



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



**World Health  
Organization**

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - Fax: (+39) 06 5705 4593 - E-mail: [codex@fao.org](mailto:codex@fao.org) - [www.codexalimentarius.org](http://www.codexalimentarius.org)

**REP15/NFSDU  
December 2014**

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

**CODEX ALIMENTARIUS COMMISSION**  
*Thirty-eighth Session*  
*Geneva, Switzerland, 6-11 July 2015*

**REPORT OF THE THIRTY-SIXTH SESSION OF THE  
CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES**  
*Bali, Indonesia, 24 - 28 November 2014*

**NOTE:** This report includes Codex Circular Letter CL 2014/33-NFSDU





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

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

**SUBJECT:** **Distribution of the Report of the Thirty-sixth Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (REP15/NFSDU)**

The report of the Thirty-sixth Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) is attached. It will be considered by the 38<sup>th</sup> Session of the Codex Alimentarius Commission (Geneva, Switzerland, 6-11 July 2015).

**MATTERS FOR ADOPTION BY THE CODEX ALIMENTARIUS COMMISSION:**

**Proposed Draft and Draft Standards and Related Texts at Steps 8 and 5/8 (with omission of Steps 6 and 7) of the Procedure**

1. Draft Revision of the *General Principles for the Addition of Essential Nutrients to Foods* (CAC/GL 9-1987) at Step 8 (REP15/NFSDU para 53 and Appendix III);
2. Proposed Draft Additional or Revised Nutrient Reference Values for Labelling Purposes in the *Guidelines on Nutrition Labelling* (CAC/GL 2-1985): NRV-R for Vitamin C, zinc, selenium, molybdenum and manganese at Step 5/8 (REP15/NFSDU para 82 and Appendix IV Part 1); and
3. Proposed Draft Nutrient Reference Value for Potassium in relation to the risk of non-communicable diseases at Step 5/8 (REP15/NFSDU para 116 and Appendix V).

**Other texts for adoption**

4. Amendments to the Annex of the *Guidelines on Nutrition Labelling* (CAC/GL 2-1985) (REP15/NFSDU para 82 and Appendix IV Part 2);
5. Amendments to the *Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten* (CODEX STAN 118-1979) to add the term "khorasan wheat" (REP15/NFSDU para 193 and Appendix X);
6. Amendments to the *Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children* (CAC/GL 10-1979) (REP15/NFSDU para 188 and Appendix VIII); and
7. Proposed Draft Revision of the list of food additives in the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CODEX STAN 72-1981) (REP15/NFSDU para 152 and Appendix VI Part 1).

Governments and interested international organizations are invited to comment on the above texts and should do so in writing, in conformity with the *Procedure for the Elaboration of Codex Standards and Related Texts* (Part 3 – Uniform Procedure for the Elaboration of Codex Standards and Related Texts, Procedural Manual of the Codex Alimentarius Commission, by e-mail to the Secretariat, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Viale delle Terme di Caracalla, 00153 Rome, Italy, [codex@fao.org](mailto:codex@fao.org), **before 31 March 2015**).

## SUMMARY AND CONCLUSIONS

The Thirty-sixth Session of the Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU36) reached the following conclusions:

### **MATTERS FOR ADOPTION BY THE 38<sup>TH</sup> SESSION OF THE CODEX ALIMENTARIUS COMMISSION:**

#### **The Committee agreed to forward:**

##### **Draft Standards for adoption at Steps 5 and 8 of the Procedure**

- Draft Revision of the *General Principles for the Addition of Essential Nutrients to Foods* (CAC/GL 9-1987), at Step 8 (para 53, Appendix III);
- Proposed Draft Additional or Revised Nutrient Reference Values for Labelling Purposes in the *Guidelines on Nutrition Labelling* NRV-R for Vitamin C, zinc, selenium, molybdenum and manganese, at Step 5/8 (para 82, Appendix IV Part 1);
- Proposed Draft Nutrient Reference Value for Potassium in relation to the risk of non-communicable diseases, at Step 5/8 (para 116, Appendix V).

##### **Other texts for adoption**

- Amendments to the Annex of the *Guidelines on Nutrition Labelling* (CAC/GL 2-1985) (para 82, Appendix IV Part 2);
- Amendments to the *Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten* (CODEX STAN 11-1979) to add the term “khorasan wheat” (para 193, Appendix X);
- Amendments to the *Advisory List of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children* (CAC/GL 10-1979) to include zinc citrates (para 188, Appendix VIII); and
- Proposed Draft Revision of the list of food additives in CODEX STAN 72-1981 to include INS 472c and INS 1450 (para 152, Appendix VI Part 1).

##### **New Work**

The Committee submitted for approval new work on:

- Definition for biofortification or biofortified foods (para 164, Appendix VII); and
- NRV-NCD for eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) long chain omega-3 fatty acids (para 191, Appendix IX).

### **MATTERS OF INTEREST TO THE COMMISSION**

#### **The Committee:**

- provided replies regarding the status of implementation of selected activities of the Codex Strategic Plan 2014 – 2019 relevant to its work (para 14 and Appendix II);
- agreed to discontinue consideration of amendment to the *Standard for Processed Cereal-based Foods for Infants and Young Children* (CODEX STAN 74-1981) to include a New Part B for Underweight Children (para 89);
- returned the revision of the *Standard for Follow-up Formula* (CODEX STAN 156-1987) to Step 2 for redrafting, circulation for comments at Step 3 and consideration at its next session (para 107);
- to keep the amended working list of additives (wish-list) up to the next session when a decision would be made on its future status (para 152, Appendix VI Part 2);
- to defer discussions on conditions for claims for trans fatty acids to its next session pending the outcome of the NUGAG review and the advice from CCMAS on methodological issues (para 157); and
- to request UNICEF, with support of Senegal, to prepare a revised discussion paper and project document on a standard for ready-to-use food (RUF) to be presented at the next session (para 183).

### **MATTERS OF INTEREST TO OTHER COMMITTEES**

#### **CCMAS**

##### **The Committee agreed:**

- to recommend to CCMAS to retain AACCI 32-45.01 Type I method for total dietary fibre and adopt AACCI 32-50.01 as Type I method for insoluble and soluble parts of dietary fibre; and to review if AOAC 2009.01 should be considered as Type IV; and to adopt AOAC 2011:25 as Type IV method (para 17); and
- to request advice on the lowest level of TFAs that current analytical methods can accurately detect as well as consistently reproduce (para 157).

#### **CCFA**

##### **The Committee agreed:**

- to ask CCFA to examine if the following: “*Additives for use in CODEX STAN 72-1981 shall require also an assessment from JECFA that explicitly states that the substance is safe to be used in infants below twelve weeks of age*” could be included in the preamble of the GSFA (para 152); and
- to ask if food additives in Sections A and B of the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CODEX STAN 72-1981) and sections 13.1.1 and 13.1.3 of the GSFA could be prioritised for alignment, in order to protect vulnerable infants (para 152).

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## INTRODUCTION

1. The thirty-sixth Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) was held in Bali, Indonesia, from 24 to 28 November 2014 at the kind invitation of the Government of Germany in cooperation with the Government of Indonesia. The Session was chaired by Dr Pia Noble, Head of Division of Specific Foods, Food Supplements and Food Additives, Federal Ministry of Food and Agriculture and co-chaired by Professor Purwiyatno Hariyadi, Professor of Food Process Engineering, Bogor Agriculture University and Director of Southeast Asian Food and Agricultural Science and Technology Centre. The Committee was attended by 299 delegates, representing 54 Member Countries, 1 Member Organisation and 25 International Organisations.

## OPENING OF THE SESSION

2. Mr Bernhard Kühnle, Director General of Food Safety and Animal Health of the Federal Ministry of Food and Agriculture and Consumer Protection, Germany and Dr. Roy A. Sparringa, Chairman of the National Agency for Food and Drug Control, Republic of Indonesia opened the Session and welcomed participants.
3. Mr Kühnle noted that this session of the Committee was an excellent example of Codex bringing its work closer to its members.
4. He underlined the importance of doing good preparatory work at the committee level and also reminded delegates that standards were not finite in nature but would continuously need to evolve based on scientific findings and socio-economic developments.
5. Mr Kühnle further reminded delegates of the need for clear definitions to avoid misuse of terms in standards. He noted the important contribution of the Committee in assisting governments to address global issues such as wasting, stunting, overweight and obesity.
6. Dr. Roy A. Sparringa, thanked the Government of Germany as the host country of the Codex Committee on Nutrition and Food for Special Dietary Uses as well as all CCNFSDU members, for their full support to Indonesia in co-hosting the 36th Session of CCNFSDU.
7. He stated how important Codex standards had become in the protection of public health. He recommended, from the trade perspective, that national-technical regulations and regional standards refer to Codex texts to support fair trade practices and avoid unnecessary technical barriers to trade.
8. Dr Sparringa reminded delegates of the key issues of the 2nd International Conference on Nutrition (ICN) held one week previously in Rome, Italy and how CCNFSDU played a pivotal role in light of the current world food and nutrition situation. He further stated that the next challenge would be to encourage and support developing countries in implementing Codex and building their capacity in terms of readiness in the food industry and in food control inspection systems.

### Division of competence<sup>1</sup>

9. The Committee noted the division of competence between the European Union and its Member States, according to paragraph 5, Rule II of the Rules of Procedure of the Codex Alimentarius Commission, as presented in CRD1.

### **ADOPTION OF THE AGENDA (Agenda Item 1)<sup>2</sup>**

10. Under Agenda Item 11 "Other Business", the Committee agreed to discuss the following items:
  - a) Paper on a standard for Ready-to-Use Foods (RUF) from UNICEF in line with the recommendation of the CAC37 (CX/NFSDU 14/36/2-Add.1);
  - b) Proposal for an extension of the method recommendation in the *Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten* (CODEX STAN 118–1979) with a method that also accurately detects the toxic fraction in gluten harmful for individuals intolerant to gluten: the ELISA G12 method (Austria);
  - c) Proposal for inclusion of zinc citrates in the *Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children* (CAC/GL 10–1979) (Switzerland);
  - d) Proposal for new work on the establishment of a Codex NRV for eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) long chain omega-3 fatty acids (IADSA);

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<sup>1</sup> CRD1

<sup>2</sup> CX/NFSDU 14/36/1

- e) Proposal to amend the *Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten* (CODEX STAN 118–1979), to add the term “khorasan wheat” (United States of America).

11. The Committee adopted the Provisional Agenda as its Agenda for the Session.

**MATTERS REFERRED TO THE COMMITTEE BY THE CODEX ALIMENTARIUS COMMISSION AND/OR OTHER CODEX COMMITTEES (Agenda Item 2a)<sup>3</sup>**

12. The Committee noted that some matters were only for information and that several matters would be considered under other agenda items.

**Monitoring of Strategic Plan 2014-2019**

13. The Committee noted that a template for monitoring the implementation of selected activities for the Codex Strategic Plan 2014-2019 had been prepared by the Secretariat. Consolidated draft replies had been prepared by the EU and Canada and accepted by the Committee with minor changes.

14. The responses of CCNFSDU are presented in Appendix II for consideration by CCEXEC70 and CAC38.

15. IACFO suggested that more guidance could be given to Member States regarding the composition of delegations in relation to conflict of interest, especially those hosting committees or eWGs, in order to ensure the protection of health. IACFO also expressed concern about consensus building to ensure that the interests of developing countries were not overlooked.

**Committee on Methods of Analysis and Sampling**

16. On the basis of CRD19, the Committee considered the CCMAS request as to whether the new method AACCI 32-50.01|AOAC 2011.25 should be included as a Type I method for dietary fibre in the *Recommended Methods of Analysis and Sampling* (CODEX STAN 234-1999). In addition, the Committee considered how to react to modifications made to AOAC 2011.25 and AOAC 2009.01.

**Conclusion**

17. The Committee agreed with the information provided in CRD19 and recommended to CCMAS:

- a) To retain AACCI 32-45.01 as the Type I method for total dietary fibre and adopt AACCI 32-50.01 as the Type I method for the insoluble and soluble parts of dietary fibre (which can be summed up to total dietary fibre) as they have different scopes and are collaboratively studied and designed to match the Codex definition.
- b) To review if AOAC 2009.01 should now be considered as Type IV because it has been modified and not been collaboratively studied and is no longer considered equivalent to AACCI 32-45.01;
- c) To adopt AOAC 2011.25 as Type IV method because it has been modified and not been collaboratively studied and is no longer considered equivalent to AACCI 32-50.01.

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

18. The Representative of FAO introduced CX/NFSDU 14/36/3 and drew the attention of the Committee to current activities and new publications including those jointly undertaken with WHO. The Representative informed the Committee about the FAO/WHO expert meeting on the microbiological safety of ready to use therapeutic and supplementary foods for severe and acute moderate malnourished populations that would take place at FAO in Rome in mid-December 2014.

19. She further pointed out that FAO and WHO had initiated a pilot Global Individual Food Consumption Data Tool (FAO/WHO GIFT) and that would be developed based on the needs of stakeholders in the field of nutrition and food safety. Ultimately, the objective would be to collect, harmonise and disseminate, through a FAO hosted platform, individual food consumption data all over the world at national and subnational level.

20. The Representative also pointed out that in Asia, individual consumption data had been made available in a harmonised format into the FAO/WHO Chronic Individual Food Consumption Database for China, Japan and Australia/New Zealand. Similarly a new effort had been undertaken in 10 members of ASEAN where data were sparse and heterogeneous and that using the EU contribution to the Codex Trust Fund individual food consumption surveys in Laos PDR and Myanmar would be carried out with technical assistance from FAO and WHO. The data in another 6-8 ASEAN countries would be harmonized and put into the FAO/WHO Global Individual Food Consumption Data Tool (FAO/WHO GIFT).

<sup>3</sup> CX/NFSDU 14/36/2; CX/NFSDU 14/36/2 Add.1; CRD2 (Comments of Ghana and African Union); CRD10 (Comments of the European Union and FoodDrinkEurope); CRD19 (Comments of the Philippines and the United States of America); CRD27 (Comments of Canada); CRD 45 (Comments of Canada and European Union).

21. The Representative said that following a recommendation from the 2011 FAO Expert Consultation on dietary protein quality evaluation in human nutrition, an expert working group had been convened by FAO from 2-5 March 2014 in Bangalore, India. The working group discussed research approaches for producing data on true amino acid digestibility of commonly eaten foods. The report of an FAO Expert Working Group on evaluating the protein quality of human foods was nearing publication and would be posted on the FAO website in December 2014.
22. The Representative of WHO informed the Committee of the Second International Conference on Nutrition (ICN2) held in Rome on 19 – 21 November 2014 and its Declaration and Framework for Action which highlighted the role of Codex in promoting healthy diets. Referring to CX/NFSDU 14/36/3, she highlighted some of the activities of relevance to the on-going work of the Committee. These included new information and advocacy materials (i.e. policy brief series on the Global Nutrition Targets 2025, WHO fact sheet on healthy diet and the UN OneHealth Tool for planning and costing nutrition actions), three new and updated guidelines (i.e. on nutrition care of children and adults with Ebola virus disease in treatment centres, sugars intake, and fortification of food-grade salt with iodine for the prevention and control of iodine deficiency disorders), two recent NUGAG meetings (i.e. on diet and health which finalized the review on recommendations on saturated fatty acids and trans-fatty acids, and on nutrition actions which reviewed and discussed recommendations on various fortifications), and three new regional strategies and action plans to address the multiple-burden of nutrition problems including childhood obesity, which were adopted by their respective Regional Committees in September/October 2014.
23. An observer welcomed WHO call for health policy setting to be safeguarded from undue commercial influence.

**DRAFT REVISION OF THE GENERAL PRINCIPLES FOR THE ADDITION OF ESSENTIAL NUTRIENTS TO FOODS (CAC/GL 9-1987) AT STEP 7 (Agenda Item 3)<sup>4</sup>**

24. The Chairperson introduced the paper and reminded delegates that CAC36 had adopted the proposed draft revision of the Principles at Step 5 and they had been circulated for comments at Step 6. For the discussion, delegates were invited to focus on the texts in square brackets with the aim of either removing the brackets or deleting the text. Editorial corrections were also invited.
25. The texts of individual amendments are not included in the body of this report, unless substantial or fundamental to understanding the discussion, but the changes are reflected directly in the amended text (Appendix III).

Definitions for mandatory and voluntary nutrient addition.

26. Several delegations supported maintaining these definitions as drafted, arguing that governments needed to ensure that nutrient addition was carried out under national legislation and Codex standards. The importance of maintaining a balance between the interests of food companies and official control systems and the need to avoid any confusion were mentioned. It was also noted that allowing food manufacturers to choose to add essential nutrients to particular foods may be easier in industrialised countries, but more problematic in developing countries due to the nature of national inspection procedures.
27. Several other delegations stated that they were not in favour of including the definitions, as the wording was misleading and that several different approaches to voluntary nutrient addition existed (from permitting all additions that were not explicitly forbidden, to not allowing any additions that were not explicitly allowed) which had been sufficiently explained in footnote 4.
28. Some delegations proposed including the text of footnote 4 in the definition of voluntary nutrient addition to avoid placing the emphasis on the choice being left to manufacturers and the footnote being overlooked.
29. Other delegations and an Observer organisation were of the opinion that definitions, if included at all in the text, should be simple.
30. It was clarified that footnotes are integral parts of Codex texts.
31. To take into account the different opinions, the Committee amended the definition for voluntary nutrient addition in line with the proposal by Australia and added a text to the definition to clearly show the connection with footnote 4:

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<sup>4</sup> REP14/NFSDU, Appendix II; CL 2014/27-NFSDU; CX/NFSDU 14/36/4 (Comments of Australia, Brazil, Canada, Costa Rica, European Union, India, Mexico, New Zealand, Norway, Paraguay, Philippines, African Union, FoodDrinkEurope, ICBA, ICGA, IFT); CRDs 15 (Comments of ISDI); CRD20 (Comments of the United States of America); CRD28 (Comments of Nigeria, Indonesia, Malaysia); CRD37 (Comments of ICGA); CRD41(Comments of Thailand); CRD46 (Comments of El Salvador).

**“2.6 Voluntary nutrient addition is when food manufacturers choose to add specified essential nutrients to particular foods or food categories as explained in footnote 4.”**

### **Conclusion**

32. The Committee adopted the wording for para 2.6 as proposed in the text above.

#### 3.1.1 Essential nutrients may be appropriately added to foods

33. There was a discussion regarding the last phrase of the paragraph and whether it was intended to be related to the monitoring (that the purposes in the list “have been” fulfilled) or related to an assessment (whether they “could be fulfilled”) both of which may be approaches of different national frameworks.
34. After a brief discussion, the sentence was reworded to be clear and unambiguous as follows:

“Competent national and/or regional authorities may request scientific rationale and evidence demonstrating fulfilment of one or more of the purposes listed above.”

35. One Observer organisation stated the need for independently funded and systematically reviewed evidence to provide the scientific rationale for such decisions.

### **Conclusion**

36. The Committee adopted the wording for para 3.1.1 as proposed in the text above.

#### 3.1.4 The labelling and advertising ...

37. One Observer organisation proposed that reference should be made to the *General Standard for the Labelling of Pre-Packaged Foods* (GSLPF) to ensure labelling of gluten containing substances if they are added for protein enrichment and called nutrient addition.
38. The Codex Secretariat clarified that this was not necessary as the GSLPF applied to all foods and thus allergens had to be labelled in any case.

#### 3.3.2 Foods to which essential nutrients may not be added ...

39. The Delegation of Norway outlined the potential risk to health of a diet high in saturated fats, trans fats, sugar and salt, (energy-dense and nutrient-poor foods such as desserts, chocolate, chips) with particular concern regarding unhealthy diets and energy imbalances in children and adolescents. They said that it should be avoided making these foods seem “healthy” by adding essential nutrients. In advocating clearer guidance from Codex on this matter the delegation preferred the inclusion of the following wording: “*nutrient addition to energy-dense and nutrient-poor foods should be avoided, unless such addition is nutritionally justified to meet national public health goals*” in the text of para 3.3.2. The delegation proposed the inclusion of a clear reference to the nutritional value of foods in the principles, and therefore sought its inclusion in section 3.3.2.
40. The Chairperson reminded the Committee that the matter had been discussed in depth at CCNFSDU35 without adopting amendments. She further noted that the wording of the sentence was open to allow national authorities to decide whether additions of essential nutrients were acceptable or not.
41. There was some support from delegations for the proposal to include a phrase to describe health concerns in this paragraph and the Representative of WHO stated that in line with the global strategy on diet, physical activity and health and the recent ICN2 declaration, the proposed addition seemed most appropriate.
42. Several other delegations argued that such an initiative could not be seen as a mere drafting change to the text but something much more fundamental that had already been extensively discussed.
43. The Representative of WHO expressed strong concern regarding the Committee’s decision not to add a phrase requested by Norway to take into consideration the nutrition value of the food to which essential nutrients may be added, and requested WHO’s concern be noted in the report of the Committee. The Representative of WHO also expressed great concern regarding the work of the Committee for it not taking into account the decisions made and strategies adopted at intergovernmental fora, such as the World Health Assembly and also the ICN2, which had highlighted the important role of Codex in promoting healthy diet and preventing obesity and diet-related noncommunicable diseases.
44. The Codex Secretariat confirmed that comprehensive proposals like those outlined in the discussion, concerning health, would be coming to Codex as the world’s food standards setting body following the outcome of ICN2. He added that adoption of the wording as currently proposed would leave room for governments to regulate the addition of nutrients to foods for the time being and could be changed in the future on the basis of a more complete proposal as to how ICN2 should input to Codex.
45. The Delegation of Chile noted that this issue had now been discussed publicly since the last meeting of the Committee and that the matter had gained greater visibility and importance. They stated their reservation to

the decision to adopt the wording before the Committee.

46. This reservation was supported by the Delegations of: Bangladesh, Brazil and South Africa; and by the Observer Organisations, IACFO and ILCA.
47. The Observer organisation of ICGA drew the attention of the Committee to CRD 37.

#### **Conclusion**

48. The Committee adopted the wording for para 3.1.1 as proposed in the original text and noted the reservations expressed.

#### 3.5.2 Monitoring

49. The Committee supported the second proposal contained in the square brackets:

“Monitoring of total nutrient intakes should in principle use the same approach as used in deciding the addition of essential nutrients unless otherwise necessary for the specific nutrient concerned.”

#### 4.2 Addition of Essential Nutrients for Restoration

50. One delegation questioned why, if the food prior to restoration was a “significant contributor to the intake of relevant essential nutrients in the population”, did it require restoration of nutrients.
51. In response, the Delegation of Australia clarified the bullet points, that in the context of a decision to consider restoration it should be shown that the original food was suffering a “reduction of relevant essential nutrients it contains during processing, storage or handling” and that before this reduction the food should have been a significant source of nutrients in the diet such as macronutrients.

#### **Conclusion**

52. The Committee agreed that the draft principles as amended could be submitted for adoption by CAC at Step 8.

#### **Status of the draft revision of the General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 9-1987)**

53. The Committee agreed to forward the draft revision to CAC38 for adoption at Step 8 (Appendix III).

#### **PROPOSED DRAFT ADDITIONAL OR REVISED NUTRIENT REFERENCE VALUES FOR LABELLING PURPOSES IN THE GUIDELINES ON NUTRITION LABELLING (OTHER VALUES THAN PROTEIN) AT STEP 3 (Agenda Item 4)<sup>5</sup>**

54. The Delegation of Australia introduced the paper and the work of the eWG which had been set up at CCNFSDU35 to recommend revised or additional NRVs-R for vitamin C, iron, zinc, selenium, manganese, molybdenum and fluoride, in accordance with the revised CCNFSDU definition of Recognized Authoritative Scientific Body (RASB) and the General Principles for establishing NRVs for the general population.
55. The Committee discussed the 13 recommendations presented by the eWG.

#### Recommendation 1 – RASBs

56. The Committee accepted the six listed scientific bodies as RASBs in accordance with GP 3.1.2:

- European Food Safety Authority (EFSA);
- United States Institute of Medicine (IOM);
- Australian National Health and Medical Research Council & New Zealand Ministry of Health (NHMRC/MOH);
- Japanese National Institute of Health and Nutrition (NIHN);
- International Zinc Nutrition Consultative Group (IZiNCG);
- Nordic Council of Ministers (Nordic countries).

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<sup>5</sup> CXNFSDU14/36/5, CXNFSDU14/36/5 Add1 (Comments of Brazil, Canada, Ghana, Malaysia, Mexico, New Zealand, Philippines, African Union, FoodDrinkEurope, ICBA, IFT); CRD9 (Comments of Thailand); CRD12 (Comments of EU, NHF); CRD21 (Comments of Japan); CRD29 (Comments of Nigeria, Indonesia); CRD38 (Comments of Rep. of Korea); CRD46 (Comments of El Salvador).

Recommendation 2 - Clarification of GP 3.2.1.1

57. The Committee agreed to the following clarification of GP 3.2.1.1:

GP 3.2.1.1: The NRVs-R should be based on Individual Nutrient Level 98 (INL98). In certain cases where there is an absence of, or an older, established INL98 for a nutrient for a specific sub-group(s), it may be more appropriate to consider the use of other daily intake reference values or ranges that have been more recently established by recognized authoritative scientific bodies. The derivation of these values should be reviewed on a case-by-case basis.

Recommendation 3 - NRV-R for Vitamin C

58. The Committee agreed to revise the NRV-R for vitamin C from 60 mg to 100 mg.

Recommendation 4 - NRV-R for Iron

59. The Delegation of the EU informed the Committee that EFSA was currently evaluating iron and the opinion was expected in 2015. Due to the importance of this nutrient, the delegation requested that the Committee postpone a decision on this recommendation.
60. Several delegations and Observer organisations supported this position.
61. Some delegations noted, that it would be more practical to have only one NRV-R for the purpose of labelling and that the value should be based on WHO/FAO DIRV (14 mg), related to 15% of absorption. It was proposed that if the Committee decided to adopt two NRVs-R according to % absorption, then there should be a footnote to allow countries to select either one of the NRVs-R based on the needs of the country.
62. The Delegation of Australia, also making reference to the footnotes for iron and zinc (see Recommendation 8), clarified that the recommendation aimed to give governments flexibility in relation to likely dietary absorptions in different countries and that having two values didn't mean that both would go on a label.
63. The Observer of the National Health Federation (NHF) disagreed that the NRV-R for iron should be based solely on the absorption percentage, arguing that it would be more important to establish separate NRVs for men and women. The Delegation of Australia then explained that the General Principles referred to an average of male and female DIRVs.

**Conclusion**

64. The Committee agreed to postpone the decision on this recommendation until CCFNSDU37.

Recommendation 5 - NRV-R for Zinc

65. Some delegations indicated they would prefer to wait for the final EFSA opinion before accepting this recommendation.
66. The Delegation of Australia noted that there had been strong support for Recommendation 5 in the eWG. She further noted that the eWG had considered the draft opinion from EFSA that proposed four adult Population Reference Intakes (PRI) (equivalent to INL98) in the range 8.5 –14.5 mg according to four levels of dietary phytate intake observed in European populations and that these values had not changed in the recently published final opinion.
67. One Observer organisation did not support reducing the NRV for zinc as current levels were already insufficient. He also argued that gender should be taken into consideration.
68. The Committee agreed to:
- a) Modify the NRV-R for zinc to refer to % dietary absorption;
  - b) Revise the NRV-R from 15 mg to 11 mg (30% dietary absorption) and 14 mg (22% dietary absorption).

Recommendation 6 - Dietary Description for Iron

69. The Committee agreed to postpone this decision until CCFNSDU37 as the recommendation was subject to agreement on Recommendation 4 above.

Recommendation 7 - Dietary Description for Zinc

70. The Committee agreed to the dietary description recommended by the eWG.

Recommendation 8 - Footnote for Iron and/or Zinc

71. The Committee agreed to postpone a decision for iron and agreed to the recommendation for zinc amended as follows:

Competent national and/or regional authorities should determine an appropriate NRV-R that best represents the dietary absorption from relevant diets.

#### Recommendation 9 - NRV-R for Selenium

72. Several Delegations, whilst not disagreeing with the value proposed, noted that EFSA had adopted a value for adequate intake at 70µg as there was not sufficient evidence for another value.
73. One Observer organisation suggested a range of 70 to 200µg.
74. The Committee agreed to establish the NRV-R for selenium at 60µg.

#### Recommendation 10 - NRV-R for Molybdenum

75. Some delegations and an Observer organisation noted the lack of data on this matter and that EFSA had decided to establish an adequate intake of 65µg based on observed intakes in the EU, which were higher than values proposed by other RASBs.
76. The Committee noted these comments but further noted that there was also general support and agreement for the recommendation considering that it would always be possible to change an NRV-R in the presence of new evidence.
77. The Committee agreed to establish the NRV-R for molybdenum at 45µg.

#### Recommendation 11 - NRV-R for Manganese

78. The Committee agreed to establish an NRV-R for manganese at 3mg.

#### Recommendation 12 - NRV-R for Fluoride

79. The Committee agreed that no NRV-R for fluoride should be established.

#### Recommendation 13 - Further Amend Working Definition of RASB

80. The Committee agreed to add a second footnote to the working definition of RASB (as contained in REP14/NFSDU, para 31) to explain the term "primary evaluation":

"Primary evaluation involves a review and interpretation of the scientific evidence to develop daily intake reference values, rather than the adoption of advice from another RASB."

#### **Conclusion**

81. The Committee agreed to establish an eWG chaired by Australia and working in English with the following TORs:
  - Recommend revised or additional NRVs-R for Vitamin A, Vitamin D, Vitamin E, Magnesium, Phosphorus, Chromium, Copper, Chloride as well as Iron, in accordance with the revised working definition of RASB and General Principles for establishing NRVs for the general population;
  - Recommend relevant supporting information for the relevant vitamins and minerals above;
  - Consider the approach for establishing NRVs-R for 6-36 Months for the nutrients for which NRVs-R are established for the general population.

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

82. The Committee agreed to forward the new and revised NRVs-R for Vitamin C, Zinc (and its dietary description and footnote), Selenium, Molybdenum and Manganese as well as the amendments to the *General Principles for Establishing Nutrient Reference Values for the General Population (para 3.2.1.1)* to CAC38 for adoption at Steps 5/8 (with the omission of Steps 6 and 7) for inclusion in the *Guidelines on Nutrition Labelling (CAC/GL 2-1985)* (Appendix IV).
83. The Committee agreed that proposed NRVs would be prepared by the abovementioned EWG at Step 2, circulation for comments at Step 3 and consideration at CCNFSDU37.

**PROPOSED DRAFT AMENDMENT OF THE STANDARD FOR PROCESSED CEREAL- BASED FOODS FOR INFANTS AND YOUNG CHILDREN (CODEX STAN 74- 1981) TO INCLUDE A NEW PART B FOR UNDERWEIGHT CHILDREN AT STEP 4 (Agenda Item 5)<sup>6</sup>**

84. The Chairperson recalled the in-depth discussion in the previous two CCNFSDU sessions that had focussed on the scope of the proposed draft amendment. She reminded delegations that in 2013 the Committee had been unable to make significant progress, and, not reaching agreement on scope, the draft had remained at Step 3. Consequently the Committee had established an eWG chaired by India.
85. The Chairperson further noted that paragraph 93 of the report of the last session of the Committee<sup>7</sup> indicated that: “if (the) eWG failed to establish the scope in line with WHO guidance documents, the Committee at its next session would recommend the discontinuation of work”.
86. The Delegation of India presented the report and the findings of the eWG and recommended to discontinue work as the eWG had not been able to reach a consensus on the definition of the scope.
87. One delegation suggested that the existing *Guidelines for Formulated Complementary Foods for Older Infants and Young Children* (CAC/GL 8-1991) could be adapted by India or SE Asia countries for use as a national or regional standard to assist them on this issue without starting new Codex work.
88. An Observer organisation, expressing concern about the cereal-based standard, proposed harmonisation of all currently existing standards for baby food that could then address the issues raised by the work of the eWG, with particular concern for sugar levels.

**Conclusion**

89. The Committee accepted India’s proposal and recommended to CAC that this work be discontinued.

**REVIEW OF THE CODEX STANDARD FOR FOLLOW-UP FORMULA (CODEX STAN 156-1987) at Step 4 (Agenda Item 6)<sup>8</sup>**

90. The Chairperson pointed out that extensive discussions on this topic had been held at the last session and while recognizing the WHO 2013 opinion that these products were not necessary, the Committee had agreed to continue work on the revision of the standard to ensure the safety and quality of these products that were traded.
91. The Delegation of New Zealand as Chair of the eWG presented the report and summarised the key findings of the eWG where general agreement had been reached as follows:
- Follow-up formula is not considered nutritionally necessary in the diets of older infants and young children;
  - A Codex standard should be retained for follow-up formula;
  - The current age range of the current follow-up formula standard, 6–36 months should be retained;
  - There should be a recognised point of differentiation at 12 months of age due to different nutritional requirements and the different role of follow-up formula in the diets of older infants compared to that of young children.
  - The Standard for Infant Formula (CODEX STAN 156-1987) should be the basis for composition of follow-up formula particularly for older infants.
92. The Committee was invited to discuss the findings of the eWG.
93. Some delegations and Observer organisations indicated that the products were not nutritionally necessary and it was also noted that they could cause confusion with infant formula and undermine the role of breastfeeding and the use of homefoods and local foods. For these reasons the Standard should be revoked.
94. The Delegation of Senegal supported by NHF said that the Standard should be revoked as, in their opinion,

<sup>6</sup> CX/NFSDU 14/36/6; CX/NFSDU 14/36/6-Add.1(not issued); CRD7 (Comments of Ghana, African Union); CRD16 (Comments of ISDI); CRD22 (Comments of Kenya, Philippines); CRD30 (Comments of Nigeria, Indonesia); CRD42 (Comments of Thailand).

<sup>7</sup> REP14/NFSDU

<sup>8</sup> CX/NFSDU 14/36/7; CRD3 (Comments of Ghana, African Union); CRD17 (Comments of ISDI); CRD23 (Comments of Japan, Kenya, Philippines); CRD31 (Comments of Morocco, Thailand, Nigeria, Indonesia, Malaysia); CRD36 (Comments of Switzerland); CRD39 (Comments of Rep. of Korea); CRD43 (Comments of NHF).

these formulas could be of potential risk. However, this was not supported by the Committee. Some delegations were of the view that should the Committee decide to continue with the work, the scope should be defined from 12-36 months of age.

95. The Delegation of South Africa, supported by Bangladesh, did not agree with the continuation of the work on the revision of the Standard and stated that as a compromise they could agree if the work on the Standard were to continue for an age range of 12-36 months.
96. The Representative of WHO indicated that WHO was pleased to note the eWG's recognition of FUF as not a necessary product. As also mentioned at the 35th Session of CCNFSDU in 2013, as far back as 1986 the World Health Assembly had adopted WHA resolution 39.28, which clearly stated that "the practice being introduced in some countries of providing infants with specially formulated milks (so-called 'follow-up milks') is not necessary". The Representative of WHO further noted that WHA resolutions reflected the collective will of the Organization's Member States to protect and improve the health and well-being of their population, including infants and young children. The Representative of WHO stated that continuing the work on this Standard risked creating policy conflict. Member States had adopted resolutions at the World Health Assembly on infant nutrition and breastfeeding and, more recently at ICN2 in Rome, the role of Codex in promoting healthy diets had explicitly been mentioned.
97. WHA resolutions, she added should therefore guide and inform the work undertaken by Codex Committees, including CCNFSDU, so as to ensure policy coherence across various intergovernmental bodies. In this context, if the Committee decided to move forward with the revision of the existing Standard, WHO would request the Committee to include some language in the revised Standard, which adequately reflected WHA resolution 39.28.
98. The Representative of WHO further raised a concern about the continuing marketing practices for FUF, which were undermining both exclusive and continued breastfeeding in many countries, both industrialized and developing countries. To this end, in 2010 WHA had adopted Resolution 63.23 in which it stated that the promotion of breast-milk substitutes and some commercial foods for infants and young children undermined progress in optimal infant and young child feeding, and called upon the infant food manufacturers and distributors to comply fully with their responsibilities under the International Code of Marketing of Breast-milk Substitutes and subsequent relevant WHA resolutions. Therefore, in the event that the Committee decided to move forward with the revision of the current Standard, WHO would request the Committee to include clear language as to the need for strong regulatory measures to avoid inappropriate marketing of FUF, not only through necessary labelling requirements, but in line with the marketing restrictions on breast-milk substitutes, as reflected in the International Code.
99. Several delegations stated that whilst fully recognising that such products were not necessary in nutritional terms, the Committee should proceed with the revision of the Standard as the products were on the market and therefore should be regulated. As such they needed to be harmonised to ensure safety and the nutritional quality of the products as these products are marketed globally.
100. The Committee noted that the majority of delegations wished to maintain the Standard and continue the revision and that this was also the result of the eWG. The majority was also in favour of product requirements differentiated in two groups (6-12 months and 12-36 months) within the one standard, thereby making a clear distinction at 12 months. One Observer called for all formulas for infants and young children to be included in a renamed Codex Infant Formula Standard.
101. Some delegations, Observer organisations and the Representative of WHO, with reference to the current *Standard on infant formula* (CODEX STAN 72– 98) requested clarification as to whether the proposed age-range groupings for follow-up formula now implied that there would be two standards for those infants in the range 6-12 months.
102. In response, the Chairperson noted that there would not be any overlapping of the standards as, notwithstanding the wording in para 2.2 of the infant formula where the term "infant" is defined as "a person not more than 12 months of age", the standard clearly stated that infant formula "means a breast-milk substitute specially manufactured to satisfy, by itself the nutritional requirements of infants during the first months of life up to the introduction of appropriate complementary feeding" which in accordance with WHO recommendations was from 6 months onwards.
103. The Delegation of India reserved its position on this agenda item as they as a Country supported exclusive breastfeeding until 6 months to be continued until 2 years with complementary feeding from 6 months onwards, as per the adopted resolutions at the World Health Assembly on Infant nutrition and breastfeeding. India requested the Committee to re-examine, by voting, the issue on the Cut-off age for Follow-up Formula which should be above 12 months of age as opposed to 6-36 months as of now. It was further reiterated that the Scope and Definition in the *Standard for Infant Formula and Formulas for Special Medical Purposes intended for Infants* (CODEX STAN 72-1981) be read completely and comprehensively.

104. The Committee accepted the recommendation of the eWG to continue the work on the standard by first looking at the composition and description, including categories and names of the products and then in a second step look at their labelling, marketing and other issues.
105. The Committee also noted that the eWG had collected a large amount of global data on the nutritional needs of the age group in question and on this basis the compositional criteria could be determined without external scientific advice.

### Conclusion

106. The Committee agreed to:
  - Continue work on the revision of the standard through an eWG and a subsequent pWG prior to the next CCNFSDU session;
  - Establish an electronic working group chaired by New Zealand and co-chaired by France and Indonesia, working in English, with the following terms of reference:
  - On the basis of the data collected so far and taking into account the discussion at CCNFSDU36 including pertinent CRDs:
  - Review the Section 2 (Description) of the current *Standard for Follow-up Formula* (CODEX STAN 156-1987) and propose drafting changes if necessary;
  - Review the compositional requirements of the current *Standard for Follow-up Formula*, 6-36 months with a point of differentiation at 12 months (Sections 3.1-3.3), and propose revised requirements.

The pWG is to be chaired by New Zealand and co-chaired by France and Indonesia, working in English, French and Spanish with the following Terms of Reference:

Taking into consideration the findings of the eWG 2015:

- Develop a draft revised Sections 2 to 3.3 of a standard for consideration by the CCNFSDU.

### Status of the Review of the Codex Standard for Follow-Up Formula (CODEX STAN 156-1987)

107. The Committee agreed to return the revision to Step 2 for redrafting by the abovementioned eWG/ pWG, circulation for comments at Step 3 and discussion at CCNFSDU37.

### PROPOSED DRAFT NUTRIENT REFERENCE VALUE FOR POTASSIUM IN RELATION TO THE RISK OF NON-COMMUNICABLE DISEASE AT STEP 4 (Agenda Item 7)<sup>9</sup>

108. The Delegation of United States of America, as Chair of the eWG, introduced document CX/NFSDU 36/14/8 and provided background information on the main aspect, importance and timeline for the work, and the outcomes of the eWG and its recommendations
109. The Delegation of the European Union stated that, in principle, they supported the work for establishing NRV-NCD for Potassium, and suggested that the Committee delay establishing NRVs-NCD for potassium to the next Session and take into account the outcome of the evaluation by the European Food Safety Authority (EFSA) that would be completed in 2015. Two Delegations and one Observer organisation supported the opinion of the EU.
110. One Observer organisation recommended that, in the future, research and reviews of the available evidence regarding the relevant nutrients be considered as much as possible all together rather than in isolation.
111. In response to the EU's request for the work to be postponed until the following year in order to wait for the on-going review of EFSA to be completed, the Representative of WHO stated that when the Committee was undertaking the work for setting up NRV-NCD for sodium and saturated-fatty acids, some Member States had requested the postponement of the work until the on-going work of the NUGAG Subgroup on Diet and Health had been completed. However, the Committee decided to move forward with progressing the work with the understanding that the Committee would review and consider the outcomes of the work of the NUGAG and revised WHO guidelines if it in fact provided different values. In the case of potassium, the WHO guideline, which was developed in 2012, was based on the latest scientific review of evidence that existed and met the requirements stated in the General Principles for Establishing NRVs and therefore, there was no reason for the Committee to postpone the work until next year, especially since the target date for completing the work approved by the Commission was 2015.

<sup>9</sup> CX/NFSDU 14/36/8; CX/NFSDU 14/36/8 Add.1 (Comments of Brazil, Canada, El Salvador, Ghana, Mexico, Philippines, African Union, FoodDrinkEurope, ICBA); CRD 9 (Comments of Thailand); CRD 32 (Comments of Indonesia and Nigeria).

Proposed NRV-NCD for Potassium

112. The Committee agreed with the recommendation by EWG that the NRV-NCD for potassium be set at 3500 mg.

Proposed Amendments to the Guidelines on Nutritional Labelling (CAC/GL 2-1985) to include a Potassium NRV-NCD

113. The Committee agreed with the option 2 to list NRVs-NCD under section 3.4.4.2 of the guideline, and that this would clarify the differences in the meaning of the NRVs-NCD for saturated fatty acids and sodium versus potassium.

Footnotes to the NRV-NCD

114. The Committee agreed to delete the last sentence of footnote 3 and added a new footnote 4 to reflect more recent WHO guidelines for sodium and potassium including the grading of quality, as follows:

*“The selection of these nutrients for the establishment of an NRV was based on “high quality” evidence for a relationship with a biomarker of NCD risk in adults as reported in the 2012 WHO guidelines on sodium and potassium intake for adults and children.”*

115. The Committee did not agree to the inclusion of footnote 5 on using the NRV with caution as had been recommended by the eWG.

**Status of the work on Proposed Draft Nutrient Reference Value for Potassium in relation to the risk of non-communicable diseases.**

116. The Committee agreed:
- a) to forward the proposed draft NRV-NCD to CAC38 for adoption at Step 5/8 (with omission of Steps 6 and 7)(Appendix V) for inclusion in the *Guidelines on Nutrition Labelling (CAC/GL 2-1985)*;
  - b) to recommend to the CAC38 to amend section 3.4.4.2 *Guidelines on nutrition Labelling (CAC/GL2-1985)* and include NRV-NCD for Potassium and also amend footnote 3 and add a new footnote 4.

117. The Delegation of the European Union expressed their reservation on the decision of the Committee to adopt the NRV-NCD for Potassium without taking into account the outcome of the EFSA evaluation due in 2015.

**PROPOSED DRAFT REVISION OF THE LIST OF FOOD ADDITIVES IN CODEX STAN 72-1981 (Agenda Item 8)<sup>10</sup>**

118. The Delegation of Switzerland, as chair of the EWG introduced the report and informed the Committee that the discussion of the eWG had concentrated on those additives proposed for addition to infant formulas covered by the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72-1981)* (sections A and B). These proposed additives and their suggested conditions of use had been listed in a “wish-list” in Appendix I of CX/NFSDU 13/35/8. Four of these additives had recently been evaluated by JECFA and it was necessary that the Committee pronounced itself on their status in the standard.
119. With the exception of Carrageenan the delegation noted that the food additives already adopted in Section A of the standard had not been discussed in the eWG. However the delegation also recalled that the question of the retrospective applicability of criterion g) for additives for use in CODEX STAN 72 -1981, “an assessment from JECFA that explicitly states that the substance is safe to be used in infants below twelve weeks of age” was a question to be addressed as well as the possible inclusion of criterion g) in the preamble of the GSFA.
120. The delegation stressed that the basic principle with regards to additives in standards for baby foods remained valid: “Baby foods should be prepared without food additives whenever possible. Where the use of a food additive becomes necessary in baby foods, great caution should be exercised regarding both the choice of additive and its level of use.” (JECFA, 1971, Annex 3 of TRS 488).
121. The delegation outlined further the process for nominating food additives (discussed in the working group) which had been successfully used for the four food additives in question by interested parties notifying to CCFA their request for an evaluation by JECFA and their commitment to make available the specific data

<sup>10</sup> CX/NFSDU 14/36/9: CRD (Comments of Ghana, African Union); CRD13 (Comments of EU); CRD24 (Comments of Kenya, Philippines, United States); CRD33 (Comments of Nigeria, Indonesia, Thailand, ISDI); CRD40 (Comments of Rep. of Korea).

needed. The fate of the wish-list had also been discussed.

122. The Committee considered the recommendations of the EWG and made the following comments and conclusions.

Recommendation 1

Food additives nominated for infant formulas covered by CODEX STAN 72-1981

The Committee took the following decisions with regards to substances on the wish-list and the current permission for Carrageenan in the standard.

123. Carrageenan (INS 407)

Status of the substance in CODEX STAN 72-1981

124. The Committee noted that Carrageenan is included in the standard with a footnote: "Not endorsed by the 39th Session of the CCFA. JECFA evaluation is pending. National authorities may restrict its use until JECFA evaluation has been completed." The summary report of JECFA79 (2014) states that "the use of carrageenan in infant formula or formula for special medical purposes at concentrations up to 1000 mg/L is not of concern".

Discussion

125. Several delegations and observers preferred to remove the substance from the standard as they did not believe that there was a technological need for it.
126. The Delegation of Bangladesh, supported by one Observer organisation, was of the view that further scientific studies were needed. Other delegations were of the opinion that role of JECFA should be respected and that the substance remain in the standard and the footnote removed.

**Conclusion**

127. The Committee agreed to defer discussion on this substance until the following session when the full JECFA report would be available. The substance should thus remain in the standard and on the wish-list. The Delegation of the Philippines expressed its reservation on the postponement of the decision on Carrageenan despite full JECFA assessment.

**Citric and fatty acid esters of glycerol (CITREM) (INS 472c)**

Status of the substance in CODEX STAN 72-1981

128. The Committee noted that CITREM is not included in the standard. JECFA79 concluded that there are no toxicological concerns about the use of CITREM in infant formula and formula for special medical purposes intended for infants at concentrations up to 9 g/l.

**Conclusion**

129. The Committee agreed to include INS 472c in part 4 section A of the standard for all types of liquid infant formula at a maximum level of 0.9 g/100 ml of the product ready for consumption, and for all types of powder infant formula at a maximum level 0.75 g/100 ml of the product ready for consumption.

**Octenyl succinic acid (OSA)-modified starch (starch sodium octenyl succinate) (INS 1450)**

Status of the substance in CODEX STAN 72-1981

130. The Committee noted that INS 1450 is not included in the standard. JECFA79 concluded that the consumption of OSA-modified starch in infant formula or formula for special medical purposes intended for infants is not of concern at concentrations up to 20 g/l.

Discussion

131. One Observer organization said that as infants could not digest starch until 5 months of age this substance should not be included in the standard.

**Conclusion**

132. The Committee agreed to include INS 1450 in part 4 section A of the standard for hydrolysed protein and/or amino acid based infant formula only, at a maximum level of 2g/100ml of the product ready for consumption noting the reservation of the European Union and Norway on this issue.

**Pectin (INS 440)**

Status of the substance in CODEX STAN 72-1981

133. The substance is not included in the standard. JECFA79 concluded that the use of pectin in infant formulas

at the maximum proposed use level (0.5%) is of concern. JECFA requested additional data to support the safety evaluation of pectin in infant formula, including an explanation for the decreased feed intake and body weight gain in neonatal pigs.

#### **Conclusion**

134. The Committee agreed to leave pectin on the wish-list until further information was available from JECFA.

#### **Sodium carboxymethylcellulose (INS 466) and Mono- and Diglycerides (INS 471)**

##### Status in CODEX STAN 72-1981

135. The Committee noted that INS 466 is not included in the standard while INS 471 is included at 0.4g/100 ml of the product ready for consumption.

#### **Conclusion**

136. The Committee agreed to remove Sodium Carboxymethylcellulose (INS 466) from the wish-list as there is limited technological need for it. The Committee also agreed to remove Mono- and Diglycerides (INS 471) from the wish-list as it is already listed in section A of the standard and an increase from 0.4 to 0.5 g/100 ml of the product ready for consumption is not technologically needed.

#### **Gum Arabic (INS 414)**

##### Status in CODEX STAN 72-1981

137. The Committee noted that INS 414 is not included in the standard. The working group proposed to delete it from the wish-list as the substance is not supported significantly demonstrating limited technological need.

##### Discussion

138. Several delegations and one Observer organisation were in favor of maintaining this substance on the wish-list as it was produced and used in their countries.

#### **Conclusion**

139. The Committee agreed to maintain INS 414 on the wish-list and noted the need for members to sponsor this substance for a JECFA assessment.

#### **Vitamin E concentrate (INS 306), Gamma tocopherol (INS 308) and Delta tocopherol (INS 309)**

##### Status in CODEX STAN 72-1981

140. The Committee noted that INS 306, INS 308 and INS 309 are not included in the standard.  
141. One Observer organisation objected to the removal of gamma tocopherol and delta tocopherol from the list.

#### **Conclusion**

142. The Committee agreed to remove the three substances from the wish-list.

##### Recommendation II

143. The Committee adopted the following structured approach (based on the Procedural Manual and the Preamble of the GSFA) to be used in future for inclusion of additives into CODEX STAN 72-1981 or the GSFA:

- Step 1: Proposal to be checked for: status at JECFA, specifications, intended technological use, and safety when used at proposed levels in infant formula. Any deficiency needs to be addressed by interested parties with CCFA and JECFA before further discussions at CCNFSDU.
- Step 2: Once all requirements are met, CCNFSDU will consider whether there is sufficient support based on technological needs that supports the use of the food additives in Sections A or B of the standard.

144. The Codex Secretariat noted that JECFA did not evaluate the technological need of additives as this was the prerogative of the CCNFSDU.

##### Recommendation III

145. The Committee considered the recommendation regarding the need for alignment of food additives in CODEX STAN 72-1981 and the corresponding GSFA food categories, and noted that infants were extremely vulnerable and therefore require protection from use of unsafe food additives.  
146. With regard to the procedure of alignment, the Codex Secretariat informed the Committee that CCFA had developed a decision tree to assist in the work of alignment of food additives provisions in commodity

standards with the GSFA and had recently tested the decision tree on meat standards. It was within the mandate of Committees to ask CCFA when the alignment work on particular food additives provisions would be done.

147. The Committee adopted the recommendation.

#### Recommendation IV

148. The Committee discussed the need to maintain a list or have it discontinued and noted that though the list was initially considered interim, it had been in existence for about 10 years and there was need to specify that it was temporary and should not be considered official.
149. Some delegations mentioned that there was a risk that the list was considered as official and that substances contained on the list were in some form endorsed for use and those not contained were forbidden.
150. The Codex Secretariat clarified that the list had no official status with JECFA or CCFA and served only as “memory” for the CCFNSDU.
151. The Committee agreed to maintain the list up to the next Session.

#### **Conclusion**

152. The Committee agreed to:
- Recommend to the 38<sup>th</sup> Session of CAC to include INS 472c and INS 1450 in part 4 of section A of CODEX STAN 72-1981 (see Appendix VI, part 1);
  - Ask CCFA to examine if criteria g) could be included in the preamble of the GSFA as follows;  
*“Additives for use in CODEX STAN 72 -1981 shall require also an assessment from JECFA that explicitly states that the substance is safe to be used in infants below twelve weeks of age”;*
  - Ask CCFA if food additives in Section A and B of CODEX STAN 72-1981 and sections 13.1.1 and 13.1.3 of the GSFA could be prioritised for alignment, in order to protect vulnerable infants;
  - To keep the amended working list of additives (wish-list) up to next session, when the decision would be made on its future status (Appendix VI, part 2).

#### **DISCUSSION PAPER ON CLAIM FOR “FREE” OF TRANS FATTY ACIDS (Agenda Item 9)<sup>11</sup>**

153. The Committee recalled that at its last Session, it had agreed that the Delegation of Canada would draft a proposal for consideration at the 36<sup>th</sup> Session and that such a proposal would take into consideration the outcome of the 6<sup>th</sup> meeting of the WHO Nutrition Guidance Expert Advisory Group (NUGAG). The Committee also noted that the proposed work on conditions for claims for trans fatty acids had been requested by the CCFL and was part of the project document for the establishment of claims for sugars, salt/sodium and trans fatty acids which had been approved by the Commission under ALINORM 10/33/22, Appendix V.
154. The Delegation of Canada, introduced document CX/NFSDU 14/36/10 and the proposed conditions for a “free” of trans fatty acids (TFAs) claim and reported that the NUGAG guidance was not yet available.
155. The Delegation noted that although current analytical methods allowed the detection of TFAs at low level accurately and reliably, some Codex members and observers had raised concern that it may not be the case at the proposed level. Therefore, it was proposed to defer the discussion until advice be sought from CCMAS as advised by AOCS on the lowest level of TFAs that current analytical methods could accurately detect as well as consistently reproduce.
156. IDF supported the proposal to defer discussion and said that ISO/IDF methods on quantification of trans fatty acids were under revision and were expected to be finalised in 2015.

#### **Conclusion**

157. The Committee agreed to defer discussions to its next session, so as to await the outcome of the NUGAG review and to request CCMAS advice on methodological issues as noted in paragraph 155 .

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<sup>11</sup> CX/NFSDU 14/36/10; CRD5 (Comments of Ghana and African Union), CRD14 (Comments of Thailand, AOCS, FEDIOL and FoodDrinkEurope); CRD25 (Comments of Kenya, Philippines and United States of America); CRD34 (Comments of Nigeria, Indonesia, Malaysia and IFMA); CRD44 (Comments of IDF); CRD46 (Comments of Costa Rica)

**DISCUSSION PAPER ON BIOFORTIFICATION (Agenda Item 10)<sup>12</sup>**

158. The Delegation of the Republic of Zimbabwe presented the paper with comments from the Delegation of the Republic of South Africa and proposed that CCNFSDU consider new work to define biofortification or biofortified foods.
159. The Committee discussed the paper and noted there was much support amongst delegations for the development of a harmonised definition.
160. Some delegations confirmed the possible benefits of biofortification techniques especially where deficiencies were a health risk, and therefore the advantages of a definition. They stated, however, that if new work were to be undertaken, then issues must be clarified to ensure consumers were not confused about the method used for obtaining the food or were not led to believe that biofortification was better than other fortification techniques leading to similar nutritional improvements. One delegation highlighted that the definition should include a reference to the methods used in the production of biofortified foods. Another delegation pointed out that any future definition of biofortification should not create confusion or overlapping with other existing related Codex and WHO definitions.
161. Delegations also commented on the need for effective risk analysis, clear labelling, the availability of land and the importance of sustainability of future biofortification initiatives.
162. The Observer organisation of IFPRI noted that HarvestPlus had focused on increasing the levels of proVitamin A in orange sweet potato, maize, and cassava; iron in beans and pearl millet; and zinc in wheat and rice. She also strongly supported new work on an internationally accepted definition of biofortification as the lack of such a definition created obstacles for countries and misuse of the term.
163. With support for the new work confirmed, the Committee proceeded to examine the draft Project Document and amended the main aspects to be covered to ensure that the definition would be broad enough to cover the various organisms and methods of biofortification and sufficiently detailed to distinguish among them.

**Conclusion**

164. The Committee agreed to forward to CAC38 the proposal to start new work to define biofortification or biofortified foods (see Appendix VII for the project document).
165. Subject to approval of new work by CAC38, the Committee further agreed to establish, an eWG, co-chaired by Zimbabwe and South Africa, working in English only to develop a proposed draft definition for comments at Step 3 and consideration by CCNFSDU37.

**OTHER BUSINESS AND FUTURE WORK (Agenda Item 11)<sup>13</sup>****Discussion paper on a standard for ready-to-use foods (RUF)**

166. The Chairperson recalled that at CAC37 the United Nations International Children's Emergency Fund (UNICEF) had presented a proposal for the development of a Codex standard for Ready to Use Foods (RUF) for the management of acutely malnourished children. CAC37 had agreed that UNICEF prepare a comprehensive discussion paper for the next session of the CCNFSDU to clarify scope and objectives of the proposed work.
167. The Representative from UNICEF introduced the paper and recommended that CCNFSDU consider the development of a Standard for RUF.
168. Some delegations and some observers, while expressing support for the work of UNICEF in preparing the proposal, raised concerns over the scientific evidence for the use of RUF in the treatment of severe acute malnutrition (SAM) and the nutritional necessity or benefits of RUF.
169. Delegations also questioned the term Ready-to-Use Therapeutic Food (RUTF), as the word "therapeutic" could be interpreted as meaning medication and, as such, beyond the scope of Codex. Care should be taken that the name of such foods was not in contradiction with Codex labelling requirements.
170. The Codex Secretariat clarified that if the term "therapeutic food" was clearly defined in the new work it would be obvious that it did not refer to medication or imply that Codex was dealing with matters outside its mandate.
171. Several delegations also noted that whilst in an emergency there could be a need for RUFs, nutrition was a

<sup>12</sup> CX/NFSDU 14/36/11; CRD6 (Comments of El Salvador, Ghana, Haiti, African Union, FoodDrinkEurope), CRD9 (Comments of Thailand), CRD11 (Nauru, Guatemala, ISDI), CRD18 (Comments of Panama, Philippines), CRD35 (Comments of Nicaragua), CRD46 (Costa Rica)

<sup>13</sup> CX/NFSDU 14/36/2 Add 1; CRD8 (Comments of Austria, Switzerland, IADSA); CRD26 (Comments of United States).

very strong cultural phenomenon and for this reason, when dealing with undernourished children, the focus should be on affordable, culturally accepted local foods. .

172. The Delegation of India, supported by the Delegation of Bangladesh, did not support the current proposal due to lack of sufficient data, lack of differentiation between therapeutic and supplementary food and strongly supported the need for using local food in accordance with national policy.
173. Several delegations were of the opinion that it would be preferable to develop a Codex guideline for RUF rather than a Codex Standard.
174. In response to issues raised, the Representative of UNICEF acknowledged the concerns of delegations and stated they were open to the development of a guideline instead of a standard. Information from the on-going review by WHO could be taken into account. She said that the composition for RUF was flexible to allow local production of these foods with local ingredients. On the issue of therapeutic feeding, she explained that while malnourishment was a medical condition, its "treatment" was food and one of the advantages of RUF was that malnourished children could remain in the community rather than being hospitalised.
175. Regarding the WHO review mentioned by UNICEF, the Representative of WHO provided further information on the systematic reviews which were currently being undertaken on the effectiveness and safety of the formulations based on the nutrient composition of RUTF provided in the *2007 Joint Statement on Community-based Management of Severe Acute Malnutrition* and the proposed nutrient composition of RUSF provided in the *2012 WHO Technical note on Supplementary foods for the management of moderate acute malnutrition in infants and children 6 – 59 months of age* as well as the longer-term effects of such products on the health of children. She informed the Committee that specific questions that were being examined by the systematic reviews included whether lipid-based nutrient supplements (LNS) were safe and effective for health, nutrition and development outcomes, whether LNS was more effective than other foods, and whether there were differences by dose and duration of the intervention, as well as the economic implications and cost-effectiveness of the intervention using LNS. She confirmed that these reviews were looking at not only children 6 to 23 months of age and pregnant women, but also at treatment of children 6 to 59 months of age with moderate acute malnutrition (MAM) and also with severe acute malnutrition (SAM). She stated that the systematic reviews were scheduled to be completed by 2015.
176. Several delegations were of the view that a decision on new work should be deferred until the WHO report was available.
177. Some Delegations strongly supported the UNICEF proposal to develop this standard as it could help to save lives of millions of children when appropriately used.
178. Some Observer organisations welcomed the UNICEF initiative and the upcoming WHO review.
179. Other Observer organisations raised concerns regarding the impact of the costs of infrastructure and production of RUF as opposed to local foods and the impact of RUF on breastfeeding and the developing taste palate of young children with possible risks of over-feeding and the potential of inappropriate marketing.
180. In response to delegates questions, the Secretariat reminded the Committee, that as with any proposal for new work, the first step would be to look at the project document and verify that it was complete and aligned with the Codex Procedural Manual and Guidelines. This would then be followed by a CCEXEC critical review and the decision of CAC to approve the new work. The Secretariat also confirmed that to form an eWG a member would be required. On the question of whether a standard or a guideline was the most appropriate option, he explained that this could be handled flexibly as could the scope of the text, which could be sufficiently general to include local products.
181. The Representative of FAO reminded the Committee about the FAO/WHO expert meeting on the microbiological safety of RUF for severe and acute moderate malnourished populations that would take place at FAO in Rome in mid-December 2014.
182. The Chairperson noted that the discussion had shown that it was premature to decide on the development of a Codex standard or guideline for RUF. The Chairperson therefore suggested that the decision be postponed until the next session of the Committee when the review from WHO would be available and there would be a better basis for a decision.

### **Conclusion**

183. The Committee agreed to request UNICEF to prepare a revised discussion paper and project document, with the support of Senegal, to be presented at the next session of CCFSNDU.

**Proposal for an extension of the method recommendation in the *Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten (CODEX STAN 118– 979)* with a method that also accurately detects the toxic fraction in gluten harmful for individuals intolerant to gluten: the ELISA G12 method.**

184. The Delegation of Austria presented the proposal and recommended that since the ELISA G12 method fulfilled all the criteria stated in 5.1 in the CODEX STAN 118-1979, and was supported by inter-laboratory validation data and international approvals, it should be incorporated into Codex Standard 118-1979 and therefore proposed to refer the proposal to CCMAS for consideration.
185. The Observer of AOECs recalled that the threshold of “gluten free” as defined in CODEX STAN 118-1979 was determined by analysing food with the R5 method. Therefore, she requested that before taking a decision, consideration should be made regarding the labelling consequences for the term ‘gluten-free’ before incorporating method G12 into the standard, should the results determined by the G12 in the same food samples be different than those determined by the R5 method.

**Conclusion**

186. The Committee agreed to ask CCMAS to examine ELISA G12 as a potential additional method.

**Proposal for inclusion of zinc citrates in the *Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young children (CAC/GL 10–1979)***

187. The Delegation of Switzerland presented the proposal and noted that when this had been discussed previously in the Committee it had been decided to include zinc citrate in the advisory list as soon as a specification became available, which was now the case in the USP.

**Conclusion**

188. The Committee agreed to forward to CAC38 for endorsement the inclusion of zinc citrate into the *Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children (CAC/GL 10–1979)* (Appendix VIII).

**Proposal for new work on the establishment of a Codex NRV for eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) long chain omega-3 fatty acids (IADSA)**

189. The Representative of IADSA presented the proposal that CCNFSDU consider new work on the establishment of a new NRV-NCD for omega-3 fatty acids based on EPA and DHA in order to achieve better public health and information to consumers. The Delegation of Japan expressed its opinion to cover all omega-3- fatty acids.
190. The Committee supported new work on this topic in general and made minor amendments to the project document.

**Conclusion**

191. The Committee agreed to propose to CAC38 to begin new work on an NRV-NCD for omega-3 fatty acids based on EPA and DHA (Appendix IX for the project document). Subject to the approval of CAC38, the Committee agreed to establish an electronic working group, co-chaired by Chile and the Russian Federation, working in English and Spanish, with the following terms of reference:
- Assess the most current scientific evidence in line with the General Principles.
  - Make recommendations to set a potential Codex NRV-NCD for the total of Omega-3 fatty acids DHA and EPA, in accordance with the general principles for NRV-NCD as set out in the Annex to the Guidelines on Nutrition Labelling (CAC/GL XXXX).

The eWG recommendations would then be presented for discussion at the CCNFSDU37, with the possibility to have the NRV-NCD for Omega-3 fatty acids DHA and EPA adopted at Step 5/8 by the CAC39 in 2016.

**Proposal to amend the *Standard for foods for special dietary use for persons intolerant to gluten (CODEX STAN 118 – 1979)*, to add the term “khorasan wheat”**

192. The Delegation of the United States of America presented the proposal that CCNFSDU reconsider amending the *Standard for Foods For Special Dietary Use For Persons Intolerant To Gluten (CODEX STAN 118 – 1979)*, to add the term “khorasan wheat,” which is marketed under the tradename KAMUT in a number of Codex member countries.

**Conclusion**

193. The Committee agreed to forward the amendment to CODEX STAN 118-1979, as proposed and further amended, to CAC38 for adoption (Appendix X).

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

194. The Committee was informed that the 37<sup>th</sup> Session was scheduled to be held in Bad Soden am Taunus, Germany from 23 to 27 November 2015, the final arrangements being subject to confirmation by the Host Country and the Codex Secretariat.

## SUMMARY STATUS OF WORK

SUBJECT MATTER	STEP	ACTION BY	DOCUMENT REFERENCE (REP15/NFSDU)
Draft Revision of the <i>General Principles for the Addition of Essential Nutrients to Foods</i>	8	Governments CAC38	Para 53 Appendix III
Proposed Draft Additional or Revised Nutrient Reference Values for Labelling Purposes in the <i>Guidelines on Nutrition Labelling (CAC/GL2-1985)</i>	5/8	Governments CAC38	Para 82 Appendix IV Part 1
Proposed Draft Nutrient Reference Value for Potassium in Relation to the Risk of Non-Communicable Disease	5/8	Governments CAC38	Para 116 Appendix V
The Amendments to the Annex of the <i>Guidelines on Nutrition Labelling (CAC/GL2-1985)</i>	Adoption	Governments CAC38	Para 82 Appendix IV Part 2
Proposed Draft Revision of the List of Food Additives in CODEX STAN 72-1981	Adoption	Governments CAC38	Para 152 Appendix VI Part 1
Proposal for inclusion of zinc citrates in the <i>Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children (CAC/GL10-1979)</i>	Adoption	Governments CAC38	Para 188 Appendix VIII
Draft Amendment to the <i>Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten (CODEX STAN 118-1979)</i> , to add the term "Khorasan wheat"	Adoption	Governments CAC38	Para 193 Appendix X
Proposed Draft Amendment of the <i>Standard for Processed Cereal-Based Foods for Infants and Young Children (CODEX STAN 74-1981)</i> to Include a New Part B for Underweight Children	Discontinued	Governments CAC38	Para 89
Proposed Draft Additional or Revised Nutrient Reference Values for Labelling Purposes in the <i>Guidelines on Nutrition Labelling (Vitamin A, D, E, Magnesium, Phosphorus, Chromium, Copper, Chloride &amp; Iron)</i>	2/3	EWG (Australia) CCNFSDU37	Para 81
Review of the <i>Standard for Follow-Up Formula (CODEX STAN 156-1987)</i>	2/3	CAC38 EWG/ PWG (New Zealand/ France/Indonesia) CCNFSDU37	Para 108

Proposed Draft Definition on Biofortification	1/2/3	CAC38 EWG (Zimbabwe, South Africa) CCNFSDU37	Para 165 Appendix VII
Proposed Draft NRV-NCD for EPA and DHA long chain omega-3 fatty acids	1/2/3	CAC38 EWG (Chile, Russian Federation) CCNFSDU37	Para 191 Appendix IX
Discussion Paper on Claim for "Free" of Trans Fatty Acids	-	CAC38 Canada CCNFSDU37	Para 157
Discussion paper on a standard for ready-to-use foods (RUF)	-	Senegal, UNICEF CCNFSDU37	Para 183

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

**CHAIRPERSON /  
PRÉSIDENT /  
PRESIDENTE**

Dr Pia NOBLE  
Head of Division 214  
Federal Ministry of Food and Agriculture  
Rochusstr. 1  
53123 Bonn  
GERMANY  
Tel: +49 228 99 529 4665  
Email: [ccnfsdu@bmel.bund.de](mailto:ccnfsdu@bmel.bund.de)

**VICE-CHAIRPERSON/  
VICE-PRÉSIDENT/  
VICEPRESIDENTE**

Prof Purwiyatno HARIYADI  
Professor of Food Process Engineering  
Dept of Food, Science & Technology  
Bogor Agriculture University and  
Director of Southeast Asian Food &  
Agriculture Science & Technology  
(SEAFast) center  
Bogor Agriculture University,  
INDONESIA  
Tel. +62 251 86267 25  
Email: [hariyadi@seafast.org](mailto:hariyadi@seafast.org)

**ASSISTANT TO THE CHAIRPERSON /  
ASSISTANT AU PRÉSIDENT /  
ASISTENTE AL PRESIDENTE**

Mrs Katharina ADLER  
Federal Ministry of Food and Agriculture  
Rochusstrasse 1  
53123 Bonn  
GERMANY  
Tel: +49 228 99 529 4647  
Email: [ccnfsdu@bmel.bund.de](mailto:ccnfsdu@bmel.bund.de)

**MEMBER COUNTRIES / PAYS MEMBRES / PAÍSES  
MIEMBROS**

**ALGERIA - ALGÉRIE – ARGELIA**

Mrs ATIKA GUENDOZ NÉE BENRIMA  
(Head of Delegation)  
Doyenne faculté S.N.V  
Université SAAD DAHLEB Blida 1  
B P 270 Blida  
9000 Blida  
ALGERIA  
Tel: +213 550693066  
Email: [atiquen@yahoo.fr](mailto:atiquen@yahoo.fr)

**ANGOLA**

Ms Maria Filomena FERNANDES DA MATA  
1<sup>st</sup> Secretary of the Codex  
Angola technical fisheries Ministry  
ANGOLA  
Email: [mariafilomata@gmail.com](mailto:mariafilomata@gmail.com)

**AUSTRALIA - AUSTRALIE**

Ms Janine LEWIS  
(Head of Delegation)  
Principal Nutritionist  
Food Standards Australia New Zealand  
PO Box 7186  
Canberra BC 2610  
AUSTRALIA  
Tel: +61 2 6271 2245  
Email: [janine.lewis@foodstandards.gov.au](mailto:janine.lewis@foodstandards.gov.au)

Mrs Victoria LANDELLS  
Fonterra  
AUSTRALIA  
Email: [victoria.landells@fonterra.com](mailto:victoria.landells@fonterra.com)

Ms Melissa TOH  
Regulatory Affairs and I&P Manager  
Nestle Nutrition Oceania  
AUSTRALIA  
Email: [melissa.toh@au.nestle.com](mailto:melissa.toh@au.nestle.com)

**AUSTRIA - AUTRICHE**

Dr Fritz WAGNER  
(Head of Delegation)  
Federal Ministry of Health  
Radetzkystrasse 2  
1030 Vienna  
AUSTRIA  
Tel: +43(1)711004426  
Email: [Fritz.wagner@bmg.gv.at](mailto:Fritz.wagner@bmg.gv.at)

**BANGLADESH**

Mr MD MOFIDUL ISLAM  
Deputy Director  
Bangladesh Standards and Testing Institution  
Agri and Food  
116-A Tejgaon Industrial Area  
1208 Dhaka  
BANGLADESH  
Tel: +88-02-8870282  
Email: [mofidulislam5@gmail.com](mailto:mofidulislam5@gmail.com)

Mr S K ROY  
(Head of Delegation)  
Chairperson  
Bangladesh Breastfeeding Foundation  
Institute of Public Health (IPH)  
Room NR 197-200 (Ground Floor)  
Mohakhali, Dhaka-1212.  
1212 Dhaka  
BANGLADESH  
Tel: +88-01943220587  
Fax: +88-02-9860801  
Email: [skroy1950@gmail.com](mailto:skroy1950@gmail.com)

#### **BELGIUM - BELGIQUE - BÉLGICA**

Ms Isabelle LAQUIÈRE  
(Head of Delegation)  
Regulatory Expert  
FPS public health.  
Food, Feed and other consumption product  
Eurostation - Place victor horta, 40 bte 10  
1060 Brussels  
BELGIUM  
Tel: +32 2 524 73 64  
Fax: +32 2 524 73 99  
Email: [isabelle.laquiere@health.belgium.be](mailto:isabelle.laquiere@health.belgium.be)

#### **BRAZIL - BRÉSIL - BRASIL**

Mrs Elisabete GONÇALVES DUTRA  
Technical Consultant  
National Health Surveillance Agency  
SIA, TRECHO 5, ÁREA ESPECIAL 57-  
71.205-050- Brasília- Brasil  
Brasília-DF  
BRAZIL  
Tel: +55(11)3462-5333  
Email: [Elisabete.goncalves@anvisa.gov.br](mailto:Elisabete.goncalves@anvisa.gov.br)

Mrs Thelma R. T. LAHÓZ MOYA  
ABIA's Technical Consultant  
ABIA- Brazilian Association of Food Industries  
Av. Brigadeiro faria lima, 1478- 11ª andar  
São Paulo/SP Brazil  
São Paulo  
BRAZIL  
Tel: 55 11 30301394 / 55 11 992758  
Email: [thelma.moya@abbott.com](mailto:thelma.moya@abbott.com)

Mr Antônio M. MANTOAN  
ABIA's Technical Consultant  
ABIA- Brazilian Association of Food Industries  
Av. Brigadeiro Faria Lima, 1478 11ª andar  
São Paulo  
BRAZIL  
Tel: +55 11 3030-1394/ +55 11 9973-  
Email: [antonio.mantoan@mjn.com](mailto:antonio.mantoan@mjn.com)

Mrs Ana Claudia MARQUIM FIRMO DE ARAÚJO  
Regulation National Health Surveillance  
National Health Surveillance Agency  
SIA, Trecho 5, área especial 57-71.205-050  
Brasília-DF  
BRAZIL  
Tel: +55(61)  
Email: [ana.firmo@anvisa.gov.br](mailto:ana.firmo@anvisa.gov.br)

#### **CANADA - CANADÁ**

Ms Maya VILLENEUVE  
(Head of Delegation)  
Associate Director  
Health Canada  
Bureau of Nutritional Sciences  
251 Sir Frederick Banting Driveway, A.L. 2203B, room  
B333  
Ottawa  
CANADA  
Tel: 613 - 960-4740  
Fax: 613-948-8470  
Email: [maya.villeneuve@hc-sc.gc.ca](mailto:maya.villeneuve@hc-sc.gc.ca)

Mrs Chantal MARTINEAU  
Manager, regulatory projects  
Bureau of Nutritional Sciences  
Health Canada  
251 Sir Frederick Banting Driveway  
A.L. 2203°  
Ottawa  
CANADA  
Tel: 613 954-2805  
Fax: 613 941-6636  
Email: [chantal.martineau@hc-sc.gc.ca](mailto:chantal.martineau@hc-sc.gc.ca)

#### **CHILE - CHILI**

Ms Ana Cristina CANALES  
Adviser  
DIRECON  
Santiago  
CHILE  
Email: [acanales@direcon.gob.cl](mailto:acanales@direcon.gob.cl)

#### **CHINA - CHINE**

Ms Wai Ling CHU  
Regulatory Affairs Manager  
Mead Johnson Pediatric Nutrition Institute (China)  
Room 03-08, 30/F, ACE Tower Windsor House 311  
Gloucester Road  
Hong Kong  
CHINA  
Tel: 852-25106483  
Email: [Amy.chu@mjn.com](mailto:Amy.chu@mjn.com)

Ms Jing HAN  
Regulatory Affairs Manager  
Abbott (China) LTD.  
Room 1709-1716, Canway Building, NO.66 Nanlishilu,  
Xi Cheng District, 100045 Beijing  
CHINA  
Tel: 86 10 68028080 EXT 130  
Fax: 86 10 68027788  
Email: [grace.han@abbott.com](mailto:grace.han@abbott.com)

Prof Junhua HAN  
professor  
China National Center for Food Safety Risk  
Assessment  
2-209, NO 37. Guangqu Road, Chaoyang District,  
100022 Beijing  
CHINA  
Tel: 86-10-52165426  
Fax: 86-10-52165424  
Email: [hanjhua@cfsa.net.cn](mailto:hanjhua@cfsa.net.cn)

Dr Yuk yin HO  
Consultant (Community Medicine)  
(Risk Assessment&Communication)  
Centre for Food Safety, Food and Environmental  
Hygiene Department  
45/F,Queensway Government Offices,66 Queensway,  
999077 Hongkong  
CHINA  
Tel: (852) 2867 5600  
Fax: (852) 2526 8279  
Email: [ykho@fehd.gov.hk](mailto:ykho@fehd.gov.hk)

Mr Fabin JIN  
Principal staff member  
China Food and Drug Administration  
Department of food safety supervision III  
No.26 Xida Street, Xuanwu Men, Xicheng District,  
100053 Beijing  
CHINA  
Tel: 010-88331035  
Fax: 010-63600373  
Email: [jinfab@cfda.gov.cn](mailto:jinfab@cfda.gov.cn)

Ms Dong LIANG  
China National Center for Food Safety Risk  
Assessment  
2-202, NO 37. Guangqu Road, Chaoyang DISTRICT,  
100022 Beijing  
CHINA  
Tel: 86-13910619647  
Fax: 86-10-52165424  
Email: [liangdong@cfsa.net.cn](mailto:liangdong@cfsa.net.cn)

Ms Yiqin LIN  
North Asia Regulatory Affairs Director  
Mead Johnson Pediatric Nutrition Institute (China)  
3<sup>rd</sup> Floor, North Tower, Beijing Kerry Centre,  
NO.1,Guanghua Road, Chaoyang District  
100020 Beijing  
CHINA  
Tel: 86-10-59373889  
Fax: 86-10-59373937  
Email: [Linda.lin@mjn.com](mailto:Linda.lin@mjn.com)

Mrs Jiongqian PANG  
National Health and Family Planning Commission of  
The People's Republic of China  
No.1 Xizhimenwainanlu, Xicheng District, 100044  
Beijing  
CHINA  
Tel: 86-10-68792403  
Fax: 86-10-68792839  
Email: [pangjq@nhfpc.gov.cn](mailto:pangjq@nhfpc.gov.cn)

Dr Changyan SUN  
Doctor  
Heilongjiang Dairy Industry Technical Development  
Center  
No.2727 Chuangxin One Road, Songbei District,  
Haerbin City, Helongjiang Province, China  
150028 Haerbin  
CHINA  
Tel: 86-13089985372  
Fax: 86-451-86630308  
Email: [SCYNEAU@163.COM](mailto:SCYNEAU@163.COM)

Mrs Yongmei WU  
Deputy Director General  
P.R.China  
No.32 Beisantiao Jiaodaokou, Dongcheng District,  
Beijing, P.R.China  
100007 CHINA  
Tel: 86-10-84088623  
Fax: 86-10-84088594  
Email: [biaozhunchu204@sina.com](mailto:biaozhunchu204@sina.com)

Ms Ruimin XU  
Senior Regulatory Affairs Manager  
Mead Johnson Pediatric Nutrition Institute (China)  
Xia Yuan Road, Dongji Industrial Estate 24/F, Sanxin  
Plaza, No. 33 West Huangpu Avenue  
510730 Guangzhou  
CHINA  
Tel: 86-20-82156105  
Fax: 86-20-82156131  
Email: [Amy.xu@mjn.com](mailto:Amy.xu@mjn.com)

Mr Hongmin XU  
Director of Technical & Regulatory  
Amway (China) Co. Ltd  
41/F CITIC Plaza, 233 Tianhe N. Road. Guangzhou,  
Guangdong, P.R. China  
510613 Guangzhou  
CHINA  
Tel: 86-20-85198811  
Fax: 86-20-38912877  
Email: [helen\\_yuan@amway.com](mailto:helen_yuan@amway.com)

Mr Xiaoming XU  
Deputy director of the clerk  
China Food and Drug Administration  
Department of food safety supervision I  
No.26 Xida Street,Xuanwu Men,Xicheng District  
100053 Beijing  
CHINA  
Tel: 010-88331035  
Fax: 010-63600373  
Email: [Xuxm@cfda.gov.cn](mailto:Xuxm@cfda.gov.cn)

Mr Weixing YAN  
Deputy Director General  
China National Center for Food Safety Risk  
Assessment  
Building 2, no 37. Guangqu road, Chaoyang District  
100022 Beijing  
CHINA  
Tel: 86-10-52165426  
Fax: 86-10-52165424  
Email: [yanweixin@cfsa.net.cn](mailto:yanweixin@cfsa.net.cn)

Prof Jinbao YANG  
Professor  
Heilongjiang Dairy Industry Technical Development  
Center  
No.2727 Chuangxin One Road, Songbei District,  
Harbin City, 150028 Haerbin  
CHINA  
Tel: 86-13704503733  
Fax: 86-451-86661773  
Email: [Jinbaoyang@vip.sina.com](mailto:Jinbaoyang@vip.sina.com)

Prof Shi-an YIN  
 Professor  
 National Institute of Nutrition and Food Safety, Chinese  
 Center for Disease Control and Prevention  
 29 Nan Wei Road, 100050 Beijing  
 CHINA  
 Tel: 86-13701212904  
 Fax: 86-83132932  
 Email: [shianyin@126.com](mailto:shianyin@126.com)

Mr Tianxiang YU  
 Agronomist  
 Jiaxing Entry-Exit Inspection and Quarantine Bureau of  
 P.R.C  
 No.1299 Wenchang Road, Jiaxing, 314001 Zhejiang  
 CHINA  
 Tel: 86-573-82660133  
 Fax: 86-573-82660138  
 Email: [ytx@jx.ziq.gov.cn](mailto:ytx@jx.ziq.gov.cn)

Prof Bing ZHANG  
 Division director of Department of Public Health  
 Nutrition  
 National Institute for Nutrition and Food Safety, Chinese  
 Center for Disease Control and Prevention  
 27 Nanwei Road, Xicheng District, Beijing City, P. R.  
 CHINA  
 Tel: 86-10-83151561  
 Fax: 86-10-83132909  
 Email: [zhangb327@aliyun.com](mailto:zhangb327@aliyun.com)

Dr Xuejun ZHAO  
 Scientific and Regulatory Affairs Director  
 Dumex Baby Food Co., Ltd  
 The 3<sup>rd</sup> Floor, 1155 Fangdian Road, Pudong New Area  
 201204 Shanghai  
 CHINA  
 Tel: 86-21-6162 8798  
 Fax: 86-21-6179 8889-8840  
 Email: [xuejun.zhao@danone.com](mailto:xuejun.zhao@danone.com)

Ms Wenjing ZOU  
 Regulatory & Scientific Affairs Executive  
 Nestle (China) LTD.  
 Level 9, Tower B, Lsh Plaza, No. 8, Wangjing Avenue,  
 Chaoyang District, 100102 Beijing  
 CHINA  
 Tel: 86-10-84347888 EXT 7765  
 Fax: 86-10-64389326  
 Email: [wenjing.zou@cn.nestle.com](mailto:wenjing.zou@cn.nestle.com)

#### COLOMBIA - COLOMBIE

Mrs Laura OTALORA  
 Farmaceutica  
 Industria  
 Carrera 83 No. 71 - 81 piso 3  
 Bogotá  
 COLOMBIA  
 Tel: 57316702781  
 Email: [lauraotalora52@hotmail.com](mailto:lauraotalora52@hotmail.com)

#### EGYPT - ÉGYPTE - EGIPTO

Mr Mohamed Abd el Hamid NASER  
 (Head of Delegation)  
 Food Standards Specialist  
 Egyptian Organization for Standardization and Quality  
 (EOS)

Food Standards  
 16, Tadreeb Al-Modarrebeen St., Ameriya  
 Cairo  
 EGYPT  
 Tel: Tel.: +20 2228 45531  
 Fax: Fax: +20 2228 45502  
 Email: [atch\\_toto3@yahoo.com](mailto:atch_toto3@yahoo.com)

Mrs Amal Mohamed KISHK  
 Agricultural Research Center  
 Alexandria  
 EGYPT  
 Email: [kishkamt@yahoo.com](mailto:kishkamt@yahoo.com)

Prof SANAA SALEH  
 Senior Researcher  
 Agriculture Research Center (ARC)  
 Regional Centre for Food and Feed -  
 9 El - Gamaa Street. Giza - Agric. Res. Center  
 Cairo  
 EGYPT  
 Tel: 20235732280  
 Fax: 00202 35713250  
 Email: [drsanaasaleh@yahoo.com](mailto:drsanaasaleh@yahoo.com)

#### EUROPEAN UNION - UNION EUROPÉENNE - UNIÓN EUROPEA

Mr Basil MATHIOUDAKIS  
 (Head of Delegation)  
 Head of Unit  
 European Commission  
 DG Sanco  
 B 232  
 1049 Brussels  
 BELGIUM  
 Email: [basil.mathioudakis@ec.europa.eu](mailto:basil.mathioudakis@ec.europa.eu)

Mr Francesco CARLUCCI  
 Administrator  
 European Commission  
 DG SANCO  
 B 232  
 1049 Brussels  
 BELGIUM  
 Email: [Francesco-Felice.CARLUCCI@ec.europa.eu](mailto:Francesco-Felice.CARLUCCI@ec.europa.eu)

Ms Barbara MORETTI  
 Administrator  
 European Commission  
 DG SANCO  
 Rue Froissart 101  
 1049 Brussels  
 BELGIUM  
 Email: [barbara.moretti@ec.europa.eu](mailto:barbara.moretti@ec.europa.eu)

Ms Ariane TITZ  
 European Food Safety Authority (EFSA)  
 Largo N. Palli 5/A  
 I-43100 Parma – ITALY  
 Email: [ariane.titz@efsa.europa.eu](mailto:ariane.titz@efsa.europa.eu)

**FINLAND - FINLANDE - FINLANDIA**

Ms Anna LEMSTRÖM  
 (Head of Delegation)  
 Senior Officer, Food Policy  
 Ministry of Agriculture and Forestry  
 P.O.Box 30  
 00023 \*Government  
 Helsinki  
 FINLAND  
 Tel: +358 295 162145  
 Email: [anna.lemstrom@mmm.fi](mailto:anna.lemstrom@mmm.fi)

**FRANCE - FRANCIA**

Mrs Alice STENGEL  
 (Head of Delegation)  
 Chargé de mission  
 Ministry of Finance  
 59, bd Vincent AURIOL  
 75013 Paris  
 FRANCE  
 Tel: 33644973325  
 Email: [Alice.Stengel@dgccrf.finances.gouv.fr](mailto:Alice.Stengel@dgccrf.finances.gouv.fr)

Dr Jolanta LEONE  
 Regulatory  
 DNA&O  
 FRANCE  
 Email: [jolanta.leone@danone.com](mailto:jolanta.leone@danone.com)

**GERMANY - ALLEMAGNE - ALEMANIA**

Dr Hartmut WALDNER  
 (Head of Delegation)  
 Federal Ministry of Food and Agriculture  
 Rochusstrasse 1  
 53123 Bonn  
 GERMANY  
 Email: [ccnfsdu@bmel.bund.de](mailto:ccnfsdu@bmel.bund.de)

Dr Gert KRABICHLER  
 Head Global Regulatory Affairs  
 Merck Consumer Health / Research and Development  
 Frankfurter Strasse 250  
 64289 Darmstadt  
 GERMANY  
 Tel: +49 6151 856 3264  
 Fax: +49 6151 7291 8009  
 Email: [gert.krabichler@merckgroup.com](mailto:gert.krabichler@merckgroup.com)

Mr Norbert PAHNE  
 Manager  
 Federation of German Dietetic Foods  
 Godesberger Allee 142 - 148  
 53175 Bonn  
 GERMANY  
 Tel: +49 228 308 5110  
 Fax: +49 228 308 5150  
 Email: [pahne@diaetverband.de](mailto:pahne@diaetverband.de)

Ms Antje PREUSSKER  
 Manager Scientific and Regulatory Affairs  
 German Federation for Food Law and Food Science  
 Claire-Waldoff-Strasse 7  
 10117 Berlin  
 GERMANY  
 Tel: +49 30 206143 146  
 Fax: +49 30 206143 246  
 Email: [apreussker@bll.de](mailto:apreussker@bll.de)

Dr Anke WEISSENBORN  
 Federal Institute for Risk Assessment  
 Unit Nutritional Risks, Allergies and Novel Foods  
 Department of Food Safety  
 Max-Dohrn-Strasse 8-10  
 10589 Berlin  
 GERMANY  
 Tel: +49 30 18412-3812  
 Fax: +49 30 18412-3715  
 Email: [Anke.Weissenborn@bfr.bund.de](mailto:Anke.Weissenborn@bfr.bund.de)

**GHANA**

Mr Jacob AMOAKO-MENSAH  
 Senior Regulatory Officer  
 Food and Drugs Authority  
 Food Safety  
 GHANA  
 Email: [jakeamoakomensah@gmail.com](mailto:jakeamoakomensah@gmail.com)

Ms POKUAA APPIAH-KUSI  
 Assistant Standards Officer  
 Ghana Standards Authority  
 Food, Material and Chemical Standards  
 P. O. BOX MB 245  
 Accra  
 GHANA  
 Tel: +233 205 152460  
 Email: [prispok@icloud.com](mailto:prispok@icloud.com)

Ms Marian GATIBA  
 Regulatory Officer 1  
 Food and Drugs Authority  
 GHANA  
 Email: [magat12001@yahoo.com](mailto:magat12001@yahoo.com)

**INDIA - INDE**

Dr Sandhya KABRA  
 Director  
 Food Safety and Standards Authority of India  
 Ministry of Health and Family Welfare  
 FDA Bhawan, Kotla Road,  
 New Delhi -110002  
 INDIA  
 Tel: 1123237418  
 Email: [sandhyak@fssai.gov.in](mailto:sandhyak@fssai.gov.in)

Ms Sukhmani SINGH  
 Technical Officer  
 Food Safety and Standards Authority of India  
 Ministry of Health and Family Welfare  
 FDA Bhawan, Kotla Road,  
 New Delhi -110002  
 INDIA  
 Email: [sukhmax@googlemail.com](mailto:sukhmax@googlemail.com)

**INDONESIA - INDONÉSIE**

Mrs Tetty Helfery SIHOMBING  
 (Head of Delegation)  
 Director for Food products Standardization  
 National Agency of Drug and Food Control  
 Directorate of Food Products Standardization  
 Jl. Percetakan Negara No. 23  
 10566 Jakarta  
 INDONESIA  
 Tel: +62 21 42875584  
 Fax: +62 21 42875784  
 Email: [tettybpom@gmail.com](mailto:tettybpom@gmail.com)

Mrs Latifah  
Staff  
National Agency of Drug and Food Control  
Jl. Percetakan Neagara No. 23  
10560 Jakarta  
INDONESIA  
Tel: +62 21 42875584  
Fax: +62 21 42875780  
Email: [subditspo2@yahoo.com](mailto:subditspo2@yahoo.com)

Mrs Adrianti  
Head of Administration Section  
National Agency of Drug and Food Control  
Jl. Percetakan Negara No.23  
10560 Jakarta  
INDONESIA  
Tel: +62 21 42875584  
Fax: +62 21 42875780  
Email: [yanti\\_adnan@yahoo.com](mailto:yanti_adnan@yahoo.com)

Ms Mutia ARDHANESWARI  
Staff for Implementation of Mandatory Standards and  
Handling Complaint  
National Standardization Agency of Indonesia  
Gd. Manggala Wanabakti, Block IV floors 4.  
Jl. Gatot Subroto, Senayan  
Jakarta  
INDONESIA  
Tel: +62 21 5747043  
Fax: +62 21 5747045  
Email: [tia@bsn.go.id](mailto:tia@bsn.go.id)

Mr Akbar ARYANTO  
Head of Subdivision for System of Network Information  
Technology  
National Standardization Agency of Indonesia  
Gd. Manggala Wanabakti, Block IV floors 4.  
Jl. Gatot Subroto, Senayan  
Jakarta  
INDONESIA  
Tel: +62 21 5747043  
Fax: +62 21 5747045  
Email: [akbar@bsn.go.id](mailto:akbar@bsn.go.id)

Mrs Sentani CHASFILA  
Staff  
National Agency of Drug and Food Control  
Jl. Percetakan Negara No. 23  
10560 Jakarta  
INDONESIA  
Tel: +62 21 42875584  
Fax: +62 21 42875780  
Email: [sentani.chasfila@gmail.com](mailto:sentani.chasfila@gmail.com)

Mrs Latifa DINAR  
Staff for Implementation of Mandatory Standards and  
Handling Complaint  
National Standardization Agency of Indonesia  
Gd. Manggala Wanabakti, Block IV floors 4.  
Jl. Gatot Subroto, Senayan  
Jakarta  
INDONESIA  
Tel: +62 21 5747043  
Fax: +62 21 5747045  
Email: [tifa@bsn.go.id](mailto:tifa@bsn.go.id)

Mrs Dedeh ENDAWATI  
Head of International Organization Cooperation Division  
National Agency of Drug and Food Control  
Jl. Percetakan Negara No. 23

10560 Jakarta  
INDONESIA  
Tel: +62 21 42875584  
Fax: +62 21 42875780  
Email: [kerjasamaln\\_bpom@yahoo.co.id](mailto:kerjasamaln_bpom@yahoo.co.id)

Mrs Ida FARIDA  
Staff  
National Agency of Drug and Food Control  
Jl. Percetakan Negara No. 23  
10560 Jakarta  
INDONESIA  
Tel: +62 21 42875584  
Fax: +62 21 42875780  
Email: [idfamilion@yahoo.com](mailto:idfamilion@yahoo.com)

Mr Ichvan HANNY  
Staff  
National Agency of Drug and Food Control  
Jl. Percetakan Negara No. 23  
10560 Jakarta  
INDONESIA  
Tel: +62 21 42875584  
Fax: +62 21 42875780  
Email: [ichvanh@gmail.com](mailto:ichvanh@gmail.com)

Mrs Irene HAPSARI  
Head of Food Safety Cooperation Subdivision  
National Agency of Drug and Food Control  
Jl. Percetakan Negara No.23  
10560 Jakarta  
INDONESIA  
Tel: +62 21 42875584  
Fax: +62 21 42875780  
Email: [kerjasamaln\\_bpom@yahoo.co.id](mailto:kerjasamaln_bpom@yahoo.co.id)

Mr Singgih HARJANTO  
Head of Subdivision for Quality Assurance System  
National Standardization Agency of Indonesia  
Gd. Manggala Wanabakti, Block IV floors 4.  
Jl. Gatot Subroto, Senayan  
Jakarta  
INDONESIA  
Tel: +62 21 5747043  
Fax: +62 21 5747045  
Email: [singgih@bsn.go.id](mailto:singgih@bsn.go.id)

Mrs Bakara LASRIDA YUNIATY  
Head of Section Directorate of Food Product  
Standardization  
National Agency of Drug and Food Control  
Jl. Percetakan Negara No.23  
10560 Jakarta  
INDONESIA  
Tel: +62 21 42875584  
Fax: +62 21 42875780  
Email: [lasridalyb@yahoo.com](mailto:lasridalyb@yahoo.com)

Mrs Ati Widya PERANA  
Head Section for Codex  
National Agency of Drug and Food Control  
Jl. Percetakan Negara No.23  
10560 Jakarta  
INDONESIA  
Tel: +62 21 42875584  
Fax: +62 21 42875780  
Email: [athee77@yahoo.com](mailto:athee77@yahoo.com)

Mrs Deksa PRESIANA  
Head of Subdirectorate of Food Processing  
National Agency of Drug and Food Control  
Jl. Percetakan Negara No.23 Jakarta  
INDONESIA  
Tel: +62 21 42875584  
Fax: +62 21 42875780  
Email: [subditspo2@yahoo.com](mailto:subditspo2@yahoo.com)

Mr Okky Krisna RACHMAN  
Staff  
Ministry of Industry  
Jl. Jenderal Gatot Subroto  
4720 Jakarta  
INDONESIA  
Tel: +62 21 5252236  
Fax: +62 21 5252236  
Email: [okkykrisnarachman@yahoo.com](mailto:okkykrisnarachman@yahoo.com)

Mrs Sari ROMAYANA  
Staff  
National Agency of Drug and Food Control  
Jl. Percetakan Negara No 23  
10560 JAKARTA  
INDONESIA  
Tel: +62 21 42877584  
Fax: +62 21 42877580  
Email: [top.spp@yahoo.com](mailto:top.spp@yahoo.com)

Mrs Ni Putu Ekayani SCORPIASANTY  
Staff  
National Agency of Drug and Food Control  
Jl. Tjut Nya Dien No. 5  
80235 Jakarta  
INDONESIA  
Tel: +62 361 223763  
Fax: +62 361 225395  
Email: [pomdenpasar@yahoo.co.id](mailto:pomdenpasar@yahoo.co.id)

Mrs Dyah SETYOWATI  
Staff  
National Agency of Drug and Food Control  
Jl. Percetakan Negara No. 23  
10560 Jakarta  
INDONESIA  
Tel: +62 21 42875584  
Fax: +62-21-42875780  
Email: [deeyas\\_fa@yahoo.com](mailto:deeyas_fa@yahoo.com)

Ms Lia SUGIHARTINI  
Head of Section for Standard Analysis  
Ministry of Marine Marine Affairs and Fisheries  
Mina Bahari 3 Building  
Jl. Medan Merdeka Timur No.16  
10110 Jakarta  
INDONESIA  
Tel: +62 21 3500187  
Fax: +62 21 3500187  
Email: [liaduta@yahoo.com.au](mailto:liaduta@yahoo.com.au)

Mr Lucky TARIGAN  
Head of Section for Standard Cooperation  
Ministry of Trade  
Jl. M.I.Ridwan Rais No. 5  
10110 JAKARTA  
INDONESIA  
Tel: +62 21 3840986  
Fax: +62 21 3840986  
Email: [lucky.tarigan@kemendag.go.id](mailto:lucky.tarigan@kemendag.go.id)

Mr Syaiful  
(Head of Delegation)  
Head of sub Division for Implementation of Mandatory  
Standards and Complaints Handling  
National Standardization Agency of Indonesia  
Center for Standard Application System  
Manggala Wanabakti Building, Block IV floors 4  
Jl. Gatot Subroto, Senayan  
10270 Jakarta  
INDONESIA  
Tel: +62 21 5747043  
Fax: +62 21 45747045  
Email: [syaiful@bsn.go.id](mailto:syaiful@bsn.go.id)

Mr Gasilan  
Deputy Director for Raw material and Food Additives  
Standardization  
National Agency of Drug and Food Control  
Jl Percetakan Negara 23 Jakarta Pusat  
10560 Jakarta  
INDONESIA  
Tel: +6221 42875584  
Fax: +6221 42875780  
Email: [subdit.bb\\_btp@yahoo.com](mailto:subdit.bb_btp@yahoo.com)

Dr Zakiyah  
Head of Center for Standard Implementation System  
National Standardization Agency of Indonesia  
Manggala Wanabakti Block IV, 4<sup>th</sup> Floor, Jl. Jend. Gatot  
Subroto, Senayan  
10270 Jakarta  
INDONESIA  
Tel: 021-5747043  
Fax: 021-5747045  
Email: [zakiyah@bsn.go.id](mailto:zakiyah@bsn.go.id)

Prof Hardinsyah  
President of Food and Nutrition Society of Indonesia  
Bogor Agricultural University  
16680 Bogor  
INDONESIA  
Tel: +62 8129192259  
Email: [hardinsyah2010@gmail.com](mailto:hardinsyah2010@gmail.com)

Dr Rimbawan  
Head of Department  
Bogor Agricultural University  
Kampus IPB Darmaga  
16680 Bogor  
INDONESIA  
Tel: +62 251 8625066  
Fax: +62 251 8622276  
Email: [rimbawan62@yahoo.com](mailto:rimbawan62@yahoo.com)

Dr Rina AGUSTINA  
Head of Research  
University of Indonesia  
Jl. Salemba Raya No. 6  
10430 JAKARTA  
INDONESIA  
Tel: +62 21 3152532  
Fax: +62 21 3913933  
Email: [dr.rinaagustina@gmail.com](mailto:dr.rinaagustina@gmail.com)

Mrs Sandhyani Ellismethia DAMAYANTI  
Staf of Law and Public Relation Bureau  
National Agency of Drug and Food Control  
Jl. Percetakan Negara  
10560 Jakarta  
INDONESIA  
Tel: +62 21 4209221  
Fax: +62 21 4209221  
Email: [humasbpom@gmail.com](mailto:humasbpom@gmail.com)

Mrs Yusra EGAYANTI  
Deputy Director Certian Food Standardization  
National Agency of Drug and Food Control  
Jl. Percetakan Negara 23  
10560 Jakarta  
INDONESIA  
Tel: +62 21 42875584  
Fax: +62 21 42875580  
Email: [subdit\\_spk@yahoo.com](mailto:subdit_spk@yahoo.com)

Mr Achmad GOZALI  
Head of Internal Cooperation Bureau  
National Agency of Drug and Food Control  
Jl. Percetakan Negara No. 23  
10560 Jakarta  
INDONESIA  
Tel: +62 21 42875379  
Fax: +62 21 42875379  
Email: [kerjasamln\\_bpom@yahoo.co.id](mailto:kerjasamln_bpom@yahoo.co.id)

Mrs Elin HERLINA  
Director of Food Safety Assessment  
National Agency of Drug and Food Control  
Jl. Percetakan Negara No.23  
10560 Jakarta  
INDONESIA  
Tel: +62 21 42800221  
Fax: +62 21-4245267  
Email: [elin\\_herlina\\_1@yahoo.com](mailto:elin_herlina_1@yahoo.com)

Dr Djoko KARTONO  
Senior Researcher  
Indonesia Nutrition Association  
Jl. Dr. Sumner No. 63  
16112 Bogor  
INDONESIA  
Tel: +62 8128093426  
Fax: +62 251 8326348  
Email: [kartono.djoko@yahoo.com](mailto:kartono.djoko@yahoo.com)

Mr Benny KODYAT  
Advisor  
Indonesian Nutritionist Association  
Kalibata City Sakura Apartement  
Jakarta  
INDONESIA  
Tel: +62 81280376338  
Email: [benikodyat@gmail.com](mailto:benikodyat@gmail.com)

Ms Anna MELIANAWATI  
Head of Division for Standard Implementation  
National Standardization Agency of Indonesia  
Gd. Manggala Wanabakti, Block IV floors 4.  
Jl. Gatot Subroto, Senayan  
Jakarta  
INDONESIA  
Tel: +62 21 5747043  
Fax: +62 21 5747045  
Email: [anna@bsn.go.id](mailto:anna@bsn.go.id)

Mr Budi Djanu PURWANTO  
Head of Law and Public Relation Bureau  
National Agency of Drug and Food Control  
Jl. Percetakan Negara No. 23  
10560 Jakarta  
INDONESIA  
Tel: +62 21 4209221  
Fax: +62 21 4209221  
Email: [humasbpom@gmail.com](mailto:humasbpom@gmail.com)

Mrs Yeni RESTIANI  
Head of Section Standardization of Functional Food  
National Agency of Drug and Food Control  
Jl. Percetakan Negara No. 23  
10560 JAKARTA  
INDONESIA  
Tel: +62 21 42875584  
Fax: +62 21 42875780  
Email: [restiani75@yahoo.com](mailto:restiani75@yahoo.com)

Dr Damayanti RUSLI SJARIF  
Head of Division  
Ministry of Health  
Jl. Diponegoro No. 17  
10430 JAKARTA  
INDONESIA  
Tel: +62 21 3915715  
Fax: +62 21 3907743  
Email: [ukk.npm.idai@gmail.com](mailto:ukk.npm.idai@gmail.com)

Dr Marudut SITOMPUL  
Researcher  
Ministry of Health  
Jl. Hang Jebat III/F 3 Kebayoran Baru  
12120 JAKARTA  
INDONESIA  
Tel: +62 81314738209  
Fax: +62 21 7395383  
Email: [mrdtsitompul@yahoo.com](mailto:mrdtsitompul@yahoo.com)

Mrs Sri Irawati SUSALIT  
Executive Director  
APPNIA  
Sovereign Plaza, 1<sup>st</sup> Floor  
Jl. TB. Simatupang Kav. 36  
12430 Jakarta  
INDONESIA  
Tel: +62 21 29400268  
Fax: +62 21 29400270  
Email: [irawati.susalit@gmail.com](mailto:irawati.susalit@gmail.com)

Mr Antonius Yudi TRIANTORO  
Deputy Director for Standardization, IPR and Dispute  
Resolution  
Ministry of Foreign Affairs  
Jl. Taman Pejambon No. 6  
10110 Jakarta  
INDONESIA  
Tel: +62 21 3812133  
Fax: +62 21 3519593  
Email: [antoniusyudi@hotmail.com](mailto:antoniusyudi@hotmail.com)

Mrs Roch Ratri WANDANSARI  
Regulatory Affairs  
APPNIA  
Sovereign Plaza 1<sup>st</sup> Floor  
Jl. TB. Simatupang Kav. 36  
12430 Jakarta  
INDONESIA  
Tel: +62 21 29400268  
Fax: +62 21 29400270  
Email: [rwandansari@yahoo.com](mailto:rwandansari@yahoo.com)

**IRAN (ISLAMIC REPUBLIC OF) -  
IRAN (RÉPUBLIQUE ISLAMIQUE D') -  
IRÁN (REPÚBLICA ISLÁMICA DEL)**

Mrs ATEFEH FOOLADI MOGHADAM  
Member of CCNFSDU  
Ministry of Health  
IRAN (ISLAMIC REPUBLIC OF)  
Email: [CODEX\\_OFFICE@INSO.GOV.IR](mailto:CODEX_OFFICE@INSO.GOV.IR)

**IRELAND - IRLANDE – IRLANDA**

Dr Mary FLYNN  
Chief Specialist Public Health Nutrition  
Food Safety Authority of Ireland  
Abbey Court  
Lower Abbey Street  
Dublin 1  
IRELAND  
Tel: +353 1 8171315  
Email: [award@fsai.ie](mailto:award@fsai.ie)

**ITALY - ITALIE - ITALIA**

Mr Ciro IMPAGNATIELLO  
Codex Contact Point  
Ministry of Agricultural Food and Forestry Policies  
Department of the European Union and International  
Policies and of the Rural Development  
Via XX Settembre, 20  
187 Rome  
ITALY  
Tel: +39 06 46654058  
Email: [c.impagnatiello@politicheagricole.it](mailto:c.impagnatiello@politicheagricole.it)

Dr Simona DE STEFANO  
Ministero della Salute  
Ufficio V - Nutrizione  
Viale Giorgio Ribotta, 5  
144 Roma  
ITALY  
Tel: +390659946574  
Email: [s.destefano@sanita.it](mailto:s.destefano@sanita.it)

Mr Gavino PERICU  
AIIPA  
ITALY  
Email: [gavino.pericu@danone.com](mailto:gavino.pericu@danone.com)

**JAPAN - JAPON - JAPÓN**

Mr Toshitaka MASUDA  
(Head of Delegation)  
Assistant Manager  
Consumer Affairs Agency  
Food Labelling Division  
5<sup>th</sup> Floor Sanno Park Tower, 2-11-1 Nagata-cho,  
Chiyoda-ku,

Tokyo  
JAPAN  
Tel: +81-3-3507-9222  
Fax: +81-3-3507-9292  
Email: [g.codex-j@caa.go.jp](mailto:g.codex-j@caa.go.jp)

Prof Hiroaki HAMANO  
Adviser  
International Life Sciences Institute Japan  
Nishikawa Bldg 5F, 3-5-19 Kojimachi, Chiyoda-ku,  
Tokyo  
JAPAN  
Tel: +81-3-5215-3535  
Email: [hhamano@ilsijapan.org](mailto:hhamano@ilsijapan.org)

Dr Yoshiko ISHIMI  
Chief, Department of Food Function and Labeling  
National Institute of Health and Nutrition  
Department of Food Function and Labeling  
1-23-1 Toyama, Shinjuku  
Tokyo  
JAPAN  
Tel: +81 3 3203 8063  
Fax: +81 3 3205 6549  
Email: [ishimi@nih.go.jp](mailto:ishimi@nih.go.jp)

Ms Hitomi KIMURA  
Section Chief  
Ministry of Agriculture, Forestry and Fisheries,  
Government of Japan  
International Affairs, Food Safety and Consumer Policy  
Division, Food Safety and Consumer Affairs Bureau  
1-2-1 Kasumigaseki Chiyoda-ku  
Tokyo  
JAPAN  
Tel: +81-3-3502-8732  
Fax: +81-3-3507-4232  
Email: [hitomi\\_kimura@nm.maff.go.jp](mailto:hitomi_kimura@nm.maff.go.jp)

Dr Shusho OKADA  
Director, Office of International Food Safety  
Ministry of Health, Labour and Welfare  
Department of Food Safety  
1-2-2 Kasumigaseki, Chiyoda-ku, Tokyo  
Tokyo  
JAPAN  
Tel: +81 3 3595 2326  
Fax: +81 3 3503 7965  
Email: [codexj@mhlw.go.jp](mailto:codexj@mhlw.go.jp)

Ms Yayoi TSUJIYAMA  
Director for International Affairs  
Ministry of Agriculture, Forestry and Fisheries,  
Government of Japan  
Food Safety and Consumer Policy Division, Food  
Safety and Consumer Affairs Bureau  
1-2-1 Kasumigaseki Chiyoda-ku  
Tokyo  
JAPAN  
Tel: +81-3-3502-8732  
Fax: +81-3-3507-4232  
Email: [yayoi\\_tsuijyama@nm.maff.go.jp](mailto:yayoi_tsuijyama@nm.maff.go.jp)

**KENYA**

Mr Peter MUTUA  
 (Head of Delegation)  
 Principle standard officer  
 Kenya Bureau of Standards  
 Standard development  
 P.O.BOX 54974 Popo Road Off Mombasa Road  
 200 Nairobi  
 KENYA  
 Tel: +254-20 6948000  
 Email: [mutuap@kebs.org](mailto:mutuap@kebs.org)

Mr James Ojiambo OLUMBE  
 Regulatory and scientific affairs Manager  
 Nestle Kenya Limited  
 Regulatory Affairs  
 P.O.Box 30265  
 100 Nairobi  
 KENYA  
 Tel: +254 20 3990000  
 Email: [james.ojiambo@ke.nestle.com](mailto:james.ojiambo@ke.nestle.com)

**LAO PEOPLE'S DEMOCRATIC REPUBLIC - LAOS**

Dr Bounthom PHENGDY  
 Director  
 Ministry of Health  
 National Nutrition Center  
 Simouang Road  
 1000 Vientiane Capital  
 LAO PEOPLE'S DEMOCRATIC REPUBLIC  
 Email: [codexcontactpoint\\_lao@yahoo.com](mailto:codexcontactpoint_lao@yahoo.com)

Ms Viengxay VANSILALOM  
 Head of Food Control Division  
 Ministry of Health  
 Food and Drug Department

LAO PEOPLE'S DEMOCRATIC REPUBLIC  
 Email: [vsysanhouth@yahoo.com](mailto:vsysanhouth@yahoo.com)

Mr Seksun JAIKHONG  
 Lao Food Industry  
 Sisavad Road, Chanthabury District  
 1000 Vientiane Capital  
 LAO PEOPLE'S DEMOCRATIC REPUBLIC  
 Email: [codexcontactpoint\\_lao@yahoo.com](mailto:codexcontactpoint_lao@yahoo.com)

**LUXEMBOURG - LUXEMBURGO**

Mrs Sarah HAUNERT  
 (Head of Delegation)  
 Chargée de mission  
 Direction de la Santé  
 Service de la sécurité alimentaire  
 9 avenue Victor Hugo  
 1750 Luxembourg  
 LUXEMBOURG  
 Email: [sarah.haunert@ms.etat.lu](mailto:sarah.haunert@ms.etat.lu)

**MALAYSIA - MALAISIE - MALASIA**

Ms NORRANI EKSAN  
 (Head of Delegation)  
 Deputy Director  
 Food Safety and Quality Division  
 Ministry of Health Malaysia  
 Level 3, Block E7, Parcel E  
 Federal Government Administration Centre

62590 Putrajaya  
 MALAYSIA  
 Tel: 603-8883 3512  
 Fax: 603-8883 3341  
 Email: [norrani@moh.gov.my](mailto:norrani@moh.gov.my)

Dr Nagendran BALA SUNDRAM  
 Head of Nutrition Unit  
 Malaysia Palm Oil Board  
 6, Persiaran Institusi  
 Bandar Baru Bangi  
 43000 Selangor  
 MALAYSIA  
 Tel: 603-8769 4216  
 Fax: 603-8925 9658  
 Email: [nagen@mpob.gov.my](mailto:nagen@mpob.gov.my)

Ms Zalma ABDUL RAZAK  
 Senior Principal Assistant Director  
 Nutrition Division  
 Ministry Of Health Malaysia  
 Level 1, Block E3, Parcel E  
 Federal Government Administration Centre  
 62590 Putrajaya  
 MALAYSIA  
 Tel: 603-8892 4753  
 Fax: 603-8892 4511  
 Email: [zalma@moh.gov.my](mailto:zalma@moh.gov.my)

Mr Mohd. Muslimin HASHIM  
 Malaysia Palm Oil Council  
 2<sup>nd</sup> Floor Wisma Sawit  
 Lot 6, SS 6, Jalan Perbandaran  
 47301 Kelana Jaya  
 MALAYSIA  
 Fax: 603-7806 2272  
 Email: [muslimin@mpoc.org.my](mailto:muslimin@mpoc.org.my)

Ms Sarafhana DOLLAH  
 Executive  
 Malaysia Palm Oil Council  
 2<sup>nd</sup> Floor, Wisma Sawit  
 Lot 6, SS6, Jalan Perbandaran  
 47301 Kelana Jaya  
 MALAYSIA  
 Tel: 603-7806 4097  
 Fax: 603-7806 2272  
 Email: [sara@mpoc.org.my](mailto:sara@mpoc.org.my)

Ms Sharidah YUSOFF  
 Federation of Malaysian Manufacturers (FMM)  
 Wisma FMM, No. 3, Persiaran Dagang, PJU 9,  
 Bandar Sri Damansara  
 52200 Kuala Lumpur  
 MALAYSIA  
 Tel: 603-5566 3326  
 Fax: 603-5569 3399  
 Email: [sharidah.yusoff@abbott.com](mailto:sharidah.yusoff@abbott.com)

Ms Rohaya MAMAT  
 Federation of Malaysian Manufacturers (FMM)  
 Wisma FMM, No. 3, Persiaran Dagang PJU 9  
 Bandar Sri Damansara  
 52200 Kuala Lumpur  
 MALAYSIA  
 Tel: 603-7882 5108  
 Fax: 603-7804 1880  
 Email: [rohaya.mamat@mjn.com](mailto:rohaya.mamat@mjn.com)

Ms Le Jong CHIN  
Federation of Malaysian Manufacturers (FMM)  
Wisma FMM, No. 3, Persiaran Dagang, PJU 9,  
Bandar Sri Damansara  
52200 Kuala Lumpur  
MALAYSIA  
Tel: 603-7882 5174  
Fax: 603-7804 1880  
Email: [lejong.chin@mjn.com](mailto:lejong.chin@mjn.com)

Ms Boon Feei CHONG  
Federation of Malaysian Manufacturers (FMM)  
Wisma FMM, No. 3, Persiaran Dagang, PJU 9,  
Bandar Sri Damansara  
52200 Kuala Lumpur  
MALAYSIA  
Fax: 603-2298 1439  
Email: [boon-feei.chong@danone.com](mailto:boon-feei.chong@danone.com)

Ms Shahrila ISHAK  
Federation of Malaysian Manufacturers (FMM)  
Wisma FMM, No. 3, Persiaran Dagang PJU9  
Bandar Sri Damansara  
52200 Kuala Lumpur  
MALAYSIA  
Fax: 603-7962 7208  
Email: [Shahrila.Ishak@my.nestle.com](mailto:Shahrila.Ishak@my.nestle.com)

Ms Lee Sheer YAP  
Federation of Malaysian Manufacturers (FMM)  
Wisma FMM, No. 3, Persiaran Dagang PJU9  
Bandar Sri Damansara  
52200 Kuala Lumpur  
MALAYSIA  
Fax: 603-7962 7208  
Email: [LeeSheer.Yap@my.nestle.com](mailto:LeeSheer.Yap@my.nestle.com)

#### **MEXICO - MEXIQUE - MÉXICO**

Ms María Guadalupe ARIZMENDI RAMÍREZ  
Verificador o Dictaminador Especializado A  
COFEPRIS/Secretaría de Salud  
Dirección de Operación Internacional  
Monterrey 33, Col. Roma, Del. Cuauhtémoc, México  
D.F.  
6700 Mexico  
MEXICO  
Email: [mgarizmendi@cofepris.gob.mx](mailto:mgarizmendi@cofepris.gob.mx)

Mrs Pamela SUÁREZ BRITO  
(Head of Delegation)  
Gerente de Asuntos Internacionales en Inocuidad  
Alimentaria  
Comisión Federal para la Protección contra Riesgos  
Sanitarios (COFEPRIS)  
Dirección Ejecutiva de Operación Internacional  
Monterrey #33 PH,  
Col. Roma Delegación Cuauhtémoc  
6700 MEXICO DISTRITO FEDERAL  
MEXICO  
Tel: 5.2555080521e+011  
Email: [psuarez@cofepris.gob.mx](mailto:psuarez@cofepris.gob.mx)

Mr Carlos ALMANZA  
Ilsi de México, A.C.  
Prolongación Paseo de La Reforma NO. 880, Lomas  
de Santa Fe 1219 D.F.  
MEXICO  
Tel: +(52)55 5950 - 4000 Ext. 4620  
Email: [carlos.almanza@ilsi-mexico.org](mailto:carlos.almanza@ilsi-mexico.org)

Ms Xochitl MORALES  
CANILEC-CODEX Representative  
Cámara Nacional de Industriales de la Leche,  
CANILEC  
Benjamín Franklin 134 Col. Escandón  
11800 MEXICO DISTRITO FEDERAL  
MEXICO  
Tel: 52-55-11039604 / 52-55-5516551  
Fax: 5.255527121e+011  
Email: [xochitl.morales@mjn.com](mailto:xochitl.morales@mjn.com)

Mr Lamberto Osorio NOLASCO  
Subdirector  
Ejecutivo de Importaciones y Exportaciones  
Oklahoma No 14, 2 Piso, Cod. Nápoles  
Deleg Benito Juárez  
3810 Mexico City  
MEXICO  
Email: [losorio@cofepris.gob.mx](mailto:losorio@cofepris.gob.mx)

Ms María Elena PALAFOX LÓPEZ  
Enlace de alto nivel de responsabilidad en evidencia de  
riesgos  
Secretaría de salud  
COFEPRIS  
Oklahoma no. 14, Colonia Nápoles, Delegación Benito  
Juárez  
3810 D.F  
MEXICO  
Tel: +(52 55) 50805200, EXT. 1100  
Email: [mepalafx@cofepris.gob.mx](mailto:mepalafx@cofepris.gob.mx)

#### **MOROCCO - MAROC - MARRUECOS**

Mr Tannaoui MOHAMED  
Chef de la Section Agricole  
Laboratoire Officiel d'Analyses et de Recherches  
Chimiques  
Ministère de l'Agriculture et de la Pêche Maritime  
25, Rue Nichakra (ex rue de Tours)  
Casablanca  
MOROCCO  
Tel: +212 522 302007  
Fax: +212 522 301972  
Email: [tannaoui1@yahoo.fr](mailto:tannaoui1@yahoo.fr)

Ms Bentahila NAWAL  
Présidente de l'AMNI  
Association Marocaine de la Nutrition Infantile  
Casablanca Business Center Mandarouna 300, 6ème  
étage N°63 Sidi Maârouf  
20270 Casablanca  
MOROCCO  
Tel: +212 661868220  
Fax: +212 522786162  
Email: [nawal.bentahila@amni.ma](mailto:nawal.bentahila@amni.ma)

Prof Mouane NEZHA  
Professeur en Pédiatrie surspécialité Gastroentérologie  
Nutrition  
Hôpital d'enfants Rabat – CH Ibn Sina  
Pédiatrie  
Hopital d'enfants Avenue Ibn Rochd , Agdal  
10100 Rabat  
MOROCCO  
Tel: +212 661208173  
Fax: +212 537775856  
Email: [nezhamouane@hotmail.com](mailto:nezhamouane@hotmail.com)

**NETHERLANDS - PAYS-BAS - PAÍSES BAJOS**

Ms Erika SMALE  
 (Head of Delegation)  
 Senior Policy Advisor  
 Ministry of Health, Welfare and Sport  
 PO Box 20350  
 0 The Hague  
 NETHERLANDS  
 Tel: +31 70 340 7968  
 Email: [bh.smale@minvws.nl](mailto:bh.smale@minvws.nl)

**NEW ZEALAND - NOUVELLE-ZÉLANDE - NUEVA ZELANDIA**

Dr Ms Jenny READ REID  
 (Head of Delegation)  
 Manager Food Science&Risk Assessment  
 Ministry for Primary Industries  
 Regulation & Assurance  
 P.O.Box 2526  
 Wellington  
 NEW ZEALAND  
 Tel: +64 4 894 2582  
 Email: [jenny.reid@mpi.govt.nz](mailto:jenny.reid@mpi.govt.nz)

Dr Ms Michelle GIBBS  
 Senior Adviser  
 Ministry of Primary Industries  
 Food Science  
 NEW ZEALAND  
 Email: [michelle.gibbs@mpi.govt.nz](mailto:michelle.gibbs@mpi.govt.nz)

Ms Jane BROUGHTON  
 Regulatory&Scientific Affairs Manager  
 Nestle NZ Ltd  
 NEW ZEALAND  
 Email: [jane.broughton@NZ.nestle.com](mailto:jane.broughton@NZ.nestle.com)

Ms Beverly WATSON  
 Nutrition & Regulatory Affairs Network Manager  
 Fonterra  
 NEW ZEALAND  
 Email: [beverly.watson@fonterra.com](mailto:beverly.watson@fonterra.com)

**NIGERIA - NIGÉRIA**

Mrs Kemisola Kikelomo AJASA  
 Regulatory Affairs Manager  
 NESTLE Nigeria PLC  
 22/24 Industrial Avenue Ilupeju, Lagos  
 Lagos  
 NIGERIA  
 Tel: +234-8052797299  
 Email: [kemisola.ajasa@ng.nestle.com](mailto:kemisola.ajasa@ng.nestle.com)

Mrs Adeyinka Elizabeth Oluwatoyin AKINBINU  
 Principal Agric. Superintendent  
 Federal Ministry of Agriculture and Rural Development  
 Federal Department of Agriculture  
 FCDA Secretariat, Area 11, Garki Abuja FCT  
 Abuja  
 NIGERIA  
 Tel: +2348059607576  
 Email: [akinadeli@yahoo.com](mailto:akinadeli@yahoo.com)

Mrs Ummulkhairi Ahmed BOBBOI  
 Chief Regulatory Officer  
 National Agency for Food and Drug Administration and Control

Food Safety and Applied Nutrition  
 Nafdac, Wuse Zone 7, Abuja Fct  
 Abuja  
 NIGERIA  
 Tel: +2348053235501  
 Email: [ummubobboi@yahoo.com](mailto:ummubobboi@yahoo.com)

Mr David Ehiabhi ERABHAHIEMEN  
 Deputy Director  
 Federal Ministry of Science and Technology  
 Physical and Life Sciences  
 Federal Secretariat Complex Phase II, Abuja  
 Abuja  
 NIGERIA  
 Tel: +234-8036092283  
 Email: [davideraa@yahoo.com](mailto:davideraa@yahoo.com)

Mrs Margaret Efiog ESHIETT  
 Deputy Director  
 Standards Organisation of Nigeria  
 Codex Contact Point (Nigeria)  
 Standards Organisation of Nigeria, 13-14, Victoria  
 Arobieke Street, Lekki Phase 1, Lagos  
 Lagos  
 NIGERIA  
 Tel: +234-8023179774  
 Email: [megesciETT@yahoo.com](mailto:megesciETT@yahoo.com)

Mr Innocent Gabriel NYOYOKO  
 Chief Regulatory Officer  
 National Agency for Food and Drug Administration and Control  
 Food Safety and Applied Nutrition  
 445 Harbert Macauley Way, Yaba, Lagos  
 NIGERIA  
 Tel: +2348136740405  
 Email: [gabnyoyoko@yahoo.com](mailto:gabnyoyoko@yahoo.com)

Mr Yaya OLANIRAN  
 Minister/Permanent Representative to FAO  
 Permanent Representation of Federal Republic of Nigeria to FAO  
 Via Cassiodoro 2/C  
 Rome  
 ITALY  
 Email: [nigeriapermrep@email.com](mailto:nigeriapermrep@email.com)

**NORWAY - NORVÈGE - NORUEGA**

Mrs Svanhild VASKINN  
 (Head of Delegation)  
 Senior Adviser  
 Norwegian Food Safety Authority  
 Head Office  
 P.O Box 383  
 0 Brumunddal  
 NORWAY  
 Tel: +47 23 21 68 00  
 Fax: + 47 23 21 68 01  
 Email: [svvas@mattilsynet.no](mailto:svvas@mattilsynet.no)

Ms Para GHILDYAL-PALANI  
 Adviser  
 Norwegian Food Safety Authority  
 Head Office  
 P.O Box 383  
 0 Brumunddal  
 NORWAY  
 Tel: + 47 23 21 68 00  
 Fax: + 47 23 21 68 01  
 Email: [paghi@mattilsynet.no](mailto:paghi@mattilsynet.no)

Mrs Linda GRANLUND  
 Director  
 Helse og Ernæring i Mills  
 Mills  
 506 Oslo  
 NORWAY  
 Tel: 4799019418  
 Email: [linda.granlund@mills.no](mailto:linda.granlund@mills.no)

**PAPUA NEW GUINEA - PAPOUASIE-  
 NOUVELLE GUINÉE - PAPUA NUEVA GUINEA**

Dr Vele Pat ILA'AVA  
 (Head of Delegation)  
 Secretary  
 Ministry of Agriculture & Livestock  
 Department of Agriculture & Livestock  
 PO Box 2033  
 Port Moresby, NCD  
 PAPUA NEW GUINEA  
 Tel: +(675) 321 3302  
 Fax: +(675) 321 226  
 Email: [vjm0962@gmail.com](mailto:vjm0962@gmail.com)

**PHILIPPINES - FILIPINAS**

Ms Helena ALCARAZ  
 (Head of Delegation)  
 Nutritionist-Dietitian III  
 Department of Health  
 Food and Drug Administration Philippines  
 Blk 2 Lot 1 Mabuhay Homes 2000 Salawag,  
 Dasmariñas City, Cavite,  
 PHILIPPINES  
 Tel: (046) 5406990  
 Fax: None  
 Email: [hsalcaraz@fda.gov.ph](mailto:hsalcaraz@fda.gov.ph)

Dr EMILIE DE GUZMAN-FLORES  
 Professor of Nutrition  
 Food & Nutrition Science  
 University of the Philippines  
 34 Norwalk, Magre Subd,  
 Bgy Holy Spirit, 2700 Quezon City  
 PHILIPPINES  
 Tel: +639285044939  
 Fax: 632-9314070  
 Email: [esgflores@yahoo.com.ph](mailto:esgflores@yahoo.com.ph)

**REPUBLIC OF KOREA - RÉPUBLIQUE DE CORÉE -  
 REPÚBLICA DE COREA**

Mrs YANG HEE CHO  
 Chairman of International Affair  
 Korea Health Supplement Association  
 REPUBLIC OF KOREA  
 Email: [yhcho@amway.com](mailto:yhcho@amway.com)

Mrs MISOON LEE  
 D.V.M Ms  
 Ministry of Food and Drug Safety  
 Livestock Product Standard Division  
 REPUBLIC OF KOREA  
 Email: [leems25@korea.kr](mailto:leems25@korea.kr)

Mrs HYEYOUNG LEE  
 Deputy director  
 Ministry of Food and Drug Safety  
 Nutrition Safety Policy Division  
 REPUBLIC OF KOREA  
 Email: [leehy96@korea.kr](mailto:leehy96@korea.kr)

Ms SERA OH  
 Codex researcher  
 Ministry of Food and Drug Safety  
 Nutrition and Safety Policy Division  
 REPUBLIC OF KOREA  
 Email: [ijoh27@korea.kr](mailto:ijoh27@korea.kr)

Mrs MISUN PARK  
 Scientific officer  
 Ministry of Food and Drug Safety  
 Food Standard Division  
 REPUBLIC OF KOREA  
 Email: [mspark@korea.kr](mailto:mspark@korea.kr)

**RUSSIAN FEDERATION - FÉDÉRATION DE RUSSIE  
 - FEDERACIÓN DE RUSIA**

Ms Elena SMIRNOVA  
 (Head of Delegation)  
 Senior Scientist  
 Russian Institute of Nutrition  
 Novel and GM food sources research  
 Ustyinskiy proezd 2/14  
 109240 Moscow  
 RUSSIAN FEDERATION  
 Tel: +7 495 698 53 89  
 Email: [smirnova@ion.ru](mailto:smirnova@ion.ru)

Mrs Julia KALINOVA  
 Scientific and Regulatory Affairs Manager, Russia,  
 Ukraine and Belarus  
 The Coca-Cola Export Corporation, Moscow  
 Representation office  
 8 Ivana Franko str.  
 121108 Moscow  
 RUSSIAN FEDERATION  
 Tel: +74956516900  
 Email: [jkalinova@coca-cola.com](mailto:jkalinova@coca-cola.com)

Mr Anatoly KUTYSHENKO  
 Vice-chair  
 Russian Union of Industrialists and Entrepreneurs  
 (RUIE)  
 Optimal Foods Committee  
 Kotelnicheskaya nab., 17  
 109240 Moscow  
 RUSSIAN FEDERATION  
 Tel: +7-495-642-6140  
 Email: [Anatol-k@rambler.ru](mailto:Anatol-k@rambler.ru)

Mr Dmitriy MIKLIN  
Regulatory Affairs Director  
Danone Baby Nutrition Russia  
Panfilova str., 19, BC  
141407 Khimki  
RUSSIAN FEDERATION  
Tel: +7 916 2014060  
Email: [dmitriy.miklin@danone.com](mailto:dmitriy.miklin@danone.com)

Mrs Veronika VYSOTSKAYA  
Regulatory Affairs Manager  
Abbott Laboratories  
Leningradskoe highway., 16A, bld.1  
125171 Moscow  
RUSSIAN FEDERATION  
Tel: +7 495 258 42 80  
Email: [veronika.vysotskaya@abbott.com](mailto:veronika.vysotskaya@abbott.com)

#### **RWANDA**

Mr BIZIMUNGU SHUKURU  
(Head of Delegation)  
Head of Industry Inspection, Nutrition and Quality and  
Food Safety Management Systems Lead Auditor  
Land O' Lakes  
Quality Assurance  
C/O Rwanda Standards Board  
P.O.Box 7099  
0 Kigali  
RWANDA  
Tel: +250788302255  
Email: [shukurub@yahoo.com](mailto:shukurub@yahoo.com)

#### **SAUDI ARABIA - ARABIE SAOUDITE - ARABIA SAUDITA**

Mr Fahad ALBADR  
(Head of Delegation)  
Senior Dietitian  
Saudi Food and Drug Authority  
Executive Department for Technical Regulations and  
Standards  
3292 North Ring road Al Nafel Area Unit (1)  
0 Riyadh  
SAUDI ARABIA  
Tel: 966 1 275 9222 Ext:3331  
Fax: +966 1 2751282  
Email: [codex.cp@sfd.gov.sa](mailto:codex.cp@sfd.gov.sa)

#### **SENEGAL - SÉNÉGAL**

Prof Guélaye SALL  
Pédiatre Nutritionniste, Chef de service de la Pédiatrie  
de l'Hopital Aristide Le Dantec de Dakar  
Dakar  
SENEGAL  
Email: [mgsall@hotmail.com](mailto:mgsall@hotmail.com)

#### **SINGAPORE - SINGAPOUR - SINGAPUR**

Ms Peik Ching SEAH  
(Head of Delegation)  
Deputy Director  
Agri-Food & Veterinary Authority of Singapore  
Regulatory Administration Group, Regulatory  
Programmes Department  
5 Maxwell Road, #18-00  
Tower Block, MND Complex  
69110 Singapore  
SINGAPORE  
Tel: +65 6325 7829

Fax: +65 6220 6068  
Email: [seah\\_peik\\_ching@ava.gov.sg](mailto:seah_peik_ching@ava.gov.sg)

Ms Yi Ling TAN  
Senior Executive Manager  
Agri-Food & Veterinary Authority of Singapore  
Regulatory Administration Group, Regulatory  
Programmes Department  
5 Maxwell Road, #18-00  
Tower Block, MND Complex  
69110 Singapore  
SINGAPORE  
Tel: +65 6325 8556  
Fax: +65 6220 6068  
Email: [tan\\_yi\\_ling@ava.gov.sg](mailto:tan_yi_ling@ava.gov.sg)

#### **SLOVAKIA - SLOVAQUIE - ESLOVAQUIA**

Dr Iveta TRUSKOVÁ  
(Head of Delegation)  
Deputy director for professional activities  
Public Health Authority of the Slovak Republic  
Trnavská 52  
0 Bratislava  
SLOVAKIA  
Tel: +421 2 492 84 392  
Fax: +421 2 443 72 641  
Email: [iveta.truskova@uvzsr.sk](mailto:iveta.truskova@uvzsr.sk)

Mrs Katarína KROMEROVÁ  
Deputy head  
Public Health Authority of the Slovak Republic  
Department on food safety  
Trnavská 52  
0 Bratislava  
SLOVAKIA  
Tel: +421249284327  
Fax: +421244455643  
Email: [katarina.kromerova@uvzsr.sk](mailto:katarina.kromerova@uvzsr.sk)

#### **SOUTH AFRICA - AFRIQUE DU SUD - SUDÁFRICA**

Mrs Andiswa NGQAKA  
(Head of Delegation)  
Assistant Director: Nutrition  
Department of Health  
Private Bag X828  
1 Pretoria  
SOUTH AFRICA  
Tel: +27 12 3958511  
Fax: +27 86 633 0226  
Email: [NggakA@health.gov.za](mailto:NggakA@health.gov.za)

Mrs Antoinette BOOYZEN  
Assistant Director: Food Control  
Department of Health  
Directorate: Food Control  
Private Bag X828  
1 PRETORIA  
SOUTH AFRICA  
Tel: +27 12 395 8792  
Fax: +27 12 395 8854  
Email: [BooyzA@health.gov.za](mailto:BooyzA@health.gov.za)

Prof Hettie SCHÖNFELDT  
University of Pretoria  
Faculty of Natural and Agricultural Sciences  
421 Sussex Avenue  
81 Lynnwood  
SOUTH AFRICA  
Email: [hettie.schonfeld@up.ac.za](mailto:hettie.schonfeld@up.ac.za)

#### SPAIN - ESPAGNE - ESPAÑA

Mrs Irene GADEA CAZALILLA  
(Head of Delegation)  
Nutritional Risks Area  
Ministry of Health, Social Services and Equality  
Spanish Agency for Consumer Affairs, Food Safety and  
Nutrition  
C Alcalá, 56  
28071 Madrid  
SPAIN  
Email: [igadea@msssi.es](mailto:igadea@msssi.es)

#### SUDAN - SOUDAN - SUDÁN

Ms Thoria ELNAGEEB AKASHA  
(Head of Delegation)  
Chemist of Food  
Sudanese Standard & Metrology  
Laboratory Sector  
Aljamaa Street Sudanese Standard & Metrology  
11111 Khartoum  
SUDAN  
Tel: +249912468700  
Email: [elnagaka@yahoo.com](mailto:elnagaka@yahoo.com)

Mrs MAHA ABDALLA MOHAMED IBRAHIM  
Manager Research & Planning  
Sudanese Standard & Metrology  
Research & Planning  
Aljamaa Street, Sudanese Standard & Metrology  
11111 Khartoum  
SUDAN  
Tel: +249912383085  
Email: [mahafreere@yahoo.com](mailto:mahafreere@yahoo.com)

#### SWEDEN - SUÈDE - SUECIA

Mrs Carmina IONESCU  
(Head of Delegation)  
Codex Coordinator  
National Food Agency  
Food Regulation Division  
Box 622  
75126 Uppsala  
SWEDEN  
Tel: +46 709245601  
Email: [carmina.ionescu@slv.se](mailto:carmina.ionescu@slv.se)

Ms Cecilia WANHAINEN  
Principal Regulatory Officer  
National Food Agency  
Food Regulation Division  
Box 622  
75121 Uppsala  
SWEDEN  
Tel: +46 727351485  
Email: [cecilia.wanhainen@slv.se](mailto:cecilia.wanhainen@slv.se)

#### SWITZERLAND - SUISSE - SUIZA

Mrs Elisabeth NELLEN-REGLI  
(Head of Delegation)  
Federal Food Safety and Veterinary Office FSVO  
Food and Nutrition Division  
3003 Bern  
SWITZERLAND  
Tel: +41 58 462 95 60  
Email: [elisabeth.nellen@blv.admin.ch](mailto:elisabeth.nellen@blv.admin.ch)

Mrs Awilo OCHIENG PERNET  
Chairperson, Codex Alimentarius Commission  
International Affairs  
Federal Food Safety and Veterinary Office FSVO  
0 Bern  
SWITZERLAND  
Tel: + 41 58 462 00 41  
Email: [awilo.ochieng@blv.admin.ch](mailto:awilo.ochieng@blv.admin.ch)

Dr Dirk CREMER  
Regulatory Affairs Manager  
DSM Nutritional Products Europe Ltd., Human Nutrition  
and Health  
P.O. Box 2676  
4002 Basel  
SWITZERLAND  
Tel: +41 61 815 79 65  
Email: [dirk.cremer@dsm.com](mailto:dirk.cremer@dsm.com)

Mrs Marie-France PAGEREY  
CT-Regulatory and Scientific Affairs  
Nestec SA  
Avenue Nestlé 55  
Post Box  
1800 Vevey  
SWITZERLAND  
Tel: +41 21 924 64 29  
Email: [MarieFrance.Pagerey@nestle.com](mailto:MarieFrance.Pagerey@nestle.com)

#### THAILAND - THAÏLANDE - TAILANDIA

Prof Kraisd TONTISIRIN  
(Head of Delegation)  
Senior Advisor  
National Bureau of Agricultural Commodity and Food  
Standards, Ministry of Agriculture and Cooperatives  
50 Phaholyothin Road, Lad Yao, Chatuchak  
10900 Bangkok  
THAILAND  
Tel: +66 (2) 561 2277  
Fax: +66 (2) 561 3357  
Email: [kraisid.tontisirin@gmail.com](mailto:kraisid.tontisirin@gmail.com)

Ms Mayuree DITMEYHAROJ  
Food and Drug Technical Officer  
Food and Drug Administration, Ministry of Public Health  
Tiwanond Road  
11000 Nonthaburi  
THAILAND  
Tel: +66 (2) 590 7185  
Fax: +66 (2) 591 8476  
Email: [bankyindy@yahoo.com](mailto:bankyindy@yahoo.com)

Mrs Jureerat HOKIARTI  
Food and Drug Technical Officer, Expert Level  
Food and Drug Administration, Ministry of Public Health  
Tiwanond Road  
11000 Nonthaburi  
THAILAND  
Tel: +66 (2) 590 7249  
Fax: +66 (2) 591 8476  
Email: [jrhk2499@hotmail.co.th](mailto:jrhk2499@hotmail.co.th)

Dr Pichet ITKOR  
Vice Chairman  
Food Processing Industry Club, The Federation of Thai Industries  
Queen Sirikit National Convention Center, Zone C 4<sup>th</sup>  
Floor, 60 New Rachadapisek Rd., Klongtoey  
10110 Bangkok  
THAILAND  
Tel: +66 (2) 725 1093  
Fax: +66 (2) 725 1082  
Email: [Pichet.itkor@mjn.com](mailto:Pichet.itkor@mjn.com)

Ms Pitchaya KAJONWAHARTH  
Committee of Food Processing Industry Club  
The Federation of Thai Industries  
Queen Sirikit National Convention Center, Zone C 4<sup>th</sup>  
Floor, 60 New Rachadapisek Rd., Klongtoey  
10110 Bangkok  
THAILAND  
Tel: +66 (2) 657 5517  
Fax: +66 (2) 657 4017  
Email: [pitchaya.kajonwaharth@abbott.com](mailto:pitchaya.kajonwaharth@abbott.com)

Ms Sanida KHOONPANICH  
Standards Officer  
National Bureau of Agricultural Commodity and Food Standards, Ministry of Agriculture and Cooperatives  
50 Phaholyothin Road, Lad Yao, Chatuchak  
10900 Bangkok  
THAILAND  
Tel: +66 (2) 561 2277 ext. 1445  
Fax: +66 (2) 561 3357  
Email: [sanida.sk@gmail.com](mailto:sanida.sk@gmail.com)

Dr Hataya KONGCHUNTUK RODBUMRUNG  
Committee of Food Processing Industry Club  
The Federation of Thai Industries  
Queen Sirikit National Convention Center, Zone C 4<sup>th</sup>  
Floor, 60 New Rachadapisek Rd., Klongtoey  
10110 Bangkok  
THAILAND  
Tel: +66 (2) 840 8450, +668 4751 48  
Fax: +66 (2) 374 4284  
Email: [khataya@amway.com](mailto:khataya@amway.com)

Ms Rungrassamee MAHAKHAPHONG  
Standards Officer  
National Bureau of Agricultural Commodity and Food Standards, Ministry of Agriculture and Cooperatives  
50 Phaholyothin Road, Lad Yao, Chatuchak  
10900 Bangkok  
THAILAND  
Tel: +66 (2) 561 2277 ext. 1447  
Fax: +66 (2) 561 3357  
Email: [mahakhaphong@gmail.com](mailto:mahakhaphong@gmail.com)

Ms Nongsuda MONGKOLSMAI  
Committee of Food Processing Industry Club  
The Federation of Thai Industries

Queen Sirikit National Convention Center, Zone C 4<sup>th</sup>  
Floor, 60 New Rachadapisek Rd., Klongtoey  
10110 Bangkok  
THAILAND  
Tel: +66 89201 4694  
Fax: +66 (2) 740 3499  
Email: [Nongsuda.mongkolsmai@danone.com](mailto:Nongsuda.mongkolsmai@danone.com)

Dr Phrapat SOPANATHORN  
Executive Director  
Pediatric Nutrition Manufacturer Association  
Athenee Tower, 23<sup>rd</sup> Floor, 63 Wireless Road, Lumpini,  
Pathumwan  
10330 Bangkok  
THAILAND  
Tel: +662 126 8104  
Fax: +662 126 8080  
Email: [prapats@pnma.or.th](mailto:prapats@pnma.or.th)

Dr Akarat SUKSOMCHEEP  
Committee of Food Processing Industry Club  
The Federation of Thai Industries  
Queen Sirikit Convention Center,  
Zone C, 4<sup>th</sup> Floor  
60 New Rachadapisek Road, Klongtoey  
10110 Bangkok  
THAILAND  
Tel: +66 (8) 1830 0717  
Email: [sakarat@coca-cola.com](mailto:sakarat@coca-cola.com)

Dr Umaporn SUTHUTVORAVUT  
Chair  
Nutrition Association of Thailand under the Patronage  
of Her Royal Highness Princess Maha Chakri  
Sirindhorn  
128/107 Phayathai Plaza Building ,9 floor, Phayathai  
Road, Thung Phayathai, Ratchathewi  
10400 Bangkok  
THAILAND  
Tel: +66 (2) 612 0860  
Fax: +66 (2) 2612 0860  
Email: [u\\_suthut@yahoo.com](mailto:u_suthut@yahoo.com)

## TOGO

Dr TCHALA KAZIA  
(Head of Delegation)  
Codex Contact Point  
Ministry of Agriculture  
Agriculture  
1, rue de l'Espérance LOME/TOGO  
LOME  
TOGO  
Tel: +22890023325  
Fax: +22822251559  
Email: [kaziatchala@yahoo.fr](mailto:kaziatchala@yahoo.fr)

## TURKEY - TURQUIE - TURQUÍA

Mr Dursun KODAZ  
(Head of Delegation)  
Engineer  
The Ministry of Food, Agriculture and Livestock  
The General Directorate of Food and Control  
Eskisehir Yolu 9. km Lodumlu  
6530 Ankara  
TURKEY  
Tel: 9.0312258776  
Fax: 9.0312258776  
Email: [dursun.kodaz@tarim.gov.tr](mailto:dursun.kodaz@tarim.gov.tr)

**UNITED REPUBLIC OF TANZANIA - RÉPUBLIQUE-  
UNIE DE TANZANIE -  
REPÚBLICA UNIDA DE TANZANÍA**

Ms Candida SHIRIMA  
Acting Manager  
Tanzania Food and Drugs Authority  
Food Risk Analysis  
P.O BOX 77150  
0 Dar Es Salaam  
UNITED REPUBLIC OF TANZANIA  
Tel: +255754379827  
Email: [candidap@yahoo.co.uk](mailto:candidap@yahoo.co.uk)

**UNITED STATES OF AMERICA - ÉTATS-UNIS  
D'AMÉRIQUE – ESTADOS UNIDOS DE AMÉRICA**

Dr Pamela PEHRSSON  
Research Leader  
ARS-Nutrient Data Laboratory  
USDA  
10300 Baltimore Avenue  
Bldg. 005, Room 105  
20705 Beltsville  
UNITED STATES OF AMERICA  
Tel: 3015040635  
Fax: 3015040632  
Email: [pamela.pehrsson@ars.usda.gov](mailto:pamela.pehrsson@ars.usda.gov)

Dr Paula TRUMBO  
(Head of Delegation)  
Leader  
US Food & Drug Administration  
Nutrition Programs  
5100 Paint Branch Parkway  
20740 College Park  
UNITED STATES OF AMERICA  
Tel: 240-402-2579  
Fax: 301-436-2579  
Email: [paula.trumbo@fda.hhs.gov](mailto:paula.trumbo@fda.hhs.gov)

Dr Leila BEKER  
Senior Interdisciplinary Scientist  
U.S. Food and Drug Administration  
Office of Nutrition, Labeling and Dietary Supplements  
5100 Paint Branch Parkway  
20740 College Park, Maryland  
UNITED STATES OF AMERICA  
Tel: 12404021851  
Fax: 1202 436 2639  
Email: [leila.beker@fda.hhs.gov](mailto:leila.beker@fda.hhs.gov)

Mrs Doreen CHEN-MOULEC  
International Issues Analyst  
U.S. Department of Agriculture  
Food Safety and Inspection Service; Office of CODEX  
1400 Independence Ave  
20250 Washington, DC  
UNITED STATES OF AMERICA  
Tel: 202-720-4063  
Fax: 202-720-3157  
Email: [Doreen.Chen-Moulec@fsis.usda.gov](mailto:Doreen.Chen-Moulec@fsis.usda.gov)

Mrs Brinda MAHADEVAN  
Abbott Laboratories  
Dept. 104070, Bildg. RP3-2  
Columbus, OH 43219  
UNITED STATES OF AMERICA  
Tel: +1 614 624 3089  
Email: [brinda.mahadevan@abbott.com](mailto:brinda.mahadevan@abbott.com)

Dr Julie MOSS  
Deputy Director  
U.S. Food and Drug Administration  
International Affairs Staff  
5100 Paint Branch Parkway  
HFS-550  
20740 College Park  
UNITED STATES OF AMERICA  
Tel: 240-402-2031  
Fax: 301-436-2618  
Email: [julie.moss@fda.hhs.gov](mailto:julie.moss@fda.hhs.gov)

Ms Mardi MOUNTFORD  
Executive Vice President  
International Formula Council  
1100 Johnson Ferry Road, Suite 300  
30342 Atlanta, GA  
UNITED STATES OF AMERICA  
Tel: 1404 252 3663  
Fax: 1 404 252 0774  
Email: [mmountford@kellencompany.com](mailto:mmountford@kellencompany.com)

**VIET NAM**

Dr LONG NGUYEN HUNG  
(Head of Delegation)  
General Deputy Director  
Ministry of Health  
Vietnam Food Administration  
Lane 135 Nui Truc Street-Ba Dinh District. Hanoi  
844 Hanoi  
VIET NAM  
Tel: 0912250527;  
Fax: 38463739  
Email: [codexvn@vfa.gov.vn](mailto:codexvn@vfa.gov.vn)

Mrs Diep LAN  
Officer  
Directorate for Standard and Quality  
Quality Assurance and Testing Center 3  
49 Pasteur-No.1 Disstrict,  
848 Ho Chi Minh City  
VIET NAM  
Tel: 918144643  
Fax: 838212609  
Email: [diepthlan@yahoo.com](mailto:diepthlan@yahoo.com)

Mrs Duong NGUYEN THUY  
Officer  
Vietnam Food Administration  
Legislation and Integration Division  
Lane 135 Nui Truc Street-Ba Dinh District. Hanoi  
844 Hanoi  
VIET NAM  
Tel: 38.464370 (ext.5040)  
Fax: 38463739  
Email: [thuyduongvfa@gmail.com](mailto:thuyduongvfa@gmail.com)

Mr Liem PHAM  
Deputy Head  
Vietnam Food Administration  
Food Standard and Analysis Division  
Lane 135 Nui Truc Street-Ba Dinh District  
844 Hanoi  
VIET NAM  
Tel: 3 8464489 (Ext.5020)  
Fax: 3 8463739  
Email: [ptlvfa@gmail.com](mailto:ptlvfa@gmail.com)

Mr Nguyen PHUONG SON  
Regulatory Affair manager  
Mead Johnson Nutrion Vietnam  
Level 9 Viglacera Tower; No.1 Thang long Avenue  
844 Hanoi  
VIET NAM  
Tel: 933805898  
Email: [codexvn@vfa.gov.vn](mailto:codexvn@vfa.gov.vn)

Mrs NGUYEN THI MINH HA  
Deputy Head  
Vietnam Codex Office  
Ministry of Health  
Lane 135 nui truc street, Ba Dinh District.  
844 Hanoi  
VIET NAM  
Tel: 904214230  
Fax: 38463739  
Email: [codexvn@vfa.gov.vn](mailto:codexvn@vfa.gov.vn)

Mr LE VAN  
Head  
Vietnam Food Administration  
Food Sub-Department of Tuyen Quang  
Tuyen Quang province  
27 Tuyen Quang province  
VIET NAM  
Tel: 912453615  
Fax: 027 3818755  
Email: [levanattp@gmail.com](mailto:levanattp@gmail.com)

#### YEMEN - YÉMEN - YEMEN

Mr Walid OTHMAN  
(Head of Delegation)  
General of the Yemen Standardization, Metrology and  
Quality Control  
Yemen Standardisations Metrology and Quality control  
Organization  
Sana'a  
YEMEN  
Tel: 00967 735069271  
Email: [codex.yemen@gmail.com](mailto:codex.yemen@gmail.com)

#### ZIMBABWE

Mr Chinyavanhu FREDY  
Ministry of Health and Childcare  
P.O.Box CY231  
Causeway  
Harare  
ZIMBABWE  
Email: [fchinyavanhu@healthnet.org.zw](mailto:fchinyavanhu@healthnet.org.zw)

#### OBSERVER ORGANIZATIONS / ORGANISATIONS OBSERVATEURS / ORGANIZACIONES OBSERVADORAS

##### AFRICAN UNION (AU)

Dr Raphael COLY  
PANSPSO PROJECT  
Coordinator  
African Union  
AU-IBAR  
Kenindia Business Park, Westlands Road  
100 Nairobi  
KENYA  
Tel: +254739622183  
Email: [raphael.coly@au-ibar.org](mailto:raphael.coly@au-ibar.org)

#### ASSOCIATION EUROPÉENNE POUR LE DROIT DE L'ALIMENTATION (AEDA/EFLA)

Mr Conrad REYNERS  
Member  
AEDA/EFLA  
Rue de l'Association 50  
1000 Brussels  
BELGIUM  
Tel: 3222091142  
Fax: 3222197342  
Email: [secretariat@efla-aeda.org](mailto:secretariat@efla-aeda.org)

#### ASSOCIATION OF EUROPEAN COELIAC SOCIETIES (AOECS)

Mrs Hertha DEUTSCH  
(Head of Delegation)  
Codex and Regulatory Affairs  
Association Of European Coeliac Societies  
Anton Baumgartner Strasse 44/C5/2302  
1230 Vienna  
AUSTRIA  
Tel: +43-1-66 71 887  
Email: [hertha.deutsch@utanet.at](mailto:hertha.deutsch@utanet.at)

#### CALORIE CONTROL COUNCIL (CCC)

Mr Ashley BETTERIDGE  
Tate & Lyle  
1 Kingsway  
WC2B6AT  
London  
UNITED KINGDOM  
Email: [victoria.betteridge@tateandlyle.com](mailto:victoria.betteridge@tateandlyle.com)

Mrs Victoria BETTERIDGE  
Vice President and Director  
Tate & Lyle  
Regulatory and Governmental Affairs  
1 Kingsway  
WC2B6AT  
London  
UNITED KINGDOM  
Email: [victoria.betteridge@tateandlyle.com](mailto:victoria.betteridge@tateandlyle.com)

#### COUNCIL FOR RESPONSIBLE NUTRITION (CRN)

Mr Harvey KAMIL  
President & CFO  
CRN - NBTY, Inc.  
NBTY, Inc.  
2100 Smithtown Avenue  
11779 Ronkonkoma  
UNITED STATES OF AMERICA  
Tel: 631-200-2020  
Email: [hkamil@nbt.com](mailto:hkamil@nbt.com)

Dr James GRIFFITHS  
(Head of Delegation)  
VP Science & International Affairs  
Council for Responsible Nutrition  
Science  
1828 L St., NW; Suite 510  
20036 Washington  
UNITED STATES OF AMERICA  
Tel: +01-202-204-7662  
Email: [jgriffiths@crnusa.org](mailto:jgriffiths@crnusa.org)

**EUROPEAN NETWORK OF CHILDBIRTH ASSOCIATIONS (ENCA)**

Dr Helen CRAWLEY  
ENCA  
112 Queens Road  
SW19 8LS London  
UNITED KINGDOM  
Email: [helen@firststepsnutrition.org](mailto:helen@firststepsnutrition.org)

Mr Jos VOSS  
ENCA  
Email: [aape@pt.lu](mailto:aape@pt.lu)

**FEDERATION OF EUROPEAN SPECIALTY FOOD INGREDIENTS INDUSTRIES (ELC)**

Dr Rob WINWOOD  
(Head of Delegation)  
Member  
ELC  
Avenue des Gaulois 9  
1040 Brussels  
BELGIUM  
Tel: +3227365354  
Email: [elc@ecco-eu.com](mailto:elc@ecco-eu.com)

Prof Stewart FORSYTH  
Member  
ELC  
Email: [elc@ecco-eu.com](mailto:elc@ecco-eu.com)

**FOODDRINKEUROPE**

Mr Dirk JACOBS  
(Head of Delegation)  
Deputy Director General  
FoodDrinkEurope  
Avenue des Nerviens 9-31  
1040 Bruxelles  
BELGIUM  
Email: [d.jacobs@fooddrinkeurope.eu](mailto:d.jacobs@fooddrinkeurope.eu)

Mrs Uti DANIAWATI  
FDE  
Email: [uti-daniawati.mahanani@unilever.com](mailto:uti-daniawati.mahanani@unilever.com)

Mrs Annie LOC'H  
Directeur Affaires Réglementaires  
FoodDrinkEurope  
Avenue des Nerviens 9-31  
1040 Bruxelles  
BELGIUM  
Email: [annie.loch@danone.com](mailto:annie.loch@danone.com)

**HELEN KELLER INTERNATIONAL (HKI)**

Ms Jane BADHAM  
(Head of Delegation)  
Consultant  
Helen Keller International  
Gauteng  
15 Mill Hill Townhouses  
Norman Avenue  
2021 Johannesburg  
SOUTH AFRICA  
Tel: +27114630679  
Email: [jane@jbconsultancy.co.za](mailto:jane@jbconsultancy.co.za)

**INSTITUTE OF FOOD TECHNOLOGISTS (IFT)**

Prof Rosemary WALZEM  
(Head of Delegation)  
Professor: Nutritional Biochemistry  
Institute of Food Technologists  
Department of Poultry Science and Faculty of Nutrition  
242D Kleberg Center, MS 2472  
Texas A&M University  
College Station, TX 77843-2472  
77843-2472 College Station  
UNITED STATES OF AMERICA  
Tel: 979.845.7537  
Email: [rwalzem@poultry.tamu.edu](mailto:rwalzem@poultry.tamu.edu)

Ms Sheila GAUTIER  
Scientist  
Institute of Food Technologists  
DSM  
3201 Brighton Court  
Woodbine, MD 21797  
21797 Woodbine  
UNITED STATES OF AMERICA  
Email: [sheila.gautier@dsm.com](mailto:sheila.gautier@dsm.com)

**INTERNATIONAL ALLIANCE OF DIETARY/FOOD SUPPLEMENT ASSOCIATIONS (IADSA)**

Mr Harunobu AMAGASE  
Member  
IADSA  
50 Rue de l'Associations  
B-1000 Brussels  
BELGIUM  
Tel: +32 2 209 11 55  
Email: [secretariat@iadsa.org](mailto:secretariat@iadsa.org)

Dr Tomoji IGARASHI  
Member  
IADSA  
Email: [secretariat@iadsa.org](mailto:secretariat@iadsa.org)

Ms YIFAN JIANG  
Advisor, Regulatory Affairs  
IADSA  
IADSA Secretariat  
3 Killiney Road,  
#07-04 Winsland House I  
239519 Singapore  
SINGAPORE  
Tel: +65 6681 0105  
Email: [yifanjiang@iadsa.org](mailto:yifanjiang@iadsa.org)

Mr Darwin LAI  
Member  
IADSA  
50 Rue de l'Associations  
B-1000 Brussels  
BELGIUM  
Tel: +32 2 209 11 55  
Email: [secretariat@iadsa.org](mailto:secretariat@iadsa.org)

Mr Xavier LAVIGNE  
Member  
IADSA  
50 Rue de l'Association  
B-1000 Brussels  
BELGIUM  
Tel: +32 2 209 11 55  
Email: [secretariat@iadsa.org](mailto:secretariat@iadsa.org)

Mr David PINEDA  
 Director, Regulatory Affairs  
 IADSA  
 50 Rue de l'Association  
 B-1000 Brussels  
 BELGIUM  
 Tel: +32 2 209 11 55  
 Email: [davidpineda@iadsa.org](mailto:davidpineda@iadsa.org)

Dr Nico RACZEK  
 Member  
 IADSA  
 50 Rue de l'Association  
 B-1000 Brussels  
 BELGIUM  
 Tel: +32 2 209 11 55  
 Email: [secretariat@iadsa.org](mailto:secretariat@iadsa.org)

Prof David RICHARDSON  
 Advisor  
 IADSA  
 50 Rue de l'Association  
 B-1000 Brussels  
 BELGIUM  
 Tel: +32 2 209 11 55  
 Email: [secretariat@iadsa.org](mailto:secretariat@iadsa.org)

Ms Michelle STOUT  
 Member  
 IADSA  
 50 Rue de l'Association  
 B-1000 Brussels  
 BELGIUM  
 Tel: +32 2 209 11 55  
 Email: [secretariat@iadsa.org](mailto:secretariat@iadsa.org)

Mr Kazuo SUEKI  
 Member  
 IADSA  
 Email: [secretariat@iadsa.org](mailto:secretariat@iadsa.org)  
 Ms Mei Yee WANG  
 Member  
 IADSA  
 50 Rue de l'Associations  
 B-1000 Brussels  
 BELGIUM  
 Tel: +32 2 209 11 55  
 Email: [secretariat@iadsa.org](mailto:secretariat@iadsa.org)

#### **INTERNATIONAL ASSOCIATION OF CONSUMER FOOD ORGANIZATIONS (IACFO)**

Mrs Patti RUNDALL  
 Policy Director  
 IACFO  
 34 Trumpington Street  
 CB2 1QY Cambridge  
 UNITED KINGDOM  
 Email: [prundall@babymilkaction.org](mailto:prundall@babymilkaction.org)

#### **INTERNATIONAL BABY FOOD ACTION NETWORK (IBFAN)**

Ms Adisti BAKRI  
 AIMI  
 Jakarta  
 INDONESIA  
 Email: [adisti.bakri@bali.aimi-asi.org](mailto:adisti.bakri@bali.aimi-asi.org)

Ms Joyce CHANETSA  
 IBFAn Africa  
 Email: [ibfan.jchanetsa@realnet.co.sz](mailto:ibfan.jchanetsa@realnet.co.sz)

Mrs Elisabeth STERKEN  
 INFACt Canada  
 Email: [esterken@infactcanada.ca](mailto:esterken@infactcanada.ca)

#### **INTERNATIONAL CHEWING GUM ASSOCIATION (ICGA) (ICGA)**

Mr Christophe LEPRÉTRE  
 (Head of Delegation)  
 Executive Director  
 International Chewing Gum Association  
 Regulatory and Scientific Affairs  
 1001 G Street NW  
 Suite 500 West  
 DC 20001 Washington  
 UNITED STATES OF AMERICA  
 Tel: +32 (0) 26455060/78  
 Email: [lepretre@gumassociation.org](mailto:lepretre@gumassociation.org)

#### **INTERNATIONAL COUNCIL OF BEVERAGES ASSOCIATIONS (ICBA)**

Ms Helen FALCO  
 Nutrition Advisor ICBA  
 International Council of Beverages Associations  
 1101 16<sup>th</sup> St NW  
 20036 Washington  
 UNITED STATES OF AMERICA  
 Tel: +404-676-4344  
 Email: [hefalco@coca-cola.com](mailto:hefalco@coca-cola.com)

Mr Hidekazu HOSONO  
 General Manager  
 Suntory Business Expert  
 2-3-3 Daiba, Minato-ku, Tokyo 135-8631  
 JAPAN  
 Tel: +81-3-5579-1521  
 Email: [Hidekazu\\_Hosono@suntory.co.jp](mailto:Hidekazu_Hosono@suntory.co.jp)

Ms Hilda OKTORA  
 Committee of Technical Policy on Food and Beverage  
 GAPMMI (Indonesia Food and Beverage Association)  
 Jl. Menteng Raya no. 9-19, Jakarta Pusat 10340  
 Tel: +62 855 820 5860  
 Email: [hoktora@coca-cola.com](mailto:hoktora@coca-cola.com)

#### **INTERNATIONAL COUNCIL OF GROCERY MANUFACTURERS ASSOCIATIONS (ICGMA)**

Ms Lynette LEE  
 Director, Nutrition and Regulatory Affairs  
 Kellogg Asia Pacific  
 238B  
 Thomson Road  
 #10-01  
 Novena Square Tower B  
 307685 Singapore  
 SINGAPORE  
 Email: [lynette.lee@kellogg.com](mailto:lynette.lee@kellogg.com)

Ms Kristen SCOTT  
 Senior Manager,  
 ICGMA  
 Health & Nutrition Policy  
 Email: [kscott@gmaonline.org](mailto:kscott@gmaonline.org)

**INTERNATIONAL COUNCIL ON AMINO ACID SCIENCE (ICAAS)**

Dr Hiromi OHTA  
Technical Advisor, Health Care Science Center  
Suntory Wellness Limited  
Shiba Park A-12<sup>th</sup> Floor  
2-4-1, Shibakoen Minato-ku  
105-0011 Tokyo  
JAPAN  
Tel: +81 3 6402 1496  
Email: [Hiromi\\_Otha@suntory.co.jp](mailto:Hiromi_Otha@suntory.co.jp)

**INTERNATIONAL DAIRY FEDERATION (IDF/FIL)**

Ms Laurence RYCKEN  
(Head of Delegation)  
Nutrition Officer  
International Dairy Federation  
België  
Boulevard Auguste Reyers 70b  
1030 Brussels  
BELGIUM  
Email: [lrycken@fil-idf.org](mailto:lrycken@fil-idf.org)

Ms Luisa CANDIDO  
Nutrition and Technical Manager  
Dairy UK  
UNITED KINGDOM  
Email: [lcandido@dairyUK.org](mailto:lcandido@dairyUK.org)

**INTERNATIONAL FOOD POLICY RESEARCH INSTITUTE**

Dr Erick BOY  
Head, Nutrition  
IFPRI  
HarvestPlus  
Email: [e.boy@cgiar.org](mailto:e.boy@cgiar.org)

Dr Anne MACKENZIE  
Head, Standards and Regulatory  
IFPRI  
HarvestPlus  
6442 Aston Rd.  
K4M 1B3 Ottawa  
CANADA  
Tel: 613 6920211  
Email: [a.mackenzie@cgiar.org](mailto:a.mackenzie@cgiar.org)

Dr Marilia NUTTI  
Manager, Latin America & Caribbean  
HarvestPlus  
Embrapa Food Technology  
Av. das Américas, 29501 - Guaratiba  
23020-470 Rio de Janeiro, RJ - Brazil  
BRAZIL  
Tel: +55 21 36229755  
Email: [m.nutti@cgiar.org](mailto:m.nutti@cgiar.org)

**INTERNATIONAL LACTATION CONSULTANT ASSOCIATION (ILCA)**

Mrs Maryse ARENDT  
Lactation Consultant IBCLC  
ILCA  
Email: [maryse.arendt@liewensufank.lu](mailto:maryse.arendt@liewensufank.lu)

**INTERNATIONAL LIFE SCIENCES INSTITUTE (ILSI)**

Ms Pauline CHAN  
(Head of Delegation)  
Director, Scientific Programs  
ILSI Southeast Asia Region  
9 Mohamed Sultan Road #02-01  
238959 Singapore  
SINGAPORE  
Tel: 65-63525220  
Email: [paulinechan@ilsisea.org.sg](mailto:paulinechan@ilsisea.org.sg)

Dr Mariela BEREZOVSKY  
Executive Director  
ILSI Brasil  
R. Isabel de Castela 450  
Vila Madalena  
05445-010 Sao Paulo  
BRAZIL  
Tel: 55-11-981611615  
Email: [mariela@ilsil.org.br](mailto:mariela@ilsil.org.br)

Ms Colleen FAROLAN  
Regional Regulatory Affairs Manager  
Mead Johnson Nutrition (Asia Pacific)  
12 Marina Boulevard #19-01  
Marina Bay Financial Centre Tower 3  
18982 Singapore  
SINGAPORE  
Tel: 65-6692-7873  
Email: [colleen.francescaguintofarolan@mjn.com](mailto:colleen.francescaguintofarolan@mjn.com)

Ms Li Lian HO Regional Regulatory Affairs Specialist  
Mead Johnson Nutrition (Asia Pacific)  
12 Marina Boulevard # 19-01  
Marina Bay Financial Centre Tower 3  
18982 Singapore  
SINGAPORE  
Tel: 65-6692-7814  
Email: [lilian.ho@mjn.com](mailto:lilian.ho@mjn.com)

Ms Eva HURT  
Head  
Nestle  
Regulatory & Scientific Affairs, Asia  
15A Changi Business Park Central 1  
486035 Singapore  
SINGAPORE  
Email: [eva.hurt@SG.nestle.com](mailto:eva.hurt@SG.nestle.com)

Dr Toshi KINOUCI  
Manager  
Meiji Company, Ltd.  
Infant Nutrition  
540 Naruda  
Odawara  
250-0862 Kanagawa  
JAPAN  
Tel: 81-465-37-3674  
Email: [toshi-kin@able.ocn.ne.jp](mailto:toshi-kin@able.ocn.ne.jp)

Mr Kazuyoshi NANBA  
Manager  
Morinaga Milk Industry Company, Ltd.  
Nutrition Development Department  
1-83, 5 Chrome, Higashihara  
Zama-city  
252-8583 Kanagawa  
JAPAN  
Tel: 81-446-252-3057  
Email: [k\\_nanba@morinagamilk.co.jp](mailto:k_nanba@morinagamilk.co.jp)

Ms Alicia NG  
Regional Head  
Nestle Health Science—AOA  
Regulatory Affairs & Advocacy  
15A Changi Business Park Central 1  
#05-02/03 Eghtrium@Changi Business Park  
486035 Singapore  
SINGAPORE  
Email: [alicia.ng@SG.nestle.com](mailto:alicia.ng@SG.nestle.com)

Mr Geoffrey SMITH  
Director  
Nutrition Strategies International  
3 Pickering Street  
#02-36 Nankin Row  
China Central Square  
48660 Singapore  
SINGAPORE  
Tel: 65-6463-7619  
Email: [geoffsmith@ilsisea.org.sg](mailto:geoffsmith@ilsisea.org.sg)

Dr Hiroshi TSUCHITA  
Advisor  
Meiji Company, Ltd.  
Research Planning Department  
6-1-2 Fijimi, Tsurugashima  
350-2201 Saitama  
JAPAN  
Tel: 81-49-279-1445  
Email: [hiroshi.tsuchita@meiji.com](mailto:hiroshi.tsuchita@meiji.com)

Mr Min-Su TZENG  
Associate Professor  
Fu Jen Catholic University  
Department of Nutritional Science  
Email: [031806@mail.fju.edu.tw](mailto:031806@mail.fju.edu.tw)

Dr Helio VANNUCCHI  
Senior Professor  
University of Sao Paulo  
School of Medicine of Ribeirao Preto  
Sao Paulo  
BRAZIL  
Tel: 55-16-991114142  
Email: [hvannucc@fmrp.usp.br](mailto:hvannucc@fmrp.usp.br)

Dr Kazuhiko YAMADA  
Professor  
Kagawa Nutrition University  
Applied Nutrition  
3-9-21, Chiyoda  
3500288 Sakado  
JAPAN  
Tel: 81-49-282-3708  
Email: [kyamada@eiyo.ac.jp](mailto:kyamada@eiyo.ac.jp)

## **INTERNATIONAL SPECIAL DIETARY FOODS INDUSTRIES (ISDI)**

Mrs Sandrine ALLONCLE  
Regulatory Affairs Manager  
ISDI  
Email: [secretariat@isdi.org](mailto:secretariat@isdi.org)

Mr Michael J BARRY  
Senior regulatory affairs manager  
Abbott  
Email: [secretariat@isdi.org](mailto:secretariat@isdi.org)

Ms Jan CAREY  
Senior Manager - Regulatory affairs  
ISDI  
Email: [secretariat@isdi.org](mailto:secretariat@isdi.org)

Mr Alejandro CASTRO III  
Executive Director  
IPNAP  
Email: [secretariat@isdi.org](mailto:secretariat@isdi.org)

Mr Todd CHERMAK  
Divisional Vice President  
Abbott  
Abbott Nutrition Regulatory Affairs  
Email: [secretariat@isdi.org](mailto:secretariat@isdi.org)

Ms Joyce FONG  
Head, Regional Regulatory Affairs, Sea & Pacific Rim  
Nestle Infant Nutrition  
Email: [secretariat@isdi.org](mailto:secretariat@isdi.org)

Mrs Marie-Odile GAILING  
Senior Scientific Officer  
ISDI  
Email: [secretariat@isdi.org](mailto:secretariat@isdi.org)

Ms Nani HIDAYANI  
Regulatory & Scientific Affairs for Consumer Health  
Mead Johnson Nutrition  
Email: [secretariat@isdi.org](mailto:secretariat@isdi.org)

Ms Vongsvat KOSULWAT  
Nutrition Science Director-Asia Pacific  
Mead Johnson Nutrition  
Email: [secretariat@isdi.org](mailto:secretariat@isdi.org)

Mrs Stephanie KRAMER-JUTANT  
Regulatory Affairs Manager  
ISDI  
Email: [secretariat@isdi.org](mailto:secretariat@isdi.org)

Mrs Venetta MIRANDA  
Regulatory Affairs  
ISDI  
Email: [secretariat@isdi.org](mailto:secretariat@isdi.org)

Ms Maria Olivia MISA-  
Mijn  
Email: [secretariat@isdi.org](mailto:secretariat@isdi.org)

Mr Manfred RUTHSATZ  
Global Head Regulatory Advocacy  
Nestle  
Email: [secretariat@isdi.org](mailto:secretariat@isdi.org)

Mr Ricky SALVADOR  
ISDI  
Email: [secretariat@isdi.org](mailto:secretariat@isdi.org)

Mr Jaap SCHRIJVER  
Regulatory Affairs Manager Baby Foods Europe  
Email: [secretariat@isdi.org](mailto:secretariat@isdi.org)

Mrs Silvia SELANDARI  
Policy Officer  
ISDI  
Email: [secretariat@isdi.org](mailto:secretariat@isdi.org)

Ms Kelly SOWDEN  
Regulatory Affairs Manager  
Abbott  
Email: [secretariat@isdi.org](mailto:secretariat@isdi.org)

Ms Karin TAN  
Regulatory Affairs Manager  
Danone  
Email: [secretariat@isdi.org](mailto:secretariat@isdi.org)

Mr Andrew WONG  
Regulatory Affairs Manager  
Abbott  
CHINA  
Email: [secretariat@isdi.org](mailto:secretariat@isdi.org)

Ms Dan YANG-  
Nutricia  
Email: [secretariat@isdi.org](mailto:secretariat@isdi.org)

Ms Ziting ZHANG  
Senior Government Affairs Desk Manager  
European Union Chamber of Commerce in China  
Email: [secretariat@isdi.org](mailto:secretariat@isdi.org)

#### **NATIONAL HEALTH FEDERATION (NHF)**

Mr Scott TIPS  
(Head of Delegation)  
President  
National Health Federation  
P.O. Box 688  
91017 Monrovia  
UNITED STATES OF AMERICA  
Tel: 6263572181  
Fax: 6263030642  
Email: [scott@rivieramail.com](mailto:scott@rivieramail.com)

Ms Katherine CARROLL  
Associate Editor  
National Health Federation  
PO Box 688  
91017 Monrovia  
UNITED STATES OF AMERICA  
Tel: 6263572181  
Fax: 6263572181  
Email: [katacarroll@gmail.com](mailto:katacarroll@gmail.com)

#### **SPECIALISED NUTRITION EUROPE (SNE)**

Mr Kevin O'BRIEN  
(Head of Delegation)  
SNE Delegation  
Specialised Nutrition Europe (SNE)  
1040 Brussels  
BELGIUM

Tel: +32 2 508 10 74  
Email: [secretariat@specialisednutritioneurope.eu](mailto:secretariat@specialisednutritioneurope.eu)

Ms Aurélie PERRICHET  
SNE Delegation  
Specialised Nutrition Europe (SNE)  
1040 Brussels  
BELGIUM  
Tel: +32 2 508 10 74  
Email: [a.perrichet@specialisednutritioneurope.eu](mailto:a.perrichet@specialisednutritioneurope.eu)

Ms Annemieke TOPS  
SNE Delegation  
Specialised Nutrition Europe (SNE)  
1040 Brussels  
BELGIUM  
Tel: +32 2 508 10 74  
Email: [secretariat@specialisednutritioneurope.eu](mailto:secretariat@specialisednutritioneurope.eu)

Mr Louis VAREILLE  
SNE Delegation  
Specialised Nutrition Europe (SNE)  
1040 Brussels  
BELGIUM  
Tel: +32 2 508 10 74  
Email: [secretariat@specialisednutritioneurope.eu](mailto:secretariat@specialisednutritioneurope.eu)

#### **UNITED NATIONS CHILDREN'S FUND (UNICEF) (UNICEF)**

Mrs Alison FLEET  
Technical Specialist  
UNICEF  
Supply Division  
Oceanvej 10-12 Freehavn  
2150 Copenhagen  
DENMARK  
Tel: +45 45335642  
Email: [afleet@unicef.org](mailto:afleet@unicef.org)

#### **FAO PERSONNEL PERSONNEL DE LA FAO PERSONAL DE LA FAO**

Dr Janice ALBERT  
Nutrition Officer  
FAO  
Viale delle Terme di Caracalla  
153 Rome  
ITALY  
Tel: +39 06 570 53552  
Email: [janice.albert@fao.org](mailto:janice.albert@fao.org)

#### **WHO PERSONNEL PERSONNEL DE L'OMS PERSONAL DE LA OMS**

Dr Chizuru NISHIDA  
Coordinator  
World Health Organization (WHO)  
Nutrition Policy and Scientific Advice  
20, avenue Appia  
Geneva 27  
SWITZERLAND  
Tel: +41227913317/+41792493549  
Email: [nishidac@who.int](mailto:nishidac@who.int)

Mr Marcus STAHLHOFER  
Technical Officer  
World Health Organization  
Maternal, Newborn, Child and Adolescent Health  
20, Avenue Appia  
CH - 1211 Geneva 27  
SWITZERLAND  
Tel: +41 22 79 12909  
Email: [stahlhoferm@who.int](mailto:stahlhoferm@who.int)

**CODEX SECRETARIAT / SECRÉTARIAT DU CODEX  
/ SECRETARÍA DEL CODEX**

Mr Tom HEILANDT  
Secretary, Codex Alimentarius Commission Joint  
FAO/WHO Food Standards Programme  
Food and Agriculture Organization of the United  
Nations (FAO)  
Viale delle Terme di Caracalla  
00153 Rome  
ITALY  
Tel: +39 06 5705 4384  
Email: [tom.heilandt@fao.org](mailto:tom.heilandt@fao.org)

Mr Patrick SEKITOLEKO  
Food Standards Officer  
Joint FAO/WHO Food Standards Programme  
Food and Agriculture Organization of the United  
Nations (FAO)  
Viale delle Terme di Caracalla  
00153 Rome  
ITALY  
Tel: +39 06 5705 6626  
Email: [patrick.sekitoleko@fao.org](mailto:patrick.sekitoleko@fao.org)

Mr Kyoungmo Kang  
Food Standards Officer  
Joint FAO/WHO Food Standards Programme  
Food and Agriculture Organization of the United  
Nations (FAO)  
Viale delle Terme di Caracalla  
00153 Rome  
ITALY  
Tel: +39 06 5705 4796  
Email: [kyoungmo.kang@fao.org](mailto:kyoungmo.kang@fao.org)

**CCNFSDU SECRETARIAT / SECRÉTARIAT DU  
CCNFSDU / SECRETARÍA DE CCNFSDU**

Mrs Ursula SIEBERT  
Federal Ministry of Food and Agriculture  
Rochusstrasse 1  
53123 Bonn  
GERMANY  
Tel: +49 228 99 529 4109  
Email: [ccnfsdu@bmel.bund.de](mailto:ccnfsdu@bmel.bund.de)

Ms Alina STEINERT  
Federal Ministry of Food and Agriculture  
Rochusstrasse 1  
53123 Bonn  
GERMANY  
Tel: +49 228 99 529 4459  
Email: [ccnfsdu@bmel.bund.de](mailto:ccnfsdu@bmel.bund.de)

APPENDIX II

2014-2019 Strategic Plan Activities for which “all committees” are responsible

Responses of the CCNFSDU

Strategic Goal	Objective	Activity	Expected Outcome	Measurable Indicators/Outputs
<p>1: Establish international food standards that address current and emerging food issues.</p>	<p>1.1: Establish new and review existing Codex standards, based on priorities of the CAC.</p>	<p>1.1.1: Consistently apply decision-making and priority-setting criteria across Committees to ensure that the standards and work areas of highest priority are progressed in a timely manner.</p>	<p>New or updated standards are developed in a timely manner.</p>	<p>- Priority setting criteria are reviewed, revised as required and applied.  - # of standards revised and # of new standards developed based on these criteria.</p>
<p><b>Question to the Committee:</b></p> <p>Is this activity relevant to the work of the Committee? <b><u>YES</u></b></p> <p>Does the Committee use any specific criteria for standards development?</p> <p><b><u>The Committee uses the criteria in the Procedural Manual, Criteria for the Establishment of Work Priorities, for standards development.</u></b></p> <p>Does the Committee intend to develop such criteria?</p> <p><b><u>The Committee fails to see the need to develop specific decision-making and priority-setting criteria for the CCNFSDU work and would be of the opinion to continue to refer to the general ones laid down in the Procedural Manual. The Committee should ensure that the provisions included in the relevant parts of the Procedural Manual are strictly applied and that no proposal for new work is submitted to the CAC if this has not been the case.</u></b></p>				
	<p>1.2: Proactively identify emerging issues and Member needs and, where appropriate, develop relevant food standards.</p>	<p>1.2.1: Develop a systematic approach to promote identification of emerging issues related to food safety, nutrition, and fair practices in the food trade.</p>	<p>Timely Codex response to emerging issues and to the needs of Members.</p>	<p>- Committees implement systematic approaches for identification of emerging issues.  - Regular reports on systematic approach and emerging issues made to the CCEXEC through the Codex Secretariat.</p>
<p><b>Question to the Committee:</b></p> <p>Is this activity relevant to the work of the Committee? <b><u>YES</u></b></p> <p>How does the Committee identify emerging issues and members needs? Is there a systematic approach? Is it necessary to develop such an approach?</p> <p><b><u>Emerging issues are identified by Members and brought to the Committee or specific issues are referred to CCNFSDU from other Committees or the FAO or WHO.</u></b> <b><u>While there is no systematic approach, however, there may be a need to develop one should the current process be found to be insufficient. Such an approach should take into consideration processes for Codex committees to work together on cross-cutting issues.</u></b></p>				

Strategic Goal	Objective	Activity	Expected Outcome	Measurable Indicators/Outputs
		1.2.2: Develop and revise international and regional standards as needed, in response to needs identified by Members and in response to factors that affect food safety, nutrition and fair practices in the food trade.	Improved ability of Codex to develop standards relevant to the needs of its Members.	<ul style="list-style-type: none"> <li>- Input from committees identifying and prioritizing needs of Members.</li> <li>- Report to CCEXEC from committees on how standards developed address the needs of the Members as part of critical review process.</li> </ul>
<b>Included in question to 1.2.</b>				
2: Ensure the application of risk analysis principles in the development of Codex standards.	2.1: Ensure consistent use of risk analysis principles and scientific advice.	2.1.1: Use the scientific advice of the joint FAO/WHO expert bodies to the fullest extent possible in food safety and nutrition standards development based on the "Working Principles of Risk Analysis for Application in the Framework of the Codex Alimentarius".	Scientific advice consistently taken into account by all relevant committees during the standard setting process.	<ul style="list-style-type: none"> <li>- # of times the need for scientific advice is:                             <ul style="list-style-type: none"> <li>- identified,</li> <li>- requested and,</li> <li>- utilized in a timely manner.</li> </ul> </li> </ul>
<p><b>Question to the Committee:</b></p> <p>Is this activity relevant to the work of the Committee? <b><u>YES</u></b></p> <p>Does the committee request scientific advice in course of its work, how often does it request such advice?</p> <p><b><u>CCNFSDU requests scientific advice, but the periodicity of such request is difficult to establish. According to the Procedural Manual, the decision to undertake new work or to revise standards should include a preliminary assessment of the need for expert scientific advice and the availability of such advice from FAO, WHO or other relevant expert bodies, and the prioritisation of that advice.</u></b></p> <p>Does the committee always use the scientific advice, if not, why not?</p> <p><b><u>The Committee always takes into consideration the advice it receives in developing standards. In addition, it uses other sources of scientific advice from recognised authoritative scientific bodies.</u></b></p>				
		2.1.2: Encourage engagement of scientific and technical expertise of Members and their representatives in the development of Codex	Increase in scientific and technical experts at the national level contributing to the development of Codex standards.	<ul style="list-style-type: none"> <li>- # of scientists and technical experts as part of Member delegations.</li> <li>- # of scientists and technical experts providing appropriate input to country positions.</li> </ul>

Strategic Goal	Objective	Activity	Expected Outcome	Measurable Indicators/Outputs
		standards.		
<p><b>Question to the Committee:</b></p> <p>Is this activity relevant to the work of the Committee? <b><u>YES</u></b></p> <p>How do members make sure that the necessary scientific input is given into country positions and that the composition of the national delegation allows to adequately present and discuss this position?</p> <p><b><u>Prior to developing and advancing a country's position, Members typically seek and engage national scientific and technical expertise from within their government and stakeholders.</u></b></p> <p>What guidance could be given by the Committee or FAO and WHO?</p> <p><b><u>The Committee does not believe that specific guidance is needed on this point.</u></b></p>				
		2.1.3: Ensure that all relevant factors are fully considered in exploring risk management options in the context of Codex standard development.	Enhanced identification, and documentation of all relevant factors considered by committees during the development of Codex standards.	<ul style="list-style-type: none"> <li>- # of committee documents identifying all relevant factors guiding risk management recommendations.</li> <li>- # of committee documents clearly reflecting how those relevant factors were considered in the context of standards development.</li> </ul>
<p><b>Question to the Committee:</b></p> <p>Is this activity relevant to the work of the Committee? <b><u>YES</u></b></p> <p>How does the Committee ensure that all relevant factors have been taken into account when developing a standard and how are these documented?</p> <p><b><u>The Procedural Manual already establishes Working Principles for Risk Analysis which stipulate that risk management should follow a structured approach including preliminary risk management activities, evaluation of risk management options, monitoring and review of the decision taken. The Committee should therefore recall the importance of applying consistently these principles.</u></b></p>				

Strategic Goal	Objective	Activity	Expected Outcome	Measurable Indicators/Outputs
		2.1.4: Communicate the risk management recommendations to all interested parties.	Risk management recommendations are effectively communicated and disseminated to all interested parties.	- # of web publication/communications relaying Codex standards. - # of media releases disseminating Codex standards.
<p><b>Question to the Committee:</b></p> <p>Is this activity relevant to the work of the Committee? <u>YES</u></p> <p>When taking a risk management decision, does the committee give guidance to members how to communicate this decision? Would more consideration of this be helpful to members?</p> <p><b><u>Communication of the risk management recommendations are done through standards, guidelines, other related texts, and the report which are posted on the Codex website. The development of a communication strategy would have a positive impact on this activity.</u></b></p>				
3: Facilitate the effective participation of all Codex Members.	3.1: Increase the effective participation of developing countries in Codex.	3.1.5: To the extent possible, promote the use of the official languages of the Commission in committees and working groups.	Active participation of Members in committees and working groups.	- Report on number of committees and working groups using the languages of the Commission.
<p><b>Question to the Committee:</b></p> <p>Is this activity relevant to the work of the Committee? <u>YES</u></p> <p>Is the use of official languages in working groups of the committee sufficient?</p> <p><b><u>The Committee would recommend using as many languages as possible in WGs in order to enhance participation of members.</u></b></p> <p>What are the factors determining the choice of languages?</p> <p><b><u>The choice of language is determined by the Committee but is also influenced by the members chairing and co-chairing the WG. Project timelines for the eWG would have to be adjusted to allow enough time for translation of documents.</u></b></p> <p>How could the situation be improved?</p> <p><b><u>A suggestion could be to promote co-chairing arrangements by countries with different languages. The co-chairs could provide support to the chair of eWGs in translating consultation documents and responses from WG members. Barriers to having documents available in many languages include ensuring consistent use of Codex language in translated documents and costs associated with translating the documents.</u></b></p>				
	3.2: Promote capacity development programs that assist countries in creating sustainable national Codex structures.	3.2.3: Where practical, the use of Codex meetings as a forum to effectively conduct educational and technical capacity building activities.	Enhancement of the opportunities to conduct concurrent activities to maximize use of the resources of Codex and Members.	-. # of activities hosted on the margins of Codex meetings.

Strategic Goal	Objective	Activity	Expected Outcome	Measurable Indicators/Outputs
<p><b>Question to the Committee:</b></p> <p>Is this activity relevant to the work of the Committee? <b><u>YES</u></b></p> <p>Does the Committee organize technical capacity activities or other activities in the margins of Committee sessions? If yes – how many and with which topics have been organized in the past.</p> <p><i>The Committee believes that any capacity building activity should be coordinated by the parent organisations in order to avoid inconsistencies and duplication of work.</i></p> <p>If no – could this be useful and what topics could be addressed?</p> <p><i>The Committee is open to any initiative in this area.</i></p>				
<p>4: Implement effective and efficient work management systems and practices.</p>	<p>4.1: Strive for an effective, efficient, transparent, and consensus based standard setting process.</p>	<p>4.1.4: Ensure timely distribution of all Codex working documents in the working languages of the Committee/ Commission.</p>	<p>Codex documents distributed in a more timely manner consistent with timelines in the Procedural Manual.</p>	<ul style="list-style-type: none"> <li>- Baseline Ratio (%) established for documents distributed at least 2 months prior to versus less than 2 months prior to a scheduled meeting.</li> <li>- Factors that potentially delay the circulation of documents identified and addressed.</li> <li>- An increase in the ratio (%) of documents circulated 2 months or more prior to meetings.</li> </ul>
<p><b>Question to the Committee:</b></p> <p>Is this activity relevant to the work of the Committee? <b><u>YES</u></b></p> <p>Does the Committee have a mechanism in place to ensure timely distribution of documents? What could be done to further improve the situation?</p> <p><b><u>The requirement for timely distribution of documents already exists and is included in the Procedural Manual. Submission of documents to the Host Secretariat may need improvement, as some discussion papers have not been distributed early enough in advance to allow full consideration of the document.</u></b></p>				
		<p>4.1.5: Increase the scheduling of Work Group meetings in conjunction with Committee meetings.</p>	<p>Improved efficiency in use of resources by Codex committees and Members.</p>	<p>- # of physical working group meetings in conjunction with committee meetings, where appropriate.</p>

Strategic Goal	Objective	Activity	Expected Outcome	Measurable Indicators/Outputs
<p><b>Question to the Committee:</b></p> <p>Is this activity relevant to the work of the Committee?</p> <p><b><u>CCNFSDU already schedules Working Group meetings in conjunction with Committee meetings when necessary.</u></b></p> <p>Does the Committee hold physical working groups independent of Committee sessions? If yes – why is this necessary?</p> <p><b><u>The Committee believes that in general the system in place today, electronic working groups combined with physical working groups organised in conjunction with Committee sessions, is sufficient to ensure the efficiency of the work of the Committee. There does not seem to be any added value of working groups independent of Committee sessions, unless it is fully justified by specific needs. Furthermore, these sessions would not be as well attended by member countries due to the additional resources that such organisation would require.</u></b></p>				
	<p>4.2: Enhance capacity to arrive at consensus in standards setting process.</p>	<p>4.2.1: Improve the understanding of Codex Members and delegates of the importance of and approach to consensus building of Codex work.</p>	<p>Members and delegates awareness of the importance of consensus in the Codex standard setting process improved.</p>	<ul style="list-style-type: none"> <li>- Training material on guidance to achieve consensus developed and made available in the languages of the Commission to delegates.</li> <li>- Regular dissemination of existing material to Members through Codex Contact Points.</li> <li>- Delegate training programs held in association with Codex meetings.</li> <li>- Impediments to consensus being achieved in Codex identified and analyzed and additional guidance developed to address such impediments, if necessary.</li> </ul>
<p><b>Question to the Committee:</b></p> <p>Is this activity relevant to the work of the Committee? <b><u>YES</u></b></p> <p><i>The Committee strongly believes that it is essential to maintain consensus-based decision making in the framework of Codex Alimentarius.</i></p> <p>Are there problems with finding consensus in the Committee? If yes – what are the impediments to consensus? What has been attempted and what more could be done?</p> <p><b><u>Problems may arise in this Committee, as well as in any other Committee. All efforts should be made to ensure that all decisions of the Committee are taken on the basis of consensus, or the standard should not be forwarded to the CAC. When encountering areas of difficulty in the past, the Committee has successfully used strategies such as: discussion to establish clear direction and support prior to submitting proposals in the step process, consensus building techniques that allow focus of effort on areas where there are divergent views; organization of informal and physical working groups to move work forward; and scoping work to areas where consensus exists. It is the role of the chair to explore all possible means to reach consensus before taking any final decision on progressing a standard on the basis of a vote.</u></b></p>				

## APPENDIX III

## PROPOSED DRAFT PRINCIPLES FOR THE ADDITION OF ESSENTIAL NUTRIENTS TO FOODS

(for adoption at Step 8)

## INTRODUCTION

The *Principles for the Addition of Essential Nutrients to Foods (the Principles)* are intended to provide guidance to competent national and/or regional authorities responsible for developing guidelines and legal texts through the establishment of a set of principles that serve as a basis for the rational and safe addition of essential nutrients to foods.<sup>1</sup>

The *Principles* take into consideration provisions in the Codex Nutritional Risk Analysis Principles and Guidelines for Application to the Work of the Committee on Nutrition and Foods for Special Dietary Uses (CAC Procedural Manual), where applicable.

Competent national and/or regional authorities may also consult FAO/WHO publications for further guidance on the addition of essential nutrients.

## 1. SCOPE

These Principles are intended to apply to all foods to which essential nutrients are added, not including vitamin and mineral food supplements<sup>2</sup>, without prejudice to the provisions in Codex standards and guidelines for foods for special dietary uses.

The *Principles* are applicable, as appropriate, to both mandatory and voluntary addition of essential nutrients.

## 2. DEFINITIONS

For the purpose of these Principles:

**2.1 Essential nutrient<sup>3</sup>** means any substance normally consumed as a constituent of food which is needed for growth and development and/or the maintenance of life and which cannot be synthesized in adequate amounts by the body.

**2.2 Substitute food** is a food which resembles a common food in appearance and texture and is intended to be used as a complete or partial replacement for the food it resembles.

**2.3 Nutritional equivalence** means that a substitute food is of similar nutritional value to its counterpart.

**2.4 Restoration** means the addition of essential nutrient(s) to a food in amounts to replace those lost during the course of good manufacturing practice, or during normal storage and handling procedures.

**2.5 Mandatory nutrient addition** is when competent national and/or regional authorities require food manufacturers to add specified essential nutrients to particular foods or food categories.

**2.6 Voluntary nutrient addition<sup>4</sup>** is when food manufacturers choose to add specified essential nutrients to particular foods or food categories as explained in footnote 4.

**2.7 Population** refers to a national population or specific population group(s) as appropriate.

## 3. GENERAL PRINCIPLES

## 3.1 Fundamental Principles

3.1.1 Essential nutrients may be appropriately added to foods for the purpose of contributing to:

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<sup>1</sup> Different types of addition of essential nutrients for the purposes described in these Principles may be described by the term 'fortification' in certain Member Countries.

<sup>2</sup> See the *Guidelines for Vitamin and Mineral Food Supplements* (CAC/GL-55-2005)

<sup>3</sup> 'Nutrient' definition: See section 2.5 of the *Guidelines on Nutrition Labelling* (CAC/GL 2-1985)

<sup>4</sup> Internationally, there are different regulatory approaches to how voluntary addition of essential nutrients is legally framed and/or managed by competent national and/or regional authorities. In all these approaches, some form of regulatory oversight is required. There are approaches whereby addition of essential nutrients is generally permitted within a regulatory framework that can restrict foods or categories of foods to which nutrients may be added and set specific limits for those nutrients. There are other approaches that may be described as conditional voluntary. In one example, the framework in place describes all the foods or categories of foods to which manufacturers may choose to add nutrients, along with the nutrients and levels of nutrients. In another of these examples, if a manufacturer chooses to make a statement on the label indicating that a nutrient has been added, then certain nutrients are required to be added at specified levels. Also, in another example, if a manufacturer chooses to add an essential nutrient to certain foods, they must do so in accordance with policies on addition of nutrients and/or meet requirements in place in relation to the nutrients and amounts for addition

- preventing/reducing the risk of, or correcting, a demonstrated deficiency of one or more essential nutrients in the population;
- reducing the risk of, or correcting, inadequate nutritional status or intakes of one or more essential nutrients in the population;
- meeting requirements and/or recommended intakes of one or more essential nutrients;
- maintaining or improving health; and/or
- maintaining or improving the nutritional quality of foods.

Competent national and/or regional authorities may request scientific rationale and evidence demonstrating fulfillment of one or more of the purposes listed above .

**3.1.2** Competent national and/or regional authorities should determine whether addition of essential nutrients should be mandatory or voluntary. This decision may be based on severity and extent of public health need as demonstrated by generally accepted scientific evidence.

**3.1.3** Specific provision may be made in food standards, regulations or guidelines that identify the food(s) and essential nutrients for addition and, where appropriate, the minimum and/or maximum amounts within which the essential nutrients should be present.

**3.1.4** The labelling and advertising of food products to which essential nutrients have been added should not mislead or deceive the consumer as to the nutritional merit of the food.

### **3.2 Selection of Nutrients and Determination of Amounts**

**3.2.1** The addition of an essential nutrient, including the amount added, should be in line with one or more of the purposes identified in 3.1.1. The amount added should not result in either an excessive intake or an insignificant intake of the added essential nutrient(s), considering total daily intakes from all relevant sources including food supplements.

**3.2.2** When an essential nutrient is added to foods, including addition for technological reasons, the total amount of the essential nutrient in the food should not exceed maximum amounts that may be set by competent national and/or regional authorities.

The maximum amounts mentioned above may be set taking into account

- a) upper levels of intake (UL) of essential nutrients established by scientific risk assessment based on generally accepted scientific data;
- b) the daily intake of essential nutrients from all sources.

When the maximum levels are set, due account may be taken of the daily intake reference values of essential nutrients for the population.

**3.2.3** Where an UL is not available, the scientific evidence to support the safe addition of an essential nutrient should be considered including evidence for intakes that are unlikely to result in adverse health effects including consideration of the Highest Observed Intake<sup>5</sup>.

**3.2.4** The severity of the adverse effect on which the UL is based may be reviewed to inform any restrictions on the addition of essential nutrients to foods.

**3.2.5** When competent national and/or regional authorities establish minimum amounts for the addition of essential nutrients to foods they should ensure that these amounts are significant and in line with the intended purpose as identified in 3.1.1. In determining significant amounts, they may also consider conditions of use for a 'source' claim in the *Guidelines for Use of Nutrition and Health Claims* (CAC/GL 23-1997).

### **3.3 Selection of Foods**

**3.3.1** The selection of foods to which essential nutrients may be added should be in line with the intended purposes of nutrient addition as identified in 3.1.1, dietary patterns, socioeconomic situations and the need to avoid any risks to health.

**3.3.2** Foods to which essential nutrients may not be added may be determined by competent national and/or regional authorities.

**3.3.3** Essential nutrients should not be added to alcoholic beverages.

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<sup>5</sup> Highest Observed Intake – the highest level of intake observed or administered as reported within (a) study(ies) of acceptable quality. It is derived only when no adverse health effects have been identified (Source: Codex *Nutritional Risk Analysis Principles*).

### **3.4 Technological Aspects**

**3.4.1** The sources of the added essential nutrient may be either natural or synthetic and their selection should be based on considerations such as safety and bioavailability of the nutrient. In addition, purity criteria should take into account FAO/WHO standards, international Pharmacopoeias or other recognized international standards.

**3.4.2** The added essential nutrient should be sufficiently stable in the food under customary conditions of processing, packaging, storage, distribution and use.

### **3.5 Monitoring**

**3.5.1** It is important that competent national and/or regional authorities monitor population intakes from all sources including the essential nutrients added to foods to assess the extent to which the purposes identified in 3.1.1 are addressed and to ensure that any risk of excessive intakes is minimised.

**3.5.2** Monitoring of total nutrient intakes should in principle use the same approach as used in deciding the addition of essential nutrients unless otherwise necessary for the specific nutrient concerned.

## **4 Principles for Specific Types of Addition of Essential Nutrients**

### **4.1 Mandatory Addition of Essential Nutrients to Address a Demonstrated Public Health Need**

**4.1.1** Where there is a demonstrated public health need for increasing the intake of an essential nutrient in the population, competent national and/or regional authorities may decide that this may be accomplished by mandatory nutrient addition. This need may be demonstrated by evidence of clinical or subclinical deficiency, suboptimal or inadequate nutritional status using biochemical indicators, estimates indicating inadequate or potentially inadequate intake of nutrients, or evidence related to another health outcome. While most addition to address a serious public health need is through mandatory nutrient addition, there may be some situations where a conditional voluntary approach may be used.

**4.1.2** The food(s) selected as a vehicle for the added essential nutrient(s) should be habitually consumed in sufficient amounts by the target population.

**4.1.3** The amount of the essential nutrient added to the food should aim to be sufficient to meet the public health need.

**4.1.4** The intake of the food selected as a vehicle should be stable and uniform and the distribution of the population intake of the food, including the lower and upper percentiles, should be known.

**4.1.5** The cost effectiveness of the mandatory nutrient addition to foods should be considered.

### **4.2 Addition of Essential Nutrients for Restoration**

**4.2.1** Where restoration is to serve as a justification for the maintenance or improvement of the nutritional quality of a food, especially in relation to a public health need, the following criteria should be considered:

- the food prior to restoration should be a significant contributor to the intake of relevant essential nutrients in the population
- the food prior to restoration would be subject to a reduction of relevant essential nutrients it contains during processing, storage or handling.

**4.2.2** A food may be considered a significant contributor to intake of an essential nutrient based on its nutrient content and/or frequency of consumption.

### **4.3 Addition of Essential Nutrients for Nutritional Equivalence**

**4.3.1** Where nutritional equivalence is to serve as a justification for the improvement of the nutritional quality of a substitute food, especially in relation to a public health need, the counterpart food should be a significant contributor to the intake of essential nutrients in the population.

**4.3.2** A food being substituted or partially substituted may be considered a significant contributor to intake of an essential nutrient based on its nutrient content and/or frequency of consumption.

## APPENDIX IV

**Part1. PROPOSED DRAFT ADDITIONAL OR REVISED NUTRIENT REFERENCE VALUES FOR LABELLING PURPOSES IN THE *GUIDELINES ON NUTRITION LABELLING (CAC/GL 2-1985)* (OTHER VALUES THAN PROTEIN)**

(for adoption at Step 5/8)

**NRVs-R**

Vitamin C (mg)	100
Zinc (mg)**	11 (30% dietary absorption; Mixed diets, and lacto-ovo vegetarian diets that are not based on unrefined cereal grains or high extraction rate (>90%) flours) 14 (22% dietary absorption; Cereal-based diets, with >50% energy intake from cereal grains or legumes and negligible intake of animal protein)
Selenium (µg)	60
Molybdenum (µg)	45
Manganese (mg)	3

\*\* Competent national and/or regional authorities should determine an appropriate NRV-R that best represents the dietary absorption from relevant diets.

**PART 2. AMENDMENTS TO THE ANNEX OF THE *GUIDELINES ON NUTRITION LABELLING (CAC/GL 2-1985)***

(for adoption)

**Amended text for clarification of 3.2.1.1 of General Principles for Establishing NRVs-R**

**GP 3.2.1.1** The NRVs-R should be based on Individual Nutrient Level 98 (INL<sub>98</sub>). In certain cases where there is an absence of, or an older, established INL<sub>98</sub> for a nutrient for a specific sub-group(s), it may be more appropriate to consider the use of other daily intake reference values or ranges that have been more recently established by recognized authoritative scientific bodies. The derivation of these values should be reviewed on a case-by-case basis.

## APPENDIX V

**PROPOSED DRAFT NUTRIENT REFERENCE VALUE FOR POTASSIUM IN RELATION TO THE RISK  
OF NON-COMMUNICABLE DISEASE*****For inclusion in the Guidelines on Nutrition Labelling (CAC/GL 2-1985)***

(for adoption at Step 5/8)

**3.4.4.2 NRVs-NCD**Intake levels not to exceed

Saturated fatty acids	20 g <sup>2, 3</sup>
Sodium	2000 mg <sup>4</sup>

Intake levels to achieve

Potassium	3500 mg <sup>4</sup>
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<sup>3</sup> The selection of this nutrient for the establishment of an NRV was based on “convincing evidence” for a relationship with NCD risk as reported in the report *Diet, Nutrition and the Prevention of Chronic Diseases*. WHO Technical Report Series 916. WHO, 2003.

<sup>4</sup> The selection of these nutrients for the establishment of an NRV was based on “high quality” evidence for a relationship with a biomarker for NCD risk in adults as reported in the respective 2012 WHO guidelines on sodium and potassium intake for adults and children.

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**Remarks:**

- a) Structure and footnotes 3 & 4 have been changed.
- b) The values for saturated fatty acids and sodium have not been changed.
- c) Footnote 2 has not been changed.

## APPENDIX VI

## PROPOSED DRAFT REVISION OF THE LIST OF FOOD ADDITIVES IN CODEX STAN 72-1981

Part 1. Food Additives for inclusion in part 4 Section A of the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CODEX STAN 72-1981)

(for adoption)

INS	Additive	Maximum level in 100 ml of the product ready for consumption
<b>4.1 Thickener</b>		
1450	Starch sodium octenyl succinate	2 g in hydrolysed protein and/or amino acid based infant formula only
<b>4.2 Emulsifier</b>		
472c	Citric and fatty acid esters of glycerol	0.9 g in all types of liquid infant formula 0.75 g in all types of powder infant formula

**Part 2. Proposals for inclusion of additional food additives for use in Infant Formula and Infant Formula as Food for Special Medical Purposes (Section 4 of CODEX STAN 72-1981)**

(Wish-list "Candidate Compounds for future consideration")

**Section A (Infant Formula):**

INS no.	Additive	Use level	Technological Justification	JECFA status	Conclusion of 36 <sup>th</sup> CCNFSDU
407	Carrageenan	0.03 g in regular milk- and soy-based liquid infant formula only 0.1 g in hydrolysed protein- and/or amino acid based liquid infant formula only	Retains homogeneity	Use accepted by 79 <sup>th</sup> meeting of JECFA (June 2014)	Maintain on the list; await final JECFA report
415	Xanthan gum	GMP	Retains homogeneity	30 <sup>th</sup> JECFA (1986): ADI NS; infants <12 weeks not mentioned Tox database: three-generation reproduction study adverse effects attributable to Xanthan gum were not found	Maintain on the list and wait whether sponsor proposes JECFA evaluation to CCFA If not added to JECFA priority in 2015: remove from list.
414	Gum Arabic (acacia)	GMP	Retains homogeneity	35 <sup>th</sup> JECFA (1989): ADI NS No effects in teratogenicity	Maintain on the list and wait whether sponsor proposes JECFA evaluation to CCFA If not added to JECFA priority in 2015: remove from list.
473	Sucrose esters of fatty acids*	12 mg in formula containing hydrolysed protein <sup>1</sup> or amino acids <sup>1</sup>	Retains homogeneity	49 <sup>th</sup> JECFA (1997) :ADI specified at 0-30 mg/kg bw; infants <12 weeks not mentioned	Maintain on the list and wait whether sponsor proposes JECFA evaluation to CCFA If not added to JECFA priority in 2015: remove from list.

INS no.	Additive	Use level	Technological Justification	JECFA status	Conclusion of 36 <sup>th</sup> CCNFSDU
472e	Tartaric and fatty acid esters of glycerol	GMP (China) 0.5 g	Retains homogeneity	61 <sup>st</sup> JECFA (2003) ADI specified at 0-50 mg/kg bw (2003); infants <12 weeks not mentioned	Maintain on the list and wait whether sponsor proposes JECFA evaluation to CCFA If not added to JECFA priority in 2015: remove from list.
472a	Acetic and fatty acid esters of glycerol	GMP (USA)		17 <sup>th</sup> JECFA (1973): ADI NS (not limited); infants <12 weeks not mentioned	Maintain on the list and wait whether sponsor proposes JECFA evaluation to CCFA If not added to JECFA priority in 2015: remove from list.
338	Phosphoric acid	0.1 g expressed as P <sub>2</sub> O <sub>5</sub> singly or in combination and within the limits for sodium, potassium and phosphorus in Section 3.1.3 (e) in all types of infant formula		15 <sup>th</sup> JECFA (1971): suitable chemical compound for baby food (not specifically mentioned); attention to Ca:P ratio MTDI: 70 mg/kg bw as P (combined for all P sources)	Maintain on the list and wait whether sponsor proposes JECFA evaluation to CCFA If not added to JECFA priority in 2015: remove from list.
306	<del>Vitamin E concentrate</del>	<del>1 mg in all types of infant formula singly or in combination</del>	<del>Protect from oxidation</del>	<del>Under this name and number not evaluated. 30<sup>th</sup> JECFA (1986) evaluated Tocopherol Concentrate, Mixed (INS 307b) synonym: Vitamin E</del>	<del>Remove from the list, as the substances does not meet the minimum criteria of a JECFA evaluation and Codex specifications, not listed in GSFA; in addition not recognized as a food additive (no INS)</del>
308	<del>Gamma tocopherol</del>	<del>1 mg in all types of infant formula singly or in combination</del>	<del>Protect from oxidation</del>	<del>Not evaluated by JECFA, no specifications available</del>	<del>Remove from the list, as the substances does not meet the minimum criteria of a JECFA evaluation and Codex specifications, not listed in GSFA</del>
309	<del>Delta tocopherol</del>	<del>1 mg in all types of infant formula singly or in combination</del>	<del>Protect from oxidation</del>	<del>Not evaluated by JECFA, no specifications available</del>	<del>Remove from the list, as the substances does not meet the minimum criteria of a JECFA evaluation and Codex specifications, not listed in GSFA</del>

**Section B (Infant Formula as Food for Special Medical Purposes):**

INS no.	Additive	Use level	Technological Justification	JECFA Status	Comments	Conclusion of 36 <sup>th</sup> CCNFSDU
<b>Thickeners</b>						
401	Sodium alginate	100 mg	Retains homogeneity	39 <sup>th</sup> JECFA (1992) , not specified, infants < 12 weeweekswear not discussed by JECFA	Limited support by few members and ISDI Request as carrier for nutrients not within the scope of the eWG.	Maintain on the list and wait whether sponsor proposes JECFA evaluation to CCFA If not added to JECFA priority in 2015: remove from list.
405	Propane 1,2-diialginate	20 mg	Retains homogeneity	44 <sup>st</sup> JECFA (1993) , not specified	<del>Not supported, no specific need for infant formula presented</del> Need in specific formula for infants at ages > 12 months not to be discussed under this entry	<del>Remove from the list, as the substance is not supported by any member/observer, no technological need.</del>
410	Carob bean gum (Locust bean gum)	0.5 g	Retains homogeneity	25 <sup>th</sup> JECFA (1981) , not specified	Supported by some members and observers	Listed at 0.1 g/100 ml in Section A. Maintained on the list and wait whether a sponsor proposes JECFA evaluation of higher level to CCFA If not added to JECFA priority in 2015: remove from list.
412	Guar gum	1 g	Retains homogeneity	19 <sup>th</sup> JECFA (1975) , not specified	Supported by some members and observers	Listed at 0.1 g/100 ml in Section A. Maintained on the list and wait whether a sponsor proposes JECFA evaluation of higher level to CCFA If not added to JECFA priority in 2015: remove from list.
414	Gum Arabic (acacia)	GMP	Retains homogeneity	35 <sup>th</sup> JECFA (1989) , not specified	No strong support for compound, no commitment to support JECFA evaluation. Carrier for fatsoluble vitamins not within the scope of eWG	Maintain on the list and wait whether sponsor proposes JECFA evaluation to CCFA If not added to JECFA priority in 2015: remove from list.

INS no.	Additive	Use level	Technological Justification	JECFA Status	Comments	Conclusion of 36 <sup>th</sup> CCNFSDU
415	Xanthan gum	0.12 g	Retains homogeneity	30 <sup>th</sup> JECFA (1986), not specified	General support for JECFA evaluation for use in Section A/B Sponsor for JECFA identified by ELC.	Maintain on the list and wait whether sponsor proposes JECFA evaluation to CCFA If not added to JECFA priority in 2015: remove from list.
440	Pectins	1 g	Retains homogeneity	79 <sup>th</sup> JECFA meeting did not establish safety of proposed conditions of use	General support Section A/B	Maintain on the list and wait until information is available from JECFA final assessment.
466	<del>Sodium carboxymethyl cellulose</del>	1g	Retains homogeneity	<del>35<sup>th</sup> JECFA (1989) , not specified</del>	<del>No strong support for compound, no commitment to support JECFA evaluation.</del>	<del>Remove from the list as substance is not supported significantly demonstrating limited technological need</del>
<b>Emulsifiers<sup>6</sup></b>						
474	<del>Mono and diglycerides</del>	0.5 g	Retains homogeneity	<del>17<sup>th</sup> JECFA (1973), not specified</del>	<del>Supported by some members and observers</del>	<del>Listed already in Section A for 0.4 g: is an additional separate entry at 0.5 g necessary and justified? Remove from the list as no technological need</del>
473	Sucrose esters of fatty acids	12 mg in formula containing hydrolysed protein, peptides or amino acids	Retains homogeneity	71st JECFA (2009) :Group ADI specified at 0-30 mg/kg bw; infants <12 weeks not mentioned, no studies with animals in weaning stage mentioned	Supported by some members and observers	Maintain on the list and wait whether a sponsor proposes JECFA evaluation of higher level to CCFA If not added to JECFA priority in 2015: remove from list.

<sup>6</sup> If emulsifiers are used in combination, the combined levels should be within the levels listed and be proportionately reduced, and with the minimum amount necessary to achieve the intended technical effect.

## APPENDIX VII

**PROPOSAL TO ESTABLISH A DEFINITION ON BIOFORTIFICATION AND/OR BIOFORTIFIED FOODS  
PROJECT DOCUMENT****1. PURPOSE AND SCOPE OF THE STANDARD**

There is no internationally recognized definition for Biofortification although some Member Governments are starting to include Biofortification in Country Regulations and also write it into National Policies i.e. Nutrition and/or Agriculture, as an intervention to combat micronutrient deficiencies in populations. The purpose of the requested new work is to bring clarity to the subject of biofortification through the development of an internationally accepted definition for biofortification and/or biofortified food. The scope of the standard is a definition of biofortification and/or biofortified food that would apply to any food or food ingredient that fits the definition. The scope to be covered would be reflected in the definition.

**2. RELEVANCE AND TIMELINESS**

The use of biofortification as an effective nutritional intervention is now under discussion or implementation in many countries. With no international guideline, standard or reference to harmonise to, many different approaches will be taken.

**3. MAIN ASPECTS TO BE COVERED**

The main aspect to be covered is the establishment of a common definition for biofortification and/or biofortified food that could describe, or be used to determine appropriate descriptors for, the foods or ingredients so fortified or enhanced, taking into account the different processes applied. Another aspect is to ensure that the definition is sufficiently broad to cover the various organisms and methods of biofortification and sufficiently detailed to distinguish among them. Consideration should be given as to whether the definition should include an indication of the size of the change in nutrient required to be considered biofortified in order to guide further standard-setting.

It would be expected that once a definition is established it could be placed in the General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 09-1987), however, this would be a committee decision.

**4. ASSESSMENT AGAINST THE CRITERIA FOR THE ESTABLISHMENT OF WORK PRIORITIES****Criteria****General criterion**

Consumer protection from the point of view of health, food safety, ensuring fair practices in the food trade and taking into account the identified needs of developing countries.

Micronutrient deficiencies have been identified by the WHO as an issue of extreme concern, particularly in developing countries. To assist in reducing micronutrient deficiencies, Biofortified crops are currently being consumed. Without a definition of biofortification, it is difficult to establish a Strategic Country Framework in which biofortification policies can be developed.

Fair practices in food trade:

Once again, in the absence of internationally accepted standards, guidelines and recommendations, trading practices can become disorganized and non-compliant.

Food security:

To be truly food secure, a country must have available an adequate supply of safe and nutritious foods for its population. Biofortified staple food crops can make a considerable contribution to enhancing the nutritional quality of traditionally consumed foods.

**Criteria applicable to general subjects**

- (a) *Diversification of national legislations and apparent resultant or potential impediments to international trade*

The lack of a definition for biofortification could result in many differing definitions being developed for the purposes of inclusion in national legislation, regulations, protocols or guidelines. Lack of standardization could result in impediments to trade. Also there could be abuse by sellers who may make claims that their product is biofortified when it is not and there is no national legislation to protect the consumer.

- (b) *Scope of work and establishment of priorities between the various sections of the work.*

The scope of work at this point is of necessity limited to the establishment of a definition.

- (c) *Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body(ies)*

The World Organisation for Animal Health (OIE) will be considering the subject of biofortification as it relates to animal products during their upcoming commissions. High Selenium and omega-3 eggs are now being produced and consumed to address certain micronutrient deficiencies in human populations.

- (d) *Amenability of the subject of the proposal to standardization*

Once a definition is established the need for further work could be ascertained.

- (e) *Consideration of the global magnitude of the problem or issue*

Over 3 billion people worldwide are micronutrient malnourished with iron, zinc and vitamin A accounting for two thirds of early childhood deaths. Societal costs include learning disabilities among children, increased morbidity and mortality rates, lower worker productivity and high healthcare costs. All factors diminish human potential and national economic development (Welch, 2002 and Welch and Gordon, 2004). Biofortification can have a substantial positive influence on this global problem. As biofortification is implemented, foods produced will increasingly enter international trade requiring a common set of terms and a common understanding of the meaning of those terms used to describe both the raw and finished products.

## **5. RELEVANCE TO THE CODEX STRATEGIC OBJECTIVES**

The proposed work is in line with the Commission's mandate for the development of international standards, guidelines and other recommendations for protecting the health of consumers and ensuring fair practices in food trade. The new work proposal will contribute to:

Strategic Goal 1, Objective 1.2. -'Proactively identify emerging issues and Member needs and, where appropriate, develop relevant food standards'

The subject of biofortification has been clearly identified as an emerging issue of great importance for developing countries who are struggling with the health issue of reducing micronutrient malnutrition. Attention to the creation of a definition will be of great assistance in institutionalizing biofortification as a potentially powerful nutrition intervention.

Strategic Goal 3, Objective 3.1. – 'Increase the effective participation of developing countries in Codex'.

The Countries where biofortification is most needed are developing Countries. Discussions on biofortification have resulted in some cases in the formation of National Biofortification Committees. Often, this is resulting in having the departments of Agriculture and Health at the same table for the first time. The fact that biofortification is now tied into the Codex process has resulted in a much heightened level of awareness and appreciation for the Codex Alimentarius and its work. In many cases, this has served as an introduction to Codex Alimentarius.

## **6. RELATION BETWEEN THE PROPOSAL AND OTHER EXISTING CODEX DOCUMENTS**

The definition, once adopted, would be available for use as appropriate in future amendments of specific commodity standards as well as nutrition-related standards and guidelines.

## **7. REQUIREMENT FOR AND AVAILABILITY OF EXPERT SCIENTIFIC ADVICE**

No expert advice other than that which is to be found in the CCNFSDU is required at this time.

## **8. REQUIREMENT FOR TECHNICAL INPUT TO THE STANDARD FROM EXTERNAL BODIES**

No technical input other than that which is to be found in the CCNFSDU is required at this time.

## **9. PROPOSED TIME-LINE FOR COMPLETION OF THE NEW WORK**

- a. Start date: 2015
- b. Proposed date for adoption at Step 5: July 2016, however if this were to go through the accelerated step procedure, it might be possible to have adoption at Step 8 in July 2016
- c. The proposed date for adoption by the Commission: July 2016

References

Welch R.M (2002) Breeding Strategies for Biofortified Staple Plant Foods to Reduce Micronutrient Malnutrition Globally. *Journal of Nutrition*132(3): 4955-59

Welch R. M and Gordon R. D. (2004) Breeding for Micronutrients in Staple Food Crops from a Human Nutrition Perspective. *Journal of Experimental Botany*55(396): 353-364

APPENDIX VIII

**AMENDMENTS TO THE ADVISORY LIST OF NUTRIENT COMPOUNDS FOR USE IN FOODS FOR SPECIAL DIETARY USES INTENDED FOR INFANTS AND YOUNG CHILDREN (CAC/GL 10 - 1979)**

(for adoption at Step 5/8)

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

Nutrient Source	Purity Requirements by		Use in Codex Food Standards Applicable to Infants and Young Children					
	CAC <sup>1</sup>	international and/or national bodies	IF		FUF <sup>4</sup>	PCBF <sup>5</sup>	CBF <sup>6</sup>	FSMP <sup>7</sup> for infants and young children
			Sec. A <sup>2</sup>	Sec. B <sup>3</sup>				
<b>8. Source of Zinc (Zn)</b>								
8.8 zinc citrate (zinc citrate dihydrate or zinc citrate trihydrate)		USP	√	√	√	√	√	√

<sup>1</sup> CAC = Codex Alimentarius Commission

<sup>2</sup> IF Sect. A = Section A of the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants

<sup>3</sup> IF Sect. B = Section B of the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants

<sup>4</sup> FUF = Follow-up Formula

<sup>5</sup> PCBF = Processed Cereal Based Foods for Infants and Young Children

<sup>6</sup> CBF = Canned Baby Food

<sup>7</sup> FSMP = Food for Special Medical Purposes other than Infant Formula

## APPENDIX IX

## PROPOSAL TO ESTABLISH AN NRV-NCD FOR EPA AND DHA

## PROJECT DOCUMENT

**1. Purpose and Scope of the Standard**

The scope of the proposed new work is to develop and add a potential new Codex nutrient reference value (NRV) for omega 3 fatty acids based on docosahexaenoic acid (DHA) and eicosapentaenoic acid (EPA) intended for general population for labelling purpose in relation to the risk of Non-Communicable Diseases (NCD) in Section 3.4.4.2 of the *Guidelines on Nutrition Labelling (CAC/GL 2-1985)*.

**2. Relevance and Timeliness**

WHO, FAO and various other international / national bodies in recent years have published extensive researches and recommended intakes of DHA and EPA based omega-3 fatty acids for the population. These available data will contribute to developing an internationally harmonized NRV-NCD for such nutrient by the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU).

**3. Main Aspects to be Covered**

The main aspects to be covered under the proposed new work is to establish a new Codex NRV-NCD for omega-3 fatty acids based on DHA and EPA for the general population, and add to Section 3.4.4.2 of the *Guidelines on Nutrition Labelling (CAC/GL 2-1985)*.

**4. Assessment Against the *Criteria for the Establishment of Work Priorities***

The proposed work fulfills the criteria on consumer protection from the point of health, food safety, ensuring fair practices in the food trade and taking into account the identified needs of developing countries.

Strong scientific data has supported a primary prevention benefit for omega 3 fatty acids based on DHA and EPA relating to cardiovascular health for the general population. In addition, overwhelming scientific evidence justifies the establishment of an NRV-NCD for total EPA and DHA for general population and individuals at every stage of their life. In view of the fact that current intakes are low compared with the recommendations made to date, it is important to note that enormous public health benefits and significant medical cost savings would be expected to accrue from an NRV-NCD on these omega-3 fatty acids.

Furthermore, from a nutrition policy perspective, having an NRV-NCD for total EPA and DHA makes it part of an overall public health policy and allows intake values to be compared with the NRV-NCD to determine whether a given population is consuming the recommended intake. Having an NRV-NCD would help develop public health messages for which there is convincing evidence of the health-enhancing effects.

The proposed new work will also help develop an internationally harmonised nutrition labelling guideline for omega-3 fatty acid content in foods that will facilitate trade.

**5. Relevance to the Codex Strategic Objectives**

The proposed work will contribute to the following Codex strategic objectives in the Codex Strategic Plan 2014-2019:

Strategic Goal 1: Establish international food standards that address current and emerging food issues.

The proposed new work will help address the scientific evidence on the population health benefits brought by recommended dietary intake of omega-3 fatty acids.

Strategic Goal 2: Ensure consistent use of risk analysis principles and scientific advice.

The development of the new NRV-NCD will be consistent with the use of scientific advice and risk assessment principles. Scientific advice from FAO/WHO as well as other international / national scientific bodies (identified and summarised in Appendix 1 of the related discussion paper) will be considered.

**6. Information on the Relation Between the Proposal and other Existing Codex Documents**

The proposed new work is relevant to the *Guidelines on Nutrition Labelling (CAC/GL 2-1985)*, Section 3.4.4.2.

**7. Identification of any Requirement for and Availability of Expert Scientific Advice**

Available expert scientific advice has been identified in Appendix 1 of the related discussion paper.

**8. Identification of any Need for Technical Input to the Standard from External Bodies so that this can be Planned for**

No technical input from external bodies is foreseen at this moment.

**9. Proposed Timeline for completion of the new work, including the start date, the proposed date for adoption at Step 5, and the proposed date for adoption by the Commission; the time frame for developing a standard should not normally exceed five years**

- a) Approval of new work: 2015
- b) Start date: 2015
- c) Proposed date for adoption at step 5/8: 2016

## APPENDIX X

**AMENDMENTS TO THE CODEX STANDARD FOR FOODS FOR SPECIAL DIETARY  
USE FOR PERSONS INTOLERANT TO GLUTEN  
(CODEX STAN 118-1979)**

(for adoption)

**2.1.1 Gluten-free foods**

Gluten-free foods are dietary foods

a) consisting of or made only from one or more ingredients which do not contain wheat (i.e., all *Triticum* species, such as durum wheat, spelt, and khorasan wheat, which is also marketed under different trademarks such as KAMUT), rye, barley, oats<sup>1</sup> or their crossbred varieties, and the gluten level does not exceed 20 mg/kg in total, based on the food as sold or distributed to the consumer, and/or

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

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

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