



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 - www.codexalimentarius.org

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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 38th 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, **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 38TH 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 competence¹

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)²

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);

¹ CRD1

² 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)³

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)³

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).

³ 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)⁴

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:

⁴ 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)⁵

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).

⁵ 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 CCFSDU37.

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)⁶

84. The Chairperson recalled the in-depth discussion in the previous two CCFSDU 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 Committee⁷ 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)⁸

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,

⁶ 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).

⁷ REP14/NFSDU

⁸ 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)⁹

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.

⁹ 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 the 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)¹⁰

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

¹⁰ 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 38th 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)¹¹

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 36th Session and that such a proposal would take into consideration the outcome of the 6th 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 .

¹¹ 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)¹²

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)¹³**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

¹² 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)

¹³ 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 37th 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 & 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

**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

**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

**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

ANGOLA

Ms Maria Filomena FERNANDES DA MATA
1st Secretary of the Codex
Angola technical fisheries Ministry
ANGOLA
Email: 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

Mrs Victoria LANDELLS
Fonterra
AUSTRALIA
Email: victoria.landells@fonterra.com

Ms Melissa TOH
Regulatory Affairs and I&P Manager
Nestle Nutrition Oceania
AUSTRALIA
Email: 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

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

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

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

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

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

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

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

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

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

CHILE - CHILI

Ms Ana Cristina CANALES
Adviser
DIRECON
Santiago
CHILE
Email: 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

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

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

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

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

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

Ms Yiqin LIN
North Asia Regulatory Affairs Director
Mead Johnson Pediatric Nutrition Institute (China)
3rd 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

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

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

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

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

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

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

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

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

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

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

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

Dr Xuejun ZHAO
 Scientific and Regulatory Affairs Director
 Dumex Baby Food Co., Ltd
 The 3rd 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

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

COLOMBIA - COLOMBIE

Mrs Laura OTALORA
 Farmaceutica
 Industria
 Carrera 83 No. 71 - 81 piso 3
 Bogotá
 COLOMBIA
 Tel: 57316702781
 Email: 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

Mrs Amal Mohamed KISHK
 Agricultural Research Center
 Alexandria
 EGYPT
 Email: 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

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

Mr Francesco CARLUCCI
 Administrator
 European Commission
 DG SANCO
 B 232
 1049 Brussels
 BELGIUM
 Email: 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

Ms Ariane TITZ
 European Food Safety Authority (EFSA)
 Largo N. Palli 5/A
 I-43100 Parma – ITALY
 Email: 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

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

Dr Jolanta LEONE
 Regulatory
 DNA&O
 FRANCE
 Email: 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

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

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

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

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

GHANA

Mr Jacob AMOAKO-MENSAH
 Senior Regulatory Officer
 Food and Drugs Authority
 Food Safety
 GHANA
 Email: 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

Ms Marian GATIBA
 Regulatory Officer 1
 Food and Drugs Authority
 GHANA
 Email: 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

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

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

Mrs Latifah
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: 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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Dr Zakiyah
Head of Center for Standard Implementation System
National Standardization Agency of Indonesia
Manggala Wanabakti Block IV, 4th Floor, Jl. Jend. Gatot
Subroto, Senayan
10270 Jakarta
INDONESIA
Tel: 021-5747043
Fax: 021-5747045
Email: 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

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

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

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

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

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

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

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

Mr Benny KODYAT
Advisor
Indonesian Nutritionist Association
Kalibata City Sakura Apartement
Jakarta
INDONESIA
Tel: +62 81280376338
Email: 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

Mr Budi Djanu PURWANTO
Head of Law and Public Relation Burreau
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

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

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

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

Mrs Sri Irawati SUSALIT
Executive Director
APPNIA
Sovereign Plaza, 1st Floor
Jl. TB. Simatupang Kav. 36
12430 Jakarta
INDONESIA
Tel: +62 21 29400268
Fax: +62 21 29400270
Email: 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

Mrs Roch Ratri WANDANSARI
Regulatory Affairs
APPNIA
Sovereign Plaza 1st Floor
Jl. TB. Simatupang Kav. 36
12430 Jakarta
INDONESIA
Tel: +62 21 29400268
Fax: +62 21 29400270
Email: 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

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

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

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

Mr Gavino PERICU
AIIPA
ITALY
Email: gavino.pericu@danone.com

JAPAN - JAPON - JAPÓN

Mr Toshitaka MASUDA
(Head of Delegation)
Assistant Manager
Consumer Affairs Agency
Food Labelling Division
5th 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

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

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

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

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

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

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

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

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

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

LAO PEOPLE'S DEMOCRATIC REPUBLIC
 Email: 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

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

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

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

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

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

Ms Sarafhana DOLLAH
 Executive
 Malaysia Palm Oil Council
 2nd 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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Ms Beverly WATSON
 Nutrition & Regulatory Affairs Network Manager
 Fonterra
 NEW ZEALAND
 Email: 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

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

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

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

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: megesciott@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

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

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

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

Mrs Linda GRANLUND
 Director
 Helse og Ernæring i Mills
 Mills
 506 Oslo
 NORWAY
 Tel: 4799019418
 Email: 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

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,
 Dasmarias City, Cavite,
 PHILIPPINES
 Tel: (046) 5406990
 Fax: None
 Email: 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

**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

Mrs MISOON LEE
 D.V.M Ms
 Ministry of Food and Drug Safety
 Livestock Product Standard Division
 REPUBLIC OF KOREA
 Email: 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

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

Mrs MISUN PARK
 Scientific officer
 Ministry of Food and Drug Safety
 Food Standard Division
 REPUBLIC OF KOREA
 Email: 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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Dr Pichet ITKOR
Vice Chairman
Food Processing Industry Club, The Federation of Thai Industries
Queen Sirikit National Convention Center, Zone C 4th
Floor, 60 New Rachadapisek Rd., Klongtoey
10110 Bangkok
THAILAND
Tel: +66 (2) 725 1093
Fax: +66 (2) 725 1082
Email: 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 4th
Floor, 60 New Rachadapisek Rd., Klongtoey
10110 Bangkok
THAILAND
Tel: +66 (2) 657 5517
Fax: +66 (2) 657 4017
Email: 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

Dr Hataya KONGCHUNTUK RODBUMRUNG
Committee of Food Processing Industry Club
The Federation of Thai Industries
Queen Sirikit National Convention Center, Zone C 4th
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

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

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

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

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

Dr Akarat SUKSOMCHEEP
Committee of Food Processing Industry Club
The Federation of Thai Industries
Queen Sirikit Convention Center,
Zone C, 4th Floor
60 New Rachadapisek Road, Klongtoey
10110 Bangkok
THAILAND
Tel: +66 (8) 1830 0717
Email: 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

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

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

**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

**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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

ZIMBABWE

Mr Chinyavanhu FREDY
Ministry of Health and Childcare
P.O.Box CY231
Causeway
Harare
ZIMBABWE
Email: 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

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

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

CALORIE CONTROL COUNCIL (CCC)

Mr Ashley BETTERIDGE
Tate & Lyle
1 Kingsway
WC2B6AT
London
UNITED KINGDOM
Email: 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

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

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

EUROPEAN NETWORK OF CHILDBIRTH ASSOCIATIONS (ENCA)

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

Mr Jos VOSS
ENCA
Email: 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

Prof Stewart FORSYTH
Member
ELC
Email: 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

Mrs Uti DANIAWATI
FDE
Email: 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

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

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

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

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

Dr Tomoji IGARASHI
Member
IADSA
Email: 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

Mr Darwin LAI
Member
IADSA
50 Rue de l'Associations
B-1000 Brussels
BELGIUM
Tel: +32 2 209 11 55
Email: 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

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

Dr Nico RACZEK
 Member
 IADSA
 50 Rue de l'Association
 B-1000 Brussels
 BELGIUM
 Tel: +32 2 209 11 55
 Email: 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

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

Mr Kazuo SUEKI
 Member
 IADSA
 Email: 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

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

INTERNATIONAL BABY FOOD ACTION NETWORK (IBFAN)

Ms Adisti BAKRI
 AIMI
 Jakarta
 INDONESIA
 Email: adisti.bakri@bali.aimi-asi.org

Ms Joyce CHANETSA
 IBFAn Africa
 Email: ibfan.jchanetsa@realnet.co.sz

Mrs Elisabeth STERKEN
 INFAC Canada
 Email: 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

INTERNATIONAL COUNCIL OF BEVERAGES ASSOCIATIONS (ICBA)

Ms Helen FALCO
 Nutrition Advisor ICBA
 International Council of Beverages Associations
 1101 16th St NW
 20036 Washington
 UNITED STATES OF AMERICA
 Tel: +404-676-4344
 Email: 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

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

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

Ms Kristen SCOTT
 Senior Manager,
 ICGMA
 Health & Nutrition Policy
 Email: 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-12th Floor
 2-4-1, Shibakoen Minato-ku
 105-0011 Tokyo
 JAPAN
 Tel: +81 3 6402 1496
 Email: 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

Ms Luisa CANDIDO
 Nutrition and Technical Manager
 Dairy UK
 UNITED KINGDOM
 Email: lcandido@dairyUK.org

INTERNATIONAL FOOD POLICY RESEARCH INSTITUTE

Dr Erick BOY
 Head, Nutrition
 IFPRI
 HarvestPlus
 Email: 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

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

INTERNATIONAL LACTATION CONSULTANT ASSOCIATION (ILCA)

Mrs Maryse ARENDT
 Lactation Consultant IBCLC
 ILCA
 Email: 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

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

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

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

Ms Eva HURT
 Head
 Nestle
 Regulatory & Scientific Affairs, Asia
 15A Changi Business Park Central 1
 486035 Singapore
 SINGAPORE
 Email: 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

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

Ms Alicia NG
Regional Head
Nestle Health Science—AOA
Regulatory Affairs & Advocacy
15A Changi Business Park Central 1
#05-02/03 Eigthrium@Changi Business Park
486035 Singapore
SINGAPORE
Email: 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

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

Mr Min-Su TZENG
Associate Professor
Fu Jen Catholic University
Department of Nutritional Science
Email: 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: hvanucc@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

INTERNATIONAL SPECIAL DIETARY FOODS INDUSTRIES (ISDI)

Mrs Sandrine ALLONCLE
Regulatory Affairs Manager
ISDI
Email: secretariat@isdi.org

Mr Michael J BARRY
Senior regulatory affairs manager
Abbott
Email: secretariat@isdi.org

Ms Jan CAREY
Senior Manager - Regulatory affairs
ISDI
Email: secretariat@isdi.org

Mr Alejandro CASTRO III
Executive Director
IPNAP
Email: secretariat@isdi.org

Mr Todd CHERMAK
Divisional Vice President
Abbott
Abbott Nutrition Regulatory Affairs
Email: secretariat@isdi.org

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

Mrs Marie-Odile GAILING
Senior Scientific Officer
ISDI
Email: secretariat@isdi.org

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

Ms Vongsvat KOSULWAT
Nutrition Science Director-Asia Pacific
Mead Johnson Nutrition
Email: secretariat@isdi.org

Mrs Stephanie KRAMER-JUTANT
Regulatory Affairs Manager
ISDI
Email: secretariat@isdi.org

Mrs Venetta MIRANDA
Regulatory Affairs
ISDI
Email: secretariat@isdi.org

Ms Maria Olivia MISA-
Mijn
Email: secretariat@isdi.org

Mr Manfred RUTHSATZ
Global Head Regulatory Advocacy
Nestle
Email: secretariat@isdi.org

Mr Ricky SALVADOR
ISDI
Email: secretariat@isdi.org

Mr Jaap SCHRIJVER
Regulatory Affairs Manager Baby Foods Europe
Email: secretariat@isdi.org

Mrs Silvia SELANDARI
Policy Officer
ISDI
Email: secretariat@isdi.org

Ms Kelly SOWDEN
Regulatory Affairs Manager
Abbott
Email: secretariat@isdi.org

Ms Karin TAN
Regulatory Affairs Manager
Danone
Email: secretariat@isdi.org

Mr Andrew WONG
Regulatory Affairs Manager
Abbott
CHINA
Email: secretariat@isdi.org

Ms Dan YANG-
Nutricia
Email: secretariat@isdi.org

Ms Ziting ZHANG
Senior Government Affairs Desk Manager
European Union Chamber of Commerce in China
Email: 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

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

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

Ms Aurélie PERRICHET
SNE Delegation
Specialised Nutrition Europe (SNE)
1040 Brussels
BELGIUM
Tel: +32 2 508 10 74
Email: 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

Mr Louis VAREILLE
SNE Delegation
Specialised Nutrition Europe (SNE)
1040 Brussels
BELGIUM
Tel: +32 2 508 10 74
Email: 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

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

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

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

**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

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

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

**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

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

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
1: Establish international food standards that address current and emerging food issues.	1.1: Establish new and review existing Codex standards, based on priorities of the CAC.	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.	New or updated standards are developed in a timely manner.	- Priority setting criteria are reviewed, revised as required and applied. - # of standards revised and # of new standards developed based on these criteria.
<p>Question to the Committee:</p> <p>Is this activity relevant to the work of the Committee? <u>YES</u></p> <p>Does the Committee use any specific criteria for standards development?</p> <p><u>The Committee uses the criteria in the Procedural Manual, Criteria for the Establishment of Work Priorities, for standards development.</u></p> <p>Does the Committee intend to develop such criteria?</p> <p><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></p>				
	1.2: Proactively identify emerging issues and Member needs and, where appropriate, develop relevant food standards.	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.	Timely Codex response to emerging issues and to the needs of Members.	- 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>Question to the Committee:</p> <p>Is this activity relevant to the work of the Committee? <u>YES</u></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><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></p> <p><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></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"> - Input from committees identifying and prioritizing needs of Members. - Report to CCEXEC from committees on how standards developed address the needs of the Members as part of critical review process.
Included in question to 1.2.				
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"> - # of times the need for scientific advice is: <ul style="list-style-type: none"> - identified, - requested and, - utilized in a timely manner.
<p>Question to the Committee:</p> <p>Is this activity relevant to the work of the Committee? <u>YES</u></p> <p>Does the committee request scientific advice in course of its work, how often does it request such advice?</p> <p><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></p> <p>Does the committee always use the scientific advice, if not, why not?</p> <p><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></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"> - # of scientists and technical experts as part of Member delegations. - # of scientists and technical experts providing appropriate input to country positions.

Strategic Goal	Objective	Activity	Expected Outcome	Measurable Indicators/Outputs
		standards.		
<p>Question to the Committee:</p> <p>Is this activity relevant to the work of the Committee? <u>YES</u></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><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></p> <p>What guidance could be given by the Committee or FAO and WHO?</p> <p><u>The Committee does not believe that specific guidance is needed on this point.</u></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"> - # of committee documents identifying all relevant factors guiding risk management recommendations. - # of committee documents clearly reflecting how those relevant factors were considered in the context of standards development.
<p>Question to the Committee:</p> <p>Is this activity relevant to the work of the Committee? <u>YES</u></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><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></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>Question to the Committee:</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><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></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>Question to the Committee:</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><u>The Committee would recommend using as many languages as possible in WGs in order to enhance participation of members.</u></p> <p>What are the factors determining the choice of languages?</p> <p><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></p> <p>How could the situation be improved?</p> <p><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></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>Question to the Committee:</p> <p>Is this activity relevant to the work of the Committee? <u>YES</u></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"> - Baseline Ratio (%) established for documents distributed at least 2 months prior to versus less than 2 months prior to a scheduled meeting. - Factors that potentially delay the circulation of documents identified and addressed. - An increase in the ratio (%) of documents circulated 2 months or more prior to meetings.
<p>Question to the Committee:</p> <p>Is this activity relevant to the work of the Committee? <u>YES</u></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><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></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>Question to the Committee:</p> <p>Is this activity relevant to the work of the Committee?</p> <p><u>CCNFSDU already schedules Working Group meetings in conjunction with Committee meetings when necessary.</u></p> <p>Does the Committee hold physical working groups independent of Committee sessions? If yes – why is this necessary?</p> <p><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></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"> - Training material on guidance to achieve consensus developed and made available in the languages of the Commission to delegates. - Regular dissemination of existing material to Members through Codex Contact Points. - Delegate training programs held in association with Codex meetings. - Impediments to consensus being achieved in Codex identified and analyzed and additional guidance developed to address such impediments, if necessary.
<p>Question to the Committee:</p> <p>Is this activity relevant to the work of the Committee? <u>YES</u></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><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></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.¹

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 supplements², 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 nutrient³ 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 addition⁴ 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:

¹ 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.

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

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

⁴ 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 Intake⁵.

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.

⁵ 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 (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.

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-NCDIntake levels not to exceed

Saturated fatty acids	20 g ^{2, 3}
Sodium	2000 mg ⁴

Intake levels to achieve

Potassium	3500 mg ⁴
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³ 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.

⁴ 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.

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
4.1 Thickener		
1450	Starch sodium octenyl succinate	2 g in hydrolysed protein and/or amino acid based infant formula only
4.2 Emulsifier		
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 th 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 th meeting of JECFA (June 2014)	Maintain on the list; await final JECFA report
415	Xanthan gum	GMP	Retains homogeneity	30 th 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 th 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 ¹ or amino acids ¹	Retains homogeneity	49 th 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 th CCNFSDU
472e	Tartaric and fatty acid esters of glycerol	GMP (China) 0.5 g	Retains homogeneity	61 st 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 th 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 ₂ O ₅ 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 th 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	Vitamin E concentrate	1 mg in all types of infant formula singly or in combination	Protect from oxidation	Under this name and number not evaluated. 30th JECFA (1986) evaluated Tocopherol Concentrate, Mixed (INS 307b) synonym: Vitamin E	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)
308	Gamma tocopherol	1 mg in all types of infant formula singly or in combination	Protect from oxidation	Not evaluated by JECFA, no specifications available	Remove from the list, as the substances does not meet the minimum criteria of a JECFA evaluation and Codex specifications, not listed in GSFA
309	Delta tocopherol	1 mg in all types of infant formula singly or in combination	Protect from oxidation	Not evaluated by JECFA, no specifications available	Remove from the list, as the substances does not meet the minimum criteria of a JECFA evaluation and Codex specifications, not listed in GSFA

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

INS no.	Additive	Use level	Technological Justification	JECFA Status	Comments	Conclusion of 36 th CCNFSDU
Thickeners						
401	Sodium alginate	100 mg	Retains homogeneity	39 th 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 st JECFA (1993) , not specified	Not supported, no specific need for infant formula presented Need in specific formula for infants at ages > 12 months not to be discussed under this entry	Remove from the list, as the substance is not supported by any member/observer, no technological need.
410	Carob bean gum (Locust bean gum)	0.5 g	Retains homogeneity	25 th 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 th 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 th 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 th CCNFSDU
415	Xanthan gum	0.12 g	Retains homogeneity	30 th 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 th 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	Sodium carboxymethyl cellulose	1 g	Retains homogeneity	35th JECFA (1989), not specified	No strong support for compound, no commitment to support JECFA evaluation.	Remove from the list as substance is not supported significantly demonstrating limited technological need
Emulsifiers⁶						
474	Mono and diglycerides	0.5 g	Retains homogeneity	17th JECFA (1973), not specified	Supported by some members and observers	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
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.

⁶ 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 ¹	international and/or national bodies	IF		FUF ⁴	PCBF ⁵	CBF ⁶	FSMP ⁷ for infants and young children
			Sec. A ²	Sec. B ³				
8. Source of Zinc (Zn)								
8.8 zinc citrate (zinc citrate dihydrate or zinc citrate trihydrate)		USP	√	√	√	√	√	√

¹ CAC = Codex Alimentarius Commission

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

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

⁴ FUF = Follow-up Formula

⁵ PCBF = Processed Cereal Based Foods for Infants and Young Children

⁶ CBF = Canned Baby Food

⁷ FSMP = Food for Special Medical Purposes other than Infant Formula

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, oats¹ 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, oats¹ 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, oats¹ 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.