codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

ALINORM 01/26

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION
Twenty-fourth Session
Geneva, 2 – 7 July 2001

REPORT OF THE 22nd SESSION OF THE CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Berlin, Germany
19 – 23 June 2000

Note: This document incorporates Codex Circular Letter 2000/22-NFSDU.

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CX 5/20.2

CL 2000/22 – NFSDU
July 2000

TO: Codex Contact Points
Interested International Organizations

FROM: Chief, Joint FAO/WHO Food Standards Programme, FAO
Viale delle Terme di Caracalla, 00100 Rome, Italy

SUBJECT: **DISTRIBUTION OF THE REPORT OF THE TWENTY-SECOND SESSION OF THE CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES (ALINORM 01/26)**

The report of the Twenty-second Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses will be considered by the 24th Session of the Codex Alimentarius Commission to be held in Geneva from 2 - 7 July 2001.

PART A. MATTERS FOR ADOPTION BY THE 24th SESSION OF THE CODEX ALIMENTARIUS COMMISSION

DRAFT TEXTS AT STEP 8:

1. GUIDELINES FOR USE OF NUTRIENT CLAIMS: DRAFT TABLE OF CONDITIONS FOR NUTRIENT CONTENTS (PART B, CONTAINING PROVISIONS ON PROTEIN, VITAMINS AND MINERALS) (ALINORM 01/26, PARAS 13-19 AND APPENDIX II);

Governments and International Organizations are invited to comment on the above draft Table and should do so in writing in conformity with the Guide to the Consideration of Standards at Step 8 of the Procedure for the Elaboration of Codex Standards Including Consideration of Any Statements Relating to Economic Impact (*Codex Alimentarius Procedural Manual*, Eleventh Edition, pp. 26-27) to the Chief, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy (fax: +39 06 5705 4593, e-mail: codex@fao.org), **not later than 31 January 2001**.

PART B. REQUEST FOR COMMENTS AND INFORMATION

1. GUIDELINES FOR USE OF NUTRITION CLAIMS: DRAFT TABLE OF CONDITIONS FOR NUTRIENT CONTENTS (PART B, CONTAINING PROVISIONS ON DIETARY FIBRE AT STEP 6) (ALINORM 01/26, PARAS 20-27 AND APPENDIX III)

Governments wishing to comment on the proposed draft Table at Step 6 should do so in writing to Dr Rolf Grossklaus, Director und Professor Bundesinstitut für Gesundheitlichen Verbraucherschutz und Veterinaermedizin (BgVV), P.O. Box 33 00 13, 14191 Berlin, Germany, Fax: +49 1888 412 - 37 15, e-mail: ccnfsdu@bgvv.de with a copy to the Chief, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy (fax: +39 06 5705 4593, e-mail: codex@fao.org), **not later than 31 January 2001**.

2. PROPOSED DRAFT GUIDELINES FOR Vitamin and Mineral Supplements at Step 3 (ALINORM 01/26 PARAS 36-57 AND APPENDIX IV)

Governments are invited to comment on the proposed Draft Guidelines and should do so in writing to Dr Rolf Grossklaus, Director und Professor Bundesinstitut für Gesundheitlichen Verbraucherschutz und Veterinaermedizin (BgVV), P.O. Box 33 00 13, 14191 Berlin, Germany, Fax: +49 1888 412 - 37 15, e-mail: ccnfsdu@bgvv.de with a copy to the Chief, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy (fax: +39 06 5705 4593, e-mail: codex@fao.org), **not later than 31 January 2001**.

3. PROPOSED DRAFT REVISED STANDARD FOR INFANT FORMULA AT STEP 3 (ALINORM 01/26, PARAS 58-87 AND APPENDIX V)

Governments are invited to comment on the proposed Draft Revised Standard and should do so in writing to Dr Rolf Grossklaus, Director und Professor Bundesinstitut für Gesundheitlichen Verbraucherschutz und Veterinaermedizin (BgVV), P.O. Box 33 00 13, 14191 Berlin, Germany, Fax: +49 1888 412 - 37 15, e-mail: ccnfsdu@bgvv.de with a copy to the Chief, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy (fax: +39 06 5705 4593, e-mail: codex@fao.org), **not later than 31 January 2001**.

4. DISCUSSION PAPER ON REVIEW OF PROVISIONS FOR VITAMINS AND MINERALS IN CODEX STANDARDS: VITAMINS AND MINERALS IN FOODS FOR SPECIAL MEDICAL USES (ALINORM 01/26, PARAS 108-115)

While considering the above Discussion Paper the Committee agreed that the document on general principles should be developed for vitamins and minerals, therefore Member Governments are invited to provide information on criteria applied in their countries for the selection of vitamins and minerals and the determination of the amounts which were chosen. The data should be directed to Germany Dr Rolf Grossklaus, Director und Professor Bundesinstitut für Gesundheitlichen Verbraucherschutz und Veterinaermedizin (BgVV), P.O. Box 33 00 13, 14191 Berlin, Germany, Fax: +49 1888 412 - 37 15, e-mail: ccnfsdu@bgvv.de with a copy to the Chief, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy (fax: +39 06 5705 4593, e-mail, codex@fao.org), **not later than 31 January 2001**.

5. DISCUSSION PAPER ON ENERGY CONVERSION FACTORS (ALINORM 01/26, PARAS 121-125)

In order to assist in revising the above discussion paper Member Governments are invited to provide their information/comments on national practices of assignment of energy factors to food components, fats and sugars and derivation of energy factors for novel food ingredients. The data should be directed to Ms Ruth Lovisolo, Manager, Codex Australia, by fax: 61 2 6272 3103 or email: ruth.lovisolo@affa.gov.au with a copy to the Chief, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy (fax: +39 06 5705 4593, e-mail, codex@fao.org), **not later than 31 January 2001**.

6. DISCUSSION PAPER ON RECOMMENDATIONS OF THE EXPERT CONSULTATION ON FOOD CONSUMPTION AND EXPOSURE ASSESSMENT OF CHEMICALS (ALINORM 01/26, PARAS 126-129)

In order to assist in revision of the above discussion paper Member Governments are invited to provide information on their experience with risk assessment for nutrition issues at the national level, including methodology and principles. The Data should be directed to Ms Ruth Lovisolo, Manager, Codex Australia, by fax: 61 2 6272 3103 or email: ruth.lovisolo@affa.gov.au with a copy to the Chief, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy (fax: +39 06 5705 4593, e-mail, codex@fao.org), **not later than 31 January 2001**.

7. SPORTS AND ENERGY DRINKS (ALINORM 01/26, PARAS 139-143)

Member Governments are invited to provide their comments on 1) sports foods and drinks as foods for special dietary uses and 2) the claim for “high energy”, as well as the distinction between "energy drinks" and "sports drinks" in order to discuss this question further at the next session and decide how to proceed further. Comments should be sent in writing to the Chief, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy (fax: +39 06 5705 4593; e-mail: codex@fao.org), **not later than 31 January 2001**.

SUMMARY AND CONCLUSIONS

The Twenty-second Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses reached the following conclusions:

MATTERS FOR ADOPTION BY THE COMMISSION

The Committee:

- Recommended the adoption at Step 8 the Draft Table of Conditions for Nutrient Contents (Part B) containing provisions on Protein and Vitamins and Minerals for inclusion into the Guidelines for Use of Nutrition Claims (para. 19 and Appendix II).

MATTERS FOR CONSIDERATION BY THE COMMISSION

The Committee:

- Recognized that there was no consensus either on levels or on the method of determination of gluten at this time, therefore decided to keep the current Draft Revised Standard for Gluten-Free Foods at Step 7 and to seek the Commission's advice on how to deal with this issue (paras 28-35);
- Recognized that it was not possible to reach consensus on the fundamental issue of Scope of the Proposed Draft Revised Standard for Processed Cereal-Based Foods for Infants and Young Children at this stage and that it would not be possible to make further progress on the revision at the current session. The Committee therefore agreed to retain the Proposed Draft Revised Standard at Step 4 for further consideration at the next session and ask the Commission how to proceed with this issue (paras 88-102);
- Agreed to discontinue work on Provisions for Fortification of Iodine, Iron and Vitamin A in the Guidelines for Use of Nutrition Claims as the Codex texts such as Guidelines for the Addition of Essential Nutrients to Foods provided adequate guidance to countries in establishing fortification programmes, and to inform the Commission accordingly (paras 126-127).

MATTERS OF INTEREST TO THE COMMISSION

- Returned the Draft Table of Conditions for Nutrient Contents (Part B) containing provisions on Dietary Fibre to Step 6 for further comments and consideration by the next session of the Committee (paras 20-27 and Appendix III);
- Returned the Proposed Draft Guidelines on Vitamin and Mineral Supplements to Step 3 for further comments and consideration (paras 36-57 and Appendix IV);
- Returned the Proposed Draft Standard for Infant Formula to Step 3 for further comments and consideration (paras 58-87 and Appendix V);
- Agreed that the document on criteria of addition and deletion of vitamins and minerals should be developed for consideration of provisions for Vitamins and Minerals in Foods for Special Medical Uses and that Member Governments would be asked for additional information (paras 108-115);
- Agreed to ask information from Member Governments on:
  - National practices of assignment of energy factors to food components, fats and sugars and derivation of energy factors to food ingredients (paras 121-125)
  - Experience with risk assessment for nutrition issues at the national level, including methodology and principles (paras128-131); and
  - Sports foods and drinks as foods for special dietary uses and the claim for "high energy", as well as the distinction between "energy drinks" and "sports drinks" in order to discuss those questions further and decide how to proceed further (paras 139-143).

- ☛ Replied to the Codex Committee on General Principles regarding the use of *Other Legitimate Factors* by the Committee (paras 132-135);
- ☛ Agreed to inform the Committee on Food Labelling that there was an agreement in principle on the possibility and opportunity of developing criteria on the scientific basis of health claims and that the Committee was prepared to proceed with this work when the definition of health claims had been further developed (paras 116-120).

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LIST OF ABBREVIATIONS

(Used in this Report)

AAA	Association Des Amidonneries de Cereales de L'U.E.
AESGP	Association of the European Self-Medication Industry
ALINORM	Reports of Codex Committees and other working papers submitted to the Codex Alimentarius Commission
AOAC	AOAC International
AOECS	Association of European Celiac Societies
CAC	Codex Alimentarius Commission
CCFL	Codex Committee on Food Labelling
CIAA	Confederation of the Food and Drink Industries of the EU
CISDA	Confederation of International Soft Drinks Associations
CRD	Conference Room Document
CX/NFSDU	Working papers for the Codex Committee on Nutrition and Foods for Special Dietary Uses
CRN	Council for Responsible Nutrition
CSPI	Center for Science in Public Interest
EC	European Commission of the European Union
EFLA	European Food Law Association
EHPM	European Federation of Associations of Health Product Manufacturers
ENCA	European Network of Childbirth Associations
IADSA	International Alliance of Dietary/Food Supplement Associations
IBFAN	International Baby Food Action Network
ICA	International Cooperative Alliance
ICGMA	International Council of Grocery Manufacturers Association
IDF	International Dairy Federation
IFMA	International Federation of Margarine Associations
IFT	Institute of Food Technologists
IFU	International Federation of Fruit Juice Producers
ISDC	International Soft Drink Council
ISDI	International Special Dietary Food Industries
NRV	Nutrient Reference Values
UNICEF	United Nations Children's Fund
WHO	World Health Organization of the United Nations

INTRODUCTION

1. The Twenty-second Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) was held from 19 to 23 June 2000 in the Federal Institute for Health protection of Consumers and Veterinary Medicine, Berlin, by courtesy of the Government of Germany. The Session was chaired by Dr Rolf Grossklaus, Director and Professor at the above Institute. The Session was attended by 137 delegates, observers and advisors representing 51 Member countries and 18 International Organizations.

OPENING OF THE SESSION

2. The Session was opened by Mr Erwin Jordan, State-Secretary of the Federal Ministry of Health who, on behalf of the Minister of Health, welcomed the participants. Mr Jordan noted the increased participation at the Sessions of the CCNFSDU and emphasized the importance of the work of the Committee and the Codex Alimentarius Commission in providing worldwide standards, guidelines and other recommendations to protect the health of consumers especially as the concept of prevention was accepted internationally during last years. He stressed the importance of the decisions being made on the basis of consensus since Codex documents were referenced under the World Trade Organization's Agreements and pointed out that if countries were deviating from the Codex standards they should provide a sound justification for those deviations. Finally Mr Jordan wished all success to the meeting and the delegates in their important work.

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

3. The Committee adopted the Provisional Agenda as the Agenda for the Session and agreed to discuss the possibility of more frequent meetings of the Committee under Agenda Item 14 "Other Business and Future Work".

MATTERS REFERRED TO THE COMMITTEE FROM THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES (Agenda Item 2)[2]

4. The Committee noted matters arising from the 23rd Session of the Codex Alimentarius Commission (CAC), 28 June-3 July 1999; the 23rd and 24th Sessions of the Codex Committee on Food Labelling (CCFL), held on 27-30 April 1999 and on 5-9 May 2000; the 22nd Session of the Codex Committee on Methods of Analysis and Sampling (CCMAS), 23-27 November 1998, and the 22nd Session of the Codex Committee on Pesticide Residues (CCPR), held on 1-8 May 2000 and decided to discuss specific concerns under the relevant Agenda Items.

5. The Committee also noted the outcome of the FAO/WHO Expert Consultation on Human Vitamin and Mineral Requirements held in Bangkok, Thailand, 21-30 September 1998. The Committee was informed that the WHO/UNICEF Technical Consultation on Infant and Young Child Feeding, had been held in Geneva, 13-17 March 2000 and a further information on this Consultation was requested.

Proposed Draft Amendment to the Guidelines on Nutrition Labelling

6. The Committee recalled that its last session had considered the request of the Committee on Food Labelling to determine if public health needs required additional mandatory labelling of all of sugars, fibre, saturated fats and sodium when nutrition labelling was applicable as a result of declaration of any of those nutrients. The Committee had agreed that this question should be discussed further at the 22nd Session. The Committee noted that the Proposed Draft Amendment had been partially redrafted and returned to Step 3 for further comments by the 28th Session of the CCFL (May 2000).[3]

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1 CX/NFSDU 00/1

2 CX/NFSDU 00/2; CX/NFSDU 00/2-Add.1; CX/NFSDU 00/2-Add.2; CRD 16 (Extract from ALINORM 99/22A; CRD 27 (comments of India)

3 ALINORM 01/22, paras. 54-64, Appendix VII

7. The Delegation of Malaysia, supported by some delegations, proposed to add the declaration of monounsaturated and trans-fatty acids where claims were made concerning the amount of fatty acids. The Committee however recalled that the request of the CCFL concerned the general issue of nutrition labelling in relation to public health, and that specific comments on the text of the Proposed Draft Amendment would be addressed in the framework of the CCFL.

8. Several delegations stressed the importance of providing information to consumers on sugars, fibre, saturated fatty acids and sodium when a claim was made for one of these nutrients, in view of public health concerns and scientific evidence regarding the relationship between diet and health, especially for the nutrients considered. This was especially relevant in view of the efforts made by many countries, including developing countries, to improve nutrition education in order to allow consumers to make informed choices and generally improve the nutritional and health status of the population. Several delegations pointed out that nutrition labelling should remain applicable on a voluntary basis or in the case where a specific claim was made.

9. The Committee agreed that in view of public health concerns and in order to improve consumer information the additional declaration of sugars, fibre, saturated fats and sodium should be required when any of one of these nutrients were mentioned in nutrition labelling. The Committee noted that the CCFL was responsible for the finalization of the Proposed Draft Amendment and that specific comments on the text would be addressed in the framework of that Committee.

Sports and Energy Drinks

10. The Committee noted that the 27th Session of the CCFL agreed to discontinue work on Proposed Draft Recommendations for Sports and Energy Drinks until the CCNFSDU provides advice on whether "sports drinks" should be considered as "foods for special dietary uses" and on the conditions for the claim for "high energy". The Committee agreed to consider this question under Agenda Item 14 Other Business and Future Work (see paras 139-143).

Other Legitimate Factors

11. The Committee noted the oral presentation of the Secretariat that the Codex Committee on General Principles while considering the Review of the Statements of Principle on the Role of Science and the Extent to which Other Legitimate Factors are Taken into Account: Role of Science and Other Legitimate Factors in Relation to Risk Analysis had agreed that the CCNFSDU should be invited to consider the integration of other legitimate factors in its activities involving risk analysis aspects. The Committee agreed to consider this question under Agenda Item 13 where the application of a risk - based approach in the work of the Committee would be discussed (see paras 132-135).

GUIDELINES FOR THE USE OF NUTRITION CLAIMS: DRAFT TABLE OF CONDITIONS FOR NUTRIENT CONTENTS (Agenda Item 3)[4]

12. The Committee recalled that the 23rd Session of the Commission had returned the Draft Table of Conditions for Protein and Vitamins and Minerals to Step 6 for further comments and consideration.

Protein – Vitamins and Minerals

13. The Committee had an exchange of views to decide whether its earlier decision on the conditions for claims concerning Protein and Vitamins and Minerals should be confirmed or revised.

14. The Delegation of the United States expressed the view that the expression of nutrient contents per serving should be retained as an option, the serving size to be determined at the national level when used. This position was supported by several delegations, which pointed out that the Guidelines should take into account current practices in different countries. Some delegations pointed out that serving size should be defined at the national level.

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[4] CX/NFSDU 00/3; CX/NFSDU 00/3-Add.1 (comments of Australia, Brazil, Cuba, Finland, Germany, Japan, Malaysia, Spain, United Kingdom); CX/NFSDU 00/3-Add.2 (Progress Report on Dietary Fibre); CRD 2 (Summary of view's of the informal Working Group on Dietary Fibre); CRD 11 (comments of Malaysia, Thailand, Uruguay); CRD 15 (comments of India, USA).

15. The Delegation of India, supported by several delegations, stressed the need to retain the expression per 100g as this provided a clear basis for comparison for consumers, whereas the size of the serving might differ widely from country to country. The Delegation also stated that the condition for "high" protein content should be higher than two times the value for "source" and proposed to consider two to three times the value for source.

16. The Committee noted that a NRV for protein of 50 g and several NRVs for vitamins and minerals were included in the Guidelines on Nutrition Labelling (CAC/GL 2-1985, Rev. 1 1991). Some delegations indicated that the expression per 100 kcal was not consistent with Part A of the Table. It was also pointed out that the energy content was expressed in kilocalories in the current text and that the values in kilojoules should be included.

17. The Observer from the European Community supported the reference to 15% of the NRV per 100g for vitamins and minerals but expressed the view that there was no justification for the value of 7.5% of NRV for liquids and that further clarification would be required on this question.

18. Several delegations pointed out that the consensus achieved at the last session resulted from detailed discussion and took into account current practices in member countries concerning the expression of nutrient contents. The Committee recognized that different expressions of conditions for claims were used at the national level and that the Table should cover them all, with the understanding that these expressions were consistent for the purposes of expressing claims. The Committee agreed that its earlier decision represented an acceptable compromise and allowed member countries to provide clear information to consumers in a form which was readily understandable at the national level.

Status of the Guidelines for Use of Nutrition Claims - Draft Table of Conditions for Nutrient Contents Claims (Protein – Vitamins and Minerals)

19. The Committee agreed to advance the Draft Table to Step 8 for adoption by the 24th Session of the Codex Alimentarius Commission (see Appendix II).

Fibre

20. The Committee recalled that a Working Group co-ordinated by the United Kingdom had been established at the last session to consider the conditions for claims concerning fibre. The Delegation of the United Kingdom indicated that the Working Group had examined several relevant issues related to the definition and determination of fibre; however it had not been possible to reach consensus on these questions due to significant difference of views between the countries concerned.

21. The Committee considered the opportunity of applying a practical approach to this problem and using a definition of fibre corresponding to the AOAC method, which was the official method in Codex, fully validated and endorsed by the CCMAS; it was noted that this method was also currently used by many countries at the national level. However, it was pointed out that this method did not measure fructo-oligosaccharides. Some delegations expressed the view that the results obtained with this method could be interpreted differently from one country to another and that it would not solve the problems related to the definition.

22. The Committee also noted that the current definition included in the Guidelines on Nutrition Labelling covered "edible plant and animal material" and several delegations supported the deletion of a reference to substances of animal origin. The Committee did not come to a conclusion on the revision of the current definition of fibre.

23. The Representative of FAO indicated that the FAO/WHO Expert Consultation on Carbohydrates in Human Nutrition[5] had considered several aspects of fibre in human nutrition, including health benefits and current methods of analysis. The Delegation of the United States noted that there was currently no NRV or recommended intake for fibre and informed the Committee that its National Academy of Science was undertaking a detailed study in this area, which would be available within one

[5] FAO Food and Nutrition Paper No.66, 1998

year. The Delegation of Sweden indicated that studies were ongoing in their country on the definition and methods of analysis for fibre.

24. The Committee recognized that it was not possible to reach consensus at this stage on the definition and determination of fibre and agreed that a Circular Letter should be sent to request additional comments and scientific information from member countries on the conditions for claims, the recommended intake and the method of analysis for fibre.

25. The Delegation of Brazil noted that the current text referred only to the expression of the claim for fibre for solids and proposed to include provisions for its expression for liquids, in order to take into account fruits juices containing significant amount of fibre.

26. The Committee agreed to refer to "dietary fibre" instead of "fibre", as proposed by the Delegation of Sweden referring to comments of Japan presented in CX/NFSDU 00/3-Add.1 and supported by India and some other delegations to ensure consistency with the definition included in the Guidelines on Nutrition Labelling.

Status of the Guidelines for Use of Nutrition Claims - Draft Table of Conditions for Nutrient Contents Claims (Dietary Fibre)

27. The Committee agreed to return the Draft Conditions for Nutrient Content Claims for Dietary Fibre to Step 6 for further comments and consideration by the next session (see Appendix III).

DRAFT REVISED STANDARD FOR GLUTEN-FREE FOODS (Agenda Item 4)[6]

28. The Committee recalled that the above Draft Revised Standard had been under revision for seven years and that the last Session of the CCNFSDU recognized that the development of a reliable method of analysis for gluten was the key point in the revision, therefore the Standard had been returned to Step 6 for further comments.

29. The Observer of the Working Group on Prolamin Analysis and Toxicity (PWG) informed the Committee that currently two approaches were used: i.e. clinical and analytical. He pointed out that the clinical approach based on dietary surveys and calculations of gluten was unreliable: analysis were carried out on a small number of patients, for some patients it did not cause problems, however for some other patients even 100mg of gliadin, as it was carried out by Catassi, was found to be toxic. The analytical approach based on the current ELISA (Skerritt) method was not sufficient, not specific and sensitive enough and a new ELISA (Mendez) method with the defined extraction, availability of gliadin standard and collaborative trials carried according to AOAC was underway. The Observer indicated that it would be possible to have a sensitive method of analysis for gluten, accurate at the low levels of detection by the end of the year 2001 and suggested to have one single limit for gluten free foods which could be kept in square brackets.

30. The Committee had an extensive debate on levels of gluten to be used for the definition of "gluten free" foods. Several delegations supported a single maximum level of gluten; however they proposed different amounts: some of them were in favour of 20 mg/kg, some preferred to have the level of 100ppm in ready to eat foods and a few delegations suggested 200 mg/kg. The Delegation of Canada supported by India and some other delegations indicated that two different levels of gluten in "gluten free" foods would be confusing for consumers and proposed 20 mg/kg of gluten while some other delegations pointed out that this type of consumers was well informed and under medical supervision. In addition there were consumers that could tolerate some amounts of gluten in their diets and it was their right to choose the type of food they consumed. Some delegations proposed that two levels of gluten be established especially for naturally gluten-free foods and reduced in gluten, however it was

[6] CX/NFSDU 00/4; CX/NFSDU 00/4-Add.1 (comments of Finland, Korea, Republic of, Poland, Spain, Sweden, AOECS, ISDI, PWG); CX/NFSDU 00/4-Add.2 (comments of AAC, AOECS); CX/NFSDU 00/4-Add.3 (comments of Sweden); CRD 5 (comments of Canada, Mexico, Thailand, Uruguay); CRD 26 (comments of India); CRD 28 (comments of Philippines).

recalled that the decision on that had been taken earlier. The Delegation of Spain wished to have only a single level established at 20 mg/kg and supported with a reliable method of determination.

31. Some delegations were in favour of having two different maximum levels of gluten: 20 mg/kg for products naturally free from gluten and 200 mg/kg for products rendered "gluten free" that were ready for consumption. It was indicated that a single level of 200 mg/kg was not acceptable as there were consumers suffering from adverse reactions to products with an amount of gluten of 70 mg/kg. The Delegation of Finland pointed out that wheat-starch based gluten-free foods had been widely available on the market for more than 30 years and that no evidence of increased morbidity and mortality had been observed among the individuals maintaining wheat starch based gluten-free diet.

32. The Observer of AOECS indicated that consumers want to have the right to choose under the well-known term "gluten-free" by nature and food rendered "gluten-free" and that wheat starch based products should have the safest possible level.

33. It was proposed to take out Sections 6 and 7 from the current Draft Standard as it was not possible to accept the proposed method which was not validated. The Delegation of Spain proposed to amend this section instead of deleting it however no decision was made.

34. Some delegations stressed that the establishment of limits for gluten without a reliable method of analysis was not scientifically justified and therefore was premature. It was pointed out that it would not be possible to implement such decision.

Status of the Draft Revised Standard for Gluten-Free Foods

35. The Committee recognized that there was no consensus either on levels or on the method of determination of gluten at this time, therefore decided to keep the current Draft Standard at Step 7 and to seek the Commission's advice on how to deal with this issue.

PROPOSED DRAFT GUIDELINES FOR VITAMIN AND MINERAL SUPPLEMENTS (Agenda Item 5)[7]

36. The Committee recalled that its last session had agreed that a discussion paper should be prepared by a Drafting Group[8] in order to facilitate further consideration of the Proposed Draft Guidelines, which had been returned to Step 4. In order to progress more efficiently the Chairman invited the Committee to structure the discussion in the following way:

- To outline the summary of the discussion paper;
- To consider whether the Committee should proceed with the elaboration of the Guidelines; and
- If the Committee decides to proceed with the Guidelines, to consider them section by section in conjunction with the Discussion paper.

37. The Delegation of the United States introduced the discussion paper which included a wide range of issues such as Description of the Covered Products, consideration of Positive and Negative Lists, Maximum and Minimum Levels, Purity Criteria, Good Manufacturing Practices (GMPs), Labelling, Packaging and Marketing and pointed out the wide range and the diversity of opinions surrounding the elaboration of provisions to address those issues.

38. The Committee had an extensive debate on the need for the elaboration of Guidelines. The Delegation of Canada strongly objected to the elaboration of the Guidelines and indicated that worldwide guidelines were not appropriate to address this very complex issue and suggested to leave the matter of regulation to national authorities. The Delegation stated that in Canada these products were currently classified as drugs and that the mandate of Codex was to develop guidelines or related

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[7] CX/NFSDU 00/5; CRD 2 (comments of Canada, Malaysia, Thailand, Uruguay, CRN, CSPI, IADSA); CRD 17 (comments of USA); CRD 28 (comments of Philippines); CRD 32 (comments of China).

[8] Brazil, Canada, European Community (EC), Mexico and the United States.

texts for foods. This view was supported by the Delegations of India, Kenya and some other delegations. The Delegation of India expressed the view that the promotion of vitamin and mineral supplements will effect good dietary practices. The Delegation of the USA stressed the importance of consumer choice and access to vitamin and mineral supplements; however the importance of a balanced diet was not questioned.

39. The Delegation of Malaysia supported by several other delegations stressed the fact that those products were widely placed on the market, sometimes with a very high dosage of vitamins and minerals and in order to avoid misleading consumers, it was necessary to regulate them and to develop general guidelines.

40. Some Delegations who supported the elaboration of guidelines suggested to develop them on the basis of RDI indicating different values for upper limits, while some other delegations and the Observer of IADSA favoured further development on the guidelines setting safe upper limits based on sound scientific risk assessment.

41. The Committee agreed to proceed with further elaboration of the guidelines and decided to consider the Proposed Draft Guidelines in conjunction with the Discussion paper section by section and made the following changes.

Preamble

42. The Committee deleted the current Preamble and reworded it as proposed in CRD 17. The term "dietary" supplements was replaced with "vitamin and mineral" supplements. The Delegation of India pointed out that natural foods provided many more nutritive substances than just vitamins and minerals.

Section 1. Scope

43. The Committee agreed to insert a sentence to the effect that "these guidelines apply to vitamin and mineral supplements which are regulated as foods" and substituted the word "regulations" by "authorities" in the second paragraph. The Committee accepted the proposal by the Delegation of India to amend the first sentence by referring to supplementation "if and when necessary", and decided to put this amendment in square brackets.

44. The Committee included a new sentence in square brackets specifying that foods for special dietary uses were not covered by the Scope and agreed that it should be discussed further at the next session.

Section 2. Definitions

45. The Committee amended the second sentence of the Definitions to read "Vitamins and minerals are concentrated sources of those nutrients alone or in combination, marketed in capsules, tablets, powders, solutions etc, not in a conventional food form and they do not provide a significant amount of energy" and put it in square brackets.

46. The Committee took out Section 2.2 as the content of this section was already covered by the amended Scope.

47. It was agreed to put Section 2.3 in square brackets as proposed by the Delegation of the USA.

Section 3. Composition

48. The Committee agreed that supplements should contain substances of "nutritive value" proven by scientific data, instead of "indispensability" in Section 3.1.1 and deleted the end of the sentence in square brackets, since the levels of use were addressed in section 3.2.

49. Section 3.1.2 was amended to reflect that criteria such as safety and bioavailability were essential in the selection of sources and the reference to FAO/WHO or Pharmacopoeias and national legislation" was placed in square brackets.

50. The Committee edited Section 3.1.3 for clarification purposes and decided to put it in square brackets.

Section 3.2 Contents of Vitamins and Minerals

51. The Committee had an extensive debate on the reference to the percentage of RDI for minimum and maximum levels of nutrients and was unable to reach a consensus at this stage, therefore decided to keep both "nutritional" and "risk assessment" approaches open for further comments and consideration.

52. The Committee agreed to delete the alternative Section 3.2.1 which was placed in square brackets, replaced the bracketed alternative wording of Section 3.2.2 by the wording of Section 3.2.2 proposed in CRD 17 and put both options in square brackets.

Sections 4, 5 Food Additives, Contaminants and 6 Hygiene.

53. The Committee accepted the proposal of the Chairman and deleted Sections 4, 5 and 6 as those Sections were more relevant in Codex Standards but not in guidelines and the numbering of Sections was changed accordingly.

Former Section 8 Labelling (new Section 5)

54. To be consistent with previous decisions the Committee substituted the reference to "dietary" supplements with "vitamin and mineral" supplements in Section 8.1; agreed to delete the reference to the Guidelines on Nutrition Labelling; and put Section 8.2 in square brackets for further consideration.

55. The Committee had an extensive debate on the declaration of vitamins and minerals. Several delegations supported reference to the "biologically active" part of vitamins and minerals as "bioavailability" was referenced as one of the criteria in Section 3 while other delegations indicated that the meaning of this wording was not clear enough. As a compromise the Committee agreed to amend the former Section 8.3 as proposed by the Observer of the EC and including the references to amounts of vitamins and minerals by units of weight, the amount per portion of the product and the percentage of the NRV mentioned and retained it in square brackets.

56. The Committee agreed to accept the proposal of the Delegation of Malaysia to specify that supplements should not replace a balanced diet and that the supplements should be taken on the basis of qualified advice and put it in square brackets.

Status of the Proposed Draft Guidelines on Vitamin and Mineral Supplements

57. The Committee agreed to return the Proposed Draft Guidelines, as amended during the session, to Step 3 for further comments and consideration by next session of the Committee (see Appendix IV).

PROPOSED DRAFT REVISED STANDARD FOR INFANT FORMULA (Agenda Item 6)[9]

58. The Committee recalled that the Proposed Draft Standard had been returned to Step 3 for further comments and consideration at the last session. The Committee discussed the Proposed Draft section by section and made the following amendments.

Section 1. Scope

59. The Delegation of Canada expressed the view that since the Standard was under revision, it would be necessary to consider the updating of the Statement on Infant Feeding. This view was supported by some delegations and opposed by others. However the Committee noted that it was not its mandate to consider the statement. This view was supported by some delegations.

60. The Delegation of Bulgaria, supported by several delegations supported the deletion of the reference to "healthy" infants, as the standard should cover the needs of all infants. The Delegation of

[9] ALINORM 99/26 APPENDIX V; CXNFSDU 00/6 (comments of Argentina, Germany, Japan, Korea, Republic of, Poland, Spain, ENCA, IBFAN, ISDI); CX/NFSDU 00/6-Add.1(The Use of Additives in Infant Formula); CRD 3 (comments of IFAC); CRD 6 (comments of Canada, India, Malaysia, Mexico, Thailand, Uruguay); CRD 18 (comments of India, USA, ILCA), CRD 28 (comments of Philippines), CRD 30 (comments of Poland)

Canada, supported by several delegations and the Observer of IBFAN, also stressed that infant formula intended for special dietary uses should meet the requirements of the standard to ensure that the product was safe and nutritionally adequate in all other aspects (composition, additives, contaminants, hygiene), with the understanding that specific provisions could be added where necessary; the current text of the second sentence should therefore be retained. The Delegation of Tanzania pointed out that the exclusion of special dietary foods from the Scope would detract from the applicability of the International Code of Marketing of Breast-Milk Substitutes, which was essential from the point of view of public health in developing countries.

61. The Delegation of Switzerland expressed the view that infant formula for medical purposes should be excluded from the standard and that the second sentence should therefore be deleted. This position was supported by several other delegations and the Observer of the EC, who pointed out that foods for special medical purposes should bear specific provisions regarding food labelling in order to avoid confusion as provided in the current standard for the Labelling of and Claims for Foods for Special Medical Purposes. It was also suggested that such products should be covered by current provisions for foods for special medical purposes. The Committee however recalled that the Standard for the Labelling of and Claims for Foods for Special Medical Purposes covered only labelling and claims but did not include composition requirements. The sentence was retained in square brackets.

62. The Representative of WHO, supported by the Representative of UNICEF, indicated that the International Code of Marketing of Breast-Milk Substitutes covered all types of formula used as a replacement for breast milk, including those intended for infants with special nutritional or medical needs, and that the definition did not refer to healthy infants.

63. The Committee could not come to a conclusion at this stage on the rewording of the Scope. It was agreed that the Delegation of Germany, in co-operation with Canada, Tanzania, ISDI and other interested delegations and observers, would prepare proposals to address the issue of infant formula for special medical purposes as related to the current standard or other relevant standards, as necessary, for consideration by the next session.

Section 1.3

64. The Committee had an extensive debate on the necessity of referring to the relevant World Health Assembly Resolutions. Several delegations, while supporting the reference to the Code in view of its essential importance for public health purposes, expressed their objections to a reference to the WHA Resolutions since it would imply that such resolutions would be automatically integrated into the text without an opportunity to review their content.

65. Several other delegations supported the inclusion of the reference to the resolutions since they were fundamental to ensure the promotion of breast-feeding and prevent practices which would be detrimental to the health of infants, especially in developing countries. They pointed out that these resolutions were well known and accepted by WHO member countries and their inclusion should not therefore cause difficulties.

66. The Delegation of the United States noted the written comments of other delegations to retain the reference to WHA Resolutions, adding “to date” in square brackets with the list of resolutions in a footnote also in square brackets as proposed by India, so that member countries would be allowed to consider them in more detail prior to the next session. The Committee agreed with this proposal as a compromise, and with the understanding that the whole issue would require further consideration. Some delegations and the Observer of EC objected to this decision and wished that the square brackets be retained on whole text "and relevant World Health Assembly Resolutions to date".

Section 2. Description

67. Several delegations and the Observer of ENCA proposed to replace the current text with a reference to the nutritional requirements of infants during the first six months of life, as this should correspond to the duration of exclusive breast-feeding. Some delegations indicated that their national legislation, based on the International Code of Marketing of Breast-Milk Substitutes, specifically

referred to the first six months. Several other delegations supported the reference to the "first four to six months of life", since it corresponded to current practice in their countries. The Delegation of Romania noted that there was no definition of infant formula and proposed a rewording of 2.1.2 to become 2.1.1.

68. Other delegations also pointed out that the notion that infant formula should satisfy nutritional requirements "by itself" was essential and should be retained. The Delegation of Malaysia proposed to retain this concept and to leave only the age in square brackets, as a compromise. The Committee could not come to a consensus on this point and the current section was retained with the reference to nutritional requirements and the age of infants in square brackets.

Section 3 Essential Composition and Quality Factors

69. The Delegation of India proposed to restrict the essential composition of infant formula to milk based products and to delete the end of section 3.1.1 which referred to other ingredients.

70. The Committee noted that due to time constraints, the detailed nature of the provisions and the extensive technical comments received, it would not be possible to review Section 3.1 in detail at the current session. The Committee therefore accepted the proposal of the Delegation of the United States that a Working Group[10], open to all interested countries and observers, and working by electronic mail should consider the comments received and prepare a revised section for consideration by the next session.

Section 3.2 Optional Ingredients

71. Section 3.2.3 was amended to reflect that when other nutrients are added, the amount should be "sufficient to achieve the intended effect" since this was more precise than the reference to "significant" amounts.

Section 3.4 Consistency and Particle Size

72. The Committee agreed that the wording should not be too prescriptive and agreed on a general recommendation that the products should be suitable for "adequate feeding of young infants".

Section 4. Additives

73. Following the decision taken at the last session, the Delegation of the Netherlands presented the list of additives prepared by a Working Group on the basis of the proposals received by several delegations and observers, for consideration by the Committee. The Delegation of India expressed the view that the entire section should be deleted as there was no need for additives in infant formula.

74. The Secretariat informed the Committee that in the framework of the General Standard for Food Additives, several sections had been adopted or were proposed for adoption at Step 8 or 5 by the Commission[11]. These sections contained additives at levels of use that did not correspond to the proposals included in the current text, and this might require further consideration in order to achieve consistency throughout Codex. The Committee did not consider the section due to time constraints and it was retained in square brackets for further consideration at the next session.

Section 5. Contaminants

75. The Committee had an exchange of views on the opportunity of referring to "free from contaminants", as proposed by the Delegation of India. The Committee agreed that it was not possible scientifically to ensure that any product was free from contaminants or pesticide residues.

76. The Secretariat informed the Committee of the general wording proposed for pesticide residue limits by the Committee on Pesticide Residues, and it was included accordingly. As regards Other Contaminants, the Committee agreed to replace the current section with a new text referring to

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[10] United States (coordinator), Australia,Austria, Bolivia, Botswana, Bulgaria,Canada, China, Cuba, Egypt, France, Germany, Hungary, India,Japan, Malaysia, Philippines, Poland, Portugal, Romania, Republic of Korea, Switzerland, Tanzania, Turkey, Thailand, United Kingdom, Uruguay, CRN, EC, EHPM, IBFAN, ISDI

[11] ALINORM 99/12A, Appendix II and ALINORM 01/12, Appendices III and V

"amounts which may represent a hazard to health" and to compliance with the limits established by the Commission, as proposed by the Delegations of France and Canada, and for consistency with the standard wording used in other commodity standards.

77. The Committee was also informed that the last session of the Committee on Additives and Contaminants had advanced to Step 8 a maximum level for lead in infant formula of 0.02 mg/kg, in the framework of the General Standard for Contaminants and Toxins in Foods[12].

Section 6. Hygiene

78. The current section was replaced with the revised wording for hygiene provisions adopted by the 23rd Session of the Commission and included in the 11th Edition of the Procedural Manual.

Section 9. Labelling

79. In section 9.1.3, the Committee agreed to specify that the label for "infant formula based on cow's milk" might be used when cow's milk was the only source of protein, to replace the earlier reference to 90% of milk protein.

80. In section 9.1.4, the Delegation of India, supported by other delegations, proposed that products containing no milk or milk derivatives must be labelled as such, especially to address the needs of allergic infants, and that in addition the labelling should refer to soybean formula when applicable. The Committee did not come to a conclusion on this question and retained the section in square brackets.

81. In section 9.1.5, the Observer from the EC proposed to delete the reference to health claims, the definition of which was still under consideration in the Committee on Food Labelling. The Committee recalled that the inclusion of foods for special medical purposes in the standard was still under consideration and agreed that no conclusion could be reached at this stage on the corresponding labelling requirements. Section 9.1.5 was therefore retained in square brackets, including the reference to health claims, for further consideration.

82. The Committee had an exchange of views on the provisions related to the declaration of iron, and could not reach a consensus at this stage. Several delegations pointed out that the current Table 1 referred to minimum and maximum levels of iron; however, this section had not been finalized and the Committee agreed to consider the labelling provisions further after finalization of the Section on Composition (including the Table).

Section 9.5 Information for Use

83. The Committee agreed with the proposal of the Delegation of Germany to transfer section 9.5.2 on the use of complementary foods to section 9.6 Additional Labelling Requirements since it did not relate to the information for use of the product.

Section 9.6 Additional Labelling Requirements

84. The Committee agreed to delete the square brackets around sections 9.6.1 and 9.6.2, since there was general agreement on the need to ensure that the label did not discourage breast-feeding. However it did not come to a consensus on the statement proposed as an example, and the protection offered by breast milk "against diarrhoea and other illnesses". Some delegations expressed the view that this was an additional health claim, and that there was not enough scientific basis to include such a general statement. Other delegations referred to the recommendations of WHO, which clearly established the positive health effects of breast milk in this respect. The section was retained in square brackets for further consideration.

85. The Committee agreed to refer to breast-feeding "and breast milk" for clarification purposes, and to the advice of an "independent" health worker, as proposed by the Delegation of Canada. It was also agreed to include a warning statement that remaining formula should be discarded after each feeding, in order to prevent contamination, as proposed by the Delegation of Mexico and other delegations. An

[12] ALINORM 01/12, Appendix XI

additional statement concerning the difference between infant formula and follow-up formula was introduced as proposed by the Delegation of India and put in square brackets.

Section 10. Methods of Analysis and Sampling

86. The Observer from AOAC informed the Committee that two methods had been adopted by AOAC for the determination of choline and Vitamin K and the Committee agreed to include them in the standard, with the understanding that they would be forwarded to the CCMAS for endorsement at a later stage.

Status of the Proposed Draft Revised Standard for Infant Formula

87. The Committee returned the Proposed Draft Standard, as amended during the current session, to Step 3 for further comments and consideration by the next session (see Appendix V).

PROPOSED DRAFT REVISED STANDARD FOR PROCESSED CEREAL-BASED FOODS FOR INFANTS AND YOUNG CHILDREN (Agenda Item 7)[13]

88. The Chairman reminded the Committee that the 23rd Session of the Codex Alimentarius Commission returned the Proposed Draft Revised Standard to Step 3 for further comments and consideration by this Committee.

89. The Representative of WHO referring to its written comments presented in document CX/NFSDU 00/7 informed the Committee that the WHO recommended that infants and children be fed exclusively on breast milk for four to six month of life and thereafter they should begin receiving nutritionally adequate and safe complementary foods, while continuing to breastfeed for up two years of age or beyond.

90. The Representative indicated that the WHO's recommendation was the subject to continual review, was based on the best available scientific and epidemiological evidence and that an age range was an intrinsic element of this population-based recommendation. He indicated that meeting the nutritional need of the individual infant, consistent with the above recommendation, should be accomplished in the light of the individual infant's specific circumstances.

91. The Representative indicated that it was essential that instructions on the recommended age of use of products covered by the Draft Revised Standard respect both the upper and the lower end of the 4 – 6 month age range. He pointed out that in order to ensure that WHO's infant-feeding recommendation continue to reflect the most up-to-date globally applicable scientific and epidemiological evidence, a systematic review of relevant scientific literature was undertaken and that the results of would be available next year. It was pointed out that WHO's multicentre growth reference study was under way in six countries involving more than 10000 children and that this study will contribute to improved understanding of the age range during which breast milk alone was sufficient to meet the healthy infant's nutritional requirements. He indicated that the results would be available by the year 2003.

92. The Representative placed emphasis on three additional issues relevant to WHO's infant-feeding recommendation and the work of this Committee:

-firstly the WHO trusted that this Committee would adopt positions, reflecting the evidence-based recommendations of its parent organizations, and that if the weight of scientific and

[13] CL 1999/20-NFSDU; CXNFSDU 00/7 (comments of Australia, Brazil, Cuba, France, Germany, Hungary, Indonesia, Italy, Korea, Republic of, Mexico, Norway, Paraguay, Poland, Senegal, Singapore, South Africa, Sri Lanka, Switzerland, United Kingdom, AOECS, ENCA, IBFAN, ISDI, WHO); CX/NFSDU 00/7Add.1 (The use of Additives in Processed Cereal-Based Foods for Infants and Young Children, prepared by the Netherlands, Canada, China, France, Germany, Romania, Slovakia, Spain, Switzerland, United Kingdom, the USA, Uruguay, EC and ISDI); CX/NFSDU 00/7-Add.2 (comments of Argentina); CX/NFSDU 00/7-Add.3 (comments of European Community); CRD 3 (comments of IFAC); CRD 7 (comments of Canada, India, Malaysia, Mexico, Thailand, Uruguay, IFOAM); CRD 19 (comments of India, USA, ILCA); CRD 29 (comments of Japan); CRD 30 (comments of Poland); CRD 32 (comments of China).

epidemiological evidence was changed, the relevant provisions of any related Codex standards would also be changed accordingly;

-secondly, there were Member governments that adopted more stringent measures with the recommended age to start of complementary feeding and this country-specific approach was endorsed by the WHO; and this possibility is explicitly provided for in the last sentence in para 8.5.4 of the Proposed Draft Revised Standard. However in the context of a Codex Standard the current population-based world-wide infant feeding recommendation should be reflected; and

-thirdly, it was essential for products labels and related information materials to scrupulously observe both the lower and the upper end of the recommended age range for exclusive breast feeding and therefore for the Draft Revised Standard on cereal-based foods the following wording should be adopted:

The label shall clearly state that the product is recommended for use from age of about 6 months and not before 4 months

93. The Delegation of India strongly opposed the reference to the age from "four to six months" in view of current scientific evidence and expressed concern at the statement of the WHO Representative. The Delegation recalled that for these reasons the Standard was not adopted at Step 5 by the 23rd Session of the CAC and was returned for further consideration by this Committee. The Delegation pointed out that the early introduction of complementary feeding undermined the invaluable advantages of breast-feeding and increased risks to infants' health. The Delegation also pointed out that since the standard was a world-wide one it was essential to take into consideration the requirements of infants and children in developing countries recognizing that early introduction of complementary foods could have serious implications on their morbidity and mortality.

94. A number of delegations proposed that the consideration of the age range be deferred until the findings of the WHO research were available. Several Delegations stated that they did not agree with the proposal of waiting for the outcome of WHO studies since that would not alter the nature of the issue, and ample scientific evidence supported the introduction of complementary feeding of "about six month".

95. The Representative of UNICEF confirmed that the review of the scientific literature, that is being currently undertaken by WHO, would provide clarification with regard to the age of introduction of complementary foods early in 2001. The Representative further clarified the difference between the Multicenter Growth Reference Study, which will lead to creation of a new growth curve, and the review which is based on the existing scientific evidence.

96. The Mexican Delegation stated that the WHO Multicentre Growth Reference Study will provide important data for an anthropometric references, but that it could not be conclusive for the recommendation of the duration of exclusive breast feeding since other important factors such as the inconvenience of an early exposure of infants to gastrointestinal and respiratory infections and the impact of exclusive breast feeding in the fertility regulation in populations should be taken into account.

97. The Delegation of Brazil indicated that its written comments did not reflect its current position and should be disregarded and stated that the age of introduction of cereal-based foods for infants and children should be at "about 6 months" and that it would be in consistency with their national policy. The Delegation indicated that it would be in line with many UNICEF and WHO publications, and that cohort study carried out in Brazil showed that infants from 3 to 5.9 months receiving breast and complementary feeding were 3.4 times more likely to be admitted in hospitals for pneumonia then were those who received breast milk alone. The Delegation questioned the applicability of WHO Multicentre Growth Reference Study to the debate on the age of introduction of complementary feeding.

98. The Chairman drew the attention of the Committee to the fact that consensus could not be reached on this sensitive issue at this stage and suggested to keep the current wording "4 to 6 months" of the Scope in square brackets.

99. The Delegation of Ghana supported retaining square brackets on the age of introduction in the Scope and indicated that Ghana followed WHA Resolution 47.5 in which the age of introduction of complementary feeding practices was from about of age of 6 months. The Delegation was in favour of further considering the Proposed Draft Revised Standard. This view was supported by the Delegations of Botswana, Tanzania and Kenya.

100. The Observer from IBFAN proposed to put the two provisions "4 to 6 months" and "about six month" in square brackets to reflect the whole discussion.

101. The Delegation of India recalled that the Commission had returned the Proposed Draft to the Committee for further discussion and that full consideration should be given to this important issue. It expressed concern at the inadequate time allowed for consideration of this important Agenda Item.

Status of the Proposed Draft Revised Standard for Processed Cereal-Based Foods for Infants and Children

102. The Committee recognized that it was not possible to reach consensus on the fundamental issue of the Scope at this stage and that it would not be possible to make further progress on the revision at the current session. The Committee therefore agreed to retain the Proposed Draft Revised Standard at Step 4 for further consideration at the next session and ask the Commission how to proceed with this issue.

PROPOSED DRAFT REVISION OF THE ADVISORY LIST(S) OF MINERAL SALTS AND VITAMIN COMPOUNDS FOR THE USE IN FOODS FOR INFANTS AND CHILDREN (CAC/GL 10-1979) (Agenda Item 8)[14]

103. The Committee recalled that following the decision of the last session to undertake a revision of the Advisory Lists, this proposal for new work had been approved by the 23rd Session of the Commission and a Circular Letter had been sent to ask for proposals for amendments to the lists.

104. The Delegation of the United States pointed out that before undertaking a detailed revision of the Lists it was essential to determine the criteria for the inclusion and deletion of vitamins and minerals therein, so as to ensure that they were appropriate for use by infants and young children, that the ingredient sources were safe and that the inclusion of any substance in the list was based on adequate scientific evidence.

105. The Delegation of Germany indicated that several aspects would need to be taken into account to achieve a thorough revision of the lists, as follows: the title, objective and structure of the list; the choice of nutrients; the purity requirements; and the use in different types of foods for infants and children.

106. Some delegations and the Observer from the EC proposed to add other nutrients to the lists, such as amino acids and essential fatty acids in order to provide useful references. The Committee however agreed that in view of its considerable workload, it would be preferable to restrict its work to vitamins and minerals at the present time. It was noted that consideration could be given to the inclusion of other nutrients after substantial progress had been made on the revision of the current lists.

107. The Chairman drew the attention of the Committee to the criteria which had been considered in earlier sessions and used to develop the current list[15]. The Committee agreed that a Circular Letter would ask for comments concerning the criteria to be used for the inclusion and deletion of mineral salts and vitamin compounds in the Lists and which categories of nutrients (e.g. vitamins, minerals, amino acids etc) should be included in the List, and that the Delegation of Germany, with the assistance

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[14] CL 1999/21-NFSDU; CXNFSDU 00/8 (comments of Brazil, Cuba, Germany, Korea, Republic of, Malaysia, Norway, Paraguay, Poland, Singapore, South Africa, Spain, United Kingdom, IDF/FIL); CX/NFSDU 00/8 Add.1 (comments of Mexico); CRD 8 (comments of Canada, Malaysia, Mexico, Thailand, Uruguay); CRD 20 (comments of USA), CRD 28 (comments of Philippines).

[15] ALINORM 89/26, para. 193

of interested countries, would prepare proposals for consideration by the next session. The Committee noted that the earlier criteria would be included in the CL as a reference.

DISCUSSION PAPER ON REVIEW OF PROVISIONS FOR VITAMINS AND MINERALS IN CODEX STANDARDS: VITAMINS AND MINERALS IN FOODS FOR SPECIAL MEDICAL USES (Agenda Item 9)[16]

108. While introducing the document CX/NFSDU 00/9 the Delegation of Germany highlighted the changes made on the basis of decisions of the last Session of the Committee, and drew attention to remaining problems such as the lack of consensus on the introduction of requirements for energy, protein, fat and carbohydrates; clarification was requested regarding the addition of other nutrients in Annexes, the limits of the ranges and the methodology on which the upper levels could be established. The Delegation pointed out that before considering the content of the Tables a decision should be made as to future status of the document; and whether a Standard or Guidelines should be developed.

109. The Committee recalled that its mandate was to develop documents for foods and substances for medical purposes were outside its Terms of Reference.

110. The Representative of FAO drew attention of the Committee to the fact that minimum levels for some nutrients such as niacin, biotin and selenium were higher than RNI levels provided by the Bangkok Consultation.

111. The Delegation of the USA questioned the necessity for such a document and raised concern regarding the broad range of age for which the levels of nutrient were set as well as on conditions of the procedure. The Delegation was of the opinion that maximum levels of nutrients could not be provided unless they were based on risk assessment relative to the intended use of these products. Instead of specific values, the delegation supported the development of guidelines for how manufacturers should make decisions based on intended uses.

112. The Delegation of the United Kingdom expressed their concern regarding the purpose of the document and suggested to limit the development of the document to general principles that might be valuable for manufacturers but not to develop a standard for the nutrient limits.

113. Some delegations and the Observer of ISDI indicated that those products were on the market therefore the development of general guidance would be useful.

114. The Observer of the EC informed the Committee that the legislation of the Community included a list and ranges of nutrient levels and if the Committee decided to proceed further consideration should be given to deviations from the specified quantities and the reasoning for such deviations should be given.

115. The Committee agreed that the document on general principles should be developed for vitamins and minerals and that Member Governments would be requested by means of Circular letter to provide information on criteria applied in their countries for the selection of vitamins and minerals and the determination of the amounts which were chosen. The data should be directed to the Delegation of Germany who should prepare a document for consideration by the next session of the Committee.

DISCUSSION PAPER ON THE SCIENTIFIC CRITERIA FOR HEALTH RELATED CLAIMS (Agenda Item 10)[17]

116. The Committee recalled that following the request of the Committee on Food Labelling for advice concerning the scientific basis for health claims, it had been agreed that the Delegations of France and the United States, with the participation of other countries, would prepare a document considering scientific criteria for health related claims

117. The Delegation of France introduced the paper, the first part of which considered questions of principle related to health claims, as follows: the definition of health claims, the definition of scientific

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16 CXNFSDU 00/9; CRD 9 (comments of Canada, Mexico, Thailand, Uruguay); CRD 21 (comments of USA).

17 CXNFSDU 00/10; CRD 12 (comments of Malaysia, Thailand, Uruguay); CRD 22 (comments of USA).

criteria relating to the safety and quality of the product, the effect claimed, the impact of the claim on the general population and specific groups, evaluation of the claimed effects, and periodic re-evaluation. The Delegation indicated that current scientific methodology allowed to evaluate the relationship between the food components and the health outcome. The second part of the document referred to experience of the United States with the regulation of health claims at the national level, and especially the scientific review of data for health claims.

118. The Committee expressed its appreciation to the Delegations of France Denmark, Germany and the United States for their constructive work which provided both theoretical and practical approaches to this complex question. Several delegations stressed the importance of work in the area of health claims in order to prevent misleading the consumer; it was recalled that the CCFL had the main responsibility for discussing labelling issues.

119. The Delegation of the United States pointed out that the Committee on Food Labelling was still in the process of considering the definitions and requirements for the use of health claims, and that it would be premature to proceed further with the development of scientific criteria for health related claims as long as those recommendations were not finalized or further advanced. The Secretariat informed the Committee that the last session of the CCFL had revised the recommendations on the use of health claims, for integration into the *Guidelines for Use of Health and Nutrition Claims*, and that the text had been returned to Step 3 for further comments and consideration by the next session of the Committee (May 2001)[18]

120. The Committee agreed to inform the Committee on Food Labelling that there was an agreement in principle on the possibility and opportunity of developing criteria on the scientific basis of health claims and that the Committee was prepared to proceed with this work when the definition of health claims had been further developed. The Committee noted that the work undertaken so far and reflected in the working document would be used as a basis for further work as necessary.

DISCUSSION PAPER ON ENERGY CONVERSION FACTORS (Agenda Item 11)[19]

121. The Delegation of Australia introduced the document and informed the Committee that this paper replaced CRD 10 which was discussed at the last session. The Delegation indicated that some energy factors for macronutrients were already included in the Codex Guidelines on Nutrition Labelling. However, no factors were assigned to other food components, such as dietary fibre, polyols, other unavailable carbohydrates and novel food ingredients, that might be fermented in the lower intestines and release some energy. This was considered important because the assignment of energy factors underpins nutrition labelling of the energy content of whole foods and low joules claims.

122. The Delegation pointed out that the Codex Guidelines did not give any indication of how energy factors for these food components should be derived and that the derivation of energy factors was very technical matter that required the development of a consistent scientific approach to establish a suitable definition of the energy content of all food components.

123. The Delegation suggested not to discuss the matter in detail and recommended that the Committee adopted it as a new work; a Working Group should be established to prepare a paper for the next meeting on the definition of energy content and guidelines for using energy factors to determine the total energy content of a whole food; and the work carried out at the international level should be taken into account in this process.

124. The Delegations of United Kingdom and the United States in general supported the further development of this matter. The Delegation of the United States suggested to start the process by setting a general set of criteria that were based on sound science and applicable across different types of substances, and that the difference in methodologies for deriving and evaluating the energy conversion factors should be addressed.

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[18] ALINORM 01/22, Appendix VIII

[19] CRD 13 (comments of Thailand, Uruguay); CRD 23 (comments of USA).

125. The Committee was of the opinion that it was premature to request the Commission's approval as new work and agreed that Member governments would be requested by means of Circular Letter to provide their comments on national practices of assignment of energy conversion factors to food components, fats and sugars and derivation of energy conversion factors for novel food ingredients. The data should be directed to the Delegation of Australia who, with the participation of all interested countries, would prepare a document for consideration by the next session of the Committee.

DISCUSSION PAPER ON PROVISIONS OF FORTIFICATION OF IODINE, IRON AND VITAMIN A IN THE GUIDELINES OF NUTRITION CLAIMS (Agenda Item 12)[20]

126. The Delegation of Thailand recalled that this question had been originally raised in the Coordinating Committee for Asia in view of micronutrient deficiencies in that Region and informed the Committee that the Codex texts such as the Guidelines for the Addition of Essential Nutrients to Foods, the revised Standard for Food Grade Salt (including iodine fortification), provided adequate guidance to countries in establishing fortification programmes. The Delegation also noted that food fortification should be addressed at the national level in view of the particular needs and problems of the population. The Delegation concluded that, in this perspective, there was no need for specific work on a revision of the Guidelines for Use of Nutrition Claims as related to fortification.

127. The Committee expressed its appreciation to the Delegation of Thailand and noted its work at the regional level on food fortification. The Committee agreed to discontinue work on provisions for fortification of iodine, vitamin A in the Guidelines for Use of Nutrition Claims and to inform the Commission accordingly.

RECOMMENDATIONS OF THE FAO/WHO EXPERT CONSULTATION ON FOOD CONSUMPTION AND EXPOSURE ASSESSMENT OF CHEMICALS: DISCUSSION PAPER (Agenda Item 13)[21]

128. The Delegation of Australia, while introducing the working paper, recalled that the risk analysis approach was being integrated into the Codex decision-making process, on the basis of the recommendations of several FAO/WHO Expert Consultations. The document considered how the recommendations of the *FAO/WHO Consultation on Food Consumption and Exposure Assessment of Chemicals* could be applied to the decision process of the Committee when considering nutrition issues. The Delegation proposed that the Committee consider the role of nutrient intake assessment in a risk-based approach, which could be applied, for example, to assess the risk of exceeding a tolerable upper level of intake, especially when determining maximum levels of nutrient content in specific foods.

129. The Committee expressed its appreciation to the Delegation of Australia for this interesting paper on complex issues and had a general discussion on how to proceed further in this area. The Chairman noted the specificity of the risks associated with nutrients, especially problems related to malnutrition or over nutrition, and that they would require a relevant methodology.

130. The Delegation of Norway pointed out that such complex issues would need further consideration before deciding what further action was required in the Committee. Some delegations stressed the fundamental difference between risk assessment for chemicals and for nutrients, and expressed the view that approach taken for nutrients should not be exclusively toxicological but should also be related to nutrition. Some delegations noted that there were no guidelines for risk assessment for nutrients, but that it would be useful to develop models and methods in this area, especially for the purpose of considering novel foods, and upper limits for nutrients.

131. The Committee agreed that a Circular Letter would invite governments to provide information on their experience with risk assessment for nutrition issues at the national level, including methodology and principles. The Delegation of Australia, in co-operation with interested delegations, would proceed

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[20] CRD 4 (comments of Thailand: Proposal for discontinuation of the work on Provisions of Fortification of Iodine, Iron and Vitamin A in the Guidelines of Nutrition Claims).

[21] CRD 14 (comments of Thailand, Uruguay); CRD 24 (comments of USA).

with the development of a methodology for the application of risk assessment, in the light of the comments received, for consideration by the next session.

Other Legitimate Factors

132. Following its earlier discussion under Agenda Item 2, the Committee considered the request of the Committee on General Principles concerning the integration of other legitimate factors (OLFs). The Secretariat recalled that this question had been forwarded to relevant committees in order to facilitate the general debate in the CCGP; it related to the decisions which had been taken in the past in relation to risk analysis by the Committees. This request also resulted from the recommendations of the *Joint FAO/WHO Expert Consultation on Risk Management and Food Safety*.

133. The Delegation of India pointed out that consumer information was an essential factor in the decision process, and referred to earlier discussion concerning the classification of vitamin and mineral supplements as foods or drugs; it noted that several factors had been taken into account implicitly in the work of the Committee, and proposed to prepare a list for consideration by CCGP. The Delegation of Ireland proposed to consider the notion of benefit for consumers in relation to nutrition issues.

134. The Delegation of the United States expressed concern that CCNFSDU was not in a position to reply on the application of OLFs. This position was supported by the Delegations of Canada and Uruguay.

135. The Committee recognized that due to time constraints, it was not possible to discuss this question further at the present session. Some delegations proposed to require comments by Circular Letter for further discussion at the next session; however, it was noted that the Committee on General Principles would meet before the next CCNFSDU (April 2001), and proceed with its general discussion on other legitimate factors. In the light of these conclusions the CCNFSDU would consider whether further discussion was necessary in this area.

OTHER BUSINESS AND FUTURE WORK: CONSIDERATION OF THE NECESSITY FOR REVIEW OF THE GENERAL PRINCIPLES FOR THE ADDITION OF ESSENTIAL NUTRIENTS TO FOODS (CAC/GL 09-1987) (Agenda Item 14)[22]

136. The Committee recalled that the last session, while replying to a question from the Committee on Processed Fruits and Vegetables on food fortification, had agreed to consider the need for a revision of the Principles for the Addition of Essential Nutrients to Foods.

137. Many delegations supported retaining the current Principles, which were adequate to their purpose, and had been used as a basis for national legislation in several countries. The Delegations of the United States, Australia and the Observer of IFU supported a revision of the Principles in order to take into account updated scientific and technological information as well as the evolution of the market. The Delegation of New Zealand noted that a paper, setting out the justification for such a review, was a necessary part of the process before the issue could be further considered by the Committee.

138. The Committee agreed that no new work should be undertaken on the revision of the Principles. It was noted that this matter could be further discussed under Other Business and Future Work at the next session if necessary.

Sports and Energy Drinks

139. The Delegation of Denmark, supported by some delegations, expressed the view that energy drinks were soft drinks and did not require a specific classification. Other delegations supported further definition of the claim for "high energy" and proposed to ask the Committee on Food Labelling to add this claim to the Guidelines for Use of Nutrition Claims, since it included only a reference to "low energy". The Observer from EC stated that products marketed for persons making intense muscular

[22] CRD 10 (comments of Canada, Thailand, Uruguay); CRD 25 (comments of USA); CX/NFSDU 00/14-Add.1 (comments of CIAA).

efforts (sports foods) and presented as satisfying special nutritional requirements of these persons, should be considered as foods for special dietary uses. So-called energy drinks intended for the population at large should be considered as ordinary foodstuffs

140. The Delegation of South Africa pointed out that the main problem with this type of product related to unsubstantiated claims; in particular reference was made to “energy” drinks which had no high energy content but contained additional substances like caffeine.

141. The Delegation of Sweden expressed its concern with the definition of such a claim, since a distinction should been made between ordinary foods and foods for special dietary uses, including those for special medical purposes.

142. The Observer from the EC informed the Committee that the Scientific Committee for Foods was about to adopt an opinion on food intended for persons making intense muscular effort (sport foods) and that considered as foods for special dietary uses.

143. The Committee, recognizing that no conclusion could be reached at this stage, agreed that a Circular Letter should ask for comments on 1) sports foods and drinks as foods for special dietary uses and 2) the claim for “high energy”, as well as the distinction between "energy drinks" and "sports drinks" in order to discuss this question further at the next session and decide how to proceed further.

DATE AND PLACE OF THE NEXT SESSION (Agenda Item 15)

144. The Committee was informed that in view of heavy workload and its horizontal nature the possibility of holding more frequent meetings in Berlin would be considered, the exact arrangements to be determined by the host Government and the Codex Secretariat.

SUMMARY STATUS OF WORK

Subject Matter	Step	For Action by	Reference in ALINORM 01/26
Guidelines for Use of Nutrition Claims: Draft Table of Conditions for Nutrient Contents (Part B, containing provisions on Protein and Vitamins and Minerals)	8	Governments 24th CAC,	paras 13-19 and Appendix II
Proposed Draft Revised Standards for Gluten-Free Foods	7	24th CAC, 23rd CCNFSDU	paras 28-35
Guidelines for Use of Nutrition Claims: Draft Table of Conditions for Nutrient Contents (Part B, containing provisions on Dietary Fibre)	6	Governments, 23rd CCNFSDU	paras 20-27 and Appendix III
Proposed Draft Revised Standard for Processed Cereal-Based Foods for Infants and Young Children	4	24th CAC, 23rd CCNFSDU	paras 88-102
Proposed Draft Revised Standard for Infant Formula	3	Governments 23rd CCNFSDU	paras 58-87 and Appendix V
Proposed Draft Guidelines for Vitamin and Mineral Supplements	3	Governments 23rd CCNFSDU	paras 36-57 and Appendix IV
Proposed Draft Revision of the Advisory List(s) of Mineral Salts and Vitamin Compounds for the Use in Foods for Infants and Young Children (CAC/GL 10-1979)	3	Governments Germany 23rd CCNFSDU	paras 103-107
Discussion Paper on the Review of Provisions for Vitamins and Minerals in Codex Standards: Vitamins and Minerals in Foods for Special Medical Uses		Governments Germany 23rd CCNFSDU	paras 108-115
Discussion Paper on Energy Conversion Factors		Governments Australia, 23rd CCNFSDU	paras 121-125
Discussion Paper on the Recommendations of the FAO/WHO Expert Consultation on Food Consumption and Exposure Assessment of Chemicals		Governments, Australia, 23rd CCNFSDU	paras 128-131
Sports and Energy Drinks		Governments, 23rd CCNFSDU	paras 139-143
Matters of Interest of other Codex Committees:			
Discussion Paper on the Scientific Criteria for Health Related Claims		CCFL 23rd CCNFSDU (if necessary)	paras 116-120
Proposals for discontinuation of work: Discussion Paper on Provisions of Fortification on Iodine, Iron and Vitamin A in the Guidelines of Nutrition Claims		CAC	paras 126-127

Appendix/Annexe/Apéndice I

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Appendix II

GUIDELINES FOR THE USE OF NUTRITION CLAIMS: DRAFT TABLE OF CONDITIONS FOR NUTRIENT CONTENTS (PART B)[23]

(At Step 8 of the Procedure)

COMPONENT	CLAIM	CONDITIONS
B.		**NOT LESS THAN**
Protein	Source	10% of NRV per 100 g (solids) 5% of NRV per 100 ml (liquids) or 5% of NRV per 100 kcal (12% of NRV per 1 MJ) or 10% of NRV per serving
	High	2 times the values for ”source”
Vitamins and Minerals	Source	15% of NRV per 100 g (solids) 7.5% of NRV per 100 ml (liquids) or 5% of NRV per 100 kcal (12% of NRV per 1 MJ) or 15% of NRV per serving
	High	2 times the values for "source"

[23] Serving size to be determined at national level

Appendix III

GUIDELINES FOR THE USE OF NUTRITION CLAIMS: DRAFT TABLE OF CONDITIONS FOR NUTRIENT CONTENTS (PART B)[24] 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 per serving
	High	6 g per 100 g or 3 g per 100 kcal or per serving

[24] Serving size to be determined at national level

Appendix IV

PROPOSED DRAFT GUIDELINES FOR VITAMIN AND MINERAL SUPPLEMENTS

(At Step 3 of the Procedure)

PREAMBLE

Most people who have access to a balanced diet can usually obtain all the nutrients they require from their normal diet. Because foods contain many substances that promote health, people should therefore be encouraged to select a balanced diet from food before considering any vitamin and mineral supplement. In cases where the intake from the diet is insufficient or where consumers consider their diet requires supplementation, vitamin and mineral supplements serve to supplement the daily diet.

1. SCOPE

1.1 These guidelines apply to vitamin and mineral supplements intended for use in supplementing the daily diet [if and where necessary] with vitamins and/or minerals. These Guidelines apply to vitamin and mineral supplements which are regulated as foods.

1.2 It is left to national authorities to decide whether vitamin and mineral supplements are drugs or foods. These Guidelines do not apply in those jurisdictions where products defined in 2.1 are regulated as drugs.

[1.3 Foods for special dietary uses as defined in the General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses (CODEX STAN 146-1985) are not covered by these Guidelines.]

2. DEFINITIONS

2.1 Vitamin and mineral supplements for the purpose of these guidelines derive their nutritional relevance primarily from the minerals and/or vitamins they contain. Vitamin and mineral supplements are [concentrated] sources of those nutrients alone or in combinations, marketed in capsules, tablets, powders, solutions etc., not in a conventional food form and do not provide a significant amount of energy. [They serve to supplement the daily diet with these nutrients in cases when the intake from food is insufficient or where the consumers consider their diet requires supplementation.]

[2.2 Vitamin and mineral supplements can serve special nutritional purposes, if their composition and contents of minerals and vitamins corresponds to particular dietary requirements that result from certain physical or physiological conditions and they are marketed for that particular purpose.]

3. COMPOSITION

3.1 SELECTION OF VITAMINS AND MINERALS

3.1.1 Vitamin and mineral supplements shall contain vitamins/provitamins and minerals in conjunction with the relevant Codex standards whose nutritional value for human beings has been proven by scientific data.

3.1.2 The selection of admissible ingredient sources of nutrient or compounds should be based on criteria such as safety and bioavailability of the [FAO/WHO or Pharmacopoeias and national legislation].

[3.1.3 The use of individual vitamins and minerals in supplements can be [limited] for reasons of health protection and consumer safety, taking into account regional or national peculiarities concerning the supply situation of the population].

3.1.4 Vitamin and mineral supplements may contain all vitamins and minerals that comply with the criteria in 3.1.1, a single nutrient or an appropriate combination of nutrients.

[The suitability of a single nutrient or a combination of several nutrients in a vitamin and mineral supplement for the special nutritional purpose for which it is marketed should be proven by scientific data.]

3.2 CONTENTS OF VITAMINS AND MINERALS

3.2.1 [The minimum level of each nutrient contained in a vitamin and mineral supplement should be [15%] of the recommended daily intake or the estimated safe and adequate daily intake.]

3.2.2 [The maximum level of each nutrient contained in a vitamin and mineral supplement should not exceed [100%] of the recommended daily intake or the estimated safe and adequate intake per daily dose.]

3.2.3 [Supplements may contain vitamins and minerals up to a level that is considered safe on the basis of science-based risk assessment considerations, as determined by appropriate risk analysis methodology, taking into account all sources of nutrients in the diet.]

3.2.4 For vitamins and minerals with a narrow safety margin between the recommended daily intake and the adverse effect level, different maximum limits for the daily dose may be established at the national level.

4. PACKAGING

4.1 The product shall be packed in containers which will safeguard the hygienic and other qualities of the food.

4.2 The containers, including packaging material, shall be made only of substances which are safe and suitable for their intended use. Where the Codex Alimentarius Commission has established a standard for any such substance used as packaging material, that standard shall apply.

4.3 Vitamin and mineral supplements should be distributed in child-resistant packagings, if necessary.

5. LABELLING

5.1 Vitamin and mineral supplements are labelled according to the Codex Standard for the Labelling of Prepackaged Foods (Codex-Stan 1-1985, Rev. 1-1991) as well as according to the General Guidelines on Claims (CAC/GL 1-1979).

[5.2 The name of the product shall be "vitamin and mineral supplement" or "dietary mineral/vitamin preparation to supplement the diet with ...", with an indication of the nutrients contained therein or

" vitamin and mineral supplement in cases of ...", with an indication of the special nutritional purposes for products that meet the criteria of 2.2 and 3.1.4.]

[5.3 The amount of the vitamins and minerals present in the product shall be declared in the labelling in numerical form. The units to be used shall be units of weight.

5.4 The amounts of the vitamin and minerals declared shall be those per portion of the product as recommended for daily consumption on the labelling and per unit dose form, as appropriate.

5.5 Information on vitamins and minerals shall also be expressed as a percentage of the reference values mentioned, as the case may be, in the Codex Guidelines on Nutrition Labelling.]

5.6 The label must indicate the recommendations on how to take the product (quantity, frequency, special conditions).

5.7 The label must contain a warning statement [if the product contains a significant amount of a nutrient with respect to the toxicity level.]

[5.8 The label must contain a statement: supplements can not be used for the replacement of meals on long term basis.

5.9 All labels shall bear a statement that the supplement should be taken on an advice of a nutritionist, a dietician or a medical doctor.]

Appendix V

PROPOSED DRAFT REVISED STANDARD FOR INFANT FORMULA

(CODEX STAN 72-1981)

(At Step 3 of the Procedure)

1. SCOPE

1.1 This standard applies to infant formula in liquid or powdered form intended for use, where necessary, as a substitute for human milk in meeting the normal nutritional requirements of healthy infants. [The provisions in this standard are intended for infants with special nutritional requirements, except for certain provisions which must be modified to meet those special requirements.]

1.2 The standard contains compositional, quality and safety requirements to ensure a safe and nutritionally adequate product.

1.3 The application of the Standard should take into account the recommendations given to countries under the International Code of Marketing of Breast-milk Substitutes and relevant World Health Assembly Resolutions [to date][25].

2. DESCRIPTION

2.1 PRODUCT DEFINITIONS

2.1.1 Infant formula, when in liquid form, may be used either directly or diluted with safe, potable, and previously boiled water before feeding, as appropriate. In powdered form it requires safe, potable, and previously boiled water for preparation.

2.1.2 Infant formula shall be nutritionally adequate to promote normal growth and development when used in accordance with its directions for use [and to satisfy by itself the nutritional requirements of infants during the first four to six months of life].

2.1.3 Infant formula is so processed by physical means only and so packaged as to prevent spoilage and contamination under all normal conditions of handling, storage and distribution in the country where the product is sold.

2.2 OTHER DEFINITIONS

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

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 ESSENTIAL COMPOSITION

3.1.1 Infant formula is a product based on milk of cows or other animals and/or other edible constituents of animal, including fish, or plant origin, which have been proved to be suitable for infant feeding.

3.1.2 Infant formula shall contain per 100 kilocalories (or 100 kilojoules) of intake, the following minimum and maximun levels of vitamins, minerals in an available form, choline, protein, fat and fatty acid, carbohydrates and energy:

[25] [WHA 33.32 1980; WHA 34.22 1981; WHA 35.26 1982; WHA 37.30 1984; WHA 39.28 1986; WHA 41.11 1988; WHA 44.33 1991; WHA 45.34 1992; WHA 47.5 1994; WHA49.15 1996]

[

	Amounts per 100 kilocalories		Amounts per 100 kJ	
	Minimum	**Maximum**	**Minimum**	**Maximum**
(a) Vitamins				
Vitamin A*	60 µg	180 µg	14 µg	43 µg
Vitamin D	40 I.U. or 1 µg	100 I.U. or 2,5 µg	10 I.U. or 0.25 µg	25 I.U. or 0.63 µg
Vitamin E (α-tocopherol equivalent TE)	0,5 mg/g linoleic acid[2], but in no case less than 0.5 mg/100 kcal	N.S.[1]	0.5 mg/g linoleic acid[2] but in no case less than 0.1 mg /100 kJ	N.S.[1]
Ascorbic Acid (Vitamin C)	8 mg	N.S.[1]	1,9 mg	N.S.[1]
Thiamine (Vitamin B_1)	40 µg	N.S.[1]	10 µg	N.S.[1]
Riboflavin (Vitamin B_2)	60 µg	N.S.[1]	14 µg	N.S.[1]
Niacin, niacin equivalents	0,8 mg	N.S.[1]	0,2 mg	N.S.[1]
Vitamin B_6	15 µg/g protein but in no case less than 35 µg/100 kcal	N.S.[1]	15 µg/g protein but in no case less than 9 µg/100 kJ	N.S.[1]
Folic acid	4 µg	N.S.[1]	1 µg	N.S.[1]
Pantothenic acid	300 µg	N.S.[1]	70 µg	N.S.[1]
Vitamin B_{12}	0.10 µg	N.S.[1]	0.025 µg	N.S.[1]
Vitamin K_1	4 µg	N.S.[1]	1 µg	N.S.[1]
Biotin (Vitamin H)	1.5 µg	N.S.[1]	0.4 µg	N.S.[1]
(b) Minerals				
Sodium (Na)	20 mg	60 mg	5 mg	15 mg
Potassium (K)	60 mg	145 mg	15 mg	35 mg
Chloride (Cl)	50 mg	125 mg	12 mg	29 mg
Calcium (Ca)[3]	50 mg	N.S.[1]	12 mg	N.S.[1]
Phosphorus (P)[3]	25 mg	90 mg	6 mg	22 mg
Magnesium (Mg)	5 mg	15 mg	1.2 mg	3,6 mg

Iron (Fe)	0.5 mg	1.5 mg	0.12 mg	0.36 mg
Iron (Fe)[4]	1 mg	2 mg	0.25 mg	0.5 mg
Iodine (I)	5 µg	N.S.[1]	1.2 µg	N.S.[1]
Copper (Cu)	20 µg	80 µg	4.8 µg	19 µg
Zinc (Zn)	0.5 mg	N.S.[1]	0.12 mg	N.S.[1]
Zinc (Zn)[4]	0.75 mg	2.4 mg	0.18 mg	0.6 mg
Manganese (Mn)	5 µg	N.S.[1]	1,2 µg	N.S.[1]
Selenium (Se)	7 µg	3 µg	N.S.[1]	0,7 µg
(c) Choline	N.S.[1]	N.S.[1]	1.7 mg	N.S.[1]

]

* expressed as retinol equivalent

[1] N.S. = Not specified

[2] Or per g polyunsaturated fatty acids, expressed as linoleic acid.

[3] The Ca: P ratio shall be not less than 1.2 and not more than [2.0].

4 In formula manufactured from soya proteins, alone or in a mixture with cow's milk protein.]

(d) Protein

(i) Protein content = nitrogen content x 6.38 for cow's milk proteins and protein partial hydrolysates.

Protein content = nitrogen content x 6.25 for soya protein isolates and protein partial hydrolysates.

The "chemical index" shall mean the lowest of the ratios between the quantity of each essential amino acid of the test protein and the quantity of each corresponding amino acid of the reference protein (breast milk, as defined in Annex 1).

(ii) The product shall contain protein at a level of not less than 1.8 g/100 kcal (0.45 g/100 kJ) and not more than 3 g/100 kcal (0.7 g/100 kJ).

For an equal energy value, the formula must contain an available quantity each essential and semi-essential amino acid at least equal to that contained in the reference protein (breast milk, as defined in Annex 1); nevertheless, for calculation purposes, the concentration of methionine and cystine may be added together.

[The minimum value set for quality and the maximum for quantity of the protein may be modified by national authorities according to their own regulations and/or local conditions.]

(iii) Isolated amino acids may be added to Infant Formula only to improve its nutritional value for infants. Essential amino acids may be added to improve protein quality, only in amounts necessary for that purpose. Only natural L forms of amino acids shall be used.

(e) Fat and Fatty Acid

The product shall contain:

- linoleic acid (in the form of glycerides) at a level of not less than 300 mg/100 kcal (or 70 mg/100 kJ) and not more than 1200 mg/100 kcal (285 mg/100 kJ);
- fat at a level not less than 4.4 g/100 kcal (1.05 g/100 kJ) and not more than 6.5 g/100 kcal (1.5 g/100 kJ);
- the alpha-linolenic acid content shall not be less than 50 mg/100 kcal (12 mg/100 kJ);
- the linoleic/alpha-linolenic acid ratio shall not be less than 5 nor greater than 15;
- the trans fatty acid content shall not exceed 4% of the total fat content;
- the erucic acid content shall not exceed 1% of the total fat content;

(f) Carbohydrates

The product shall contain carbohydrates at a level of not less than 7 g/100kcal (1.7 g/100 kJ) and not more than 14 g/100kcal (3.4 g/100 kJ).

(g) Energy content

The energy content of the product shall not be less than 60 kcal/100 ml (250 kJ/100 ml) and not more than 75 kcal/ 100 ml (315 kJ/100 ml).

3.2 OPTIONAL INGREDIENTS

3.2.1 In addition to the vitamins and minerals listed under 3.1.2(a), (b) and (c), other nutrients may be added when required in order to provide nutrients ordinarily found in human milk and to ensure that the formulation is suitable as the sole source of nutrients of the infant.

3.2.2 The usefulness and safety of these nutrients shall be scientifically shown.

3.2.3 When any of these nutrients is added, the formula shall contain sufficient amounts of these nutrients to achieve the intended effect, based on levels in human milk.

3.2.4 Only L(+) producing lactic acid cultures may be used**.**

3.3 VITAMIN COMPOUNDS AND MINERAL SALTS

3.3.1 Vitamins and minerals added in accordance with Section 3.1.2 (a,b,c,d) and 3.2.1 should be selected from the Advisory Lists of Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Children (CAC/GL 10-1979).

3.4 CONSISTENCY AND PARTICLE SIZE

When prepared according to the label directions for use, the product shall be free of lumps and of large coarse particles and suitable for adequate feeding of young infants.

3.5 PURITY REQUIREMENTS

All ingredients shall be clean, of good quality, safe and suitable for ingestion by infants. They shall conform with their normal quality requirements, such as colour, flavour and odour.

3.6 SPECIFIC PROHIBITION

The product and its components shall not have been treated by ionizing radiation.

4. FOOD ADDITIVES

The following additives are permitted in the preparation of Infant Formula, as described in Section 1 of this Standard, and with the restrictions stated below:

[

			Maximum level in 100 ml of the ready-to-drink product
4.1	**THICKENING AGENTS**		
4.1.1	Guar gum		0.1 g in all types of infant formula
4.1.2	Locust bean gum[26]		0.1 g in all types of infant formula
4.1.3	Distarch phosphate	}	0.5 g singly or in combination in soy-
4.1.4	Acetylated distarch phosphate	}	based infant formulae only
4.1.5	Phosphated distarch phosphate	}	
4.1.6	Hydroxypropyl starch	}	2.5 g singly or in combination in
		}	hydrolyzed protein and/or amino acid
		}	acid-based infant formulae only
4.1.7	Carrageenan	}	0.03 g in regular, milk- and soy-
		}	based liquid infant formulae only
		}	
		}	0.1 g in hydrolyzed protein and/or amino acid-based liquid infant formulae only
4.2	**EMULSIFIERS**		
4.2.1	Lecithin		0.5 g in all types of infant formulae
4.2.3	Mono- and diglycerides		0.4 g in all types of infant formulae
4.3	**pH-ADJUSTING AGENTS**		
4.3.1	Sodium hydroxide	}	
4.3.2	Sodium hydrogen carbonate	}	
4.3.3	Sodium carbonate	}	Limited by good manufacturing practice
4.3.4	Potassium hydroxide	}	and within the limits for sodium and
4.3.5	Potassium hydrogen carbonate	}	potassium in Section 3.1.2 (c) in all
4.3.6	Potassium carbonate	}	types of infant formulae
4.3.7	Calcium hydroxide	}	
4.3.8	Sodium citrate	}	
4.3.9	Potassium citrate	}	
4.3.10	L(+) Lactic acid	}	Limited by good manufacturing practice
4.3.12	Citric acid		in all types of infant formulae
4.4	**ANTIOXIDANTS**		
4.4.1	Mixed tocopherols concentrate	}	1 mg in all types of infant formulae
4.4.2	L-Ascorbyl palmitate	}	

]

[26] Temporarily endorsed.

4.5 CARRY-OVER OF FOOD ADDITIVES

No food additives shall be present as a result of carry-over from raw materials and other ingredients with the exception:

(a) of the food additives listed under Sections 4.1 to 4.4 of this standard within the limits of the maximum levels stipulated in this standard; and

(b) of the carrier substances mentioned in the Advisory List of Vitamin Compounds for Use in Foods for Infants and Children within the limits of the maximum levels stipulated in that List.

5. CONTAMINANTS

5.1 PESTICIDE RESIDUES

The product shall be prepared with special care under good manufacturing practices, so that residues of those pesticides which may be required in the production, storage or processing of the raw materials or the finished food ingredient do not remain, or, if technically unavoidable, are reduced to the maximum extent possible.

5.2 OTHER CONTAMINANTS

Infant formula shall not contain contaminants or undesirable substances (e.g. biologically active substances) in amounts which may represent a hazard to the health of the infant

The product covered by the provisions of the Standard shall comply with those maximum residue limits and maximum levels established by the Codex Alimentarius Commission

6. HYGIENE

6.1 It is recommended that the product covered by the provisions of this standard be prepared and handled in accordance with the appropriate sections of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1 1969, Rev. 3- 1997), and other relevant Codex texts such as the Recommended International Code of Hygienic Practice for Foods for Infants and Children (CAC/RCP 21-1979).

6.2 The products should comply with any microbiological criteria established in accordance with the Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-1997)

7. PACKAGING

7.1 The product shall be packed in containers which will safeguard the hygienic and other qualities of the food. When in liquid form, the product shall be packed in hermetically sealed containers; nitrogen and carbon dioxide may be used as packing media.

7.2 The containers, including packaging materials, shall be made only of substances which are safe and suitable for their intended uses. Where the Codex Alimentarius Commission has established a standard for any such substance used as packaging materials, that standard shall apply.

8. FILL OF CONTAINER

In the case of products in ready-to-eat form, the fill of container shall be:

(i) not less than 80% v/v for products weighing less than 150 g (5 oz.);

(ii) not less than 85% v/v for products in the weight range 150-250 g (5-8 oz.); and

(iii) not less than 90% v/v for products weighing more than 250 g (8 oz.)

of the water capacity of the container. The water capacity of the container is the volume of distilled water at 20^{o} C which the sealed container will hold completely filled.

9. LABELLING

In addition to the requirements of the Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985 (Rev. 1-1991), the following specific provisions apply:

9.1 THE NAME OF THE FOOD

The text of the label and all other information accompanying the product shall be written in the appropriate language**.**

9.1.1 The name of the product shall be either "Infant Formula" or any appropriate designation indicating the true nature of the product, in accordance with national usage.

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

9.1.3 If cow's milk is the only source of protein, the product may be labelled "Infant Formula Based on Cow's Milk".

[9.1.4 A product which contains neither milk or any milk derivative [may] be labelled "contains no milk or milk products" or an equivalent phrase.]

[9.1.5 A product intended for infants with special nutritional requirements shall be labelled to show clearly the special requirement for which the formula is to be used and the dietary property or properties on which this is based. [No health claims shall be made regarding the dietary properties of the product.]]

9.1.6 [Products containing not less than 0.5 mg Iron (Fe)/ 100 kilocalories shall be labelled "Infant Forumula with added Iron"].

or

[Products containing less than 0.5 mg Iron (Fe)/ 100 kcal shall be labelled with a statement to the effect that when the product is given to infants over the age of four months, their total iron requirements must be met from other additional sources.]

9.2 LIST OF INGREDIENTS

9.2.1 A complete list of ingredients shall be declared on the label in descending order of proportion except that in the case of added vitamins and added minerals, these ingredients shall be arranged as separate groups for vitamins and minerals, respectively, and within these groups the vitamins and minerals need not be listed in descending order of proportion.

9.2.2 The specific name shall be declared for ingredients of animal or plant origin and for food additives. In addition, appropriate class names for these ingredients and additives may be included on the label.

9.3 DECLARATION OF NUTRITIVE VALUE

The declaration of nutrition information shall contain the following information in the following order:

(a) the amount of energy, expressed in kilocalories (kcal) and/or kilojoules (kJ), and the number of grammes of protein, carbohydrate and fat per 100 grammes of the food as sold as well as per 100 milliliter of the food ready for use, when prepared according to the instructions on the label.

(b) the total quantity of each vitamin, mineral, choline and any optional ingredient as listed in pragraphs 3.1.2 an 3.2 of this Standard per 100 grammes of the food as sold as well as per 100 milliliter of the food ready for use, when prepared according to the instructions on the label. In addition, the declaration per 100 kilocalories (or per 100 kilojoules) is permitted.

9.4 DATE MARKING AND STORAGE INSTRUCTIONS

9.4.1 The date of minimum durability (preceded by the words "best before") shall be declared by the day, month and year in uncoded numerical sequence except that for products with a shelf-life of more than three months, the month and year will suffice. The month may be indicated by letters in those countries where such use will not confuse the consumer.

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

9.4.2 In addition to the date, any special conditions for the storage of the food shall be indicated if the validity of the date depends thereon.

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

9.5 INFORMATION FOR USE

9.5.1 Directions as to the preparation and use of the food, and its storage and keeping after the container has been opened shall appear on the label or on the accompanying leaflet.

9.6 ADDITIONAL LABELLING REQUIREMENTS

9.6.1 Labels should not discourage breastfeeding. Each container label shall have a clear, conspicuous and easily readable message which includes the following points: a) the words "important notice" or their equivalent; b) a statement of the superiority of breastfeeding or breastmilk [or: the statement: Breastmilk is the best food for your baby, it protects against diarrhea and other illnesses]; c) a statement that the product should only be used on advice of a independent health worker as to the need for its use and the proper method of use; d) instructions for appropriate preparation; e) a warning against the health hazards of inappropriate preparation; and a warning that formula remaining after each feeding should be discarded.

9.6.2 The label shall have no pictures of infants nor any other picture or text which idealizes the use of infant formula. The label may have graphics illustrating the method of preparation of the product.

9.6.3 The terms "humanized", "maternalized" or other similar terms shall not be used.

9.6.4 Information that infants [over six months of age] should receive supplemental foods in addition to the formula shall appear on the label.

9.6.5 [The products shall be labelled in such a way as to avoid any risk of confusion between infant formula and follow-up formula.]

10. METHODS OF ANALYSIS AND SAMPLING

See Codex Alimentarius Volume 13 and add:

Determination of choline

AOAC 999.14 (Enzymatic method)

Determination of Vitamin K

AOAC 999.15 (LC method)

ANNEX 1

Essential and Semi-Essential Amino Acids in Breast Milk

For the purpose of this Standard the essential and semi-essential amino acids in breast milk, expressed in mg per 100 kJ and 100 kcal, are the following:

	per 100 kJ	**per 100 kcal**
Arginine	25	107
Cystine	11	44
Histidine	12	47
Isoleucine	20	83
Leucine	40	167
Lysine	28	119
Methionine	6	23
Phenylalanine	18	75
Threonine	18	77
Tryptophan	7	31
Tyrosine	20	85
Valine	24	99