codex alimentarius commission



FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS WORLD HEALTH ORGANIZATION



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ALINORM 07/30/41 May 2007

JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX ALIMENTARIUS COMMISSION

Thirtieth Session Roma, Italy, 2-7 July 2007

REPORT OF THE 1st SESSION OF THE CODEX COMMITTEE ON CONTAMINANTS IN FOODS

Beijing, China 16-20 April 2007

Note: This report includes Codex Circular Letter CL 2007/13-CF

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CX 4/35.2

CL 2007/13-CF May 2007

- 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 First Session of the Codex Committee on Contaminants in Foods (ALINORM 07/30/41)

The Report of the First Session of the Codex Committee on Contaminants in Foods is attached. It will be considered by the Thirtieth Session of the Codex Alimentarius Commission (Rome, Italy, 2-7 July 2007).

MATTERS FOR ADOPTION BY THE $30^{\rm TH}$ 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 Tin in Canned Foods (other than beverages) and in Canned Beverages at Step 8 (ALINORM 07/30/41 para. 82 and Appendix IX)
- 2. Proposed Draft Code of Practice for the Prevention and Reduction of Ochratoxin A Contamination in Wine (N05-2006) at Step 5/8 (ALINORM 07/30/41 para. 77 and Appendix VIII)

Governments and interested international organizations wishing to submit comments on the above texts should do so in writing, <u>preferably by E-mail</u>, 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 2007**.

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

- 3. Proposed Draft Maximum Levels for 3-MCPD in Liquid Condiments containing Acid-Hydrolyzed Vegetable Proteins (Excluding Naturally Fermented Soy Sauce) (N08-2004) at Step 5 (ALINORM 07/30/41 para. 88 and Appendix X)
- 4. Proposed 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 5 (ALINORM 07/30/41 para. 93 and Appendix XI)

Governments and interested international organizations wishing to submit comments on the above texts should do so in writing, <u>preferably by E-mail</u>, 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 2007**.

Proposed amendments to the Procedural Manual

- 5. Proposed amendments to the Terms of Reference of the Codex Committee on Contaminants in Foods (ALINORM 07/30/41 para. 15 and Appendix II)
- 6. Proposed amendments to the "Risk Analysis Principles Applied by the Codex Committee on Food Additives and Contaminants (ALINORM 07/30/41 para. 18 and Appendix III)
- 7. Proposed amendments to the "CCFAC Policy for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups (ALINORM 07/30/41 para. 18 and Appendix IV)
- 8. Definition for "Codex Maximum Level for a Contaminant in Food or Feed Commodity" (ALINORM 07/30/41 para. 38 and Appendix V)

Governments and international organizations wishing to submit comments on the above proposed amendments and definition should do so in writing, preferably by E-mail to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00153 Rome, Italy (Email: codex@fao.org, fax : +39 06 57054593) **before 30 May 2007**.

SUMMARY AND CONCLUSIONS

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

Matters for consideration by the 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 Tin in Canned Foods (other than beverages) and in Canned Beverages to the Commission for adoption at Step 8 (para. 82 and Appendix IX); and
- Proposed Draft Code of Practice for the Prevention and Reduction of Ochratoxin A in Wine (N05-2006) to the Commission for adoption at Step 5/8 (para. 77 and Appendix VIII)).

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

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

- Proposed Draft Maximum Levels for 3-MCPD in Liquid Condiments containing Acid-Hydrolyzed Vegetable Proteins (excluding Naturally Fermented Soy Sauce) (N08-2004) (para. 88 and Appendix X); and
- Proposed 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) (para. 93 and Appendix XI).

Proposed amendments to the Procedural Manual

The Committee agreed to forward the following three proposed amendments and one definition to the Commission for adoption and inclusion in the Procedural Manual:

- Proposed amendments to the Terms of Reference of the Codex Committee on Contaminants in Foods (para. 15 and Appendix II);
- Proposed amendments to the "Risk Analysis Principles Applied by the Codex Committee on Food Additives and Contaminants (para. 18 and Appendix III);
- Proposed amendments to the "CCFAC Policy for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups" (para. 18 and Appendix IV); and
- Definition for "Codex Maximum Level for a Contaminant in Food or Feed Commodity" (para. 38 and Appendix V).

Proposals for new work

The Committee agreed to submit to the Commission, through the Executive Committee, the proposal for new work on a "Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Dried Figs" (paras 120 - 121 and Appendix XIII).

Others **Others**

The Committee agreed:

- to forward the proposed amendments to Schedule I of the General Standards for Contaminants and Toxins in Foods to the Commission for adoption (para. 46); and
- to recommend that the Commission revoke CODEX STAN 248-2005 (para.46).

Matters for consideration by other committees and task forces

The Committee agreed:

- to forward to the Codex Committee on Methods of Analysis and Sampling (CCMAS) the ranges for the determination of dioxin and PCBs as well as the matrices for which these levels were to be applied and to request the CCMAS to also indicate for the different methods the highest level that can be reliably analysed (para. 24 and Appendix XIV Part 1); and
- to forward to the CCMAS the general remark on the Method of Analysis for Determination of Dioxins and PCBs"(para. 25. and Appendix XIX Part 2).

Matters of Interest to the Commission

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. 43);
- to retain the draft maximum levels for Ochratoxin A in wheat, barley and rye at Step 7 (see Appendix VI) and inform the Executive Committee that work on this item would be completed by 2007 (para. 50);
- to hold at Step 7 both draft maximum level of 15 μg/kg for total aflatoxins in almonds, hazelnuts and pistachios "for further processing" and the draft maximum level of 8 μg/kg for total aflatoxin in almonds, hazelnuts and pistachios "ready-to-eat" and to resume discussion on these draft maximum levels at its next session, after the results of the forthcoming 68th JECFA evaluation are available (para. 57 and Appendix VII);
- that the proposed draft Sampling Plan for Aflatoxin Contamination in Almonds, Brazil nuts, Hazelnuts and Pistachios (N07-2004) 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 return the proposed draft Code of Practice for the Reduction of Acrylamide in Food (N06-2006) to Step 2 for redrafting by an electronic working group, with a view to circulation for comments at Step 3 and consideration at Step 4 at the next session of the Committee (para. 97);
- to return the proposed draft Code of Practice for the Reduction of Contamination of Food with Polycyclic Aromatic Hydrocarbons (PAH) from Smoking and Direct Drying Process (N07-2006) to step 2 for redrafting by an electronic working group, with a view to circulation for comments at Step 3 and consideration at Step 4 at the next session of the Committee (para. 102);
- to establish an electronic working group to prepare a draft proposed Code of Practice on the Prevention and Reduction of Aflatoxin contamination in Dried Figs 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 Commission (para. 121); and
- to update / revised the following discussion papers for consideration at the next session of the Committee:
 - Discussion Paper on Maximum Levels for Total Aflatoxins in "Ready-to-eat" Almonds, Hazelnuts and Pistachios (para. 58);
 - Discussion Paper on Aflatoxin Contamination in Brazil nuts (para. 66);
 - Discussion Paper on Ochratoxin A in coffee (para. 113); and
 - Discussion Paper on Ochratoxin A in Cocoa (para. 117).

The Committee reaffirmed the decision made by the 38th Session of the Committee on Food Additives and Contaminants (ALINORM 06/29/12 para.192) to postpone consideration of the need to revise the guideline levels for methylmercury in fish pending the outcomes of a joint FAO/WHO expert consultation on health risks associated with methylmercury and dioxins and dioxin-like PCBs in fish and the health benefits of fish consumption and to retain the current Codex guideline levels for the time being (para. 35).

Other matters

The Committee endorsed the priority list of contaminants and naturally occurring toxicants for JECFA evaluation (see Appendix XIII). The Committee recommended that an in-session working group be convened during the next session of the Committee, in order to review the priority list in light of comments received (para. 134).

LIST OF ABBREVIATIONS USED IN THIS REPORT

3-MCPD	3-monochloropropane-1,2-diol
CCCF	Codex Committee on Contaminants in Foods
CCFAC	Codex Committee on Food Additives and Contaminants
CCMAS	Codex Committee on Methods of Analysis and Sampling
CL	Circular Letter
CRD	Conference Room Document
DON	Deoxynivalenol
FAO	Food and Agriculture Organization of the United Nations
GEMS	Global Environment Monitoring System
GSCTF	General Standard for Contaminants and Toxins in Foods
GLs	Guideline Levels
GSFA	General Standard for Food Additives
HVP	Hydrolyzed Vegetable Protein
JECFA	Joint FAO/WHO Expert Committee on Food Additives
OIV	International Organisation of Vine and Wine
OTA	Ochratoxin A
РАН	Polycyclic Aromatic Hydrocarbons
PCBs	Polychlorinated biphenyls
PTWI	Provisional Tolerable Weekly Intake
TEF	Toxic Equivalency Factors
WHO	World Health Organization

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INTRODUCTION

1. The First Session of the Codex Committee on Contaminants in Foods was held in Beijing, China, from 16-20 April 2007, at the kind invitation of the Government of the Netherlands in cooperation with the Government of the People's Republic of China. Mr Ger de Peuter, Deputy Director of Food Quality and Animal Health, Ministry of Agriculture, Nature and Food Quality of the Netherlands, chaired the Session. The Session was attended by 171 delegates representing 59 Member Countries, one Member Organization, and 16 International Organizations. The List of Participants is attached to this report as Appendix I.

OPENING OF THE SESSION

2. Mr Dirk Jan van den Berg, the Ambassador of the Netherlands in China, welcomed the establishment of the new Codex Committee on Contaminants in Foods and thanked the Government of China for its hospitality in holding the First Session of this Committee in Beijing. He stressed the importance of broad participation of Members and Observers in the Committee, especially developing countries. In this regard, he invited potential and current donor countries to provide or continue to provide their support to the Codex Trust Fund for Enhanced Participation. He stressed the need to generate scientific data and to support the provision of scientific advice as the basis of the work of the Committee.

3. Mr Ma Xiaowei, the Vice-Minister of Health of the People's Republic of China, welcomed the participants and highlighted the growing importance of food safety issues for public health and fair practices in international food trade. Physical, chemical and biological contaminants remain a prominent issue of concern. The Government of China is giving high priority to the development of new policies and legislation to promote food safety. He emphasized the importance of science-based and technologically sound worldwide standards on contaminants in food. Finally, he thanked Codex Members for their support of the nomination of China as host country of the Codex Committees on Food Additives and on Pesticide Residues.

Division of Competence

4. 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

5. The Committee noted that the proposal from Japan and the Netherlands requesting the inclusion of a specific item on the Agenda had been placed on a supplementary list. The Committee, after noting that the concrete proposals were provided in document CX/CF 07/1/6 and noting that the proposals were linked to Provisional Agenda Item 5, agreed to discuss the additional item as a new Agenda Item 5(b) as part of Agenda Item 5.

6. The Committee also agreed that the Agenda Items below would be discussed together because they were interrelated:

- Item 7(a), 7(b), and 7(c);
- Item 7(d) and 7(e);
- Item 4(b) and 4(c).

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

8. The Committee agreed to establish an in-session physical working group on the priority list of contaminants and naturally occurring toxicants proposed for evaluation by JECFA under the Chairmanship of the Netherlands, with the understanding that its report would be considered under Agenda Item 15.

APPOINTMENT OF THE RAPPORTEUR (Agenda Item 2)

9. The Committee agreed to appoint Dr Kelly Hislop (Canada) as Rapporteur for the Session.

¹ CX/CF 07/1/1, CX/CF 07/1/1 Add.1

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

10. The Committee noted that most of the information presented in document CX/CF 07/1/2 was for information purposes. The Committee also noted that document CX/CF 07/1/2 Add.1, prepared by the Codex Secretariat, proposed changes to the two texts on risk analysis relevant to the Committee, contained in the Procedural Manual.

11. In particular, the Committee commented and/or made decision on the following matters:

Terms of Reference of the Codex Committee on Contaminants in Foods

12. The Committee noted the request of the 29th Session of the Commission to review its Terms of Reference at its First Session.

13. The Committee considered the proposal from the Delegation of Germany, speaking on behalf of the Member States of the European Community, to delete the reference to guideline levels (GLs) in point (a) of its Terms of Reference to align it with the Commission's decision that the preferred format of a Codex standard for a contaminant in food or feed was a maximum level. In this regard, it was noted that the deletion of the reference to GLs would also imply the conversion of GLs already contained in the General Standard of Contaminants and Toxins in Foods (GSCTF) into maximum levels, which might require further discussion. While acknowledging that in the future no new GLs would be elaborated by the Committee and that the current GLs should eventually be reviewed for consideration as maximum levels, the Committee agreed that it was premature to delete the reference to GLs from its Terms of Reference at this stage. It was therefore agreed to revise point (a) to read "To establish or endorse permitted maximum levels, and where necessary revise existing guideline levels, for contaminants and naturally occurring toxicants in food and feed" to reflect the current status of work of the Committee.

14. The Committee agreed to revise point (c) to better clarify that the Committee could initiate elaboration of methods of analysis and sampling for the determination of contaminants and naturally occurring toxicants in food and feed and for consistency with the language used in point (d) in relation to the consideration and elaboration of standards or codes of practice for related subjects.

15. The Committee agreed to forward the proposed amendments to its Terms of Reference to the 30th Session of the Commission, through the 59th Session of the Executive Committee, for consideration and approval (see Appendix II).

Proposed Changes to the "Risk Analysis Principles Applied by the Codex Committee on Food Additives and Contaminants" and the "CCFAC Policy for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups"

16. The Committee noted that the proposed changes in "Risk Analysis Principles Applied by the Codex Committee on Food Additives and Contaminants" and "CCFAC Policy for Exposure Assessment of Contaminants and Toxins in Foods or Food Group", as presented in document CX/CF 07/1/2 Add.1, were intended to reflect the split of the Codex Committee on Food Additives and Contaminants into two Committees and were in line with the changes proposed in paragraphs 3-5 of document CX/CF 07/1/7-rev. "Proposed draft revision of the Preamble of the General Standard for Contaminants and Toxins in Foods (GSCTF)". The Committee also noted that an identical proposal for changes to "Risk Analysis Principles Applied by the Codex Committee on Food Additives and Contaminants" would be considered by the 39th Session of the Codex Committee on Food Additives, to be held on 24-28 April 2007.

17. The Committee agreed to the changes proposed by the Codex Secretariat with a few minor editorial changes. It also agreed to replace "GEMS/Food Regional diets" with "GEMS/Food Consumption Cluster Diet" throughout the text on "CCCF Policy for Exposure Assessment in Contaminant and Toxins in Foods or Food Groups".

² CX/CF 07/1/2, CX/CF 07/1/2 Add.1, CRD 7 (comments of European Community), CRD 13 (comments of Cuba)

18. The Committee agreed to forward the proposed amendments to the "Risk Analysis Principles Applied by the Codex Committee on Food Additives and Contaminants" and "CCFAC Policy for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups" to the 30th Session of the Commission, through the 59th Session of the Executive Committee, for adoption and inclusion in the Procedural Manual (see Appendices III and IV).

Questions from the 27th Session of the Codex Committee on Methods of Analysis and Sampling³

19. The Committee noted that the Codex Committee on Methods of Analysis and Sampling (CCMAS) had agreed at its 27th Session to request the Committee on Contaminants in Foods to provide precise information on the range of levels to be considered as well as on the matrices for which these levels were to be applied, in order to resume its work on the Methods of Analysis for the Determination of Dioxins and PCBs for the screening of the presence of dioxins and dioxin like-PCBs in feed and food.

20. The Committee agreed to establish an in-session working group⁴, chaired by the Delegation of the European Community, and working in English, to prepare a draft reply to the request of the 27^{th} Session of the CCMAS.

21. The Delegation of the European Community, speaking as the Chair of the in-session working group, informed the Committee that the working group had prepared a list of matrices and corresponding ranges of levels to be considered, based on the information contained in CRD 7.

22. The Committee further noted that the proposed ranges of levels probably covered all levels found in surveys but, ranges might eventually need to be enlarged in light of the results of other surveys. An updated list might be prepared, if necessary, at the next session of the Committee.

23. The Committee agreed that all levels be expressed using the 2005 World Health Organization (WHO) Re-evaluation of Human and Mammalian Toxic Equivalency Factors (WHO 2005 TEF).

24. The Committee agreed to forward to the CCMAS the ranges for the determination of dioxin and PCBs as well as the matrices for which these levels were to be applied (see Appendix XIV, Part 1) and to request the CCMAS to also indicate for the different methods the highest level that can be reliably analysed.

25. The Committee also agreed to forward to the CCMAS the general remarks on the document CX/MAS 06/27/8 "Methods of Analysis for the Determination of Dioxins and PCBs" (see Appendix XIV, Part 2).

INFORMATION ON MATTERS OF INTEREST ARISING FROM FAO, WHO AND OTHER INTERNATIONAL INTERGOVERNMENTAL ORGANIZATIONS (Agenda Item 4a)⁵

26. The Representatives of FAO and WHO, referring to documents CX/CF 07/1/3 and CX/CF 07/1/3 Add.1 rev., informed the Committee of activities undertaken by FAO and WHO on scientific advice and capacity building, which were of interest to the Committee. It was reported that total diet study training courses were planned by WHO for several regions in 2007, including Africa, Eastern Mediterranean and Southeast Asia. In addition the fourth WHO-coordinated global survey of human milk for persistent organic pollutants was ongoing and countries were encouraged to participate.

27. Among others, the Committee noted that FAO and WHO had started a preparatory process for organizing an expert consultation on the health risks associated with methylmercury and dioxins and dioxinlike PCBs in fish and the health benefits of fish and other seafood consumption⁶. Countries were also encouraged to promote and support total diet studies at the national level. The Committee noted that FAO and WHO had started the organization of an expert consultation on the use of 'active chlorine' in food processing, as requested by the Committees on Food Additives and Contaminants and on Food Hygiene. It was emphasized that it was important to provide expertise and information in response to the calls for information and for experts as published on the FAO and WHO websites.

³ CRD 7 (comments of the European Community), CRD 19 (report of the in-session working group to prepare a reply to CCMAS on their request as regard the determination of dioxins and PCBs)

⁴ Canada, Belgium, France, China, Finland, Germany, Hungary, Japan, Madagascar, the Netherlands, the Philippines, United Kingdom, United States of America, CIAA, IDF, IFT and WHO participated in the in-session working group.

⁵ CX/CF 07/1/3, CX/CF 07/1/3 Add.1 rev., CRD 13 (comments of Cuba)

⁶ ALINORM 06/29/41 para.195, ALINORM 06/29/12 para.191

28. One delegation requested additional capacity building activities in support of total diet studies in Latin America and Caribbean region.

29. The Committee noted that it was essential for countries to submit relevant data to FAO and WHO in order to assist them in the timely provision of scientific advice. The Committee also noted that developing countries require technical assistance to build capacities in laboratory analysis so as to generate scientific data.

MATTERS OF INTEREST OF THE 67TH MEETING OF THE JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES (JECFA) (Agenda Item 4b)⁷

ACTION REQUIRED AS A RESULT OF CHANGES IN TOXICOLOGICAL RECOMMENDATIONS (Agenda Item 4c)⁸

30. The WHO Representative, speaking on behalf of FAO and WHO JECFA Secretariats, informed the Committee of the outcome of the evaluation, conducted by the 67th JECFA, for the following three substances; i) *Aluminium*; ii) *Chloropropanols*; and iii) *Methylmercury* in 2006, in response to the requests made by the Codex Committee on Food Additives and Contaminants. The highlight of the discussion and decisions of the Committee on those three substances is as follows:

i) Aluminium

31. A delegation noted that food contact utensils and containers made of aluminium could contribute to human exposure of aluminium and asked whether this issue had been considered by JECFA. The WHO Representative clarified that exposure through food contact utensils and containers had also been considered during the evaluation by JECFA and that it was concluded that they were not main contributors for human exposure to aluminium.

ii) Chloropropanol

32. The Committee was reminded that the outcome of the JECFA evaluation on 3-chloro-1,2- propanediol (3-MCPD) and 1,3-dichloro-2-propanol (DCP) would be taken into consideration during discussion under Agenda Items 10 and 11 at the present session of the Committee.

iii) Methylmercury

33. The Committee was informed that JECFA concluded that the setting of guideline levels for methylmercury in fish might not be an effective way of reducing exposure for the general population. In this regard, a delegation wondered whether the current Codex guideline levels for methymercury in fish would not sufficiently protect the health of consumers against risks associated with methylmercury in fish.

34. The WHO Representative explained that JECFA's conclusion with respect to guideline levels must be considered in relation to the fact that guidelines already in place in some national jurisdictions had already influenced the range of observed mercury concentrations by eliminating fish containing high concentrations of mercury from the market.

35. The Committee reaffirmed the decision made by the 38th Session of the Committee on Food Additives and Contaminants to postpone consideration of the need to revise the guideline levels for methylmercury in fish pending the outcomes of a joint FAO/WHO expert consultation on health risks associated with methylmercury and dioxins and dioxin-like PCBs in fish and the health benefits of fish consumption and to retain the current Codex guideline levels for the time being⁹.

⁷ CX/CF 07/1/4, CRD 13 (comments of Cuba)

⁸ CX/CF 07/1/5

⁹ ALINORM 06/29/12 para.192

PROPOSED DRAFT REVISION OF THE PREAMBLE OF THE GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOODS (GSCTF) (N04-2006) (Agenda Item 5a)¹⁰

36. The Delegation of the European Community, as the Chair of the Working Group on the Revision of the Preamble of the General Standard for Contaminants and Toxins in Foods (GSCTF), described the proposed revisions to the Preamble of the GSCTF, as presented in document CX/CF 07/1/7 rev. The need for these revisions arose as a result of the recent incorporation of two policy documents on the working principles of the former Codex Committee on Food Additives and Contaminants (CCFAC) (i.e. Risk Analysis Principles applied by the CCFAC and CCFAC Policy for Exposure Assessment of Contaminants and Toxins in Food or Food Groups) into the Procedural Manual. The splitting of the former CCFAC into the Codex Committees on Food Additives also caused the need for textual changes in these two working principles documents. In revising of the Preamble of the GSCTF, the guiding rationale was that texts relevant only to the Codex Alimentarius Commission and its subsidiary bodies should be incorporated in the Procedural Manual whereas texts that constitute recommendations for member governments should remain in the Preamble.

37. It was acknowledged that the 29th Session of the Codex Alimentarius Commission had already agreed on some text changes in the Procedural Manual because of the replacement of the CCFAC by the new Codex Committees on Food Additives and on Contaminants in Foods, and the Committee noted that the required changes to the text of the policy documents, as described above, had been agreed upon by the Committee under Agenda Item 3 (see para. 18).

38. The Committee agreed to the proposal in paragraph 7 of the working document and decided to recommend to the Commission to include the definition of a Codex maximum level for a contaminant in the Procedural Manual, in the section on Definitions (see Appendix V).

39. The proposed amendments to the Preamble as set out in Appendix I of the working document were discussed in detail. The second sentence, regarding pesticide residues, in the second bullet point of Section 1.2.2 "Contaminant" was proposed to be deleted because the Codex Committee on Pesticide Residues also deals with pesticide residues resulting from former agricultural or other uses. The wording for exclusion of processing aids from the scope of the General Standard on Contaminants and Toxins in Foods should be further studied.

40. Several delegations advocated retention of the definition of "guideline levels" as well as the footnote regarding possible conversion of existing and proposed "guideline levels" to "maximum levels". In their view, guideline levels should not be converted to maximum levels without proper review. Since "guideline levels" would therefore continue to exist in the GSCTF, it was agreed that both texts would be retained in a footnote.

41. The texts contained in sections 1.4.2 and 1.4.3, which had been proposed for deletion, were considered by several delegations to be suitable for retention because these provisions were not present in the Risk Analysis section of the Procedural Manual. The Delegation of the European Community indicated that these sections could be incorporated in the proposed Appendix II of the working document, which would be transferred to the Procedural Manual. It was suggested that it be verified that the texts were in line with existing texts in the Risk Analysis section of the Procedural Manual.

42. In the discussion on the proposed deletion of Annex II of the Preamble, a delegation proposed the retention of the risk management decision scheme, because this was not recorded in the Risk Analysis Principles section of the Procedural Manual. It was agreed to further consider this issue, recognizing that updates to the scheme might be necessary.

¹⁰ CX/CF 07/1/7 rev., CX/CF 07/1/7 Add.1 (comments of Japan), CRD 12 (comments of Thailand), CRD 13 (comments of Cuba)

<u>Status of the proposed draft Revision of the Preamble of the General Standard for Contaminants and</u> <u>Toxins in Foods (GSCTF) (N04-2006)</u>

43. The Committee noted that there were still a number of proposed changes to the Preamble of the GSCTF that had not been fully considered and discussed by the Committee and that the time for reflection had been too brief because of the late circulation of the working document. It was therefore agreed that the proposed draft Revision be sent back to Step 2 for redrafting by an electronic working group¹¹, led by the Delegation of the European Community¹², working in English, in light of the comments made at the present session, with a view to circulation of the revised proposal for comments at Step 3 and consideration at Step 4 by the next session of the Committee.

PROPOSAL TO AMEND SCHEDULE I OF THE GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOODS (Agenda Item 5b)¹³

44. The Delegation of Japan presented document CX/CF 07/1/1 Add.1 as submitted by Japan and the Netherlands. Specific proposals, as presented in document CX/CF 07/1/6, consisted of a proposal for two amendments to Schedule I of the General Standard for Contaminants and Toxicants in Foods (GSCTF) and a proposal for recommending to the Commission that it formally revoke CODEX STAN 248-2005 concerning maximum levels for cadmium in a number of commodities, since Schedule I also contained these maximum levels.

45. The first proposed amendment to Schedule I concerned replacing certain commodity standard references by the year of adoption by the Codex Alimentarius Commission. The second proposed amendment to Schedule I was to change the categorization of the contaminants included in Schedule I, by renaming the category 'heavy metals' to 'metals' and adding a separate category 'radionuclides'.

46. The Committee agreed to endorse the recommendation of the *ad hoc* Working Group on Contaminants and Toxins in Foods, which met prior to the current session of the Committee, to accept the proposed amendments to Schedule I. The Committee therefore decided to forward for adoption by the Commission the following amendments to Schedule I: 1) deletion of references 'CS 248-2005' and their replacement by the adoption year '2005'; 2) reorganization of contaminants into the following four categories: metals, mycotoxins, other chemicals and radionuclides. It was also decided to recommend that the Commission revoke CODEX STAN 248-2005 concerning the maximum levels for cadmium in *Brassica* vegetables; bulb vegetables; fruiting vegetables, cucurbits; fruiting vegetables, other than curcurbits; leafy vegetables; potato; root and tuber vegetables; stalk and stem vegetables; and wheat.

47. It was suggested that the Committee consider bringing the presentation of Schedule I in line with the General Standard for Food Additives (GSFA), which is published on the Codex website and on CD-ROM in the form of a database. In this presentation of the GSFA, no references regarding the adoption year or to associated commodity standards were included. It was noted that currently the inclusion of references for maximum levels in Schedule I was prescribed in the Preamble of the GSCTF, while the adoption year was contained in the working document for Information and Use in Discussions related to Contaminants and Toxins of the GSCTF (CX/CF 07/1/6), which is presented at each session of the Committee.

48. A delegation indicated that the food categorization system for the GSCTF was not yet completed and, for the time being, the references in Schedule I to commodity standards provided useful guidance. In consideration of the fact that revisions to the Preamble to the GSCTF were still under examination, it was agreed by the Committee that the issue of the format of Schedule I would be discussed at the next session of the Committee.

¹¹ The procedures for the operation of working groups are provided in the Codex Procedural Manual.

¹² Australia, Belgium, Brazil, France, India, Japan, Malaysia, the Netherlands and the Philippines expressed their willingness to participate in the electronic working group.

¹³ CX/CF 07/1/1 Add.1, CX/CF 07/1/6, CX/CF 07/1/6 Add.1 Corrigendum, CRD 2 (Report of the *ad hoc* Working Group on Contaminants and Toxins in Foods)

DRAFT MAXIMUM LEVEL FOR OCHRATOXIN A IN WHEAT, BARLEY AND RYE (at Step 7) (Agenda Item 6)¹⁴

49. The Committee noted that the Maximum Level for Ochratoxin A (OTA) in wheat, barley and rye had been included in the agenda of the present session for procedural reasons. It further noted that JECFA would re-evaluate OTA during its 68th meeting in June 2007 and that the summary report and the full draft report of the meeting would be available in electronic form by end of July/August 2007 and January/February 2008 respectively.

Status of the draft Maximum Level for Ochratoxin A in wheat, barley and rye

50. The Committee agreed to retain the draft Maximum Level for Ochratoxin A at Step 7 (see Appendix VI) and to inform the Executive Committee that work on this item would be completed by 2009.

DRAFT MAXIMUM LEVEL FOR TOTAL AFLATOXINS IN ALMONDS, HAZELNUTS AND PISTACHIOS "FOR FURTHER PROCESSING" (at Step 7) (Agenda Item 7a)

DRAFT MAXIMUM LEVEL FOR TOTAL AFLATOXINS IN ALMONDS, HAZELNUTS AND PISTACHIOS "READY-TO-EAT" (at Step 7) (Agenda Item 7b)

DISCUSSION PAPER ON MAXIMUM LEVELS FOR TOTAL AFLATOXINS IN "READY-TO-EAT" ALMONDS, HAZELNUTS AND PISTACHIOS (Agenda Item 7c)¹⁵

51. The Committee recalled that the Codex Committee on Food Additives and Contaminants, at its 38^{th} Session, agreed to hold the Draft Maximum Level of 15 µg/kg for total Aflatoxins in Almonds, Hazelnuts and Pistachios for further processing at Step 7^{16} . The Committee also recalled that the 29^{th} Session of the Codex Alimentarius Commission adopted the Proposed Draft Maximum Level of 8 µg/kg for total Aflatoxins in Almonds, Hazelnuts and Pistachios "ready-to-eat" at Step 5 and advanced it to Step 6 for comments and consideration at Step 7 at the First Session of the Committee¹⁷.

52. The Committee, at the present session, discussed these draft maximum levels, taking into account the information as presented in document CX/CF 07/1/9 and the written comments received.

53. Some delegations stated that, as a compromise, an alternative draft maximum level of 10 μ g/kg for "ready-to-eat" was acceptable and proposed to forward this draft maximum level to the Commission for adoption, in consideration of the European Food Safety Authority (EFSA) evaluation which concluded that changing the maximum levels for total aflatoxins from 4 to 8 or 10 μ g/kg in almonds, hazelnuts and pistachios would have minor effect on the estimates of dietary exposure for the general population.

54. A number of delegations expressed the view that the Committee should discuss the draft maximum levels at the next session of the Committee in light of the forthcoming outcomes of the 68^{th} JECFA meeting to evaluate the potential impact on exposure of different aflatoxin maximum levels of 4, 8, 10, and 15 µg/kg as well as 20 µg/kg if there is sufficient data. The Delegation of the European Community expressed their reservation to the inclusion of the hypothetical maximum level of 20 µg/kg in the JECFA evaluation. The JECFA Secretariat noted that the summary and the full draft reports of the JECFA meeting would be available in electronic form in July/August 2007 and January/February 2008, respectively.

55. Several delegations noted that EFSA could not accurately evaluate the health risk for certain population sub-groups which could be more vulnerable, such as children, due to the scarcity of consumption data available for such sub-groups. Giving the EFSA report, the Delegation of European Community stated that it was important to have more detailed, concrete information on the impact of the application of the code of practice on the levels of aflatoxin contamination so that maximum levels be set as low as reasonably achievable.

¹⁴ ALINORM 04/27/12 Appendix XVII, CRD 4 (comments of the European Community), CRD 15 (comments of Indonesia)

¹⁵ ALINORM 06/29/12 Appendix XXII, CL 2006/42-CF, CX/CF 07/1/8, CX/CF 07/1/9, CX/CF 07/1/9 Add.1, CRD 5 (comments of the Philippines), CRD 8 (comments of the European Community), CRD 13 (comments of Cuba), CRD 15 (comments of Indonesia), CRD 16 (comments of Turkey)

¹⁶ ALINORM 06/29/12 para.132

¹⁷ ALINORM 05/28/41 paras 97 and 104 and Appendix V

56. One observer expressed the view that levels lower than 10 μ g/kg would not be achievable for industry by applying the code of practice during the production of almonds, hazelnuts and pistachios. The observer expressed willingness to provide comprehensive data on aflatoxin contamination being collected in the previous two years so as to assist in identifying the lowest achievable level of aflatoxin in these products.

Status of the draft maximum level for total aflatoxins in almonds, hazelnuts and pistachios "for further processing" and the draft maximum level for total aflatoxins in almonds, hazelnuts and pistachios "ready to eat"

57. The Committee agreed to hold both the draft maximum level of 15 μ g/kg for total aflatoxins in almonds, hazelnuts and pistachios "for further processing" and the draft maximum level of 8 μ g/kg for total aflatoxin in almonds, hazelnuts and pistachios "ready-to-eat" at Step 7 (see Appendix VII) and to resume discussion on these draft maximum levels at its next session, after the results of the forthcoming 68th JECFA evaluation are available.

58. The Committee also agreed to establish an electronic working group¹⁸ led by the European Community, working in English, to update the discussion paper which would provide useful information for further discussion on the maximum levels at its next session.

PROPOSED DRAFT SAMPLING PLAN FOR AFLATOXIN CONTAMINATION IN ALMONDS, BRAZIL NUTS, HAZELNUTS AND PISTACHIOS (N07-2004) (at Step 4) (Agenda Item 7d)¹⁹

59. The Committee recalled that the 38th Session of the Committee on Food Additives and Contaminants had agreed to retain the proposed draft Sampling Plan for Aflatoxin in Almonds, Brazil Nuts, Hazelnuts and Pistachios at Step 4.²⁰

60. The Delegation of the United States of America introduced this item, noting that further work on the proposed draft Sampling Plan was closely linked to progress on the establishment of maximum levels of aflatoxins in these commodities.

61. Several delegations pointed out that further review was required of the proposed draft Sampling Plan, and in particular of the sampling design, taking into account the influence of sample size relative to lot size and weight and number of incremental samples composing aggregate samples and of sampling method on the Sampling Plan's accuracy.

Status of the Proposed Draft Sampling Plan for Aflatoxin Contamination in Almonds, Brazil nuts, Hazelnuts and Pistachios (N07-2004)

62. The Committee agreed that the Proposed Draft Sampling Plan for Aflatoxin Contamination in Almonds, Brazil Nuts, Hazelnuts and Pistachios be returned to Step 2 for redrafting by an electronic working group, led by the United States of America²¹, working in English, with a view to circulation at Step 3 and consideration at Step 4 at the next session of the Committee. It was also agreed that the working document to be considered at the next session of the Committee incorporate a revised proposed draft Sampling Plan as well as an explanatory text in support of the consideration of the proposed draft Sampling Plan.

¹⁸ Brazil, Iran, India, Indonesia, Turkey, United Kingdom, United States of America, WHO and INC expressed their willingness to participate in the electronic working group.

 ¹⁹ ALINORM 06/29/12 Appendix XXI, CRD 8 (comments of the European Community), CRD 16 (comments of Turkey)

²⁰ ALINORM 06/29/12, paras 124-126

²¹ Brazil, European Community, Iran, Turkey, United Kingdom, and INC expressed their willingness to take part in the working group.

DISCUSSION PAPER ON AFLATOXIN CONTAMINATION IN BRAZIL NUTS (Agenda Item 7e)²²

63. The Delegation of Brazil, speaking as the Chair of the electronic Working Group, introduced the revised discussion paper. One delegation noted that they had limited data suggesting that aflatoxin contamination of Brazil nuts was associated more with the kernel of Brazil nuts than with the shell. Support was also expressed to the recommendation of the discussion paper that further study be carried out on in-shell verses kernel contamination.

64. In regard to the recommendation b) in Part IV, paragraph 49 of the discussion paper, the Delegation of the European Community opposed to inclusion of a hypothetical standard of 20 μ g/kg in the forthcoming JECFA dietary exposure assessment on aflatoxins in tree nuts since there was no evidence that this was the lowest achievable level.

65. The Representative of WHO, speaking on behalf of the FAO and WHO JECFA Secretariats, clarified that the JECFA Secretariats had already made the decision to consider the hypothetical maximum level of 20 μ g/kg if the data were sufficient to permit this. This would also allow to put the assessment in the context of the previous JECFA assessment which included 20 μ g/kg. The Representative of WHO also explained that countries were entitled to make requests for evaluation directly to JECFA and that the JECFA Secretariat itself could forward a request to JECFA, as appropriate, without formal request from the Committee on Contaminants in Foods.

66. The Committee endorsed the recommendations a), c), and d) in Part IV, paragraph 49 of the discussion paper. The Committee agreed that the Discussion Paper on Aflatoxin Contamination in Brazil nuts would be updated by the Delegation of Brazil, incorporating additional data that would become available on the contribution of the shell to aflatoxin contamination of Brazil nuts, for consideration at the next session of the Committee.

PROPOSED DRAFT CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF OCHRATOXIN A CONTAMINATION IN WINE (N05-2006) (at Step 4) (Agenda Item 8)²³

67. The Observer from the International Organisation of Vine and Wine (OIV) presented to the Committee the proposed draft Code of Practice as contained in document CX/CF 07/1/11. The Committee noted that the proposed draft Code had been developed based on the OIV "Code of sound vitivicultural practices in order to minimize levels of Ochratoxin A in vine based products", adopted by the OIV Member States in October 2005. The draft Code addressed all measures that had been proven to prevent and reduce Ochratoxin A (OTA) contamination in wine and that covered all stages of the production chain. It was also noted that the preventive measures in the Code were meant to be applied in viticulture in regions where OTA had been found at significant levels in wine. A specific statement to this effect was included in the section on Cultivation Practices in the Vineyards, as agreed by the 38th Session of the Codex Committee on Food Additives and Contaminants²⁴.

68. The Delegation of the United Kingdom, speaking as the Chair of the *ad hoc* physical Working Group on Contaminants and Toxins in Foods²⁵, which met immediately prior to the current session of the Committee, informed the Committee that the *ad hoc* Working Group had considered document CX/CF 07/1/11, had proposed some editorial and other amendments to the proposed draft Code on the basis of the comments received, and had recommended to advance the proposed draft Code to Step 5/8.

²² CX/CF 07/1/10, CX/CF 07/1/10 Add.1 (comments at Step 4 submitted by the European Community), CRD 13 (comments of Cuba), CRD 15 (comments of Indonesia)

²³ CX/CF 07/1/11, CX/CF 07/1/11 Add.1 (comments of Kenya), CX/CF 07/1/11 Add.2 (comments of the European Community), CRD 2 (Report of the *ad hoc* physical Working Group on Contaminants and Toxins in Foods), CRD 13 (comments of Cuba), CRD 14 (comments of China), CRD 17 (comments of Brazil), CRD 18 (comments of Côte d' Ivoire)

²⁴ ALINORM 06/29/12 para. 140

²⁵ Attended by delegates of 50 Members (Australia, Austria, Belgium, Brazil, Cameroon, Canada, China, Côte d'Ivoire, Cuba, Denmark, Egypt, European Community, Finland, France, Gambia, Germany, Ghana, Greece, Hungary, Indonesia, Iran, Iraq, Ireland, Italy, Japan, Kenya, Malaysia, Mali, Morocco, Mozambique, Netherlands, New Zealand, Nigeria, Norway, Oman, Philippines, Poland, Republic of Korea, Romania, Russian Federation, Saudi Arabia, South Africa, Sudan, Sweden, Switzerland, Thailand, Turkey, United Kingdom, United

69. The Committee agreed to examine, paragraph by paragraph, the proposed draft Code on the basis of the text prepared by the *ad hoc* physical Working Group on Contaminants and Toxins in Foods, as contained in Annex 1 to CRD 2.

70. The Committee agreed to the amendments proposed by the *ad hoc* physical Working Group as well as to the following additional changes:

Training of Producers

71. The Committee added in the second bullet point "or the presence of mould spoilage, especially black mould" to recognize that small producers might not always possess the laboratory equipment and expertise necessary to identify ochratoxinogenic fungi.

Vineyard establishment

72. The Committee replaced the second sub-bullet of the second bullet point to read "avoid direct contact of grape bunches with the soil" to more clearly describe this requirement.

Pest and Disease Control

73. The Committee added a new bullet point regarding the removal of shrivelled/desiccated berries. In the last bullet point, the Committee clarified the first sentence by adding "using appropriate management to avoid fungal resistance"; and in the second sentence, the term "specific" was replaced with "appropriate".

Fermentation treatments

74. In the last bullet point, the Committee specified that the recommendation applied to the production of red wine. This amendment was made in order to avoid possible contradiction with the provisions in the section on "maturing and clarification treatments".

Maturing and clarification treatments

75. The Committee deleted the last bullet point recognizing that this particular recommendation was not specific to the prevention of OTA in wine.

General Conditions for Food Contact Materials

76. The Committee specified that food contact materials should not give rise to either contaminant migration or cross-contamination.

<u>Status of the proposed draft Code of Practice for the Prevention and Reduction of Ochratoxin A</u> <u>Contamination in Wine (N05-2006)</u>

77. The Committee agreed to forward the proposed draft Code of Practice to the 30^{th} Session of the Codex Alimentarius Commission for adoption at Step 5/8, with the recommendation to omit Steps 6 and 7 (see Appendix VIII).

DRAFT MAXIMUM LEVELS FOR TIN IN CANNED FOODS (OTHER THAN BEVERAGES) AND IN CANNED BEVERAGES (at Step 7) (Agenda Item 9)²⁶

78. The Committee recalled that the 29th Session of the Codex Alimentarius Commission had adopted proposed draft Maximum Levels for Tin in Canned Foods (other than beverages) and in Canned Beverages at levels of 250 mg/kg and 150 mg/kg respectively at Step 5 and had advanced them to Step 6, as proposed by the 38th Session of the Codex Committee on Food Additives and Contaminants²⁷.

States of America and Uzbekistan), 9 Observers (CIAA, ICBA, ICGMA, IFAC, IFT, IGCT, IHPC, INC and OIV), FAO and WHO.

 ²⁶ ALINORM 06/29/12 Appendix XXVIII, CL 2006/43-CF, CX/CF 07/1/12 (comments of Brazil and the European Community), CRD 5 (comments of Philippines), CRD 12 (comments of Thailand), CRD 13 (comments of Cuba), CRD 15 (comments of Indonesia)
 ²⁷ ALD/DM 06/29/12 Appendix XXVIII, CL 2006/43-CF, CX/CF 07/1/12 (comments of Brazil and the European Community), CRD 5 (comments of Philippines), CRD 12 (comments of Thailand), CRD 13 (comments of LDD 06/29/12 CL 2006/43-CF, CX/CF 07/1/12 (comments of Brazil and the European Community), CRD 5 (comments of Philippines), CRD 12 (comments of Thailand), CRD 13 (comments of LDD 06/29/12 CL 2006/43-CF, CX/CF 07/1/12 (comments of Thailand), CRD 13 (comments of Cuba), CRD 15 (comments of Indonesia)

ALINORM 06/29/12, paras 97 and 106 and Appendix V

79. The Delegation of the European Community stated that it maintained the reservation expressed at the 38th Session of the Codex Committee on Food Additives and Contaminants and at the 29th Session of the Codex Alimentarius Commission, and proposed maximum levels of 100 mg/kg and 200 mg/kg for canned beverages and canned foods (other than beverages) respectively, because acceptance of higher levels than those proposed could lead to an exceedance the JECFA PTWI for certain vulnerable groups, such as toddlers and small children of the population. The Delegation also stated that, in accordance with the criteria mentioned in the Preamble of the Codex General Standard for Contaminants and Toxins in Foods (GSCTF), maximum levels should be set as low as reasonably achievable and that data available in the European Community had shown that lower levels were actually achievable. The Delegation further noted that the functional / technological need of tin for some canned products did not provide a justification for the levels currently proposed by the Committee. This position was supported by some other delegations. It was also noted that the proposed maximum did not provide a margin against analytical uncertainty. Moreover, it was stated that a high level of tin might result in a metallic taste.

80. Several delegations supported the advancement of the draft maximum levels for adoption at Step 8 by the 30th Session of the Codex Alimentarius Commission. They stated that the levels proposed were reasonable and technologically justified and that the available data and information indicated that the proposed maximum levels did not present a significant health risk for consumers. It was noted that, according to the conclusion of the 64th JECFA, there were insufficient data to establish an acute reference dose; that according to the 55th JECFA, the mean dietary intakes of tin reported by seven countries were considerably lower than the PTWI set by the 33rd JECFA and that, according to the 64th JECFA, there were sub-populations that were particularly sensitive to tin. In this regard, it was also noted that the toxic effects of tin are relatively minor. In addition, it was stated that lowering the maximum levels of tin could have a negative impact on product shelf-life because tin coating was important for ensuring adequate shelf-life and the year-round availability of certain seasonal products (e.g. pineapple) in international trade.

81. One delegation stated that after the adoption of Maximum Levels for Tin, the maximum levels for tin for food in non-tin layered containers would become unnecessary.

<u>Status of the draft Maximum Levels for Tin in Canned Foods (other than beverages) and in Canned Beverages</u>

82. The Committee agreed to forward the draft Maximum Levels in Tin to the 30th Session of the Codex Alimentarius Commission for adoption at Step 8 (see Appendix IX). The Delegations of the European Community and Switzerland reserved their position to this decision. The Committee also noted that the eventual adoption by the Commission of the draft Maximum Level for Tin in Canned Foods (other than beverages) would result in consequential changes to maximum levels for tin in certain canned products (i.e. products in tin-layered cans), currently included in Schedule I of the Codex General Standard for Contaminants and Toxins in Foods (GSCTF).

PROPOSED DRAFT MAXIMUM LEVEL FOR 3-MCPD IN LIQUID CONDIMENTS CONTAINING ACID-HYDROLYZED VEGETABLE PROTEINS (EXCLUDING NATURALLY FERMENTED SOY SAUCE) (N08-2004) (at Step 4) (Agenda Item 10)²⁸

83. The Committee recalled that the Codex Committee on Food Additives and Contaminants, at its 38th Session, had agreed to maintain the proposed draft Maximum Level of 0.4 mg/kg at Step 4, and agreed to establish an electronic working group for updating the discussion paper on chloropropanols derived from the manufacture of acid-HVP and the heat processing of foods in view of the results of the JECFA evaluation and other information relevant for discussion²⁹. It was agreed to reconsider the proposed Maximum Level in light of this revised document.

ALINORM 06/29/12 Appendix XXVII, CX/CF 07/1/13, CX/CF 07/1/13 Add. 1 (comments of the European Community and Norway), CRD 5 (comments of the Philippines), CRD 9 (comments of Japan), CRD 12 (comments of Thailand), CRD 13 (comments of Cuba), CRD 14 (comments of China), CRD 15 (comments of Indonesia)

²⁹ ALINORM 06/29/12 para.175-177

84. The Delegation of the United Kingdom, speaking as the Chair of the electronic Working Group, briefly introduced the revised discussion paper, which included the outcome of the 3-MCPD evaluation by the 67th JECFA. It was noted that a Code of Practice for the reduction of 3-MCPD during the production of acid-hydrolysed vegetable proteins (acid-HVPs) and products that contain acid-HVPs was currently being developed (see Agenda Item 11).

85. Several delegations indicated that they would consider a draft Maximum Level of 0.1 mg/kg to be acceptable, recognizing the technological difficulties and costs, especially in developing countries, to achieve lower levels.

86. The Committee noted recent results from Japan, as described in CRD 9, on 3-MCPD levels in acid-HVPs and soy sauces made with acid-HVPs, mainly produced by small-scale plants. The results showed that under strictly controlled manufacturing parameters, the level of 3-MCPD could be reduced. One delegation informed the Committee that its Government and industries work together in modifying the process of production and brought the levels down considerably. Currently, the levels of 3-MCPD in about 25% of products coming from industries were above the current proposed draft Maximum Level, but mostly below 1 mg/kg. The delegation, therefore, proposed that a Codex Maximum Level of 0.4 mg/kg be maintained and be considered again a few years after the finalization and implementation of a Code of Practice.

87. Several other delegations supported the proposal to maintain the proposed draft Maximum Level of 0.4 mg/kg and await the completion of the Code of Practice and the collection of surveillance data after its implementation by Codex Members. Some delegations brought it to the attention of the Committee that simplified methods of analysis should be developed in order for developing countries to be able to monitor the levels of 3-MCPD in acid-HVPs and soy sauce.

<u>Status of the proposed draft Maximum Level for 3-MCPD in Liquid Condiments Containing Acid-</u> <u>Hydrolyzed Vegetable Proteins (Excluding Naturally Fermented Soy Sauce) (N08-2004)</u>

88. The Committee agreed to forward the proposed draft Maximum Level of 0.4 mg/kg to the 30th Session of the Codex Alimentarius Commission for adoption at Step 5 (see Appendix X). It was agreed that the draft Maximum Level should be further considered in light of finalization and implementation of the Code of Practice for the Reduction of 3-MCPD during the Production of Acid-Hydrolysed Vegetable Proteins (acid-HVPs) and Products that Contain Acid-HVPs.

89. The European Community and Norway expressed their reservation to the decision to advance the draft Maximum Level of 0.4 mg/kg.

PROPOSED 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) (at Step 4) (Agenda Item 11)³⁰

90. The Committee recalled that the Codex Committee on Food Additives and Contaminants at its 38th Session agreed to return the renamed proposed draft Code of Practice for the Reduction of 3-monochloropropane-1,2-diol (3-MCPD) during the Production of Acid-Hydrolyzed Vegetable Protein (HVPs) and Products that Contain acid HVPs to Step 2 for revision by an electronic Working Group led by the United Kingdom, for circulation, comments at Step 3 and consideration at Step 4 at the First Session of the Codex Committee on Contaminants in Foods³¹.

91. The Committee agreed to examine the proposed draft Code on the basis of the text prepared by the *ad hoc* physical Working Group on Contaminants and Toxins in Foods, as contained in Annex 2 to CRD 2.

³⁰ ALINORM 06/29/12, CX/CF 07/1/14, CX/CF 07/1/14 Add. 1 (Comments of Japan), CX/CF 07/1/14 Add. 2 (corrigendum to the working document CX/CF 07/1/14), CX/CF 07/1/14 Add. 3 (comments of the European Community), CRD 2 (Report of the *ad hoc* Working Group on Contaminants and Toxins in Foods), CRD 5 (comments of the Philippines), CRD 9 (comments of Japan), CRD 12 (comments of Thailand), CRD 13 (comments of Cuba), CRD 15 (comments of Indonesia), CRD 20 (coments of Nigeria)

³¹ ALINORM 06/29/12 paras 173-174

92. The Committee agreed to most of the amendments proposed by the *ad hoc* physical working group and to the following additional changes:

- In paragraph 14, the last sentence proposed by the *ad hoc* physical working group was replaced with "at the national level, manufacturers may need to adjust the measures in their own production processes";
- In paragraph 21, the last sentence regarding the results of a survey on soy sauce manufactured using low 3-MCPD acid-HVP was deleted.

Status of the proposed 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).

93. The Committee agreed to forward the proposed draft Code of Practice, as amended at the present session, to the 30th Session of the Codex Alimentarius Commission for adoption at Step 5 (see Appendix XI).

PROPOSED DRAFT CODE OF PRACTICE FOR THE REDUCTION OF ACRYLAMIDE IN FOOD (N06-2006) (at Step 4) (Agenda Item 12) 32

94. Document CX/CF 07/1/15 was introduced by the Delegation of the United States of America, which had led an electronic working group, together with the United Kingdom, that prepared the proposed draft Code of Practice at Step 2. The proposed draft had subsequently been circulated for comments at Step 3. The Delegation explained that the proposed draft contained measures that were still being researched as well as measures that were established and shown to be effective for the reduction of acrylamide during the processing of food.

95. The Committee was informed that the *ad hoc* Working Group on Contaminants and Toxins, which had met immediately prior to the present session of the Committee, had discussed whether recommendations to national authorities on consumer practices as described in paragraphs 52 and 53 of the proposed draft Code of Practice should be retained in the Code. Since consumer practices were considered to add significantly to acrylamide exposure and similar recommendations had already been incorporated in other codes of practice, it was decided to maintain paragraphs 52 and 53. The Committee noted that data from a Japanese study on the formation of acrylamide by consumer practices would be available in 2009 and that correct references for paragraph 7 would be provided by the JECFA Secretariat.

96. The Committee, noting the opinion of the *ad hoc* physical working group that this document was not yet ready for advancement in the Codex Procedure, agreed that a revised proposed draft should be prepared, taking account of additional data and information which would become available in the coming year from ongoing studies.

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

97. The Committee agreed to return the proposed Draft Code of Practice to Step 2 for redrafting by an electronic working group³³ chaired by the United States of America and the United Kingdom, and working in English, on the basis of the written comments received and the discussion in the *ad hoc* Working Group and in the present session of the Committee, with a view to circulation for comments at Step 3 and consideration at Step 4 at the next session of the Committee.

 ³² CX/CF 07/1/15, CX/CF 07/1/15 Add.1 (comments of Brazil), CX/CF 07/1/15 Add. 2 (comments of the European Community and Kenya), CRD 2 (Report of the *ad hoc* Working Group on Contaminants and Toxins, CRD 13 (comments of Cuba), CRD 15 (comments of Indonesia)

³³ Australia, Belgium, Canada, China, Cuba, Denmark, the European Community, Germany, Japan, the Netherlands, Philippines, Republic of Korea, Sweden, Switzerland, Thailand, Turkey, CIAA, ICGMA, IFT, FAO, and WHO expressed their willingness to take part in the working group.

PROPOSED DRAFT CODE OF PRACTICE FOR THE REDUCTION OF CONTAMINATION OF FOOD WITH POLYCYCLIC AROMATIC HYDROCARBONS (PAH) FROM SMOKING AND DIRECT DRYING PROCESES (N07-2006) (at Step 4) (Agenda Item 13)³⁴

98. The Delegation of Denmark, as the Chair of the electronic working group on the Code of Practice for the Reduction of Contamination of Food with Polycyclic Aromatic Hydrocarbons (PAHs) from Smoking and Direct Drying Processes,³⁵ introduced the proposed draft code of practice as presented in working document CX/CF 07/1/16. It was mentioned that the *ad hoc* Working Group on Contaminants and Toxins in Foods that had met immediately before the session, had recommended that smoke flavours be addressed in the introductory part only. The Committee agreed to the recommendations of the *ad hoc* physical working group.

99. The Delegation indicated that the proposed draft code of practice aimed at providing tools to optimize smoking and direct drying processes in the production of foods and that more information was required for the further development of the Code, such as on the type of wood used as fuel in the smoking which would reduce contamination of PAHs. The Delegation of the United Kingdom, speaking as the Chair of the *ad hoc* physical working group, stated that many improvements were still necessary by incorporating new data into the proposed draft Code.

100. Some delegations offered to contribute additional information so that this proposed draft Code of Practice should be further developed with respect to products such as cereals, vegetables, fats and oils.

101. Another delegation expressed the opinion that the use of active carbon should be required for oil seed and pomace olive oil as the only way to reduce the content of PAHs when direct drying processing was used.

<u>Status of the proposed draft Code of Practice for the Reduction of Contamination of Food with</u> <u>Polycyclic Aromatic Hydrocarbons (PAH) from Smoking and Direct Drying Processes (N07-2006)</u>

102. The Committee agreed to return the proposed Draft Code of Practice to Step 2 for redrafting by an electronic working group led by Denmark³⁶, working in English, with a view to circulation for comments at Step 3 and consideration at Step 4 at the next session of the Committee.

DISCUSSION PAPER ON DEOXYNIVALENOL (DON) (Agenda Item 14a)³⁷

103. The Committee recalled that the 38th Session of the Committee on Food Additives and Contaminants re-established an electronic working group led by the United States of America to revise and update the Discussion Paper on Deoxynivalenol (DON)³⁸.

104. The Delegation of the United States of America introduced document CX/CF 07/1/17, which contained an update on toxicology, sampling, analysis, occurrence of deoxynivalenol in cereals and in processed products and on relevant studies, regulatory framework and ongoing research.

105. The Committee noted the conclusions of the discussion paper which identified the need for data from surveys of levels of DON, for more research on resistant cereal cultivars and strategies aimed at preventing the production of trichothecenes in cereals grains, on methods to prevent and/or reduce contamination of cereals in the field and for the development and validation of methods capable of detecting multi-mycotoxin residues.

³⁴ CX/CF 07/1/16, CX/CF 07/1/16 Add.1, CRD 2 (Report of the *ad hoc* physical Working Group on Contaminants and Toxins in Foods), CRD 4 (comments of the European Community), CRD 5 (comments of Philippines), CRD 11 (comments of Latvia), CRD 12 (comments of Thailand), CRD 13 (comments of Cuba), CRD 15 (comments of Indonesia), CRD 20 (comments of Nigeria)

³⁵ ALINORM 06/29/12 para.188

³⁶ Australia, Austria, Belgium, Cuba, European Community, France, Germany, Ghana, Italy, Japan, the Netherlands, Nigeria, Philippines, Poland, Republic of Korea, South Africa, Spain, Thailand, the United Kingdom, the United States of America and CPA expressed their willingness to participate in the electronic working group.

³⁷ CX/CF 07/1/17, CRD 4 (comments of the European Community), CRD 13 (comments of Cuba), CRD 15 (comments of Indonesia)

³⁸ ALINORM 06/29/12 para. 138

106. The Committee was informed that the data from Brazil on occurrence of deoxynivalenol as contained in the document referred to both domestic and imported products. Other delegations highlighted the importance of securing best practices throughout the entire food chain in order to reduce the presence of deoxynivalenol; that the selection of cultivars should also aim to control factors for other trichothecenes; and that research should have a holistic and consistent approach. It was noted that the PTWI could be exceeded by children consuming a high quantity of cereals, and that efforts should be made to reduce the presence of trichothecenes in cereals and to possibly develop a code of practice in the future.

107. The WHO Representative welcomed the submission of data on DON to the GEMS/Food Databases and clarified that all GEMS/Food data on a contaminant were provided automatically to JECFA when the substance was scheduled for evaluation.

108. The Committee agreed with the conclusions and recommendations in paragraphs 92-97 of the discussion paper. In view of the need for more occurrence data, including regional data on incidence and levels of DON in cereals over a period of several years, and for adequate information on consumption patterns for various countries as a pre-requisite to developing international standards, the Committee agreed to discontinue consideration of this item for the time being and to encourage countries to submit data on DON contamination to GEMS/Food Databases electronically and in the prescribed format³⁹.

DISCUSSION PAPER ON OCHRATOXIN A (OTA) IN COFFEE (Agenda Item 14b)⁴⁰

109. The Committee recalled that the 38th Session of the Committee on Food Additives and Contaminants established an electronic working group led by Brazil to prepare a discussion paper on OTA in coffee, for consideration at the First Session of the Committee on Contaminants in Foods⁴¹.

110. The Delegation of Brazil introduced document CX/CF 07/1/18 and stated that there was the need for developing a Code of Practice for the prevention and reduction of OTA in coffee, and that at a later stage the establishment of a maximum level should be considered. Several delegations supported this position.

111. An observer questioned the need for a Codex Code of Practice, noting that FAO had already published the document "Guidelines for the Prevention of Mould Formation in Coffee"⁴², while some delegations suggested that if the Committee was to start new work, the FAO document could be used as a starting point, thus avoiding duplication of efforts. It was also stated that various climate and other agricultural conditions of coffee production should be taken into account when developing a code of practice.

112. Some delegations stated that the establishment of a maximum level might not be necessary, or should be considered after several years' experience of implementing a future Code of Practice had been gained. One delegation stated that should a maximum level for OTA in coffee be developed, the accompanying sampling plans should ensure that sufficiently appropriate representative sample be collected.

113. After some discussion, the Committee decided to establish an electronic working group⁴³, to be chaired by Brazil, working in English, to prepare a revised discussion paper for consideration at the next session of the Committee. The revised discussion paper should incorporate new data and other relevant information including those submitted to the present session of the Committee, and be accompanied by a project document proposing new work and possibly an outline of the proposed draft Code of Practice.

³⁹ See <u>http://www.who.int/foodsafety/publications/chem/gems_instructions/en/index.html</u>.

 ⁴⁰ CX/CF 07/1/18, CX/CF 07/1/18 Add.1 (comments of Japan, Peru and ICO), CX/CF 07/1/18 Add.2 (comments of the European Community), CRD 5 (comments of the Philippines), CRD 10 (comments of Vietnam), CRD 13 (comments of Cuba), CRD 15 (comments of Indonesia), CRD 18 (comments of Côte d'Ivoire)

⁴¹ ALINORM 06/29/12 para. 145

⁴² Available at <u>http://www.coffee-ota.org</u>.

⁴³ Cameroon, China, Côte d'Ivoire, the European Community, Ghana, Madagascar, the Philippines, Sweden, Switzerland, Thailand, Uganda, the United Kingdom and FAO expressed their willingness to participate in the working group.

DISCUSSION PAPER ON OCHRATOXIN A (OTA) IN COCOA (Agenda Item 14c)⁴⁴

114. The Committee recalled that the 38th Session of the Committee on Food Additives and Contaminants established an electronic working group led by Ghana to prepare a discussion paper on OTA in cocoa for circulation, comments and consideration at the First Session of the Committee on Contaminants in Foods so that the Committee could decide whether it would be appropriate to develop a Code of Practice⁴⁵.

115. The Delegation of Ghana introduced document CX/CF 07/1/19 and acknowledged the written comments contained in the addenda to the document as well as in conference room documents. While noting that cocoa represented a relatively small proportion of the overall dietary exposure to OTA, the Delegation stressed the need for developing internationally harmonized, appropriate methods of analysis and for collecting more data on the occurrence of OTA in cocoa. Such data would be important for any future request to JECFA for an evaluation and would help to facilitate the elaboration of a Code of Practice. Additionally, more research was desirable, for example, on identifying lactobacillus strains that inhibited growth of OTA producing moulds. In light of these circumstances, it was recommended that the need for a code of practice be considered by the Committee at a later stage.

116. The Committee agreed that it was premature to initiate the development of a code of practice and a decision in this regard should wait until more data had been collected. One observer stated that if the Committee was to consider the establishment of a maximum level in the future, such decision should be taken after producers, of which many were small holders, have had sufficient time to implement a code of practice. Another observer, noting that some of the data contained in the discussion paper were dated and did not reflect the current situation, offered to contribute new data.

117. After some discussion, the Committee decided to establish an electronic working group⁴⁶, to be chaired by Ghana, working in English, to update the discussion paper with new data and other relevant information, and taking into account the comments made at the present session, for consideration at the next session of the Committee.

DISCUSSION PAPER ON AFLATOXIN IN DRIED FIGS (Agenda Item 14d)⁴⁷

118. The Delegation of Turkey, referring to document CX/CF 07/1/20, highlighted the importance of dried figs in international trade and the significance of potential food safety problems associated with dried figs, for which aflatoxin contamination was known to occur in all producing countries.

119. Many delegations supported the initiation of new work on the elaboration of a code of practice for the prevention and reduction of aflatoxin contamination in dried figs, but were of the opinion that it was premature to consider the need for a maximum level for aflatoxins in dried figs, which should be considered only after a code of practice had been developed and implemented in producing regions and countries.

120. The Committee agreed to forward the project document proposing new work (see Appendix XII) to the 59^{th} Session of the Executive Committee for critical review and for approval by the 30^{th} Session of the Commission.

121. The Committee also agreed to establish an electronic working group led by Turkey,⁴⁸ working in English, to prepare a draft proposed Code of Practice on the Prevention and Reduction of Aflatoxin Contamination in Dried Figs 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 Commission.

⁴⁴ CX/CF 07/1/19, CX/CF 07/1/19 Add.1, CX/CF 07/1/19 Add.2, CRD 5 (comments of the Philippines), CRD 6 (comments of Ghana), CRD 13 (comments of Cuba), CRD 15 (comments of Indonesia), CRD 18 (comments of Côte d'Ivoire), CRD 20 (comments of Nigeria)

⁴⁵ ALINORM 06/29/12 para 145

⁴⁶ Belgium, Brazil, Cameroon, Côte d'Ivoire, the European Community, Nigeria, Sweden, Switzerland, Togo, CIAA, CPA and WHO and expressed their interest in taking part in the working group.

 ⁴⁷ CX/CF 07/1/20, CRD 4 (comments of the European Community), CRD 13 (comments of Cuba), CRD 15 (comments of Indonesia), CRD 16 (comments of Turkey)

⁴⁸ The European Community, Greece, Iran, Spain, Sweden, Thailand, the United Kingdom and INC expressed their willingness to participate in the electronic working group.

PRIORITY LIST OF CONTAMINANTS AND NATURALLY OCCURRING TOXICANTS PROPOSED FOR EVALUATION BY JECFA (Agenda Item 15)⁴⁹

122. The Delegation of the Netherlands, speaking as the Chair of the in-session physical working group on the priority list of contaminants and naturally occurring toxicants proposed for evaluation by JECFA⁵⁰, introduced the report of the working group as presented in CRD 3. The Delegation emphasized the importance of giving due regard to the criteria for prioritization listed in paragraph 20 of the Risk Analysis Principles Applied by the Codex Committee on Food Additives and Contaminants when the Committee discussed the priority list of substances for JECFA evaluation. It was suggested to indicate these criteria in the Codex Circular Letter requesting comments on the priority list.

123. The Representatives of FAO and WHO, on behalf of the JECFA Secretariats, stressed that prioritization processes in the Committee were important in order to allow JECFA to efficiently plan and make arrangements within its limited resources. Governments were urged not only to provide scientific data in response to specific requests for data but also to submit to the JECFA Secretariat information on the progress of new data submission and the timing of data availability. The Committee was reminded that a call for data submission is launched approximately one year before each JECFA meeting.

124. Based on the above discussion, the Committee recommended that a Codex Circular Letter on the priority list explicitly request comments and information on: i) new substances for nomination, and ii) substances already included in the priority list, including the expected timeline for data availability. Furthermore, the Circular Letter should list the criteria shown in paragraph 20 of the Risk Analysis Principles Applied by the Codex Committee on Food Additives and Contaminants, included in the Procedure Manual.

125. The Committee discussed the substances contained in CRD 3. Highlights of the discussion and conclusion are as follows:

i) Deoxynivalenol

126. The Committee noted that sufficient data on deoxynivalenol occurrence in food and fate at processing would not be available before the end of 2008 and that no information was provided on the availability of toxicological data. The Committee agreed that deoxinivalenol remain on the priority list.

ii) Patulin

127. The Committee agreed to take patulin out of the priority list, noting that there was an existing maximum level and this topic was no longer considered a high priority.

iii)Phenyl hydrazines

128. The Committee agreed to retain phenyl hydrazines on the priority list but with low priority.

129. It was pointed out that phenyl hydrazines were found in one of the most commonly cultivated mushroom of the Agaricus species (e.g. in the European region). The mushroom was eaten raw as well as traded in dried form internationally.

iv) Furan

130. The Committee noted that furan was formed in food during thermal processing and was detected in many foods, including canned food. It was an animal carcinogen and classified as a probable human carcinogen by International Agency for Research on Cancer (IARC). In view of data being made available by 2008, the Committee agreed to include furan in the priority list with the indication that it was of high priority.

⁴⁹ CL 2006/46-CF, CX/CF 07/1/21, CRD 3 (Report of the in-session working group on priority list of contaminants and naturally occurring toxicants proposed for evaluation by JECFA)

⁵⁰ Australia, Belgium, Brazil, Canada, China, France, the European Community, Finland, Denmark, Ireland, Iran, Japan, Malaysia, Norway, Philippines, Poland, Turkey, Netherlands, New Zealand, Thailand, Sweden, United Kingdom, United States of America, CIAA, ICBA, ICGMA, IFAC, IFT, OIV and WHO participated in the working group.

v) Perchlorate

131. The Committee noted that perchlorate was both a naturally occurring and man-made chemical that could contaminate food through water and soil. In light of the fact that occurrence data were being collected, the Committee agreed to include perchlorate in the priority list with the indication of high priority (but of slightly lower priority than deoxinivalenol and furan).

132. It was clarified that effects on thyroid function observed in a recent study on perchlorate was related to women of child bearing age with sub-optimal iodine uptake.

133. The Committee endorsed the priority list of contaminants and naturally occurring toxicants for JECFA evaluation, as amended above (see Appendix XIII).

134. The Committee recommended that an in-session physical working group be convened during the next session of the Committee, in order to review the priority list in light of comments received.

OTHER BUSINESS AND FUTURE WORK (Agenda Item 16)

Fumonisins

135. Some delegations proposed the inclusion of fumonisins on the priority list for JECFA evaluation in order to update the exposure/risk assessment, since high corn consumption may lead to increased exposure to fumonisins. In this regard, the Representative of WHO, speaking on behalf of the JECFA Secretariats, clarified that there was no plan for JECFA to update the risk assessment conducted by the 56th JECFA meeting and that an updated risk assessment could be conducted only when new data became available.

Food Category System in the General Standard of Contaminants and Toxins in Foods (GSCTF)

136. A delegation, noting that the ongoing revision of the Codex Classification of Foods and Animal Feeds by the Committee on Pesticide Residues was focused on inclusion of specialty crops, proposed that the Committee take the lead in including, in the supplementary list of the food categorization system, some products of relevance to the GSCTF, such as fish and fish products. The Committee noted that this work would fall within the terms of reference of the electronic working group on the revision of the Preamble of the GSCTF (see para. 43) and invited interested Members to actively contribute to the work of the working group regarding the possible revision of the food category system.

Ethyl carbamate

137. One delegation proposed that the Committee consider ethyl carbamate contamination at its next session. The Committee noted that the 64th JECFA had 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.

DATE AND PLACE OF THE NEXT SESSION (Agenda Item 17)

138. The Committee was informed that the Second Session of the Committee would be held probably in the Netherlands, from 31 March to 4 April, 2008. The exact venue and date would be determined by the Codex Secretariat in consultation with the host government.

139. A delegation suggested that the next session of the Committee be held back-to-back with the 40th Session of the Committee on Food Additives in order to facilitate the participation of delegates from developing countries in both Codex committees. The Committee noted that this suggestion would be recorded but that the dates and venues of Codex sessions would have to be determined within the overall session planning process.

140. Some delegations wondered whether an *ad hoc* working group on the Codex General Standard for Contaminants and Toxins in Foods would be convened immediately prior to the next session of the Committee next year. The Committee noted that during the present session it did not make a decision to establish a physical working group that would meet prior to the next session of the Committee. In this connection, the Committee recalled that the Codex Alimentarius Commission had decided to divide the former Codex Committee on Food Additives and Contaminants into two committees, in order to allocate sufficient time to discuss all agenda items during the formal session of the Committee, where full interpretation and document translation is available, thereby ensuring maximum transparency and participation of Members, including non-English speaking delegates. The Committee noted that the Committee and that the Committee would evaluate the need for working groups on an *ad hoc* basis base on the need of such working groups in the future.

SUMMARY STATUS OF WORK

SUBJECT MATTERS	STEP	ACTION BY:	DOCUMENT
			REFERENCE (ALINORM 07/30/41)
Draft Maximum Levels for Tin in Canned Foods (other than beverages) and in Canned Beverages	8	Members and Observers, 30 th CAC	Para. 82 and Appendix IX
Proposed Draft Code of Practice for the Prevention and Reduction of Ochratoxin A Contamination in Wine (N05-2006)	5/8	Members and Observers, 30 th CAC	Para. 77 and Appendix VIII
Proposed Amendments to the Terms of Reference of the Codex Committee on Contaminants in Foods	Approval	30 th CAC	Para. 15 and Appendix II
Proposed Amendments to the "Risk Analysis Principles Applied by the Codex Committee on Food Additives and Contaminants"	Adoption	30 th CAC	Para. 18 and Appendix III
Proposed Amendments to the "CCFAC Policy for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups"	Adoption	30 th CAC	Para. 18 and Appendix IV
Definition for "Codex Maximum Level for a Contaminant in Food or Feed Commodity"	Adoption	30 th CAC	Para. 38 and Appendix V
Amendments to Schedule I of the General Standard for Contaminants and Toxins in Foods,	Adoption	30 th CAC	Para. 46
Recommendation to revoke CODEX STAN 248-2005	Revocation	30 th CAC	Para. 46
Draft Maximum Level for Ochratoxin A in Wheat, Barley and Rye	7	2 nd Session of the Committee	Para. 50 and Appendix VI
Draft Maximum Level for Total Aflatoxins in Almonds, Hazelnuts and Pistachios "For Further Processing"	7	2 nd Session of the Committee	Para. 57 and Appendix VII
Draft Maximum Level for Total Aflatoxins in Almonds, Hazelnuts and Pistachios "Ready-to-Eat"	7	2 nd Session of the Committee	Para. 57 and Appendix VII
Proposed Draft Maximum Level for 3-MCPD in Liquid Condiments Containing Acid- Hydrolyzed Vegetable Proteins (Excluding Naturally Fermented Soy Sauce) (N08-2004)	5	Members and Observers, 30 th CAC,	Para. 88 and Appendix X
Proposed 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)	5	Members and Observers, 30 th CAC,	Para. 93 and Appendix XI
Proposed Draft Revision of the Preamble of the GSCTF (N04-2006)	2/3/4	Electronic working group, Members and Observers, 2 nd Session of the	Para. 43

SUBJECT MATTERS	STEP	ACTION BY:	DOCUMENT REFERENCE (ALINORM 07/30/41)
		Committee	
Proposed Draft Sampling Plan for Aflatoxin Contamination in Almonds, Brazil nuts, Hazelnuts and Pistachios (N07-2004)	2/3/4	Electronic working group, Members and Observers, 2 nd Session of the Committee	Para. 62
Proposed Draft Code of Practice for the Reduction of Acrylamide in Food (N06-2006)	2/3/4	Electronic working group, Members and Observers, 2 nd Session of the Committee	Para. 97
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)	2/3/4	Electronic working group, Members and Observers, 2 nd Session of the Committee	Para. 102
Proposed draft Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Dried Figs (new work)	1/2/3	Electronic working group.	Paras 120-121 and Appendix XII
Discussion Paper on Maximum Levels for Total Aflatoxins in "Ready-to-Eat" Almonds, Hazelnuts and Pistachios		Electronic working group	Para. 58
Discussion Paper on Aflatoxin Contamination in Brazil Nuts		Delegation of Brazil	Para. 66
Discussion Paper on Ochratoxin A in Coffee		Electronic working group	Para. 113
Discussion Paper on Ochratoxin A in Cocoa		Electronic working group	Para. 117
Priority List of Contaminants and Naturally Occurring Toxicants Proposed for Evaluation by JECFA		Codex Secretariat	Paras 133-134 and Appendix XIII

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ALINORM 07/30/41 Appendix I

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Appendix II

PROPOSED AMENDMENTS TO THE TERMS OF REFERENCE OF THE CODEX COMMITTEE ON CONTAMINANTS IN FOODS

Terms of reference:

- (a) to establish or endorse permitted maximum levels, or and where necessary revise existing guideline levels, for contaminants and naturally occurring toxicants in food and feed;
- (b)to prepare priority lists of contaminants and naturally occurring toxicants for risk assessment by the Joint FAO/WHO Expert Committee on Food Additives;
- (c) to consider <u>and elaborate</u> methods of analysis and sampling for the determination of contaminants and naturally occurring toxicants in food and feed;
- (d) to consider and elaborate standards or codes of practice for related subjects; and
- (e) to consider other matters assigned to it by the Commission in relation to contaminants and naturally occurring toxicants in food and feed.

Appendix III

PROPOSED AMENDMENTS TO THE RISK ANALYSIS PRINCIPLES APPLIED BY THE CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS (For adoption and inclusion in the Procedural Manual)

RISK ANALYSIS PRINCIPLES APPLIED BY THE <u>CODEX COMMITTEE ON FOOD ADDITIVES AND THE</u> <u>CODEX COMMITTEE ON CONTAMINANTS IN FOODS</u> CODEX COMMITTEE ON FOOD ADDITIVES AND <u>CONTAMINANTS</u>

SECTION 1. SCOPE

- This document addresses the respective applications of risk analysis principles by the Codex Committee on Food Additives and Contaminants (CCFAC) Codex Committee on Food Additives (CCFA) and the Codex Committee on Contaminants in Foods (CCCF) and the Joint FAO/WHO Expert Committee on Food Additives (JECFA). For matters which cannot be addressed by JECFA, this document does not preclude the possible consideration of recommendations arising from other internationally recognized expert bodies, as approved by the Commission.
- 2) This document should be read in conjunction with the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius.

SECTION 2. CCFAC CCFA/CCCF and JECFA

- 3) CCFAC <u>CCFA/CCCF</u> and JECFA recognize that communication between risk assessors and risk managers is critical to the success of their risk analysis activities.
- 4) CCFAC <u>CCFA/CCCF</u> and JECFA should continue to develop procedures to enhance communication between the two committees.
- 5) CCFAC CCFA/CCCF and JECFA should ensure that their contributions to the risk analysis process involve all interested parties and are fully transparent and thoroughly documented. While respecting legitimate concerns to preserve confidentiality, documentation should be made available, upon request, in a timely manner to all interested parties.
- 6) JECFA, in consultation with CCFAC CCFA/CCCF, should continue to explore developing minimum quality criteria for data requirements necessary for JECFA to perform risk assessments. These criteria are used by CCFAC CCFA/CCCF in preparing its their Priority List for JECFA. The JECFA Secretariat should consider whether these minimum quality criteria for data have been met when preparing the provisional agenda for meetings of JECFA.

SECTION 3. CCFAC CCFA/CCCF

- 7) CCFAC CCFA/CCCF is are primarily responsible for recommending risk management proposals for adoption by the CAC.
- 8) CCFAC CCFA/CCCF shall base its their risk management recommendations to the CAC on JECFA's risk assessments, including safety assessments¹, of food additives, naturally occurring toxicants, and contaminants in food.

¹ A Safety Assessment is defined as a scientifically-based process consisting of: 1) the determination of a NOEL (No Observed Effect Level) for a chemical, biological, or physical agent from animal feeding studies and other scientific considerations; 2)

- 9) In cases where JECFA has performed a safety assessment and CCFAC CCFA/CCCF or the CAC determines that additional scientific guidance is necessary, CCFAC CCFA/CCCF or CAC may make a more specific request to JECFA to obtain the scientific guidance necessary for a risk management decision.
- CCFAC <u>CCFA</u>'s risk management recommendations to the CAC with respect to food additives shall be guided by the principles described in the Preamble and relevant annexes of the Codex General Standard for Food Additives.
- 11) CCFAC CCCF's risk management recommendations to the CAC with respect to contaminants and naturally occurring toxicants shall be guided by the principles described in the Preamble and relevant annexes of the Codex General Standard for Contaminants and Naturally Occurring Toxins in Food.
- 12) CCFAC CCFA/CCCF's risk management recommendations to the CAC that involve health and safety aspects of food standards shall be based on JECFA's risk assessments and other legitimate factors relevant to the health protection of consumers and to ensuring fair practices in food trade in accordance with the *Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principles*.
- 13) CCFAC CCFA/CCCF's risk management recommendations to the CAC shall take into account the relevant uncertainties and safety factors described by JECFA.
- 14) <u>CCFAC CCFA</u> shall endorse maximum use levels only for those additives for which 1) JECFA has established specifications of identity and purity and 2) JECFA has completed a safety assessment or has performed a quantitative risk assessment.
- 15) CCFAC CCCF shall endorse maximum levels only for those contaminants for which 1) JECFA has completed a safety assessment or has performed a quantitative risk assessment and 2) the level of the contaminant in food can be determined through appropriate sampling plans and analysis methods, as adopted by Codex. CCFAC CCCF should take into consideration the analytical capabilities of developing countries unless public health considerations require otherwise.
- 16) CCFAC CCFA/CCCF shall take into account differences in regional and national food consumption patterns and dietary exposure as assessed by JECFA when recommending maximum use levels for additives or maximum levels for contaminants and naturally occurring toxicants in food.
- 17) Before finalising proposals for maximum levels for contaminants and naturally occurring toxicants, CCFAC CCCF shall seek the scientific advice of JECFA about the validity of the analysis and sampling aspects, about the distribution of concentrations of contaminants and naturally occurring toxicants in foods and about other relevant technical and scientific aspects, including dietary exposure, as necessary to provide for a suitable scientific basis for its advice to CCFAC CCCF.
- 18) When establishing its standards, codes of practice, and guidelines, CCFAC CCFA/CCCF shall clearly state when it applies any other legitimate factors relevant to the health protection of consumers and to ensuring fair practices in food trade in accordance with the *Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principles*, in addition to JECFA's risk assessment, and specify its reasons for doing so.

the subsequent application of safety factors to establish an ADI or tolerable intake; and 3) comparison of the ADI or tolerable intake with probable exposure to the agent (Temporary definition to be modified when JECFA definition is available).

- 19) CCFAC <u>CCFA/CCCF</u>'s risk communication with JECFA includes prioritising substances for JECFA review with the view towards obtaining the best available risk assessment for purposes of elaborating safe conditions of use for food additives and elaborating safe maximum levels or codes of practice for contaminants and naturally occurring toxicants in food.
- CCFAC <u>CCFA/CCCF</u> shall consider the following when preparing its <u>their</u> priority list of substances for JECFA review:
 - Consumer protection from the point of view of health and prevention of unfair trade practices;
 - CCFAC CCFA/CCCF's Terms of Reference;
 - JECFA's Terms of Reference;
 - The Codex Alimentarius Commission's Strategic Plan, its relevant plans of work and Criteria for the Establishment of Work Priorities;
 - The quality, quantity, adequacy, and availability of data pertinent to performing a risk assessment, including data from developing countries;
 - The prospect of completing the work in a reasonable period of time;
 - The diversity of national legislation and any apparent impediments to international trade;
 - The impact on international trade (i.e., magnitude of the problem in international trade);
 - The needs and concerns of developing countries; and,
 - Work already undertaken by other international organizations;
- 21) When referring substances to JECFA, <u>CCFAC CCFA/CCCF</u> shall provide background information and clearly explain the reasons for the request when chemicals are nominated for evaluation;
- 22) CCFAC CCFA/CCCF may also refer a range of risk management options, with a view toward obtaining JECFA's guidance on the attendant risks and the likely risk reductions associated with each option.
- 23) CCFAC /CCFA/CCCF requests JECFA to review any methods and guidelines being considered by CCFAC CCFA/CCCF for assessing maximum use levels for additives or maximum levels for contaminants and naturally occurring toxicants. CCFAC CCFA/CCCF makes any such request with a view toward obtaining JECFA's guidance on the limitations, applicability, and appropriate means for implementation of a method or guideline for CCFAC CCFA/CCCF's work.

SECTION 4. JECFA

- 24) JECFA is primarily responsible for performing the risk assessments upon which <u>CCFAC</u> <u>CCFA/CCCF</u> and ultimately the CAC base their risk management decisions.
- 25) JECFA's scientific experts should be selected on the basis of their competence and independence, taking into account geographical representation to ensure that all regions are represented.

- 26) JECFA should strive to provide CCFAC CCFA/CCCF with science-based risk assessments that include the four components of risk assessment as defined by CAC and safety assessments that can serve as the basis for CCFAC CCFA/CCCF's risk-management discussions. For contaminants and naturally occurring toxicants, JECFA should determine to the extent possible the risks associated with various levels of intake. Because of the lack of appropriate information, including data in humans, however, this may be possible in only a few cases for the foreseeable future. For additives, JECFA should continue to use its safety assessment process for establishing ADIs.
- 27) JECFA should strive to provide CCFAC CCFA/CCCF with science-based quantitative risk assessments and safety assessments for food additives, contaminants, and naturally occurring toxicants in a transparent manner.
- 28) JECFA should provide CCFAC CCFA/CCCF with information on the applicability and any constraints of the risk assessment to the general population to particular sub-populations and should as far as possible identify potential risks to populations of potentially enhanced vulnerability (e.g., children, women of child-bearing age, the elderly).
- 29) JECFA should also strive to provide CCFAC CCFA with specifications of identity and purity essential to assessing risk associated with the use of additives.
- 30) JECFA should strive to base its risk assessments on global data, including data from developing countries. These data should include epidemiological surveillance data and exposure studies.
- 31) JECFA is responsible for evaluating exposure to additives, contaminants, and naturally occurring toxicants.
- 32) When evaluating intake of additives or contaminants and naturally occurring toxicants during its risk assessment, JECFA should take into account regional differences in food consumption patterns.
- 33) JECFA should provide to CCFAC CCCF its scientific views on the validity and the distribution aspects of the available data regarding contaminants and naturally occurring toxicants in foods which have been used for exposure assessments, and should give details on the magnitude of the contribution to the exposure from specific foods as may be relevant for risk management actions or options of CCFAC CCCF.
- 34) JECFA should communicate to CCFAC CCFA/CCCF the magnitude and source of uncertainties in its risk assessments. When communicating this information, JECFA should provide CCFAC CCFA/CCCF with a description of the methodology and procedures by which JECFA estimated any uncertainty in its risk assessment.
- 35) JECFA should communicate to CCFAC CCFA/CCCF the basis for all assumptions used in its risk assessments including default assumptions used to account for uncertainties.
- 36) JECFA's risk assessment output to CCFAC CCFA/CCCF is limited to presenting its deliberations and the conclusions of its risk assessments and safety assessments in a complete and transparent manner. JECFA's communication of its risk assessments should not include the consequences of its analyses on trade or other non-public health consequence. Should JECFA include risk assessments of alternative risk management options, JECFA should ensure that these are consistent with the Working Principles for Risk Analysis for the Application in the Framework of the Codex Alimentarius and Risk Analysis Principles applied by the Codex Committee on Food Additives and Contaminants Codex Committee on Food Additives and the Codex Committee on Contaminants in Foods.

- 37) When establishing the agenda for a JECFA meeting, the JECFA Secretariat work closely with CCFAC <u>CCFA/CCCF</u> to ensure that <u>CCFAC CCFA/CCCF</u>'s risk management priorities are addressed in a timely manner. With respect to food additives, the JECFA Secretariat should normally give first priority to compounds that have been assigned a temporary ADI, or equivalent. Second priority should normally be given to food additives or groups of additives that have previously been evaluated and for which an ADI, or equivalent, has been estimated, and for which new information is available. Third priority should normally be given to food additives that have not been previously evaluated. With respect to contaminants and naturally occurring toxicants, the JECFA Secretariat should give priority to substances that present both a significant risk to public health and are a known or expected problem in international trade.
- 38) When establishing the agenda for a JECFA meeting, the JECFA Secretariat should give priority to substances that are known or expected problems in international trade or that present an emergency or imminent public health risk.

Appendix IV

PROPOSED AMENDMENTS TO THE CCFAC POLICY FOR EXPOSURE ASSESSMENT OF CONTAMINANTS AND TOXINS IN FOODS OR FOOD GROUPS

(For adoption and inclusion in the Procedural Manual)

CCFAC POLICY OF THE CODEX COMMITTEE ON CONTAMINANTS IN FOODS FOR EXPOSURE ASSESSMENT OF CONTAMINANTS AND TOXINS IN FOODS OR FOOD GROUPS

SECTION 1. INTRODUCTION

- 1. Maximum <u>Levels</u> <u>Limits</u> (MLs) do not need to be set for all foods that contain a contaminant or a toxin. The Preamble of the Codex General Standard for Contaminants and Toxins in Foods (GSCTF) states in Section 1.3.2 that "maximum levels (MLs) shall only be set for those foods in which the contaminant may be found in amounts that are significant for the total exposure of the consumer. They should be set in such a way that the consumer is adequately protected". Setting standards for foods that contribute little to dietary exposure would mandate enforcement activities that do not contribute significantly to health outcomes.
- 2. Exposure assessment is one of the four components of risk assessment within the risk analysis framework adopted by Codex as the basis for all standard-setting processes. The estimated contribution of specific foods or food groups to the total dietary exposure to a contaminant as it relates to a quantitative health hazard endpoint (e.g., PMTDI, PTWI) provides further information needed for the setting of priorities for the risk management of specific foods/food groups. Exposure assessments must be guided by clearly articulated policies elaborated by Codex with the aim of increasing the transparency of risk management decisions.
- 3. The purpose of this Annex is to outline steps in contaminant data selection and analysis undertaken by JECFA when requested by CCFAC the Codex Committee on Contaminants in Foods (CCCF) to conduct a dietary exposure assessment.
- 4. The following components highlight aspects of JECFA's exposure assessment of contaminants and toxins that contribute to ensuring transparency and consistency of science-based risk assessments. Exposure assessments of contaminants and toxins in foods are performed by JECFA at the request of <u>CCFACCCCF</u>. <u>CCFACCCCF</u> will take this information into account when considering risk management options and making recommendations regarding contaminants and toxins in foods.

SECTION 2. ESTIMATION OF TOTAL DIETARY EXPOSURE TO A CONTAMINANT OR TOXIN FROM FOODS/FOOD GROUPS

- 5. JECFA uses available data from member countries and from GEMS/Food Operating Program for analytical laboratories system on contaminant levels in foods and the amount of foods consumed to estimate total dietary exposure to a contaminant or toxin. This is expressed as a percentage of the tolerable intake (e.g., PTDI, PTWI, or other appropriate toxicological reference point). For a carcinogen with no clear threshold, JECFA uses available data on intake combined with data on carcinogenic potency to estimate potential population risks.
- 6. Median/mean contaminant levels in foods are determined from available analytical data submitted by countries and from other sources. These data are combined with information available for the <u>GEMS/Food_Regional_dietsGEMS/Food_Consumption_Cluster_Diets</u> to generate dietary exposure estimates for regions in the world. JECFA provides an estimate as to which of the <u>GEMS/Food_Regional_dietsGEMS/Food_Consumption_Cluster_Diets</u> are likely to approach or exceed the tolerable intake.
- 7. In some cases, available national contaminant and/or individual food consumption data may be used by JECFA to provide more accurate estimates of total dietary exposure, particularly for vulnerable groups such as children.
- 8. JECFA performs exposure assessments if requested by <u>CCFAC-CCCF</u> using the <u>GEMS/Food Regional</u> <u>dietsGEMS/Food Consumption Cluster Diets</u> and, if needed, available national consumption data to estimate the impact on dietary exposure of proposed alternative maximum levels to inform <u>CCFAC</u> <u>CCCF</u> about these risk management options.

SECTION 3. IDENTIFICATION OF FOODS/FOOD GROUPS THAT CONTRIBUTE SIGNIFICANTLY TO TOTAL DIETARY EXPOSURE OF THE CONTAMINANT OR TOXIN

- 9. From dietary exposure estimates JECFA identifies foods/food groups that contribute significantly to the exposure according to <u>CCFAC'sCCCF's</u> criteria for selecting food groups that contribute to exposure.
- 10. The <u>CCFACCCCF</u> determines criteria for selecting foods/food groups that contribute significantly to total dietary exposure of a contaminant or toxin. These criteria are based upon the percentage of the tolerable intake (or similar health hazard endpoint) that is contributed by a given food/food group and the number of geographic regions (as defined by the <u>GEMS/Food Regional dietsGEMS/Food Consumption</u> <u>Cluster Diets</u> for which dietary exposures exceed that percentage.
- 11. The criteria are as follows:
 - a) Foods or food groups for which exposure to the contaminant or toxin contributes approximately 10%¹ or more of the tolerable intake (or similar health hazard endpoint) in one of the GEMS/Food Regional dietsGEMS/Food Consumption Cluster Diets;

or,

b) Foods or food groups for which exposure to the contaminant or toxin contributes approximately 5%¹ or more of the tolerable intake (or similar health hazard endpoint) in two or more of the GEMS/Food Regional dietsGEMS/Food Consumption Cluster Diets;

or,

c) Foods or food groups that may have a significant impact on exposure for specific groups of consumers, although exposure may not exceed 5% of the tolerable intake (or similar health hazard endpoint) in any of the <u>GEMS/Food Regional dietsGEMS/Food Consumption Cluster Diets</u>. These would be considered on a case-by-case basis.

SECTION 4. GENERATION OF DISTRIBUTION CURVES FOR CONCENTRATIONS OF THE CONTAMINANT IN SPECIFIC FOODS/FOOD GROUPS (CONCURRENT WITH SECTION 2, OR SUBSEQUENT STEP)

- 12. If requested by <u>CCFACCCCF</u>, JECFA uses available analytical data on contaminant or toxin levels in foods/food groups identified as significant contributors to dietary exposure to generate distribution curves of contaminant concentrations in individual foods. <u>CCFACCCCF</u> will take this information into account when considering risk management options and, if appropriate, for proposing the lowest achievable levels for contaminants/toxins in food on a global basis.
- 13. Ideally, individual data from composite samples or aggregated analytical data would be used by JECFA to construct the distribution curves. When such data are not available, aggregated data would be used (for example mean and geometric standard deviation). However, methods to construct distribution curves using aggregated data would need to be validated by JECFA.
- 14. In presenting the distribution curves to <u>CCFACCCCF</u>, JECFA should, to the extent possible, provide a comprehensive overview of the ranges of contamination of foods (i.e., both the maximum and outlier values) and of the proportion of foods/food groups that contain contaminants/toxins at those levels.

SECTION 5. ASSESSMENT OF THE IMPACT OF AGRICULTURAL AND PRODUCTION PRACTICES ON CONTAMINANT LEVELS IN FOODS/FOOD GROUPS (CONCURRENT WITH SECTION 2, OR SUBSEQUENT STEP)

15. If requested by <u>CCFACCCCF</u>, JECFA assesses the potential impact of different agricultural and production practices on contaminant levels in foods to the extent that scientific data are available to support such assessments. <u>CCFACCCCF</u> takes this information into account when considering risk management options and for proposing Codes of Practice.

¹

Rounded to the nearest 1/10th of a percent.

16. Taking this information into account, <u>CCFACCCCF</u> proposes risk management decisions. To refine them, <u>CCFACCCCF</u> may request JECFA to undertake a second assessment to consider specific exposure scenarios based on proposed risk management options. The methodology for assessing potential contaminant exposure in relation to proposed risk management options needs to be further developed by JECFA.

Appendix V

DEFINITION FOR "CODEX MAXIMUM LEVEL FOR A CONTAMINANT IN A FOOD OR FEED COMMODITY"

(For adoption and inclusion in the Procedural Manual)

Codex maximum level for a contaminant in a food or feed commodity is the maximum concentration of that substance recommended by the Codex Alimentarius Commission to be legally permitted in that commodity.

Appendix VI

DRAFT MAXIMUM LEVEL FOR OCHRATOXIN A IN RAW WHEAT, BARLEY, AND RYE

(At Step 7 of the Procedure)

Code No.	Food	ML (µg/kg)	Step	Remarks
GC 0654				
GC 0640	Raw Wheat, Barley, and Rye	5	7	
GC 0650				

Appendix VII

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

(At Step 7 of the Procedure)

Code No.	Food	ML(µg/kg)	Step	Remarks
	Almonds, Hazelnuts and Pistachios "for further processing"	15	7	
	Almonds, Hazelnuts and Pistachios "ready-to-eat"	8	7	

Appendix VIII

PROPOSED DRAFT CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF OCHRATOXIN A CONTAMINATION IN WINE

(N05-2006)

(At Step 5/8 of the Procedure)

1. PREAMBLE

Mycotoxins, in particular Ochratoxin A (OTA), are secondary metabolites produced by filamentous fungi found in soil and organic matter, which spread and thrive on grapes during the berry ripening phase.

The formation of OTA in grapes is mainly due to berry contamination by certain mould species, and particular strains thereof, belonging essentially to the *Aspergillus* species (in particular *A. carbonarius* species and to a lesser extent *A. niger*).

The presence and spread of such fungi in vineyards are influenced by environmental and climatic factors, nocturnal dampening condition of grapes, grape bunch shape, susceptibility of vine varieties, aeration level of grape bunches, health status of grapes and berry injuries which are the main entry points for ochratoxinogenic fungi.

2. CULTIVATION PRACTICES IN THE VINEYARDS

Application of the following preventive measures is recommended, in viticulture regions in which the climatic conditions are favourable to the formation of OTA in vine products in order to reduce endemic risk which favours the onset of the most damaging vine diseases:

2.1 REGIONAL RISK INFORMATION

- Ensure that regional authorities and grower organisations:
 - analyse and identify the species and strains of toxinogenic fungi present in their region;
 - combine this information with regional risk factors including meteorological data and viticultural techniques and propose appropriate management;
 - communicate this information to growers.

2.2 TRAINING OF PRODUCERS

- Ensure training of producers with regards to:
 - risk of mould and mycotoxins;
 - the identification of ochratoxinogenic fungi or the presence of mould spoilage, especially black mould, and period of infection;
 - knowledge of preventive measures to be applied to vineyards and wineries.

2.3 VINEYARD ESTABLISHMENT

- Favour vine establishment in well aerated areas while avoiding very humid areas.
- Draw up plots of land with adequate planting disposition, and vegetation architecture (trellising system) to:
 - facilitate planting operations,
 - avoid direct contact of grapes bunches with the soil,
 - ensure good pest and disease control,
 - minimise the risk of grapes sun burn,

- promote the uniform ripening of the grape.

2.4 PLANT MATERIAL

- Choose less vigorous rootstock and varieties which are less prone to developing mould and grape rot.
- Choose clones or biotypes within a variety which are better adapted to climatic and soil conditions in specific cultivation areas and less sensitive to mould and rot development, which are oftentimes characterised by less compact grape bunches.
- Lay out homogeneous plots of land (varieties, clones) to facilitate growing operations and to ensure better crop and disease control and to obtain uniform ripening of the grapes.

2.5 GROWING TECHNIQUES

- Apply management practices which favour leaf/fruit balance for vines and which reduce excess vigour, in particular, avoiding inappropriate nitrogenous fertilizer applications.
- Favour vegetation or organic cover of soils and avoid working the soil between the beginning of the grape ripening and grape harvest period in order to limit the transfer of soil particles and the associated fungi to the grapes.
- Favour placing grape bunches in an orderly manner to avoid overcrowding.
- If water input is necessary, irrigate as regularly as possible in order to avoid berry splitting and the onset of cracks on the skin which are sources of mould penetration and development especially in warm regions.
- Avoid using marc containing toxinogenic fungi as a fertilizer in the vineyards.

2.6 PEST AND DISEASE CONTROL

- Carry out leaf removal in the grape cluster zone whilst recognising the need to limit the risk of sun burn. This must enable the aeration of clusters. This is particularly necessary under hot and humid weather conditions while the grapes are ripening.
- Avoid lesions on the berries and skin damage caused by diseases, insects, phytotoxicity and sun burn.
- Remove shriveled/desiccated berries.
- Apply vine protection plans in order to control dangerous fungal diseases affecting grape quality (oïdium disease, acidic rot).
- Prevent attacks of grape berry moths, grape mealybugs and grape leafhoppers which favour mould development on damaged berries; pest control needs to be carried out according to biological and epidemic risk; under high risk conditions preventive treatments must be applied by using specific products and taking into account the warnings of plant protection regional services.
- Apply appropriate and registered protective programmes against grape rot and mould using appropriate management to avoid fungal resistance. Appropriate treatments are recommended in all situations which are favourable to the development of toxin producing species.

3. PRACTICES AT HARVEST

Only a healthy grape harvest can ensure optimal quality and safety of vitivinicultural products. Consequently, only a healthy grape harvest can be used for human consumption without the risk of quality loss and without food safety problems for consumers.

The date of harvest must be decided taking into account grape ripeness, sanitary level, and forecasted climatic changes and endemic risk. In high risk OTA areas, it is recommended to advance the harvest date.

When grapes are extensively contaminated by mould:

- the grapes can not be used for making concentrated musts or wine;

- the grapes can only be used for distillation.

3.1 PRODUCTION OF RAISINED GRAPES FOR WINE PRODUCTION

For production used to obtain raisined grapes for wine production (sweet wine), the following actions are recommended:

- Ensure the hygiene of containers to be used for the harvest and/or the drying of grapes.
- Use only grapes not damaged by insects and not contaminated by mould.
- Sort grapes by eliminating damaged or contaminated grapes.
- Place grapes to be dried or raisined in just one layer to avoid overstacking.
- Favour progressive and uniform drying of all parts of the grape bunch.
- Take the necessary measures to avoid development of fruit fly infestation.
- For particular conditions of drying in open air, it is recommended to dry in well ventilated conditions and to cover the grapes at night to prevent condensation and humidity.

3.2 PRODUCTION OF WINE GRAPES

The following actions are recommended when the harvest is moderately contaminated with toxinogenic mould and is to be used in wine production:

- Grapes damaged by insects, mould, or contaminated by dirt particles must be eliminated before the harvest or at harvest time depending on harvesting technique.
- Grapes need to be sorted, in order to separate the damaged grape bunches or parts of bunches. It is important to discard grapes with black mould.
- Harvested grapes must be transported as quickly as possible to the winery in order to avoid extended waiting, especially for grapes with a high proportion of juice.
- It is important to clean containers after each load, especially in the case of harvests where the containers may have been used to harvest grapes that may be rotten.

4. TREATMENT AT THE WINERY

Under conditions with a risk of OTA contamination, it is recommended to measure the level of OTA in the musts to be used in winemaking.

4.1 PRE-FERMENTATION OPERATIONS AND TREATMENTS

- Avoid skin maceration in the case of OTA high risk harvests or carry out short maceration.
- In the case of a significant contamination of red grapes, evaluate possibility of carrying out rosé winemaking.
- Adapt pressing rate to the health status of the grape; in case of contamination, carry out small volume, low pressure quick pressings. Avoid continuous press.
- In the case of contaminated grapes, avoid using pectolytic enzymes for racking must or maceration. Quick clarifications with must filtration, centrifugation and flotation are preferable.
- Avoid harvest heating treatments and aggressive and prolonged macerations.
- In the case of contamination, it is preferable to treat the grapes and the musts with the lowest possible and most effective doses of oenological charcoal in order to avoid possible loss of aromatic and polyphenolic compounds when the treatment is carried out on wine.

4.2 FERMENTATION TREATMENTS

• Carry out, as much as it is possible, fermentation and maturing in smooth walled containers to avoid sources of contamination linked to previous fermentations or maturing and in order to facilitate cleaning.

- Dry active yeasts or inactive yeasts can help reduce the OTA level.
- For alcoholic or malolactic fermentations, use yeasts or bacteria which have adsorbent properties for OTA; ensure that these characteristics are guaranteed by the supplier. Note that the usage of these products only enables a partial reduction of OTA.
- It is recommended to devat as quickly as possible following fermentation for red wine.

4.3 MATURING AND CLARIFICATION TREATMENTS

- Maturing on lees can help in reducing the OTA level. The risks of this technique related to the organoleptic quality of wine must be evaluated.
- Current clarification products (organic or inorganic fining agents) have variable levels of efficiency for reducing the level of OTA:
 - Oenological charcoal is the most effective.
 - Certain cellulose and silica gels associated with fining with gelatine only enable a partial reduction

Before usage:

- Become informed of effectiveness of product used and application technology,
- Carry out trials with different dosages to ascertain sensorial repercussions and application rate.

5. GENERAL CONDITIONS FOR FOOD CONTACT MATERIALS

Food contact materials used during harvesting, transport and production in the winery should not give rise to contaminant migration or cross-contamination which can endanger human health.

6. CONCLUSION

These recommendations are based on current knowledge and can be updated according to the findings of research to be pursued.

Preventive measures are essentially carried out in vineyards and treatments undertaken at the wineries are solely corrective measures.

Appendix IX

DRAFT MAXIMUM LEVELS FOR TIN IN CANNED FOODS (OTHER THAN BEVERAGES) AND IN CANNED BEVERAGES

(At Step 8 of the Procedure)

Code No.	Food	ML(mg/kg)	Step	Remarks
	Canned Foods (other than Beverages)	250	8	
	Canned Beverages	150	8	

Appendix X

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

(N08-2004)

(At Step 5 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	5	

PROPOSED 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 5 of the Procedure)

INTRODUCTION

- 1. 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.
- 2. 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 discovered⁷ 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.⁸
- 3. 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 %.
- 4. The occurrence of chloropropanols in acid-HVP arises from their formation during the hydrochloric acid mediated hydrolysis step of the manufacturing process.⁹ 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.
- 5. 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.
- 6. A range of techniques may be employed in the manufacture of soy sauces.¹⁰ Generally, products made exclusively by means of fermentation do not contain chloropropanols, or, if present, they only occur in trace amounts. Indeed, a recent Japanese survey of 104 samples of naturally fermented soy sauce showed that levels in 93 of the samples were less than the limit of quantification (0.004 mg/kg).¹¹ 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.
- 7. 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 hydrosylates.¹² 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-2-propanol (2,3-DCP).
- 8. 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 g/kg bw/day.¹³ The Committee re-evaluated¹⁴ 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.

- 9. It should be noted that 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. Some manufacturers of acid-HVP have stated that, whilst it is technically possible to reduce 3-MCPD levels to below 0.1 mg/kg, the organoleptic qualities of such products are adversely affected.¹⁵ Some producers of acid-HVP containing soy sauces stated that the flavour and taste (umami) directly reflect the quality of the acid-HVP. This is particularly true in aged acid-HVP products.
- 10. 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.) Many western European 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 manufacturers modified the production processes to result in products with lower levels of chloropropanols whilst minimising the effect on organoleptic properties. It should be noted that 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 aicd-HVP may also be necessary.
- 11. 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.^{1,16,17} Chloropropanols have also been observed in food ingredients produced using methods that do not involve acid hydrolysis of vegetable proteins; examples of such ingredients include meat extracts, malts, modified starches and seasonings. Recent studies¹⁸ have shown that production of chloropropanols in these foods and ingredients, is promoted by high temperatures and low water content. Manufacture of these products is 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. 1). Common vegetable raw materials used in the production of acid-HVP include defatted oil seeds^{19,20} (soy and peanut), and protein from corn maize, wheat, casein, yeast and rice.^{19,20,21,22,23,24} 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-MPCD 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.
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- 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,^{16,21,25} 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.²¹
- 16. 3-MCPD that is formed during the acid hydrolysis step may be removed by a secondary alkaline hydrolysis.^{23,24,21,25,26,27} 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. 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 0.01 mg/kg.²³ 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.²⁸ 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^{29,30} 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.^{10,31,32}

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.³⁰ 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.³⁰ 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.



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

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Appendix XII

Project Document

<u>Proposal for new work on a "Code of practice for the prevention and reduction of aflatoxin</u> <u>contamination in dried figs."</u>

<u>1. The purpose and scope of the standard</u>

To develop a Code of Practices for the prevention and reduction of aflatoxin contamination in dried figs. The code will cover cultivation practices, drying, storage and transportation of dried figs.

2. Its relevance and timeliness

Measures can be taken to prevent and reduce the presence of aflatoxin in dried figs. Aflatoxins, especially aflatoxin B_1 (AFB₁) are genotoxic carcinogens, hazardous to human health. They can be formed in many foodstuffs including milk and dried fruits. JECFA concluded at its 49th session that reducing the permitted quantity of AFB₁ in peanuts from 20 µg/kg to 10 µg/kg would not result in any observable difference in rates of liver cancer. The 38th Session of CCFAC agreed to request JECFA to conduct a dietary exposure assessment on tree nuts (ready to eat), in particular, almonds, hazelnuts, pistachios and Brazil nuts, and the impact on exposure of taking into account hypothetical maximum levels of 4, 8, 10 and 15 µg/kg, putting in the context of exposure from other sources and previous exposure assessments on maize and groundnuts.

3. The main aspects to be covered

The Code of Practice will cover all possible measures that have been proven to prevent and reduce aflatoxin contamination in dried figs. It will also cover all stages of the production chain (cultivation, harvesting, drying, storage, transportation).

4. An assessment against the criteria for the establishment of work priorities

This proposal is consistent with the following criteria for the establishment of work priorities: a) Consumer protection from the point of view of health by minimizing consumer dietary exposure to aflatoxin from dried figs.

5. Relevance to Codex strategic objectives

This proposal is consistent with the Strategic Vision statement of the strategic Framework 2003 – 2007.

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

This new work is recommended in the Discussion Paper on Aflatoxin in Dried Figs to be presented and discussed at the 1st Session of Codex Committee on Contaminants in Foods (CCCF).

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

Not currently available.

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

As the International Tree Nut Council has "Observer Status" in the Codex Alimentarius Commission (CAC) and participates in the activities of CAC and will continue to participate in the activities of CCCF, there is no need for additional technical input from external bodies.

9. The proposed time line for completion of the new work, including the start date, proposed date for adoption at step 5/8 and the proposed date for the adoption by the Commission

If the Commission accepts, in 2007, the proposal for new work, the draft Code of Practice will be drafted and will be circulated for consideration at step 3 at the 2^{nd} meeting of CCCF. Adoption at Step 5 is planned for 2009 and adoption at Step 8 can be expected in 2010.

Appendix XIII

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

Contaminants and naturally occurring	Question(s) to be answered	Data availability	Proposed by
toxicants		(when, what)	
Deoxynivalenol (DON) ¹	Exposure assessment on a more global basis taking new	Sufficient occurrence and	CCFAC
	data into account, also review of toxicological data and	processing data not before	
	considering the need for an acute reference dose (taking	end 2008	
	into account data also in finished products, but also in raw		
	wheat and other commodities as they are traded	Availability of	
	internationally and consideration of processing factors)	toxicological data unknown	
	Toxicity of 3-acetyl and the 15-acetyl DON (data		
	availability unknown)		
Phenyl hydrazines (including agaritine)	Full evaluation	2004 (available)	Denmark
New Requests			
Furan ¹	Full evaluation (toxicological assessment and exposure	Occurrence data:	US, supported by
	assessment)	USA: summer 2008	Australia, Canada, EC
		EC: late 2008	
		Australia: late 2008	
		Canada: late 2008	
		Toxicological data:	
		EFSA preliminary risk	
		assessment available	
Perchlorate ¹	Full evaluation (toxicological assessment and exposure	Occurrence data:	US, supported by
	assessment)	USA and Canada: late 2008	Canada, EC, WHO
		Toxicological data:	
		USA risk assessment	
		available, other	
		toxicological data available	

¹ High priority for evaluation by JECFA

Appendix XIV

Reply to the Question from the 27th Session of the Codex Committee on Methods of Analysis and Sampling

Part. 1 - Ranges and Matrices for the Determination of Dioxin and PCBs

All levels are expressed in World Health Organization (WHO) toxic equivalent using the 2005 WHO-TEFs (toxic equivalency factors)

Matrix	Dioxins and furans	Dioxin-like PCBs	Sum of dioxins, furans and
			dioxin-like PCBs
Foodstuff			
Meat and meat products (incl. poultry)	0.2 – 12 pg/g fat	0.2 - 12.0 pg/g fat	0.3-24.0 pg/g fat
Fish and fishery products (incl. shell fish)	0.3 – 8.0 pg/g fresh weight*	$1.0 - 12.0 \text{ pg/g fresh weight}^*$	1.0 – 18.0 pg/g fresh weight*
Milk and dairy products	0.5 - 6.0 pg/g fat	0.5 - 6.0 pg/g fat	1.0 – 12.0 pg/g fat
Eggs and egg products	0.5 - 6.0 pg/g fat	0.5 – 6.0 pg/g fat	1.0 – 12.0 pg/g fat
Animal fat	0.2 - 12.0 pg/g fat	0.2 – 12.0 pg/g fat	0.3 – 24.0 pg/g fat
Vegetable oils and fats	0.15 – 1.5 pg/g fat	0.15 – 1.5 pg/g fat	0.3 – 3.0 pg/g fat
Marine oils	0.4 - 4.0 pg/g fat	1.5 – 12.0 pg/g fat	2.0 – 15.0 pg/g fat
Fruits, vegetables, nuts and cereals and	0.1 – 1.0 pg/g fresh weight*	0.1 - 0.5 pg/g fresh weight*	0.2 - 1.5 pg/g fresh weight*
derived products			
Foods for infants and young children			
- infant formulae	0.2 – 1.5 pg/g fat	0.1 – 1.5 pg/g fat	0.2 - 3.0 pg/g fat
- baby food (meat, egg and dairy based)	0.2 - 2.0 pg/g fat	0.2 - 2.0 pg/g fat	0.3 – 4.0 pg/g fat
- baby food (grain, vegetable, fish based)	0.025 - 0.2 pg/g product*	0.025 – 0.2 pg/g product*	0.05 – 0.4 pg/g product*
Food supplements	0.15 - 4.0 pg/g fat	0.15 – 12.0 pg/g fat	0.3 – 15.0 pg/g fat

* Ranges of levels are expressed on a fresh weight or product basis given the very wide range of fat content that can be observed in the concerned foodstuffs or the very low content of fat in the foodstuff. If results are expressed on a fat/lipid basis, the lower end of the range remains valid but much higher levels than the upper end of the range can be observed.

Matrix	Dioxins and furans	Dioxin-like PCBs	Sum of dioxins, furans and dioxin-like PCBs
Feed material / Feedingstuff			
Feed materials of plant origin	0.15 -1.5 pg/g product**	0.15 -1.5 pg/g product**	0.25 -2.5 pg/g product**
Feed materials and additives of mineral	$0.2 - 10 \text{ pg/g product}^{**}$	0.2 – 10 pg/g product**	$0.3 - 20 \text{ pg/g product}^{**}$
origin, trace elements			
Animal fat	$0.2 - 6 \text{ pg/g product}^{**}$	$0.2 - 6 \text{ pg/g product}^{**}$	0.3 – 9 pg/g product**
Feed materials of animal origin other than fat	0.15 –1.5 pg/g product**	0.15 –1.5 pg/g product**	0.25 –2.5 pg/g product**
Fish meal	$0.25 - 4 \text{ pg/g product}^{**}$	$0.5 - 15 \text{ pg/g product}^{**}$	0.75 – 16 pg/g product**
Fish oil	1–12 pg/g product/fat	3 – 24 pg/g product/fat	4 – 30 pg/g product/fat
Fish feed / pet food	0.5 – 4.5 pg/g product**	$1 - 10 \text{ pg/g product}^{**}$	$1 - 10 \text{ pg/g product}^{**}$
Premixtures	0.2 – 10 pg/g product**	0.2 – 10 pg/g product**	0.3 – 20 pg/g product**
Compound feed	0.15 –1.5 pg/g product**	0.15 –1.5 pg/g product**	0.3 – 3 pg/g product**

All levels are expressed in World Health Organization (WHO) toxic equivalent using the 2005 WHO-TEFs (toxic equivalency factors)

** Levels are relative to a feedingstuff with a moisture content of 12 %. Ranges of levels are expressed on product basis given the very wide range of fat content that can be observed in feed materials / feedingstuffs or the very low content of fat in the feed materials / feedingstuffs. If results are expressed on a fat/lipid basis, the lower end of the range remains valid but much higher levels than the upper end of the range can be observed.

Part. 2 - General Remarks on the Document CX/MAS 06/27/8 "Methods of Analysis for the Determination of Dioxin and PCBs

The Codex Committee on Contaminants in Foods wishes to make at this stage the following non-exhaustive remarks as regards document CX/MAS 06/27/8:

- In the background section, 3rd paragraph, The Code of Practice for the Prevention and Reduction of Dioxin and Dioxin-like PCB Contamination in Food and Feeds was adopted by the Codex Alimentarius Commission at its 29th session, Geneva Switzerland, 3-7 July 2006;
- In the background section, it is proposed to delete the last three paragraphs as they contain inaccurate information;
- In the document the reference to GC/MS, HR GC-MS, HRGC/HRMS should be used in a more structured and consistent manner to avoid any confusion.
- In the section "Methods used to determine dioxins and related compounds", reference should be made to the recently adopted new 2005 WHO-TEF values¹. Furthermore the statement that "data for these dioxin-like PCB congeners are still scarce" seems to be no longer true.
- The concept of "methods of analysis fit for the purpose" has to be better reflected in the method description section.
- As the EC Directive 2002/69/EC of 26 July 2002 has been replaced by "Commission Regulation (EC) No 1883/2006 of 19 December 2006 laying down methods of sampling and analysis for the official control of levels of dioxins and dioxin-like PCBs in certain foodstuffs, reference in the document to Directive 2002/69/EC needs to be updated.
- It has to be made clear that the criteria mentioned in the Annex 1, such as the criterion as regards the limit of quantification, are not to be regarded as required criteria.
- It is noted that the validated method referred to in footnote 9 of the document is not mentioned in the Annex 2 of the document "Methods reported by governments and organisations".

¹ The 2005 World Health Organization Reevaluation of Human and Mammalian Toxic Equivalency Factors for Dioxins and Dioxin-like Compounds. Van den Berg et al., Tox. Sci. 93(2), 223-241 (2006).