

# codex alimentarius commission



FOOD AND AGRICULTURE  
ORGANIZATION  
OF THE UNITED NATIONS

WORLD  
HEALTH  
ORGANIZATION



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

**ALINORM 03/26A**

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

### **CODEX ALIMENTARIUS COMMISSION**

**Twenty-sixth Session**

**Rome, Italy, 30 June– 5 July 2003**

### **REPORT OF THE 24<sup>th</sup> SESSION OF THE CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES**

**Berlin, Germany**

**4 – 8 November 2002**

**Note:** This document incorporates Circular Letter CL 2002/51-NFSDU

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CX 5/20.2

CL 2002/51-NFSDU  
November 2002

**TO:** Codex Contact Points  
Interested International Organizations

**FROM:** Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme  
FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy

**SUBJECT:** Distribution of the Report of the 24<sup>th</sup> Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (ALINORM 03/26A)

## REQUEST FOR COMMENTS AND INFORMATION

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

1. **Proposed Draft Revised Standard for Infant Formula at Step 3 (para. 54 and Appendix II)**
2. **Proposed Draft Revised Standard for Cereal - Based Foods for Infants and Young Children (para. 86 and Appendix III)**

Governments and international organizations wishing to comment on points 1. and 2. should do so in writing to: Dr Rolf Grossklaus, Director and Professor, Federal Institute for Risk Assessment, P.O. Box 33 00 13, 14191 Berlin, Germany, Fax: +49 1888 412 - 37 15, e-mail: ccnfsdu@bgrv.de with a copy to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy (fax: +39 06 5705 4593, e-mail: codex@fao.org) , **before 30 May 2003**.

Comments on Section 3. Food Additives of both Proposed Draft Standards should be directed to: Mrs Awilo **Ochieng Pernet**, Codex Contact Point of Switzerland, Main Unit Food Safety, Swiss Federal Office of Public Health, 3003 Bern, Switzerland, Fax:+41 (31) 3 22 95 74, email:awilo.ochieng@bag.admin.ch with a copy to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy (fax: +39 06 5705 4593, e-mail: codex@fao.org), **before 30 May 2003**

3. **Proposed Draft Guidelines for Vitamin and Mineral Supplements at Step 3 (para. 100 and Appendix IV)**

Governments and international organizations wishing to comment should do so in writing to: Dr Rolf Grossklaus, Director and Professor, Federal Institute for Risk Assessment, P.O. Box 33 00 13, 14191 Berlin, Germany, Fax: +49 1888 412 - 37 15, e-mail: ccnfsdu@bgrv.de with a copy to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy (fax: +39 06 5705 4593, e-mail: codex@fao.org) , **before 30 May 2003**.



## SUMMARY AND CONCLUSIONS

The summary and conclusions of the 24<sup>th</sup> Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses are as follows:

### **Matters for consideration by the Commission**

The Committee:

- agreed to initiate new work on Proposed Draft Recommendations on the Scientific Basis of Health Claims in conjunction with the Draft Guidelines for Use of Health and Nutrition Claims elaborated by the Committee on Food Labelling (para. 4).

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

The Committee:

- agreed to return to Step 3 the Proposed Draft Revised Standard for Infant Formula (para. 54, Appendix II);
- agreed to return to Step 3 the Proposed Draft Revised Standard for Processed Cereal-Based Foods for Infant and Young Children (para. 86, Appendix III);
- agreed to return to Step 3 the Proposed Draft Guidelines on Vitamin and Mineral Supplements (para. 100, Appendix IV);
- agreed to return to Step 2/3 for redrafting and comments the Proposed Draft Revised Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Use by Infants and Young Children (para. 112 );
- agreed to consider the Draft Table of Conditions for Nutrient Contents (Dietary Fibre) and the Draft Revised Standard for Gluten-Free Foods at Step 7 at its next session in the light of the scientific evidence available at that time (paras. 20 and 131).

## TABLE OF CONTENTS

	<b>Paragraphs</b>
INTRODUCTION .....	1
OPENING OF THE SESSION .....	2
ADOPTION OF THE AGENDA .....	3
MATTERS REFERRED TO THE COMMITTEE BY THE CODEX ALIMENTARIUS COMMISSION AND/OR OTHER CODEX COMMITTEES .....	4-14
GUIDELINES FOR USE OF NUTRITION CLAIMS: DRAFT TABLE OF CONDITIONS FOR NUTRIENT CONTENTS (PART B CONTAINING PROVISIONS ON DIETARY FIBRE) .....	15-20
PROPOSED DRAFT REVISED STANDARD FOR INFANT FORMULA .....	21-54
PROPOSED DRAFT REVISED STANDARD FOR PROCESSED CEREAL-BASED FOODS FOR INFANTS AND YOUNG CHILDREN .....	55-86
PROPOSED DRAFT GUIDELINES FOR VITAMIN AND MINERAL SUPPLEMENTS .....	87-100
PROPOSED DRAFT REVISION OF THE ADVISORY LIST(S) OF MINERAL SALTS AND VITAMIN COMPOUNDS FOR THE USE IN FOODS FOR INFANTS AND YOUNG CHILDREN (CAC/GL 10-1979) .....	101-112
DISCUSSION PAPER ON THE FINDINGS OF FAO/WHO EXPERT CONSULTATION IN RELATION TO ENERGY CONVERSION FACTORS .....	113-115
DISCUSSION PAPER ON PROGRESS OF WORK BY FAO/WHO AND NATIONAL SCIENTIFIC BODIES IN RELATION TO RISK-BASED APPROACH FOR THE ESTABLISHMENT OF UPPER LIMITS FOR NUTRIENTS .....	116-126
OTHER BUSINESS AND FUTURE WORK .....	127-134
DATE AND PLACE OF THE NEXT SESSION .....	135

## LIST OF APPENDICES

	<b>Pages</b>
APPENDIX I LIST OF PARTICIPANTS .....	18
APPENDIX II PROPOSED DRAFT REVISED STANDARD FOR INFANT FORMULA .....	38
APPENDIX III PROPOSED DRAFT REVISED STANDARD FOR PROCESSED CEREAL-BASED FOODS FOR INFANTS AND YOUNG CHILDREN .....	49
APPENDIX IV PROPOSED DRAFT GUIDELINES FOR VITAMIN AND MINERAL SUPPLEMENTS .....	56

## INTRODUCTION

1) The Twenty-fourth Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) was held from 4 to 8 November 2002 in the Federal Institute for Risk Assessment, Berlin, by courtesy of the Government of Germany. Dr. Rolf Grossklaus, Director and Professor at the above Institute, chaired the session. The Session was attended by 223 delegates, observers and advisors representing 55 Member countries and 28 International Organizations.

## OPENING OF THE SESSION

2) Mr. Alexander Müller, speaking as State-Secretary on behalf of the Federal Ministry of Consumer Protection, Food and Agriculture, welcomed the participants on behalf of the Minister and opened the Session. Mr. Müller noted the importance and relevance of the work of the Committee and encouraged the widest range of opinions to be expressed during discussions of the Committee to ensure the highest standards worldwide to protect the health of consumers and to ensure fair trade practices. He noted the positive impact of Codex standards in improving food quality and their important role in the SPS and TBT Agreements of the WTO. Attention was drawn to the 40 years of Codex work that had taken place and the positive impact on the quality and variety of foods available to consumers. Mr. Müller emphasized the importance of basing decisions on standards on state of the art science. He noted that the intense national debate that had taken place on food safety had focused public attention on specific issues that led to restructuring of the Ministry to enhance and guarantee food safety for consumers. Attention was also drawn to the recent restructuring of its subsidiary bodies to further encourage science and consumer interests and to separate risk assessment from risk management. Mr. Müller wished success to the meeting and to the delegates in their important work.

## ADOPTION OF THE AGENDA (Agenda item 1)

3) The Committee adopted the Provisional Agenda as the Agenda for the Session and agreed to discuss Agenda Item 9 following discussion of Agenda Item 3. It was agreed that under Item 10. Other Business and Future Work, the Report of the Prolamin Working Group and a paper on the revision of the Recommended Code of Hygiene Practice for Foods for Infants and Children (CAC/RCP 21-1979) prepared by the Delegation of the United States would be considered (CRD 11).

## MATTERS REFERRED BY THE CODEX ALIMENTARIUS COMMISSION AND/OR OTHER CODEX COMMITTEES (Agenda item 2)<sup>1</sup>

### Committee on Food Labelling

4) The Committee considered the request from the Committee on Food Labelling to develop criteria for the scientific basis of health claims, in conjunction with the Proposed Draft Guidelines for Use of Health and Nutrition Claims, subsequently adopted at Step 5 by the Executive Committee. The Committee recalled that it had considered this question at its 22<sup>nd</sup> Session and had suspended work pending further progress in the elaboration of the Guidelines.

5) The Committee agreed to initiate new work on the elaboration of Proposed Draft Recommendations on the Scientific Basis of Health Claims, with the understanding that further consideration would be given to the title and status of the document as a separate text or as a section of the Draft Guidelines<sup>2</sup>. The Committee agreed that the Delegation of France, assisted by other delegations and observers,<sup>3</sup> would prepare a working paper including Proposed Draft Recommendations for comments at Step 3, subject to the approval of the Commission as new work.

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<sup>1</sup> CX/NFSDU 02/2, *Guidelines for the Evaluation of Probiotics in Food* – Report of a Joint FAO/WHO Working Group on Drafting Guidelines for the Evaluation of Probiotics in Food

<sup>2</sup> ALINORM 03/22, Appendix VII

<sup>3</sup> Brazil, Canada, Denmark, Germany, Hungary, Italy, Japan, Kenya, Malaysia, Netherlands, Russian Federation, South Africa, Sweden, Switzerland, Thailand, United States, EC, CIAA, ISDI, ENCA, IACFO, EFLA, IBFAN, IFT

6) The Committee recalled that according to the Draft Guidelines "*[Nutrition and] Health claims are not permitted for foods for infants and young children unless specifically provided for in relevant Codex standards*" and had an exchange of views on whether the recommendations on scientific criteria should include such claims. Some delegations and observers pointed out that the development of scientific criteria should be consistent with the text of the Draft Guidelines and should not apply to foods for infants and children. Other delegations expressed the view that the scientific criteria should be generally applicable to all products for which a claim was made. The Committee agreed to discuss this question further in the development of the criteria.

7) The Representative of FAO presented the conclusions and recommendations of the *FAO/WHO Expert Consultation on Evaluation of Health and Nutritional Properties of Probiotics in Food including Powder Milk with Live Acid Bacteria*, convened in October 2001 at the request of the Government of Argentina. The complete report that had already been presented to the CCFL was available at the session and the summary and recommendations were available in CX/NFSDU 02/2. The Representative indicated that the Consultation had considered the need for specific and substantiated health claims for probiotics, and that its recommendations were especially relevant in relation to the Draft Guidelines for Use of Health and Nutrition Claims.

8) In addition, the Representative of FAO presented the "Guidelines for the Evaluation of Probiotics in Food", prepared by a Joint FAO/WHO Working Group. The Guidelines, as outlined in a scheme included in the report, addressed the following aspects: genus/species/strain identification; *in vitro* tests to screen potential probiotics; safety considerations; *in vivo* studies for substantiation of effects; health claims and labelling. The FAO/WHO Working Group report recommended use of the guidelines as a prerequisite for calling bacterial strains "probiotic" and also recommended allowing specific health claims on probiotic food in cases where scientific evidence existed, as per the Guidelines. It was explained that the Guidelines were a possible model for scientific criteria for the evaluation of health claims, as part of the science-based risk assessment process and not a management recommendation.

9) Some delegations and observers expressed their concern with the inclusion in the Guidelines of recommendations relating to health claims in foods for infants, because they might be used as a basis for misleading claims and could discourage breast-feeding. The Representative of FAO indicated that the purpose of the Expert Consultation was to provide a framework for the evaluation of probiotics from the scientific point of view and did not address management or regulatory aspects. Some delegations pointed out that they needed to consider these recommendations in detail at the national level and that it was too early to recommend their use in the framework of the criteria for the scientific basis of health claims to be developed. The Observer from ENCA pointed out that the recommendations of the Consultation recognized the need for further research, including long-time research on probiotics.

#### Other matters

10) The Committee noted the reply of the Committee on Pesticide Residues concerning the endorsement of the section on Pesticide Residues<sup>4</sup>. The Committee noted the comments of the Committee on Food Additives and Contaminants concerning matters referred by the last session of the CCNFSDU on food additives<sup>5</sup> and agreed to discuss this question in more detail when discussing the Proposed Draft Standards under consideration.

#### Matters arising from FAO and WHO

11) The FAO Representative reported on the following three joint activities undertaken by the FAO with WHO and other UN bodies:

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<sup>4</sup> ALINORM 03/24, paras 8-10

<sup>5</sup> ALINORM 03/12, paras 8-9

### FAO/WHO/UNU Expert Consultation on Energy Requirements

12) This Joint Expert Consultation was held in Rome in October 2001 and was reported to the CCNFSDU at its 23<sup>rd</sup> session in November 2001. The FAO representative updated the status of this consultation by reporting on the post-consultation work as well as the additional work commissioned on the review and development of predictive equations for Basal Metabolic Rates in humans to complete the draft. He informed the Committee that the draft report was ready and would be circulated to all the Experts for signing off by the end of November 2002. It was expected that the final report would be posted on the FAO website by the end of the current year and would be published by the end of March 2003.

### FAO/WHO/UNU Expert Consultation on Protein and Amino Acids in Human nutrition:

13) The Joint Expert Consultation on protein and amino acids was held from 9<sup>th</sup> to 16<sup>th</sup> April 2002 at WHO Headquarters in Geneva. This Consultation reviewed the latest scientific evidence on the requirements of proteins and amino acids in humans. The main features of this Consultation were the emerging new scientific data much of it from the developing world based on studies using newer stable isotopic techniques using labelled amino acids. Discussions also centred around approaches by which the numbers of individuals likely to be at risk of inadequate intakes of amino acids in the diet and issues related to protein quality and labelling were also considered. A preliminary draft of this Report has now been produced and it is expected that WHO would be publishing the definitive report sometime before the end of 2003.

### WHO/FAO Expert Consultation on Diet, Nutrition and the Prevention of Chronic diseases

14) This Joint Expert Consultation was held at WHO headquarters in Geneva from 28<sup>th</sup> January to 1<sup>st</sup> February 2002 and raised the problem of increasing morbidity and mortality due to chronic non-communicable diseases (NCDs) globally; reviewed the relationship between diet, physical activity and NCDs and made recommendations with regard to reducing the burden of NCDs and preventing its occurrence in adults both in developing and developed societies by promoting healthy diets and physical activity. The draft report of the Experts was circulated and two meetings were organized to receive feed back both from the private sector and the food industry and with consumer groups and NGOs on 15 and 16<sup>th</sup> of April 2002 in Geneva. The time frame for the receipt of comments and feedback was extended at the request of these two groups of stakeholders and the comment and feedback received were considered by a group of the Experts at a meeting subsequently held at WHO Headquarters on the 19<sup>th</sup> and 20<sup>th</sup> of August 2002. A subsequent draft of the Report is now in preparation incorporating many of the comments and the feedback received hitherto. It is expected that the final report will be published by WHO sometime early in 2003.

### **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)<sup>6</sup>**

15) The Committee recalled that it had not been possible to reach a conclusion on the definition of fibre, the method of analysis and the claim for fibre at the last session. The Draft Condition for Fibre had therefore been retained at Step 7 for further consideration when new scientific evidence became available.

16) The Delegation of the United States informed the Committee that the National Academy of Sciences had completed its review of macronutrient intake including fibre. The report<sup>7</sup> concluded that "total fibre" included two types of fibre: "dietary fibre" and "functional fibre". Dietary fibre was defined as mostly intact (not altered by processing) and included non-digestible carbohydrates, in particular non-starch polysaccharides (pectin, cellulose), inulin, oligosaccharides, lignin and resistant starches. Functional fibre was defined as non-digestible carbohydrates that could have been synthetically produced or altered by processing, including substances of animal origin where evidence existed of their physiological effects. This two-step approach took into account the diversity in the types of fibre and allowed more flexibility, especially to add new substances as research evolved.

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<sup>6</sup> CRD 6 (comments of IDF)

<sup>7</sup> Dietary Reference Intakes for Energy, Carbohydrates, Fiber, Fat, Protein and Amino Acids (Macronutrients) (2002) <http://www.nap.edu/books/0309085373/html>

17) The Committee expressed its appreciation to the Delegation of the United States for this important information and agreed that it would prepare a summary of the NAS report for consideration by the next session.

18) The Delegation of Sweden indicated that studies on reference intake for fibre were underway in Sweden and the Nordic countries, to be completed in 2004, and this work could be of use in relation to conditions for claims. The Delegation of France also indicated that their national experts had been working on the definition, method and levels of fibre. The Observer from IDF referred to the written comments (CRD 6) mentioning the beneficial effects of certain types of animal fibre that were substantiated by scientific evidence and the availability of improved methods for the analysis of oligosaccharides.

19) The Committee agreed that the Delegation of France, in cooperation with other delegations and observers<sup>8</sup> would prepare a discussion paper including proposals for a definition, method of analysis and conditions for fibre content, in order to facilitate further discussion.

**Status of the Guidelines for the Use of Nutrition Claims: Draft Table of Conditions for Nutrient Content (Dietary Fibre)**

20) The Committee agreed to retain the Draft Condition for Nutrient Content (Fibre) at Step 7 for further consideration at the next session in the light of the relevant scientific evidence to be presented in the above-mentioned documents

**PROPOSED DRAFT REVISED STANDARD FOR INFANT FORMULA (Agenda Item 4)<sup>9</sup>**

21) The Chairman recalled that the last session had returned the Proposed Draft to Step 3 for further comments and consideration as no consensus could be reached on a number of issues and especially the Scope. It had also been agreed to circulate the document prepared by the United States on composition requirements in CL 2001/47-NFSDU. The comments received were considered by a Working Group chaired by Germany prior to the current session.

**General Aspects and Scope**

22) The Committee had an extensive debate on whether the standard should cover foods for special medical purposes or whether these products should be included in a new standard.

23) The Representative of WHO drew the Committee's attention to the fact that, irrespective of the final decision whether to have one standard covering *all* products, or two standards covering, respectively, infant formula and infant formula for special medical purposes, both products were breast-milk substitutes and consequently fell within the scope of the International Code of Marketing of Breast-Milk Substitutes. The Representative pointed out that certain provisions of the Code such as its Article 9 concern infant formula.

24) The Committee noted that the Delegation of Germany had prepared a document (CRD 12) with two versions of the standard whereby foods for special medical purposes intended for infants were 1) excluded (Option A) or 2) included (Option C). Some delegations proposed to use that document as a basis for further discussion while other delegations expressed the view that only the current standard should be considered.

25) Several delegations and observers stressed that the development of a separate standard for foods for special medical purposes intended for infants was not justified as the use of such products was very limited and few amendments were required to the current standard to accommodate these products. Several other delegations and observers expressed the view that two separate standards were necessary for regulatory purposes, since foods for

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<sup>8</sup> Cuba, Japan, Netherlands, New Zealand, Poland, South Africa, Sweden, Switzerland, United Kingdom, United States, EC, CIAA, IBFAN, IDF, ISDI

<sup>9</sup> ALINORM 03/26, Appendix III, CL 2001/47-NFSDU, CX/NFSDU 02/4 (comments of Argentina, Australia, Brazil, Colombia, Costa Rica, Cuba, Czech Republic, Hungary, Iran, Malaysia, New Zealand, Nigeria, Slovak Republic, South Africa, Turkey, United States, EC, ISDI, WHO); CX/NFSDU 02/4-Add.1 (Comments of Cuba, ENCA); CRD 1 (Report of the Working Group on Essential Composition of Infant Formula, 2 November 2002); CRD 4 (Malaysia, Mexico, United States, EC); CRD 8 (Philippines); CDR 9 (India); CDR 10 (UNICEF); CRD 12 (Germany); CRD 12 (IACFO); CRD 14 (Indonesia); CRD 15 (IBFAN)

special medical purposes had a different composition, specific labelling requirements and differences in the additives used.

26) Some delegations and observers pointed out that the development of a new standard would create confusion for regulatory authorities and consumers. They noted that it could also facilitate the multiplication of unjustified health claims for products that did not correspond to the definition of foods for special medical purposes.

27) Some delegations expressed the view that if two standards existed, this would allow for clarity and easily understandable standards.

28) Some delegations indicated that although they supported the development of a single standard in principle, they could accept as a compromise the development of a new standard, but only in parallel with the current standard, as it was essential to establish provisions covering foods for special medical purposes intended for infants.

29) Some delegations pointed out that foods for special medical purposes and the corresponding physiological conditions should be defined and asked for clarification from WHO in this respect.

30) The Representative of WHO drew the Committee's attention to that fact that the World Health Assembly, in May 1986, discussed *Guidelines concerning the main health and socioeconomic circumstances in which infants have to be fed on breast-milk substitutes*. As noted in the guidelines, the choice as to the best alternative to breastfeeding depended on the nature of the circumstances, and for this reasons it was useful to distinguish between:

- a. infants who cannot be fed at the breast, for example those with sucking difficulties, but for whom breast milk remains the food of choice;
- b. infants who should not receive breast milk, or any other milk, including the usual breast-milk substitutes, for example those with rare metabolic disorders; and
- c. infants for whom breast milk is not available, for whatever reason.

31) The Representative indicated that, whereas situations (a) and (c) were not relevant to the present debate, situation (b) was a useful point of departure – as indeed was the brief passage dealing with this principle in the guidelines – for understanding the scope of a standard, or standards, dealing with infant formula for special medical purposes.

32) After an extensive debate, the Committee considered a new proposal prepared during the session by the Delegation of Australia in cooperation with others (Option D), presenting an outline of a standard with the working title "infant formula for special medical purposes".

33) Several delegations pointed out that the provisions presented in the outline could be easily integrated into the current text as an Annex or a part of the standard, while other delegations supported the development of new work on a separate standard for foods for medical purposes.

34) The Committee could not reach a consensus and agreed that a Drafting Group working electronically and coordinated by the Delegation of Germany<sup>10</sup> should consider this question. Their mandate would be to prepare a working document for consideration at the next session, including the following:

- (a) an integrated standard based on the current Proposed Draft Revised Standard for Infant Formula, that also includes provisions for infant formula for special medical purposes. These provisions might be included in an Annex or as a separate part of the Standard (part A or B);
- (b) a draft of a new standard applying only to infant formula for special medical purposes, which is intended to be developed in conjunction with the current Proposed Draft Revised Standard, as an alternative to the integrated approach; and
- (c) a discussion of the advantages and disadvantages of each approach.

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<sup>10</sup> Australia, Brazil, Canada, Denmark, France, India, Kenya, Mexico, Netherlands, Russian Federation, Romania, South Africa, Switzerland, Tanzania, Thailand, Uruguay, EC, CIAA, ENCA, ISDI, IDACE, IBFAN, IACFO,

35) The Delegation of Brazil expressed the view that although it would participate in the Drafting Group, it supported the development of a single standard for infant formula, as did several other delegations.

### **Section 2.1 Product Definition**

36) The Committee agreed that paragraph 2.1.2 should be moved to the beginning of the section. The first sentence was replaced with the existing definition of infant formula in the International Code of Marketing of Breast-Milk Substitutes (Article 3), referring to a breast-milk substitute “specially manufactured” (rather than “formulated industrially”). The second sentence was transferred to the Scope as it concerned the products covered by the standard. The Observer from the EC also proposed to amend the second sentence in order to prevent the presentation of other products than infant formula as suitable for satisfying by themselves the nutritional requirements of infants.

37) Some delegations and observers proposed to delete the reference to “normal” nutritional requirements of infants as it was not clearly defined. Other delegations indicated that it was premature to decide on this term as the Scope was still under discussion. The Committee agreed to retain “normal” in square brackets.

38) The Delegation of Tanzania, supported by other delegations, proposed to mention the “first six months of life” to ensure consistency with World Health Assembly Resolution WHA54.2 (2001). Other delegations pointed out that the Resolution was based on studies concerning breast-fed and not formula-fed infants, and that the current text resulted from extensive discussions at the last session.

39) Section 2.1.1 was retained with some changes for clarification and for further discussion and was renumbered as Section 2.1.2.

### **Section 3. Composition requirements**

40) The Delegation of Germany presented the report of the Working Group that had met prior to the Session, in order to consider the comments put forward on Section 3.1 Composition requirements and provide revised provisions (CRD 1).

41) The WG had proposed some amendments to the general principles for establishing minimum and maximum values initially included in CL 2001/47-NFSDU and had considered the values for micronutrients, but not the other provisions due to time constraints.

42) The Committee noted that the Delegation of Tanzania and the Observers from IBFAN and ENCA did not support the conclusion of the Working Group concerning the first principle referring to “normal nutritional requirements” and “healthy infants” (section A.1 of CRD 1).

43) Some delegations pointed out these principles were not intended for inclusion in the standard, but should only facilitate the review of composition requirements. The Delegation of Denmark, speaking on behalf of the European Community and supported by other delegations, proposed to develop general principles, not only for the composition of infant formula, but more generally for composition requirements in foods for special dietary uses. The Committee could not reach a conclusion and agreed to discuss this question further at the next session.

44) The Committee could not discuss in detail the conclusions of the Working Group and agreed that in order to allow for comments on the conclusions and the other aspects that had not been discussed in the Working Group, its report (CRD 1) would be circulated in a separate Circular Letter, with a deadline of March 2003.

45) The Committee agreed that a Drafting Group<sup>11</sup> coordinated by the Delegations of Germany and the United States would work electronically to develop revised proposals for all composition requirements under Section 3.1 and the general principles, without prejudice to the status of these principles. This document would be available by the end of September 2003 and would be considered by a Working Group to be held prior to the 25<sup>th</sup> Session.

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<sup>11</sup> France, Germany, Netherlands, Norway, Tanzania, United States EC, ENCA, IBFAN, ISDI, CIAA

### **Section 3.2 Optional ingredients**

46) In section 3.2.1, the Committee amended some of the terms used in the section, as proposed by the Delegation of the United States, and included alternative terms to “nutrients” in square brackets for further consideration. The Committee discussed whether only substances found in human milk should be added. Some delegations pointed out that several nutrients currently added to infant formula were not present in human milk, such as vegetable fats. The current text was retained pending further discussion on composition requirements.

47) In Section 3.2.2, the Committee considered proposals to replace the concept of “usefulness” of nutrients with “suitability” or “beneficial effects” and placed these alternative terms in square brackets for further consideration. Some delegations objected to the mention of beneficial effects as it would imply that health claims could be made.

### **Section 4. Additives**

48) The Delegation of Switzerland presented the report of the Working Group that had reviewed the additives provisions, on the basis of the criteria specified in the Preamble to the General Standard for Food Additives. The Working Group had agreed that colours and sweeteners should not be allowed in infant formula and had proposed revised levels for several additives.

49) The Committee recognized the importance of ensuring consistency between the provisions in specific standards and those of the GSFA, and noted that the food category system was also under review. For some additives, the technological functions listed in the INS and in JECFA evaluations were different and this question was under consideration in the Committee on Food Additives and Contaminants<sup>12</sup>. The Committee noted that it was the responsibility of the Committee to establish a section on additives that would be submitted to the Committee on Food Additives and Contaminants for endorsement.

50) The Delegation of India expressed the view that thickeners, emulsifiers and antioxidants should not be allowed in infant formula and that clear technological justification should be provided for the use of additives.

51) The Committee could not discuss the proposals in detail due to lack of time and agreed to include the revised section in the standard as an alternative to the existing section (both in square brackets), for further comments. The Committee also noted that the section might need further amendments if foods for special medical purposes were integrated into the standard.

52) The Committee agreed that the Working Group chaired by Switzerland would consider the comments received and revise the additives section for consideration by the next session, and that technological justification would be documented for the additives proposed.

### **Section 9. Labelling**

53) The Committee agreed that the labelling provisions would be considered when the issues related to the Scope had been addressed.

### **Status of the Proposed Draft Revised Standard for Infant Formula**

54) The Committee agreed to return the Proposed Draft Standard, as amended at the current session, to Step 3 for comments and consideration at the next session (see Appendix II).

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<sup>12</sup> ALINORM 03/12, para. 97

## **PROPOSED DRAFT REVISED CEREAL-BASED FOODS FOR INFANTS AND YOUNG CHILDREN (Agenda Item 5)<sup>13</sup>**

55) The Committee recalled that its last session had returned the Proposed Draft to Step 3 because several important issues remained to be solved and some sections had not been discussed thoroughly. The Committee discussed the text section by section and made the following amendments and comments.

### **Scope**

56) The Committee discussed the alternative proposals resulting from the discussions of the last session, both of which referred to the introduction of complementary feeding “from the age of 6 months onwards”. The first proposal mentioned the introduction of complementary feeding “upon the advice of an independent health worker” while the second did not.

57) The Delegation of India, supported by several delegations and observers, proposed to include the second option as it was consistent with WHA Resolution WHA54.2 (2001) and would promote its implementation in member countries for the purposes of public health.

58) The Delegation of Denmark, speaking on behalf of the European Community, and supported by other delegations and observers, proposed to use the first option as it provided more flexibility and allowed to take into account the nutritional requirements of the infants, while adhering to the WHA Resolution.

59) The Delegation of New Zealand, supported by other delegations, proposed to include the term “generally” (from the age of six months) in the second proposal as a compromise and to allow for flexibility.

60) Several delegations objected to the mention of an independent health worker in the first option as this term was not clearly defined and would create confusion as to the advice that should be provided on infant feeding; in addition it was not recognized in certain national health systems. It was also noted that the reference to such advice was covered under section 8.6.4. The Committee noted the proposal of the Delegation of the Philippines, supported by Japan, to refer to “national health strategies” and the proposal to include the WHO definition of a health worker. After some discussion the Committee agreed to delete the reference to an independent health worker.

61) The Representative of WHO pointed out that two aspects should be considered in the discussion: the WHO population-based Feeding Recommendation in Resolution WHA54.2 (2001) and the need to take into account the nutritional needs of the individual infant to determine the age of introduction.

62) The Observer from the EC proposed to add to the second option “taking into account infants’ individual requirements”. After some further discussion, the Committee agreed to amend the text of the second option to reflect that complementary feeding was introduced “generally from the age of six months onwards, taking into account infants’ individual requirements”.

### **Section 2 Description**

63) The Committee discussed whether cereal-based foods were prepared “primarily” or only from cereals, and on the minimum percentage of 25% of the final mixture. It was agreed to retain the current text as it allowed for the addition of other ingredients, as agreed in earlier discussions.

### **Section 2.1 Product Definition**

64) The Committee agreed that the term “reconstituted” should be replaced by “prepared for consumption” as this described more precisely the nature of the operation and corresponded to the wording used in section 3.1.2.

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<sup>13</sup> ALINORM 03/26, Appendix IV, CX/NFSDU 02/5 (comments of Argentina, Australia, Brazil, Colombia, Cuba, Czech Republic, Hungary, New Zealand, Nigeria, Slovak Republic, South Africa, AAC, EC, ENCA, ISDI, WHO), CX/NFSDU 02/5-Add.1 (Report of the Working Group on the revision of Section 3: Essential Composition and Quality factors); CX/NFSDU 02/5- Add.2 (Report of the Working Group on Food Additives); CX/NFSDU 02/5- Add.2 (comments of Costa Rica); CRD 3 (EC); CRD 5 (Norway, United States); CRD 8 (Philippines); CRD 9 (India); CRD 10 (UNICEF).

65) It was agreed that section 2.1.1 covered “Products consisting of cereals” rather than “only of cereals” as this was consistent with the wording of the other definitions and as other ingredients were allowed. In section 2.1.2 it was agreed that the products should be prepared with “appropriate protein-free liquid”.

### **Section 3. Essential Composition and Quality Factors**

66) The Delegation of Malaysia presented the report of the electronic Working Group that had revised composition requirements. The section on protein had been amended in the light of the comments received; the section on lipids had been revised; and new proposals had been included in square brackets for further consideration. It was noted that several comments proposed to prohibit the use of partially hydrogenated fats.

67) The Committee expressed its appreciation to the Delegation of Malaysia and to the Working Group for the substantial progress achieved on complex issues. There was a general discussion and the following proposals were put forward: to take into account the bioavailability of nutrients; to establish a maximum limit for dietary fibre; and to clarify the nutrients defined as “lipids”.

68) As it was not possible to discuss the values proposed for specific nutrients due to lack of time, the Committee agreed that these provisions would be included in the Proposed Draft for further comments and consideration by the next session.

### **Section 4. Additives**

69) The Delegation of Switzerland presented the report of the Working Group that had reviewed the additives provisions, on the basis of the criteria specified in the Preamble to the General Standard for Food Additives. The Working Group had agreed that colours and sweeteners should not be allowed in processed cereal-based foods for infants and young children and had proposed revised levels for several additives. The Committee expressed its appreciation to the Delegation of Switzerland and to the Working Group for their constructive work and the progress made in the revision.

70) The Committee noted that the expression of maximum levels was different for cereal-based foods (per 100 g of the product) and for infant formula (per 100 ml of the ready-to-drink product), and that this would require further consideration. It was also recalled that technological justification should be provided for the additives proposed, (see also para..)

71) The Committee could not discuss the proposals due to lack of time and agreed to include the revised section in the standard for further comments and consideration at the next session. The Committee agreed that the Working Group chaired by Switzerland would consider the comments received and revise the additives section for consideration by the next session.

### **Section 8. Labelling – General provisions**

72) In section 8.1.2, the Committee amended the text to reflect that several languages might be required in the country where the product is sold (“language(s)”), as proposed by the Delegation of India.

73) In section 8.1.3, the Committee discussed extensively whether pictures of children should be prohibited or allowed in the label under certain conditions in order to prevent misleading representations.

74) The Delegation of the United States proposed to simplify the section to reflect that the label should have no pictures or text which suggest an inappropriate age of introduction, as this was the main issue to be addressed.

75) The Delegation of India, supported by several delegations, stressed that the main problem was not the age of introduction as it was difficult for pictures to suggest a specific age. The main issue was the idealization of the product through the representation of healthy children, that might give a misleading idea about the properties of the product, its effect on the health of children and could also discourage from breast-feeding. Several delegations supported the wording proposed by WHO in its written comments (CX/NFSDU 02/5).

76) Other delegations pointed out that the provisions of the Code of Marketing of Breast-Milk Substitutes could not be extended to cereal-based foods, as they were not breast-milk substitutes and the question of idealization was not relevant for such products.

77) The Delegation of Nigeria, supported by some other delegations, pointed out that the use of pictures was necessary in countries where the rate of illiteracy was high in order to explain how the product should be

prepared. Other delegations expressed the view that the use of pictures would create more confusion in the case of illiteracy and should not be allowed in any case.

78) The Delegation of Australia expressed the view that the General Standard for the Labelling of Prepackaged Foods generally addressed this issue in Section 7.1. The Delegation and the Observer from the EC presented the following proposal in order to facilitate compromise: introducing in section 8.1.1 a specific reference to Section 7.1 of the General Standard; adding a sentence to the effect that “national authorities may further restrict the use of pictorial devices”; deleting the current section 8.1.3; and amending section 8.6.4.

79) The Delegation of Tanzania, supported by other delegations, objected to this proposal as it did not address the specific issue under discussion. The Delegation of Brazil pointed out that it was essential to achieve harmonization at the international level to address such important questions, and not to leave them entirely to national legislation, especially in view of the WHO Global Strategy on Infant and Young Child Feeding. The Delegations of Brazil and Uruguay proposed, as a way to help reaching a compromise, that the text suggested by the United States with an amendment for the inclusion of the concept of "idealization", should be retained for consideration.

80) The Committee could not come to a consensus and agreed that the text proposed by Australia/EC and by Brazil/Uruguay would be placed in square brackets, as alternatives for further consideration.

81) The Delegation of Uruguay, supported by other delegations, proposed to add an additional sentence prohibiting the use of nutrition and health claims in the products covered by the standard, to be included in the standard pending finalization of the *Draft Guidelines for Use of Health and Nutrition Claims*<sup>14</sup>. The Delegation of the United States noted that this question was under discussion from a general perspective in the Committee on Food Labelling and that it was premature to consider additional provisions in individual standards. The Committee did not discuss this proposal and it was included in square brackets for further consideration.

#### **Section 8.4**

82) The Observer from the EC indicated that the section did not correspond to the decision of the 22<sup>nd</sup> Session (ALINORM 99/23, para. 77), whereby the amendments proposed by the EC had been accepted. However, the amendment had not been made in the Annex and had not been corrected later as the section had not been reviewed. The Committee agreed that the text should be corrected accordingly.

#### **Section 8.6 Information for Utilization**

83) The Committee agreed that the presence or absence of gluten on the label should be generally declared, irrespective of the age for which the product was intended, and amended the text of section 8.6.3 accordingly.

84) In section 8.6.4, some delegations proposed to delete the reference to the health worker and it was placed in square brackets for further discussion. The Observer from the EC proposed to include a reference to exceptions from the age limit of six months. Some delegations objected to this proposal but it was not discussed in detail and was included in the text for further consideration. Some editorial changes were also introduced for clarification purposes. In the light of the discussion of the Scope, the Delegation of Australia and the Observer from the EC proposed to add a sentence reflecting that the labelling should not be in conflict with the provisions of the paragraph (see also para. 78). The whole section was retained in square brackets for further consideration.

85) In section 8.7, the Committee confirmed that the products covered by the standard were not breast-milk substitutes and amended the text accordingly, deleting the square brackets. The Committee noted that some Observers (IBFAN, ENCA, IACFO) had not had the opportunity to intervene on this subject.

#### **Status of the Proposed Draft Revised Standard for Processed Cereal-based Foods for Infants and Young Children**

86) The Committee agreed to return the Proposed Draft Revised Standard, as amended at the current session, to Step 3 for comments and consideration by the next session (see Appendix III).

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<sup>14</sup> ALINORM 03/22, Appendix VII

## PROPOSED DRAFT GUIDELINES FOR VITAMIN AND MINERAL SUPPLEMENTS

### (Agenda Item 6)<sup>15</sup>

87) The Chairman recalled that the Proposed Draft Guidelines had been discussed for several sessions and stressed the importance of a risk-based approach, and especially the work of FAO and WHO on the establishment of safe upper limits for vitamins and minerals. In this perspective and in order to achieve consensus, it would be preferable to concentrate on principles rather than to discuss specific figures for vitamin and mineral contents. The Committee agreed to concentrate on the questions that had not been addressed at the last session.

#### **Title**

88) The Committee agreed with the proposal of the Observer from the EC that the Title should refer to “food supplements” as it would clarify that the products considered were foods.

#### **Preamble**

89) The Delegation of South Africa, supported by the Observer from NHF, expressed the view that the need for vitamins and mineral supplements in the general population was clearly demonstrated by scientific evidence. The Delegation therefore proposed to include a new Preamble as follows: “People should be encouraged to select a balanced diet. However, vitamins and mineral supplements are useful in cases where the dietary intake of vitamins and minerals is inadequate to correct nutrient deficiencies or to supply prevention such as to reduce risk of disease.”

90) Several delegations objected to this proposal as it was not the purpose of the Guidelines or the mandate of the Committee to consider the prevention, treatment or cure of diseases. In addition this proposal had not been included in the written comments of South Africa and such a major change could not be discussed at short notice.

91) The Delegation of Brazil proposed to retain the current Preamble and to delete the end of the last sentence referring to the case where “consumers consider their diet requires supplementation...”. The Delegation of Indonesia, supported by Japan, proposed to specify that supplements should be taken based on the advice of a nutritionist, a dietician or a medical doctor in order to avoid excessive intake. After some discussion, the Committee retained the current text of the Preamble.

#### **Scope**

92) In section 1.1, the Committee agreed to delete “if and when necessary” in relation to the supplementation of the daily diet as this was not relevant in the Scope. The Observer from the EC proposed to delete the first sentence from the Scope and to include it in the Definition.

93) The Committee agreed to delete the second sentence of section 1.1 as the applicability of the Guidelines was addressed in section 1.2. The Committee noted some proposals to delete or reword section 1.2 but retained the current text as it addressed the situation of countries that regulated supplements as drugs.

94) The Delegation of the Russian Federation proposed to include natural antioxidants, such as beta-carotenes and flavonoids, in the Guidelines. The Committee however recalled that it had been decided earlier that the Scope would be limited to vitamins and minerals. However, when the Guidelines were completed, their extension to other substances could be considered.

### **Section 3.2 Contents of Vitamins and Minerals**

95) The Committee discussed the options presented in section 3.2.2 for the establishment of maximum levels of vitamins and minerals.

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<sup>15</sup> ALINORM 03/26, Appendix II, CX/NFSDU 02/6 (comments of Australia, Brazil, Cuba, Germany, Hungary, Malaysia, New Zealand, South Africa, IADSA), CRD 2 (Norway, United States, EC); CRD 8 (Philippines); CRD 9 (India); CRD 14 (Indonesia)

96) Several delegations supported the second option referring to the establishment of safe upper limits on the basis of scientific risk assessment, as it was essential to apply risk analysis on the basis of safety considerations.

97) Several other delegations supported the first option whereby the maximum level should not exceed 100% of the recommended daily intake, in order to prevent excessive intake.

98) The Delegation of the United States, supported by other delegations, also proposed to delete the last sentence of section 3.2.2 (second option) as its purpose was not clear and the reference intake values for the population would be taken into account in the scientific assessment.

99) The Committee could not reach a consensus and agreed to retain both options in square brackets for further consideration at the next session.

### **Status of the Proposed Draft Guidelines for Vitamin and Mineral Supplements**

100) The Committee agreed to return the Proposed Draft Guidelines for Vitamin and Mineral Supplements to Step 3 for further comments and consideration at the next session (see Appendix IV). It was agreed that this Item would be included earlier in the Agenda of the next session in order to allow for a full discussion.

### **PROPOSED DRAFT REVISION OF THE ADVISORY LIST(S) OF MINERAL SALTS AND VITAMIN COMPOUNDS FOR USE IN FOODS FOR INFANTS AND CHILDREN (CAC/GL 10-1979) (Agenda Item 7)<sup>16</sup>**

101) The Delegation of Germany informed the Committee of changes that had been made in the proposed advisory lists of vitamins in view of the comments provided at the last session. Changes to further improve the lists included a proposal to expand the scope of the lists to include other nutrients and foods for special medical purposes as well as infant formula; a new title; preamble; the addition of criteria for the inclusion and deletion of nutrient compounds from the advisory lists; expansion of the lists to include amino acids, purity requirements and various food categories. Attention was drawn to the comments received in response to the Circular Letter that offered further improvements.

102) The Committee reviewed the Proposed Draft Advisory Lists section by section and agreed to the following changes:

#### **Title**

103) The proposed new title of the lists was amended to add “food for special dietary uses” and to include “young” children. The title was adopted as follows: Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses intended for use by Infants and Young Children.

#### **Preamble**

104) The Preamble proposed by Germany was revised along the lines of the text accepted for the title and the proposal of the Delegation of the United States of America as follows:

*“These lists include nutrient compounds, which may be used for nutritional purposes in foods for special dietary uses intended for use by infants and young children in accordance with 1) the criteria and conditions of use identified below and 2) other criteria for their use stipulated in the respective standards. As noted in the respective standards, their use may either be essential or optional.”*

#### **Scope**

105) The Committee did not agree to add a new section for Scope as elements of the proposed Scope had been merged into the Preamble and reflected in the title.

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<sup>16</sup> CL 2002/7-NSFDU; CX/NSFDU 07/7 (comments of Costa Rica, Cuba, Germany, New Zealand, Switzerland, United States of America, European Community); CX/NSFDU 02/7 Add.1 (comments of ISDI); CRD 7 (comments of Malaysia).

### **Criteria for the inclusion and deletion of nutrient compounds from the advisory lists**

106) The Committee discussed the necessity and the possible processes to be used to add or remove nutrient compounds from the Advisory Lists. The proposal of the Delegation of France to add a provision for adding substances to the Lists under "Criteria" was accepted. While there was discussion of how additions and deletions should be handled, the Committee recognized that the Criteria section should be considered as an integral part of the Advisory Lists. Once adopted, the Lists become official Codex text and, as such, they are the responsibility of the CCNSFDU and Codex on the basis of the established criteria. It was not considered necessary to add a statement to this effect in the document.

107) The Committee added an additional criterion related to acceptance of nutrient compounds on the basis of "generally accepted scientific criteria."

108) The Committee agreed on the following text concerning inclusion and/or deletion of nutrient compounds in the Advisory Lists:

#### ***2. Criteria for the Inclusion and Deletion of Nutrient Compounds from the Advisory Lists***

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

- a) they are shown to be safe and appropriate for the intended use as nutrient sources for infants and young children*
- b) it is demonstrated by appropriate studies in animals and/or humans that the nutrients are biologically available*
- c) the purity requirements of the nutrient compounds are established in an internationally recognized specification or, if there is no internationally recognized specification, national purity requirements may be considered*
- d) the stability of nutrient compounds in the food(s) in which it is/they are to be used can be demonstrated.*
- e) the fulfillment of the above criteria shall be demonstrated by generally accepted scientific criteria.*

*2.2 Nutrient compounds shall be deleted from the Lists if they are found no longer to meet the above criteria. Nutrient compounds may be added to the list based on the criteria above.*

109) In discussing comments on the tables of individual nutrient compounds the Committee accepted the proposal of the United States of America to add a footnote to the tables to the effect that certain forms of compounds (such as calcium lactate, sodium lactate and potassium lactate) should not be used in infant foods.

110) The Committee agreed that the process of acceptance or deletion of nutrient compounds should be fully transparent and that additions to the Advisory List should have been reviewed by the appropriate national and/or international committees. It was agreed the lists should indicate in footnotes those substances that have been subject to review or evaluation.

111) In selecting the most user-friendly format for the Advisory Lists, the Committee accepted the format proposed by the European Community (in CX/NFSDU 02/7). The Delegation of Germany was requested to look into the purity criteria for nutrient compounds and those that may have also been evaluated as additives by JECFA and other national and international scientific bodies. The Delegation of Germany expressed its willingness to accept assistance with this task from other Delegations.

### **Status of the Proposed Draft Revision of the Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses intended for use by Infants and Young Children**

112) The Committee expressed its appreciation to the Delegation of Germany for the excellent work that had been done and agreed that although progress had been achieved, the Proposed Draft Advisory Lists should be returned to Step 2/3 for redrafting, comments and further discussion.

**DISCUSSION PAPER ON THE FINDINGS OF FAO/WHO EXPERT CONSULTATION IN RELATION TO ENERGY CONVERSION FACTORS (Agenda Item 8)<sup>17</sup>**

113) The Committee recalled that a discussion paper on the need for harmonization of energy conversion factors prepared by the Australian Delegation was introduced at the 23<sup>rd</sup> session of CCNFSDU in Berlin, November 2001. It was the recommendation of the Committee that FAO prepare an Expert Report on this topic. Accordingly FAO initiated steps to produce an expert report on the Harmonisation of Energy Conversion Values and its uses in the context of nutrition, food regulation, food quality, safety and food security.

114) The FAO representative informed the Committee that the above meeting of experts was now scheduled for the first week in December 2002 and that arrangements had already been made to ensure that the report would be drafted and be available on the FAO website by the end of February 2003 and published soon after. It was the recommendation of the Committee to make the report of the Technical Workshop available to delegates of CCNFSDU. The Delegation of Australia proposed to prepare a discussion paper on the need to undertake new work on energy conversion factors in view of the results of the Consultation.

115) The Chairman took note of the report and expressed the hope that the report would be available for the 25<sup>th</sup> Session as it would be of importance to the Committee's work to determine a consistent basis for the derivation of energy conversion factors for individual food components to enable uniformity in labelling. He thanked the FAO Representative for the report and wished success in its work in this field.

**DISCUSSION PAPER ON PROGRESS OF WORK BY FAO/WHO AND NATIONAL SCIENTIFIC BODIES IN RELATION TO RISK-BASED APPROACH FOR THE ESTABLISHMENT OF UPPER LIMITS FOR NUTRIENTS (Agenda Item 9)<sup>18</sup>**

116) The Committee recalled its earlier discussions of a paper prepared by the Delegation of Australia on the incorporation of nutrient intake risk assessment in the CCNSFDU decision-making process. There had been support for further study of the potential for the Committee to apply a risk-based approach in establishing upper limits for nutrients. The Committee had been informed at its 22<sup>nd</sup> Session of FAO considerations to hold a follow-up meeting to the Expert Consultation on vitamins and minerals held in Bangkok in 1998. The follow-up Expert Consultation would concentrate on a few specific vitamins and minerals where scientific evidence had been developed.

117) The 23<sup>rd</sup> Session of CCNFSDU considered the paper on the Application of Methodology of Risk Assessment for Nutrient Issues and the discussion that ensued centred around risk-based approaches to establish safe upper levels of consumption for vitamins and minerals. The Committee then requested FAO/WHO to extend their work on recommended nutrient intakes to include recommendations on upper levels (ULs) for vitamins and minerals. The FAO representative had informed the Committee that the draft report on Vitamin and Mineral requirements had in fact looked at this issue for some of the micronutrients.

118) The FAO Representative informed the Committee that the report of the Bangkok Expert consultation on Vitamins and Minerals was posted on the FAO website soon after the last session in November 2001 and subsequently a hard copy of the report was published and available from FAO Headquarters. The definitive report of this Expert Consultation was to be published by WHO shortly as per the agreement between the two UN agencies and was expected to be available in 2003.

119) The FAO Representative also informed the Committee that FAO had looked into the matter of science-based risk assessment approaches to defining upper levels for several vitamins and minerals as a part of the programme to update vitamin and mineral requirements since the 1998 Bangkok Consultation. It had been decided to first produce a generic technical report on general principles to be adopted in approaching the topic of ULs for vitamins and minerals. This scheme would follow the Draft Working Principles for Risk Analysis for Application in the Framework of Codex Alimentarius with risk assessment being the responsibility of the FAO/WHO Expert bodies and Consultations (risk assessors).

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<sup>17</sup> CX/NSFDU 02/8

<sup>18</sup> CX/NSFDU 02/9.

120) FAO has had recent communication with the WHO International Programme on Chemical Safety who had proposed a project within the mandate of JECFA to develop general principles and methods for risk assessment of chemicals in food. It was agreed between the two UN organizations that the matter related to ULs for vitamins and minerals could well be considered under this broad remit. The first meeting to initiate this activity between FAO and WHO is scheduled for January 2003 and the CCNFSDU will be kept informed of progress in this area. The FAO representative also thanked the Australian Delegation for its contribution and efforts in ensuring that this request of the Committee was pursued by FAO and WHO.

121) The Chairman thanked FAO for the report and noted that international agreement was essential in these areas and encouraged FAO and WHO to continue their work to produce internationally agreed working principles.

122) The Delegation of Australia cautioned the Committee that this work will take many years to be able to complete a data base in this area and expressed the view that the Committee should adopt a risk-based approach to its work. Several delegations expressed support for this proposal. The Chairman noted the recommendation of the Codex Committee on General Principles that called on all Codex Committees to use a risk-based approach. He also noted that it had been agreed to take a risk-based approach in the development of Guidelines for Vitamin and Mineral Supplements.

123) The Delegation of Denmark, supported by other delegations, questioned the risk-based approach, meaning that addition of vitamins and minerals are based on the establishment of safe upper limits substance by substance. Science in this area still leaves many open questions, and there is no justification for adding biologically active substances at levels far beyond the nutritional needs of human beings. Caution should therefore be exercised. In consequence nutritional needs should be included as a basis for establishing levels of addition. The Delegation added that the principle of limiting chemical substances to the level needed for achieving the intended purpose is well known in Codex, as demonstrated by the example of provisions for food additives and pesticide residues. The Delegation of France recalled that the Draft Working Principles for Risk Analysis under discussion in the Committee on General Principles recognized the possibility to take into account other factors than risk assessment when taking decisions on risk management (in this case, particularly nutritional factors).

124) The Delegations of Tanzania, Kenya, and Zimbabwe expressed concern that developing countries would require assistance in establishing risk assessment programmes and risked being excluded from this work. The Representative of FAO referred to FAO activities to provide training and technical assistance to developing countries in the area of risk analysis for microbiological and chemical hazards, especially through regional workshops held prior to Regional Codex Committees.

125) The Observer from CRN supported the concept of a risk-based approach in setting limits and emphasized the necessity to have an actual risk analysis carried out on this. The Observer of the NHF expressed the view that it is not necessary to do risk assessment for most vitamins because many studies already show them to be safe and that limits were only necessary, if at all, on selected vitamins. The Observer noted that different people have different assimilation needs, as well as other issues. A risk analysis would need to take into account all factors.

126) The Chairman emphasized that FAO and WHO should be supported in establishing a scientific basis for setting upper limits. It was felt that these should be harmonized worldwide. It was agreed that the Delegation of Australia would kindly prepare a paper on the application of risk analysis applied to the work of this Committee.

#### **OTHER BUSINESS AND FUTURE WORK (Agenda Item 10)<sup>19</sup>**

##### **a) Status Report: Working Group on Prolamin Analysis and Toxicity (WGPAT)**

127) The Committee was informed by the Observer of WGPAT of the progress that had been made by the Working Group related to gluten analysis and research on “toxicity” of food for celiac patients. The Observer noted that the European gliadin reference used for the detection of gliadin/gluten in food samples is now available and currently in the process of certification. The collaborative study of the R5 ELISA system for detection of gliadin samples was finished in July 2002 and is now being evaluated by the organizer of the study.

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<sup>19</sup> Statement of the Prolamin Working Group; CRD 11 (United States of America).

The Observer considered the first data received on the limit of detection, recovery and sensitivity, on robustness and reproducibility of the test system to be promising. The final report of the study would be issued by March 2003. The WGPAT Observer considered that the scientific basis for discussions of “levels” continues to be inadequate and renewed discussion on gluten-free diet would be premature at this time.

128) The Delegation of Sweden, supported by Denmark, was of the opinion that it should be possible to discuss “levels” in 2003 and asked that the Draft Standard for Gluten Free Foods be discussed early in the agenda of the 26<sup>th</sup> Session. As the ELISA method is commercially available worldwide the Delegation was of the opinion that the Committee should consider incorporating the proposed method in the standard at Step 7.

129) While the Observer of the European Community wished the Working Group success in developing a detection method, the Observer expressed a reservation about adding the ELISA method to the standard as an official method as this can make it more difficult to update the method and sought clarification on whether the method was required in order to finalize the standard.

130) The Chairman recalled the decision of the Executive Committee that the draft standard could not proceed in the adoption process until an official method has been established. The Secretariat indicated that a method of analysis must be proposed by the CCNSFDU and then endorsed by the Committee on Methods of Analysis and Sampling (CCMAS) to be recognized as an official method.

131) The Committee agreed that the Draft Standard for Gluten Free Foods would be considered as a separate agenda item at the next session and that the information provided to the Committee would include the report of the WGPAT and any other scientific information that would become available in the meantime.

#### **b) Comments from the United States of America on Pathogens in Infant Formula (CRD 11)**

132) The Delegation of the United States of America informed the Committee of an emerging foodborne pathogen in that country and other countries, *Enterobacter sakazakii*, that can cause sepsis, meningitis or necrotizing enterocolitis in newborn infants, particularly premature infants or other infants with weakened immune systems. The case-fatality rate among infected newborn infants has been reported to be as high as 50 percent. Outbreaks of *E. sakazakii* infections have occurred in neonatal intensive care units worldwide; several investigations have shown that some of the outbreaks are associated with milk-based powdered infant formulas.

133) The Delegation requested CCNFSDU to contact the Codex Committee on Food Hygiene (CCFH) to request that it undertake new work as soon as possible to update the Recommended International Code of Hygienic Practice for Foods for Infants and Children (CAC/RCP 21-1979) to address concerns with pathogens in infant formula, including *E. sakazakii* infections. The Delegation also recommended that the Committee on Food Hygiene evaluate the need for an FAO/WHO Expert Consultation on *E. sakazakii* in connection with the revision of the Code.

134) Delegations and Observers expressed overwhelming support to the request in the interest of public health. The Delegation of Canada informed the Committee that the request was particularly opportune as the Committee on Food Hygiene has requested updating of the Recommended International Code of Hygienic Practice for Foods for Infants and Children (CAC/RCP 21-1979). The Observer from IACFO also considered that this matter should be looked at from the standpoint of labelling as these products are often mistaken to be sterile.

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

135) The Committee was informed that the next session would take place from 3 to 7 November 2003 in Germany and further details would be determined by the host Government and the Codex Secretariat.

### SUMMARY STATUS OF WORK

Subject Matter	Step	For Action by	Reference in ALINORM 03/26A
Guidelines for Use of Nutrition Claims: Draft Table of Conditions for Nutrient Contents (Part B, containing provisions on Dietary Fibre)	7	United States - France 25 <sup>th</sup> CCNFSDU*	para. 20
Draft Revised Standard for Gluten-Free Foods	7	25 <sup>th</sup> CCNFSDU*	paras.127-131
Proposed Draft Revised Standard for Infant Formula	3	Governments 25 <sup>th</sup> CCNFSDU	para. 54 and Appendix II
Proposed Draft Revised Standard for Processed Cereal-Based Foods for Infants and Young Children	3	Governments, 25 <sup>th</sup> CCNFSDU	para. 86 and Appendix III
Proposed Draft Guidelines for Vitamin and Mineral Supplements	3	Governments, 24 <sup>th</sup> CCNFSDU	para. 100 and Appendix IV
Proposed Draft Revision of the Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses intended for use by Infants and Young Children	2/3	Germany Governments 24 <sup>th</sup> CCNFSDU	para. 112
Proposed Draft Recommendations on the Scientific Basis of Health Claims	1/2/3	26 <sup>th</sup> CAC Governments 25 <sup>th</sup> CCNFSDU	para. 5

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\* Consideration at Step 7 in the light of scientific evidence available at the time of the 25<sup>th</sup> Session

**LIST OF PARTICIPANTS  
LISTE DES PARTICIPANTS  
LISTA DE PARTICIPANTES**

**Chairman/Président/Presidente**

Dr Rolf Grossklaus  
Director and Professor  
Federal Institute for Risk Assessment (BfR)  
P.O. Box 33 00 13  
14191 Berlin  
Germany  
Tel: +49 (1888) 4 12 – 32 30  
Fax: +49 (1888) 4 12 – 37 15  
Email: [r.grossklaus@bfr.bund.de](mailto:r.grossklaus@bfr.bund.de)

**ARGENTINA / ARGENTINE**

**Juan Erbar**  
Leiter der Handels- und Wirtschaftsabteilung  
Botschaft der Republik Argentinien  
Tel.: +49 (30) 22 66 89 27 / 32  
Fax: +49 (30) 22 91 40  
Email: [juan.erbar@argentinische-botschaft.de](mailto:juan.erbar@argentinische-botschaft.de)

**AUSTRALIA / AUSTRALIE**

Ms Janine **Lewis**  
Principal Nutritionist  
Food Standards Australia New Zealand  
P.O. Box 7186  
Canberra BC ACT 2610  
Australia  
Tel.: +61 (2) 62 71 22 45  
Fax: +61 (2) 62 71 22 09  
Email: [janine.lewis@foodstandards.gov.au](mailto:janine.lewis@foodstandards.gov.au)

**AUSTRIA / AUTRICHE**

Dr Fritz **Wagner**  
Federal Ministry for Social Security and Generations  
Radetzkystrasse 2  
1030 Vienna  
Austria  
Tel.: +43 (1) 7 11 00 44 26  
Email: [fritz.wagner@bmsg.gv.at](mailto:fritz.wagner@bmsg.gv.at)

**BELGIUM / BELGIQUE / BÉLGICA**

Paul **Van den Meerssche**  
Inspecteur sanitaire-directeur f.f.  
Service public fédéral de la Santé publique  
Sécurité de la Chaîne alimentaire et Environnement  
C.A.E. Quartier Esplanade  
Boulevard Pachéco 19, bte 5  
1010 Bruxelles  
Belgium  
Tel.: +32 (2) 2 10 48 33  
Fax: +32 (2) 2 10 48 16  
Email: [paul.vandenmeerssche@health.fgov.be](mailto:paul.vandenmeerssche@health.fgov.be)

**José Bontemps**

Conseiller scientifique et nutritionnel  
SPADEL  
Rue Colonel Bourg 103  
1030 Bruxelles  
Belgium  
Tel.: +32 (2) 7 02 38 11  
Fax: +32 (2) 7 02 38 12

**BENIN / BÉNIN**

Ahoukpo Denis **Mikode**, PhD  
Directeur de l'Alimentation et de la Nutrition  
Appliquée du Bénin (DANA)  
BP 295  
Porto-Novo  
République du Bénin (Afrique de l'Ouest)  
Tel.: +229 21 26 70  
Fax: +229 21 39 63  
Email: [danamdr@leland.bj](mailto:danamdr@leland.bj)

**Ichola Issiakou Alimi**

Chef Service Qualité, Analyses et Législation  
Alimentaires/DANA  
BP 295  
Porto-Novo  
République du Bénin (Afrique de l'Ouest)  
Tel.: +229 21 26 70  
Fax: +229 21 39 63  
Email: [danamdr@leland.bj](mailto:danamdr@leland.bj)

**BOLIVIA / BOLIVIE**

Dr Oscar **Lanza V.**  
Miembro de la Directiva del Comité Nal. Del Codex  
Alimentarius de Bolivia  
Comité Nal. Del Codex Alimentarius de Bolivia  
P.O. Box 568  
La Paz  
Bolivia  
Tel.: +591 (2) 2 22 29 87  
Fax: +591 (2) 2 22 29 87

Guido **Landa Durán**  
 Vicepresidente  
 Comité Nacional del Codex Alimentarius - Bolivia  
 Calle 9 # 4 Dpto 002  
 Achumani  
 La Paz, Bolivia  
 Tel.: +591 (2) 2 79 99 64  
 Fax: +591 (2) 2 79 99 41  
 Email: [glanda@adesabolivia.com](mailto:glanda@adesabolivia.com)

**BOTSWANA**

Mrs Rosina P. **Diseko**  
 Chief Health Officer - Ministry of Health  
 Community Health Services Division  
 Private Bag 00269  
 Gaborone, Botswana  
 Tel.: +267 - 3 97 43 51  
 Fax: +267 - 3 97 43 54  
 Email: [nfcbgabs@global.bw](mailto:nfcbgabs@global.bw)

Mr Hussein H.T. **Tarimo**  
 Principal Scientific Officer (Food Control)  
 Ministry of Health  
 Community Health Services Division  
 Private Bag 00269  
 Gaborone, Botswana  
 Tel.: +267 - 3 97 43 51  
 Fax: +267 - 3 97 43 54  
 Email: [nfcbgabs@global.bw](mailto:nfcbgabs@global.bw)

**BRAZIL / BRÉSIL / BRASIL**

Ana Beatriz **Vasconcellós**  
 Ministry of Health  
 National Sanitary Surveillance Agency  
 SEPN 515, Bloco B Edifício ômega 3 Andar  
 Brasília - DF, Brazil  
 Tel.: +55 (61) 4 48 11 26  
 Fax: +55 (61) 4 48 10 80  
 Email: [ana.beatriz@anvisa.gov.br](mailto:ana.beatriz@anvisa.gov.br)

Leonardo **Mourão Coelho de Souza**  
 Segundo Secretário da Embaixada do Brasil em Berlim  
 Embaixada do Brasil em Berlim  
 Wallstrasse 57  
 10179 Berlin, Germany  
 Tel.: +49 (30) 72 62 82 31  
 Fax: +49 (30) 72 62 83 20  
 Email: [lsouza@brasemberlim.de](mailto:lsouza@brasemberlim.de)

**BULGARIA / BULGARIE**

Dr Mariela **Todorova**  
 Master, Nutritionist  
 President of National Agency "Saved Future"  
 National Expert of Mother's and Child's Health Care by  
 MH  
 P.O. Box 141  
 Sofia 1233, Bulgaria  
 Tel.: +359 (2) 98 25 03 96  
 Email: [muri@gbg.bg](mailto:muri@gbg.bg)

Valentina **Pirinjieva**  
 Nutritionist - Consultant on Nutrition, MH  
 Ministry of Health  
 "Seliolu" N 10  
 Sofia, Bulgaria  
 Tel.: +359 (2) 98 22 94 06  
 Email: [pirinjieva@gbg.bg](mailto:pirinjieva@gbg.bg)

**CANADA / CANADÁ**

Ms Christina **Zehaluk**  
 Senior Scientific Evaluator  
 Health Products and Food Branch, Health Canada  
 Sir Frederick Banting Research Centre  
 Tunney's Pasture  
 Ottawa, Ontario K1A 0L2, Canada  
 Tel.: +1 (613) 9 57 17 39  
 Fax: +1 (613) 9 41 66 36  
 Email: [christina\\_zehaluk@hc-sc.gc.ca](mailto:christina_zehaluk@hc-sc.gc.ca)

**CUBA**

Dra Delia **Plasencia Concepción**  
 Médico Especialista en Nutrición  
 Instituto de Nutrición e Higiene de los Alimentos del  
 Ministerio Salud Pública  
 Calzada de Infanta No. 1158  
 La Habana 10300, Cuba  
 Tel.: +53 (7) 870 07 16  
 Fax: +53 (7) 873 83 13  
 Email: [inha@infomed.sld.cu](mailto:inha@infomed.sld.cu)

**DENMARK / DANEMARK / DINAMARCA**

Knud **Østergaard**  
 Head - International Affairs  
 Danish Veterinary and Food Administration  
 Mørkhøj Bygade 19  
 2860 Søborg, Denmark  
 Tel.: +45 33 95 60 00  
 Fax: +45 33 95 62 99  
 Email: [koe@fdir.dk](mailto:koe@fdir.dk)

Ms Bente **Koch**  
 Scientific Adviser  
 Danish Veterinary and Food Administration  
 Mørkhøj Bygade 19  
 2860 Søborg, Denmark  
 Tel.: +45 33 95 61 72  
 Fax: +45 33 95 60 60  
 Email: [bmK@fdir.dk](mailto:bmK@fdir.dk)

Laila **Lundby**  
 Food Scientist  
 Danish Dairy Board  
 Frederiks Allé 22  
 8000 Aarhus C  
 Denmark  
 Tel.: +45 87 31 21 99  
 Fax: +45 87 31 20 01  
 Email: [llu@mejeri.dk](mailto:llu@mejeri.dk)

Tamara Theresa **Mosegaard**  
 MayDay - International Committee  
 Postbox 8  
 3520 Farum, Denmark  
 Tel.: +45 44 99 88 98  
 Fax: +45 44 99 88 98  
 Email: [ttm@mayday-info.dk](mailto:ttm@mayday-info.dk)

Ellen **Trolle**  
 Senior Research Nutritionist  
 Danish Veterinary and Food Administration  
 Mørkhøj Bygade 19  
 2860 Søborg, Denmark  
 Tel.: +45 33 95 64 21  
 Fax: +45 33 95 11 19  
 Email: [etr@fdir.dk](mailto:etr@fdir.dk)

**ECUADOR / ÉQUATEUR**

Jose Eduardo **Proaño-Armijos**  
 Botschaftssekretär  
 Leiter der Handelsabteilung  
 Botschaft der Republik Ecuador  
 Kaiser-Friedrich-Strasse 90  
 D-10585 Berlin, Germany  
 Tel.: +49 (30) 2 38 62 17  
 Fax: +49 (30) 34 78 71 26  
 Email: [mecuadoral@t-online.de](mailto:mecuadoral@t-online.de)

**EGYPT / EGYPT / EGIPTO**

Dr S.H. **Abo Raiia**  
 Professor of Food Science  
 Cairo University  
 Faculty of Agric.  
 34 Taiba St. Mohandseen  
 Giza, Egypt  
 Tel.: +20 - 7 49 37 95  
 Fax: +20 - 3 37 50 03  
 Mob. +20 - 1 23 19 99 31

**FINLAND / FINLANDE / FINLANDIA**

Ms Kaija **Hasunen**  
 Chief Counsellor  
 Ministry of Social Affairs and Health  
 P.O. Box 33  
 00023 Government, Finland  
 Tel.: +358 (9) 16 07 40 35  
 Fax: +358 (9) 16 07 41 44  
 Email: [kaija.hasunen@stm.vn.fi](mailto:kaija.hasunen@stm.vn.fi)

Ms Anna **Lemström**  
 Senior Adviser  
 Ministry of Trade and Industry  
 P.O. Box 32  
 00023 Government  
 Finland  
 Tel.: +358 (9) 16 06 35 36  
 Fax: +358 (9) 16 06 26 70  
 Email: [anna.lemstrom@ktm.fi](mailto:anna.lemstrom@ktm.fi)

**FRANCE / FRANCIA**

Catherine **Rioux**  
 Ministère de l'Economie, des Finances et de l'Industrie  
 DGCCRF - Bureau D3  
 Télédéc 251  
 29, boulevard Vincent Auriol  
 75703 Paris Cedex 13, France  
 Tel.: +33 (1) 44 97 29 18  
 Fax: +33 (1) 44 97 30 48  
 Email: [catherine.rioux@dgccrf.finances.gouv.fr](mailto:catherine.rioux@dgccrf.finances.gouv.fr)

Pascal **Audebert**  
 SGCI Gestion du Codex Alimentarius  
 2, boulevard Diderot  
 75572 Paris Cedex 12, France  
 Tel.: +33 (1) 44 87 16 03  
 Fax: +33 (1) 44 87 16 04  
 Email: [pascal.audebert@sgci.finances.gouv.fr](mailto:pascal.audebert@sgci.finances.gouv.fr)

Françoise **Costes**  
 ATLA  
 42, rue de Châteaudun  
 75314 Paris Cedex 09, France  
 Tel.: +33 (1) 49 70 72 69  
 Fax: +33 (1) 42 80 63 62  
 Email: [fcostes@atla.asso.fr](mailto:fcostes@atla.asso.fr)

Marie-Odile **Gailing**  
 NESTLE France  
 7, boulevard Pierre Carle  
 BP 900 Noisiel  
 77446 Marne-la-Vallee Cedex 02  
 France  
 Tel.: +33 (1) 60 53 20 40  
 Fax: +33 (1) 60 53 54 65  
 Email: [marie-odile.gailing@fr.nestle.fr](mailto:marie-odile.gailing@fr.nestle.fr)

Jacques **Ghisolfi**  
 CHU Toulouse  
 Hôpital des Enfants  
 330 avenue de Grande Bretagne  
 BP 3119  
 31026 Toulouse-Cedex 3  
 France  
 Tel.: +33 (5) 34 55 85 59  
 Fax: +33 (5) 34 55 85 67  
 Email: [ghisolfi.j@chu-toulouse.fr](mailto:ghisolfi.j@chu-toulouse.fr)

Brigitte **Lelievre**  
 Alliance 7  
 Diététique et Compléments Alimentaires  
 194, rue de Rivoli  
 75001 Paris, France  
 Tel.: +33 (1) 44 77 85 85  
 Fax: +33 (1) 42 61 95 34  
 Email: [blelievre@alliance7.com](mailto:blelievre@alliance7.com)

**Jolanta Leone**  
 Bledina S.A  
 383, rue Philippe Héron  
 B.P. 432  
 69654 Villefranche-sur-Saone, France  
 Tel.: +33 (4) 74 62 63 74  
 Fax: +33 (4) 74 62 61 95  
 Email: [jleone@bledina.danone.com](mailto:jleone@bledina.danone.com)

**Annie Loc'h**  
 Food Law Director  
 DANONE Group  
 7, rue de Téhéran  
 75008 Paris, France  
 Tel.: +33 (1) 44 35 20 20  
 Fax: +33 (1) 44 35 24 45  
 Email: [aloch@groupe.danone.com](mailto:aloch@groupe.danone.com)

**Pierre Merel**  
 Ministère de l'Agriculture, de l'Alimentation, de la  
 Pêche et des Affaires Rurales  
 DGAL  
 251, rue de Vaugirard  
 75732 Paris Cedex 15, France  
 Tel.: +33 (1) 49 55 58 63  
 Fax: +33 (1) 49 55 59 48  
 Email: [pierre.merel@agriculture.gouv.fr](mailto:pierre.merel@agriculture.gouv.fr)

**Jean-Louis Ramet**  
 MILUPA  
 Immeuble l'Européen  
 4, rue Joseph Monier  
 92859 Rueil-Malmaison Cedex, France  
 Tel.: +33 (1) 47 10 23 50  
 Fax: +33 (1) 47 10 23 99  
 Email: [jean-louis.ramet@nutricia.com](mailto:jean-louis.ramet@nutricia.com)

**GERMANY / ALLEMAGNE / ALEMANIA**

**Dr Pia Noble**  
 Regierungsdirektorin  
 Bundesministerium für Verbraucherschutz, Ernährung  
 und Landwirtschaft  
 Rochusstrasse 1  
 53123 Bonn  
 Germany  
 Tel.: +49 (228) 5 29 46 65  
 Fax: +49 (228) 5 29 49 65  
 Email: [pia.noble@bmvel.bund.de](mailto:pia.noble@bmvel.bund.de)

**Prof Dr Hildegard Przyrembel**  
 Direktorin und Professorin  
 Federal Institute for Risk Assessment (BfR)  
 P.O. Box 33 00 13  
 14191 Berlin  
 Germany  
 Tel.: +49 (1888) 4 12 - 32 21  
 Fax: +49 (1888) 4 12 - 35 15

**Dr Regina Berwind**  
 Scientific Advisor Nutrition  
 Nestlé Alete GmbH  
 Prinzregentenstrasse 155  
 81677 München  
 Germany  
 Tel.: +49 (89) 4 11 62 03  
 Fax: +49 (89) 41 16 92 03  
 Email: [regina.berwind@de.nestle.com](mailto:regina.berwind@de.nestle.com)

**Dr Joachim Bollmann**  
 Regierungsdirektor  
 Bundesministerium für Verbraucherschutz, Ernährung  
 und Landwirtschaft  
 Rochusstrasse 1  
 53123 Bonn  
 Germany  
 Tel.: +49 (228) 5 29 37 84  
 Fax: +49 (228) 5 29 49 65  
 Email: [joachim.bollmann@bmvel.bund.de](mailto:joachim.bollmann@bmvel.bund.de)

**Dr Anja Brönstrup**  
 Department of Science  
 German Nutrition Society (DGE e.V.)  
 Godesberger Allee 18  
 53175 Bonn  
 Germany  
 Tel.: +49 (228) 3 77 66 23  
 Fax: +49 (228) 3 77 68 02  
 Email: [broenstrup@dge.de](mailto:broenstrup@dge.de)

**Dr Angelika Domke**  
 Wissenschaftliche Direktorin  
 Federal Institute for Risk Assessment (BfR)  
 P.O. Box 33 00 13  
 14191 Berlin  
 Germany  
 Tel.: +49 (1888) 4 12 - 32 13  
 Fax: +49 (1888) 4 12 - 37 15

**Dr J. Fritsche**  
 European Health & Nutrition Manager (SCC)  
 Unilever R&D Vlaardingen  
 Olivier van Noortlaan 120  
 3133 AT Vlaardingen  
 The Netherlands  
 Tel.: +31 (10) 4 60 52 92  
 Fax: +31 (10) 4 60 52 55  
 Email: [jan.fritsche@unilever.com](mailto:jan.fritsche@unilever.com)

**Gertrud Granel**  
 Lebensmittelchemikerin  
 Fachverband der Stärke Industrie  
 Postfach 19 01 65  
 53037 Bonn  
 Germany  
 Tel.: +49 (228) 91 42 30  
 Fax: +49 (228) 9 14 23 19  
 Email: [g.granel@verbaende.hees.de](mailto:g.granel@verbaende.hees.de)

**Dr Gerda Jost**

Corporate & Regulatory Affairs  
Milupa GmbH & Co. KG  
Bahnstrasse 14-30  
61381 Friedrichsdorf, Germany  
Tel.: +49 (6172) 99 14 23  
Fax: +49 (6172) 99 12 50  
Email: [gerda.jost@milupa.de](mailto:gerda.jost@milupa.de)

**Berthold Koletzko, M.D.**

Professor of Paediatrics  
Chairman, ESPGHAN Nutrition Committee  
Chairman, Committee on Nutrition  
German Society of Paediatrics  
Dr von Hauner Children's Hospital  
Univ of Munich  
Lindwurmstrasse 4  
80337 München, Germany  
Tel.: +49 (89) 51 60 39 67  
Fax: +49 (89) 51 60 33 36  
Email: [bkoletz@helios.med.uni-muenchen.de](mailto:bkoletz@helios.med.uni-muenchen.de)

**Thomas König**

Advisor  
Aktionsgruppe Babynahrung e.V.  
Untere-Masch-Strasse 21  
37073 Göttingen, Germany  
Tel.: +49 (551) 53 10 34  
Fax: +49 (511) 53 10 35  
Email: [info@babynahrung.org](mailto:info@babynahrung.org)

**Dr Gert Krabichler**

Director External Affairs  
Roche Vitamines Europe Ltd.  
P.O. Box 3255  
4002 Basel, Switzerland  
Tel.: +41 (61) 6 88 54 30  
Fax: +41 (61) 6 88 90 22  
Email: [gert.krabichler@roche.com](mailto:gert.krabichler@roche.com)

**Alexander Maier**

Lawyer  
Hipp-Werk Georg Hipp  
Georg-Hipp-Strasse 7  
85276 Pfaffenhofen, Germany  
Tel.: +49 (8441) 75 73 21  
Fax: +49 (8441) 75 73 00  
Email: [alexander.maier@hipp.de](mailto:alexander.maier@hipp.de)

**Dr Karin Meissner**

Humana GmbH  
Regulatory Affairs  
Bielefelder Strasse 66  
32051 Herford,  
Germany  
Tel.: +49 (5221) 18 12 54  
Fax: +49 (5221) 18 14 66  
Email: [karin.meissner@humana.de](mailto:karin.meissner@humana.de)

**Angelika Michel-Drees**

Referentin für Ernährung  
VZbV  
Markgrafenstrasse 66  
10969 Berlin  
Tel. +49 30 2 58 00 434

**Dr Michael Packert**

Advisor  
Südzucker AG  
Mannheim / Ochsenfurt  
Forchheimer Strasse 2  
90425 Nürnberg, Germany  
Tel.: +49 (911) 9 34 44 65  
Fax: +49 (911) 9 34 45 60

**Norbert Pahne**

Manager  
Diätverband e.V.  
Godesberger Allee 142-148  
53175 Bonn, Germany  
Tel.: +49 (228) 3 08 51 10  
Fax: +49 (228) 3 08 51 50  
Email: [diatverband@t-online.de](mailto:diatverband@t-online.de)

**Renate Scherer**

Chemisches Landes- und Staatliches  
Veterinäruntersuchungsamt  
Sperlichstrasse 19  
48151 Münster, Germany  
Tel.: +49 (251) 98 21 - 2 28  
Fax: +49 (251) 98 21 - 2 50  
Email: [scherer@cvua.nrw.de](mailto:scherer@cvua.nrw.de)

**Dr Wolfgang Schubert**

Head of research infant and dietetic food/nutrition  
Diätverband e.V.  
Humana GmbH  
Bielefelder Strasse 66  
32051 Herford, Germany  
Tel.: +49 (5221) 18 13 27  
Fax: +49 (5221) 18 14 66  
Email: [wolfgang.schubert@humana.de](mailto:wolfgang.schubert@humana.de)

**Dr Helene Steinhausen-Kibler**

Head of Nutritional Sciences  
Hipp GmbH & Co Vertrieb KG  
Georg-Hipp-Strasse 7  
85276 Pfaffenhofen, Germany  
Tel.: +49 (8441) 75 73 03  
Fax: +49 (8441) 75 76 68

**Michael Welsch**

Secretary  
Bund für Lebensmittelrecht und Lebensmittelkunde  
e.V.  
Godesberger Allee 142-148  
53175 Bonn, Germany  
Tel.: +49 (288) 8 19 93 24  
Fax: +49 (228) 37 50 69  
Email: [mwelsch@bll-online.de](mailto:mwelsch@bll-online.de)

**GREECE / GRÈCE / GRECIA**

Catherine **Moraiti**  
 Head of Dietetic Section  
 National Organisation for Medicines  
 284 Messogion Av.  
 15562 Cholargos  
 Greece  
 Tel.: +30 (1) 6 50 72 22  
 Fax: +30 (1) 6 54 70 02

**HUNGARY / HONGRIE / HUNGRIA**

Dr Márta **Horacsek**  
 Head of Department of Registered Food  
 National Institute of Food Hygiene and Nutrition  
 Gyáli út 3/a  
 1097 Budapest  
 Hungary  
 Tel.: +36 (1) 2 15 - 41 30  
 Fax: +36 (1) 2 15 - 15 45  
 Email: [h86h9rod@elle.hu](mailto:h86h9rod@elle.hu)

**INDIA / INDE**

Amit **Dasgupta**  
 Deputy Chief of Mission  
 Embassy of India  
 Indische Botschaft  
 Tiergartenstrasse 17  
 10785 Berlin  
 Tel.: +49 (30) 25 79 52 01/02  
 Fax: +49 (30) 25 79 81 12  
 Email: [dcm@indianembassy.de](mailto:dcm@indianembassy.de)

Dr Sri Ram **Khanna**  
 Managing Trustee  
 VOICE  
 F-71, Lajpat Nagar - II  
 New Delhi - 110024  
 India  
 Tel.: +91 (11) 6 31 53 75 and 6 91 89 69  
 Fax: +91 (11) 6 31 92 30  
 Email: [cvoice@vsnl.net](mailto:cvoice@vsnl.net)  
[testing@consumer-voice.org](mailto:testing@consumer-voice.org)

**INDONESIA / INDONESIA**

Mr Mochamed **Ridwan**  
 Embassy of Indonesia Berlin  
 Lehrter Strasse 16-17  
 10557 Berlin, Germany  
 Tel: + 49 (30) 47807279  
 Fax: + 49 (30) 44737142

Ms Esdella **Anwar Bey**  
 Embassy of Indonesia Berlin  
 Lehrter Strasse 16-17  
 10557 Berlin, Germany  
 Tel: + 49 (30) 47807279  
 Fax: + 49 (30) 44737142

**IRELAND / IRELANDE / IRLANDA**

Dr Dominique **Crowley**  
 Chief Specialists in Public Health  
 Food Safety Authority of Ireland  
 Abbey Court  
 Lower Abbey Street  
 Dublin 1, Ireland  
 Tel.: +353 (1) 8 17 13 30  
 Fax: +353 (1) 8 17 13 01  
 Email: [dcrowley@fsai.ie](mailto:dcrowley@fsai.ie)

Joan **Regan**  
 Assistant Principal  
 Food Unit  
 Dept. Health and Children  
 Hawkins House  
 Dublin 2, Ireland  
 Tel.: +353 (1) 6 35 42 47  
 Fax: +353 (1) 6 35 45 52  
 Email: [Joan\\_regan@health.irlgov.ie](mailto:Joan_regan@health.irlgov.ie)

**ISRAEL / ISRAËL**

Ms Nili **Arbel**  
 Coordinator for Nutrition  
 Nutrition Department  
 Ministry of Health  
 Jerusalem, Israel  
 Tel.: +972 (2) 6 22 88 55  
 Fax: +972 (2) 6 24 71 73  
 Email: [nili.arbel@moh.health.gov.il](mailto:nili.arbel@moh.health.gov.il)

**ITALY / ITALIE / ITALIA**

Dra Lucia **Guidarelli**  
 Ministry of Health  
 DGSPVAN - Medical Director  
 Dietetics - Nutrition Office  
 P. le Marconi 25  
 00144 Roma, Italy  
 Tel.: +39 (06) 59 94 68 28  
 Fax: +39 (06) 59 94 62 17  
 Email: [l.guidarelli@sanita.it](mailto:l.guidarelli@sanita.it)

Dra Albina **De Marco**  
 Ministry of Agriculture  
 Via Sallustiana, 10  
 08187 Roma, Italy  
 Tel.: +39 (06) 46 65 65 20  
 Fax: +39 (06) 4 88 02 73

Mr Josef **Hasselberger**  
 Federsalus  
 Via San Damaso 23/A  
 00165 Roma  
 Italy  
 Tel.: +39 (6) 63 58 84  
 Fax: +39 (6) 63 21 96  
 Email: [sepp@lastrega.com](mailto:sepp@lastrega.com)

Dr Ivan **Ingrillí**  
 La Leva di Archimede  
 President  
 Rampa Brancaleone 58  
 00165 Rome, Italy  
 Tel.: +39 (6) 63 58 84  
 Email: [ivan@laleva.cc](mailto:ivan@laleva.cc)

Dra Brunella **Lo Turco**  
 Secrétaire général du Comité National du Codex  
 Alimentarius  
 Ministero / Politiche / Agricole  
 Via XX Settembre 20  
 00100 Roma, Italy  
 Tel.: +39 (6) 46 65 65 12  
 Fax: +39 (6) 4 88 02 73  
 Email: [BLTURCO@tiscali.it](mailto:BLTURCO@tiscali.it)

Dra Anna **Paonessa**  
 AIIPA (Italian Association of Food Industries)  
 Corso di Porta Nuova 34  
 20121 Milano, Italy  
 Tel.: +39 (2) 65 61 84  
 Fax: +39 (2) 65 68 22

Dr Andrea **Pagella**  
 Via Bel Casule  
 20100 Milan, Italy  
 Tel.: +39 (2) 52 56 34 01  
 Email: [andrea.pagella@glaswon.it](mailto:andrea.pagella@glaswon.it)

**JAPAN / JAPON / JAPÓN**

Mr Tsuyoshi **Ogata**  
 Director  
 Office of Health Policy on Newly Developed Foods  
 Policy Planning Division  
 Department of Food Safety, Pharmaceutical and Food  
 Safety Bureau  
 Ministry of Health, Labour and Welfare  
 1-2-2 Kasumigaseki  
 Chiyoda-ku - Tokyo 100-8916, Japan  
 Tel.: +81 (3) 52 53 11 11 (ex. 2456)  
 Fax: +81 (3) 35 01 48 67  
 Email: [ogata-tsuyoshi@mhlw.go.jp](mailto:ogata-tsuyoshi@mhlw.go.jp)

Mr Hiroaki **Hamano**  
 Technical Advisor  
 Japan Health Food and Nutrition Food Association  
 2-7-27 Ichigaya-Sadohara-cho  
 Shinjuku-ku  
 Tokyo 162-0842  
 Japan  
 Tel.: +81 (3) 32 68 31 34  
 Fax: +81 (3) 32 68 31 36  
 Email: [hiroaki.hamano@danisco.com](mailto:hiroaki.hamano@danisco.com)

Dr Hiramitsu **Suzuki**  
 Chief of physiological function laboratory  
 National Food Research Institute  
 2-1-12 Kannondai  
 Tsukubadel  
 Ibaraki 305-8642, Japan  
 Tel.: +81 (288) 38 80 89  
 Fax: +81 (288) 38 80 89

Mr Kaoru **Koide**  
 Technical Advisor  
 The Japanese National Committee of IDF  
 Nyugyo-Kaikan  
 1-14-19 Kudankita  
 Chiyoda-ku  
 Tokyo 102-0073, Japan  
 Tel.: +81 (3) 32 64 37 31  
 Fax: +81 (3) 32 64 37 32

Mr Kazuyoshi **Nanba**  
 Technical Advisor  
 The Japanese National Committee of IDF  
 Nyugyo-Kaikan  
 1-14-19 Kudankita  
 Chiyoda-ku  
 Tokyo 102-0073, Japan  
 Tel.: +81 (3) 32 64 37 31  
 Fax: +81 (3) 32 64 3732

Mr Tetsuji **Shimizu**  
 Technical Advisor  
 Japan Health Food and Nutrition Food Association  
 2-7-27 Ichigaya-Sadohara-cho  
 Shinjuku-ku  
 Tokyo 162-0842, Japan  
 Tel.: +81 (3) 32 68 31 34  
 Fax: +81 (3) 32 68 31 36  
 Email: [jhnfa@mx1.alpha-web.ne.jp](mailto:jhnfa@mx1.alpha-web.ne.jp)

Mr Mitsunori **Takase**  
 Technical Advisor  
 The Japanese National Committee of IDF  
 Nyugyo-Kaikan  
 1-14-19 Kudankita - Chiyoda-ku  
 Tokyo 102-0073, Japan  
 Tel.: +81 (3) 32 64 37 31  
 Fax: +81 (3) 32 64 - 37 32

Mr Hiroyuki **Tanaka**  
 Food Safety Specialist  
 Office of Health Policy on Newly Developed Foods  
 Policy Planning Division  
 Department of Food Safety Pharmaceutical and Food  
 Safety Bureau  
 Ministry of Health, Labour and Welfare  
 1-2-2 Kasumigaseki  
 Chiyoda-ku  
 Tokyo 100-8916, Japan  
 Tel.: +81 (3) 52 53 11 11 (ex. 2458)  
 Fax: +81 (3) 35 01 48 67  
 Email: [tanaka-hiroyukith@mhlw.go.jp](mailto:tanaka-hiroyukith@mhlw.go.jp)

Mr **Fujita** Toshifumi  
 Section Chief  
 Center for Food Quality, Labeling and Consumers  
 Services Headquarters  
 1-21-1 Kitafukuro-cho  
 Saitama City  
 Saitama 330-9731, Japan  
 Tel.: +81 (48) 6 00 27 35  
 Fax: +81 (49) 6 00 23 75  
 Email: [toshifumi\\_fujita@cfqlcs.go.jp](mailto:toshifumi_fujita@cfqlcs.go.jp)

Mr Hiroshi **Tsuchita**  
 Technical Advisor  
 The Japanese National Committee of IDF  
 Nyugyo-Kaikan  
 1-14-19 Kudankita - Chiyoda-ku  
 Tokyo 102-0073, Japan  
 Tel.: +81 (3) 32 64 37 31  
 Fax: +81 (3) 32 64 37 32

Dr Kazuhiko **Yamada**  
 Director  
 Division of Applied Food Research  
 National Institute of Health and Nutrition  
 1-23-1 Toyama - Shinjuku-ku  
 Tokyo 162-8636, Japan  
 Tel.: +81 (3) 32 03 56 02  
 Fax: +81 (3) 32 02 32 78  
 Email: [peaceboy@nih.go.jp](mailto:peaceboy@nih.go.jp)

#### **KENYA**

Samuel J. **Ochieng**  
 Chief Executive  
 Consumer Information Network  
 Solai Plaza  
 Off. Kamunde Road  
 Kariobangi, 3rd Floor, Room 305  
 P.O. Box 75 69  
 Nairobi-00300, Kenya  
 Tel.: +254 (2) 78 11 31  
 Fax: +254 (2) 79 79 44  
 Email: [cin@insightkenya.com](mailto:cin@insightkenya.com)

T.K. **Olielo**  
 Kenya Bureau of Standards  
 P.O. Box 54974  
 Nairobi, Kenya  
 Tel.: +254 (2) 50 22 11  
 Fax: +254 (2) 50 32 93  
 Email: [tkolielo@kebs.org](mailto:tkolielo@kebs.org)

#### **KOREA, REPUBLIC OF / CORÉE, RÉPUBLIQUE DE / COREA, REPUBLICA DE**

Ms Mi-Young **Lee**  
 Senior Researcher  
 Food Sanitation Council  
 Ministry of Health and Welfare  
 I Jongang-Dong  
 Kwachung City  
 Kyungi-Do, Republic of Korea  
 Tel.: +82 (2) 504 - 62 33  
 Fax: +82 (2) 504 - 14 56  
 Email: [codexkorea@kfda.go.kr](mailto:codexkorea@kfda.go.kr)

Sung Hee **Choi**  
 Senior Researcher  
 Quality Assessment Center  
 Korea Health Industry Development Institute  
 51-1 Noryangin-Dong  
 Dongjak-Gu - Seoul, Korea  
 Tel.: +82 (2) 21 94 73 39  
 Fax: +82 (2) 21 94 74 49  
 Email: [choish@khidi.or.kr](mailto:choish@khidi.or.kr)

Tal Soo **Lee**  
 Director of Natural Food Additive  
 Korea Food and Drug Administration  
 5 Nokbeon dong  
 Eunpyeong-gu  
 Seoul, Korea  
 Tel.: +82 (2) 3 80 - 16 91  
 Fax: +82 (2) 3 80 - 16 75  
 Email: [tslee@kfda.go.kr](mailto:tslee@kfda.go.kr)

#### **MALAYSIA / MALASIE**

Dr Tony Ng Kock **Wei**  
 Head - Cardiovascular Disease Unit  
 Institute for Medical Research  
 Jalan Pahang  
 50588 Kuala Lumpur  
 Malaysia  
 Tel.: +603 - 40 40 23 90  
 Fax: +603 - 26 94 35 75  
 Email: [tonyng@imr.gov.my](mailto:tonyng@imr.gov.my)

Ms Eunice **Choa**  
 Region Scientific Regulatory Affairs Manager  
 Federation of Malaysian Manufacturers  
 Wisma FMM, No. 3  
 Persiaran Dasang  
 PJU 9, Bandar Sri Damansara  
 52200 Kuala Lumpur  
 Malaysia  
 Tel.: +603 - 26 76 12 11  
 Email: [echoa@apal.ko.com](mailto:echoa@apal.ko.com)

Ms Norrani **Eksan**  
Principal Assistant Director  
Food Quality Control Division  
Department of Public Health  
Ministry of Health Malaysia  
Block B, 3rd Floor  
Kompleks Pejabat - Pejabat Kesihatan  
Jalan Cenderasari  
50590 Kuala Lumpur  
Malaysia  
Tel.: +603 - 26 94 66 01  
Fax: +603 - 26 94 65 17  
Email: [norrani@moh.gov.my](mailto:norrani@moh.gov.my)

Ms Siti Norjannah **Moin**  
Malaysian Breast - Feeding Association  
7a, Jalan Kolam Air  
Kg Klang Gate Baru  
53100 Kuala Lumpur  
Malaysia  
Tel.: +603 - 41 05 38 72  
Fax: +603 - 41 06 89 14  
Email: [norjannah@bibmalaysia.com](mailto:norjannah@bibmalaysia.com)

Dr Koh Chu **Sing**  
Head  
Technical Marketing Dept  
Malaysian Palm Oil Promotion Council  
2nd Floor, Wisma Sawit  
Lot 6 SS6 Jalan Perbandaran  
Kelana Jaya 47301  
Selangor  
Malaysia  
Tel.: +60 (3) 78 06 40 97  
Fax: +60 (3) 78 80 62 72  
Email: [koh@mpopc.org.my](mailto:koh@mpopc.org.my)

Ms Sharidah **Yusoff**  
Regulatory Manager  
Federation of Malaysian Manufacturer  
Wisma FMM, No. 3  
Persiaran Dasang  
PJU 9, Bandar Sri Damansara  
52200 Kuala Lumpur  
Malaysia  
Tel.: +603 - 62 76 12 11  
Email: [Sharidah.Yusoff@my.nestle.com](mailto:Sharidah.Yusoff@my.nestle.com)

#### **MEXICO**

Lic en Nut Laura **Gonzalez Paxtian**  
Jefe del Depto de Normalización Sanitaria  
Secretaría de Salud  
Donceles No. 39  
Col. Centro  
México D.F.  
Tel.: +52 - 55 18 - 36 96  
Fax: +52 - 55 12 - 9628  
Email: [lgonzalezpax86@hotmail.com](mailto:lgonzalezpax86@hotmail.com)

Ernesto Salinas **Gómez-Roel**  
Jefe unidad Normas Alimentarias  
Nestlé México  
Av. Ejercito Nacional 453 col. Granada  
Del. Miguel Hidalgo  
CP 11520 Distrito Federal  
México  
Tel.: +52 - 58 81 92 05  
Fax: +52 - 55 31 25 21  
Email: [ernesto.salinas@mx.nestle.com](mailto:ernesto.salinas@mx.nestle.com)

#### **MOROCCO / MAROC / MARRUECOS**

Jamal **Ennassir**  
Laboratoire Officiel d'Analyses et de Recherches  
Chimiques  
(Ministère de l'Agriculture, du Développement Rural,  
des Eaux et Forêts)  
Rue Nichakra Rahal, n 25  
Casablanca  
Royaume du Maroc  
Tel.: +212 (22) 30 21 96  
Fax: +212 (22) 30 19 72

#### **NETHERLANDS / PAYS BAS / PAÍSES BAJOS**

Mr Bas **van der Heide**  
Policy Officer  
Ministry of Health, Welfare and Sports  
Department for Nutrition and Health Protection  
Food and Nutrition Division  
P.O. Box 2 03 50  
2500 EJ The Hague  
The Netherlands  
Tel.: +31 (70) 3 40 56 19  
Fax: +31 (70) 3 40 55 54  
Email: [b.vd.heide@minvws.nl](mailto:b.vd.heide@minvws.nl)

Lybrich **Kramer**  
Project staff  
WEMOS  
P.O. Box 1693  
1000 BR Amsterdam  
The Netherlands  
Tel.: +31 (20) 4 68 83 88  
Fax: +31 (20) 4 68 60 08  
Email: [lybrich.kramer@wemos.nl](mailto:lybrich.kramer@wemos.nl)

Mr Aad F. **Onneweer**  
Policy Officer  
Ministry of Agriculture, Nature Management and  
Fisheries  
P.O. Box 20401  
2500 EK The Hague  
The Netherlands  
Tel.: +31 (70) 3 70 43 61  
Fax: +31 (70) 3 70 61 41  
Email: [A.F.Onneweer@vva.agro.nl](mailto:A.F.Onneweer@vva.agro.nl)

Barbara M. **Schouten**  
 Secretary General  
 VAI (Dutch Food and Drink Industry) / VNFKD  
 (Association of Dutch Infant and Dietetic Foods  
 Industry)  
 Tourniairestraat 3  
 P.O. Box 90445  
 1006 BK Amsterdam, The Netherlands  
 Tel.: +31 (20) 7 13 07 00  
 Fax: +31 (20) 7 13 07 10  
 Email: [vnfkd@vnfkd.nl](mailto:vnfkd@vnfkd.nl)

Dr Jaap **Schrijver**  
 Manager Corporate Regulatory Affairs  
 VAI (Dutch Food and Drink Industry) / VNFKD  
 (Association of Dutch Infant and Dietetic Foods  
 Industry)  
 c/o Royal Numico N.V.  
 P.O. Box 1  
 2700 MA Zoetermeer, The Netherlands  
 Tel.: +31 (79) 3 53 94 66  
 Fax: +31 (79) 3 53 90 50  
 Email: [jaap.schrijver@numico.com](mailto:jaap.schrijver@numico.com)

Piet **van Doorninck**, MSc  
 Public Health Officer  
 Inspectorate for Health Protection and Veterinary  
 Public Health  
 P.O. Box 16108  
 2500 BC The Hague  
 The Netherlands  
 Tel.: +31 (70) 3 40 50 70  
 Fax: +31 (70) 3 40 54 35  
 Email: [piet.van.doorninck@kvw.nl](mailto:piet.van.doorninck@kvw.nl)

Ms Trudy **van Ommeren**  
 Project Leader  
 WEMOS  
 P.O. Box 1693  
 1000 BR Amsterdam, The Netherlands  
 Tel.: +31 (20) 4 68 83 88  
 Fax: +31 (20) 4 68 60 08  
 Email: [trudy.van.ommeren@wemos.nl](mailto:trudy.van.ommeren@wemos.nl)

*NEW ZEALAND / NOUVELLE-ZÉLANDE / NUEVA ZELANDIA*

Jenny **Reid**  
 Senior Advisor (Nutrition)  
 New Zealand Food Safety Authority  
 P.O. Box 2835  
 Wellington  
 New Zealand  
 Tel.: +64 (4) 4 63 25 82  
 Fax: +64 (4) 4 63 25 83  
 Email: [jenny.reid@nzfsa.govt.nz](mailto:jenny.reid@nzfsa.govt.nz)

*NIGERIA / NIGÉRIA*  
 Mrs Margaret **Eshiett**  
 Codex Contact Point Officer  
 Standards Organisation of Nigeria  
 Lekki Lagos, Nigeria  
 Email: [info@sononline-ng.org](mailto:info@sononline-ng.org)

Mr Fred **Chiazor**  
 Quality Assurance Manager  
 Intercontinental Distillers Ltd.  
 Plot 2 No 3 Lapipo Oluwole Street  
 Off Oba Akran Avenue  
 Ikeja - Lagos, Nigeria  
 Tel.: +237 (1) 7 74 81 81  
 Fax: +237 (1) 4 97 41 01  
 Email: [fredndukachiazor@hotmail.com](mailto:fredndukachiazor@hotmail.com)

*NORWAY / NORVÈGE / NORUEGA*

Ms Bente **Mangschou**  
 Adviser  
 Section for Quality and Consumer Affairs  
 Norwegian Food Control Authority  
 P.B. 8187 Dep.  
 0034 Oslo, Norway  
 Tel.: +47 23 21 67 89  
 Email: [bente.mangschou@snt.no](mailto:bente.mangschou@snt.no)

Ms Turid **Ose**  
 Senior Adviser  
 Section for Quality and Consumer Affairs  
 Norwegian Food Control Authority  
 P.B. 8187 Dep.  
 0034 Oslo, Norway  
 Tel.: +47 23 21 67 42  
 Fax: +47 23 21 70 01  
 Email: [turid.ose@snt.no](mailto:turid.ose@snt.no)

Ms Kari **Sygnestveit**  
 Adviser  
 Norwegian Directorate for Health and Social Welfare  
 (NHDS)  
 P.O. Box 8054 Dep.  
 0033 Oslo, Norway  
 Tel.: +47 24 16 34 46  
 Fax: +47 24 16 30 05  
 Email: [kari.sygnestveit@shdir.no](mailto:kari.sygnestveit@shdir.no)

*PERU / PÉROU / PERÚ*

Carlos Felipe **Pastor Talledo**  
 Director Ejecutivo de Higiene Alimentaria y Control de  
 la Zoonosis  
 Ministerio de Salud - Direccion General de Salud  
 Ambiental (Digesa)  
 Calle las Amapolas 350 Urb. San Eugenio-Lince  
 Lima 14, Peru  
 Tel.: +51 (1) 4 40 65 62  
 Fax: +51 (1) 4 40 67 97  
 Email: [cpastor@digesa.sld.pe](mailto:cpastor@digesa.sld.pe)

Javier **Ruiz-Eldredge Vargas**  
 Lawyer  
 Member of the Codex Alimentarius Committee  
 Comité Peruano Pro-Alimentación Infantil/Cesip  
 Coronel Zegarra 722 - Jesús María  
 Lima 11, Peru  
 Tel.: +51 (1) 4 71 34 10  
 Fax: +51 (1) 4 70 24 89  
 Email: [javier@cesip.org.pe](mailto:javier@cesip.org.pe)

**PHILIPPINES / FILIPPINAS**

Ms MA. Victoria D. **Pinion**  
 Nutritionist - Dietitian III  
 Bureau of Food and Drugs  
 Department of Health  
 Civic Drive  
 Filinvest Corporate City, Alabang  
 Multinlupa City, Philippines  
 Tel.: +63 (2) 8 42 - 45 38  
 Fax: +63 (2) 8 07 - 82 85  
 Email: [bfad@gov.ph](mailto:bfad@gov.ph)

Lea Tito **Ausan**

Third Secretary and Vice Consul  
 Philippine Embassy - Berlin  
 Uhlandstrasse 97  
 10715 Berlin, Germany  
 Tel.: +49 (30) 8 64 95 00  
 Fax: +49 (30) 8 73 25 51  
 Email: [berlinpe@t-online.de](mailto:berlinpe@t-online.de)

**POLAND / POLOGNE / POLONIA**

Dr Lucjan **Szponar**  
 Head of the Department of Hygiene of Food and  
 Nutrition - National Food and Nutrition Institute  
 61/63 Powsinska Street  
 02-903 Warsaw, Poland  
 Tel.: +48 (22) 5 50 96 20  
 Fax: +48 (22) 8 42 11 03  
 Email: [l.szponar@izz.waw.pl](mailto:l.szponar@izz.waw.pl)

Prof Dr Hanna **Kunachowicz**  
 Deputy Director for Scientific Research  
 National Food and Nutrition Institute  
 61/63 Powsinska Street  
 02-903 Warsaw, Poland  
 Tel.: +48 (22) 5 50 97 08  
 Fax: +48 (22) 8 42 11 03  
 Email: [Kunachowicz@izz.waw.pl](mailto:Kunachowicz@izz.waw.pl)

Mrs Maria **Kundzicz**

Research Assistant  
 Department of Food Hygiene and Nutrition  
 National Food and Nutrition Institute  
 61/63 Powsinska Street  
 02-903 Warsaw, Poland  
 Tel.: +48 (22) 5 50 96 89  
 Fax: +48 (22) 8 42 11 28  
 Email: [mkundzicz@izz.waw.pl](mailto:mkundzicz@izz.waw.pl)

Ms Katarzyna **Wolnicka**  
 Chief of Food Safety Legislation Division  
 National Food and Nutrition Institute  
 61/63 Powsinska Street  
 02-903 Warsaw, Poland  
 Tel.: +48 (22) 5 50 97 17  
 Fax: +48 (22) 6 51 63 30  
 Email: [kwolnick@izz.waw.pl](mailto:kwolnick@izz.waw.pl)

**PORTUGAL**

Prof Dr José António **Amorim Cruz**  
 (Investigator Coordinator)  
 INSA-Instituto Nacional de Saúde Dr Ricardo Jorge  
 Av. Padre Cruz  
 1649-016 Lisboa, Portugal  
 Tel.: +351 (21) 7 51 93 08  
 Fax: +351 (21) 7 59 04 41  
 Email: [amorim.cruz@insa-min.saude.pt](mailto:amorim.cruz@insa-min.saude.pt)

**ROMANIA / ROMANIE / RUMANIA**

Daniela-Eugenia **Cucu**  
 Manager - RENAR  
 General Berthelot 24 - Sector 1  
 Bucharest, Romania  
 Tel.: +40 (21) 3 10 22 74  
 Fax: +40 (21) 3 10 13 90  
 Email: [dcucu@renar.ro](mailto:dcucu@renar.ro)

Alin **Stanescu**

General Medical Director  
 Ministry of Health and Family  
 Institute for Mother and Child Care  
 Bd. Lacu Tei, Mo. 120, Sector 2  
 Bucharest, Romania  
 Tel.: +40 (21) 2 42 22 81  
 Fax: +40 (21) 2 42 85 93  
 Email: [dr-stanescu@yahoo.com](mailto:dr-stanescu@yahoo.com)

**RUSSIAN FEDERATION / FÉDÉRATION RUSSE /  
 FEDERACIÓN DE RUSIA**

Alexander **Baturin**  
 Deputy Director  
 Institute of Nutrition Russian Academy of Medical  
 Science  
 Ustinsky proezd 2/14  
 109240 Moscow, Russian Federation  
 Tel.: +7 (095) 2 98 18 72  
 Fax: +7 (095) 2 98 18 72  
 Email: [baturin@ion.ru](mailto:baturin@ion.ru)

**SENEGAL / SÉNÉGAL**

Diakhaidia **Diarra**  
 Nutritionniste à la Division de l'Alimentation et de la  
 Nutrition  
 Coordonnateur du Comité National du Codex  
 Dakar, République du Sénégal  
 Tel.: +221 - 8 25 77 32, +221 - 6 38 34 56  
 Email: [zak@sentoo.sn](mailto:zak@sentoo.sn)

**SOUTH AFRICA / AFRIQUE DU SUD / SUDÁFRICA**

Mrs Antoinette **Booyzen**  
 Assistant Director: Regulatory Nutrition  
 Directorate: Food Control  
 Department of Health  
 Private Bag X828  
 0001 Pretoria, South Africa  
 Tel.: +27 (12) 3 12 01 63  
 Fax: +27 (12) 3 26 43 74  
 Email: [booyza@health.gov.za](mailto:booyza@health.gov.za)

**Ann Behr**

Assistant Director: Dietary Services  
 National Department of Health, Directorate Nutrition  
 National Department of Health  
 Private Bag X828  
 0001 Pretoria, South Africa  
 Tel.: +27 (12) 3 12 00 43  
 Fax: +27 (12) 3 23 74 57  
 Email: [Behra@health.gov.za](mailto:Behra@health.gov.za)

**SPAIN / ESPAGNE / ESPAÑA**

Dra Mercedes **del Pozo Lozano**  
 Técnico Superior  
 Subdirección General de Gestión de Riesgos  
 Alimentarios  
 AESAS (Agencia Española de Seguridad Alimentaria)  
 M Sanidad y Consumo  
 Paseo del Prado 18,20  
 28071 Madrid, Spain  
 Tel.: +34 (91) 5 96 19 69  
 Fax: +34 (91) 5 96 44 87  
 Email: [MPOZO@MSC.ES](mailto:MPOZO@MSC.ES)

**Dra Pilar Contreras Gordo**

Técnico Superior  
 Subdirección General de Gestión de Riesgos  
 Alimentarios  
 AESAS (Agencia Española de Seguridad Alimentaria)  
 M Sanidad y Consumo  
 Paseo del Prado 18,20  
 28071 Madrid, Spain  
 Tel.: +34 (91) 5 96 16 21  
 Fax: +34 (91) 5 96 44 87  
 Email: [MCONTRERAS@MSC.ES](mailto:MCONTRERAS@MSC.ES)

**Dra Sandra Ribas Malagrida**

Secretaria General de Andi  
 Asociación Nacional de Dietética Infantil (ANDI)  
 Diego de León - 44  
 28006 Madrid, Spain  
 Tel.: +34 (91) 411 72 11  
 Email: [sandra.andi@terra.es](mailto:sandra.andi@terra.es)

**SWAZILAND / SWAZILANDE / SWAZILANDIA**

Ms Khanyisile **Mabuza-Imam**  
 Principal Home Economics and Nutrition Officer  
 Ministry of Agriculture and Cooperatives  
 P.O. Box 162  
 Mbabane, Swaziland  
 Tel.: +268 - 4 04 27 31/9  
 Fax: +268 - 4 04 47 00  
 Email: MOAC [SADP@realnet.Co.SZ](mailto:SADP@realnet.Co.SZ)

**SWEDEN / SUÈDE / SUECIA**

Mrs Kristina **Sjölin**  
 Principal Adm. Officer  
 Livsmedelsverket - Box 622  
 SE-75126 Uppsala, Sweden  
 Tel.: +46 (18) 17 55 00  
 Fax: +46 (18) 10 58 48  
 Email: [livsmedelverket@slv.se](mailto:livsmedelverket@slv.se)

**SWITZERLAND / SUISSE / SUIZA**

Dr PD Jürg **Lüthy**  
 Food Safety, Nutrition Unit  
 Swiss Federal Office of Public Health  
 3003 Bern, Switzerland  
 Tel.: +41 (31) 3 22 94 75  
 Fax: +41 (31) 3 22 95 74  
 Email: [juerg.luethy@bag.admin.ch](mailto:juerg.luethy@bag.admin.ch)

**Mr Jörg Cselovszky**

Roche Vitamins Ltd. - VML  
 Bldg. 241/823  
 4070 Basel, Switzerland  
 Tel.: +41 (61) 6 87 32 76  
 Fax: +41 (61) 6 88 16 35  
 Email: [joerg.cselovszky@roche.com](mailto:joerg.cselovszky@roche.com)

**Mrs Irina du Bois**

Nestec S.A.  
 Avenue Nestlé 55  
 1800 Vevey, Switzerland  
 Tel.: +41 (21) 9 24 22 61  
 Fax: +41 (21) 9 24 45 47  
 Email: [irina.dubois@nestle.com](mailto:irina.dubois@nestle.com)

**Mr Beat Hodler**

Fédération des Industries Alimentaires Suisse FIAL  
 Elfenstrasse 19  
 3000 Bern 16, Switzerland  
 Tel.: +41 (31) 3 52 11 88  
 Fax: +41 (31) 3 52 11 85  
 Email: [beat.hodler@hodler.ch](mailto:beat.hodler@hodler.ch)

Dr Marquard **Imfeld**  
 Chemist ETH - Head of Nutrition Regulatory Affairs  
 Novartis Consumer Health HQ  
 Site Basle WSJ 503 509  
 Lichtstrasse 35  
 4056 Basel, Switzerland  
 Tel.: +41 (61) 3 24 68 35  
 Fax: +41 (61) 3 24 68 34  
 Email: [marquard.imfeld@ch.novartis.com](mailto:marquard.imfeld@ch.novartis.com)

Mr Hervé **Nordmann**  
 Director Regulatory & Scientific Affairs  
 Ajinomoto Switzerland AG  
 En Crochet 1  
 1143 Apples (VD), Switzerland  
 Tel.: +41 (21) 8 00 37 63  
 Fax: +41 (21) 8 00 40 87  
 Email: [herve.nordmann@asg.ajinomoto.com](mailto:herve.nordmann@asg.ajinomoto.com)

Mrs Awilo **Ochieng Pernet**, lic. Iur.  
 Responsible Codex  
 Swiss Federal Office of Public Health  
 3003 Bern, Switzerland  
 Tel.: +41 (31) 3 22 00 41  
 Fax: +41 (31) 3 22 95 74  
 Email: [awilo.ochieng@bag.admin.ch](mailto:awilo.ochieng@bag.admin.ch)

Dr Otto **Raunhardt**  
 Consultant  
 Rossmattenweg 6  
 8932 Mettmenstetten, Switzerland  
 Tel.: +41 (1) 7 68 26 06  
 Fax: +41 (1) 7 68 26 19  
 Email: [otto.raunhardt@bluewin.ch](mailto:otto.raunhardt@bluewin.ch)

**TANZANIA, UNITED REPUBLIC OF / TANZANIE,  
 RÉPUBLIQUE UNIE DE / TANZANIA (REPÚBLICA UNIDA)**  
 Obadiah N. **Msaki**  
 Technical Advisor - Africa Codex Project  
 Centre for Counselling, Nutrition and Health Care  
 (COUNSENUTH)  
 P.O. Box 8218  
 Dar es Salaam, Tanzania  
 Email: [obadiah@ud.co.tz](mailto:obadiah@ud.co.tz)

**THAILAND / THAÏLANDE / TAILANDIA**  
 Dr Songsak **SriAnujata**  
 Director, Institute of Nutrition  
 Mahidol University  
 Salaya, Putthamonthon  
 Nakhonpathom 73170  
 Thailand  
 Tel.: +66 24 41 97 40 or +66 - 28 00 - 23 80 ext. 2 08  
 Fax: +66 - 24 41 - 93 44  
 Email: [rassn@mahidol.ac.th](mailto:rassn@mahidol.ac.th)  
[directnu@mahidol.ac.th](mailto:directnu@mahidol.ac.th)

Ms Chatsiri **Pinmuangngam**  
 Standards Officer  
 National Bureau of Agriculture Commodity and Food  
 Standards  
 Ministry of Agriculture and Cooperatives  
 Ratchadamnoen nok avenue  
 Bangkok 10200, Thailand  
 Tel.: +662 - 2 80 - 15 42  
 Fax: +662 - 6 29 - 89 78  
 Email: [acfs@acfs.go.th](mailto:acfs@acfs.go.th)

Mr Sommart **Prapertchob**  
 Vice Chairman  
 Food Processing Industry Club  
 The Federation of Thai Industries  
 Queen Strikit National Convention Center  
 Zone C, 4th Floor  
 60 New Rachadapisek Rd.  
 Klongtoey  
 Bangkok 10110, Thailand  
 Tel.: +662 - 6 57 81 25  
 Fax: +662 - 6 57 83 82  
 Email: [sommart.prapertchob@th.nestle.com](mailto:sommart.prapertchob@th.nestle.com)

**TUNISIA / TUNISIE / TÚNEZ**  
 Ben **Khedija** Houda  
 Pharmacien  
 Agence Nationale de Controle Sanitaire et  
 Environnemental des Produits  
 Immeuble Idriss. Bloc 9 - Cité M'hiri 2045  
 Les Berges du Loc  
 Tunisie  
 Tel.: +216 (71) 96 00 14  
 Fax: +216 (71) 96 01 46

**TURKEY / TURQUIE / TURQUÍA**  
 Leyla **Alma**, MSc  
 Food Engineer  
 General Directorate of Protection and Control  
 Ministry of Agriculture and Rural Affairs  
 Koruma ve Kontrol Genel Müdürlüğü  
 Akay Cad. No: 3 Bakanliklar  
 Ankara, Turkey  
 Tel.: +90 (312) 4 17 41 76  
 Fax: +90 (312) 4 18 65 23  
 Email: [levlaalma@yahoo.com](mailto:levlaalma@yahoo.com)

Müesser Akegim **Akkaya**  
 Regulatory Affairs Supervisor  
 Nestlé Türkiye Gıda Sanayi A.Ş  
 Büyükdere Cad. No: 71  
 Nurol Plaza A Blok Kat. 5  
 80670 Maslak Istanbul, Turkey  
 Tel.: +90 (212) 3 29 58 83  
 Fax: +90 (212) 3 29 60 42  
 Email: [muesser.akkaya@tr.nestle.com](mailto:muesser.akkaya@tr.nestle.com)

**UGANDA / OUGANDA**

Mr Henry Richard **Kimera**  
 Chief Executive  
 Consumer Education Trust of Uganda  
 Plot 4 Parliament Avenue  
 Desai Homes  
 G.P.O. Box 1433  
 Kampala, Uganda  
 Tel.: +256 (31) 26 04 31; +256 (41) 23 18 24  
 Fax: +256 (31) 26 04 32  
 Email: [consentug@yahoo.com](mailto:consentug@yahoo.com)  
[heriki@hotmail.com](mailto:heriki@hotmail.com)

**UNITED KINGDOM / ROYAUME-UNI / REINO UNIDO**

Vivien **Lund**  
 Senior Scientific Officer  
 Food Standards Agency  
 Room 115B  
 Aviation House  
 125 Kingsway  
 London WC2B 6NH, United Kingdom  
 Tel.: +44 (20) 72 76 81 69  
 Fax: +44 (20) 72 76 81 93  
 Email: [vivien.lund@foodstandards.gsi.gov.uk](mailto:vivien.lund@foodstandards.gsi.gov.uk)

Samantha **Church**  
 Senior Scientific Officer  
 Food Standards Agency  
 Aviation House  
 125 Kingsway  
 London WC2B 6NH, United Kingdom  
 Tel.: +44 (20) 72 76 89 77  
 Fax: +44 (20) 72 76 89 10  
 Email: [sam.church@foodstandards.gsi.gov.uk](mailto:sam.church@foodstandards.gsi.gov.uk)

**UNITED STATES OF AMERICA / ETATS-UNIS  
D'AMÉRIQUE / ESTADOS UNIDOS DE AMÉRICA**

Dr Elizabeth A. **Yetley**  
 Lead Scientist for Nutrition  
 Center for Food Safety & Applied Nutrition  
 Food and Drug Administration (HFS-006)  
 5100 Paint Branch Parkway  
 College Park, MD 20740, USA  
 Tel.: +1 (301) 4 36 19 03  
 Fax: +1 (301) 4 36 26 41  
 Email: [eyetley@cfsan.fda.gov](mailto:eyetley@cfsan.fda.gov)

Dr Christine **Taylor**  
 Director  
 Office of Nutritional Products, Labeling and Dietary  
 Supplements  
 Center for Food Safety & Applied Nutrition  
 Food and Drug Administration (HFS-830)  
 5100 Paint Branch Parkway  
 College Park, MD 20740  
 USA  
 Tel.: +1 (301) 4 36 23 73  
 Fax: +1 (301) 4 36 26 36  
 Email: [CLT@cfsan.fda.gov](mailto:CLT@cfsan.fda.gov)

Dr Sukh D. **Bassi**  
 Vice President  
 New Products and Technology Innovation  
 Midwest Grain Products, Inc.  
 1300 Main Street  
 Atchison, KS 66002, USA  
 Tel.: +1 (913) 3 67 89 21  
 Fax: +1 (913) 3 67 18 38  
 Email: [sbassi@midwestgrain.com](mailto:sbassi@midwestgrain.com)

Ms Nancy T. **Crane**  
 Nutritionist  
 Office of Nutritional Products, Labeling and Dietary  
 Supplements  
 Center for Food Safety & Applied Nutrition  
 Food and Drug Administration (HFS-830)  
 5100 Paint Branch Parkway  
 College Park, MD 20740, USA  
 Tel.: +1 (301) 4 36 14 50  
 Fax: +1 (301) 4 36 2636  
 Email: [nancy.crane@cfsan.fda.gov](mailto:nancy.crane@cfsan.fda.gov)

Dr Deborah A. **Diersen-Schade**  
 Senior Principal Research Scientist  
 Scientific Regulatory Affairs  
 Mead Johnson Nutritionals  
 2400 W. Lloyd Expressway R14  
 Evansville, IN 47721, USA  
 Tel.: +1 (812) 4 29 73 41  
 Fax: +1 (812) 4 29 50 54  
 Email: [deb.diersen-schade@bms.com](mailto:deb.diersen-schade@bms.com)

Mr Robert **Earl**  
 Senior Director  
 Nutrition Policy  
 National Food Processors Association  
 1350 I Street, NW, Suite 300  
 Washington, DC 20005, USA  
 Tel.: +1 (202) 6 39 59 70  
 Fax: +1 (202) 6 39 59 91  
 Email: [rearl@nfpa-food.org](mailto:rearl@nfpa-food.org)

Dr Paulette **Gaynor**  
 Consumer Safety Officer  
 Office of Food Additive Safety  
 Center for Food Safety & Applied Nutrition  
 Food and Drug Administration (HFS-255)  
 5100 Paint Branch PKWY  
 College Park, MD 20740, USA  
 Tel.: +1 (202) 4 18 30 79  
 Fax: +1 (202) 4 18 31 31  
 Email: [paulette.gaynor@cfsan.fda.gov](mailto:paulette.gaynor@cfsan.fda.gov)

Mr Byron J. **Johnson**  
 Industry Relations Director  
 Access Business group  
 7575 E. Fulton  
 Ada, MI 49355, USA  
 Tel.: +1 (616) 7 87 75 77  
 Fax: +1 (616) 7 87 56 25  
 Email: [byron.johnson@accessbusinessgroup.com](mailto:byron.johnson@accessbusinessgroup.com)

Ms Ellen Y. **Matten**  
 Staff Officer  
 U.S. Codex Office  
 Food Safety and Inspection Service  
 U.S. Department of Agriculture  
 Room 4861 - South Building  
 1400 Independence Avenue, SW  
 Washington, DC 20250  
 USA  
 Tel.: +1 (202) 2 05 77 60  
 Fax: +1 (202) 7 20 31 57  
 Email: [ellen.matten@usda.gov](mailto:ellen.matten@usda.gov)

Mr James **Roza**  
 Director of Quality Assurance  
 NOW Foods  
 395 S. Glen Ellyn Road  
 Bloomingdale, IL 60108, USA  
 Tel.: +1 (630) 5 45 90 98  
 Fax: +1 (630) 8 58 86 56  
 Email: [jroza@nowfoods.com](mailto:jroza@nowfoods.com)

#### **URUGUAY**

Cecilia Muxí **Muñoz**  
 Senior Technical Advisor to the General Direction of Health  
 General Direction of Health - Ministry of Health  
 18 de Julio 1892 - Piso 2 - Oficina 219  
 CP 11100  
 Montevideo, Uruguay  
 Tel.: +598 (2) 4 09 78 00 - 4 00 10 02  
 Fax: +598 (2) 4 01 38 70  
 Email: [cmuxi@msp.gub.uy](mailto:cmuxi@msp.gub.uy)

#### **ZIMBABWE**

David B. **Nhari**  
 Government Analyst Laboratory  
 Ministry of Health and Child Welfare - Zimbabwe  
 Box CY 231  
 Causeway  
 Harare, Zimbabwe  
 Tel.: +263 (4) 79 20 26  
 Fax: +263 (4) 70 85 27  
 Email: [dbnhari@africaonline.co.zw](mailto:dbnhari@africaonline.co.zw)

#### **OBSERVER**

##### **CZECH REPUBLIC / RÉPUBLIQUE TCHEQUE / REPUBLICA CHECA**

Daniela **Winklerová**  
 Head of National Reference Laboratory for Food Additives  
 National Institute of Public Health  
 Šrobárova 48  
 Prague 10 100 42, Czech Republic  
 Tel.: +420 (2) 67 08 23 18  
 Fax: +420 (2) 67 08 23 41  
 Email: [winklerova@szu.cz](mailto:winklerova@szu.cz)

#### **INTERNATIONAL GOVERNMENTAL ORGANIZATIONS**

##### **EUROPEAN COMMISSION / COMMISSION EUROPÉENNE / COMISIÓN EUROPEA**

Mr Basil **Mathioudakis**  
 European Commission  
 Health and Consumer Protection Directorate-General  
 F101 8/86  
 1049 Brussels, Belgium  
 Tel.: +32 (2) 2 95 91 82  
 Fax: +32 (2) 2 96 09 51  
 Email: [basil.mathioudakis@cec.eu.int](mailto:basil.mathioudakis@cec.eu.int)

Ms Helen **Lee**  
 European Commission  
 Health and Consumer Protection Directorate-General  
 B232 8/48  
 1049 Bruxelles, Belgium  
 Tel.: +32 (2) 2 99 86 68  
 Fax: +32 (2) 2 96 09 51  
 Email: [helen.lee@cec.eu.int](mailto:helen.lee@cec.eu.int)

##### **COUNCIL OF THE EUROPEAN UNION**

Mr Kari **Tölli**  
 Council of the EU  
 Rue de la Loi 175  
 1048 Brussels, Belgium  
 Tel.: +32 (2) 2 85 78 41  
 Fax: +32 (2) 2 85 61 98  
 Email: [secretariat.dgb2@consilium.eu.int](mailto:secretariat.dgb2@consilium.eu.int)

#### **INTERNATIONAL NON-GOVERNMENTAL ORGANIZATIONS**

##### **AAC - ASSOCIATION DES AMINONNERIES DE CÉRÉALES DE L'UNION EUROPÉENNE**

Mrs Maryse **Herve**  
 Regulatory Affairs Manager - AAC  
 43 avenue des Arts  
 1040 Brussels, Belgium  
 Tel.: +32 (2) 2 89 67 60  
 Fax: +32 (2) 5 13 55 92  
 Email: [m.herve@aac-eu.org](mailto:m.herve@aac-eu.org)

##### **AEDA / EFLA - ASSOCIATION EUROPÉENNE POUR LE DROIT DE L'ALIMENTATION / EUROPEAN FOOD LAW ASSOCIATION**

Patrick **Coppens**  
 Manager Legal Affairs and Quality Assurance  
 NUTRICIA  
 Rijksweg 64  
 2880 Bornem, Belgium  
 Tel.: +32 (3) 8 90 22 84  
 Fax: +32 (3) 8 90 23 29  
 Email: [patrick.coppens@nutricia.be](mailto:patrick.coppens@nutricia.be)

**Dietrich Gorny**  
 Vice President  
 EFLA/AEDA/ -European Food Law Association  
 Ziegelhüttenweg 43a  
 60598 Frankfurt am Main, Germany  
 Tel.: +49 (69) 63 15 34 91  
 Fax: +49 (69) 15 35 53  
 Email: [gornylaw@t-online.de](mailto:gornylaw@t-online.de)

**Thomas Mettke**  
 Member of EFLA  
 EFLA/AEDA -European Food Law Association  
 Kolbergerstrasse 13  
 81679 München, Germany  
 Tel.: +49 (89) 98 15 76

**Daniela Muchna**  
 Council Member  
 EFLA/AEDA -European Food Law Association  
 Im Brunnen 1  
 5330 Fuschl am See, Austria

***AESGP AND WSMI - ASSOCIATION OF THE EUROPEAN SELF-MEDICATION INDUSTRY / WORLD SELF-MEDICATION INDUSTRY***

**Melinda Friend**  
 Food Manager  
 7, avenue de Tervuren  
 1040 Brussels, Belgium  
 Tel.: +32 (2) 7 35 51 30  
 Fax: +32 (2) 7 35 52 22  
 Email: [M.Friend@aesgp.be](mailto:M.Friend@aesgp.be)

***AOECS - ASSOCIATION OF EUROPEAN COELIAC SOCIETIES***

**Hertha Deutsch**  
 Codex/Labeling Affairs  
 Anton Baumgartner Strasse 44/C5/2302  
 1230 Vienna, Austria  
 Tel.: +43 (1) 6 67 18 87  
 Fax: +43 (1) 6 67 18 87

**Mr Björn Johansson**  
 Director  
 Association of European Coeliac Societies (AOECS)  
 c/o Swedish Coeliac Society  
 Box 1160 - 17123 Solna, Sweden  
 Tel.: +46 (8) 7 34 01 05  
 Fax: +46 (8) 7 30 05 02  
 Email: [aoecs@celiaki.se](mailto:aoecs@celiaki.se)

***BIOPOLYMER - BIOPOLYMER INTERNATIONAL***

**Jean-Claude Attale**  
 Director  
 Biopolymer International  
 85 Boulevard Haussmann  
 75008 Paris, France  
 Tel.: +33 (1) 42 65 41 58  
 Fax: +33 (1) 42 65 02 05  
 Email: [biopol@iway.fr](mailto:biopol@iway.fr)

***CI - CONSUMERS INTERNATIONAL***

**Ms Indah Suksharningsih**  
 YLKI (Indonesian Consumer Organization)  
 21, Pancoran Barat VII  
 Duren Tiga  
 Jakarta-12760  
 Indonesia  
 Tel.: +62 (21) 7 97 13 78/79; 19 17 98 18 58  
 Fax: +62 (21) 7 98 - 10 38  
 Email: [konsumen@net.id](mailto:konsumen@net.id)

***CIAA - CONFÉDÉRATION DES INDUSTRIES AGRO-ALIMENTAIRES DE L'UE***

**Mrs Marie Christine Secretin**  
 Scientific Adviser - CIAA  
 43 Avenue des Arts  
 1040 Bruxelles, Belgium  
 Tel.: +32 (2) 5 14 11  
 Fax: +32 (2) 5 11 29 05  
 Email: [ciaa@ciaa.be](mailto:ciaa@ciaa.be)

***CRN - COUNCIL FOR RESPONSIBLE NUTRITION***

**John Hathcock, Ph.D**  
 Vice President, Nutritional and Regulatory Science  
 Council for Responsible Nutrition  
 1875 I St., NW, Suite 400  
 Washington, DC 20006-5409, USA  
 Tel.: +1 (202) 2 63 10 22  
 Fax: +1 (202) 8 72 95 94  
 Email: [jhathcock@crnusa.org](mailto:jhathcock@crnusa.org)

**Mark A. LeDoux**

Natural Alternatives International  
 1185 Linda Vista Drive  
 San Marcos, CA 92069, USA  
 Tel.: +1 (760) 7 44 73 40  
 Fax: +1 (760) 5 91 96 37  
 Email: [mledoux@nai-online.com](mailto:mledoux@nai-online.com)

***EHPM - EUROPEAN FEDERATION OF ASSOCIATIONS OF HEALTH PRODUCT MANUFACTURERS***

**Mr Derek Shrimpton**  
 Scientific Adviser  
 EHPM - European Federation of Associations of Health Product Manufacturers  
 Rue de l'Association 50  
 1000 Brussels, Belgium  
 Tel.: +32 (2) 2 09 11 45  
 Fax: +32 (2) 2 23 30 64  
 Email: [secretariat@ehpm.be](mailto:secretariat@ehpm.be)

**Mr Conny Svensson**

EHPM - European Federation of Associations of Health Product Manufacturers  
 Rue de l'Association 50  
 1000 Brussels, Belgium  
 Tel.: +32 (2) 2 09 11 45  
 Fax: +32 (2) 2 23 30 64

**ENCA - EUROPEAN NETWORK OF CHILDBIRTH ASSOCIATIONS**

Maryse **Lehners Arendt**  
 Scientific Advisor  
 ENCA European Network of Childbirth Associations  
 Initiativ Liewensufank asbl  
 20 rue de Contern  
 5955 Itzig, Luxemburg  
 Tel.: +3 52 36 05 97 11  
 Fax: +3 52 36 61 34

**IACFO - INTERNATIONAL ASSOCIATION OF CONSUMER FOOD ORGANIZATIONS**

Patti **Rundall**  
 Policy Director - Baby Milk Action / IBFAN  
 23 St Andrew's St  
 Cambridge CB2 3AX, United Kingdom  
 Tel.: +44 (1223) 46 44 20  
 Fax: +44 (1223) 46 44 17

**IADSA - INTERNATIONAL ALLIANCE OF DIETARY / FOOD SUPPLEMENT ASSOCIATIONS**

Simon **Pettman**  
 Executive Director  
 International Alliance of Dietary/Food Supplement Associations (IADSA)  
 50, Rue de l'Association  
 1000 Brussels, Belgium  
 Tel.: +32 (2) 2 09 11 55  
 Fax: +32 (2) 2 23 30 64  
 Email: [secretariat@iadsa.be](mailto:secretariat@iadsa.be)

Ric **Hobby**  
 Observer  
 International Alliance of Dietary/Food Supplement Associations (IADSA)  
 50, Rue de l'Association  
 1000 Brussels, Belgium  
 Tel.: +32 (2) 2 09 11 55  
 Fax: +32 (2) 2 23 30 64  
 Email: [secretariat@iadsa.be](mailto:secretariat@iadsa.be)

Dr Hirobumi **Ohama**  
 International Alliance of Dietary/Food Supplement Associations (IADSA)  
 50, Rue de l'Association  
 1000 Brussels, Belgium  
 Tel.: +32 (2) 2 09 11 55  
 Fax: +32 (2) 2 23 30 64  
 Email: [secretariat@iadsa.be](mailto:secretariat@iadsa.be)

Boris **Pimentel**  
 Secretariat  
 International Alliance of Dietary/Food Supplement Associations (IADSA)  
 50, Rue de l'Association  
 1000 Brussels, Belgium  
 Tel.: +32 (2) 2 09 11 55  
 Fax: +32 (2) 2 23 30 64  
 Email: [secretariat@iadsa.be](mailto:secretariat@iadsa.be)

Prof David **Richardson**  
 Scientific Advisor  
 International Alliance of Dietary/Food Supplement Associations (IADSA)  
 50, Rue de l'Association  
 1000 Brussels, Belgium  
 Tel.: +32 (2) 2 09 11 55  
 Fax: +32 (2) 2 23 30 64  
 Email: [secretariat@iadsa.be](mailto:secretariat@iadsa.be)

**IBFAN - INTERNATIONAL BABY FOOD ACTION NETWORK**

Elisabeth **Sterken**  
 International Baby Food Action Network (IBFAN)  
 6 Trinity Square  
 Toronto, Ontario M5G 1B1, Canada  
 Tel.: +1 (416) 5 95 - 98 19  
 Fax: +1 (416) 5 91 - 93 55

Lída **Lhotská**  
 Regional Coordinator for Europe  
 IBFAN  
 P.O. Box 157  
 1211 Geneva 19, Switzerland  
 Tel.: +41 (22) 7 98 91 64  
 Fax: +41 (22) 7 98 44 43  
 Email: [Lida.Lhotska@gifa.org](mailto:Lida.Lhotska@gifa.org)

Izeta **Softic**  
 A. Lebenicnik ZA  
 7500 Tuzla  
 Bosnia and Herzegovina  
 Tel.: +387 (35) 2 51 - 4 69  
 Fax: +387 (35) 2 51 - 4 69  
 Email: [ssoftic@hotmail.com](mailto:ssoftic@hotmail.com)

**ICA - INTERNATIONAL CO-OPERATIVE ALLIANCE**

Hiroshi **Suzuki**  
 Japanese Consumers' Co-operative Union (JCCU)  
 CO-OP Plaza 3-29-8  
 Shibuya  
 Shibuya-ku  
 Tokyo 150-8913, Japan  
 Tel.: +81 (3) 57 78 81 09  
 Fax: +81 (3) 57 78 80 08  
 Email: [hiroshi.suzuki@jccu.coop](mailto:hiroshi.suzuki@jccu.coop)

**ICGMA - INTERNATIONAL COUNCIL OF GROCERY MANUFACTURERS ASSOCIATION**

Ms Alison **Krester**  
 Director, Scientific and Nutrition Policy  
 International Council of Grocery Manufacturers Associations (ICGMA)  
 1010 Wisconsin Avenue, NW, Suite 900  
 Washington, DC 20007, USA  
 Tel.: +1 (202) 3 37 94 00  
 Fax: +1 (202) 3 37 45 08  
 Email: [akretser@gmabrands.com](mailto:akretser@gmabrands.com)

**Mark Mansour**

Partner - Keller & Heckman, LLP  
 1001 G Street NW  
 Suite 500 West  
 Washington, DC 20001, USA  
 Tel.: +1 (202) 4 34 42 33  
 Fax: +1 (202) 4 34 46 46  
 Email: [mansour@khlaw.com](mailto:mansour@khlaw.com)

**IDACE - ASSOCIATION DES INDUSTRIES DES ALIMENTS  
DIÉTÉTIQUES DE L'UNION EUROPÉENNE****Ms Alice Gravereaux**

Scientific and Regulatory Affairs  
 Association of the Food Industries for Particular  
 Nutritional Uses of the European Union (IDACE)  
 194 rue de Rivoli - 75001 Paris, France  
 Tel.: +33 (1) 53 45 87 87  
 Fax: +33 (1) 53 45 87 80  
 Email: [alice.gravereaux@wanadoo.fr](mailto:alice.gravereaux@wanadoo.fr)

**Ms Ruth Birt**

Association of the Food Industries for Particular  
 Nutritional Uses of the European Union (IDACE)  
 194 rue de Rivoli - 75001 Paris, France  
 Tel.: +33 (1) 53 45 87 87  
 Fax: +33 (1) 53 45 87 80  
 Email: [alice.gravereaux@wanadoo.fr](mailto:alice.gravereaux@wanadoo.fr)

**Mr André Carrier**

Association of the Food Industries for Particular  
 Nutritional Uses of the European Union (IDACE)  
 194 rue de Rivoli - 75001 Paris, France  
 Tel.: +33 (1) 53 45 87 87  
 Fax: +33 (1) 53 45 87 80  
 Email: [alice.gravereaux@wanadoo.fr](mailto:alice.gravereaux@wanadoo.fr)

**Ms Sarah Jacobs**

Association of the Food Industries for Particular  
 Nutritional Uses of the European Union (IDACE)  
 194 rue de Rivoli - 75001 Paris, France  
 Tel.: +33 (1) 53 45 87 87  
 Fax: +33 (1) 53 45 87 80  
 Email: [alice.gravereaux@wanadoo.fr](mailto:alice.gravereaux@wanadoo.fr)

**Dr Elaine Underwood**

Association of the Food Industries for Particular  
 Nutritional Uses of the European Union (IDACE)  
 194 rue de Rivoli - 75001 Paris, France  
 Tel.: +33 (1) 53 45 87 87  
 Fax: +33 (1) 53 45 87 80  
 Email: [alice.gravereaux@wanadoo.fr](mailto:alice.gravereaux@wanadoo.fr)

**IDF - INTERNATIONAL DAIRY FEDERATION****Dr Nils Kühlsen**

Consultant for nutrition and health  
 Verband der Deutschen Milchwirtschaft e.V.  
 Meckenheimer Allee 137  
 53115 Bonn, Germany  
 Tel.: +49 (228) 9 82 43 16  
 Fax: +49 (228) 9 82 43 20  
 Email: [n.kuehlsen@vdm-deutschland.de](mailto:n.kuehlsen@vdm-deutschland.de)

**Dr Willem A. Roelfsema**

Friesland Coberco Dairy Foods  
 Postbus 226  
 8901 MA Leeuwarden, Netherlands  
 Tel.: +31 (58) 2 99 26 68  
 Fax: +31 (58) 2 99 24 50  
 Email: [wa.roelfsema@fdf.nl](mailto:wa.roelfsema@fdf.nl)

**IFT - INSTITUTE OF FOOD TECHNOLOGISTS****Ms Gloria Brooks-Ray**

Exponent, Inc. (formerly Novigen Sciences)  
 P.O. Box 97  
 Mountain Lakes, NJ 07046, USA  
 Tel.: +1 (973) 3 34 46 52  
 Fax: +1 (973) 3 34 46 52

**IOCCC - INTERNATIONAL OFFICE OF COCOA,  
CHOCOLATE AND SUGAR CONFECTIONERY****Janet Lambert**

IOCCC  
 rue Defacqz 1  
 1000 Brussels, Belgium  
 Tel.: +44 (14) 91 61 40 81  
 Fax: +44 (14) 91 61 40 86

**ISDI - INTERNATIONAL SPECIAL DIETARY FOODS  
INDUSTRIES****Dr Andrée Bronner**

International Special Dietary Foods Industries (ISDI)  
 194 Rue de Rivoli  
 75001 Paris, France  
 Tel.: +33 (1) 53 45 87 87  
 Fax: +33 (1) 53 45 87 80  
 Email: [andree.bronner@wanadoo.fr](mailto:andree.bronner@wanadoo.fr)

**Ms Gayle Crozier-Willi**

International Special Dietary Foods Industries (ISDI)  
 194 Rue de Rivoli  
 75001 Paris, France  
 Tel.: +33 (1) 53 45 87 87  
 Fax: +33 (1) 53 45 87 80  
 Email: [andree.bronner@wanadoo.fr](mailto:andree.bronner@wanadoo.fr)

**Mr Marc de Skowronski**

International Special Dietary Foods Industries (ISDI)  
 194 Rue de Rivoli  
 75001 Paris, France  
 Tel.: +33 (1) 53 45 87 87  
 Fax: +33 (1) 53 45 87 80  
 Email: [andree.bronner@wanadoo.fr](mailto:andree.bronner@wanadoo.fr)

**Ms Christina Drotz**

International Special Dietary Foods Industries (ISDI)  
 Chemin Auguste Pidou 3  
 1007 Lausanne, Switzerland  
 Tel.: +33 (1) 53 45 87 87  
 Fax: +33 (1) 53 45 87 80  
 Email: [andree.bronner@wanadoo.fr](mailto:andree.bronner@wanadoo.fr)

**Kathie Bolognese**

Consultant - ISDI  
 Rue de Rivoli, 94  
 75001 Paris  
 Tel.: +33 (1) 53 45 87 87  
 Fax: +33 (1) 53 45 87 80

**Ms Marieke Lugt**

International Special Dietary Foods Industries (ISDI)  
 194 Rue de Rivoli  
 75001 Paris, France  
 Tel.: +33 (1) 53 45 87 87  
 Fax: +33 (1) 53 45 87 80  
 Email: [andree.bronner@wanadoo.fr](mailto:andree.bronner@wanadoo.fr)

**Ms Mardi Mountford**

International Special Dietary Foods Industries (ISDI)  
 194 Rue de Rivoli  
 75001 Paris, France  
 Tel.: +33 (1) 53 45 87 87  
 Fax: +33 (1) 53 45 87 80  
 Email: [andree.bronner@wanadoo.fr](mailto:andree.bronner@wanadoo.fr)

**Andries Trenning**

International Special Dietary Foods Industries (ISDI)  
 194 Rue de Rivoli  
 75001 Paris, France  
 Tel.: +33 (1) 53 45 87 87  
 Fax: +33 (1) 53 45 87 80  
 Email: [andree.bronner@wanadoo.fr](mailto:andree.bronner@wanadoo.fr)

**IWGA - INTERNATIONAL WHEAT GLUTEN ASSOCIATION**

**Marcel Feys**  
 Chairman - Regulatory Committee  
 International Wheat Gluten Association (IWGA)  
 Amylum Europe NV  
 Burchstraat 10  
 9300 Aalst, Belgium  
 Tel.: +32 (53) 73 33 15  
 Fax: +32 (53) 73 30 28  
 Email: [FEYSM@amylum.com](mailto:FEYSM@amylum.com)

**MARINALG INTERNATIONAL**

**Pierre P. Kirsch**  
 General Secretary  
 MARINALG INTERNATIONAL  
 85 Boulevard Haussmann  
 75008 Paris, France  
 Tel.: +33 (1) 42 65 41 58  
 Fax: +33 (1) 42 65 02 05  
 Email: [marinalg@iway.fr](mailto:marinalg@iway.fr)

**NHF - NATIONAL HEALTH FEDERATION**

**Scott C. Tips**  
 Legal Counsel  
 National Health Federation  
 807 Montgomery Street  
 San Francisco, CA 94133  
 USA  
 Tel.: +1 (415) 2 96 - 70 03  
 Fax: +1 (305) 8 32 - 03 88

**Dr Susan J. Negus**

Scientific Advisor  
 National Health Federation  
 807 Montgomery Street, F 401  
 San Francisco, CA 94133  
 USA  
 Tel.: +1 (310) 7 87 - 70 02  
 Fax: +1 (310) 7 87 - 72 76

**WGPAT- WORKING GROUP ON PROLAMIN ANALYSIS AND TOXICITY**

**Enrique Mendez**  
 Professor  
 Centro Nacional de Biotecnologia  
 C.S.I.C.  
 Campus Universidad Autonoma  
 Cantoblanco  
 28049 Madrid  
 Spain  
 Tel.: +34 (91) 5 85 48 42  
 Fax: +34 (91) 5 85 45 06  
 Email: [emendez@cnb.uam.es](mailto:emendez@cnb.uam.es)

**Dr Martin Stern**

Professor of Paediatrics  
 Chairman, Prolamin Working Group  
 University of Tübingen  
 University Children's Hospital  
 Hoppe-Seyler-Strasse 1  
 72074 Tübingen  
 Germany  
 Tel.: +49 (7071) 2 98 37 81  
 Fax: +49 (7071) 29 54 77  
 Email: [martin.stern@med.uni-tuebingen.de](mailto:martin.stern@med.uni-tuebingen.de)

**FAO - FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS**

**Dr Prakash Shetty**  
 Chief  
 Nutrition Planning Assessment and Evaluation Service  
 of the Food and Nutrition Division  
 FAO  
 Via delle Terme di Caracalla  
 00100 Rome, Italy  
 Tel.: +39 (06) 57 05 33 41  
 Fax: +39 (06) 57 05 45 93  
 Email: [Prakash.Shetty@fao.org](mailto:Prakash.Shetty@fao.org)

Dr Maya **Pineiro**  
 Nutrition Officer (Food Control)  
 Food Quality and Standards Service  
 Food and Nutrition Division  
 Via delle Terme di Caracalle  
 00100 Rome  
 Italy  
 Tel.: +39 (06) 57 05 33 08  
 Fax: +39 (06) 57 05 45 93  
 Email: [Maya.Pineiro@fao.org](mailto:Maya.Pineiro@fao.org)

**WHO - WORLD HEALTH ORGANIZATION**

James **Akré**, BA, MPIA  
 Technical Officer  
 Nutrition for Health & Development  
 World Health Organization  
 1211 Geneva 27  
 Switzerland  
 Tel.: +41 (22) 7 91 - 33 25  
 Fax: +41 (22) 7 91 41 56  
 Email: [akrej@who.int](mailto:akrej@who.int)

**CODEX SECRETARIAT**

Ms Selma **Doyran**  
 Food Standards Officer  
 Joint FAO/WHO Food Standards Programm  
 Viale delle Terme di Caracalla  
 00100 Rome  
 Italy  
 Tel.: +39 (06) 57 05 58 26  
 Fax: +39 (06) 57 05 45 93  
 Email: [Selma.Doyran@fao.org](mailto:Selma.Doyran@fao.org)

Mr Michael **Canon**  
 Food Standards and Nutrition Officer  
 FAO Subregional Office for Central and Eastern  
 Europe  
 Benczur utca 34  
 1068 Budapest  
 Hungary  
 Tel.: +36 (1) 4 61 20 21  
 Fax: +36 (1) 3 51 70 29  
 Email: [michael.canon@fao.org](mailto:michael.canon@fao.org)

**GERMAN SECRETARIAT**

Dr Petra **Schulte-Herbrüggen**  
 Federal Institute for Risk Assessment (BfR)  
 P.O. Box 33 00 13  
 14191 Berlin  
 Germany  
 Tel.: +49 (1888) 4 12 - 3227  
 Fax: +49 (1888) 4 12 - 37 15  
 Email: [ccnfsdu@bfr.bund.de](mailto:ccnfsdu@bfr.bund.de)

Ms Dorothea **Kunze**  
 Federal Institute for Risk Assessment (BfR)  
 P.O. Box 33 00 13  
 14191 Berlin  
 Germany  
 Tel.: +49 (1888) 4 12 - 48 11  
 Fax: +49 (1888) 4 12 - 37 15  
 Email: [ccnfsdu@bfr.bund.de](mailto:ccnfsdu@bfr.bund.de)

Ms Gabriele **Restle**  
 Apostel-Paulus-Strasse 18  
 10825 Berlin  
 Germany  
 Tel.: +49 (30) 7 81 55 13

**PROPOSED DRAFT REVISED STANDARD FOR INFANT FORMULA****(At Step 3 of the Procedure)****1. SCOPE**

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

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

1.3 The application of the Standard should take into account the recommendations given to countries under the International Code of Marketing of Breast-milk Substitutes and the World Health Assembly resolution WHA54.2 (2001).

**2. DESCRIPTION****2.1 PRODUCT DEFINITION**

2.1.1 Infant formula means a breast-milk substitute specially manufactured to satisfy, by itself, the [normal] nutritional requirements of infants during the first months of life up to the introduction of appropriate complementary feeding. ~~Only products that comply with the criteria laid down in the provisions of this standard would be accepted for marketing as infant formula.~~(moved to Scope)

2.1.2 When in liquid form, infant formula may be used either directly or prepared with safe, and previously boiled water before feeding according to directions for use. In powdered form infant formula also requires safe, and previously boiled water for preparation.

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

**2.2 OTHER DEFINITIONS**

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

**3. ESSENTIAL COMPOSITION AND QUALITY FACTORS****[3.1 ESSENTIAL COMPOSITION**

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

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

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	Amounts per 100 kilocalories		Amounts per 100 kJ	
	Minimum	Maximum	Minimum	Maximum
<b>(a) Vitamins</b>				
Vitamin A*	60 µg	180 µg	14 µg	43 µg
Vitamin D	40 I.U. or 1 µg	100 I.U. or 2,5 µg	10 I.U. or 0.25 µg	25 I.U. or 0.63 µg
Vitamin E (α-tocopherol equivalent TE)	0,5 mg/g linoleic acid <sup>2</sup> , but in no case less than 0.5 mg/100 kcal	N.S. <sup>1</sup>	0.5 mg/g linoleic acid <sup>2</sup> but in no case less than 0.1 mg /100 kJ	N.S. <sup>1</sup>
Ascorbic Acid (Vitamin C)	8 mg	N.S. <sup>1</sup>	1,9 mg	N.S. <sup>1</sup>
Thiamine (Vitamin B <sub>1</sub> )	40 µg	N.S. <sup>1</sup>	10 µg	N.S. <sup>1</sup>
Riboflavin (Vitamin B <sub>2</sub> )	60 µg	N.S. <sup>1</sup>	14 µg	N.S. <sup>1</sup>
Niacin, niacin equivalents	0,8 mg	N.S. <sup>1</sup>	0,2 mg	N.S. <sup>1</sup>
Vitamin B <sub>6</sub>	15 µg/g protein but in no case less than 35 µg/100 kcal	N.S. <sup>1</sup>	15 µg/g protein but in no case less than 9 µg/100 kJ	N.S. <sup>1</sup>
Folic acid	4 µg	N.S. <sup>1</sup>	1 µg	N.S. <sup>1</sup>
Pantothenic acid	300 µg	N.S. <sup>1</sup>	70 µg	N.S. <sup>1</sup>
Vitamin B <sub>12</sub>	0.10 µg	N.S. <sup>1</sup>	0.025 µg	N.S. <sup>1</sup>
Vitamin K <sub>1</sub>	4 µg	N.S. <sup>1</sup>	1 µg	N.S. <sup>1</sup>
Biotin (Vitamin H)	1.5 µg	N.S. <sup>1</sup>	0.4 µg	N.S. <sup>1</sup>
<b>(b) Minerals</b>				
Sodium (Na)	20 mg	60 mg	5 mg	15 mg
Potassium (K)	60 mg	145 mg	15 mg	35 mg
Chloride (Cl)	50 mg	125 mg	12 mg	29 mg
Calcium (Ca) <sup>3</sup>	50 mg	N.S. <sup>1</sup>	12 mg	N.S. <sup>1</sup>
Phosphorus (P) <sup>3</sup>	25 mg	90 mg	6 mg	22 mg
Magnesium (Mg)	5 mg	15 mg	1.2 mg	3,6 mg
Iron (Fe)	0.5 mg	1.5 mg	0.12 mg	0.36 mg
Iron (Fe) <sup>4</sup>	1 mg	2 mg	0.25 mg	0.5 mg
Iodine (I)	5 µg	N.S. <sup>1</sup>	1.2 µg	N.S. <sup>1</sup>
Copper (Cu)	20 µg	80 µg	4.8 µg	19 µg
Zinc (Zn)	0.5 mg	N.S. <sup>1</sup>	0.12 mg	N.S. <sup>1</sup>
Zinc (Zn) <sup>4</sup>	0.75 mg	2.4 mg	0.18 mg	0.6 mg
Manganese (Mn)	5 µg	N.S. <sup>1</sup>	1,2 µg	N.S. <sup>1</sup>

Selenium (Se)	7 µg	3 µg	N.S. <sup>1</sup>	0,7 µg
(c) <b>Choline</b>	N.S. <sup>1</sup>	N.S. <sup>1</sup>	1.7 mg	N.S. <sup>1</sup>

\* expressed as retinol equivalent

<sup>1</sup> N.S. = Not specified

<sup>2</sup> Or per g polyunsaturated fatty acids, expressed as linoleic acid.

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

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

**(d) Protein**

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

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

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

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

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

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

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

**(e) Fat and Fatty Acid**

The product shall contain:

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

**(f) Carbohydrates**

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

**(g) Energy content**

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

### 3.2 OPTIONAL INGREDIENTS

3.2.1 In addition to the compositional requirements listed under 3.1, other [nutrients/ingredients] may be added in order to provide [nutrients/substances] ordinarily found in human milk and to ensure that the formulation is suitable as the sole source of nutrition for the infant.

3.2.2 [The usefulness/suitability/beneficial effect] for the particular nutritional uses of infants and safety of these nutrients shall be scientifically demonstrated.

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

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

### 3.3 VITAMIN COMPOUNDS AND MINERAL SALTS

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

### 3.4 CONSISTENCY AND PARTICLE SIZE

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

### 3.5 PURITY REQUIREMENTS

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

### 3.6 SPECIFIC PROHIBITION

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

## 4. FOOD ADDITIVES

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

[	<b>Maximum level in 100 ml of the ready-to-drink product</b>
<b>4.1 THICKENING AGENTS</b>	
5.1.1 Guar gum	0.1 g in all types of infant formula
4.1.2 Locust bean gum <sup>2</sup>	0.1 g in all types of infant formula
4.1.3 Distarch phosphate	} 0.5 g singly or in combination in soy-based infant formulae only
4.1.4 Acetylated distarch phosphate	
4.1.5 Phosphated distarch phosphate	
4.1.6 Hydroxypropyl starch	} 2.5 g singly or in combination in hydrolyzed protein and/or amino acid acid-based infant formulae only
4.1.7 Carrageenan	} 0.03 g in regular, milk- and soy-based liquid infant formulae only

<sup>2</sup> Temporarily endorsed

} 0.1 g in hydrolyzed protein and/or amino acid-based liquid infant formulae only

## 4.2 EMULSIFIERS

4.2.1 Lecithin 0.5 g in all types of infant formulae

4.2.2 Mono- and diglycerides 0.4 g in all types of infant formulae

## 4.3 PH-ADJUSTING AGENTS

4.3.1 Sodium hydroxide }

4.3.2 Sodium hydrogen carbonate }

4.3.3 Sodium carbonate } Limited by good manufacturing practice

4.3.4 Potassium hydroxide } and within the limits for sodium and

4.3.5 Potassium hydrogen carbonate } potassium in Section 3.1.2 (c) in all

4.3.6 Potassium carbonate } types of infant formulae

4.3.7 Calcium hydroxide }

4.3.8 Sodium citrate }

4.3.9 Potassium citrate }

4.3.10 L(+) Lactic acid } Limited by good manufacturing practice

4.3.11 Citric acid in all types of infant formulae

## 4.4 ANTIOXIDANTS

4.4.1 Mixed tocopherols concentrate } 1 mg in all types of infant formulae

4.4.2 L-Ascorbyl palmitate } ]

### [ALTERNATIVE PROPOSAL

			Maximum level in 100 ml of the ready-to-drink product
<b>4.1</b>	<b>Thickening Agents</b>		
	<b>INS no.</b>		
4.1.1	412	Guar gum	0.1 g in all types of infant formula
4.1.2	410	Carob bean gum (Locust bean gum)	0.1 g in all types of infant formula
4.1.3	1412	Distarch phosphate	} 0.5 g singly or in combination in soy-based infant formula only
4.1.4	1414	Acetylated distarch phosphate	
4.1.5	1413	Phosphated distarch phosphate	
4.1.6	1440	Hydroxypropyl starch	} 2.5 g singly or in combination in hydrolyzed protein and/or amino acid-based infant formula only
4.1.7	407	Carrageenan	0.03 g in regular milk- and soy-based liquid infant formula only 0.1 g in hydrolyzed protein and/or amino acid-based infant formula only
<b>4.2</b>	<b>Emulsifiers</b>		
4.2.1	322	Lecithin	0.5 g in all types of infant formula *
4.2.2	471	Mono- and diglycerides	0.4 g in all types of infant formula *

4.2.3	472 c	Citric and fatty acid esters of glycerol	0.75 g in powder formula * 0.9 g in liquid formula containing partially hydrolyzed protein, peptides or amino acids *
4.2.4	473	<b>Sucrose esters of fatty acids</b>	12 mg in formula containing hydrolyzed protein, peptides or amino acids *
			* If more than one of the substances INS Nos. 322, 471, 472c and 473 are added, the maximum level for each of those substances is lowered with the relative part as present of the other substances
<b>4.3 pH-Adjusting Agents</b>			
4.3.1	524	Sodium hydroxide	} Limited by GMP and within the limits for sodium and potassium in Section 3.1.2 (c) in all types of infant formula
4.3.2	500ii	Sodium hydrogen carbonate	
4.3.3	500i	Sodium carbonate	
4.3.4	525	Potassium hydroxide	
4.3.5	501ii	Potassium hydrogen carbonate	
4.3.6	501i	Potassium carbonate	
4.3.7	526	Calcium hydroxide	
4.3.8	331 (i, iii)	Sodium citrate	
4.3.9	332 (i, ii)	Potassium citrate	
4.3.10	270	L(+)- Lactic acid	} Limited by GMP in all types of infant formula
4.3.11	330	Citric acid	
4.3.12	338	Orthophosphoric acid	} Limited by GMP and within the limits for sodium and potassium in Section 3.1.2 (c) in all types of infant formula
4.3.13	339 (i, ii, iii)	Sodium orthophosphates	
4.3.14	340 (i, ii, iii)	Potassium orthophosphates	
<b>4.4 Antioxidants</b>			
4.4.1	306	Mixed tocopherols concentrate	} 1 mg in all types of infant formula singly or in combination
4.4.2	307	Alpha-Tocopherol	
4.4.3	304	L-Ascorbyl palmitate	1 mg in all types of infant formula
<b>4.5 Packaging Gas (Propellants)</b>			
4.5.1	290	Carbon dioxide	GMP
4.5.2	941	Nitrogen	GMP
4.5.3	942	Nitrous oxide	GMP
4.5.4	938	Argon	GMP
4.5.5	939	Helium	GMP
4.5.6	948	Oxygen	GMP
4.5.7	949	Hydrogen	GMP

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#### 4.5 CARRY-OVER OF FOOD ADDITIVES

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

- (a) of the food additives listed under Sections 4.1 to 4.4 (or 4.5) of this standard within the limits of the maximum levels stipulated in this standard; and
- (b) of the carrier substances mentioned in the Advisory List of Vitamin Compounds for Use in Foods for Infants and Children within the limits of the maximum levels stipulated in that List.

## 5. CONTAMINANTS

### 5.1 PESTICIDE RESIDUES

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

### 5.2 OTHER CONTAMINANTS

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

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

	Maximum level
Lead	0.02 mg/kg (in the ready-to-use product)

## 6. HYGIENE

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

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

## 7. PACKAGING

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

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

## 8. FILL OF CONTAINER

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

- (i) not less than 80% v/v for products weighing less than 150 g (5 oz.);
- (ii) not less than 85% v/v for products in the weight range 150-250 g (5-8 oz.); and
- (iii) not less than 90% v/v for products weighing more than 250 g (8 oz.)

of the water capacity of the container. The water capacity of the container is the volume of distilled water at 20° C which the sealed container will hold completely filled.

## 9. LABELLING

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

## 9.1 THE NAME OF THE FOOD

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

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

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

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

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

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

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

or

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

## 9.2 LIST OF INGREDIENTS

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

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

## 9.3 DECLARATION OF NUTRITIVE VALUE

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

- (a) the amount of energy, expressed in kilocalories (kcal) and/or kilojoules (kJ), and the number of grammes of protein, carbohydrate and fat per 100 grammes of the food as sold as well as per 100 milliliter of the food ready for use, when prepared according to the instructions on the label.
- (b) the total quantity of each vitamin, mineral, choline as listed in paragraph 3.1.2 and any other ingredient as listed in paragraph 3.2 of this Standard per 100 grammes of the food as sold as well as per 100 milliliter of the food ready for use, when prepared according to the instructions on the label.
- (c) In addition, the declaration of nutrients in a) and b) per 100 kilocalories (or per 100 kilojoules) is permitted.

## 9.4 DATE MARKING AND STORAGE INSTRUCTIONS

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

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

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

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

## 9.5 INFORMATION FOR USE

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

## 9.6 ADDITIONAL LABELLING REQUIREMENTS

9.6.1 Labels should not discourage breastfeeding. Each container label shall have a clear, conspicuous and easily readable message which includes the following points:

a) the words "important notice" or their equivalent;

b) [a statement of the superiority of breastfeeding or breastmilk, for example the statement: Breastmilk is the best food for your baby, it protects against diarrhea and other illnesses];

or:

b) [The statement "Breastfeeding is the best food for your baby" or a similar statement as to the superiority of breastfeeding or breastmilk.]

c) a statement that the product should only be used on advice of an independent health worker as to the need for its use and the proper method of use;

d) instructions for appropriate preparation;

e) a warning against the health hazards of inappropriate preparation; and a warning that formula remaining after each feeding should be discarded.

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

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

9.6.4 Information shall appear on the label to the effect that infants should receive supplemental foods in addition to the formula, from an age that is appropriate for their specific growth and development needs, as advised by an independent health worker, and in any case from the age over six months.

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

## 10. METHODS OF ANALYSIS AND SAMPLING

Dietary fibre, total	AOAC 991.43	Vitamin A in foods in which carotenes have been added as a source of vitamin A	AOAC 942.15
Iodine (milk based formula)	AOAC 992.24	Vitamin K <sub>1</sub>	AOAC 992.27
Pantothenic acid	AOAC 992.07	Vitamin D (D <sub>3</sub> , milk based infant formula)	AOAC 992.26
Pantothenic acid	<i>The Analyst</i> 89 (1964)(1) 3-6, 232 US Dept Agr., <i>Agr. Handbook</i> 97 (1965)	Vitamin E	AOAC 971.30
Vitamin A	AOAC 974.29	Vitamin E (milk based infant formula)	AOAC 992.03
Vitamin A (retinol isomers)	AOAC 992.04	Vitamin B12	AOAC 952.20
Vitamin A (retinol)	AOAC 992.06		

Vitamin B6	AOAC 961.15
Vitamin C	AOAC 967.22; AOAC 967.21
Determination of choline	AOAC 999.14 (Enzymatic method)
Determination of Vitamin K	AOAC 999.15 (LC method)
Detection of Irradiated Foods	Codex General Methods
Determination of Lead	Codex General Methods
Calcium	AOAC 984.27
Chloride	
Carbohydrates	Method described in CAC/VOL IX-Ed.1, Part III
Crude protein	Method described in CAC/VOL IX-Ed.1, Part III
Fat	CAC/RM 55-1976
Fill of containers	CAC/RM 46-1972
Folic acid	AOAC 944.12

Linoleate (in the form of glycerides)	AOAC 922.06; 969.33; 963.22; 979.19
Loss of drying	AOAC 934.01; AOAC 925.23
Nicotinamide for foods not based on milk	AOAC 961.14
Nicotinamide for milk- based foods	AOAC 944.13
Phosphorus	AOAC 986.24
Protein efficiency ratio (PER)	AOAC 960.48
Riboflavin	AOAC 970.65
Sodium and potassium	AOAC 984.27
Sodium and potassium	ISO 8070:1987 IDF 119A/1987
Thiamine	AOAC 942.23
Total dietary fibre	AOAC 985.29

**ANNEX 1****Essential and semi-essential amino acids in breast milk**

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

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

## PROPOSED DRAFT REVISED STANDARD FOR PROCESSED CEREAL-BASED FOODS FOR INFANTS AND YOUNG CHILDREN

(At Step 3 of the Procedure)

### 1. SCOPE

This standard covers processed cereal-based foods intended for feeding infants as a complementary food generally from the age of 6 months onwards, taking into account infants' individual nutritional requirements, and for feeding young children as part of a progressively diversified diet, in accordance with World Health Assembly Resolution WHA54.2 (2001).

### 2. DESCRIPTION

Processed cereal-based foods are prepared primarily from one or more milled cereals, which should constitute at least 25% of the final mixture on a dry weight basis.

#### 2.1. PRODUCT DEFINITIONS

Four categories are distinguished:

2.1.1 Products consisting of cereals which are or have to be prepared for consumption with milk or other appropriate nutritious liquids;

2.1.2 Cereals with an added high protein food which are or have to be prepared for consumption with water or other appropriate protein-free liquid

2.1.3 Pasta which are to be used after cooking in boiling water or other appropriate liquids;

2.1.4 Rusks and biscuits which are to be used either directly or, after pulverization, with the addition of water, milk or other suitable liquids.

#### 2.2 OTHER DEFINITIONS

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

2.2.2 The term **young children** means persons from the age of more than 12 months up to the age of three years (36 months).

### 3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

#### 3.1 ESSENTIAL COMPOSITION

3.1.1 *The four categories listed in 2.1.1 to 2.1.4* are prepared primarily from one or more milled cereal products, such as wheat, rice, barley, oats, rye, maize, millet, sorghum and buckwheat. It may also contain legumes (pulses), starchy roots (such as arrow root, yam or cassava) or starchy stems or oil seeds in smaller proportions.

3.1.2 The requirements concerning energy and nutrients refer to the product ready for use as marketed or prepared according to the instructions of the manufacturer, unless otherwise specified.

#### 3.2 ENERGY DENSITY

The energy density of cereal-based foods should not be less than 0.8 kcal/g (3.3/kJ/g).

#### 3.3 PROTEIN

3.3.1 The chemical index of the added protein shall be equal to at least 80% of that of the reference protein casein or the Protein Efficiency Ratio (PER) of the protein in the mixture shall be equal to at least 70% of

that of the reference protein casein. In all cases, the addition of amino acids is permitted solely for the purpose of improving the nutritional value of the protein mixture, and only in the proportions necessary for that purpose. Only natural forms of L-amino acids should be used.

3.3.2 For products mentioned in points 2.1.2 and 2.1.4, the protein content shall not exceed 1.3 g/100 kJ (5.5 g/100 kcal)]

3.3.3 For products mentioned in point 2.1.2 the added protein content shall not be less than 0.48 g/100 kJ (2 g/100 kcal)]

3.3.4 For biscuits mentioned in point 2.1.4 made with the addition of a high protein food, and presented as such, the added protein shall not be less than 0.36 g/100 kJ (1.5 g/ 100 kcal).

### 3.4 CARBOHYDRATES

3.4.1 If sucrose, fructose, glucose, glucose syrup or honey are added to products mentioned in points 2.1.1 and 2.1.4

- the amount of added carbohydrates from these sources shall not exceed 1.8 g/100 kJ (7.5 g/100 kcal)
- the amount of added fructose shall not exceed 0.9 g/100 kJ (3.75 g/100 kcal)

3.4.2 If sucrose, fructose, glucose, glucose syrup or honey are added to products mentioned in point 2.1.2

- the amount of added carbohydrates from these sources shall not exceed 2g/100 kJ (8.4 g/100 kcal)
- the amount of added fructose shall not exceed 0.6 g/100 kJ (2.5 g/100 kcal)]

### 3.5 LIPIDS

For products mentioned in point 2.1 the lipid content shall not exceed 1.1g/100 kJ (4.5 g/100 kcal) If the lipid content exceeds 0.8g/100kJ (3.3g/100kcal):

- the amount of linoleic acid (in the form of triglycerides=linoleates) shall not be less than 70 mg/100 kJ (300 mg/100 kcal) and shall not exceed 285 mg/100 kJ (1200 mg/100 kcal).

*[ - the amount of lauric acid shall not exceed 15% of the total lipid content*

*- the amount of myristic acid shall not exceed 15% of the total lipid content”]*

[The use of partially hydrogenated fats for these products is prohibited]

*[Product category 2.1.2 should have a minimum lipid content of 3.3 g/100 kcal (0.8 g /100 kJ)]*

### 3.6 MINERALS

3.6.1 The sodium content of the products described in Sections 2.1.1 to 2.1.4 of this Standard shall not exceed [100 mg/100 kcal] of the ready-to-eat product, except in the case of products intended for children over one year of age, where the sodium content shall not exceed [200 mg/100 kcal].

3.6.2 The calcium content shall not be less than 20 mg/100 kJ (80 mg/100 kcal) for products mentioned in points 2.1.2.

3.6.3 The calcium content shall not be less than 12 mg/100 kJ (50 mg/100 kcal) for products mentioned in point 2.1.4 containing milk.

### 3.7 VITAMINS

3.7.1 The amount of vitamin B1 (thiamin) shall not be less than [15µg/100 kJ] [(60µg/100 kcal)].

3.7.2 For products mentioned in 2.1.2, the amount of vitamin A and vitamin D expressed in µg/100 kcal shall be within the following limits:

	µg/100kcal	µg/100kJ
vitamin A (µg retinol equivalents)	60 - 180	14-43
vitamin D	1 - 3	0.25-0.75

These limits are also applicable to other processed cereal-based foods when vitamin A or D are added.

3.7.3 Derogations to the maximum amounts for vitamin A and Vitamin D referred to in 3.7.2 and the addition of vitamins and minerals for which specifications are not set above shall be in conformity with the legislation of the country in which the product is sold.

3.7.4 Vitamins and/or minerals added should be selected from the Advisory Lists of Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Children (CAC/GL 10-1979).

### 3.8 OPTIONAL INGREDIENTS

3.8.1 In addition to the ingredients listed under 3.1, other ingredients suitable for infants who are more than six months of age and for young children can be used.

3.8.2 Products containing honey or maple syrup should be processed in such a way as to destroy spores of *Clostridium botulinum*, if present.

3.8.3 Cocoa can be used only in products to be consumed after [nine] months of age, and at the maximum level of 1.5% m/m in the ready-to-eat product.

### 3.9 QUALITY FACTORS

3.9.1 All ingredients, including optional ingredients, shall be clean, safe, suitable and of good quality.

3.9.2 All processing and drying should be carried out in a manner that minimizes loss of nutritive value, particularly protein quality.

3.9.3 The moisture content of the products shall be governed by good manufacturing practice for the individual product categories and shall be at such a level that there is a minimum loss of nutritive value and at which microorganisms cannot multiply.

### 3.10 CONSISTENCY AND PARTICLE SIZE

3.10.1 When prepared according to the label directions for use, processed cereal-based foods should have a texture appropriate for the [spoon feeding] of infants or young children of the age for which the product is intended.

3.10.2 Rusks and biscuits may be used in the dry form so as to permit and encourage chewing or they may be used in a liquid form, by mixing with water or other suitable liquid, that would be similar in consistency to dry cereals.

### 3.11 SPECIFIC PROHIBITION

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

## 4. FOOD ADDITIVES

The following additives are permitted in the preparation of processed cereal-based foods for infants and children, as described in Section 2.1 of this Standard (in 100 g of product, on a dry weight basis unless otherwise indicated)

Maximum level in 100 g of the product			
<b>4.1</b>	<b>Emulsifiers</b>		
4.1.1	322	Lecithin	1.5 g
4.1.2	471	Mono- and diglycerides	1.5 g
4.1.3	472a	Acetic and fatty acid esters of glycerol	} 0.5 g singly or in combination
4.1.4	472b	Lactic and fatty acid esters of glycerol	

4.1.5	472c	Citric and fatty acid esters of glycerol		
<b>4.2 pH-Adjusting Agents</b>				
4.2.1	500ii	Sodium hydrogen carbonate	GMP, within the limits for sodium	
4.2.2	501ii	Potassium hydrogen carbonate	} GMP	
4.2.3	170I	Calcium carbonate		
4.2.4	270	L(+) Lactic acid		
4.2.5	330	Citric acid	1.5 g	
4.2.6	260	Acetic acid (Acetic acid, glacial)	2.5 g	
4.2.7	261	Potassium acetates	} Only for pH adjustment GMP	
4.2.8	262 (i, ii)	Sodium acetates		
4.2.9	263	Calcium acetate		
4.2.1	296	Malic acid (DL) - L(+)-form only		
4.2.1	325	Sodium lactate (solution) - L(+)-form only		
4.2.1	326	Potassium lactate (solution) - L(+)-form only		
4.2.1	327	Calcium lactate - L(+)-form only		
4.2.1	331 (i, ii)	Sodium citrate		
4.2.1	332 (i, ii)	Potassium citrate		
4.2.1	333	Calcium citrate		
4.2.1	507	Hydrochloric acid		
4.2.1	524	Sodium hydroxide		
4.2.1	525	Potassium hydroxide		
4.2.2	526	Calcium hydroxide		
4.2.2	575	Glucono delta-lactone		} 0.5 g singly or in combination Tartrates as residue in biscuits and rusks
4.2.2	334; 335 i, ii; 336 i, ii; 337	Tartrates - L(+)-forms only		
4.2.2	338	Orthophosphoric acid	} Only for pH adjustment 0.1 g as P <sub>2</sub> O <sub>5</sub>	
4.2.2	339i-iii	Sodium orthophosphates		
4.2.2	340i-iii	Potassium orthophosphates		
4.2.2	341i-iii	Calcium orthophosphates		
<b>4.3 Antioxidants</b>				
4.3.1	306	Mixed tocopherols concentrate	} 300 mg/kg fat, singly or in combination	
4.3.2	307	Alpha-tocopherol		
4.3.3	304	L-Ascorbyl palmitate	200 mg/kg fat	

4.3.4	300, 301, 303	L-Ascorbic acid and its sodium and potassium salts	50 mg, expressed as ascorbic acid and within the limits for sodium
4.3.5	302	Calcium ascorbate	20 mg, expressed as ascorbic acid
<b>4.4 Flavours</b>			
4.4.1		Vanilla extract	GMP
4.4.2		Ethyl vanillin	} 7 mg on an as consumed basis
4.4.3		Vanillin	
<b>4.5 Enzymes</b>			
4.5.1		Malt carbohydrases	GMP
<b>4.6 Leavening Agents</b>			
4.6.1	503I	Ammonium carbonate	} Limited by GMP
4.6.2	503ii	Ammonium hydrogen carbonate	
4.6.3	500 (i, ii)	Sodium carbonates	Limited by GMP
4.6.4	501 (i, ii)	Potassium carbonates	Limited by GMP
<b>4.7 Thickening Agents</b>			
4.7.1	410	Carob bean gum	} Singly or in combination: 1 g in weaning food 2 g in gluten-free cereal based foods
4.7.2	412	Guar gum	
4.7.3	414	Gum Arabic	
4.7.4	425	Xanthan gum	
4.7.5	440	Pectins (Amidated and Non-Amidated)	
4.7.6	1404	Oxidized starch	} 5 g singly or in combination
4.7.7	1410	Monostarch phosphate	
4.7.8	1412, 1413, 1414, 1422	Modified starches	
4.7.9	1420	Starch acetate esterified with acetic anhydride	
4.7.10	1450	Starch sodium octenyl succinate	
4.7.11	1451	Acetylated oxidized starch	
<b>4.8 Anti-caking Agent</b>			
4.8.1	551	Silicon dioxide (amorphous)	0.2 g, for dry cereals only
<b>4.9 Packaging Gas (Propellants)</b>			
4.9.1	290	Carbon dioxide	GMP
4.9.2	941	Nitrogen	GMP
4.9.3	942	Nitrous oxide	GMP
4.9.4	938	Argon	GMP
4.9.5	939	Helium	GMP
4.9.6	948	Oxygen	GMP
4.9.7	949	Hydrogen	GMP

## **5. CONTAMINANTS**

### **5.1 PESTICIDE RESIDUES**

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

These measures shall take into account the specific nature of the products concerned and the specific population group for which they are intended.

### **5.2 OTHER CONTAMINANTS**

The product shall be free from residues of hormones, antibiotics as determined by means of agreed methods of analysis and practically free from other contaminants, especially pharmacologically active substances.

## **6. HYGIENE**

It is recommended that the product covered by the provision of this standard be prepared and handled in accordance with the appropriate sections of the Recommended International Code of Practice – General Principle of Hygiene (CAC/RCP 1 1969, Rev. 3, 1997), and other relevant Codex texts such as Codes of Hygienic Practice and Codes of Practice.

The product should comply with any microbiological criteria established in accordance with the Principles for the Establishment and application of microbiological Criteria for Foods (CAC/GL 21-1997).

## **7. PACKAGING**

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

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

## **8. LABELLING**

8.1.1 [The requirements of the Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985 (Rev. 1-1991), Codex Alimentarius Volume 1) apply to this standard. With specific reference to section 7 of that Standard national jurisdictions may further restrict the use of pictorial devices.]

**or**

8.1.1 [The label shall have no pictures or text which idealizes or suggests an inappropriate age of introduction of these products.]

[No nutrition and health claims shall be made regarding the dietary properties of the products covered by the provisions of this standard.]

8.1.2 Any indication required in the labelling should be made in the appropriate language(s) of the country in which the product is sold.

### **8.2 THE NAME OF THE FOOD**

The name of the food shall be "Dry Cereal for Infants (and/or Young Children)", "Rusks for Infants (and/or Young Children)" or "Biscuits (or "Milk Biscuits") for Infants (and/or Young Children)" or "Pasta for Infants (and/or Young Children)", or any appropriate designation indicating the true nature of the food, in accordance with national legislation.

### **8.3 LIST OF INGREDIENTS**

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

8.3.2 The specific name shall be declared for ingredients and food additives. In addition, appropriate class names for these ingredients and additives may be included on the label.

#### **8.4 DECLARATION OF NUTRITIVE VALUE**

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

- (a) The energy value, expressed in kilocalories (kcal) and kilojoules (kJ), and the amount of protein, carbohydrate and fat expressed in grammes (g) per 100 g or 100 ml of the food as sold, and where appropriate, as per specified quantity of the food as suggested for consumption;
- (b) The average amount of each vitamin and mineral for which specific levels are defined in section 3.6 and 3.7 expressed in numerical form per 100g or 100 ml of the food as sold and, where appropriate, as per specified quantity of the food as suggested for consumption;
- (c) Any other nutritional information required by national legislation.

8.4.2 The labelling may bear the average amount of the vitamins and minerals when their declaration is not covered by the provisions of section 8.3.1 (b) expressed in numerical form per 100g or 100 ml of the product as sold and, where appropriate, per specified quantity of the food as suggested for consumption.

#### **8.5 DATE MARKING AND STORAGE INSTRUCTIONS**

8.5.1 The date of minimum durability (preceded by the words "best before") shall be declared by the day, month and year in uncoded numerical sequence except that for products with a shelf-life of more than three months, the month and year will suffice. The month may be indicated by letters in those countries where such use will not confuse the consumer. In the case of products requiring a declaration of month and year only, and the shelf-life of the product is valid to the end of a given year, the expression "end (stated year)" may be used as an alternative.

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

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

#### **8.6 INFORMATION FOR UTILIZATION**

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

8.6.2 For products covered by 2.1.1, directions on the label shall state "Milk or formula but no water shall be used for dilution or mixing" or an equivalent statement.

8.6.3 The presence or absence of gluten should be indicated on the label.

[8.6.4 The label shall indicate clearly from which age the product is intended for use. The label shall clearly state that the product is not recommended for use below 6 months. In addition, the label shall include a statement indicating that the decision when precisely to begin complementary feeding, including any exception from that age limit, should be made in consultation with a [health worker], based on the infant specific growth and development needs. Additional requirements in this respect may be made in accordance with the legislation of the country in which the product is sold. The labelling should not be in conflict with the provisions of this paragraph]

#### **8.7 ADDITIONAL REQUIREMENTS**

The products covered by this standard are not breast-milk substitutes and shall not be presented as such.

### **9. METHODS OF ANALYSIS AND SAMPLING**

See Section on methods in the Proposed Draft Revised Standard for Infant Formula.

In addition:

#### **Detection of Irradiated Foods**

Codex General Methods.

**PROPOSED DRAFT GUIDELINES FOR VITAMIN AND MINERAL FOOD SUPPLEMENTS**  
**(At Step 3 of the Procedure)**

**PREAMBLE**

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

**1. SCOPE**

1.1 These guidelines apply to vitamin and mineral supplements intended for use in supplementing the daily diet with vitamins and/or minerals.

1.2 It is left to national authorities to decide whether vitamin and mineral supplements are drugs or foods. These Guidelines do apply in those jurisdictions where products defined in 2.1 are regulated as foods.

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

**2. DEFINITIONS**

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

**3. COMPOSITION****3.1 SELECTION OF VITAMINS AND MINERALS**

3.1.1 Vitamin and mineral supplements should contain vitamins/provitamins and minerals whose nutritional value for human beings has been proven by scientific data and whose status as vitamins and minerals is recognised by FAO and WHO.

3.1.2 The selection of admissible vitamin and mineral sources should be based on criteria such as safety and bioavailability. In addition, purity criteria should take into account the FAO/WHO or Pharmacopoeias [and national legislation, where applicable].

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

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

**3.2 CONTENTS OF VITAMINS AND MINERALS**

3.2.1 The minimum level of each vitamin and/or mineral contained in a vitamin and mineral supplement per daily portion of consumption as suggested by the manufacturer should be [15% to 33%] of the recommended daily intake as determined by FAO/WHO.

3.2.2 [The maximum level of each vitamin and/or mineral contained in a vitamin and mineral supplement per daily portion of consumption as suggested by the manufacturer should not exceed [100%] of the recommended daily intake as determined by FAO/WHO.]

or

3.2.2 [Maximum amounts of vitamins and minerals in vitamin and mineral supplements per daily portion of consumption as recommended by the manufacturer shall be set, taking the following criteria into account:

(a) upper safe levels of vitamins and minerals established by scientific risk assessment based on generally accepted scientific data, taking into consideration, as appropriate, the varying degrees of sensitivity of different consumer groups;

(b) the daily intake of vitamins and minerals from other dietary sources.

When the maximum levels are set, due account should be taken to the reference intake values of vitamins and minerals for the population.]

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

#### **4. PACKAGING**

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

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

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

#### **5. LABELLING**

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

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

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

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

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

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

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

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

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