



**Food and Agriculture
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**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

REP14/CF

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

37th Session

Geneva, Switzerland, 14-18 July 2014

REPORT OF THE EIGHTH SESSION OF THE CODEX COMMITTEE ON CONTAMINANTS IN FOODS

The Hague, The Netherlands

31 March – 4 April 2014



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To: Codex Contact Points
Interested International Organisations

From: Secretariat,
Codex Alimentarius Commission,
Joint FAO/WHO Food Standards Programme,
Fax: +39 (06) 5705 3057
E-mail: codex@fao.org,
Viale delle Terme di Caracalla,
00153 Rome, Italy

Subject: DISTRIBUTION OF THE REPORT OF THE EIGHTH SESSION OF THE CODEX COMMITTEE ON CONTAMINANTS IN FOODS (REP14/CF)

The Report of the Eighth Session of the Codex Committee on Contaminants in Foods is attached. It will be considered by the Thirty-seventh Session of the Codex Alimentarius Commission (Geneva, Switzerland, 14 - 18 July 2014).

PART I: MATTERS FOR ADOPTION BY THE 37TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION

Proposed draft standards and related texts at Step 8 and 5/8 of the Procedure

1. **Proposed draft maximum levels for lead in infant formula and formula for special medical purposes intended for infants and follow up formula (as consumed)** (para 33, Appendix II);
2. **Proposed draft maximum level for inorganic arsenic in polished rice** (para 46, Appendix III);
3. **Proposed draft maximum levels for fumonisins in maize and maize products and associated sampling plans** (para 72, Appendix IV);
4. **Proposed draft Annex for the Prevention and Reduction of Aflatoxins and Ochratoxin A Contamination in Sorghum (Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals (CAC/RCP 51-2003))** (para 77, Appendix V); and
5. **Proposed draft Code of Practice for Weed Control to prevent and reduce Pyrrolizidine Alkaloid Contamination in Food and Feed** (para 83, Appendix VI).

Governments and international organisations wishing to submit comments on the above documents should do so in writing, in conformity with the *Procedures 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 above address, **before 15 June 2014**.

PART II: REQUEST FOR COMMENTS AND INFORMATION

6. **Priority list of contaminants and naturally occurring toxicants for evaluation by JECFA** (para 130, Appendix XIII).

The Priority List of Contaminants and Naturally Occurring Toxicants for Evaluation by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) has been endorsed by the Committee on Contaminants in Foods as indicated in para 130 and presented in Appendix XIII of this Report. Submission of comments and/or information is requested as follows:

- Comments on substances that are already included in the Priority List (information on data availability of those substances should also be submitted where applicable); and/or
- Nomination of new substances for the Priority List (information on details of new substances, expected timeline for data availability should also be submitted).

For the second bullet point, it is requested to fill in the form as contained in Appendix XIV of this Report.

Governments and international organisations wishing to submit comments and/or information on the Priority List of Contaminants and Naturally Occurring Toxicants for Evaluation by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) should do so in writing, **by e-mail**, to the above address, **before 15 January 2015**.

SUMMARY AND CONCLUSIONS

The Eighth Session of the Codex Committee on Contaminants in Foods reached the following conclusions:

MATTERS FOR ADOPTION/CONSIDERATION BY THE 37TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION

Proposed draft standards and related texts for adoption

The Committee agreed to forward:

- Proposed draft maximum levels for lead in infant formula and formula for special medical purposes intended for infants and follow up formula (para 33, Appendix II);
- Proposed draft maximum levels for inorganic arsenic in polished rice (para 46, Appendix III);
- Proposed draft maximum levels for fumonisins in maize and maize products and associated sampling plans (para 72, Appendix IV);
- Proposed draft Annex for the prevention and reduction of aflatoxins and ochratoxin A contamination in sorghum (*Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals* (CAC/RCP 51-2003)) (para 77, Appendix V);
- Proposed draft Code of Practice for Weed Control to prevent and reduce Pyrrolizidine Alkaloid Contamination in Food and Feed (para 83, Appendix VI); and
- Editorial amendments to the *General Standard for Contaminants and Toxins in Food and Feed* (CODEX STAN 193-1995) (para 92, Appendix VII).

New work

The Committee agreed to submit to the Commission, through the Executive Committee, the proposals for the following new work on:

- Code of Practice for the Prevention and Reduction of Arsenic Contamination in Rice (para 95, Appendix VIII);
- Revision of the *Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals* (para 99, Appendix IX);
- Maximum level for total aflatoxins in ready-to-eat peanuts and associated sampling plan (para 119, Appendix X); and
- Maximum levels for cadmium in chocolate and cocoa-derived products (para 142, Appendix XI).

Revocation of standards

- The Committee agreed to recommend the revocation of the maximum level of 0.02 mg/kg for lead in infant formula in the GSCTFF (para 34) and to request the Committee on Nutrition and Foods for Special Dietary Uses to remove this ML from the section on contaminants in the *Standard for Infant Formula and Formulas for Special Medical Purposes intended for Infants* (CODEX STAN 72-1981) and to make a reference to the *General Standard for Contaminants and Toxins in Food and Feed*.

Other matters

- The Committee agreed to recommend the removal of maximum levels for contaminants in the standards for “cooked cured chopped meat”, “cooked cured ham”, “cooked cured pork shoulder” “corned beef” and “luncheon meat” and to align the section on contaminants with the standard text for contaminants as provided in the Procedural Manual (para 92).

Matters of interest to the Codex Alimentarius Commission

The Committee:

- agreed to retain the current maximum levels for lead for assorted (sub)tropical fruits, edible peel, assorted (sub)tropical fruits, inedible peel, citrus fruits, pome fruits, stone fruits, bulb vegetables, leafy vegetables, root and tuber vegetables and secondary milk products together with their accompanying explanatory notes (para 21); and continue the consideration of the MLs for lead in selected fruits and vegetables and in fruit juices and nectars, canned fruits and canned vegetables (paras 23 – 27) at its next session;
- agreed to return the ML for arsenic in husked rice for redrafting, comments and consideration by its next session (para 47);
- agreed to hold the MLs for DON in cereals and cereal-based products (and associated sampling plans) at Step 7 (paras 57 – 59, Appendix XII) and that it was premature to extend any MLs for DON to its acetylated derivatives until further information became available (para 62);
- agreed to consider a guidance paper on submission and use of data from GEMS/Food and their use by working groups (paras 13 - 14); and to develop discussion papers on radionuclides (para 18); the phasing in of lower maximum levels (para 57); methylmercury in fish (para 114); and mycotoxin contamination in spices (paras 137 and 140); and that no further work would be undertaken on the establishment of maximum levels for aflatoxins in cereals for the timebeing while encouraging countries to submit data to GEMS/Food (para 103); and
- endorsed the *Priority list of contaminants and naturally occurring toxicants for JECFA evaluation* (para 130, Appendix VII).

Matters of interest to Codex committees and task forces

Committee on Fats and Oils (CCFO)

- The Committee agreed not to transfer the levels for halogenated solvents from the *Standard for Olive Oils and Pomace Oils* (CODEX STAN 33-1981) to the GSCTFF, and to recommend CCFO maintain these levels in CODEX STAN 33-1981 until more information on environmental contamination became available (para 124).

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INTRODUCTION

1. The Codex Committee on Contaminants in Foods (CCCF) held its 8th Session in The Hague (the Netherlands) from 31 March to 4 April 2014, at the kind invitation of the Government of the Netherlands. Dr Wieke Tas, Department of Animal Health and Market Access, Ministry of Economic Affairs, chaired the meeting. The Session was attended by 64 Member countries, 1 Member Organisation and 17 international organisations. The list of participants is given in Appendix I to this report.

OPENING OF THE SESSION

2. Mr Hans Hoogeveen, Director-General for Agriculture of the Ministry of Economic Affairs, opened the Session on behalf of the Government of the Netherlands.

Division of Competence¹

3. The Committee noted the division of competence between the European Union and its Member States, according to paragraph 5, Rule II of the Procedure of the Codex Alimentarius Commission, as presented in CRD 1. The Delegation of the European Union represented the 19 member states present at the session.

ADOPTION OF THE AGENDA (Agenda Item 1)²

4. The Committee adopted the Provisional Agenda as its Agenda for the Session with some rearrangements in the sequence of items scheduled for discussion to jointly address certain interrelated items.

MATTERS REFERRED TO THE COMMITTEE BY THE CODEX ALIMENTARIUS COMMISSION AND/OR ITS SUBSIDIARY BODIES (Agenda Item 2)³

5. The Committee noted matters for information and that matters for action would be considered under the relevant agenda items.

MATTERS OF INTEREST ARISING FROM FAO AND WHO (INCLUDING JECFA) (Agenda Item 3)⁴

6. The JECFA Secretariat informed the Committee on the outcome of the JECFA evaluation regarding the exposure assessment to cadmium from cocoa and cocoa products. In summary JECFA concluded that total cadmium exposure including for high consumers of cocoa and cocoa products was not considered to be of concern.

7. The Committee agreed to discuss the possible establishment of maximum levels (MLs) for cadmium in cocoa and cocoa products under Agenda Item 20 Other Business.

8. FAO and WHO representatives informed the Committee of progress on the FAO/WHO project on mycotoxins in sorghum funded by the Codex Trust Fund (CTF) and related to the on-going discussions in the Committee on the possible need for MLs. Sample collection from four countries (Sudan, Mali, Ethiopia and Burkino Faso) at three different periods: at harvest, immediately prior to the wet season and before yearly stocks end, had been finalised and samples from the first two collection periods were analysed for a large number of mycotoxins. Only a small number of samples were positive, with the following mycotoxins being most detected: aflatoxins, fumonisins, OTA, sterigmatocystin and diactoxyscirpenol. The two latter mycotoxins have not been evaluated by JECFA.

9. In addition, national value chain studies are being completed to enable an analysis of the linkage between mycotoxin occurrence levels and specific agro-ecological conditions and practices along the production chain. FAO and WHO acknowledged and thanked all contributors to the project, including the European Union funding, and noted the interest of participating countries to follow up on the project findings, and implement risk mitigation measures as appropriate.

10. A detailed report on all analytical results, statistical analysis and correlations between occurrence data and specific production conditions and practices along the sorghum chain will be presented at the next meeting of the Committee.

11. The Committee was informed about ongoing activities on capacity building and encouraged countries to review the information on FAO and WHO activities related to on-line sampling tools, risk analysis training materials, early warning and rapid alert systems.

12. The Committee was briefed on the International Workshop on Feed Risk Assessment for Chemicals organised by FAO and the Government of the Netherlands in September 2013. The purpose of this meeting was to conduct a first exploration of the state of the art in methods and tools for the risk assessment of chemicals in feed for farm animals, with a focus on possible health risks for consumers of animal products as well as for animal health and welfare. Preliminary results would be presented during the side event on feed safety and a summary with recommendations of the workshop would be distributed. The side event would be held during the CCCF to raise awareness on the importance of ensuring feed safety within the food production chain and to inform on FAO dedicated Capacity Development activities and initiatives.

¹ CRD 1.

² CX/CF 14/8/1; CRD 20 (Comments of Chile).

³ CX/CF 14/8/2.

⁴ CX/CF 14/8/3; CRD 29 (Summary of the side event on feed safety).

13. The Representative of WHO informed the Committee on new achievements of the GEMS/Food programme and emphasised the importance of linking this to the work of CCCF. Data collected by electronic working groups (EWGs) need to be included in the GEMS/food database and EWGs need to be able to extract and analyse data from this global database. In order to assure best linkage and assure consistent use of data the Representative of WHO recommended the elaboration of a guidance document for EWGs on submission and use of data from GEMS/Food.

14. The Committee agreed with this proposal and requested the GEMS/Food Secretariat to develop such a guidance paper, in collaboration with FAO and EWG chairs whose work includes data collection and analysis. The paper will be presented at the next meeting.

MATTERS OF INTEREST ARISING FROM OTHER INTERNATIONAL ORGANISATIONS (Agenda Item 4)⁵

15. The Representative of IAEA reported on the activities of IAEA relevant to the work of CCCF since the last session of the Committee.

16. In particular, the Representative noted IAEA's work on preparedness and response to nuclear and radiological emergencies affecting food and agriculture and the outcome of the Inter-Agency Working Group led by IAEA on the review of standards related to food and drinking (potable) water contaminated with radionuclides. The Representative indicated that, as regards work relevant to CCCF, the Inter-Agency Working Group concluded that there are no major gaps in the international standards for radionuclides in food and water, however, there are still some technical issues to be resolved such as (i) the stage of food production to which the Codex guideline levels apply, (ii) the period of time these GLs should apply in food trade following a nuclear or radiological emergency, (iii) the identification of internationally validated methods of analysis for radionuclides in foods and (iv) the development of sampling plans to enhance the implementation of the Codex GLs.

17. The Committee welcomed the information provided by the Representative of IAEA. As regards the outcome of the Inter-Agency Working Group, the Committee recalled the decision taken at its last session to discontinue work on the development of guidance to facilitate the interpretation and implementation of the GLs for radionuclides in food in the *General Standard for Contaminants and Toxins in Food and Feed* (CODEX STAN 193-1995) (GSCTFF) and that after completion of the work carried out by the Inter-Agency Working Group, the CCCF could decide to start new work on radionuclides as necessary.

Conclusion

18. In view of the above, the Committee agreed to establish an EWG led by the Netherlands and co-chaired by Japan, working in English only, to follow-up on the conclusions and recommendations of the Inter-Agency Working Group to determine the need and feasibility to pursue work on the matters raised in points (i) to (iv) of paragraph 16. The Committee further agreed to request the EWG to look into the opportunity to develop guidance to facilitate the interpretation and implementation of the GLs for radionuclides in food in the GSCTFF for consideration at its next session. If further work is identified, proposals e.g. analytical methods, sampling plans, guidance, should be presented for consideration by the Committee.

PROPOSED DRAFT REVISION OF MAXIMUM LEVELS FOR LEAD IN SELECTED COMMODITIES IN THE GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOOD AND FEED (Agenda Item 5)⁶

19. The Delegation of the United States of America introduced the document and reminded the Committee that the approach taken for the review of MLs for lead in the selected fresh fruits and vegetables, infant formula and secondary milk products followed the same approach taken for the review of MLs for other groups of processed foods considered in 2013 as indicated in paragraphs 8-12 of CX/CF 14/8/5.

20. The Committee noted that following the analysis of the occurrence data on lead in the selected commodities it was possible to lower MLs for some of them, but lowering the MLs for others would be more difficult. The Committee agreed to discuss the recommendations of the EWG as follows:

Commodities for which the current MLs in the GSCTFF are retained

21. The Committee noted wide support for the retention of the current MLs in the GSCTFF for "assorted (sub)tropical fruits, edible peel", "assorted(sub)tropical fruits, inedible peel", "citrus fruits", "pome fruits", "stone fruits", "bulb vegetables", "leafy vegetables", "root and tuber vegetables" and "secondary milk products" and therefore no further action needed to be taken in regard to these MLs. The Committee noted that retention of these MLs implied that the relevant accompanying explanatory notes should be retained.

⁵ CF/CF 14/8/4; CRD 3 (Comments of African Union).

⁶ CX/CF 14/8/5; CX/CF 14/8/5-Add.1 (Comments at Step 3 - Costa Rica, El Salvador, African Union and FoodDrinkEurope); CX/CF 14/8/5-Add.2 (Comments at Step 3 - European Union and United States of America); CRD 4 (Comments of Chile, Ghana, India, Indonesia, Malaysia, Russian Federation and Thailand).

Commodities for which revised MLs are proposed

Selected fresh fruits and vegetables – “berries and other small fruits”, “brassica vegetables”, “fruiting vegetables, cucurbits”, “fruiting vegetables other than cucurbits” and “legume vegetables”

22. The Committee noted that for the commodity group “berries and other small fruits” the proposed lower ML may be acceptable when applied to the occurrence data of this group as a whole. However, when the data are split into the individual species or varieties of berries and small fruits, the proposed reduction may be problematic for some berries such as cranberries, currants, elderberries and strawberry tree. Therefore, it was advisable to postpone the discussion of this ML until the 9th CCCF to allow interested countries to submit new or additional data to GEMS/Food for analysis on the understanding that if no data were made available, the Committee would accept the proposed lower ML for adoption at its 9th session. The Committee recalled that this approach was similar to the one taken on infant formula at its 8th Session.

23. The Committee noted several comments on the need to collect more occurrence data, in particular better distribution of data among regions, before proceeding with the revision of the MLs for those fresh fruits and vegetables for which lower MLs were proposed. The cut-off levels should be selected carefully especially when the occurrence data were not well geographically distributed. The Committee agreed to take the same approach as for “berries and other small fruits” and to encourage countries concerned to submit new or additional data on lead contamination in these commodities to GEMS/Food for further consideration in the EWG and finalisation by the 9th CCCF.

24. Considering that the next session will take place in mid-March 2015, data should be submitted to GEMS/Food by no later than mid-September 2014 in order to allow timely and adequate consideration of the data and to inform the Chair of the EWG accordingly. The Committee noted the commitment of a number of countries to submit data in this regard.

New work on fruits and vegetables – “dried fruits and vegetables” and “stalk/stem vegetables”

25. The Committee noted that in view of the significant amount of work still pending for review or finalisation by the 9th CCCF, it would be advisable not to take a decision on new work on these products until finalisation of work on existing MLs for fresh and processed fruits and vegetables.

Maximum levels for fruit juices and nectars (ready-to-drink); canned fruits and canned vegetables

26. The Committee recalled the decision of the Commission to adopt the proposed draft MLs for fruit juices and nectars (ready-to-drink), canned fruits and canned vegetables at Step 5 only, on the understanding that countries concerned with the proposed lower MLs would submit relevant data to GEMS/Food within a year to allow the 9th CCCF to reconsider these MLs for submission to the 38th CAC in 2015, and consequently all the current MLs for lead in the individual standards for canned fruits and vegetables were retained. Following the decision of the Commission, the Codex Secretariat issued a circular letter, CL 2013/23-CF, requesting countries to submit new or additional data on lead contamination in fruit juices and nectars, canned fruits and canned vegetables to GEMS/Food by no later than 31 July 2014.

27. In view of the above, the Committee agreed to request the EWG to also undertake the review of the data submitted on these products with a view to facilitating their discussion and finalisation at the 9th CCCF. The Committee further agreed that the EWG will be led by the United States of America and will be working in English only.

Infant Formula

28. The Committee recalled the decision taken at its 7th session to reconsider the ML for infant formula at its 8th session and to encourage countries to submit relevant data to GEMS/Foods in order to facilitate the finalisation at its next session and that if no additional data were made available it would consider the proposed lower ML for adoption to further ensure health protection of infants as they were within the most vulnerable groups to lead exposure. The Committee further recalled that no objections or reservations were recorded in relation to this decision.

29. The Chair of the EWG informed the Committee that new or additional data submitted did not significantly change the cut-off values for compliance with the proposed lower MLs (97% for the samples analysed in 2014 against 99% for samples analysed in 2013). Therefore, the proposed lower ML of 0.01 mg/kg as opposed to the current ML of 0.02 mg/kg would still provide some reduction in lead levels without having a negative impact on international trade. The Chair further explained that the ML of 0.01 mg/kg applied to the product “as consumed” and that this term refers to the “reconstituted” form when these products are prepared in accordance with the preparation instructions on the label.

30. In addition, the following views were noted: more representative data from other regions were necessary before proceeding with the finalisation of the MLs; infant formulas were products produced by a limited number of countries and data available represented those concerned countries trading these products; and consideration should be given to the fact that high levels of lead together with other contaminants added to the overall contamination of the product which is intended for one of the most vulnerable population groups, any efforts in lowering the ML should be made to ensure the safety of this product.

31. The Delegation of the European Union indicated that it could agree to an ML of 0.01 mg/kg for liquid infant formula but would reserve its position if the ML applied also to “powdered” infant formula “as consumed”, as the ML may not be appropriate to “powdered” formula depending on the conversion factors applied.

32. The Committee noted wide support for a more stringent ML of 0.01 mg/kg “as consumed” and therefore agreed to forward this ML to the Commission for adoption. The Delegations of the European Union and Norway expressed their reservation to this decision.

STATUS OF THE PROPOSED DRAFT MAXIMUM LEVEL FOR LEAD IN INFANT FORMULA AND FORMULA FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS AND FOLLOW UP FORMULA (AS CONSUMED)

33. The Committee agreed to forward the proposed draft ML for lead in infant formula and formula for special medical purposes intended for infants and follow up formula (as consumed) to Step 5/8 (with omission of Steps 6/7) for adoption by the 37th Session of the Commission (Appendix II).

34. In taking this decision, the Committee further agreed to request the Commission to revoke the current ML of 0.02 mg/kg for lead in infant formula in the GSCTFF and to request the Committee on Nutrition and Foods for Special Dietary Uses to remove this ML from the section on contaminants in the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CODEX STAN 72-1981) and instead to make reference to the *General Standard for Contaminants and Toxins in Food and Feed* (CODEX STAN 193-1995).

PROPOSED DRAFT MAXIMUM LEVELS FOR ARSENIC IN RICE (POLISHED AND HUSKED) (Agenda Item 6)⁷

35. The Delegation of China introduced the document and highlighted the main conclusions and recommendations regarding the establishment of MLs for inorganic arsenic in husked and polished rice as presented in Appendix I of CX/CF 14/8/6.

36. The Committee noted wide support for the establishment of MLs for inorganic arsenic in husked rice and polished rice. A few views were expressed to retain only the ML for polished rice as this was the main commodity traded internationally with a 79% share of the international market. Proposals were also made for an additional ML for rice-based products for infants and young children in view of the health risks associated with their consumption by this population group.

37. The Committee noted extensive support for an ML of 0.2 mg/kg of inorganic arsenic for polished rice and analysis for total arsenic as screening method. However, divergent views were expressed as to what the ML for husked rice should be in terms of protection of human health while not having a negative impact on international trade, in particular as rice was a major staple-food in Asian countries and the ML established may affect availability of rice. Possible levels discussed were 0.25 mg/kg, 0.3 mg/kg and the proposed ML of 0.4 mg/kg.

38. Delegations in support of an ML of 0.25 mg/kg indicated that the application of the ALARA principle on husked rice imported into their countries from rice-producing countries shows that this ML was technologically achievable.

39. Delegations in favour of an ML of 0.4 mg/kg indicated that this together with an ML of 0.2 mg/kg for polished rice contribute to a reduction of inorganic arsenic intake while at the same time the violation rates were relatively low (violation rates were 2.0% for polished rice at an ML of 0.2 mg/kg and 0.8% for husked rice at an ML of 0.4 mg/kg). Proposals for 0.25 or 0.3 mg/kg in husked rice contribute to the reduction of the intake of inorganic arsenic, however the violation rate was 5.2% at an ML of 0.3 mg/kg which was considered high by some delegations. Therefore proposals for lowering the ML below 0.4 mg/kg might be achievable and further reduce inorganic arsenic intake but could negatively affect trade and compromise food security. These delegations indicated that it was preferable to have an ML rather than none even if this ML resulted in exceedance in some of the GEMS/Food cluster diets but still provided an overall reduction in exposure to inorganic arsenic across the cluster. It was noted that proposals for MLs higher than those proposed for polished and husked rice, e.g. 0.3 mg/kg and 0.5 mg/kg, respectively, the violation rates were almost zero, but they did not contribute significantly to the reduction of inorganic arsenic intake. It was noted that 0.3 mg/kg for husked rice could be a compromise including the possibility to having an additional ML between 0.3 and 0.4 with violation rates of 2 – 3% in line with the principles for the establishment of MLs in the GSCTFF.

40. A proposal to defer the establishment of an ML for husked rice until more occurrence data based on the implementation of a code of practice (COP) to contain arsenic contamination be collected did not receive much support as the development and implementation of a COP would take some time, while measures should be taken by CCCF to reduce human health risk to inorganic arsenic exposure from both types of rice.

41. Another proposal to request JECFA to conduct an exposure assessment on the proposed MLs and other hypothetical MLs in order to determine the health risk associated with MLs lower or higher than 0.4 mg/kg was put forward. In this regard, the JECFA Secretariat clarified that the JECFA assessment resulted in identification of a health concern because estimated exposure from food and drinking water was close to a range of exposure from which health effects had been identified in epidemiological studies. Performing a quantitative risk assessment and estimating the reduction in cancer risk when different hypothetical MLs are enforced was possible, but based on the information included in the discussion paper, would most likely not lead to a measurable reduction in health risk at the proposed levels. Regarding health effects in children new data could be considered, but JECFA already concluded that despite limited data for infants and children exposure on a kg body weight basis is higher as compared to adults, hence any health concern might even be higher. Overall the outcome of such additional assessments might not help the discussion of the Committee.

⁷ CX/CF 14/8/6; CX/CF 14/8/6-Add.1 (Not issued); CRD 5 (Comments of Chile, Egypt, El Salvador, European Union, Ghana, India, Indonesia, Nicaragua, Nigeria, Philippines, Russian Federation, Thailand, United States of America, African Union and NHF).

Conclusion

42. The Committee could not reach agreement on an ML for husked rice. However, in view of the relevance of this matter for many Codex members, the Committee encouraged countries, especially rice-producing countries to submit data to GEMS/Food. Data submitted could then be considered in the EWG in order to facilitate the discussion of this matter at the 9th CCCF before taking a final decision on the feasibility to establish an ML for this product.

43. In view of this, the remaining recommendations on the development of a “polishing procedure” and the establishment of a worldwide “conversion factor” were not considered.

44. The Committee however noted the support for the establishment of an ML of 0.2 mg/kg for polished rice and agreed to forward this proposal to the Commission for adoption.

45. The Committee further agreed to re-establish the EWG led by China and co-chaired by Japan, working in English only, to prepare a proposed draft ML for husked rice for circulation and comments at Step 3 and further consideration by the 9th CCCF.

STATUS OF THE PROPOSED DRAFT MLs FOR ARSENIC IN RICE (HUSKED AND POLISHED)

46. The Committee agreed to forward the proposed draft ML for inorganic arsenic in polished rice to Step 5/8 (with omission of Steps 6/7) for adoption by the 37th Session of the Commission (Appendix III).

47. The Committee agreed to return the proposed draft ML for inorganic arsenic in husked rice to Step 2/3 for further elaboration in the EWG, circulation for comments at Step 3 and consideration at the next session of the Committee.

DRAFT MAXIMUM LEVELS FOR DEOXYNIVALENOL (DON) IN CEREALS AND CEREAL-BASED PRODUCTS AND ASSOCIATED SAMPLING PLANS (Agenda Item 7)⁸

48. The Committee recalled that MLs for DON in raw cereals (wheat, maize and barley) and associated sample plans; and MLs for flour, meal, semolina and flakes derived from wheat, maize or barley were forwarded to Step 5, while an ML for cereal-based foods for infants and young children was forwarded to Step 5/8 for adoption by the 36th Session of the Commission. The Commission had adopted all the MLs at Step 5 and required clarification on whether the ML for cereal-based foods for infants and young children applied to the product “as consumed” or “on a dry matter basis”. In addition, CCMAS had not endorsed the sampling plans, nor the methods criteria and had requested further clarification on certain aspects of the sampling plans (see Agenda Item 2).

MLs for raw cereal grains (wheat, maize and barley) and flour, meal, semolina and flakes derived from wheat, maize or barley

49. There were varying views on the commodities for which MLs should be set: support for both MLs; support only for the ML for the flour, meal, semolina and flakes derived from wheat, maize or barley; support for a different ML for flour, meal, semolina and flakes from wheat; or completely different MLs for all the categories.

50. Those in support of the ML of 2 mg/kg for raw cereal grains expressed the view that MLs were necessary as these cereal grains were widely traded, but that clarification was needed on the description of the products to which they applied. For example, whether the MLs for the raw cereal grains should apply to the product prior to or after sorting, and whether wheat referred to only common wheat, or also durum, spelt and emmer. Also it would be important to stipulate that the ML for raw cereal grains would apply to grains for human consumption and not for animal feed.

51. Those in support of only establishing MLs for the flour, meal, semolina and flakes derived from wheat, maize or barley were of the opinion that if MLs were set for these products, an ML for the raw cereal grains was not necessary as milling could reduce DON levels and could be trade restrictive and negatively impact global food supply, and thus food security. The latter would be particularly the case in years where climatic conditions were favourable for high prevalence of DON.

52. Proposals were made for a lower ML for flour, meal, semolina and flakes derived from wheat for consumer health protection, as the proposed ML of 1 mg/kg would not guarantee safety, taking into account high consumption of these products in certain regions. Proposals were made for 0.75 mg/kg as well as 0.5 mg/kg.

53. Noting the diverse views on the MLs and that no conclusion or agreement could be reached, discussion was not considered necessary on the sampling plans.

MLs for cereal-based foods for infants and young children

54. There was general agreement that the ML should apply to the product on a “dry matter basis”, however, agreement could not be reached on the appropriate ML.

⁸ REP13/CF Appendix II; CX/CF 14/8/7 (Comments at Step 6 – Brazil, Costa Rica, Japan and Kenya); CX/CF 14/8/7-Add.1 (El Salvador, European Union, Nicaragua, Nigeria, Norway, African Union and IFFA); CRD 6 (Comments of Chile, Egypt, Ghana, Japan, Malaysia, Russian Federation, Thailand and United States of America); CRD 21 (Comments of Canada).

55. There was support for the level of 0.2 mg/kg as agreed at the last session of the Committee, as these products were intended for a very vulnerable group, the ML should be set as low as possible and data had shown that the level of 0.2 mg/kg was achievable. However, proposals were also made to consider the level of 0.5 mg/kg as originally proposed to the 6th CCCF, since this level was based on the outcomes of the 72nd JECFA meeting which had concluded that 0.5 mg/kg for DON was sufficiently protective of human health relative to acute health risks and that lower MLs would not result in any additional risk reduction; and that there was uncertainty whether a lower level of 0.2 mg/kg was readily achievable by industry as the data on which that level was based were mainly sourced from European countries, where a level of 0.2 mg/kg had been in place for some time. Other views expressed were that the level of 0.2 mg/kg “as consumed” which corresponded to 1 mg/kg “on dry matter basis” was too high and that it was necessary to lower the level to give extra protection to the vulnerable group of consumers, namely, infants and young children, as there was reason to be concerned about the intake of DON in infants and young children, in accordance with conclusions of the Norwegian Scientific Committee for Food Safety.

56. The Representative of JECFA explained that JECFA had identified exceedances of the PMTDI at high consumption levels in several age groups and geographic regions. Children are particularly susceptible to the effects of DON and limiting exposure would be important from a public health point of view.

57. In light of the lack of agreement the WHO Representative suggested that there might be a need to explore additional ways of developing MLs, such as phasing in of lower MLs over a defined period of time. The Representative suggested that FAO and WHO together with the Codex Secretariat prepare a discussion paper for consideration at the next session of the Committee laying out a process for such an approach, which might then help to find agreement on MLs for several contaminants over a defined period of time. Consideration would be given to implications of such an approach under the WTO-SPS Agreement, codes of practice, Codex rules and procedures and other relevant aspects.

Conclusion

58. The Committee noted that it was not possible to reach agreement on the MLs for raw cereal grains (wheat, maize and barley); flour, meal, semolina and flakes derived from wheat, maize or barley, nor for the ML for cereal-based foods for infants and young children and agreed to hold the MLs at Step 7 for consideration at the next session of the Committee in light of the discussion paper to be developed by FAO, WHO and the Codex Secretariat. The Committee agreed that the ML for cereal-based foods should be set on a “dry matter basis”.

STATUS OF THE DRAFT MAXIMUM LEVELS FOR DEOXYNIVALENOL (DON) IN CEREALS AND CEREAL-BASED PRODUCTS AND ASSOCIATED SAMPLING PLANS

59. The Committee agreed to hold at Step 7 the draft MLs for raw cereal grains (wheat, maize and barley); flour, meal, semolina and flakes derived from wheat, maize or barley; and cereal-based foods for infants and young children and associated sampling plans (Appendix XII).

PROPOSED DRAFT MAXIMUM LEVELS FOR ACETYLATED DERIVATIVES (DON) IN CEREALS AND CEREAL-BASED PRODUCTS (Agenda Item 8)⁹

60. The Delegation of Canada introduced the document and concluded that the ML for DON should be extended to its acetylated derivatives, but noted that it might be premature to consider the extension of the proposed MLs for DON to its acetylated derivatives at this time as the limited available occurrence data showed that acetylated derivatives account for a small fraction of overall DON, and that there was a need for further collection of more occurrence data to demonstrate that acetylated DON concentrations have a significant impact on total DON concentrations in cereals and cereal products. It was, however, also noted that there was still a lack of an internationally validated method of analysis for these derivatives.

61. The Committee, noting the decision taken on MLs for DON (Agenda Item 7) and the conclusions of the EWG, agreed that it was premature to continue with work on the extension of the MLs for DON in cereals and cereal products to its acetylated derivatives. The Committee encouraged members to continue collecting and submitting data on occurrence of acetylated DON to GEMS/Food and noted the need for development of an internationally validated method for analysis of acetylated DON.

Conclusion

62. The Committee agreed that no further consideration would be given to acetylated derivatives of DON as a separate item, but that when further information became available, it could be considered as part of the discussion on the MLs for DON in cereals and cereal-based products.

⁹ CX/CF 14/8/8(Rev); CX/CF 14/8/8-Add.1 (Not issued); CRD 7 (Comments of Chile, Egypt, European Union, Ghana, India, Russian Federation, Thailand, United States of America and African Union).

PROPOSED DRAFT MAXIMUM LEVELS FOR FUMONISINS IN MAIZE AND MAIZE PRODUCTS AND ASSOCIATED SAMPLING PLANS (Agenda Item 9)¹⁰

63. The Delegation of Brazil introduced the document and explained that it was an update of the paper presented to the 6th CCCF in light of written comments received and that three points were considered: the concept that the product to which the MLs apply should be clearly defined; the fact that fumonisins are not carried over from feed to animal products; and the need for harmonizing the sampling plans for fumonisins and DON in maize. The Delegation highlighted the conclusions and recommendations as presented in Appendix I of CX/CF 14/8/9 and noted that unprocessed maize grain included grain intended for human consumption and that a note to this effect had been added to the presentation of the ML. The Delegation also pointed out that further consideration should be given to whether to refer to raw maize grain or unprocessed maize grain, but that the ML as proposed applied to the commodity as traded. The MLs as proposed provided a balance between providing appropriate consumer health protection while avoiding undue rejections of maize and maize products and thus impacting food security.

Maize grain unprocessed

64. African delegations indicated that the establishment of MLs for maize was long overdue and necessary to protect consumer health, especially since maize was a staple food in most parts of the continent. These delegations however could not support the proposed ML of 5 000 µg/kg as this would not be health protective. It was explained that in most parts of Africa, around 400 to 500 g of maize were consumed on a daily basis. Furthermore, while acknowledging that there were methods for reducing fumonisin levels, such as milling, it was necessary to recognise that in many parts of the continent there were no sophisticated milling industries to achieve this. However, noting that an ML was necessary and in the spirit of compromise, these delegations could support a level of 4 000 µg/kg and proposed that consideration be given to including a footnote to this ML to clarify that African countries could set lower MLs for human health protection.

65. There was support for the proposal of 4 000 µg/kg and that this would apply to raw maize grain. It was however noted that a footnote would not be necessary as countries could establish lower MLs if there was justification for this.

66. In addition, it was agreed that a note "intended for human consumption" was not necessary, as GSCTFF clearly stated that MLs applied to foods intended for human consumption, unless otherwise stated (see Agenda Item 12).

Maize flour/meal

67. There was wide support for the proposed ML of 2 000 µg/kg for maize flour and maize meal. African delegations, however, proposed an ML of 1 000 µg/kg for similar reasons as indicated in the discussion on the raw maize grains, and in addition these delegations questioned whether data from Africa had been considered. Further questions were raised on the cluster diets, noting that it wasn't necessarily reflective of actual dietary intake in many countries.

68. The JECFA Secretariat clarified that JECFA had undertaken an impact assessment of the different proposed MLs and that the different estimated exposures between the MLs of 2 000 and 1 000 µg/kg would be very low, however the rejection rate was very different. So aspects of food security and food safety had to be carefully considered and balanced. Moreover, in JECFA's analyses the highest daily average consumption applied from one of the GEMS/Food cluster diets was about 300 g of maize per person per day, and overall 11% of the samples considered were from African countries (over 12 000 samples).

69. In noting the need for the ML and progress on this work, and in the spirit of compromise, African delegations, while having a preference for 1 000 µg/kg, agreed to the ML of 2 000 µg/kg.

Sampling Plans

70. The Committee noted that the sampling plans were based on OC curves derived for MLs of 2 000 and 5 000 µg/kg, but that the sampling plan for raw maize grain was not expected to change with the change in ML for these products, and agreed to the sampling plans as proposed for both the raw maize grains and the maize flour and maize meal. It was noted that the issues raised by Committee on Methods of Analysis and Sampling on the sampling plans for DON did not apply to these sampling plans.

Conclusion

71. Noting that there were no outstanding issues on the MLs and sampling plans, the Committee agreed that the ML of 4 000 µg/kg for raw cereal grains and 2 000 µg/kg for maize flour and maize meal were ready for adoption by the Commission. In relation to the ML for maize flour and maize meal, the Committee agreed that these would be advanced for adoption with the understanding that exposure and impact assessment should be undertaken by JECFA within three years for reconsideration of the levels.

¹⁰ CX/CF 14/8/9; CX/CF 14/8/9-Add.1 (Comments at Step 3 – European Union, Japan, Republic of Korea and African Union); CX/CF 14/8/9-Add.2 (Comments of El Salvador, Nigeria and United States of America); CRD 8 (Comments of Chile, Egypt, Ghana, India, Indonesia, Japan and Russian Federation).

STATUS OF THE PROPOSED DRAFT MAXIMUM LEVELS FOR FUMONISINS IN MAIZE AND MAIZE PRODUCTS AND ASSOCIATED SAMPLING PLANS

72. The Committee agreed to forward the proposed draft MLs with associated sampling plans to Step 5/8 (with omission of Steps 6/7) for adoption by the 37th Session of the Commission (Appendix IV). The sampling plans would be sent for endorsement by CCMAS.

PROPOSED DRAFT ANNEX FOR THE PREVENTION AND REDUCTION OF AFLATOXINS AND OCHRATOXIN A CONTAMINATION IN SORGHUM (CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF MYCOTOXIN CONTAMINATION IN CEREALS (CAC/RCP 51-2003) (Agenda Item 10)¹¹

73. The Delegation of Nigeria introduced the report of the EWG and highlighted that the EWG had taken into account the recommendations of the last session of the Committee to delete those measures which were too restrictive; to add measures that are effective on large-scale; and in the preparation of the annex had taken into account the work of other working groups on the revision of the *Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals* and the discussion paper on aflatoxins. In order to facilitate discussion in the Committee, the Delegation had prepared a further revised draft annex taking up the written comments received, which related mainly to linguistic corrections, the need for the annex to be consistent with the COP and removal of texts or flow charts which were already covered by the main text in the COP, and since sorghum was not only used for African traditional beer, but also other beers, this was deleted.

74. The Delegation of Brazil as lead of the EWG on the possible revision of the *Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals* (Agenda item 14) proposed that the critical points covered in the annex for the control of aflatoxins and OTA in sorghum should be integrated in the revision of the COP, especially since an annex on aflatoxins was being proposed as part of this revision exercise.

75. However, there was general support to finalise the annex and to advance it for adoption by the Commission, acknowledging the considerable work already undertaken and that there were no further need for changes. Finalisation of this annex would provide guidance to countries on measures to prevent or reduce aflatoxins and OTA in sorghum while the revision of the COP was underway. Consideration could still be given to the integration of the adopted annex into the revision of the COP after adoption.

Conclusion

76. The Committee agreed that in view of the considerable progress made on the annex that it would be advanced for adoption, with an amendment to paragraph 10 to indicate that the harvest product addressed in this paragraph referred to those produce with high moisture content, with the understanding that the annex would be integrated into the COP and its annexes in the new work on the revision of the COP (Agenda Item 14).

STATUS OF THE PROPOSED DRAFT ANNEX FOR THE PREVENTION AND REDUCTION OF AFLATOXINS AND OCHRATOXIN A CONTAMINATION IN SORGHUM (Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals)

77. The Committee agreed to forward the proposed draft Annex to Step 5/8 (with the omission of Steps 7) for adoption by the 37th Session of the Commission (Appendix V).

PROPOSED DRAFT CODE OF PRACTICE FOR WEED CONTROL TO PREVENT AND REDUCE PYRROLIZIDINE ALKALOID CONTAMINATION IN FOOD AND FEED (Agenda Item 11)¹²

78. The Delegation of the Netherlands introduced the revised document and referred to the structure of the COP based on management practices with sub-sections for specific measures applicable to different land types. A non-exhaustive list of PA-containing plants was considered useful to assist national authorities in the identification of local plants that could be targeted for weed control and therefore a reference was made to Annex I of CX/CF 11/15/14 in the COP. The Delegation further introduced CRD 27 containing a revised version of the COP addressing written comments submitted to this session that provide for consistency and further clarity in the provisions of the COP.

79. The Committee noted wide support for the availability of a list of PA-containing plants that should be maintained and regularly updated with inputs from Codex members and that it would be preferable to include or reference that list in the COP. The Committee noted that such an approach was not encouraged in Codex due to the difficulty to maintain and update such lists. However the Committee on General Principles was considering how best to make available such supportive documents in Codex.

80. The Committee agreed that for the time-being it would keep the reference to the non-exhaustive list of PA-containing plants (Annex I of CX/CF 11/15/14) in the report for further consultation noting that reports of Codex committee meetings' are available to Codex members and the general public on the Codex website. Consequently, the reference to this list was removed from the COP.

¹¹ CX/CF 14/8/10; CX/CF 14/8/10-Add.1 (Comments at Step 3 – Costa Rica, El Salvador, European Union, Japan, Republic of Korea and African Union); CX/CF 14/8/10-Add.2 (Comments at Step 3 – Nigeria and United States of America); CRD 18 (Comments of Chile, Egypt, Ghana and Russian Federation); CRD 24 (revised Annex 5 – Prevention and reduction of aflatoxins and ochratoxin A in sorghum and sorghum products prepared by Nigeria).

¹² CF/CF 14/8/11; CX/CF 14/8/11-Add.1 (Comments of Costa Rica and African Union); CX/CF 14/8/11-Add.2 (Comments of European Union and United States of America); CRD 19 (Comments of Chile, Egypt, Ghana, India and Russian Federation); CRD 27 (revised Code of practice for weed control to prevent and reduce pyrrolizidine alkaloid contamination in food and feed prepared by the Netherlands).

81. The Committee further amended paragraph 42 regarding the application of antimethanogenic therapy in ruminants to clarify that the use of this therapy with bacteria might increase ruminant resistance to PA toxicity.

Conclusion

82. The Committee agreed with the document as presented in CRD 27 with the additional amendments indicated above.

STATUS OF THE PROPOSED DRAFT CODE OF PRACTICE FOR WEED CONTROL TO PREVENT AND REDUCE PYRROLIZIDINE ALKALOID CONTAMINATION IN FOOD AND FEED

83. The Committee agreed to forward the proposed draft COP to Step 5/8 (with omission of Steps 6/7) for adoption by the 37th Session of the Commission (Appendix VI).

EDITORIAL AMENDMENTS TO THE *GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOOD AND FEED* (CODEX STAN 193-1995) (Agenda Item 12)¹³

84. The Delegation of the European Union introduced the document outlining the editorial amendments made to the GSCTFF and the rationale for such adjustments. The Delegation noted that the proposed changes did not entail changes in the content of the Standard but were limited to editorial revisions following discontinuation of use of commodity codes of the *Classification of Foods and Animal Feeds* (CAC/MISC 4-1993).

85. The Delegation further noted that following the adoption of the revised definition of “contaminant” to include a reference to “feed”, the EWG considered a request from the Commission to look into the relevant sections of the GSCTFF e.g. sections 1.1 (scope) and 1.2.2 (list of substances that meet the definition of contaminants) to fix any possible discrepancy in relation to the revised definition including the issue that feed additives / feed additive residues be excluded from the definition of “contaminants” and to this end, sections 1.1 and 1.2.2 were amended accordingly as shown in CX/CF 14/8/12.

86. The Delegation drew the attention of the Committee to a number of pending matters for consideration by CCCF as highlighted in the “points of discussion” and recommended to focus the debate on these points in order to complete work on the editorial amendments to the GSCTFF.

87. The Committee agreed with this recommendation and considered the issues of keeping (i) short information notes on the substance at the end of the provisions on contaminants in Schedule I, (ii) scientific references and (iii) operating characteristic curves (OC curves) in the sampling plans. The Committee noted views in favour of retaining such information as being useful to facilitate the understanding and application of the provisions in the GSCTFF and as they were adopted as such by the Commission. Other views supported the deletion of this information, as they were not essential for the application of the provisions in the GSCTFF and could therefore be kept in a separate document available for consultation by CCCF and Codex members. In addition, some of this information was relevant for the development and agreement of the provisions but they were no longer necessary once the provisions had been adopted by the Commission.

88. The Codex Secretariat indicated that use of scientific and technical references in Codex standards and related texts should be avoided as much as possible as scientific facts became outdated while Codex standards and related texts, once adopted, stayed for some time and it was difficult to update scientific references regularly. The Secretariat further noted that Codex standards, although of voluntary nature, could be taken up into national or regional regulations and become mandatory, in addition, Codex standards are benchmark standards under the WTO/SPS Agreement and could be used as reference in trade dispute settlements, therefore, due consideration should be given to limiting information in the Standard to the extent possible and necessary to fit the purposes of the GSCTFF as to the application of maximum levels (MLs) or guideline levels (GLs).

89. Based on the above considerations, the Committee agreed to delete the information indicated in points (i) to (iii) of paragraph 87. The Committee however noted that the information notes for the GLs for radionuclides in food should be kept in the GSCTFF as integral to the implementation of the GLs. The Committee further agreed that all information that is deleted would be transferred to INF 1 containing extensive supplemental information in support of the provisions in the GSCTFF. How to make this document available would depend on the outcome of the discussion in CCGP on how to make available supportive/explanatory documents on the Codex website. The Committee agreed to establish an in-session Working Group, chaired by the European Union, to make the changes on the basis of the decision taken by the Committee in points (i) to (iii) and to further discuss the pending issues related to the editorial amendments of the GSCTFF.

¹³ CF/CF 14/8/12; CX/CF 14/8/12-Add.1 (Not issued); CRD 9 (Comments of Chile, European Union, Ghana, India, Indonesia, Japan and Russian Federation); CRD 28 (Report of the in-session working group on editorial amendments to the GSCTFF prepared by the European Union).

90. The Delegation of the European Union introduced CRD 28 containing an outline of the editorial amendments following the decision of the Committee to delete the information notes, scientific references and OC curves in the GSCTFF and, in addition, informed the Committee of the agreements achieved in the in-session WG as follows: the inclusion of provisions to clarify how to reference Codex standards when the application of the ML matches the scope of the standard or covers other relevant non-standardised products and that a full description of the product under the column notes/remarks will be given as necessary; the *Classification of Foods and Animal Feeds* allocates different inter-related codes to “wheat”, “durum wheat”, “spelt” and “emmer” and therefore there was some doubt to which extent the term “wheat” covered also “durum wheat, spelt and emmer”. After discussion it was agreed that for the purpose of setting MLs for wheat in the GSCTFF, the term “wheat” encompasses all the aforesaid terms; to refer “preserved” tomatoes to CODEX STAN 13-1981; to limit the scope of the ML for lead to jams and jellies and not to include marmalades in line with the provisions adopted in Codex; in addition to “infant formula” to include reference to “formula for special medical purposes intended for infants” as CODEX STAN 72-1981 provides that the same ML applies to both products; to delete the reference to “whole commodity” in the GLs for radionuclides as this was not provided for in the adopted provisions; other editorial amendments to simplify the information given under Notes/Remarks and consistency with provisions in the GSCTFF or commodity standards were also introduced. The Delegation reasserted the fact that additional changes made in the in-session WG following the pending issues identified in CX/CF 14/8/12 and based on the written comments submitted in CRD 9 were of editorial nature only and in accordance with the decision taken in plenary for the removal of the information notes, scientific references and OC curves.

91. The Committee agreed with the changes proposed by the in-session WG and in addition agreed to amend the definition for tree nuts “ready-to-eat” and dried figs “ready-to-eat” to provide further clarification on the description of the products they apply to and that this definition would also apply to peanuts (see Agenda Item 17) and that concentration factors should apply to milks when an ML was established in the GSCTFF for consistency with provisions in this regard. The Committee noted that MLs for contaminants in a number of standards related to meat had already been updated or transferred to the GSCTFF and therefore they should be removed from the corresponding commodity standards while aligning the section on contaminants with the standard text in the Procedural Manual. The Committee further noted that MLs apply to food unless otherwise stated and there was no need to make specific entries related to the use for human consumption.

Conclusion

92. The Committee agreed to forward the editorial amendments to the GSCTFF for adoption (Appendix VII) and to request the Commission to remove the MLs for contaminants in the standards for “cooked cured chopped meat”, “cooked cured ham”, “cooked cured pork shoulder” “corned beef” and “luncheon meat” and to align the section on contaminants with the standard text for contaminants as provided in the Procedural Manual.

DISCUSSION PAPER ON THE DEVELOPMENT OF A CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF ARSENIC CONTAMINATION IN RICE (Agenda Item 13)¹⁴

93. The Delegation of China introduced the document and noted that the conclusions and recommendations laid down in Appendix I to CX/CF 14/8/13 indicated that there are risk management measures that are readily available to prevent and reduce arsenic contamination in rice and they could provide the basis for a preliminary development of a COP. In this regard, based on all the available data and information, source directed measures, processing and cooking, agricultural measures such as control of water irrigation and selection of cultivars were identified to be readily available for preventing and reducing arsenic contamination in rice. Other measures related to the use of soil amendments and fertilizers as well as those listed in paragraph 5 CX/CF 14/8/5, Appendix I required further data and information to support their inclusion in the COP.

94. The Committee noted wide support for the development of the COP as supportive for the implementation of the MLs. A proposal however was made that current available management practices for containing arsenic contamination in rice mainly relate to source directed measures and whether it would be more appropriate to revise the *Code of Practice for Source Directed Measures* (CAC/RCP 49-2001) to address measures to reduce arsenic contamination rather than proceeding with the development of a separate COP at this point in time. In this regard, it was noted that although most of the management measures readily available at present mainly refer to source directed measures, other management measures were also available and relevant and should be included in the COP.

Conclusion

95. The Committee agreed to initiate new work on a Code of Practice for the Prevention and Reduction of Arsenic Contamination in Rice for approval by the 37th Session of the Commission (Appendix VIII).

96. The Committee agreed to establish an EWG, led by Japan and co-chaired by China, and working in English only, to develop the COP for comments at Step 3 and consideration at the next session of the Committee.

¹⁴ CX/CF 14/8/13; CRD 10 (Comments of Chile, Egypt, European Union, Ghana, India, Nicaragua, Nigeria, Philippines, Russian Federation, Thailand, United States of America and African Union); CRD 23 (Project document on new work on a Code of practice for the prevention and reduction of arsenic contamination in rice prepared by Japan).

DISCUSSION PAPER ON THE POSSIBLE REVISION OF THE CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF MYCOTOXIN CONTAMINATION IN CEREALS (CAC/RCP 51-2003) (Agenda Item 14)¹⁵

97. The Delegation of Brazil introduced the document and informed the Committee that in undertaking this work consideration had been given to the work on the Annex for the Prevention and Reduction of Aflatoxins and OTA in Sorghum. The Delegation highlighted the main points identified for revision of the COP, such as incorporation of the HACCP system; inclusion of an annex on aflatoxins, a new section on processing; use of biological control, such as those commercially available for control of *Aspergillus flavus* in maize and use of predictive models. The EWG had made proposals for a revised COP with justification for changes together with a project document for consideration by the Committee.

98. The Committee agreed the revision of the COP was timely in view of the newer technologies and practices available to prevent and reduce mycotoxin contamination in cereals.

Conclusion

99. The Committee agreed to initiate new work on the revision of the *Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals* (CAC/RCP 51-2003) for approval by the 37th Session of the Commission (Appendix IX). The Committee agreed to establish an EWG lead by Brazil and co-chaired by United States of America and Nigeria, and working in English only, to prepare a proposed draft revision of the COP, including the integration of the annex on the prevention and reduction of aflatoxins and OTA in sorghum, for comments at Step 3 and consideration by the next session, subject to approval by the Commission.

DISCUSSION PAPER ON AFLATOXINS IN CEREALS (Agenda Item 15)¹⁶

100. The Delegation of Brazil introduced the document and informed the Committee that the EWG had conducted a preliminary risk assessment and exposure assessment based on an updated literature search and on data submitted to GEMS/Food; and had only considered data on maize, sorghum, wheat and rice. The Delegation highlighted the conclusions and recommendations in CX/CF 14/8/15. It was further noted that since the last JECFA assessment for aflatoxins had been conducted in 1998 and that a lot of new data were available, consideration should be given to request JECFA to conduct a new risk assessment for aflatoxins. The attention of the Committee was also drawn to a point raised by Japan (as member of the EWG) that the Committee should consider an annex for aflatoxins in rice as a priority before establishing an ML for rice.

101. On the issue of a new risk assessment by JECFA, the JECFA Secretariat commented that there are likely to be additional data available since the last risk assessment which may justify an update of the risk assessment. However conclusions may not change in that aflatoxins are potent carcinogens and exposure should be reduced to the extent possible. An updated risk assessment could be undertaken but possibly not as a matter of priority, and efforts on risk management measures should continue to reduce exposure. The Representative also mentioned the WHO project to estimate the global burden of disease from aflatoxins that might also provide useful data.

102. There was general support that rice should remain the focus of work until more data became available on other cereals, but that priority should be given to the revision of the *Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals*, noting that an annex on aflatoxins (see Agenda Item 14), would take into account measures for control aflatoxins in rice and other cereals, rather than on establishing an ML for aflatoxins in rice. Countries were encouraged to continue submitting data, especially for wheat, maize and sorghum to GEMS/Food.

Conclusion

103. The Committee agreed that countries would submit data to GEMS/Food and no further work would be undertaken on the establishment of MLs for aflatoxins in cereals for the timebeing.

DISCUSSION PAPER ON THE REVIEW OF THE GUIDELINE LEVELS FOR METHYLMERCURY IN FISH AND PREDATORY FISH (AGENDA ITEM 16)¹⁷

104. The Delegation of Japan introduced document and informed the Committee that three main points were discussed, viz. to which compounds MLs or GLs should apply, classification of fish and exceedance rates for the current GLs.

105. There was no agreement in the EWG on the compound for which GLs or MLs should apply. Proposals were made for levels for total mercury, levels for methyl mercury, or revocation of levels.

106. On the classification of fish species, the EWG, taking into account the data submitted, could statistically classify fish species into two groups, namely "tunas, billfish and sharks" and "other species", but it was clear that having two groups was not sufficient to cover all species. Therefore more detailed classification was necessary.

¹⁵ CX/CF 14/8/14; CRD 11 (Comments of Chile, Egypt, European Union, Ghana, Philippines, Russian Federation, Sudan, United States of America and African Union).

¹⁶ CX/CF 14/8/15; CRD 12 (Comments of Brazil, Chile, El Salvador, European Union, Ghana, India, Russian Federation, Thailand, United States of America and African Union).

¹⁷ CX/CF 14/8/16; CRD13 (Comments of Chile, European Union, Ghana, India, Norway, Republic of Korea and Russian Federation).

107. When considering the exceedance rates, it would appear that the current GL of 0.5 mg/kg might not be necessary for fish other than predatory fish, but that the current GL of 1 mg/kg for predatory fish should be reviewed. However it was also noted that lack of exceedance rates for the current GL of 0.5 mg/kg may be influenced by the current GL having been in place for a number of years.

108. The Delegation of Japan also informed the Committee that a request had been made to consider as an alternative to MLs or GLs, the provision of consumption advice as a risk management tool, but that this was outside the mandate of the EWG and had not been considered.

109. The Delegation of Japan therefore proposed that the Committee consider what the most appropriate risk management tool was and then to agree on the review of the levels.

110. Delegations opposed to the establishment of levels, were of the opinion that consumer advice was more appropriate and that the benefits of fish should be taken into account, in line with the outcomes of the *Joint FAO/WHO Expert Consultation on the Risk and Benefits of Fish Consumption*; that establishment of a level would give the impression that there was a problem with fish, and that very few fish had excessive levels of mercury, this was mostly in very large predatory or piscivorous fish.

111. Those in favour of establishing MLs were of the opinion that such levels were needed to ensure fair practices in food trade, while being health protective, and that consumer advice at the national level could be used in combination with an ML. There was wide support for an ML for methylmercury. However, recognizing the difficulties with chemical analysis for methylmercury, it was proposed to use total mercury for screening purposes. Some views were expressed that levels should be established for total mercury as it would be easier to analyse, especially in developing countries, and that a conversion factor could be used to determine the levels of methylmercury. There was however doubt with regard to the appropriate conversion factor to be used.

112. The Delegation of Japan explained that there was a strong correlation between total mercury and methylmercury concentration in fish with a slope of 0.837 as presented in the discussion paper (CX/CF 14/8/16, Figure 2(b) and that it would only be necessary to analyse for methylmercury in cases where the measurement of total mercury exceeded the ML for methylmercury. The statistical analysis had found that in the case of blue marlin, the ratio of methylmercury to total mercury was significantly lower and therefore a higher probability to analyse for methyl mercury, when the total mercury exceeds the ML for methylmercury.

Conclusion

113. Noting that there was wide support for establishment of an ML for methylmercury, the Committee agreed that this would be the approach with the use of total mercury for screening purposes, but that further consideration was needed on an appropriate level or levels; and the fish classification would have to be further developed as proposed by the chair of the EWG. The Committee further noted that this decision did not preclude the usefulness of consumer advice and confirmed the decision of the last session of the Committee that consumer advice should be developed at the national or regional level as the advice would vary between countries because of the risk of mercury exposure from the diet would depend on, amongst others, the patterns of consumption of fish and the types of fish consumed; and that no further work would be done at the international level.

114. The Committee agreed to re-establish the EWG, led by Japan and co-chaired Norway, working in English only, to develop a discussion paper to provide proposals for ML(s) for methylmercury, to express to which fish species these should apply, and to include a project document for a new work proposal for consideration by the next session of the Committee.

DISCUSSION PAPER ON THE ESTABLISHMENT OF A MAXIMUM LEVEL FOR TOTAL AFLATOXINS IN READY-TO-EAT PEANUTS AND ASSOCIATED SAMPLING PLAN (Agenda Item 17)¹⁸

115. The Delegation of India introduced the document and explained that currently there were MLs for aflatoxins in peanuts for further processing, but not for ready-to-eat (RTE) peanuts. It was explained that an ML for total aflatoxins in RTE peanuts would help ensure consumer health protection and fair practices in food trade, especially taking into account the needs of developing countries. The RTE peanuts included several categories of peanuts, such as raw shelled peanuts, raw-in-shell peanuts, roasted in shell peanuts, roasted / blanced shelled peanuts, fried shelled peanuts with or without skin, coated peanuts in all types of packing (consumer or bulk), and any other products having preparation of more than 20% of peanuts. The EWG had proposed a level for total aflatoxins of 10 µg/kg with existing Codex sampling plans, based on the occurrence data submitted.

116. The Committee noted the wide support for the establishment of an ML for total aflatoxin in RTE peanuts. However, concerns were raised on the definition of RTE as there appeared to be overlap with peanuts for further processing. Establishing an ML without clarification of the definition or scope of RTE peanuts could result in difficulties in establishing the ML.

117. In order to facilitate this work, the Committee noted that a definition for RTE was proposed as part of the editorial amendments to the GSCTFF and agreed to amend that definition for tree nuts and dried figs (Agenda Item 12 and Appendix VII) and to also apply this definition to RTE peanuts for which the MLs are to be established.

¹⁸ CX/CF 14/8/17; CRD 14 (Comments of Chile, El Salvador, European Union, Ghana, Indonesia, Nicaragua, Philippines, Republic of Korea, Russian Federation, United States of America and African Union); CRD 25 (Project document on new work on the establishment of an ML for total aflatoxins in ready-to-eat peanuts and associated sampling plan prepared by India).

118. A proposal was made to consider establishing levels for aflatoxin B1 rather than total aflatoxins as this aflatoxin was considered the most widespread and toxic compound among aflatoxins. If not, then consideration should be given to levels for both total aflatoxins and aflatoxin B1. However, there was no wide support for this proposal.

Conclusion

119. The Committee agreed to forward the proposal to initiate new work on MLs for total aflatoxins in RTE peanuts for approval by the 37th Session of the Commission (Appendix X). The Delegation of the Russian Federation expressed its reservation to this decision.

120. The Committee agreed to establish an EWG led by India, and working in English only, to prepare proposals for MLs for total aflatoxins in RTE peanuts, for comments at Step 3 and consideration at the next session of the Committee.

DISCUSSION PAPER ON HALOGENATED SOLVENTS (Agenda Item 18)¹⁹

121. The 7th Session of the Committee considered a request from the Committee on Fats and Oils (CCFO) on the transfer of MLs for halogenated solvents from the *Standard for Olive Oils and Pomace Oils* (CODEX STAN 33-1981) to the *General Standard for Contaminants and Toxins in Food and Feed* (CODEX STAN 193-1995) and agreed that the Delegation of the European Union would prepare a discussion paper on what substances were included under the term "halogenated solvents" and whether the MLs in section 5.8 of CODEX STAN 33-1981 related to food safety or food quality.

122. The Delegation introduced the document and highlighted the main points addressed in the paper namely, chemistry of halogenated solvents, toxic effects on human health, current and past uses (the latter applying to the extraction of olive pomace oil), JECFA work on some halogenated solvents, legislation on maximum levels or maximum residue levels for certain halogenated solvents and relevant changes to the *Standard for Olive Oils and Pomace Oils* to address the "no longer in-use of halogenated solvents in the extraction of olive pomace oil" (e.g. sections 5.2 and 5.3 of the Standard). The Delegation noted that these MLs referred to the use of these substances as processing aids/extraction solvents when such substances were allowed in the production of these oils.

123. The Delegation further noted that JECFA had evaluated halogenated solvents and had limited their use to extraction solvent for spice oleoresins and decaffeination of coffee and tea and that there was no information on presence of halogenated solvents in olive oils or pomace oils from other uses than as extraction solvents, however their use as such was no longer allowed in the production of these oils. In addition, there was no information on potential public health implications resulting from exposure to halogenated solvents in olive oil and olive pomace oils nor information on environmental contamination resulting from the use of these substances in food products.

Conclusion

124. Following this presentation, the Committee noted that there was no support for the transfer of the levels for halogenated solvents from the *Standard for Olive Oils and Pomace Oils* (CODEX STAN 33-1981) to the GSCTFF, however it agreed to recommend CCFO to maintain these levels in CODEX STAN 33-1981 until such time more information on environmental contamination became available that would allow CCCF to make a decision on this matter. The Delegation of European Union agreed to follow-up on this issue and report back to the Committee in the future.

PRIORITY LIST OF CONTAMINANTS AND NATURALLY OCCURRING TOXICANTS PROPOSED FOR EVALUATION BY JECFA (Agenda Item 19)²⁰

125. The Delegation of the United States of America presented the report on the outcome of the discussion of the in-session working group (CRD 2).

126. The Committee was informed that four substances remain on the priority list, viz. 3-MCPD esters, glycidyl esters, pyrrolizidine alkaloids, and non-dioxin like PCBs. The Working Group proposed that two compounds, sterigmatocystin and diacetoxyscirpenol, should be added to the list as a result of discussions under Agenda Item 3.

127. Sterigmatocystin and diacetoxyscirpenol are two mycotoxins which have been detected in sorghum samples analysed in the FAO/WHO Mycotoxins in Sorghum Project (CX/CF14/8/3). These mycotoxins have not been assessed by JECFA and a full safety assessment may be warranted to facilitate the interpretation of the analytical results.

128. The Committee agreed with the recommendations of the Working Group with some editorial amendments to the priority list.

129. The Committee agreed to add the assessments of two mycotoxins, fumonisins and aflatoxins, already evaluated by JECFA, to the priority list. An updated exposure assessment for fumonisins shall be performed by JECFA after three years once more occurrence data from countries where limited data are available have been collected (see paragraph 71). An update of the risk assessment of aflatoxins may be desirable in view of additional data that have become available since the last full assessment by JECFA. The Committee agreed that the risk assessment of aflatoxins would not be a high priority.

¹⁹ CX/CF 14/8/18; CRD 15 (Comments of Chile, Russian Federation, United States of America and African Union).

²⁰ REP13/CF, Appendix VII; CX/CF 14/8/19; CRD 2 (Report of the in-session working group on priorities prepared by the United States of America); CRD 16 (Comments of Chile and Japan).

Conclusion

130. The Committee endorsed the priority list of contaminants and naturally occurring toxicants for JECFA evaluation as proposed by the Working Group (Appendix XIII) and agreed to re-convene the in-session Working Group at its next session. The Committee further agreed to continue to request comments and/or information on the Priority List for consideration by the next session of the Committee.

OTHER BUSINESS AND FUTURE WORK (Agenda Item 20)²¹

PROPOSAL FOR NEW WORK ON THE ESTABLISHMENT OF MAXIMUM LEVELS FOR AFLATOXINS IN SPICES (Agenda Item 20a)

PROPOSAL FOR NEW WORK ON THE ESTABLISHMENT OF MAXIMUM LEVELS FOR AFLATOXINS B₁ AND TOTAL AFLATOXINS IN NUTMEG AND ASSOCIATED SAMPLING PLANS (Agenda Item 20b)

131. The Committee considered the proposals jointly as they both related to the establishment of MLs for spices.

132. The Delegation of India introduced the proposal for MLs for aflatoxins in spices and explained that a harmonised ML for total aflatoxins and aflatoxin B₁ should be established in spices to facilitate trade and protect consumer health. It was noted that regulations for spices varied widely across the globe and that a lack of harmonisation affected global trade in spices. The Delegation proposed that the Committee consider establishing MLs for total aflatoxins and aflatoxin B₁ for chilli and nutmeg as an initial step because these spices were most widely traded internationally.

133. The Delegation of Indonesia introduced the proposal for MLs for aflatoxins in nutmeg and explained that nutmeg was one of the most widely traded spices internationally, and internationally harmonised MLs for total aflatoxin and aflatoxin B₁ for this particular spice were necessary to protect consumer health and facilitate global trade. The Delegation further informed the Committee that the newly established Committee on Spices and Culinary Herbs (CCSCH) would be considering a proposal for a standard on nutmeg at its next session and that the work on the ML would be complementary to this work in CCSCH.

134. The Committee had a general discussion on how best to approach the establishment of MLs in spices and considered a proposal by the Chairperson that a review of mycotoxins in spices first be conducted to allow the Committee to understand which mycotoxins to address and in which spices. Such a study could allow for a possible prioritisation of the work on spices for the Committee.

135. There was general support for such an approach. It was however pointed out that a paper was necessary before the Committee could proceed with establishment of MLs in spices. It was also noted that in terms of the GSCTFF, "*MLs shall only be set for foods in which the contaminant may be found in amounts that are significant for the total exposure of the consumer*".

136. Several suggestions were made to consider a wider range of spices; such as the priority list to be established by the CCSCH or the spice categories in the *Classification for Foods and Animal Feeds* (CAC/MISC 4-1993) as a basis for discussing the establishment of MLs in spices.

Conclusion

137. The Committee agreed to establish an EWG, led by India and co-chaired by the European Union and Indonesia, and working in English only, to prepare a discussion paper as outlined in the proposal by the Chairperson (paragraph 134) for consideration at the next session.

PROPOSAL FOR NEW WORK ON A CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF OCHRATOXIN A CONTAMINATION IN PAPRIKA (Agenda Item 20c)

138. The Delegation of Spain presented their proposal for new work on a code of practice for the prevention and reduction of OTA in paprika and highlighted that the COP would serve as a guide of good hygiene practices in order to prevent and reduce OTA content in paprika. The Delegation explained that such a COP had been developed by Spain for national application which had been well received, and could be developed for international application.

139. Following the previous discussion on the MLs for aflatoxins in spices, the Committee agreed that a more general approach should also be taken for this COP, similar to the *Code of Practice for Prevention and Reduction of Mycotoxin Contamination in Cereals*; and that consideration could be given to development of annexes for specific mycotoxin-spice combinations.

Conclusion

140. The Committee agreed to establish an EWG, led by Spain and co-chaired by the Netherlands, and working in English and Spanish, to prepare a discussion paper on the feasibility for a code of practice for mycotoxins in spices with specific annexes for consideration at the next session.

²¹ CX/CF 14/8/20; CX/CF 14/8/21; CX/CF 14/8/22; CRD 17 (Comments of Chile, European Union, India and Russian Federation); CRD 22 (Comments of India); CRD 26 (Comments of Ecuador including project document on new on the establishment of MLs for cadmium in chocolate and cocoa-derived products).

PROPOSAL FOR MAXIMUM LEVELS FOR CADMIUM IN CHOCOLATE AND COCOA-DERIVED PRODUCTS (Agenda Item 20d)

141. The Delegation of Ecuador introduced their proposal for new work on MLs for cadmium in chocolate and cocoa-derived products. The Delegation informed the Committee that the proposal had been discussed in the in-session Working Group on Priorities (Agenda Item 19), which had proposed that a project document be presented to the plenary. The Delegation noted that while the evaluation of JECFA (77th meeting) had noted that the intake of cadmium from the consumption of chocolate and cocoa-derived products is not a health concern, the lack of an ML for cadmium in cocoa and its derived products could threaten exports from some Member Countries, especially developing countries who were the major exporters of cocoa.

Conclusion

142. The Committee agreed to initiate new work on MLs for cadmium in chocolate and cocoa-derived products for approval by the 37th Session of the Commission (Appendix XI). The Committee agreed to establish an EWG led by Ecuador, co-chaired by Ghana and Brazil, and working in English and Spanish, to prepare proposals for MLs for comments at Step 3 and consideration at the next session of the Committee, subject to approval by the Commission.

DATE AND PLACE OF THE NEXT SESSION (Agenda Item 21)

143. The Committee was informed that its ninth session would be held in New Delhi, India in approximately one year's time. The exact venue and date would be determined by the Host Government in consultation with the Codex Secretariat. The Delegation of India extended its appreciation to the Government of the Netherlands for the opportunity to co-host the Committee.

SUMMARY STATUS OF WORK

SUBJECT MATTER	STEP	ACTION BY:	DOCUMENT REFERENCE (REP14/CF)
Proposed draft maximum levels for lead in infant formula and formula for special medical purposes intended for infants and for follow up formula	5/8	Governments 37 th CAC	para 33, Appendix II
Proposed draft maximum levels for inorganic arsenic in polished rice	5/8		para 46, Appendix III
Proposed draft maximum levels for fumonisins in maize and maize products and associated sampling plans	5/8		para 72, Appendix IV
Proposed draft Annex for the prevention and reduction of aflatoxins and ochratoxin A contamination in sorghum (<i>Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals – CAC/RCP 51-2003</i>)	5/8		para 77, Appendix V
Proposed draft Code of Practice for Weed Control to prevent and reduce Pyrrolizidine Alkaloid Contamination in Food and Feed	5/8		para 83, Appendix VI
Editorial amendments to the <i>General Standard for Contaminants and Toxins in Food and Feed</i> (CODEX STAN 193-1995)	-		para 92, Appendix VII
Proposed draft maximum levels for DON in raw cereal grains (wheat, maize and barley) including sampling plans and in flour, meal, semolina and flakes derived from wheat, maize or barley	7	9 th CCCF	para 59, Appendix XII
Maximum levels for lead in fruit juices and nectars (ready-to-drink), canned fruits and canned vegetables	6	EWG (USA) Governments 9 th CCCF	paras 26 - 27
Maximum levels for lead in selected fruits and vegetables	2/3	EWG (USA) Governments 9 th CCCF	paras 23 - 24
Proposed draft maximum levels for inorganic arsenic in husked rice	2/3	EWG (China / Japan) Governments 9 th CCCF	para 47
Proposed draft Code of Practice for the Prevention and Reduction of Arsenic Contamination in Rice	1/2/3	EWG (Japan / China) Governments 9 th CCCF	para 95, Appendix VIII
Proposed draft revision of the <i>Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals</i> (CAC/RCP 51-2003)	1/2/3	EWG (Brazil / USA / Nigeria) Governments 9 th CCCF	para 99, Appendix IX
Proposed draft maximum level for total aflatoxins in ready-to-eat peanuts	1/2/3	EWG (India) Governments 9 th CCCF	para 119, Appendix X
Proposed draft maximum levels for cadmium in chocolate and coca-derived products	1/2/3	EWG (Ecuador / Ghana / Brazil) Governments 9 th CCCF	para 142, Appendix XI
Proposed draft maximum levels for acetylated derivatives (DON) in cereals and cereal-based products	-	CCCF	para 62

SUBJECT MATTER	STEP	ACTION BY:	DOCUMENT REFERENCE (REP14/CF)
Discussion Papers			
Paper on submission and use of data from GEMS/Food	-	GEMS/Food Secretariat/FAO/WG chairs 9 th CCCF	paras 13 -14
Discussion paper on radionuclides	-	EWG (The Netherlands / Japan) 9 th CCCF	para 18
Discussion paper on approaches for phasing in of lower MLs	-	FAO/WHO/ Codex Secretariat 9 th CCCF	para 57
Discussion paper on maximum levels for methylmercury in fish	-	EWG (Japan / Norway) 9 th CCCF	para 114
Discussion paper on mycotoxin contamination in spices (prioritisation for potential work on MLs in spices)	-	EWG (India / EU / Indonesia) 9 th CCCF	para 137
Discussion paper on feasibility to develop a Code of practice for mycotoxins in spices	-	EWG (Spain / The Netherlands) 9 th CCCF	para 140
Priority list of contaminants and naturally occurring toxicants proposed for evaluation by JECFA	-	Governments 9 th CCCF	para 130, Appendix XIII

APPENDIX I**LIST OF PARTICIPANTS/ LISTE DES PARTICIPANTS / LISTA DE PARTICIPANTES**

CHAIR/PRÉSIDENT/PRESIDENTE

Ms Wieke TAS

Chair of CCCF

Ministry of Economic Affairs

Animal Agri Chains and Animal Welfare Department

P.O. Box 20401

2500 EK The Hague

NETHERLANDS

Tel: 0031 070 3798208

E-mail: info@codexalimentarius.nl

CHAIR'S ASSISTANT/ADJOINT DU PRÉSIDENT/ASISTENTE DEL PRESIDENTE

Mr Rob THEELEN

Netherlands Food and Consumer Product Safety Authority

BuRO

PO Box 43006

3540 AA Utrecht

NETHERLANDS

Tel: +31611882558

E-mail: r.m.c.theelen@vwa.nl**MEMBER COUNTRIES/PAYS MEMBRES/
PAÍSES MIEMBROS**

ANGOLA

Mr Rosalina BRÁS

Coordenadora do Sub-Comité de Leite e Produtos

Lacteos do Codex-Angola

Codex-Angola

Instituto de Serviços Veterinários

Rua Comandante Gika-Largo Antonio Jacinto

527 Luanda

ANGOLA

Tel: 00244 928 38 22 01

Fax: 00244 222 32 37 24

E-mail: secretariado.codexangola@hotmail.com

ARGENTINA/ARGENTINE

Ms Silvana RUARTE

Head of food chemical analysis

National Food Institute

National Administration of Drugs, Food and Medical

Products

Estados Unidos 25

1101 Buenos Aires City

ARGENTINA

Tel: +541143400800 ext 3501/3529

Fax: +541143400800 ext 3521

E-mail: suarte@anmat.gov.ar

AUSTRALIA/AUSTRALIE

Ms Leigh HENDERSON

Section Manager, Product Safety Standards

Food Standards Australia New Zealand

108 The Terrace

6143 Wellington

NEW ZEALAND

Tel: 6449785650

Fax: 6444739855

E-mail: leigh.henderson@foodstandards.gov.au

AUSTRIA/AUTRICHE

Ms Daniela HOFSTAEDTER

Group Leader

Austrian Agency for Health and Food Safety GmbH

Data, Statistics & Risk Assessment

Spargelfelgasse 191

1220 Vienna

AUSTRIA

Tel: +43 50555-25703

Fax: +43 50555-25802

E-mail: daniela.hofstaedter@ages.at

BELGIUM/BELGIQUE/BÉLGICA

Ms Christine VINKX

Expert food additives, enzymes, processing aids and

contaminants in food

FPS Health, Food Chain Safety and Environment

Place Victor Horta 40, Box 10

1060 Brussels

BELGIUM

Tel: 3225247359

Fax: 3225247399

E-mail: Christine.vinkx@health.belgium.be

BENIN/BÉNIN/BENÍN

Mr S. Germain DANSI

Cadre a la Direction Nationale de Sante Publique
Ministere de la Sante
Direction Nationale de Sante Publique
04 BP 1070
229

BENIN

Tel: +229 95068343 / 21336679

Fax: +229 21336679

E-mail: ds.germano40@yahoo.fr

BRAZIL/BRÉSIL/BRASIL

Ms Lígia SCHREINER

Specialist on Regulation and Health Surveillance
National Health Surveillance Agency
General Office of Food
SIA Trecho 5 Setor Especial 57, Bloco D, 2º andar
71205-050 Brasília

BRAZIL

Tel: + 55 61 34625399

Fax: +55 61 34625313

E-mail: ligia.schreiner@anvisa.gov.br

Ms Silésia AMORIM

Regulation and Health Surveillance Specialist
National Health Surveillance Agency - Ministry of Health
General Office of Laboratories
SIA, Trecho 05, Area Especial 57, Bloco D, 1 o Andar
71.205-050 Brasilia

BRAZIL

Tel: 55 61 3462 5470

Fax: 55 61 3462 5469

E-mail: silesia.amorim@anvisa.gov.br

Ms Patricia Diniz ANDRADE

Food Engineer
University of Brasilia
Faculty of Healty Science
Campus Universitario Darcy Ribeiro
70910-900 Brasilia

BRAZIL

Tel: 0055 61 31072017

Fax: 0055 61 31071871

E-mail: patriciadiniz@unb.br

Ms Deise BAGGIO RIBEIRO

Professor
Universidade Federal de Santa Catarina
Rod. Ademar Gonzaga, 1346
88034-001 Florianopolis

BRAZIL

Tel: +5548 3721 2897

E-mail: deise.baggio@ufsc.br

Mr Rafael BARROCAS

Federal Inspector
Ministry of Agriculture, Livestock and Food Supply
Department of Vegetal Products Inspection
Esplanada dos ministérios, Bloco D, Anexo B, Sala 348
70043-900 Brasília

BRAZIL

Tel: +55 61 32183073

E-mail: rafael.barrocas@agricultura.gov.br

Mr Milton CABRAL DE VASCONCELOS NETO

Analyst and Researcher of Health and Technology
Fundação Ezequiel Dias
Health Public Laboratory
Rua Conde Pereira Carneiro, 80
30510-010 Belo Horizonte

BRAZIL

Tel: 55 31 33144654

E-mail: milton.cabral@funed.mg.gov.br

Ms Eloisa CALDAS

Professor
University of Brasilia
Pharmacy
Campus Darcy Ribeiro
70910-900 Brasília

BRAZIL

Tel: +5561 3107 1871

E-mail: eloisa@unb.br

Ms Flavia Beatriz CUSTODIO

Postdoctoral Researcher
Federal University of Minas Gerais
Pharmacy College
Castigliano Street, nº 552
30720 310 Belo Horizonte

BRAZIL

Tel: 55 31 9105 9193

E-mail: flaviabcustodio@gmail.com

Mr Fabio Ribeiro Campos DA SILVA

Regulation and Health Surveillance Specialist
National Health Surveillance Agency - Ministry of Health
General Office of Food
SIA, Trecho 05, Area Especial 57, Bloco D, 2 andar
71205-050 Brasilia

BRAZIL

Tel: +55 61 34625399

Fax: +55 61 34625388

E-mail: fabio.silva@anvisa.gov.br

Mr Wilkson REZENDE

Official Inspector
Ministry of Agriculture, Livestock and Food Supply
Feed Department
Esplanada dos Ministérios, Bloco D, Sala 443 A
70043-900 Brasilia

BRAZIL

Tel: +55 61 32182438

E-mail: wilkson.rezende@agricultura.gov.br

Mr André SANTOS

Deputy Coordinator of the Brazilian Codex Committee
National Institute of Metrology, Quality and Technology
Quality Directory
Rua Estrela, 67 - 4 Andar - Rio Comprido
20251-900 Rio de Janeiro
BRAZIL
Tel: 55 21 32161020
Fax: 55 21 32161085
E-mail: alsantos@inmetro.gov.br

BURUNDI

Ms Fabien NDAYISHIMIYE

CAMEROON/CAMÉROUN/CAMERÚN
Ms Garone Josiane CHOUYA TCHAKOUTE
Cameroon Contact Point of CCAFRICA
Standards and Quality Agency
Generale Directorate
PO Box 14966
Yaounde
CAMEROON
Tel: +237 99 542384
Fax: +237 22 206368
E-mail: pointfocalcodexcameroun@yahoo.fr /
garwene@yahoo.fr

Mr Hermann Henri NKANDI

Inspecteur Phytosanitaire Assermenté
Ministere de l'Agriculture et du developpement Rural
Direction de la Reglementation et Controle de Qualité
BP 2082
Yaounde
CAMEROON
Tel: +237 90808724
E-mail: nkandihermann@yahoo.fr

CANADA/CANADÁ

Mr Mark FEELEY

Associate Director, Bureau of Chemical Safety
Bureau of Chemical Safety, Food Directorate
Food Directorate
251 Sir Frederick Banting Driveway, PL 2204C
K1A0K9 Ottawa
CANADA
Tel: 16139571314
Fax: 16139571688
E-mail: mark.feeley@hc-sc.gc.ca

Mr Henri BIETLOT

National Manager Chemical Evaluation
Canadian Food Inspection Agency
Food Safety and Consumer Protection
1400 Mercale Rd, T2 - 4G
K1A 0Y9 Ottawa
CANADA
Tel: +1613 7735835
Fax: 16137735958
E-mail: henri.bietlot@inspection.gc.ca

Ms Kelly HISLOP

Chief, Chemical Health Hazard Assessment Division
Health Canada
Bureau of Chemical Safety, Food Directorate
251 Sir Frederick Banting Driveway, PL 2203B
K1A 0K9 Ottawa
CANADA
Tel: 1613-957-1700
Fax: 1613-990-1543
E-mail: kelly.hislop@hc-sc.gc.ca

CAPE VERDE/CAP-VERT/CABO VERDE

Ms Marlene DUARTE GOMES

Head of Division
ARFA – Regulatory Agency for Food and Pharmaceutical
Products
Regulation and Supervision Division
Achada de Sto. António
296 - A Praia
CAPE VERDE
Tel: +238 262 64 57
Fax: +238 262 49 70
E-mail: marlene.gomes@arfa.gov.cv

CHILE/CHILI

Ms Enedina LUCAS

Coordinadora del Subcomite de Contaminantes de Chile
Instituto de Salud Publica de Chile, Ministerio de Salud
Departamento de Salud Ambiental
Avenida Marathon N° 1000
Santiago
CHILE
Tel: 5625755478
Fax: 5625755589
E-mail: elucas@ispch.cl

CHINA/CHINE

Mr Yongning WU

Professor, Chief Scientist
China National Center for Food Safety Risk Assessment
(CFSA)
Key Lab of Food Safety Risk Assessment
Building 2, No. 7 Guangqu Road, Chaoyang District
100022 Beijing
CHINA
Tel: 86-10-52165589,67779118
Fax: 86-10-52165489
E-mail: wuyongning@cfsa.net.cn.china_cdc@yahoo.cn

Mr Chor-yiu CHOW

Head (Risk Assessment Section)
Food and Environmental Hygiene Department, HKSAR
Government
Centre for Food Safety
43/F Queensway Government Office,66 Queensway
Hong Kong
CHINA
Tel: 852-28675508
Fax: 852-28933547
E-mail: cychow@fehd.gov.hk

Ms Ping JING

Senior Engineer
 Technical Center of Shandong Entry-Exit Inspection and
 Quarantine Bureau
 266002 Qingdao
 Tel: 86-15192010681
 Fax: 86-532-80885626
 E-mail: 190462259@qq.com

Mr Xiao LI

Vice Section Chief
 Shanghai Entry-Exit Inspection and Quaranting Bureau of
 China, Division for supervision on food safety, Section 3
 Rm.1215, No. 1208 Mingsheng Road, Pudong, Shanghai
 P.R.China
 200135 Shanghai
 CHINA
 Tel: 86-13482208390
 Fax: 86-21-68545464
 E-mail: lix@shciq.gov.cn

Ms Zhan Hua LIU

Director
 Guangxi Zhuang Autonomous Region Center for Disease
 Prevention and Control
 Institute of Monitoring and Evaluation of Safety Risk of
 Food
 18 Jinzhou Road Nanning, Guangxi Province, China
 530028 NanNing
 CHINA
 Tel: 86-13878128096
 Fax: 86-0771-2518885
 E-mail: hzliu326@sina.com

Ms Jun WANG

Division Director
 China National Center for Food Safety Risk Assessment
 Division II of Food Safety Standard
 Building 2, No. 37, Guangqu Road, Chaoyang District
 100022 Beijing
 CHINA
 Tel: 86-10-52165411
 Fax: 86-10-52165414
 E-mail: lotuswj@126.com

Mr Songxue WANG

Associate Researcher
 Academy of State Administration of Grain
 No.11 Baiwanzhuang Street, Xicheng District, Beijing
 100037 Beijing
 CHINA
 Tel: 86-13522649591
 Fax: 86-10-58523599
 E-mail: wsx@chinagrains.org

Ms Ruimin XU

Senior Regulatory Affairs Manager
 Mead Johnson Pediatric Nutrition Institute (China) Ltd.
 Regulatory Affairs
 Xia Yuan Road, Dongji Industrial District, GETDD,
 Guangzhou, P.R.C.
 510730 Guangzhou
 Tel: 86-20-82156105
 Fax: 86-20-82156131
 E-mail: amy.xu@mjn.com

Mr Tin Chung Arthur YAU

Scientific officer (Toxicology)
 Food and Environmental Hygiene Department, HKSAR
 Government
 Centre for Food Safety
 43/F, Queensway Government Offices, 66
 Queensway, HongKong
 HongKong
 CHINA
 Tel: (852)6311 5852
 Fax: (852)2893 3547
 E-mail: atcyau@fehd.gov.hk

Mr Zhiguang ZHU

Director/Professor
 Standards & Quality Center of State Administration of
 Grain
 Liangke Building, No.11, Baiwanzhuang
 Street, Beijing, China
 100037 Beijing,
 CHINA
 Tel: 86-13801378791
 Fax: 86-10-58523408
 E-mail: LYBZZZG@163.com

Mr Zhifei ZOU

Professor /Deputy director
 Quarantine Technology center Guangdong Entry-Exit
 Inspection Quarantine Bureau
 Room 1402, B Tower, Guojia Building No.66 Huacheng
 Avenue, Guangzhou
 510627 Guangzhou
 CHINA
 Tel: 86-13711120124
 Fax: 86-20-38290325
 E-mail: zouzhifei@126.com

COLOMBIA/COLOMBIE

Mr Julio VANEGAS

Instituto Nacional de Vigilancia de Medicamentos y
 Alimentos - INVIMA
 Carrera 68D No. 17 - 11
 Bogotá
 COLOMBIA
 Tel: 57 1 2948700
 E-mail: jvanegasr@invima.gov.co

COOK ISLANDS/ÎLES COOK/ISLAS COOK/

Ms Tereapii NIMEROA

COSTA RICA

Ms María Elena AGUILAR SOLANO

Regulador de la Salud
 Ministerio de Salud
 Dirección de Regulación de Productos de Interés
 Sanitario, Unidad de Normalización y Control
 Calle 16, Ave 6 y 8
 10123-1000 San Jose
 COSTA RICA
 Tel: (506) 2233-6922
 Fax: (506) 2255-4512
 E-mail: maguilar@ministeriodesalud.go.cr

Ms Ana Marcela CALDERON GARBANZO

Ministro Consejero
 Embajada de Costa Rica
 Laan Copes van Cattenburch 46,
 2585GB
 NETHERLANDS
 Tel: 0031 703540780
 Fax: 0031 70 358 47 54
 E-mail: calderon.anamarcela@gmail.com;
mcalderon@rree.go.cr

Mr Gustavo CAMPOS FALLAS

Ministro Consejero
 Embajada de Costa Rica
 Laan Copes van Cattenburch 46,
 2585GB
 NETHERLANDS
 Tel: 0031 703540780
 Fax: 0031 70 358 47 54
 E-mail: gcampos@embacr.nl

CROATIA/CROACIA

Ms Nelija VRZINA

Third Secretary
 Embassy of Croatia
 Amaliastraat 16
 The Hague
 NETHERLANDS
 Tel: +31 0 64 6085788
 E-mail: nvrzina@mvep.hr

CUBA

Mr Osvaldo Vladimir PUÑALES SOSA

Coordinador Nacional Programa Contaminantes en
 Alimentos
 Ministerio de Salud Publica
 Higiene de los Alimentos
 Calle 23 esquina N Edificio Soto
 Plaza 10400 La Habana
 CUBA
 Tel: 537 8300022
 E-mail: nc@ncnorma.cu - ovps@infomed.sld.cu

DENMARK/DANEMARK/DINAMARCA

Ms Dorthe Licht CEDERBERG

Scientific advisor
 Danish Veterinary and Food Administration
 Stationsparken 31
 2600 Glostrup
 DENMARK
 Tel: 4572276628
 E-mail: DLI@FVST.DK

Ms Lulu KRÜGER

Scientific Officer
 Danish Veterinary and Food Administration
 Stationsparken 31
 2600 Glostrup
 DENMARK
 E-mail: lchk@fvst.dk

ECUADOR/ÉQUATEUR

Mr Rommel Aníbal BETANCOURT HERRERA

Director Nacional de Inocuidad de los Alimentos
 Agencia Ecuatoriana de Aseguramiento de la Calidad del
 AGRO - AGROCALIDAD
 Avenidas Amazonas y Eloy Alfaro esquina
 170516 Quito
 ECUADOR
 Tel: 593 2 567 232
 Fax: 593 2 567 232
 E-mail: rommel.betancourt@agrocalidad.gob.ec

EGYPT/ÉGYPTE/EGIPTO

Mr Nasser MOHAMED

Chief Researcher and Head of The Minerals lab
 Regional Center for Food & Feed (RCFF)
 Food & Feed Contamination
 9 El - Gamaa Street. Giza - Agric. Res. Center
 Cairo
 EGYPT
 Tel: 35732280 - 35731989
 Fax: 00202 35713250 -
 E-mail: nasserkhalil_23@hotmail.com

Ms Amel ABO HAGER

Head of Mycotoxins Department
 Agriculture Research Center (ARC)
 Regional Centre for Food and Feed,
 9 El - Gamaa Street. Giza - Agric. Res. Center
 Cairo
 EGYPT
 Tel: 35732280 - 35731989 -
 Fax: 00202 35713250 -
 E-mail: amel_Hagger@yahoo.com

Mr Alaa ELKHAWAGA

Commercial Councillor Egyptian Embassy The Hague
 Egyptian Embassy - The Hague
 Commercial section
 Koninginnegracht 35
 2514 AC The Hague
 EGYPT
 Tel: +31 6 59475950
 Fax: +31 070 3641703
 E-mail: thehague@tamseel-ecs.gov.eg

Mr Mohamed HELMY

Commercial second secretary
 Commercial Office for the Egyptian Embassy
 Koninginnegracht 35
 2514 AC The Hague
 EGYPT
 Tel: +31 0703604075
 Fax: +31 070 3641703
 E-mail: mhelmyn@hotmail.com

Ms Rania OMARA

Food Standards Specialist
 Egyptian Organization for Standardization and
 Quality(EOS)
 Food Standards
 16 Tadreeb El- Modarrebeen st.,Ameriya,Cairo
 02 Cairo
 EGYPT
 Tel: +20222845531
 Fax: +20222845507
 E-mail: raniaahmed49@yahoo.com

ESTONIA/ESTONIE

Ms Maia RADIN

Chief Specialist
 Ministry of Agriculture
 Food Safety Department
 Lai street 39/ Lai street 41
 15056 Tallinn
 ESTONIA
 Tel: 3726256529
 Fax: 3726256210
 E-mail: maia.radin@agri.ee

EUROPEAN UNION/
UNION EUROPÉENNE/
UNIÓN EUROPEA**Ms BARBARA MORETTI**

Administrator
 European Commission
 Directorate General for Health and Consumers
 Rue Froissart 101
 1049 Brussels
 BELGIUM
 Tel: +32 2 2992362
 E-mail: barbara.moretti@ec.europa.eu

Mr FRANK SWARTENBROUX

Legislative Officer
 European Commission
 AG Sanco Unit E.3.
 Rue Froissard 101
 1049 Brussels
 BELGIUM
 Tel: 3222993854
 Fax: 3222991856
 E-mail: frank.swartenbroux@ec.europa.eu

Mr Frans VERSTRAETE

Administrator/European Commission
 DG Health and Consumers Directorate-General
 Rue Froissart 101
 1040 Brussels
 BELGIUM
 Tel: +32 22956359
 E-mail: frans.verstraete@ec.europa.eu

FINLAND/FINLANDE/FINLANDIA

Ms Liisa RAJAKANGAS

Senior Officer, Food Policy
 Ministry of Agriculture and Forestry
 Department of Food
 P.O. Box 30
 00023 Government Helsinki
 FINLAND
 Tel: +358-50-3697613
 E-mail: liisa.rajakangas@mmm.fi

FRANCE/FRANCIA

Mr David BROUQUE

Adjoint au chef du bureau de la législation alimentaire
 Ministère de l'agriculture, de l'agroalimentaire, et de la
 forêt
 Direction générale de l'alimentation, bureau de la
 législation alimentaire
 251, rue de Vaugirard
 75732 Paris cedex 15
 FRANCE
 Tel: +33 (0)149555010
 Fax: +33 (0)149555948
 E-mail: david.brouque@agriculture.gouv.fr

Mr Herve LAFFORGUE

Food Safety Leader
 Danone
 Danone Food Safety Centre
 Route Departementale 128
 91767 Palaiseau
 FRANCE
 Tel: 33623763973
 Fax: 33169357697
 E-mail: herve.lafforgue@danone.com

GERMANY/ALLEMAGNE/ALEMANIA

Ms Annette REXROTH

PhD Chemist, Food Scientist
Federal Ministry for Food and Agriculture
Divison 322
Rochusstrasse 1
D-53123 Bonn
GERMANY
Tel: + 49 (0) 228 99 529 3776
Fax: + 49 (0) 228 99529 4943
E-mail: annette.rexroth@bmel.bund.de

Ms Klara JIRZIK

Food Chemist
Federal Office of Consumer Protection and Food Safety
(BVL)
Unit 101
Mauerstr. 39-42
D-10117 Berlin
Tel: +49 30 18444 10128
Fax: +49 30 18444 89999
E-mail: klara.jirzik@bvl.bund.de

Ms Angelika PREISS-WEIGERT

Head of Unit Contaminants
Federal Institute for Risk Assessment
Safety in the Food Chain
Max-Dohrn-Str. 8-10
10589 Berlin
GERMANY
Tel: + 49 (0) 30 18412 3352
Fax: + 49 (0) 30 18412 3457
E-mail: angelika.preiss-weigert@bfr.bund.de

GHANA

Ms GENEVIEVE OFOSUHEMAA BAAH MANTE

HEAD, FOOD LABORATORY
GHANA STANDARDS AUTHORITY
FOOD AND AGRIC
P. O. BOX MB 245, ACCRA
+233 ACCRA
GHANA
Tel: +233 244 662 735
E-mail: obaah@yahoo.com

Mr EBENEZER KOFI ESSEL

Head of Food Inspectorate Department
Food and Drugs Board
Food Division
P.O. Box CT 2783 Cantonments
+233 Accra
GHANA
Tel: +233244655943/ +233244337251
Fax: +233 302 225502
E-mail: kooduntu@yahoo.co.uk

Ms KAFUI AKUWA KPODO

RETIRED DEPUTY DIRECTOR, HEAD OF FOOD
CHEMISTRY
CSIR-FOOD RESEARCH INSTITUTE
FOOD CHEMISTRY
P.O.BOX M. 20
ACCRA
GHANA
Tel: +233 244 650 635
E-mail: kafui@kpododo.net

Mr EBENEZER OPOKU-AGYEMANG

SENIOR QUALITY CONTROL MANAGER
GHANA COCOA BOARD
QUALITY CONTROL CO. LTD
P. O. MB 54
+233 ACCRA
GHANA
Tel: 233202469376
E-mail: opokuagyemang.nana@yahoo.com

Mr JONATHAN AKWEI PAPPPOE

Senior Regulatory Officer
Food And Drugs Authority
Food Evaluation and Registration Department
P. O. BOX CT 2783, CANTONMENTS
+233 ACCRA
GHANA
Tel: 233202469376
E-mail: jonathanakweipappoe@yahoo.com

Mr ROBERT BAFFOUR TANDOR

Ag. DIRECTOR
MINISTRY OF TRADE AND INDUSTRY
STANDARDS
P.O. BOX MB 47
+233 ACCRA
GHANA
Tel: +233 277 422434
E-mail: robtandor

GREECE/GRÉCE/GRECIA

Mr Konstantinos BARMPERIS

Director
Hellenic Food Authority (EFET)
Directorate of Laboratory Controls
124, Kifisias ave & 2, Iatridou str
115 26 Athens
GREECE
Tel: +30 210 6971550, +30 694860072
Fax: +30 210 6971785
E-mail: kbarberis@efet.gr, kbarmper@otenet.gr

Mr Leonidas PALILIS

Officer
Hellenic Food Authority (EFET)
Directorate of Laboratory Controls
124, Kifisias Ave & 2, Iatridou Str
115 26 Athens
GREECE
Tel: +30 210 6971693
Fax: +30 2106971785
E-mail: lpalilis@efet.gr

Mr Guido SALA CHIRI

Administrator
General Secretariat of the Council of the European Union
DG B 2 B
rue de la Loi 175
B-1048 Brussels
BELGIUM
Tel: +32 2 281 5734
Fax: +32 2 281 6198
E-mail: secretariat.codex@consilium.europa.eu

HUNGARY/HONGRIE/HUNGRIA

Ms Mária SZERLETICSNÉ TÚRI

Head of Risk Assessment Department
National Food Chain Safety Office, Directorate for Food
Safety Risk Assessment
Risk Assessment Department
Tábornok u. 2.
H-1143 Budapest
HUNGARY
Tel: 0036 1/368-8815/101
Fax: 0036 1/387-9400
E-mail: SzerleticsneM@nebih.gov.hu

INDIA/INDE

Mr Arun Kumar PANDA

Joint Secretary
Ministry of Health & Family Welfare
Ministry of Health & Family Welfare
254-A Wing, Nirman Bhawan, Maulana Azad Road, New
Delhi
110001 New Delhi
INDIA
Tel: +91 11 23063155, +91 11 230631
Fax: + 91 11 23063156
E-mail: arun.panda@nic.in

Ms Kanika AGGARWAL

Technical Officer
Food Safety and Standards Authority of India
Quality Assurance
FSSAI, Ministry of Health & Family Welfare, FDA Bhawan,
Kotla Road, New Delhi
110002 Delhi
INDIA
E-mail: kanika.aggarwal31@gmail.com

Mr Sunil Kumar BAKSHI

Deputy General Manager
National Dairy Development Board
National Dairy Development Board
NDDDB House, Safdarjung Enclave, New Delhi
110029 New Delhi
INDIA
Tel: 91- 11 49883000
Fax: 91- 11 49883006
E-mail: sbakshi@nddb.coop

Mr Dinesh Singh BISHT

Scientist 'B'
Spices Board
Quality Evaluation
Spices Board (Ministry of Commerce & Industry, Govt. of
India), Quality Evaluation Laborat
110040 Delhi
INDIA
Tel: 011-27785379
E-mail: sbqelnarela@gmail.com

Mr Perumal KARTHIKEYAN

Assistant Director
Food Safety and Standards Authority of India
Quality Assurance & Standards
FSSAI, Ministry of Health & Family Welfare, FDA Bhawan,
Kotla Road, New Delhi
110002 Delhi
INDIA
E-mail: baranip@yahoo.com

Mr Devendra PRASAD

Assistant General Manager
Agricultural and Processed Food Products Export
Development Authority (APEDA), Ministry of Commerce &
Industry, Govt. of India
3rd Floor, NCU Auditorium Building, 3, Siri Institutional
Area, August Kranti Marg, Opp.
110016 New Delhi
INDIA
Tel: +91-11-26534175
E-mail: dprasad@apeda.gov.in

Mr PARMOD SIWACH

Assistant Director (Tech.)
Export Inspection Council of India
Ministry of Commerce & Industry
3rd Floor, NDYMCA Cultural Centre Building, 1, Jai Singh
Road
110001 New Delhi
INDIA
Tel: +91 11 2374 8189
Fax: +91 11 2374 8024
E-mail: tech5@eicindia.gov.in

Mr Kishore TANNA

Chairman
 Indian Oilseeds and produce export promotion council
 78/79, Bajaj Bhawan, Nariman Point, Mumbai
 400021 Mumbai
 INDIA
 Tel: (91-22)22023225
 Fax: (91-22)22029236
 E-mail: chairman@iopepc.org

Ms SIRUGURI VASANTHI

Scientist D
 National Institute of Nutrition (ICMR)
 Food and Drug Toxicology Research Centre, National
 Institute of Nutrition (ICMR), Hyderabad
 500007 Hyderabad
 INDIA
 E-mail: vasanthi.siruguri@gmail.com

INDONESIA/INDONÉSIE

Ms Anny SULISTIOWATI

Director
 National Agency of Drug and Food Control
 National Quality Control Laboratory
 Jl. Percetakan Negara 23
 10560 JAKARTA
 INDONESIA
 Tel: +62 21 4245075
 Fax: +62 21 4245150
 E-mail: asulis@yahoo.com

Ms Triyani Dewi -

Researcher
 Indonesian Agricultural Environment Research Institute
 Jl. Jakenan-Jaken Km 5
 59182 PATI
 INDONESIA
 Tel: +62 295 3351277
 Fax: +62 295 3351399
 E-mail: triyaniidewi@yahoo.com

Mr Iwan HIDAYAT

First Secretary, Indonesian Embassy
 Embassy of Indonesia
 Economics
 Tobias Asserlaan 8
 2517 KC The Hague
 NETHERLANDS
 Tel: +31 070 3108 100
 E-mail: iwan.nur.hidayat@gmail.com

Ms Pratiwi MARTOYO

Head of Section Food Raw Material
 National Agency of Drug and Food Control
 Jl. Percetakan Negara
 10560 JAKARTA
 INDONESIA
 Tel: +62 21 42875584
 Fax: +62 21 42875780
 E-mail: pratiwiuniarti@gmail.com

Mr Joni MUNARSO

Principal Researcher
 Ministry of Agriculture
 Jl. Tentara Pelajar 12, Cimanggu
 16114 BOGOR
 INDONESIA
 Tel: +62 251 8321762
 Fax: +62 251 8350920
 E-mail: joni_munarso@yahoo.co.id

Ms Endang Yuli PURWANI

Researcher
 Indonesian Agency for Agricultural Research and
 Development, Ministry of Agriculture
 Jl. Tentara Pelajar 12, Cimanggu
 16114 BOGOR
 INDONESIA
 Tel: +62 251 8321762
 Fax: +62 251 8350920
 E-mail: eylab@gmail.com

Mr Tjahjohutomo RUDY

Director
 Indonesian Agency for Agricultural Research and
 Development, Ministry of Agriculture
 Jl. Tentara Pelajar 12, Cimanggu
 16114 BOGOR
 INDONESIA
 Tel: +62 251 8321762
 Fax: +62 251 8350920
 E-mail: rudyhutomo@litbang.deptan.go.id,
rudyhutomo@yahoo.com

Mr Rudy TJAHOHUTOMO

Director
 Ministry of Agriculture
 Jl. Tentara Pelajar No.12, Kampus Penelitian Pertanian,
 Cimanggu
 16114 Bogor - West Java
 INDONESIA
 Tel: +62 251 8321762
 Fax: +62 251 8321762
 E-mail: rudyhutomo@litbang.deptan.go.id

ISLAMIC REPUBLIC OF IRAN/
 RÉPUBLIQUE ISLAMIQUE D'IRAN/
 REPÚBLICA ISLÁMICA DEL IRÁN

Ms MANSOOREH MAZHERY

Codex Secretariat of Iran food contaminants
 Institute of Standard and Industrial Research of Iran
 Food Department
 Institute of Standard and Industrial Research of Iran,
 Industrial City
 31585-163 Karaj
 IRAN (ISLAMIC REPUBLIC OF)
 Tel: ++98-9125474843
 Fax: ++98-261-2803889
 E-mail: man2r2001@yahoo.com

Ms AAZAMOSADAT MESHKANI

Member of Irans CCCF
 Marjankhatam Co.
 Food Department
 No. 44, Shaghayegh St., Abdollahzadeh Ave. Keshavarz
 Blvd
 1415633341 Tehran
 IRAN (ISLAMIC REPUBLIC OF)
 Tel: +989123175235
 Fax: +98 21 88966518
 E-mail: ameshkani@yahoo.com

IRELAND/IRLANDE/IRLANDA

Mr Rhodri EVANS

Chief Specialist Toxicology
 Food Safety Authority of Ireland
 Abbey Court, Lower Abbey Street
 1 Dublin
 IRELAND
 Tel: + 353 1 817 1303
 Fax: +353 1 817 1203
 E-mail: revans@fsai.ie

ISRAEL/ISRAËL

Ms Ziva HAMAMA-ELISHOV

risk management unit of food contaminants
 ministry of health
 Food Control Services
 Haarbaa st.
 61203 Tel-Aviv
 ISRAEL
 Tel: 972-3-6270182
 Fax: 972-3-6270140
 E-mail: ziva.elishov@moh.health.gov.il

ITALY/ITALIE/ITALIA

Mr CIRO IMPAGNATIELLO

Italian Codex Contact Point
 Ministry of Agricultural, Food and Forestry Policies
 Via XX Settembre, 20
 00187 Rome
 ITALY
 Tel: +39 0646654058
 E-mail: c.impagnatiello@mpaaf.gov.it

JAMAICA/JAMAÏQUE

Ms Linnette PETERS

Director of Veterinary Public Health
 Ministry of Health
 2-4 King Street
 Kingston
 JAMAICA
 Tel: 1-876-450-8099
 Fax: 1-876-967-1280
 E-mail: petersl@moh.gov.jm; Impeters2010@hotmail.com

JAPAN/JAPON/JAPÓN

Ms Yukiko YAMADA

Advisor, Chief Scientific Advisor
 Ministry of Agriculture, Forestry and Fisheries
 1-2-1 Kasumigaseki, Chiyoda-ku
 100-8950 Tokyo
 JAPAN
 Tel: 81-3-3501-6869
 Fax: 81-3-3502-8308
 E-mail: yyamada1201@gmail.com

Mr Kenji ASAKURA

Director
 Ministry of Agriculture Forestry and Fisheries
 Plant Products Safety Division, Food Safety and
 Consumer Affairs Bureau
 1-2-1 Kasumigaseki Chiyoda-ku,
 100-8950 Tokyo
 JAPAN
 Tel: +81-3-6744-2026
 Fax: +81-3-3580-8592
 E-mail: kenji_asakura@nm.maff.go.jp

Mr Jin FUKUMOTO

Deputy director
 Ministry of Health, Labour and Welfare, Japan
 Department of Food Safety
 1-2-2, Kasumigaseki, Chiyoda-ku,
 100-8916 Tokyo
 JAPAN
 Tel: (81-3) 3595-2341
 Fax: (81-3) 3501-4868
 E-mail: codexj@mhlw.go.jp

Ms Mitsuko IMAI

Assistant Director
 Food Safety Commission Secretariat
 First Risk Assessment Division
 5-2-20, Akasaka, Minato-ku
 107-6122 Tokyo
 JAPAN
 Tel: +81-3-6234-1190
 Fax: +81-3-3584-7391
 E-mail: mitsuko.imai@cao.go.jp

Mr Fumio SATO

Section Chief
 Food Safety Commission Secretariat
 First Risk Assessment Division
 5-2-20, Akasaka, Minato-ku
 107-6122 Tokyo
 JAPAN
 Tel: +81-3-6234-1098
 Fax: +81-3-3584-7391
 E-mail: fumio.sato@cao.go.jp

Ms Mio TODA

Senior Scientist
National Institute of Health Sciences
Division of Safety Information on Drug, Food and
Chemicals
1-18-1, Kamiyoga, Setagaya-ku
154-8501 Tokyo
JAPAN
Tel: +81-3-3700-1141
Fax: +81-3-3700-1483
E-mail: miou@nihs.go.jp

Mr Haruo TOMINAGA

Associate Director
Ministry of Agriculture, Forestry and Fisheries
Fisheries Agency
1-2-1 Kasumigaseki, Chiyoda-ku
100-8907 Tokyo
JAPAN
Tel: +81-3-3502-8203
Fax: +81-3-3508-1357
E-mail: haruo_tominaga@nm.maff.go.jp

Mr Tetsuo URUSHIYAMA

Associate Director, Scientific adviser
Ministry of Agriculture, Forestry and Fisheries
Plant Products Safety Division, Food safety and
Consumer Affairs Bureau
1-2-1, Kasumigaseki, Chiyoda-ku
100-8950 Tokyo
JAPAN
Tel: 81-3-3592-0306
Fax: 81-3-3580-8597
E-mail: tetsuo_urushiyama@nm.maff.go.jp

Mr Eiichi YOKOTA

Assistant Director
Ministry of Health, Labour and Welfare
Department of Food Safety
1-2-2 Kasumigaseki, Chiyoda-ku
100-8916 Tokyo
JAPAN
Tel: +81-3-3595-2326
Fax: +81-3-3503-7965
E-mail: codexj@mhlw.go.jp

KENYA

Ms Alice Akoth Okelo ONYANGO

Manager Kenya National Codex Contact Point
Kenya Bureau of Standards
National Codex Contact point dept/Standards Developm.
and Intern Trade
B.O. Box 54974
00200 Nairobi
KENYA
Tel: +25420 6948303
Fax: +25420609660
E-mail: akothe@kebs.org

Mr WACHIRA GITHENYA

analytical chemist
KEPHIS
LABORATORY
49592
00100 NAIROBI
KENYA
Tel: 254720722665
E-mail: gwachira@kephis.org

Mr OGOLA SAMUEL ONYANGO

TECHNICAL SERVICE MANAGER
TEA BOARD OF KENYA
TECHNICAL SERVICES
20064
00200 NAIROBI
KENYA
Tel: 254 7222000556
E-mail: ogolas@teaboard.or.ke

Mr JOHN WANYOKO

CHIEF RESEARCH OFFICER
TEA RESEARCH
PROGRAM
BOX820
20200 KERICHO
KENYA
Tel: 254522020598
E-mail: jkwanyoko@gmail.com

LUXEMBOURG/LUXEMBURGO

Mr Danny ZUST

Ministère de la Santé
Direction de la Santé -Secualim
1750 Luxembourg
LUXEMBOURG
E-mail: danny.zust@ms.etat.lu

MALAYSIA/MALAISIE/MALASIA

Mr ZEHNDER JARROOP AUGUSTINE MERCER

DIRECTOR
MALAYSIAN PEPPER BOARD
MALAYSIAN PEPPER BOARD
LOT 1115, JALAN UTAMA, BINTAWA INDUSTRIAL
AREA
93450 KUCHING, SARAWAK
MALAYSIA
Tel: 60198263261
Fax: 6082336877
E-mail: jarroop@gmail.com

MEXICO/MEXIQUE/MÉXICO

Mr Alejandro Abad Lara TERRÓN

Director General Adjunto de Normalizacion
Agroalimentaria
Secretaria de Agricultura, Ganaderia, Desarrollo Rural,
Pesca y Alimentacion
Municipio Libre no. 377 Piso 4 Ala B Col
C.P. 03310 Santa Cruz Atoyac
MEXICO
Tel: +52 55 3871 1000 ext. 34214
E-mail: alejandro.lara@sagarpa.gob.mx

MOROCCO/MAROC/MARRUECOS

Mr Nabil ABOUCHOAIB

Veterinarian
Office National de Securite Sanitaire des Produits
Alimentaires
Rue Cherkaoui Agdal
10000 Rabat
MOROCCO
Tel: +212 673997844
Fax: +212 537682049
E-mail: nabilabouchoaib@gmail.com

Mr Mohamed BOUJNAH

Institut National de la Recherche Agronomique
Ministère de l'Agriculture
Avenue Annasr, Agdal
Rabat
MOROCCO
E-mail: boujnahm@hotmail.com

Ms Keltoum DARRAG

chef de division promotion de la qualité
Etablissement Autonome de Contrôle et de Coordination
des Exportations
Département de l'Agriculture
72, Angle Boulevard Mohamed Smiha et Rue Moulay
Mohamed El Baâmrani
Casablanca
MOROCCO
Tel: +212 661153710
Fax: +212 522305168 /522302567
E-mail: darrag@eacce.org.ma

Mr Omar GUERMAZ

Chef de Division
laboratoire Officiel d'Analyses et de Recherches
Chimiques
Ministère de l'Agriculture
25, rue Nichakra Rahal
Casablanca
MOROCCO
Tel: +212 522 302007
Fax: +212 522 301972
E-mail: oguermaz@yahoo.fr

Mr Hamid TALEB

Institut National de Recherche Halieutique
Ministère de l'Agriculture
2, rue de Tiznit
Casablanca
MOROCCO
Tel: +212 522 220249
E-mail: htaleb@hotmail.com

MOZAMBIQUE

Mr Carlos RQUIXO

Quality Manager
Ministry of Fisheries
National Institute for Fish Inspection
Rua Bagamoyo 143
Maputo
MOZAMBIQUE
Tel: +258 829754620
Fax: +258 21315230
E-mail: cricuixo@yahoo.co.uk

NETHERLANDS/PAYS-BAS/PAÍSES BAJOS

Ms Karin BEAUMONT

Senior Policy Officer
Ministry of Health, Welfare and Sport Department for
Nutrition, Health Protection and Prevention
P.O. Box 20350
2500 EJ The Hague
NETHERLANDS
Tel: +31 70 340 71 11
E-mail: kg.beaumont@minvws.nl

Ms Astrid BULDER

Senior Risk Assessor
National Institute for Public Health and the Environment
(RIVM)
Centre for Nutrition, Prevention and Health Services (VPZ)
P.O. Box 1
3720 BA Bilthoven
NETHERLANDS
Tel: +31 30 274 7048
E-mail: astrid.bulder@rivm.nl

Mr Teetske GORCUM, VAN

National Institute of Public Health and the Environment
(RIVM)
Centre for Nutrition, Prevention and Health Services (VPZ)
PO Box 1
3720 BA Bilthoven
NETHERLANDS
Tel: +31 30 274 2728
E-mail: teetske.van.gorcum@rivm.nl

Ms Lianne WIT, DE

National Institute of Public Health and the Environment
(RIVM)
Centre for Nutrition, Prevention and Health Services (VPZ)
PO Box 1
3720 BA Bilthoven
NETHERLANDS
Tel: +31 30 274 7050
E-mail: lianne.de.wit@rivm.nl

Mr Gerrit WOLTERINK

National Institute of Public Health and the Environment
(RIVM)
Centre for Nutrition, Prevention and Health Services (VPZ)
PO Box 1
3720 BA Bilthoven
NETHERLANDS
Tel: +31 30 274 4531
E-mail: gerrit.wolterink@rivm.nl

NEW ZEALAND/NOUVELLE-ZÉLANDE/
NUEVA ZELANDIA

Mr John REEVE

Principal Advisor (Toxicology)
Ministry for Primary Industries
Science and Risk Assessment Directorate | Standards
Branch
P.O. Box 2526
6011 Wellington
NEW ZEALAND
Tel: +64 4 8942533
Fax: +64 4 8942530
E-mail: john.reeve@mpi.govt.nz

Mr Andrew PEARSON

Senior Advisor Toxicology
Food Risk Assessment
Level 10, Pastoral House, 25 The Terrace
6011 Wellington
NEW ZEALAND
Tel: +64 4 894 2535
E-mail: andrew.pearson@mpi.govt.nz

NICARAGUA

Ms Juana CASTELLÓN CASTELLÓN

Evaluador de Registro Sanitario de Alimentos
Ministerio de Salud
Direccion de Regulacion de Alimentos
Complejo Nacional de Salud, Complejo Concepcion
Palacios
107 Managua
NICARAGUA
Tel: 00505 22894700
Fax: 00505 22894839
E-mail: alimentofortificado@minsa.gob.ni

NIGERIA/NIGÉRIA

Mr Adekunle ADEBAMBO

Assistant Director
Federal Ministry of Industry, Trade and Investment
(FMITI)
Federal Produce Inspection Service
FMITI, AREA 1, Old Federal Secertariat, Garki, Abuja
+234 Abuja
NIGERIA
Tel: +234-8032481788
E-mail: adekunle_adebambo@yahoo.com

Mr Abimbola ADEGBOYE

Assistant Director
National Agency for Food and Drug Administration and
Control
445, Herbert Macaulay Way, Yaba, Lagos
Lagos
NIGERIA
Tel: +2348053170810
E-mail: adegboye.a@nafdac.gov.ng,
bimbostica@yahoo.com

Ms Nelly Chimezie ANSELM-ONUWA

Principal Regulatory Officer
National Agency for Food and Drug Administration and
Control
445, Herbert Macaulay Way, Yaba, Lagos
Lagos
NIGERIA
Tel: +2348034375040
E-mail: nelansel@yahoo.com

Mr Julius Oreyemi APANISILE

Director
Federal Ministry of Industry, Trade and Investment (FMTI)
Federal Produce Inspection Service
FMTI, Area 1 Old Federal Secertariat, Garki
Abuja
NIGERIA
Tel: +234-8033124256
E-mail: mrapanisile@yahoo.com

NORWAY/NORVÉGE/NORUEGA

Ms An-Katrin EIKEFJORD

Senior Adviser
Norwegian Food Safety Authority
P.O Box 383 N-2381 Brumunddal
NORWAY
Tel: +47 95276165
E-mail: An-Katrin.Eikefjord@mattilsynet.no

Ms Kirstin FAERDEN

Senior Adviser
Norwegian Food Safety Authority - Head Office
Staff - Department of Legislation
P.O.Box 383
N-2381 Brumunddal
NORWAY
Tel: +47 959 94 157
E-mail: kifar@mattilsynet.no

PAKISTAN/PAKISTÁN

Mr MUBARIK AHMED

Director-General
Ministry of National Food Security & Research
Department of Plant Protection
Jinnah Avenue, Malir Halt
- Karachi
Pakistan
Tel: ++9221-99248607
Fax: ++9221-99248673
E-mail: gqtl_parc@yahoo.com

Mr ITRAT RASOOL MALHI

Plant Specialist
 Ministry of National Food Security and Research
 National Animal and Plant Health Inspection Services
 (Naphis)
 32-Nazim-Ud-Din Road, F-8/1, Islamabad
 44000 Islamabad
 Pakistan
 Tel: ++9251-9261336
 Fax: ++9251-9261341
 E-mail: naphis.pk@live.com

PHILIPPINES/FILIPINAS

Ms Flordeliza ABRAHAN

Food-Drug Regulation Officer IV
 Food and Drug Administration
 Center for Food Regulation & Research –Laboratory
 Support Division
 Civic Drive, Filinvest Corporate City, Alabang
 1770 Muntinlupa
 PHILIPPINES
 Tel: +632 8571948
 Fax: +632 8070751
 E-mail: fcabrahan@fda.gov.ph

POLAND/POLOGNE/POLONIA

Ms MONIKA MANIA

National Institute of Public Health - National Institute of
 Hygiene
 Department of Food Safety
 Chocimska 24 St.
 00-791 Warsaw
 POLAND
 Tel: 48225421369
 Fax: 48225421225
 E-mail: mmania@pzh.gov.pl

REPUBLIC OF KOREA/RÉPUBLIQUE DE CORÉE/

REPÚBLICA DE COREA

Ms Hae Jung YOON

Director
 Ministry of Food and Drug Safety
 Food Safety Evaluation Department Food Contaminants
 Division
 Osong Health Technology Administration Complex, 187
 Osongsaengmyeong2(i)-ro, Osong-eup, Ch
 363-700 Chungcheongbuk-do
 REPUBLIC OF KOREA
 Tel: +82-43-719-4251
 Fax: +82-43-719-4250
 E-mail: hjyoon@korea.kr

Mr Jae-Min AN

Researcher
 Ministry of Agriculture, Food and Rural Affairs
 Safety Analysis
 5-3, Gimcheon innocity, Nam-myeon, Gimcheon City,
 Gyeongsangbuk-do Province, Korea
 740-871 Gimcheon
 REPUBLIC OF KOREA
 Tel: +82-54-429-7762
 Fax: +82-54-429-7779
 E-mail: ahjm@korea.kr

Mr Keum Yong HONG

Ministry of Agriculture, Food and Rural Affairs
 Consumer policy
 94, Dasom 2-ro, Sejong-si, Korea
 339-012 Sejong
 REPUBLIC OF KOREA
 Tel: +82-44-201-2425
 Fax: +82-44-868-0461
 E-mail: tears990@korea.kr

Mr Cheon Ho JO

Scientific Officer
 Ministry of Food and Drug Safety
 Food Standard Division
 Osong Health Technology Administration Complex, 187
 Osongsaengmyeong2(i)-ro, Osong-eup, Ch
 363-700 Chungcheongbuk-do
 REPUBLIC OF KOREA
 Tel: +82-43-719-2421
 Fax: +82-43-719-2400
 E-mail: jch77@korea.kr

Mr Joon Goo LEE

Scientific Officer
 Ministry of Food and Drug Safety
 Food Safety Evaluation Department Food Contaminants
 Division
 Osong Health Technology Administration Complex, 187
 Osongsaengmyeong2(i)-ro, Osong-eup, Ch
 363-700 Chungcheongbuk-do
 REPUBLIC OF KOREA
 Tel: +82-43-719-4264
 Fax: +82-43-719-4250
 E-mail: capbox@korea.kr

Ms Hyun-Mee PARK

Korea Institute of Science & Technology
 Advanced Analysis Center
 136-NPD Kist. Sung Bukau Hawolgokdong 3e-1
 Seoul
 REPUBLIC OF KOREA
 Tel: 0082 2 958 5980 / 8200 8212 5
 E-mail: phmu556@kost.re.kr

Ms Jiyoung YANG

Assistant Manager
EPIS
International Trade Supporting Team
#1314 Bangbae Dawoo Diovill, Seocho-daero, Seocho-gu,
Seoul, Korea
137-838 Seoul
REPUBLIC OF KOREA
Tel: +82-10-8829-8980
Fax: +82-31-460-8949
E-mail: yjiyoung@epis.or.kr

Mr Jihyock YOO

National Academy of Agricultural Science, Rural
Development Administration
Crop Life Safety
126 Suin-ro, Gwonseon-gu Soowon City Gyonggi-do
Province, Korea
740-871 Soowon
Tel: +82-31-290-0529
Fax: +82-31-290-0506
E-mail: idisryu@korea.kr

RUSSIAN FEDERATION/FÉDÉRATION DE RUSSIE/
FEDERACIÓN DE RUSIA

Mr Nikolay BALAN

Chief Expert
Federal Service for Surveillance on Consumer Rights
Protection and Human Well-being (Rosпотребнадзор)
International Cooperation Division
Bldg. 18/constr.5 and 7, Vadkovskiy per.
127994 Moscow
RUSSIAN FEDERATION
Tel: +7 499 973 3012
Fax: +7 499 973 1652
E-mail: balan_ng@gсен.ru

Ms Anna MISHINA

Deputy Chief of Department
Federal Service for Surveillance on Consumer Rights
Protection and Human Well-being (Rosпотребнадзор)
E-mail: balan_ng@gсен.ru

Ms Irina SEDOVA

Scientific researcher
National Research Institute of Nutrition of the Russian
Academy of Medical Science
Laboratory of Enzymology of Nutrition
Ustinskij minor street 2/14
109240 Moscow
RUSSIAN FEDERATION
Tel: +74956985365
Fax: +74956985379
E-mail: isedova@ion.ru

Ms Tatyana ZAVISTYAEVA

Chief of Department
Federal Service for Surveillance on Consumer Rights
Protection and Human Well-being (Rosпотребнадзор)
18/5 and 7, Vadkovskiy per.
127994 Moscow
RUSSIAN FEDERATION
Tel: +7 499 973 15 59
E-mail: Zavistyaeva_TY@gсен.ru

SINGAPORE/SINGAPOUR/SINGAPUR

Ms Shoo Peng KOH

Principal Scientist
Agri-Food & Veterinary Authority of Singapore
VPHL Chemistry Dept
10, PERAHU ROAD
SINGAPORE 718837 SINGAPORE
SINGAPORE
Tel: +65 67952 814/ +65 67952 885
Fax: +65 68619491
E-mail: KOH_SHOO_PENG@AVA.GOV.SG

Ms Mui Lee NEO

Senior Executive Manager (Regulatory Programmes)
Agri-Food & Veterinary Authority, Singapore
Regulatory Administration Department
5 Maxwell Road, #18-00 Tower Block, MND Complex
069110 Singapore
SINGAPORE
Tel: +65 6325 8551
Fax: +65 6220 6068
E-mail: neo_mui_lee@ava.gov.sg

Ms Yun Wei YAT

Scientific Officer
Health Sciences Authority
Food Safety Division, Applied Sciences Group
11 Outram Road
169078 Singapore
SINGAPORE
Tel: +65 6213 8972
Fax: +65 6213 0749
E-mail: yat_yun_wei@hsa.gov.sg

SLOVAKIA/SLOVAQUIE/ESLOVAQUIA

Mr Milo BYSTRICKY

state officer
Ministry of Agriculture and Rural Development of the
Slovak Republic
Food Safety and Nutrition
Dobrovicova 12
812 66 Bratislava
SLOVAKIA
Tel: +421259266555
Fax: +421259266704
E-mail: milo.bystricky@land.gov.sk

SPAIN/ESPAGNE/ESPAÑA

Ms ANA MARIA LOPEZ-SANTACRUZ

Head of Service in the Chemical Risks Area
Spanish Consumer, Food Safety and Nutrition Agency
Sub Directorate General for Food Safety Promotion
C\ Alcalá, 56
28071 Madrid
SPAIN
E-mail: alopezasantacruz@msssi.es

SUDAN/SOUDAN/SUDÁN

Ms HAYAT ABDELRAHMAN HASSAN

Associate Professor
Food Research Center /Ministry of Science &
Communication
Cereal Department
Shambat P.O.Box 213
+11111 Khartoum
SUDAN
Tel: +249912849520
E-mail: hayat0200@hotmail.com

Mr Nagi AWAD MASOUD

Agriculture Censutant
Sudan embassy in Netherland
Management
Sudan embassy in Netherland
The Hague
NETHERLANDS
Tel: 0031685542049
E-mail: agriculturalattache@sudanembassy.nl

Ms Ibtihag ELMUSTAFA

Head of mycotoxins center
sudanese standards &metrology organization
planning/research &scientific centers
P.O. Box 13573
+249 Khartoum
SUDAN
Tel: +249915388777
Fax: +249-83-741768
E-mail: ibtihagbur@hotmail.com

Mr Sirageldin MOHAMED AHMED

Environmental Health and food safety advisor
Federal Ministry of Health
Public Health emergency
El Nile Avenue
+11111 Khartoum
Tel: +249912135286
Fax: +2498378035
E-mail: sirageldinmust@yahoo.com

Mr Gaafar MOHAMED ALI

National Expert (Mycology)Cochair National Codex
Committee
Sudanese Standard &Metrology Organization
Mycology
Aljaama street
+11111 Khartoum
SUDAN
Tel: +249912888440
E-mail: gaafaribrahim80@hotmail.com

SWEDEN/SUÈDE/SUECIA

Ms Karin BÄCKSTRÖM

Principal Regulatory Officer
National Food Agency
Box 622
751 26 Uppsala
SWEDEN
Tel: +46 709 245664
E-mail: karin.backstrom@slv.se

THAILAND/THAÏLANDE/TAÏLANDIA

Mr Pisan PONGSAPITCH

Deputy Secretary General
National Bureau of Agricultural Commodity and Food
Standards
Ministry of Agriculture and Cooperatives
50 Paholyothin Road, Lad Yao, Chatuchak
10900 Bangkok
THAILAND
Tel: 662-561-3717
Fax: 662-561-3712
E-mail: pisan@acfs.go.th

Ms Kulpipith CHANBUEY

Standards Officer
Office of Standard Development
National Bureau of Agricultural Commodity and Food
Standards
50 Paholyothin Rd., Ladyao, Chatuchak
10900 Bangkok
THAILAND
Tel: +662 561 2277 Ext. 1415
Fax: +662 561 3357
E-mail: kulpipith@acfs.go.th

Ms Chutiwan JATUPORN PONG

Standards Officer
Office of Standard Development
National Bureau of Agricultural Commodity and Food
Standards
50 Paholyothin Rd., Ladyao, Chatuchak
10900 Bangkok
THAILAND
Tel: +662 561 2277 Ext. 1414
Fax: +662 561 3357
E-mail: chutiwan@acfs.go.th

Ms Pilai KAVISARASAI

Scientist, Senior Professional Level
 Department of Livestock Development
 Bureau of Quality Control of Livestock Products
 Tiwanon Road, Bangadi, Muang District
 12000 Pathumthani
 THAILAND
 Tel: +6629679749
 Fax: +6629679745
 E-mail: pilai_kavis@yahoo.com

Ms Kwantawee PAUKATONG

Member of Food Processing Industry Club
 The Federation of Thai Industries
 Queen Sirikit National Convention Center, Zone C, 4th
 Floor, 60 New Rachadapisek Rd., Klon
 10110 Bangkok
 THAILAND
 Tel: 662 955 0777
 Fax: 662 955 0708
 E-mail: kwantawee.paukatong@th.nestle.com

Ms Supanoi SUBSINSERM

Food Technologist, Senior professional level
 Fish Inspection and Quality Control Division
 Department of Fisheries
 50 Paholyothin Road, Kaset-klang, Chatuchak
 10900 Bangkok
 THAILAND
 Tel: 662 5620600 Ext. 13300
 Fax: 662 558 0139
 E-mail: Supanois@dof.mail.go.th, supanois@ymail.com

Ms Chanikan THANUPITAK

Trade and Technical Manager of Fisheries Products
 Thai Food Processors' Association
 170/21-22 9th Fl Ocean Tower 1 Bld., New Ratchadapisek
 Road
 10110 Bangkok
 THAILAND
 Tel: 662 261 2684-6
 Fax: 662 261 2996-7
 E-mail: fish@thaifood.org; chanikan@thaifood.org

Ms Jiraratana THESASILPA

Food and Drug Technical Officer, Senior Professional
 Level
 Food and Drug Administration
 Tiwanon Road, Muang District
 11000 Nonthaburi
 THAILAND
 Tel: 6625907209
 Fax: 6625907011
 E-mail: jirarate@fda.moph.go.th/jiraratanat@gmail.com

Ms Mayuree URAROONGROJ

Medical Scientist, Senior Professional Level
 Bureau of Quality and Safety of Food
 Department of Medical Sciences
 Tiwanon Road, Muang District
 11000 Nonthaburi
 THAILAND
 Tel: 662 951 0000 Ext. 99578
 Fax: 662 951 1023
 E-mail: mayureeu@hotmail.com

TUNISIA/TUNISIE/TÚNEZ

Mr Mejri HAMDJ

Chief Service of Food Control
 Agence Nationale de Controle Sanitaire des Produits
 Direction de Controle Sanitaire des Produits
 2 rue Ibn Nadim Montplaisir
 1073 Tunis
 TUNISIA
 Tel: 00216 2 4251502
 Fax: 00216 71909233
 E-mail: mejry@yahoo.fr

Ms Zohra SOUALHIA TOUATI

Ingenieur en Chef
 Agence Nationale de Controle Sanitaire et
 Environnemental de Produits
 Direction de Controle Environnemental des Produits
 ANCSEP, 2 Rue Lnb Nadim-Montplaisir
 1073 Montplaisir
 TUNISIA
 Tel: 21671903942
 Fax: 21671909943
 E-mail: zohra.soualhia@yahoo.fr

TURKEY/TURQUIE/TURQUÍA

Ms BETUL VAZGECER

Engineer
 Ministry of Food, Agriculture and Livestock
 Food Establishments and Codex Department
 Eskisehir Yolu 9. km Lodumlu
 06530 Ankara
 TURKEY
 Tel: 00903122587754
 Fax: 00903122587760
 E-mail: betul.vazgecer@tarim.gov.tr

UNITED KINGDOM/ROYAUME-UNI/REINO UNIDO

Ms Christina BASKARAN

UK Food Standards Agency
 125 Kingsway
 WC2B 6NH London
 UNITED KINGDOM
 Tel: 020 7276 8661
 E-mail: Christina.Baskaran@foodstandards.gsi.gov.uk

Ms Aattifah TELADIA

Agricultural Contaminants Policy Advisor
 UK Food Standards Agency
 Aviation House, 125 Kingsway
 WC2B 6NH London
 UNITED KINGDOM
 Tel: +44 20 7276 8715
 Fax: +44 20 7276 8446
 E-mail: Aattifah.Teladia@foodstandards.gsi.gov.uk

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

Mr Mathias NG'IMBA MISSANGA

Standards Officer
 Tanzania Bureau of Standards
 Standards Development
 P.O Box 9524
 +255 Dar Es Salaam
 United Republic of Tanzania
 Tel: +255784633116
 Fax: +255222450959
 E-mail: obuzeva@yahoo.com

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

Mr Nega BERU

Director, Office of Food Safety
 Center for Food Safety and Applied Nutrition
 Food and Drug Administration
 5100 Paint Branch Parkway
 20740 College Park, Maryland
 UNITED STATES OF AMERICA
 Tel: 1240 403 2021
 Fax: 13014362632
 E-mail: nega.beru@fda.hhs.gov

Mr Kyd BRENNER

Senior Consultant
 DTB Associates LLP
 1700 Pennsylvania Avenue, NW, Suite 200
 Washington, DC 20006
 UNITED STATES OF AMERICA
 Tel: +1 202 684 2508
 Fax: +1 202 684 2234
 E-mail: kbrenner@dtbassociates.com

Mr Kerry DEARFIELD

Chief Scientist
 Office of Public Health Science
 USDA, Food Safety and Inspection Service
 1400 Independence Avenue, SW
 20250 Washington, DC
 UNITED STATES OF AMERICA
 Tel: +12026906451
 Fax: +12026906337
 E-mail: kerry.dearfield@fsis.usda.gov

Mr Paul B. GREEN

International Trade Consultant
 North American Millers' Association
 600 Maryland Av. SW, Suite 825W
 20024 Washington, DC
 UNITED STATES OF AMERICA
 Tel: 202-236-3732
 Fax: 202-488-7416
 E-mail: pbgreendc@gmail.com

Mr Paul HANLON

Associate Director of Regulatory Affairs
 Abbott Nutrition
 3300 Stezler Road Dept. 104070, Bldg. RP3-2
 43219 Columbus OHIO
 UNITED STATES OF AMERICA
 Tel: 1 614 624 3213
 Fax: 1 614 727 3213
 E-mail: paul.hanlon@abbot.com

Mr Timothy HERRMAN

Director Feed Control Service State of Texas
 Texas A&M University System
 Office of the Texas State Chemist
 PO Box 3160
 77841 College Station, Texas
 UNITED STATES OF AMERICA
 Tel: 979-845-1121
 E-mail: ljz@ots.tamu.edu

Mr Henry KIM

Supervisory Chemist
 U.S. Food and Drug Administration
 Center for Food Safety and Applied Nutrition
 5100 Paint Branch Parkway
 College Park, MD, 20740
 UNITED STATES OF AMERICA
 Tel: 1 240 402 2023
 Fax: 13014362651
 E-mail: henry.kim@fda.hhs.gov

Ms Wu LI

Director, Food Safety
 PepsiCo Corp
 Frito-Lay North America Division
 7701 Legacy Drive 3T-218
 Plano, TX, 75024
 UNITED STATES OF AMERICA
 Tel: 9723344204
 Fax: 9723346830
 E-mail: wu.li@pepsico.com

Mr Abdul MABUD

Director, Scientific Services Division
 Alcohol and Tobacco Tax and Trade Bureau (TTB)
 Scientific Services Division
 6000 Ammendale Road
 20705 Beltsville, Maryland
 UNITED STATES OF AMERICA
 Tel: 12402641661
 Fax: 12024357369
 E-mail: md.mabud@ttb.gov

Ms Doreen MOULEC

International Issues Analyst
 U.S. Codex office
 U.S. Department of Agriculture
 1400 Independence Avenue SW
 20250-3700 Washington DC
 UNITED STATES OF AMERICA
 Tel: 202 205 7760
 Fax: 202 720 3157
 E-mail: doreen.chen-moulec@fsis.usda.gov

Mr Langley REECE

Vice President, Government Affairs
 USA Rice Federation
 2010 Wilson Boulevard, Suite 610
 22201 Arlington VA
 UNITED STATES OF AMERICA
 Tel: 1 703 236-1471
 E-mail: Rlangley@usarice.com

Ms Lauren ROBIN

Review Chemist
 Center for Food Safety and Applied Nutrition
 US Food & Drugs Administration
 5100 Paint Branch Pkwy
 College Park, MD, 20740
 UNITED STATES OF AMERICA
 Tel: 301-436-1639
 Fax: 301-436-2651
 E-mail: lauren.robin@fda.hhs.gov

Mr Stephen SAUNDERS

Managing Director
 HCTox
 112 Hummingbird Lane
 28604 Beech Mountain, NC
 UNITED STATES OF AMERICA
 Tel: 1828 387 9050
 E-mail: steve@hctox.com

Mr Paul SOUTH

U.S. Food and Drug Administration
 Center for Food Safety and Applied Nutrition
 5100 Paint Branch Parkway
 College Park, MD 20740
 UNITED STATES OF AMERICA
 Tel: 12404021640
 Fax: 13014362632
 E-mail: paul.south@fda.hhs.gov

Mr Scott WEBER

Scientific Analyst
 Foreign Agricultural Service
 U.S. Department of Agriculture
 1400 Independence Ave SW
 Washington DC
 UNITED STATES OF AMERICA
 Tel: 202 720 6868
 Fax: 202 720 0433
 E-mail: scott.weber@fas.usda.gov

URUGUAY

Ms CLAUDIA BOULLOSA

Inspector
 Ministerio de Salud Publica
 18 de Julio 1892.
 11200 Montevideo
 URUGUAY
 Tel: 598 2 4000101 / 04
 E-mail: cboullosa@msp.gub.uy

**UN OBSERVERS/
 OBSERVATEURS DE L'ONU/
 OBSERVADORES DE LA ONU**

International Atomic Energy Agency

Mr Igor GUSEV

Radiation Protection Specialist
 International Atomic Energy Agency
 Nuclear Safety
 Wagramerstrasse, 5
 1400 Vienna
 AUSTRIA
 Tel: +(431) 2600 22744
 Fax: +(421) 26007
 E-mail: i.gusev@iaea.org

Mr James Jacob SASANYA

Food Safety Specialist (Veterinary Drugs)
 International Atomic Energy Agency
 Nuclear Sciences and Application, Joint FAO/IAEA
 Division of Nuclear Techniques in Food and Agriculture,
 Food and Environmental Protection Section
 Vienna International Center
 Po Box 100, 1400 Vienna
 AUSTRIA
 Tel: 00431260026058
 E-mail: j.sasanya@iaea.org

**INTERNATIONAL GOVERNMENTAL ORGANIZATIONS/
 ORGANISATIONS GOUVERNEMENTALES
 INTERNATIONALES/
 ORGANIZACIONES GUBERNAMENTALES
 INTERNACIONALES**

African Union

Mr ANDREW EDEWA

Food Safety Officer
 AFRICAN UNION
 Westlands Road, Kenindia Business Park
 00100 Nairobi
 KENYA
 Tel: +254203674000
 Fax: +254203674341
 E-mail: Andrew.Edewa@au-ibar.org

Mr Gordon SHEPHARD

Chief Specialist Scientist
 Medical Research Council
 PROMEC Unit
 PO Box 19070, Tygerberg
 7505 Cape Town
 SOUTH AFRICA
 Tel: 0027 938 0279
 Fax: 0027 938 0260
 E-mail: gordon.shephard@mrc.ac.za

Food and Agricultural Organization

Ms Daniela A. BATTAGLIA

Livestock Production Officer
 Food and Agricultural Organization
 Animal Production and Health Division
 Viale delle Terme di Caracalla
 00153 Rome
 ITALY
 Tel: +39 065 705 67 73
 Fax: +39 065 705 57 49
 E-mail: daniela.battaglia@fao.org

Ms Mary KENNY

Food Safety and Quality Officer
 Food and Agricultural Organization
 Food Safety and Codex Unit
 Rome
 ITALY
 Tel: +39 065 705 3653
 E-mail: mary.kenny@fao.org

Mr Manfred LUETZOW

FAO Consultant
 FAO
 Feldhofweg 38
 5432 Neuenhof
 SWITZERLAND
 Tel: +41 76 332 1259
 E-mail: manfred.luetzow@luetzow.ch

Inter-American Institute for Cooperation on Agriculture

Mr Marcos SÁNCHEZ

Food Safety Specialist
 IICA
 Agribusiness and Commercialization Program
 5757 Blue Lagoon Drive, Suite 200
 Miami, FL 33126 Miami
 UNITED STATES OF AMERICA
 Tel: 1 (305) 260-9010 Ext. 225
 E-mail: Marcos.Sanchez@iica.int

United States Pharmacopeial Convention

Ms Laurvick KRISTIE

Senior Scientific Liaison
 United States Pharmacopeia
 12601 Twinbrook Parkway
 20852 Rockville, MD
 UNITED STATES OF AMERICA
 Tel: +1-301-816-8356
 E-mail: kxb@usp.org

World Health Organization

Ms Angelika TRITSCHER

WHO JECFA Secretary
 World Health Organization
 Department of Food Safety and Zoonoses
 20, Avenue Appia
 1211 Geneva 27
 SWITZERLAND
 Tel: +41227913569
 Fax: +41227914807
 E-mail: tritschera@who.int

**INTERNATIONAL NON-GOVERNMENTAL
 ORGANIZATIONS/
 ORGANISATIONS NON-GOUVERNEMENTALES
 INTERNATIONALES /
 ORGANIZACIONES NO GUBERNAMENTALES
 INTERNACIONALES**

Association européenne pour le droit de l'alimentation

Mr ALESSANDRO FIORELLI

AEDA-EFLA
 RUE DE L ASSOCIATION 50
 1000 BRUSSELS
 BELGIUM
 Tel: +3222091142
 Fax: +3222197342
 E-mail: secretariat@efla-aeda.org

FoodDrinkEurope

Mr Patrick FOX

Manager Food Policy, Science and R&D
 FoodDrinkEurope
 Science and R&D
 Avenue des Nerviens 9-31- 1040
 Bruxelles
 BELGIUM
 Tel: +32 2 5008756
 Fax: +32 2 5112905
 E-mail: p.fox@fooddrinkeurope.eu

Mr Nicolas FABRE

Regulatory Toxicology Leader
 Unilever
 Regulatory Affairs
 Olivier van Noortlaan 120
 3133 AT Vlaardingen
 NETHERLANDS
 E-mail: Nicolas.Fabre@unilever.com

Mr Helmut GUENTHER

Principal Scientist
Mondelēz International
Scientific Affairs EU
Langemarckstraße 4-20
28299 BREMEN
GERMANY
Tel: 49 421 599 3274
Fax: +49 421 599 8 3274
E-mail: hguenther@mdlz.com

Ms Irene LOMER

Global contaminants specialist
Unilever
Regulatory Affairs
Olivier van Noortlaan 120
3133 AT Vlaardingen
NETHERLANDS
Tel: +31-615045645
E-mail: irene.lomer@unilever.com

Mr Paul WHITEHOUSE

Head of Regulatory Affairs, Foods & Refreshment
Unilever
Regulatory Affairs
Olivier van Noortlaan 120
3133 AT Vlaardingen
NETHERLANDS
Tel: +31104607336
E-mail: paul.whitehouse@unilever.com

International Alliance of Dietary/Food Supplement
Associations

Ms Yifan JIANG

Advisor, Regulatory Affairs
IADSA
IADSA Secretariat
3 Killiney Road #07-04 Winsland House I
239519 Singapore
SINGAPORE
Tel: +65 6681 0105
E-mail: yifanjiang@iadsa.org

Mr Xavier LAVIGNE

International Alliance of Dietary/Food Supplement
Associations (IADSA)
Rue de l'Association 50
1000 Brussels
BELGIUM
Tel: +32 2 209 11 55
Fax: +32 2 223 30 64
E-mail: secretariat@iadsa.org

International Council of Beverages Associations

Ms Paivi JULKUNEN

Chair, ICBA Committee for Codex
International Council of Beverages Associations
1101 16th Street NW
20036 Washington
UNITED STATES OF AMERICA
Tel: +14046762677
Fax: +14045982677
E-mail: pjulkunen@coca-cola.com

International Council of Grocery Manufacturers
Associations

Mr Richard WHITE

Director, Codex and International Standards Policy
Grocery Manufacturers Association
1350 I Street, NW, Suite 300
20005 Washington, DC
Tel: 202 639 5922
E-mail: rwhite@gmaonline.org

International Council of Grocery Manufacturers
Associations

Mr Brent KOBIELUSH

Manager of Toxicology
Global Product Safety and Regulatory Affairs
General Mills, Inc
Number 1 General Mills Blvd, W01-B
55426 Minneapolis, MN
UNITED STATES OF AMERICA
Tel: 763 764 5752
E-mail: brent.kobielush@genmills.com

Institute of Food Technologists

Mr James COUGHLIN

President
Coughlin & Associates
8 Camillo
92656 Aliso Viejo, California
UNITED STATES OF AMERICA
Tel: 19499166217
E-mail: jrcoughlin@cox.net

International Life Sciences Institute

Mr Ryuji YAMAGUCHI

Executive Director
ILSI Japan
Nishikawa Building 5F, 3-5-19, Kojimachi, Chiyoda-ku
102-0083 Tokyo
JAPAN
Tel: 81-3-5215-3535
Fax: 81-3-5215-3537
E-mail: ryamaguchi@ilsijapan.org

International Nut and Dried Fruit Council Foundation

Ms IRENE GIRONES

Scientific and Technical Projects Manager
International Nut and Dried Fruit Council Foundation (INC)
Carrer de la Fruita Seca 4, Polígon Tecnoparc
43204 Reus
SPAIN
Tel: 34977331416
Fax: 34977315028
E-mail: irene.girones@nutfried.org

National Health Federation

Mr Scott TIPS

President
National Health Federation
P.O. Box 688
91017 Monrovia, California
UNITED STATES OF AMERICA
Tel: 16263572181
Fax: 16263030642
E-mail: scott@rivieramail.com

National Health Federation

Mr Rik CRUYS

NHF
E-mail: rikcruys@hotmail.com

Organisation des fabricants de produits cellulosesques
alimentaires

Mr Huub SCHERES

Vice Chair
OFCA
Archimedesweg 30
2333 CN Leiden
NETHERLANDS
Tel: + 31 6 2909 3600
E-mail: huub.scheres@dupont.com

Safe Supply of Affordable Food Everywhere

Ms Ludovica VERZEGNASSI

Corporate Regulatory & Scientific Affairs
Nestec
Avenue Nestle 55
CH-1800 Vevey
SWITZERLAND
Tel: 41219243501
Fax: 41219244547
E-mail: Ludovica.Verzegnassi@nestle.com

SECRETARIAT/SECRÉTARIAT/SECRETARÍA

CODEX SECRETARIAT/SECRÉTARIAT DU CODEX/
SECRETARÍA DEL CODEX

Ms Gracia BRISCO

Food Standards Officer
Joint FAO/WHO Food Standards Programme
Viale delle Terme di Caracalla
00153 Rome
ITALY
Tel: +39065 7052700
Fax: +39065 7054593
E-mail: gracia.brisco@fao.org

Ms Verna CAROLISSEN-MACKAY

Food Standards Officer
FAO/WHO Food Standards Programme
Viale delle Terme di Caracalla
00153 Rome
ITALY
Tel: +39065 7055629
Fax: +39065 7054593
E-mail: verna.carolissen@fao.org

**HOST GOVERNMENT SECRETARIAT/
SECRÉTARIAT DU PAYS HÔTE/
SECRETARÍA DEL PAÍS ANFITRIÓN**

DUTCH HOST GOVERNMENT SECRETARIAT/
SECRÉTARIAT DU GOUVERNEMENT DES PAYS-BAS/
SECRETARÍA DEL GOBIERNO DE LOS PAÍSES BAJOS

Mr Jeroen FRIEDERICY

Policy Officer
Ministry of Economic Affairs
Plant Agri Chain and Food Quality Department
P.O. Box 20401
2500 EK The Hague
NETHERLANDS
Tel: 31703784924
Fax: 31703786134
E-mail: info@codexalimentarius.nl

Ms Judith AMATKARIJO

Ministry of Economic Affairs
European Agricultural Policy and Food Security
Department
PO Box 20401
2500 EK The Hague
NETHERLANDS
Tel: +31 70 379 8962
E-mail: info@codexalimentarius.nl

Ms Tanja ÅKESSON

Codex Contact Point

Ministry of Economic Affairs

Plant Agri Chains and Food Quality Department

P.O. Box 20401

2500 EK The Hague

NETHERLANDS

Tel: 3170378 4045

Fax: 3170378 6134

E-mail: t.z.j.akesson@mineleni.nl

APPENDIX II

**PROPOSED DRAFT MAXIMUM LEVEL FOR LEAD IN INFANT FORMULA,
FORMULA FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS
AND FOLLOW-UP FORMULA**

(Step 5/8)

LEAD

Commodity / Product Name	Maximum Level (ML) mg/kg	Portion of the commodity to which the ML applies	Notes/remarks
Infant formula Formula for special medical purposes intended for infants and Follow-up formula	0.01	Whole commodity	Relevant Codex commodity standards are the <i>Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants</i> (CODEX STAN 72-1981) and the <i>Standard for Follow-up formula</i> (CODEX STAN 156-1987) The ML applies to formula as consumed.

APPENDIX III**PROPOSED DRAFT MAXIMUM LEVEL FOR INORGANIC ARSENIC IN POLISHED RICE**

(Step 5/8)

ARSENIC

Commodity / Product Name	Maximum Level (ML) mg/kg	Portion of the commodity to which the ML applies	Notes/remarks
Rice, polished	0.2	Whole commodity	<p>The ML is for inorganic arsenic (As-in).</p> <p>Countries or importers may decide to use their own screening when applying the ML for As-in in rice by analysing total arsenic (As-tot) in rice. If the As-tot concentration is below the ML for As-in, no further testing is required and the sample is determined to be compliant with the ML. If the As-tot concentration is above the ML for As-in, follow-up testing shall be conducted to determine if the As-in concentration is above the ML.</p>

APPENDIX IV**PROPOSED DRAFT MAXIMUM LEVELS FOR FUMONISINS IN MAIZE AND MAIZE PRODUCTS
AND ASSOCIATED SAMPLING PLANS
(Step 5/8)****FUMONISINS**

Commodity / Product Name	Maximum Level (ML) µg/kg	Portion of the commodity/product to which the ML Applies	Notes/Remarks
Raw maize grain	4 000	Whole commodity	For sampling plans, see Annex
Maize flour and maize meal	2 000	Whole commodity	For sampling plans, see Annex

ANNEX

SAMPLING PLAN FOR FUMONISINS (FB1 + FB2) IN MAIZE GRAIN AND MAIZE FLOUR AND MAIZE MEAL

Raw Maize Grain

Maximum level	4 000 µg/kg FB1 + FB2
Increments	increments of 100 g, depending on the lot weight (≥ 50 tonnes)
Aggregate sample size	5 kg (lot ≥ 50 tonnes)
Sample preparation	dry grind with a suitable mill (particles smaller than 0.85 mm – 20 mesh)
Laboratory sample size	1 kg
Number of laboratory samples	1
Test portion	25 g test portion
Method	HPLC
Decision rule	If the fumonisin-sample test result for the laboratory samples is equal or less than 4 000 µg/kg, accept the lot. Otherwise, reject the lot.

Maize Flour and Maize Meal

Maximum level	2 000 µg/kg FB1 + FB2
Increments	10 x 100 g
Aggregate sample size	1 kg
Sample preparation	None
Laboratory sample size	25 g test portion
Number of laboratory samples	1
Test portion	same as laboratory sample
Method	HPLC
Decision rule	If the fumonisin-sample test result is equal or less than 2 000 µg/kg, accept the lot. Otherwise, reject the lot.

DEFINITION

Lot - an identifiable quantity of a food commodity delivered at one time and determined by the official to have common characteristics, such as origin, variety, type of packing, packer, consignor, or markings.

Sublot - designated part of a larger lot in order to apply the sampling method on that designated part. Each sublot must be physically separate and identifiable.

Sampling plan - is defined by a fumonisin test procedure and an accept/reject level. A fumonisin test procedure consists of three steps: sample selection, sample preparation and analysis or fumonisin quantification. The accept/reject level is a tolerance usually equal to the Codex maximum level (ML).

Incremental sample – the quantity of material taken from a single random place in the lot or sublot.

Aggregate sample - the combined total of all the incremental samples that is taken from the lot or sublot. The aggregate sample has to be at least as large as the laboratory sample or samples combined.

Laboratory sample – the smallest quantity of shelled maize comminuted in a mill. The laboratory sample may be a portion of or the entire aggregate sample. If the aggregate sample is larger than the laboratory sample(s), the laboratory sample(s) should be removed in a random manner from the aggregate sample.

Test portion – a portion of the comminuted laboratory sample. The entire laboratory sample should be comminuted in a mill. A portion of the comminuted laboratory sample is randomly removed for the extraction of the fumonisin for chemical analysis.

Operating characteristic (OC) curve – a plot of the probability of accepting a lot versus lot concentration for a specific sampling plan design. The OC curve provides an estimate of the chances of rejecting a good lot (exporter's risk) and the chances of accepting a bad lot (importer's risk) by a specific fumonisin sampling plan design. A good lot is defined as having a fumonisin concentration below the ML; a bad lot is defined as having a fumonisin concentration above the ML.

SAMPLING PLAN DESIGN CONSIDERATIONS

MATERIAL TO BE SAMPLED

- Each lot of maize, which is to be examined for fumonisin, must be sampled separately. Lots larger than 50 tonnes should be subdivided into sublots to be sampled separately. If a lot is greater than 50 tonnes, the lot should be subdivided into sublots according to Table 1.

Table 1. Subdivision of maize sublots according to lot weight

Lot weight (ton)	Weight or number of lots	Number of incremental sample	Aggregate sample weight
≥ 1 500	500	100	5
> 300 and < 1 500	3 sublots	100	5
≥ 50 and ≤ 300	100 tonnes	100	5
< 50	-	3 - 100*	1 - 5

* see Table 2

- Taking into account that the weight of the lot is not always an exact multiple of the weight of sublots, the weight of the sublot may exceed the mentioned weight by a maximum of 20%.

INCREMENTAL SAMPLE

- The suggested minimum weight of the incremental sample should be approximately 100 g for lots of 50 metric tonnes (50 000 kg) or higher
- For lots less than 50 tonnes, the sampling plan must be used with 10 to 100 incremental samples, depending on the lot weight, resulting in an aggregate sample of 1 to 5 kg. For very small lots (≤ 0.5 tonnes) a lower number of incremental samples may be taken, but the aggregate sample uniting all incremental samples shall be also in that case at least 1 kg. Table 2 may be used to determine the number of incremental samples to be taken.

Table 2. Number of incremental samples to be taken depending on the weight of the lot of

Lot weight (ton)	Number of incremental sample
≥ 0.05	3
> 0.05 - ≤ 0.5	5
> 0.5 - ≤ 1	10
> 1 - ≤ 3	20
> 3 - ≤ 10	40
> 10 - ≤ 20	60
> 20 - ≤ 50	100

STATIC LOTS

5. A static lot can be defined as a large mass of shelled maize contained either in a large single container such as a wagon, truck or railcar or in many small containers such as sacks or boxes and the maize is stationary at the time a sample is selected. Selecting a truly random sample from a static lot can be difficult because all containers in the lot or subplot may not be accessible.
6. Taking incremental samples from a static lot usually requires the use of probing devices to select product from the lot. The probing devices should be specifically designed for the commodity and type of container. The probe should (1) be long enough to reach all products, (2) not restrict any item in the lot from being selected, and (3) not alter the items in the lot. As mentioned above, the aggregate sample should be a composite from many small incremental samples of product taken from many different locations throughout the lot.
7. For lots traded in individual packages, the sampling frequency (SF), or number of packages that incremental samples are taken from, is a function of the lot weight (LT), incremental sample weight (IS), aggregate sample weight (AS) and the individual packing weight (IP), as follows:
$$SF = (LT \times IS) / (AS \times IP)$$
8. The sampling frequency (SF) is the number of packages sampled. All weights should be in the same mass units such as kg.

DYNAMIC LOTS

9. Representative aggregate samples can be more easily produced when selecting incremental samples from a moving stream of shelled maize as the lot is transferred from one location to another. When sampling from a moving stream, take small incremental samples of product from the entire length of the moving stream; composite the incremental samples to obtain an aggregate sample; if the aggregate sample is larger than the required laboratory sample(s), then blend and subdivide the aggregate sample to obtain the desired size laboratory sample(s).
10. Automatic sampling equipment such as a cross-cut sampler is commercially available with timers that automatically pass a diverter cup through the moving stream at predetermined and uniform intervals. When automatic sampling equipment is not available, a person can be assigned to manually pass a cup through the stream at periodic intervals to collect incremental samples. Whether using automatic or manual methods, incremental samples should be collected and composited at frequent and uniform intervals throughout the entire time the maize flow past the sampling point.
11. Cross-cut samplers should be installed in the following manner: (1) the plane of the opening of the diverter cup should be perpendicular to the direction of the flow; (2) the diverter cup should pass through the entire cross sectional area of the stream; and (3) the opening of the diverter cup should be wide enough to accept all items of interest in the lot. As a general rule, the width of the diverter cup opening should be about two to three times the largest dimensions of items in the lot.
12. The size of the aggregate sample (S) in kg, taken from a lot by a cross cut sampler is:
$$S = (D \times LT) / (T \times V),$$
where D is the width of the diverter cup opening (cm), LT is the lot size (kg), T is interval or time between cup movement through the stream (seconds), and V is cup velocity (cm/sec).
13. If the mass flow rate of the moving stream, MR (kg/sec), is known, then the sampling frequency (SF), or number of cuts made by the automatic sampler cup can be computed as a function of S, V, D, and MR.
$$SF = (S \times V) / (D \times MR)$$

PACKAGING AND TRANSPORTATION OF SAMPLES

14. Each laboratory sample shall be placed in a clean, inert container offering adequate protection from contamination, sunlight, and against damage in transit. All necessary precautions shall be taken to avoid any change in composition of the laboratory sample, which might arise during transportation or storage. Samples should be stored in a cool dark place.
15. Each laboratory sample taken for official use shall be sealed at the place of sampling and identified. A record must be kept of each sampling, permitting each lot to be identified unambiguously and giving the date and place of sampling together with any additional information likely to be of assistance to the analyst.

SAMPLE PREPARATION

16. Sunlight should be excluded as much as possible during sample preparation, since fumonisin may gradually break down under the influence of ultra-violet light. Also, environmental temperature and relative humidity should be controlled and not favor mold growth and fumonisin formation.
17. As the distribution of fumonisin is extremely non-homogeneous, laboratory samples should be homogenised by grinding the entire laboratory sample received by the laboratory. Homogenisation is a procedure that reduces particle size and disperses the contaminated particles evenly throughout the comminuted laboratory sample.

18. The laboratory sample should be finely ground and mixed thoroughly using a process that approaches as complete homogenisation as possible. Complete homogenisation implies that particle size is extremely small and the variability associated with sample preparation approaches zero. After grinding, the grinder should be cleaned to prevent fumonisin cross-contamination.

TEST PORTION

19. The suggested weight of the test portion taken from the comminuted laboratory sample should be approximately 25 g.
20. Procedures for selecting the test portion from the comminuted laboratory sample should be a random process. If mixing occurred during or after the comminuting process, the test portion can be selected from any location throughout the comminuted laboratory sample. Otherwise, the test portion should be the accumulation of several small portions selected throughout the laboratory sample.
21. It is suggested that three test portions be selected from each comminuted laboratory sample. The three test portions will be used for enforcement, appeal, and confirmation if needed.

ANALYTICAL METHODS

22. A criteria-based approach, whereby a set of performance criteria is established with which the analytical method used should comply, is appropriate. The criteria-based approach has the advantage that, by avoiding setting down specific details of the method used, developments in methodology can be exploited without having to reconsider or modify the specific method. A list of possible criteria and performance levels are shown in Table 3 (EC Regulation No 401/2006). Utilizing this approach, laboratories would be free to use the analytical method most appropriate for their facilities.

Table 3. Performance criteria for Fumonisin B1 and B2

Level ($\mu\text{g}/\text{kg}$)	Precision		Recovery (%)
	RSDr (%)	RSDR (%)	
≤ 500	≤ 30	≤ 60	60 to 120
> 500	≤ 20	≤ 30	70 to 110

APPENDIX V**CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF MYCOTOXIN CONTAMINATION IN CEREALS
(CAC/RCP 51-2003)****PROPOSED DRAFT ANNEX 5 - PREVENTION AND REDUCTION OF AFLATOXINS AND OCHRATOXIN A CONTAMINATION
IN SORGHUM AND SORGHUM PRODUCTS****(Step 5/8)****INTRODUCTION**

1. Good Agricultural Practices include methods to reduce the development of aflatoxin- and ochratoxin A- producing fungi and their toxins contamination consequently of sorghum in the field during planting, harvest, storage and transport; and processing.

PLANTING

2. Refer to paragraphs 4-9 of General Code of Practice.

3. Avoid planting sorghum on the land where groundnut or other highly susceptible crops were cultivated in the previous year because such soils are likely to be contaminated with *Aspergillus flavus* and *A. parasiticus*.

4. Do not grow sorghum in or close to cocoa trees, coffee bean plants or grape vines as these crops are highly susceptible to ochratoxigenic fungi and ochratoxin A contamination and thus will inoculate the soil with *Aspergillus ochraceus* or *Penicillium verrucosum* in tropical and temperate climates, respectively with consequent carryover to the sorghum grains.

5. As far as practical, crop planting should be timed in such a manner to avoid high humidity during the period of pollination, flowering and/or fertilization. Fungi tend to produce mycotoxins (particularly ergot alkaloids) in such climate conditions.

6. If available and cost effective, extension officers should assist the farmers in procuring and releasing atoxigenic *A.flavus* and *A.parasiticus* into the agricultural environment to suppress the natural occurrence of the aflatoxigenic fungi following the instructions of the manufacturer.

PREHARVEST

7. Refer to paragraphs 10-15 in the General Code of Practice.

HARVEST

8. Refer to paragraphs 16-21 in the General Code of Practice.

9. Plants damaged and/or infested by pests should be harvested separately.

10. Avoid stacking the harvested produce when it has a high moisture content, including the panicle, for unduly long periods to prevent fungal growth as spores from panicle will serve as inocula.

11. Sun drying should be done on clean surfaces; grains should be protected from rain and dew during this process. Drying could also be done using mechanical dryers. Flat bed and re-circulating batch driers are adequate for small scale operations while using continuous flow-dryer will suffice for large scale drying for long storage periods.

STORAGE

12. Refer to paragraphs 26 and 31 of the General Code of Practice for types of storage facility to use and documentation of harvesting and storage procedure.

13. Packaging materials that allow aeration of their contents are preferable.

TRANSPORT

14. Refer to paragraphs 16 in the General Code of Practice for transport to and from storage.

PROCESSING

15. Sorghum grains for human consumption are usually processed to sorghum flour, from which sorghum dough, meals and other foods are prepared. In general, the process consists of husking, polishing, grinding and scouring. Sorghum grains are also used as feed and care must be taken to maintain proper isolation between good lots and bad lots so that mycotoxin contamination can be avoided.

FLOUR

16. Start with high quality, mature grains which are free from mechanical, insect or mould damage.

17. Precaution must be taken to reject grains with signs of pest damage or mould growth because of the risk of their bearing aflatoxins and ochratoxin A. Aflatoxins and ochratoxin A test results should be known before allowing lots of raw grains to be processed. Any lot showing raw grains with unacceptable levels of mycotoxins should not be accepted.

18. Mould infected and/or damaged kernels should be separated and discarded in order to prevent their entry into the food chain and feed manufacturing process.
19. Cleanse processing equipment and environment thoroughly before and after grinding a batch of produce using approved disinfectant in order to reduce risk of cross contamination.
20. Commence grain processing with at least one of the following food processing techniques that have been shown to reduce aflatoxin levels in grains: washing, wet and dry milling, grain cleaning, dehulling, roasting, baking and frying.
21. A major source of mycotoxin contamination in the sorghum traditional processing line is unwholesome household storage of sorghum flour before use. Therefore avoid keeping flour for long periods of time, but if it is unavoidable then it should be stored in proper storage containers and conditions at safe moisture levels with minimum temperature changes. Such containers must deter insect and rodent infestation.

BEER

22. The steeping process (soaking and germination phases) raises the seed moisture level to about 45% which is favourable for fungal growth and mycotoxin production. The situation is problematic if the process is done under open, poor sanitary conditions. Therefore, steeping should be carried out in weatherproof containers under controlled atmosphere.
23. Poorly preserved starter cultures are significant sources of mycotoxin contamination in the traditional brewing system which underscores the need for starter cultures to be stored in clean, weatherproof jars, free from infestation, and sealed to prevent water, pest and mould from reaching them before use.

PACKAGING AND MARKETING

24. Package sorghum grains and products in containers with qualities described in paragraphs 22-23 above. Such containers should allow for adequate aeration of the produce during transit and marketing.

APPENDIX VI**PROPOSED DRAFT CODE OF PRACTICE FOR WEED CONTROL TO PREVENT AND REDUCE
PYRROLIZIDINE ALKALOID CONTAMINATION IN FOOD AND FEED****(Step 5/8)****INTRODUCTION**

1. Pyrrolizidine alkaloids (PAs) are natural toxins occurring in a wide variety of plants. Over 6 000 plant species throughout the world are expected to contain PAs. PAs are probably the most widely distributed natural toxins that can affect wildlife, livestock and humans.
2. PAs have a common toxicity profile with the liver being the main target organ of toxicity. Major signs of toxicity in all animal species include various degrees of progressive liver damage (centrilobular hepatocellular necrosis), and veno-occlusive disease. Furthermore, the International Agency for Research on Cancer (IARC) has classified three PAs, lasiocarpine, monocrotaline and riddelliine, as 'possibly carcinogenic to humans' (Group 2B). PAs may differ in potency, the relative potencies are currently not known due to lack of oral toxicity data on individual PAs, which hampers risk assessment for PAs.
3. Risks to humans may arise from the intake of PA contaminated food of vegetable or animal origin and outbreaks of toxicity in farm animals cause economic losses to farmers and rural communities. Direct human cases of poisoning via food are well-documented, which in some cases have resulted in deaths. Also, consumption of grain or grain products (flour or bread) contaminated with PA-containing seeds has caused outbreaks of poisoning. Further, plant parts which contain PAs have been identified in foods prepared from agricultural crops, i.e. salad leaves. PAs were also found in products from animal origin, i.e. milk and eggs, indicating transfer of PAs from feed to edible tissues.
4. Although there are gaps in the information available on the toxicity and relative potency of individual PAs, and the contribution of different foods to overall exposure, dietary exposure to PAs should be as low as possible due to the potential health-threatening effects that can be caused by ingestion of these toxins via feed or food. To achieve this, management practices aimed at the prevention and reduction of contamination of food and feed with PAs must be undertaken.
5. Management practices to prevent or reduce PA contamination of food and feed can comprise weed management (removal/reduction) practices to reduce exposure of food-producing animals, including livestock and bees, to PA-containing plants, and practices to reduce presence of PAs in raw and processed commodities. This Code of Practice focuses on weed control. Deliberate use of PA-containing plants for foods and feed cannot be justified for any reason without appropriate assessment.
6. It should be emphasised that total eradication of PA-containing plants is not feasible or ecologically desirable. Also, grazing animals usually avoid eating most growing plant species containing PAs under normal circumstances. Generally, livestock graze on PA-containing plants when feed gets scarce in conditions of drought or on over-grazed pastures. Livestock may also consume PA-containing plants when they are present in dried form in feed. Therefore, good feeding practice is important besides management through weed control.

OBJECTIVE

7. This Code of Practice aims to provide good management practices for weed control of PA-containing plants to prevent and reduce the contamination of food and feed with PAs. In this regard, this code will cover control measures for the management of the PA-containing plant as well as measures for control of plant release and spread.

SCOPE

8. The scope of this Code of Practice is to provide guidance to prevent contamination of food and feed with PAs on the one hand and, where contamination cannot be completely avoided, to reduce the PA contamination in food and feed by weed control. This Code of Practice should be read in conjunction with other relevant Codes of Practice for the prevention and reduction of other contaminants in food and feed.

EVALUATION OF COMPLIANCE WITH RELEVANT LEGISLATION

9. All management practices presented in this Code of Practice shall be followed in compliance with relevant national or international legislation and standards, including general requirement for consumer and worker protection.

LIMITATIONS

10. It should be recognised that the implementation of the management measures described in this Code of Practice may be difficult in a number of countries. This may be either due to lack of knowledge or resources or due to geographical, environmental or practical limitations, such as the area of land being too large, or inaccessibility of certain regions for agricultural machinery. The measures described in this Code of Practice serve therefore as guidance and each measure described in this Code of Practice should be assessed by national authorities or other professional and advisory bodies to ensure that it is appropriate and practical for their country-specific conditions.

11. There is currently insufficient information concerning the effectiveness of the various management measures and therefore no full evaluation of the management measures can be conducted. When such information becomes available, an evaluation of the effectiveness of the proposed management measures would be helpful in identifying the most appropriate combination of practices for management of PA-containing plants thereby lowering the chance of PA-contamination of food and feed.

GENERAL PRINCIPLES FOR WEED CONTROL OF PA-CONTAINING PLANTS

12. To ensure adequate prevention of the spread of PA-containing plants, and to lower the costs of control measures, early detection and identification of these plants is essential followed by action to prevent contamination of food and feed.

13. To achieve an early detection, raising awareness by providing good information to the farmers and local population (including contractors and roadside maintenance staff) is critical. Information could be provided by using materials such as leaflets and website information with an overview and description of the most important PA-containing plants, their ecology, the need to proceed to action and how/where. In this respect, it is important to adapt the type of recommendations to the situation of the person involved, i.e. private persons keeping horses, sheep etc. on a small piece of land need other instructions than professional farmers. Communication with relevant national and local government organisations should also take place.

14. Once PA-containing plants are detected, if suitable data are available, the risks for human and animal health must be established in order to identify the need for an integrated weed management plan. In this respect, it must be recognised that the different PA-containing plants may react in a different way to a particular management measure. Therefore, it is always important to keep the ecology of the specific plant in mind. Additionally, influences of weather or climate must be taken into account. When seeking to prevent the spread of the PA-containing plants, all landowners, occupiers and managers must take a collective responsibility to ensure that effective control of the spread is achieved.

EVALUATION OF THE NEED TO PROCEED TO ACTION

15. Before considering any action, the need to proceed to action should be established by identifying the risks posed by the presence of PA-containing plants. This could be done by setting up a tiered risk characterisation approach based on:

- toxicity of the particular PAs, if known, present in the plant;
- the relevant contributions of the various PA-containing plants to the specific or total PA intake of the livestock or presence in food/feed, if known;
- proximity of the PA-containing plants to arable fields and meadows/pastures/grasslands;
- level of infestation;
- local circumstances;
- climate;
- soil type; and
- vegetation cover of receiving land.

The likelihood of PA-containing plants spreading to land used for agricultural practices or grazing and/or feed/forage production should be the determining factor for assessment of the risk.

16. As an example, principles for assessing and managing the risk posed to livestock by ragwort (*Jacobaea vulgaris*), a common PA-containing plant, have been identified. These have been based on practical considerations of the proximity of the ragwort to pastures for livestock (bullet 3 above):

- high risk: ragwort is present and flowering/seeding within 50 m of land used for grazing by food-producing animals or land used for feed/forage production;
- medium risk: ragwort is present within 50 m to 100 m of land used for grazing by food-producing animals or land used for feed/forage production;
- low risk: the land on which ragwort is present is more than 100 m from land used for grazing by food-producing animals or land used for feed/forage production.

17. In the example of ragwort control, when a “high risk” situation is identified, the guidance is that immediate action should be taken to control the spread of PA-containing plants using appropriate control techniques taking account of the status of the land. In case of a medium risk, a control policy may be established to ensure that when the situation changes from a medium to a high risk of spread, it is identified and dealt with in a timely manner using appropriate control techniques taking account of the status of the land. In case of a low risk, no immediate action is required.

18. Similar risk assessments and resulting actions could be carried out for other PA-containing plants, but noting that defining risk zones and appropriate actions in other situations, will require the different ecology of the relevant PA-containing plants to be taken into account alongside the bullets in paragraph 16.

RECOMMENDED PRACTICES

1. MANAGEMENT OF THE PRESENCE OF PA-CONTAINING PLANTS

19. For managing the presence of PA-containing plants, preferably a combination of non-chemical and chemical methods, i.e. integrated weed management, should be applied to obtain the most effective results.

20. The use of an integrated weed management plan could reduce the use of and reliance on herbicides, thereby lowering the chance of herbicide resistance, and allows weed management in most environments. However, it should be noted that in those cases where appropriate herbicides are available, their application alone could be sufficiently effective to manage weed presence.

21. Furthermore, an integrated weed management plan should be accompanied with practices to reduce the spread of PA-containing plants thereby preventing infestations to spread.

22. It should be kept in mind for the management practices described in this section that their application should not result in harmful consequences for agriculture, the livestock or the pasture. Some methods may be destructive for other plant species (such as the crop) as well as to the target species. Applying these methods must be directed to the eradication of individual plants and done after good planning taking into account possible risks to the environment.

Mechanical methods

23. PA-containing plants can be controlled by mechanical methods such as pulling, ploughing, milling and slashing. The timing of applying mechanical methods is important. These practices are best applied before flowering of the PA-containing plants to prevent seed production and seed spread. When handling the PA-containing plants, suitable precautions should be taken to protect operators' skin (contact with some plants might cause an allergic reaction) and prevent inhalation of pollen.

24. Effective manual control requires removal of the root crown and all larger roots. Therefore, manual control may only be effective for seedlings and young rosettes in contrast to bigger plants, which normally develop deep roots. In addition, effective hand pulling is useful for small infestations but is not cost-effective for large ones nor is it suitable for large areas of land. In case of hand pulling, the plants should be handled and transported in a manner that prevents their spread, e.g. in hermetically sealed bags, and destroyed (burned) afterwards. It should be noted that disturbance of the soil may lead to more germination since buried seeds will be exposed to (sun) light.

Chemical methods

25. When applied carefully at the recommended dose of the herbicide, chemical spraying with appropriate herbicides may be an effective way of controlling PA-containing plants. Herbicides used should be registered for application in that specific situation. Also, herbicides should preferably be used in combination with other control methods to increase their effectiveness. The choice of herbicide depends on the specific PA-containing plant species and availability of appropriate herbicides.

26. For most PA-containing plants, in general the most effective time to spray herbicides is when the plants are actively growing and commencing flowering, i.e. in the spring before bloom and in the autumn applied to the new rosettes. Some herbicides require other timing due to their mode of action. PA-containing plants should not be sprayed when the plants are stressed either through lack of water, too much water, disease, insect or mechanical damage, as spray effectiveness will diminish.

27. The use of non-selective herbicides may damage the crop species and surrounding crops, pastures and environment. Hence, it is better to use selective herbicides or limit the use of non-selective herbicides for spray topping the PA-containing plant. Further, some PA-containing plants may develop resistance against a particular herbicide over time. It should be ensured that active substances are registered for the specific purpose in each country. In addition, as these substances are herbicides they may still have an inhibiting effect on crops, so care should be taken in case of possible bordering arable land.

28. In case of established PA-containing perennial plants, it is better to use systemic herbicides. Systemic herbicides are absorbed either by roots or foliar parts of a plant and are then translocated within the plant system to tissues that may be remote from the point of application.

29. In addition, care should be taken that herbicides are applied in suitable weather conditions, since the effective concentration of herbicides could be reduced when applied in unfavourable weather conditions, such as rain falls within 5 hours of application.

Biological methods

30. Natural enemies of a plant may be used to control PA-containing plants. It may be an economical and effective method. However, efficacy must have been established and the natural enemy must not present an environmental problem itself.

31. Tansy ragwort (*Jacobaea vulgaris*) densities may for example be reduced by the natural enemies *Longitarsus jacobaeae* (ragwort flea beetle) and a combination of *Longitarsus jacobaeae* and *Tyria jacobaeae* (cinnabar moth). Also *Cochylis atricapitana*, a ragwort stem and crown boring moth from Europe, was found to reduce the plant height of flowering plants and reduced the size and survival of rosettes. Another biocontrol agent used is *Platyptillia isodactyla* (ragwort plume moth) which has as common host marsh ragwort (*Senecio aquaticus*). *Deuterocampta quadrijuga* (blue heliotrope leaf-beetle) can completely defoliate blue heliotrope (*Heliotropium amplexicaule*), with both the larvae and adults feeding on the leaves.

32. However, good bio control is only feasible for a limited number of species as costs associated with finding, screening and testing potential agents can be very high. As such, successful biological control requires extensive development and establishment phases and costs. For most of the PA-containing plants no effective biological control agent is available. Research has shown that these methods are generally only very effective in the case of non-native plants.

Other methods

33. Soil solarisation, flaming (burning) and use of boiling water are other controlling methods that may be used for small infestations.

34. As there is some evidence that changing soil moisture and nutrient availability may influence the PA content of the roots, leaves and flowers of PA-containing plants, cultivation methods may change the PA content of remaining plants. For example, increasing soil moisture will lead to higher PA-concentrations in the roots. PA concentrations are expected to be higher when nutrient availability is low, i.e. higher concentrations were found in plants grown in sand without nutrients than with nutrients. It is, however, not clear whether the same effect may be expected in flowering plants.

35. Do not transport PA-containing plants unnecessarily and only when stored in hermetically sealed bags or containers.

36. Not all management practices are suitable to be used on every type of land. Therefore, specific management practices to control PA-containing plants are discussed separately hereafter specified by type of land: arable fields, pastures, and areas bordering the crop or pasture.

Arable fields

37. In the case of crops, the best timing of applying mechanical methods is at the start of crop growth. Once the crops are dense, weeds have little chance to grow. In crops such as wheat and millet etc., fields should be weeded prior to planting and periodically during the first six weeks of the growth cycle. A final weeding, about two weeks before harvest, if feasible, could reduce the possibility of contamination of the harvest with toxic plant parts significantly. In fact, in legume crops, mechanical or manual weeding may be the only option if infestation is large. Attention should be paid to areas bordering the crop, as these may constitute a continuous reservoir for the weed infestation.

Pastures and areas bordering the crop or pasture

38. Landowners are generally not legally responsible for the areas bordering the crop or pasture, such as road verges, sides of a ditch and ruderal places. Therefore, for this type of land it is extremely important that all landowners, occupiers and managers take a collective responsibility to ensure that effective control of possible spread of PA containing plants is achieved.

39. For large-scale restorations in pastures, mowing and cutting can be more easily applied. Cutting or slashing tansy ragwort (*Jacobaea vulgaris*) at the start or end of anthesis will reduce the number of flower heads. Therefore, it is recommended to do the first mowing when half of the plants start anthesis, and the second mowing when half of the re-established plants start anthesis again. On the other hand, fireweed (*Senecio madagascariensis*) should not be slashed in late spring or when more than 25% of the plants are flowering, as the mature plant, that otherwise might have died, may begin re-shooting. However, these mechanical methods are not always effective in killing the plants and may even encourage them to re-shoot as is observed with tansy ragwort (*Jacobaea vulgaris*) and Paterson's curse (*Echium plantagineum*). As a consequence, slashing or mowing may need to be executed on a very regular basis and be applied in combination with other control measures as part of an integrated weed management plan. For example, high mowing frequencies can be combined with the use of additional nitrogen that will lead to the promotion of fast growing grass species which will impair the germination and establishment of PA-containing plants.

40. Attention should be paid to areas bordering the pasture, as these may constitute a continuous reservoir for the weed infestation.

41. In pastures, PA-resistant livestock can be quite effectively used in grazing management to reduce PA-containing plants since it may weaken the plants and prevent prolific seeding. Antimethanogenic therapy with bacteria may be used to increase ruminant resistance to PA toxicity. Animals with no previous exposure to PAs are very susceptible to poisoning while animals with prior exposure to PA-containing plants show enhanced rumen detoxifying activity. The bacterium *Peptostreptococcus heliotrinreducans* most likely plays an important role in this process.

42. In addition, preferably non-food producing animals should be used as PAs may transfer from feed into milk and edible tissues. The best livestock to use are sheep, especially non-pregnant, non-food producing Merino sheep, or goats. If food-producing animals are used, the edible products could potentially contain high levels of PAs, and as a precautionary approach, these edible products must be segregated and not sold for human consumption until it is confirmed that they do not contain PAs. When removing animals from affected areas it is necessary to avoid transfer of seeds on their hooves, coats and digestive tracts, which can infest a new area. That is, livestock can spread seeds by consuming and passing viable seeds through their digestive tract. The seeds that survive the digestive tract are eliminated in the manure, which is rich in nutrients that can increase weed emergence. Thus, for some weed species it may be appropriate to prevent animal grazing when the plants are setting seeds, or the spreading of seeds by livestock can be prevented by placing them into quarantine. Grazing management can be applied on low-level, widespread infestations. However, significant numbers of grazing animals must be available; water and fencing or herding to control movement must be set up and the timing, intensity and duration of grazing must be closely monitored and managed to prevent overgrazing. It must be recognised that overgrazing may lead to loss of the competitive nature of the pasture or of native plants, allowing PA-containing plants to return and spread over the bare soil, which could result in livestock poisoning. Hence, it is recommended to stop grazing during flowering of (a number of) PA-containing plants as their PA-production is then very high.

2. CONTROL OF PLANT RELEASE AND SPREAD

Identify alternative plant sources to reduce undesirable growth

43. For crops, sound crop rotations can also minimise weed problems, since it will help to build up soil fertility and structure to produce increasing yields. Increased fertility in its turn will reduce the impact of weeds, and rotating crops can reduce the seeding and germination of weeds. In pastures and areas bordering the crop or pasture, use alternative plant sources to reduce undesirable growth, i.e. by planting vigorous perennials that will suppress the introduction and growth of PA-containing plants. This can be achieved by 1) sowing winter pasture species; 2) allowing a stand over of summer pasture feed; and 3) growing combinations of winter and summer pastures. Pasture management must also often go along with other forms of weed control, such as herbicides and mechanical means. This should be done in accordance with Good Agricultural Practice, such as appropriate sowing time and depth, adequate fertility and moisture at sowing, which is important to ensure good pasture management. Furthermore, it is recommended to use agricultural methods such as water and nutrient management or mulching. The plant material used for mulching must be free of PA-plants and their seeds.

Control movement of plants/seeds over agricultural zones and pastures

44. Assure planting of high quality, weed-free crops and weed-free grass seeds. When possible by national or regional laws and directives, use seed for planting that is not contaminated (e.g. certified seed).

Control plant seed movement on vehicles and agricultural machinery

45. Clean vehicles, machinery and equipment that are used in infested areas to prevent introduction of the PA-containing plant to pastures or other agricultural land by spread of seeds. Weed-free buffer zones between infested and un-infested lands will help to contain any infestation.

Control plant seed movement on animals

46. In case that livestock has grazed in infested areas, place them into quarantine for several days as seed can be carried on the hooves and coats, and in the digestive tracts of livestock. Inspect these quarantine areas regularly to assure no PA-containing plants will start infesting those areas.

Control of plant and seed movement from urban to agricultural lands and pastures

47. Provide educational material to horticulturists and neighbouring property owners to correctly identify PA-containing plants to prevent propagation of unwanted plant species. This information may be supported with national or regional regulations on the propagation, sale and distribution of PA-containing plants. Advise the general public on how to prevent the spread of unwanted, PA-containing plants from urban environments into agricultural and other lands.

APPENDIX VII**EDITORIAL AMENDMENTS TO THE GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOOD AND FEED
(CODEX STAN 193-1995)
(for adoption by CAC)****1.1 SCOPE**

This Standard contains the main principles which are recommended by the Codex Alimentarius in dealing with contaminants and toxins in food and feed, and lists the maximum levels and associated sampling plans of contaminants and natural toxicants in food and feed which are recommended by the CAC to be applied to commodities moving in international trade.

This Standard includes only maximum levels of contaminants and natural toxicants in feed in cases where the contaminant in feed can be transferred to food of animal origin and can be relevant for public health.

1.2.2 Contaminant

Codex Alimentarius defines a contaminant as follows:

“Any substance not intentionally added to food or feed for food producing animals, which is present in such food or feed as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food or feed, or as a result of environmental contamination. The term does not include insect fragments, rodent hairs and other extraneous matter”.

This Standard applies to any substance that meets the terms of the Codex definition for a contaminant, including contaminants in feed for food-producing animals, except:

- 1) Contaminants having only food and feed quality significance (e.g. copper), but no public health significance, in the food(s) given that the standards elaborated within the Codex Committee on Contaminants in Foods (CCCF) has the objective to protect public health.
 - 2) Pesticide residues, as defined by the Codex definition that are within the terms of reference of the Codex Committee on Pesticide Residues (CCPR).
 - 3) Residues of veterinary drugs, as defined by the Codex definition, and residues of feed additives (*), that are within the terms of reference of the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF).
 - 4) Microbial toxins, such as botulinum toxin and staphylococcus enterotoxin, and microorganisms that are within the terms of reference of the Codex Committee on Food Hygiene (CCFH).
 - 5) Residues of processing aids that are within the terms of reference of the Codex Committee on Food Additives (CCFA (**)).
- (*) Feed additives as defined in the Code of Practice on Good Animal Feeding (CAC/RCP 54-2004): “Any intentionally added ingredient not normally consumed as feed by itself, whether or not it has nutritional value, which affects the characteristics of feed or animal products.

Residues of feed additives include the parent compounds and/or their metabolites in any edible portion of the animal product, and include residues of associated impurities of the feed additive concerned.

- (**) Processing aids are any substance or material, not including apparatus or utensils, and not consumed as a food ingredient by itself, intentionally used in the processing of raw materials, foods or its ingredients, to fulfil a certain technological purpose during treatment or processing and which may result in the non-intentional but unavoidable presence of residues or derivatives in the final product.

FORMAT OF THE GSCTFF

Introduction

The format for the Schedule shall contain the following elements:

- **Name of the contaminant**
- **Synonyms:** symbols, synonyms, abbreviations, scientific descriptions shall be mentioned.
- **Reference to JECFA meetings** (in which the contaminant was discussed).
- **PMTDI, PTWI or similar toxicological guidance value:** when the situation is complex a short statement and further references may be necessary here.
- **Contaminant definition:** definition of the contaminant as it shall be analyzed and to which the maximum level or guideline level applies.
- **Reference** to a source-directed measure or a related code of practice for the contaminant, if appropriate.
- **List of Codex maximum levels or guideline levels for that contaminant;** this list shall be composed of the following elements, in columns:
 - feed/food commodity/product name;
 - Numerical value of maximum level or guideline level and units in which it is expressed;
 - Portion of the Commodity/Product to which the maximum level or guideline level applies;
 - Notes/Remarks, including reference to relevant Codex commodity standards and where necessary, definition of the commodity product

**SCHEDULE - MAXIMUM AND GUIDELINE LEVELS FOR CONTAMINANTS
AND TOXINS IN FOODS**

INDEX OF CONTAMINANTS

NAME	PAGE
Mycotoxins	
Aflatoxins, Total	
Aflatoxin M1	
Ochratoxin A	
Patulin	
Metals	
Arsenic	
Cadmium	
Lead	
Mercury	
Methylmercury	
Tin	
Radionuclides	
Others	
Acrylonitrile	
Chloropropanols	
Hydrocyanic acid	
Melamine	
Vinylchloride monomer	

EXPLANATORY NOTES

Reference to JECFA	References to the JECFA meeting in which the contaminant was evaluated and the year of that meeting.
Toxicological guidance value	Toxicological advice about the tolerable intake level of the contaminant for humans, expressed per kg body weight (bw). The year of recommendations and additional explanation are included.
Contaminant definition	Definition of the contaminant in the form of which the ML or GL applies or which may or should be analyzed in commodities/products.
Synonyms	Symbols, synonyms abbreviations, scientific descriptions and identification codes used to define the contaminant.
Commodity/ product name	<p>The commodities or products, to which the ML or GL applies, other than the terms feed or food, are those that are intended for human consumption, unless otherwise specified.</p> <p>The ML or GL contained in Codex commodity standards apply to the commodities within the scope of the Codex commodity standard. Reference to the Codex Standard is provided and the definition of the commodity/product is the definition as provided in the Codex commodity standard.</p> <p>When the ML or GL applies only to the commodity within the scope of the Codex commodity standard then the reference is mentioned as "Relevant Codex commodity standard(s) is (are) ...". In case the reference to Codex commodity standards is provided as example for commodities to which the ML or GL applies then the reference is mentioned as "Relevant Codex Commodity standards include ..."</p> <p>For the other commodities or products not contained in Codex commodity standards the definition of the commodity or product is provided in the Classification of Foods and Animal Feeds (CAC/MISC 4), unless otherwise specified.</p> <p>In case a ML or GL applies to a product group (e.g. legume vegetables), the ML or GL applies to all individual products belonging to the group as defined in CAC/MISC 4</p> <p>For any other commodities or products other than those described above, where necessary, the definition of the commodity/product is provided in "Notes/Remarks".</p>

Portion of the Commodity/Product to which the maximum level (ML) or guideline level (GL) applies	The portion of the feed or food to which the ML or GL applies, is the portion defined in the Codex commodity standard or CAC/MISC 4 or defined at the establishment of the ML or GL, unless otherwise specified.
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DEFINITIONS OF SOME TOXICOLOGICAL TERMS

PMTDI	<p>Provisional Maximum Tolerable Daily Intake</p> <p>The endpoint used for contaminants with no cumulative properties. Its value represents permissible human exposure as a result of the natural occurrence of the substance in food and in drinking-water. In the case of trace elements that are both essential nutrients and unavoidable constituents of food, a range is expressed, the lower value representing the level of essentiality and the upper value the PMTDI.</p>
PTWI	<p>Provisional Tolerable Weekly Intake</p> <p>An endpoint used for food contaminants such as heavy metals with cumulative properties. Its value represents permissible human weekly exposure to those contaminants unavoidably associated with the consumption of otherwise wholesome and nutritious foods.</p>
PTMI	<p>Provisional Tolerable Monthly Intake</p> <p>An endpoint used for a food contaminant with cumulative properties that has a very long half-life in the human body. Its value represents permissible human monthly exposure to a contaminant unavoidably associated with otherwise wholesome and nutritious foods.</p>

AFLATOXINS, TOTAL

Reference to JECFA: 31 (1987), 46 (1996), 49 (1997), 68 (2007)
 Toxicological guidance: Carcinogenic potency estimates for aflatoxins B, G, M (1997, Intake should be reduced to levels as low as reasonably possible)
 Contaminant definition: Aflatoxins total (B1 + B2 + G1 + G2)
 Synonyms: Abbreviations, AFB, AFG, with numbers, to designate specific compounds
 Related Code of Practice: Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Peanuts (CAC/RCP 55-2004)
 Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Tree Nuts (CAC/RCP 59-2005)
 Code of Practice for the Reduction of Aflatoxin B1 in Raw Materials and Supplemental Feedingstuffs for Milk Producing Animals (CAC/RCP 45-1997)
 Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Dried Figs (CAC/RCP 65-2008)

Commodity / Product Name	Maximum Level (ML) µg/kg	Portion of the Commodity/Product to which the ML Applies	Notes/Remarks
Almonds	10	Whole commodity after removal of shell.	The ML applies to almonds “ready-to-eat” (**). For sampling plan, see Annex 2.
Almonds	15	Whole commodity after removal of shell.	The ML applies to almonds intended for further processing (*) For sampling plan, see Annex 2.
Brazil nuts	10	Whole commodity	The ML applies to shelled Brazil nuts ready-to-eat (**). For sampling plan, see Annex 2.
Brazil nuts	15	Whole commodity	The ML applies to shelled Brazil nuts intended for further processing (*) For sampling plan, see Annex 2.
Hazelnuts	10	Whole commodity after removal of shell.	The ML applies to hazelnuts, also known as filberts, “ready to eat” (**). For sampling plan, see Annex 2.
Hazelnuts	15	Whole commodity after removal of shell.	The ML applies to hazelnuts, also known as filberts, intended for further processing (*) For sampling plan, see Annex 2.
Peanuts	15	Unless specified, seed or kernels, after removal of shell or husk.	The ML applies for peanuts, also known as groundnuts, intended for further processing (*). For sampling plan, see Annex 1.
Pistachios	10	Whole commodity after removal of shell.	The ML applies to pistachios “ready to eat” (**). For sampling plan, see Annex 2.
Pistachios	15	Whole commodity after removal of shell.	The ML applies to pistachios intended for further processing (*) For sampling plan, see Annex 2.
Dried figs	10	Whole commodity	The ML applies to dried figs “ready-to-eat” (**). For sampling plan see Annex 3.

Commodity / Product Name	Maximum Level (ML) $\mu\text{g}/\text{kg}$	Portion of the Commodity/Product to which the ML Applies	Notes/Remarks
(*)			<p>“destined for further processing” means intended to undergo an additional processing/treatment that has proven to reduce levels of aflatoxins before being used as an ingredient in foodstuffs, otherwise processed or offered for human consumption. Processes that have proven to reduce levels of aflatoxins are shelling, blanching followed by colour sorting, and sorting by specific gravity and colour (damage). There is some evidence that roasting reduces aflatoxins in pistachios but for other nuts the evidence is still to be supplied.</p>
(**)			<p>“ready-to-eat” means “not intended to undergo an additional processing/treatment that has proven to reduce levels of aflatoxins before being used as ingredient in foodstuffs, otherwise processed or offered for human consumption.</p>

Annex 1

SAMPLING PLAN FOR TOTAL AFLATOXINS IN PEANUTS INTENDED FOR FURTHER PROCESSING**INTRODUCTION**

1. The sampling plan calls for a single 20 kg laboratory sample of shelled peanuts (27 kg of unshelled peanuts) to be taken from a peanut lot (sub-lot) and tested against a maximum level of 15 µg/kg total aflatoxins.

2. This sampling plan has been designed for enforcement and controls concerning total aflatoxins in bulk consignments of peanuts traded in the export market. To assist member countries in implementing the Codex sampling plan, sample selection methods, sample preparation methods and analytical methods required to quantify aflatoxin in bulk peanut lots are described in this document.

A. DEFINITIONS

Lot	an identifiable quantity of a food commodity delivered at one time and determined by the official to have common characteristics, such as origin, variety, type of packing, packer, consignor or markings.
Sublot	designated part of a large lot in order to apply the sampling method on that designated part. Each sublot must be physically separate and identifiable.
Sampling plan	is defined by an aflatoxin test procedure and an accept/reject limit. An aflatoxin test procedure consists of three steps: sample selection, sample preparation and aflatoxin quantification. The accept/reject limit is a tolerance usually equal to the Codex maximum level.
Incremental sample	a quantity of material taken from a single random place in the lot or sublot.
Aggregate sample	the combined total of all the incremental samples taken from the lot or sublot. The aggregate sample has to be at least as large as the 20 kg laboratory sample.
Laboratory sample	smallest quantity of peanuts comminuted in a mill. The laboratory sample may be a portion of or the entire aggregate sample. If the aggregate sample is larger than 20 kg, a 20 kg laboratory sample should be removed in a random manner from the aggregate sample. The sample should be finely ground and mixed thoroughly using a process that approaches as complete a homogenisation as possible.
Test portion	portion of the comminuted laboratory sample. The entire 20 kg laboratory sample should be comminuted in a mill. A portion of the comminuted 20 kg sample is randomly removed for the extraction of the aflatoxin for chemical analysis. Based upon grinder capacity, the 20 kg aggregate sample can be divided into several equal sized samples, if all results are averaged.

B. SAMPLING**Material to be sampled**

3. Each lot which is to be examined must be sampled separately. Large lots should be subdivided into sublots to be sampled separately. The subdivision can be done following provisions laid down in Table 1 below.

4. Taking into account that the weight of the lot is not always an exact multiple of the weight of the sublots, the weight of the sublot may exceed the mentioned weight by a maximum of 20%.

Table 1: Subdivision of Large Lots into Sublots for Sampling

Commodity	Lot weight – tonne (T)	Weight or number of sublots	Number of incremental samples	Laboratory sample weight (kg)
Peanuts	≥ 500	100 tonnes	100	20
	> 100 and < 500	5 sublots	100	20
	≥ 25 and ≤ 100	25 tonnes	100	20
	> 15 and ≤ 25	--1 sublot	100	20

Number of incremental samples for lots of less than 15 tonnes

5. The number of incremental samples to be taken depends on the weight of the lot, with a minimum of 10 and a maximum of 100. The figures in the following Table 2 may be used to determine the number of incremental samples to be taken. It is necessary that the total sample weight of 20 kg is achieved.

Table 2: Number of Incremental Samples to be Taken Depending on the Weight of the Lot

Lot weight tonnes – (T)	N° of incremental samples
$T \leq 1$	10
$1 < T \leq 5$	40
$5 < T \leq 10$	60
$10 < T < 15$	80

Incremental sample selection

6. Procedures used to take incremental samples from a peanut lot are extremely important. Every individual peanut in the lot should have an equal chance of being chosen. Biases will be introduced by the sample selection methods if equipment and procedures used to select the incremental samples prohibit or reduce the chances of any item in the lot from being chosen.

7. Since there is no way to know if the contaminated peanut kernels are uniformly dispersed throughout the lot, it is essential that the aggregate sample be the accumulation of many small portions or increments of the product selected from different locations throughout the lot. If the aggregate sample is larger than desired, it should be blended and subdivided until the desired laboratory sample size is achieved.

Static lots

8. A static lot can be defined as a large mass of peanuts contained either in a single large container such as a wagon, truck, or railcar or in many small containers such as sacks or boxes and the peanuts are stationary at the time a sample is selected. Selecting a truly random sample from a static lot can be difficult because the container may not allow access to all peanuts.

9. Taking an aggregate sample from a static lot usually requires the use of probing devices to select product from the lot. The probing devices used should be specially designed for the type of container. The probe should (1) be long enough to reach all product, (2) not restrict any item in the lot from being selected, and (3) not alter the items in the lot. As mentioned above, the aggregate sample should be a composite from many small increments of product taken from many different locations throughout the lot.

10. For lots traded in individual packages, the sampling frequency (SF), or number of packages that incremental samples are taken from, is a function of the lot weight (LT), incremental sample weight (IS), aggregate sample weight (AS) and the individual packing weight (IP), as follows:

$$\text{Equation 1: } SF = (LT \times IS) / (AS \times IP)$$

The sampling frequency (SF) is the number of packages sampled. All weights should be in the same mass units such as kg.

Dynamic lots

11. True random sampling can be more nearly achieved when selecting an aggregate sample from a moving stream of peanuts as the lot is transferred, for example, by a conveyor belt from one location to another. When sampling from a moving stream, take small increments of product from the entire length of the moving stream; composite the peanuts to obtain an aggregate sample; if the aggregate sample is larger than the required laboratory sample, then blend and subdivide the aggregate sample to obtain the desired size laboratory sample.

12. Automatic sampling equipment such as cross-cut samplers are commercially available with timers that automatically pass a diverter cup through the moving stream at predetermined and uniform intervals. When automatic equipment is not available, a person can be assigned to manually pass a cup through the stream at periodic intervals to collect incremental samples. Whether using automatic or manual methods, small increments of peanuts should be collected and composited at frequent and uniform intervals throughout the entire time peanuts flow past the sampling point.

13. Cross-cut samplers should be installed in the following manner: (1) the plane of the opening of the diverter cup should be perpendicular to the direction of flow; (2) the diverter cup should pass through the entire cross sectional area of the stream; and (3) the opening of the diverter cup should be wide enough to accept all items of interest in the lot. As a general rule, the width of the diverter cup opening should be about three times the largest dimensions of the items in the lot.

14. The size of the aggregate sample (S) in kg, taken from a lot by a cross cut sampler is:

$$\text{Equation 2: } S = (D \times LT) / (T \times V)$$

D is the width of the diverter cup opening (in cm), LT is the lot size (in kg), T is interval or time between cup movement through the stream (in seconds), and V is cup velocity (in cm/sec).

15. If the mass flow rate of the moving stream, MR (kg/sec), is known, then the sampling frequency (SF), or number of cuts made by the automatic sampler cup is:

$$\text{Equation 3: } SF = (S \times V) / (D \times MR)$$

16. Equation 2 can also be used to compute other terms of interest such as the time between cuts (T). For example, the required time (T) between cuts of the diverter cup to obtain a 20 kg aggregate sample from a 30 000 kg lot where the diverter cup width is 5.08 cm (2 inches), and the cup velocity through the stream 30 cm/sec. Solving for T in Equation 2.

$$T = (5.08 \text{ cm} \times 30\,000 \text{ kg}) / (20 \text{ kg} \times 30 \text{ cm/sec}) = 254 \text{ sec}$$

17. If the lot is moving at 500 kg per minute, the entire lot will pass through the sampler in 60 minutes and only 14 cuts (14 incremental samples) will be made by the cup through the lot. This may be considered too infrequent, in that too much product passes through the sampler between the time the cup cuts through the stream.

Weight of the incremental sample

18. The weight of the incremental sample should be approximately 200 g or greater, depending on the total number of increments, to obtain an aggregate sample of 20 kg.

Packaging and transmission of samples

19. Each laboratory sample shall be placed in a clean, inert container offering adequate protection from contamination and against damage in transit. All necessary precautions shall be taken to avoid any change in composition of the laboratory sample which might arise during transportation or storage.

Sealing and labelling of samples

20. Each laboratory sample taken for official use shall be sealed at the place of sampling and identified. A record must be kept of each sampling, permitting each lot to be identified unambiguously and giving the date and place of sampling together with any additional information likely to be of assistance to the analyst.

C. SAMPLE PREPARATION

Precautions

21. Daylight should be excluded as much as possible during the procedure, since aflatoxin gradually breaks down under the influence of ultra-violet light.

Homogenisation – Grinding

22. As the distribution of aflatoxin is extremely non-homogeneous, samples should be prepared - and especially homogenised - with extreme care. All laboratory sample obtained from aggregate sample is to be used for the homogenisation/grinding of the sample.

23. The sample should be finely ground and mixed thoroughly using a process that approaches as complete a homogenisation as possible.

24. The use of a hammer mill with a #14 screen (3.1 mm diameter hole in the screen) has been proven to represent a compromise in terms of cost and precision. A better homogenisation (finer grind – slurry) can be obtained by more sophisticated equipment, resulting in a lower sample preparation variance.

Test portion

25. A minimum test portion size of 100 g taken from the laboratory sample.

D. ANALYTICAL METHODS

Background

26. A criteria-based approach, whereby a set of performance criteria is established with which the analytical method used should comply, is appropriate. The criteria-based approach has the advantage that, by avoiding setting down specific details of the method used, developments in methodology can be exploited without having to reconsider or modify the specified method. The performance criteria established for methods should include all the parameters that need to be addressed by each laboratory such as the detection limit, repeatability coefficient of variation, reproducibility coefficient of variation, and the percent recovery necessary for various statutory limits. Utilising this approach, laboratories would be free to use the analytical method most appropriate for their facilities. Analytical methods that are accepted by chemists internationally (such as AOAC) may be used. These methods are regularly monitored and improved depending upon technology.

Performance criteria for methods of analysis**Table 3: Specific requirements with which methods of analysis should comply**

Criterion	Concentration Range	Recommended Value	Maximum Permitted Value
Blanks	All	Negligible	-
Recovery-Aflatoxins Total	1 – 15 µg/kg	70 to 110%	
	> 15 µg/kg	80 to 110%	
Precision RSD _R	All	As derived from Horwitz Equation	2 x value derived from Horwitz Equation
Precision RSD _r may be calculated as 0.66 times Precision RSD _R at the concentration of interest			

- The detection limits of the methods used are not stated as the precision values are given at the concentrations of interest;
- The precision values are calculated from the Horwitz equation, i.e.:

$$RSD_R = 2^{(1-0.5\log C)}$$

where:

- * RSD_R is the relative standard deviation calculated from results generated under reproducibility conditions $[(S_r / \bar{x}) \times 100]$
- * C is the concentration ratio (i.e. 1 = 100 g/100 g, 0.001 = 1 000 mg/kg)

27. This is a generalised precision equation which has been found to be independent of analyte and matrix but solely dependent on concentration for most routine methods of analysis.

Annex 2

SAMPLING PLANS FOR AFLATOXIN CONTAMINATION IN READY-TO-EAT TREENUTS AND TREENUTS DESTINED FOR FURTHER PROCESSING: ALMONDS, HAZELNUTS, PISTACHIOS AND SHELLED BRAZIL NUTS

DEFINITION

Lot	an identifiable quantity of a food commodity delivered at one time and determined by the official to have common characteristics, such as origin, variety, type of packing, packer, consignor, or markings.
Sublot	designated part of a larger lot in order to apply the sampling method on that designated part. Each sublot must be physically separate and identifiable.
Sampling plan	is defined by an aflatoxin test procedure and an accept/reject limit. An aflatoxin test procedure consists of three steps: sample selection, sample preparation and aflatoxin quantification. The accept/reject limit is a tolerance usually equal to the Codex maximum level.
Incremental sample	the quantity of material taken from a single random place in the lot or sublot.
Aggregate sample	the combined total of all the incremental samples that is taken from the lot or sublot. The aggregate sample has to be at least as large as the laboratory sample or samples combined.
Laboratory sample	the smallest quantity of tree nuts comminuted in a mill. The laboratory sample may be a portion of or the entire aggregate sample. If the aggregate sample is larger than the laboratory sample(s), the laboratory sample(s) should be removed in a random manner from the aggregate sample.
Test portion	aportion of the comminuted laboratory sample. The entire laboratory sample should be comminuted in a mill. A portion of the comminuted laboratory sample is randomly removed for the extraction of the aflatoxin for chemical analysis.
Ready-to-eat treenuts	nuts, which are not intended to undergo an additional processing/treatment that has proven to reduce levels of aflatoxins before being used as an ingredient in foodstuffs, otherwise processed or offered for human consumption.
Treenuts destined for further processing	nuts, which are intended to undergo an additional processing/treatment that has proven to reduce levels of aflatoxins before being used as an ingredient in foodstuffs, otherwise processed or offered for human consumption. Processes that have proven to reduce levels of aflatoxins are shelling, blanching followed by colour sorting, and sorting by specific gravity and colour (damage). There is some evidence that roasting reduces aflatoxins in pistachios but for other nuts the evidence is still to be supplied.
Operating Characteristic (OC) Curve	a plot of the probability of a accepting a lot versus lot concentration when using a specific sampling plan design. The OC curve provides an estimate of good lots rejected (exporter's risk) and bad lots accepted (importer's risk) by a specific aflatoxin sampling plan design.

SAMPLING PLAN DESIGN CONSIDERATIONS

1. Importers may commercially classify treenuts as either "ready-to-eat" (RTE) or "destined for further processing" (DFP). As a result, maximum levels and sampling plans are proposed for both commercial types of treenuts. Maximum levels need to be defined for treenuts destined for further processing and ready-to-eat treenuts before a final decision can be made about a sampling plan design.
2. Treenuts can be marketed either as in-shell or shelled nuts. For example, pistachios are predominately marketed as in-shell nuts while almonds are predominately marketed as shelled nuts.
3. Sampling statistics, shown in Annex, are based upon the uncertainty and aflatoxin distribution among laboratory samples of shelled nuts. Because the shelled nut count per kg is different for each of the treenuts, the laboratory sample size is expressed in number of nuts for statistical purposes. However, the shelled nut count per kg for each treenut, shown in Annex, can be used to convert laboratory sample size from number of nuts to mass and vice versa.
4. Uncertainty estimates associated with sampling, sample preparation, and analysis, shown in Annex, and the negative binomial distribution are used to calculate operating characteristic (OC) curves that describe the performance of the proposed aflatoxin-sampling plans.
5. In Annex, the analytical variance reflects a reproducibility relative standard deviation of 22%, which is based upon Food Analysis Performance Assessment Scheme (FAPAS) data. A relative standard deviation of 22% is considered by FAPAS as an appropriate measure of the best agreement that can be reliably obtained between laboratories. An analytical uncertainty of 22% is larger than the within laboratory variation measured in the sampling studies for the four treenuts.

6. The issue of correcting the analytical test result for recovery is not addressed in this document. However, Table 2 specifies several performance criteria for analytical methods including suggestions for the range of acceptable recovery rates.

AFLATOXIN TEST PROCEDURE AND MAXIMUM LEVELS

7. An aflatoxin-sampling plan is defined by an aflatoxin test procedure and a maximum level. A value for the maximum level and the aflatoxin test procedure are given below in this section.

8. The maximum levels for total aflatoxins in treenuts (almonds, hazelnuts, pistachios and shelled Brazil nuts) “ready-to-eat” and “destined for further processing” are 10 and 15 µg/kg, respectively.

9. Choice of the number and size of the laboratory sample is a compromise between minimizing risks (false positives and false negatives) and costs related to sampling and restricting trade. For simplicity, it is recommended that the proposed aflatoxin sampling plans use a 20 kg aggregate sample for all four treenuts.

10. The two sampling plans (RTE and DFP) have been designed for enforcement and controls concerning total aflatoxins in bulk consignments (lots) of treenuts traded in the export market.

Treenuts destined for further processing

Maximum level – 15 µg/kg total aflatoxins

Number of laboratory samples – 1

Laboratory sample size – 20 kg

Almonds – shelled nuts

Hazelnuts – shelled nuts

Pistachios – in-shell nuts (equivalent to about 10 kg shelled nuts that is calculated on the basis of the actual edible portion in the sample)

Brazil nuts – shelled nuts

Sample preparation – sample shall be finely ground and mixed thoroughly using a process, e.g., dry grind with a vertical cutter mixer type mill, that has been demonstrated to provide the lowest sample preparation variance. Preferably, Brazil nuts should be ground as slurry.

Analytical method – performance based (see Table 2)

Decision rule – If the aflatoxin test result is less than or equal to 15 µg/kg total aflatoxins, then accept the lot. Otherwise, reject the lot.

Ready-to-eat treenuts

Maximum level – 10 µg/kg total aflatoxins

Number of laboratory samples – 2

Laboratory sample size – 10 kg

Almonds – shelled nuts

Hazelnuts – shelled nuts

Pistachios – in-shell nuts (equivalent to about 5 kg shelled nuts per test sample that is calculated on the basis of the actual edible portion in the sample)

Brazil nuts – shelled nuts

Sample preparation – sample shall be finely ground and mixed thoroughly using a process, e.g., dry grind with a vertical cutter mixer type mill, that has been demonstrated to provide the lowest sample preparation variance. Preferably, Brazil nuts should be ground as slurry.

Analytical method – performance based (see Table 2)

Decision rule – If the aflatoxin test result is less than or equal to 10 µg/kg total aflatoxin in both test samples, then accept the lot. Otherwise, reject the lot.

11. To assist member countries implement these two Codex sampling plans, sample selection methods, sample preparation methods, and analytical methods required to quantify aflatoxin in laboratory samples taken from bulk treenut lots are described in the following sections.

SAMPLE SELECTION

MATERIAL TO BE SAMPLED

12. Each lot, which is to be examined for aflatoxin, must be sampled separately. Lots larger than 25 tonnes should be subdivided into sublots to be sampled separately. If a lot is greater than 25 tonnes, the number of sublots is equal to the lot weight in tonnes divided by 25 tonnes. It is recommended that a lot or a subplot should not exceed 25 tonnes. The minimum lot weight should be 500 kg.

13. Taking into account that the weight of the lot is not always an exact multiple of 25 tonne sublots, the weight of the subplot may exceed the mentioned weight by a maximum of 25%.

14. Samples should be taken from the same lot, i.e. they should have the same batch code or at the very least the same best before date. Any changes which would affect the mycotoxin content, the analytical determination or make the aggregate samples collected unrepresentative should be avoided. For example do not open packaging in adverse weather conditions or expose samples to excessive moisture or sunlight. Avoid cross-contamination from other potentially contaminated consignments nearby.

15. In most cases any truck or container will have to be unloaded to allow representative sampling to be carried out.

INCREMENTAL SAMPLE SELECTION

16. Procedures used to take incremental samples from a treenut lot are extremely important. Every individual nut in the lot should have an equal chance of being chosen. Biases will be introduced by sample selection methods if equipment and procedures used to select the incremental samples prohibit or reduce the chances of any item in the lot from being chosen.

17. Since there is no way to know if the contaminated treenut kernels are uniformly dispersed throughout the lot, it is essential that the aggregate sample be the accumulation of many small incremental samples of product selected from different locations throughout the lot. If the aggregate sample is larger than desired, it should be blended and subdivided until the desired laboratory sample size is achieved.

NUMBER OF INCREMENTAL SAMPLES FOR LOTS OF VARYING WEIGHT

18. The number and size of the laboratory sample(s) will not vary with lot (subplot) size. However, the number and size of the incremental samples will vary with lot (subplot) size.

19. The number of incremental samples to be taken from a lot (subplot) depends on the weight of the lot. Table 1 shall be used to determine the number of incremental samples to be taken from lots or sublots of various sizes below 25 tonnes. The number of incremental samples varies from a minimum of 10 and to a maximum of 100.

Table 1. Number and size of incremental samples composited for an aggregate sample of 20 kg^a as a function of lot (orsublot) weight

Lot or subplot weight ^b (T in tonnes)	Minimum number of incremental samples	Minimum incremental sample size ^c (g)	Minimum aggregate sample size (Kg)
T < 1	10	2 000	20
1 ≤ T < 5	25	800	20
5 ≤ T < 10	50	400	20
10 ≤ T < 15	75	267	20
15 ≤ T	100	200	20

a/ Minimum aggregate sample size = laboratory sample size of 20 kg

b/ 1 Tonne = 1 000 kg

c/ Minimum incremental sample size = laboratory sample size (20 kg)/minimum number of incremental samples, i.e. for 0.5 < T < 1 tonne, 2 000 g = 20 000/10

WEIGHT OF THE INCREMENTAL SAMPLE

20. The suggested minimum weight of the incremental sample should be approximately 200 g for lots of 25 metric tonnes (25 000 kg). The number and/or size of incremental samples will have to be larger than that suggested in Table 1 for lots sizes below 25 000 kg in order to obtain an aggregate sample greater than or equal to the 20 kg laboratory sample.

STATIC LOTS

21. A static lot can be defined as a large mass of treenuts contained either in a large single container such as a wagon, truck or railcar or in many small containers such as sacks or boxes and the nuts are stationary at the time a sample is selected. Selecting a truly random sample from a static lot can be difficult because all containers in the lot or subplot may not be accessible.

22. Taking incremental samples from a static lot usually requires the use of probing devices to select product from the lot. The probing devices should be specifically designed for the commodity and type of container. The probe should (1) be long enough to reach all products, (2) not restrict any item in the lot from being selected, and (3) not alter the items in the lot. As mentioned above, the aggregate sample should be a composite from many small incremental samples of product taken from many different locations throughout the lot.

23. For lots traded in individual packages, the sampling frequency (SF), or number of packages that incremental samples are taken from, is a function of the lot weight (LT), incremental sample weight (IS), aggregate sample weight (AS) and the individual packing weight (IP), as follows:

$$\text{Equation 1: } SF = (LT \times IS) / (AS \times IP)$$

24. The sampling frequency (SF) is the number of packages sampled. All weights should be in the same mass units such as kg.

DYNAMIC LOTS

25. Representative aggregate samples can be more easily produced when selecting incremental samples from a moving stream of treenuts as the lot is transferred from one location to another. When sampling from a moving stream, take small incremental samples of product from the entire length of the moving stream; composite the incremental samples to obtain an aggregate sample; if the aggregate sample is larger than the required laboratory sample(s), then blend and subdivide the aggregate sample to obtain the desired size laboratory sample(s).

26. Automatic sampling equipment such as a cross-cut sampler is commercially available with timers that automatically pass a diverter cup through the moving stream at predetermined and uniform intervals. When automatic sampling equipment is not available, a person can be assigned to manually pass a cup through the stream at periodic intervals to collect incremental samples. Whether using automatic or manual methods, incremental samples should be collected and composited at frequent and uniform intervals throughout the entire time the nuts flow past the sampling point.

27. Cross-cut samplers should be installed in the following manner: (1) the plane of the opening of the diverter cup should be perpendicular to the direction of the flow; (2) the diverter cup should pass through the entire cross sectional area of the stream; and (3) the opening of the diverter cup should be wide enough to accept all items of interest in the lot. As a general rule, the width of the diverter cup opening should be about two to three times the largest dimensions of items in the lot.

28. The size of the aggregate sample (S) in kg, taken from a lot by a cross cut sampler is:

$$\text{Equation 2: } S = (D \times LT) / (T \times V)$$

where D is the width of the diverter cup opening (cm), LT is the lot size (kg), T is interval or time between cup movement through the stream (seconds), and V is cup velocity (cm/sec).

29. If the mass flow rate of the moving stream, MR (kg/sec), is known, then the sampling frequency (SF), or number of cuts made by the automatic sampler cup can be computed from Equation 3 as a function of S, V, D, and MR.

$$\text{Equation 3: } SF = (S \times V) / (D \times MR)$$

30. Equations 2 and 3 can also be used to compute other terms of interest such as the time between cuts (T). For example, the time (T) required between cuts of the diverter cup to obtain a 20 kg aggregate sample from a 20 000 kg lot where the diverter cup width is 5.0 cm and the cup velocity through the stream 30 cm/sec. Solving for T in Equation 2.

$$T = (5.0 \text{ cm} \times 20\,000 \text{ kg}) / (20 \text{ kg} \times 30 \text{ cm/sec}) = 250 \text{ sec.}$$

31. If the lot is moving at 500 kg per minute, the entire lot will pass through the sampler in 40 minutes (2 400 sec) and only 9.6 cuts (9 incremental samples) will be made by the cup through the lot (Equation 3). This may be considered too infrequent, in that too much product (2 083.3 kg) passes through the sampler between the time the cup cuts through the stream.

PACKAGING AND TRANSPORTATION OF SAMPLES

32. Each laboratory sample shall be placed in a clean, inert container offering adequate protection from contamination, sunlight, and against damage in transit. All necessary precautions shall be taken to avoid any change in composition of the laboratory sample, which might arise during transportation or storage. Samples should be stored in a cool dark place.

SEALING AND LABELLING OF SAMPLES

33. Each laboratory sample taken for official use shall be sealed at the place of sampling and identified. A record must be kept of each sampling, permitting each lot to be identified unambiguously and giving the date and place of sampling together with any additional information likely to be of assistance to the analyst.

SAMPLE PREPARATION**PRECAUTIONS**

34. Sunlight should be excluded as much as possible during sample preparation, since aflatoxin gradually breaks down under the influence of ultra-violet light. Also, environmental temperature and relative humidity should be controlled and not favour mould growth and aflatoxin formation.

HOMOGENIZATION - GRINDING

35. As the distribution of aflatoxin is extremely non-homogeneous, laboratory samples should be homogenized by grinding the entire laboratory sample received by the laboratory. Homogenization is a procedure that reduces particle size and disperses the contaminated particles evenly throughout the comminuted laboratory sample.

36. The laboratory sample should be finely ground and mixed thoroughly using a process that approaches as complete homogenization as possible. Complete homogenization implies that particle size is extremely small and the variability associated with sample preparation (Annex I) approaches zero. After grinding, the grinder should be cleaned to prevent aflatoxin cross-contamination.

37. The use of vertical cutter mixer type grinders that mix and comminute the laboratory sample into a paste represent a compromise in terms of cost and fineness of grind or particle size reduction. A better homogenization (finer grind), such as a liquid slurry, can be obtained by more sophisticated equipment and should provide the lowest sample preparation variance.

TEST PORTION

38. The suggested weight of the test portion taken from the comminuted laboratory sample should be approximately 50 g. If the laboratory sample is prepared using a liquid slurry, the slurry should contain 50 g of nut mass.

39. Procedures for selecting the 50 g test portion from the comminuted laboratory sample should be a random process. If mixing occurred during or after the comminution process, the 50 g test portion can be selected from any location throughout the comminuted laboratory sample. Otherwise, the 50 g test portion should be the accumulation of several small portions selected throughout the laboratory sample.

40. It is suggested that three test portions be selected from each comminuted laboratory sample. The three test portions will be used for enforcement, appeal, and confirmation if needed.

ANALYTICAL METHODS**BACKGROUND**

41. A criteria-based approach, whereby a set of performance criteria is established with which the analytical method used should comply, is appropriate. The criteria-based approach has the advantage that, by avoiding setting down specific details of the method used, developments in methodology can be exploited without having to reconsider or modify the specific method. The performance criteria established for methods should include all the parameters that need to be addressed by each laboratory such as the detection limit, repeatability coefficient of variation (within lab), reproducibility coefficient of variation (among lab), and the percent recovery necessary for various statutory limits. Analytical methods that are accepted by chemists internationally (such as AOAC, ISO) may be used. These methods are regularly monitored and improved depending upon technology.

PERFORMANCE CRITERIA FOR METHODS OF ANALYSIS

42. A list of criteria and performance levels are shown in Table 2. Utilizing this approach, laboratories would be free to use the analytical method most appropriate for their facilities.

Table 2: Specific Requirements with which Methods of Analysis Should Comply

Criterion	Concentration range (ng/g)	Recommended value	Maximum permitted value
Blanks	All	Negligible	n/a
Recovery	1 to 15	70 to 100%	n/a
	> 15	80 to 110%	n/a
Precision or relative standard deviation RSD _R (Reproducibility)	1 to 120	Equation 4	2 x value derived from Equation 4
	> 120	Equation 5	2 x value derived from Equation 5
Precision or relative standard deviation RSD _r (Repeatability)	1 to 120	Calculated as 0.66 times Precision RSD _R	n/a
	> 120	Calculated as 0.66 times Precision RSD _r	n/a

n/a = not applicable

43. The detection limits of the methods used are not stated. Only the precision values are given at the concentrations of interest. The precision values are calculated from equations 4 and 5.

Equation 4: $RSD_R = 22.0$ (for $C \leq 120 \mu\text{g/kg}$ or $c \leq 120 \times 10^{-9}$)

Equation 5: $RSD_R = 2^{(1-0.5\log c)}$ (for $C > 120 \mu\text{g/kg}$ or $c > 120 \times 10^{-9}$)

where:

- RSD_R = the relative standard deviation calculated from results generated under reproducibility conditions
- RSD_r = the relative standard deviation calculated from results generated under repeatability conditions = 0.66 RSD_R
- c = the aflatoxin concentration ratio (i.e. 1 = 100 g/100 g, 0.001 = 1 000 mg/kg)
- C = aflatoxin concentration or mass of aflatoxin to mass of tree nuts (i.e. $\mu\text{g/kg}$)

44. Equations 4 and 5 are generalized precision equations, which have been found to be independent of analyte and matrix but solely dependent on concentration for most routine methods of analysis.

45. Results should be reported on the edible portion of the sample.

Annex

Uncertainty, as measured by the variance, associated with sampling, sample preparation, and analytical steps of the aflatoxin test procedure used to estimate aflatoxin in almonds, hazelnuts, pistachios and shelled Brazil nuts.

Sampling data for almonds, hazelnuts, pistachios and shelled Brazil nuts were supplied by the United States, Turkey, Iran and Brazil, respectively.

Sampling, sample preparation, and analytical variances associated with testing almonds, hazelnuts, pistachios and shelled Brazil nuts are shown in Table 1 below.

Table 1. Variances^a associated with the aflatoxin test procedure for each treenut.

Test Procedure	Almonds	Hazelnuts	Pistachios	Shelled Brazil Nuts
Sampling ^{b,c}	$S_s^2 = (7\ 730/ns) 5.759C^{1.561}$	$S_s^2 = (10\ 000/ns) 4.291C^{1.609}$	$S_s^2 = 8\ 000/ns) 7.913C^{1.475}$	$S_s^2 = (1\ 850/ns) 4.8616C^{1.889}$
Sample Prep ^d	$S_{sp}^2 = (100/nss) 0.170C^{1.646}$	$S_{sp}^2 = (50/nss) 0.021C^{1.545}$	$S_{sp}^2 = (25/nss) 2.334C^{1.522}$	$S_{ss}^2 = (50/nss) 0.0306C^{0.632}$
Analytical ^e	$S_a^2 = (1/na) 0.0484C^{2.0}$	$S_a^2 = (1/na) 0.0484C^{2.0}$	$S_a^2 = (1/na) 0.0484C^{2.0}$	experimental $S_a^2 = (1/n) 0.0164C^{1.117}$ or FAPAS $S_a^2 = (1/n) 0.0484C^{2.0}$
Total variance	$S_s^2 + S_{sp}^2 + S_a^2$	$S_s^2 + S_{sp}^2 + S_a^2$	$S_s^2 + S_{sp}^2 + S_a^2$	$S_s^2 + S_{sp}^2 + S_a^2$

a/ Variance = S² (s, sp, and a denote sampling, sample preparation, and analytical steps, respectively, of aflatoxin test procedure)

b/ ns = laboratory sample size in number of shelled nuts, nss =test portion size in grams, na = number of aliquots quantified by HPLC, and C = aflatoxin concentration in µg/kg total aflatoxin.

c/ Shelled nut count/kg for almonds, hazelnuts, pistachios and Brazil nuts is 773, 1 000, 1 600 and 185, respectively.

d/ Sample preparation for almonds, hazelnuts, and pistachios reflect Hobart, Robot Coupe, Marjaan Khatman and Turrax type mills, respectively. Laboratory samples were dry ground into a paste for each treenut except for Brazil nut that were prepared as a slurry Brazil nut/water 1/1 w/w.

e/ Analytical variances reflect FAPAS recommendation for upper limit of analytical reproducibility uncertainty. A relative standard deviation of 22%, which is based upon FAPAS data, is considered, as an appropriate measure of the best agreement that can be obtained between laboratories. An analytical uncertainty of 22% is larger than the within laboratory uncertainty measured in the sampling studies for the four treenuts.

SAMPLING PLAN FOR AFLATOXIN CONTAMINATION IN DRIED FIGS**DEFINITION**

Lot	an identifiable quantity of a food commodity delivered at one time and determined by the official to have common characteristics, such as origin, variety, type of packing, packer, consignor, or markings.
Sublot	designated part of a larger lot in order to apply the sampling method on that designated part. Each sublot must be physically separate and identifiable.
Sampling plan	is defined by an aflatoxin test procedure and an accept/reject level. An aflatoxin test procedure consists of three steps: sample selection of sample(s) of a given size, sample preparation and aflatoxin quantification. The accept/reject level is a tolerance usually equal to the Codex maximum level.
Incremental sample	the quantity of material taken from a single random place in the lot or sublot.
Aggregate sample	the combined total of all the incremental samples that is taken from the lot or sublot. The aggregate sample has to be at least as large as the laboratory sample or samples combined.
Laboratory sample	the smallest quantity of dried figs comminuted in a mill. The laboratory sample may be a portion of or the entire aggregate sample. If the aggregate sample is larger than the laboratory sample(s), the laboratory sample(s) should be removed in a random manner from the aggregate sample.
Test portion	a portion of the comminuted laboratory sample. The entire laboratory sample should be comminuted in a mill. A portion of the comminuted laboratory sample is randomly removed for the extraction of the aflatoxin for chemical analysis.
Ready-to-eat dried figs	dried figs, which are not intended to undergo an additional processing/treatment that have proven to reduce levels of aflatoxin before being used as an ingredient in foodstuffs, otherwise processed or offered for human consumption.
Operating Characteristic (OC) Curve	a plot of the probability of accepting a lot versus lot concentration when using a specific sampling plan design. The OC curve also provides an estimate of good lots rejected (exporter's risk) and bad lots accepted (importer's risk) by a specific aflatoxin sampling plan design.

SAMPLING PLAN DESIGN CONSIDERATIONS

1. Importers commercially classify dried figs mostly as "ready-to-eat" (RTE). As a result, maximum levels and sampling plans are established only for ready-to-eat dried figs.
2. The performance of the sampling plan was computed using the variability and aflatoxin distribution among laboratory samples of dried figs taken from contaminated lots. Because the dried fig count per kg is different for different varieties of dried figs, the laboratory sample size is expressed in number of dried figs for statistical purposes. However, the dried fig count per kg for each variety of dried figs can be used to convert laboratory sample size from number of dried figs to mass and vice versa.
3. Uncertainty estimates (variances) associated with sampling, sample preparation, and analysis and the negative binomial distribution are used to calculate operating characteristic (OC) curves that describe the performance of the aflatoxin-sampling plans for dried figs.
4. The analytical variance measured in the sampling study reflects within laboratory variance and was replaced with an estimate of analytical variance reflects a reproducibility relative standard deviation of 22%, which is based upon Food Analysis Performance Assessment Scheme (FAPAS) data. A relative standard deviation of 22% is considered by FAPAS as an appropriate measure of the best agreement that can be reliably obtained between laboratories. An analytical uncertainty of 22% is larger than the within laboratory variation measured in the sampling studies for dried figs.
5. The issue of correcting the analytical test result for recovery is not addressed in this document. However, Table 2 specifies several performance criteria for analytical methods including suggestions for the range of acceptable recovery rates.

AFLATOXIN TEST PROCEDURE AND MAXIMUM LEVELS

6. An aflatoxin sampling plan is defined by an aflatoxin test procedure and a maximum level. A value for the maximum level and the aflatoxin test procedure are given below in this section.
7. The maximum level for "ready-to-eat" dried figs is 10 ng/g total aflatoxins.

8. Choice of the number and size of the laboratory sample is a compromise between minimizing risks (false positives and false negatives) and costs related to sampling and restricting trade. For simplicity, it is recommended that the aflatoxin sampling plan uses three 10 kg aggregate samples of dried figs.

9. The RTE sampling plan has been designed for enforcement and controls concerning total aflatoxins in bulk consignments (lots) of dried figs traded in the export market.

Maximum level – 10 µg/kg total aflatoxins

Number of laboratory samples – 3

Laboratory sample size – 10 kg

Sample preparation – water-slurry grind and a test portion that represents 55 g mass of dried figs

Analytical method – performance based (see Table 2)

Decision rule – If the aflatoxin test result is less than or equal to 10 µg/kg total aflatoxins for all three 10 kg laboratory samples, then accept the lot. Otherwise, reject the lot.

10. To assist member countries implement the above Codex sampling plan, sample selection methods, sample preparation methods, and analytical methods required to quantify aflatoxin in laboratory samples taken from bulk dried fig lots are described in the following sections.

SAMPLE SELECTION

MATERIAL TO BE SAMPLED

11. Each lot, which is to be examined for aflatoxin, must be sampled separately. Lots larger than 15 tonnes should be subdivided into sublots to be sampled separately. If a lot is greater than 15 tonnes, the number of sublots is equal to the lot weight in tonnes divided by 15 tonnes. It is recommended that a lot or a subplot should not exceed 15 tonnes.

12. Taking into account that the weight of the lot is not always an exact multiple of 15 tonnes, the weight of the subplot may exceed the mentioned weight by a maximum of 25%.

13. Samples should be taken from the same lot, i.e. they should have the same batch code or at the very least the same best before date. Any changes which would affect the mycotoxin content, the analytical determination or make the aggregate samples collected unrepresentative should be avoided. For example do not open packaging in adverse weather conditions or expose samples to excessive moisture or sunlight. Avoid cross-contamination from other potentially contaminated consignments nearby.

14. In most cases any truck or container will have to be unloaded to allow representative sampling to be carried out.

INCREMENTAL SAMPLE SELECTION

15. Procedures used to take incremental samples from a dried fig lot are extremely important. Every individual fig in the lot should have an equal chance of being chosen. Biases will be introduced by sample selection methods if equipment and procedures used to select the incremental samples prohibit or reduce the chances of any item in the lot from being chosen.

16. Since there is no way to know if the contaminated figs are uniformly dispersed throughout the lot, it is essential that the aggregate sample be the accumulation of many small incremental samples of product selected from different locations throughout the lot. If the aggregate sample is larger than desired, it should be blended and subdivided until the desired laboratory sample size is achieved.

17. For lots less than 10 tonnes, the size of the aggregate sample is reduced so that the aggregate sample size doesn't exceed a significant portion of the lot or subplot size.

NUMBER AND SIZE OF INCREMENTAL SAMPLES FOR LOTS OF VARYING WEIGHT

18. The number of incremental samples to be taken from a lot (subplot) depends on the weight of the lot. Table 1 shall be used to determine the number of incremental samples to be taken from lots or sublots of various sizes. The number of incremental samples varies from 10 to 100 for lots or sublots of various sizes.

Table 1. Number and size of incremental samples composited for an aggregate sample of 30 kg^a as a function of lot (or subplot) weight

Lot or subplot weight ^b (T in tonnes)	Minimum number of incremental samples	Minimum incremental sample size ^c (g)	Minimum aggregate sample size (Kg)	Laboratory sample size (Kg)	Number of laboratory samples
15.0 ≥ T > 10.0	100	300	30	10	3
10.0 ≥ T > 5.0	80	300	24	8	3
5.0 ≥ T > 2.0	60	300	18	9	2
2.0 ≥ T > 1.0	40	300	12	6	2
1.0 ≥ T > 0.5	30	300	9	9	1
0.5 ≥ T > 0.2	20	300	6	6	1
0.2 ≥ T > 0.1	15	300	4.5	4.5	1
0.1 ≥ T	10	300	3	3	1

a/ Minimum aggregate sample size = laboratory sample size of 30 kg for lots above 10 tonnes

b/ 1 Tonne = 1 000 kg

c/ Minimum incremental sample size = laboratory sample size (30 kg)/minimum number of incremental samples, i.e. for 10 < T ≤ 15 tonnes, 300 g = 30 000/100

19. The suggested minimum weight of the incremental sample is 300 g for lots and sublots of various sizes.

STATIC LOTS

20. A static lot can be defined as a large mass of dried figs contained either in a large single container such as a wagon, truck or railcar or in many small containers such as sacks or boxes and the dried figs are stationary at the time a sample is selected. Selecting a truly random sample from a static lot can be difficult because all containers in the lot or subplot may not be accessible.

21. Taking incremental samples from a static lot usually requires the use of probing devices to select product from the lot. The probing devices should be specifically designed for the commodity and type of container. The probe should (1) be long enough to reach all products, (2) not restrict any item in the lot from being selected, and (3) not alter the items in the lot. As mentioned above, the aggregate sample should be a composite from many small incremental samples of product taken from many different locations throughout the lot.

22. For lots traded in individual packages, the sampling frequency (SF), or number of packages that incremental samples are taken from, is a function of the lot weight (LT), incremental sample weight (IS), aggregate sample weight (AS) and the individual packing weight (IP), as follows:

$$\text{Equation 1: } SF = (LT \times IS) / (AS \times IP)$$

23. The sampling frequency (SF) is the number of packages sampled. All weights should be in the same mass units such as kg.

DYNAMIC LOTS

24. Representative aggregate samples can be more easily produced when selecting incremental samples from a moving stream of dried figs as the lot is transferred from one location to another. When sampling from a moving stream, take small incremental samples of product from the entire length of the moving stream; composite the incremental samples to obtain an aggregate sample; if the aggregate sample is larger than the required laboratory sample(s), then blend and subdivide the aggregate sample to obtain the desired size laboratory sample(s).

25. Automatic sampling equipment such as a cross-cut sampler is commercially available with timers that automatically pass a diverter cup through the moving stream at predetermined and uniform intervals. When automatic sampling equipment is not available, a person can be assigned to manually pass a cup through the stream at periodic intervals to collect incremental samples. Whether using automatic or manual methods, incremental samples should be collected and composited at frequent and uniform intervals throughout the entire time the figs flow past the sampling point.

26. Cross-cut samplers should be installed in the following manner: (1) the plane of the opening of the diverter cup should be perpendicular to the direction of the flow; (2) the diverter cup should pass through the entire cross sectional area of the stream; and (3) the opening of the diverter cup should be wide enough to accept all items of interest in the lot. As a general rule, the width of the diverter cup opening should be about two to three times the largest dimensions of items in the lot.

27. The size of the aggregate sample (S) in kg, taken from a lot by a cross cut sampler is:

$$\text{Equation 2: } S = (D \times LT) / (T \times V)$$

where D is the width of the diverter cup opening (cm), LT is the lot size (kg), T is interval or time between cup movement through the stream (seconds), and V is cup velocity (cm/sec).

28. If the mass flow rate of the moving stream, MR (kg/sec), is known, then the sampling frequency (SF), or number of cuts made by the automatic sampler cup can be computed from Equation 3 as a function of S, V, D, and MR.

$$\text{Equation 3: } SF = (S \times V) / (D \times MR)$$

29. Equations 2 and 3 can also be used to compute other terms of interest such as the time between cuts (T). For example, the time (T) required between cuts of the diverter cup to obtain a 30 kg aggregate sample from a 20 000 kg lot where the diverter cup width is 5.0 cm and the cup velocity through the stream 20 cm/sec. Solving for T in Equation 2.

$$T = (5.0 \text{ cm} \times 20\,000 \text{ kg}) / (30 \text{ kg} \times 20 \text{ cm/sec}) = 167 \text{ sec.}$$

30. If the lot is moving at 500 kg per minute, the entire lot will pass through the sampler in 40 minutes (2 400 sec) and only 14.4 cuts (14 incremental samples) will be made by the cup through the lot (Equation 3). This may be considered too infrequent, in that too much product (1 388.9 kg) passes through the sampler between the time the cup cuts through the stream.

PACKAGING AND TRANSPORTATION OF SAMPLES

31. Each laboratory sample shall be placed in a clean, inert container offering adequate protection from contamination, sunlight, and against damage in transit. All necessary precautions shall be taken to avoid any change in composition of the laboratory sample, which might arise during transportation or storage. Samples should be stored in a cool dark place.

SEALING AND LABELLING OF SAMPLES

32. Each laboratory sample taken for official use shall be sealed at the place of sampling and identified. A record must be kept of each sampling, permitting each lot to be identified unambiguously and giving the date and place of sampling together with any additional information likely to be of assistance to the analyst.

SAMPLE PREPARATION

PRECAUTIONS

33. Sunlight should be excluded as much as possible during sample preparation, since aflatoxin gradually breaks down under the influence of ultra-violet light. Also, environmental temperature and relative humidity should be controlled and not favour mould growth and aflatoxin formation.

HOMOGENIZATION - GRINDING

34. As the distribution of aflatoxin is extremely non-homogeneous, the laboratory samples should be homogenized by grinding the entire laboratory sample received by the laboratory. Homogenization is a procedure that reduces particle size and disperses the contaminated particles evenly throughout the comminuted laboratory sample.

35. The laboratory sample should be finely ground and mixed thoroughly using a process that approaches as complete homogenization as possible. Complete homogenization implies that particle size is extremely small and the variability associated with sample preparation approaches zero. After grinding, the grinder should be cleaned to prevent aflatoxin cross-contamination.

36. The use of vertical cutter mixer type grinders that mix and comminute the laboratory sample into a paste represent a compromise in terms of cost and fineness of grind or particle size reduction. A better homogenization (finer grind), such as a liquid slurry, can be obtained by more sophisticated equipment and should provide the lowest sample preparation variance.

TEST PORTION

37. The suggested weight of the test portion taken from the comminuted laboratory sample should be approximately 50 g. If the laboratory sample is prepared using a liquid slurry, the slurry should contain 50 g of fig mass.

38. Procedures for selecting the 50 g test portion from the comminuted laboratory sample should be a random process. If mixing occurred during or after the comminution process, the 50 g test portion can be selected from any location throughout the comminuted laboratory sample. Otherwise, the 50 g test portion should be the accumulation of several small portions selected throughout the laboratory sample.

39. It is suggested that three test portions be selected from each comminuted laboratory sample. The three test portions will be used for enforcement, appeal, and confirmation if needed.

ANALYTICAL METHODS

BACKGROUND

40. A criteria-based approach, whereby a set of performance criteria is established with which the analytical method used should comply, is appropriate. The criteria-based approach has the advantage that, by avoiding setting down specific details of the method used, developments in methodology can be exploited without having to reconsider or modify the specific analytical method. The performance criteria established for analytical methods should include all the parameters that need to be addressed by each laboratory such as the detection limit, repeatability coefficient of variation (within lab), reproducibility coefficient of variation (among lab), and the percent recovery necessary for various statutory limits. Analytical methods that are accepted by chemists internationally (such as AOAC) may be used. These methods are regularly monitored and improved depending upon technology.

PERFORMANCE CRITERIA FOR METHODS OF ANALYSIS

41. A list of criteria and performance levels are shown in Table 2. Utilizing this approach, laboratories would be free to use the analytical method most appropriate for their facilities.

Table 2: Specific Requirements with which Methods of Analysis Should Comply

Criterion	Concentration range (ng/g)	Recommended value	Maximum permitted value
Blanks	All	Negligible	n/a
Recovery	1 to 15	70 to 100%	n/a
	> 15	80 to 110%	n/a
Precision or relative standard deviation RSD_R (Reproducibility)	1 to 120	Equation 4	2 x value derived from Equation 4
	> 120	Equation 5	2 x value derived from Equation 5
Precision or relative standard deviation RSD_r (Repeatability)	1 to 120	Calculated as 0.66 times Precision RSD_R	n/a
	> 120	Calculated as 0.66 times Precision RSD_r	n/a

n/a = not applicable

42. The detection limits of the methods used are not stated. Only the precision values are given at the concentrations of interest. The precision values (expressed as a %) are calculated from equations 4 and 5.

$$\text{Equation 4: } RSD_R = 22.0$$

$$\text{Equation 5: } RSD_R = 45.25C^{-0.15}$$

where:

- RSD_R = the relative standard deviation calculated from results generated under reproducibility conditions
- RSD_r = the relative standard deviation calculated from results generated under repeatability conditions = $0.66RSD_R$
- C = aflatoxin concentration or mass of aflatoxin to mass of dried figs (i.e. ng/g)

43. Equations 4 and 5 are generalized precision equations, which have been found to be independent of analyte and matrix but solely dependent on concentration for most routine methods of analysis.

44. Results should be reported on the sample.

UNCERTAINTY, AS MEASURED BY THE VARIANCE, ASSOCIATED WITH THE SAMPLING, SAMPLE PREPARATION, AND ANALYTICAL STEPS OF THE AFLATOXIN TEST PROCEDURE USED TO DETECT AFLATOXIN IN DRIED FIGS

45. The sampling, sample preparation, and analytical variances associated with the aflatoxin test procedure for dried figs are shown in Table 3.

Table 3. Variances^a associated with the aflatoxin test procedure for dried figs

Test Procedure	Variances for Dried Figs
Sampling ^{b,c}	$S^2_s = (590/ns) 2.219C^{1.433}$
Sample Prep ^d	$S^2_{sp} = (55/nss) 0.01170C^{1.465}$
Analytical ^e	$S^2_a = (1/na) 0.0484C^{2.0}$
Total	$S^2_t = S^2_s + S^2_{sp} + S^2_a$

a/ Variance = S^2 (t, s, sp, and a denote total, sampling, sample preparation, and analytical steps, respectively, of aflatoxin test procedure)

b/ ns = laboratory sample size in number of dried figs, nss = test portion size in grams of fig mass, na = number of aliquots quantified by HPLC, and C = aflatoxin concentration in ng/g total aflatoxins

c/ Count/kg for dried figs averaged 59/kg

d/ Sample preparation variance reflects a water-slurry method and a test portion that reflects 55 g fig mass

e/ Analytical variances reflect FAPAS recommendation for upper limit of analytical reproducibility uncertainty. A relative standard deviation of 22% is based upon FAPAS data and considered as an appropriate measure of the best agreement that can be obtained between laboratories. An analytical uncertainty of 22% is larger than the within laboratory uncertainty measured in the sampling studies for the three dried figs.

AFLATOXIN M1

Reference to JECFA: 56 (2001)

Toxicological guidance: Cancer potency estimates at specified residue levels (2001, Using worst-case assumptions, the additional risks for liver cancer predicted with use of proposed maximum levels of aflatoxin M1 of 0.05 and 0.5 µg/kg are very small. The potency of aflatoxin M1 appears to be so low in HBsAg- individuals that a carcinogenic effect of M1 intake in those who consume large quantities of milk and milk products in comparison with non- consumers of these products would be impossible to demonstrate. Hepatitis B virus carriers might benefit from a reduction in the aflatoxin concentration in their diet, and the reduction might also offer some protection in hepatitis C virus carriers).

Contaminant definition: Aflatoxin M1

Synonyms: AFM1

Related Code of Practice: Code of Practice for the Reduction of Aflatoxin B1 in Raw Materials and Supplemental Feedingstuffs for Milk Producing Animals (CAC/RCP 45-1997)

Commodity / Product Name	Maximum Level (ML) (µg/kg)	Portion of the Commodity/Product to which the ML Applies	Notes/Remarks
Milks	0.5	Whole commodity	Milk is the normal mammary secretion of milking animals obtained from one or more milkings without either addition to it or extraction from it, intended for consumption as liquid milk or for further processing. A concentration factor applies to partially or wholly dehydrated milks.

OCHRATOXIN A

Reference to JECFA: 37 (1990), 44 (1995), 56 (2001), 68 (2007)
 Toxicological guidance: PTWI 0.0001 mg/kg bw (2001)
 Contaminant definition: Ochratoxin A
 Synonyms: (The term “ochratoxins” includes a number of related mycotoxins (A, B, C and their esters and metabolites), the most important one being ochratoxin A)
 Related Code of Practice: Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals, including Annexes on Ochratoxin A, Zearalenone, Fumonisin and Tricothecenes (CAC/RCP 51-2003)
 Code of Practice for the Prevention and Reduction of Ochratoxin A Contamination in Wine (CAC/RCP 63-2007)
 Code of Practice for the Prevention and Reduction of Ochratoxin A Contamination in Coffee (CAC/RCP 69-2009)
 Code of Practice for the Prevention and Reduction of Ochratoxin A contamination in Cocoa (CAC/RCP 72-2013)

Commodity / Product Name	Maximum Level (ML) (µg/kg)	Portion of the Commodity/Product to which the ML Applies	Notes/Remarks
Wheat	5	Whole commodity	The ML applies to raw common wheat, raw durum wheat, raw spelt and raw emmer.
Barley	5	Whole commodity	The ML applies to raw barley.
Rye	5	Whole commodity	The ML applies to raw rye.

PATULIN

Reference to JECFA: 35 (1989), 44 (1995)
 Toxicological guidance: PMTDI 0.0004 mg/kg bw (1995)
 Contaminant definition: Patulin
 Related Code of Practice: Code of Practice for the Prevention and Reduction of Patulin Contamination in Apple Juice and Apple Juice Ingredients in Other Beverages (CAC/RCP 50-2003)

Commodity / Product Name	Maximum Level (ML) (µg/kg)	Portion of the Commodity/Product to which the ML Applies	Notes/Remarks
Apple juice	50	Whole commodity (not concentrated) or commodity reconstituted to the original juice concentration.	Relevant Codex commodity standard include CODEX STAN 247-2005 (apple products only). The ML applies also to apple juice used as an ingredient in other beverages.

ARSENIC

Reference to JECFA: 5 (1960), 10 (1967), 27 (1983), 33 (1988), 72 (2010)

Toxicological guidance: At the 72nd meeting of JECFA (2010), the inorganic arsenic lower limit on the benchmark dose for a 0.5% increased incidence of lung cancer (BMDL 0.5) was determined from epidemiological studies to be 3.0 µg/kg bw/day (2–7 µg/kg bw/day based on the range of estimated total dietary exposure) using a range of assumptions to estimate total dietary exposure to inorganic arsenic from drinking-water and food. The JECFA noted that the provisional tolerable weekly intake (PTWI) of 15 µg/kg bw (equivalent to 2.1 µg/kg bw/day) is in the region of the BMDL 0.5 and therefore was no longer appropriate. The JECFA withdrew the previous PTWI.

Contaminant definition: Arsenic: total (As-tot) when not otherwise mentioned; inorganic arsenic (As-in); or other specification

Synonyms: As

Related Code of Practice: Code of Practice for Source Directed Measures to Reduce Contamination of Foods with Chemicals (CAC/RCP 49-2001)

Commodity / Product Name	Maximum Level (ML) (mg/kg)	Portion of the Commodity/Product to which the ML Applies	Notes/Remarks
Edible fats and oils	0.1	Whole commodity	Relevant Codex commodity standards are CODEX STAN 19-1981, CODEX STAN 33-1981, CODEX STAN 210-1999 and CODEX STAN 211-1999.
Fat spreads and blended spreads	0.1		Relevant Codex commodity standard is CODEX STAN 256-2007.
Natural mineral waters	0.01		Relevant Codex commodity standard is CODEX STAN 108-1981. Calculated as total As in mg/l.
Salt, food grade	0.5		Relevant Codex commodity standard is CODEX STAN 150-1985.

CADMIUM

Reference to JECFA: 16 (1972), 33 (1988), 41 (1993), 55 (2000), 61 (2003), 64 (2005), 73 (2010)

Toxicological guidance: In view of the long half-life of cadmium, daily ingestion in food has a small or even a negligible effect on overall exposure. In order to assess long- or short-term risks to health due to cadmium exposure, dietary intake should be assessed over months, and tolerable intake should be assessed over a period of at least 1 month. To encourage this view, at the 73rd meeting (2010) the JECFA decided to express the tolerable intake as a monthly value in the form of a provisional tolerable monthly intake (PTMI) and established a PTMI of 25 µg/kg bw.

Contaminant definition: Cadmium, total

Synonyms: Cd

Related Code of Practice: Code of Practice for Source Directed Measures to Reduce Contamination of Foods with Chemicals (CAC/RCP 49-2001)

Commodity / Product Name	Maximum Level (ML) (mg/kg)	Portion of the Commodity/Product to which the ML applies	Notes/Remarks
Brassica vegetables	0.05	Head cabbages and kohlrabi: whole commodity as marketed, after removal of obviously decomposed or withered leaves. Cauliflower and broccoli: flower heads (immature inflorescence only). Brussels sprouts: "buttons" only.	The ML does not apply to Brassica leafy vegetables.
Bulb vegetables	0.05	Bulb/dry onions and garlic: whole commodity after removal of roots and adhering soil and whatever parchment skin is easily detached.	
Fruiting vegetables	0.05	Whole commodity after removal of stems. Sweet corn and fresh corn: kernels plus cob without husk.	The ML does not apply to tomatoes and edible fungi.
Leafy vegetables	0.2	Whole commodity as usually marketed, after removal of obviously decomposed or withered leaves.	The ML also applies to Brassica leafy vegetables.
Legume vegetables	0.1	Whole commodity as consumed. The succulent forms may be consumed as whole pods or as the shelled product.	
Pulses	0.1	Whole commodity	The ML does not apply to soya bean (dry).
Root and tuber vegetables	0.1	Whole commodity after removing tops. Remove adhering soil (e.g. by rinsing in running water or by gentle brushing of the dry commodity). Potato: peeled potato.	The ML does not apply to celeriac.

Commodity / Product Name	Maximum Level (ML) (mg/kg)	Portion of the Commodity/Product to which the ML applies	Notes/Remarks
Stalk and stem vegetables	0.1	Whole commodity as marketed after removal of obviously decomposed or withered leaves. Rhubarb: leaf stems only. Globe artichoke: flower head only. Celery and asparagus: remove adhering soil.	
Cereal grains	0.1	Whole commodity	The ML does not apply to buckwheat, cañihua, quinoa, wheat and rice.
Rice, polished	0.4	Whole commodity	
Wheat	0.2	Whole commodity	The ML applies to common wheat, durum wheat, spelt and emmer.
Marine bivalve molluscs	2	Whole commodity after removal of shell.	The ML applies to clams, cockles and mussels but not to oysters and scallops.
Cephalopods	2	Whole commodity after removal of shell.	The ML applies to cuttlefishes, octopuses and squids without viscera
Natural mineral waters	0.003		Relevant Codex commodity standard is CODEX STAN 108-1981. The ML is expressed in mg/l.
Salt, food grade	0.5		Relevant Codex commodity standards is CODEX STAN 150-1985.

LEAD

Reference to JECFA:	10 (1966), 16 (1972), 22 (1978), 30 (1986), 41 (1993), 53 (1999), 73 (2010)
Toxicological guidance:	Based on the dose–response analyses, at the 73 rd meeting (2010), JECFA estimated that the previously established PTWI of 25 µg/kg bw is associated with a decrease of at least 3 intelligence quotient (IQ) points in children and an increase in systolic blood pressure of approximately 3 mmHg (0.4 kPa) in adults. While such effects may be insignificant at the individual level, these changes are important when viewed as a shift in the distribution of IQ or blood pressure within a population. The JECFA therefore concluded that the PTWI could no longer be considered health protective and withdrew it.
Contaminant definition:	Lead, total
Synonyms:	Pb
Related Code of Practice:	Code of Practice for the Prevention and Reduction of Lead Contamination in Foods (CAC/RCP 56-2004) Code of Practice for Source Directed Measures to Reduce Contamination of Foods with Chemicals (CAC/RCP 49-2001)

Commodity / Product Name	Maximum Level (ML) (mg/kg)	Portion of the Commodity/Product to which the ML Applies	Notes/remarks
Fruits with the exception of berries and other small fruits	0.1	Whole commodity. Pome fruits: whole commodity after removal of stems. Stone fruits, dates and olives: whole commodity after removal of stems and stones, but the level calculated and expressed on the whole commodity without stem. Pineapple: whole commodity after removal of crown. Avocado, mangos and similar fruit with hard seeds: whole commodity after removal of stone but calculated on whole fruit.	
Berries and other small fruits	0.2	Whole commodity after removal of caps and stems. Currants: fruit with stem.	
Brassica vegetables	0.3	Head cabbages and kohlrabi: whole commodity as marketed, after removal of obviously decomposed or withered leaves. Cauliflower and broccoli: flower heads (immature inflorescence only). Brussels sprouts: “buttons” only.	The ML does not apply to kale and leafy Brassica vegetables.

Commodity / Product Name	Maximum Level (ML) (mg/kg)	Portion of the Commodity/Product to which the ML Applies	Notes/remarks
Bulb vegetables	0.1	Bulb/dry onions and garlic: whole commodity after removal of roots and adhering soil and whatever parchment skin is easily detached.	
Fruiting vegetables	0.1	Whole commodity after removal of stems Sweet corn and fresh corn: kernels plus cob without husk.	The ML does not apply to mushrooms.
Leafy vegetables	0.3	Whole commodity as usually marketed,, after removal of obviously decomposed or withered leaves.	The ML applies to leafy Brassica vegetables but does not apply to spinach.
Legume vegetables	0.2	Whole commodity as consumed. The succulent forms may be consumed as whole pods or as the shelled product.	
Pulses	0.2	Whole commodity	
Root and tuber vegetables	0.1	Whole commodity after removing tops. Remove adhering soil (e.g. by rinsing in running water or by gentle brushing of the dry commodity). Potato: peeled potato.	
Canned fruit cocktail	1		Relevant Codex commodity standard is CODEX STAN 78-1981.
Canned grapefruit	1		Relevant Codex commodity standard is CODEX STAN 254-2007.
Canned mandarin oranges	1		Relevant Codex commodity standard is CODEX STAN 254-2007.
Canned mangoes	1		Relevant Codex commodity standard is CODEX STAN 159-1987.
Canned pineapple	1		Relevant Codex commodity standard is CODEX STAN 42-1981.
Canned raspberries	1		Relevant Codex commodity standard is CODEX STAN 60-1981.
Canned strawberries	1		Relevant Codex commodity standard is CODEX STAN 62-1981.
Canned tropical fruit salad	1		Relevant Codex commodity standard is CODEX STAN 99-1981.
Jams (fruit preserves) and jellies	1		Relevant Codex commodity standard is CODEX STAN 296-2009 (for jams and jellies only).

Commodity / Product Name	Maximum Level (ML) (mg/kg)	Portion of the Commodity/Product to which the ML Applies	Notes/remarks
Mango chutney	1		Relevant Codex commodity standard is CODEX STAN 160-1987.
Preserved tomatoes	1		Relevant Codex commodity standard is CODEX STAN 13-1981. In order to consider the concentration of the product, the determination of the maximum levels for contaminants shall take into account the natural total soluble solids, the reference value being 4.5 for fresh fruit.
Table olives	1		Relevant Codex commodity standard is CODEX STAN 66-1981.
Canned asparagus	1		Relevant Codex commodity standard is CODEX STAN 297-2009.
Canned carrots	1		Relevant Codex commodity standard is CODEX STAN 297-2009.
Canned green beans and canned wax beans	1		Relevant Codex commodity standard is CODEX STAN 297-2009.
Canned green peas	1		Relevant Codex commodity standard is CODEX STAN 297-2009.
Canned mature processed peas	1		Relevant Codex commodity standard is CODEX STAN 297-2009.
Canned mushrooms	1		Relevant Codex commodity standard is CODEX STAN 297-2009.
Canned palmito	1		Relevant Codex commodity standard is CODEX STAN 297-2009.
Canned sweet corn	1		Relevant Codex commodity standard is CODEX STAN 297-2009.
Pickled cucumbers (cucumber pickles)	1		Relevant Codex commodity standard is CODEX STAN 115-1981.
Processed tomato concentrates	1.5		Relevant Codex commodity standard is CODEX STAN 57-1981. In order to consider the concentration of the product, the determination of the maximum levels for contaminants shall take into account the natural total soluble solids, the reference value being 4.5 for fresh fruit.

Commodity / Product Name	Maximum Level (ML) (mg/kg)	Portion of the Commodity/Product to which the ML Applies	Notes/remarks
Canned chestnuts and canned chestnuts puree	1		Relevant Codex commodity standard is CODEX STAN 145-1985.
Fruit juices	0.05	Whole commodity (not concentrated) or commodity reconstituted to the original juice concentration, ready to drink.	The ML applies also to nectars, ready to drink. Relevant Codex commodity standards include CODEX STAN 247-2005.
Cereal grains	0.2	Whole commodity	The ML does not apply to buckwheat cañihua and quinoa.
Meat of cattle, pigs and sheep	0.1	Whole commodity (without bones)	The ML also applies to fat from the meat.
Meat and fat of poultry	0.1	Whole commodity (without bones)	
Cattle, edible offal of	0.5	Whole commodity.	
Pig, edible offal of	0.5	Whole commodity.	
Poultry, edible offal of	0.5	Whole commodity.	
Edible fats and oils	0.1	Whole commodity as prepared for wholesale or retail distribution.	Relevant Codex commodity standards are CODEX STAN 19-1981, CODEX STAN 33-1981, CODEX STAN 210-1999 and CODEX STAN 211-1999.
Fat spreads and blended spreads	0.1		Relevant Codex commodity standard is CODEX STAN 256-2007.
Milk	0.02	Whole commodity	Milk is the normal mammary secretion of milking animals obtained from one or more milkings without either addition to it or extraction from it, intended for consumption as liquid milk or for further processing. A concentration factor applies to partially or wholly dehydrated milks
Secondary milk products	0.02	Whole commodity	The ML applies to the food as consumed.
Infant formula and formula for special medical purposes intended for infants	0.02	Whole commodity	Relevant Codex commodity standard is CODEX STAN 72-1981. The ML applies to formula as consumed.
Fish	0.3	Whole commodity (in general after removing the digestive tract)	

Commodity / Product Name	Maximum Level (ML) (mg/kg)	Portion of the Commodity/Product to which the ML Applies	Notes/remarks
Natural mineral waters	0.01		Relevant Codex commodity standard is CODEX STAN 108-1981. The ML is expressed in mg/l.
Salt, food grade	2		Relevant Codex commodity standard is CODEX STAN 150-1985.
Wine	0.2		

MERCURY

Reference to JECFA:	10 (1966), 14 (1970), 16 (1972), 22 (1978), 72 (2010)
Toxicological guidance:	At the 72 nd meeting (2010), JECFA established a PTWI for inorganic mercury of 4 µg/kg bw. The previous PTWI of 5 µg/kg bw for total mercury, established at the sixteenth meeting, was withdrawn. The new PTWI for inorganic mercury was considered applicable to dietary exposure to total mercury from foods other than fish and shellfish. For dietary exposure to mercury from these foods the previously established PTWI for methyl mercury should be applied.
Contaminant definition:	Mercury, Total
Synonyms:	Hg
Related Code of Practice:	Code of Practice for Source Directed Measures to Reduce Contamination of Foods with Chemicals (CAC/RCP 49-2001)

Commodity / Product Name	Maximum Level (ML) (mg/kg)	Portion of the Commodity/Product to which the ML Applies	Notes/Remarks
Natural mineral waters	0.001		Relevant Codex commodity standard is CODEX STAN 108-1981. The ML is expressed in mg/l.
Salt food grade	0.1		Relevant Codex commodity standard is CODEX STAN 150-1985.

METHYLMERCURY

Reference to JECFA: 22 (1978), 33 (1988), 53 (1999), 61 (2003), 67 (2006)
 Toxicological guidance: PTWI 0.0016 mg/kg bw (2003, confirmed in 2006)
 Contaminant definition: Methylmercury
 Related Code of Practice: Code of Practice for Source Directed Measures to Reduce Contamination of Foods with Chemicals (CAC/RCP 49-2001)

Commodity / Product Name	Guideline Level (GL) (mg/kg)	Portion of the Commodity/Product to which the GL Applies	Notes/Remarks
Fish	0.5	Whole commodity (in general after removing the digestive tract)	The GL does not apply to predatory fish. The guideline levels are intended for methylmercury in fresh or processed fish and fish products moving in international trade.
Predatory fish	1	Whole commodity (in general after removing the digestive tract)	Predatory fish such as shark, swordfish, tuna, pike and others. The guideline levels are intended for methylmercury in fresh or processed fish and fish products moving in international trade.

Lots should be considered as being in compliance with the guideline levels if the level of methylmercury in the analytical sample, derived from the composite bulk sample, does not exceed the above levels. Where these Guideline levels are exceeded, governments should decide whether and under what circumstances, the food should be distributed within their territory or jurisdiction and what recommendations, if any, should be given as regards restrictions on consumption, especially by vulnerable groups such as pregnant women.

TIN

Reference to JECFA: 10 (1966), 14 (1970), 15 (1971), 19 (1975), 22 (1978), 26 (1982), 33 (1988), 55 (2000), 64 (2005)
 Toxicological guidance: PTWI 14 mg/kg bw (1988, expressed as Sn; includes tin from food additive uses; maintained in 2000)
 Contaminant definition: Tin, total (Sn-tot) when not otherwise mentioned; inorganic tin (Sn-in); or other specification
 Synonyms: Sn
 Related Code of Practice: Code of Practice for the Prevention and Reduction of Inorganic Tin Contamination in Canned Foods (CAC/RCP 60-2005)
 Code of Practice for Source Directed Measures to Reduce Contamination of Foods with Chemicals (CAC/RCP 49-2001)

Commodity / Product Name	Maximum Level (ML) (mg/kg)	Portion of the Commodity/Product to which the ML applies	Notes/rRemarks
Canned foods (other than beverages)	250		The ML does not apply to non-tinplate canned cooked cured chopped meat, cooked cured ham, cooked cured pork shoulder, corned beef and luncheon meat. Relevant Codex commodity standards include CODEX STAN 62-1981, CODEX STAN 254-2007, CODEX STAN 296-2009, CODEX STAN 242-2003, CODEX STAN 297-2009, CODEX STAN 78-1981, CODEX STAN 159-1987, CODEX STAN 42-1981, CODEX STAN 60-1981, CODEX STAN 99-1981, CODEX STAN 160-1987, CODEX STAN 66-1981, CODEX STAN 13-1981, CODEX STAN 115-1981, CODEX STAN 57-1981, CODEX STAN 145-1981, CODEX STAN 98-1981, CODEX STAN 96-1981, CODEX STAN 97-1981, CODEX STAN 88-1981, CODEX STAN 89-1981.
Canned beverages	150		Relevant Codex commodity standards include CODEX STAN 247-2005.
Cooked cured chopped meat	50		The ML applies to products in containers other than tinplate containers. Relevant Codex commodity standard is CODEX STAN 98-1981.
Cooked cured ham	50		The ML applies to products in containers other than tinplate containers. Relevant Codex commodity standard is CODEX STAN 96-1981.
Cooked cured pork shoulder	50		The ML applies to products in containers other than tinplate containers. Relevant Codex commodity standard is CODEX STAN 97-1981.
Corned beef	50		The ML applies to products in containers other than tinplate containers. Relevant Codex commodity standard is CODEX STAN 88-1981.
Luncheon meat	50		The ML applies to products in containers other than tinplate containers. Relevant Codex commodity standard is CODEX STAN 89-1981.

RADIONUCLIDES

TABLE 1

Commodity / Product Name	Guideline Level (GL) (Bq/kg)	Representative radionuclides	Portion of the Commodity/Product to which the GL applies	Notes/Remarks
Infant foods	1	Pu-238, Pu-239, Pu-240, Am-241		The GL applies to foods intended for consumption by infants.
Infant foods	100	Sr-90, Ru-106, I-129, I-131, U-235		The GL applies to foods intended for consumption by infants.
Infant foods	1 000	S-35 (*), Co-60, Sr-89, Ru-103, Cs-134, Cs-137, Ce-144, Ir-192		The GL applies to foods intended for consumption by infants.
Infant foods	1 000	H-3(**), C-14, Tc-99		The GL applies to foods intended for consumption by infants.
Foods other than infant foods	10	Pu-238, Pu-239, Pu-240, Am-241		
Foods other than infant foods	100	Sr-90, Ru-106, I-129, I-131, U-235		
Foods other than infant foods	1 000	S-35 (*), Co-60, Sr-89, Ru-103, Cs-134, Cs-137, Ce-144, Ir-192		
Foods other than infant foods	10 000	H-3(**), C-14, Tc-99		

(*) This represents the value for organically bound sulphur

(**) This represents the value for organically bound tritium

Scope: The Guideline Levels apply to radionuclides contained in foods destined for human consumption and traded internationally, which have been contaminated following a nuclear or radiological emergency¹. These guideline levels apply to food after reconstitution or as prepared for consumption, i.e., not to dried or concentrated foods, and are based on an intervention exemption level of 1 mSv in a year.

Application: As far as generic radiological protection of food consumers is concerned, when radionuclide levels in food do not exceed the corresponding Guideline Levels, the food should be considered as safe for human consumption. When the Guideline Levels are exceeded, national governments shall decide whether and under what circumstances the food should be distributed within their territory or jurisdiction. National governments may wish to adopt different values for internal use within their own territories where the assumptions concerning food distribution that have been made to derive the Guideline Levels may not apply, e.g., in the case of wide-spread radioactive contamination. For foods that are consumed in small quantities, such as spices, that represent a small percentage of total diet and hence a small addition to the total dose, the Guideline Levels may be increased by a factor of 10.

Radionuclides: The Guideline Levels do not include all radionuclides. Radionuclides included are those important for uptake into the food chain; are usually contained in nuclear installations or used as a radiation source in large enough quantities to be significant potential contributors to levels in foods, and; could be accidentally released into the environment from typical installations or might be employed in malevolent actions. Radionuclides of natural origin are generally excluded from consideration in this document.

¹ For the purposes of this document, the term "emergency" includes both accidents and malevolent actions.

In the Table, the radionuclides are grouped according to the guideline levels rounded logarithmically by orders of magnitude. Guideline levels are defined for two separate categories “infant foods” and “other foods”. This is because, for a number of radionuclides, the sensitivity of infants could pose a problem. The guideline levels have been checked against age-dependent ingestion dose coefficients defined as committed effective doses per unit intake for each radionuclide, which are taken from the “International Basic Safety Standards” (IAEA, 1996)².

Multiple radionuclides in foods: The guideline levels have been developed with the understanding that there is no need to add contributions from radionuclides in different groups. Each group should be treated independently. However, the activity concentrations of each radionuclide within the same group should be added together³.

² Food and Agriculture Organization of the United Nations, International Atomic Energy Agency, International Labour Office, OECD Nuclear Energy Agency, Pan American Health Organization, World Health Organization (1996) International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources, IAEA, Vienna.

³ For example, if ¹³⁴Cs and ¹³⁷Cs are contaminants in food, the guideline level of 1 000 Bq/kg refers to the summed activity of both these radionuclides.

SCIENTIFIC JUSTIFICATION FOR THE GUIDELINE LEVELS FOR RADIONUCLIDES IN FOODS CONTAMINATED FOLLOWING A NUCLEAR OR RADIOLOGICAL EMERGENCY

The Guideline Levels for Radionuclides in Foods and specifically the values presented in Table 1 above are based on the following general radiological considerations and experience of application of the existing international and national standards for control of radionuclides in food.

Significant improvements in the assessment of radiation doses resulting from the human intake of radioactive substances have become available since the Guideline Levels were issued by the Codex Alimentarius Commission in 1989¹ (CAC/GL 5-1989).

Infants and adults: The levels of human exposure resulting from consumption of foods containing radionuclides listed in Table 1 at the suggested guideline levels have been assessed both for infants and adults and checked for compliance with the appropriate dose criterion.

In order to assess public exposure and the associated health risks from intake of radionuclides in food, estimates of food consumption rates and ingestion dose coefficients are needed. It is assumed that 550 kg of food is consumed by an adult in a year. The value of infant food and milk consumption during first year of life used for infant dose calculation equal to 200 kg is based on contemporary human habit assessments. The most conservative values of the radionuclide-specific and age-specific ingestion dose coefficients, i.e. relevant to the chemical forms of radionuclides which are most absorbed from the gastro-intestinal tract and retained in body tissues, are taken from the IAEA.

Radiological criterion: The appropriate radiological criterion, which has been used for comparison with the dose assessment data below, is a generic intervention exemption level of around 1 mSv for individual annual dose from radionuclides in major commodities, e.g. food, recommended by the International Commission on Radiological Protection as safe for members of the public.

Naturally occurring radionuclides: Radionuclides of natural origin are ubiquitous and as a consequence are present in all foodstuffs to varying degrees. Radiation doses from the consumption of foodstuffs typically range from a few tens to a few hundreds of microsieverts in a year. In essence, the doses from these radionuclides when naturally present in the diet are unamenable to control; the resources that would be required to affect exposures would be out of proportion to the benefits achieved for health. These radionuclides are excluded from consideration in this document as they are not associated with emergencies.

One-year exposure assessment: It is conservatively assumed that during the first year after major environmental radioactive contamination caused by a nuclear or radiological emergency it might be difficult to readily replace foods imported from contaminated regions with foods imported from unaffected areas. According to FAO statistical data the mean fraction of major foodstuff quantities imported by all the countries worldwide is 0.1. The values in Table 1 as regards foods consumed by infants and the general population have been derived to ensure that if a country continues to import major foods from areas contaminated with radionuclides, the mean annual internal dose of its inhabitants will not exceed around 1 mSv (see Annex 2). This conclusion might not apply for some radionuclides if the fraction of contaminated food is found to be higher than 0.1, as might be the case for infants who have a diet essentially based on milk with little variety.

Long-term exposure assessment: Beyond one year after the emergency the fraction of contaminated food placed on the market will generally decrease as a result of national restrictions (withdrawal from the market), changes to other produce, agricultural countermeasures and decay.

Experience has shown that in the long term the fraction of imported contaminated food will decrease by a factor of a hundred or more. Specific food categories, e.g. wild forest products, may show persistent or even increasing levels of contamination. Other categories of food may gradually be exempted from controls. Nevertheless, it must be anticipated that it may take many years before levels of individual exposure as a result of contaminated food could be qualified as negligible.

¹ The Codex Alimentarius Commission at its 18th Session (Geneva 1989) adopted Guideline Levels for Radionuclides in Foods Following Accidental Nuclear Contamination for Use in International Trade (CAC/GL 5-1989) applicable for six radionuclides (⁹⁰Sr, ¹³¹I, ¹³⁷Cs, ¹³⁴Cs, ²³⁹Pu and ²⁴¹Am) during one year after the nuclear accident.

ASSESSMENT OF HUMAN INTERNAL EXPOSURE WHEN THE GUIDELINE LEVELS ARE APPLIED

For the purpose of assessment of the mean public exposure level in a country caused by the import of food products from foreign areas with residual radioactivity, in implementing the present guideline levels the following data should be used: annual food consumption rates for infants and adults, radionuclide- and age-dependent ingestion dose coefficients and the import/production factors. When assessing the mean internal dose in infants and adults it is suggested that due to monitoring and inspection the radionuclide concentration in imported foods does not exceed the present guideline levels. Using cautious assessment approach it is considered that all the foodstuffs imported from foreign areas with residual radioactivity are contaminated with radionuclides at the present guideline levels.

Then, the mean internal dose of the public, E (mSv), due to annual consumption of imported foods containing radionuclides can be estimated using the following formula:

$$E = GL(A) M(A) e_{ing}(A) IPF$$

where:

$GL(A)$ is the Guideline Level (Bq/kg)

$M(A)$ is the age-dependent mass of food consumed per year (kg)

$e_{ing}(A)$ is the age-dependent ingestion dose coefficient (mSv/Bq)

IPF is the import/production factor¹ (dimensionless)

Assessment results presented in Table 2 both for infants and adults demonstrate that for all the twenty radionuclides doses from consumption of imported foods during the 1st year after major radioactive contamination do not exceed 1 mSv. It should be noted that the doses were calculated on the basis of a value for the IPF equal to 0.1 and that this assumption may not always apply, in particular to infants who have a diet essentially based on milk with little variety.

It should be noted that for ²³⁹Pu as well as for a number of other radionuclides the dose estimate is conservative. This is because elevated gastro-intestinal tract absorption factors and associated ingestion dose coefficients are applied for the whole first year of life whereas this is valid mainly during suckling period recently estimated by ICRP to be as average first six months of life. For the subsequent six months of the first year of life the gut absorption factors are much lower. This is not the case for ³H, ¹⁴C, ³⁵S, iodine and caesium isotopes.

As an example, dose assessment for ¹³⁷Cs in foods is presented below for the first year after the area contamination with this nuclide.

For adults: $E = 1\,000 \text{ Bq/kg} \cdot 550 \text{ kg} \cdot 1.3 \cdot 10^{-5} \text{ mSv/Bq} \cdot 0.1 = 0.7 \text{ mSv}$;

For infants: $E = 1\,000 \text{ Bq/kg} \cdot 200 \text{ kg} \cdot 2.1 \cdot 10^{-5} \text{ mSv/Bq} \cdot 0.1 = 0.4 \text{ mSv}$

¹ The import/production factor (IPF) is defined as the ratio of the amount of foodstuffs imported per year from areas contaminated with radionuclides to the total amount produced and imported annually in the region or country under consideration.

TABLE 2

ASSESSMENT OF EFFECTIVE DOSE FOR INFANTS AND ADULTS FROM INGESTION OF IMPORTED FOODS IN A YEAR

Radionuclide	Guideline Level (Bq/kg)		Effective dose (mSv)	
	Infant foods	Other foods	1 st year after major contamination	
			Infants	Adults
²³⁸ Pu	1	10	0.08	0.1
²³⁹ Pu			0.08	0.1
²⁴⁰ Pu			0.08	0.1
²⁴¹ Am			0.07	0.1
⁹⁰ Sr	100	100	0.5	0.2
¹⁰⁶ Ru			0.2	0.04
¹²⁹ I			0.4	0.6
¹³¹ I			0.4	0.1
²³⁵ U			0.7	0.3
³⁵ S*	1 000	1 000	0.2	0.04
⁶⁰ Co			1	0.2
⁸⁹ Sr			0.7	0.1
¹⁰³ Ru			0.1	0.04
¹³⁴ Cs			0.5	1
¹³⁷ Cs			0.4	0.7
¹⁴⁴ Ce			1	0.3
¹⁹² Ir			0.3	0.08
³ H**	1 000	10 000	0.002	0.02
¹⁴ C			0.03	0.3
⁹⁹ Tc			0.2	0.4

* This represents the value for organically bound sulphur

** This represents the value for organically bound tritium

See for "Scientific justification for the Guideline Levels" (Annex 1) and the "Assessment of human internal exposure when the Guideline Levels are applied" (Annex 2)

ACRYLONITRILE

Reference to JECFA: 28 (1984)
 Toxicological guidance: Provisional Acceptance (1984, the use of food-contact materials from which acrylonitrile may migrate is provisionally accepted on condition that the amount of the substance migrating into food is reduced to the lowest level technologically attainable)
 Contaminant definition: acrylonitrile (monomer)
 Synonyms: 2-Propenenitrile; vinyl cyanide (VCN); cyanoethylene; abbreviations, AN, CAN.
 Related Code of Practice: Code of Practice for Source Directed Measures to Reduce Contamination of Foods with Chemicals (CAC/RCP 49-2001)

Commodity / Product Name	Guideline Level (GL) (mg/kg)	Portion of the Commodity/Product to which the GL Applies	Notes/Remarks
Food	0.02		

CHLOROPROPANOLS

Reference to JECFA: 41 (1993; for 1,3-dichloro-2-propanol only), 57 (2001), 67 (2006)

Toxicological guidance: PMTDI 0.002 mg/kg bw (2001, for 3-chloro-1,2-propanediol); maintained in 2006. Establishment of tolerable intake was considered to be inappropriate for 1,3-dichloro-2-propanol because of the nature of the toxicity (tumorigenic in various organs in rats and the contaminant can interact with chromosomes and/or DNA).
BMDL 10 cancer, 3.3 mg/kg bw/day (for 1,3-dichloro-2-propanol); MOE, 65 000 (general population), 2 400 (high level intake, including young children).

Contaminant definition: 3-MCPD

Synonyms: Two substances are the most important members of this group: 3-monochloropropane-1,2-diol (3-MCPD, also referred to as 3-monochloro-1,2-propanediol) and 1,3-dichloro-2-propanol (1,3-DCP).

Related Code of Practice: Code of Practice for the Reduction of 3-Monochloropropane-1,2-diol (3-MCPD) during the production of Acid-Hydrolyzed Vegetable Proteins (Acid-HVPs) and Products that Contain Acid-HVPs (CAC/RCP 64-2008).

Commodity / Product Name	Maximum Level (ML) (mg/kg)	Portion of the Commodity/Product to which the ML Applies	Notes/Remarks
Liquid condiments containing acid hydrolyzed vegetable proteins	0.4		The ML does not apply to naturally fermented soy sauce.

HYDROCYANIC ACID

Reference to JECFA: 39 (1992), 74 (2011)
 Toxicological guidance: ARfD 0.09 mg/kg bw as cyanide (2011, this cyanide-equivalent ARfD applies only to foods containing cyanogenic glycosides as the main source of cyanide)
 PMTDI 0.02 mg/kg bw as cyanide (2011)
 Contaminant definition: See explanatory notes in the column "Notes/Remarks"
 Synonyms: HCN
 Related Code of Practice: Code of Practice for the Reduction of Hydrocyanic Acid (HCN) in Cassava and Cassava products (CAC/RCP 73-2013)

Commodity / Product Name	Maximum Level (ML) (mg/kg)	Portion of the Commodity/Product to which the ML applies	Notes/Remarks
Gari	2	Whole commodity	The ML is expressed as free hydrocyanic acid. Relevant Codex commodity standards include CODEX STAN 151-1989.
Cassava flour	10		The ML is expressed as total hydrocyanic acid. Relevant Codex commodity standards include CODEX STAN 176-1989.

MELAMINE

Reference to JECFA: FAO/WHO Expert Meeting (2008)
 Toxicological guidance: TDI 0.2 mg/kg bw (2008)
 Contaminant definition: melamine

Commodity / Product Name	Maximum Level (ML) (mg/kg)	Portion of the Commodity/Product to which the ML Applies	Notes/Remarks
Food (other than infant formulae) and feed	2.5		<p>The ML applies to food other than infant formula.</p> <p>The ML applies to levels of melamine resulting from its non-intentional and unavoidable presence in feed and food.</p> <p>The ML does not apply to feed and food for which it can be proven that the level of melamine higher than 2.5 mg/kg is the consequence of:</p> <ul style="list-style-type: none"> - authorised use of cyromazine as insecticide. The melamine level shall not exceed the level of cyromazine. - migration from food contact materials taking account of any nationally authorised migration limit. <p>The ML does not apply to melamine that could be present in the following feed ingredients / additives: guanidine acetic acid (GAA), urea and biuret, as a result of normal production processes.</p>
Powdered infant formula	1		
Liquid infant formula	0.15		The ML applies to liquid infant formula as consumed.

VINYL CHLORIDE MONOMER

Reference to JECFA:	28 (1984)
Toxicological guidance:	Provisional Acceptance (1984, the use of food-contact materials from which vinyl chloride may migrate is provisionally accepted, on condition that the amount of the substance migrating into food is reduced to the lowest level technologically achievable.
Contaminant definition:	Vinylchloride monomer
Synonyms:	Monochloroethene, chloroethylene; abbreviation VC or VCM
Related Code of Practice:	Code of Practice for Source Directed Measures to Reduce Contamination of Foods with Chemicals (CAC/RCP 49-2001)

Commodity / Product Name	Guideline Level (GL) (mg/kg)	Portion of the Commodity/Product to which the GL Applies	Notes/Remarks
Food	0.01		The GL in food packaging material is 1.0 mg/kg.

PROJECT DOCUMENT**PROPOSAL FOR NEW WORK ON A CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF ARSENIC CONTAMINATION IN RICE****(for approval by CAC)****1. The purpose and scope of the project**

This project aims to establish a Code of practice for the prevention and reduction of arsenic contamination in rice.

2. Relevance and timeliness

In 2010, the 72nd meeting of JECFA withdrew the PTWI for inorganic arsenic of 15 µg/kg bw (equivalent to 2.1 µg/kg bw per day) because the PTWI is in the region of the BMDL_{0.5} (3.0 µg/kg bw per day with the range of 2–7 µg/kg bw per day) from lung cancer epidemiological studies. On the basis of occurrence data, JECFA identified that rice tends to be a major source of inorganic arsenic from food, particularly in Asia and other countries where it is a staple food.

According to the GSCTFF, contaminant levels in food and feed shall be as low as reasonably achievable through best practice such as Good Agricultural Practice (GAP) and Good Manufacturing Practice (GMP) following an appropriate risk assessment. Therefore, it is necessary to elaborate a Code of Practice for the prevention and reduction of arsenic contamination in rice, comprising source related measures, GAP and GMP to reduce arsenic contamination in rice.

It is expected that a Code of Practice will contribute to reduction of arsenic concentration in rice, thus help protecting consumers' health.

3. The main aspects to be covered

The Code of Practice will compile measures to prevent and reduce arsenic concentration in rice supported by scientific evidence. Such measures include:

- i. Source directed measures;
- ii. Agricultural measures;
- iii. Processing and cooking measures; and
- iv. Monitoring.

4. Assessment against the criteria for the establishment of work priorities***General Criterion***

To protect consumers' health, it is essential to keep arsenic levels, in particular inorganic arsenic levels in rice as low as reasonably achievable through best practices. A Code of Practice compiling such practices will ensure that Members will take adequate, reasonable action to prevent or reduce arsenic contamination. A Code of Practice will also ensure fair trade to help farmers to produce rice that complies with ML, which is to be established by the Committee.

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

Without a Code of Practice, impediment to international trade is expected because varying arsenic levels in rice among countries would result in different legislations reflecting their own situations.

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

The Code of Practice will provide measures to prevent and reduce arsenic contamination in rice and consist of source directed measures, agricultural measures, processing and cooking measures and monitoring.

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

None.

(d) Amenability of the subject of the proposal to standardisation

Rice was identified by JECFA as a major source in inorganic arsenic intake. So it is important to reduce arsenic intake from rice. Some measures to reduce arsenic contamination have already been implemented in countries and information on agricultural practices and measures on processing and cooking has been obtained. In addition, studies on more effective measures are ongoing in some countries. Therefore, compiling the measures and information to reduce arsenic contamination in rice will be a solid basis for developing the Code of Practice.

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

- Rice is a staple commodity and regularly consumed by more than half of the world population. The Code of Practice will protect the health of people by reducing the intake of arsenic from rice.
- Rice produced in line with the Code of Practice will contain less concentrations of arsenic and is more likely to comply with MLs for inorganic arsenic. This could lead to reduced food loss and consequently contribute to food security.

5. Relevance to Codex Strategic Goals

The proposed work falls under the following Codex Strategic Goals:

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

Considering the result of the risk assessment by JECFA, inorganic arsenic in rice is a current food safety issue.

Strategic Goal 2: Ensure the application of risk analysis principles in the development of Codex standards.

As JECFA identified that rice can be a major source of inorganic arsenic from food in their risk assessment, Codex should conduct risk management. Establishment of a Code of Practice is a risk management measure and in line with the Preamble of the *General Standard for Contaminants and Toxins in Food and Feed* (CODEX STAN 193-1995) as it will help reduction of contaminant concentrations to “as low as reasonably achievable” through best practice.

6. Information on the relationship between the proposal and other existing Codex documents

In the Codex framework, it has become a common practice to develop and adopt codes of practice for prevention and reduction of chemical contaminants such as:

- *Code of Practice for Source Directed Measures to Reduce Contamination of Food with Chemicals* (CAC/RCP 49-2001);
- *Code of Practice for Prevention and Reduction of Lead Contamination in Foods* (CAC/RCP 56-2004);
- *Code of Practice for Prevention and Reduction of Dioxin and Dioxin-like PCB Contamination in Food and Feeds* (CAC/RCP 62-2006).

7. Identification of any requirement for any availability of expert scientific advice

None.

8. Identification of any need for technical input to the standard from external bodies

None (Inputs from Codex Members will be sought).

9. The proposed time line for completion of the new work, including the starting date, proposed date for adoption at Step 5 and the proposed date for adoption by the Commission

Approval of new work by the Codex Alimentarius Commission in 2014. Completion of work for final adoption by the Commission in 2017 or before.

APPENDIX IX**PROJECT DOCUMENT****PROPOSAL FOR NEW WORK ON THE REVISION OF THE CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF MYCOTOXIN CONTAMINATION IN CEREALS, INCLUDING ANNEXES ON OCHRATOXIN A, ZEARELENONE, FUMONISINS, TRICHOHECENES (CAC/RCP 51-2003)****(for approval by CAC)****1. Purpose and scope of the new work**

The purpose of the proposed new work is to provide to member countries, cereal producers and industry guidance on how to prevent and reduce mycotoxin contamination in cereals. This guidance will include the latest developments in good agricultural practices (GAPs) and good manufacturing practices (GMPs) in use worldwide.

2. Relevance and timeliness

The *Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals including Annexes on Ochratoxin A, Zearalenone, Fumonisins and Trichothecenes* (CAC/RCP 51-2003) was adopted by the Codex Alimentarius Commission in 2003. Since then, a wide range of research was conducted to understand the fungus-plant interaction, mycotoxin biosynthesis and metabolism and measures for the prevention and reduction of mycotoxin contamination in food, such as use of predictive models and biological control. Hence, a revision of the Code taking into consideration these new developments in science and technology is necessary. In addition, specific management measures to control aflatoxin contamination in cereals are also necessary and will be addressed in a separate annex to the Code.

3. Main aspects to be covered

Specific measures for the control of aflatoxins and additional measures for the prevention and reduction of mycotoxins in cereals, not currently included in the Code, in order to bring the document in line with current GAPs and GMPs and other relevant methodologies and technologies currently in use and widely applied, such as the use of biological control methods and predictive models.

4. Assessment against the criteria for the establishment of work priorities

Consumer protection from the health point of view, food safety, ensuring fair practices in the food trade and taking into account the needs of developing countries. The new work will provide additional and updated guidance to countries in order to prevent and reduce mycotoxin contamination and consequently minimizing consumer dietary exposure from cereals and cereal-based products thereby improving the overall quality of these products.

5. Relevance to Codex Strategic Goals

The proposed work falls under 3 Codex Strategic Goals of the *Codex Strategic Plan 2014-2019*:

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

Mycotoxin contamination in cereals is a safety issue that impacts on public health, food security and trade.

Goal 2. Ensure the application of risk analysis principles in the development of Codex standards

This work will help in establishing risk management options and strategies to prevent and reduce mycotoxin levels in cereals. After these practices are implemented, new data can be obtained and a new risk analysis can be performed to evaluate the impact of this revision and may also facilitate the establishment of maximum levels for mycotoxins in cereals and cereal-based products.

Goal 4. Implement effective and efficient work management system and practices.

Reviewing and implementing the recommended practices from primary production to industry level can help to control mycotoxin contamination.

6. Information on the relationship between the proposal and other existing Codex documents

The Code of Practice for the Prevention and Reduction of Mycotoxin in Cereals is an inclusive document addressing general GAPs and GMPs applying across cereals and includes specific management measures for certain mycotoxins. This Code supports the application of maximum levels for mycotoxins in cereals available in the *General Standard for Contaminants and Toxins in Food and Feed* (CODEX STAN 193-1995). The Code will also complement other relevant Codex texts in existence or under development such as the Code of Hygienic Practice for Low-Moisture Foods (Committee on Food Hygiene)

7. Identification of any requirement for and availability of expert scientific advice

Additional scientific advice is not necessary.

8. Identification of any need for technical input to the standard from external bodies

There is no need for additional technical input from external bodies.

9. The proposed timeline for completion of the new work

Approval of new work by the Codex Alimentarius Commission in 2014. Completion of work for final adoption by the Commission in 2017 or before.

APPENDIX X**PROJECT DOCUMENT****PROPOSAL FOR NEW WORK ON ESTABLISHMENT OF AN MAXIMUM LEVEL FOR
TOTAL AFLATOXINS IN READY-TO-EAT PEANUTS (AND ASSOCIATED SAMPLING PLAN)****(for approval by CAC)****1. Purpose and Scope**

The proposal seeks to undertake new work on establishment of Maximum Levels (MLs) for Total Aflatoxins (AFs) and associated sampling plans. The term “ready to eat” is as defined in the *General Standard for Contaminants and Toxins in Food and Feed* (CODEX STAN 193-1995). Presently MLs of AFs established by Codex are only for peanuts for further processing. Thus, there is a need to establish MLs of AFs in RTE peanuts and associated sampling plans. Establishment of Codex MLs of AFs in RTE peanuts will provide an internationally harmonized standard and will help to address the potential impediments to fair trade of RTE peanuts.

2. Relevance of the work

AFs are considered the most important group of mycotoxins in the world's food supply and are now known to be produced by at least 10 *Aspergillus* species. However, most are rare or rarely found in foods. The main fungi producing AFs remain *Aspergillus flavus* and *Aspergillus parasiticus*.

JECFA verified results of groundnuts using limited available data (Europe, US): if “all groundnuts are included, the average aflatoxin concentration would be 15 µg/kg. The average aflatoxin concentration would be 0.6 µg/kg if all samples with levels above 20 µg/kg were excluded and 0.5 and 0.4 µg/kg if all samples with levels above 15 and 10 µg/kg, respectively, were excluded.” (WHO FAS 40).

JECFA at the 69th meeting confirmed the hazard characterization of aflatoxins as genotoxic carcinogens that induce tumours in the liver of animals and humans and for which no tolerable levels can be established (WHO TRS 947, pp. 159-169; WHO FAS 59, pp. 305-356).

3. Main aspects to be covered

The main aspects to be covered would be establishing MLs of total AFs in RTE peanuts

4. Assessment against the Criteria for the establishment of work priorities

This proposal complies with the following criteria for establishing priorities of work:

- **Consumer protection from the point of view of health and food safety** (by establishing uniform MLs of AFs in RTE peanuts).

5. Relevance to the Codex Strategic Objectives**Goal -1: Promoting sound regulatory frameworks**

Harmonized Codex MLs of AFs of RTE peanuts for developed and developing countries would lead to enhanced fair trade practices.

Goal -2: Promoting consistent application of scientific principles and risk analysis

It would help the establishment of MLs of AFs of RTE peanuts based on risk assessment.

Goal -3: Promoting maximum application of Codex Standard

It would promote maximum application of Codex standards.

6. Information on the relation between the proposal and other existing Codex documents

None at this stage.

7. Identification of any requirement for and availability of expert scientific advice

No requirement of expert scientific advice identified.

8. Identification of any need for technical input to the standard from external bodies

No anticipated need for external contributions.

9. Proposed time-line for completion of the work

Approval of new work by the Codex Alimentarius Commission in 2014. Completion of work for final adoption by the Commission in 2017 or before.

APPENDIX XI**PROJECT DOCUMENT****PROPOSAL FOR NEW WORK ON THE ESTABLISHMENT OF MAXIMUM LEVELS
FOR CADMIUM IN CHOCOLATE AND COCOA-DERIVED PRODUCTS****(for approval by CAC)****1. Purpose and Scope of the new work**

The purpose of the new work is to provide harmonised maximum levels (MLs) for cadmium in chocolate and cocoa-derived products in order to protect consumer health and to facilitate international trade.

2. Relevance and timeliness

Cocoa is economically and strategically important for producing and importing countries and harmonised levels in order to improve commercial relationships. Additionally, JECFA already performed an assessment of exposure to cadmium from chocolate and cocoa-derived products at its 77th Meeting (2013).

3. Main aspects to be covered

To establish new MLs based on cadmium occurrence in chocolate and cocoa-derived products and its JECFA evaluation in order to ensure food safety and fair trade practices.

4. Assessment against the criteria for the establishment of work priorities

The new work will increase consumer protection from the health point of view, food safety, ensuring fair practices in the food trade and taking into account the needs of producers and importing countries. Additional and updated guidance to countries in order to prevent and reduce cadmium contamination and consequently minimizing consumer dietary exposure, improving the overall quality of these products.

There are a diversity of national (different) legislation, which could lead to an apparent resultant or potential impediment to international trade.

The scope of the work is to establish MLs for cadmium in chocolate and cocoa-derived products and the establishment of priorities between the various sections of the related work.

Additionally, it is important to mention that the work has not been undertaken by any other international organisations in this field and or suggested by any relevant international intergovernmental bodies.

There are around 20 countries of the Latin American and the Caribbean region as well as some from the Africa region that can collaborate for developing of the proposed MLs.

The JECFA risk assessment (77th Meeting - 2013) provides the scientific basis that will allow harmonisation of an ML.

Lack of harmonisation results in trade impediments. According to the International Cocoa Organisation, ICCO, Latin American countries contribute with 12.1% of the world cocoa production and are the main producers of fine cocoa, with 93% of the world production. There are 500 000 cocoa farms in the region, with more than 3 500 000 small farmers, for whom cocoa production is the base for their family economy.

5. Relevance to Codex Strategic Goals

The proposed work falls under 2 Codex Strategic Goals of the Codex Strategic Plan 2014-2019:

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

Cadmium contamination in chocolate and cocoa-derived products is a trade issue that impacts on economic growth of producing countries (in particular developing countries from Africa, Central America, South America and The Caribbean).

Goal 2. Ensure the application of risk analysis principles in the development of Codex standards.

This work will help in establishing risk management options and strategies (i.e. MLs) to prevent and reduce the intake of cadmium in chocolate and cocoa derived products.

6. Information on the relationship between the proposal and other existing Codex documents

The MLs will follow the Guidelines of the Procedure Manual and the *General Standard for Contaminants and Toxins in Food and Feed* (CODEX STAN 193-1995).

7. Identification of any requirement for and availability of expert scientific advice

Additional scientific advice is not necessary.

8. Identification of any need for technical input to the standard from external bodies

There is no need for additional technical input from external bodies.

9. The proposed timeline for completion of the new work

Approval of new work by the Codex Alimentarius Commission in 2014. Completion of work for final adoption by the Commission in 2017 or before.

APPENDIX XII**PROPOSED DRAFT MAXIMUM LEVELS FOR DEOXYNIVALENOL (DON)****(Step 7)**

Product name	Maximum level (mg/kg)	Notes/Remarks
Cereal-based foods for infants and young children*	0.2	ML applies to the commodity as consumed

* All cereal-based foods intended for infants (up to 12 months) and young children (12 to 36 months)

Proposed Draft Maximum Levels for Deoxynivalenol (DON)**(Step 7)**

Product name	Maximum level (mg/kg)	Notes/Remarks
Raw cereal grains (wheat, maize and barley)	2	ML applies to raw cereal grains prior to sorting and removal of damaged kernels For sampling plan, see Annex below
Flour, semolina, meal and flakes derived from wheat, maize or barley	1	

PROPOSED DRAFT SAMPLING PLANS FOR DEOXYNIVALENOL (DON) IN RAW CEREALS

(Step 7)

DEFINITIONS

Lot - an identifiable quantity of a food commodity delivered at one time and determined by the official to have common characteristics, such as origin, variety, type of packing, packer, consignor, or markings.

Sublot - designated part of a larger lot in order to apply the sampling method on that designated part. Each sublot must be physically separate and identifiable.

Sampling plan - is defined by a deoxynivalenol test procedure and an accept/reject level. A deoxynivalenol test procedure consists of three steps: sample selection, sample preparation and analysis or deoxynivalenol quantification. The accept/reject level is a tolerance usually equal to the Codex maximum level (ML).

Incremental sample - the quantity of material taken from a single random place in the lot or sublot.

Aggregate sample - the combined total of all the incremental samples that is taken from the lot or sublot. The aggregate sample has to be at least as large as the laboratory sample or samples combined.

Laboratory sample - the smallest quantity of cereal/cereal based product comminuted in a mill. The laboratory sample may be a portion of or the entire aggregate sample. If the aggregate sample is larger than the laboratory sample(s), the laboratory sample(s) should be removed in a random manner from the aggregate sample.

Test portion - a portion of the comminuted laboratory sample. The entire laboratory sample should be comminuted in a mill. A portion of the comminuted laboratory sample is randomly removed for the extraction of the deoxynivalenol for chemical analysis.

Operating characteristic (OC) curve – a plot of the probability of a accepting a lot versus lot concentration for a specific sampling plan design. The OC curve provides an estimate of the chances of rejecting a good lot (exporter's risk) and the chances of accepting a bad lot accepted (importer's risk) by a specific deoxynivalenol sampling plan design. A good lot is defined as having a deoxynivalenol concentration below the ML; a bad lot is defined as having a deoxynivalenol concentration above the ML.

SAMPLE SELECTION

MATERIAL TO BE SAMPLED

Sampling procedure for cereals and cereal products for lots ≥ 50 tonnes

Each lot, which is to be examined for deoxynivalenol must be sampled separately. Lots larger than 50 tonnes should be subdivided into sublots to be sampled separately. If a lot is greater than 50 tonnes, the lot has to be subdivided into sublots following Table 1

Table 1 Subdivision of lots into sublots depending on product and lot weight

Commodity	Lot weight (ton)	Weight or number of sublots	No incremental samples	Aggregate sample Weight (kg)
Raw wheat and barley	$\geq 1\ 500$	500 tonnes	100	1
	> 300 and $< 1\ 500$	3 sublots	100	1
	≥ 50 and ≤ 300	100 tonnes	100	1
	< 50	--	3-100*	1
Raw maize	$\geq 1\ 500$	500 tonnes	100	5
	> 300 and $< 1\ 500$	3 sublots	100	5
	≥ 50 and ≤ 300	100 tonnes	100	5
	< 50	--	3-100*	1-5

* Depending on the lot weight - see Table 2

Taking into account that the weight of the lot is not always an exact multiple of the weight of the sublots, the weight of the sublot may exceed the mentioned weight by a maximum of 20%.

- Each sublot must be sampled separately.

- Number of incremental samples: 100

- If it is not possible to carry out the method of sampling set out in this point because of the commercial consequences resulting from damage to the lot such as packaging forms, means of transport, an alternative method of sampling may be applied provided that it is as representative as possible and is fully described and documented.

Sampling procedure for cereals and cereal products for lots < 50 tonnes

For lots of cereals and cereal products less than 50 tonnes, the sampling plan must be used with 10 to 100 incremental samples, depending on the lot weight, resulting in an aggregate sample of 1 to 5 kg. For very small lots (≤ 0.5 tonnes) a lower number of incremental samples may be taken, but the aggregate sample uniting all incremental samples shall be also in that case at least 1 kg.

The figures in Table 2 may be used to determine the number of incremental samples to be taken.

Table 2: Number of incremental samples to be taken depending on the weight of the lot of cereals and cereal products

Lot weight (tonnes)	No of incremental samples
≤ 0.05	3
$> 0.05 - \leq 0.5$	5
$> 0.5 - \leq 1$	10
$> 1 - \leq 3$	20
$> 3 - \leq 10$	40
$> 10 - \leq 20$	60
$> 20 - \leq 50$	100

Sampling procedure for cereals and cereal products for lots >>> 500 tonnes

Number of incremental samples (of about 100 g) to be taken:

100 incremental samples + $\sqrt{\text{metric tonnes}}$

Static Lots

A static lot can be defined as a large mass of cereals/cereal-based product contained either in a large single container such as a wagon, truck or railcar or in many small containers such as sacks or boxes and the cereal/cereal-based product is stationary at the time a sample is selected. Selecting a truly random sample from a static lot can be difficult because all containers in the lot or subplot may not be accessible.

Taking incremental samples from a static lot usually requires the use of probing devices to select product from the lot. The probing devices should be specifically designed for the commodity and type of container.

The probe should (1) be long enough to reach all products, (2) not restrict any item in the lot from being selected, and (3) not alter the items in the lot. As mentioned above, the aggregate sample should be a composite from many small incremental samples of product taken from many different locations throughout the lot.

For lots traded in individual packages, the sampling frequency (SF), or number of packages that incremental samples are taken from, is a function of the lot weight (LT), incremental sample weight (IS), aggregate sample weight (AS) and the individual packing weight (IP), as follows:

$$SF = (LT \times IS) / (AS \times IP).$$

The sampling frequency (SF) is the number of packages sampled. All weights should be in the same mass units such as kg.

Dynamic Lots

Representative aggregate samples can be more easily produced when selecting incremental samples from a moving stream of cereals/cereal-based product as the lot is transferred from one location to another. When sampling from a moving stream, take small incremental samples of product from the entire length of the moving stream; composite the incremental samples to obtain an aggregate sample; if the aggregate sample is larger than the required laboratory sample(s), then blend and subdivide the aggregate sample to obtain the desired size laboratory sample(s).

Automatic sampling equipment such as a cross-cut sampler is commercially available with timers that automatically pass a diverter cup through the moving stream at predetermined and uniform intervals. When automatic sampling equipment is not available, a person can be assigned to manually pass a cup through the stream at periodic intervals to collect incremental samples. Whether using automatic or manual methods, incremental samples should be collected and put together at frequent and uniform intervals throughout the entire time the flow past the sampling point.

Cross-cut samplers should be installed in the following manner: (1) the plane of the opening of the diverter cup should be perpendicular to the direction of the flow; (2) the diverter cup should pass through the entire cross sectional area of the stream; and (3) the opening of the diverter cup should be wide enough to accept all items of interest in the lot. As a general rule, the width of the diverter cup opening should be about two to three times the largest dimensions of items in the lot.

The size of the aggregate sample (S) in kg, taken from a lot by a cross cut sampler is:

$$S = (D \times LT) / (T \times V),$$

where D is the width of the diverter cup opening (cm), LT is the lot size (kg), T is interval or time between cup movement through the stream (seconds), and V is cup velocity (cm/sec).

If the mass flow rate of the moving stream, MR (kg/sec), is known, then the sampling frequency (SF), or number of cuts made by the automatic sampler cup can be computed as a function of S, V, D, and MR.

$$SF = (S \times V) / (D \times MR).$$

Packaging and Transportation of Samples

Each laboratory sample shall be placed in a clean, inert container offering adequate protection from contamination, sunlight, and against damage in transit. All necessary precautions shall be taken to avoid any change in composition of the laboratory sample, which might arise during transportation or storage. Samples should be stored in a cool dark place.

Sealing and Labelling of Samples

Each laboratory sample taken for official use shall be sealed at the place of sampling and identified. A record must be kept of each sampling, permitting each lot to be identified unambiguously and giving the date and place of sampling together with any additional information likely to be of assistance to the analyst.

SAMPLE PREPARATION

PRECAUTIONS

Sunlight should be excluded as much as possible during sample preparation, since some mycotoxins may gradually break down under the influence of ultra-violet light. Also, environmental temperature and relative humidity should be controlled and not favour mould growth and deoxynivalenol formation.

HOMOGENISATION - GRINDING

As the distribution of deoxynivalenol is non-homogeneous, laboratory samples should be completely homogenised by grinding the entire laboratory sample received by the laboratory. Homogenisation is a procedure that reduces particle size and disperses the contaminated particles evenly throughout the comminuted laboratory sample.

The laboratory sample should be finely ground and mixed thoroughly using a process that approaches as complete homogenisation as possible. Complete homogenisation implies that particle size is extremely small and the variability associated with sample preparation approaches zero. After grinding, the grinder should be cleaned to prevent deoxynivalenol cross-contamination.

TEST PORTION

The suggested weight of the test portion taken from the comminuted laboratory sample should be approximately 25 g.

Procedures for selecting the 25 g test portion from the comminuted laboratory sample should be a random process. If mixing occurred during or after the comminution process, the 25 g test portion can be selected from any location throughout the comminuted laboratory sample. Otherwise, the 25 g test portion should be the accumulation of several small portions selected throughout the laboratory sample.

It is suggested that three test portions be selected from each comminuted laboratory sample. The three test portions will be used for enforcement, appeal, and confirmation if needed.

ANALYTICAL METHODS**BACKGROUND**

A criteria-based approach, whereby a set of performance criteria is established with which the analytical method used should comply, is appropriate. The criteria-based approach has the advantage that, by avoiding setting down specific details of the method used, developments in methodology can be exploited without having to reconsider or modify the specific method. The performance criteria established for methods should include all the parameters that need to be addressed by each laboratory such as the detection limit, repeatability coefficient of variation (within lab), reproducibility coefficient of variation (among lab), and the percent recovery necessary for various statutory limits. Analytical methods that are accepted by chemists internationally (such as AOAC) may be used. These methods are regularly monitored and improved depending upon technology.

PERFORMANCE CRITERIA FOR METHODS OF ANALYSIS

A list of possible criteria and performance levels are shown in Table 3. Utilizing this approach, laboratories would be free to use the analytical method most appropriate for their facilities.

Table 3 Performance characteristics for deoxynivalenol

Level µg/kg	Deoxynivalenol		
	RSD _r %	RSD _R %	Recovery%
> 100 - ≤ 500	≤ 20	≤ 40	60 to 110
> 500	≤ 20	≤ 40	70 to 120

APPENDIX XIII**PRIORITY LIST OF CONTAMINANTS AND NATURALLY OCCURRING TOXICANTS FOR EVALUATION BY JECFA**

Contaminants and naturally occurring toxicants	Background and Question(s) to be answered	Data availability(when, what)	Proposed by
3-MCPD esters	Full evaluation (toxicological assessment and exposure assessment)	Germany: Occurrence data and data on hydrolysis (humans – in vivo) available. Japan: Subchronic toxicity data and occurrence data available. China: Total Diet Study on 3-MCPD esters available. Canada: Surveillance data. EU: Occurrence data. US: Occurrence data. Netherlands: Occurrence data.	Germany, supported by EU, Canada, Japan
Glycidyl ester	Full evaluation (toxicological assessment and exposure assessment) Bioavailability of free compounds	Japan: Subchronic toxicity data and occurrence data in fats and oils available. USA: Occurrence data available. EU: Occurrence data available.	Germany; USA
Pyrrrolizidinealkaloids (PAs)	Identify most relevant PAs (occurrence and toxicity) for human health Full risk assessment Identify of data gaps Consideration of PAs in feed as it carries over from feed to Animal products	All data collected by the EWG. Australia additional toxicological data will be available 2015. EU: On-going occurrence data collection (DATEX unit of EFSA). Netherlands: Genotoxicity testing, milk transfer, PBPK modeling, occurrence data available in 2015. UK: Occurrence data available in 2014. Japan: Reference reagents are being synthesised. Occurrence data in food and feed items available in 2015.	CCCF

<i>Contaminants and naturally occurring toxicants</i>	<i>Background and Question(s) to be answered</i>	<i>Data availability(when, what)</i>	<i>Proposed by</i>
Non dioxin-likePCBs	Full risk assessment	Canada: Data from total diet studies available (TDS samples collected up to 2010) and fish monitoring data available. Netherlands: Provides monitoring data to EFSA database. R of Korea: Monitoring data – available. EU: To assure that EFSA data will be made available. Belgium: Total diet study available end 2012. Tunisia: Monitoring data – available.	Republic of Korea, Canada
*Sterigmatocystin	Safety assessment	EU: Survey data 2014 -2015. EFSA risk assessment.	CCCF
*Diacetoxyscirpenol	Safety assessment	Unknown	CCCF
*Fumonisin	Update exposure assessment	After new occurrence data have been collected.	CCCF
*Aflatoxins	Update of the risk assessment	New data available in public literature and occurrence data in GEMS/Food.	CCCF

* Proposals for new contaminants and naturally occurring toxicants for JECFA Priority List

APPENDIX XIV**NOMINATION OF NEW SUBSTANCES FOR THE PRIORITY LIST OF CONTAMINANTS
AND NATURALLY OCCURRING TOXICANTS FOR EVALUATION BY JECFA****1. Basic information**

- 1) Proposal for inclusion submitted by:
- 2) Name of compound; chemical name(s):
- 3) Identification of (additional) data (toxicology, metabolism, occurrence, food consumption) which could be provided to JECFA:
- 4) List of countries where surveillance data are likely to be available, and if possible list of contact person who could provide such data, including quality assurance information on the data.
- 5) Timeline for data availability:

2. Detail information

- 1) Whether or not the occurrence of the compound in commodities will have potential to cause public health and/or trade problems;
- 2) Whether or not commodities containing the compound are in international trade and represent a significant portion of the diet; and,
- 3) Commitment that a dossier (as complete as possible) will be available for evaluation by the JECFA.
- 4) Relevant justification and information on the following prioritization criteria¹
 - Consumer protection from the point of view of health and prevention of unfair trade practices;
 - Compliance with CCCF's Terms of Reference;
 - Compliance with JECFA's Terms of Reference;
 - Compliance with the Codex Alimentarius Commission's Strategic Plan, its relevant plans of work and Criteria for the Establishment of Work Priorities;
 - The quality, quantity, adequacy, and availability of data pertinent to performing a risk assessment, including data from developing countries;
 - The prospect of completing the work in a reasonable period of time;
 - The diversity of national legislation and any apparent impediments to international trade;
 - The impact on international trade (i.e. magnitude of the problem in international trade);
 - The needs and concerns of developing countries; and,
 - Work already undertaken by other international organizations.

¹ Section 3, para.10 of the Risk Analysis Principles Applied by the Codex Committee on Contaminants in Foods (See Procedural Manual of the Codex Alimentarius Commission).