CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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ALINORM 10/33/41

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Thirty-third Session
Geneva, Switzerland, 5-9 July 2010

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

Izmir, Turkey,
26 – 30 April 2010

NOTE: This report includes Codex Circular Letter CL 2010/13-CF

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CX 4/35.2 **CL 2010/13-CF**
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To: Codex Contact Points
Interested International Organizations

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Subject: **DISTRIBUTION OF THE REPORT OF THE FOURTH SESSION OF THE CODEX COMMITTEE ON CONTAMINANTS IN FOODS (ALINORM 10/33/41)**

The Report of the Fourth Session of the Codex Committee on Contaminants in Foods is attached. It will be considered by the Thirty-third Session of the Codex Alimentarius Commission (Geneva, Switzerland, 5-9 July 2010).

PART I: MATTERS FOR ADOPTION BY THE 33RD SESSION OF THE CODEX ALIMENTARIUS COMMISSION

Proposed Draft Standards and Related Texts at Step 5/8 of the Procedure

1. **Proposed Draft Maximum Levels for Melamine in Food (powdered *infant formula and foods other than infant formula*) and Feed** (para. 68, Appendix IV);
2. **Proposed Draft Maximum Levels for Total Aflatoxins in Shelled, Ready-to-Eat Brazil Nuts and Shelled, Destined for Further Processing Brazil Nuts (including sampling plans)** (para. 76, Appendix V);
3. **Proposed Draft Revision of the Code of Practice for the Prevention and Reduction of Aflatoxin in Tree Nuts (Additional Measures for Brazil Nuts)** (para. 85, Appendix VI).

Governments and international organizations wishing to submit comments on the above documents should do so in writing, in conformity with the *Procedure for the Elaboration of Codex Standards and Related Texts* (Part 3 – Uniform Procedure for the Elaboration of Codex Standards and Related Texts, Procedural Manual of the Codex Alimentarius Commission), ***preferably by e-mail***, to the above address, **before 4 June 2010**.

PART II: REQUEST FOR COMMENTS AND INFORMATION

4. **Proposed Draft Code of Practice for the Prevention and Reduction of Ethyl Carbamate Contamination in Stone Fruit Distillates** (para. 54, Appendix III)

Governments and international organizations wishing to submit comments on this matter should do so in writing, in conformity with the *Procedure for the Elaboration of Codex Standards and Related Texts* (Part 3 – Uniform Procedure for the Elaboration of Codex Standards and Related Texts, Procedural Manual of the Codex Alimentarius Commission), ***preferably by e-mail***, to the above address, **before 31 August 2010**.

5. **Proposed Draft Maximum Level for Melamine in Food (*liquid infant formula*)** (para. 68, Appendix IV)

Governments and international organizations wishing to submit comments on this matter should do so in writing, in conformity with the *Procedure for the Elaboration of Codex Standards and Related Texts* (Part 3 – Uniform Procedure for the Elaboration of Codex Standards and Related Texts, Procedural Manual of the Codex Alimentarius Commission), ***preferably by e-mail***, to the above address, **before 31 October 2010**.

6. **Priority List of Contaminants and Naturally Occurring Toxicants for Evaluation by JECFA** (para. 102, Appendix VII)

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 Codex Committee on Contaminants in Foods as indicated in para. 102 and presented in Appendix VII 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 VIII of this Report.

Governments and international organizations 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, ***preferably by e-mail***, to the above address, **before 31 January 2011**.

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SUMMARY AND CONCLUSIONS

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

MATTERS FOR ADOPTION/CONSIDERATION BY THE 33RD SESSION OF THE CODEX ALIMENTARIUS COMMISSION

Proposed Draft Standards and Related Texts for Adoption

The Committee agreed to forward:

- Proposed Draft Maximum Levels for Melamine in Food (*powdered infant formula and foods other than infant formula*) and Feed (para. 68, Appendix IV);
- Proposed Draft Maximum Levels for Total Aflatoxins in Shelled, Ready-to-Eat Brazil Nuts and Shelled, Destined for Further Processing Brazil Nuts (including sampling plans) (para. 76, Appendix V);
- Proposed Draft Revision of the Code of Practice for the Prevention and Reduction of Aflatoxin in Tree Nuts (additional measures for Brazil nuts) (para. 85, Appendix VI);
- Proposed Maximum Level for Tin in Canned Food (excluding beverages) to various general standards for canned fruits and vegetables in the Codex Standard for Contaminants and Toxins in Food and Feed (paras. 18-21, Appendix II);
- Editorial amendments to the Codex Standard for Contaminants and Toxins in Food and Feed (para. 121);
- endorsed the sections on contaminants in standards for milk and milk products as proposed by the Codex Committee on Milk and Milk Products (para. 9).

Proposals for New Work

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

- Maximum Levels for Deoxynivalenol (DON) and its Acetylated Derivatives in Cereals and Cereal-based Products (para. 110);
- Maximum Levels for Total Aflatoxins in Dried Figs (para. 114, Appendix IX).

Matters of Interest to the Codex Alimentarius Commission

The Committee:

- maintained the temporary endorsement of sections 3.2.17 (surface active agents), 3.2.18 (pesticides and PCBs), 3.2.19 (mineral oil) and 3.2.20 (polynuclear aromatic hydrocarbons) in the Standard on Natural Mineral Waters and established a working group to determine more appropriate maximum levels for the substances listed in the aforesaid sections or specific identifed substances within these groups (paras. 9-17);
- retained the maximum level for lead in individual standards for canned fruits and vegetables pending the outcome of the JECFA evaluation on lead (paras. 18-22);
- agreed to return the Proposed Draft Code of Practice for the Prevention and Reduction of Ethyl Carbamate Contamination in Stone Fruit Distillates to Step 3 for comments and consideration at its next session (para. 54);
- agreed to return a Proposed Draft Maximum Level for Melamine in Food (*liquid infant formula*) to Step 3 for for comments and consideration at its next session (para. 68);
- retained Proposed Draft Maximum Levels for Fumonisins in Maize and Maize-Products and Associated Sampling Plans at Step 4 until further advice was provided by JECFA (para. 95);
- endorsed the Priority List of Contaminants and Naturally Occurring Toxicants for JECFA evaluation and agreed to re-convene the physical working group at its next session to review the Priority List (para. 102);
- agreed on a number of recommendations in relation to mitigation measures for acrylamide (para. 105).

INTRODUCTION

1. The Codex Committee on Contaminants in Foods (CCCF) held its Fourth Session in Izmir (Turkey) from 26 to 30 April 2010, at the kind invitation of the Government of Turkey. Mr. Martijn Weijtens, Member of the Management Team, Ministry of Agriculture, Nature and Food Quality, Department of Food, Animal Health and Welfare and Consumer Policy, the Netherlands, chaired the meeting. Mr Nihat Pakdil, Deputy Undersecretary, Ministry of Agriculture and Rural Affairs, Turkey, served as co-chair. The Session was attended by 182 delegates representing 64 Member countries, one Member Organization and 12 International Organizations. The list of participants, including the Secretariat, is given in Appendix I to this report.

OPENING OF THE SESSION

2. Mr Nihat Pakdil on behalf of the Minister of Agriculture and Rural Affairs welcomed the participants and opened the session. Mr. Jan Paul Dirkse, the Ambassador of the Netherlands to Turkey, also addressed the session and thanked the Turkish Government for their initiative to host this meeting of the Committee.

Division of Competence[1]

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.

ADOPTION OF THE AGENDA (Agenda Item 1)[2]

4. The Committee agreed to discuss Items 7 (Proposed Draft Revision of the Code of Practice for the Prevention and Reduction of Aflatoxin in Tree Nuts (additional measures for Brazil Nuts)) before Item 6 (Proposed Draft Maximum Levels for Total Aflatoxins in Brazil Nuts).

5. It also agreed to discuss following new proposals under Item 11 (Other Business and Future Work):

- Ochratoxin A in cocoa (proposal by Brazil);
- Furan in foods (proposal by the United States of America);
- Maximum level for total aflatoxins in dried figs (proposal by Turkey);
- Arsenic in rice (proposal by Iran);
- Presence of pyrrolizidine alkaloids in food and feed and consequences for human health (proposal by the European Union);
- Editorial amendments to the General Standard for Contaminants and Toxins in Food and Feed (proposal by the Secretariat).

6. The Committee adopted the Provisional Agenda as the Agenda for the Session with the amendments noted above.

7. The Committee agreed to establish an in-session physical Working Group on the Priority List of Contaminants and Naturally Occurring Toxicants for Evaluation by JECFA under the Chairmanship of The Netherlands, with the understanding that its report would be considered under Agenda Item 10.

MATTERS REFERRED TO THE COMMITTEE BY CODEX ALIMENTARIUS COMMISSION AND/OR OTHER CODEX COMMITTES/TASK FORCES (Agenda Item 2)[3]

8. The Committee noted that Part A of document CX/CF 10/4/2 was for information purposes while part B and addenda 1 and 2 were for action. The Committee commented and /or made decisions as follows:

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1 CRD 1 (Annotated Agenda – Division of competence between the European Union and its Member States).

2 CX/CF 10/4/1.

3 CX/CF 10/4/2; CX/CF 10/4/2-Add.1; CX/CF 10/4/2-Add.2; CRD 4 (comments of Kenya); CRD 6 (comments of Thailand); CRD 16 (comments of Japan).

Sections on contaminants in Standards for milk and milk products

9. The Committee considered the proposals by the Committee on Milk and Milk Products for the sections on contaminants in milk product standards and in CODEX STAN 250-2006 (Standard for Blend of Evaporated Skimmed Milk and Vegetable Fat), 251-2006 (Standard for a Blend of Skimmed Milk and Vegetable Fat in Powdered Form) and 252-2006 (Standard for a Blend of Sweetened Condensed Skimmed Milk and Vegetable Fat), which were additional to the standard wording for contaminants, noted that these were for purposes of consistency and technical correctness and endorsed the proposed sections. The Delegation of Thailand expressed its reservation to the decision noting that requirements in commodity standards should be for the final products only and not for the raw materials and that requirements for raw materials were more appropriately addressed in codes of practice.

Standard for Natural Mineral Waters

10. The Committee noted that sections 3.2.17 (surface active agents), 3.2.18 (pesticides and PCBs), 3.2.19 (mineral oil) and 3.2.20 (polynuclear aromatic hydrocarbons) in the Standard on Natural Mineral Waters had previously been temporarily endorsed pending elaboration of appropriate methods of analysis. In view of the identification of methods of analysis by the Committee on Methods of Analysis and Sampling for these substances the Committee therefore considered whether to lift the temporary endorsement and to fully endorse these sections.

11. Some delegations did not support the endorsement of sections 3.2.17 to 3.2.20 noting that section 3.2 states that substances in 3.2.17 to 3.2.20 shall be below the limit of quantification (LOQ) when tested with relevant ISO methods; that the methods identified by CCMAS did not provide the LOQ, but cited minimum applicable ranges which were very low levels and that this had the unintended effect of setting *defacto* maximum levels (ML) which were not consistent with much higher guideline values established by WHO for these chemicals in drinking water; and therefore questioned the appropriateness of meeting these levels in natural mineral waters.

12. These delegations recommended that the sections 3.2.17 – 3.2.20 be referred to the Committee on Natural Mineral Waters to clarify the types of surface active agents, mineral oil, PCBs, pesticides and PAHs for which MLs should be established and noted that there were many pesticides, many congeners of PCBs and PAHs and that it did not appear that one ML should be set for all pesticides and all PAHs. It was also noted that the WHO had established guideline values for specific pesticides and not pesticides in general and only one specific PAH (e.g. benzo(a)pyrene) in drinking water.

13. It was clarified that the Committee on Natural Minerals Waters had been adjourned *sine die* and that it was within the remit of this Committee to consider the proposed MLs in the Standard for Natural Mineral Waters, to determine whether they were safety parameters and if so, to make proposals on more appropriate MLs.

14. In addition to consideration of the endorsement of sections 3.2.17 – 3.2.20, the Committee recalled that the 2nd Session of the Committee had endorsed section 3.2 of the Standard on Natural Mineral Waters, in particular sections 3.2.1 to 3.2.16 and at the time had considered how to integrate the MLs into the General Standard for Contaminants and Toxins in Food and Feed (GSCTFF), but that the Committee had postponed the decision on inclusion of those substances into the GSCTFF since some of the substances in section 3.2 were considered either quality factors or both quality and safety factors.

15. It was therefore proposed that the Committee in addition to considering how to deal with sections 3.2.17 to 3.2.20 also considers which of the substances in sections 3.2.1 to 3.2.16 of the Standard on Natural Mineral Waters could be considered safety parameters and how to integrate them into the GSCTFF.

16. Two delegations noted that determining the status of the substances in section 3.2 in relation to their being quality or safety parameters were beyond the remit of the Committee.

17. The Committee agreed to establish an electronic Working Group led by the United States of America with assistance of The Netherlands and working in English with the following terms of reference:

- Develop criteria to differentiate between safety and quality parameters;
- Based on these criteria, determine which of the compounds in section 3.2 of the Standard on Natural Mineral Waters are also safety parameters;
- For compounds listed in sections 3.2.17 to 3.2.20 determine more appropriate MLs for these substances or specific identified substances within these groups; and
- Consider whether all safety parameters identified in section 3.2 should be integrated into the GSCTFF or retained in the Standard for Natural Mineral Waters.

Maximum levels for processed fruits and vegetables

18. The Committee noted that the Committee on Processed Fruits and Vegetables had elaborated several general standards for groups of canned fruits and vegetables thereby replacing individual standards for canned fruits and vegetable which were revoked by the Commission on adoption of the general standards. It was further noted that the scope of these general standards had also been expanded to include other commodities for which individual standards had not previously existed. These general standards contained the general statement on contaminants from the Procedural Manual.

19. At the same time, several MLs for tin and lead for canned fruits and vegetables from the revoked standards were listed in the General Standard for Contaminants in Toxins in Food and Feed. The Committee therefore considered whether the levels for tin and lead applied to the more general standards with particular regard to whether these levels could also be extended to those commodities now included in these general standards for which levels had not previously been established.

20. It was recalled that the GSCTFF provided for a ML for tin in canned foods (excluding beverages) and considered whether this level could apply to the aforementioned general standards.

21. The Committee agreed to apply the ML for tin in canned food (excluding beverages) to the general standards for canned fruits and vegetables and to replace product name in the GSCTFF by the group name in the general standards (i.e. canned stone fruits, canned citrus fruits, jams, jellies and marmalades and certain canned vegetables) and to insert the corresponding references associated general standards for canned fruits and vegetables (for ease of reference, these changes are presented in Appendix II).

22. In the case of ML for lead, the Committee noted that lead would be evaluated by the 73rd meeting of JECFA in June 2010 and agreed to not take action until JECFA had completed its evaluation.

Risk Analysis Policies

23. The Committee noted that the 26th Session of the Committee on General Principles (CCGP) had agreed that the risk analysis policies developed by Codex Committees were generally consistent with the Working Principles for Risk Analysis and that it had agreed to forward the review presented in CL 2010/1-GP to the committees concerned for their consideration and review of their risk analysis policies.

24. The Committee agreed that no action on revising the Risk Analysis Principles for the Committee was necessary at this time noting that the risk analysis principles had only recently been revised to take into account the separation of the Committee on Food Additives and Contaminants (CCFAC) into the Committee on Food Additives and the Committee on Contaminants in Foods.

MATTERS OF INTEREST ARISING FROM FAO AND WHO AND FROM THE 72ND MEETING OF THE JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES (JECFA) (Agenda Item 3a)[4]

25. The Representatives of FAO and WHO informed the Committee on the outcome of recent activities related to the provision of scientific advice.

Principles and Methods for the Risk Assessment of Chemicals in Food

26. The purpose of this activity was to update the risk assessment methods to take account of developments in JECFA and JMPR over the years and take account of new scientific developments. Another important aspect was to harmonize risk assessment methods as applied in JECFA and JMPR to the extent useful. This very extensive guidance document will be published electronically as separate chapters and also as book shortly. Follow up work will include development of practical examples.

FAO/WHO Expert Meetings

Chlorine Expert Meeting

27. The report of the expert meeting to evaluate the benefits and risks of the use of chlorine-containing disinfectants in food production and food processing has been published. Current disinfection practices, including non-chlorine alternatives, have been reviewed for various food categories. In summary, where data were available, no health concerns have been identified in relation to residues of disinfectants or occurrence of disinfection by-products. Some benefits were identified, mainly related to reduction of microbial cross-contamination in poultry processing.

4 CX/CF 10/4/3.

Bisphenol A (BPA) Expert Meeting

28. The FAO and WHO are organizing an expert meeting, to be held in the first week of November 2010, to evaluate the possible health impact of low exposure to BPA. Focus is on exposure from food contact material, but other sources of exposure will also be considered. The organization of a stakeholder meeting on the day preceding the expert meeting is also under consideration. A call for data is still open and delegates are encouraged to make possible data holders aware of this activity and to submit all relevant data. This activity is supported by Canada, USA and the EU.

JECFA call for experts for WHO Roster

29. A call for experts to serve the WHO panel of JECFA has just been published. Qualified experts can apply until 31 July 2010. After internal and external evaluation, qualified experts will be placed on the WHO roster for 2010-2015, and can be called upon for any future JECFA meeting.

Nanotechnology Ad Hoc Expert Meeting

30. The Committee was informed on the outcome of the FAO/WHO Expert Meeting convened on 1-5 June 2009 on the use of nanotechnology in food production and processing and the potential associated human health risks. The expert consultation agreed that FAO/WHO should continue to review its risk assessment strategies and encourage innovative and interdisciplinary research that may lead to novel risk assessment strategies for the application of nanotechnologies in food, water and feed, in order to address specific, emerging issues associated with the application of nanotechnologies in the food chain. In addition, she informed the Committee about the International Conference on Food and Agriculture Applications of Nanotechnologies (NANOAGRI 2010) scheduled to take place 20-25 June 2010 in Brazil, hosted by the Brazilian Ministry of Agriculture with technical support from FAO.

Risk-benefit of Fish Consumption Expert Meeting

31. The FAO/WHO Expert Consultation on the risks and benefits of fish consumption was held on 25-29 January 2010. A summary would be made available in electronic format in the near future and the full report published for possible discussion of the implications of the results by the Committee at its next meeting.

Global Initiative for Food-related Scientific Advice (GIFSA)

32. The JECFA Secretariat urged the delegations to consider future financial support of the work of FAO and WHO on the provision of scientific advice through the Global Initiative for Food-related Scientific Advice (GIFSA) funds and through other in kind support, in order to enable FAO and WHO to respond to all requests by Codex and member countries for scientific advice and associated capacity building activities. The Committee was informed of the imminent finalization of the FAO work strategy document in this area, that would be distributed to country representatives and other stakeholders.

The 72nd JECFA Meeting (February 2010)

Acrylamide

33. JECFA considered a significant amount of new data in the re-evaluation. In conclusion, JECFA confirmed its previous assessment and considered that for a compound that is both genotoxic and carcinogenic the calculated Margins of Exposure indicate a health concern. JECFA noted that mitigation has been reported for food types with high acrylamide level which might significantly reduce exposure to some individuals or population subgroups, but this will have little effect on the mean dietary exposure estimates of the general population in all countries.

Arsenic

34. JECFA withdrew the PTWI. It noted that this level is no longer appropriate, based on dose-response modelling from epidemiological studies. The estimated upper confidence limit for a 0.5% increased risk in lung cancer is within the range of the PTWI.

35. In its evaluation JECFA considered a large amount of new data. JECFA based its assessment on epidemiological studies and concluded that animal models are not appropriate to estimate human cancer risk. Since these human studies were not designed for risk assessment purposes, the exposure assessments were very limited and JECFA had to develop several exposure scenarios to take total oral exposure from food and drinking water into account when estimating cancer risk.

36. JECFA considered three different exposure scenarios depending on the level of inorganic arsenic in drinking water. If the level of inorganic arsenic in drinking water is below the WHO drinking water guideline level of 10 µg/l, food can contribute a relatively high proportion to oral exposure to inorganic arsenic, but total exposure (from food and drinking water) may be of low health concern. In areas where levels in drinking water are in the range of 10-50 µg/l there is significant exposure to inorganic arsenic through food and drinking water and possible health effects could occur. However, they would occur at low incidence and would be difficult to detect in epidemiological studies. In areas where drinking water levels of inorganic arsenic of 50-100 µg/l occur, some epidemiological studies provide evidence for adverse effects.

Deoxynivalenol (DON) and its metabolites

37. JECFA extended the existing PMTDI for DON and established a group PMTDI of 1 µg/kg body weight for DON and its acetylated derivatives. An acute reference dose (ARfD) of 8 µg/kg body weight was established for DON and its acetylated derivatives.

Furan

38. The information available suggests that the major route of exposure is through consumption of heat-treated foods and beverages such as coffee and canned and jarred baby foods. The average and high dietary exposure was estimated to 0.001 mg/kg bw and 0.002 mg/kg bw, respectively. Furan is a carcinogenic compound and JECFA concluded that the estimated margins of exposure indicate a potential human health concern. However, there is currently a lack of quantitative data for all types of foods and ways on how furan levels may be reduced in heat-treated foods.

Mercury

39. JECFA reviewed toxicological data on inorganic mercury and established a new PTWI of 0.004 mg/kg. The old PTWI for total mercury 0.005 mg/kg was withdrawn. Since normally only total mercury is measured in foods, the available total mercury data were used to estimate exposure. JECFA estimated the upper limits of average dietary exposure to total mercury from foods other than fish and shell-fish were for adults 0.001 mg/kg bw per week and for children 0.004 mg/kg bw per week.

Perchlorate

40. Perchlorate is present in the environment, water, soil and fertilizers, and are considered potential sources for contamination of food. JECFA established a PMTDI of 0.01 mg/kg bw and the estimated dietary exposure through food and drinking water (highest 0.7 µg/kg bw and day) did not indicate a human health concern.

41. In view of the above-mentioned information, the Committee agreed that the in-session Working Group on Priorities (see Agenda Item 1) should also consider this information and make recommendations on future new work for the Committee. In making their recommendations, the Committee also agreed that this working group should consider the proposals for new work made under Agenda Item 1 and that the recommendations of the working group would be discussed under Agenda Item 11 – Other business and future work.

MATTERS OF INTEREST ARISING FROM OTHER INTERNATIONAL ORGANISATIONS (Agenda Item 3b)[5]

42. The Committee noted the information provided by the International Atomic Energy Agency as provided in document CX/CF 10/4/3-Add.1 especially with regard to the activities of the Coordinated Research Project on *Applications of Radiotracer and Radio-assay Technologies to Seafood Safety Risk Analysis* and the conclusions of the research coordination meeting related to Codex activities.

PROPOSED DRAFT CODE OF PRACTICE FOR THE REDUCTION OF ETHYL CARBAMATE IN STONE FRUIT DISTILLATES (Agenda Item 4)[6]

43. The Delegation of Germany introduced Conference Room Document 12 highlighting the main revisions made to working document CX/CF 10/4/4 based on the written comments submitted in the addenda to this document. The Delegation indicated that the revision related to both the structure and content of the document in order to facilitate the understanding and implementation of the Code.

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5 CX/CF 10/4/3-Add.1.

6 CX/CF 10/4/4; CX/CF 10/4/4-Add.1 (comments of Brazil, Canada, Chile, Japan, United States of America, FAO and CIAA); CX/CF 10/4/6-Add.2 (comments of Thailand); CRD 4 (comments of Kenya); CRD 9 (comments of the EU); CRD 12 (Code of Practice for the Prevention and Reduction of Ethyl Carbamate Contamination in Stone Fruit 1st revision, Germany); CRD 20 (Code of Practice for the Prevention and Reduction of Ethyl Carbamate Contamination in Stone Fruit, 2nd revision, Germany).

44. The Committee considered the revised Code as presented in CRD 12 and made a number of editorial amendments and agreed on a number of changes in relation to scientific references, use of copper ions, re-distillation of tails and the reference to the concentration of hydrocyanic acid in the distillate. In order to facilitate the finalization of the proposed draft Code, a revised version was presented for consideration by the Committee as contained in CRD 20.

45. The Committee considered the revised version of the Code as follows:

General Considerations – *Scientific References in Codex texts*

46. The Committee agreed to delete the scientific references throughout the Code in compliance with its previous decision not to keep scientific references in Codex texts that are for adoption by the Commission[7] and taking into account that codes of practice should be written in a general manner.

Specific Considerations

Use of copper ions

47. The JECFA Secretariat drew the attention of the Committee to the provisions on the use of copper ions which were not clear on when copper ions described to promote the formation of cyanate and when they could be used to prevent for the formation of cyanate. It was noted that the use of copper ions before distillation would inhibit the co-distillation of hydrocyanic acid by binding the cyanide to an insoluble salt, while the presence of copper ions in the distillate could promote the conversion of cyanate to ethyl carbamate. Hence copper ions should carefully be used in the production of stone fruit distillates. It was emphasized that copper (I) ions as opposed to copper (II) ions should be used in the process described in the relevant sections.

48. The Committee agreed to amend the paragraphs containing provisions on copper ions to clearly define their use in the production of stone fruit distillates.

Use of re-distillates

49. The Committee had an exchange of views on the re-distillation of separated tails as this may increase the risk of higher concentrations of ethyl carbamate in the final product. In this regard, it was noted that it was not clear from the text whether the purpose of re-distillation of tails was to elaborate a different or lower quality product or to mix the re-distillate with the distillate obtained from the primary distillation process.

50. The Committee noted that, although it was preferable to discard the tail, if re-distillation of tails was to be performed, it should be done separately, and amended the provision accordingly.

Reference to hydrocyanic acid concentration

51. Some delegations questioned the use of a signal value of 1 mg/l for hydrocyanic acid in the distillate as it could be considered a *de facto* maximum level of hydrocyanic acid and/or ethyl carbamate which was not the objective of the new work agreed to by the last session of the Committee and should not be part of a code of practice.

52. The Delegation of Germany indicated that this value should not be considered as a maximum level but that it was necessary to signal this figure as a cut-off point for the formation of increased levels of ethyl carbamate in the distillate. The Delegation further explained that without this value the implementation of the Code would not be effective as keeping the concentration of hydrocyanic acid at levels below 1 mg/l would aid in the control of ethyl carbamate.

53. In view of the above, the Committee agreed to retain the value of 1 mg/l to monitor the concentration of hydrocyanic acid in the distillate while deleting the reference to 1 mg/l to control the concentration of hydrocyanic acid in the stored distillates as in this case the value could be view as a maximum level rather than a monitoring level.

Status of the Proposed Draft Code of Practice for the Prevention and Reduction of Ethyl Carbamate Contamination in Stone Fruit Distillates

54. The Committee agreed to return the proposed draft Code to Step 3 for further comments and consideration by the next session of the Committee (Appendix III).

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[7] ALINORM 08/31/41, para. 70; ALINORM 09/32/41 para. 47.

55. The Committee further agreed to establish an electronic Working Group led by Germany, working in English, that would prepare a revised version, based on the comments submitted at Step 3, for consideration by the Committee.

PROPOSED DRAFT MAXIMUM LEVELS FOR MELAMINE IN FOOD AND FEED (Agenda Item 5)[8]

56. The Delegation of Canada introduced document CX/CF 10/4/5. The Delegation explained that the purpose of the document was to provide background information on the sources of melamine in food and feed and to present proposed draft maximum levels (MLs). It was noted that these MLs applied to melamine resulting from non-intentional and unavoidable presence in food or feed from approved uses of melamine and from the use of substances which can give rise to melamine contamination and not the deliberate addition of melamine to food or feed.

57. The Committee considered the recommendations made by the electronic working group, in particular the MLs of 1.0 mg/kg for powdered infant formula and 2.5 mg/kg for foods (other than infant formula) and animal feed, including the possible lower ML of 0.5 mg/kg for ready-to-consume.

58. Many delegations supported both the proposed MLs for powdered infant formula and for foods (other than infant formula) and animal feed.

59. One delegation, while supporting the level of 2.5 mg/kg for all foods and animal feed, proposed a level of 0.5 mg/kg for liquid and powdered infant formula, while another delegation proposed a level of 0.5 mg/kg for not only infant formula, but also follow-up formula and foods for special dietary uses. A number of delegations expressed support for the proposal to set a level of 0.5 mg/kg for liquid infant formula. Other delegations supported a lower level for liquid formula.

60. The Observer from the National Health Federation (NHF) expressed concern with the setting of a maximum level for melamine and expressed the view that melamine was not a naturally occurring substance, but that its presence in food was manmade. The Observer stated that a zero tolerance level would be preferred, but in the case that a ML was needed, questioned why a level of 1 mg/kg could not apply to all foods when it was practically possible to achieve such a level in powdered infant formula.

61. The Delegation of the European Union while supporting the ML proposed for powdered infant formula, expressed the view that consideration should be given to 3 exemptions for the maximum level of 2.5 mg/kg for foods and animal feed where higher levels of melamine could occur due to presence of melamine from cyromazine application; from migration from food contact materials (e.g. melaware); and presence in certain feed additives/ingredients. It was stated that in the case of cyromazine application especially in mushrooms, the level of melamine could be as high as the residue level of cyromazine itself. In the case of feed additives or ingredients such as guanidine acetic acid, urea and biuret, it was explained that melamine could be present as an unavoidable impurity even when applying good manufacturing practices.

62. The Committee considered how to deal with the proposed exemptions and agreed to the inclusion of clarification notes, in particular that:

- MLs did not apply to food and feed in cases where it can be proven that levels higher than 2.5 mg/kg was a consequence of authorised use of cyromazine or migration from food contact materials; and
- the ML did not apply to melamine that could be present in the following feed ingredients/ additives: guanidine acetic acid, urea and biuret as a result of their normal production process.

63. The Observer of NHF expressed concern with the clarification notes and recommended that the Committee on Food Labelling develop labelling provisions to ensure disclosure of high melamine levels in foods.

64. To a proposal to request JECFA to evaluate mixtures of melamine and melamine analogs, the JECFA Secretariat explained that interaction of melamine with its analogs had been addressed in the WHO expert consultation on melamine (December 2008) and that no additional data was available at present. The representative also reminded the Committee that the incident which triggered the need for the setting of MLs for melamine was due to more than 95% melamine contamination and therefore it was important to set levels for melamine alone.

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8 CX/CF 10/4/5; CX/CF 10/4/5-Add.1 (comments of Egypt, EU, Kenya, Libya, Mali, the Philippines, Thailand, CIAA and IDF); CRD 10 (comments of NHF); CRD 11 (comments of Ghana); CRD15-rev (comments of ISDI); CRD 22 (comments of Ecuador).

65. In view of the discussion, the Committee agreed to advance the maximum levels for powdered infant formula and for foods (other than infant formula) and animal feeds at Step 5/8 and the maximum level of 0.5 mg/kg for liquid infant formula for comments at Step 3.

66. In relation to methods of analysis for verification of compliance with the MLs, it was agreed to request the Committee on Methods and Sampling (CCMAS) to identify appropriate methods for the measurement of melamine in powdered infant formula and foods (other than infant formula) and feeds.

67. It was also noted that there was a need for the development of new quantitative protein methods with a higher discriminatory power against the presence of non-protein nitrogen sources and complimentary qualitative authentication techniques capable of detecting the presence of unexpected non-protein compounds in food and feed.

Status of the Proposed Draft Maximum Levels for Melamine in Food and Feed

68. The Committee agreed to forward the proposed draft maximum levels for powdered infant formula and foods (other than infant formula) and animal feed to the 33rd Session of the Codex Alimentarius Commission for adoption at Step 5/8 (with omission of Steps 6 and 7) and the maximum level for liquid infant formula to Step 3 for comments and consideration by the next session (Appendix IV).

PROPOSED DRAFT MAXIMUM LEVELS FOR TOTAL AFLATOXINS IN BRAZIL NUTS (including sampling plans) (Agenda Item 6)[9]

Maximum Levels for Brazil Nuts

69. The Delegation of Brazil introduced the document outlining the main issues associated with this matter, in particular, the establishment of different maximum levels for shelled and in-shell Brazil nuts. The Delegation stressed the need for differentiating between the shelled and in-shell Brazil nuts in view of the unique characteristics of the product, i.e. a wild tree nut growing in the Amazon rain forest, therefore, complete control of the collection-production chain was not possible. In addition, the processing technology of in-shell Brazil nuts did not allow the complete segregation of rotten nuts without removing the shell.

70. Several delegations expressed support for Maximum Levels for Shelled, ready-to-eat Brazil nuts at 10 µg/kg and Shelled, destined for further processing Brazil nuts at 15 µg/kg. However, these delegations indicated that maximum levels should be established on the basis of the intended use of the nuts (ready-to-eat or for further processing) without distinction between shelled and in-shell nuts. This was in line with the previous decision of the Committee in relation to maximum levels for total aflatoxins in various tree nuts (almonds, hazelnuts and pistachios) which were also traded internationally in-shell and would also ensure a consistent approach throughout Codex in the setting of maximum levels for tree nuts. In addition, these delegations noted that the burden of selecting good nuts should not be placed on consumers but on the producers and regulatory institutions in order to guarantee the safety of the product.

71. Some delegations indicated that the implementation of the revised Appendix on Additional Measures for Brazil Nuts (Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Tree Nuts) would also assist in-shell Brazil nuts in complying with the maximum levels proposed for shelled Brazil nuts.

72. Other delegations noted that in-shell Brazil nuts found non-compliant with the proposed maximum levels could undergo further treatment, i.e. shelling and sorting including other alternative processing, so that the Brazil nut kernels could meet the maximum levels thereby limiting the economic damage resulting from non-compliance. In this regard, it was noted that the sampling plans for in-shell Brazil nuts could be revised to refer to the kernels as opposed to the in-shell nut in order to accommodate non-compliant in-shell Brazil nuts as the edible part of the product was the kernel. It was also noted that the Criteria for the Establishment of Maximum Levels of Contaminants in Food and Feed[10] states that for contaminant purposes analysis and consequently MLs will preferably be on the basis of the edible part of the product.

73. An Observer indicated that tolerances in international marketing standards for various tree nuts traded shelled and in-shell already incorporated tolerances for defects e.g. rotting or any other of deterioration, loose shells, shell fragments, etc. and that a similar approach should be taken for the establishment of maximum levels for aflatoxins in this type of products.

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9 CX/CF 10/4/6; CX/CF 10/4/6-Add.1 (comments of Argentina and Norway); CX/CF 10/4/6-Add.2 (comments of Japan); CRD 4 (comments of Kenya); CRD 5 (comments of Iran); CRD 9 (comments of the EU); CRD 14 (comments of Bolivia); CRD 22 (comments of Ecuador).

10 General Standard for Contaminants and Toxins in Food and Feed (CODEX STAN 193-1995).

74. In view of the above discussion, the Committee agreed to retain the proposed MLs for Shelled, ready to eat Brazil Nuts at 10 µg/kg and Shelled, destined for further processing Brazil Nuts at 15 µg/kg and not to set any maximum level for in-shell Brazil nuts. The Delegation of Brazil expressed its reservation to the decision on in-shell Brazil nuts.

Sampling Plans for Brazil Nuts

75. The Committee agreed that the sampling plans for total aflatoxins in Brazil nuts should be integrated into the sampling plans for aflatoxin contamination in ready-to-eat treenuts and treenuts destined for further processing and amended the document accordingly. The Committee further noted that only those sections relating to Brazil nuts were for adoption by the Commission.

Status of the Proposed Draft Maximum Levels for Total Aflatoxins in Shelled, Ready-to-Eat Brazil Nuts and Shelled, Destined for Further Processing Brazil Nuts (including sampling plans)

76. The Committee agreed to forward the proposed draft Maximum Levels (including sampling plans) to the 33rd Session of the Codex Alimentarius Commission for adoption at Step 5/8 (with omission of Steps 6 and 7) (Appendix V).

PROPOSED DRAFT REVISION OF THE CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF AFLATOXIN CONTAMINATION IN TREE NUTS (Appendix on Additional Measures for Brazil nuts) (Agenda Item 7)[11]

77. The Delegation of Brazil introduced the document highlighting the additional measures for Brazil nuts that should be incorporated in the Appendix on Additional Measures for Brazil Nuts of the Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Tree Nuts (CAC/RCP 59-2005) following the completion of the Standards and Trade Development Facility (STDF) SafeNut Project which addressed the factors causing aflatoxin contamination in the Brazil nut production chain and the methods of control available.

78. Some delegations requested clarification as to what the "safe moisture level" should be to avoid aflatoxin formation as humidity was one of the critical environmental factors for fungal growth, especially in the rain forest, and therefore, a target level for moisture content was required in order to facilitate the application of the Code. These delegations further noted that the level of available water was the most important factor for aflatoxin producing fungi so that both moisture content and the corresponding water activity (a_w) should be specified to ensure that neither fungal growth nor production of the associated toxin could take place.

79. The Delegation of Brazil explained that the provision in paragraph 8 could be amended by linking the moisture level to a water activity below 0.70, as already indicated in paragraph 11, since the actual moisture level was not yet possible to define because it may vary depending on the size of the nut. In this regard, the Delegation informed about ongoing studies in Brazil to determine the correlation between the safe moisture level and the associated water activity and that, when finished, the outcome of this study could be made available to the Committee for incorporation in the Code. An Observer indicated that a safe moisture level for Brazil nuts had already been identified as 5% which corresponded to a water activity of 0.70.

80. In view of the above considerations, the Committee agreed to refer to a safe moisture level corresponding to a water activity lower than 0.70 in the first sentence of paragraph 8.

81. Some delegations requested clarification on the scientific basis for the recommended period of 10 days between the collection and the processing (drying) of the nuts as laid down in the first sentence of paragraph 8. Several delegations indicated that, as sun-drying was not normally sufficient to reach a safe moisture level due to the high relative humidity in the rain forest, an additional provision by which transport of Brazil nuts should be done within 10 days after collection to an appropriate drying facility should be included at the end of the second sentence of paragraph 8.

82. The Delegation of Brazil explained that, in view of the unique characteristics of this product, which was not cultivated, a certain degree of flexibility should be allowed in order to take into account certain factors like distance between the collection and the manufacture points, weather conditions, etc., that may affect the collection of the nuts and their transport to the processing plants.

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[11] CX/CF 10/4/7; CX/CF 10/4/7-Add.1 (comments of Canada and Norway); CX/CF 10/4/7-Add.2 (comments of Japan and Thailand); CRD 9 (comments of the EU); CRD 14 (comments of Bolivia); CRD 17 (comments of Brazil); CRD 22 (comments of Ecuador).

83. In view of the above considerations, the Committee agreed to leave the second sentence in paragraph 8 as currently drafted while changing the term "preferentially" to "preferably" throughout the document as more appropriate.

84. In addition, the Committee agreed to delete the last sentence of paragraph 9 as storage practices should be implemented by both processors and communities.

Status of the Proposed Draft Revision of the Code of Practice for the Prevention and Reduction of Aflatoxin Contamination Tree Nuts (Appendix on Additional Measures for Brazil Nuts)

85. The Committee agreed to forward the proposed draft revision to the 33rd Session of the Codex Alimentarius Commission for adoption at Step 5/8 (with omission of Steps 6 and 7) (Appendix VI).

PROPOSED DRAFT MAXIMUM LEVELS FOR FUMONISINS IN MAIZE AND MAIZE-PRODUCTS AND ASSOCIATED SAMPLING PLANS (Agenda Item 8)[12]

86. The Delegation of Brazil introduced document CX/CF 10/4/8 and explained that it had not been the objective of Brazil to conduct an extensive risk assessment as this was the role of JECFA and that fumonisins in maize would be assessed by JECFA in the near future. The Delegation explained the rationale (as presented in Annex III to the document) for the proposals for MLs for different commodities. The Delegation further noted that there were some errors in the background information provided, and that based on the comments received, these errors would be corrected.

87. The Committee had a general discussion on the proposed maximum levels and sampling plans for the different commodities of maize and maize-products (Annex I and II of CX/CF 10/4/8).

88. While there was general agreement on the need for MLs for fumonisin (B1 and B2) in maize and maize-products, many delegations did not support the levels proposed and questioned the setting of a ML at a level higher than the highest observed levels (e.g. for popcorn grain). Many African delegations indicated that maize was a staple food in their countries and that consumption could be as high as 500 g/person/day and that in such cases, the PMTDI of 2 µg/kg/ bw/day would be exceeded when maize containing 1 mg/kg was or more consumed. Questions were raised on the commodities selected and some proposals were made for inclusion of additional commodities such as traditional maize-based foods. In this regard, it was noted that more data were needed on the occurrence of fumonisins in maize and maize-products as well as data on dietary intake in order to determine the commodities for which MLs should be set.

89. In response to the need for clarification on whether the ML for maize grain applied to food or feed, it was explained that in many cases it was difficult to determine its final use.

90. A delegation further proposed the inclusion of fumonisin B3 (FB3) given that occurrence of FB3 was well documented and that JECFA in 2001 had allocated a PMTDI of 2 µg/kg/ bw/day for FB1, FB2 and FB3 alone or in combination.

91. It was noted that FB3 made up only 10% of total intake; that the routine laboratory testing for FB3 was expensive and that not all countries tested for FB3, but that consideration could be given to their inclusion in the standard.

92. In relation to the sampling plans, a delegate questioned the requirement for two laboratory samples in the case of sampling of maize grain and popcorn.

93. The Committee noted that fumonisins in maize and maize-products were proposed for evaluation by JECFA, and considered whether to suspend work until such time that the evaluation was completed. The JECFA Secretariat informed the Committee that evaluation of fumonisins in maize was not yet scheduled, but that if the Committee requested, then JECFA could give it a high priority. The Committee therefore agreed to request the working group on priorities to consider this matter further.

94. In view of the discussion, the Committee agreed to suspend this work until the finalization of the evaluation by JECFA.

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[12] CX/CF 10/4/8; CX/CF 10/4/8-Add.1 (comments of Egypt, EU, Ghana, Japan, Kenya, Norway, the Philippines, Thailand, COCERAL and IAEA); CRD 13 (comments of Indonesia); CRD 18 (comments of Republic of Korea); CRD 22 (comments of Ecuador).

Status of the Proposed Draft Maximum Levels for Fumonisins in Maize and Maize-Products and Associated Sampling Plans

95. The Committee agreed to retain the proposed draft ML and sampling plans at Step 4 until further advice was provided by JECFA.

DISCUSSION PAPER ON MYCOTOXINS IN SORGHUM (Agenda Item 9)[13]

96. The Committee recalled that it had agreed at its last session that the Delegation of Tunisia would prepare a discussion paper on mycotoxins in sorghum for discussion at this session. However, the Committee noted that the discussion paper was not available and had an exchange of views on how to proceed further with this agenda item.

97. The Delegation of Sudan, supported by a number of other delegations, proposed to keep this agenda item and volunteered to take the lead on collecting all available data and preparing an overview document for discussion by the Committee at the next session.

98. It was agreed that the Delegation of Sudan with assistance from Algeria, Brazil, Tanzania, Cote d'Ivoire, Japan, Mali, Senegal, Sweden, Nigeria, Kenya, Saudi Arabia, Tunisia and the United States of America would prepare a discussion paper and that the paper would focus on two main areas as follows:

- the types of mycotoxins and mycotoxin-producing fungi which had been reported and could be found in sorghum; and
- the levels of mycotoxins in sorghum.

PRIORITY LIST OF CONTAMINANTS AND NATURALLY OCCURRING TOXICANTS PROPOSED FOR EVALUATION BY JECFA (Agenda Item 10)[14]

99. The Delegation of the Netherlands, as Chair of the in-session Working Group on the Priority List of Contaminants and Naturally Occurring Toxicants for evaluation by JECFA, presented the report on the outcome of the discussion of the Working Group (Part I, CRD 2).

100. The Committee noted that lead and cadmium were scheduled for evaluation by the 73rd JECFA Meeting (June 2010) and therefore removed from the priority list. The Committee agreed with the recommendations of the working group in regard to 3-MCPD esters, fumonisins and cyanogenic glycosides.

101. It was reported that, with the current available methods, the levels of 3-MCPD esters in food were determined as the total content of ester bound 3-MCPD and glycidol, and that a more accurate direct method for the determination of 3-MCPD esters was under development. In view of this, the Delegations of Japan and Thailand indicated that reliable occurrence data would be provided by 2013.

CONCLUSION

102. The Committee endorsed the priority list of contaminants and naturally occurring toxicants for JECFA evaluation as proposed by the working group (Appendix VII) and agreed 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 11)[15]

Follow-up on results of JECFA evaluations for CCCF

103. The Delegation of The Netherlands presented the report of the in-session Working Group on Priorities (Part 2, CRD 2). It was reported that the working group was only able to discuss 3 of the 6 substances evaluated by JECFA, namely, acrylamide, arsenic and deoxynivalenol (DON).

104. The Chairperson of the Working Group noted the value of this exercise and the Committe may wish to consider the same approach in future.

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13 CX/CF 10/4/9 (no document available at the session); CRD 4 (comments of Kenya).

14 ALINORM 09/32/41 Appendix IX; CX/CF 10/4/10 (comments of Australia and the United Kingdom); CRD 2-Part 1 (Report of the in-session Working Group on Priorities); CRD 4 (comments of Kenya); CRD 8 (comments of Mali); CRD 19 (comments of Philippines).

15 CRD 2-Part 2 (Report of the in-session Working Group on Priorities) CRD 3 (Arsenic in rice); CRD 7 (Maximum levels for total aflatoxins in dried figs); CRD 17 ((proposal for work on Ochratoxin A in cocoa).

Acrylamide

105. The Committee considered the proposals of the working group and agreed with the recommendations to:

- Encourage the use of the Code of Practice to reduce acrylamide formation;
- To stimulate research on the mitigation measures and their impact on acrylamide production;
- To reconsider work on acrylamide in future to allow sufficient time for the implementation of the Code of Practice.

Arsenic

106. It was reported that JECFA had withdrawn the PTWI indicating that it does not adequately protect human health and had emphasized that exposure to inorganic arsenic was strongly related to its presence in drinking water. Arsenic in food resulting from irrigation and cooking water can seriously contribute to the total intake and in this regard the proposal of Iran for new work on MLs for arsenic in rice had been considered. Due to some technical details in their proposal not being very clear, the WG recommended that a discussion paper on the feasibility of establishing MLs in rice be developed.

107. The Committee agreed that an electronic Working Group, led by China and working in English, would prepare a discussion paper that would review the current state of knowledge and provide a summary of possible risk management options including the feasibility of setting MLs in rice for consideration at the next session.

Deoxynivalenol (DON)

108. The Committee recalled that work on MLs for DON was discontinued by the Committee on Food Additives and Contaminants (CCFAC) in 2004 due to lack of available occurrence data and that the development of a discussion paper was started in 2005. This work was discontinued in 2007. In view of the availability of sufficient data and the evaluation by JECFA, the Committee agreed with the recommendation to restart work on MLs for DON and its acetylated derivatives in cereals and cereal-based products.

109. It was clarified that this work on DON was only relevant to cereals for human consumption and not feed. The JECFA Secretariat indicated that it was unlikely that animals would consume feed with high DON levels, as DON induces emesis. Consideration for a discussion paper on DON transfer from animal feed to food for human consumption was given, but no decision was taken on this matter.

110. The Committee agreed that the Delegation of Canada would prepare a project document for submission through the Secretariat to the 63rd Executive Committee for consideration. Subject to approval of the Commission, the proposed draft Maximum Levels for DON and its acetylated derivatives in cereals and cereal-based products would be prepared by an electronic Working Group led by the Delegation of Canada, working in English, for circulation at Step 3 for comments and consideration at the next session.

Risk management guidance

111. The Committee considered the proposal of the working group for the development of guidance for risk management options on how to deal with the results from new risk assessment methodologies. It was agreed that an electronic Working Group, working in English and led by the Delegation of the United States of America would prepare a discussion paper concerning risk management options in relation to new risk assessment outcomes.

MLs for total aflatoxins in dried figs

112. The Committee considered the proposal for establishment of MLs for total aflatoxins in dried figs prepared by the Delegation of Turkey (CRD 7). Several delegations supported the proposal. One delegation questioned the need for MLs at this point and was of the view that sufficient time should be given to the implementation of the Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Dried Figs. Another delegation pointed out that according to the principles for establishment of MLs in the GSCTFF, MLs should only be established when there was a real public health need and that according to JECFA dried figs only contributed to a small percentage of total dietary intake and therefore more justification for this new work was needed.

113. The Delegation of Turkey clarified that it had generated data following the implementation of the Code of Practice and that this data would be considered in the development of the MLs. Accordingly paragraph 3 of the project document was revised to take this into account.

114. In conclusion, the Committee agreed to initiate new work on maximum levels for total aflatoxins in dried figs, as presented in the project document (Appendix IX). Subject to approval by the Commission, the Committee agreed that the proposed draft maximum levels would be developed by an electronic Working Group led by Turkey, working in English, for comments at Step 3 and consideration at the next session.

Ochratoxin A in cocoa

115. The Delegation of Brazil recalled that the 2nd Session of the Committee suspended consideration of ochratoxin A (OTA) in cocoa due to the need for generation of new data and that this matter would be reconsidered once new data became available. The Committee was informed that a new study on the incidence of ochratoxigenic fungi and OTA had been carried out in Brazil and that the study could provide the elements to develop a code of practice to reduce or prevent OTA in cocoa. In view of this, the Committee agreed that an electronic Working Group, working in English, led by Ghana, and co-chaired by Brazil, would prepare a discussion paper on the occurrence of ochratoxigenic fungi and OTA in cocoa to assess whether a code of practice should be developed.

Furan

116. Given the findings of the JECFA evaluation of furan, the United States of America proposed to conduct a review of furan exposure, its toxicities and available technologies to reduce furan in foods with a view to exploring the possibility of developing a code of practice. The Committee agreed that a discussion paper prepared by an electronic Working Group, working in English, led by the Delegation of the United States of America would be presented to the next session of the Committee for consideration.

Pyrrolizidine alkaloids in food and feed

117. The Delegation of the European Union informed the committee that alkaloids were secondary plant metabolites with high toxicity which could have serious health implications, that this occurred in a wide variety of plants and their resultant food products consumed worldwide. It was therefore proposed to develop a discussion paper to look at the chemistry of alkaloids; its toxicity; what methods of analysis were available for detecting alkaloids; occurrence in plants, food and feed; and the carry-over from feed to food.

118. The Committee agreed that an electronic Working Group, working in English, led by The Netherlands would develop the discussion paper for consideration at the next session.

Editorial amendments to the General Standard for Contaminants and Toxins in Food and Feed

119. The Committee recalled the decision taken at the last session to discontinue work on the food categorization system, but to instead provide a clear description of the food/feed for which a maximum level applies and to also screen the existing MLs and to provide where necessary a clearer description of the food/feed to which the ML applies.

120. The Committee agreed that an electronic Working Group, working in English, led by the Delegation of the European Union could prepare proposals on description for commodities in the GSCTFF for consideration at the next session.

121. In addition, the Committee agreed to the following editorial corrections:

- deletion of the entry for dioxin as no ML had been established for this compound in line with its previous decision not to list compounds without MLs in the GSCTFF; and
- in the column "*notes/remarks for Codex Alimentarius*" to delete "*for Codex Alimentarius*".

122. The Committee noted that the Commission would be informed of these editorial corrections.

123. In view of the decision not to list compounds for which no MLs exist, the Committee noted that usefulness of continuing to elaborate the INF 1, which provides background information on the decisions taken on contaminants including toxicological information available on these compounds. The Committee therefore invited the Delegations of The Netherlands and Japan to continue preparing this information document for use during discussions in the Committee.

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

124. The Committee was informed that its fifth session was tentatively scheduled to be held in The Netherlands in March 2011. The exact venue and date would be determined by the host Government in consultation with the Codex Secretariat.

SUMMARY STATUS OF WORK

SUBJECT MATTERS	STEP	ACTION BY:	DOCUMENT REFERENCE (ALINORM 10/33/41)
Proposed Draft Maximum Levels for Melamine in Food (*powdered infant formula and foods other than infant formula*) and Feed	5/8	Governments 33rd CAC	para. 68, Appendix IV
Proposed Draft Maximum Levels for Total Aflatoxins in Shelled, Ready-to-Eat Brazil Nuts and Shelled, Destined for Further Processing Brazil Nuts (including sampling plans)	5/8		para. 76, Appendix V
Proposed Draft Revision of the Code of Practice for the Prevention and Reduction of Aflatoxin in Tree Nuts (additional measures for Brazil nuts)	5/8		para. 85, Appendix VI
Proposed Draft Maximum Level for Melamine in Food (*liquid infant formula*)	3	Governments 5th CCCF	para. 85, Appendix VI
Proposed Draft Code of Practice for the Prevention and Reduction of Ethyl Carbamate Contamination in Stone Fruit Distillates	3	Governments Electronic Working Group (Germany) 5th CCCF	para. 54, Appendix III
Proposed Draft Maximum Levels for Fumonisins in Maize and Maize-Products and Associated Sampling Plans	4	---	para. 95
Proposed Draft Maximum Levels for Deoxynivalenol (DON) and its Acetylated Derivatives in Cereals and Cereal-based Products (new work)	1/2/3	33rd CAC Electronic Working Group (Canada) Governments 5th CCCF	para. 110
Proposed Draft Maximum Levels for Total Aflatoxins in Dried Figs (new work)	1/2/3	33rd CAC Electronic Working Group (Turkey) Governments 5th CCCF	para. 114, Appendix VIII
Priority List of Contaminants and Naturally Occurring Toxicants proposed for evaluation by JECFA	-	Governments 5th CCCF	para. 102, Appendix VII
Endorsement of provisions for health-related limits for certain substances in the Standard for Natural Mineral Waters	-	Electronic Working Group United States of America 5th CCCF	para. 17
Discussion Paper on Mycotoxins in Sorghum	-	Delegation of Sudan 5th CCCF	para. 98
Discussion Paper on Arsenic in Rice	-	Electronic Working Group (China) 5th CCCF	para. 107
Discussion Paper on Guidance for Risk Management Options on How to Deal with the Results from New risk Assessment Methodologies	-	Electronic Working Group (United States of America) 5th CCCF	para. 111
Discussion Paper on Ochratoxin A in Cocoa	-	Electronic Working Group (Ghana) 5th CCCF	para. 115

SUBJECT MATTERS	STEP	ACTION BY:	DOCUMENT REFERENCE (ALINORM 10/33/41)
Discussion Paper on Furan in Foods	-	Electronic Working Group (United States of America) 5th CCCF	para. 116
Discussion Paper on Pyrrolizidine Alkaloids in Food and Feed	-	Electronic Working Group (The Netherlands) 5th CCCF	para. 118
Editorial amendments to the General Standard on Contaminants and Toxins in Foods and Feeds	-	Electronic Working Group (European Union) 5th CCCF	para. 120

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CODEX GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOOD AND FEED

(CODEX STAN 193-1995)

MAXIMUM LEVELS FOR TIN IN CANNED FRUITS AND VEGETABLES

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.)

Residue 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 Code	Name	Level mg/kg	Suffix	Type	Reference	Notes/Remarks
	Canned citrus fruits	250	C	ML		The scope of the Standard (CX STAN 254-2007) includes canned mandarin oranges, canned grapefruits, canned pummelos and canned sweet oranges offered for direct consumption, including for catering purposes or for repacking if required.
	~~Canned grapefruit~~	~~250~~	~~C~~	~~ML~~	~~CS 15-1981~~	
	~~Canned mandarin oranges~~	~~250~~	~~C~~	~~ML~~	~~CS 68-1981~~	
	Jams, jellies and marmalades	250	C	ML		The scope of the Standard (CX STAN 296-2009) covers jams, jellies and marmalades made from all fruits and vegetables offered for direct consumption, including for catering purposes or for repacking if required excluding: a. products when indicated as being intended for further processing such as those intended for use in the manufacture of fine bakery wares, pastries or biscuits; b. products which are clearly intended or labelled as intended for special dietary uses; c. reduced sugar products or those with a very low sugar content; d. products where the foodstuffs with sweetening properties have been replaced wholly or partially by food additive sweeteners.
	~~Jams (fruit preserves) and jellies~~	~~250~~	~~C~~	~~ML~~	~~CS 79-1981~~	

Commodity/Product Code	Name	Level mg/kg	Suffix	Type	Reference	Notes/Remarks
	Canned vegetables	250	C	ML		The scope of the Standard (CX STAN 297-2009) includes canned asparagus, canned carrots, canned green peas, canned green beans and wax beans, canned mature processed peas, canned palmito, canned sweet corn and canned baby corn offered for direct consumption, including for catering purposes or for repacking if required.
	~~Canned asparagus~~	~~250~~	~~C~~	~~ML~~	~~CS 56-1981~~	
	~~Canned carrots~~	~~250~~	~~C~~	~~ML~~	~~CS 116-1981~~	
	~~Canned green and wax beans~~	~~250~~	~~C~~	~~ML~~	~~CS 16-1981~~	
	~~Canned green peas~~	~~250~~	~~C~~	~~ML~~	~~CS 58-1981~~	
	~~Canned mature processed peas~~	~~250~~	~~C~~	~~ML~~	~~CS 81-1981~~	
	~~Canned palmito~~	~~250~~	~~C~~	~~ML~~	~~CS 144-1985~~	
	~~Canned sweet corn~~	~~250~~	~~C~~	~~ML~~	~~CS 18-1981~~	
	Canned stone fruits	250		ML		The scope of the Standard (CX STAN 242-2003) includes canned peaches, canned plums, canned apricots and canned cherries offered for direct consumption, including for catering purposes or for repacking if required.
	~~Canned peaches~~	~~250~~		~~ML~~	~~CS 14-1981~~	
	~~Canned plums~~	~~250~~		~~ML~~	~~CS 59-1981~~	
	~~Canned apricots~~	~~250~~		~~ML~~	~~CS 1291981~~	

PROPOSED DRAFT CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF ETHYL CARBAMATE CONTAMINATION IN STONE FRUIT DISTILLATES

(AT STEP 3 OF THE PROCEDURE)

INTRODUCTION

1. Ethyl carbamate is a compound that occurs naturally in fermented foods and alcoholic beverages such as bread, yoghurt, soy sauce, wine, beer, and particularly in stone fruit spirits and stone fruit marc spirits, mainly those made from cherries, plums, mirabelles and apricots.

2. Ethyl carbamate can be formed from various substances inherent in food and beverages, including hydrogen cyanide (or hydrocyanic acid), urea, citrulline, and other N-carbamyl compounds. Cyanate is probably the ultimate precursor in most cases, reacting with ethanol to form ethyl carbamate. Therefore measures should focus on hydrocyanic acid and other precursors of ethyl carbamate.

3. Ethyl carbamate is genotoxic and a multisite carcinogen in animals and is probably carcinogenic to humans.

4. Stone fruit and stone fruit marc spirits, in particular, contain ethyl carbamate in manyfold higher concentrations than other fermented foods and beverages. In stone fruit distillates (stone fruit spirits and stone fruit marc spirits) ethyl carbamate can be formed from cyanogenic glycosides that are natural constituents of the stones. When mashing the fruit, the stones may be damaged and cyanogenic glycosides from the stones may come into contact with enzymes in the fruit mash. Cyanogenic glycosides are then degraded to hydrocyanic acid/cyanides. Hydrocyanic acid may also be released from intact stones during a prolonged storage of the fermented mash. The presence of copper ions before the distillation will inhibit the co-destillation of hydrocyanic acid by binding the cyanide to an insoluble salt. Otherwise, during the distillation process hydrocyanic acid may be enriched in all fractions. Cyanide in the distillates may be oxidized to cyanate, which can react with ethanol to form ethyl carbamate. The presence of copper ions in the distillate promotes this reaction which leads to increased levels of ethyl carbamate. Certain other environmental conditions such as exposure to light promote the formation of ethyl carbamate in the distillate.

5. Although no strong correlation between the level of hydrocyanic acid and ethyl carbamate has been established so far, it is evident that under certain conditions high concentrations of hydrocyanic acid lead to higher levels of ethyl carbamate. A potential increase in ethyl carbamate formation has been associated with levels at or above 1 mg/l hydrocyanic acid in the final distillate.

SCOPE AND DEFINITIONS

6. This Code of Practice intends to provide national and local authorities, manufacturers and other relevant bodies with guidance to prevent and/or reduce formation of ethyl carbamate in stone fruit spirits and stone fruit marc spirits. Ethyl carbamate formation in other alcoholic beverages and foods is not covered in this Code.

7. The definitions below apply to this Code:

(a) **Stone Fruit** means a fruit which is produced on trees belonging to the genus Prunus of the rose family (Rosaceae).

(b) **Distillates** means alcohol-rich products obtained after the distillation process.

(c) **Stone Fruit Spirits** means the distillates for consumption, obtained after distillation process of the mash prepared by fermentation of crushed stone fruit at first hand or secondly by maceration of crushed and/or whole stone fruit in alcoholic beverages.

(d) **Stone Fruit Marc Spirits** means the distillates for consumption, obtained after distillation process of fermented stone fruit marc (pomace).

GENERAL REMARKS

8. This Code covers all possible measures that have been proven to prevent and/or reduce high levels of ethyl carbamate in stone fruit spirits and stone fruit marc spirits. When applying the Code for specific stone fruit spirits and stone fruit marc spirits, measures should be carefully chosen from the viewpoint of benefit and feasibility. In addition, measures should be implemented in accordance with the relevant national and international legislation and standard.

9. It is recognised that reasonably applicable technological measures - Good Manufacturing Practices - can be taken to prevent and reduce significantly high ethyl carbamate levels in stone fruit distillates. The reduction of ethyl carbamate could be achieved using two different approaches: first, by reducing the concentration of the main precursor substances (e.g. hydrocyanic acid and cyanides); second, by reducing the tendency of these substances to react to form cyanate.

TYPICAL PRODUCTION PROCESS

10. The production process for stone fruit spirits and stone fruit marc spirits involves preparing mash by using whole stone fruits or their mark as ingredients, , followed by fermentation and distillation. The process typically follows the steps listed below:

(a) Preparing mash by crushing the whole ripe fruit (for stone fruit spirits) or by using stone fruit marc (for stone fruit marc spirits);

(b) fermenting the mash in stainless steel tanks or other suitable fermentation vessels;

(c) in the case of using a maceration process, the mash is prepared by macerating crushed or whole fruit into alcoholic beverages and stored for a period, without fermentation process;

(d) transferring the fermented mash into the distillation device, often a copper pot;

(e) heating the fermented mash by a suitable heating method in order to slowly boil off the alcohol;

(f) cooling the alcohol vapour in an appropriate (e. g. stainless steel) column where it condenses and is collected;

(g) separation of three different fractions of alcohol: ‘heads’, ‘hearts’ and ‘tails’;

(h) dilution to the final alcoholic grade.

11. During distillation, the heads boil off first. Components with low boiling point e.g. methanol are part of the heads. This fraction is generally unsuitable for consumption and should be discarded.

12. During the middle distillation run (the ‘hearts’), the principal alcohol in all spirits, ethyl alcohol (ethanol), is distilled. This part of the distilling run, where the content of volatiles other than ethanol is lowest and the purest fruit aromas are present, is always collected.

13. The ‘tails’ of the distillation include acetic acid and fusel oils, which are often identified by unpleasant vinegary and vegetal aromas. They are also discarded, but they may be re-distilled because some ethanol is invariably included with the tails.

RECOMMENDED PRACTICES BASED ON GOOD MANUFACTURING PRACTICES (GMP)

RAW MATERIALS AND PREPARATION OF FRUIT MASH

14. The raw materials and preparation of the fruit mash should be suitable to avoid the release of hydrocyanic acid, a precursor of ethyl carbamate.

15. The stone fruits should generally be of a high quality, not mechanically damaged and not microbiologically spoiled, as damaged and spoiled fruit may contain more free cyanide.

16. The fruit should preferably be de-stoned.

17. If the fruits are not de-stoned and/or the residues of fruits (marc) are used for preparing mash, they should be mashed gently avoiding the crushing of stones. If possible, stones should be removed from the mash.

FERMENTATION

18. Selected yeast preparations for the production of spirit drinks should be added to the mashed fruits, according to the manufacture's instructions for users, for a fast and "clean" fermentation.

19. Mashed fermented fruits should be handled with high standards of hygiene, and exposure to light should be minimised. Fermented fruit mashes containing stones should be stored as briefly as possible before distillation since hydrocyanic acid may also be released from intact stones during prolonged storage..

20. If the mash is prepared by macerating stone fruit into alcoholic beverages, the stone fruit should be removed soon after the aroma of stone fruit is adequately extracted.

DISTILLATION EQUIPMENT

21. Distillation equipment and the distillation process should be suitable, to ensure that hydrocyanic acid is not transferred into the distillate

(a) Use of a copper still will limit carryover of ethyl carbamate–forming precursors into the distillate.

(b) Use of a stainless steel condenser rather than a copper condenser will limit presence of copper in the distillate, where copper can promote formation of ethyl carbamate.

22. The distillation equipment should preferably include automatic rinsing devices and copper catalytic converters. The automatic rinsing devices will keep the copper stills cleaned while the copper catalytic converters will bind hydrocyanic acid before it passes into the distillate.

23. Automatic rinsing devices are not necessary in the case of discontinuous distillation. The distillation equipment should be cleaned by systematic and thorough cleaning procedures.

24. When copper catalytic converters or other dedicated cyanide separators are not available, copper(I) chloride can be added to the fermented fruit mash before distillation. The purpose of these copper (I) ions is to bind hydrocyanic acid. Copper (II) ions should not be used.

DISTILLATION PROCESS

25. Stones settled in the fermented mash should not be pumped into the distillation device.

26. Distillation should be carried out in such a way that alcohol is boiled off slowly and in a controlled matter (e.g. by using steam instead of a direct flame as the heating source).

27. The first fractions of the distillate, called 'heads', should be separated carefully.

28. The middle fraction, called 'hearts', should then be collected and should be stored in the dark. When the alcohol content reaches 50% vol. in the receiver, collection should be switched to the 'tails', so that any ethyl carbamate that may have been formed is separated in the tail fraction.

29. Some manufacturers may redistill the separated tails, possibly containing ethyl carbamate. If the tails are used for re-distilling, they should be re-distilled separately, however for reduction of ethyl carbamate concentration it is preferable to discard the tail.

CHECKS ON THE DISTILLATE, RE-DISTILLATION AND STORAGE

Hydrocyanic acid

30. Testing for hydrocyanic acid may be used as a simple test for ethyl carbamate in distillates,. Therefore, the distillates should be regularly checked for their levels of hydrocyanic acid. The determination could be carried out by specific tests including kits for rapid testing of the hydrocyanic acid levels.

31. If the concentration of hydrocyanic acid in the distillate exceeds a level of 1 mg/l, re-distillation with catalytic converters or copper agents is recommended (see points 24, 25 and 27).

32. Distillates should be stored in bottles that are lightproof (or filter ultraviolet light) or in covering boxes and storage time should be kept as short as possible.

Ethyl carbamate

33. Testing of ethyl carbamate is recommended for distillates in which the compound may already have been formed (e.g. distillates with unknown history of production, distillates with higher levels of cyanide, or storage at light or at high temperatures).

34. Additional distillation is effective in order to reduce ethyl carbamate in distillates (see point 33).

GENERAL RECOMMENDATIONS

35. The national, state and local governments as well as the non-governmental organizations (NGOs, commercial associations and cooperatives) should provide their own basic training and update the information on the risks associated with contamination by ethyl carbamate in stone fruit spirits and fruit marc spirits.

36. The non-industrial, small-scale preparation of these drinks should have available material with information on the specific recommendations based on good manufacturing practices and guidance on prevention and reduction of ethyl carbamate in the stone fruit distillates.

PROPOSED DRAFT MAXIMUM LEVEL FOR MELAMINE IN FOOD AND FEED

(AT STEP 5/8 OF THE PROCEDURE)

Product Name	ML (mg/kg)	Remarks
Powdered Infant formula	1	
Food (other than infant formula) and animal feed	2.5	**Note 1** The maximum level applies to levels of melamine resulting from its non-intentional and unavoidable presence in feed and food. The maximum level 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 - 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. **Note 2** The maximum level does not apply to melamine that could be present in the following feed ingredients/additives: guanidino acetic acid (GAA), urea and biuret, as a result of normal production process.

PROPOSED DRAFT MAXIMUM LEVEL FOR MELAMINE IN FOOD

(AT STEP 3 OF THE PROCEDURE)

Product Name	ML (mg/kg)
Liquid infant formula	0.5

PROPOSED DRAFT MAXIMUM LEVEL FOR TOTAL AFLTOXINS IN BRAZIL NUTS

(AT STEP 5/8 OF THE PROCEDURE)

Product Name	ML (μg/kg)
Brazil nut, shelled, ready to eat	10
Brazil nut, shelled, destined for further processing	15

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 – 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 treenuts – nuts, which are not intended to undergo an additional processing/treatment that has proven to reduce levels of aflatoxins.

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 color sorting, and sorting by specific gravity and color (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 inshell or shelled nuts. For example, pistachios are predominately marketed as inshell nuts while almonds are predominately marketed as shelled nuts.
3. Sampling statistics, shown in Annex I, 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 I, 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 I, and the negative binomial distribution[1],[2],[3] are used to calculate operating characteristic (OC) curves that describe the performance of the proposed aflatoxin-sampling plans (Annex II).

[1] Whitaker, T., Dickens, J., Monroe, R., and Wiser, E. 1972. Comparison of the negative binomial distribution of aflatoxin in shelled peanuts to the negative binomial distribution. J. American Oil Chemists' Society, 49:590-593.

5. In Annex I, the analytical variance reflects a reproducibility relative standard deviation of 22%, which is suggested by Thompson and is based upon Food Analysis Performance Assessment Scheme (FAPAS) data[2]. 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. The within laboratory analytical uncertainty for almonds, hazelnuts and pistachios can be found at the website http://www5.bae.ncsu.edu/usda/www/ResearchActDocs/treenutwg.html and for Brazil nuts in the CONFORCAST[3].

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 proposed 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 – inshell nuts (equivalent to about 10kg 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.

The operating characteristic curve describing the performance of the sampling plan for the three treenuts destined for further processing is shown in Annex II.

Ready-to-eat treenuts

Maximum level – 10 µg/kg total aflatoxins

Number of laboratory samples – 2

Laboratory sample size - 10 kg

[2] Thompson, M. 2000. Recent trends in inter-laboratory precision at ppb and sub-ppb concentrations in relation to fitness for purpose criteria in proficiency testing. J. Royal Society of Chemistry, 125:385-386.

[3] CONFORCAST. Ferramentas Analíticas para Capacitação do Brasil na Garantia da Conformidade da Castanha-Do-Brasil (Bertholletia Excelsa) quanto ao Perigo aflatoxina. Projeto nº 1.265/05, Aprovado pela FINEP na Chamada Pública, "Ação Transversal - TIB - 06/2005 - Linha 1". MAPA. Minist~erio da Agricultura, pecuária e do Abasteciento. Secretaria de Defesa Agropecuária - DAS, Departamento de Inspeção de Produtos de Origem Vegetal – DIPOV. Coordenação-Geral de Apoio Laboratorial – CGAL, Laboratório Nacional Agropecuário – LANAGRO/MG, United States Department of Agriculture (Thomas Whitaker and Andy Slate).

Almonds – shelled nuts
Hazelnuts – shelled nuts
Pistachios – inshell 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.

The operating characteristic curve describing the performance of the sampling plan for the four ready-to-eat treenuts is shown in Annex II.

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 sublot 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 sublot 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 (sublot) size. However, the number and size of the incremental samples will vary with lot (sublot) size.

19. The number of incremental samples to be taken from a lot (sublot) 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 (or sublot) weight.

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

Lot or Sublot Weight[b] (T in Tonnes)	Minimum Number of Incremental Samples	Minimum Incremental Sample Size[c] (g)	Minimum Aggregate Sample Size (kg)
T<1	10	2000	20
1≤T<5	25	800	20
5≤T<10	50	400	20
10≤T<15	75	267	20
15≤T	100	200	20

b/ 1 Tonne = 1000 kg

c/ Minimum incremental sample size = laboratory sample size (20 kg)/minimum number of incremental samples, i.e.

for 0.5<T< 1 tonne, 2000 g = 20000/10

Weight of the Incremental Sample

20. The suggested minimum weight of the incremental sample should be approximately 200 grams 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 sublot 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:

    Equation 1: SF=(LT x IS)/(AS x 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:

    Equation 2: S=(D x LT) / (T x 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.

    Equation 3: SF = (S x V) / (D x 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 cm x 20,000 kg)/(20 kg x 20 cm/sec) = 250 sec.

31. If the lot is moving at 500 kg per minute, the entire lot will pass through the sampler in 40 minutes (2400 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 favor mold 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[4]. 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[5].

Test portion

38. The suggested weight of the test portion taken from the comminuted laboratory sample should be approximately 50 grams. 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 110%	n/a
	>15	80 to 110%	n/a
Precision or Relative Standard Deviation RSD_R (Reproducibility)	1 to 120	Equation 4 by Thompson	2 x value derived from Equation 4
	>120	Equation 5 by Horwitz	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

[4] Ozay, G., Seyhan, F., Yilmaz, A., Whitaker, T., Slate, A., and Giesbrecht, F. 2006. Sampling hazelnuts for aflatoxin: Uncertainty associated with sampling, sample preparation, and analysis. J. Association Official Analytical Chemists, Int., 89:1004-1011.

[5] Spanjer, M., Scholten, J., Kastrup, S., Jorissen, U., Schatzki, T., Toyofuku, N. 2006. Sample comminution for mycotoxin analysis: Dry milling or slurry mixing?, Food Additives and Contaminants, 23:73-83.

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 developed by Thompson[2] and Horwitz and Albert[6], respectively.
Equation 4: $RSD_R = 22.0$ (for $C \leq 120$ µg/kg or $c \leq 120x10^{-9}$)
Equation 5: $RSD_R = 2^{(1-0.5\log c)}$ (for $C > 120$ µg/kg or $c > 120x10^{-9}$)
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 = $0.66RSD_R$
    - c = the aflatoxin concentration ratio (i.e. 1 = 100g/100g, 0.001 = 1,000 mg/kg)
    - C = aflatoxin concentration or mass of aflatoxin to mass of treenuts (i.e. µg/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.

[6] Horwitz, W. and Albert, R. 2006. The Horwitz ratio (HorRat): A useful index of method performance with respect to precision. J. Association of Official Analytical Chemists, Int., 89:1095-1109.

Annex I

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.

Variance estimates and the negative binomial distribution[1] were used to compute operating characteristic curves for each treenut in Annex II. Sampling, sample preparation, and analytical variances associated with testing almonds, hazelnuts, pistachios and shelled Brazil nuts are shown in Table 1 below.

Because of the computational complexities associated with use of the negative binomial distribution to compute operational characteristic (OC) curves for various sampling plan designs, the effect of various laboratory sample sizes, various numbers of laboratory samples, and various maximum levels on the performance (OC curves) of sampling plan designs is provided at the website address http://www5.bae.ncsu.edu/usda/www/ResearchActDocs/treenutwg.html and for Brazil nuts in the CONFORCAST[3].

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

Test Procedure	Almonds	Hazelnuts	Pistachios	Shelled Brazil nuts
Sampling[b,c]	$S^2_s = (7{,}730/ns)5.759C^{1.561}$	$S^2_s = (10{,}000/ns)4.291C^{1.609}$	$S^2_s = 8{,}000/ns)7.913C^{1.475}$	$s_s^2 = (1850/ns)\ 4.8616C^{1.889}$
Sample Prep[d]	$S^2_{sp} = (100/nss)0.170C^{1.646}$	$S^2_{sp} = (50/nss)0.021C^{1.545}$	$S^2_{sp} = (25/nss)2.334C^{1.522}$	$s_{ss}^2 = (50/nss)0.0306C^{0.632}$
Analytical[e]	$S^2_a = (1/na)0.0484C^{2.0}$	$S^2_a = (1/na)0.0484C^{2.0}$	$S^2_a = (1/na)0.0484C^{2.0}$	experimental $s_a^2 = (1/n)\ 0.0164C^{1.117}$ or FAPAS $s_a^2 = (1/n)\ 0.0484C^{2.0}$
Total variance	$S^2_s + S^2_{sp} + S^2_a$	$S^2_s + S^2_{sp} + S^2_a$	$S^2_s + S^2_{sp} + S^2_a$	$S^2_s + S^2_{sp} + S^2_a$

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a/ Variance = S^2 (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, 1000, 1600 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.

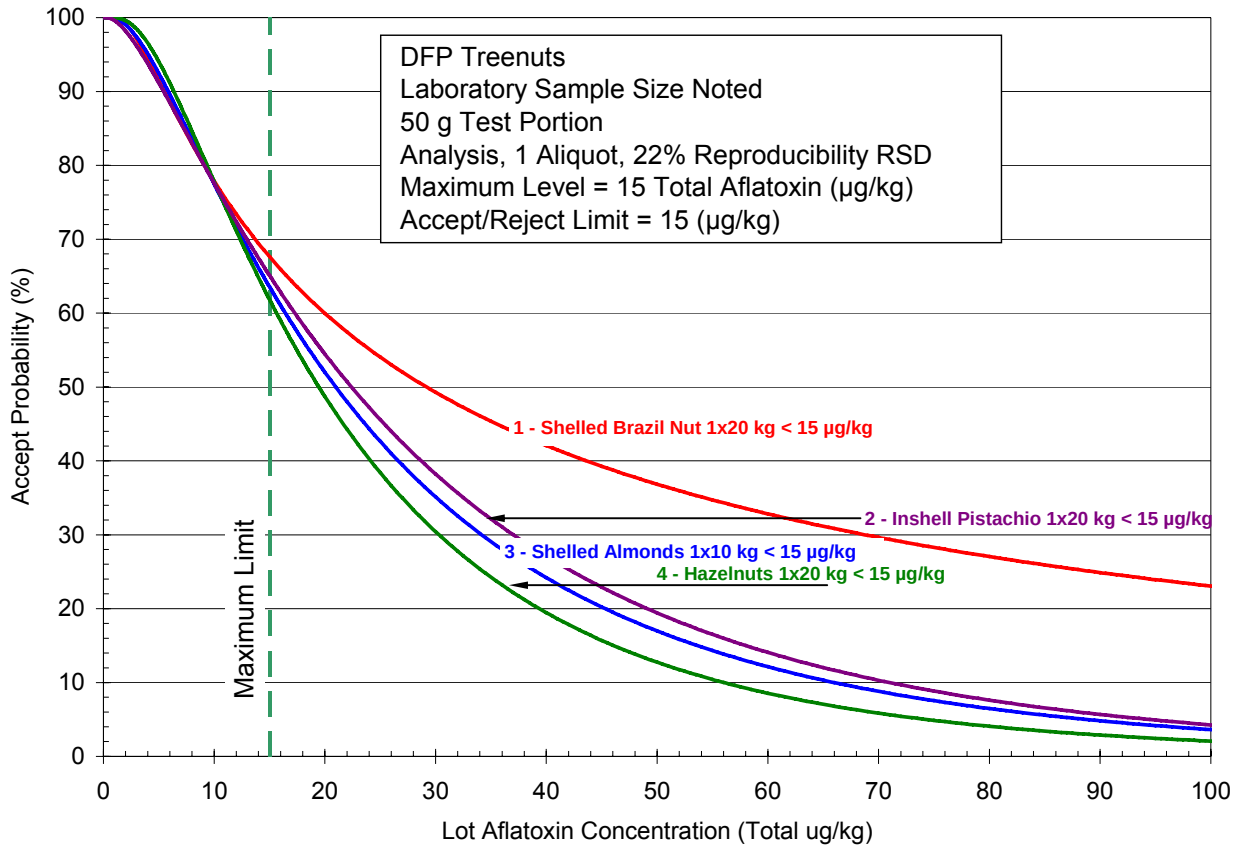
e/ Analytical variances reflect FAPAS recommendation for upper limit of analytical reproducibility uncertainty. A relative standard deviation of 22% is considered by Thompson[2] (based upon FAPAS data) as an appropriate measure of the best agreement that can be obtained between laboratories. An analytical uncertainty of 22% is larger than the within laboratory uncertainty measured in the sampling studies for the four treenuts.

Annex II

Operating Characteristic Curves describing the performance of aflatoxin sampling plans for almonds, hazelnuts, pistachios and shelled Brazil nuts.

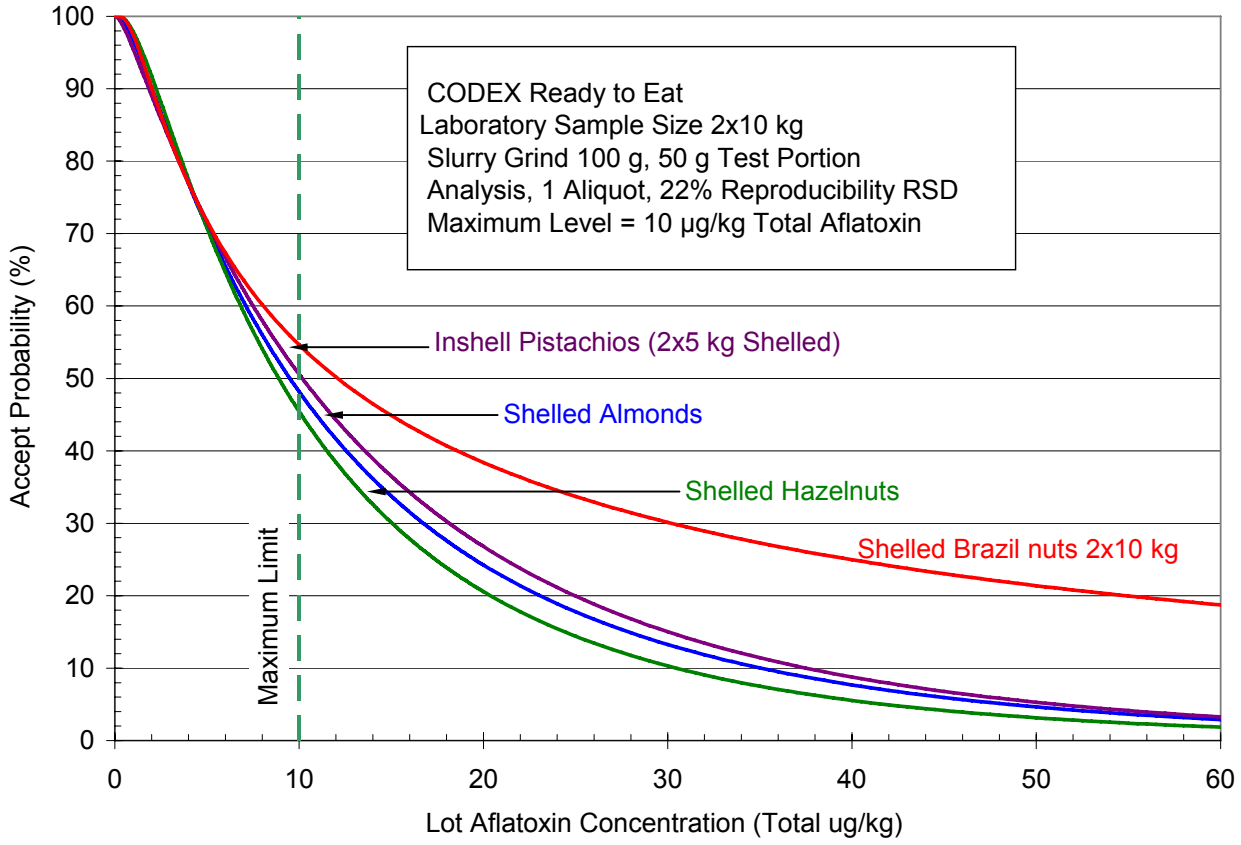
Treenuts Destined for Further Processing

Operating Characteristic curve describing the performance of the aflatoxin sampling plan for almonds, hazelnuts, pistachios and shelled Brazil nuts destined for further processing using a single laboratory sample of 20 kg and a maximum level of 15 µg/kg for total aflatoxins. The operating characteristic curve reflects uncertainty associated with a 20 kg laboratory sample of shelled nuts for almonds, hazelnuts and shelled Brazil nuts and a 20 kg laboratory sample of inshell nuts (about 10kg shelled nuts) for pistachios with dry grind with a vertical cutter mixer type mill almonds, hazelnuts and pistachios and slurry preparation for shelled Brazil nuts, 50 g test portion, and quantification of aflatoxin in the test portion by HPLC.



Ready-to-Eats Treenuts

Operating Characteristic curve describing the performance of the aflatoxin sampling plan for ready-to-eat almonds, hazelnuts, pistachios and shelled Brazil nuts using two laboratory samples of 10 kg each and a maximum level of 10 µg/kg for total aflatoxins, with dry grind with a vertical cutter mixer type mill almonds, hazelnuts and pistachios and slurry preparation for shelled Brazil nuts, 50 g test portion, and quantification of aflatoxin in the test portion by HPLC.



PROPOSED DRAFT REVISION OF THE ADDITIONAL MEASURES FOR THE PREVENTION AND REDUCTION OF AFLATOXIN CONTAMINATION IN BRAZIL NUTS

(AT STEP 5/8 OF THE PROCEDURE)

INTRODUCTION

1. The formulation and acceptance of an appendix to the Code of Practice for the Prevention and Reduction of Aflatoxins Contamination in Tree Nuts will provide uniform guidelines for producing countries to consider in attempting to control and manage contamination of Brazil nuts by aflatoxins. In order for these measures to be effective, it will be necessary for collectors, processors and other members of the production chain to consider the general principles established by the Code, while taking into account the fact that Brazil nut tree (*Bertholletia excelsa*) is not cultivated. This specie exists all over the Amazon Region, however the largest concentrations of trees are in the Brazilian Amazon.

2. This appendix applies only to Brazil nuts, given the very specific conditions related to their collection and processing.

RECOMMENDED PRACTICES BASED ON GOOD EXTRACTIVISTIC PRACTICES (GEP)

PRE-COLLECTION

3. **The extractivists should clear the area under the Brazil nut trees, removing residual pods and nuts from the former crop.** Pods left from the last crop season should never be mixed with pods from the present crop season, as they represent a potential source of contamination with *Aspergillus.*

COLLECTION

4. **Collection should proceed continuously as soon as possible after the pods have fallen from the trees.** A certain delay in the collection is expected because during the crop season remaining pods may fall, posing a risk to the lives of the collectors.

5. **Pods should be sorted to remove damaged ones and gathered in piles, if possible, in thin layers, for only a short period of time (preferably less than 5 days) .**

POST COLLECTION

6. Pods should be opened as soon as possible after collection, with the nuts being removed and separated from the pods and placed on clean and dry floor or plastic canvas in good condition, to avoid contact with the soil. During the opening of the pods care should be taken to avoid damage to the nuts as much as possible. **The nuts should be sorted to remove damaged and empty ones.**

7. Initial transportation of the nuts, from the forest to a storage facility, should occur as soon as possible, using containers that are clean, dry and protected against rain and insects, to the greatest extent possible.

8. **To avoid aflatoxin formation the nuts should be dried to a safe moisture level corresponding to a water activity below 0.70 preferably within 10 days from the collection. Sun-drying is normally not sufficient to reach a safe moisture level due to the high relative humidity in the rain forest environment. This recommendation is particularly important when producing Brazil nuts to be traded as "in-shell" where contaminated nuts are difficult to distinguish from sound nuts without cracking the nut. The nuts should be protected against rain and pests, such as birds, rodents and insects and any other source of contamination.**

9. **After drying, the nuts should be placed in a storage facility with a floor at least 50 cm above ground level; protected against rain and pests and that allow good air circulation. For the purpose of identification and traceability, nuts, in bulk or in bags, from different origins and/or days of collection should preferably be handled separately and kept separated until the final processing and packaging.**

10. During the transportation of the nuts from the primary storage facility, in bulk or in bags, either to an intermediate location or to a processing facility, the nuts should be separated from other goods, in containers that are clean, dry, protected against humidity and free from insects and visible fungal growth. Conveyances for transporting nuts should be made of material that will permit thorough cleaning and maintenance so as not to constitute a potential source of contamination for the Brazil nuts.

11. If the nuts are stored at an intermediate location, before reaching the processing facility, the storage facility should have the following:

a) protection from rain and pests;

b) a washable and impermeable floor;

c) drainage of ground water;

d) good air circulation;

e) sufficient area and proper divisions to allow separation of lots .

This intermediate storage is only recommended if the moisture content of the nuts corresponds to a water activity below 0.70. Otherwise no intermediate storage is recommended, especially for nuts expected to be marketed in-shell.

GENERAL RECOMMENDATIONS

12. National, State and local governments, as well as Non Governmental Organizations – NGOs, trade associations and cooperatives should provide basic education and update information on the hazards associated with aflatoxin contamination to the agents involved in the Brazil nuts production chain.

13. Local people (extractivists) involved in the collection of Brazil nuts should be regularly trained in personal hygienic and sanitary practices that must be implemented at all stages of production including the pre-collection, collection, post-collection and processing.

14. It is recommended that further development and validation of the current quality control system, used in most processing plants, by checking the percentage of “bad” nuts in the incoming lots be undertaken. This method may be used as a tool for decision if a lot can be commercialized as “in-shell” nuts or should be shelled and sorted to eliminate the bad nuts.

PRIORITY LIST OF CONTAMINANTS AND NATURALLY OCCURRING TOXICANTS PROPOSED 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[1]	Full evaluation (toxicological assessment and exposure assessment)	Germany: end 2010 Japan: subchronic toxicity test and occurrence end 2013 China: Total Diet Study on 3-MCPD esters available	Germany, supported by EC, Canada, Japan
Fumonisins[1]	Update toxicological evaluation taking into account all new data Occurrence in feed and carry-over to address public health relevance Recent occurrence data in food (including bound fumonisins in processed products) and exposure assessment Evaluation of potential adverse health effects of co-occurrence of Fumonisins with other mycotoxins, in particular aflatoxins in maize and cereals Perform a impact assessment of different hypothetical maximum levels in different products	<u>Occurrence data:</u> EC: maize and maize products Brazil: maize and maize products US: new surveillance data Australia: occurrence data in breakfast cereals and other products Ghana: maize, maize products Tanzania: maize, maize flour (dec 2010), maize based baby food Japan: maize and other cereals Nigeria: updated data on maize with respect to the data submitted to Brazil China: Data on maize in GEMS/FOOD format Rep. of Korea: monitoring data on maize <u>Toxicological data:</u> Published literature	CCCF
Cyanogenic Glycosides	Review of new data on toxicity, occurrence, effect on processing (food and feed) to decide if risk assessment is feasible and appropriate	To be determined in response to call for data	CCCF

[1] High priority for evaluation by JECFA.

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 criteria[1]

- 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.20 of the Risk Analysis Principles Applied by the Codex Committee on Food Additives and the Codex Committee on Contaminants in Foods (See Procedural Manual of the Codex Alimentarius Commission).

PROJECT DOCUMENT

PROPOSAL FOR NEW WORK ON

A MAXIMUM LEVEL FOR TOTAL AFLATOXIN IN DRIED FIG

1. The purpose and scope of the project

This project aims to establish a maximum level for total aflatoxin in ready-to eat dried figs.

2. Relevance and timeliness

Aflatoxins were evaluated by the JECFA at its 31st, 46th, 49th and its 56th meetings (AFM1 only). At its 49th meeting in 1997, JECFA considered estimates of the carcinogenic potency of aflatoxin and the potential risks associated with their intake. In the evaluation at its 68th meeting in 2008, the JECFA reported that Turkey is the main country producing dried figs, covering approximately 63% of the world market. The proportion of rejected dried figs samples from the world market would be between 1% for an ML set at 20 µg/kg or 10 µg/kg and 3% for an ML set at 4 µg/kg.

"A Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Dried Figs (N10-2007)" was adopted by the Codex Alimentarius Commission at its 31st Session. Therefore, there is a need for an international regulatory level, based upon scientific evidence, having as its goal the protection of human health with a minimum of economic impact on international trade.

3. The main aspects to be covered

It is proposed to establish a maximum level for total aflatoxin in ready-to-eat, dried figs, considering the following:

a) Toxicological evaluations of aflatoxin by JECFA

b) Occurrence data in dried figs between years 2003 – 2006

c) Updated occurrence data in dried figs between years 2007 – 2009

d) Consumption in g/day for figs as given by 13 GEMS/Food Consumption Cluster Diets in 2006 and additional information on national consumption data for dried figs

e) New data following the implementation of the Code of Practice for the prevention and reduction of aflatoxin contamination in dried figs

4. Assessment against the criteria for the establishment of work priorities

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

The new work will establish a maximum level for total aflatoxin in dried figs.

2. *Diversification of national legislations and apparent resultant or potential impediments to international trade.*

The new work will provide an internationally-harmonized standard.

International market potential has been increasing.

5. Relevance to Codex Strategic Goals

The proposed work falls under the following Codex Strategic Goals:

Goal 1. Promoting sound regulatory frameworks

The result of this work will assist in promoting sound regulatory frameworks in international trade by using scientific knowledge. With a view to promoting maximum application of Codex standards, this work will provide harmonized regulations for developed and developing countries, leading to enhanced fair trade.

Goal 2. Promoting widest and consistent application of scientific principles and risk analysis

This work will help establish risk-management options based upon scientific evaluation.

Goal 3. Strengthening Codex work-management capabilities

The establishment of a maximum level for total aflatoxin in dried figs is a way to manage risks associated with the consumption of highly-contaminated food.

Goal 4. Promoting maximum application of Codex standards

Due to the international nature of this problem, this work will support and embrace all aspects of this objective by accompanying participation of both developed and developing countries to conduct the work.

6. Information on the relationship between the proposal and other existing Codex documents

This new work is recommended in the Discussion Paper on a Maximum Level for Aflatoxins in Dried Figs presented and discussed at the 4th Session of Codex Committee on Contaminants in Foods.

7. Identification of any requirement for any availability of expert scientific advice

It is not yet foreseen.

8. Identification of any need for technical input to the standard from external bodies

Occurrence data on and evaluation of aflatoxin limits are reported by JECFA in 2008.

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

Subject to approval by the Commission, the proposed draft Maximum Level for Total Aflatoxin in Dried Figs will be considered by the 5th Session of the CCCF with a view to its finalization in 2012.