

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
HEALTH
ORGANIZATION



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ALINORM 09/32/26

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Thirty second Session

Rome, Italy, 29 June - 4 July 2009

REPORT OF THE 30th SESSION OF THE CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

*Cape Town, South Africa
3 - 7 November 2008*

Note: This report includes Circular Letter CL 2008/35-NFSDU

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CX 5/20.2

CL 2008/35-NFSDU
November 2008

TO: Codex Contact Points
Interested International Organizations

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SUBJECT: Distribution of the Report of the 30th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (ALINORM 09/32/26)

A. MATTERS FOR ADOPTION BY THE 32ND SESSION OF THE COMMISSION:

1. Guidelines for Use of Nutrition and Health Claims: Table of Conditions for Nutrient Contents (Part B Provisions on Dietary Fibre) (ALINORM 09/32/26 para. 54 and Appendix II)

Governments and international organizations wishing to comment on the above text should do so in writing, preferably by email to the above address **before 1 April 2009.**

2. Draft Advisory List of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children: Section D: Advisory List of Food Additives for Special Nutrient Forms: Provisions on Gum Arabic (Gum acacia) (ALINORM 09/32/26, para. 62 and Appendix III)

Governments and international organizations wishing to comment on the above text should do so in writing, preferably by email to the above address **before 1 April 2009.**

3. Draft Nutritional Risk Analysis Principles and Guidelines for Application to the Work of the Committee on Nutrition and Foods for the Special Dietary Uses (ALINORM 09/32/26, para. 82 and Appendix IV)

Governments and international organizations wishing to comment on the above text should do so in writing, preferably by email to the above address **before 1 April 2009.**

4. Proposed Draft Annex on Recommendations on the Scientific Substantiation of Health Claims to the Codex Guidelines for Use of Nutrition and Health at Step 4 (ALINORM 09/32/26, para. 102 and Appendix V)

Governments and international organizations wishing to comment on the above text should do so in writing, preferably by email to the above address **before 1 April 2009.**

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

Methods of Analysis for Dietary Fibre

The Committee noted that the list of recommended methods presented in Appendix II of ALINORM 08/31/26 was elaborated a few years ago and that a number of provisions for dietary fibre were newly introduced at this session, recommended that the list of methods presented in this Appendix needed to be updated.

In view of this, Governments and international organizations are invited to submit any information that they deem would be necessary to fulfill the mandate of the electronic working group on methods of analysis for dietary fibre (see paras 51 – 53) and should do so in writing, preferably by email to Mr Pascal Audebert, Point de Codex du Codex alimentarius en France, Premier Ministre Secrétariat général des Affaires européennes, 2 boulevard Diderot, 75572 Paris Cedex 12, France, Fax: +33 (1) 44871604, e-mail: pascal.audebert@sgae.gouv.fr with a copy to the Secretary, Codex Alimentarius Commission, Viale delle Terme di Caracalla, 00153 Rome, Italy (fax: +39 06 5705 4593, e-mail: codex@fao.org) **before 1 March 2009**;

SUMMARY AND CONCLUSIONS

The 30th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses reached the following conclusions:

MATTERS FOR FINAL ADOPTION BY THE 32ND SESSION OF THE CODEX ALIMENTARIUS COMMISSION:

The Committee:

- agreed to forward to the Commission the Draft Table of Conditions for Nutrient Content (Part B Containing Provisions for Dietary Fibre) for adoption at Step 8 (ALINORM 09/32/26 para. 54 and Appendix II);
- agreed to forward to the Commission the Draft Advisory List of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children: Section D: Advisory List of Food Additives for Special Nutrient Forms: Provisions on Gum Arabic (Gum acacia) for adoption at Step 8 (ALINORM 09/32/26, para. 62 and Appendix III);
- agreed to forward to the Commission the Draft Nutritional Risk Analysis Principles and Guidelines for Application to the Work of the Committee on Nutrition and Foods for the Special Dietary Uses (ALINORM 09/32/26, para. 82 and Appendix IV);
- agreed to forward to the Commission the Proposed Draft Annex on Recommendations on the Scientific Substantiation of Health Claims to the Codex Guidelines for Use of Nutrition and Health for adoption at Step 5/8 with the recommendation to omit Steps 6 and 7 (ALINORM 09/32/26, para. 102 and Appendix V).

MATTERS OF INTEREST TO THE 32ND SESSION OF THE COMMISSION

The Committee:

- agreed to consider how to proceed with new work on the revision of General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 9-1987); development of the separate Standard for Cereal Based-Foods for Underweight Children; revision of the Guidelines on Formulated Supplementary Foods for Older Infants and Young Children (CAC/GL 8-1991); and the development of Nutrient Reference Values (NRVs) associated with increased or decreased risk of non-communicable diseases at the next session of the Committee (paras 123-154).

MATTERS REFERRED TO OTHER COMMITTEES

Codex Committee on Methods of Analysis and Sampling (CCMAS)

The CCNFSDU refers some responses to the questions on several methods in the standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants and the List of methods for which advice of the CCMAS is sought (paras 17-21 and Appendix VI).

Codex Committee on Food Additives (CCFA)

The Committee refers a level of 10 mg/kg of Gum Arabic (Gum acacia) to the CCFA for endorsement as a coating agent for inclusion in Section D Advisory List of Food Additives for Special Nutrient Forms in the Advisory List of Nutrient Compounds for Use in Foods for Special Dietary Use by Infants and Young Children (CAC/GL 10-1979) (paras 55-62 and Appendix III).

Codex Committee on Food Labelling (CCFL)

The Committee refers the Draft Table (Provisions on Dietary Fibre including the definition of dietary fibre, Appendix II, para. 48) and the proposed draft Annex on Recommendations on the Scientific Substantiation of Health Claims to the Guidelines for Nutrition and Health Claims, para. 102, Appendix V) for information by the CCFL.

Codex Committee on General Principles (CCGP)

The Committee refers the draft Nutritional Risk Analysis Principles and Guidelines for Application to the Work of the Committee on Nutrition and Foods for Special Dietary Uses to the CCGP for their review and endorsement (paras 82, Appendix IV).

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INTRODUCTION

1. The Thirtieth Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) was held in Cape Town, South Africa from 3 to 7 November 2008 at the kind invitation of the Government of South Africa in cooperation with the Government of Germany. The Session was chaired by Dr Rolf Grossklauss, Director and Professor, the Federal Institute for Risk Assessment, Berlin and co-chaired by Mrs Lynn Moeng, Director Nutrition, the South African National Department of Health. The Committee was attended by 240 delegates, observers and advisors representing 52 member countries, one member organization and 27 international organizations.

OPENING OF THE SESSION

2. Ms Barbara Hogan, Minister of Health of the Republic of South Africa welcomed the participants to Cape Town and indicated that it was an honor for South Africa to have been selected as co-hosting country especially since this had allowed more African delegations to participate. She said food insecurity, high rates of malnutrition and high food prices were big threats to consumers in Africa and that a lot of efforts had been made in South Africa to ensure equitable health services to all citizens and drew the attention of the delegates to the fact that participation in Codex work had helped South Africa to develop science based regulations that would help to reach this goal. She also informed the Committee that South Africa had implemented a successful food fortification programme. Ms Hogan acknowledged the challenges before the Committee to develop science based guidance for both developing and developed countries to ensure safe, good food for everyone and stressed the importance of the work on a scientific basis for health claims and also of new work on a Standard for Processed Cereal-Based Foods for Underweight Infants and Young Children. and wished the delegates all the best in their deliberations.

3. Mr Bernhard Kühnle, Director General for Food Safety and Veterinary Affairs – Federal Ministry of Food, Agriculture and Consumer Protection, Germany addressed the Committee on behalf of the German Federal Minister, Ms Ilse Aigner and expressed his gratitude to South Africa for offering to co-host the session. He said that the CCNFSDU had the predominant task to protect consumers and especially those most vulnerable or with special needs such as infants and small children. He pointed out three areas in which it was particularly important to reach consensus in the Committee: (1) the contribution of the Committee to the implementation of the WHO Global Strategy on Diet Physical Activity and Health; (2) the adoption on Nutritional Risk Analysis Principles for the CCNFSDU; and (3) the work on a scientific basis for health claims to avoid that consumers can be misled; and also stressed the responsibility of the Committee to develop new standards which would ensure adequate nutritional supplements for underweight infants and young children.

Division of competence

4. Following Rule II.5 of the Rules of Procedure of the Codex Alimentarius Commission the Committee was informed about CRD 11 on the division of competence between the European Community (EC) and its Member States and noted that 14 Member States of the EC were present at the current session.¹

ADOPTION OF THE AGENDA (Agenda Item 1)²

5. The Committee agreed to the proposal to considered items 9 and 10 together as they were closely interlinked.

6. The Committee also agreed to consider the outcome of the Physical Working Group held prior to the session on issues related to the implementation of the WHO Global Strategy on Diet, Physical Activity and Health under Agenda Item 10 “Other Business and Future Work”.

¹ CRD 11 (Annotated Provisional Agenda on the Division of Competence between the European community and its Member States according to Rule II paragraph 5 of the Codex Alimentarius Commission.

² CX/NFS DU 08/30/1.

7. The Committee noted the considerable amount of comments received on the Draft Nutritional Risk Analysis Principles and Guidelines for Application to the Work of the Committee on Nutrition and Foods for Special Dietary Uses and agreed to establish a physical in-session working group led by Australia and working in English only with the mandate to consider the text in square brackets and to provide a revised document for consideration by the Committee.

8. With these modifications the Committee adopted the Provisional Agenda as the Agenda for the Session.

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

9. The Committee noted the matters referred by the 31st session of the Commission for information and in particular the adoption of standards and related texts submitted by the CCNFSDU as well as the approval of new work on the revision of nutrient reference values of vitamins and minerals in the *Guidelines on Nutrition Labelling* (CAC/GL 2-1985).

Review of Codex Committee Structure and Mandates of Codex Committees and Task Forces

10. The Committee noted that the 60th Session of the Executive Committee⁴ and the 31st Session of the Commission⁵ had discussed the work on nutrition in Codex when reviewing the Codex committee structure and mandates of Codex committees and task forces and had found that the current structure allowed tasks related to nutrition to be adequately covered in the CCFL and the CCNFSDU.

11. The Committee noted further the information given by FAO and WHO to the Executive Committee and the Commission on discussions on a mechanism to provide scientific advice to the CCNFSDU.

12. Regarding the update on progress of developing mechanisms for providing scientific advice to the CCNFSDU, the Representative of WHO indicated that FAO and WHO were not yet in a position to inform on a definitive joint mechanism, given the need for high-level policy decision and legal and administrative process clearance within each Organization to establish a joint expert body. Both Organizations indicated that they were very much committed to strengthen their roles in providing scientific advice on nutrition-related matters and efforts were being made in WHO to strengthen its present structure and capacity to provide scientific advice to Member States and to the Codex.

13. The Representative of FAO informed the Committee that the establishment of a joint FAO/WHO Expert body could be expedited if CCNFSDU would request such a committee to provide scientific advice. Australia indicated its strong support for the establishment of such a body.

Amendments to Codex standards and related texts

14. The Committee noted that when adopting the Proposed Draft Code of Hygienic Practice for Powdered Formulae for Infants and Young Children it had also revoked the *Recommended International Code of Hygienic Practice for Foods for Infants and Children* (CAC/RCP 21-1979) which had contained end-product microbiological specifications of advisory nature for a number of products which are not contained in the new code.

15. This had created an inconsistency as the section on food hygiene in the *Guidelines on Formulated Supplementary Foods for Infants and Young Children* (CAC/GL 08-1991) contains a reference to the revoked CAC/RCP 21-1979.

³ CX/NFSDU 08/30/2-Rev; CX/NFSDU 08/30/2-Add.1 (Report of the electronic working group on methods of analysis for infant formula and formulas for special medical purposes (CODEX STAN 72-1981), CX/NFSDU 08/30/2-Add.2 (Summary of activities from FAO/WHO of interest to the CCNFSDU), CRD 2 (Comments from Malaysia and ISDI), CRD 12 (WHO/UNICEF/WFP/UNHCR Informal consultation on the management of moderate malnutrition in under-5 children) and CRD 15 (Comments from the United States).

⁴ ALINORM 08/31/3, paras 27-38.

⁵ ALINORM 08/31/REP, paras 162-163.

16. The Committee noted that this matter was outside its mandate and decided to refer it to the Committee on Food Hygiene for appropriate action.

Methods of Analysis in the Codex Standard for Infant Formula and Formulas for Special Medical Purposes for Infants

17. The Committee recalled that the 29th Session of the Committee had agreed to establish an electronic working group led by New Zealand to prepare a list of methods of analysis for infant formulae for consideration by this session of the Committee.

18. The Delegation of New Zealand introduced the report of the electronic working group and recalled that in preparing the list of methods of analysis it had been requested to review the methods of analysis for provisions listed in Section 3.1 of the *Standard for Infant Formula and Formulas for Special Medical Purposes for Infants* (CODEX STAN 72-1991) and to follow the *Principles for the Establishment of Codex Methods of Analysis* in the Codex Procedural Manual, including the *General Criteria for the Selection of Methods of Analysis*.

19. The electronic working group recommended that the Committee:

- Submit the methods contained in Table 1 of the report of the electronic working group to the Committee on Method of Analysis and Sampling (CCMAS) for endorsement and inclusion in the *Recommended Methods of Analysis and Sampling* (CODEX STAN 234) in the section titled “Foods for Special Dietary Uses” with the description “Infant Formula” in the column titled “Commodity Standard” with notes to explain that some methods are for specific forms of the provisions in section 3.1 and that methods should include the units of expression when it was part of the provision (see Appendix VI).
- Request advice from the CCMAS on the criteria for selecting Type II methods from a list of Type III methods because the working group had not found an agreement on such selection criteria. As an interim measure the working group had proposed some of the methods as Type III for endorsement until clarification was received from the CCMAS how to select the appropriate Type II methods; these methods are indicated as III* in the Appendix.
- Periodically review the methods in the proposed infant formula list in CODEX STAN 234 to keep them updated.
- Consider whether to recommend methods for moisture content, total solids and ash which were not in the original scope of the working group but which were needed to calculate carbohydrates and calories.

20. In response to the questions raised by the 28th and 29th Session of the Committee on Methods of Analysis and Sampling the working group proposed to reply that:

- Methods using microbioassay had been reviewed and more updated methods for total carbohydrates (AOAC 986.25, determination by difference) and for fats (AOAC 989.05 and ISO 8381 | IDF 123:2008 or ISO 8262-1 | IDF 124-1:2005) were being recommended;
- Vitamin C was expressed as ascorbic acid and the difference between the proposed methods for Vitamins K, B12 and B6 was provided in the list of methods submitted for endorsement; and
- A method for dietary fibre was not necessary to calculate the total energy as there was insignificant indigestible carbohydrate in infant formula.

21. The Committee expressed its appreciation to the Delegation of New Zealand and the working group for their work and after some discussion, agreed to follow the recommendations of the working group and also to provide the responses to the questions posed by CCMAS as recommended by the Working Group. It was noted that the method for total fats had been published as ISO 8381 | IDF 123-2008 and amended the list of methods accordingly. It was clarified that comments on the proposed methods could be submitted to CCMAS for their consideration during the endorsement process.

22. The Committee considered the need to re-establish the electronic working group but decided to first await a reply from the CCMAS.

Codex Committee on Food Additives

Applicability of ADIs to Infants and Young Children

23. The Committee noted the response by the Committee on Food Additives regarding questions from the CCNFSDU on the applicability of an ADI for infants below 12 weeks of age. The Committee also noted that WHO had no plan to update the scientific opinion on an ADI for infants below 12 weeks at present. The Committee noted the report of the CCFA and also noted that it would be desirable that WHO should update the Committee on this matter as new information became available.

Codex Committee on Food Labelling (CCFL)

24. The Committee noted the work of the CCFL on the implementation of the WHO Global Strategy on Diet, Physical Activity and Health and that this would be taken into account when discussing the issue of nutrient reference values (Agenda Item 7) and the WHO Global Strategy (Agenda Item 10b)

Activities from FAO/WHO of Interest to CCNFSDU

25. The Representative of the WHO referring to document CX/NFSDU 08/30/2-Add.2, informed the Committee of the reports of scientific work undertaken and of several on-going and future work to be completed in 2009 including the development of a FAO/WHO Procedural Manual for the formulation and implementation of regional and country-specific food-based dietary guidelines (FBDG) (scheduled for completion June 2009), and a joint WHO/UNICEF consultation to update the guidelines for vitamin A supplementation with new scientific evidence (expected in 2009).

26. The Representative of the FAO added information on the FAO/WHO Expert consultation on Fat and Fatty Acids in Human Nutrition which will be held in Geneva on 10 – 14 November 2008 where experts will develop recommendations on requirements for infants, children, adults and women during pregnancy and lactation and review scientific evidence related to inadequate and excess intakes of fats and fatty acids to health risks and benefits. The report of this consultation will be available in early 2009. The Representative indicated that an expert consultation on Biodiversity and food consumption and an expert consultation on risk-benefit-analysis is planned in 2009 and that the Food Composition Study Guide to be published in 2009 is a distance learning tool and will allow learners to acquire and evaluate their knowledge in food composition.

GUIDELINES FOR THE USE OF NUTRITION CLAIMS: DRAFT TABLE OF CONDITIONS FOR NUTRIENT CONTENTS (PART B CONTAINING PROVISIONS ON DIETARY FIBRE) AT STEP 7 (Agenda Item 3)⁶

27. The Committee recalled that its last session had agreed to return the Draft Table of Conditions for Claims (dietary fibre) to Step 6 asking for comments and additional input on the definition, conditions for claims and methods of analysis for dietary fibre in the light of the results of the FAO/WHO scientific update of carbohydrates in human nutrition.

28. The Representative of WHO drew the attention of the Committee to the fact that following the request for scientific advice, FAO/WHO had provided a recommendation on the definition of dietary fibre derived from the Joint FAO/WHO expert consultation and the Joint FAO/WHO scientific update on carbohydrates in human nutrition. However, in order to facilitate progress of the discussion the Representative of WHO informed the Committee that Professor J. Cummings, as scientist participating in the FAO/WHO carbohydrate consultation and scientific update, would suggest alternative wording

⁶ CL 2007/43-NFSDU; ALINORM 08/31/26, Appendix II, CX/NFSDU 08/30/3 (comments from Australia, Costa Rica, Guatemala, New Zealand, AAF, AIDGUM, IDF, ILSI, ISDI); CX/NFSDU 08/30/3- Add.1 (comments of Brazil, South Africa); CX/NFSDU 08/30/3-Add. 2 (comments from Mali, Thailand, IFAC); CRD 3 (comments from Canada, European Community, India, Indonesia, Kenya, Philippines, United States of America, CIAA).

for the definition, taking into account the new work and reports published by some Member States since the 29th Session of the Committee.

29. Prof Cummings indicated that when considering the definition of dietary fibre, the expert groups had reviewed existing definitions, including the currently proposed definition by this Committee and that of the US National Academy of Sciences (Institute of Medicine 2005).

30. Recognising the need to move to an agreed definition of fibre by the Committee, Professor Cummings noted three main areas where the proposed Codex definition and that of the Scientific Update differed. The Codex definition includes the phrase “neither digested nor absorbed in the small intestine”, a concept also incorporated into two other existing definitions of fibre, that of the US National Academy of Sciences and of the European Community. Having pointed out that digestibility is poorly defined and very difficult to measure, especially in the human small intestine, professor Cummings stated that intrinsic plant cell wall polysaccharides were essentially not digested in the human small intestine, and that this historical concept could remain as part of the definition.

31. However, included in the category of non-digestibility are the non α -glucan oligosaccharides (DP 3-9) (non digestible oligosaccharides, NDO). The Scientific Update had felt strongly that NDO should not be included in the definition of dietary fibre. This was because the Codex definition includes the assertion that “Dietary fibre generally has properties such as: decrease intestinal transit time and increase stools bulk; fermentable by colonic microflora; reduce blood total and/or LDL cholesterol levels; reduce post-prandial blood glucose and /or insulin levels”. It was felt that there was no convincing evidence that NDO had a significant effect on gut transit time or stool weight, on blood lipids in healthy people, since they are not glycaemic carbohydrates, nor on the control of blood glucose and insulin. Whilst they are fermented this was felt to be part of normal digestive physiology and not something that conferred a specific health benefit. Therefore, inclusion of these water-soluble low molecular weight carbohydrates was potentially misleading for the consumer. Nevertheless the Joint FAO/WHO Scientific Update had acknowledged that NDO were important carbohydrates with unique properties, likely to be shown of importance to other aspects of health after further research. In such case, NDO should be recognized on its own right, but not as dietary fibre.

32. Professor Cummings indicated that the use of the terms “intrinsic”, “extrinsic”, “functional” and “synthetic” in existing definitions, and the incorporation of this categorization of dietary fibre into the Committee’s proposed definition as “carbohydrate polymers, which have been obtained from food raw material by physical, enzymatic or chemical means” and “synthetic carbohydrate polymers”. The Joint FAO/WHO Scientific Update had wanted the definition to be closely linked to health and felt that the established epidemiological support for the health benefits of dietary fibre was based on diets that contain fruits, vegetables and whole grain foods, which are rich in intrinsic plant cell wall polysaccharides. Although isolated or extracted fibre preparations have been shown to have physiological effects experimentally, these have not been translated into health benefits directly because of a lack of epidemiological and longer term evidence. He therefore suggested that the inclusion of categories of dietary fibre other than those intrinsic to the plant cell wall should be required to show “a beneficial physiological effect demonstrated by generally accepted scientific evidence” as specified in the definition of the European Community.

33. The Committee considered proposed changes and made the following comments and conclusions.

34. The Delegation of South Africa indicated that in order to protect consumers from misleading claims carbohydrate polymers obtained from raw materials by enzymatic or chemical means and synthetic carbohydrate polymers could be allowed only if beneficial physiological effects were demonstrated by scientific evidence to provide a ‘long-term’ benefit to health.

35. The Delegation of Canada supported to link the definition for dietary fibre to physiological effects and explained that the fact that a substance was not digested or absorbed in the small intestine did not necessarily mean that it had the properties of a dietary fibre. Therefore the inclusion of such compounds needed to be justified by data on physiological efficacy. The delegation also proposed to

move the text on fermentability by colonic microflora from the section on properties to the definition section as this was a defining characteristic of dietary fibre.

36. Some delegations from developing countries were of the view that their dietary recommendations were designed to promote consumption of fruits, vegetables and whole grain cereal foods which were naturally rich in dietary fibre and that inclusion of the concept of synthetic and isolated fibres might mislead consumers regarding potential health benefits and supported the approach proposed by the WHO.

37. Some observers were of the view that the concept of independent scientific evaluation or review to obtain or validate scientific data for health benefits of fibre should be stressed.

38. The Delegation of the European Community proposed to simplify and clarify the draft Codex definition as proposed in CRD 3 so that *Dietary fibre means carbohydrate polymers with three or more monomeric units, which are neither digested nor absorbed in the small intestine and belong to the following categories* as described in the Codex definition, to add “edible” to more precisely characterize the nature of carbohydrate polymers and also to add “beneficial” before “physiological effect” and to move the section on properties as preamble to the definition and that the criteria to quantify physiological effects or evaluate demonstrated scientific evidence should be left to national competent authorities to decide. Some delegations and observers supported this proposal as a pragmatic way forward.

39. Several other proposals were put forward to amend the definition, however there was no agreement to accept any of these proposals, therefore after a long discussion the Committee decided to ask small drafting group to find an appropriate wording on how to amend the definition.

40. The Delegation of Thailand, on behalf of this drafting group, informed the Committee that a revised version had been prepared in which the entire section on properties was deleted and that the definition was much simplified to specify that dietary fibre meant carbohydrate polymers which were not hydrolysed in the small intestine of humans with degree of polymerization not lower than three and that the decision on whether to include carbohydrates with the degree of polymerization from 3 to 10 should be left to national authorities to decide. The definition took into account that three main categories of carbohydrate polymers were distinguished: (a) naturally occurring carbohydrate polymers; (b) carbohydrate polymers obtained from raw material by physical, enzymatic or chemical means and (c) and synthetic polymers with the understanding that physiological effect and benefit to health for categories (b) and (c) should be demonstrated by generally accepted scientific evidence to competent authorities.

41. The Delegation of the United States was of the view that before finally agreeing on a dietary fibre definition a number of questions presented in their comments (CRD 3) should be considered. For example the scientific evidence to indicate that a revised Codex definition was needed to improve public health; on whether international consensus on the terms and definitions used exists; or on the presence of validated methods or validated procedures for combining methods to measure total fibre content based on proposed definitions should be clarified.

42. The Committee noted that the major unresolved issue was the inclusion of oligosaccharides with a degree of polymerization from 3 to 10 and had a long discussion on this matter.

43. Some delegations were of the view that these carbohydrates should not be included in the definition as they did not have the properties traditionally attributed to dietary fibre and felt that their inclusion might mislead consumers.

44. Other delegations and some observers believed that these carbohydrates were naturally associated with dietary fibre and might have some health benefits and therefore should be included in the definition

45. After some discussion, the Committee agreed to refer to monomeric units rather than to degree of polymerization and that the decision on whether to include carbohydrates with monomeric units from 3 to 9 should be left to national authorities to decide. As a consequence the sentence referring to exclusion of mono and disaccharides was deleted from the definition.

Conditions for claims

46. The Committee agreed to express conditions both per 100g and 100 kcal as well as per serving and that conditions for dietary fibre claims per serving should be expressed in terms of daily reference value instead of “recommended intake” with 10 % or more for “source”, and 20 % or more for “high”. After some discussion, it was also agreed that conditions for nutrient content claims in liquid foods are to be determined at national level and should appear in a footnote.

47. To clarify that amounts for content claims for dietary fibre should be expressed on “ready-to-use” basis, the Committee noted that there were no such requirement in the table of conditions for the other nutrient contents in the Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997) and asked that the Codex Committee on Food Labelling should address this matter for all claims in the table of conditions.

48. The Committee agreed to forward the amended Draft Table (Provisions on Dietary Fibre) including the definition on dietary fibre to the CCFL for information.

Methods of analysis

49. The Committee, in noting that the list of recommended methods presented in Appendix II of ALINORM 08/31/26 was elaborated a few years ago and that a number of provisions for dietary fibre were newly introduced at this session, recommended that the list of methods presented in this Appendix needed to be updated.

50. The Committee noted that footnote 1 would also need to be further considered in relation to methods of analysis.

51. The Committee therefore agreed to establish an Electronic Working Group in order to:

- review and update, as appropriate, the list of methods of analysis in Appendix II, taking into account the new provisions in the draft definition of dietary fibre that would require the selection of methods of analysis, and possible information of new available methods;
- consider how the results from different methods specific to different types of dietary fibre could be combined together to arrive at the total dietary fibre content in a food;
- evaluate the performance of methods in measuring different types of dietary fibre;
- make recommendations for methods of analysis for dietary fibre in different food matrices;
- consider the footnote 1 and prepare a recommendation as to its revision with regard to the methods of analysis, if necessary.

52. The Electronic Working Group will be led by the Delegation of France, be open to all Codex members and observers and will work in English only.

53. The Delegation of the United States expressed concerns that the proposed definition contained significant modifications to the previous text considered by the Committee and incorporated new text that appeared to be subject to different interpretations as well as inclusion of text that was not considered by the Committee (i.e. footnote 1). In this regard, the United States recommended that the Committee have additional time to reflect on the proposed definition and its implications before the definition is advanced for adoption.

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

54. The Committee agreed to forward the Draft Table (Provisions on Dietary Fibre) including the definition on dietary fibre to the 32nd Session of the Commission for adoption at Step 8 (see Appendix II).

DRAFT REVISION OF THE ADVISORY LIST OF NUTRIENT COMPOUNDS FOR USE IN FOODS FOR SPECIAL DIETARY USES INTENDED FOR THE USE BY INFANTS AND YOUNG CHILDREN: SECTION D ADVISORY LIST OF FOOD ADDITIVES FOR SPECIAL NUTRIENT FORMS AT STEP 7 (Agenda Item 4)⁷

55. The Committee recalled that at its last session it agreed to return the provisions for Gum Arabic (Acacia gum) (INS 414) to Step 6 for comments as the Committee did not come to a conclusion on levels of 10 or 100 mg to be recommended in the advisory list of food additives for special nutrient forms.

56. The Observer from AIDGUM indicated that the use of Gum Arabic at 100 mg/kg as a coating agent was necessary for adequate protection of vitamins and other minor ingredients from oxidation in finished, packaged foods for infants and young children and that, if used for this purpose, the level in the [finished product check all these with Food additives report] would be below 10 mg/kg.

57. The Delegation of the European Community was of the view that there was no technological need for a level higher than 10 mg/kg of gum Arabic in finished products.

58. The Delegation of Australia informed the Committee that the CCFA was considering inclusion of Gum Arabic in infant formulae, follow-up formulae, formulae for special medical purposes for infants and complementary foods for infants and young children at the level of GMP (ALINORM 08/31/12, Appendix VI) and that the Codex Standard for Processed Cereal-Based Foods (CODEX STAN 74-1981, Rev.1-2006) allowed the use of Gum Arabic as a thickener in the final product at a level which was significantly higher.

59. The Secretariat informed the Committee that the selection of food additives for inclusion in commodity standards or other texts was the responsibility of Codex Committees which elaborated those standards and that any request for endorsement and inclusion of proposed food additives in the GSFA has to be technologically justified. The Secretariat indicated that there was no functional class for coating agents in GSFA and therefore the CCNFSDU should ask the CCFA how to accommodate it. A delegation indicated that such functional class could be indicated under “carriers”.

60. A delegation, supported by some observers, was of the view that this food additive should not be allowed in products for use by infants below 12 weeks of age.

61. After some discussion, the Committee agreed to send the level of 10 mg/kg of Gum Arabic (gum acacia) to the CCFA for endorsement as a coating agent for inclusion in Section D: Advisory list of food additives for special nutrient forms of the Advisory List of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Use by Infants and Young Children (CAC/GL 10-1979)

Status of the revision of the advisory list of nutrient compounds for use in foods for special dietary uses intended for the use by infants and young children: Section D Advisory list of food additives for special nutrient forms

62. The Committee agreed to advance the provision on Gum Arabic at a level of 10 mg/kg in the ready-to-use product to the 32nd Session of the Commission for adoption at Step 8 (see Appendix III).

⁷ ALINORM 08/31/26, Appendix V; CX/NFSDU 08/30/4 (comments from Australia, Guatemala, AIDGUM); CX/NFSDU 08/31/4-Add.1 (comments from the European Community); CRD 4 (comments from Brazil, India, Indonesia, Kenya, Mali, Philippines).

DRAFT NUTRITIONAL RISK ANALYSIS PRINCIPLES AND GUIDELINES FOR APPLICATION TO THE WORK OF THE COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES AT STEP 7 (Agenda Item 5)⁸

63. The Delegation of Australia introduced CRD 21 and indicated that following the decision of the Committee (see para. 7) an in-session working group had made proposals for most of the issues remaining in square brackets in the draft text with the exception of those in paragraphs 32 and 34 because of time constraints and that the working group additionally proposed a number of editorial changes to the text. The Committee thanked the Delegation of Australia and the working group for their excellent work.

64. The Committee then discussed the document section by section, agreed to most of the editorial changes and made the following modifications and comments:

Section 1 - Background

65. Paragraph 6 from the section Scope and Application as amended by the working group was moved to section 1 as it was considered to be more relevant to the background.

Section 2 – Introduction

66. Several delegations were of the view that the term “related substances” as defined in footnote 2 was not clear. A number of proposals were made on how to improve the definition. The Delegation of Australia clarified that the term “related substances” was taken from a *Model for Establishing Upper Levels of Intake for Nutrients and Related Substances, Report of the Joint FAO/WHO Technical Workshop*, (WHO, 2006) publication to describe constituents of food other than nutrients which have favourable physiological effects. After some discussion the Committee adopted the text as amended by the working group.

67. In paragraph 3, the words “inherent constituents such as” and “inherent constituents that” were deleted as they were found to be superfluous and the wording on microbiological pathogens and contaminants were placed together as other examples of hazards.

68. In paragraph 5 several delegations felt that the last sentence related to the choice of “other sources of scientific advice” did not clearly describe what other sources of scientific advice could be used and how they were verified. The Secretariat recalled that the Draft Principles were intended for use by the CCNFSDU and should be based on the *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* as contained in the Procedural Manual. After some discussion the paragraph was amended to align it with the Working Principles, acknowledging FAO/WHO as primary source of nutritional risk assessment advice and requesting that the use of any other expert bodies should be approved by the Commission.

69. Subsequently it was decided to move the amended paragraph 5 to replace existing paragraph 32 in order to avoid duplication.

70. One observer expressed the view that conflict of interest in relation to the selection of international expert groups was not addressed in the text. The Committee however noted that the general reference to the *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* was sufficient to address this and similar concerns.

Section 3 – Scope and Application

71. The Committee agreed to the proposal of the working group regarding clarification of the last sentence in paragraph 7.

⁸ ALINORM 08/31/26, Appendix VI; CX/NFSDU 08/30/5 (comments from Australia, Brazil, Costa Rica, Ghana, Guatemala, Malaysia, New Zealand, the Philippines, South Africa, Thailand, the United States, CRN, IDF and NHF); CX/NFSDU 08/30/5-Add.1 (comments from Argentina, the United States and IADSA); CRD 5 (comments from Canada, the European Community, India, Indonesia, Kenya, Malaysia and the Philippines); CRD 21 (Text revised by the in-session working group)

72. There was a lengthy discussion on the wording of paragraph 8 on how to better describe the food constituents of primary interest in nutritional risk analysis as well as the risk of increasing the adverse effects of the food matrix. The Committee decided to leave the introductory phrase and the first two bullets as originally drafted, to delete the third bullet and to insert a new paragraph to read: “When favourable effects of the nutrient or related substance of primary interest are being assessed, consideration should be given to whether the food matrix could increase the risk of an adverse health effect.”

73. In paragraphs 9 and 10, the first occurrence of the term “risk analysis” was replaced with “risk assessment” to clarify that “quantitative” only related to this part of risk analysis.

Section 4 – Definitions

74. Several proposals were made to amend definitions on intake (exposure) assessment, nutrient-related hazard and homeostatic mechanism however after some discussion, the Committee decided to leave them as originally drafted.

75. Concerning the proposal to delete the definition for dose response assessment because it was not used in the text, the Committee felt that it was useful to retain it as it had been adapted from the definition in the Codex Procedural Manual to show how it could be applied in nutritional risk analysis and that this useful information should not be lost.

Section 5 – Principles for Nutritional Risk Analysis

76. In paragraph 17 the term “relevant route(s) of exposure” was replaced with “relevant source(s) of intake”

77. The Committee discussed how to proceed with paragraph 29 as text related to the impact of nutritional risk management decisions on consumers’ behaviour had been left in square brackets with three different options proposed by the in-session working group to address the issue.

78. After some discussion, the Committee decided to insert a new paragraph after paragraph 29 to read: “Nutritional risk management decisions should take into account their impact on dietary patterns and consumer behaviour. Such information should be supported by relevant research.”

79. In paragraph 31 the word “Risk” was included before “Analysis”.

Section 6 – Selection of Risk Assessor by CCNFSDU

80. In paragraph 33 the words “relevant Codex subsidiary body” were replaced with “CCNFSDU”.

Section 7 – Review Process

81. The Committee decided to delete this section as relevant guidance on this matter was included in the Procedural Manual.

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

82. The Committee agreed to forward the Proposed Draft Nutritional Risk Analysis Principles and Guidelines for Application to the Work of the Committee on Nutrition and Foods for the Special Dietary Uses as amended during the session to the Committee on General Principles (CCGP) for endorsement and to the 32nd Session of the Codex Alimentarius Commission for adoption at Step 8 (see Appendix IV).

PROPOSED DRAFT RECOMMENDATIONS ON THE SCIENTIFIC BASIS OF HEALTH CLAIMS AT STEP 4 (Agenda Item 6)⁹

83. The Committee recalled that the last session of the Committee had agreed to return the Proposed Draft Recommendations to Step 2/3 for redrafting by an electronic working group led by France.

84. The Delegation of France informed the Committee of the outcome of the physical working group that had met prior to the session to prepare proposals to the plenary on the recommendations on the scientific basis of health claims (see CRD 17).

85. The Delegation explained that the physical working group had focused discussions on sections not discussed at the last session of the Committee, i.e. from section 3 onwards, but that it had not been able to complete its discussions. Therefore it had only made proposals for sections 3.1 and 3.2 and paragraph 5 (a) of section 3.1 had been retained in square brackets for further discussion in the Committee.

86. The Committee agreed to consider the working document including the recommendations of the working group section by section, and in addition to editorial corrections, made the following comments and changes.

General amendment

87. The Committee agreed to replace throughout the text “governments” by “competent national authorities” for consistency with the parent document. The Committee noted concerns by several delegations that these terms were not consistently used throughout Codex texts and noted the information given by the Codex Secretariat that a document on amendments to Codex standards addressing such and other issues would be prepared for discussion by the 32nd Session of the Commission.

2. Definitions

88. The Committee amended section 2.2 to clarify that the definition for food or food constituent applied to food as well as a whole food or a category of foods and that a health effect can be more correctly described as a health outcome as defined in sections 2.2.1 to 2.2.3 of the *Codex Guidelines for the Use of Nutrition and Health Claims*.

3.1 Process for the substantiation of health claims

89. The Committee discussed whether to retain paragraph 5 (a) (new 3.1 (a)). Several delegations proposed to delete this step as it did not add useful information. Other Delegations and Observers supported to retain the text as it provided useful guidance and clarifications to governments on what criteria and policies were needed to make judgments on health claims.

90. The Committee however took the view that the preamble to the *Guidelines for Use of Nutrition and Health Claims* (CAC/GL 23-1997) already stated that health claims needed to be consistent with various policies and as the Annex was an integral part of the Guidelines, the Committee agreed to delete paragraph 5 (a).

91. The Committee did not agree to a proposal by some Observers to indicate in paragraph 5 (e) (new 3.1 e) that assessment of conflict of interest was a necessary criterion. The Committee also did not agree to the proposal by some observers to indicate explicitly that in particular for health claims

⁹ CX/NFSDU 08/30/6; CX/NFSDU 08/30/6-Add.1 (comments from Brazil, Guatemala, United States of America, EHPM, IADSA, ISDI, WSRO); CRD 1 (Report of the *ad hoc* Physical Working Group on Health Claims, Nutrient Reference Values and Matters Related to Consideration of the WHO Global Strategy on Diet, Physical Activity and Health); CRD 6 (comments from European Community, India, Indonesia, Kenya, Malaysia, Mexico, Philippines, EFLA); CRD 17 (Proposals from the *ad hoc* Physical Working Group on Health Claims, Nutrient Reference Values and Matters Related to Consideration of the WHO Global Strategy on Diet, Physical Activity and Health); CRD 19 (comments from IADSA).

for breastmilk substitutes, independently funded research was needed and that the reviews of the health claims should be conducted by independent bodies.

92. The Committee was of the view that these aspects were sufficiently covered in the parent document and by adding a reference to *The Working Principles for Risk Analysis for Food Safety for Application by Governments* in a footnote to the title of the Annex.

93. The Committee agreed with other editorial amendments proposed in paragraphs 5 (b), (c), (d), (e) and (f) (new 3.1 (a), (b), (c), (d) and (e)).

3.2 Criteria for the substantiation of health claims

94. Paragraph 7(b) (new 3.2.2 (b)) was amended to ensure that epidemiological studies used as evidence should provide a consistent body of evidence from well-designed studies, and to include “authoritative statements” in addition to evidence-based dietary guidelines to enable all categories of evidence generally available to be taken into account to substantiate some health claims.

95. One Observer highlighted the dilemma of scientific substantiation by human trials and the ethical considerations relating to trials on infants under 12 weeks and possibly one year, and proposed to include a recommendation in this paragraph that health claims should not be permitted for foods for infants and young children because they cannot be substantiated according to the criterion.

96. The Committee however felt that these concerns were already taken into account by other criteria in the text.

3.3 Consideration of the evidence

97. The Committee amended the second sentence of paragraph 10 (new 3.3.3) by inserting “or mediates the effect” after “target site” for purposes of clarity and also inserted an example “forms of the constituents” to clarify what was meant by factors that could affect absorption or utilization of a constituent for which a health claim was made.

98. The Committee agreed to insert a new paragraph after paragraph 11 (new 3.3.5) to clarify under what conditions studies should be excluded from further review and exclusion from relevant scientific data.

99. One Observer proposed to include a reference also to a “special diet required for a specific disease or condition” in addition to a balanced diet in paragraph 12 (new 3.3.6). The Committee however was of the view that such a reference would not be appropriate as health claims were directed to a generally healthy population and the Guidelines themselves were applicable to all foods. The Committee agreed to amend this section to indicate that the evidence should provide information relating to a balanced diet as it related to the target population for which the claim was intended.

5 Re-evaluation

100. The Committee agreed with the principle that health claims should be re-evaluated and agreed to indicate that such re-evaluation should be undertaken by national competent authorities either periodically or following emergence of significant new evidence.

Conclusion

101. In view of the considerable progress made on the document, the Chairperson proposed to advance the document to Step 5/8 with the omission of Steps 6 and 7 for adoption by the next Session of the Commission. The Delegation of Australia, supported by the Observer from NHF, however expressed its concern with this proposal in view of the considerable changes made to the text and proposed that the document be advanced for adoption at Step 5 to allow more time for its consideration.

Status of the Proposed Draft Annex on Recommendations on the Scientific Substantiation of Health Claims to the Codex Guidelines for Use of Nutrition and Health Claims

102. The Committee agreed to forward the proposed draft Annex to the Committee on Food Labelling for their information and to the 32nd Session of the Commission for adoption at Step 5/8 with the recommendation to omit Steps 6 and 7 (see Appendix V).

PROPOSED DRAFT ADDITIONAL OR REVISED NUTRIENT REFERENCE VALUES FOR LABELLING PURPOSES IN THE CODEX GUIDELINES ON NUTRITION LABELLING AT STEP 4 (Agenda Item 7)¹⁰

103. The Committee recalled that the 31st Session of the Commission had approved new work on additional or revised vitamin and mineral Nutrient Reference Values (NRVs) for labelling purposes and that the document elaborated by the Republic of Korea with assistance from other interested parties had been circulated before this session of the Committee. The Committee also recalled that the physical working group was held prior to this session in order to review comments received and prepare proposals on how to revise the document for consideration by the Plenary.

104. The Delegation of Republic of Korea informed the Committee that the physical working group proposed to use the terms from the United Nations University/FAO/WHO/UNICEF workshop on harmonization of approaches for developing nutrient-based dietary standards¹¹ and that these terms were included in footnotes. The Delegation drew the attention of the Committee to the fact that in order to proceed with the work, the Committee should decide on the selection basis for NRVs for which two options were proposed; decide on how to determine general population NRVs; take a decision on upper levels of intake and on how to select data sources to establish NRVs.

105. The Committee expressed its appreciation to the Delegation of Republic of Korea and the working group for their work and considered the options proposed by the working group.

106. The Committee agreed to use the terminology proposed by the above mentioned workshop on international harmonization.

Preamble

107. The Committee agreed to editorial amendments proposed in the Preamble. The Delegation of the United States noted the importance of the second paragraph to clarify that countries should be able to select their own values based on scientific justification including consideration of country- and region- specific factors.

Selection of the appropriate basis

108. The Committee noted the concern expressed by the Delegation of Japan and their request not to delete Option 1 since their NRVs were based on Average Nutrient Requirements (ANR) because the nutrition problem they are facing was excessive nutrient intake, however the Committee did not agree to this request as many delegations preferred to use Option 2 - Individual Nutrient Level (INLx). The Delegation of Japan accepted the decision of the Committee on condition that government in establishing its own NRVs for labelling purposes may consider the suitability of the general principles taking into account the characteristic of its own nutrition problems. The Committee made some

¹⁰ CX/NFSU 08/30/7; CX/NFSU 08/0/7-Add. 1 (comments from United States of America and South Africa); CRD 1 (Report of the Physical Working Group); CRD 7 (comments from the European Community, Indonesia, Kenya, Philippines); CRD 12 (WHO/UNICEF/WFP/UNHCR Information on Informal Consultation on management of moderate malnutrition in under-5 children); CRD 13 (Summaries of the comments from EWG members (Australia, Brazil, China, Costa Rica, European Community, Malaysia, New Zealand, Switzerland, CRN, IADSA and NHF) and recommendations); CRD 18 (Results of the Physical Working Group on NRVs).

¹¹ International Harmonization of Approaches for Developing Nutrient-Based Dietary Standards, Janet King and Cutberto Garza, Guest editors, Food and Nutrition Bulletin, vol 28, No1, 2007.

amendments to Option 2 to read: Individual Nutrient Level (INL_x)¹², the estimated nutrient intake value that meets the requirements of most (98 percent) of an apparently healthy specific sub-group of the population (e.g., considering the subgroup's sex and lifestage such as age and pregnancy/lactation). In cases where there is an absence of an established INL_x for a nutrient for a specific sub-group, it may be appropriate to consider the use of other reference values or ranges that have been established by authoritative scientific bodies. It is necessary to review how these values were derived on a case-by-case basis.

Consideration of different age-sex specific values

109. The Committee had a long discussion on how general population NRVs should be determined. Some delegations indicated that they were using the Option 1 i.e. the highest values from different age-sex groups while some other delegations were of the view that the most preferred should be Option 2: which considers the specific sub-group population weighted means such as means of adult males and females values.

110. Some delegations drew the attention of the Committee to their experience in arriving at NRVs and indicated that in order to protect consumers an intermediate decision between options for some nutrients might be required.

111. To the concerns expressed by the Delegation of China that for example different values for vitamin A are needed, the Chairperson clarified that the calculated differences between the two options were negligible. Generally NRVs should compare the nutrient content of the food items in the standardised form to avoid misleading of consumer.

112. The Delegation of Australia proposed an approach to choose an average of male and female nutrient values from FAO/WHO Vitamin and Mineral Requirements in Human Nutrition (2004) from one population group which would reasonably represent all population groups over three years. The following wording for Option 2 was proposed: *Average mean value for chosen reference population group that reasonably represents the general population above 3 years of age, such as means of adult male and female values.*

113. The Committee noted that practical implications of choosing one approach were not clear and that it was difficult to decide on how this option could work in practice.

114. The Delegation of the United States requested that further consideration be given to both options presented by the working group for age-sex specific once values were calculated to illustrate the implications of each choice. Other delegations indicated that this information could be useful.

115. The Committee decided to put both options in square brackets for further consideration.

Consideration of upper levels of intake

116. The Committee noted the proposal to make consideration of the establishment of NRVs more flexible, however after some discussion agreed to retain the text as proposed by the working group.

117. The Committee noted that the proposed new definitions including Upper Nutrient Level (UNL) that appeared in this section were placed in a footnote and agreed that it would be more useful to move the terminology from the footnote into a new section on definitions.

Selection of suitable data sources to establish NRVs

118. After some discussion the Committee agreed that recent and relevant FAO/WHO values would be the basis for NRVs and if such FAO/WHO values are not available, relevant and recent values from recognized authoritative scientific bodies other than FAO/WHO could be used.

119. In response to the question from the Delegation of Japan regarding the representativeness of data used to develop the FAO/WHO Vitamin and Mineral Requirements in Human Nutrition (2nd

¹² "Individual Nutrient Level (INL_x)" is used as the generic term. Different countries may use other terminologies for this concept: for example, Recommended Dietary Allowance (RDA), Recommended Daily Allowance (RDA), Reference Nutrient Intake (RNI), Population Reference Intake (PRI), or Ingestion Diaria Recomendada (IDR).

edition, 2004), the Representative of WHO informed the Committee that this document used data from around the world which was available to the experts at that time.

120. The Committee considered whether the actual NRVs should be elaborated by FAO/WHO or would be determined by the CCNFS DU. The Committee noted that an assessment part containing actual human requirements for vitamins and minerals was available from FAO/WHO Vitamin and Mineral Requirements in Human Nutrition (2004), therefore agreed that elaboration of actual NRVs was the responsibility for the Committee.

121. The Committee noted that the General Principles for Establishing Vitamin and Mineral NRVs especially to determine which options should be used for different age-sex groups needed more elaboration, therefore agreed to re-establish the electronic working group lead by Republic of Korea to prepare a revised version of the document based on decisions made at the current session with the understanding that the Delegation of Australia would help in calculating actual values of NRVs based on options 1 and 2 using data from FAO/WHO Vitamin and Mineral Requirements in Human Nutrition (2004). Working group will be opened to all interested parties and work in English only.

Status of the General Principles for Establishing Nutrient Reference Values of Vitamins and Minerals for General Population

122. The Committee agreed to return the General Principles for Establishing Nutrient Reference Values of Vitamins and Minerals for General Population to Step 2/3 for redrafting by the above electronic working group to prepare a revised version for circulation for comments and consideration by the next session of the Committee.

DISCUSSION PAPER ON THE PROPOSAL FOR NEW WORK TO AMEND THE CODEX GENERAL PRINCIPLES FOR THE ADDITION OF ESSENTIAL NUTRIENTS TO FOODS (CAC/GL 09-1987) (Agenda Item 8)¹³

123. The Committee recalled the request of the last session of the committee that the Delegation of Canada should prepare a revised discussion paper narrowing its scope in light of the comments made at that session.

124. The Delegation of Canada introduced their revised discussion paper taking into account comments made at the last session. The delegation indicated that since the adoption in 1987 of the General Principles and their last amendment in 1991, changes in lifestyle and dietary habits have led to an increased availability of foods with added vitamins and mineral nutrients that go beyond the purposes set out in Section 3 – “Basic Principles” of the General Principles: restoration; nutritional equivalence of substitute foods; fortification; and ensuring the appropriate nutrient composition of a special purpose food.

125. The Delegation explained that there were concerns that the General Principles no longer adequately addressed current practices, limited consumer choice and the development of new products and could result in barriers to trade that are not justified based on safety considerations.

126. The Delegation proposed to revise the General Principles and in particular the Basic Principles to expand their applicability to include the discretionary addition of vitamins and mineral nutrients to foods for purposes beyond the prevention or correction of demonstrated deficiencies. The Delegation stressed that it was not their intent to replace the Basic Principles which have a public health basis but to extend them to also set out principles for the safe discretionary addition of vitamin and mineral nutrients to acknowledge current practices and to ensure that they are safe.

127. The Delegation recommended using a risk-based approach including for example: restrictions for which foods it would be prohibited to add vitamins and mineral nutrients at the discretion of the manufacturer (e.g. beverages exceeding a certain alcoholic content, foods considered to have negligible nutritional value; foods exceeding a certain level of risk increasing nutrients etc.); which nutrients could be added; and maximum and minimum levels to which permitted nutrients could be added.

¹³ CX/NFS DU 08/30/8; CRD 8 (Comments from the European Community).

128. The Delegation pointed out that in carrying out the revision, changes would be needed to the “intent” of the General Principles and to the Basic Principles to make provision for discretionary nutrient addition in addition to the four current purposes. Additionally a new Section to address the prevention of the indiscriminate addition of vitamins and mineral nutrients would have to be developed.

129. The Delegation also pointed out the need that the applicability of the General Principles to non-traditional or indirect addition of essential nutrients should be affirmed within the General Principles as these methods were of growing importance. Consideration should be given to the need for any potential additional restrictions for this type of nutrient enhancement e.g., its prohibition for certain types of foods.

130. The Delegation of the European Community warmly welcomed the suggestion to include the concept of discretionary fortification, however reiterated its position that it does not consider appropriate at this stage to enlarge the scope of the General Principles beyond the direct addition of nutrients to foods and that biofortification as well as other forms of indirect fortification should be eventually addressed by a separate activity due to their complexity. The Delegation suggested a number of changes to the draft project document in accordance with their comments in CRD 8 and with these amendments could support initiation of new work.

131. The Delegation of New Zealand supported the revision of the General Principles as outlined by Canada and amended by the European Community but felt that the issue of non-traditional addition of nutrients was an area of work that needed to be addressed at some point.

132. The Delegation of the United States appreciated that Canada had made some revisions to their proposal but noted that it had had very little time to review it. The Delegation was of the opinion that the document as presented did not seem to be consistent with its stated purpose and still included areas where it might not be possible to reach agreement. The Delegation did not support new work at this moment but could support further efforts to narrow the focus so that the work was more clearly defined and did not contradict the principles of fortification. The Delegation supported by Australia suggested continuing to develop the proposal in an electronic working group in order to give more time to study the issue and receive comments from more members.

133. The Delegation of Norway supported the revision of the General Principles but considered that the primary reason for fortification should be a demonstrated need in the population and any revision of the General Principles should take this aspect into account.

134. The Committee agreed to establish an electronic working group led by Canada and working in English only to revise the document in line with the comments made at the Session and for consideration by the 31st Session of the CCNFSDU.

DISCUSSION PAPER ON THE PROPOSAL FOR NEW WORK TO ESTABLISH A STANDARD FOR PROCESSED CEREAL-BASED FOODS FOR UNDERWEIGHT INFANTS AND YOUNG CHILDREN (Agenda Item 9)¹⁴

OTHER BUSINESS AND FUTURE WORK

SUMMARY OF THE PROPOSAL TO REVISE THE CODEX GUIDELINES ON FORMULATED SUPPLEMENTARY FOODS FOR OLDER INFANTS AND YOUNG CHILDREN (Agenda Item 10a)¹⁵

135. The Committee recalled its earlier decision to consider items 9 and 10 together since the two items were interlinked (see para. 5).

¹⁴ CX/NFSDU 08/30/9; CRD 9 (comments from Mali); CRD 12 (prepared by WHO); CRD 20 (comments from IBFAN).

¹⁵ CX/NFSDU 08/30/10; CRD 12 (prepared by WHO); CRD 14 (Technical support paper on separate Codex Standard for Processed Cereal-based Foods for Underweight Infants and Young Children for Developing Countries).

136. The Committee recalled that at its last session it had agreed that the Delegation of India with assistance from other interested parties would revise the document presented at that session and prepare a more structured project document for consideration by this session of the Committee.

137. The Delegation of India introduced their revised proposal (CX/NFSDU 08/30/9) and explained that a separate standard for processed cereal-based foods for underweight infants and young children was necessary to address the needs of the large numbers of underweight infants in developing countries.

138. The Delegation emphasized that the problem of malnutrition was intergenerational in nature. The problem of iron deficient anaemia was widely prevalent in both children under five years of age and in women. In order to address this problem India is implementing a scheme of Integrated Child Development Services (ICDS) under which around 84 million children, pregnant women and lactating mothers are provided with supplementary nutrition, immunization and vaccination. However, 43% of children in India are still malnourished.

139. The Delegation further explained that when complementary foods were introduced to infants after 6 months of age, their energy requirements are not completely met by breast milk. Therefore, adequate intake of energy, protein and other nutrients is required through complementary food of adequate nutrient level for normal growth of children.

140. The Delegation explained that the intention of the proposed new standard was to address three main components: 1) cereal content, 2) protein content and 3) energy density. The Delegation further emphasized that they did not intend to reopen discussions on the already *adopted Standard for Processed Cereal-Based Foods for Infants and Young Children* (CODEX STAN 74-1981).

141. The Delegation urged the Committee to consider this proposal separately from the proposal of Ghana, which also dealt with a strategy to reduce malnutrition but with a different approach namely to introduce a new category of fortified food supplements to the *Guidelines on Formulated Supplementary Foods for Older Infants and Young Children* (CAC/GL 08-1991) as a strategy to improve the quality of home made foods.

142. The Delegation of Ghana introduced their proposal (CX/NFSDU 08/30/10) and agreed that it differed from the proposal from India, while also having the goal of reducing malnutrition in infants and young children. The Delegation informed the Committee that in Ghana, infants were generally exclusively breastfed until the age of 6 months and did generally well until that age. Problems occurred after this period when they started receiving complementary foods which in most cases were generally low in energy and nutrients including minerals and vitamins.

143. The Delegation explained that their proposal was to introduce a new category of foods to the *Guidelines for Formulated Supplementary Foods for Older Infants and Young Children* (CAC/GL 08-1991) to ensure the safety and efficacy of these foods and prevent their misuse. The Delegation stated that their proposal was restricted to the revision of Section 6 of the Guidelines to reflect new information and evidence of energy needs for breastfed children.

144. The Representative of the WHO informed the Committee of the Joint WHO/UNICEF/WFP/UNHCR technical meeting on the management of moderate malnutrition in children under 5 years of age held in Geneva (30 September – 3 October 2008) with the overall aim to answer questions on the type of diets to be recommended to feed moderately malnourished children. The Representative said further that the report of this meeting would be released in early 2009 containing recommendations on the formulation, effectiveness, and efficacy of diets and food supplements to be given to moderately malnourished children. The Representative also informed the Committee that WHO had been asked to form an expert advisory group in collaboration with other agencies (UNICEF, WFP and Codex) within the next 6 months to develop specifications for food supplements for moderately wasted children based on recommendations formulated during this meeting which could possibly be of assistance to both Ghana and India in the development of their proposals to the CCNFSU.

145. The Representative was also of the opinion that the two proposals should be considered separately as the Ghana proposal aimed at developing complementary food supplements that can be made without cereals, while the India proposal was for cereal-based foods.

146. A number of delegations expressed their support for both proposals and for considering them separately, while a number of other delegations supported considering them together.

147. The Delegation of Thailand proposed to consider developing an Annex to the *Standard for Processed Cereal-based Foods for Infants and Young Children*, rather than a new separate standard to address the proposal of India.

148. Some Observers cautioned against the development of a new standard as proposed by India, since several standards already existed and agreed to the proposal made by Thailand. The Observers indicated further that foods referred to in the two proposals were usually distributed by aid agencies and were not commercially available. The Observers also expressed concern that such products if introduced commercially could damage breastfeeding programmes and reduce the use of traditional foods.

149. The Delegation of the European Community while acknowledging that the two proposals intended to tackle very serious problems associated with malnutrition and under-nourishment, noted that several questions remained on both proposals such as (a) who the intended population for the products were, (b) that the proposal of Ghana targeted specifically breastfed infants and did not address the situation of non-breastfed children, (c) that the true nature of these cereal-based foods or supplements was unclear (d) that the composition requirements of these foods needed to be clarified as well as the channels for distribution of these products (commercially available or not) and if commercially available, how risk of confusion by potential users would be avoided and how the work of WHO/UNICEF/WFP/UNHCR could contribute to the consideration of the proposed work. The Delegation also asked that consideration should be given to the options available to the Committee to take forward this work within the Codex process.

150. Some Delegations were of the view that before proceeding with the request for new work on these two distinct proposals, implications of the above concerns should be clarified in more detail for both proposals.

151. The Committee agreed to establish two electronic working groups, led by Ghana and India respectively to prepare revised proposals taking into account the comments and concerns above for consideration by the next session of the Committee. The electronic working groups will be open to all members and observers and work in English only.

MATTERS RELATED TO CONSIDERATION OF THE WHO GLOBAL STRATEGY ON DIET, PHYSICAL ACTIVITY AND HEALTH (Agenda Item 10b)¹⁶

152. The Committee noted the report of the *ad hoc* Physical Working Group and agreed with the recommendation that the Committee should not delay consideration of new work on the development of NRVs associated with increased or decreased risk on non-communicable diseases (CRD 1) but did not consider how to proceed in this respect due to time constraints.

153. The Committee therefore agreed to convene a physical working group to be led by the United States of America and Thailand, open to all members and observers and working in English, French and Spanish that would meet prior to the next session of the Committee and:

- would develop principles and criteria for the development of NRVs for nutrients associated with risk of non-communicable disease; and
- based on the agreed upon principles and criteria, to select and prioritize nutrients for development of NRVs.

¹⁶ CRD 1 (Report of the *ad hoc* Physical Working Group on Health Claims, Nutrient Reference Values and Matters Related to Consideration of the WHO Global Strategy on Diet, Physical Activity, and Health).

154. The Committee agreed that the Delegations of the United States of America and Thailand will prepare a background paper well in advance of the next session of the Committee for circulation to members and observers for comments. The background paper and comments will be considered by the above physical working group in developing their proposals.

DATE AND PLACE OF NEXT SESSION (Agenda Item 11)

155. The Committee was informed that its 31st Session would take place in Germany from 2 to 6 November 2009, subject to confirmation by the Host Government and the Codex Secretariat.

SUMMARY STATUS OF WORK

Subject Matter	Step	For Action by	Reference in ALINORM 09/32/26
Guidelines for Use of Nutrition and Health Claims: Table of Conditions for Nutrient Contents (Part B: Provisions on Dietary Fibre)	8	Governments; CCFL; 32 nd CAC	para. 54 and Appendix II
Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children: Section D Advisory List of Food Additives for Special Nutrient Forms: Provisions on Gum Arabic (Gum acacia)	8	Governments, 41 st CCFA; 32 nd CAC	paras 61-62 and Appendix III
Draft Nutritional Risk Analysis Principles and Guidelines for Application to the Work of the Committee on Nutrition and Foods for the Special Dietary Uses	8	Governments; 25 th - CCGP; 32 nd CAC	para. 82 and Appendix IV
Proposed Draft Recommendations on the Scientific Basis of Health Claims	5/8	Governments, 30 th CCNFSU	para. 102 and Appendix V
List of Methods for Dietary Fibre	6	EWG led by France; Governments; 31 st CCNFSU	paras 49-53
Proposed Draft Additional or Revised Nutrient Reference Values (NRVs)	2/3	EWG led by Republic of Korea; Governments; 31 th CCNFSU	para. 122
Discussion papers			
Proposal for New Work to Amend the Codex General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 09-1987)	-	EWG led by Canada; 31 th CCNFSU	para. 134
Proposal for New Work to Establish a Standard for Processed Cereal-Based Foods for Underweight Infant and Young Children; and	-	India with assistance of EWG; 31 st CCNFSU	paras 135-151
Proposal to Revise the Codex Guidelines on Formulated Supplementary Foods for Older Infants and Young Children	-	EWG led by Ghana, 31 st CCNFSU	paras 137-151
Nutrient Reference Values (NRVs) for Nutrients Associated with Risk of Non-Communicable Disease	-	EWG led by the US, Governments; Physical Working Group Co-Chaired by the US and Thailand	paras 152-154

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APPENDIX II

**GUIDELINES FOR THE USE OF NUTRITION CLAIMS: TABLE OF CONDITIONS FOR
NUTRIENT CONTENTS (PART B) DIETARY FIBRE
(At Step 8 of the Procedure)**

COMPONENT	CLAIM	CONDITIONS
B. NOT LESS THAN		
Dietary Fibre	Source	3 g per 100 g [*] or 1.5 g per 100 kcal or 10 % of daily reference value per serving ^{**}
	High	6 g per 100 g [*] or 3 g per 100 kcal or 20 % of daily reference value per serving ^{**}

* Conditions for nutrient content claims for dietary fibre in liquid foods to be determined at national level.

** Serving size and daily reference value to be determined at national level.

Definition:

Dietary fibre means carbohydrate polymers¹ with ten or more monomeric units², which are not hydrolysed by the endogenous enzymes in the small intestine of humans and belong to the following categories:

- Edible carbohydrate polymers naturally occurring in the food as consumed,
- carbohydrate polymers, which have been obtained from food raw material by physical, enzymatic or chemical means and which have been shown to have a physiological effect of benefit to health as demonstrated by generally accepted scientific evidence to competent authorities,
- synthetic carbohydrate polymers which have been shown to have a physiological effect of benefit to health as demonstrated by generally accepted scientific evidence to competent authorities

Methods of Analysis for Dietary Fibre

→ To be agreed.

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

² Decision on whether to include carbohydrates from 3 to 9 monomeric units should be left to national authorities.

APPENDIX III

**DRAFT ADVISORY LIST OF NUTRIENT COMPOUNDS FOR USE IN FOODS FOR SPECIAL
DIETARY USES INTENDED FOR INFANTS AND YOUNG CHILDREN****(At Step 8 of the Procedure)****Section D: ADVISORY LIST OF FOOD ADDITIVES FOR SPECIAL NUTRIENT FORMS**

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

APPENDIX IV

DRAFT NUTRITIONAL RISK ANALYSIS PRINCIPLES AND GUIDELINES FOR APPLICATION TO THE WORK OF THE COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES**(At Step 8 of the Procedure)****SECTION 1 – BACKGROUND**

1. The *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* (hereafter cited as “Working Principles”) has established general guidance on risk analysis to Codex Alimentarius. These Working Principles were adopted in 2003 and published in this Procedural Manual.
2. The objective of the Working Principles is “to provide guidance to the Codex Alimentarius Commission and the joint FAO/WHO expert bodies and consultations so that food safety and health aspects of Codex standards and related texts are based on risk analysis”. By its reference to health aspects in addition to food safety, the objective provides clearer direction for risk analysis to apply to nutritional matters that are within the mandate of the Codex Alimentarius Commission and its subsidiary bodies.
3. The Nutritional Risk Analysis Principles are established to guide the Codex Alimentarius Commission and its subsidiary bodies - primarily but not exclusively the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) - in applying nutritional risk analysis to their work. This guidance may be used for the work of other Committees since CCNFSDU is also mandated, in accordance with its 4th term of reference, “to consider, amend if necessary, and endorse provisions on nutritional aspects” of foods including those resulting from application of nutritional risk analysis that are developed by other Codex subsidiary bodies.

SECTION 2 – INTRODUCTION

4. Codex nutritional risk analysis addresses nutrients¹ and related substances² and the risk to health from their inadequate and/or excessive intake. Nutritional risk analysis applies the same general approach as traditional food safety risk analysis to consideration of excessive intakes of nutrients and related substances. However, unlike many constituents of food that are the subject of traditional food safety risk analysis (such as food additives, chemical (pesticide and veterinary drug) residues, microbiological pathogens, contaminants and allergens) nutrients and related substances are biologically essential (in the case of essential nutrients) or in other ways potentially favourable to health. Nutritional risk analysis therefore adds a new dimension to traditional risk analysis by also considering risks directly posed by inadequate intakes.
5. The *Nutritional Risk Analysis Principles and Guidelines for Application to the Work of the Committee on Nutrition and Foods for Special Dietary Uses* presented in this document (hereafter cited as “Nutritional Risk Analysis Principles”) are subsidiary to and should be read in conjunction with the Working Principles.

¹ **Nutrient** is defined by Codex *General Principles for the Addition of Essential Nutrients to Foods* (CAC/GL 09-1987) to mean: any substance normally consumed as a constituent of food:

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

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

² A **related substance** is a constituent of food (other than a nutrient) that has a favourable physiological effect.

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

SECTION 3 – SCOPE AND APPLICATION

7. Nutritional risk analysis considers the risk of adverse health effects from inadequate and/or excessive intakes of nutrients and related substances, and the predicted reduction in risk from proposed management strategies. In situations that address inadequate intakes, such a reduction in risk through addressing the inadequacy might be referred to as a nutritional benefit.
8. The food constituents of primary interest in nutritional risk analysis are inherent components of food and/or intentionally added to food and are identified as:
 - nutrients that may reduce the risk of inadequacy and those that may increase the risk of adverse health effects; and/or
 - related substances² that may increase the risk of adverse health effects at excessive intake and may also reduce the risk of other adverse health effects at lower intake.
9. When favourable effects of the nutrient or related substance of primary interest are being assessed, consideration should be given to whether the food matrix could increase the risk of an adverse health effect.
10. Where appropriate, the application of quantitative nutritional risk assessment may guide decision making on quantitative content provisions for nutrients and related substances in certain Codex texts.
11. Nutritional risk assessment should be as quantitative as possible, although a qualitative risk-based approach drawing on the principles of nutritional risk analysis could assist the development of Codex texts in such situations as:
 - formulating general principles related to nutritional composition (e.g. principles for the addition of nutrients to foods);
 - formulating general principles for assessing or managing risks related to foods for which a nutrition or health claim has been requested;
 - managing risks by labelling advice in relation to consumption of foods of certain nutrient-related³ composition, including foods for special dietary use; and
 - advising on risk-risk analysis (e.g. risk associated with a significantly reduced or entirely avoided consumption of a nutritious, staple food in response to a dietary hazard such as a contaminant present in that food).

SECTION 4 – DEFINITIONS

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

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

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

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

Adverse health effect⁴ – A change in the morphology, physiology, growth, development, reproduction or life span of an organism, system, or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress, or an increase in susceptibility to other influences.

Nutrient-related³ hazard – A nutrient or related substance in food that has the potential to cause an adverse health effect depending on inadequate or excessive level of intake.

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

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

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

Upper level of intake⁴ – the maximum level of habitual intake from all sources of a nutrient or related substance judged to be unlikely to lead to adverse health effects in humans.

Highest observed intake⁴ – the highest level of intake observed or administered as reported within a stud(ies) of acceptable quality. It is derived only when no adverse health effects have been identified.

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

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

Bioavailability⁵ – The proportion of the ingested nutrient or related substance that is absorbed and utilised through normal metabolic pathways. Bioavailability is influenced by dietary factors such as chemical form, interactions with other nutrients and food components, and food processing/preparation; and host-related intestinal and systemic factors.

Homeostatic mechanism⁴ – A mechanism effected through a system of controls activated by negative feedback that allow the maintenance of normal body functions in the presence of a variable nutrition environment.

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

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

SECTION 5 – PRINCIPLES FOR NUTRITIONAL RISK ANALYSIS

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

PRELIMINARY NUTRITIONAL RISK MANAGEMENT ACTIVITIES

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

Nutritional Problem Formulation⁴

16. Nutritional Problem Formulation is necessary to identify the purpose of a nutritional risk assessment and is a key component of preliminary nutritional risk management activity because it fosters interactions between risk managers and risk assessors to help ensure common understanding of the problem and the purpose of the risk assessment.
17. Such considerations should include whether a nutritional risk assessment is needed and if so:
- the priority it should be accorded;
 - who should conduct and be involved in the nutritional risk assessment, nutritional risk management and nutritional risk communication processes;
 - the need for development of nutritional risk assessment policy;
 - how the nutritional risk assessment will provide the information necessary to support the nutritional risk management decision;
 - whether data are available to embark on an evaluation of nutritional risks;
 - what level of resources are available; and
 - the timeline for completing the assessment.
18. Specific information to be gathered for nutritional problem formulation may include:
- a detailed inventory of prior knowledge;
 - identification of the (sub)populations to be the focus for the risk assessment, geographical areas or consumer settings to be covered;
 - relevant source(s) of intake ; and
 - the health endpoints to be considered.

NUTRITIONAL RISK ASSESSMENT

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

Nutrient-Related Hazard Identification and Hazard Characterization

20. These two steps are often globally relevant because they are based on available scientific and medical literature that contribute data from diverse population groups. This global relevance for characterization of hazard does not, however, preclude the possibility of a (sub)population-specific hazard.
21. Nutritional risk assessment should take into consideration the nutrient-related hazard(s) posed by both inadequate and excessive intakes. This may include consideration of hazard(s) posed by excessive intakes of accompanying risk-increasing nutrients in the food vehicle(s) under consideration.
22. Nutrient-related hazard identification and characterization should recognize current methodological differences in assessment of nutritional risk of inadequate and excessive intakes, and scientific advances in these methodologies.
23. Nutrient-related hazard characterization should take into account homeostatic mechanisms for essential nutrients, and limitations in the capacity for homeostatic adaptations. It may also take into account bioavailability including factors affecting the bioavailability of nutrients and related substances such as different chemical forms.
24. Nutrient reference standards that may be used to characterize nutrient-related hazard(s) related to adequacy include measures of average requirement. Some globally applicable nutrient reference standards for average requirement have been published by FAO/WHO. Official regional and national nutrient reference standards are also available and have been periodically updated to reflect scientific advances. These are more likely to relate to nutrients than to related substances.
25. Nutrient reference standards that may be used to characterize nutrient-related hazard(s) related to excessive intakes include upper levels of intake. Some globally applicable reference standards of upper level of intake have been published by FAO/WHO. In addition, the establishment of international upper levels of intake and highest observed intake that build on recommendations⁴ may be considered in the future. Some periodically-updated nutrient reference standards are available from regional and national authorities. For some related substances, such standards developed from a systematic review of the evidence are available only in the peer-reviewed scientific literature.
26. The assessment of inadequate and excessive levels of intake of particular nutrients and related substances should take into account the availability of all such scientifically determined reference sources, as appropriate. When using such reference standards for nutrient and related substances in nutritional risk assessment, the basis for their derivation should be explicitly described.

Nutrient-Related Intake Assessment and Risk Characterization

27. These two steps are generally specific to the (sub)population(s) under consideration for risk assessment. The populations relevant to Codex consideration are populations at large in Codex member countries or particular subpopulation groups in these countries defined according to physiological parameters such as age or state of health.
28. Nutrient-related intake assessment and risk characterization should be applied within a total diet context. Where feasible, it would typically involve the evaluation of the distribution of habitual total daily intakes for the target population(s). This approach recognizes that nutrient-related risks are often associated with total intakes from multiple dietary sources, including fortified foods, food supplements⁶, and in the case of certain minerals, water. It may also take into account the bioavailability and stability of nutrients and related substances in the foods consumed.

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

NUTRITIONAL RISK MANAGEMENT

29. The risk management section of the Codex *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* is generally applicable to nutritional risk management. Additional nutritional risk management principles to consider within the Codex framework are identified below.
30. Nutritional risk management can be effected through quantitative measures or qualitative guidance elaborated in Codex texts. Such risk management could involve decisions about nutrient composition, consideration of the suitability of foods containing risk-increasing nutrients for certain purposes or (sub) populations, labelling advice intended to mitigate nutritional risks to public health, and formulation of relevant general principles.

Nutritional risk management decisions should take into account their impact on dietary patterns and consumer behaviour. Such information should be supported by relevant research.

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

NUTRITIONAL RISK COMMUNICATION

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

SECTION 6 – SELECTION OF RISK ASSESSOR BY CCNFSDU

33. Consistent with their important role in providing scientific advice to the Codex Alimentarius Commission and its subsidiary bodies, FAO and WHO are acknowledged as the primary source of nutritional risk assessment advice to Codex Alimentarius. This acknowledgement however, does not preclude the possible consideration of recommendations arising from other internationally recognised expert bodies, as approved by the Commission.
34. All requests for risk assessment advice should be accompanied by terms of reference and where appropriate risk assessment policy to provide guidance to the risk assessor. These parameters should be established by CCNFSDU.

APPENDIX V

DRAFT ANNEX TO THE CODEX GUIDELINES FOR USE OF NUTRITION AND HEALTH CLAIMS: RECOMMENDATIONS ON THE SCIENTIFIC SUBSTANTIATION OF HEALTH CLAIMS¹**(at Step 5/8 of the Procedure)****1. SCOPE**

1.1 These Recommendations are intended to assist competent national authorities in their evaluation of health claims in order to determine their acceptability for use by the industry. The recommendations focus on the criteria for substantiating a health claim and the general principles for the systematic review of the scientific evidence. The criteria and principles apply to the three types of health claims as defined in Section 2.2 of the Guidelines for use of nutrition and health claims.

1.2 These recommendations include consideration of safety in the evaluation of proposed health claims, but are not intended for the complete evaluation of the safety and the quality of a food, for which relevant provisions are laid out by other Codex Standards and Guidelines or general rules of existing national legislations.

2. DEFINITIONS

For the purposes of this Annex:

2.1 Food or food constituent refers to energy, nutrients, related substances, ingredients, and any other feature of a food, a whole food, or a category of foods on which the health claim is based. The category of food is included in the definition because the category itself may be assigned a common property of some of the individual foods making it up.

2.2 Health effect refers to a health outcome as defined in sections 2.2.1 to 2.2.3 of the Guidelines.

3. SCIENTIFIC SUBSTANTIATION OF HEALTH CLAIMS**3.1. Process for the substantiation of health claims**

The systematic review of the scientific evidence for health claims by competent national authorities takes into account the general principles for substantiation. Such a process typically includes the following steps:

- (a) Identify the proposed relationship between the food or food constituent and the health effect;
- (b) Identify appropriate valid measurements for the food or food constituent and for the health effect;
- (c) Identify and categorise all the relevant scientific data;
- (d) Assess the quality of and interpret each relevant scientific study;
- (e) Evaluate the totality of the available relevant scientific data, weigh the evidence across studies and determine if, and under what circumstances, a claimed relationship is substantiated.

¹ Note: This document is intended as an annex to the *Codex Guidelines for the Use of Nutrition and Health Claims* (CAC/GL 23-1997, Rev. 1-2004) and should be read in conjunction with the *Working Principles for Risk Analysis for Food Safety for Application by Governments* (CAC/GL 62-2007)

3.2. Criteria for the substantiation of health claims

3.2.1 The following criteria are applicable to the three types of health claims as defined in section 2.2 of the Guidelines for use of nutrition and health claims:

- (a) Health claims should primarily be based on evidence provided by well-designed human intervention studies. Human observational studies are not generally sufficient *per se* to substantiate a health claim but where relevant they may contribute to the totality of evidence. Animal model studies, *ex vivo* or *in vitro* data may be provided as supporting knowledge base for the relationship between the food or food constituent and the health effect but cannot be considered as sufficient *per se* to substantiate any type of health claim.
- (b) The totality of the evidence, including unpublished data where appropriate, should be identified and reviewed, including: evidence to support the claimed effect; evidence that contradicts the claimed effect; and evidence that is ambiguous or unclear.
- (c) Evidence based on human studies should demonstrate a consistent association between the food or food constituent and the health effect, with little or no evidence to the contrary.

3.2.2 Although a high quality of scientific evidence should always be maintained, substantiation may take into account specific situations and alternate processes, such as:

- (a) 'Nutrient function' claims may be substantiated based on generally accepted authoritative statements by recognised expert scientific bodies that have been verified and validated over time.
- (b) Some Health claims, such as those involving a relationship between a food category and a health effect, may be substantiated based on observational evidence such as epidemiological studies. Such studies should provide a consistent body of evidence from a number of well-designed studies. Evidence-based dietary guidelines and authoritative statements prepared or endorsed by a competent authoritative body and meeting the same high scientific standards may also be used.

3.3. Consideration of the evidence

3.3.1 The scientific studies considered relevant for the substantiation of health claim are those addressing the relationship between the food or food constituent and the health effect. In case of a claimed health effect that cannot be measured directly, relevant validated biomarkers may be used (e.g. plasma cholesterol concentrations for cardiovascular disease risk).

3.3.2 The scientific data should provide adequate characterization of the food or food constituent considered as responsible for the health effect. Where applicable, the characterization includes a summary of the studies undertaken on production conditions, batch-to-batch variability, analytical procedures, results and conclusions of the stability studies, and the conclusions with respect to storage conditions and shelf-life.

3.3.3 The relevant data and rationale that the constituent for which the health claim is made is in a form that is available to be used by the human body should be provided where applicable. If absorption is not necessary to produce the claimed effect (e.g. plant sterols, fibres, lactic acid bacteria), the relevant data and rationale that the constituent reaches the target site or mediates the effect are provided. All available data on factors (e.g. forms of the constituents) that could affect the absorption or utilisation in the body of the constituent for which the health claim is made should also be provided.

3.3.4 The methodological quality of each type of study should be assessed, including study design and statistical analysis.

- (a) The design of human intervention studies should notably include an appropriate control group, characterize the study groups' background diet and other relevant aspects of lifestyle, be of an adequate duration, take account of the level of consumption of the food or food constituent that

can be reasonably achieved in a balanced diet, and assess the influence of the food matrix and total dietary context on the health effect.

- (b) (b) Statistical analysis of the data should be conducted with methods recognized as appropriate for such studies by the scientific community and with proper interpretation of statistical significance.

3.3.5 Studies should be excluded from further review and not included in the relevant scientific data if they do not use appropriate measurements for the food or food constituent and health effect, have major design flaws, or are not applicable to the targeted population for a health claim.

3.3.6 By taking into account the totality of the available relevant scientific data and by weighing the evidence, the systematic review should demonstrate the extent to which:

- (c) the claimed effect of the food or food constituent is beneficial for human health;
- (d) a cause and effect relationship is established between consumption of the food or food constituent and the claimed effect in humans such as the strength, consistency, specificity, dose-response, where appropriate, and biological plausibility of the relationship;
- (e) the quantity of the food or food constituent and pattern of consumption required to obtain the claimed effect could reasonably be achieved as part of a balanced diet as relevant for the target population for which the claim is intended;
- (f) the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.

3.3.7 Based on this evaluation and the substantiation criteria, competent national authorities can determine if, and under what circumstances, a claimed relationship is substantiated.

4. SPECIFIC SAFETY CONCERNS

4.1 When the claim is about a food or food constituent, the amount should not expose the consumer to health risks and the known interactions among constituents should be considered.

4.2 The expected level of consumption should not exceed relevant upper levels of intake for food constituents.

4.3 The exposure assessment should be based on an evaluation of the distribution of usual total daily intakes for the general population^{2,3} and, where relevant, those for vulnerable population groups. It should account for the possibility of cumulative intake from all dietary sources, and of nutritional imbalance due to changes in dietary patterns in response to information to consumers that lays emphasis on the food or food constituent.

5. RE-EVALUATION

Health claims should be re-evaluated. Competent national authorities should re-evaluate health claims either periodically or following the emergence of significant new evidence that has the potential to alter previous conclusions about the relationship between the food or food constituent and the health effect.

² Food and Nutrition Board, Institute of Medicine, National Academy of Sciences. Dietary Reference Intakes: A Risk Assessment Model for Establishing Upper Intake Levels for Nutrients. Washington, D.C. National Academy Press, 1998, p. 8.

³ European Commission, Scientific Committee on Food. Guidelines of the Scientific Committee on Food for the Development of Tolerable Upper Intake Levels for Vitamins and Minerals. SCF/CS/NUT/UPPLEV/11 Final. 28 November 2000. p.4.

APPENDIX VI

**METHODS OF ANALYSIS FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS,
CODEX STAN 72-1981**

Table.1 Methods of analysis recommended for endorsement

Type III method recommendations which are suitable for consideration as the Type II Reference Method using the guidance on selection criteria requested from CCMAS.*

Provision	Requirement	Method	Principle	Type
Calories (by calculation)	Minimum 60kcal (250kJ), maximum 70kcal (295kJ), per 100ml prepared ready for consumption. Compositional provisions are generally specified per 100 kcal or 100 kJ.	Method described in CAC/Vol IX-Ed.1, Part III	Calculation method	Type III <i>Notes</i> - Currently adopted as a Type III method for Special foods in CODEX STAN 234-1999, amended 2007. - The references in this method (methods of analysis and conversion factors for specific food ingredients) need to be updated.
Total fat	Minimum 4.4g/100kcal (1.05g/100kJ); maximum 6.0g/100kcal (1.4g/100kJ).	AOAC 989.05 ISO 8381 IDF 123:2008	Gravimetry (Röse-Gottlieb)	Type I. This method should apply to milk-based infant formula containing ≤ 5% starch or dextrin, <i>Notes</i> - Validated for milk-based infant formulae, except formulae containing starch or dextrin. Reference: Bulletin of the IDF (1988), N°235, J Eisses, <i>Methods for the determination of the fat content, part 3, Infant foods, edibles ices, milk and milk products (special cases), Determination of the fat content according to Röse-Gottlieb or Weibull-Berntrop</i> - Normally regarded as a defining method (Type I).

Total fat	Minimum 4.4g/100kcal (1.05g/100kJ); maximum 6.0g/100kcal (1.4g/100kJ).	ISO 8262-1 IDF 124-1: 2005	Gravimetry (Weibull-Berntrop)	Type I, this method should apply to milk-based infant formula <i>Notes</i> - Validated. References: Schuller, P.L. <i>Report of the collaborative study of CX/MAS on fat determination in infant foods</i>. Codex Committee on Methods of Analysis and Sampling, CX/MAS 75/10, 1975 Bulletin of the IDF (1988), N°235, J Eisses, <i>Methods for the determination of the fat content, part 3, Infant foods, edibles ices, milk and milk products (special cases), Determination of the fat content according to Röse-Gottlieb or Weibull-Berntrop</i> - Normally regarded as a defining method (Type I).
Fatty acids	Lauric and myristic fatty acids combined <20% total fatty acids. Erucic acid <1% total fatty acids. LA ¹ minimum 300mg/100kcal (70mg/100kJ); no maximum; GUL 1400mg/100kcal (330mg/100kJ). ALA ²³ minimum 50mg/100kcal (12mg/100kJ); no maximum limit nor GUL specified. PUFA ⁴ is needed for calculation of α -TE content (see vitamin E).	AOAC 996.06	Gas chromatography	Type III* <i>Notes</i> - Validated (but not for infant formulas). References: J.AOAC Int. <u>80</u>: 555 - 563 (1997). J.AOAC Int. <u>82</u>: 1146 - 1155 (1999). - Adopted as Type II for determination of saturated fat for nutrition labelling purposes. - Information should be adequate for listing as a reference method (Type II), or if not, a tentative method (Type IV).

¹ Linoleic acid
² Guidance Upper Level
³ Alpha-linoleic acid
⁴ Polyunsaturated fatty acids

Trans fatty acids	$\leq 4\%$ of total fatty acids	AOCS Ce 1h-05	Gas liquid chromatography	Type III*, for infant formulae not containing milkfat <i>Notes</i> 1. Method for Determination of <i>cis</i>, <i>trans</i>, Saturated, Monounsaturated and Polyunsaturated Fatty Acids in Vegetable or Non-Ruminant Animal Oils and Fats. 2. Validated (but not for infant formula). Performance statistics were extracted from the collaborative study report and are included with the method. 3. Adopted as Type II for the purposes of the Guidelines for Nutrition Labelling 4. The method states “The method is not suitable for the analysis of dairy, ruminant, marine, long chain polyunsaturated (PUFA) fats and oils, or products supplemented with conjugated linoleic acid (CLA).” The method should therefore be endorsed for infant formulae not containing milkfat.
Trans fatty acids	$\leq 3\%$ of total fatty acids	AOAC 996.06	Gas chromatography	Type IV, with optimisation for the determination of TFAs <i>Notes</i> 1. Method for quantitation of individual fatty acids, including trans 2. A publication describing an improved procedure for the determination of trans fatty acids is available under "Proposed Modifications to AOAC 996.06, Optimizing the Determination of Trans Fatty Acids: Presentation of Data; Rozemat at.: <i>J. AOAC Int'l</i>, VOL. 91, NO. 1, 2008" 3. Validated (but not for infant formulas). References: <i>J.AOAC Int.</i> <u>80</u>: 555 - 563 (1997). <i>J.AOAC Int.</i> <u>82</u>: 1146 - 1155 (1999).
Total phospholipids	$\leq 300\text{mg}/100\text{kcal}$ ($72\text{mg}/100\text{kJ}$)	AOCS Ja7b-91	Gas liquid chromatography	Type IV with suitable extraction and preparation procedures <i>Notes</i> 1. The method is applicable to oil-containing lecithins, deoiled lecithins, lecithin fractions; not applicable to lyso-PC and lyso-PE. 2. Validated. Reference <i>Pure Appl. Chem.</i> 64: 447 - 454 (1992). A summary of statistics from the IUPAC phospholipid collaborative study is included with the method. 3. Suitable extraction and preparation procedures applicable to infant formulae are needed in conjunction with this method. The Walstra & de Graaf procedure for the extraction of the fat is suitable. Reference:

				Walstra, P. & de Graaf, J. J. (1962) <i>Note on the determination of the phospholipid content of milk products</i>. Netherlands Milk & Dairy J., 16, 283-287. 4. Recommended as a tentative method (Type IV) since the method is not validated for infant formula.
Total carbohydrates	Minimum 9.0g/100kcal (2.2g/100kJ); maximum 14.0g/100kcal (3.3g/100kJ).	AOAC 986.25	Determination by difference, i.e. the remainder after deducting fat, ash and crude protein from total solids.	Type II. <i>Notes</i> 1. Validated. Reference: JAOAC 69: 777 - 785 (1986).
Moisture/Total Solids		AOAC 934.01 AOAC 925.23 or IDF 12B:1987 ISO 6731:1989	Gravimetry	Type I <i>Notes</i> No provision for moisture/total solids, however estimation of moisture content (total solids) is needed for calculation of carbohydrates and calories.
Ash		AOAC 942.05	Gravimetry	Type I <i>Notes</i> No provision for ash, however estimation of ash content is needed for calculation of carbohydrates and calories
Vitamin A	Note on the form of Vitamin A in Codex Standard 72 Footnote from Codex Stan 72, 3.1 Essential Composition, Vitamin A <i>Vitamin A: expressed as retinol equivalents (RE).</i> <i>1 µg RE = 3.33 IU Vitamin A = 1 µg all-trans retinol. Retinol contents shall be provided by preformed retinol, while any contents of carotenoids should not be included in the calculation and declaration of vitamin A activity.</i> <u>Comment:</u> Carotenoids are unequivocally excluded from declaration of vitamin A content. The requirement that vitamin A content shall be provided by “preformed retinol” implies only naturally present retinol, and excludes the common vitamin A acetate and palmitate supplements. These forms are physiologically active and may be quantified either specifically as intact esters and aggregated with natural retinol, or converted to retinol during analysis. It would seem that the standard should provide for all forms of retinol present in			

	infant formula, whether preformed or derived from supplemental acetate and/or palmitate forms. It does not make sense to exclude vitamin A added for nutrient purposes from this provision and it seems at the least, that “preformed” should be removed from the standard			
Vitamin A	Minimum 60µg/100kcal (14µg/100kJ); maximum 180µg/100kcal (43µg/100kJ).	AOAC 992.04 (retinol isomers) Vitamin A (both natural + supplemental ester forms) aggregated and quantified as individual retinol isomers (13, cis and all-trans)	High performance liquid chromatography	Type III* <i>Notes</i> - Currently adopted as Type II method for follow-up formula in CODEX STAN 234-1999 rev 2007 and previously listed for infant formula in rev 2006. - Validated: Study matrices included powdered infant formula, powdered milk, and liquid infant formula - Reference: <u>J.AOAC Int. 76</u>.
Vitamin A	Minimum 60µg/100kcal (14µg/100kJ); maximum 180µg/100kcal (43µg/100kJ).	AOAC 992.06 (retinol) Vitamin A (both natural + supplemental ester forms) aggregated and quantified as individual retinol isomers (13, cis and all-trans) 12823-1:2000	High performance liquid chromatography	Type III* <i>Notes</i> - Currently adopted as Type II method for follow-up formula in CODEX STAN 234-1999, amended 2007. - Reference: <u>J. AOAC Int. 76</u>: 300-414 (1993).
Vitamin A	Minimum 60µg/100kcal (14µg/100kJ); maximum 180µg/100kcal (43µg/100kJ).	EN 12823-1:2000 (all-trans-retinol and 13-cis-retinol) Vitamin A (both natural + supplemental ester forms) aggregated and quantified as individual retinol isomers (13, cis and all-trans)	High performance liquid chromatography	Type III <i>Notes</i> - Validated. Precision data for various foods is in CCNFSDU 29th session CRD 15. - Collaboratively tested according to ISO 5725, among others an enriched milk powder was included in the validation. In accordance with the EU MAT Certification Study Guidelines, the parameters for margarine (CRM 122) and milk powder (CRM 421) have been defined in an interlaboratory test. The study was organised by the Institute of Food Research, Norwich, United Kingdom. - Reference: Finglas, P.M., van den Berg, H. & de Froidmont-Gortz, I., 1997. The certification of the mass fractions of vitamins in three reference materials: margarine (CRM 122), milk powder (CRM 421), and lyophilized Brussels sprouts (CRM 431). EUR-Report 18039, Commission of the European Union, Luxembourg.
Vitamin D	Note on the form of Vitamin D in Codex Standard 72 Footnote from Codex Stan 72, 3.1 Essential Composition, Vitamin D			

	<i>Calciferol. 1 µg calciferol = 40 IU vitamin D</i> Comment: Calciferol is not specific and conceivably includes all forms of vitamin D. This currently generic descriptor could therefore include the parent forms of vitamin D2 and D3 and the physiologically antirachitic hydroxylated metabolites. For food nutritional labelling requirements it is however implicit that the parent cholecalciferol (vitamin D3) is the target nutrient, given that this is the form commonly added to infant formulas. The current definition does not discriminate ergocalciferol (vitamin D2) which is rarely added to foods.			
Vitamin D	Minimum 1µg/100kcal (0.25µg/100kJ); maximum 2.5µg/100kcal (0.6µg/100kJ).	AOAC 992.26 (D2 and/or D3 measured as single components. Hydroxylated forms not measured.)	High performance liquid chromatography	Type III, with limitations on applicability to infant formula containing 488-533 IU/L The minimum requirement for vitamin D in Codex STAN 72 is 280 IU/L <i>Notes</i> 1. Validated. The method is applicable to ready-to-feed milk-based infant formulas containing 488 to 533 IU/L vitamin D3. 2. References: <u>J. AOAC 68</u>: 177- 182 (1985) <u>J. AOAC Int. 76</u>: 1042 - 1056 (1993). 3. The method was listed for use with milk based infant formula in CODEX STAN 234-1999, rev. 2006. 4. The minimum requirement for vitamin D3 (1 µg /100 kcal = 40 IU/100 kcal) means 280 IU/L vitamin D3, calculating the maximal energy density (70 kcal/100 ml prepared ready for consumption infant formula) laid down by CODEX STAN 72. This concentration is outside of the applicable concentration range of method AOAC 992.26 (488-533 IU/L). 5. D₂ and/or D₃ measured as single component. Method cannot discriminate if both present. Hydroxylated forms not measured.
Vitamin D	Minimum 1µg/100kcal (0.25µg/100kJ); maximum 2.5µg/100kcal (0.6µg/100kJ).	EN 12821:2000 (D2 and/or D3 measured as single components. Hydroxylated forms not measured.)	High performance liquid chromatography	Type III*. <i>Notes</i> 1. Precision data for various foods is in CCNFSDU 29th session CRD 15 2. Validated. Collaboratively tested according to ISO 5725, among others an enriched milk powder was included in the validation. 3. Reference: EN 12821:2000. Foodstuffs - Determination of vitamin D by high performance liquid chromatography - Measurement of cholecalciferol (D3) and ergocalciferol (D2) 4. The parameters on margarine (CRM 122) and milk powder (CRM 421) have been defined in an interlaboratory test, in accordance with the EU MAT Certification Study Guidelines. The study was organized by the Laboratory of the Government Chemist, UK. Reference: Finglas, P.M.,

				van den Berg, H. and de Froidmont-Görtz, I., 1997. The certification of the mass fractions of vitamins in three reference materials: margarine (CRM 122), milk powder (CRM 421), and lyophilized Brussels sprouts (CRM 431). EUR-Report 18039, Commission of the European Union, Luxembourg. 5. The parameters on milk, liquid infant, formula, cooking oil, margarine, infant formula and fish oil have been defined in an interlaboratory test according to AOAC Guidelines for collaborative study procedures to validate characteristics of a method of analysis. The study was organized by NMKL (Nordic Committee on Food Analysis). Reference: Staffas A, Nyman A. JAOAC Int., 2003, 86:400-406 6. D2 and D3 measured as single component. Method cannot measure the content of vitamin D if both forms are present. Hydroxylated forms not measured. The method is capable to quantitate D2 and D3 in the same sample, it is just not described.
Vitamin D	Minimum 1µg/100kcal (0.25µg/100kJ); maximum 2.5µg/100kcal (0.6µg/100kJ).	AOAC 995.05 (D ₂ or D ₃ . Method can discriminate if both present. Hydroxylated forms not measured).	High performance liquid chromatography	Type III* <i>Notes</i> 1. Official Methods of AOAC Int. (18th ed., 2005): 50.1.23. 2. References: <u>J. AOAC Int. 75</u>: 566 - 571 (1992). <u>J. AOAC Int. 79</u>: 73 - 80 (1996). 3. Validated. The method is applicable to the determination of 8 to 2600 IU (International Unit; 1 microgram vitamin D = 40 IU) vitamin D/quart (1 quart = 0.946 L) in infant formulas and enteral products. The results of the interlaboratory study supporting acceptance of the method are included in the method. 4. Method can discriminate between D₂ or D₃, if both present. Hydroxylated forms not measured.
Vitamin E	Note on the form of Vitamin E in Codex Standard 72 Footnote from Codex Stan 72, 3.1 Essential Composition, Vitamin E <i>1 mg α-TE (alpha-tocopherol equivalent) = 1 mg d-α-tocopherol</i> <i>Vitamin E content shall be at least 0.5 mg α-TE per g PUFA, using the following factors of equivalence to adapt the minimal vitamin E content to the number of fatty acid double bonds in the formula: 0.5 mg -TE/g linoleic acid (18:2 n-6); 0.75 α-TE/g α-linolenic acid (18:3 n-3); 1.0 mg α-TE/g arachidonic acid (20:4 n-6); 1.25 mg α-TE/g eicosapentaenoic acid (20:5 n-3); 1.5 mg α-TE/g docosahexaenoic acid (22:6 n-3).</i> <u>Comment:</u> The standard does not provide conversion factors to determine tocopherol equivalents derived from the multiple vitamin E congeners potentially present in an infant formula. Neither the congeners (α, β, γ, δ), their tocotrienol equivalents or the supplemental α -tocopheryl acetate form			

	are specified.			
Vitamin E	Minimum 0.5mg/100kcal (0.12mg/100kJ); no maximum limit. GUL 5mg/100kcal (1.2mg/100kJ). Minimum 0.5mg α -TE per g PUFA ⁶ using specified factors of equivalence.	AOAC 992.03 (Measures all-rac-vitamin E (both natural + supplemental ester forms) aggregated and quantified as individual α -congeners)	High performance liquid chromatography	Type III* <i>Notes</i> 1. Reference: J. AOAC Int. 76: 399 - 413 (1993). 2. Validated. The results of the interlaboratory study supporting acceptance of the method (milk-based liquid, ready-to-feed) are stated in the method. 3. The method was listed for use with infant formula in CODEX STAN 234-1999, rev. 2006. 4. Measures all-rac-vitamin E (both natural + supplemental ester forms) aggregated and quantified as individual α-congeners.
Vitamin E	Minimum 0.5mg/100kcal (0.12mg/100kJ); no maximum limit. GUL 5mg/100kcal (1.2mg/100kJ). Minimum 0.5mg α -TE per g PUFA ⁶ using specified factors of equivalence.	EN 12822: 2000 (Measures Vitamin E (both natural + supplemental ester forms) aggregated and quantified as individual tocopherol congeners (α , β , γ , δ)).	High performance liquid chromatography	Type III* <i>Notes</i> 1. Validated. Precision data for various foods incl. milk powder is in CCNFS DU 29th session CRD 15. Collaboratively tested according to ISO 5725, among others, an enriched milk powder was included in the validation. 2. The parameters on margarine (CRM 122) and milk powder (CRM 421) of different methods for the determination of Vitamin E (α-tocopherol) have been defined in an international comparison study organised by the European Commissions Standard, Measurement and Testing program. Reference: Finglas, P.M., van den Berg, H. and de Froidmont-Gortz, I., 1997. The certification of the mass fractions of vitamins in three reference materials: margarine (CRM 122), milk powder (CRM 421), and lyophilized Brussels sprouts (CRM 431). EUR-Report 18039, Commission of the European Union, Luxembourg. 3. In accordance with ISO 5725 : 1986 [19], the validation data on milk powder and oat powder have been defined in an inter-laboratory test. The test was conducted by the Max von Pettenkofer-Institute of the Federal Health Office, Food Chemistry Department, Berlin, Germany. Reference: Untersuchung von Lebensmitteln - Bestimmung von Tocopherolen und Tocotrienolen in diätätischen Lebensmitteln L 49.00-5 September 1998 (Food Analysis - Determination of tocopherols and tocotrienols in dietetic foodstuffs L 49.00-5 September

				1998) in: Amtliche Sammlung von Untersuchungsverfahren nach § 35 LMBG: Verfahren zur Probenahme und Untersuchung von Lebensmitteln, Tabakerzeugnissen, kosmetischen Mitteln und Bedarfsgegenständen/Bundesgesundheitsamt (In: Collection of official methods under article 35 of the German Federal Foods Act, Methods of sampling and analysis of foods, tobacco products, cosmetics and commodity goods/Federal Health Office), Loseblattausgabe September 1998, Bd. 1 (Loose leaf edition as of 1998-09, Vol.1) Berlin, Köln: Beuth Verlag GmbH 4. Measures Vitamin E (both natural + supplemental ester forms) aggregated and quantified as individual tocopherol congeners (α, β, γ, δ).
Vitamin K	Note on the form of Vitamin K in Codex Standard 72. The standard provides no qualification on the definition of forms of vitamin K. Comment: Vitamin K present in infant formulas can include cis and/or trans K₁, dihydro-K₁, and the menaquinone series, and a more rigorous definition may be required.			
Vitamin K	Minimum 4µg/100kcal (1µg/100kJ); no maximum limit; GUL 27µg/100kcal (6.5µg/100kJ)	AOAC 992.27 (trans-K₁).	High performance liquid chromatography.	Type III with limitations on applicability to ready-to-feed milk-based infant formulas containing 75 to 130 micrograms/L <i>trans</i>-vitamin K₁, the minimum requirement for vitamin K in CODEX STAN 72 is 28 µg/L <i>Notes</i> 1. The method was listed for use with infant formula in CODEX STAN 234-1999, rev. 2006. 2. Validated. The method is applicable to ready-to-feed milk-based infant formulas containing 75 to 130 micrograms/L <i>trans</i>-vitamin K₁. 3. The minimum requirement for vitamin K (4 µg /100 kcal) means 28 µg /L vitamin K, calculating the maximal energy density (70 kcal/100 ml prepared ready for consumption infant formula) laid down by the Codex Standard. This concentration is outside of the applicable concentration range of method AOAC 992.27 (75-130 µg /L). 4. References: <u>J. AOAC 68</u>: 684 - 689 (1985) <u>J. AOAC Int. 76</u>: 1042 - 1056 (1993) AOAC 992.27 5. Measures trans-K₁.
Vitamin K	Minimum 4µg/100kcal (1µg/100kJ); no maximum limit;	AOAC 999.15 (Measures either aggregated cis + trans K₁ or can measure individual	High performance liquid chromatography with	Type III* <i>Notes</i> 1. Validated. The method is applicable to the determination of total vitamin K₁ (phyloquinone) in infant formula and milk (fluid, ready-to-

	GUL 27µg/100kcal (6.5µg/100kJ)	cis and trans forms depending on LC column. Can also discriminate and measure dihydro-K ₁ and menaquinones).	C30 column to separate the cis- and the trans-K vitamins	feed, and powdered) containing > 1 microgram vitamin K₁/100 g solids). - Reference: J. AOAC Int. 83: 121- 130 (2000). - Measures either aggregated cis + trans K₁ or can measure individual cis and trans forms depending on LC column. Can also discriminate and measure dihydro-K₁ and menaquinones. Proposed by CCNFSDU 28. CCMAS 28 asked for clarification of the differences from AOAC 992.27. Consideration needs to be given to i) ability to discriminate the cis and trans-forms of K₁ which can be accomplished with a C30 column, ii) whether the menaquinones (K₂) be included. AOAC 999.15 is a more specific fluorescence method than AOAC 999.27 and has a better sample preparation with enzyme instead of a labor-intensive multistep procedure. AOAC 995.15 & EN 14148 are based on a joint AOAC/EN collaborative study. The main weakness with this procedure is that both cis- and trans- K₁ (total K₁) are determined. The cis-form is inactive. To overcome this problem, the C18 HPLC column must be replaced by a C30 HPLC column which separates the two vitamers.
Vitamin K	Minimum 4µg/100kcal (1µg/100kJ); no maximum limit; GUL 27µg/100kcal (6.5µg/100kJ)	EN 14148:2003 (vitamin K ₁) (Measures either aggregated cis + trans K ₁ or can measure individual cis and trans forms depending on LC column.)	High performance liquid chromatography	Type III* - Precision data for various foods including a range of infant formulae is in CCNFSDU 29th session CRD 15. - Validated. The precision data have been defined in an international collaborative study: - Reference: Indyk, H. E. and Woollard, D. C.: Vitamin K in Milk and Infant Formulas by Liquid Chromatography: Collaborative study. J. AOAC intern. 83, 2000, 121-130. - Measures either aggregated cis + trans K₁ or can measure individual cis and trans forms depending on LC column.
Thiamin	Note on the form of Thiamin in Codex Standard 72. The standard provides no qualification on the definition of forms of thiamine. <u>Comment:</u> Several endogenous phosphorylated forms exist in infant formulas, although vitamin B1 is usually dominated by the supplement thiamine hydrochloride. In this case, units of expression (free base vs hydrochloride salt) need to be defined.			
Thiamin	Minimum 60µg/100kcal	AOAC 942.23	Fluorimetry	Type III or IV

	(14µg/100kJ); no maximum limit; GUL 300µg/100kcal (72µg/100kJ)	(Measures all vitamin B ₁ forms and aggregates as thiamine)		1. Currently adopted as Type II method for Special foods in CODEX STAN 234-1999, rev 2007. 2. Validated on many food matrixes, but not infant formula or similar food matrixes. 3. The method has been used traditionally 4. The method is not applicable in presence of materials that adsorb thiamin or which contain extraneous materials which affect thiochrome. 5. References: <u>JAOAC 25</u>: 456- 458 (1942); <u>JAOAC 27</u>: 534 - 537 (1944) ; <u>JAOAC 28</u>: 554 - 559 (1945); <u>JAOAC 31</u>: 455 - 459 (1948); <u>JAOAC 43</u>: 45 - 46 (1960); <u>JAOAC 43</u>: 55 - 57 (1960); AND <u>JAOAC 64</u>: 1336 - 1338 (1981). 6. Measures all vitamin B₁ forms and aggregates as thiamine. Subject to significant spectral interference.
Thiamin	Minimum 60µg/100kcal (14µg/100kJ); no maximum limit; GUL 300µg/100kcal (72µg/100kJ)	AOAC 986.27 (Measures all vitamin B ₁ forms as thiamine)	Fluorimetry	Type III* 1. Validated 2. Reference: JAOAC <u>69</u>: 777 - 785 (1986). 3. Measures all vitamin B₁ forms as thiamine. Subject to significant spectral interference.
Thiamin	Minimum 60µg/100kcal (14µg/100kJ); no maximum limit; GUL 300µg/100kcal (72µg/100kJ)	EN 14122:2003 (Measures all vitamin B ₁ forms (natural and added free, bound and phosphorylated) following extraction and conversion to thiamine)	High performance liquid chromatography with pre-or post column derivatization to thiochrom	Type III* 1. Validated. Precision data for various foods is in CCNFSDU 29th session CRD 15 2. Collaboratively tested according to ISO 5725, among others, an enriched milk powder was included in the validation. In accordance with the EU SMT Certification Study guidelines, the data given for CRM 121 (wholemeal flour), CRM 421 (milk powder), CRM 485 (mixed vegetables) and CRM 487 (pig's liver) have been defined in an interlaboratory test. The Institute of Food Research, Norwich, UK on behalf of the EU Community Bureau of Reference, conducted the study. Reference: Finglas, P. M., Scott, K. J., Witthoft, C. M., van den Berg, H. and de Froidmont-Gortz, I.: The certification of the mass fractions of vitamins in four reference materials: Wholemeal flour

				(CRM 121), milk powder (CRM 421), lyophilised mixed vegetables (CRM 485) and lyophilised pig's liver (CRM 487). EUR-report 18320, Office for Official Publications of the European Communities, Luxembourg, 1999. - The data given for tube feeding solution, baby food, powdered milk, meal with fruits, yeast and cereal, chocolate powder and food supplement have been defined in a French interlaboratory test.. Reference: Arella, F., Lahély, S., Bourguignon, J. B. and Hasselmann, C.: Liquid chromatographic determination of vitamin B1 and B2 in foods. A collaborative study. Food Chem. 56, 1996, 81-86. - Measures all vitamin B₁ forms (natural and added free, bound and phosphorylated) following extraction and conversion to thiamine.
Riboflavin	Note on the form of Riboflavin in Codex Standard 72. The standard provides no qualification on the form of riboflavin. <u>Comment:</u> Several endogenous phosphorylated forms exist in infant formulas, eg free and/or bound riboflavin, FMN, FAD etc. Vitamin B2 is generally enhanced through supplementation with either free riboflavin or FMN.			
Riboflavin	Minimum 80µg/100kcal (19µg/100kJ); no maximum limit; GUL 500µg/100kcal (119µg/100kJ)	AOAC 985.31 (Measures free and bound forms. Uncertain whether phosphorylated forms captured)	Fluorimetry	Type III* - Validated - AOAC 985.31 Riboflavin in Ready-to-Feed Milk-Based Infant Formula, Fluorometric Method. First Action 1985; Final Action 1988. Official Methods of AOAC Int. (18th ed., 2005): 50.1.07. - Reference: <u>IAOAC</u> 68: 514 - 522 (1985). Official Methods of AOAC Int. (18th ed., 2005) cross-references AOAC 985.31 to AOAC 970.65 [45.1.08; Riboflavin (Vitamin B2) in Foods and Vitamin Preparations, Fluorometric method, First Action 1970; Final Action 1971]. AOAC 970.65 dates from the 1970s. - Literature references for AOAC 970.65 date to 1940 and are not included here. - Measures free and bound forms. Uncertain whether phosphorylated forms captured. Subject to significant spectral interference.
Riboflavin	Minimum 80µg/100kcal (19µg/100kJ); no maximum limit; GUL	EN 14152:2003 (Measures natural and supplemental forms, free, bound and phosphorylated (FMN and FAD))	High performance liquid chromatography	Type III* - Validated. Precision data for various foods is in CCNFSDU 29th session CRD 15. - Collaboratively tested according to ISO 5725, an enriched milk powder was included in the validation.

	500µg/100kcal (119µg/100kJ)	aggregated and measured as riboflavin.)		The parameters on CRM 421 (milk powder) and CRM 487 (pig liver) of different methods for the determination of riboflavin (Vitamin B2) have been defined in an international comparison study organised by the European Commissions Standard, Measurement and Testing programme. Reference: Finglas, P. M., Scott, K. J., Witthoft, C. M., van den Berg, H. & de Froidmont-Gortz, I.: The certification of the mass fractions of vitamins in four reference materials: Wholemeal flour (CRM 121), milk powder (CRM 421), lyophilised mixed vegetables (CRM 485) and lyophilised pig's liver (CRM 487). EU Report 18320, Office for Official Publications of the European Communities, Luxembourg, 1999. 3. Both natural and supplemental forms, free, bound and phosphorylated (FMN and FAD) aggregated and measured as riboflavin.
Niacin	Note on the form of Niacin in Codex Standard 72. <i>Niacin refers to preformed niacin.</i> <u>Comment:</u> Niacin is the generic descriptor for two vitamers, nicotinic acid and nicotinamide. However terminology differs between the USA and Europe for this vitamin and this standard needs to be unambiguous. Other forms also exist, eg NAD, NADH etc. It is therefore unclear what is meant by “preformed niacin”.			
Niacin	Minimum 300µg/100kcal (70µg/100kJ); no maximum limit; GUL 1500µg/100kcal (360µg/100kJ)	AOAC 985.34 (niacin (preformed) and nicotinamide)	Microbioassay and turbidimetry	Type III - CCMAS recommended review and replacement with a more modern method. - Validated - AOAC 985.34 Niacin and Niacinamide (Nicotinic Acid and Nicotinamide) in Ready-to-Feed Milk-Based Infant Formula; Microbiological-turbidimetric method. First Action 1985; Final Action 1988. Official Methods of AOAC Int. (18th ed., 2005): 50.1.19. - Reference: <u>JAOAC</u> 68: 514 - 522 (1985). - The method is applicable to baby foods (meat based), beverages, juices, cereal products, cheese, dairy products, fruits and potato products. - Free and bound forms aggregated and measured as nicotinic acid.
Niacin	Minimum 300µg/100kcal (70µg/100kJ); no maximum limit;	prEN 15652:2007 (Free and bound and phosphorylated forms measured either as	High performance liquid chromatography	Type III* when published as EN method - Validated. Precision data for various foods is in CCNFS DU 29th session CRD 15 - Collaboratively tested according to ISO 5725, among others, an

	GUL 1500µg/100kcal (360µg/100kJ)	aggregate of nicotinic acid + nicotinamide, or as individual forms)		enriched milk powder was included in the validation. The precision data for the determination of niacin were established according to ISO 5725-2 in 2002 by an international collaborative study organised by AÉRIAL (CRT: Centre de Ressources technologiques) and the CGd'UMA (Commission Générale d'Unification des Méthodes d'Analyses) according to ISO 5725-2 in 1999 by a French collaborative study organized by CGd'UMA, 3. Reference: - To be published: Bergantzlé M., Validation study on the determination of niacin by HPLC in several matrices; - Lahély S., Bergantzlé M., Hasselmann, C.: Fluorimetric determination of niacin in foods by highperformance liquid chromatography with post-column derivatization Food chem., 65, 129-133 (1999) 4. Free and bound and phosphorylated forms measured either as aggregate of nicotinic acid + nicotinamide, or as individual forms
Vitamin B ₆	Note on the form of Vitamin B₆ in Codex Standard 72. The standard provides no qualification on the form of vitamin B₆. <u>Comment:</u> This means all forms are potentially included, i.e. pyridoxine, pyridoxal, pyridoxamine and the related phosphorylated forms. Vitamin B₆ is generally enhanced through supplementation with pyridoxine, and could be expressed as either the free base or hydrochloride salt. Methods for vitamin B₆ can therefore measure and report single or aggregate forms.			
Vitamin B ₆	Minimum 35µg/100kcal (8.5µg/100kJ); no maximum limit. GUL 175µg/100kcal (45µg/100kJ).	AOAC 985.32 (Aggregates free and bound pyridoxal, pyridoxine and pyridoxamine and measures as pyridoxine.)	Microbioassay	Type III - CCMAS 28 states in general, methods using microbioassay as a principle should be reviewed in order to replace them with more modern methods, and asked for clarification of the differences from AOAC 961.15. - Validated AOAC Method 985.32. (Pyridoxine, Pyridoxal, Pyridoxamine) in Ready-to Feed Milk-Based Infant Formula Microbiological Method. First Action 1985; Final Action 1988. Official Methods of AOAC Int. (18th ed., 2005): 50.1.18. Reference: <u>JAOAC</u> 68: 514 - 522 (1985). - Aggregates free and bound pyridoxal, pyridoxine and pyridoxamine and measures as pyridoxine.

Vitamin B ₆	Minimum 35µg/100kcal (8.5µg/100kJ); no maximum limit. GUL 175µg/100kcal (45µg/100kJ).	AOAC 2004.07 (Free and bound phosphorylated forms (pyridoxal, pyridoxine and pyridoxamine) converted and measured as pyridoxine.)	High performance liquid chromatography	Type III* Validated. The method is applicable to the determination of vitamin B₆ in milk- and soy based liquid infant formula at 0 -1mg/100g. Reference: <u>JAOAC Int.</u> 88: 30 - 37 (2005) Results of the interlaboratory study for vitamin B₆ in reconstituted infant formula (milk- and soy-based) are included with the method. Measures free and bound phosphorylated forms (pyridoxal, pyridoxine and pyridoxamine) converted and measured as pyridoxine.
Vitamin B ₆	Minimum 35µg/100kcal (8.5µg/100kJ); no maximum limit. GUL 175µg/100kcal (45µg/100kJ).	EN 14166:2008 (Aggregates free and bound pyridoxal, pyridoxine and pyridoxamine (including phosphorylated forms) and measures as pyridoxine.)	Microbioassay	Type III - CCMAS 28 states in general, methods using microbioassay as a principle should be reviewed in order to replace them with more modern methods. - Validated. Precision data for various foods is in CCNFSDU 29th session CRD 15 Foodstuffs - Determination of vitamin B₆ by microbiological assay The following data were obtained in an interlaboratory trial held in 1996 between participating European laboratories. Reference: The certification of the mass fractions of vitamins in four reference materials: wholemeal flour (CRM 121), milk powder (CRM 421), lyophilised mixed vegetables (CRM 485) and lyophilised pigs liver (CRM 487). Finglas, P.M., Scott, K.J., Witthoft, C., van den Berg, H. & Froidmont-Görtz, I. (1999); EUR-report 18320, Office for Official Publications of the European Communities, Luxembourg. - Aggregates free and bound pyridoxal, pyridoxine and pyridoxamine (including phosphorylated forms) and measures as pyridoxine.
Vitamin B ₆	Minimum 35µg/100kcal (8.5µg/100kJ); no maximum limit. GUL 175µg/100kcal (45µg/100kJ).	EN 14663:2005 (includes glycosylated forms) (Free and bound phosphorylated and glycosylated forms measured as the individual forms pyridoxal, pyridoxine and	High performance liquid chromatography	Type III Validated. Precision data for various foods (semolina with milk, powder; potato puree, powder; vegetables with ham (baby food); multi vitamin drink) is in CCNFSDU 29th session CRD 15 The precision data for the determination of vitamin B₆ were established in an interlaboratory test according to ISO 5725 carried out by the former BgVV (Bundesinstitut für gesundheitlichen Verbraucherschutz und Veterinärmedizin, German Federal Institute

		pyridoxamine.)		for Consumer protection and veterinary medicine). Reference: Bognár, A.: Bestimmung von Vitamin B6 in Lebensmitteln mit Hilfe der Hochdruckflüssig-Chromatographie (HPLC). Z Lebensm Unters Forsch A, 1985, 181: 200 – 205 2. Free and bound phosphorylated and glycosylated forms measured as the individual forms pyridoxal, pyridoxine and pyridoxamine.
Vitamin B ₆	Minimum 35µg/100kcal (8.5µg/100kJ); no maximum limit. GUL 175µg/100kcal (45µg/100kJ).	EN 14164:2008 (Free and bound phosphorylated forms (pyridoxal, pyridoxine and pyridoxamine) converted and measured as pyridoxine.)	High performance liquid chromatography	Type III* 1. Precision data for the determination of vitamin B6 in baby food, biscuit, cereal, yeast, tube-feeding solution, chocolate powder and powdered milk were established in an interlaboratory test according to ISO 5725 carried out by DGCCRF (Direction Générale de la Concurrence, de la Consommation et de la Repression des Fraudes). Reference: Bergaentzle M., Arella F., Bourguignon J.B., Hasselmann C., Determination of vitamin B6 in foods by HPLC: a collaborative study. Food Chem (1995), 52, 81-86 2. The precision data for the determination of vitamin B6 in reconstituted infant formula were established in an interlaboratory test according to AOAC Guidelines for collaborative study procedures to validate characteristics of a method of analysis. Reference: Mann D.L., Ware G.W., Bonnin E. Liquid Chromatographic analysis of vitamin B6 in reconstituted infant formula: Collaborative Study. JAOAC (2005), 88,1:30-37 3. Free and bound phosphorylated forms (pyridoxal, pyridoxine and pyridoxamine) converted and measured as pyridoxine.
Vitamin B ₁₂	Note on the form of Vitamin B₁₂ in Codex Standard 72. The standard provides no qualification on the form of vitamin B₁₂. <u>Comment:</u> This means all forms are potentially included. However cyanocobalamin is the form used in food supplementation and most extraction conditions employed will convert multiple endogenous forms to a single cyano form.			
Vitamin B ₁₂	Minimum 0.1µg/100kcal (0.025µg/100kJ); no maximum	AOAC 986.23 (Measures total vitamin B₁₂ as cyanocobalamin	Turbidimetric Method	Type III* 1. CCMAS asked for clarification of the differences from AOAC 952.20. A great difference between AOAC 952.20 and AOAC 986.23 methods is the sample matrix; the first is applicable in vitamin

	limit; GUL 1.5µg/100kcal (0.36µg/100kJ)			preparations, but not in infant formulae. 2. Validated AOAC Method 986.23 Cobalamin (Vitamin B12 Activity) in Milk-Based Infant Formula. Turbidimetric method (microbiological). First Action 1986; Final Action 1988. Official Methods of AOAC Int. (18th ed., 2005): 50.1.20. Reference: <u>JAOAC</u> 69: 777 - 785 (1986). 3. Measures total vitamin B₁₂ as cyanocobalamin.
Pantothenic acid	Note on the form of Pantothenic acid in Codex Standard 72. The standard provides no qualification on the form of pantothenic acid. <u>Comment:</u> This means all forms are potentially included eg the free calcium pantothenate supplement and that derived from Coenzyme A. It is important to define units of expression either as pantothenic acid or the calcium salt.			
Pantothenic acid	Minimum 400µg/100kcal (96µg/100kJ); no maximum limit; GUL 2000µg/100kcal (478µg/100kJ)	AOAC 992.07 (Measures total pantothenate (free pantothenic acid + CoA- + ACP-bound) and measured as D-pantothenic acid (or calcium D-pantothenate).)	Microbioassay	Type III. In line with the CCMAS 28 request to review methods using microbioassay as a principle, the suggestion is this method which has been used traditionally should currently be endorsed as Type III and recommended as Type IV when another method can be recommended as Type II or III 1. The method was listed for use with infant formula in CODEX STAN 234-1999, rev. 2006. 2. CCMAS 28 states in general, methods using microbioassay as a principle should be reviewed in order to replace them with more modern methods. 3. Validated. Results of the interlaboratory study supporting acceptance of the method (milk-based liquid, ready-to-feed) are presented in the method. Reference: <u>J. AOAC Int.</u> 76: 399 - 413 (1993). 4. Measures total pantothenate (free pantothenic acid + CoA- + ACP-bound) and measured as D-pantothenic acid (or calcium D-pantothenate).
Folic acid	Note on the form of Folic acid in Codex Standard 72. The standard is specific for folic acid. <u>Comment:</u> Currently the provision is specific for folic acid which implies that only the free supplemental form should be quantified during analysis, and expressed as ug (despite DFE gaining common usage). However, such a test method would exclude all natural forms present in milk, and therefore invalidate currently recommended microbiological assay methods.			
Folic acid	Minimum 10µg/100kcal (2.5µg/100kJ); no	AOAC 992.05 (Measures free folic acid +	Microbioassay	Type III In line with the CCMAS 28 request to review methods using microbioassay as a principle, the suggestion is this method which has been used traditionally should currently be endorsed as Type III and recommended

	maximum limit; GUL 50µg/100kcal (12µg/100kJ)	free, unbound natural folates, aggregated and measured as folic acid.)		as Type IV when another method can be recommended as Type II or III. 1. 2. CCMAS 28 states in general, methods using microbioassay as a principle should be reviewed in order to replace them with more modern methods. 3. Validated. Results of the interlaboratory study supporting acceptance of the method (milk-based, ready-to-feed) are listed in the method. Reference: <u>J. AOAC Int.</u> 76: 399 - 413 (1993). 4. Measures free folic acid + free, unbound natural folates, aggregated and measured as folic acid.
Folic acid	Minimum 10µg/100kcal (2.5µg/100kJ); no maximum limit; GUL 50µg/100kcal (12µg/100kJ)	EN 14131:2003 (Total folate (free + bound), aggregated and measured as folic acid.)	Microbioassay	Type III In line with the CCMAS 28 request to review methods using microbioassay as a principle, this method which has been used traditionally should currently be endorsed as Type III and recommended as Type IV when another method can be recommended as type II or III 1. 2. Validated. Precision data for various foods is in CCNFSDU 29 th session CRD 15 The precision of the method was established by interlaboratory tests conducted within the European Union's Standards, Measurement and Testing (EU SMT) programme, and carried out in accordance with ISO 5725. Reference: Finglas, P.M., et al., The certification of the mass fractions of vitamins in four reference materials: wholemeal flour (CRM 121), milk powder (CRM 421), lyophilized mixed vegetables (CRM 485) & lyophilized pig's liver (CRM 487). B1, B6 & folate in CRM 121; B1, B2, B6, B12 & folate in CRMs 421 & 487, and B1, B6, folate & carotenoids in CRM 485. 1999, Luxembourg: Office for Official Publications of the European Communities. 3. Equivalent to AOAC 992.05. Note that these methods quantify total folate, including folates of natural source and not folic acid alone, which is used as source for fortification. 4. Measures total folate (free + bound), aggregated and measured as folic acid.
Folic acid	Minimum 10µg/100kcal (2.5µg/100kJ); no	J AOAC Int. 2000:83; 1141-1148 (Measures free folic acid +	Optical Biosensor Immunoassay	Not recommended as Type III as it is not established as official methodology. In line with the CCMAS 28 request to review methods using microbioassay as a principle, this method which is recently introduced and

	maximum limit; GUL 50µg/100kcal (12µg/100kJ)	proportion of free, natural folate)		currently under AOAC collaborative study should be endorsed as Type IV 1. Reference: Indyk HE, Evans EA, et al. J AOAC Intl. 2000;83:1141-1148, Determination of Biotin and Folate in Infant Formula and Milk by Optical Biosensor-Based Immunoassay. http://www.atyponlink.com/AOAC/doi/abs/10.5555/jaoi.2000.83.5.1141 2. Measures free folic acid + proportion of free, natural folate.
Folic acid	Minimum 10µg/100kcal (2.5µg/100kJ); no maximum limit; GUL 50µg/100kcal (12µg/100kJ)	J Chromatogr. A., 928, 77-90, 2001 (Measures total folates after conversion to, and measurement as 5-Me-H4PteGlu)	High performance liquid chromatography, incorporating immunoaffinity clean-up and conversion to 5-methyltetrahydrofolate	Not recommended as Type III as it is not established as official methodology. In line with the CCMAS 28 request to review methods using microbioassay as a principle, this method which is recently introduced and currently under AOAC collaborative study should be endorsed as Type IV 1. Under evaluation by CEN TC275/WG9 2. Measures total folates after conversion to, and measurement as 5-Me-H4PteGlu.
Vitamin C	Note on the form of Vitamin C in Codex Standard 72. <i>“expressed as ascorbic acid”</i> Comment: Further clarification of form(s) of vitamin C is required, eg ascorbic acid (AA), oxidised dehydroascorbic acid (DHA), or total ascorbate (AA + DHA), since both forms are physiologically active. However, the enantiomeric D-forms are not antiscorbutic and need to be discriminated.			
Vitamin C	Minimum 10µg/100kcal (2.5µg/100kJ); no maximum limit; GUL 70µg/100kcal (17µg/100kJ)	AOAC 985.33 (measures ascorbic acid (AA))	2,6-dichloroindophenol titrimetry	Type III* 1. . 2. CCMAS asked for clarification on how vitamin C was expressed. Determines only L(+) ascorbic acid and not the total amount for which the amount of dehydroascorbic acid has to be included. This method is specific for reduced ascorbic acid only 3. Validated References: <u>J. AOAC</u> 68: 514 - 522 (1985).
Vitamin C	Minimum 10µg/100kcal (2.5µg/100kJ); no maximum limit; GUL 70µg/100kcal (17µg/100kJ)	EN 14130:2003 (Measures ascorbic acid + dehydroascorbic acid).	High performance liquid chromatography	Type III* 1. . 2. Validated. Precision data for various foods is in CCNFSDU 29 th session CRD 15. Validated Collaboratively tested according to ISO 5725, an enriched milk powder was included in the validation. The precision parameters for orange juice, liquid soup, powder milk,

				freeze-dried soup, breakfast cereals and fruits baby food have been defined in a collaborative study 3. Reference: Arella F., Deborde J.L., Bourguignon J.B., Hasselmann C., (1997), Ann. Fals. Exp. Chim., 90, N°940:217-233. 4. Measures total L-ascorbate (Ascorbic acid + dehydroascorbic acid).
Biotin	Note on the form of Biotin in Codex Standard 72 The standard provides no qualification on the form of biotin. <u>Comment:</u> Free d-biotin is generally used as a supplement. However, endogenous biotin is mostly present as a protein-bound form, which may be liberated as bioactive d-biocyten. Attention needs to be given to which forms are to be quantified.			
Biotin	Minimum 1.5µg/100kcal (0.4µg/100kJ); no maximum limit. GUL 10µg/100kcal (2.4µg/100kJ)	EN 15607:2008 (d-biotin) (Measures total D-biotin (free + D-biocyten))	High performance liquid chromatography	Type III* 1. 2. Validated. Precision data for various foods including infant milk powder is in CCNFSDU 29th session CRD 15. Collaboratively tested according to ISO 5725, among others, an enriched infant milk powder was included in the validation. The data were obtained in an interlaboratory study organized by CGd'UMA (Commission Générale d'Unification des Méthodes d'Analyses) in 2000. It was organized in accordance with ISO 5725-2. Reference: Arella, F., Deborde, J.L., Bourguignon, J.B., Bergaentlze, M., Ndaw, S., Hasselmann, C.: Liquid chromatographic determination of biotin in foods. A collaborative study. Ann. Fals. Exp. Chim., 93, 951,193-200 (2000) 3. Measures total D-biotin (free + D-biocyten)
Iron	Minimum 0.45mg/100kcal (0.1mg/100kJ); no maximum limit. GUL footnote: "levels may need to be determined by national authorities".	AOAC 985.35	Atomic absorption spectrophotometry	Type II The method is applicable to the determination of Ca, Mg, Fe, Zn, Cu, Mn, Na, and K. Validated. Interlaboratory study matrices include enteral product, ready-to-feed soy formula, soy powder and whey powder (same matrices as AOAC 986.24 Phosphorus). The results of the interlaboratory study supporting acceptance of the method are presented in the method. References: <u>JAOAC</u> 68: 514 - 522 (1985), <u>J. AOAC Int.</u> 80: 834 - 844 (1997).

Iron	Minimum 0.45mg/100kcal (0.1mg/100kJ); no maximum limit. GUL footnote: "levels may need to be determined by national authorities".	AOAC 984.27	ICP emission spectroscopy	Type III Validated Reference: <u>JAOAC 67</u> : 985 - 992 (1984).
Calcium	Minimum 50mg/100kcal (12mg/100kJ); no maximum limit; GUL 140mg/100kcal (35mg/100kJ). Calcium to phosphorus ratio: minimum 1:1 and maximum 2:1	ISO 8070 IDF 119: 2007	Flame atomic absorption spectrophotometry	Type II Current Codex method for special foods, and adopted by CAC 31 for infant formula, Type II, for determination of Na and K. Reference of the collaborative study: International Dairy Journal, Volume 18, Issue 9, September 2008, Pages 899-904, Determination of sodium, potassium, calcium and magnesium content in milk products by flame atomic absorption spectrometry (FAAS): A joint ISO/IDF collaborative study, Laurent Noël, Michael Carl, Christelle Vastel and Thierry Guérin
Calcium	Minimum 50mg/100kcal (12mg/100kJ); no maximum limit; GUL 140mg/100kcal (35mg/100kJ). Calcium to phosphorus ratio: minimum 1:1 and maximum 2:1	AOAC 985.35	Atomic absorption spectroscopy	Type III Validated. Interlaboratory study matrices include enteral product, ready-to-feed soy formula, soy powder and whey powder (same matrices as AOAC 986.24 Phosphorus). The results of the interlaboratory study supporting acceptance of the method are presented in the method. References: <u>JAOAC 68</u> : 514 - 522 (1985), <u>J. AOAC Int. 80</u> : 834 - 844 (1997).
Calcium	Minimum 50mg/100kcal (12mg/100kJ); no maximum limit; GUL 140mg/100kcal	AOAC 984.27	ICP emission spectroscopy	Type III Current Codex method (Type III) for Special foods. Validated Reference: <u>JAOAC 67</u> : 985 - 992 (1984).

	(35mg/100kJ). Calcium to phosphorus ratio: minimum 1:1 and maximum 2:1			
Phosphorus	Minimum 25mg/100kcal (6mg/100kJ); no maximum limit; GUL 100mg/100kcal (24mg/100kJ)	AOAC 986.24	Spectrophotometry (molybdovanadate)	Type II Current Codex method for special foods. . Validated. The collaborative study was performed with soy powder infant formula, whey powder infant formula, soy ready-to-feed formula and enteral formula. The results of the interlaboratory study supporting acceptance of the method are included in the method. References: JAOAC 69: 777-785 (1986) J. AOAC Int. 80: 834-844 (1997)
Phosphorus	Minimum 25mg/100kcal (6mg/100kJ); no maximum limit; GUL 100mg/100kcal (24mg/100kJ)	AOAC 984.27	ICP emission spectroscopy	Type III Calcium, Copper, Iron, Magnesium, Manganese, Phosphorus, Potassium, Sodium, and Zinc in Infant Formula. In this method, a test portion is digested in HNO_3 / HClO_4 and elements are determined by ICP emission spectroscopy. Official Methods of AOAC Int. (18th ed., 2005): 50.1.15. Reference: <u>JAOAC 67</u>: 985 - 992 (1984).
Magnesium	Minimum 5mg/100kcal (1.2mg/100kJ); no maximum limit. GUL 15mg/100kcal (3.6mg/100kJ)	ISO 8070 IDF 119: 2007	Flame atomic absorption spectrophotometry	Type II Current Codex method for special foods and infant formula, Type II, for determination of Na and K. Reference of the collaborative study: International Dairy Journal, Volume 18, Issue 9, September 2008, Pages 899-904, Determination of sodium, potassium, calcium and magnesium content in milk products by flame atomic absorption spectrometry (FAAS): A joint ISO/IDF collaborative study, Laurent Noël, Michael Carl, Christelle Vastel and Thierry Guérin
Magnesium	Minimum 5mg/100kcal (1.2mg/100kJ); no maximum limit. GUL 15mg/100kcal	AOAC 985.35	Atomic absorption spectroscopy	Type III Validated for infant formula. Interlaboratory study matrices include enteral product, ready-to-feed soy formula, soy powder and whey powder (same matrices as AOAC 986.24 Phosphorus). The results of the interlaboratory

	(3.6mg/100kJ)			study supporting acceptance of the method are presented in the method. References: <u>JAOAC 68</u> : 514 - 522 (1985), <u>J. AOAC Int. 80</u> : 834 - 844 (1997).
Magnesium	Minimum 5mg/100kcal (1.2mg/100kJ); no maximum limit. GUL 15mg/100kcal (3.6mg/100kJ)	AOAC 984.27	ICP emission spectroscopy	Type III Validated Reference: <u>JAOAC 67</u> : 985 - 992 (1984).
Chloride	Minimum 50mg/100kcal (12mg/100kJ); maximum 160mg/100kcal (38mg/100kJ); no GUL	AOAC 986.26	Potentiometry	Type II Validated Reference: <u>JAOAC 69</u> : 777 - 785 (1986).
Manganese	Minimum 1µg/100kcal (0.25µg/100kJ); no maximum limit. GUL 100µg/100kcal (24µg/100kJ)	AOAC 985.35	Atomic absorption spectrophotometry	Type II Validated. Interlaboratory study matrices include enteral product, ready-to-feed soy formula, soy powder and whey powder (same matrices as 986.24 phosphorus). References: <u>JAOAC 68</u> : 514 - 522 (1985) <u>J. AOAC Int. 80</u> : 834 - 844 (1997).
Manganese	Minimum 1µg/100kcal (0.25µg/100kJ); no maximum limit. GUL 100µg/100kcal (24µg/100kJ)	AOAC 984.27	ICP emission spectroscopy	Type III Validated Reference: <u>JAOAC 67</u> : 985 - 992 (1984).
Iodine	Minimum 10µg/100kcal (2.5µg/100kJ); no maximum limit; GUL 60	AOAC 992.24	Ion-selective potentiometry	Type II, for milk-based formula Current Codex method for milk-based follow-up formula, and was listed in CODEX STAN 234 (2006 revision) for milk-based infant formula (Type II method).

	µg/100kcal (14µg/100kJ)			Validated. The method is applicable to ready-to-feed milk-based infant formula containing 75-150 microgram/L iodide. The results of the interlaboratory study supporting acceptance of the method (ready-to-feed milk-based infant formula) are stated in the method. Reference: <u>J AOAC Int.</u> <u>76</u> : 1042 - 1056 (1993).
Selenium	Minimum 1µg/100kcal (0.24µg/100kJ); no maximum limit; GUL 9µg/100kcal (2.2µg/100kJ)	AOAC 996.17	Continuous hydride generation atomic absorption spectrometry (HGAAS)	Type IV Validated (not with infant formula). Interlaboratory study included samples with selenium levels from 0.25 to 5,450 micrograms/g. Accuracy of method was substantiated by in-house analyses of NIST SRMs (1657 Wheat Flour; 1577a Bovine Liver; 1643c Trace Elements in Water). The results of the interlaboratory study supporting acceptance of the method are listed in the method. Reference: <u>J. AOAC Int.</u> <u>80</u> : 469 - 480 (1997).
Selenium	Minimum 1µg/100kcal (0.24µg/100kJ); no maximum limit; GUL 9µg/100kcal (2.2µg/100kJ)	EN 14627	Hydride generation atomic absorption spectrometry (HGAAS)	Type IV Foodstuffs. Determination of trace elements. Determination of total arsenic and selenium by hydride generation atomic absorption spectrometry (HGAAS) after pressure digestion Not validated for infant formulas
Selenium	Minimum 1µg/100kcal (0.24µg/100kJ); no maximum limit; GUL 9µg/100kcal (2.2µg/100kJ)	AOAC 2006.03	ICP emission spectroscopy	Type IV Validated (not with infant formula). Interlaboratory study included samples with selenium levels from 0.25 to 257 micrograms/g. The results of the interlaboratory study supporting acceptance of the method are included in the method. Reference: <u>J. AOAC Int.</u> <u>89</u> : 1447 - 1466 (2006).
Copper	Minimum 35µg/100kcal (8.5µg/100kJ); no maximum limit. GUL 120µg/100kcal (29µg/100kJ). Footnote: “adjustment may	AOAC 985.35	Atomic absorption spectroscopy	Type II Validated. Interlaboratory study matrices include enteral product, ready-to-feed soy formula, soy powder and whey powder (same matrices as 986.24 Phosphorus). The results of the interlaboratory study supporting acceptance of the method are presented in the method. References: <u>JAOAC</u> <u>68</u> : 514 - 522 (1985) <u>J. AOAC Int.</u> <u>80</u> : 834 - 844 (1997).

	be needed in these levels for IF made in regions with a high content of copper in the water supply".			
Copper	Minimum 35µg/100kcal (8.5µg/100kJ); no maximum limit. GUL 120µg/100kcal (29µg/100kJ). Footnote: "adjustment may be needed in these levels for IF made in regions with a high content of copper in the water supply".	AOAC 984.27	ICP emission spectroscopy	Type III Validated for infant formula Reference: <u>JAOAC 67</u> : 985 - 992 (1984).
Zinc	Minimum 0.5mg/100kcal (0.12mg/100kJ); no maximum limit. GUL 1.5mg/100kcal (0.36mg/100kJ)	AOAC 985.35	Atomic absorption spectroscopy	Type II Applicable to Ca, Mg, Fe, Zn, Cu, Mn, Na, and K. Validated. Interlaboratory study matrices include enteral product, ready-to-feed soy formula, soy powder and whey powder (same matrices as 986.24 Phosphorus). The results of the interlaboratory study supporting acceptance of the method are presented in the method References: <u>JAOAC 68</u> : 514 - 522 (1985) <u>J. AOAC Int. 80</u> : 834 - 844 (1997).
Zinc	Minimum 0.5mg/100kcal (0.12mg/100kJ); no maximum limit. GUL 1.5mg/100kcal	AOAC 984.27	ICP emission spectroscopy	Type III Validated for infant formula. Reference: <u>JAOAC 67</u> : 985 - 992 (1984).

	(0.36mg/100kJ)			
Choline	Note on the form of Choline in CODEX STAN 72. The standard provides no qualification on the form of choline. <u>Comment:</u> Free choline is one of a number of salts used as supplement. However a number of bound forms are also present in infant formulas including added lecithin and endogenous components of milk phospholipid. Units of expression also require definition (eg as choline hydroxide).			
Choline	Minimum 7mg/100kcal (1.7mg/100kJ); no maximum limit; GUL 50mg/100kcal (12mg/100kJ)	AOAC 999.14	Enzymatic Colorimetric Method	Type II, with limitations on applicability due to choline and ascorbate concentration. 4. Validated. 5. The method is applicable to the determination of choline in milk and infant formula containing 45-175 mg solids/100 g. The method does not apply to powdered infant formula/milk containing more than 100 mg vitamin C/100 g solids because of ascorbate suppression of color development. The results of the interlaboratory study supporting acceptance of the method are included in the method. 6. References: <u>J.AOAC Int.</u> 83: 131 - 138 (2000). <u>JAOAC</u> 87: 1297-1304 (2004)
Chromium (Section B of STAN 72 only)	Minimum 1.5µg/100kcal (0.4µg/100kJ); no maximum limit. GUL 10µg/100kcal (2.4µg/100kJ)	EN 14082	AAS after dry ashing	Type IV Foodstuffs. Determination of lead, cadmium, zinc, copper, iron, and chromium by AAS after dry ashing. Infant formula was not included in the validation.
Chromium (Section B of STAN 72 only)	Minimum 1.5µg/100kcal (0.4µg/100kJ); no maximum limit. GUL 10µg/100kcal (2.4µg/100kJ)	EN 14083	Graphite furnace AAS after pressure digestion	Type IV. Foodstuffs. Determination of lead, cadmium, chromium and molybdenum by GF-AAS after pressure digestion. Infant formula was not included in the validation.
Chromium (Section B of STAN 72 only)	Minimum 1.5µg/100kcal (0.4µg/100kJ); no maximum limit. GUL	AOAC 2006.03	ICP emission spectroscopy	Type IV Arsenic, Cadmium, Cobalt, Chromium, Lead, Molybdenum, Nickel, and Selenium in Fertilizers (Microwave Digestion and Inductively Coupled Plasma-Optimal Emission Spectrometry). Infant formula was not included in the validation.

	10µg/100kcal (2.4µg/100kJ)			Reference: <u>J. AOAC Int. 89</u> : 1447 - 1466 (2006).
Molybdenum (Section B of STAN 72 only)	Minimum 1.5µg/100kcal (0.4µg/100kJ); no maximum limit. GUL 10µg/100kcal (2.4µg/100kJ)	EN 14083	Graphite furnace AAS after pressure digestion	Type IV Foodstuffs. Determination of lead, cadmium, chromium and molybdenum by GF-AAS after pressure digestion. Infant formula was not included in the validation.
Molybdenum (Section B of STAN 72 only)	Minimum 1.5µg/100kcal (0.4µg/100kJ); no maximum limit. GUL 10µg/100kcal (2.4µg/100kJ)	AOAC 2006.03	ICP emission spectroscopy	Type IV Arsenic, Cadmium, Cobalt, Chromium, Lead, Molybdenum, Nickel, and Selenium in Fertilizers (Microwave Digestion and Inductively Coupled Plasma-Optimal Emission Spectrometry). Reference: <u>J. AOAC Int. 89</u> : 1447 - 1466 (2006).