

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

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ORGANIZATION



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ALINORM 08/31/41

JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX ALIMENTARIUS COMMISSION
Thirty-first Session
Geneva, Switzerland, 30 June - 4 July 2008

**REPORT OF THE 2nd SESSION OF THE
CODEX COMMITTEE ON CONTAMINANTS IN FOODS**
The Hague, The Netherlands
31 March – 4 April 2008

Note: This report includes Codex Circular Letter CL 2008/8-CF

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CX 4/35.2

CL 2008/8-CF
April 2008

To: Codex Contact Points
Interested International Organizations

From: Secretary,
Codex Alimentarius Commission,
Joint FAO/WHO Food Standards Programme,
Viale delle Terme di Caracalla,
00153 Rome, Italy

Subject: Distribution of the Report of the Second Session of the Codex Committee on Contaminants in Foods (ALINORM 08/31/41)

The Report of the Second Session of the Codex Committee on Contaminants in Foods is attached. It will be considered by the Thirty-first Session of the Codex Alimentarius Commission (Geneva, Switzerland, 30 June – 4 July 2008).

MATTERS FOR ADOPTION BY THE 31ST SESSION OF THE CODEX ALIMENTARIUS COMMISSION

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

1. Draft Maximum Levels for 3-MCPD in Liquid Condiments containing Acid-Hydrolyzed Vegetable Proteins (Excluding Naturally Fermented Soy Sauce) (N08-2004) at Step 8 (ALINORM 08/31/41 para. 67 and Appendix III)
2. Draft Code of Practice for the Reduction of 3-Monochloropropane-1,2-diol (3-MCPD) during the Production of Acid-Hydrolyzed Vegetable Protein (Acid-HVPs) and Products that Contain Acid-HVPs (N09-2005) at Step 8 (ALINORM 08/31/41 para. 73 and Appendix IV)
3. Draft Maximum Level for Ochratoxin A in Raw Wheat, Barley and Rye at Step 8 (ALINORM 08/31/41 para. 112 and Appendix VII)
4. Draft Maximum Levels for Total Aflatoxins in Almonds, Hazelnuts and Pistachios “For further processing” and “Ready-to-eat” at Step 8 (ALINORM 08/31/41 para. 127 and Appendix VIII)
5. Proposed Draft Aflatoxin Sampling Plans for Aflatoxin Contamination in Ready-to-eat Treenuts and Treenuts Destined for Further Processing: Almonds, Hazelnuts and Pistachios (N07-2004) at Step 5/8 (ALINORM 08/31/41 para. 142 and Appendix IX)
6. Proposed Draft Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Dried Figs (N10-2007) at Step 5/8 (ALINORM 08/31/41 para. 163 and Appendix XI)

Governments and interested international organizations wishing to submit comments on the above texts should do so in writing, preferably by E-mail, to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Viale delle Terme di Caracalla, 00153 Rome, Italy (Email: codex@fao.org; Fax +39 06 570 54593) **before 30 May 2008**.

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

- 7. Proposed Draft Code of Practice for the Reduction of Acrylamide in Food (N06-2006) at Step 5 (ALINORM 08/31/41 para. 95 and Appendix V)**
- 8. Proposed Draft Code of Practice for the Reduction of Contamination of Food with Polycyclic Aromatic Hydrocarbons (PAH) from Smoking and Direct Drying Processes (N07-2006) at Step 5 (ALINORM 08/31/41 para. 109 and Appendix VI)**

Governments and interested international organizations wishing to submit comments on the above texts should do so in writing, preferably by E-mail, to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Viale delle Terme di Caracalla, 00153 Rome, Italy (Email: codex@fao.org; Fax +39 06 570 54593) **before 30 May 2008.**

Others

- 9. Proposed Draft Provisions Applied to Contaminants in the “Relations between Commodity Committees and General Committees” (ALINORM 08/31/41 para.14 and Appendix II)**
- 10. Priority List of Contaminants and Naturally Occurring Toxicants Proposed for Evaluation by JECFA (ALINORM 08/31/41 para. 187 and Appendix XIII)**

Governments and interested international organizations wishing to submit comments on the above texts should do so in writing, preferably by E-mail, to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Viale delle Terme di Caracalla, 00153 Rome, Italy (Email: codex@fao.org; Fax +39 06 570 54593) **before 30 May 2008.**

SUMMARY AND CONCLUSIONS

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

Matters for consideration by the Codex Alimentarius Commission

Draft and Proposed draft Standards and Related Texts at Steps 8 or 5/8 of the Procedure

The Committee agreed to forward:

- Draft Maximum Levels for 3-MCPD in Liquid Condiments containing Acid-Hydrolyzed Vegetable Proteins (Excluding Naturally Fermented Soy Sauce) (N08-2004) at Step 8 (ALINORM 08/31/41 para. 67 and Appendix III);
- Draft Code of Practice for the Reduction of 3-Monochloropropane-1,2-diol (3-MCPD) during the Production of Acid-Hydrolyzed Vegetable Protein (Acid-HVPs) and Products that Contain Acid- HVPs (N09-2005) at Step 8 (ALINORM 08/31/41 para. 73 and Appendix IV);
- Draft Maximum Level for Ochratoxin A in Raw Wheat, Barley and Rye at Step 8 (ALINORM 08/31/41 para. 112 and Appendix VII);
- Draft Maximum Levels for Total Aflatoxins in Almonds, Hazelnuts and Pistachios “For further processing” and “Ready-to-eat” at Step 8 (ALINORM 08/31/41 para. 127 and Appendix VIII);
- Proposed Draft Aflatoxin Sampling Plans for Aflatoxin Contamination in Ready-to-eat Treenuts and Treenuts Destined for Further Processing: Almonds, Hazelnuts and Pistachios (N07-2004) at Step 5/8 (ALINORM 08/31/41 para. 142 and Appendix IX); and
- Proposed Draft Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Dried Figs (N10-2007) at Step 5/8 (ALINORM 08/31/41 para. 163 and Appendix XI).

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

The Committee agreed to forward the following texts to the Codex Alimentarius Commission for adoption at Step 5:

- Proposed Draft Code of Practice for the Reduction of Acrylamide in Food (N06-2006) (ALINORM 08/31/41 para. 95 and Appendix V) ; and
- Proposed Draft Code of Practice for the Reduction of Contamination of Food with Polycyclic Aromatic Hydrocarbons (PAH) from Smoking and Direct Drying Processes (N07-2006) (ALINORM 08/31/41 para. 109 and Appendix VI).

Proposed amendments to the Procedural Manual

The Committee agreed to forward the following text to the 61st Session of the Executive Committee for consideration with a view to adoption by the Codex Alimentarius Commission and inclusion in the Procedural Manual:

- Proposed Draft Provisions Applied to Contaminants in the “Relations between Commodity Committees and General Committees” (ALINORM 08/31/41 para. 14 and AppendixII).

Proposals for new work

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

- “Maximum Levels for Total Aflatoxins in Brazil Nuts” (ALINORM 08/31/41 para. 147 and Appendix X); and
- a “Code of Practice for the Prevention and Reduction of Ochratoxin A Contamination in Coffee” (ALINORM 08/31/41 para. 167 and Appendix XII).

Others

The Committee agreed to forward to the Codex Alimentarius Commission the Priority List of Contaminants and Naturally Occurring Toxicants Proposed for Evaluation by JECFA for adoption (ALINORM 08/31/41 para. 187 and Appendix XIII).

Matters of Interest to the Codex Alimentarius Commission

The Committee:

- endorsed the propose draft amendments to Section 3.2 “Health-Related Limits for Certain Substances” of the Codex Standard for Natural Mineral Waters (para. 27); and
- provisionally endorsed the proposed levels for marine biotoxins in the Draft Standard for Live and Raw Bivalve Molluscs (para. 31).

The Committee agreed:

- that the Proposed Draft Revision of the Preamble of the GSCTF (N04-2006) be returned to Step 2 for redrafting by an electronic working group, with a view to circulation at Step 3 and consideration at Step 4 at the next session of the Committee (para. 62);
- to establish an electronic working group to prepare proposed draft maximum levels for total aflatoxins in Brazil nuts at Step 2, with a view to its circulation for comments at Step 3 and its consideration at Step 4 at the next session of the Committee, pending the formal approval of new work by the Codex Alimentarius Commission (para. 148);
- to establish an electronic working group to prepare a draft proposed Code of Practice on the Prevention and Reduction of Ochratoxin A contamination in Coffee at Step 2, with a view to its circulation for comments at Step 3 and its consideration at Step 4 at the next session of the Committee, pending the formal approval of new work by the Codex Alimentarius Commission (para. 168);
- that the following discussion papers be prepared for consideration at the next session of the Committee:
 - Discussion paper on fumonisins (para. 177);
 - Discussion paper on benzene in soft drinks (para. 179);
 - Discussion paper on cyanogenic glycosides (para. 180);
 - Discussion paper on mycotoxins in sorghum (para. 186); and
 - Discussion paper on ethyl carbamate in alcoholic beverages (para. 191).

LIST OF ABBREVIATIONS USED IN THIS REPORT

3-MCPD	3-monochloropropane-1,2-diol
ALARA	As Low As Reasonably Achievable
CAC	Codex Alimentarius Commission
CCCF	Codex Committee on Contaminants in Foods
CCEXEC	Executive Committee of the Codex Alimentarius Commission
CCFAC	Codex Committee on Food Additives and Contaminants
CCNMW	Codex Committee on Natural Mineral Waters
CCFFP	Codex Committee on Fish and Fishery Products
CL	Circular Letter
COP	Code of Practice
CRD	Conference Room Document
DON	Deoxynivalenol
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agriculture Practice
GMP	Good Manufacture Practice
GEMS	Global Environment Monitoring System
GSCTF	General Standard for Contaminants and Toxins in Foods
GLs	Guideline Levels
HACCP	Hazard Analysis and Critical Control Point
HVP	Hydrolyzed Vegetable Protein
JECFA	Joint FAO/WHO Expert Committee on Food Additives
MLs	Maximum levels
OTA	Ochratoxin A
PAH	Polycyclic Aromatic Hydrocarbons
PTWI	Provisional Tolerable Weekly Intake
WHO	World Health Organization

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INTRODUCTION

1. The Second Session of the Codex Committee on Contaminants in Foods was held in The Hague, The Netherlands, from 31 March – 4 April 2008, at the kind invitation of the Government of The Netherlands. Mr Ger de Peuter, the Executive Board's Office, Ministry of Agriculture, Nature and Food Quality of The Netherlands, chaired the Session. The Session was attended by 241 delegates representing 63 Member Countries, one Member Organization, and 19 International Organizations. The List of Participants is attached to this report as Appendix I.

OPENING OF THE SESSION

2. Ms Annemie Burger, the Director General of Ministry of Agriculture, Nature and Food Quality of The Netherlands, opened the session and welcomed the participants on behalf of the Government of The Netherlands.

Division of Competence

3. The Committee noted the division of competence between the European Community 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)¹

4. The Committee agreed that Items 6 and 7 be discussed in reverse order, to discuss Item 11 in a more logical order and that some other Items be rearranged and agreed to the following order of the Agenda Items: Item 1, 2, 3, 4, 5, 7, 6, 11 (b) and 11(d), 11(a), 11(e), 11(c), 10, 8, 12, 9, 14, 13(a), 13(b), 15, 16, and 17 as a logical order for discussion.

5. The Committee agreed to discuss a proposal on differences between primary and processed products in relation to the use of concentration factors in those concentrated and re-diluted products (proposed by Morocco) and ethyl carbamate in alcoholic beverages (proposed by Germany) under Item 15 (other business and future work).

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. It was agreed that this working group would also consider the following new substances: fumonisins (proposed by Cuba), benzene in soft drinks (proposed by Nigeria), mycotoxins in sorghum (proposed by Sudan) and substances raised under relevant Items, where necessary, with the understanding that its report would be considered under Item 14.

8. The Committee further agreed to establish an in-session physical working group to revise the Proposed Draft Code Practice for the Reduction of Contamination of Food with Polycyclic Aromatic Hydrocarbons (PAH) from Smoking and Direct Drying Processes as presented in CX/CF 08/2/9, taking into account the comments submitted to the present session with a view to facilitating the discussion under Item 9.

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

9. The Committee noted that most information presented in document CX/CF 08/2/2 was for information purposes.

10. In particular, the Committee commented and/or made decisions on the following matters:

¹ CX/CF 08/2/1-rev.1, CRD 13 (comments of Brazil), CRD 14 (comments of Nigeria)

² CX/CF 08/2/2, CRD 4 (comments of Cuba), CRD 5 (comments of European Community), CRD 11 (comments of Indonesia)

Proposed draft provisions applied to contaminants in the “Relations between Commodity Committees and General Committees”

11. The Committee considered the proposed draft provisions applied to contaminants in the “Relations between Commodity Committees and General Committees, prepared by the Secretariat as presented in Annex I to CX/CF 08/8/2.

12. Some delegations were of the view that the proposed texts should align with the language contained in the provision applied to food additives in the Relations between Commodity Committee and General Committees since those two committees should have the same role for endorsement.

13. It was also proposed to include additional texts related to “Format of Codex Commodity Standards”.

14. The Committee amended the proposed provision taking into account the comments above and agreed to send it to the forthcoming Executive Committee for consideration (see Appendix II).

15. The Committee was informed that the Secretariat was in the process to provide a draft revision on the “Relation between Commodity Committees and General Committees” for consideration by the Executive Committee, with a view to removing the texts on formats and including them into the “Format of Codex Commodity Standards”.

Elaboration of new standards and related texts

16. With regard to project documents for new work, the Committee was informed that the 30th Session of the Commission had noted that some project documents submitted in the past years were of low quality and not addressing all criteria with ample explanation/justification and had requested that in the future all project documents should be prepared correctly in accordance with the provisions in the Procedural Manual.

Strategic Plan 2008-2013 of the Codex Alimentarius Commission

17. The Committee noted the Activities 1.1, 2.2, 2.3, 2.5, 3.3, 4.1, 5.5 of the Strategic Plan 2008-2013, and in particular noted that the assignments given in relation to the implementation of the Strategic Plan were ongoing work in the Committee and that committee-specific decision making and priority setting criteria had been developed and were currently being implemented by the Committee.

Review of Codex Committee Structure and Mandates of Codex Committees and Task Forces - Proposal 3 (interval of meetings) and Proposal 4 (duration of meetings)

18. The Committee agreed that the current duration and interval of meetings of the Committee were appropriate, especially given the fact that this was a new committee and concerns were raised that matters would not be finalized as quickly as they should be if a longer interval was applied. The Committee suggested that inter-session working groups should work in an effective way to ensure that all working documents be provided in principle two months in advance to each plenary session as required in the Rule XI of the Rule of Procedure.

Draft Standard for Bitter Cassava

19. The Committee considered the criterion based on the level of hydrogen cyanide to distinguish bitter from sweet cassava and considered the need for a re-evaluation of cyanogenic glycosides by JECFA. The Committee noted that the levels in the draft Standard applied to differentiate bitter from sweet cassava were not to be seen as safety levels for endorsement by the Committee.

20. The Committee noted that potential excessive intake of cyanogenic glycosides, mainly from cassava but also from other products, was assessed at the 39th Meeting of JECFA (1992) and that, due to lack of quantitative toxicological and epidemiological information, JECFA could not conclude on a safety level of intake for this natural occurring toxicant. However, JECFA had also concluded that a level of up to 10 mg/kg hydrogen cyanide in the Standard for Edible Cassava Flour (CODEX STAN 176-1989) was not associated with acute toxicity.

21. The Representative of FAO informed the Committee that there were a number of FAO publications addressing good agricultural and manufacturing practices for the growing and processing of cassava, including other ongoing work in this field, to assist countries with the cultivation, processing and handling of this product.

22. The Committee agreed to refer this issue to the in-session physical working group on Priority List of Contaminants and Naturally Occurring Toxicants for Evaluation by JECFA to determine the availability of scientific data to perform the risk assessment of cyanogenic glycosides in cassava (see Item 14).

Proposed draft amendments to Section 3.2 of the Codex Standard for Natural Mineral Waters (referred by the Codex Committee on Natural Mineral Waters)

23. The Committee considered the proposed draft amendments to Section 3.2 “Health-Related Limits for Certain Substances” of the Codex Standard for Natural Mineral Waters, referred by the 8th Session of the Codex Committee on Natural Mineral Waters (CCNMW).

24. With regard to borate / boron, the Representative of WHO pointed out that there was a significant difference between the proposed level of 5mg/l in Section 3.2 and the level of 0.5 mg/l in the WHO Guidelines on Drinking Water Quality and informed the Committee that the WHO Guideline value was currently under revision and the level of 0.5 mg/l would be revised in late 2009.

25. The Delegations of Chile and Morocco opposed to endorse Section 3.2 due to the discrepancy of the level for boron and some other substances. The Delegation of Switzerland as Chairperson of the Committee on Natural Mineral Waters clarified that some discrepancy between Section 3.2 and WHO Guidelines was due to the specific characteristics of natural mineral water such as the underground origin and that some substances would be reviewed when new scientific evidence became available in future.

26. The Committee also considered whether the health-related provision in Section 3.2 should be included in Schedule I of the General Standard for Contaminants and Toxins in Foods (GSCTF). It was pointed out that iron, zinc and copper had been considered as quality factors rather than safety factors and therefore the levels for those substances had been currently not included in Schedule I of the GSCTF. It was noted that some delegations believed that the level for copper was based on both safety and quality parameters of mineral water.

27. After some discussion, the Committee endorsed Section 3.2. The Delegations of Chile and Morocco expressed their reservation to this decision. The Committee decided to postpone the decision on inclusion of those substances in the GSCTF.

Draft Standard for Live and Raw Bivalve Molluscs (elaborated by the 29th Session of the Codex Committee on Fish and Fishery Products)

28. The Committee discussed the endorsement of the levels for marine biotoxins as proposed by the Committee on Fish and Fishery Products (CCFFP).

29. The Representative of WHO, speaking on behalf of FAO and WHO, explained that an FAO/IOC/WHO Expert Consultation had been held at the request of the CCFFP to provide scientific advice on marine biotoxins and that it had made several proposals for acute reference doses and some maximum levels for the various marine biotoxins which had been presented to the CCFFP. The Representative however noted that the levels proposed by the CCFFP were different to those proposed by the Expert Consultation and expressed concern that the current proposed levels could lead to exceedance of the acute reference dose for several marine biotoxins at normal consumption levels. The Representative also expressed the view that further review of the proposed levels would be necessary, but that data may currently be limited.

30. The Delegation of the European Community supported endorsement of the proposed levels and their inclusion in the General Standard for Contaminants and Toxins in Foods (GSCTF). Some delegations were of the view that it would be difficult to endorse the levels without some understanding on how the levels had been reached in the CCFFP and supported the concern of the WHO with regard to potentially high exposure to biotoxins. The Delegation of Japan, while noting that the Expert Consultation had been unable to complete a risk assessment on brevetoxins due to the lack of sufficient data, requested clarification on how the CCFFP had set a level for this biotoxin. In reply, it was clarified that the CCFFP had agreed to the level of 200 Mouse Units/kg in view of the findings of the Expert Consultation as well as the knowledge resulting from the existing history of regulatory programmes and the absence of human illness in commercially harvested shellfish where these programmes were implemented.

31. After some discussion the Committee agreed to provisionally endorse the proposed levels, with the recommendation that the levels would require complete review in the coming few years with the view to revising these levels where necessary, when more data became available.

MATTERS OF INTEREST ARISING FROM FAO, WHO AND OTHER INTERNATIONAL INTERGOVERNMENTAL ORGANIZATIONS (Agenda Item 3)³

32. The Representatives of FAO and WHO, referring to document CX/CF 08/2/3 rev.1, informed the Committee of activities undertaken by FAO and WHO on scientific advice to Codex and Member countries, as well as other activities which are of interest of the Committee.

33. The Representative of FAO, speaking on behalf of FAO and WHO, highlighted that the recent increase in requests from member states of FAO and WHO and Codex subsidiary bodies for scientific advice related to food safety required more resources to be mobilised so as to facilitate the provision of scientific advice particularly among others in the area of new and emerging issues. The Representative urged member countries to contribute to the Global Initiative for Food Safety Related Scientific Advice (GIFSA) currently established by FAO and WHO to facilitate collecting extra budgetary resources from members and civil society to maintain adequate budgetary level for the provision of scientific advice.

34. The Representative further informed about the progress of the planning to convene an expert consultation on the risk and benefit of fish consumption, and in particular the intention of the organizations to focus on the risks and benefits in the most vulnerable groups of the population, pre- and post-natal brain development of children up to the age where the brain is fully developed. The risk scenarios would cover methylmercury, dioxin and dioxin-like PCBs and the benefits of fish consumption would include effects of omega-3 fatty acids, amino acids, vitamins, minerals, trace elements and possibly other nutrients. The expert consultation is now planned for 2009, but adequate funding has not yet been secured for this activity.

35. The Representative of WHO informed the Committee of training courses on total diet studies that were planned for 2008 in Hong Kong and Brazil⁴. The Representative encouraged delegates to contact WHO to become participants in a global survey of human milk, which was particularly useful for assessing exposure to difficult and/or expensive analytes, such as dioxins and dibenofurans⁵.

36. It was also informed that the revised International Health Regulations which were legally binding to Member States of WHO came into force in June 2007 and that it required mandatory reporting of public health incidents of international significance to WHO through INFOSAN⁶ and that a High-level International Forum on Food Safety was held in Beijing, 26 and 27 November 2007 and the Beijing Declaration on Food Safety was adopted⁷.

37. The Representative of IAEA, referring to document CX/CF 08/2/3-Add.1, informed of its ongoing coordinated research project on Applications of Radiotracer and Radioassay Technologies to Seafood Safety Risk Analysis. The Representative highlighted that the project was focusing on generating data on cadmium in oysters, scallops and cephalopods, including natural background contamination and exposures related to specific edible tissues, on harmful algal bloom paralytic shellfish poisoning toxin (PSP) and on ciguatoxin fish poisoning (CFP).

MATTERS OF INTEREST OF THE 68TH MEETING OF THE JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES (JECFA) (Agenda Item 4)⁸

38. The Representative of WHO, speaking on behalf of FAO and WHO JECFA Secretariats, informed the Committee of the outcome of the evaluations on aflatoxins and ochratoxin A, conducted by the 68th JECFA meeting.

³ CX/CF 08/2/3 Rev. 1, CX/CF 08/2/3-Add.1, CRD 4 (comments of Cuba), CRD 11 (comments of Indonesia)

⁴ <http://www.who.int/foodsafety/chem/gems/en/index3.html>.

⁵ <http://www.who.int/foodsafety/chem/pops/en/index.html>.

⁶ http://www.who.int/foodsafety/fs_management/infosan/en/index.html

⁷ http://www.who.int/foodsafety/fs_management/meetings/forum07/en/index.html.

⁸ CX/CF 08/2/4

Aflatoxins

39. JECFA evaluated the impact of several hypothetical Maximum Levels for aflatoxins in almonds, Brazil nuts, hazelnuts pistachios and dried figs, and estimated contribution to total aflatoxin intake from these foods. Over 100 000 data points were considered and JECFA decided to base its analysis on the impact of various Maximum Levels on data from producing countries in order to have a more representative picture. For only 5 of the 13 GEMS/Food Consumption Cluster Diets the contribution to total aflatoxin exposure from these foods exceeded 5%, and with the exception of pistachios setting of a Maximum Level had no impact in total aflatoxin exposure. Only for pistachios an impact on exposure could be noted by setting a Maximum Level.

40. JECFA noted that the reduction of aflatoxin exposure was an important public health goal, in particular in populations who consume high amounts of potentially contaminated foods.

Ochratoxin A

41. The new data available did not give reason to change the current PTWI of 100 ng/kg bw. Moreover, the use of a Maximum Level of 5 or 20 µg/kg for cereals would be unlikely to have an impact on dietary exposure to ochratoxin A. This analysis was based mainly on European data, very few data from other regions were submitted to JECFA.

PROPOSED DRAFT REVISION OF THE PREAMBLE OF THE CODEX GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOODS (GSCTF) (Agenda Item 5)⁹

42. The Delegation of the European Community as Chairperson of the electronic working group on the Revision of the Preamble of the General Standard for Contaminants and Toxins in Foods (GSCTF) introduced document CX/CF 08/2/5. The Delegation recalled that the task of the electronic working group was to extract the procedural provisions from the Preamble of the GSCTF and to include them in the Procedural Manual; to revise the “Complementary food categorization system for the GSCTF”; to update the provisions on the Procedural Manual as regards the contaminants; and to align the language of the Preamble with the language contained in the Procedural Manual.

43. The Delegation explained that the electronic working group had agreed to consider the revisions of the Preamble taking into account that texts or provisions applying to the Codex Alimentarius Commission and its subsidiary bodies should be part of the Procedural Manual and that texts or provisions relevant for Codex members for example, provisions for contaminants in the GSCTF should be published as part of the Codex Alimentarius. The Delegation pointed out that due to diverging views on the retention of the procedural provisions for Codex in the Preamble in addition to their inclusion in the Procedural Manual, these texts had been retained for consideration by the Committee to decide whether those texts be deleted from the Preamble. It was also highlighted that the electronic working group had some discussion on feed and how to better integrate feed aspects within the current GSCTF or to eventually explore the possibility to elaborate a specific general standard for contaminants and toxins in feeds, noting that the scope of the GSCTF deals with foods and feeds of public health relevance, however, no changes were made to the Preamble. The Delegation further indicated that when maximum levels were set for commodities which could be used for human consumption as well as for animal feeding, it should be specified to what intended use the maximum level was related to and that it might be appropriate to specify, in specific instances, the intended use of the commodities for which a maximum level or guideline level had already been established in Schedule I.

44. With regard to the retention of texts in the Preamble that related to procedural matters, the Committee recalled that the new work approved by the 29th Session of the Commission was based on a Project Document submitted by the 38th Session of the Codex Committee on Food Additives and Contaminants (CCFAC)¹⁰ which clearly stated that the purpose of the work was, amongst others, to revise the Preamble by deleting the procedural provisions that applied to Codex for inclusion in the Procedural Manual.

⁹ CX/CF 08/2/5, CX/CF 08/2/5-Add.1 (comments of Brazil, Cuba, European Community, Japan, Morocco and The Netherlands), CX/CF 08/2/5-Add.2 (Preliminary draft of the revised Complementary Food Categorization System for the GSCTF), CRD 4 (comments of Cuba), CRD 8 (comments of Philippines), CRD 9 (comments of India), CRD 11 (comments Indonesia), CRD 12 (comments of Thailand)

¹⁰ ALINORM 06/29/12, Appendix XIX

45. The Committee agreed to first consider the proposed draft revision of the Preamble of the GSCTF as presented in Appendix I of document CX/CF 08/2/5 and its Appendix II (a proposed draft Annex to the “Risk Analysis Principles Applied by the Codex Committee on Food Additives and the Codex Committee on Contaminants in Foods”) section by section. Discussion held and decisions made are summarised below.

Title

46. The Committee agreed to amend the title to include reference to feeds in accordance with the scope.

1.2.2 Contaminant

47. The Committee did not agree to the proposed amendments to the paragraph relating to the definition for contaminants noting that the definition had been taken from the Procedural Manual and that any changes in the Preamble would also require amendments to the definition in the Procedural Manual.

48. The Committee agreed to amend bullet 1) to refer to food safety to emphasize that the Committee on Contaminants in Foods (CCCF) deals with food safety matters rather than with quality.

49. The Committee agreed to the proposal to amend paragraph 5) to indicate that processing aids referred to were those within the terms of reference of the Committee on Food Additives.

1.2.3 Natural toxins included in this standard and 1.2.4 Maximum level and related terms

50. The Committee agreed to the proposals to amend the first and third paragraphs of section 1.2.3 and section 1.2.4.

1.3 General Principles Regarding Contaminants in Foods

51. The Committee agreed to amend the title of this section to “Principles Regarding Contaminants in Foods” in order to distinguish between those general principles and principles for establishing maximum levels in foods and feeds.

1.3.1 General

52. The Committee agreed to reorder the 1st paragraph of this section in order to emphasize the importance of food safety.

53. The Committee had considerable discussion on the amendments to the 2nd paragraph with a view to indicating that contaminant levels in foods should be based on risk assessments and be as low as reasonably achievable (ALARA) through best practice such as Good Agricultural Practice (GAP) and Good Manufacturing Practice (GMP).

54. Some delegations were of the opinion that the principle of ALARA was difficult to interpret and proposed to indicate that contaminant levels in foods should be established by consideration of risk assessments and best practice such as GAP and GMP. A Delegation expressed the view that reference to ALARA should be maintained since the levels of contaminants in foods depended not only on best practice but also on the analytical possibilities and the kind of rejection rates that are considered reasonable.

55. Another Delegation proposed that in addition to referring to best practice and risk assessments reference to ALARA should also be maintained.

56. The Committee agreed to align the 2nd indent of the 2nd paragraph with the definition for contaminant as outlined in section 1.2.2.

57. In view of the extensive discussion, the changes proposed and the considerable work still required to improve the text in plenary, it was agreed to discontinue further discussion on the document at the present Session.

Appendix II

58. It was noted that the 2nd indent in paragraph 22 should be aligned with an earlier decision to also refer to best practice and risk assessments in addition to ALARA (see paragraph 53).

59. The Delegation of The Netherlands, referring to its written comments in CX/CF 08/2/5-Add.1, proposed some amendments to paragraph 24 so as to align the information with the previous decisions made by the CCFAC that a working document be presented at each session of the Committee to provide a complete list of Codex Standards for contaminants in foods. It was clarified by another delegation that the working document, which was currently available as information document CF/2 INF/1, was to facilitate discussion related to contaminants and toxins and that in view of this, consideration should be given to either delete the paragraph from Appendix II or to revise the paragraph to better reflect the purpose of the document and its contents.

Revision of the Food Categorization System

60. The Delegation of Japan introduced document CX/CF 08/2/5-Add.2 containing a preliminary draft revised complementary food categorization system for the GSCTF. It was clarified that the preliminary draft was not considered by the electronic working group due to the lateness of the document, therefore the Delegation proposed that the Committee not discuss the document but provide guidance on the approach to be taken for further revision.

61. There was general agreement with the approach taken in the preliminary draft food categorization system. It was noted that the codification system proposed by the Delegation of Morocco could also be taken into account, where appropriate.

Status of the Proposed Draft Revision of the Preamble of the General Standard for Contaminants and Toxins in Foods (GSCTF) (N04-2006)

62. The Committee agreed to reconvene an electronic working group¹¹ led by the Delegation of the European Community open to all members and working in English only, to prepare a revised draft, including the revision of the food categorization system, for circulation at Step 3 for comments and consideration by the next session of the Committee. The electronic working group should take into account the revisions agreed by the Committee at the present Session and written comments received. The terms of reference of the working group was amended to include consideration on how to integrate feeds into the Preamble.

DRAFT MAXIMUM LEVEL FOR 3-MCPD IN LIQUID CONDIMENTS CONTAINING ACID-HYDROLYZED VEGETABLE PROTEINS (ACID-HVPS) (EXCLUDING NATURALLY FERMENTED SOY SAUCE) (Agenda Item 6)¹²

63. The Committee considered the draft Maximum Level of 0.4 mg/kg of 3-MCPD in liquid condiments containing acid-hydrolyzed vegetable proteins (excluding naturally fermented soy sauce).

64. The Delegation of the European Community recalled that, based on the outcome of the 67th JECFA Meeting, as well as data submitted and discussion held at previous sessions of the Committee, the Delegation could consider supporting a maximum level of 0.4 mg/kg. The Delegation however stated that more time would be needed to evaluate the outcome of new scientific data on exposure to 3-MCPD associated with consumption of other products e.g. vegetable oils and fats containing 3-MCPD esters. As these foods were used as food ingredients and contributed to the overall intake of this contaminant, the Delegation proposed to defer the adoption of the draft maximum level until the next session of the Committee to allow for more time to fully evaluate the new data vis-à-vis the potential to exceeding the PTWI established by JECFA. The Delegation stated that if the draft Maximum Level was adopted by the Commission, the European Community would not align the EC legislation with the Codex Maximum Level until a full assessment of the recent and emerging scientific evidence in relation to exposure to 3-MCPD esters in foodstuff have been performed.

¹¹ Australia, Belgium, Brazil, China, Finland, France, India, Italy, Japan, Kenya, Malaysia, Morocco, The Netherlands, New Zealand, Philippines, Poland, Switzerland, Thailand, Tunisia, Turkey, United Kingdom, United States of America, CIAA, IADSA and ICBA expressed their willingness to participate in the electronic working group.

¹² ALINORM 07/30/41-Appendix X; CX/CF 08/2/6 (comments of Brazil, Cuba, Japan, Uruguay, EUVEPRO and IHPC); CRD 3 (comments of Kenya); CRD 4 (comments of Cuba); CRD 8 (comments of Philippines) and CRD 12 (comments of Thailand).

65. The Representative of WHO, speaking on behalf of FAO and WHO JECFA Secretariats, informed that 3-MCPD had been comprehensively re-evaluated at its 67th Meeting by including products other than soy sauce and sauces from acid-HVPs that might contribute to the overall intake of this contaminant and concluded that the main source of 3-MCPD contamination continue to be soy sauce while contribution from other foods to the total dietary intake of 3-MCPD was very low (see Item 14). The Representative also noted that vegetable oils were not considered as staple foods.

66. A number of delegations supported the adoption of the draft maximum level of 0.4 mg/kg which was technically achievable and reduced exposure to 3-MCPD containing products. Other delegations pointed out that the draft level did not lead to exceeding the PTWI established by JECFA including those high-level consumers of soy sauce and related products. Those delegations were of the view that ongoing research on exposure to foods other than those evaluated by JECFA should not preclude the advancement of the draft maximum level in the Codex Step Procedure and that a re-evaluation of 3-MCPD can be examined in the future based on new data available to perform the risk assessment. Another Delegation stated that the implementation of the Code of Practice would allow for consideration of a lower level of 3-MCPD in soy sauce in the future, when data became available (see Item 7).

Status of the Draft Maximum Level for 3-MCPD in Liquid Condiments containing Acid-Hydrolyzed Vegetable Proteins (acid-HVPs) (excluding naturally fermented soy sauce) (N08-2004)

67. The Committee agreed to forward the Draft Maximum Level of 0.4 mg/kg for 3-MCPD in Liquid Condiments containing Acid-hydrolyzed Vegetable Proteins (excluding naturally fermented soy sauce) to the 31st Session of the Codex Alimentarius Commission for adoption at Step 8 and consequent inclusion in the General Standard for Contaminants and Toxins in Foods (see Appendix III).

68. The Delegations of European Community, Norway and Switzerland expressed their reservation to this decision.

DRAFT CODE OF PRACTICE FOR THE REDUCTION OF 3-MONOCHLOROPROPANE-1,2-DIOL (3-MCPD) DURING THE PRODUCTION OF ACID HYDROLYZED VEGETABLE PROTEINS (ACID-HVPS) AND PRODUCTS THAT CONTAIN ACID-HVPS (Agenda Item 7)¹³

69. The Committee considered the draft Code of Practice as contained in Appendix XI to ALINORM 07/30/41. In view of the finalization of the Code, the Committee made a number of general and specific changes to align the format language of the Code of Practice with those used in Codex as follows:

70. The Committee considered deletion of scientific references in the document. It recalled that the 38th Session of CCFAC noted a request to use scientific references in preparing discussion papers and codes of practice. It had been acknowledged that scientific references should not be part of the final document when it was adopted at Step 8 but could be available as useful information for discussion. The Committee noted that inclusion of scientific references such as names of persons, specific regional/national legislations and other sources of information (e.g. website address) in the final Codex texts should be avoided as much as possible as scientific facts would become outdated, while Codex texts, once adopted, should remain relevant for some time and replacing or updating scientific references regularly could be difficult. In addition, since Codex texts have certain status in the WTO context, questions may arise as to the legal status of these reference material included in Codex texts. The Committee also noted that all working documents for Codex meetings were available on the Codex website and could thus be traced back for further consultation as per the scientific basis used for the development of Codex documents.

71. Considering the above, the Committee agreed to delete the scientific references throughout the Code of Practice. The Delegations of Denmark and Poland expressed their concern to this decision.

72. The Committee also considered other general adjustments. It agreed to delete or amend some paragraphs in view of the deletion of the scientific references (paragraphs 6, 8, 9, 10 and 11) and introduce a new Section 2 (Scope) incorporating language from paragraphs 1 and 11.

¹³ ALINORM 07/30/41-Appendix XI; CX/CF 08/2/7 (comments of Cuba, European Community, Japan, Uruguay, AIIBP/FAIBP and IHPC); CRD 3 (comments of Kenya); CRD 4 (comments of Cuba); CRD 10 (comments of Malaysia); CRD 11 (comments of Indonesia); CRD 12 (comments of Thailand).

Status of the Draft Code of Practice for the Reduction of 3-Monochloropropane-1,2-DIOL (3-MCPD) during the Production of Acid Hydrolyzed Vegetable Proteins (acid-HVPs) and Products that contain acid-HVPs (N09-2005)

73. The Committee agreed to forward the Draft Code of Practice to the 31st Session of the Codex Alimentarius Commission for adoption at Step 8 (see Appendix IV).

PROPOSED DRAFT CODE OF PRACTICE FOR THE REDUCTION OF ACRYLAMIDE IN FOOD (N06-2006) (at Step 3) (Agenda Item 8)¹⁴

74. The Committee recalled that its First Session had agreed to return the Proposed Draft Code of Practice for the Reduction of Acrylamide in Food for redrafting by an electronic working group, chaired by the United States of America and the United Kingdom¹⁵.

75. The Delegation of the United Kingdom, speaking as co-Chairperson of the electronic working group, introduced document CX/CF 08/2/8. It was highlighted that the focus of the document was mainly on foods produced from potatoes and cereals reflecting their importance in terms of dietary exposure to acrylamide.

General Remarks

76. The Delegation of Switzerland, referring to its written comments in CRD 6, expressed the opinion that the Proposed Draft Code of Practice did not offer prospects of substantial reduction of acrylamide for foods derived from potatoes and that the proposal for setting a high sugar limit could encourage the use of potatoes with high sugar content which would be inappropriate for frying or roasting purposes.

77. One delegation stated that an occasional consumption of fries, crisps, crackers would not add much to the overall dietary exposure so that in order for the Code of Practice to be more useful, this Code of Practice should cover broader diet types.

78. The Committee considered the document paragraph by paragraph. Discussion held and decisions made to amend the text are as follows.

Title

79. The Committee did not agree to change the title to reflect that the Code of Practice at this point mainly covered potato products, since the title was of a general nature and could allow the Code of Practice to be revised at a later stage to include other types of products at risk of high acrylamide formation.

Introduction

80. The Committee agreed to include in paragraph 1 “roasting, toasting and grilling” as further examples of high temperature cooking.

81. Paragraph 3 was amended to clarify that the full extent of acrylamide present throughout the diet remains unclear.

Scope

82. It was agreed to revise paragraph 4 to indicate who the Code of Practice was aimed at and to include this in a new section “scope”. In addition, it was agreed to add a new paragraph to explain that as technology and data for the mitigation of acrylamide formation in other products became available, the Code of Practice would be updated accordingly.

Toxicology

83. Discussion was held on the need to retain the section “toxicology” in the Code of Practice noting that such information was already widely available and was not necessary in the final Code. It was agreed to transfer the section on toxicology to an Annex.

¹⁴ CX/CF 08/2/8, CX/CF 08/2/8 Add.1 (comments of Brazil, Japan, and CIAA), CX/CF 08/2/8 Add. 2 (comments of the European Community and Cuba), CRD 6 (comments of Switzerland), CRD 9 (comments of India), CRD 11 (comments of Indonesia).

¹⁵ ALINORM 07/30/41, para. 97

General Considerations and Constraints in Developing Preventative Measures

84. Bullets iii, iv, v, vi, vii were transferred to relevant paragraphs of the section on “food processing and heating” as more appropriate.

Recommended Practices to Industry for the Manufacture of Potato Products (e.g. French Fries, Potato Crisps, Potato Snacks)

Mitigation Measures

85. It was agreed to indicate that the products mentioned in the title of this section were only examples.

86. In the box on types of potatoes to be used as raw material, some discussion was held on whether the target level of 0.3% for reducing sugars should be lowered to 0.03% for potato crisps in order to decrease acrylamide production. It was clarified that the level of 0.3% was currently achievable. The Committee therefore agreed to retain the target level of 0.3%.

87. The Committee did not agree to change the storage temperature for potatoes to not lower than 9 °C for short-term storage and not lower than 7 °C for storage over several months. It was noted that additional measures would then be needed to prevent sprout formation at temperatures higher than 6 °C.

88. The Committee did not agree with the proposal to include cassava flour as an example of other ingredients that could be used to replace potato in potato-based snacks. It was noted that the example was merely for illustrative purposes and therefore cassava was not necessarily excluded from the ingredients used in these products.

Raw materials

89. Bullet iv was amended to clarify that the decision to recondition stored potatoes should be based on results of fry testing.

Control/addition of other ingredients

90. Paragraph 23 was amended to clarify that screening of all incoming lots should only be done where feasible.

91. Paragraph 24 was amended to allow more flexibility with regard to the use of other ingredients to partially replace some of the potato.

Recommended practices to industry for the manufacture of cereal based products

Mitigation measures

92. With regard to breakfast cereals, it was agreed to indicate that consideration should be given not only on the kinds of ingredients to be added to these products, but also where these were necessary especially if they were in a form that potentially could add significant levels of acrylamide.

Control/addition of other ingredients

93. The first paragraph in the section on control/addition of other ingredients was amended to indicate that when the use of different types of flours of varying asparagine content was being considered, the choice should be balanced between nutritional value and the minimization of acrylamide.

Consumer practice

94. The section on consumer practices was amended to indicate that industry should provide advice to consumers on the appropriate preparation and handling measures to limit acrylamide formation in products, while acknowledging that national authorities were the key role-players in providing advice to consumers.

Status of the Proposed Draft Code of Practice for the Reduction of Acrylamide in Food (N06-2006)

95. The Committee agreed to forward the Proposed Draft Code of Practice to the 31st Session of the Codex Alimentarius Commission for adoption at Step 5 (see Appendix V).

PROPOSED DRAFT CODE OF PRACTICE FOR THE REDUCTION OF CONTAMINATION OF FOOD WITH POLYCYCLIC AROMATIC HYDROCARBONS (PAH) FROM SMOKING AND DIRECT DRYING PROCESS (Agenda Item 9)¹⁶

96. The Delegation of Denmark presented the revised Proposed Draft Code of Practice as presented in CRD 15, prepared by the in-session physical working group¹⁷. As Chairperson of the in-session physical working group, the Delegation highlighted the main changes introduced based on the written comments submitted and those provided by members of the in-session physical working group.

97. The Committee considered the document Section by Section and, in addition to editorial and other changes of organizational and structural nature, agreed on the following amendments:

98. Paragraph numbers and Appendices indicated below in this report correspond to those in the Proposed Draft Code of Practice as presented in CRD 15.

Introduction

99. The reference to the JECFA Meeting evaluating PAHs was moved from paragraph 5 to paragraph 2 as more appropriate. In addition, the recommendation to keep the content of these contaminants as low as reasonably achievable was deleted from paragraph 5. In paragraph 4, the term “fields” was corrected to “fume”.

Definitions

100. In paragraphs:

- 16 - the reference to “closed system” was removed as combustion of gas in indirect drying process not always required closed systems as long as the gas did not get in contact with the food.
- 17 - the definition of “Hazard Analysis” was replaced with that of “HACCP” contained in the Annex on Hazard Analysis and Critical Control Point System and Guidelines for its Application (Recommended International Code of Practice: General Principles for Food Hygiene – CAC/RCP 1-1969).
- 18 – coconut shell was added as an example of plant materials. It was indicated that coconut shell was a better fuel than coconut husks.

Smoking and Drying Process – General Remarks

101. After paragraph 34 a new provision was added to indicate that application of the HACCP System was one of the tools available for reduction of PAHs contamination in relevant foods and to have a general approach to the use of this System throughout the Code.

Smoking Process – Processing

102. The reference to the use of ultraviolet radiation was removed from paragraph 48 as the safety of UV treatment had not yet been proven i.e. use of this UV radiation might lead to changes of PAHs in other toxicants.

Smoking Process – Post smoking treatment

103. The last part of paragraph 52 was moved to paragraph 47 as it was more related to smoking processes as opposed to a post smoking treatment.

¹⁶ CX/CF 08/2/9; CX/CF 08/2/9-Add.1 (comments of Brazil and Japan); CX/CF 08/2/9-Add.2 (comments of Cuba and European Community); CRD 8 (comments of Philippines); CRD 12 (comments of Thailand) and CRD 15 (Revised Proposed Draft Code of Practice for the Reduction of Contamination of Food with Polycyclic Aromatic Hydrocarbons (PAHs) from Smoking and Direct Drying Processes, prepared by the in-session physical working group).

¹⁷ Led by Denmark. Australia, Austria, Belgium, Brazil, European Community, France, Germany, Japan, Latvia, Netherlands, Norway, Poland, Sweden, Thailand, United States of America, CIAA and IFT participated in the in-session physical working group.

Important Points and Recommendations – Foodstuff smoked

104. In paragraph 58, bullet (a) was amended to refer to the food and smoke chamber for consistency with corresponding provisions in paragraph 39. In addition, bullet (b) was amended to acknowledge that composition and chemical properties of the food might lead to different level of PAH contamination in the final product.

Important points to consider and recommendations – Smoked Foods

105. An amendment was made to indicate that the application of HACCP was included to reinforce the use of this system to reduce PAHs and to ensure consistency as per the approach taken in relation to HACCP across the document. Along these lines, paragraph 80 was amended accordingly.

Direct Drying Process other than Sun Drying – Foodstuff dried

106. In paragraph 70, coconut was removed as an example of food that can undergo this process.

Direct Drying Process, other than Sun Drying - Direct Drying Process

107. In paragraph 72, an additional example of source of PAH contamination was inserted e.g. drying oil seeds prior to oil extraction.

Appendices I to IV

108. The Committee made some adjustment in Appendices I and II. Appendices III to IV remained unchanged. In light of the discussion and decision taken under Agenda Item 7 that scientific references should not be part of the final Code of Practice, the Committee agreed to retain Appendices I to IV with a view to their revision or deletion from the Code of Practice.

Status of the Proposed Draft Code of Practice for the Reduction of Contamination of Food with Polycyclic Aromatic Hydrocarbons (PAHs) from Smoking and Direct Drying Process (N07-2006)

109. The Committee agreed to forward the Proposed Draft Code of Practice to the 31st Session of the Codex Alimentarius Commission for adoption at Step 5 (See Appendix VI).

DRAFT MAXIMUM LEVEL FOR OCHRATOXIN A IN WHEAT, BARLEY AND RYE (Agenda Item 10)¹⁸

110. The last session of the Committee had agreed to retain the Draft Maximum Level of 5 µg/kg for ochratoxin A in raw wheat, barley and rye at Step 7 and to consider it again at its following session in light of the outcome of the re-evaluation of ochratoxin A (OTA) by the 68th JECFA Meeting (see Item 4).

111. The Delegation of India requested that the maximum level be set at 20 µg/kg and opposed the use of the ALARA Principle. The Representative of WHO, speaking on behalf of FAO and WHO JECFA Secretariats clarified that the impact assessment of different maximum levels of 5 and 20 µg/kg showed little effect when considering mean contamination and exposure levels, however, if higher percentiles were considered, a more pronounced effect could be observed. A Delegation stated that the level of 5 µg/kg was reasonably achievable by implementing the Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals (CAC/RCP 51-2003), which contains Annexes on various mycotoxins including ochratoxin A. In the opinion of this Delegation the reason was that the presence of ochratoxin A was mainly a storage problem of these commodities.

Status of the Draft Maximum Level for Ochratoxin A in Raw Wheat, Barley and Rye

112. The Committee agreed to forward the Draft Maximum Level of 5 µg/kg for Ochratoxin A in Raw Wheat, Barley and Rye to the 31st Session of the Codex Alimentarius Commission for adoption at Step 8 and subsequent inclusion in the General Standard for Contaminants and Toxins in Foods (see Appendix VII). The Delegation of India expressed its reservation to this decision.

¹⁸ ALINORM 07/30/41-Appendix VI; CRD 4 (comments of Cuba); CRD 5 (comments of the European Community); CRD 9 (comments of India); and CRD 12 (comments of Thailand).

DRAFT MAXIMUM LEVEL FOR TOTAL AFLATOXINS IN ALMONDS, HAZELNUTS AND PISTACHIOS “FOR FURTHER PROCESSING” (Agenda Item 11a)**DRAFT MAXIMUM LEVEL FOR TOTAL AFLATOXINS IN ALMONDS, HAZELNUTS AND PISTACHIOS “READY-TO-EAT” (Agenda Item 11b)****DISCUSSION PAPER ON MAXIMUM LEVELS FOR TOTAL AFLATOXINS IN “READY-TO-EAT” ALMONDS, HAZELNUTS AND PISTACHIOS (Agenda Item 11d)¹⁹**

113. The Committee recalled that it had been agreed at its First Session to hold the Draft Maximum Levels of 15 µg/kg for total aflatoxins in almonds, hazelnuts and pistachios “for further processing” and 8 µg/kg for total aflatoxins in those nuts “ready-to-eat” at Step 7.

114. In view of the earlier decision to reorder discussion on Item 11 (see Item 1) and the fact that the discussion paper on maximum levels for total aflatoxins needed to be taken into account for the discussion on the draft maximum levels for total aflatoxins in almonds, hazelnuts and pistachios “ready-to-eat”, the Committee agreed to consider Items 11a, 11b and 11d together.

115. The Delegation of the European Community as Chairperson of the electronic working group introduced the discussion paper and recalled the decision of the First Session of the Committee that the discussion paper be revised and that it could provide information for discussion on the maximum levels for almonds, hazelnuts and pistachios “ready-to-eat” and those “for further processing”.

116. It was explained that the paper dealt with detailed data on distribution of aflatoxins between lots; consumer health risk assessment of different levels of aflatoxins in “ready-to-eat” tree nuts; effects of codes of practice; and terminology of “ready-to-eat” and “for further processing”.

117. The Committee was informed of the conclusions of JECFA that enforcing an Maximum Level of 15, 10, 8 or 4 µg/kg would have little impact on the overall dietary exposure to aflatoxins in all five of the highest exposed population groups in the GEMS/Food Consumption Cluster Diets compared to setting an Maximum Level of 20 µg/kg and that reduction of aflatoxins was a public health goal; that GMPs, GAPs and COPs assist in reducing the presence of aflatoxins in raw nuts; and that definitions for “consumer-ready nuts” or “ready-to-eat” and “nuts for further processing” had been proposed. It was indicated that one delegation of the working group had disagreed with the term for “ready-to-eat” since roasting was required for pistachios and that the term could be misleading to consumers and had proposed using “ready-for-roasting”.

118. The Delegation as Chairperson of the electronic working group also explained the view of the majority of the electronic working group that the current draft maximum levels of 8 µg/kg for total aflatoxins in almonds, hazelnuts and pistachios “ready-to-eat” and 15 µg/kg for total aflatoxins in almonds, hazelnuts and pistachios “for further processing”, respectively, should be assessed in the context of the conclusion of JECFA and that it might be appropriate to discuss a slightly higher maximum level for pistachios, almonds and hazelnuts “ready-to-eat” in the context of achievability and the impact of GAP and GMP on the levels of total aflatoxins.

119. The attention of the Committee was also drawn to the fact that roasting of pistachios could result in the reduction of aflatoxins.

120. In view of the information provided the Committee proceeded to discuss the Draft Maximum Level for total aflatoxins in almonds, hazelnuts and pistachios “ready-to-eat”.

121. The Delegation of European Community noting the new information provided in the discussion paper expressed its support for the maximum level of 8 µg/kg proposed for almonds, hazelnuts and pistachios “ready-to-eat”. Several Delegations, noting the conclusion of the discussion paper that a slightly higher level could be considered, proposed a level of 10 µg/kg. The Delegation of Norway, highlighting the heterogeneity of aflatoxins in nuts and the increasing consumption of these products due to their health benefits, proposed that the level of 8 µg/kg be accepted. Some other Delegations, noting that JECFA had concluded that the setting of maximum levels between 4, 8, 10 and 15 µg/kg for total aflatoxins would have little further impact on the overall dietary exposure to total aflatoxins compared to setting a maximum level of 20 µg/kg. Those

¹⁹ ALINORM 07/30/41, Appendix VII, CX/CF 08/2/11, CRD 4 (Comments of Cuba), CRD 9 (Comments of India), CRD 7 (comments of Iran)

delegations did not support the principle of “as low as reasonably achievable” (ALARA) and proposed that the Committee consider a level of 20 µg/kg.

122. The Representative of WHO, speaking on behalf of FAO and WHO JECFA Secretariats, reiterated the earlier clarification that the impact of assessment of different Maximum Levels showed little effect when considering mean contamination and exposure levels (see Item 10). To the remark about ALARA, the Committee noted that this was an accepted principle applied to the work of Codex.

123. The Delegation of Iran referring to their written comments in CRD 7 informed the Committee that a level of 10 µg/kg would have a major negative economic impact on the trade of pistachios, that setting the level as low as possibly achievable was difficult to achieve in practice, and that the effect of roasting on levels of aflatoxins had to be taken into account and proposed that a level of 12 µg/kg be considered.

124. After discussion, it was agreed that a level of 10 µg/kg would be set for hazelnuts, almonds and pistachios “ready-to-eat”.

125. The Committee discussed the use of the definitions as proposed in the discussion paper. Noting that there was some information and evidence on the possible effects of roasting to reduce aflatoxins in pistachios, but the evidence for other nuts still needed to be provided, the Committee agreed to use the definition for “for further processing” with necessary amendments and to insert this definition and the definition for “ready-to-eat” as a footnote to the two food groups.

126. The Committee noted the offer of an Observer to provide information on the effect of roasting methods for reduction of aflatoxin levels.

Status of Draft Maximum Levels for Total Aflatoxins in almonds, hazelnuts and pistachios “For Further processing” and “Ready-to-eat”

127. The Committee agreed to the maximum level of 15 µg/kg for total aflatoxins in almonds, hazelnuts and pistachios “for further processing” and to establish a maximum level of 10 µg/kg for total aflatoxins in almonds, hazelnuts and pistachios “ready-to-eat” and to advance them to the 31st Session of the Codex Alimentarius Commission for adoption at Step 8 (see Appendix VIII).

128. The Delegation of Iran expressed its reservation to the decision for pistachios “ready-to-eat”.

PROPOSED DRAFT SAMPLING PLAN FOR AFLATOXIN IN ALMONDS, BRAZIL NUTS, HAZELNUTS AND PISTACHIOS (Agenda Item 11c)²⁰

129. The Committee recalled that the First Session of the Committee had entrusted an electronic working group led by the United States of America to redraft the sampling plan for circulation for comments at Step 3 and consideration by the present Session.

130. The Committee noted that the proposed draft sampling plan as presented in document CX/CF 08/2/10 had been developed on the basis of the draft maximum levels of 8 µg/kg for total aflatoxins in almonds, hazel nuts and pistachios “ready-to-eat” and 15 µg/kg for total aflatoxins in those nuts “for further processing”, and that following the agreement to recommend the maximum level of 10 µg/kg in almonds, hazelnuts and pistachios “ready-to-eat” (see Item 11b), technical aspects of the proposed draft sampling plan needed revision. Therefore an in-session physical working group²¹ was established to redraft the proposed draft sampling plan.

131. The Delegation of the United States of America as Chairperson of both the electronic and in-session physical working groups introduced the revised proposed draft as presented in CRD 17.

²⁰ CX/CF 08/2/10, CX/CF08/2/10-Add.1 (comments of Cuba and Iran), CRD 11 (comments of Indonesia), CRD 17 (Revised Proposed Draft Sampling Plans for Aflatoxin Contamination in Almonds, Brazil Nuts, Hazelnuts and Pistachios, prepared by the in-session physical working group)

²¹ Led by the United States of America. Australia, Austria, Brazil, European Community, Iran, Japan, The Netherlands, Norway, Turkey, United Kingdom, and INC participated in the in-session physical working group.

132. The Committee was informed that in the revised proposed draft sampling plans a sample size of 20 kg for “ready-to-eat” shelled almonds and hazelnuts and for in-shell pistachios, was recommended. The reason for in-shell pistachios rather than shelled pistachios was that most pistachios in international trade were in-shell while most almonds and hazelnuts in international trade are shelled and that the sampling statistical analysis was on a kernel basis and that pistachios contain more kernels on a unit mass basis. A sample size of 20 kg for those nuts for further processing was recommended.

133. With regard to sample number, it was reported that the in-session physical working group had agreed that a 20 kg sample for nuts “for further processing” would be tested as a single sample with the sample being required to be below the Maximum Level of 15 µg/kg. For nuts “ready-to-eat”, it was reported that considerable discussion had taken place in the working group and that one delegation had suggested that the 20 kg sample should be divided into two 10 kg sub-samples with both sub-samples being required to be below the Maximum Level of 10 µg/kg taken into account measurement uncertainties,. Other delegations were of the opinion that agreeing to a Maximum Level of 10 µg/kg but requiring that the 20 kg sample size be tested as two 10 kg sub samples with both sub samples complying with the Maxim Level was equivalent to lowering the Maximum Level to considerably less than 10 µg/kg. However, agreement was reached on proposing a sampling regime consisting of a 20 kg sample that is tested as two 10 kg sub-samples with both sub-samples being required to be below the Maximum Level of 10 µg/kg was recommended.

134. It was also reported that the in-session physical working group agreed to delete Annex IV which had been for explanatory purposes and was not part of the sampling plan.

135. The Delegation, with support from many delegations, proposed that the Committee consider the amended proposed draft sampling plans with the view to advancing it for final adoption at Step 5/8. Some other delegations were of the opinion that more time was needed to consider the document and were in favour of its advancement to Step 5 only.

Specific amendments

136. The Committee considered the amended proposed draft paragraph by paragraph and in addition to some editorial changes, made the following amendments and comments.

137. The Committee agreed to transfer the definitions in Annex I to a new section “Definitions” for consistency with other similar Codex documents and to renumber all subsequent sections.

138. In Paragraph 20, “may” was changed to “shall” for enforcement purposes.

139. Paragraph 37 was amended to indicate that after grinding, the grinder should be cleaned to prevent aflatoxin cross-contamination.

140. The Committee had some discussion on the amendment of the title to exclude reference to Brazil nuts. Noting that the sampling plans should be linked to the maximum levels for almonds pistachio and hazelnuts, but not to Brazil nuts as no Maximum Level for brazil nuts was yet established, the Committee agreed to amend the title by deleting reference to Brazil nuts, with understanding that, when Maximum Levels for Brazil nuts were established, the sampling plans would be revised to include an Annex covering these products, taking into account data on uncertainty and distribution sampling studies.

141. As a consequence, references to Brazil nuts in the section on “sampling plan design considerations” were also deleted

Status of the Proposed Draft Aflatoxin Sampling Plans for Aflatoxin Contamination in Ready-to-eat Treenuts and Treenuts Destined for Further Processing: Almonds, Hazelnuts, and Pistachios

142. The Committee agreed to advance the Proposed Draft Aflatoxin Sampling Plans for adoption by the 31st Session of the Codex Alimentarius Commission at Step 5/8 with the recommendation to omit Steps 6 and 7 (see Appendix IX).

DISCUSSION PAPER ON AFLATOXIN CONTAMINATION IN BRAZIL NUTS (Agenda Item 11e)²²

143. The Delegation of Brazil introduced document CX/CF 08/2/12 and noted that Brazil nuts could be traded worldwide for further processing (shelled and in-shell) and ready-to-eat (shelled nut) and hence recommended that maximum levels for total aflatoxins in both products be established. The Delegation further noted that data presented in this paper, including the outcome of the 68th JECFA Meeting, indicated that a maximum level for total aflatoxins in Brazil nuts ready-to-eat (shelled nut) of 20 µg/kg did not have effect on the total dietary aflatoxin exposure, was safe for consumers and had an acceptable economic impact and proposed to start new work on elaboration of Maximum Levels for total aflatoxins in Brazil nuts.

144. A question was raised with regard to the procedure to undertake new work, in particular, as to whether a project document would be necessary to elaborate Maximum Levels for contaminants, noting that in the case of contaminants and other similar chemicals e.g. pesticides, the decision to start new work or revision of maximum levels shall follow the procedures established by the Committee and endorsed by the Commission²³.

145. The Committee noted that the Preamble of the GSCTF provides the grounds for the development of Codex maximum levels for contaminants, and that proposals of new work should be accompanied by a project document, for approval by the Commission.

146. The Committee agreed to discuss a draft project document as presented in CRD 16.

147. A Delegation pointed out that maximum levels for aflatoxins should be based on the ALARA principle and to this purpose, it would be advisable to wait for the implementation of the Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Tree Nuts (CAC/RCP 59-2006) to determine what level could be practically achievable before considering the establishment of maximum levels for aflatoxins in this product. The Committee agreed to start new work on draft Maximum Levels for Total Aflatoxins in Brazil Nuts, subject to approval by the 31st Session of the Codex Alimentarius Commission, as contained in the Project Document, with an amendment (see Appendix X).

148. The Committee further agreed that an electronic working group²⁴ led by Brazil open to all members and working in English prepare a document on proposed draft Maximum Levels for Total Aflatoxins in Brazil Nuts with a view to circulation for comments at Step 3 and consideration at Step 4 by the next session of the Committee. The document should be forwarded to the Codex Secretariat by the end of 2008 for distribution.

PROPOSED DRAFT CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF AFLATOXIN CONTAMINATION IN DRIED FIGS (Agenda Item 12)²⁵

149. The Committee recalled the decision of its First Session to develop a code of practice to provide guidance on the control of aflatoxins in dried figs. The Delegation of Turkey as Chairperson of the electronic working group introduced document CX/CF 08/2/13 and explained its structure and critical points for the reduction and/or prevention of aflatoxins and that the proposed Draft Code of Practice provided guidance on measures to be taken in the production of dried figs.

150. It was highlighted that dried figs had to be produced in accordance with the Recommended International Code of Practice – General Principles of Food Hygiene (CAC/RCP 1 – 1969) and the Recommended International Code of Hygienic Practice for Dried Fruits (CAC/RCP 3 – 1969) as well as the importance of GAPs and GMPs.

151. The Committee discussed the Proposed Draft Code of Practice paragraph by paragraph. Discussion held and decisions made are as follows.

²² CX/CF 08/2/12; CRD 4 (comments of Cuba) and CRD 16 (draft Project Document on Maximum Levels for draft Maximum Levels for Total Aflatoxins in Brazil Nuts prepared by Brazil, The Netherlands and INC).

²³ Codex Alimentarius Commission, Procedural Manual, Part 2. Critical Review, para. 4.

²⁴ European Community, Turkey, United Kingdom, United States of America and INC expressed their willingness to participate in the electronic working group.

²⁵ CX/CF 08/2/13, CX/CF 08/2/13-Add.1 (comments from Brazil and Morocco), CRD 4 (comments from Cuba), CRD 11 (comments from Indonesia).

Introduction

152. The Committee agreed to include packaging as one of the production and processing steps where effective control was necessary.

153. In paragraph 7, it was agreed to replace “epidemic risk” with “aflatoxin contamination” and “risk analysis” with “information on contamination risk” for purposes of clarity and correctness. It was further agreed to amend the 2nd bullet point in section a) to indicate that sampling should reflect differences in areas, time of year, and stage from production to consumption and the 5th bullet point, to indicate that the use of labelling was important to inform consumers and handlers on storage conditions. The Committee agreed to introduce an additional bullet point to section b) to indicate that training of producers needed to include techniques on pest control, and a new section d) to indicate that related research should be encouraged.

Drying

154. The Committee agreed to refer to a water activity of 0.65 in paragraph 38 and to make this change throughout the document, where appropriate.

Transport

155. In order to reflect different practices with regard to the location of drying and processing, the Committee agreed to indicate that measures for the transportation of dried figs from farm to processor was only needed where required.

156. The last sentence of paragraph 40 was deleted since the concept was captured in the preceding sentence.

Storage

157. It was agreed to insert reference to cold storage in paragraph 46 as it was recognised that although dried figs had a low water activity and that cold storage was not necessary in all cases, that for long-term holding of these products, cold storage might be necessary.

Processing

158. A concern was raised with regard to the washing of already dried figs and the need to avoid increasing their moisture content, it was clarified that in some instances a rapid washing process was used to remove debris but that it did not negatively affect the moisture content of these products.

159. Paragraph 47 was amended in line with an earlier decision regarding the use of pest control agents in order to allow for their use during processing.

160. In paragraph 48, the sentence was amended to reflect that dried figs contaminated with aflatoxins can have a correlation with BGYF under long wave UV light, to avoid giving the impression that this correlation was complete.

161. The Committee also agreed not to refer to other mycotoxins throughout the Code of Practice, since the aim of the Code of Practice was the reduction of aflatoxins while recognising that the measures proposed could also result in the reduction of other mycotoxins such as ochratoxin A.

162. The Committee agreed to delete section 4 since it was considered inappropriate to refer to future considerations in a Code of Practice.

Status of the Proposed Draft Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Dried Figs

163. The Committee agreed to forward the Proposed Draft Code of Practice to the 31st Session of the Codex Alimentarius Commission for adoption at Step 5/8 with the recommendation to omit Steps 6 and 7 (see Appendix XI).

DISCUSSION PAPER ON OCHRATOXIN A (OTA) IN COFFEE (Agenda Item 13a)²⁶

164. The Delegation of Brazil, as Chairperson of the electronic working group, explained the main aspects of ochratoxin A (OTA) contamination in coffee addressed in document CX/CF 08/2/14.

165. The Delegation stressed the need to develop a Code of Practice which would assist countries to reduce the OTA contamination in this product as indicated in the proposed Project Document contained in CX/CF 08/2/14. An outline of a proposed draft Code of Practice for the Prevention and Reduction of Ochratoxin A Contamination in Coffee was also presented in Annex III of the same document which was based on the FAO Guidelines on the Prevention of Mould Formation in Coffee.

166. The Committee noted the concern relating to the quality of the translation of the document and reassured that due consideration would be given to ensure the accuracy of translation into French and Spanish.

167. The Committee agreed to start new work on a proposed draft Code of Practice for the Prevention and Reduction of Ochratoxin A Contamination in Coffee, subject to approval by the 31st Session of the Codex Alimentarius Commission, as presented in the Project Document appended to this Report (see Appendix XII).

168. The Committee further agreed that an electronic working group²⁷ led by Brazil open to all members and working in English prepare a proposed Draft Code of Practice for comments at Step 3 and consideration at Step 4 by the next session of the Committee. The document should be forwarded to the Codex Secretariat by the end of 2008 for distribution.

DISCUSSION PAPER ON OCHRATOXIN A (OTA) IN COCOA (Agenda Item 13b)²⁸

169. The Delegation of Ghana, as Chairperson of the electronic working group, outlined the main aspects of ochratoxin A (OTA) contamination in cocoa addressed in document CX/CF 08/2/15. The Delegation stated that there was a need to generate new data on occurrence of OTA in cocoa and that ongoing studies when become available would enable to update the document for consideration by the Committee.

170. The Committee noted the recommendation of the electronic working group and agreed to suspend the consideration of this matter with the understanding to re-consider ochratoxin A contamination in cocoa in light of the new data available in the near future.

PRIORITY LIST OF CONTAMINANTS AND NATURALLY OCCURRING TOXICANTS PROPOSED FOR EVALUATION BY JECFA (Agenda Item 14)²⁹

171. The Delegation of the Netherlands, as Chairperson of the in-session physical working group on Priority List of Contaminants and Naturally Occurring Toxicants for Evaluation by JECFA³⁰, presented the report on the outcome, as described in CRD 2. The Delegation informed the Committee that due to the fact that the majority of the data needed for the evaluation of the substances on the current priority list would only be available at the end of 2008, the JECFA Secretariat had not scheduled contaminants for evaluation this year, but had informed the working group that a meeting on contaminants would be tentatively scheduled in 2009.

172. The Committee discussed the substances listed in CRD 2. Highlights of the discussion and conclusion are as follows:

²⁶ CX/CF 08/2/14; CRD 8 (comments of Philippines); CRD 11 (comments of Indonesia) and CRD 12 (comments of Thailand).

²⁷ China, Costa Rica, European Community, Ghana, Indonesia, Jamaica, Kenya, Thailand and United States of America expressed their willingness to participate in the electronic working group.

²⁸ CX/CF 08/2/15; CRD 11 (comments of Indonesia) and CRD 13 (comments of Brazil).

²⁹ CL 2007/33-CF, ALINORM 07/30/41 Appendix XIII, CRD 2 (Report of the in-session physical working group on Priority List of Contaminants and Naturally Occurring Toxicants for Evaluation by JECFA)

³⁰ Attended by Australia, Austria, Belgium, Brazil, Canada, China, France, European Community, Finland, Germany, Ireland, Japan, Malaysia, The Netherlands, New Zealand, Nigeria, Norway, the Philippines, Poland, Thailand, Sweden, United States of America, CIAA, FAO, ICBA, ICGMA, ICA, IAEA and WHO.

i) DON, Furan and Perchlorate

173. The Committee agreed to maintain the high prioritization for DON, furan and perchlorate for evaluation by JECFA.

174. With regard to DON, the Committee noted that occurrence data from ongoing surveys would be made available by the end of 2008 and that some data had already been submitted to the GEMS/Food data base.

ii) Phenyl hydrazines

175. The Committee agreed that phenyl hydrazines (including agaritine) was removed from the current priority list, as these substances were of low priority and the dossier was not up-to-date.

iii) 3-MCPD

176. The Committee agreed to include fatty acid esters of 3-MCPD in the priority list, but not to assign a high priority, due to the fact that there were currently only limited data available and kinetic studies and collection of exposure data were still ongoing.

iv) Fumonisin

177. The Committee endorsed the recommendation of the in-session physical working group and agreed to establish an electronic working group led by Brazil³¹ open to all members and working in English, to prepare a discussion paper, which should include an overview of available data and scope of the problem of fumonisin contamination for consideration at the its next Session. The electronic working group should take into account the previous discussion paper presented at 32nd Session of the Committee on Food Additives and Contaminants.

v) Benzene

178. The Committee considered problems related to the formation of benzene in soft drinks. The Committee noted that guidance on the mitigation of benzene formation was already available to the soft drink industry.

179. The Committee, after some discussion, endorsed the recommendation of the in-session physical working group and agreed to establish an electronic working group³², led by Nigeria, open to all members and working in English, to prepare a discussion paper with a view to clarifying the state of knowledge and the extent of the problem.

vi) Cyanogenic glycosides

180. The Committee endorsed the recommendation of the in-session physical working group and agreed to establish an electronic working group³³, led by Australia, open to all members and working in English, to prepare a discussion paper which should include an overview of available data on cyanogenic glycoside with a view for possible re-evaluation by JECFA.

vii) Mycotoxins in sorghum

181. The Committee noted that the in-session physical working group did not discuss this matter. The Delegation of Sudan stated that sorghum was a main crop in African countries and requested to consider this issue at the plenary session.

182. The Representative of FAO noted that sorghum was an important staple food, but stressed that to consider the request it was necessary for member countries to have more specific information on which mycotoxins were present and the levels in this food category as well as information of different cultivars and growing conditions.

³¹ Cuba, Costa Rica, Philippines and Tanzania expressed their willingness to participate the electronic working group.

³² Belgium, Brazil, Canada, Cuba, European Community, Ghana, Japan, Kenya, Nigeria, Turkey, ICBA and IFT expressed their willingness to participate the electronic working group.

³³ Brazil, Cuba, Denmark, European Community, Ghana, The Netherlands, New Zealand, Nigeria, Thailand and United Kingdom expressed their willingness to participate the electronic working group.

183. Several delegations expressed support and requested that FAO and WHO should assist in generating such data. The Representative of FAO indicated in her reply that the organization considered data gathering and capacity building important activities for the support of food safety assessment, and consider this with priority.

184. The Representatives of FAO and WHO stated that, due to very limited resources for this type of activity, increased financial support from member countries and donor organizations were essential to meet the demand in order to strengthen the capacity in developing countries.

185. The Committee recalled that a discussion paper had previously been prepared on the issue of mycotoxins in sorghum and that at that time only Japan had submitted occurrence data³⁴. It was noted that occurrence data from one or only a few countries would not be sufficient for an evaluation by JECFA. The Delegation of Tunisia indicated that it had also submitted data on mycotoxins in sorghum and believed that more data from other countries were available.

186. After some discussion, the Committee agreed to establish an electronic working group³⁵ led by Tunisia, open to all members and working in English, to prepare a discussion paper.

Conclusion on Priority List

187. The Committee endorsed the priority list of contaminants and naturally occurring toxicants for JECFA evaluation as amended above and agreed to send it to the Codex Alimentarius Commission for adoption (see Appendix XIII).

188. The Committee endorsed the recommendation to consider to convene an in-session physical working group during the next session of the Committee, in order to review the priority list taking into account comments received.

OTHER BUSINESS AND FUTURE WORK (Agenda Item 15)

Differences between primary and processed products in relation to the use of concentration factors in concentrated and re-diluted products

189. The Delegation of Morocco stated that maximum levels for pesticides and contaminants developed in Codex were mainly related to primary products and that maximum levels for corresponding processed foods that were concentrated and re-diluted needed to be considered in certain cases. The Committee had an exchange of views on how to approach this matter and agreed that consideration of this issue may be given in the framework of the revision of Preamble of the GSCTF. The Committee therefore requested the electronic working group on Revision of the Preamble of the GSCTF (see Item 5) to consider this matter, where appropriate, with a view to determining as to whether there was a need for further work in this area.

Ethyl carbamate in alcoholic beverages

190. The Committee considered a proposal from the Delegation of Germany to discuss ethyl carbamate contamination in alcoholic beverages. The Committee recalled that this matter had been discussed at the last session of the Committee and that the 64th JECFA meeting concluded that health risks for the general population were low and that only sub-populations consuming a high quantity of specific alcoholic beverages might be exposed to certain health risks.

191. The Committee agreed that the Delegation of Germany would prepare a Discussion Paper on ethyl carbamate in alcoholic beverages for consideration by the next session of the Committee with a view to determining how and to what extent this matter could be approached within the Committee.

DATE AND PLACE OF THE NEXT SESSION (Agenda Item 16)

192. The Committee was informed that the Third Session of the Committee would be held probably in The Netherlands in April 2009. The exact date and venue would be determined by the Host Government in consultation with the Codex Secretariat. The Delegation of Turkey expressed its willingness to host the next Session of the Committee.

³⁴ ALINORM 05/28/12 para.152

³⁵ Australia, Brazil, China, Eritrea, Indonesia, Nigeria, Sudan, Sweden, Switzerland and Thailand expressed their willingness to participate in the electronic working group.

193. Some delegations reiterated that the next session of the Committee be held back-to-back with the Committee on Food Additives in order to facilitate the participation of delegates from developing countries in both Codex meetings. The Committee noted that the dates and venues of Codex sessions would have to be determined within the overall Codex session planning process.

SUMMARY STATUS OF WORK

SUBJECT MATTERS	STEP	ACTION BY:	DOCUMENT REFERENCE (ALINORM 08/31/41)
Proposed Draft Provisions Applied to Contaminants in the “Relations between Commodity Committees and General Committees” in the Procedural Manual	Adoption	61 st CCEXEC Members and Observers, and 31 st CAC	Para. 14 and Appendix II
Draft Maximum Level for 3-MCPD in Liquid Condiments Containing Acid-Hydrolyzed Vegetable Proteins (Excluding Naturally Fermented Soy Sauce) (N08-2004)	8	Members and Observers, 31 st CAC	Para. 67 and Appendix III
Draft Code of Practice for the Reduction of 3-Monochloropropane-1,2-diol (3-MCPD) during the Production of Acid-Hydrolyzed Vegetable Protein (Acid-HVPs) and Products that Contain Acid- HVPs (N09-2005)	8	Members and Observers, 31 st CAC	Para. 73 and Appendix IV
Draft Maximum Level for Ochratoxin A in Raw Wheat, Barley and Rye	8	Members and Observers, 31 st CAC	Para. 112 and Appendix VII
Draft Maximum Levels for Total Aflatoxins in Almonds, Hazelnuts and Pistachios “For further processing” and “Ready-to-eat”	8	Members and Observers, 31 st CAC	Para. 127 and Appendix VIII
Proposed Draft Aflatoxin Sampling Plans for Aflatoxin Contamination in Ready-to-eat Treenuts and Treenuts Destined for Further Processing: Almonds, Hazelnuts and Pistachios (N07-2004)	5/8	Members and Observers, 31 st CAC	Para. 142 and Appendix IX
Proposed Draft Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Dried Figs	5/8	Members and Observers, 31 st CAC	Para. 163 and Appendix XI
Proposed Draft Code of Practice for the Reduction of Acrylamide in Food (N06-2006)	5	Members and Observers, 31 st CAC	Para. 95 and Appendix V
Proposed Draft Code of Practice for the Reduction of Contamination of Food with Polycyclic Aromatic Hydrocarbons (PAH) from Smoking and Direct Drying Processes (N07-2006)	5	Members and Observers, 31 st CAC	Para. 109 and Appendix VI
Priority List of Contaminants and Naturally Occurring Toxicants Proposed for Evaluation by JECFA	Adoption	Members and Observers, 31 st CAC	Para. 187 and Appendix XIII
Proposed Draft Revision of the Preamble of the GSCTF (N04-2006)	2/3/4	Electronic working group, Members and Observers, 3 rd Session of the CCCF	Para. 62

SUBJECT MATTERS	STEP	ACTION BY:	DOCUMENT REFERENCE (ALINORM 08/31/41)
Proposed Draft Maximum Levels for Total Aflatoxins in Brazil Nuts (new work)	1/2/3	Electronic working group, Members and Observers, 3 rd Session of the CCCF	Para. 148 and Appendix X
Proposed Draft Code of Practice for the Prevention and Reduction of Ochratoxin A Contamination in Coffee (new work)	1/2/3	Electronic working group, Members and Observers, 3 rd Session of the CCCF	Para. 168 and Appendix XII
Discussion paper on fumonisins	---	Electronic working group	Para. 177
Discussion paper on benzene in soft drinks	---	Electronic working group	Para. 179
Discussion paper on cyanogenic glycosides	---	Electronic working group	Para. 180
Discussion paper on mycotoxins in sorghum	---	Electronic working group	Para. 186
Discussion paper on ethyl carbamate in alcoholic beverages	---	Delegation of Germany	Para. 191

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APPENDIX II

**PROPOSED DRAFT PROVISIONS APPLIED TO CONTAMINANTS IN THE
“RELATIONS BETWEEN COMMODITY COMMITTEES AND GENERAL COMMITTEES”****(for inclusion in the Procedural Manual)****Contaminants**

Codex Commodity committees shall examine the General Standard for Contaminants and Toxins in Foods with a view toward incorporating a reference to the General Standard.

All proposals for additions or revisions to the General Standard in order to establish a reference to the General Standard shall be referred to the Codex Committee on Contaminants in Foods. The Codex Committee on Contaminants in Foods shall consider such proposals for endorsement. Revisions of a substantive nature that are endorsed by the Committee on Contaminants in Foods will be referred back to the commodity committee in order to achieve consensus between both committees at an early stage of the step procedure.

Should the Codex commodity committee consider that a general reference to the General Standard for Contaminants and Toxins in Foods does not serve its purpose, a proposal should be prepared and forwarded to the Codex Committee on Contaminants in Foods for consideration and endorsement. When doing so, the commodity committee shall provide a justification why a general reference to the General Standards would not be appropriate.

All proposals should be referred to the Codex Committee on Contaminants in Foods, preferably before the advancement of the draft commodity standards concerned to Step 5 of the Procedure for Elaboration of Codex Standards or before they are considered by the commodity committee concerned at Step 7, though such referral should not be allowed to delay the progress of the Standard to the subsequent Steps of the Procedure.

In accordance with the agreed Format for Codex Commodity Standards, the section on contaminants in the Standard developed by the commodity committee should contain only the following reference to the General Standard for Contaminants and Toxins in Foods without reference to specific provisions on contaminants:

“The products covered by this Standard shall comply with the maximum levels of the Codex General Standard for Contaminants and Toxins in Foods (CODEX/STAN 193-1995) and the maximum residue limits for pesticides and veterinary drugs established by the Commission.”

APPENDIX III

**DRAFT MAXIMUM LEVEL FOR 3-MCPD IN LIQUID CONDIMENTS CONTAINING
ACID-HYDROLYZED VEGETABLE PROTEINS (EXCLUDING NATURALLY
FERMENTED SOY SAUCE) (N08-2004)**

(At Step 8 of the Procedure)

Code No.	Food	ML (mg/kg)	Step	Remarks
	Liquid condiments containing acid-hydrolyzed vegetable proteins (excluding naturally fermented soy sauce)	0.4	8	

DRAFT CODE OF PRACTICE FOR THE REDUCTION OF 3-MONOCHLOROPROPANE-1,2-DIOL (3-MCPD) DURING THE PRODUCTION OF ACID-HYDROLYSED VEGETABLE PROTEINS (ACID-HVPs) AND PRODUCTS THAT CONTAIN ACID-HVPs

(N09-2005)

(At Step 8 of the Procedure)

INTRODUCTION

1. 3-Monochloropropane-1,2-diol (3-MCPD) is one of a series of compounds referred to as chloropropanols. These compounds are contaminants that are formed during the processing and manufacture of certain foods and ingredients. They were originally discovered in acid hydrolysed vegetable protein (acid-HVP) in the 1980s. Subsequent research in the 1990s revealed their presence in soy sauces manufactured using acid-HVP as an ingredient.
2. Acid-HVPs are produced *via* the hydrolysis of various proteinaceous vegetable and animal materials with hydrochloric acid. They are used widely as flavour enhancers and as ingredients in processed savoury food products and pre-prepared meals. Typical levels in foods range from *ca.* 0.1 to 20%.
3. The occurrence of chloropropanols in acid-HVP arises from their formation during the hydrochloric acid mediated hydrolysis step of the manufacturing process. During this hydrolytic stage the acid also reacts with residual lipids and phospholipids present in the raw material, resulting in the formation of chloropropanols. It has been industry experience that chloropropanol formation cannot be avoided through the use of defatted protein sources.
4. In addition to formation of chloropropanols during the manufacture of acid-HVP for use as an ingredient, chloropropanols may also be formed in those soy sauces, and related condiments, where the manufacturing process of the sauce itself includes hydrochloric acid treatment of soybean meal. As with acid-HVP the mode of formation also involves acidic hydrolysis of residual lipids and phospholipids.
5. A range of techniques may be employed in the manufacture of soy sauces. Generally, products made exclusively by means of fermentation do not contain chloropropanols, or, if present, they only occur in trace amounts. It is those products that utilise acid-HVP as an ingredient that may contain chloropropanols. Soy sauces, and related products, that are subject to acid treatment during manufacture may also contain chloropropanols.
6. Generally, 3-MCPD is the most widely occurring chloropropanol in foods that contain acid-HVP. It is present as a racemic mixture of (*R*) and (*S*) isomers in protein hydrolysates. Other chloropropanols that can occur, albeit usually in smaller amounts, are 2-monochloropropane-1,3-diol (2-MCPD), 1,3-dichloro-2-propanol (1,3-DCP) and 2,3-dichloro-1-propanol (2,3-DCP).
7. The presence of chloropropanols in food is of concern owing to their toxicological properties. The Joint FAO/WHO Expert Committee on Food Additives (JECFA) considered 3-MCPD and 1,3-DCP in June 2001 and assigned a provisional maximum tolerable daily intake (PMTDI) for 3-MCPD of 2 µg/kg bw/day. The Committee re-evaluated chloropropanols in June 2006 and decided to retain the previously established PMTDI. On evaluating 3-MCPD, the Committee commented that reduction in the concentration of 3-MCPD in soy sauce and related products made with acid-HVP could substantially reduce the intake of this contaminant by consumers of these condiments.
8. Different regional markets may require products with different organoleptic qualities to accommodate specific regional tastes. The individual approaches and combinations thereof, outlined later in this document, to minimise levels of 3-MCPD will have different effects on the organoleptic qualities of the final product and as such, manufacturers should take these effects into account when selecting a strategy to minimise 3-MCPD formation. Whilst it is technically possible to reduce 3-MCPD levels to below 0.1 mg/kg, the organoleptic qualities of such products may be adversely affected as the flavour and taste (umami) directly reflect the quality of the acid-HVP. This is particularly true in aged acid-HVP products.

9. Manufacturers have implemented measures to reduce the levels of chloropropanols in acid-HVPs and related products. Details of the general procedures used to manufacture acid-HVPs with low levels of chloropropanols are given in the following section. Some manufacturers undertook reformulation of their products during the early 1990s so that the effects of changes in organoleptic properties experienced when using the improved methods of manufacture could be minimised. Other production processes resulted in products with lower levels of chloropropanols whilst minimising the effect on organoleptic properties. Implementing manufacturing procedures to reduce 3-MCPD in acid-HVP to low levels can be technically difficult and very expensive, often with new equipment being required. Reformulation of the recipes for processed foods made using acid-HVP may also be necessary.
10. Chloropropanols have also been detected in a range of other foods that are not subject to acid hydrolysis during manufacture. These foods include processed fruits and vegetables, cereals and bakery products, processed meats, smoked fish and beer.

SCOPE

11. The purpose of this Code of Practice is to describe and disseminate best practice for the manufacture of acid-HVP and soy sauces and related condiments, whose production involves acid hydrolysis, with the aim of facilitating a reduction in the levels of 3-MCPD. Food ingredients produced using methods that do not involve acid hydrolysis of vegetable proteins are not covered by this Code of Practice.

RECOMMENDED PRACTICES BASED ON GOOD MANUFACTURING PRACTICE (GMP)

Acid-HVPs

12. The manufacturing process for acid-HVPs will vary depending on the desired organoleptic properties of the end product. The source of the raw material, molarity of the acid, temperature of the reaction, time of the reaction and other factors can all affect the organoleptic properties of the final product. A generalised description of the acid-HVP manufacturing process can be given (see fig. in Annex). Common vegetable raw materials used in the production of acid-HVP include defatted oil seeds (soy and peanut), and protein from corn maize, wheat, casein, yeast and rice. These are hydrolysed with hydrochloric acid ranging from below 4 M to 9 M, at a temperature between 70 °C and 135 °C for up to 8 hours, although times of up to 20 – 35 hours have been reported, at pressures usually greater than atmospheric pressure. After cooling, the hydrolysate is neutralised with either sodium carbonate or sodium hydroxide to a pH of 5 to 9 at a temperature between 90 to 100 °C for 90 to 180 minutes and then hydrochloric acid is added to the mixture to adjust the pH to between 4.8 and 5.2. The hydrolysate is filtered to remove the insoluble carbohydrate fraction (humin) and then bleached or refined. Activated carbon treatment can be employed to remove both flavour and colour components, to the required specification. Following further filtration, the acid-HVP may, depending upon the application, be fortified with additional flavouring components. Thereafter, the product can be stored as a liquid at 30 – 50% dry matter (corresponding to 2 – 3% total nitrogen), or alternatively it may be vacuum dried, spray-dried, or steamed and stored as a solid (97 – 98% dry matter).

Methods that can be employed to reduce the levels of 3-MCPD in acid-HVP

13. Three main approaches may be adopted to minimise the concentration of 3-MCPD in the final product. The first of these involves careful control of the acid hydrolysis step; the second, subsequent neutralisation to minimise 3-MCPD formation; and the third employs the use of sulfuric acid as a substitute for hydrochloric acid in the hydrolysis step. These methods can reduce the levels of 3-MCPD in acid-HVPs.
14. Manufacturers should consider the three options below and decide which are most suitable for their method of acid-HVP production. The three approaches are detailed in the following paragraphs, with specific examples given. These approaches are based on a limited amount of information that is available in the public domain; therefore, it has not been possible to provide a full account of how to manufacture low 3-MCPD acid-HVP. The information that follows is general advice; at the national level, manufacturers may need to adjust the measures in their own production processes.

15. With regard to the first strategy, the temperature and the heating time of the acid hydrolysis step must be simultaneously controlled and careful attention paid to the reaction conditions in the subsequent neutralisation step. Typically, the hydrolysis reaction is initially carried out at a temperature between 60 and 95 °C for up to 150 minutes. The temperature of the reaction is then increased gradually until a temperature of 103 – 110 °C is attained. Once this maximum temperature is reached, it should be maintained for 2 - 35 hours and then the resulting hydrolysate cooled over 3 hours, neutralised and filtered. Careful control of the acid hydrolysis step has been shown to reduce levels of 3-MCPD in the hydrolysate to below 10 mg/kg.
16. 3-MCPD that is formed during the acid hydrolysis step may be removed by a secondary alkaline hydrolysis. This alkaline treatment is, in essence, an extension of the neutralisation process that follows acid hydrolysis of the starting material; it causes degradation of the chloropropanols present in the hydrolysate. The alkaline treatment can be performed before or after filtration of the hydrolysate, although alkaline treatment is preferable before filtration because the residue will also then be free of 3-MCPD. The hydrolysed protein is treated with food-acceptable alkali such as potassium hydroxide, sodium hydroxide, ammonium hydroxide or sodium carbonate to increase the pH to 8 – 13. This mixture is then heated in the range 110 – 140 °C for up to 5 minutes, other reported conditions involved heating in the range 60 – 100 °C for 90 - 900 minutes. Generally, alkaline treatments at higher pH and temperature will require shorter processing times. After cooling, the pH of the resulting hydrolysate should be alkaline (ideally above pH 8 at 25 °C); if the pH is lower, the treatment was most probably not effective and corrective measures should be taken. Following alkaline treatment, the pH of the hydrolysed protein is readjusted to a pH of 4.8 – 5.5 using a suitable acid (e.g. hydrochloric acid) at a temperature of 10 – 50 °C. The hydrolysate may now be filtered to remove any insoluble residues and the final product obtained. Use of an alkaline treatment when manufacturing acid-HVP has been shown to yield a final product with 3-MCPD levels below 1 mg/kg. It should be noted that a harsh alkaline treatment will reduce the organoleptic qualities of the final products; therefore, it is advised to start the alkaline treatment with a hydrolysate with low levels of 3-MCPD, which can be achieved through careful control of the acid hydrolysis step. Of course, it is important to pay attention to possible recontamination if secondary alkaline hydrolysis is used to further reduce the 3-MCPD content of acid-HVP produced by careful control of the acid hydrolysis step. The alkali treated hydrolysate (with low levels of 3-MCPD) must be kept away from equipment (e.g. reaction vessels, pipes, pumps and filter presses) that is used when performing the initial acid hydrolysis step.
17. It is possible to manufacture acid-HVP using sulfuric acid, thus eliminating the presence of chloride ions that lead to the formation of 3-MCPD. Soybean meal and sulfuric acid are mixed together for 8 hours at a pressure of 10 psi. The resulting hydrolysate is neutralised and the final product is filtered and washed. The diminished organoleptic properties of sulfuric acid-HVP are improved by combination of the final product with flavourings (e.g. monosodium glutamate, caramel, disodium inosinate, disodium guanylate and lactic acid).

Soy sauces and related products

18. A number of different manufacturing processes are employed in the production of soy sauces and the method used will impact on whether the product contains 3-MCPD.

Soy sauces produced by fermentation

19. Soy sauces that are produced solely by fermentation contain non-quantifiable or, in rare cases, extremely low levels of 3-MCPD. Soybeans (whole or defatted) and other cereal grains such as wheat are the main ingredients used for naturally fermented soy sauce. At the start of the process these materials are pre-cooked, mixed and inoculated with *Aspergillus oryzae* and/or *Aspergillus sojae*. After incubation for 1 to 3 days, at 25 – 30 °C, salt water is added and the mixture is fermented and aged at a temperature below 40 °C for not less than 90 days. Short-term fermented soy sauce is produced in a similar manner except that the salt water fermentation/ageing stage takes place at or above 40 °C and the process is completed within 90 days.

Soy sauces whose manufacture involves an acid treatment stage

20. Alternatively, soy sauces may be manufactured using acid-HVP and other ingredients such as sugars and salt. These products may contain 3-MCPD and measures to prevent its occurrence are described above for acid-HVP. Use of these processes will yield products with low levels of 3-MCPD.
21. A further manufacturing technique involves mixing fermented soy sauces with those derived from acid-HVP. Manufacture of some products involves ageing after mixing. Such products (commonly known as semi-chemical soy sauces) may also contain 3-MCPD and appropriate measures to minimise its presence in the acid-HVP are described earlier.

Annex

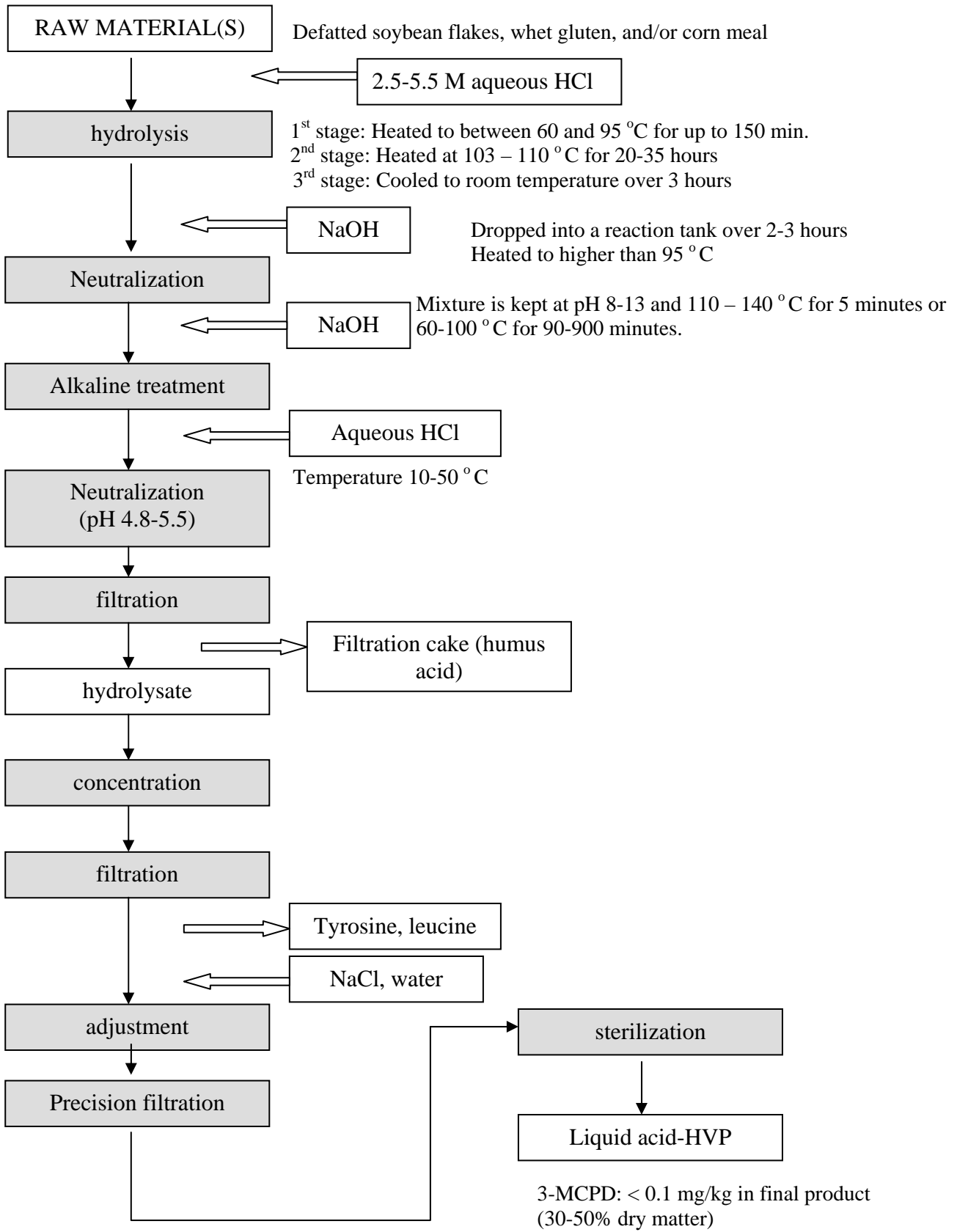


Fig: Manufacturing process of acid-HVP at commercial scale.

APPENDIX V

PROPOSED DRAFT CODE OF PRACTICE FOR THE REDUCTION OF ACRYLAMIDE IN FOODS (N06-2006)**(At Step 5 of the Procedure)****INTRODUCTION**

1. Recent concern over the presence of acrylamide in food dates from 2002. Swedish scientists⁵ reported that up to “mg/kg” quantities of acrylamide could be formed in carbohydrate-rich foods during high-temperature cooking, e.g. during frying, baking, roasting, toasting and grilling. These findings were rapidly confirmed by other researchers;⁶ subsequently, major international efforts have been mounted to investigate the principal sources of dietary exposure, assess the associated health risks and develop risk management strategies.^{7,8,9,10,11,12} Details of these global research initiatives are provided on the WHO/FAO Acrylamide Information Network (<http://www.acrylamide-food.org/>) and the "Acrylamide Information Base"^a http://ec.europa.eu/food/food/chemicalsafety/contaminants/acryl_database_en.htm.
2. Acrylamide is mainly formed in food by the reaction of asparagine (an amino acid) with reducing sugars (particularly glucose and fructose) as part of the Maillard Reaction;^{13,14} acrylamide may also be formed *via* reactions involving 3-aminopropionamide.^{15,16} Acrylamide formation primarily takes place under conditions of high temperature (usually in excess of 120 °C) and low moisture.
3. The Joint FAO/WHO Expert Committee on Food Additives (JECFA)¹¹ has undertaken a comprehensive analysis of acrylamide occurrence data from 24 countries, the majority originating from Europe and North America. It was concluded that the major contributing food groups were French fries^b, potato crisps^c, coffee, biscuits^d/pastries, bread and rolls/toasted bread. The full extent of acrylamide present throughout the diet remains unclear.

SCOPE^e

4. This Code of Practice intends to provide national and local authorities, manufacturers and other relevant bodies with guidance to prevent and reduce formation of acrylamide in potato products and cereal products. The guidance covers three strategies (where information is available) for reducing acrylamide formation in particular products:
 - i. Raw materials;
 - ii. Control / addition of other ingredients; and
 - iii. Food processing and heating.

GENERAL CONSIDERATIONS AND CONSTRAINTS IN DEVELOPING PREVENTATIVE MEASURES

5. Measures aimed at reducing levels of acrylamide cannot be taken in isolation from other considerations. Precautions need to be taken to avoid compromising the existing chemical and microbiological safety of the food. The nutritional qualities of products also need to remain unimpaired, together with their organoleptic properties and associated consumer acceptability. This means all minimisation strategies need to be assessed with regards to their benefits and any possible adverse effects. For example:

^a A database containing information on projects and activities relating to acrylamide in the EU Member States.

^b Potato products that are thickly sliced and fried (referred to as French fries in some regions including North America, or as chips in the UK).

^c Potato snack product that is thinly sliced and fried (includes foods called potato chips in some regions including North America).

^d Baked cereal products (referred to as cookies in some regions, including North America).

^e As technology and data for the mitigation of acrylamide formation in other products (e.g. coffee) become available, the Code of Practice will be updated accordingly.

- i. When preventative measures for acrylamide are considered, checks should be made to ensure that they will not result in an increase in other process contaminants. These include N-nitrosamines,⁴⁴ polycyclic aromatic hydrocarbons,⁴⁵ chloropropanols,⁴⁶ ethyl carbamate,⁴⁷ furan,⁴⁸ heterocyclic aromatic amines and amino acid pyrolysates.⁴⁹
 - ii. Preventative measures devised for acrylamide must not compromise the microbiological stability of the final product. In particular, regard needs to be paid to the moisture content of the final product.
 - iii. Precautions should be taken to avoid detrimental changes to the organoleptic properties of the final product. The formation of acrylamide is intimately associated with the generation of the characteristic colour, flavour and aroma of cooked foods. Proposed changes to cooking conditions, or indeed raw materials and other ingredients, must be assessed from the perspective of the acceptability of the final product to the consumer.
6. Formal safety assessments, efficacy-in-use demonstration and regulatory approval may be needed for potential new additives and processing aids such as asparaginase. Two companies are now producing asparaginase for use in food products and as of September 2007, the following information was available on the regulatory status of these enzymes. The US FDA has stated that it does not object to the companies' conclusions that their enzyme preparations are Generally Recognized as Safe (GRAS) under the intended conditions of use.⁵⁶ In Europe, approval has been received for asparaginase in France and Denmark as a processing aid.
7. It should be noted that the extent of acrylamide formation can be quite variable e.g. within a production batch made at the same manufacturing plant, or between plants using the same process, ingredients and formulations.⁵⁷
8. Manufacturers need to be aware that variability in incoming raw materials and poorly controlled heating devices can complicate trials of mitigation strategies, by obscuring changes in acrylamide levels. For optimal results, manufacturers should control asparagine and reducing sugar levels and have well-controlled heating elements before investigating possible minimisation strategies.

RECOMMENDED PRACTICES TO INDUSTRY FOR THE MANUFACTURE OF POTATO PRODUCTS (E.G. FRENCH FRIES, POTATO CRISPS, POTATO SNACKS).

THE MITIGATION MEASURES DISCUSSED IN THE FOLLOWING SECTIONS ARE NOT LISTED IN ORDER OF PRIORITY. IT IS RECOMMENDED THAT ALL REDUCTION MEASURES ARE TESTED TO IDENTIFY THE MOST SUCCESSFUL FOR YOUR OWN PRODUCT.

Production Stage	Reduction Measures
Raw Materials	<p>Choose potato cultivars with low concentrations of reducing sugars (target less than 0.3% sugar on a fresh weight basis for crisps and 0.4% for French Fries; subject to regional and seasonal variability). Test incoming deliveries of potatoes for levels of reducing sugars, or fry test them (aim for a light golden colour).</p> <p>Avoid using potatoes stored below 6 °C. Control storage conditions from farm to factory and in cold weather, protect potatoes from cold air. Avoid leaving deliveries of potatoes that have been standing outside (unprotected) in freezing conditions for long periods of time, e.g. overnight. Recondition potatoes that have been stored at low temperatures over a period of a few weeks at higher temperatures (e.g. 12 – 15 °C). Fry test potatoes that have been stored at low temperatures for long periods of time.</p>
Control / addition of other ingredients	<p>In the case of potato-based snacks produced from doughs, where possible, replace some of the potato with other ingredients with lower reducing sugar/asparagine content e.g. rice flour Avoid addition of reducing sugars (e.g. as browning agent, spice carrier or coating).</p> <p>The addition of asparaginase has been shown to reduce asparagine and thus acrylamide in potato dough based products.</p> <p>Treatment of French fries with sodium pyrophosphate and treatment of potato products with di- and trivalent cations e.g. calcium salts before processing can contribute to the reduction of acrylamide.</p>
Food Processing and heating	<p>French Fries: Blanch potato strips in water to lower levels of reducing sugars before cooking. Lowering the pH with addition of sodium acid pyrophosphate during the latter stages of blanching can reduce levels further. Cut thicker strips; 14x14mm strips have been shown to have lower acrylamide levels than fine cut strips (8x8mm). If appropriate, par fry french fries.</p> <p>Potato crisps: Optimise time, temperature and cooker settings to produce a crisp product with a golden yellow colour. If available, consider vacuum frying to process high reducing sugar potatoes. Rapid cooling is recommended if flash frying is being used. Carry out in line colour sorting to remove dark crisps</p>

Raw materials

9. A number of factors influence reducing sugar levels including:
- i. Climatic conditions^{58,59} and fertilizer application rate⁶⁰ – These factors are known to influence levels of reducing sugars, however, no specific information on reduction measures applicable to manufacturers are currently available.
 - ii. Cultivar⁵⁸ - Select cultivars with reducing sugar contents of less than 0.3 % for crisps, 0.4% for French fries on a wet weight basis for high temperature cooking processes such as frying and baking.⁴
 - iii. Storage temperature and time⁶¹ – Control storage conditions from farm to factory; >6° C has been identified as good practice for long storage for processing.^{4,62} Avoid using potatoes that have been subject to excessive low-temperature sweetening during storage (at, or below 4-6 °C⁶³) for frying, roasting and oven-baking. In cold weather protect potatoes from cold air. Avoid leaving deliveries of potatoes standing outside (unprotected) over night in freezing conditions.⁴ Some cultivars are less prone than others to low temperature sweetening.^{64,65} Information on some cultivars is contained in a database available from the European Cultivated Potato Database⁹³ and the German Federal Office of Plant Varieties.⁶⁶
 - iv. Reconditioning temperature and time^{59,62} - Potatoes that have been stored at low temperatures should be reconditioned over a period of a few weeks at higher temperatures (e.g. 12 – 15 °C).^{59,62} The decision to recondition stored potatoes should be made on the basis of the results of fry testing.
 - v. Tuber size/immature tubers⁶⁷ - Immature tubers have higher reducing sugar levels and produce darker fried products with potentially higher levels of acrylamide. The presence of immature tubers should be avoided by selecting, sorting or grading of potatoes at some stage before processing.
10. Sprout suppressant is often essential in stores held at temperatures over 6 °C,⁶⁸ although regional regulations in some cases do not permit the use of sprout suppressants.
11. Manufacturers of French fries and potato crisps should where feasible screen incoming lots by measuring reducing sugar content or assessing the colour of a fried sample.^{4,62} In particular, fry test potatoes that have been stored at low temperatures for long periods of time. When using cultivars with not sufficiently low reducing sugar contents, reconditioning and blanching before high temperature cooking processes, and vacuum frying for heating may lower the level of acrylamide.

Control/addition of other ingredients

12. For reconstituted or formed potato-based snacks produced from potato doughs, other ingredients with lower reducing sugar/asparagine content can sometimes be used in some products to partially replace the potato⁶² e.g. rice flour.
13. Addition of the enzyme asparaginase has been shown to reduce asparagine and thus acrylamide levels in potato products made from potato doughs.^{62,69,70} Asparaginase may be best suited for food products manufactured from liquidised or slurried materials.⁶⁹
14. Treatment with various other reagents i.e., sodium pyrophosphate and calcium salts^{4,62} prior to the frying stage has also been demonstrated to reduce acrylamide formation.
15. The use of reducing sugars as a browning agent, spice carrier or coating should also be avoided where possible because they can cause the formation of significant levels of acrylamide.⁵³

Food processing and heating

16. Decrease of the surface area can be employed; for example in French fries, by cutting potatoes into thicker slices; 14x14mm strips have been shown to have lower acrylamide levels than fine cut strips (8x8mm) or removal of fines (fine pieces of potato) before or after frying to reduce levels of acrylamide in fried or roasted potatoes.^{62,71,72}

17. Washing, blanching or par-boiling treatments can be employed to leach the asparagine/reducing sugar reactants from the surface of the potato before the cooking step.^{73,74} Various reagents for lowering pH can also be added during the latter stages of blanching to further reduce levels of acrylamide, these include, treatment of French fries with sodium acid pyrophosphate,^{4,62} treatment with calcium salts,⁶² and the salts of a number of other di- and trivalent cations (this method has been shown to reduce acrylamide formation in French fries made from potato dough⁷⁵) and blanching in sodium chloride solution⁷⁶ (though this method may increase dietary exposure to sodium).
 - i. Blanching or soaking potatoes has shown to reduce acrylamide levels but can also have an adverse effect on the flavour and texture of the final product. Blanching can also lead to leaching of vitamin C and minerals from potatoes. A blanching step before frying/roasting may lower the fat content of the final product,⁵⁰ but there is contradictory information on this topic.^{51,52}
 - ii. Blanching may also be unsuitable for some products e.g. potato crisps, as it may cause unacceptable moisture uptake, leading to loss of consistency/ crispness or possible microbiological spoilage.⁵³
18. Acrylamide levels in potato crisps can be reduced by controlling the thermal input.⁴ Vacuum frying might offer the opportunity to reduce acrylamide levels in crisps made from potatoes with high reducing sugar content. Rapid cooling potato crisps that are cooked by flash frying can also reduce levels of acrylamide in the final product. The use of in-line optical sorting to remove dark coloured crisps has been proved to be an effective measure to reduce acrylamide.⁴ Par cooking and dry steam treatments used to make low fat crisps may also reduce acrylamide.⁶²
19. In order to achieve significant reductions in the acrylamide content of French fries, when cooking the product immediately prior to consumption, set the temperature of the oil at the start of frying to no more than 175 °C and cook to a golden-yellow rather than a golden-brown colour.^{77,78} Depending on the relative proportions of raw potato to cooking oil, the temperature of the frying oil will drop after the raw French fries are added. Such a decrease in temperature may help to reduce acrylamide formation, although too great a temperature drop will adversely affect the culinary quality of the product.⁷⁹
 - i. Frying of potato products at too low a temperature may lead to an increased fat content of the final product.⁴
 - ii. When cooking French fries to a golden-yellow rather than a golden-brown colour it is essential to ensure that the final product is properly cooked.
20. “Oven” French fry manufacturers should ensure that their on-pack cooking instructions are consistent with the need to minimise acrylamide formation.⁴ Where frying is one of the on-pack suggestions for “Oven” French fries, the recommended frying temperature should not be greater than 175 °C.⁸⁰ The cooking instructions should also mention that consumers should reduce the cooking time when cooking small amounts.⁴
21. Some “Oven” French fries or prefabricated potato products are manufactured with a view to storage under refrigerated rather than frozen conditions. Storage at these conditions may be conducive to low-temperature sweetening⁸¹ due to residual amylase activity which leads to reducing sugar formation from starch. Should this be the case, blanching must be adapted (longer time and/or higher temperature) in order to fully inactivate the amylase activity.

RECOMMENDED PRACTICES TO INDUSTRY FOR THE MANUFACTURE OF CEREAL BASED PRODUCTS (BREAD, CRISPBREAD, BISCUITS/BAKERY WARES, BREAKFAST CEREALS).

THE MITIGATION MEASURES DISCUSSED IN THE FOLLOWING SECTIONS ARE NOT LISTED IN ORDER OF PRIORITY. IT IS RECOMMENDED THAT ALL REDUCTION MEASURES ARE TESTED TO IDENTIFY THE MOST SUCCESSFUL FOR YOUR OWN PRODUCT.

Production Stage	Reduction Measures
Raw Materials	Sulphur deficient soil should be avoided, or well fertilised.
Control / addition of other ingredients	<p>General: Consider the type of flour to be used. High extraction flours contain significantly less asparagine than wholemeal flours. However, lowering the wholemeal content will reduce the nutritional benefits of the final product. Consider part replacement of wheat flour by rice flour.</p>
	<p>Biscuits/bakery wares: When ammonium containing raising agents are used, consider replacements with other raising agents e.g. potassium and sodium containing raising agents. In the production of gingerbread replace fructose with glucose. The addition of asparaginase has been shown to reduce asparagine and thus acrylamide in hard, wheat-dough based products such as cookies and crackers.</p>
	<p>Bread: Avoid using reducing sugars in the recipe. The addition of calcium salts, e.g. calcium carbonate may reduce the formation of acrylamide.</p>
<p>Breakfast cereals: Minimize reducing sugars in the cook phase. Consider the contribution of other inclusions e.g. roasted nuts, dried fruits and whether they are necessary if they are in a form that potentially can add a significant level of acrylamide.</p>	
Food Processing and heating	<p>Biscuits/bakery wares: Do not over bake.</p>
	<p>Bread: Adjust the time-temperature profile of the baking process, i.e., decrease temperatures of the final stages when product reaches low moisture phase. Extend fermentation times of bread doughs.</p>
	<p>Crispbread: Control the final moisture content. In non-fermented crispbread control the process temperature and oven speed.</p>
	<p>Breakfast cereals: Do not over-bake or over-toast. Manage the toasting to achieve a uniform colour for the product.</p>

Raw materials

22. Typically, asparagine can range from 75 to 2200 mg/kg in wheat, from 50 to 1400 mg/kg in oats, from 70 to 3000 mg/kg in maize, from 319 to 880 mg/kg in rye⁸² and from 15 to 25 mg/kg in rice.⁸³ This level of variation suggests that there may be scope for reducing acrylamide by exploiting the variability of asparagine content in the cultivar pool. However, as in the similar case for potatoes, such approaches are likely to have a significant lead time, and other factors, such as yield and resistance to fungal infections (field mycotoxin formation), would need to be considered.
23. Deficiencies in the sulphur content of soil can cause an increase in asparagines levels in wheat and barley.⁸⁴ Therefore, sulphur deficient soil should be avoided, or well fertilised.
24. In mixed cereal products, there may be scope for reducing the proportion of the predominant source of acrylamide by incorporating cereals with lower asparagine content. For example, this strategy could include replacing rye and wheat with rice, however, nutritional and organoleptic implications must be considered.

Control/addition of other ingredients

25. Thought should be given to the type of flours used in products. High extraction flours contain significantly less asparagine than wholemeal flours. Part replacement of wheat flour by rice flour has been shown to reduce acrylamide in short sweet biscuits and gingerbread.⁸⁵ However, lowering the wholemeal content will reduce the nutritional benefits of the final product. Types of flours vary in asparagines content and choice should be balanced between nutritional value and minimization of acrylamide formation.
26. Ammonium bicarbonate has been shown to increase the potential yield of acrylamide from a baked product.^{85,86} Thus, manufacturers need to consider whether the use of ammonium-containing raising agents can be reduced. Replacement leavening agents used commercially include:^{85,55}
 - i. Sodium bicarbonate + acidulants;
 - ii. Disodium diphosphate, sodium bicarbonate and organic acids;
 - iii. Potassium bicarbonate + potassium bitartrate;
 - iv. Sodium bicarbonate + sodium acid pyrophosphate (SAPP).
 - v. Replacement of ammonium-containing raising agents with those containing sodium may increase dietary exposure to sodium and may also adversely affect the physical properties of gingerbread and the organoleptic qualities of biscuits.⁴ Combination of sodium bicarbonate and organic acids e.g. tartaric acid and citric acid, may result in a product with somewhat lesser leavening.⁵⁴ The amount of organic acids added needs to be limited because an acidic taste may be developed and gas release in the dough may be too fast.⁵⁵
27. Greater amounts of acrylamide are formed if the reducing sugar is fructose rather than glucose. Commercial investigations have shown removal of sources of fructose or replacement by glucose in the product ingredients (sugar syrups, fruit puree, honey) to be successful in reducing acrylamide formation.⁸⁵ If glucose syrup (also known as corn syrup in North America) is necessary, the level of fructose in this syrup should be as low as possible.⁴ The replacement of reducing sugars by sucrose is another effective way to significantly reduce acrylamide in sweet baked goods if browning is less important.⁵⁴
28. The addition of asparaginase has been shown to reduce asparagine and thus acrylamide in hard, wheat-dough based products such as cookies and crackers.^{4,62}
29. Care should also be exercised in the usage of reducing sugars during the manufacture of breakfast cereals. When such sugars are used they are usually added after the baking process, in which case no additional acrylamide formation will occur. However, addition of reducing sugars prior to baking represents an avoidable source of acrylamide formation.

30. Other minor ingredients can also have an influence. Increases in acrylamide formation have been shown to occur in some recipes when ingredients such as ginger, honey and cardamom are added during biscuit production.⁸³ Conversely, nutmeg has been shown, in some cases, to result in a decrease in acrylamide.⁸⁷ In order to reduce acrylamide levels in final products, manufacturers could investigate the effect of different spices in their own recipes.
31. Use of rework (the practice of re-using scraps) has been shown to increase acrylamide levels in some cases, but not in others.⁴ Manufacturers need to examine production processes for individual products to determine whether reducing rework can be used to mitigate acrylamide levels in their products.

Food processing and heating

32. Yeast fermentation of wheat bread doughs reduces the free asparagine content.⁸⁸ Fermentation for two hours utilises most of the asparagine in wheat flour dough models; shorter times are less effective, as is sourdough fermentation.
33. Acrylamide formation can be reduced by modifying the time–temperature profile of the baking process,⁸⁵ in particular by decreasing the temperature of the final stages when the product reaches the crucially vulnerable, low moisture phase. Compensation by increasing the temperature of the earlier stages of baking should not lead to a significant increase in acrylamide, since the moisture content at this stage should be sufficiently great so as to prevent acrylamide formation. Careful control of oven temperatures and time profiles can be effective in reducing acrylamide levels. These principles have been applied successfully in both a biscuit model and in non-fermented crispbreads.⁸³

COFFEE

34. No commercial measures for reducing acrylamide in coffee are currently available.
35. Studies have shown that acrylamide is not stable in coffee powder in closed containers over extended storage periods^{4,89,90,91} and work is underway to identify the underlying mechanisms that may provide future opportunities for mitigation. However, any changes to the roasting profile, or deliberate use of extended storage, to decrease acrylamide levels are likely to have a significant impact on the organoleptic properties and consumer acceptability of the product^{4,87,92}

CONSUMER PRACTICES

36. National and local authorities should consider advising consumers to avoid over-heating potato and cereal-based foodstuffs when using high temperature cooking processes. Such advice could include recommendations that French fries and roast potatoes be cooked to a golden-yellow rather than golden-brown colour, whilst still ensuring that the food is fully cooked. Similarly, the consumer could be advised to aim for a light brown colour when toasting bread and related products.
37. National and local authorities should also consider encouraging consumers to avoid storing potatoes intended for high-temperature cooking under cold and/or refrigerated conditions.
38. Where relevant, industry should endeavour to provide advice to consumers on appropriate cooking and handling instructions that can help to mitigate acrylamide formation in the product.

TOXICOLOGY

1. JECFA reviewed acrylamide at the request of CCFAC in 2005.^{11,17} The following section summarises the major conclusions of the JECFA review.
2. Acrylamide is an important industrial chemical used since the mid 1950s as a chemical intermediate in the production of polyacrylamides, which are used as flocculants for clarifying drinking water and in other industrial applications. The neurotoxicity of acrylamide in humans is well known from occupational and accidental exposures. In addition, experimental studies with acrylamide in animals have shown reproductive, genotoxic, and carcinogenic properties.
3. JECFA analysed acrylamide occurrence data from 24 countries and national dietary intake data from 17 countries. The committee identified an average acrylamide intake of 1 µg/kg bw/day for the general population and 4µg/kg bw/day for high-level consumers based on national intake estimates ranging from 0.3 – 2.0 µg/kg bw/day for average consumers and 0.6 –5.1 µg/kg bw/day for high level consumers (90 – 99th percentile).
4. JECFA concluded that the critical effects of acrylamide toxicity are genotoxicity and carcinogenicity. In order to estimate the level of concern of acrylamide exposure from food, JECFA calculated a Benchmark Dose Lower Limit (BMDL) for mammary tumour formation from rodent carcinogenicity studies and then calculated the margin of exposure (MOE) between the BMDL and human acrylamide intake. For average intakes (1µg/kg bw/day), the MOE was 300; for high intakes (4 µg/kg bw/day), the MOE was 75. For comparison, JECFA calculated the MOEs for average and high exposure to polycyclic aromatic hydrocarbons to be 25,000 and 10,000, respectively. For ethyl carbamate, the MOEs were 20,000 for average and 3,800 for high exposure.
5. JECFA also calculated MOEs for neurological effects of 200 and 50 for average and high intakes; for reproductive, developmental, and other non-neoplastic effects, JECFA calculated MOEs of 2000 and 500 for average and high intakes. Based on these MOEs, JECFA concluded that adverse neurological, reproductive, and developmental effects are unlikely for the average consumer, but that morphological changes in nerves cannot be excluded for some individuals with very high intake. The Committee also stated that ongoing studies of neurotoxicity and neurodevelopmental effects in rats will more clearly define whether neurotoxic or neurodevelopmental effects may arise from long-term, low doses of acrylamide.
6. In summary, JECFA considered these MOEs to be low for a compound that is genotoxic and carcinogenic and concluded that the MOEs may indicate a human health concern.
7. JECFA made the following recommendations:
 - i. acrylamide should be re-evaluated when results of ongoing carcinogenicity and long-term neurotoxicity studies become available,
 - ii. work should be continued on using pharmacologically based pharmacokinetic (PBPK) modelling to better link human biomarker data with exposure assessments and toxicological effects in experimental animals,
 - iii. appropriate efforts to reduce acrylamide concentrations in food should continue, and
 - iv. it would be useful to have occurrence data on acrylamide in foods as consumed in developing countries.
8. JECFA evaluated the safety of the enzyme asparaginase from *Aspergillus oryzae* expressed in *Aspergillus oryzae* for use as a food additive at its 68th meeting in June 2007.⁴³ [JECFA also evaluated the safety of the enzyme asparaginase from *Aspergillus niger* for use as food additives at its 69th Meeting in June 2008.] Asparaginase has potential use in depleting levels of the acrylamide precursor asparagine in food. JECFA found that asparaginase [from *Aspergillus oryzae* expressed in *Aspergillus oryzae*] had an Acceptable Daily Intake (ADI) that was “not specified” when used in the applications specified and in accordance with good manufacturing practice. ADI ‘not specified’ is used to refer to a food substance of very low toxicity which, on the basis of the available data (chemical, biochemical, toxicological and other) and the total dietary intake of the substance arising from its use at the levels necessary to achieve the desired effects and from its acceptable background levels in food, does not, in the opinion of JECFA, represent a hazard to health.⁴³

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APPENDIX VI

PROPOSED DRAFT CODE OF PRACTICE FOR THE REDUCTION OF CONTAMINATION OF FOOD WITH POLYCYCLIC AROMATIC HYDROCARBONS (PAH) FROM SMOKING AND DIRECT DRYING PROCESSES (N07-2006)**(Step 5 of the Procedure)****INTRODUCTION**

1. Many chemical contaminants are formed during the combustion of fuel both in the smoking and in the direct drying process. Examples include polycyclic aromatic hydrocarbons (PAH), dioxins, formaldehyde, nitrogen and sulfur oxides (relevant for formation of e.g. nitrosamines). Furthermore, heavy metals are also found in combustion gases. The types and amount depend on the fuel used, the temperature and possible other parameters (Nielsen and Illerup, 2003).

2. This Code of Practice covers contamination of food with PAH from smoking and direct drying, only. PAH are chemical contaminants, which can be found in food. A list of PAH included in the Joint FAO/WHO Expert Committee on Food Additives (JECFA) risk assessment of PAH in 2005 (WHO 2006) is found in **Annex I**.

3. Sources of PAH are contamination during food processing or the environment. PAH may be formed during food processing in both commercial and domestic food preparation, notably:

- Smoking,
- Drying,
- Cooking (roasting, baking, frying and barbecuing).

Furthermore, PAH can be present in the raw materials due to environmental contamination from the air or uptake by plants from contaminated soils. Presence of PAH in e.g. vegetable oils can also originate from smoking and drying processes used to dry oil seeds prior to oil extraction.

4. Contamination of food with PAH via environmental contamination should be controlled either by source-directed measures like filtering the smoke from relevant industries (e.g. cement work, incinerator and metallurgy) and limiting the exhaust fumes of PAH from cars. Good agricultural practices (GAPs), including the selection of appropriate farmland/fishing waters, could also decrease the environmental contamination of foods with PAH. However, this contribution to the PAH intake from the food is not included in this Code of Practice.

5. Toxicological information is included in **Annex II**. In the EU, benzo[*a*]pyrene is used as a marker for the occurrence of PAH in food; however, the suitability of benzo[*a*]pyrene as a marker is currently under review by the European Food Safety Authority (EFSA).

6. In its opinion on PAH, JECFA recommended that efforts should be made to reduce contamination with PAH during drying and smoking processes, e.g. by replacing direct smoking (with smoke developed in the smoking chamber, traditionally in smokehouses) with indirect smoking (JECFA, WHO, 2006).

7. The PAH content of thermally treated food differs depending on the processes used and how they are conducted. Occurrence data from the JECFA monograph (WHO 2006), in the EU SCOOP report (European Commission, 2004) and some national studies are found in **Annex III**.

8. From the data reviewed by the EU Scientific Committee on Food (SCF) (now the EFSA), cereals, vegetables, fats and oils were the major contributors to PAH in the diet, with grilled/smoked /barbecued fish and meat making a relatively low contribution except in populations where they are a significant part of the diet (European Commission, 2002). However, grilled/smoked/barbecued fish and meat can contribute significantly to the intake of PAH where such foods are the usual part of the diet. For example, grilled/barbecued meat was the second highest contributor, after the “bread, cereal and grain” group, in a study in the U.S. (Kazerouni *et al.*, 2001). With respect to the relative contribution of fats and oils, one recent study (COT, 2002) showed that these foods contribute far less to PAH intake in the UK diet than previously shown (Dennis *et al.*, 1983): 6% versus 59% for benzo[*a*]pyrene, and 3% versus 34% for total PAH.

OBJECTIVES

9. The objective of this Code of Practice is to identify important points to consider for a reduction of contamination of food with PAH during smoking and direct drying processes. The smoking and drying processes are used both in industry and in private households. Consumers might smoke food and would often use a direct process, while drying can be done either direct or indirectly, e.g. in the sun or in a microwave oven. The Code of Practice and the guidance given is mainly directed to the industry, but could be used as the basis for information to consumers.

10. The Code of Practice is intended to provide tools to optimise smoking and drying processes in order to reduce PAH in the final foodstuffs. The Code of Practice must recognise the benefits of smoking and drying including the availability of traditional smoked food products, prevention of spoilage and microbiological contamination and growth and the potential for lowering the risks to human health from PAH formed in foods during processing.

SCOPE

11. The scope of this Code of Practice is PAH contamination during commercial smoking, both direct and indirect, and direct drying processes.

12. The Code of Practice does not cover PAH contamination in food originating from

- a. Use of herbs and spices in the smoking process¹;
- b. Indirect drying;
- c. Other food processes, including barbecuing and other types of cooking in private homes or the catering sector; and
- d. Environmental contamination.

13. This Code of Practice covers contamination with PAH only. It should, however, be emphasized that conditions that lead to a reduction of one contaminant might lead to increases in the levels of other contaminants or could lower the microbiological standard of the food products. The possible interplay among levels of contaminants like PAH, heterocyclic amines, and nitrosamines is not always well understood, but these contaminants can be food safety problems either as such or due to the reaction of e.g. nitrogen oxide with components in the food leading to the formation of nitrosamines. It should be underlined that any guidance given to minimize PAH should not lead to increase in other contaminants.

DEFINITIONS

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

15. *Drying, direct* is a drying process where the combustion gas is used directly as the drying gas in contact with the foods. The direct drying process can be drying in the sun or by using combustion gases.

16. *Drying, indirect* is a drying process where the combustion gas is not coming into direct contact with the foods, where the drying gas is heated via a heat exchanger, electricity or by other means. As indirect drying is not regarded as a significant source of PAH, it is not covered by the Code of Practice and will not be addressed in this Code of Practice.

¹ In the *traditional smoking process*, the fuel used is often various wood species, in some cases with herbs and spices, e.g. juniper berries, to give a characteristic flavour. Such herbs and spices may be a potential source for PAH contamination. However, many different types of herbs and spices can be used, but normally only in smaller quantities and knowledge about the influence of using herbs and spices is limited. Their use is therefore not considered in this Code of Practice.

17. *HACCP*: A system which identifies, evaluates, and controls hazards which are significant for food safety (CAC/RCP 1-1969).
18. *Plant materials, other* is covering other types of fuels than woods used in the smoking or drying process e.g. bagasse, corn cobs and coconut husk and shell.
19. *Polycyclic aromatic hydrocarbons (PAH)* are a group of contaminants that constitute a large class of organic compounds containing two or more fused aromatic rings made up of carbon and hydrogen atoms. Hundreds of individual PAH may be formed and released as a result of incomplete combustion or pyrolysis of organic matter, during forest fires and volcanic eruptions as well as industrial processes or other human activities, including the processing and preparation of food and the carbonization of wood and other plant materials to make charcoal (WHO, 2006).
20. *Pyrolysis* is the chemical decomposition of organic materials by heating in the absence of oxygen or any other reagents, except possibly steam (http://en.wikipedia.org/wiki/Main_Page).
21. *Smoke* consists of liquid and solid particulates suspended in a gaseous phase. Particles in the smoke, generally of a size of 0.2-0.4 µm (or as low as 0.05 to 1 µm (Guillén *et al.*, 2000)), are estimated to constitute 90% of its overall weight. The chemical composition of smoke is complex and more than 300 components have been identified (Möhler, K, 1978; Solttes and Elder, 1981; Simko, P, 2005).
22. *Smoking* of food is a process used as a preservation method to prolong the shelf life of food due to components of the smoke inhibiting growth of some microorganisms. The smoking process is furthermore used to achieve the characteristic taste and appearance of smoked food.
23. *Smoking, direct* is the traditional type of smoking process, where the smoke is developed in the chamber in which the food is processed. Direct smoking requires less equipment than indirect smoking but can result in higher levels of PAH in the final food product.
24. *Smoking indirect* is a process where smoke generators are used, and the smoke is being developed in a chamber, separate from where the food is smoked. The smoke is possibly cleaned in various ways e.g. by use of a water filter or a tar condenser before being fed into the smoke chamber.
25. *Wood* is a solid material derived from woody plants, notably trees but also shrubs. Wood from the latter is only produced in small sizes, reducing the diversity of uses. In its most common meaning, "wood" is the secondary xylem of a woody plant, but this is an approximation only: in the wider sense, wood may refer to other materials and tissues with comparable properties (http://en.wikipedia.org/wiki/Main_Page). Wood consists of three main components: cellulose, hemicellulose and lignin (Andersen and Rissum, 1994) in a 2:1:1 ratio, and represent 95% of dry matter. *Wood* is often divided into two groups: Hardwood and softwood. Generally, there is more hemicellulose in hardwoods than in softwoods and more lignin in conifers, which are covered by the group of softwoods. On average, hardwood is of higher density and hardness than softwood, but there is considerable variation in actual wood hardness in both groups, with a large amount of overlap; some hardwoods (e.g. balsa) are softer than most softwood, while yew is an example of hard softwood. The dominant feature separating hardwoods from softwoods is the presence of pores, or vessels. Hardwood species are more varied than softwood. There are about a hundred times as many hardwood species as softwoods. The vessels may show considerable variation in size, shape of perforation plates (simple, scalariform, reticulate, foraminate), and structure of cell wall (e.g. spiral thickenings) (<http://en.wikipedia.org/wiki/Hardwood>).
26. *Wood, hardwood* is a term designating wood from broad-leaved (mostly deciduous, but not necessarily, in the case of tropical trees) or angiosperm trees. Hardwoods have broad leaves and enclosed nuts or seeds such as acorns. They often grow in subtropical regions like Africa and also in Europe and other regions such as Asia (<http://en.wikipedia.org/wiki/Hardwood>).
27. *Wood, softwood* is a term used for wood from conifer trees.

PREVENTIVE MEASURES AND GENERAL CONDITIONS IN GOOD MANUFACTURING PROCESSING OF FOOD.

28. The food producer should carry out an analysis of important points to consider in processes used or intended to be used in food production.

29. Information on PAH and conditions leading to presence of PAH of significance for food safety should be considered. The information would be on:

- ⇒ Possible sources of contaminants such as PAH during the process
- ⇒ Possible effects on consumer health
- ⇒ Controllability
- ⇒ Feasibility and effectiveness of controls (cost, commercial availability, occupational hazards)

In the Code of Practice for the smoking and drying process, important points to consider are highlighted in the flow sheets in **Annex IV**.

30. Other factors may also legitimately be considered, such as

- ⇒ Microbiological status of the product
- ⇒ Effects of the processes on organoleptic properties and quality of the product (the ideal method would have no adverse effects on the appearance, odour, taste or nutritional properties of the product)
- ⇒ Compliance with relevant legislation and relevant code of practices.

EVALUATION OF COMPLIANCE WITH RELEVANT LEGISLATION

31. Processed food shall be in compliance with relevant national or international legislation and standards, including general requirements for consumer protection. Furthermore, food shall be produced in accordance with relevant Codex or national codes of practice. Some of these may contain further information about drying or smoking, which should also be considered.

GENERAL REMARKS ON SMOKING AND DRYING PROCESSES

32. Traditional processes such as smoking and direct drying provide a wide variety of food textures and flavours and consequently a broader choice for consumers. Many types of smoked and dried foods are traditional food items, where these types of processes have been used to prolong storage times and quality and provide flavour and consistency required by consumers. The extension of shelf life may also have an effect on the nutritional value of foodstuffs, such as preservation of the vitamin content.

33. The formation of PAH during smoking and drying are dependent on a number of variables, including
- a. Fuel (woods and other plant materials, diesel, gases, liquid/solid waste and other fuels)
 - b. Cooking method (smoking or drying - direct or indirect)
 - c. Smoke generation process in relation with the temperature of pyrolysis and with the airflow in case of smoke generator (friction, smouldering, auto-combustion, thermostated plates) or in relation with other methods such as regenerated smoke (liquid smoke vaporisation and direct smoking).
 - d. The distance between the food and the heat source
 - e. Position of the food in relation to the heat source
 - f. Fat content of the food and what happens to it during processing
 - g. Duration of processing
 - h. Temperature during processing
 - i. Cleanliness and maintenance of equipment
 - j. Design of the smoking chamber and the equipment used for smoke/air mixture (which influence the smoke density on the smoking chamber).

34. In general, changes in processing techniques can in some cases reduce the amount of PAH formed during processing and found in the processed food. Alteration of the process could be done in different ways after evaluation of the important points for consideration, e.g. by using indirect drying or smoking processes instead of direct drying or smoking; via the selection of fuel for drying or of wood species and other plant materials used in the smoking process; and by adjusting times and processing temperatures.

35. Application of an HACCP system in accordance with the principles and steps as recommended by Codex is one of options for reducing PAH. An HACCP system can be used for this purpose, if feasible.

SMOKING PROCESS

36. Foodstuffs such as meat and fish, some types of cheese have been smoked in many countries for centuries. Originally the purpose was to preserve the food, partly by reducing the moisture content and partly through the transfer of anti-microbial and antioxidant components such as phenolic compounds from the smoke to the food.

Fuel used in processing

37. For smoking of food, woods are normally used, but other types of fuels like bagasse (plant material from sugarcane), corn cob and coconut husk and shell are used (information from Thailand). Fuel used is an important point to consider for the potential contaminants of the food, e.g. the PAH contamination of food differs if woods or straw is used (Nielsen and Illerup, 2003).

38. More technical background information is in Annex III, and the conclusion is that the wood species used have an influence on PAH formation. However, it has not been possible to find references to provide more specific recommendations on the use of wood species or other plant materials. Therefore, it is recommended, that the individual species of woods and other plant materials used in smoking processes have to be studied in relation to PAH formation before use.

39. For some foods, the effect of fuel choice on taste may be the important point to consider in choosing a fuel. In any event, fuels like e.g. diesel, rubber (e.g. tires) or waste oil should not be used even as a partial component, as they may well lead to increased PAH levels. The use of other fuels than wood and other plant materials for the purpose of smoking foodstuffs should be discouraged.

Foodstuffs processing

40. The position of the food in the smoke chamber and the distance between the food and the heat source is an important point to consider in the smoking process. As PAH is particle bound, longer distance might give lower content of PAH in the smoked food.

41. The fat content of the food fat drippings into the source for the smoke, e.g. the glowing wood or other plant materials might increase the content of PAH in the smoke and thereby in the smoked food. In order to avoid an increase in the PAH content through fat dripping into the open fire, perforated metal sheets can be installed between the food to be smoked and the fire.

42. The microbiological quality of the final food product must be evaluated to ensure that there is no potential growth of pathogens during processing and in the final food.

43. The organoleptic properties of the final products are an essential part of its characteristics. Changes of the methods might not necessary result in the organoleptical acceptable products.

Processing

44. Smoke is produced by pyrolysis of the fuel at temperatures of around 300-450 °C (and up to 600 °C) in the glow zone. Pyrolysis is the destruction of wood or other plant materials by a heating process. Activation energy provided by electricity allows wood to vaporize into combustible gas, which mix with the combustive agent (air). To avoid flames, airflow needs to be adjusted and controlled in order to prevent going beyond the temperature of inflammation of wood or other plant materials. In this meaning, it is an incomplete combustion, which leads to PAH production.

45. Differences in the smoking processes can lead to highly variable PAH levels in the final food product (European Commission, 2002). The choice of technology for processing is very important for the final concentration of PAH. The different variables in the processes used should be identification of important points to consider e.g. of the parameters critical for potential formation of PAH in a specific process used.

46. The traditional smoking processes are often divided into three groups after the temperatures used in the smoke chamber during processes:

- a. *Cold* smoking with temperature 18-25 °C. Used for e.g. some fish species and salami-type sausages
- b. *Semi-warm* with temperatures from 30- 40 °C. Used for e.g. some fish species, bacon and pork loin
- c. *Warm* smoking is smoking combined with heating resulting in a temperature of 70-90 °C. Used for e.g. some fish species, and frankfurter type sausages.

47. Replacing direct smoking with indirect smoking can significantly reduce contamination of smoked foods. In modern industrial kilns, an external smoke generator can be operated automatically under controlled conditions to clean the smoke and regulate its flow as it is brought into contact with the food. For more traditional or smaller scale operations, this may not, however, be an option.

48. The type of generator used should be based on an assessment of possible reduction of the PAH content in the final food and where possible include washing of the smoke after the generator and before the smoke chamber. Good results are achieved by installing baffles after the smoke generator equipped with a device for decantation of tar. A more efficient way is to manage the pyrolysis temperature and decanting of heavy phase tanks to a cooling device with baffles. The scientific background and data to illustrate the exact influence of the use of different types of fuel, time, temperature etc. is limited and specific testing is needed in the identification of important points to consider in the individual processes. Also other methods like use of long pipes in the equipment can reduce the PAH.

49. As PAH are particulate bound, a filter may be used to remove particulate material from the smoke. This should reduce potential contamination with PAH.

50. Oxygen needs to be adequate to ensure partial/incomplete combustion of the fuel. Too much oxygen may raise the temperature in the glow zone and lead to increased formation of PAH. A lack of oxygen may lead to the formation of more PAH in the smoke, as well as producing carbon monoxide, which may be hazardous to operators.

51. Temperature is of importance for the partial/incomplete combustion of the fuel. The composition of the smoke depends on the temperature, which should be adjusted to minimize PAH formation. However, more data is needed to document which temperatures would be recommendable.

52. In principle, the smoking time should be as short as possible to minimize the exposure of the food surfaces to PAH-bearing smoke. However, in the case of hot smoking, when the product is being cooked at the same time, it will be essential to allow sufficient time for the product to be cooked thoroughly. In case hot smoke is the only heat source (traditional smoke houses), the smoking chamber should be heated before the food products are placed into the smoking chamber. Dependency of time in the smoking and charcoal grilling processes is illustrated by data obtained by Chen and Lin in 1997. Smoking time is not an important parameter as long as the source for smoke is well managed. Moreover, short smoking times may have an impact on food safety and shelf life.

Post smoking treatment

53. There are two types of cleaning steps to be used either during processing or as post process treatment:

- a. The cleaning of smoke before it enters the smoking chamber. This can be achieved by washing (scrubbing), using a tar condenser, cooling or filtering. All measures to remove particle-bound PAH from the smoke
- b. The cleaning of the smoked product itself. In this case rinsing the product or immersing it into water may remove soot and particles containing PAH on the surface of the food. This type of cleaning would not be possible to use for all types of products, e.g. not for smoked fish and fishery products.

54. When possible, washing or water-cooling of smoke should be used to reduce the content of PAH in the final food. Water-cooling is already used in the meat industry, and this kind of washing of the product after the process may remove PAH-containing particles from the surface of the product (Fabech, B and Larsen, J.C., 1986).

55. However, washing of the product should not be used for fishery products as it could result in lower organoleptic quality and increased microbiological risk. Fish products are often smoked as the whole fish with the skin, and if the skin is not eaten, part of the PAH contamination are removed together with the skin. The recommendation could be to prioritise smoking of fish with the skin on.

IMPORTANT POINTS TO CONSIDER AND RECOMMENDATIONS FOR PRODUCTION OF SMOKED FOOD

56. PAH content of smoked foods can be minimised by identifying the important points to consider mentioned below. An HACCP system might be applied.

57. Fuel:

- a. The type and composition of wood used to smoke foods, including age of and water content in the wood used.
- b. When individual species of woods and other types of fuels like bagasse (from sugarcane), corn cob and coconut husk and shell are use, the use should be evaluated in light of PAH contamination.
- c. Do not use woods treated with chemicals
- d. The use of other fuels: Avoiding the use of fuels as diesel fuel, waste products, especially rubber tyres, olive residues and waste oil which may already contain significant levels of PAH
- e. Particle sizes (saw dust, wood shavings etc.)
- f. Influence on the taste of the final food.

58. Smoke developed and used in the process:

- a. The composition of the smoke depending of e.g. the type of wood or other plant materials, the amount of oxygen present and the temperature of pyrolysis and possibly the length of time for which the plant materials are burned.
- b. The design of the smoking chamber and of the equipment used for smoke/air mixture
- c. Filtering or cooling the smoke where possible
- d. Install baffles after the smoke generator equipped with a device for decantation of tar if possible

59. Foodstuffs smoked:

- a. The position of the food in the smoke chamber and the distance between the food and the heat source
- b. Chemical properties and composition of food, e.g. the fat content of the food to be smoked
- c. Deposits of smoke particles on the surface and the suitability of the surface for human consumption. For fish, the recommendation could be to prioritise smoking of fish with the skin on
- d. The microbiological quality after processing
- e. The organoleptic properties of the final food.

60. Smoking process:

- a. Whether the smoking process is a direct or indirect process
- b. Prior assessment of smoke generators by taking account of the resulting PAH content in the smoke
- c. Adjusting of the airflow to avoid too high temperature in the glowing zone during smoke generation
- d. Selecting appropriate smoking chamber and device for treatment of air/smoke mixture
- e. The accessibility of oxygen during the smoking process

- f. Smoking time: Reducing the time that food is in contact with smoke, this should take the consequences for microbiological safety and quality into consideration
 - g. Reducing the residence time of vapours in the reactor
 - h. Temperatures: Temperature in the glow zone (in the smoke generation step) and temperature of the smoke in the smoking chamber
 - i. In order to avoid an increase in the PAH content through fat dripping into the open fire, perforated metal sheets can be installed between the food to be smoked and the fire.
 - j. Filtering of smoke or the use of a tar condenser
 - k. The cleaning method and schedule applied in the processing unit.
61. Post smoking processes:
- a. The cleaning of the smoked product itself. In this case soot and particles containing PAH on the surface of the food may be removed by rinsing the product or immersing it into water
 - b. Washing/water cooling might lower organoleptic quality and increased the microbiological safety risk.

DIRECT DRYING

62. One of the oldest methods of food preservation is by drying, which reduces water activity sufficiently to delay or prevent bacterial growth. Drying food using the sun and wind to prevent spoilage has been known since ancient times. Water is usually removed by evaporation (air drying, sun drying, smoking or wind drying) but, in the case of freeze-drying food is first frozen, and then water is removed by sublimation.
63. Drying works by removing the water from food. As the bacteria and micro-organisms within the food and from the air need water to grow, drying is preserving the food. The drying process also creates a hard outer-layer, helping to stop micro-organisms from entering the food.
64. With regard to direct and indirect drying processes, direct drying requires less equipment than indirect but could result in higher levels of PAH in the final, dried food.
65. Direct drying can be done either using drying in the sun or using hot combustion gases from burning gases, oil, wood, solid/liquid waste etc.

This section is divided in direct drying using a) sun, b) other fuels.

Sun drying

66. When drying by use of the heat from the sun, the potential source of PAH is the environment as a contamination from soil/dust or/and from combustion from industry and traffic as well as forest fires and volcanic eruptions.
67. Sun drying of crops should not take place near industrial point sources of combustion of gas, such as roads with heavy traffic, incinerators, coal-fired power stations, cement works etc., or in the immediate proximity of roads with intense traffic. Contamination from drying in such place is expected to be a special problem for foodstuff with a big surface area like, spices. However, covered dryers may protect crops from industrial sources to some extent.

Direct drying processes, other than sun drying.

Fuel used

68. Drying in the sun is used in many countries, and besides this different types of fuel are used, e.g. natural gas, peat and mineral oils. Furthermore fuel like woods, rubber, and solid waste might be used in drying processes.
69. For some foods, the effect of fuel choice on taste may be the important points to consider in choosing a fuel. In any event, fuels like e.g. diesel, rubber e.g. tires or waste oil should generally not be used even as a partial component, as they may well lead to increased PAH levels. Some background information on the drying process and the fuel used is given in Annex III.

Combustion gasses

70. Drying with combustion gases increased the contamination by 3- to 10-fold; use of coke as fuel resulted in much less contamination than use of oil (Bolling, 1964). Direct contact of oil seeds or cereals with combustion products during drying processes has been found to result in the formation of PAHs and should therefore be avoided, and JECFA recommend that contact of food with combustion gasses be minimized (WHO, 2006).

Foodstuffs dried

71. Many types of food like meat, many fruits like apples, pears, bananas, mangos, papaya, and apricot are usually dried. Drying is also the normal means of preservation for cereal grains such as wheat, maize, oats, barley, rice, millet and rye.

72. Contamination of vegetable oils (including olive residue oils) with PAH usually occurs during technological processes like direct fire drying, where combustion products may come into contact with the oil seeds or oil (Speer *et al.*, 1990; Standing Committee on Foodstuffs, 2001). Direct contact of oil seeds or cereals with combustion products during drying processes has been found to result in formation of PAH and should therefore be avoided. For more data, see also **Annex III**

Direct drying process

73. Common direct drying/heating operations and applications include drying to remove water (and/or other solvents/chemicals) added, left or produced during processing. During direct drying, hot air is blown directly into the foodstuffs and combustion products can therefore directly enter the food. One example of PAH contamination from direct drying in contamination of vegetable oils (including olive residue oils) in which oil has been contaminated with PAH during technological processes (Antonopoulos, K *et al.*, 2006; Menichini, S. *et al.*, 1991). Another example can be drying oil seeds prior to oil extraction.

74. Continuous flow drying, where cereals pass the drying area continuously, is a widespread grain drying method. This technique can be used for drying cereals for food. Direct heating is mainly used with temperatures up to 120 °C for feeds. For foods, indirect heating (external heat generation) and temperatures between 65 and 80 °C are mainly used (bread, malt etc.). The time span for both types of drying is between ½ and 1 hour, depending on the initial moisture content of the grain.

75. Temperature should be optimal for drying without the opportunity for PAH formation. A good homogeneity of the temperature of the air is important to avoid overheating.

76. The drying time should be as short as possible to decrease the exposure of the food to the potentially contaminating gasses as much as possible.

77. The use of active carbon is required during refining of the oil as a way to reduce the PAH content after direct drying. A monitoring system for the PAH content should be established and additional refining steps (with active carbon) must be used when the PAH level in the food is unacceptable.

78. As drying processes could be a potential source of PAH in cereals and oil seeds, there is also a need to control the levels of PAH in agriculture crops post-harvest, with particular reference to the source of contamination, as these crops can have a major impact on PAH intake from food. JECFA recommend avoiding fire drying of seeds, and seek alternative drying techniques (WHO, 2006).

79. Numerous factors, including equipment cost and availability of energy sources often result in similar foods being dried in very different ways.

80. Replacing direct drying with indirect drying can significantly reduce contamination of dried foods. JECFA has recommended that direct drying be replaced with indirect drying (WHO, 2006).

IMPORTANT POINTS TO CONSIDER AND RECOMMENDATIONS ON DIRECT DRYING, EXCEPT SUN DRYING

81. An HACCP system might be applied.

82. Fuel used in the process:
 - a. The type and composition of fuel used to dry foods
 - b. If woods are use, use hard wood rather than softwood and do not use woods treated with chemicals
 - c. The use of other fuels: Avoiding the use of fuels as diesel fuel, waste products, especially rubber tyres, olive residues and waste oil which may already contain significant levels of PAH
 - d. Influence on the taste of the final food.
83. Combustion gases developed and used in the process:
 - a. Contact of food with combustion gasses be minimize
84. Foodstuffs dried:
 - a. Direct contact of oil seeds or cereals with combustion products should be avoided.
85. Drying process:
 - a. Temperature should be optimal for drying without the opportunity for PAH formation. A good homogeneity of the temperature of the air is important to avoid overheating
 - b. Reduce the time that food is in contact with combustion gasses
 - c. Keep equipment clean and well maintained (especially driers).

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Annex I

Polycyclic aromatic hydrocarbons included in the JECFA Risk Assessment

Common name	CAS name	CAS Registry No.
Acenaphthene	Acenaphthylene	83-32-9
Acenaphthylene	Acenaphthylene, 1,2-dihydro-	208-96-8
Anthanthrene	Dibenzo[<i>def,mno</i>]chrysene	191-26-4
Anthracene	Anthracene	120-12-7
Benz[<i>a</i>]anthracene	Benz[<i>a</i>]anthracene	56-55-3
Benzo[<i>a</i>]fluorine	11 H-Benzo[<i>a</i>]fluorine	238-84-6
Benzo[<i>b</i>]fluorene	11 H-Benzo[<i>b</i>]fluorene	243-17-4
Benzo[<i>b</i>]fluoranthene	Benz[<i>e</i>]acephenanthrylene	205-99-2
Benzo[<i>ghi</i>]fluoranthene	Benzo[<i>ghi</i>]fluoranthene	203-12-3
Benzo[<i>j</i>]fluoranthene	Benzo[<i>j</i>]fluoranthene	205-82-3
Benzo[<i>k</i>]fluoranthene	Benzo[<i>k</i>]fluoranthene	207-08-9
Benzo[<i>ghi</i>]perylene	Benzo[<i>ghi</i>]perylene	191-24-2
Benzo[<i>c</i>]phenanthrene	Benzo[<i>c</i>]phenanthrene	195-19-7
Benzo[<i>a</i>]pyrene	Benzo[<i>a</i>]pyrene	50-32-8
Benzo[<i>e</i>]pyrene	Benzo[<i>e</i>]pyrene	192-91-2
Chrysene	Chrysene	218-01-9
Coronene	Coronene	191-07-1
Cyclopenta[<i>cd</i>]pyrene	Cyclopenta[<i>cd</i>]pyrene	27208-37-3
Dibenz[<i>a,h</i>]anthracene	Dibenz[<i>a,h</i>]anthracene	53-70-3
Dibenzo[<i>a,e</i>]pyrene	Naphtho[1,2,3,4- <i>def</i>]chrysene	192-65-4
Dibenzo[<i>a,h</i>]pyrene	Dibenzo[<i>b,def</i>]chrysene	189-64-0
Dibenzo[<i>a,i</i>]pyrene	Benzo[<i>rst</i>]pentaphene	189-55-9
Dibenzo[<i>a,l</i>]pyrene	Dibenzo[<i>def,p</i>]chrysene	191-30-0
Fluoranthene	Fluoranthene	206-44-0
Fluorene	9H-Fluorene	86-73-7
Indeno[1,2,3- <i>cd</i>]pyrene	Indeno[1,2,3- <i>cd</i>]-pyrene	193-39-5
5-Methylchrysene	Chrysene, 5-methyl-	3697-24-3
1-Methylphenanthrene	Phenanthrene, 1-methyl-	932-69-9
Naphthalene	Naphthalene	91-20-3
Perylene	Perylene	198-55-0
Phenanthrene	Phenanthrene	85-01-8
Pyrene	Pyrene	129-00-0
Triphenylene	Triphenylene	217-59-4

TOXICOLOGICAL CONSIDERATIONS, Summary

1. JECFA reviewed PAH in February 2005 (WHO 2006).
 - a. The Committee concluded that the critical effect of PAH is carcinogenicity. As a number of PAH are also genotoxic, it is not possible to assume a threshold mechanism and a PTWI could not be established. Most epidemiological data refer to occupational and environmental exposure. The available evidence regarding oral exposure to PAH was indirect and did not include data on quantitative exposure, and thus was not suitable for use in the risk assessment for PAH.
 - b. JECFA used benzo[*a*]pyrene as a marker of the carcinogenic PAH and evaluated results of recent carcinogenicity studies in mice and rats on benzo[*a*]pyrene and used a margin of exposure approach for the risk assessment of PAH.
 - c. The present JECFA evaluation focused on 13 PAH that the Committee identified as being genotoxic and carcinogenic: benz[*a*] anthracene, benzo[*b*]fluoranthene, benzo[*j*]fluoranthene, benzo[*k*]fluoranthene, benzo[*a*]pyrene, chrysene, dibenzo[*a,h*]anthracene, dibenzo[*a,i*]pyrene, dibenzo[*a,h*]pyrene, dibenzo[*a,l*]pyrene, indeno[1,2,3-*cd*]pyrene and 5- methylchrysene.
 - d. JECFA compared mean and high-level intakes of PAH with the calculated benchmark dose lower confidence limit for PAH and calculated margins of exposure (MOEs) of 25 000 and 10 000, respectively. The MOEs were based on available intake data, and can be a useful tool to prioritize risks. Based on these MOEs, JECFA concluded that the estimated intakes of PAHs were of low concern for human health.
 - e. JECFA noted that measures to reduce intake of PAH could include avoiding contact of foods with flames, and cooking with the heat source above rather than below the food. Efforts should be made to reduce contamination with PAH during drying and smoking processes, e.g. by replacing direct smoking (with smoke developed in the smoking chamber, traditionally in smokehouses) with indirect smoking.
 - f. JECFA recommended that future monitoring should include, but not be restricted to, analysis of the 13 PAH identified as being genotoxic and carcinogenic, i.e. benzo[*a*]anthracene, benzo[*b*]-, benzo[*j*]-, and benzo[*k*]fluoranthene, benzo[*a*]pyrene, chrysene, dibenzo[*a,h*]anthracene, dibenzo[*a,e*]-, dibenz[*a,h*]-, dibenzo[*a,i*]- and dibenzo[*a,l*]pyrene, indeno[1,2,3-*cd*]pyrene and 5-methylchrysene. In addition, analysis of benzo[*c*]fluorine in food may help to inform future evaluations.
 - g. In the European Union, thirty-three PAH were evaluated by the Scientific Committee on Food (European Commission, 2002). Among these, 15, namely benzo[*a*]anthracene, benzo[*b*]-, benzo[*j*]- and benzo[*k*]fluoranthene, benzo[*ghi*]perylene, benzo[*a*]pyrene, chrysene, cyclopenta[*cd*]pyrene, dibenz[*a,h*]anthracene, dibenzo[*a,e*]-, dibenzo[*a,h*]-, dibenzo[*a,i*]-, dibenzo[*a,l*]pyrene, indeno[1,2,3-*cd*]pyrene and 5-methylchrysene, show clear evidence of mutagenicity/genotoxicity in somatic cells in experimental animals *in vivo*.
 - h. For most PAH, the carcinogenic potential constitutes the critical effect for the hazard and risk characterization. In general, the evidence of genotoxicity shows considerable overlapping with carcinogenicity in agreement with the mechanistic link between DNA adduct formation, mutations, and cancer outcome following PAH exposure.
 - i. With the exception of benzo[*ghi*]perylene, the 15 genotoxic PAH (evaluated by the European Union Scientific Committee on Food) have also shown clear carcinogenic effects in various types of bioassays in experimental animals. Although only benzo[*a*]pyrene has been adequately tested using dietary administration, these compounds may be regarded as potentially genotoxic and carcinogenic to humans. They represent a priority group in the assessment of the risk of long-term adverse health effects following dietary intake of PAH.
 - j. In the JECFA Summary report (Joint FAO/WHO Expert Committee on Food Additives, February 2005), the Committee note that they have not received any data on occurrence in the GEMS/food format. However, based on data from the European Union SCOOP task force and from IPCS reports, it was noted that the major foods containing higher concentrations of PAH are meat and fish products, particularly grilled and barbecued products, oils and fats, cereals and dry foods.

2. Example

Some examples are given of the content of PAH in foods after processing of food such as drying and smoking and cooking of foods at high temperatures (grilling, roasting, frying):

- In uncooked foods the average background values are usually in the range 0.01–0.1 µg/kg.
- In barbecued meat levels of the individual PAH, benzo[*a*]pyrene have been found as high as 157 µg/kg.
- In traditional smoked food, an average of benzo[*a*]pyrene was 1.2 µg/kg with a sum of carcinogenic compounds of 9 µg/kg. For modern kilns the values were 0.1 µg/kg and 4.5 µg/kg respectively.
- A level of 10.7 µg/kg of benzo[*a*]pyrene as been reported in corn oil.

However, national studies has shown much higher concentrations, like e.g. in Finland² where in a study from 2003 the concentrations of benzo[*a*]pyrene varied from zero to 34 µg /kg and that of the total PAH compounds (19 compounds) from 42 to 9000 µg /kg. The study shows that the total PAH concentrations can be very high for instance in smoked meat products.

² National Food Agency, Finland, 2003.

Annex III

PAH CONTENT IN SOME SMOKED AND DRIED FOODS

The Annex gives background information on formation and content of PAH in some foodstuffs.

Formation of PAH from fuel used for smoked of food.

a. The main groups of chemicals in the smoke are phenolic and carbonylic compounds, acids, PAH and nitrogen oxides and their reaction products. Some examples of components found to be contributing to the smoke flavour are: phenolic compounds, carbonylated phenolic compounds, derivatives, including cyclopentenone, cresols/alkylated phenolic compounds (of guaiacol type) (Selttes, E.J., Elder, T. J. 1981), phenolaldehydes, pentaenone, and alcyphenols of the guajacol type (Selttes, E.J and Elder, T.J., 1981).

b. PAH are formed in wood smoke by two main routes: either by HACA (hydrogen abstraction/acetylene addition), i.e. by consecutive additions of an acetylenic motif), or by thermodegradation of lignin. During pyrolysis, thermodegradation breaks down furan and pyran heterocycles in lignin, producing a large diversity of volatile compounds while more stable aromatic cores only lose some side groups. This explains why the use of conifer woods, with their higher lignin content and the possibility of a higher contamination of PAH should be avoided.

c. There are some indications that the use of hardwoods for smoking leads to lower PAH levels than the use of soft woods. However, there is conflicting literature on this. Hard woods can be used in form of chips, sawdust or logs³. Benzo[a]pyrene reaches the highest concentration upon application of spruce, hazel-tree, plum-tree and aspen, whereas the lowest concentration was brought about by apple-tree, alder and maple (Jākabsone and Bartkevics, 2006).

d. Maga *et al* (1986) reported that the use of the softwood species: mesquite wood resulted in increased levels of benzo[a]pyrene compared to the use of hard wood and charcoal. Maga, 1988 proposed to use hard woods instead of soft woods to reduce the PAH content. However, limited investigations are conducted and they are not in total agreement (Guillén *et al.*, 2000). The use of conifer woods should be avoided as they result in very acid products and raise safety concerns in particular increased fire risks because of bistre build-up in chimney (a highly flammable material derived from soot). PAH formation is higher using coconut husk as fuel than using coconut shell due to the higher lignin content of the husk (Lozada *et al.* 1998).

e. Woods treated with chemicals for preserving, waterproofing, fireproofing etc. should not be used. Such treatments may result in tainting of the food as well as the introduction of other contaminants e.g. dioxin from woods treated with pentachlorophenol (PCP) (Hansen and Hansen, 2003). The woods used for smoking and the woods used for the production of primary products (liquid smokes) shall not have been treated, intentionally or not, with chemical substances during the last six months immediately before felling or after felling, unless it can be demonstrated that the compound used for this treatment does not produce potentially toxic substances during burning.

Formation of PAH from fuel used for drying of food.

f. The hot drying gasses can be produced by using various types of fuel resulting in different types of contaminants in the air.

The heat energy of a system must:

- Heat the drying feed to the vaporization temperature of the "light" components
- Vaporize and/or free the liquid/by-products above the solids surface
- Heat solids to the final desired temperature, for the desired duration of time, and
- Heat the vapour to the final desired temperature.

g. The type and composition of fuel used in the drying process has an influence on the formation of PAH (Nielsen and Illerup, 2003), but insufficient data are available to recommend specific fuels. It is recommended to conduct an analysis of the fuel intended to be used, the actual process and foodstuffs to be dried. This assessment should take into account the benefit of using filtering of the gasses.

³ Logs are used to produce smoke by friction.

PAH content in some foodstuffs.

- h. Roasting and drying of coffee beans and tea leaves increase the PAH content (Stall and Eisenbrand, 1988). A Finnish study showed that roasted ground coffee and dried tea leaves contained high levels of PAH namely 100-200 microgram/kg and 480-1400 microgram/kg, respectively. However, PAH could not be detected in tea and coffee beverages (Hietaniemi *et al.*, 1999; limits of detection not available). In other studies it has been shown that the PAH contents in the coffee brew were only a few ng/L (Kayali-Sayadi *et al.*, 1999).
- i. For most non-meat products benzo[*a*]pyrene levels were low (Kazerouni *et al.*, 2000). From the SCOOP project average benzo[*a*]pyrene levels of 0.2 µg/kg were reported for both bread and rolls (n = 103) and cereals (n = 63) (European Commission, 2004). For popcorn benzo[*a*]pyrene average concentrations of 0.5 µg/kg was found. The bread/cereal/grain intake for average consumer has been found to cover approximately 30% of the total intake of benzo[*a*]pyrene (Larsson, 1986; Kazerouni *et al.*, 2001, European Commission, 2002; Duedahl-Olesen *et al.*, 2006), even though individual items in this food group have low levels of benzo[*a*]pyrene.
- j. For dried fruits 71% of 158 samples had benzo[*a*]pyrene levels below 2 µg/kg. However 10% of the total number of samples had concentrations of benzo[*a*]pyrene above 100 µg/kg (European Commission, 2004). No comments or explanation of the increased levels was included.
- k. Van der Wielen and co-workers (2006) reported benzo[*a*]pyrene concentrations up to 85 µg/kg in olive oils (n=170), while other vegetable oils (n=170) for human consumption only showed benzo[*a*]pyrene concentrations up to 9 µg/kg. Benzo[*a*]pyrene concentrations ranging from not detected levels to 64 µg/kg have been reported previously for vegetable oils (Dennis *et al.*, 1991, Moret *et al.*, 2000; European Commission, 2004).
- l. Examples of the effect that differences in smoking process can have on PAH levels, are the content of 12 PAH in smoked fishery products from modern smoking kilns that use external smoke generation and have procedures in place to remove compounds with high boiling points such as PAH and particles potentially containing PAH has been compared with products from traditional smoking kilns where the smoke is generated in direct contact with the product.
- m. The average benzo[*a*]pyrene concentration determined was 1.2 µg/kg for the traditional kilns and 0.1 µg/kg for the modern kilns (Karl and Leinemann, 1996). Levels of benzo[*a*]pyrene being higher for traditional smoked fish compared to external smoked fish were confirmed by results on eel (n=7) and salmon (n=3), with even lower concentrations of benzo[*a*]pyrene for cold smoked salmon (Karl and Leinemann, 1996).
- n. In 2005, Yurchenko and Mölder confirmed the trend, where cold smoked mackerel (n=6) and herring (n=4) did not have detectable levels of benzo[*a*]pyrene (< 0.2 µg/kg) in comparison to varieties (n=4) processed by hot smoking with benzo[*a*]pyrene concentrations of 0.7 µg/kg. Analysis of herring (n=7) and mackerel (n=9) produced by either direct or indirect smoking did however not show statistically significant different average concentrations of benzo[*a*]pyrene (Duedahl-Olesen *et al.*, 2006). Increased levels were however found for both one mackerel (0.7 µg/kg) and one herring (3.9 µg/kg) smoked by a direct smoking processes using common alder wood for smoke formation. Recent results on studies on different processing methods of fish are listed in table 1.
- o. Furthermore, collection of data in the European Union Scientific Cooperation Task (European Commission, 2004) revealed an average benzo[*a*]pyrene concentration for fresh fish of 0.2 µg/kg (n=454) including 11 samples from monitoring in contaminated areas. For smoked fish average concentrations of benzo[*a*]pyrene for fish smoked with unknown smoking methods (n=127) and for fish smoked by traditional methods (n=213) were reported as 1.4 µg/kg and 5.3 µg/kg, respectively (European Commission, 2004). In comparison addition of liquid smoke flavouring to fish (n=12) resulted in average benzo[*a*]pyrene concentrations of 0.03 µg/kg.

p. For fish with edible parts exposed to the smoke increased benzo[a]pyrene concentrations were found. This is illustrated by mackerel fillets with concentrations of benzo[a]pyrene of 0.4 and 0.9 µg/kg compared to <0.08 µg/kg for whole mackerel (Duedahl-Olesen *et al.*, 2006). In 1996, Karl and Leinemann reported that external smoking of mackerel fillets resulted in a benzo[a]pyrene concentration of 0.15 µg/kg (n=11), while traditional smoking of mackerel fillets resulted in levels of 0.6 µg/kg (n=7).

q. Benzo[a]pyrene levels of smoked meat products produced today do not seem to impose problems. The concentration of benzo[a]pyrene is well below 5 ppb. Duedahl-Olesen and co-workers reported benzo[a]pyrene levels for Danish produced products such as bacon, small sausages and salami well below the maximum of 0.6 µg/kg reported by WHO in 1998 for meat, fish and poultry. Jira (2004) found benzo[a]pyrene concentrations of 0.12 µg/kg ranging from 0.05 to 0.35 µg/kg for smoked ham and sausage (n=18).

r. Larsson concluded already in 1983 that the benzo[a]pyrene formation in meat is largely affected by the cooking method and the time for which it is cooked. Kazerouni *et al* (2001) reported concentrations of benzo[a]pyrene for other commercially produced products such as bacon, salami, smoked ham and sausages prepared as package directions of less than 0.1 µg/kg.

s. In the tables below, both drying and smoking terms such as direct or indirect drying or smoking are used. For direct or traditional smoking or drying the smoke formation source is placed in the same chamber as the final food product, while for indirect smoking or drying, a generator forms smoke externally.

Table 1. Fish

Benzo[a]pyrene concentrations in fish smoked under different processing conditions (µg/kg) n.d. not detected

Food item	Indirect	Direct	Other	Reference
Fresh fish			0.2 (± 0.7)	European Commission, 2004
Smoked fish	1.4 (± 7.2) (method unknown)	5.3 (± 21.7) (traditional)	0.03 (± 0.02) (liquid smoke flavouring)	European Commission, 2004
Canned smoked fish	2,2 (n=119)	13,4 (n=30)		Joffe and Bartkevics, 2003
Mackerel	<0.08 (n = 5)	0.18 (n = 4)	One sample, direct 0.72	Duedahl-Olesen <i>et al.</i> , 2006
Herring	<0.10 (n = 3)	0.15 (n = 4)	One sample, direct 3.9	Duedahl-Olesen <i>et al.</i> , 2006
Mackerel fillets		0.44 – 0.93		Duedahl-Olesen <i>et al.</i> , 2006
Mackerel fillets	0.15	0.6		Karl and Leinemann, 1996
Eel	0.02 (n.d. – 0,1)	1.1 (0.3 – 3.9)		Karl and Leinemann, 1996
Salmon	0.06	1.0	0.04 (cold smoked)	Karl and Leinemann, 1996
Herring/mackerel		0.7 (hot smoked)	n.d. (cold smoked, LOD = 0.24) n.d. (Fresh herring)	Yurchenko and Mölder, 2005
Salmon		0.8 (hot smoked)	0.4 (cold smoked)	Yurchenko and Mölder, 2005
Fish, not specified	n.d (7 samples; sawdust) n.d.; bagasse and corn cob	5.1; hard wood		Information provided from Thailand; 18 January 2008

Table 2. MeatBenzo[a]pyrene concentrations ($\mu\text{g}/\text{kg}$) in meat products smoked or grilled under different conditions

Food item				References
Smoked meat products	1.7 \pm 6.7 (n= 145, method unknown)	3.3 \pm 11.7(n = 1023, Traditional smoking)	0.02 \pm 0.03 (n=198, Liquid flavouring)	European Commission, 2004
Frankfurter	0.3 (charcoal fire) 0.2 (electric oven) 0.1 (frying pan)	54.2 (log fire) 7.7 (log fire embers) 17.6 (cone fire)		Larsson <i>et al.</i> , 1983
Hamburger	0.01 (oven-broiled)	0.01 (pan-fried)	Grilled/barbecued 0.09 (medium), 0.6 (well), 1.5 (very well)	Kazerouni <i>et al.</i> , 2001
Hamburger, restaurant grilled/barbecued	0.73 (medium)	1.2 (well)	1.4 (very well)	Kazerouni <i>et al.</i> , 2001
Steak	0.01 (Oven-broiled)	0.01 (pan-fried)	4.2 (medium) 4.8 (well) (grilled/barbecued)	Kazerouni <i>et al.</i> , 2001
Meat, barbecued	1.5			Lodovici <i>et al.</i> , 1995
Pork, barbecued	0.1			Lodovici <i>et al.</i> , 1995
Cooked Pattie (70-90% lean)	n.d. – 0.1 (hardwood, charcoal)	26 – 42 (mesquite wood)		Maga, 1986
Smoked meat products	0.12 (smoked cured ham n=8, smoked raw sausage, n=10)			Jira., 2004
Lamb sausage	0.32 \pm 0.02 (standard barbecue practice)	2.81 \pm 0.04 (barbecued under severe conditions)		Mottier <i>et al.</i> , 2000
Pork products	0.5 – 2.3 (wood smoked)	2.5 (grilled)	0.2 (liquid flavourings)	Gomaa <i>et al.</i> , 1993
Chicken with skin and bone	0.08 (oven-broiled)	0.12 (pan-fried)	4.6 (grilled/barbecued)	Kazerouni <i>et al.</i> , 2001
Chicken, whole	0.01 (stewed)	0.01 (roasted)		Kazerouni <i>et al.</i> , 2001
Chicken boneless	0.12 (Oven-broiled)	0.10 (pan-fried)	0.4 (grilled/barbecued)	Kazerouni <i>et al.</i> , 2001
Duck breast steak	6.9 (0.5 hr smoking) 6.9 (1 hr smoking)	9.0 (1.5 hr smoking) 10.6 (2 hr smoking)	13.9 (3 hr smoking)	Chen and Lin, 1997
Duck breast steak	9.2 Charcoal grilled without skin (0.5 hr) 3.7 Charcoal grilled with skin (0.5 hr)	8.4 Charcoal grilled without skin (1 hr) 5.0 Charcoal grilled with skin (1 hr)	8.5 Charcoal grilled without skin (1.5 hr) 5.0 Charcoal grilled with skin (1.5 hr)	Chen and Lin, 1997
Chicken	n.d. – 0.1 (flavouring, wood smoked)	0.7 – 0.8 (barbecued)		Gomaa <i>et al.</i> , 1993
Turkey breast, sausage and bacon	0.1 – 0.4 (wood smoked)		n.d. (LOD = Liquid flavouring)	Gomaa <i>et al.</i> , 1993

Table 3. Average, ranges and median of benzo[a]pyrene concentration in µg/kg for vegetable oils analyzed with country of origin including values for references (from Fromberg *et al.*, 2007)

Vegetable oil	N	Average	Range	Median	Origin
Olive oil, extra virgin	46	0.15	<0.2-0.4	0.10	IT, ES, GR, FR, NL
Olive oil	6	0.12	<0.2-0.2	0.10	IT, ES
Rapeseed oil	8	0.15	<0.2-0.3	0.10	DK, BE, DE, AT
Sunflower oil	3	0.4	<0.2-0.8	0.3	IT
Sunflower oil	1	11			NL
Grape seed oil	4	1.0	0.2-1.8	1.0	IT, ES, BE
Sesame oil	1	0.2			DE

					Reference
Virgin olive oil	671	0.4	0.015 - 32	0.2	European Comm., 2004
Virgin olive oil	2		<0.02 - 0.7		Hopia <i>et al.</i> , 1986
Virgin olive oil	52		<0.015 - 1.2		Moret <i>et al.</i> , 1997
Virgin olive oil	6		< 3		Menichini <i>et al.</i> , 1991
Virgin olive oil	3	0.1			Lodovici <i>et al.</i> , 1995
Olive oil	280	1.7	0.03 - 89	0.3	European Comm., 2004
Olive oil	32		0.5 - 164		Pupin and Toledo, 1996
Olive pomace oil	268	18	<0.1 - 206	9.6	European Comm., 2004
Olive oil	7	0.7	0.2 - 1.2		Speer <i>et al.</i> , 1990
Rapeseed oil, deod.	2	0.8	0.3 - 1.3		Larsson <i>et al.</i> , 1987
Rapeseed oil	18	0.3	<0.03 - 1.3	0.1	European Comm., 2004
Refined rapeseed oil	24	1.8	0.3 - 69		Dennis <i>et al.</i> , 1991
Sunflower oil	5	0.7	<0.1 - 0.8		Speer <i>et al.</i> , 1990
Sunflower oil	201	3.1	<0.015 - 232	0.4	European Comm., 2004
Grape seed oil	92	4.2	0.05 - 73	0.6	European Comm., 2004
Grape seed oil	20	20	8.6-44		Moret <i>et al.</i> , 2000

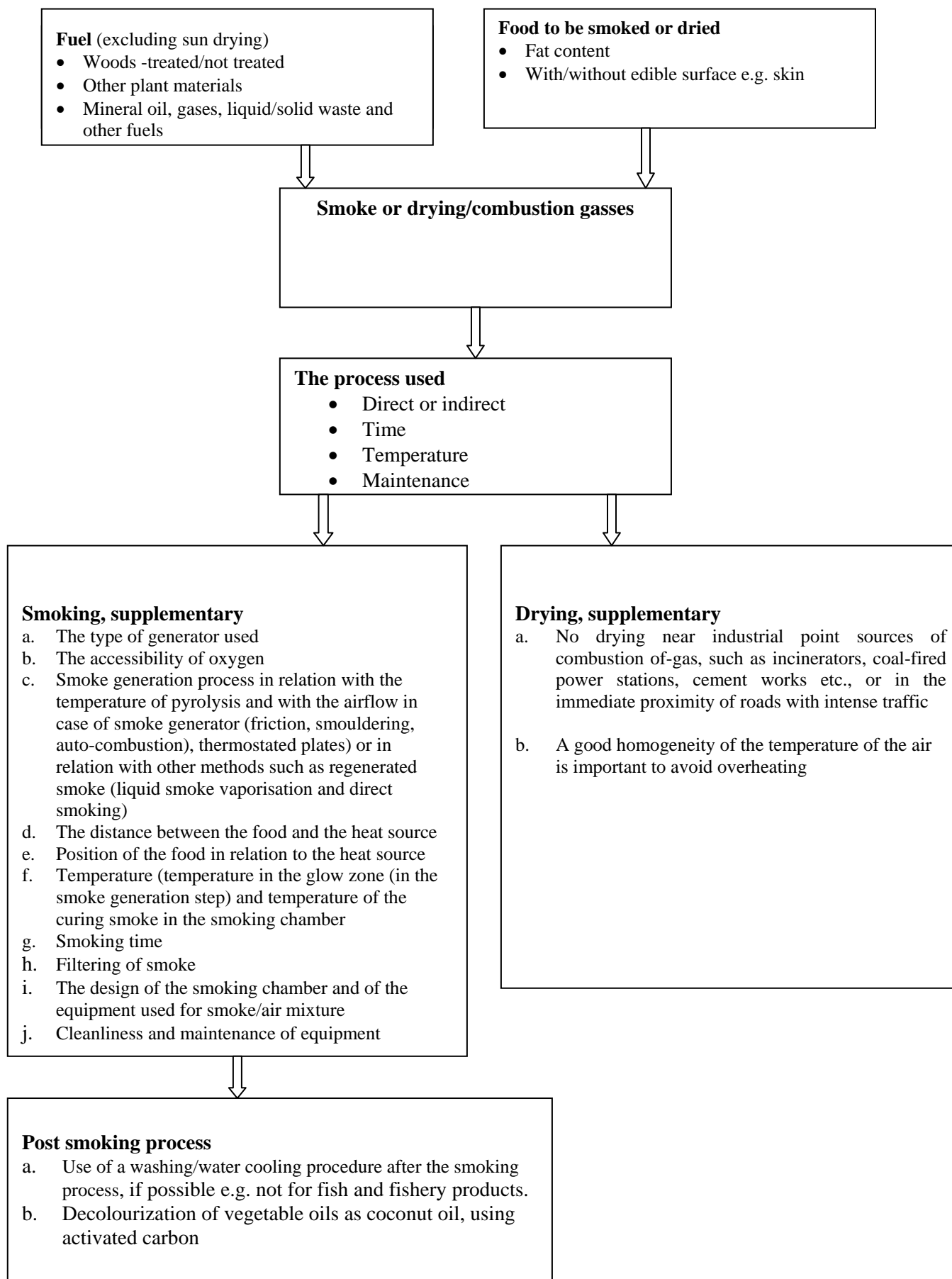
Deod. = deodorized oil.

Origin codes: AT = Austria, BE = Belgium, DE = Germany, DK = Denmark, ES = Spain, FR = France, GR = Greece, IT = Italy, NL = Holland.

Table 4. Other foodstuffs. Benzo[a]pyrene concentrations (µg/kg) in other types of food.

Food item	N	BaP average	Median	Reference
Bread and rolls	103	0.16 (± 0.55)	0.05	European Commission, 2004
Cereals	63	0.16 (± 0.31)	0.05	European Commission, 2004
Dried fruits	158	48.1 (± 5.30)	0.25	European Commission, 2004

Flow chart indicating important points to consider



APPENDIX VII

**DRAFT MAXIMUM LEVEL FOR OCHRATOXIN A
IN
RAW WHEAT, BARLEY, AND RYE
(At Step 8 of the Procedure)**

Code No.	Food	ML ($\mu\text{g}/\text{kg}$)	Step	Remarks
GC 0654 GC 0640 GC 0650	Raw Wheat, Barley, and Rye	5	8	

APPENDIX VIII

**DRAFT MAXIMUM LEVELS FOR TOTAL AFLATOXINS IN ALMONDS, HAZELNUTS AND
PISTACHIOS “FOR FURTHER PROCESSING”
AND “READY-TO-EAT”**

(At Step 8 of the Procedure)

Code No.	Food	ML($\mu\text{g}/\text{kg}$)	Step	Remarks
TN 0660 TN 0666 TN 0675	Almonds, Hazelnuts and Pistachios “for further processing” ¹	15	8	
TN 0660 TN 0666 TN 0675	Almonds, Hazelnuts and Pistachios “ready-to-eat” ²	10	8	

¹ Nuts which are intended to undergo an additional processing/treatment that has proven to reduce levels of aflatoxins before being used as ingredient in foodstuffs, otherwise processed or offered for human consumption.

² Nuts which are not intended to undergo an additional processing/treatment that has proven to reduce levels of aflatoxins.

Processes that have been proven to reduce aflatoxin are shelling, blanching sorting by size, specific gravity, and colour (damage), while processes that haven't been proven to reduce aflatoxin are packaging, foreign material removal, drying, salting, flavouring. There is some evidence that roasting reduces aflatoxin in pistachios. Evidence for other nuts still needs to be provided.

APPENDIX IX**PROPOSED DRAFT AFLATOXIN SAMPLING PLANS FOR AFLATOXIN CONTAMINATION IN READY-TO-EAT TREENUTS AND TREENUTS DESTINED FOR FURTHER PROCESSING: ALMONDS, HAZELNUTS AND PISTACHIOS**

(At Step 5/8 of the Procedure)

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 subplot 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 subplot.

Aggregate sample - the combined total of all the incremental samples that is taken from the lot or subplot. 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 three 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 distribution¹ are used to calculate operating characteristic (OC) curves that describe the performance of the proposed aflatoxin-sampling plans (Annex II).
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) data². 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 three treenuts. The within laboratory analytical uncertainty for each treenut can be found at the website <http://www5.bae.ncsu.edu/usda/www/ResearchActDocs/treenutwg.html>.
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, and pistachios) “ready-to-eat” and “destined for further processing” are 10 and 15 ng/g, 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 three 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 ng/g 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)

Sample preparation – dry grind with vertical cutter mixer type mill and a 50 g test portion

Analytical method – performance based (see Table 2)

Decision rule – If the aflatoxin test result is less than or equal to 15 ng/g 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 ng/g total aflatoxins

Number of laboratory samples – 2

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.

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.

Laboratory sample size - 10 kg

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)

Sample preparation – dry grind with vertical cutter mixer type mill and a 50 g test portion

Analytical method – performance based (see Table 2)

Decision rule – If the aflatoxin test result is less than or equal to 10 ng/g 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 three 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 subplot) weight.

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

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

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 subplot may not be accessible.
22. Taking incremental samples from a static lot usually requires the use of probing devices to select product from the lot. The probing devices should be specifically designed for the commodity and type of container. The probe should (1) be long enough to reach all products, (2) not restrict any item in the lot from being selected, and (3) not alter the items in the lot. As mentioned above, the aggregate sample should be a composite from many small incremental samples of product taken from many different locations throughout the lot.
23. For lots traded in individual packages, the sampling frequency (SF), or number of packages that incremental samples are taken from, is a function of the lot weight (LT), incremental sample weight (IS), aggregate sample weight (AS) and the individual packing weight (IP), as follows:

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

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

Dynamic Lots

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

26. Automatic sampling equipment such as a cross-cut sampler is commercially available with timers that automatically pass a diverter cup through the moving stream at predetermined and uniform intervals. When automatic sampling equipment is not available, a person can be assigned to manually pass a cup through the stream at periodic intervals to collect incremental samples. Whether using automatic or manual methods, incremental samples should be collected and composited at frequent and uniform intervals throughout the entire time the nuts flow past the sampling point.
27. Cross-cut samplers should be installed in the following manner: (1) the plane of the opening of the diverter cup should be perpendicular to the direction of the flow; (2) the diverter cup should pass through the entire cross sectional area of the stream; and (3) the opening of the diverter cup should be wide enough to accept all items of interest in the lot. As a general rule, the width of the diverter cup opening should be about two to three times the largest dimensions of items in the lot.
28. The size of the aggregate sample (S) in kg, taken from a lot by a cross cut sampler is:
Equation 2: $S = (D \times LT) / (T \times V)$,
where D is the width of the diverter cup opening (cm), LT is the lot size (kg), T is interval or time between cup movement through the stream (seconds), and V is cup velocity (cm/sec).
29. If the mass flow rate of the moving stream, MR (kg/sec), is known, then the sampling frequency (SF), or number of cuts made by the automatic sampler cup can be computed from Equation 3 as a function of S, V, D, and MR.
Equation 3: $SF = (S \times V) / (D \times MR)$.
30. Equations 2 and 3 can also be used to compute other terms of interest such as the time between cuts (T). For example, the time (T) required between cuts of the diverter cup to obtain a 20 kg aggregate sample from a 20,000 kg lot where the diverter cup width is 5.0 cm and the cup velocity through the stream 30 cm/sec. Solving for T in Equation 2,
 $T = (5.0 \text{ cm} \times 20,000 \text{ kg}) / (20 \text{ kg} \times 30 \text{ cm/sec}) = 250 \text{ sec}$.
31. If the lot is moving at 500 kg per minute, the entire lot will pass through the sampler in 40 minutes (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 reduction³. A better homogenization (finer grind), such as a liquid slurry, can be obtained by more sophisticated equipment and should provide the lowest sample preparation variance⁴.

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) 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.

³ 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.

⁴ 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.

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

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 Thompson² and Horwitz and Albert⁵, respectively.

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

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

where:

- RSD_R = the relative standard deviation calculated from results generated under reproducibility conditions
- RSD_r = the relative standard deviation calculated from results generated under repeatability conditions = $0.66RSD_R$
- 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. ng/g)

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.

⁵ 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, and pistachios.

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

Variance estimates and the negative binomial distribution¹ were used to compute operating characteristic curves for each treenut in Annex II. Sampling, sample preparation, and analytical variances associated with testing almonds, hazelnuts, and pistachios 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>.

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

Test Procedure	Almonds	Hazelnuts	Pistachios
Sampling ^{b,c}	$S_s^2 = (7,730/ns)5.759C^{1.561}$	$S_s^2 = (10,000/ns)4.291C^{1.609}$	$S_s^2 = 8,000/ns)7.913C^{1.475}$
Sample Prep ^d	$S_{sp}^2 = (100/nss)0.170C^{1.646}$	$S_{sp}^2 = (50/nss)0.021C^{1.545}$	$S_{sp}^2 = (25/nss)2.334C^{1.522}$
Analytical ^e	$S_a^2 = (1/na)0.0484C^{2.0}$	$S_a^2 = (1/na)0.0484C^{2.0}$	$S_a^2 = (1/na)0.0484C^{2.0}$
Total variance	$S_s^2 + S_{sp}^2 + S_a^2$	$S_s^2 + S_{sp}^2 + S_a^2$	$S_s^2 + S_{sp}^2 + S_a^2$

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 ng/g total aflatoxin.

c/ Shelled nut count/kg for almonds, hazelnuts, and pistachios is 773, 1000, and 1600, respectively.

d/ Sample preparation for almonds, hazelnuts, and pistachios reflect Hobart, Robot Coupe, and Marjaan Khatman type mills, respectively. Laboratory samples were dry ground into a paste for each treenut.

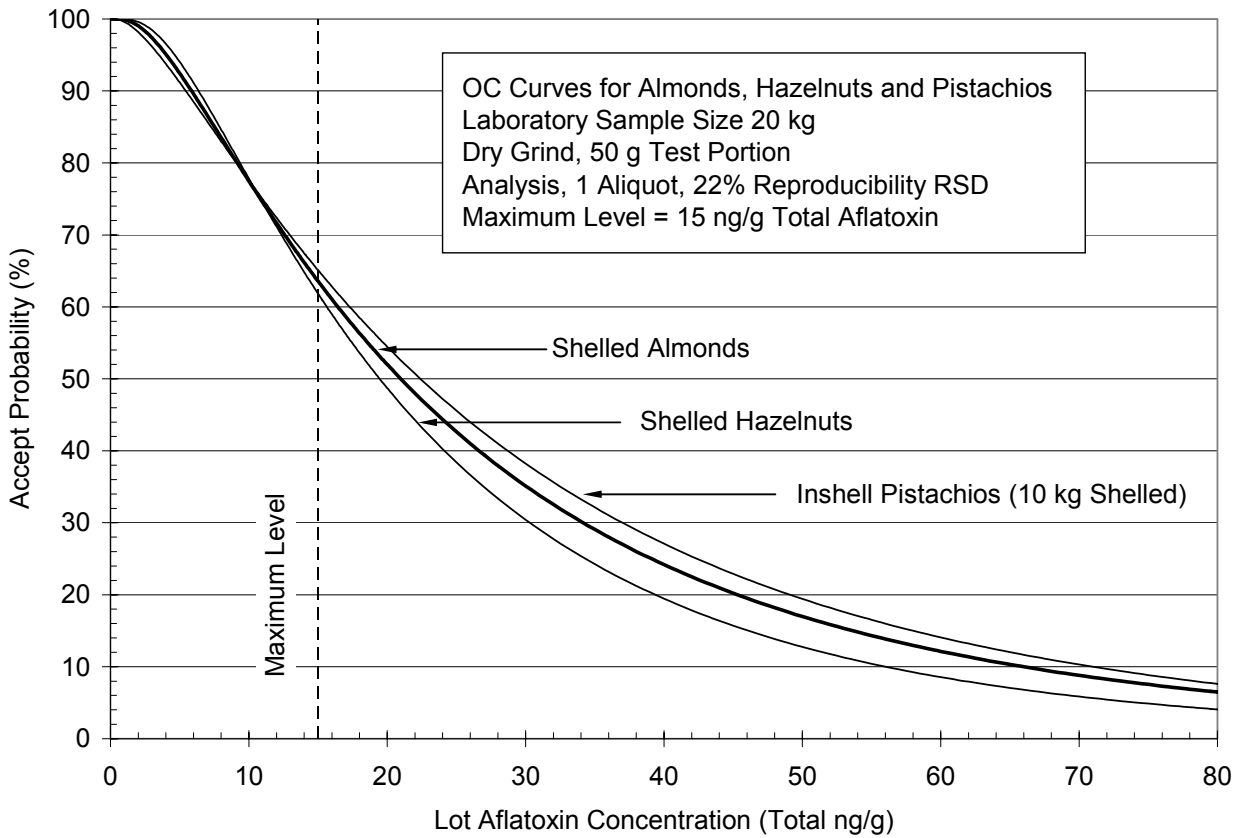
e/ Analytical variances reflect FAPAS recommendation for upper limit of analytical reproducibility uncertainty. A relative standard deviation of 22% is considered by Thompson² (based upon FAPAS data) as an appropriate measure of the best agreement that can be obtained between laboratories. An analytical uncertainty of 22% is larger than the within laboratory uncertainty measured in the sampling studies for the three treenuts.

Annex II

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

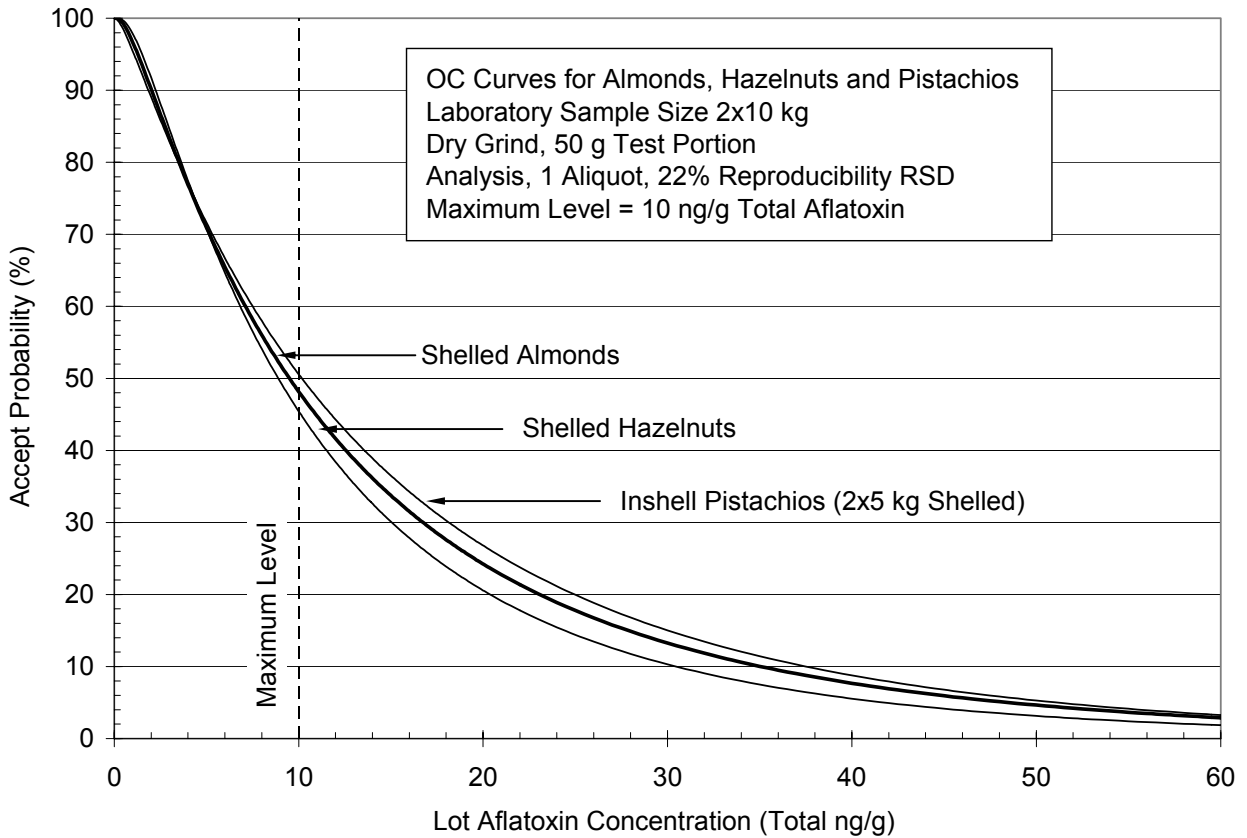
Treenuts Destined for Further Processing

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



APPENDIX X**PROJECT DOCUMENT****PROPOSAL FOR NEW WORK ON “DRAFT MAXIMUM LEVELS FOR
TOTAL AFLATOXINS IN BRAZIL NUTS”****1. The purpose and scope of the project**

This project aims to establish maximum levels for total aflatoxins in Brazil nuts destined for further processing and ready-to-eat Brazil nuts, both in-shell and shelled nuts.

2. Relevance and timeliness

Aflatoxin contamination can be a potential problem in tree nuts, including Brazil nuts, which is the only extractivistic crop among the main internationally traded tree nuts. This activity is important for the native people in the growing countries, stimulating a sustainable use of renewable natural resources while conciliating social development with forest preservation.

A Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Tree Nuts was adopted by the CAC at its 28th Session. A specific Appendix, addressing Good Extractivistic Practice for Brazil Nuts, was included in the Code of Practice and adopted by the CAC at its 29th Session.

Furthermore, there is a need for an international regulatory level, based on scientific evidence, aiming at the protection of human health with a minimum economical impact on international trade.

3. The main aspects to be covered

It is proposed to discuss a maximum level for total aflatoxins in Brazil nuts, considering:

- a) The results of the JECFA dietary exposure assessment on tree nuts (ready-to-eat), including Brazil nuts, and the impact on exposure to human health taking into account hypothetical standards for aflatoxin contamination.
- b) The application of good practices to prevent aflatoxin contamination as much as reasonably achievable in particular as regards collection, transport, storage and processing of Brazil nuts.
- c) Brazil nuts can be traded internationally either as for further processing and ready-to-eat. Therefore, maximum levels for both products are needed.
- d) There is a significant difference between the level of aflatoxin contamination in shelled and in-shell nuts.

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 the food trade and taking into account the identified needs of developing countries.

The new work will provide maximum levels for aflatoxin in Brazil nuts which are safe for the consumers and have an acceptable economic impact on the producers.

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

The new work will provide an internationally harmonized standard.

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 fair trade.

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

This work will help in establishing risk management options, based on scientific evaluation.

Goal 3. Strengthening Codex work-management capabilities

The establishment of maximum levels for total aflatoxins in Brazil nuts is a way to manage risks associated with the consumption of high contaminated kernels, especially by high-level consumers.

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 requiring participation of both developed and developing countries to conduct the work.

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

The establishment of a maximum level for aflatoxin in Brazil nuts is recommended in the Discussion Paper on Aflatoxin Contamination in Brazil Nuts (CX/CF 08/12/12-rev.1) which was updated and presented at the 2nd Session of the Codex Committee on Contaminants in Foods.

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

It is not yet foreseen. The INC and the Foundation Scientific Committee may provide some advice.

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

JECFA has already assessed the risk of aflatoxin in tree nuts, including Brazil nuts. Data currently available do not allow a conclusive in-shell/shelled nut ratio for total aflatoxin level. The Brazilian Government is finalizing a study that might clarify this issue and should support a maximum level for in-shell nuts destined for further processing in a near future.

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 levels for aflatoxins in Brazil nuts will be considered by the 3rd Session of the Committee (2009), adoption at Step 5 (2010) and final adoption by the Commission (2011).

PROPOSED DRAFT CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF AFLATOXIN CONTAMINATION IN DRIED FIGS

(At Step 5/8 of the Procedure)

INTRODUCTION

1. The elaboration and acceptance of a Code of Practice for dried figs by Codex will provide uniform guidance for all countries to consider in attempting to control and manage contamination by various mycotoxins, specifically aflatoxins. It is of high importance in order to ensure protection from aflatoxin contamination in both producer and importer countries. All dried figs should be prepared and handled in accordance with the Recommended International Code of Practice – General Principles of Food Hygiene¹ and Recommended International Code of Hygienic Practice for Dried Fruits² which are relevant for all foods being prepared for human consumption and specifically for dried fruits. It is important for producers to realize that Good Agricultural Practices (GAP) represent the primary line of defence against contamination of dried figs with aflatoxins, followed by the implementation of Good Manufacturing Practices (GMP) and Good Storage Practices (GSP) during the handling, processing, storage and distribution of dried figs for human consumption. Only by effective control at all stages of production and processing, from the ripening on the tree through harvest, drying, processing, packaging, storage, transportation and distribution can the safety and quality of the final product be ensured. However, the complete prevention of mycotoxin contamination in commodities, including dried figs, has been very difficult to achieve.
2. This Code of Practice applies to dried figs (*Ficus carica* L.) of commercial and international concern, intended for human consumption. It contains general principles for the reduction of aflatoxins in dried figs that should be sanctioned by national authorities. National authorities should educate producers, transporters, storage keepers and other operators of the production chain regarding the practical measures and environmental factors that promote infection and growth of fungi in dried figs resulting in the production of aflatoxin in orchards. Emphasis should be placed on the fact that the planting, pre-harvest, harvest and post-harvest strategies for a particular fig crop depends on the climatic conditions of a particular year, local production, harvesting and processing practices followed in a particular country or region.
3. National authorities should support research on methods and techniques to prevent fungal contamination in the orchard and during the harvesting, processing and storage of dried figs. An important part of this is the understanding of the ecology of *Aspergillus* species in connection with dried figs.
4. Mycotoxins, in particular aflatoxins are secondary metabolites produced by filamentous fungus found in soil, air and all plant parts and can be toxic to human and animals through consumption of contaminated food and feed entering into food chain. There are a number of different types of aflatoxin, particularly aflatoxin B1 have been showed toxigenic effects i.e. it can cause cancer by reacting with genetic material. Aflatoxins are produced by mould species that grow in warm, humid conditions. Aflatoxins are found mainly in commodities imported from tropical and subtropical countries with in particular peanuts (groundnuts) and other edible nuts and their products, dried fruit, spices and maize. Milk and milk products may also be contaminated with aflatoxin M1 owing to the consumption of aflatoxin contaminated feed by ruminants.
5. Aflatoxigenic fungi are spread on fig fruits during fruit growth, ripening and drying but thrive especially during the ripening and overripening phase. The formation of aflatoxins in dried figs is mainly due to contamination by *Aspergillus* species and particularly *A. flavus* and *A. parasiticus*. The presence and spread of such fungus in fig orchards are influenced by environmental and climatic factors, insects, (insect abundance or control in an orchard is related to the applied plant protection measures so could be included in cultural practices but to point out its significance can be left as another factor), cultural practices, floor management and susceptibility of fig varieties.

¹ Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1- 1969)

² Recommended International Code of Hygienic Practice for Dried Fruits (CAC/RCP 3- 1969)

6. The aflatoxin-producing *Aspergillus* species and consequently dietary aflatoxin, contamination is ubiquitous in areas of the world with hot humid climates. *A. flavus/A. parasiticus* cannot grow or produce aflatoxins at water activities less than 0,7; relative humidity below 70% and temperatures below 10 °C. Under stress conditions such as drought or insect infestation, aflatoxin contamination is likely to be high. Improper storage conditions can also lead to aflatoxin contamination after crops have been harvested. Usually, hot humid conditions favour mould growth on the stored food which can lead to high levels of aflatoxins.
7. Application of the following preventive measures is recommended in dried fig producing regions in order to reduce aflatoxin contamination by application of good practices:
- a) Information on contamination risk
Ensure that regional/national authorities and grower organisations:
 - Sample dried figs representatively for analysis to determine the level and frequency of aflatoxin contamination; sampling should reflect differences in areas, time of the year and stage from production to consumption
 - Combine this information with regional risk factors including meteorological data, cultural practices and propose adapted risk management measures;
 - Communicate this information to growers and other operators along the chain. Use labelling to inform consumers and handlers on storage conditions.
 - b) Training of producers.
Ensure training of producers with regards to:
 - Risk of mould and mycotoxins;
 - Conditions favouring aflatoxigenic fungi and period of infection;
 - Knowledge of preventive measures to be applied in fig orchards;
 - Pest control techniques.
 - c) Training of transporters, storage keepers and other operators of the production chain.
Ensure training regarding the practical measures and environmental factors that promote infection and growth of fungi in dried figs resulting in a possible secondary production of aflatoxins at post harvest handling and processing stages. Besides these, all applications should be documented.
 - d) Encourage related research.
8. In developing training programs or gathering risk information, emphasis should be placed on the fact that the planting, pre-harvest, harvest and post-harvest strategies for a particular fig crop depends on the climatic conditions of a particular year, local production, harvesting and processing practices followed in a particular country or region.

1. SCOPE

9. This document is intended to provide guidance for all interested parties producing and handling dry figs for entry into international trade for human consumption. All dried figs should be prepared and handled in compliance with the Recommended International Code of Practice – General Principles of Food Hygiene and Recommended International Code of Hygienic Practice for Dried Fruits, which are relevant for all foods being prepared for human consumption. This code of practice indicates the measures that should be implemented by all persons that have the responsibility for assuring that food is safe and suitable for human consumption.
10. Fig differs from other fruits, which has potential risk of aflatoxin contamination, with its fruit formation and properties. Its increased sensitivity is due to juicy and pulpy skin, and the cavity inside the fruit and the suitable composition rich in sugar. Thus, toxigenic fungi may grow and form aflatoxins on the outer surface or inside the cavity even if no damage occurs on the skin. The critical periods for aflatoxin formation in dried fig fruits starts with the ripening of figs on the tree, continues during the over-ripe period when they lose water, shrivel and fall down onto the ground and until they are fully dried on drying trays. Fungal growth and toxin formation can occur on the outer fleshy skin and/or inside the fruit cavity. Some insect pests as the Dried Fruit Beetle (*Carpophilus spp.*) or Vinegar flies (*Drosophila spp.*) that are active at fruit ripening stage may act as vectors in transferring the aflatoxigenic fungi to the fruit cavity.

11. The main requirement is to obtain a healthy plant and good quality product by applying necessary agricultural techniques for prevention/reduction of aflatoxin formation.

2. DEFINITION

12. **Fig**, *Ficus carica* L., as a dioecious tree has male and female forms that bear two to three cycles of fruits per year.
13. **Caprification** is a process applied in case female fig fruits of a certain variety require pollination for fruit set. The “*profichi*” (ilek) fruits of male figs possessing fig wasps (*Blastophaga psenes* L.) and pollen grains are either hung or placed on female fig trees to pollinate and fertilize the main and second crop (iyilop) fruits. The pollen shedding period of the male flowers in male fig fruits should coincide with the ripening of the female flowers in female fig fruits.
14. **Ostiole** or **eye** is the opening at the distant end of the fruit that may, if open, provide entrance to the vectors, Dried Fruit Beetle (*Carpophilus spp.*) or Vinegar flies (*Drosophila spp.*) for dissemination of aflatoxigenic fungi.

3. RECOMMENDED PRACTICES BASED ON GOOD AGRICULTURAL PRACTICES (GAP), GOOD MANUFACTURING PRACTICES (GMP) AND GOOD STORAGE PRACTICES (GSP)

3.1 SITE SELECTION and ORCHARD ESTABLISHMENT (PLANTING)

15. Fig trees grow in subtropical and mild temperate climates and have a short dormancy period which restricts fig growing in low temperatures in winter rather than high temperatures in summer. Low temperatures right after bud-break in the spring and during October – November before shoots are hardened, can damage the tree. Freezing temperatures in winter may affect the fig wasps over-wintering in male fruits and may create problems in fruit set.
16. High temperatures and arid conditions in spring and summer can increase sun-scald, result in early leaf fall if severe, cause substantial problems in quality and trigger aflatoxin formation.
17. The fig varieties may vary regarding their tendency for cracking/splitting however high relative humidity and rainfall during the ripening and drying period must be taken into account before establishing the orchard. High humidity and rainfall can increase ostiole-end cracking, development of fungi and decrease of quality.
18. Fig trees can be grown in a wide range of soils such as sandy, clayey or loamy. A soil depth of at least 1-2 m accelerates the growing of fig trees which have fibrous and shallow roots. The optimum pH range for soil is 6.0 – 7.8. The chemical (such as pH) and physical properties of the orchard soil can influence the intake of plant nutrients and consequently dried fig quality and resistance to stress conditions, thus soil properties must be fully evaluated before orchard establishment.
19. The level of the underground water table must not be limiting. Availability of irrigation water is an asset to overcome drought stress.
20. The orchards should be established with healthy nursery trees that are free from any insects and diseases. Adequate space, which is generally 8 m to 10 m, should be given between the rows and the trees to allow the use of necessary machinery and equipments. Before planting the way the fruits will be utilized (fresh, dried or both) need to be considered. Other species present in the orchard should also be considered. Species which are susceptible to aflatoxin formation such as maize should not be produced around the fig orchards. Materials remaining from the previous crops and foreign materials should be cleaned and if it is needed the field can be fallowed in the following few years.

3.2 ORCHARD MANAGEMENT

21. Practices such as caprification, pruning, tillage, fertilization, irrigation, and plant protection should be applied on time and with a preventive approach in the framework of “Good Agricultural Practice”.
22. Cultivation practices, both in the orchard and in the vicinity, that might disperse *A. flavus/A. parasiticus*, and other fungal spores in the soil to aerial parts of trees should be avoided. Soil as well as fruits and other plant parts in fig orchards can be rich in toxigenic fungi Soil tillage practices must be terminated one month before the harvest. During the growing seasons, roadways near the orchards should be watered or

oiled periodically to minimise outbreaks of mites as a result of dusty conditions. The devices and equipments should not damage fig trees or cause cross contamination with pests and/or diseases.

23. Fig trees must be pruned lightly and all the branches and other plant parts must be removed from the orchard in order to avoid further contamination. Direct incorporation of all parts into the soil must be avoided. After soil and leaves analysis, based on the expert proposal proper composting can be recommended prior to incorporation of the organic matter.
24. Fertilization affects the composition of fruit and stress conditions may trigger toxin formation. Also excess nitrogen is known to enhance fruit moisture content which may extend the drying period. Fertilizer applications must be based on soil and plant analysis and all recommendations must be made by an authorized body.
25. An integrated pest management programme must be applied and fruits or vegetables that promote infestation with dried fruit beetles or vinegar flies should be removed from the fig orchards since these pests act as vectors for the transmission of fungi especially into the fruit cavity. Pesticides approved for use on figs, including insecticides, fungicides, herbicides, acaricides and nematocides should be used to minimise damage that might be caused by insects, fungal infections, and other pests in the orchard and adjacent areas. Accurate records of all pesticide applications should be maintained.
26. Irrigation should be implemented in regions or during periods with high temperatures and/or inadequate rainfall during the growing season to minimise tree stress, however, irrigation water should be prevented from contacting the figs and foliage.
27. Water used for irrigation and other purposes (e.g. preparation of pesticide sprays) should be of suitable quality, according to the legislation of each country and/or country of import, for the intended use.

3.3 CAPRIFICATIONS

28. Caprifigs (male fig fruits) are important for fig varieties, which require for fruit set. Caprifigs should be healthy, free from fungi and should have plenty and live pollen grains and wasps (*Blastophaga psenes* L.). During pollination of female fig fruits by fig wasps, which pass their life cycle in caprifig fruits, *Fusarium*, *Aspergillus spp* and other fungi can be transported to the female fig fruits from the male fruits through these wasps. Since male trees are the major sources of these fungi, male trees are generally not allowed to grow in female fig orchards. It is important to use clean caprifigs, rotten and/or soft caprifigs should be removed prior to caprification. Because caprifigs, which are allowed to stay on the tree and/or in the orchard, can host other fungal diseases and/or pests therefore after caprification they must be collected and destroyed outside the orchard. To make the removal of caprifigs easier, it is recommended to place caprifigs in nets or bags.

3.4 PRE-HARVEST

29. All equipment and machinery, which is to be used for harvesting, storage and transportation of crops, should not constitute a hazard to health. Before harvest time, all equipment and machinery should be inspected to ascertain that they are clean and in good working condition to avoid contamination of the figs with soil and other potential hazards.
30. Trade Associations, as well as local and national authorities should take the lead in developing simple guidelines and informing growers of the hazards associated with aflatoxin contamination of figs and how they may practice safe harvesting procedures to reduce the risk of contamination by fungi, microbes and pests.
31. Personnel that will be involved in harvesting figs should be trained in personal hygienic and sanitary practices that must be implemented in processing facilities throughout the harvesting season.

3.5 HARVEST

32. Harvesting of dried figs is different from harvest of figs for fresh consumption. The figs to be dried are not harvested when they mature but kept on the trees for over-ripening. After they lose water, partially dry and shrivel, an abscission layer forms and the fig fruits naturally fall from the trees onto the ground. The most critical aflatoxin formation period begins with ripening and continues when shriveled until fully dried. The fig fruits need to be collected from the ground daily to reduce aflatoxin formation and other

losses, caused by diseases or pests. On the other hand, the collecting containers should be suitable, preventing any mechanical damage and should be free of any fungal sources and clean.

33. Dried fig harvest should be done regularly at short intervals daily to minimize the contacts with soil and thus contamination risks. Frequent harvest also reduces insect infestation especially of dried fruit beetles (*Carpophilus spp.*) and fig moths (*Ephestia cautella* Walk. and *Plodia interpunctella* Hübner).
34. In case of a significant difference between day and night temperatures, dew formation that may trigger aflatoxin production may occur. This is important since wet surfaces favouring the growth of fungi may be formed even after complete drying of the fruit.

3.6 DRYING

35. Drying area and time are important factors in aflatoxin formation. The moisture content of the partially dried and shriveled fig, fallen down from the tree, is approximately 30-50% and these fruits are more susceptible to physical damage than the fully dried fig fruits that have approximately 20-22% moisture content. Good soil management that reduces particle size and smoothens the surface before harvest is therefore necessary to reduce the risk of damaging.
36. Fig fruits can be dried artificially in driers or under the sun with the help of solar energy. In artificial driers, the fig fruits are dried in a shorter period and more hygienic products with less pest damage can be obtained. Good drying practice can help preventing aflatoxin formation. Sun-drying is cost efficient and environmentally friendly, however may as a result increase the likelihood of aflatoxin contamination.
37. Fruits shall not be placed directly on the soil surface or on some vegetation. Drying beds should be arranged as single layers in a sunny part of the orchard where air currents are present. The drying trays shall be covered with a material to protect the figs from rain fall in case there is a risk or to prevent infestation of fig moths that lay eggs in the evening. Drying trays that are 10-15 cm above the ground should be preferred in sun-drying since fruits can benefit from the heat at the soil surface and are well aerated. They can dry quickly and the contamination of fruits by foreign materials and sources of infection such as soil particles or plant parts are eliminated.
38. Figs that are dried, possessing moisture $\leq 24\%$ and water activity ≤ 0.65 , should be picked from the trays. The fully dried fruits should be collected from the trays preferably in the morning before the temperature of the fruits increase and soften but after the dew goes away. The trays should be re-visited at short intervals to collect fully dried figs. Dried figs taken from drying trays must be treated to prevent storage pests with a method allowed in the legislation of each country, for the intended use.
39. Low quality figs which are separated as cull and have the risk of contamination should be dried and stored separately to prevent cross contamination. Staff who conduct the harvesting or work in storage rooms should be trained in this respect to ensure that these criteria are followed..

3.7 TRANSPORTATION

If transportation is required the following provisions apply:

40. During the transportation of dried figs from farm to processor, the quality of figs should not be affected adversely. Dried figs should not be transported with products that pungent odours or have the risk of cross contamination. During transportation, increase of moisture and temperature must be prevented.
41. The dried figs should be moved in suitable containers to an appropriate storage place or directly to the processing plant as soon as possible after harvesting or drying. At all stages of transportation, boxes or crates allowing aeration should be used instead of bags. Containers used in transportation shall be clean, dry, and free of visible fungal growth, insects or any other source of contamination. The containers should be strong enough to withstand all handling without breaking or puncturing, and tightly sealed to prevent any access of dust, fungal spores, insects or other foreign material. Vehicles (e.g. wagons, trucks) to be used for collecting and transporting the harvested dried figs from the farm to drying facilities or to storage facilities after drying, should be clean, dry, and free of insects and visible fungal growth before use and re-use and be suitable for the intended cargo.
42. At unloading, the transport container should be emptied of all cargo and cleaned as appropriate to avoid contamination of other loads.

3.8 STORAGE

43. Figs must be properly cleaned, dried and labelled when placed in a storage facility equipped with temperature and moisture controls. The shelf life of dried figs can be prolonged, if they are dried to a water activity value at which molds, yeasts and bacteria cannot grow (water activity < 0.65). In case further hot spots are formed where temperature and moisture increases, secondary aflatoxin formation may occur. Because of this reason, any possible source enhancing humidity of the dried fruits or of the surrounding environment must be eliminated. Direct contact of dried fig containers with floors or walls need to be prevented by placing a palette or a similar separator.
44. The storage rooms should be far from sources of contamination as in the case of mouldy figs or animal shelters if any are present at the farm, and fruits must not be stored with materials that possess unusual odours. Precautions should be taken to avoid insect, bird or rodent entrance or similar problems especially under farm storage conditions.
45. Low quality figs that are not destined for direct human consumption should be stored separately those intended for human consumption. The storage rooms should be disinfected with effective disinfectants. Areas like cleavage and cavity should be repaired and windows and doors should be netted. The walls should be smoothened and cleaned every year. The storage rooms should be dark, cool and clean.
46. The optimum storage conditions for dried figs are at temperatures of 5-10 °C and relative humidity less than 65%. Therefore, cold storage is recommended

3.9 PROCESSING

47. Dried figs are fumigated, stored, sized, washed, cleaned, sorted and packed in processing units. Among these processes, removal of aflatoxin-contaminated figs, storage and package material may exert the major impact on aflatoxin levels of the final products. Processed figs must be treated to prevent storage pest with a method allowed in the legislation of each country for the intended use.
48. Dried fig lots entering into the processing plant must be sampled and analyzed as an initial screening for quality moisture content and ratio of bright greenish yellow fluorescent (BGYF) figs. Dried figs contaminated with aflatoxins can have a correlation with BGYF under long wave (360 nm) UV light. BGYF may occur on the outer skin but also inside the fruit cavity; the ratio being dependent on the fruit characteristics and on prevalence of vectors. Dried figs fruits are examined under long wave UV light and the fluorescent ones are removed to obtain a lower aflatoxin content of the lot. Work conditions such as the length of working, break intervals, the aeration and cleanliness of the room, should provide worker safety and product safety.
49. Contaminated figs must be separated, labelled and then destroyed in an appropriate manner in order to prevent their entry into the food chain and further risk of environmental pollution.
50. The moisture content and water activity level of dried fig fruits must be below the critical level (moisture content can be set at 24% and water activity of less than 0.65). Higher levels may trigger fungal growth and toxin formation. Higher water activity levels may trigger aflatoxin formation in areas of high temperature storage at the processing plant or at retail level especially in moisture tight packaging material.
51. Dried figs are washed if demanded by the buyer. The water temperature and the duration of washing should be arranged according to the moisture content of the figs in order to avoid the elevation of the initial moisture content of fruits to critical levels. In case the moisture and water activity levels are increased, a second drying step must be integrated in the process. The water should have the specifications of drinking water.
52. Good storage practices must be applied at the processing plant and should be kept at this standard until the product reaches the consumer (see section 3.8).
53. All equipment, machinery and the infrastructure at the processing plant should not constitute hazard to health, and good working conditions should be provided to avoid contamination of figs.
54. These recommendations are based on current knowledge and can be updated according to the research to be pursued. Preventive measures are essentially carried out in fig orchards and precautions or treatments undertaken at the processing stage are solely corrective measures to prevent any aflatoxin formation.

PROJECT DOCUMENT**PROPOSAL FOR NEW WORK ON A “CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF OCHRATOXIN A CONTAMINATION IN COFFEE”****1. Purpose and Scope of the new work**

The purpose of the proposed new work is to provide to member countries and the coffee industry a guidance to prevent and reduce Ochratoxin A (OTA) contamination in coffee. The scope of the new work encompasses the development of a Code of Practice for the Prevention and Reduction of OTA Contamination in Coffee, which will cover all the stages of the coffee chain, excluding consumers' practices. It is anticipated that this new work would be undertaken based on FAO Guidelines for the Prevention of Mould Formation in Coffee.

2. Relevance and timeliness

The toxicity of OTA has been reviewed by the International Agency for Research on Cancer (IARC), that has classified OTA as a possible human carcinogen (group 2B), and by the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

OTA can be found in different food, including coffee, which represents a significant source of dietary exposure in some countries. Besides that, coffee is an important commodity for international trade, which means, there is a high human consumption of this product.

The most effective way to prevent and reduce OTA contamination in coffee is the use of Good Practices in all coffee chain stages.

3. Main aspects to be covered

The proposed new work will focus on identifying, preventing and controlling relevant aspects associated with:

- Coffee infection by OTA producing fungi;
- Ochratoxigenic fungal growth; and
- OTA production.

The code will cover all stages of the coffee production chain (cultivation, harvest, post harvest, and transportation practices) developing strategies to prevent and reduce OTA contamination in coffee.

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 the food trade and taking into account the identified needs of the developing countries.

The new work will provide additional guidance for countries in order to improve coffee quality, preventing and reducing OTA contamination and consequently minimizing consumer dietary exposure to OTA from coffee.

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

The new work would provide internationally recognized scientific guidance in order to improve to the enhancement of international trade.

3. Work already undertaken by other organizations in this field.

This new work will be based on FAO Guidelines for the Prevention of Mould Formation in Coffee.

5. Relevance to Codex Strategic Goals

The work proposed fall under all five 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 and practical experience for prevention and reduction of OTA contamination in coffee.

With a view to promoting maximum application of Codex Standards, due to the importance of coffee international trade, this work will harmonize procedures for developed and developing countries, leading to a fair trade.

Goal 2. Promoting Widest and Consistent Application of Scientific Principles and Risk Analysis.

This work will help in establishing risk management options and strategies to control OTA in coffee.

Goal 3. Strengthening Codex Work-Management Capabilities.

By establishing a general framework for the management of food safety risks associated with the Prevention and Reduction of OTA Contamination in Coffee will provide a general document that can be referenced by CCCF and it can be used by many countries.

Goal 4. Promoting Cooperation between Seamless Linkages between Codex and Other Multilateral Bodies.

The involvement of FAO in Codex activities has already formed a close link and the work developed by FAO on this issue will be the base of this new Codex work.

Goal 5: 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 requiring 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 OTA in coffee (CX/CF 08/2/14) which was presented and discussed at the Second Session of Codex Committee on Contaminants in Foods (CCCF).

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

Additional scientific advice is not necessary at this moment, as FAO has already published the Guidelines for the Prevention of Mould Formation in Coffee as a result of the project Enhancement of Coffee Quality through the Prevention of Mould Formation.

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

There is no need for additional technical input from external bodies.

9. The proposed timeline for completion of the new work, including the starting date, proposed date for adoption at step 5 and the proposed date for the adoption by the Commission, the timeframe for developing a standard should not normally exceed 5 years.

If the Commission approves, the proposed draft Code of Practice will be circulated for comments at Step 3 and consideration at Step 4 at the 3rd Session of CCCF in 2009. Adoption at Step 5 is planned for 2010 and adoption at Step 8 can be expected by 2011.

APPENDIX XIII

PRIORITY LIST OF CONTAMINANTS AND NATURALLY OCCURRING TOXICANTS PROPOSED FOR EVALUATION BY JECFA

<i>Contaminants and naturally occurring toxicants</i>	<i>Question(s) to be answered</i>	<i>Data availability (when, what)</i>	<i>Proposed by</i>
Deoxynivalenol (DON) ¹	Exposure assessment on a more global basis taking new data into account, also review of toxicological data and considering the need for an acute reference dose (taking into account data also in finished products, but also in raw wheat and other commodities as they are traded internationally and consideration of processing factors) Toxicity of 3-acetyl and the 15-acetyl DON (data availability unknown)	Sufficient occurrence and processing data not before end 2008 Japan, Canada and EC have occurrence data by end 2008 Availability of toxicological data not known	(since 37 th CCFAC)
Furan ¹	Full evaluation (toxicological assessment and exposure assessment)	<u>Occurrence data:</u> USA: late 2008 EC: late 2008 Australia: late 2008 Canada: late 2008 Japan: end 2008 <u>Toxicological data:</u> EFSA preliminary risk assessment available Canada: some toxicology studies available	US, supported by Australia, Canada, EC
Perchlorate ¹	Full evaluation (toxicological assessment and exposure assessment)	<u>Occurrence data:</u> USA (including data from total diet study) and Canada: late 2008 <u>Toxicological data:</u> USA risk assessment available, other toxicological data available	US, supported by Canada, EC
<i>New Requests</i>			
3-MCPD esters	Full evaluation (toxicological assessment and exposure assessment)	Limited data in vegetable oils	Germany, supported by EC, Canada

¹ High priority for evaluation by JECFA