 30% of children born in the country whose birth weight was reported, had low birth weight. Micronutrient deficiencies are also wide spread and 79% of children between 6 month to 3 years suffer from anemia. The Delegation indicated that in developing countries 146 million children under 5 years are underweight. Of these more than a half live in south Asia and 57 million live in India. The Delegation also emphasized that about 30000 children die each day and most of these children live in developing countries. Malnutrition contributes to these deaths.

164. The Delegation of India also pointed out that improving nutritional standards, particularly in the early years, is crucial for achieving the "Millennium Development Goals", and that priorities must be altered for reducing child malnutrition by half by 2015. The delegation stated that while multiple strategies are required for addressing the problems of under nutrition in children, issues of timely and adequate complementary feeding with appropriate levels of nutritional density foods are very important.

165. The Delegation of India therefore urged the Committee to start working on a separate standard for Processed Cereal-Based Foods for Underweight Infants and Young Children so that nutritionally and energy dense composition in the proposed standard will help to reduce the burden of malnutrition in the developing countries.

166. The Delegation of the EC, while acknowledging the importance of this problem in developing countries, was of the view that the proposal for this work came in the beginning of the meeting and that it was not enough time to study this question in detail. The Delegation indicated that a number of issues such as nature of standard (regional or world-wide) and products concerned should be clarified. The delegation indicated that more thorough analysis of the problem was needed and proposed to prepare a more structured project document on this matter for consideration by the next session of the Committee.

[13] CRD 9 (prepared by India).

167. The Delegation of Australia questioned whether the existing Codex Guidelines on Formulated Supplementary Foods for Older Infants and Young Children could help to address this problem.

168. Several delegations and observers supported the spirit of the document and volunteered to join India to develop the revised version of supporting document containing analysis and proposals on how the Committee could address this issue.

169. The Committee agreed that the Delegation of India with assistance from other interested parties[14] working electronically would revise the document in the light of comments at the current session and prepare a more structured project document for consideration by the next session of the Committee.

Information from the Committee on Food Labelling

170. The Delegation of Canada, speaking as the Chair of the Committee on Food Labelling (CCFL), informed the Committee of the decisions taken by the CCFL on eight recommendations contained in the Draft Action Plan from WHO and FAO on the implementation of the WHO Global Strategy on Diet, Physical Activity and Health as related to labeling. It was also recalled that a physical working group would be held prior to the next CCFL session to discuss pending issues (ALINORM 07/30/22, paras. 20-64). The Delegation expressed the view that there was a need to consider what mechanisms were available for inter-committee communication and cooperation and seek guidance from WHO and FAO as to what were their roles, responsibilities and obligations in assisting with the implementation of the Global Strategy in relation to Codex activities.

171. The Chairperson thanked the Delegation of Canada for this information and recalled that the Committee was also intensifying its work on nutrition issues identified by the Global Strategy, and welcomed continued cooperation with the CCFL in order to ensure that Codex standards were consistent with the Global Strategy.

172. The Delegation of the EC expressed the view that the Committee should consider the Action Plan and for this purpose establish a physical working group prior to the next session in order to consider additional issues that may arise from the discussions of the Committee on Food labelling, or any other relevant nutritional issue relevant to the Global Strategy.

173. The Secretariat recalled that the Committee had complied with the request from the Commission concerning the implementation of the Global Strategy, as it had replied specifically to the proposals from WHO related to its mandate and was currently considering specific work of direct relevance to the Global Strategy. There had been no request for consideration of other issues related to the Global Strategy by the Commission, by other Committees or by any delegation for inclusion in the Agenda prior to the Committee or as Other Business when adopting the Agenda, as only a presentation of CCFL work for information purposes had been mentioned. The Secretariat noted that this Committee and the Committee on Food Labelling regularly exchanged advice and cooperated quite efficiently, as had been the case regarding Global Strategy issues of common relevance (NRVs). As regards procedures and mechanisms, any matter directed by any Codex Committee to another was systematically brought to the attention of that Committee under Matters Referred, while overall coordination regarding work on the Global Strategy was exercised by the Commission. The Secretariat also recalled that if a working group was established, it should have a clear mandate in application of the Guidelines for Physical Working Groups.

174. The Delegation of the United States suggested that in order to focus the discussion, a working group could consider some issues related to current work which is related to the Global Strategy, such as the extension of NRVs and substantiation of health claims. The Delegation of the European Community supported this view and also suggested to consider the issues that may be coming from the discussions of the CCFL or the Commission.

175. The Chairperson pointed out that in order to avoid confusion, it was important to give a clear mandate if a working group was established, and recalled that important items of work related to the Global

[14] Australia, Brazil, Ghana, Guatemala, Indonesia, Republic of Korea, Malaysia, Mexico, South Africa, Thailand, CI, IBFAN, ISDI and NHF.

Strategy were currently under consideration: the scientific basis of health claims and NRVs for labelling purposes. Discussion of these issues in a working group prior to the session might facilitate progress in the Plenary Session, as it had been the case with other issues. Several delegations supported the consideration of health claims and NRVs in a working group.

176. As regards other issues related to the Global Strategy, the Committee noted that it was not possible at that stage to anticipate if any questions or requests would be referred to the CCNFSDU from either CCFL or the Commission. The Committee therefore agreed with the proposal of the Delegation of France to insert a general reference to other matters related to the WHO Global Strategy as this would allow the working group to consider any relevant matters if required.

177. After some further discussion, the Committee agreed to convene a physical working group prior to the next session, with the following mandate:

Within the context of the mandate of CCNFSDU, the Working Group is asked to consider:

- Issues of relevance to the implementation of the Global Strategy on Diet, Physical Activity and Health which are under consideration by CCNFSDU
    - NRVs; Health Claims; and
    - any other matters related to the WHO Global Strategy

178. The Committee agreed that the physical Working Group, to be held immediately prior to the 30th Session, would be co-chaired by France and the Republic of Korea and by the United States and that it would work in English, French and Spanish.

Other Matters

Correction of report of the 28th session of the Committee

179. The Committee noted that the last sentence in paragraph 160 of ALINORM 07/30/26 should be deleted as the Delegation of Norway had not supported the proposal on the revision of the Standard for Processed Cereal-Based Foods for Infants and Young Children (Sections 3.2, 3.3 and 3.4) and that this was not corrected at the adoption of of the report at the last session of the Committee.

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

180. The Committee was informed that its 30th Session would take place in South Africa from 3 to 7 November 2008, subject to confirmation by the host government and the Codex Secretariat. The Committee thanked the Delegation of South Africa for its kind offer to host the next Session of the Committee.

SUMMARY STATUS OF WORK

Subject Matter	Step	For Action by	Reference in ALINORM 08/31/26
Draft Revised Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten	8	Governments, 31th CAC	para. 64 and Appendix III
Draft Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children	8	Governments, 31th CAC	para. 78 and Appendix IV
Guidelines for Use of Nutrition Claims: Draft Table of Contents for Nutrient Contents (Part B Containing Provisions on Dietary Fibre)	6	Governments; 30th CCNFSDU	para. 41 and Appendix II
Draft Advisory List of Nutrient Compounds for Use in Foods for Special Dietary Uses Intende for Infants and Young Children: Part D Advisory List of Food Additives for Special Nutrient Forms: Provisions on gum arabic (gum acacia)	6	Governments, 30th CCNFSDU	paras 75-78 and Appendix V
Establishment and Application of Risk Analysis Principles by the Codex Committee on Nutrition and Foods for Special Dietary Uses.	5	Governments; 31th CAC; 30th CCNFSDU	para. 121 and Appendix VI
Proposed Draft Recommendations on the Scientific Basis of Health Claims	2/3	France with assistance of EWG; Governments; 30th CCNFSDU	para. 97
Proposal for New Work to Amend the Codex General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 09-1987)		Canada; 30th CCNFSDU	paras 141-148
Proposal for New Work to Establish a Standard for processed cereal-Based Foods for Underweight Infant and Young Children	-	India with assistance of EWG; 30th CCNFSDU	paras 160169
New work			
Additional or Revised Nutrient Reference Values (NRVs); Project document is available in Appendix VII of CX/NFSDU 08/29/8.	1/2/3	61st CCEXEC, 31st CAC; Republic of Korea with assistance of EWG; Governments; 30th CCNFSDU	paras 122-133; Appendix VII

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APPENDIX II

GUIDELINES FOR THE USE OF NUTRITION CLAIMS:
DRAFT TABLE OF CONDITIONS FOR NUTRIENT CONTENTS (PART B CONTAINING PROVISIONS ON DIETARY FIBRE)

(At Step 6 of the Procedure)

COMPONENT	CLAIM	CONDITIONS
B.		**NOT LESS THAN**
Dietary Fibre	Source	3 g per 100 g or 1.5 g per 100 kcal or [10 % of recommended intake] per serving* [(liquid foods: 1.5 g per 100 ml)]
	High	6 g per 100 g or 3 g per 100 kcal or [20 % of recommended intake] per serving* [(liquid foods: 3 g per 100 ml)]

* Serving size [and recommended intake] to be determined at national level.

Definition and properties of dietary fibre:

DEFINITION:

Dietary fibre means carbohydrate polymers[1] with a degree of polymerisation (DP) not lower than 3, which are neither digested nor absorbed in the small intestine. A degree of polymerisation not lower than 3 is intended to exclude mono- and disaccharides. It is not intended to reflect the average DP of a mixture. Dietary fibre consists of one or more of:

- Edible carbohydrate polymers naturally occurring in the food as consumed,
- carbohydrate polymers , which have been obtained from food raw material by physical, enzymatic or chemical means,.
- synthetic carbohydrate polymers.

[1] When derived from a plant origin, dietary fibre may include fractions of lignin and/or other compounds when associated with polysaccharides in the plant cell walls and if these compounds are quantified by the AOAC gravimetric analytical method for dietary fibre analysis : Fractions of lignin and the other compounds (proteic fractions, phenolic compounds, waxes, saponins, phytates, cutin, phytosterols, etc.) intimately "associated" with plant polysaccharides are often extracted with the polysaccharides in the AOAC 991.43 method. These substances are included in the definition of fibre insofar as they are actually associated with the poly- or oligo-saccharidic fraction of fibre. However, when extracted or even re-introduced into a food containing non digestible polysaccharides, they cannot be defined as dietary fibre. When combined with polysaccharides, these associated substances may provide additional beneficial effects.

Properties:

Dietary fibre generally has properties such as:

- Decrease intestinal transit time and increase stools bulk
- Fermentable by colonic microflora
- Reduce blood total and/or LDL cholesterol levels
- Reduce post-prandial blood glucose and /or insulin levels.

With the exception of non-digestible edible carbohydrate polymers naturally occurring in foods as consumed where a declaration or claim is made with respect to dietary fibre, a physiological effect should be scientifically demonstrated by clinical studies and other studies as appropriate. The establishment of criteria to quantify physiological effects is left to national authorities.

RECOMMENDATIONS TO CODEX COMMITTEES USING THIS DEFINITION OF DIETARY FIBRES

Codex Committees, when making use of this definition, may wish to consider that:

- Food safety requirements should be met by the substances purporting to be presented as source of dietary fibres;
- The physiological effects listed in the definition may vary with the substances present in the foods and the justification for the use of the nutrition and health claims must accommodate this diversity;
- If the dietary fibre does not derive from plants, it may be appropriate to consider, when establishing labelling provisions, that consumers in many countries generally regard foods designated as sources of dietary fibre as having a plant origin.

Methods of Analysis for Dietary Fibre[1]

Name	Quantified compounds	Reference	Type	Chapter[2]
AOAC 991.43	Soluble + insoluble polysaccharides (including RS 3)+ lignin	Lee et al	Enzymatic-gravimetric	32.1.17
AOAC 985.29	Soluble + insoluble polysaccharides (including RS 3)+ lignin	Prosky *et al.* 1992	Enzymatic-gravimetric	45.4.07
AOAC 994.13	Soluble + insoluble polysaccharides (including RS 3)+ lignin	Theander et al.	Enzymatic-chemical	45.4.11
AOAC 995.16	beta-glucans	McCleary & Codd, 1991	Enzymatic	32
AOAC 2002.02	Resistant starch and algal fibre	McCleary & Monaghan, 2002	Enzymatic	45.4.15

[1] As presented in CX/NFSDU 04/3-Add.1.

[2] Official Methods of Analysis of AOAC International. 17th edition. Volume II. Horwitz, editor.

Name	Quantified compounds	Reference	Type	Chapter[2]
AOAC 999.03	Fructans (oligofructans, inulin derivatives, fructooligosaccharides)	McCleary & Blakeney, 1999 McCleary *et al*., 2000	Enzymatic & colorimetric	45.4.06B
AOAC 997.08	Fructans (oligofructans, inulin derivatives, fructooligosaccharides)	Hoebregs, 1997	Enzymatic & HPAEC	45.4.06A
AOAC 2001.02	Trans-galacto-oligosaccharides	De Slegte	HPAEC-PAD	45.4.12
AOAC 2001.03	Total dietary fibre in foods containing resistant maltodextrin		Enzymatic gravimetric and Liquid chromatography	45.4.13
AOAC 2000.11	Polydextrose	Craig *et al*. 2001	HPAEC	45.6.06C

All the above methods are approved AOAC techniques. These methods have the advantage of being used world-wide as well as being easily used in routine analysis.

The AOAC 985.29 and 991.43 are the general methods for measuring 'total dietary fibre' in most foods. The other methods can be used for complementary assessment of other fibre components/fractions not measured by the general methods due to their solubility in aqueous alcohol or for analysis of certain foods or raw materials for which the standard methods may be less suitable. The methods for total or soluble+insoluble dietary fibre give satisfactory results for foods that contain neither added non-digestible oligosaccharides (e.g. FOS) nor resistant starch[3] fractions RS1 and RS2 which are not measured by these AOAC method.

The AOAC 991.43 includes part of the resistant starch fractions (retrograded starches, RS3). Therefore, in order to include total RS, it is necessary to analyse RS independently and correct for the RS in the fibre residue.

The Englyst method, which is not used world-wide, is complicated and may therefore be less suitable for routine analysis. However, this or similar methods may be necessary in some foods difficult to analyse with the routine methods, e.g. infant formula.

[3] Resistant starch (RS) is defined as the fraction of starch not absorbed in the small intestine. It consists of physically enclosed starch (RS1), certain types of raw starch granules (RS2) and retrograded amylose (RS3). Modified starches used as food additives may also be partially resistant (RS4).

APPENDIX III

DRAFT REVISED CODEX STANDARD FOR FOODS FOR SPECIAL DIETARY USE FOR PERSONS INTOLERANT TO GLUTEN

(At Step 8 of the Procedure)

1. SCOPE

1.1 This standard applies to foods for special dietary uses that have been formulated, processed or prepared to meet the special dietary needs of people intolerant to gluten.

1.2 Foods for general consumption which by their nature are suitable for use by people with gluten intolerance may indicate such suitability in accordance with the provisions of section 4.3.

2. DESCRIPTION

2.1 Definitions

The products covered by this standard are described as follows:

2.1.1 Gluten-free foods

Gluten-free foods are dietary foods

a) consisting of or made only from one or more ingredients which do not contain wheat (i.e., all *Triticum* species, such as durum wheat, spelt, and kamut), rye, barley, oats[1] or their crossbred varieties, and the gluten level does not exceed 20 mg/kg in total, based on the food as sold or distributed to the consumer, and/or

b) consisting of one or more ingredients from wheat (i.e., all *Triticum* species, such as durum wheat, spelt, and kamut), rye, barley, oats[1] or their crossbred varieties, which have been specially processed to remove gluten, and the gluten level does not exceed 20 mg/kg in total, based on the food as sold or distributed to the consumer.

2.1.2 Foods specially processed to reduce gluten content to a level above 20 up to 100 mg/kg

These foods consist of one or more ingredients from wheat (i.e., all *Triticum* species, such as durum wheat, spelt, and kamut), rye, barley, oats[1] or their crossbred varieties, which have been specially processed to reduce the gluten content to a level above 20 up to 100 mg/kg in total, based on the food as sold or distributed to the consumer.

Decisions on the marketing of products described in this section may be determined at the national level.

2.2 Subsidiary Definitions

2.2.1 Gluten

For the purpose of this standard, "gluten" is defined as a protein fraction from wheat, rye, barley, oats[1] or their crossbred varieties and derivatives thereof, to which some persons are intolerant and that is insoluble in water and 0.5M NaCl.

2.2.2 Prolamins

Prolamins are defined as the fraction from gluten that can be extracted by 40 - 70% of ethanol. The prolamin from wheat is gliadin, from rye is secalin, from barley hordein and from oats[1] avenin.

It is however an established custom to speak of gluten sensitivity. The prolamin content of gluten is generally taken as 50%.

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 For products referred to in 2.1.1 a) and b), the gluten content shall not exceed 20 mg/kg in the food as sold or distributed to the consumer.

[1] Oats can be tolerated by most but not all people who are intolerant to gluten. Therefore, the allowance of oats that are not contaminated with wheat, rye or barley in foods covered by this standard may be determined at the national level.

3.2 For products referred to in 2.1.2 the gluten content shall not exceed 100 mg/kg in the food as sold or distributed to the consumer.

3.3. Products covered by this standard substituting important basic foods, should supply approximately the same amount of vitamins and minerals as the original foods they replace.

3.4 The products covered by this standard shall be prepared with special care under Good Manufacturing Practice (GMP) to avoid contamination with gluten.

4. LABELLING

In addition to the general labelling provisions contained in the General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985) and the General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses (CODEX STAN 146-1985), and any specific labelling provisions set out in a Codex standard applying to the particular food concerned, the following provisions for the labelling of "gluten-free foods" shall apply:

4.1 The term "gluten-free" shall be printed in the immediate proximity of the name of the product in the case of products described in section 2.1.1.

4.2 The labelling of products described in section 2.1.2 should be determined at the national level. However these products must not be called gluten-free. The labelling terms for such products should indicate the true nature of the food, and shall be printed in the immediate proximity of the name of the product.

4.3 A food which, by its nature, is suitable for use as part of a gluten-free diet, shall not be designated "special dietary", "special dietetic" or any other equivalent term. However, such a food may bear a statement on the label that "this food is by its nature gluten-free" provided that it complies with the essential composition provisions for gluten-free as set out in section 3.1 and provided that such a statement does not mislead the consumer. More detailed rules in order to ensure that the consumer is not misled may be determined at the national level.

5. METHODS OF ANALYSIS AND SAMPLING

5.1 General outline of the methods

- The quantitative determination of gluten in foods and ingredients shall be based on an immunologic method or other method providing at least equal sensitivity and specificity.
- The antibody used should react with the cereal protein fractions that are toxic for persons intolerant to gluten and should not cross-react with other cereal proteins or other constituents of the foods or ingredients.
- Methods used for determination should be validated and calibrated against a certified reference material,, if available.
- The detection limit has to be appropriate according to the state of the art and the technical standard. It should be 10 mg gluten/kg or below.
- The qualitative analysis that indicates the presence of gluten shall be based on relevant methods (e.g. ELISA-based methods, DNA methods).

5.2 Method for determination of gluten

Enzyme-linked Immunoassay (ELISA) R5 Mendez Method.

APPENDIX IV

DRAFT ADVISORY LISTS OF NUTRIENT COMPOUNDS FOR USE IN FOODS FOR SPECIAL DIETARY USES INTENDED FOR INFANTS AND YOUNG CHILDREN

(At Step 8 of the Procedure)

1. PREAMBLE

These lists include nutrient compounds, which may be used for nutritional purposes in foods for special dietary uses intended for infants and young children in accordance with 1) the criteria and conditions of use identified below and 2) other criteria for their use stipulated in the respective standards. In addition, the sources from which the nutrient compound is produced may exclude the use of specific substances where religious or other specific dietary restrictions apply. As noted in the respective standards, their use may either be essential or optional.

2. CRITERIA FOR THE INCLUSION AND DELETION OF NUTRIENT COMPOUNDS FROM THE ADVISORY LISTS

2.1 Nutrient compounds that are to be added for nutritional purposes to foods for infants and young children may be included in the Lists only if:

(a) they are shown to be safe and appropriate for the intended use as nutrient sources for infants and young children

(b) it is demonstrated by appropriate studies in animals and/or humans that the nutrients are biologically available

(c) the purity requirements of the nutrient compounds conform with the applicable Specifications of Identity and Purity recommended by the Codex Alimentarius Commission, or in the absence of such specifications, with another internationally recognised specification. If there is no internationally recognised specification, national purity requirements that have been evaluated according to or similar to a FAO/WHO process may be considered

(d) the stability of nutrient compound(s) in the food(s) in which it is (they are) to be used can be demonstrated

(e) the fulfilment of the above criteria shall be demonstrated by generally accepted scientific criteria.

2.2 Nutrient compounds may be added to the Lists based on the criteria above. Nutrient compounds shall be deleted from the Lists if they are found no longer to meet the above criteria. If a country proposes to add or delete a nutrient compound to/from a list, the country should provide information that addresses how the nutrient compound satisfies/does not satisfy the criteria in Section 2.1.

3. Optional ingredients

The Optional Ingredients sections in Codex standards for foods for infants and young children do not identify all optional ingredients that may be considered for use in foods for special dietary uses intended for infants and young children. Optional ingredients added for nutritional purposes to foods for special dietary uses intended for infants and young children should meet the criteria specified in Section 2.1. They should also meet the provisions for optional ingredients in the respective Codex standard for foods for infants and young children.

A: ADVISORY LIST OF MINERAL SALTS AND TRACE ELEMENTS FOR USE IN FOODS FOR SPECIAL DIETARY USES INTENDED FOR INFANTS AND YOUNG CHILDREN

Nutrient Source	Purity Requirements by		Use in Codex Food Standards Applicable to Infants and Young Children					
	CAC[1]	international and/or national bodies	IF		FUF[4]	PCBF[5]	CBF[6]	FSMP[7] for infants and young children
			Sec. A[2]	Sec. B[3]				
1. Source of Calcium (Ca)								
1.1 Calcium carbonate	√ (1981)	JECFA (1973), Ph Int, FCC, USP, NF, Ph Eur, BP, DAB	√	√	√	√	√	√
1.2 Calcium chloride	√ (1979)	JECFA (1975), FCC, USP, Ph Eur, JP, BP, DAB	√	√	√	√	√	√
1.3 Tricalcium dicitrate (Calcium citrate)	√ (1979)	JECFA (1975), FCC, USP, DAC	√	√	√	√	√	√
1.4 Calcium gluconate	√ (1999)	JECFA (1998), Ph Int, FCC, USP, Ph Eur, BP, DAB	√	√	√	√	√	√
1.5 Calcium glycerophosphate		FCC, Ph Eur, Ph Franc	√	√	√	√	√	√

[1] CAC = Codex Alimentarius Commission
[2] IF Sect. A = Section A of the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants
[3] IF Sect. B = Section B of the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants
[4] FUF = Follow-up Formula
[5] PCBF = Processed Cereal Based Food for Infants and Young Children
[6] CBF = Canned Baby Food
[7] FSMP = Food for Special Medical Purposes other than Infant Formula

1.6 Calcium L-lactate	√ (1978)	JECFA (1974), FCC, USP, Ph Eur (tri- and penta-hydrate), BP, DAB	√	√	√	√	√	√
1.7 Calcium hydroxide	√ (1979)	JECFA (1975), FCC, USP, Ph Eur, BP	√	√	√	√	√	√
1.8 Calcium oxide	√ (1979)	JECFA (1975), FCC, DAC	-	√	-	√	√	√
1.9 Calcium dihydrogen phosphate (Calcium phosphate, monobasic)	√ (1997)	JECFA (1996), Ph Int, FCC	√	√	√	√	√	√
1.10 Calcium hydrogen phosphate (Calcium phosphate, dibasic)	√ (1979)	JECFA (1975), FCC, USP, Ph Eur, BP, DAB	√	√	√	√	√	√
1.11 Tricalcium diphosphate (Calcium phosphate, tribasic)		JECFA (1973), Ph Int, FCC, BP	√	√	√	√	√	√
1.12 Calcium sulphate	√ (1979)	JECFA (1975), Ph Int, FCC, Ph Eur (dihydrate), DAB	-	√	-	-	-	√
2. Source of Iron (Fe)								
2.1 Ferrous carbonate, stabilised with saccharose		DAB	-	√	-	√	√	√
2.2 Ferrous fumarate		Ph Int, FCC, USP, Ph Eur, BP	√	√	√	√	√	√

2.3 Ferrous gluconate	√ (2001)	JECFA (1999), FCC, USP, Ph Eur, DAB, BP	√	√	√	√	√	√
2.4 Ferrous lactate	√ (1991)	JECFA (1989), FCC, NF	√	√	√	√	√	√
2.5 Ferrous sulphate	√ (2001)	JECFA (1999), Ph Int, FCC, USP, Ph Eur, BP, DAB	√	√	√	√	√	√
2.6 Ferric ammonium citrate	√ (1987)	JECFA (1984), FCC, DAC	√	√	√	√	√	√
2.7 Ferric citrate		FCC	√	√	√	√	√	√
2.8 Ferric diphosphate (pyrophosphate)		FCC	√	√	√	√	√	√
2.9 Hydrogen reduced iron		FCC, DAB	-	√	-	√	√	√
2.10 Electrolytic iron		FCC	-	√	-	√	√	√
2.11 Carbonyl iron		FCC	-	√	-	√	√	√
2.12 Ferric saccharate		Ph Helv, DAB, ÖAB	-	√	-	√	√	√
2.13 Sodium ferric diphosphate		FCC	-	√	-	√	√	√
2.14 Ferrous citrate		FCC, FSANZ	√	√	√	√	√	√
2.15 Ferrous succinate		MP, MI, FSANZ	√	√	√	√	√	√
2.16 Ferrous bisglycinate		JECFA (2003)	√	√	√	√	√	√

2.17 Ferric orthophosphate		FCC	-	-	-	√	-	-
3. Source of Magnesium (Mg)								
3.1 Magnesium hydroxide carbonate		JECFA (1979), USP, BP, DAB	√	√	√	√	√	√
3.2 Magnesium chloride	√ (1979)	JECFA (1979), FCC, USP, Ph Eur (-4,5-hydrate), BP, DAB	√	√	√	√	√	√
3.3 Magnesium gluconate	√ (2001)	JECFA (1998), FCC, DAC	√	√	√	√	√	√
3.4 Magnesium glycero-phosphate		Ph Eur, BPC	-	√	-	√	√	√
3.5 Magnesium hydroxide	√ (1979)	JECFA (1975), Ph Int, FCC, USP, Ph Eur, BP, DAB	√	√	√	√	√	√
3.6 Magnesium lactate	√ (1987)	JECFA (1983) (Mg-DL-Lactate, Mg-L-Lactate)	-	√	-	√	√	√
3.7 Magnesium oxide		JECFA (1973), Ph Int, FCC, USP, Ph Eur, BP, DAB	√	√	√	√	√	√
3.8 Magnesium hydrogen phosphate Magnesium phosphate, dibasic)	√ (1985)	JECFA (1982), FCC, DAB	√	√	√	√	√	√
3.9 Trimagnesium phosphate (Magnesium phosphate, tribasic)	√ (1981)	JECFA (1982), FCC	√	√	√	√	√	√

3.10 Magnesium sulphate		Ph Eur (heptahydrate), FCC, USP, JP, BP, DAB, DAC	√	√	√	√	√	√
3.11 Magnesium acetate		Ph Eur, DAC	-	√	-	-	-	√
3.12 Magnesium salts of citric acid		USP, DAC	√	√	√	√	√	√
3.13 Magnesium carbonate		JECFA (1973), FCC, USP, Ph Eur, BP, DAB	√	√	√	√	√	√
4. Source of Sodium (Na)								
4.1 Sodium carbonate	√ (1979)	JECFA (1975), FCC, USP, NF, Ph Eur, BP, DAB	√	√	√	-	-	√
4.2 Sodium hydrogen carbonate (Sodium bicarbonate)	√ (1979)	JECFA (1975), Ph Int, FCC, USP, Ph Eur, BP, DAB	√	√	√	-	-	√
4.3 Sodium chloride		Ph Int, FCC, USP, Ph Eur, JP, BP, DAB	√	√	√	-	-	√
4.4 Trisodium citrate (Sodium citrate)		JECFA (1975), Ph Int, FCC, USP, Ph Eur, BP, DAB	√	√	√	-	-	√
4.5 Sodium gluconate	√ (1999)	JECFA (1998), FCC, USP, DAC	√	√	√	-	-	√
4.6 Sodium L-lactate	√ (1978)	JECFA (1974), FCC, USP, Ph Eur, BP, DAB	√	√	√	-	-	√

4.7 Sodium dihydrogen phosphate (Sodium phosphate, monobasic)	√ (1995)	JECFA (1963), FCC, USP, Ph Eur (dihydrate)	√	√	√	-	-	√
4.8 Disodium hydrogen phosphate (Sodium phosphate, dibasic)		JECFA (1975), Ph Int, FCC, USP, BP	√	√	√	-	-	√
4.9 Trisodium phosphate (Sodium phosphate, tribasic)		JECFA (1975), FCC, DAC	√	√	√	-	-	√
4.10 Sodium hydroxide	√ (1979)	JECFA (1975), Ph Int, FCC, USP, NF, Ph Eur, JP, BP, DAB	√	√	√	-	-	√
4.11 Sodium sulphate		JECFA (2000), Ph Int, FCC, USP, Ph Eur, BP, DAB, FSANZ	√	√	√	-	-	√
5. Source of Potassium (K)								
5.1 Potassium carbonate	√ (1979)	JECFA (1975), FCC, USP, Ph Eur, DAC	√	√	√	-	-	√
5.2 Potassium hydrogen carbonate (Potassium bicarbonate)	√ (1979)	JECFA (1975), FCC, USP, Ph Eur, BP, DAB	√	√	√	-	-	√
5.3 Potassium chloride	√ (1983)	JECFA (1979), Ph Int, FCC, USP, Ph Eur, BP, DAB	√	√	√	√	√	√

5.4 Tripotassium citrate (Potassium citrate)		JECFA (1975), Ph Int, FCC, USP, Ph Eur, BP, DAB	√	√	√	√	√	√
5.5 Potassium gluconate	√ (1999)	JECFA (1998), FCC, USP, DAC	√	√	√	√	√	√
5.6 Potassium glycero-phosphate		FCC	-	√	-	√	√	√
5.7 Potassium L-lactate	√ (1978)	JECFA (1974), FCC, DAB	√	√	√	√	√	√
5.8 Potassium dihydrogen phosphate (Potassium phosphate, monobasic)	√ (1979)	JECFA (1982), FCC, NF, Ph Eur, BP, DAB	√	√	√	-	-	√
5.9 Dipotassium hydrogen phosphate (Potassium phosphate, dibasic)	√ (1979)	JECFA (1982), FCC, BP	√	√	√	-	-	√
5.10 Potassium phosphate, tribasic	√ (1979)	JECFA (1982)	√	√	√	-	-	√
5.11 Potassium hydroxide	√ (1979)	JECFA (1975), FCC, NF, Ph Eur, JP, BP, DAC	√	√	√	-	-	√
6. Source of Copper (Cu)								
6.1 Cupric gluconate (Copper gluconate)		FCC, USP	√	√	√	√	√	√
6.2 Cupric sulphate (Copper sulphate)	√ (1981)	JECFA (1973), FCC, USP, Ph Eur, DAB	√	√	√	√	√	√
6.3 Cupric carbonate		MI	√	√	√	√	√	√

6.4 Cupric citrate		FCC, USP	√	√	√	√	√	√
7. Source of Iodine (I)								
7.1 Potassium iodide		Ph Int, FCC, USP, Ph Eur, BP, DAB	√	√	√	√	√	√
7.2 Sodium iodide		Ph Eur, USP, BP, DAB	√	√	√	√	√	√
7.3 Potassium iodate	√ (1991)	JECFA (1988), FCC	√	√	√	√	√	√
7.4 Sodium iodate		FCC	-	√	-	√	√	√
8. Source of Zinc (Zn)								
8.1 Zinc acetate		USP, Ph Eur (dihydrate)	√	√	√	√	√	√
8.2 Zinc chloride		USP, Ph Eur, JP, BP, DAB	√	√	√	√	√	√
8.3 Zinc gluconate		FCC, USP, DAC	√	√	√	√	√	√
8.4 Zinc lactate		FCC	√	√	√	√	√	√
8.5 Zinc oxide		Ph Int, FCC, USP, Ph Eur, BP, DAB	√	√	√	√	√	√
8.6 Zinc sulphate		FCC, USP, Ph Eur, BP	√	√	√	√	√	√
8.7 Zinc carbonate		USP, BP (hydroxide carbonate)	-	√	-	-	-	√
9. Source of Manganese (Mn)								
9.1 Manganese(II) chloride		FCC	√	√	√	√	√	√
9.2 Manganese(II) citrate		FCC	√	√	√	√	√	√
9.3 Manganese(II) glycero-phosphate		FCC	-	√	-	√	√	√

9.4 Manganese(II) sulphate		FCC, USP, Ph Eur (monohydrate)	√	√	√	√	√	√
9.5 Manganese(II) gluconate		FCC	√	√	√	√	√	√
9.6 Manganese(II) carbonate		MI	√	√	√	√	√	√
10. Source of Selenium (Se)								
10.1 Sodium selenate		MI	√	√	√	√	-	√
10.2 Sodium selenite		Ph Eur, USP, MP, MI	√	√	√	√	-	√
10.3 Sodium hydrogen selenite		DVFA	-	√	-	-	-	√
11. Chromium (Cr III)								
11.1 Chromium (III) sulphate		USP, MI	-	√	-	-	-	√
11.2 Chromium (III) chloride		USP, MI	-	√	-	-	-	√
12. Molybdenum (Mo VI)								
12.1 Sodium molybdate		Ph Eur (dihydrate), BP, DAB	-	√	-	-	-	√
12.2 Ammonium molybdate		FCC, USP	-	√	-	-	-	√
13. Fluoride (F)								
13.1 Sodium fluoride		FCC, USP, Ph Eur, BP, DAB	-	√	-	-	-	√
13.2 Potassium fluoride		FCC, DAB	-	√	-	-	-	√
13.3 Calcium fluoride		DAB	-	√	-	-	-	√

B: ADVISORY LIST OF VITAMIN COMPOUNDS FOR USE IN FOODS FOR SPECIAL DIETARY USES INTENDED FOR INFANTS AND YOUNG CHILDREN

Nutrient Source	Purity Requirements by		Use in Codex Food Standards Applicable to Infants and Young Children					
	CAC[1]	international and/or national bodies	IF		FUF[4]	PCBF[5]	CBF[6]	FSMP[7] for infants and young children
			Sec. A[2]	Sec. B[3]				
1. Vitamin A								
1.1 all trans Retinol		FCC (vitamin A), USP, Ph Eur (vitamin A)	√	√	√	√	√	√
1.2 Retinyl acetate		FCC (vitamin A), USP, Ph Eur (vitamin A), Jap Food Stan	√	√	√	√	√	√
1.3 Retinyl palmitate		FCC (vitamin A), USP, Ph Eur (vitamin A), Jap Food Stan	√	√	√	√	√	√
2. Provitamin A								
2.1 Beta-Carotene	√ (1991)	JECFA (1987), FCC, USP, Ph Eur, Jap Food Stan	√	√	√	√	√	√

[1] CAC = Codex Alimentarius Commission
[2] IF Sect. A = Section A of the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants
[3] IF Sect. B = Section B of the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants
[4] FUF = Follow-up Formula
[5] PCBF = Processed Cereal Based Foods for Infants and Young Children
[6] CBF = Canned Baby Food
[7] FSMP = Food for Special Medical Purposes other than Infant Formula

3. Vitamin D								
3.1 Vitamin D_2 = Ergocalciferol		Ph Int, FCC, USP, Ph Eur, Jap Food Stan, DAB	√	√	√	√	√	√
3.2 Vitamin D_3 = Cholecalciferol		Ph Int, FCC, USP, Jap Food Stan, BP, DAB	√	√	√	√	√	√
4. Vitamin E								
4.1 D-alpha-Tocopherol	√ (2001)	JECFA (2000), FCC, USP, NF, Ph Eur	√	√	√	√	√	√
4.2 DL-alpha-Tocopherol	√ (1989)	JECFA (1986), FCC, USP, NF, Ph Eur, Jap Food Stan	√	√	√	√	√	√
4.3 D-alpha-Tocopheryl acetate		FCC, USP, NF, Ph Eur	√	√	√	√	√	√
4.4 DL-alpha-Tocopheryl acetate		FCC, USP, NF, Ph Eur, BP	√	√	√	√	√	√
4.5 D-alpha-Tocopheryl acid succinate		FCC, USP, Ph Eur	-	√	-	-	-	√
4.6 DL-alpha-Tocopheryl acid succinate		NF, MP, MI, USP, Ph Eur	-	√	-	-	-	√
4.7 DL-alpha-Tocopheryl polyethylene glycol 1000 succinate		FCC, USP	-	√	-	-	-	√
5. Vitamin C								
5.1 L-Ascorbic acid	√ (1981)	JECFA (1973), Ph Int, FCC, USP, Ph Eur, JP, Jap Food Stan, BP, DAB	√	√	√	√	√	√

5.2 Calcium-L-ascorbate	√ (1983)	JECFA (1981), FCC, USP, Ph Eur	√	√	√	√	√	√
5.3 6-Palmitoyl-L-ascorbic acid (Ascorbyl palmitate)		JECFA (1973), FCC, USP, NF, Ph Eur, Jap Food Stan, BP, DAB	√	√	√	√	√	√
5.4 Sodium-L-ascorbate		JECFA (1973), FCC, USP, Ph Eur, Ph Franc, Jap Food Stan, DAC	√	√	√	√	√	√
5.5 Potassium-L-ascorbate		FCC	√	√	√	√	√	√
6. Vitamin B_1								
6.1 Thiaminchloride hydrochloride		Ph Int, FCC, USP, Ph Eur, Jap Food Stan, DAB	√	√	√	√	√	√
6.2 Thiamin mononitrate		Ph Int, FCC, USP, Ph Eur, Jap Food Stan, DAB	√	√	√	√	√	√
7. Vitamin B_2								
7.1 Riboflavin	√ (1991)	JECFA (1987), Ph Int, FCC, USP, Ph Eur, JP, Jap Food Stan, BP, DAB	√	√	√	√	√	√
7.2 Riboflavin-5'-phosphate sodium	√ (1991)	JECFA (1987), USP, Ph Eur, JP, Jap Food Stan, BP, DAB	√	√	√	√	√	√

8. Niacin								
8.1 Nicotinic acid amide (Nicotinamide)		Ph Int, FCC, USP, Ph Eur, Jap Food Stan, BP, DAB	√	√	√	√	√	√
8.2 Nicotinic acid		Ph Int, FCC, USP, Ph Eur, Jap Food Stan, BP, DAB	√	√	√	√	√	√
9. Vitamin B_6								
9.1 Pyridoxine hydrochloride		Ph Int, FCC, USP, Ph Eur, Jap Food Stan, DAB	√	√	√	√	√	√
9.2 Pyridoxal 5-phosphate		MI, FCC, USP	√	√	√	√	√	√
10. Folic acid								
10.1 N-Pteroyl-L-glutamic acid		Ph Int, FCC, USP, Ph Eur, Jap Food Stan	√	√	√	√	√	√
10.2 Calcium-L-methyl-folate		JECFA (2005)	-	√	-	-	-	√
11. Pantothenic acid								
11.1 Calcium-D-pantothenate		FCC, USP, Ph Eur, Jap Food Stan, DAB	√	√	√	√	√	√
11.2 Sodium-D-pantothenate		Jap Food Stan, DAB	√	√	√	√	√	√
11.3 D-Panthenol/		FCC, USP, Ph Eur	√	√	√	√	√	√
11.4 DL-Panthenol		FCC, USP, Ph Eur	√	√	√	√	√	√
12. Vitamin B_{12}								
12.1 Cyanocobalamin		Ph Int, FCC, USP, Ph Eur, BP, DAB	√	√	√	√	√	√

12.2 Hydroxo-cobalamin		Ph Int, USP, NF, Ph Eur (hydro-chloride)	√	√	√	√	√	√
13. Vitamin K_1								
13.1 Phytomenadione (2-Methyl-3-phytyl-1,4-naphthoquinone/ Phylloquinone/ Phytonadione)		Ph Int, FCC (vitamin K), USP, Ph Eur, BP	√	√	√	√	√	√
14. Biotin								
14.1 D-Biotin		FCC, USP, Ph Eur	√	√	√	√	√	√

C: ADVISORY LIST OF AMINO ACIDS AND OTHER NUTRIENTS FOR USE IN FOODS FOR SPECIAL DIETARY USES INTENDED FOR INFANTS AND YOUNG CHILDREN

Nutrient Source	Purity Requirements by		Use in Codex Food Standards Applicable to Infants and Young Children					
	CAC[1]	international and/or national bodies	IF		FUF[4]	PCBF[5]	CBF[6]	FSMP[7] for infants and young children
			Sec. A[2]	Sec. B[3]				
1. Amino acids[8]								
1.1 L-Arginine		FCC, USP, Ph Eur, BP, DAB	only for improving the nutritional quality of the protein (when the protein is nutritionally inadequate for its intended use)	√	only for improving the nutritional quality of the protein (when the protein is nutritionally inadequate for its intended use)			√
1.2 L-Arginine hydrochloride		FCC, USP, Ph Eur, BP, DAB		√				√
1.3 L-Cystine		FCC, USP, Ph Eur		√				√
1.4 L-Cystine dihydrochloride		MI		√				√
1.5 L-Cysteine		DAB		√				√
1.6 L-Cysteine hydrochloride		FCC, Ph Eur		√				√
1.7 L- Histidine		FCC, USP, Ph Eur, DAB		√				√
1.8 L- Histidine hydrochloride		FCC, Ph Eur, DAB		√				√
1.9 L-Isoleucine		FCC, USP, Ph Eur, DAB		√				√
1.10 L-Isoleucine hydrochloride		FCC, USP		√				√

[1] CAC = Codex Alimentarius Commission
[2] IF Sect. A = Section A of the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants
[3] IF Sect. B = Section B of the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants
[4] FUF = Follow-up Formula
[5] PCBF = Processed Cereal Based Foods for Infants and Young Children
[6] CBF = Canned Baby Food
[7] FSMP = Food for Special Medical Purposes other than Infant Formula
[8] As far as applicable, also the free, hydrated and anhydrous forms of amino acids, and the hydrochloride, sodium, and potassium salts of amino acids may be used for FSMP.

1.11 L-Leucine		FCC, USP, Ph Eur, DAB		√				√
1.12 L-Leucine hydrochloride		MI, FCC, USP		√				√
1.13 L-Lysine		USP	only for improving the nutritional quality of the protein (when the protein is nutritionally inadequate for its intended use)	√	only for improving the nutritional quality of the protein (when the protein is nutritionally inadequate for its intended use)			√
1.14 L-Lysine monohydrochloride		FCC, USP, Ph Eur, DAB		√				√
1.15 L-Methionine		Ph Int, FCC, USP, Ph Eur, DAB		√				√
1.16 L-Phenylalanine		FCC, USP, Ph Eur		√				√
1.17 L-Threonine		FCC, USP, Ph Eur, DAB		√				√
1.18 L-Tryptophan		FCC, USP, Ph Eur, DAB		√				√
1.19 L-Tyrosine		FCC, USP, Ph Eur, DAB		√				√
1.20 L-Valine		FCC, USP, Ph Eur, DAB		√				√
1.21 L-Alanine		FCC, USP, Ph Eur, DAB	-	√	-	-	-	√
1.22 L-Arginine L-aspartate		FP	-	√	-	-	-	√
1.23 L-Aspartic acid		FCC, USP, Ph Eur	-	√	-	-	-	√
1.24 L-Citrulline		USP, DAC	-	√	-	-	-	√
1.25 L- Glutamic acid		JECFA (1987), FCC, USP, Ph Eur	-	√	-	-	-	√
1.26 L-Glutamine		FCC, USP, DAB	-	√	-	-	-	√
1.27 Glycine		FCC, USP, Ph Eur	-	√	-	-	-	√

1.28 L-Ornithine		MI, FCC	-	√	-	-	-	√
1.29 L-Ornithine monohydrochloride		DAB	-	√	-	-	-	√
1.30 L-Proline		FCC, USP, Ph Eur, DAB	-	√	-	-	-	√
1.31 L-Serine		USP, Ph Eur, DAB	-	√	-	-	-	√
1.32 N-Acetyl-L-cysteine		USP, Ph Eur, DAB	-	√	-	-	-	√
1.33 N-Acetyl-L-methionine		FCC	-	-	-	-	-	√ not for infants
1.34 L-Lysine acetate		FCC, USP, MP; Ph Eur	-	√	-	-	-	√
1.35 L-Lysine L-Aspartate		Jap Food Stan	-	√	-	-		√
1.36 L-Lysine L-glutamate dihydrate		Jap Food Stan	-	√	-	-	-	√
1.37 Magnesium L-aspartate		Ph Eur	-	√	-	-	-	√
1.38 Calcium L-glutamate	√ (1991)	JECFA, FCC, FSANZ, Jap Food Stan	-	√	-	-	-	√
1.39 Potassium L-glutamate		JECFA, FCC, FSANZ, Jap Food Stan	-	√	-	-	-	√
2. Carnitine								
2.1 L-Carnitine		FCC, USP, Ph Eur	√	√	√	√	√	√
2.2 L-Carnitine hydrochloride		FCC	√	√	√	√	√	√
2.3 L-Carnitine tartrate		FCC, Ph Eur	√	√	√	-	-	√
3. Taurine								
3.1 Taurine		USP, JP	√	√	√	-	-	√

4. Choline								
4.1 Choline		FCC, USP	√	√	√	√	√	√
4.2 Choline chloride		FCC, DAC, DAB	√	√	√	√	√	√
4.3 Choline citrate		NF	√	√	√	√	√	√
4.4 Choline hydrogen tartrate		DAB	√	√	√	√	√	√
4.5 Choline bitartrate		FCC, NF, DAB	√	√	√	√	√	√
5. Inositols								
5.1 Myo-Inositol (=meso-Inositol)		FCC, DAC	√	√	√	√	√	√
6. Nucleotides								
6.1 Adenosine 5-mono-phosphate (AMP)		FSANZ	√	√	√	-	-	√
6.2 Cytidine 5-mono-phosphate (CMP)		FSANZ, Jap Food Stan	√	√	√	-	-	√
6.3 Guanosine 5-mono-phosphate (GMP)		JECFA (1985)	√	√	√	-	-	√
6.4 Inosine 5-monophos-phate (IMP)		JECFA (1974)	√	√	√	-	-	√
6.5 Disodium Uridine 5-monophosphate salt		FSANZ, Jap Food Stan	√	√	√	-	-	√
6.6 Disodium Guanosine 5-monophosphate salt		FCC, JECFA, FSANZ, Jap Food Stan	√	√	√	-	-	√
6.7 Disodium Inosine 5-monophosphate salt		FCC, JECFA, FSANZ, Jap Food Stan	√	√	√	-	-	√

D: ADVISORY LIST OF FOOD ADDITIVES FOR SPECIAL NUTRIENT FORMS

For reasons of stability and safe handling, some vitamins and other nutrients have to be converted into suitable preparations, e.g. gum arabic coated products, dry rubbed preparations. For this purpose, the food additives included in the respective specific Codex standard may be used. In addition, the following food additives may be used as nutrient carriers:

	INS no.	Additive/ Carrier	Maximum Level in Ready-to-use Food for infants and young children (mg/kg)
(a)	551	Silicon dioxide	10
(b)	421	Mannitol (for vitamin B_{12} dry rubbing, 0,1% only)	10
(c)	1450	Starch sodium octenyl succinate	100
(d)	301	Sodium L-ascorbate (in coating of nutrient preparations containing polyunsaturated fatty acids)	75

Abbreviations:

BP	=	British Pharmacopoeia
BPC	=	British Pharmaceutical Codex
DAB	=	Deutsches Arzneibuch
DAC	=	Deutscher Arzneimittel-Codex
DVFA	=	Danish Veterinary and Food Administration
FCC	=	Food Chemicals Codex
FSANZ	=	Food Standards Australia New Zealand
FU	=	Farmacopoea Ufficiale della Republica Italiana
JP	=	The Pharmacopeia of Japan
Jap Food Stan	=	Japanese Food Standard
MI	=	Merck Index
MP	=	Martindale Pharmacopoeia
ÖAB	=	Österreichisches Arzneibuch
Ph Eur	=	Pharmacopoeia Europaea
Ph Franç	=	Pharmacopée Française
Ph Helv	=	Pharmacopoeia Helvetica
Ph Int	=	International Pharmacopoeia
USP	=	The United States Pharmacopoeia

APPENDIX V

PROPOSED DRAFT ADVISORY LIST OF NUTRIENT COMPOUNDS FOR USE IN FOODS FOR SPECIAL DIETARY USES INTENDED FOR INFANTS AND YOUNG CHILDERN

(At Step 6 of the Procedure)

D: ADVISORY LIST OF FOOD ADDITIVES FOR SPECIAL NUTRIENT FORMS

	INS no.	Additive/ Carrier	Maximum Level in Ready-to-use Food for infants and young children [mg/kg]
[(a)	414	Gum arabic (gum acacia)	[10] or [100]]

APPENDIX VI

PROPOSED DRAFT NUTRITIONAL RISK ANALYSIS PRINCIPLES AND GUIDELINES FOR APPLICATION TO THE WORK OF THE COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

(At Step 5 of the Procedure)

SECTION 1 – BACKGROUND

1. The *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* (hereafter cited as "Working Principles") has established general guidance on risk analysis to Codex Alimentarius. These Working Principles were adopted in 2003 and published in this Procedural Manual.

2. The objective of the Working Principles is "to provide guidance to the Codex Alimentarius Commission and the joint FAO/WHO expert bodies and consultations so that food safety and health aspects of Codex standards and related texts are based on risk analysis". By its reference to health aspects in addition to food safety, the objective provides clearer direction for risk analysis to apply to nutritional matters that are within the mandate of the Codex Alimentarius Commission and its subsidiary bodies.

SECTION 2 – INTRODUCTION

3. Codex nutritional risk analysis addresses nutrients[1] and related substances[2] and the risk to health from their inadequate and/or excessive intake. Nutritional risk analysis applies the same general approach as traditional food safety risk analysis to consideration of excessive intakes of nutrients and related substances. However, unlike many constituents of food that are the subject of traditional food safety risk analysis such as food additives, chemical (pesticide and veterinary drug) residues inherent constituents such as allergens, nutrients and related substances are inherent constituents that are biologically essential (in the case of essential nutrients) or in other ways potentially favourable to health. Nutritional risk analysis therefore adds a new dimension to traditional risk analysis by also considering risks directly posed by inadequate intakes., microbiological pathogens, contaminants and

4. The [*Nutritional Risk Analysis Principles and Guidelines for Application to the Work of the Committee on Nutrition and Foods for Special Dietary Uses*] presented in this document (hereafter cited as "Nutritional Risk Analysis Principles") are subsidiary to and should be read in conjunction with the Working Principles.

These Nutritional Risk Analysis Principles are framed within the three-component structure of the Working Principles, but with an added initial step to formally recognize Problem Formulation as an important preliminary risk management activity.

5. Consistent with their important role in providing scientific advice to the Codex Alimentarius Commission and its subsidiary bodies, FAO and WHO and their joint expert consultations [and expert bodies] are acknowledged as the primary source of nutritional risk assessment advice to Codex

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[1] Nutrient is defined by Codex *General Principles for the Addition of Essential Nutrients to Foods* (CAC/GL 09-1987) to mean:

Any substance normally consumed as a constituent of food:

(a) which provides energy; or
(b) which is needed for growth and development and maintenance of healthy life; or
(c) a deficit of which will cause characteristic biochemical or physiological changes to occur.

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.

[2] [A related substance is an inherent constituent of food (other than a nutrient) that has a [potential] nutritional or physiological effect.]

Alimentarius. This role however, does not preclude the choice of other sources of scientific advice such as appropriate international expert groups or organizations if and when justified.

SECTION 3 – SCOPE AND APPLICATION

6. [The Nutritional Risk Analysis Principles are established to guide the Codex Alimentarius Commission and its subsidiary bodies - primarily but not exclusively the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) - in applying nutritional risk analysis to their work. This guidance potentially extends beyond CCNFSDU since the Committee is also mandated, in accordance with its 4th term of reference, "to consider, amend if necessary, and endorse provisions on nutritional aspects" of foods including those resulting from application of nutritional risk analysis that are developed by other Codex subsidiary bodies.]

7. Nutritional risk analysis considers the risk of adverse health effects from inadequate and/or excessive intakes of nutrients and related substances, and the predicted reduction in risk from proposed management strategies. In situations that address inadequate intakes, such a reduction in risk might be referred to as [one form of] a nutritional benefit.

8. The food constituents of primary interest in nutritional risk analysis are inherent components of food and/or intentionally added to food [and are identified as:

   - nutrients that may reduce the risk of inadequacy and those that may increase the risk of adverse health effects; or

   - related substances[2] that may increase the risk of adverse health effects at excessive intake and may also reduce the risk of other adverse health effects at lower intake;

   - [nutrients that increase the risk of adverse health effects that exist in a food matrix with a nutrient(s) or related substance(s) associated with reduction of the risk of inadequacy or adverse health effects at lower intake];].

9. Where appropriate, the application of quantitative nutritional risk analysis may guide decision making on quantitative content provisions for nutrients and related substances in certain Codex texts.

10. Nutritional risk analysis should be as quantitative as possible, although a qualitative risk-based approach drawing on the principles of nutritional risk analysis could assist the development of Codex texts in such situations as:

    - formulating general principles related to nutritional composition (e.g. principles for the addition of nutrients to foods);

    - formulating general principles for assessing or managing risks related to foods for which a nutrition or health claim has been requested;

    - managing risks by labelling advice in relation to consumption of foods of certain nutrient-related[3] composition, including foods for special dietary use; and

    - advising on risk-risk analysis (e.g. risk associated with a significantly reduced or entirely avoided consumption of a nutritious, staple food in response to a dietary hazard such as a contaminant present in that food.

[3] For the purpose of these Nutritional Risk Analysis Principles, the descriptive term 'nutrient-related' refers to one or more nutrients and/or related substances, as the case may be.

SECTION 4 – DEFINITIONS

11. The *Definitions of Risk Analysis Terms Related to Food Safety* in this Procedural Manual provide suitable generic definitions of risk analysis, risk assessment, risk management, risk communication and risk assessment policy. When applied in a nutritional risk analysis context, these high-level risk analysis terms should be prefaced by 'nutritional' and their existing definitions appropriately adapted by replacement of relevant existing terms and definitions with those listed below.

12. However, other *Definitions of Risk Analysis Terms Related to Food Safety* have been modified to reference inadequate intake as a nutritional risk factor. Some new terms also have been defined to provide further clarity. The modified or newly developed subsidiary definitions are as follows:

Nutritional risk – A function of the probability of an adverse health effect associated with inadequate or excessive intake of a nutrient or related substance and the severity of that effect, consequential to a nutrient-related hazard(s) in food.

Adverse health effect[4] – A change in the morphology, physiology, growth, development, reproduction or life span of an organism, system, or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress, or an increase in susceptibility to other influences.

Nutrient-related[3] hazard – A nutrient or related substance in food that has the potential to cause an adverse health effect depending on inadequate or excessive level of intake.

Nutrient-related hazard identification – The identification of a nutrient-related hazard in a particular food or group of foods.

Nutrient-related hazard characterization – The qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with a nutrient-related hazard.

Dose response assessment – The determination of the relationship between the magnitude of intake of (or exposure to) (i.e. dose) a nutrient or related substance and the severity and/or frequency of associated adverse health effects (i.e. response).

Upper level of intake[4] – 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.

Highest observed intake[4] – the highest level of intake observed or administered as reported within a stud(ies) of acceptable quality. It is derived only when no adverse health effects have been identified.

Intake (Exposure) assessment – The qualitative and/or quantitative evaluation of the likely intake of a nutrient or related substance from food as well as intake from other relevant sources such as food supplements.

Nutrient-related risk characterization – The qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on nutrient-related hazard identification, nutrient-related hazard characterization and intake assessment.

Bioavailability[5] – The proportion of the ingested nutrient or related substance that is absorbed and utilised through normal metabolic pathways. Bioavailability is influenced by dietary factors such as

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[4] *A Model for Establishing Upper Levels of Intake for Nutrients and Related Substances*. Report of a joint FAO/WHO technical workshop 2005, WHO, 2006.

[5] Gibson R.S. The role of diet- and host-related factors in nutrient bioavailability and thus in nutrient-based dietary requirement estimates. Food and Nutrition Bulletin 2007;28(suppl):S77-100.

chemical form, interactions with other nutrients and food components, and food processing/preparation; and host–related intestinal and systemic factors.

Homeostatic mechanism[4] – A mechanism effected through a system of controls activated by negative feedback that allow the maintenance of normal body functions in the presence of a variable nutrition environment.

SECTION 5 – PRINCIPLES FOR NUTRITIONAL RISK ANALYSIS

13. Nutritional risk analysis comprises three components: risk assessment, risk management and risk communication. Particular emphasis is given to an initial step of Problem Formulation as a key preliminary risk management activity.

PRELIMINARY NUTRITIONAL RISK MANAGEMENT ACTIVITIES

14. Preliminary nutritional risk management activities should have regard to the particular sections in the Working Principles titled General Aspects of Risk Analysis, and Risk Assessment Policy.

Nutritional Problem Formulation[4]

15. Nutritional Problem Formulation is necessary to identify the purpose of a nutritional risk assessment and is a key component of preliminary nutritional risk management activity because it fosters interactions between risk managers and risk assessors to help ensure common understanding of the problem and the purpose of the risk assessment.

16. Such considerations should include whether a nutritional risk assessment is needed and if so:

- the priority it should be accorded;
- who should conduct and be involved in the nutritional risk assessment, nutritional risk management and nutritional risk communication processes;
- the need for development of nutritional risk assessment policy;
- how the nutritional risk assessment will provide the information necessary to support the nutritional risk management decision;
- whether data are available to embark on an evaluation of nutritional risks;
- what level of resources are available; and
- the timeline for completing the assessment.

17. Specific information to be gathered for nutritional problem formulation may include:

- a detailed inventory of prior knowledge;
- identification of the (sub)populations to be the focus for the risk assessment, geographical areas or consumer settings to be covered;
- relevant route(s) of exposure; and
- the health endpoints to be considered.

NUTRITIONAL RISK ASSESSMENT

18. The risk assessment section of the Codex *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* is generally applicable to nutritional risk assessment. Additional nutritional risk assessment principles to consider within the Codex framework are identified below.

Nutrient-Related Hazard Identification and Hazard Characterization

19. These two steps are often globally relevant because they are based on available scientific and medical literature that contribute data from diverse population groups. This global relevance for characterization of hazard does not, however, preclude the possibility of a (sub)population-specific hazard.

20. Nutritional risk assessment should take into consideration the nutrient-related hazard(s) posed by both inadequate and excessive intakes. This may include consideration of hazard(s) posed by excessive intakes of accompanying risk-increasing nutrients in the food vehicle(s) under consideration.

21. Nutrient-related hazard identification and characterization should recognize current methodological differences in assessment of nutritional risk of inadequate and excessive intakes, and scientific advances in these methodologies.

22. Nutrient-related hazard characterization should take into account homeostatic mechanisms for essential nutrients, and limitations in the capacity for homeostatic adaptations. It may also take into account bioavailability including factors affecting the bioavailability of nutrients and related substances such as different chemical forms.

23. Nutrient reference standards that may be used to characterize nutrient-related hazard(s) related to adequacy include measures of average requirement. Some globally applicable nutrient reference standards for average requirement have been published by FAO/WHO. Official regional and national nutrient reference standards are also available and have been periodically updated to reflect scientific advances. These are more likely to relate to nutrients than to related substances.

24. Nutrient reference standards that may be used to characterize nutrient-related hazard(s) related to excessive intakes include upper levels of intake. Some globally applicable reference standards of upper level of intake have been published by FAO/WHO. In addition, the establishment of international upper levels of intake and highest observed intake that build on recommendations[4] may be considered in the future. Some periodically-updated nutrient reference standards are available from regional and national authorities. For some related substances, such standards developed from a systematic review of the evidence are available only in the peer-reviewed scientific literature.

25. The assessment of inadequate and excessive levels of intake of particular nutrients and related substances should take into account the availability of all such scientifically determined reference sources, as appropriate. When using such reference standards for nutrient and related substances in nutritional risk assessment, the basis for their derivation should be explicitly described.

Nutrient-Related Intake Assessment and Risk Characterization

26. These two steps are generally specific to the (sub)population(s) under consideration for risk assessment. The populations relevant to Codex consideration are populations at large in Codex member countries or particular subpopulation groups in these countries defined according to physiological parameters such as age or state of health.

27. Nutrient-related intake assessment and risk characterization should be applied within a total diet context. Where feasible, it would typically involve the evaluation of the distribution of habitual total daily intakes for the target population(s). This approach recognizes that nutrient-related risks are often

associated with total intakes from multiple dietary sources, including fortified foods, food supplements[6], and in the case of certain minerals, water. [It may also take into account the bioavailability and stability of nutrients and related substances in the foods consumed.]

NUTRITIONAL RISK MANAGEMENT

28. The risk management section of the Codex *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* is generally applicable to nutritional risk management. Additional nutritional risk management principles to consider within the Codex framework are identified below.

29. Nutritional risk management can be effected through quantitative measures or qualitative guidance elaborated in Codex texts. Such risk management could involve decisions about nutrient composition, consideration of the suitability of foods containing risk-increasing nutrients for certain purposes or (sub)populations, labelling advice intended to mitigate nutritional risks to public health, and formulation of relevant general principles.

    [Nutritional risk management decisions should take into account the actual, or likely, impact on consumers' behaviour, such as dietary patterns and preparation practices, which are cultural habits, in order to anticipate possible product substitutions and to ensure an overall risk reduction.]

30. Nutritional risk assessment policy should be articulated as appropriate for the selected risk assessor prior to the conduct of the nutritional risk assessment.

NUTRITIONAL RISK COMMUNICATION

31. The risk communication section of the Codex *Working Principles for Analysis for Application in the Framework of the Codex Alimentarius* is generally applicable to nutritional risk communication.

SECTION 6 – SELECTION OF RISK ASSESSOR BY CCNFSDU

32. Consistent with their important role in providing scientific advice to Codex Alimentarius and its subsidiary bodies, FAO and WHO are acknowledged as the primary source of nutritional risk assessment advice to Codex Alimentarius. However, this role does not preclude the choice of other sources of advice such as appropriate international expert groups or organizations [as well as national relevant expertise,] if and when justified.

33. All requests for risk assessment advice should be accompanied by terms of reference and where appropriate risk assessment policy to provide guidance to the risk assessor. These parameters should be established by the relevant Codex subsidiary body.

SECTION 7 – REVIEW PROCESS

34. These Nutritional Risk Analysis Principles should be reviewed by CCNFSDU at appropriate intervals after implementation to ensure currency and consistency with [good regulatory practice] and subsequent to any future amendments to the Codex Working Principles.

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[6] Codex *Guidelines for Vitamin and Mineral Food Supplements* (CAC/GL 55 – 2005) define food supplements as sources in concentrated forms of those nutrients or related substances alone or in combinations, marketed in forms such as capsules, tablets, powders solution, etc., that are designed to be taken in measured small unit quantities but are not in a conventional food form and whose purpose is to supplement the intake of nutrients or related substances from the diet.

APPENDIX VII

PROJECT DOCUMENT OF A PROPOSAL FOR NEW WORK TO REVISE NUTRIENT REFERENCE VALUES OF VITAMINS AND MINERALS (CAC/GL 2-1985)

1. PURPOSE AND THE SCOPE OF THE PROPOSED NEW WORK

Section 3.4.4 of the *Codex Guidelines for Nutrition Labelling* (CAC/CL 2-1985, Rev. 1-1993) provides that numerical information on vitamins, minerals and protein should be expressed as a percentage of the reference labeling value referred to as "Nutrient Reference Value" (NRV). Since the first introduction of this guideline in 1985, Section 3.4.4 was amended once in 1993 following the Report of a Joint FAO/WHO Consultation on Recommended Allowances of Nutrients for Food Labelling Purposes (Helsinki, Finland, 12-16 September 1988). At that time, it was indicated that the definition and review of these values was on ongoing process, subject to revision according to new scientific data by the Committee of Food Labelling (CCFL). The CCFL also recognized a need for general principles to guide the choice and amendment of NRVs, and had requested the advice of the Committee on Nutrition and Foods for Special Dietary Uses in this respect (ALINORM 93/40)

Currently the list of NRVs in *Codex Guidelines for Nutrition Labelling* covers 9 vitamins (A, D, C, thiamin, riboflavin, niacin, B_6, folic acid and B_{12}), 5 minerals (Calcium, Magnesium, Iron, Zinc, Iodine) and protein, which were in general based on the Reference RDAs for adult men. These values are indicated as a basis for expressing nutrient content in nutrition labeling of food supplements in the *Codex Guidelines for Vitamin and Mineral Food Supplements* (CAC/GL 55-2005). Also the *Codex Guidelines for Use of Nutrition and Health Claims* (CAC/GL 23-1997, Rev. 1-2004) indicates NRVs as a basis for criteria for nutrition and health claims.

At the 25th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSUD) agreed that the current list of NRVs in the *Codex Guidelines for Nurition Labelling* was incomplete and required additions and updates. It was also pointed out that a set of principles should be developed for the establishment of NRVs taking into account the experience of member countries in the establishment of reference values for the purpose of labelling.

The purpose of the proposed new work is to develop the science-based general principles for establishing NRVs and to revise the list of NRVs in the *Codex Guidelines for Nutrition Labelling*, taking full account of the prior work related to nutrient reference values.

2. ITS RELEVANCE AND TIMELINESS

WHA Resolution 57.17 endorsing the Global Strategy requested the Codex Alimentarius Commission to continue to give full consideration within the framework of its operational mandate, to measures which it might take to contribute towards the improvement of health standards of foods consistent with the aims and objectives of the Global Strategy.

Accordingly, the 28th Session of the Commission agreed to ask WHO and FAO to prepare a document

focused on actions that could be taken by Codex including specific proposals for new work for consideration by the CCNFSDU and the CCFL. At its 29th Session of the Commission, it was agreed to complete a document containing concrete proposals for possible actions by Codex and to circulate for comments and consideration by the CCNFSDU and CCFL.

The CCNFSDU and CCFL had discussed extensively the proposals for actions and both Committees agreed for CCNFSDU to revise the NRVs of vitamins and minerals in the *Guidelines for Nutrition Labelling* (ALINORM 07/30/26). Therefore the proposal of this new work is timely as well as relevant.

3. THE MAIN ASPECTS TO BE COVERED

This work would involve a process to develop the general principles for establishment of vitamin and mineral NRVs for the general population as a first step.

The next step would be a process to review all available reference values and their scientific basis by the principles agreed upon and, if appropriate, update and extend the current list of vitamin and mineral NRVs in the *Guidelines for the Nutrition Labelling*.

Once the above is completed, the Committee would establish vitamin and mineral NRVs for labelling for individuals 6 months to 36 months of age. The Committee could then beginn to work to establish principles that would apply to NRVs for this age group, using as a basis the principles identified for NRVs for the general population and modifying them as appropriate. Once those principles are developed, the NRVs for this age group would be established.

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

Consumer protection from the point of view of health, food safety, ensuring fair practices in the food trade and taking into account the identified needs of developing countries: This proposed new work would provide Codex and national/regional authorities principles to be used in establishing NRVs, thus assisting in establishing appropriate level of protection for consumers. The project could particularly assist countries that have limited experience with NRVs, particularly for selecting NRVs for labelling purposes.

Diversification of national legislations and apparent resultant or potential impediments to international trade: This proposed new work would provide internationally-recognized scientific general principles that Codex and national/regional authorities may use to carry out establishing NRVs for labelling purposes. Such internationally-agreed principles can help ensure consistent approaches for establishing NRVs for labelling purposes.

Scope of work and establishment of priorities between the various sections of the work: The scope of the work relates to work previously undertaken by Codex on a high priority basis.

- ***Work already undertaken by other organizations in this field:*** This proposed new work is consistent with, complements, and builds upon work already undertaken by CCFL.

5. RELEVANCE TO THE CODEX STRATEGIC OBJECTIVES

This proposal is consistent with the following strategic goals presented in the Codex Strategic Plan 2008-2013:

Promoting Sound Regulatory Frameworks (Activity 1.3);

Promoting Widest and Consistent Application of Scientific Principles and Risk Analysis (Activities 2.3).

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

The *Codex Guidelines on Nutrition Labelling* (CAC/GL 2-1985, Rev. 1-1993) and *Codex Guidelines for Vitamin and Mineral Food Supplements* (CAC/GL 55-2005) indicate the NRVs as a basis for expressing nutrient content in nutrition labelling of all foods including conventional foods and food supplements. The *Codex Guidelines for Use of Nutrition and Health Claims* (CAC/GL 23-1997, Rev. 1-2004) also indicates NRVs as a basis for criteria for nutrition and health claims.

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

Scientific advice from FAO/WHO could be identified at a later stage.

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 STEP 5 AND THE PROPOSED DATE FOR ADOPTION BY THE COMMISSION: THE TIME FRAME FOR DEVELOPING GUIDELINE SHOULD NOT NORMALLY EXCEED FIVE YEARS

Activity	Step/date
The CCNFSDU agrees the work to be undertaken	Nov, 2007
Commission approves New Work	July 2008
Step 5	2009/2010
Adoption by the Commission	2011/2012