CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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REP11/CF

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Thirty-fourth Session
Geneva, Switzerland, 4-9 July 2011

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

The Hague, The Netherlands,
21 – 25 March 2011

NOTE: This report includes Codex Circular Letter CL 2011/6-CF

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CX 4/35.2 **CL 2011/6-CF**
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Interested International Organizations

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Subject: **DISTRIBUTION OF THE REPORT OF THE FIFTH SESSION OF THE CODEX COMMITTEE ON CONTAMINANTS IN FOODS (REP11/CF)**

The Report of the Fifth Session of the Codex Committee on Contaminants in Foods is attached. It will be considered by the Thirty-fourth Session of the Codex Alimentarius Commission (Geneva, Switzerland, 4-9 July 2011).

PART I: MATTERS FOR ADOPTION BY THE 34TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION

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

1. **Proposed Draft Code of Practice for the Prevention and Reduction of Ethyl Carbamate Contamination in Stone Fruit Distillates** (para. 26, Appendix II);
2. **Proposed Draft Maximum levels for Melamine in Food (*Liquid Infant Formula)*** (para. 33, Appendix III);

Governments and international organizations wishing to submit comments on the above documents should do so in writing, ***preferably by e-mail***, to the above address, **before 15 May 2011**.

PART II: REQUEST FOR COMMENTS AND INFORMATION

3. **Priority List of Contaminants and Naturally Occurring Toxicants for Evaluation by JECFA** (para. 93, Appendix V)

The Priority List of Contaminants and Naturally Occurring Toxicants for Evaluation by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) has been endorsed by the Codex Committee on Contaminants in Foods as indicated in para. 93 and presented in Appendix V of this Report. Submission of comments and/or information is requested as follows:

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

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

Governments and international organizations wishing to submit comments and/or information on the Priority List of Contaminants and Naturally Occurring Toxicants for Evaluation by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) should do so in writing, ***preferably by e-mail***, to the above address, **before 31 January 2012**.

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SUMMARY AND CONCLUSIONS

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

MATTERS FOR ADOPTION/CONSIDERATION BY THE 34TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION

Proposed Draft Standards and Related Texts for Adoption

The Committee agreed to forward:

- Proposed Draft Code of Practice for the Prevention and Reduction of Ethyl Carbamate Contamination in Stone Fruit Distillates (para. 26, Appendix II);
- Proposed Draft Maximum Levels for Melamine in Food (*Liquid Infant Formula)* (para. 33, Appendix III);

Proposals for New Work

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

- Maximum Levels for Arsenic in Rice (para. 64, Appendix IV);

Other matters

The Committee agreed to request:

- the removal of footnote 3 regarding the temporary endorsement of sections 3.2.17 (surface active agents), 3.2.18 (pesticides and PCBs), 3.2.19 (mineral oil) and 3.2.20 (polynuclear aromatic hydrocarbons) in the Standard on Natural Mineral Waters as these were considered quality parameters and did not require endorsement by CCCF (paras 85-90).

Matters of Interest to the Codex Alimentarius Commission

The Committee:

- agreed to return the Proposed Draft Maximum Levels for DON and its acetylated derivatives in cereals and cereal-based products to Step 2 for redrafting, comments and consideration at its next session (paras. 34-43);
- agreed to return the Proposed Draft Maximum Level for Total Aflatoxin in Dried Figs to Step 2/3 for elaboration of a sampling plan for an ML of 10µg/kg, comments and consideration at its next session (paras 44-50);
- agreed to defer discussion on editorial amendments to the GSCTFF to the next session (para. 51);
- agreed to continue developing discussion papers on mycotoxins in sorghum (paras 52-59), risk management options from different risk asessment outcomes (paras 65-70), ochratoxin A in cocoa (71-75), and pyrrolizidine alkaloids in foods (paras 80-83);
- endorsed the Priority List of Contaminants and Naturally Occurring Toxicants for JECFA evaluation and agreed to re-convene the physical working group at its next session to review the Priority List (para. 93, Appendix IV);
- agreed to consider maximum levels for lead in various foods in the GSCTFF and the related Code of Practice for the Prevention and Reduction of Lead Contamination in Foods and the Code of Practice for Source Directed Measures to Reduce Contamination of Foods with Chemicals (paras 96-97).

INTRODUCTION

1. The Codex Committee on Contaminants in Foods (CCCF) held its fifth session in The Hague (the Netherlands) from 21 to 25 March 2011, at the kind invitation of the Government of the Netherlands. Mr. Martijn Weijtens, Member of the Management Team, Ministry of Agriculture, Nature and Food Quality, Department of Food, Animal Health and Welfare and Consumer Policy, the Netherlands, chaired the meeting. The Session was attended by 184 delegates representing 62 Member countries, one Member Organization and 15 International Organizations. The list of participants, including the Secretariat, is given in Appendix I to this report.

OPENING OF THE SESSION

2. Dr. Hans Hoogeveen, Director General, Member of the Board of Directors, Dutch Ministry of Economic Affairs, Agriculture and Innovation, welcomed the participants and opened the session on behalf of the Government of The Netherlands.

Division of Competence[1]

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

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

4. The Committee adopted the Provisional Agenda as the Agenda for the Session and agreed to discuss the Agenda Items in the following order: 1, 2, 3a, 3b, 4, 6, 9b, 5, 9f, 7, 8, 9a, 9c, 9d, 9e, 10, 11, 12, 14.

5. The Committee confirmed the decision of its last session to establish an in-session physical Working Group on the Priority List of Contaminants and Naturally Occurring Toxicants for Evaluation by JECFA under the chairmanship of The Netherlands (Item 11).

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

6. The Committee noted those matters for information and took the following decisions:

Review of the Risk Analysis Principles Applied by the Codex Committee on Food Additives and the Codex Committee on Contaminants in Foods

7. The Committee recalled that the CCGP had agreed that the risk analysis policies developed by Codex committees were generally consistent with the Working Principles for Risk Analysis and had agreed that no action was necessary on the revision of the Principles, but in view of the decision of 43rd sesssion of CCFA to advocate separate Risk Analysis Principles on food additives and on contaminants, agreed to proceed with this separation.

Revision of *Risk Analysis Principles Applied by the Codex Committee on Food Additives and the Codex Committee on Contaminants in Foods* and the *Code of Practice for Source Directed Measures to Reduce Contamination of Food with Chemicals* as to their applicability to animal feed

8. Some delegations expressed the view that there was no need to revise the Principles as the issue of animal feed was already well covered as proposed in Annexes 1 and 2 of CX/CF 11/5/2. Another delegation proposed that the Committee instead consider the amendment of the definition for contaminants to more adequately cover feeds.

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

2 CX/CF 11/5/1.

3 CX/CF 11/5/2; CX/CF 11/5/2-Add.1; CRD 3 (comments of Kenya); CRD 9 (comments of Thailand); CRD 13 (comments of Indonesia); CRD 15 (comments of India); CRD 16 (comments of Nigeria); and CRD 18 (comments of Japan).

Conclusion

9. The Committee agreed to establish an electronic Working Group led by The Netherlands with the following terms of reference:

- to prepare separate Risk Analysis Principles for contaminants and natural toxins in food and feed;
- to examine whether it was necessary to further specify the applicability to feed in the Principles as well as the Code of Practice as proposed in Annexes 1 and 2 of CX/CF 11/5/2, respectively; taking into account the proposal for the amendment of the definition of contaminant as presented in CRD 18; and
- to consider any other revisions that might be necessary to update the terminology in the Principles for consistency with the current risk assessment terminology.

Proposal for Revision of the Definition of Hazard in the Procedural Manual

10. Noting that the proposal was in relation to nutrient risk assessment and the decision of the 32nd session of the Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) not to amend the definition, the Committee agreed that further discussion on this matter was no longer necessary.

Standard for Olive Oils and Olive Pomace Oils

11. The Committee considered the request from CCFO on whether halogenated solvents could be considered as contaminants for inclusion in the GSCTFF. The Committee concluded that halogenated solvents could be considered as processing aids and therefore did not fall within the remit of the CCCF. The Committee also noted that solvents were only allowed for the production of olive pomace oils according to the *Standard for Olive Oils and Olive Pomace Oils* (CODEX STAN 33-1981) and that the presence of these solvents in olive oil and virgin olive oils would be considered as contaminants. The Committee agreed to request CCFO to consider whether the use of halogenated solvents in the production of olive pomace oils were necessary in view of the potential health concerns associated with these compounds and the consequential general trend to reduce their industrial use.

Entries for fat spreads and blended spreads in the *General Standard for Contaminants and Toxins in Food and Feed*

12. The Committee agreed to replace "margarine and minarine" with "fat spreads and blended spreads" as proposed by the CCFO.

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

13. The Representatives of FAO and WHO, while referring to CX/CF 11/5/3, informed the Committee about the results of activities carried out in the area of scientific advice to Codex and to Member countries of interest to the Committee, including the results and recommendations of the 73rd meeting of JECFA.

Outcome of the 73rd JECFA meeting

14. JECFA in its re-evaluation of cadmium considered all new data and based its risk assessment on human studies, using as a starting point a meta-analysis provided by the European Food Safety Authority (EFSA). JECFA noted that because of the very long half life of cadmium in the body the health-based guidance value should be expressed on a monthly rather than a weekly basis. JECFA therefore withdrew the PTWI and established a provisional tolerable monthly intake (PTMI) of 25µg/kg body weight for cadmium. Exposure estimates taking different age groups and dietary habits (e.g. vegetarians) into account resulted in no exceedance of the PTMI.

4 CX/CF 11/5/3.

15. Also the risk assessment of lead was based on human data and JECFA considered the most relevant health point for infants from lead exposure, impaired neurodevelopment as measured in reduction in IQ, and for adults increase in blood pressure. Based on dose-response analysis of new data JECFA concluded that the PTWI was no longer health protective and therefore withdrew it. Moreover, since there is no indication for a threshold of effect JECFA was not able to establish a new tolerable intake level. JECFA noted that other non-food sources of lead exposure need to be considered also for an overall exposure assessment.

FAO and WHO activities

16. The Representatives informed the Committee that the Environmental Health Criteria document 240: Principles and Methods for the Risk Assessment of Chemicals in Food has now been published, and is also available on the internet. This extensive document is considered as the up-to-date methodology guidance and should serve as a guide for both international risk assessment bodies and for governments and institutions engaged in risk assessment of chemicals in food.

17. The Committee was informed of the outcome of the joint FAO/WHO expert meeting to review toxicological and health aspects of bisphenol A, which was held in November 2010. Preceeding the expert meeting was a stakeholder meeting and an extensive summary report was published on the WHO and FAO websites. Extensive background papers and a final report are in preparation.

18. The FAO Representative informed the Committee about recent activities in the field of nanotechnology, and in particular the implementation in 2010 of an international conference in cooperation with the Government of Brazil and other stakeholders on issues related to new and emerging applications of nano-materials and technologies in food and agriculture. In addition, as a follow up of the Joint FAO/WHO Expert Meeting on nanotechnology applications in agriculture and food industry held in 2009, work on the development of a guide to a tiered or decision tree approach for risk assessment of nano-materials had been initiated.

19. The Representatives stressed the importance of the continuous need of adequate financial resources for the work on scientific advice and asked the delegations to consider supporting these important normative activities. In particular, the possibility of funding through the mechanism of the Global Initiative for Food Related Scientific Advice (GIFSA)[5] was once again highlighted.

20. The Committee was informed of the recent establishment in FAO of a programme on Emergency Prevention and Response (EMPRES) to global food safety issues, aimed to complement the work of FAO in the area of plant health and animal health and the activities of the INFOSAN Network, to better assist countries. In particular, the setting up of a roster of experts to consult in food safety emergency situations was noted.

21. In view of the above, the Committee agreed to establish an in-session Working Group led by the European Union and working in English only to consider the outputs of the 73rd JECFA meeting in addition to any other outstanding matters from the 72nd JECFA meeting and other FAO/WHO expert consultations with the understanding that the report of the in-session working group would be considered under Agenda Item 12.

MATTERS OF INTEREST ARISING FROM OTHER INTERNATIONAL ORGANISATIONS – IAEA (Agenda Item 3b)[6]

22. The Committee noted the information provided by the International Atomic Energy Agency as provided in document CX/CF 10/5/3-Add.1.

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5 Contact points FAO: Dominique Di Biase, Dominique.DiBiase@fao.org; WHO: Angelika Tritscher, tritschera@who.int.

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

PROPOSED DRAFT CODE OF PRACTICE FOR THE REDUCTION OF ETHYL CARBAMATE IN STONE FRUIT DISTILLATES (Agenda Item 4)[7]

23. The Delegation of Germany, speaking as Chair of the electronic Working Group, introduced the report of the working group and informed the Committee that the revised proposed draft Code of Practice (COP) was presented in Annex I of CX/CF 11/5/4.

24. The Committee noted that the main changes related to the clarification of measures proposed for removal of hydrocyanic acid and the prevention of ethyl carbamate formation during the process of distillation and that the term "stone fruit distillate" was defined and applied consistently in the COP.

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

- to use "stone fruit distillates" instead of "stone fruit spirits" and "stone fruit marc spirits" consistently throughout the document;
- to better define "stone fruit" in paragraph 7a;
- to replace "methanol" with "acetaldehyde" as more appropriate in paragraph 11; and
- to add "or ethyl alcohol" after "alcoholic beverages" in paragraph 20 for completeness.

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

26. The Committee agreed to forward the proposed draft Code of Practice to the 34th Session of the Commission for adoption at Step 5/8 (with omission of Steps 6 and 7) (Appendix II).

PROPOSED DRAFT MAXIMUM LEVELS FOR MELAMINE IN FOOD (*LIQUID INFANT FORMULA)* (Agenda Item 5)[8]

27. The Committee recalled that its last session had agreed to circulate for comments at Step 3 the proposed draft Maximum Level of 0.5 mg/kg for melamine in liquid infant formula.

28. The Committee was informed that liquid infant formula was a unique product retailed in a ready-to-consume form and was not obtained through reconstitution of powdered infant formula. It was further clarified that the proposed draft ML was based on the knowledge of the product and on the assumption that its consumption would not lead to an exceedance of the WHO tolerable daily intake level.

29. While some delegations supported the proposed level of 0.5 mg/kg, several other delegations questioned the need for such a high level that was not equivalent with the level for reconstituted powdered infant formula. These delegations were of the opinion that the level for liquid infant formula should be equivalent to that of reconstituted powdered infant formula even if the product underwent a different manufacturing process. It was also noted that a lower level could be achieved by industry. These delegations therefore proposed either a ML of 0.125 mg/kg or 0.15 mg/kg (as rounded from 0.14 mg/kg) to be equivalent to reconstituted powdered infant formula by different reconstitution factors. A delegation, supported by several other delegations, further noting that the purpose of the establishment of MLs for melamine was to primarily differentiate adulterated products from those which could contain melamine through possible migration from the packing material, proposed to include a note to indicate that the ML did not apply if it could be proven that a higher level was as a consequence of migration from food contact materials taking into account any national

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7 CX/CF 11/5/4; CX/CF 11/5/4 Add.1 (comments of Costa Rica); CRD 3 (comments of Kenya); CRD 4 (comments of Mali); CRD 7 (comments of the European Union); and CRD 17 (comments of Cameroon).

8 ALINORM 10/33/41, Appendix IV; CX/CF 10/5/5 (comments of Brazil, Canada, New Zealand, Peru and IDF); CRD 4 (comments of Mali); CRD 6 (comments of Philippines); CRD 7 (comments of the European Union); CRD 8 (comments of Egypt); CRD 12 (comments of Tanzania); CRD 13 (comments of Indonesia); CRD 15 (comments of India); CRD 16 (comments of Nigeria); CRD 17 (comments of Cameroon); CRD 20 (comments of Republic of Korea); and CRD 22 (comments of NHF).

authority migration limits. A number of delegations while supporting the level of 0.15 mg/kg, were opposed to the note. These delegations indicated that packaging materials from which melamine could migrate should be avoided especially as these were products for a vulnerable group, namely, infants. It was clarified that migration of melamine could be from the cap sealings or the coatings of the cans in which liquid infant formulae were packed and that such migration was unavoidable. It was necessary therefore to include the note.

30. A delegation further proposed that the level be set at 1 mg/kg on a dry matter basis and that CCMAS should be requested to identify methods of analysis for melamine in liquid infant formula. It was clarified that the 32nd Session of CCMAS had identified methods for melamine in milk, milk products and infant formula[9].

31. In view of the discussion, the Committee agreed to set a level of 0.15 mg/kg for liquid infant formula as consumed with a note as proposed.

32. The Delegations of Costa Rica, Peru and Nicaragua expressed their reservation to the inclusion of the note. The Observer of NHF also expressed concern with the inclusion of the note and pointed out that the level should be set as low as possible, taking into account that the product was for vulnerable infants and that no exemptions should be allowed.

Status of the Proposed Draft Maximum Levels for Melamine in Food (*Liquid Infant Formula*)

33. The Committee agreed to forward the proposed draft maximum level for liquid infant formula to the 34th Session of the Codex Alimentarius Commission for adoption at Step 5/8 (with omission of Steps 6 and 7) (Appendix III).

PROPOSED DRAFT MAXIMUM LEVELS FOR DEOXYNIVALENOL (DON) AND ITS ACETYLATED DERIVATIVES IN CEREALS AND CEREAL-BASED PRODUCTS (Agenda Item 6)[10]

34. The Delegation of Canada, speaking as Chair of the Working Group on DON presented the report of the working group as presented in CX/CF 11/5/6. The Delegation highlighted the recommendations made by the working group, in particular, that MLs be set for DON only or that the Committee consider further data collection before proceeding with the elaboration of MLs for DON and its acetylated derivatives. The Delegation pointed out that currently there were insufficient data on acetylated derivatives of DON also due to the lack of validated methods for their detection.

35. The Committee had an exchange of views on whether there was a need for further data collection or whether the information was sufficient to establish MLs for DON and/or its acetylated derivatives.

36. The JECFA Secretariat clarified that the 72nd JECFA meeting had established a group TDI for DON and its acetylated derivatives and that the latter contributed to overall DON exposure. In addition, in relation to the proposal for further data collection, it was clarified that JECFA had looked at several sets of occurrence data, both for DON and its acetylated derivatives. The Committee was reminded that the 72nd JECFA had considered several data reports. Even though most of the data considered were from the European region, data were also available and considered from other regions, including Africa and Asia. Data on acetylated derivatives had also been available. It was further noted that repeated requests for more data had been made over the years by the Committee. The JECFA assessment had been based on a large number of data and it was unlikely that a lot of new data would be available.

37. Several delegations supported the collection of further data, in particular that monitoring of DON and DON derivatives occurrence in wheat, maize and other cereals be continued: (i) to provide a

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9 REP11/MAS, para 25 and Appendix III.

10 CX/CF 10/5/6; CX/CF 11/5/6-Add.1 (comments of Chile, Costa Rica, Japan and Kenya); CRD 4 (comments of Mali); CRD 7 (comments of the European Union); CRD 8 (comments of Egypt); CRD 12 (comments of Tanzania); CRD 15 (comments of India); CRD 16 (comments of Nigeria); and CRD 20 (comments of Republic of Korea).

more complete picture of seasonal and regional differences and (ii) to provide more complete data sets including individual data rather than aggregated data. It was also proposed that attention be paid to mitigation methods to allow the review of the *Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals* (CAC/RCP 51-2003) and its possible revision.

38. Several other delegations noted that the decision of the last session of the Committee to establish MLs for DON was based on the fact that there was currently sufficient occurrence data to proceed. Also noting that DON was a human health concern, it was proposed that the Committee proceed with MLs, but that the Committee first focus on MLs for DON together with associated sampling plans before proceeding with MLs for its acetylated derivatives due to the lack of complete data and availability of analytical methods.

39. There was some exchange of views of the MLs proposed by the working group. A delegation pointed out that setting an ML for raw commodities could be trade restrictive. This delegation noted that DON levels could be considerably reduced during the milling process. A few other delegations however supported setting levels for raw cereals (wheat, maize and barley) as these were widely used commodities in some regions and indicated that the 2 mg/kg was achievable with application of good agricultural practices. Questions were also raised on the level proposed for infant foods and proposals were made for more stringent levels and the need to take into account high consumption of certain infant foods derived from cereals such as wheat, in some regions. While delegations expressed support for the level of 1 mg/kg in foods derived from wheat, barley and/or maize, some delegations expressed the view that this category needed to be more accurately defined and that it should be based on evidence of significance to international trade.

40. The Committee also considered a proposal to request JECFA to do an impact assessment of various hyptothetical MLs as recommended by the electronic Working Group. The JECFA Secretariat noted that it was possible to undertake such work in parallel with the development of MLs. It was therefore agreed that this matter could be discussed further in the priorities in-session Working Group (Agenda Item 11).

41. In view of the discussion, the Committee agreed to proceed with the establishment of MLs for DON in cereals and that it would at the 8th Session of the Committee consider the extension of the ML to acetylated derivatives of DON. The Committee reconfirmed that the ML would not be for cereals intended for animal feed as DON barely carries over to animal products for human consumption. In view of this decision, it was agreed to reconvene the electronic Working Group led by Canada to further continue this work, including the development of associated sampling plans. The electronic Working Group was also requested to explore the possibility to revise the *Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals* (CAC/RCP 51-2003) and report the result at the next session.

42. The Committee also encouraged members and industry to continue monitoring occurrence of DON and its derivatives and agreed that these data should be submitted to the GEMS Food Programme. In addition, it was agreed to request CCMAS to identify methods for acetylated derivatives of DON in order to allow for its monitoring.

Status of the Proposed Draft Maximum Levels for DON and its Acetylated Derivatives in Cereals and Cereal-based Products

43. The Committee agreed to return the proposed draft MLs for DON to Step 2/3 for further development by the electronic Working Group, circulation for comments and further consideration by the next session of the Committee.

PROPOSED DRAFT MAXIMUM LEVEL FOR TOTAL AFLATOXINS IN DRIED FIGS (Agenda Item 7)[11]

44. The Delegation of Turkey, as Chair of the electronic Working Group on Dried Figs, introduced the document highlighting the main issues associated with the establishment of the proposed maximum level of 10 µg/kg as laid down in working document CX/CF 11/43/7. In particular, the Delegation informed the Committee that the proposed ML ensures protection of consumers' health while ensuring fair trade practices as consumption of dried figs as such or as ingredients was lower than other products traded worldwide such as tree nuts for which the same level had been established. The Delegation also highlighted that the proposed ML was based on the appropriate application of the *Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Dried Figs* (CAC/RC 65-2008)

45. A delegation while not opposed to the proposed ML for dried figs, suggested that in future the Committee should strictly apply the principle in the General Standard for Contaminants and Toxins in Food and Feed when agreeing to new work for establishment of MLs.

46. The Committee noted that there was wide support for the proposed ML however some delegations stated that it was not possible to agree with the proposed ML without having full clarity about the sampling plan. Other delegations also emphasized the importance of the sampling plans in view of the heterogeneous distribution of aflatoxins in dried figs. This would in turn allow proper enforcement of the ML. It was noted that the proposed ML represented a good balance between cost benefits of dried fig production and protection of human health.

47. In addition, some delegations, while not necessarily opposed to the proposed ML, questioned whether occurrence and processing data should not also be gathered from other producing countries so that the ML more accurately reflected current industry practices, and that consumption of dried figs had been increased in certain countries especially among certain population groups like children. A delegation also questioned whether the proposed ML accurately reflected good implementation of the Code of Practice and whether the term "dried figs" covered all types of dried figs or only ready-to-eat product.

48. The Delegation of Turkey highlighted that the sampling plan referred to in CX/CF 11/5/7 was already in use for many years in European countries.

49. The Delegation of Turkey indicated that the country accounts for the major portion of the world market in trade of dried figs and that other major producing countries that had participated in the working group had not provided data that could give rise to lower MLs and had neither disagreed with the proposed ML. In this regard, it was pointed out a similar situation applied to the establishment of MLs for tree nuts where data on different nuts were mainly based on data provided by one or a few major producing countries. The Delegation noted that provisions in the COP had been in place for a long time in Turkey even before the Code was adopted by Codex. The Delegation clarified that the term "dried figs" applied to "ready-to-eat" product in line with the decision of the last session of the Committee, this being the major form of dried figs traded worldwide. As regards the need for accompanying sampling plans, the Delegation explained that sampling plans were closely linked to the ML therefore there should first be agreement with the proposed ML before pursuing a development of sampling plans although reference was made in the working document to sampling plans. The Delegation agreed that sampling plans would be described and justified together with the proposed level for consideration by the next session of the Committee.

Status of the Proposed Draft Maximum Level for Total Aflatoxins in Dried Figs

50. The Committee agreed to return the Proposed Draft Maximum Level for Dried Figs to Step 2/3 so that the sampling plans according to the proposed ML of 10 µg/kg can be developed for

[11] CX/CF 11/5/7. CX/CF 11/5/7-Add.1 (comments of Brazil, Costa Rica and Norway). CRD 3 (comments of Kenya); CRD 4 (comments of Mali); CRD 7 (comments of the European Union); CRD 8 (comments of Egypt); CRD 9 (comments of Thailand); and CRD 21 (comments of INC).

consideration by the next session of the Committee.

EDITORIAL AMENDMENTS TO THE GSCTFF (Agenda Item 8)[12]

51. The Committee agreed to discuss this Agenda Item at the next session as there was no document available at this session.

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

52. The Delegation of Sudan, as the Chair of the electronic Working Group (e-WG) on Mycotoxins in Sorghum, introduced the report of the working group, as presented in CX/CF 11/5/9.

53. It was reported that records and information on the occurrence of mycotoxins in grain sorghum was incomplete. However, available information showed that 9 mycotoxin types in 12 countries were reported on sorghum. The main toxigenic fungi in sorghum were found to be *Aspergillus flavus, A. parasiticus, A. ochraceus, Alternaria alternata, Claviceps africana, Fusarium verticilliodes, F. proliferatum, F. graminearum and F. semitectum*, and aflatoxins were the most researched mycotoxins in sorghum. Other types of mycotoxins including fumonisins, ochratoxins, zearalenone, trichothecenes, deoxynivalenol, nivalenol and ergosine were also reported in sorghum in some countries.

54. The Committee noted that the electronic Working Group made recommendations which concerned two points: (i) more collection of data and research to be done on the occurrence of mycotoxins in sorghum; and (ii) the development of a Code of Practice (COP) for the management of aflatoxins in sorghum as an additional annex to the existing *Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals* (CAC/RCP 51-2003).

55. Noting that sorghum was the fifth largest cereal in the world with an annual production of 65 million tons and consumed as a staple crop for many African population groups, the Committee supported the recommendations proposed by the e-WG to update the discussion paper to explore the feasibility of including an additional annex in the existing COP, while countries continue collection of data on the occurrence of mycotoxins in sorghum and sorghum-based food products at the pre- and post-harvest levels as well as data on dietary intake especially from major producing countries. The Committee considered that it was important to update data especially from major sorghum producing countries.

56. The Representative of WHO informed the Committee that following the previous discussions in the Committee on the lack of data on mycotoxins in sorghum, sufficient funding had been secured through the Codex Trust Fund to enable FAO and WHO to jointly implement a project covering 4 pilot countries in Africa to collect samples, possibly from 2 harvests, and analyse mycotoxins and mycotoxin-producing fungi in sorghum. The project will start in 2011 and run for 3 years and will, to the extent possible, also gather information, on agricultural practices related to the sorghum production in these countries.

57. A delegation stressed that developing a COP for sorghum was very relevant to its country as the majority of the population consumed sorghum as a main cereal and pointed out that the small-scale subsistence farming practices of sorghum should be taken into account to ensure that these farmers could comply with the COP.

Conclusion

58. The Committee agreed to re-establish the electronic Working Group, under the chairmanship of Nigeria, working in English only and open to all Codex members and observers, to update the discussion paper to screen the general part of the exiting *Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals* (CAC/RCP 51-2003) to ascertain whether it was relevant and feasible for the production of sorghum and to explore the feasibility of including an

12 CX/CF 11/5/8 (not available).

13 CX/CF 11/5/9; CRD 3 (comments of Kenya); CRD 4 (comments of Mali); CRD 7 (comments of the European Union); CRD 9 (comments of Thailand); CRD 12 (comments of Tanzania); CRD 13 (comments of Indonesia); CRD 16 (comments of Nigeria); and CRD 17 (comments of Cameroon).

additional Annex for "Prevention and reduction of contamination by aflatoxins in grain sorghum" to the COP for consideration by the next session.

59. The Committee noted that data would be collected in the Codex Trust Fund pilot study on mycotoxins in sorghum, and no further discussion on MLs would be held at this point, but further data collection and submission to GEMs Food Programme is encouraged.

DISCUSSION PAPER ON ARSENIC IN RICE (Agenda Item 9b)[14]

60. The Delegation of China, as Chair of the electronic Working Group on Arsenic in Rice, introduced the document summarizing the main issues surrounding rice contamination with arsenic as presented in working document CX/CF 11/5/10. The Delegation drew the attention of the Committee to the recommendation of the working group for the consideration of establishing maximum levels for arsenic in rice and whether they should address total or inorganic arsenic only or the need for further data collection before considering the establishment of MLs.

61. The Committee had an exchange of views on the appropriateness to set MLs for arsenic as opposed to further data collection, especially occurrence data on inorganic arsenic from various countries and sources, in order to clearly identify the products to which the ML should apply, before taking a decision on how to proceed further. In this regard, a delegation noted that based on monitoring data of arsenic in rice and other foods, it was not clear if rice was the major source of arsenic contamination compared to other types of foods and that in view of JECFA's withdrawal of the PTWI of inorganic arsenic there was no adequate information to estimate the dietary risk of arsenic for the general population. In view of this, consideration should be given to first develop a Code of Practice before proceeding with the establishment of MLs. Another delegation indicated that countries should continue monitoring arsenic occurrence in rice and rice-based products (in particular those species forming total and inorganic arsenic) taking into account regional and seasonal differences in arsenic levels in rice and to submit complete data sets including individual sample results rather than only aggregate data.

62. The Committee also exchanged views on, if MLs were to be established, whether they should apply to inorganic arsenic or the sum of both organic and inorganic arsenic. Most delegations were in support of development of MLs for total arsenic in rice as a first step. Some delegations felt that the ML should only address the main contributor and most toxic form i.e. inorganic arsenic. Other delegations favoured the establishment of MLs for total arsenic as differentiation between both forms of arsenic required more complex analytical methods and due to the need for validated analytical procedures for determination of inorganic arsenic. It was noted that the fraction of inorganic arsenic might have wide variation ranging from 40% to 80%. It could be more appropriate to establish MLs for total arsenic for the time-being. In addition, it was noted that development of MLs for arsenic in rice-based products should be established by applying processing factors calculated from inorganic arsenic concentrations in raw product and the corresponding processed commodity resulting from appropriate processing studies and that separated MLs would be needed for vulnerable groups such as infants and young children.

63. The JECFA Secretariat explained that the PTWI was established for inorganic arsenic, based on the relevant toxicological data. Arsenic in food was more in the inorganic form and less organic, however routine analytical methods mostly measure total arsenic. Differentiation between arsenic species required more complicated analytical procedures. The JECFA Secretariat reminded the Committee that in the case of mercury the MLs were also set on total mercury rather than on the speciated forms. In addition, the JECFA Secretariat recalled that the 72nd JECFA Meeting had made recommendations on the need for validated methods and reference materials for the determination of inorganic arsenic in foods. Subsequently, more comprehensive occurrence data of inorganic arsenic in foods such as rice could be generated, to provide the basis of improved dietary exposure estimates and impact assessment of different MLs.

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[14] CX/CF 11/5/10. CRD 3 (comments of Kenya); CRD 6 (comments of Philippines; CRD 7(comments of the European Union) CRD 9 (comments of Thailand); CRD 10 (comments of Thailand); CRD 11 (comments of Argentina); CRD 12(comments of Tanzania) and CRD 17 (comments of Cameroon).

Conclusion

64. The Committee agreed to initiate new work on maximum levels for arsenic in rice subject to approval by the 34th Session of the Commission. The Committee also agreed to re-convene the electronic Working Group, led by China, working in English only and open to all Codex members and observers, who would prepare a working paper considering MLs for arsenic in rice based on the considerations made at plenary for deliberation at the next session of the Committee (Appendix IV). The electronic Working Group should specify in the paper whether the MLs apply to total and/or inorganic arsenic in rice.

DISCUSSION PAPER ON GUIDANCE FOR RISK MANAGEMENT OPTIONS ON HOW TO DEAL WITH THE RESULTS FROM NEW RISK ASSESSMENT METHODOLOGIES (Agenda Item 9c)[15]

65. The Delegation of the United States of America, as the Chair of the electronic Working Group on Risk Management Options, introduced the report of the working group, as presented in CX/CF 11/5/11. The Delegation reported that in the preparation of the paper many recommendations were made on how to proceed, and on the purpose of the document some of which were contradictory and that there was a need for guidance on how to take this forward; and on whether the description on the risk assessment context as presented was appropriate; on what, if any, case studies would be appropriate; and on what ideas could be provided to further develop the risk management options section.

66. There was general acknowledgement that the paper contained useful information in particular for member countries and that it should be updated, but that it should be prepared in a more balanced way, focusing on the interface between risk assessment and risk management options, with less detailed information on risk assessment methodologies, and more on the interpretation of the outcome of risk assessment, and that it should be prepared in a language more understandable to risk managers. The WHO JECFA Secretariat pointed out the risk assessment methodologies used by JECFA are described in detail in the new publication Environmental Health Criteria No 240 (see Agenda Item 3) and that the paper should only briefly describe the different risk assessment outcomes for the purpose of the development of risk management options and recommendation to countries.

67. There was little support for development of case studies at this stage.

68. A few delegations questioned the need for the work on risk management options in view of the fact that there was already sufficient guidance for the Committee in the Procedural Manual.

69. It was clarified that the purpose of the paper was to describe risk management options other than maximum levels and codes of practice for the Committee in light of different risk assessment outcomes, and to provide descriptions of the underlying risk assessment outcomes. It was further clarified that at this stage the work was still exploratory and that it did not impact on the current guidance to the Committee as outlined in the Procedural Manual.

Conclusion

70. Due to the general support for further work, the Committee agreed to re-establish the electronic Working Group, under the lead of the United States of America, co-chaired by The Netherlands, working in English only and open to all Codex members and observers with the following terms of reference:

- To prepare a discussion paper for consideration at the next session on risk management options in addition to MLs and codes of practice in light of different risk assessment outcomes focusing on:
    - A description of different risk assessment outcomes in language understandable for risk managers and related uncertainties; and

[15] CX/CF 11/5/11; CRD 7 (comments of the European Union); CRD 9 (comments of Thailand); CRD 15 (comments of India); and CRD 19 (comments of the CIAA).

- Implications of different risk assessment outcomes and description of possible risk management options.

DISCUSSION PAPER ON OCHRATOXIN A IN COCOA (Agenda Item 9d)[16]

71. The Delegation of Ghana, as Chair of the electronic Working Group on Ochratoxin A (OTA) in Cocoa, introduced the document highlighting the main issues associated with the production of cocoa in relation to contamination with ochratoxin A as contained in working document CX/CF 11/43/12. In particular, the Delegation highlighted the recommendations of the working group concerning the future possible development of a code of practice for the prevention/reduction of ochratoxin A contamination in cocoa taking into account the knowledge currently available.

72. Most of the delegations supported the recommendations as set out in paragraph 81 of the working document in particular those related to encourage the cocoa processing industry to monitor the levels of OTA in cocoa and cocoa products, develop studies directed to small holder farms to generate data on levels of OTA over a period of several years, conduct dietary intake studies of OTA in cocoa and cocoa products for infants and children and the potential development of a code of practice once more information become available.

73. Some delegations were of the view that the Committee was ready to start new work on the development of a code of practice based on the information available to date.

74. Other delegations expressed the view that the elaboration of a code of practice might be premature and that more information on OTA contamination in cocoa should be collected from producing countries before taking a decision to proceed with the development of such a code. In this regard, they stressed the need to take into account agricultural and processing practices of small scale producers as cocoa production in many producing countries was mainly run by small scale farmers. Therefore, in elaborating further the proposal for the development of a code of practice, more information should be gathered on such practices and OTA contamination so that the code can accurately reflect good agricultural and manufacturing practices in the production of cocoa worldwide which would facilitate the implementation of the code by small scale farmers once adopted.

Conclusion

75. The Committee agreed to re-establish the electronic Working Group led by Ghana, working in English only and open to all Codex Members and Observers, to update the discussion paper based on the above considerations with a view to the development of a code of practice, for consideration by the next session of the Committee.

DISCUSSION PAPER ON FURAN (Agenda Item 9e)[17]

76. The Delegation the United States of America, as Chair of the electronic Working Group on Furan, introduced the report of the working group, as presented in CX/CF 11/5/13.

77. The Committee noted that to date research on furan had not been successful in identifying practical and consistently effective solutions for decreasing furan in food and that it was premature to develop a Code of Practice at this stage.

78. It was clarified that more information on mitigation approaches might provide more practical solutions that could form the basis for the future development of a Code of Practice and that furan analogues (e.g., 2-methylfuran, 3-methylfuran) in mitigation studies could be included.

79. The Committee agreed that this work could be taken up in the future when more adequate

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[16] CX/CF 11/5/12. CRD 3 (comments of Kenya); CRD 4 (comments of Mali); CRD 5 (comments of Côte d'Ivoire); CRD 6 (comments of Philippines); CRD 7 (comments of the European Union); CRD 9 (comments of Thailand); CRD 12 (comments of Tanzania); CRD 16 (comments of Nigeria); and CRD 17 (comments of Cameroon).

[17] CX/CF 11/5/13; CRD 7 (comments of the European Union); CRD 8 (comments of Egypt); CRD 9 (comments of Thailand); CRD 15 (comments of India); CRD 17 (comments of Cameroon); and CRD 19 (comments of CIAA).

data became available and that at that time the re-establishment of the electronic Working Group to further develop the discussion paper could be considered.

DISCUSSION PAPER ON PYRROLIZIDINE ALKALOIDS (Agenda Item 9f)[18]

80. The Delegation of the Netherlands, as Chair of the electronic Working Group on PAs, introduced the document highlighting the main issues associated with PA contamination in food and feed as presented in CX/CF 11/5/14.

81. The Committee noted that there was general agreement with the recommendations of the working group as set out in paragraphs 167-171 of the discussion paper namely: to encourage Codex members and observers to develop more analytical reference standards for PA to enable the development and validation of analytical methods; to generate more occurrence data on PA contamination in food and feed; to request JECFA to identify which PA in food and feed (as carry over from feed to animal products) were of key interest to human health and to perform a full risk assessment based on the available data for the identified PA and/or to identify data gaps if full risk assessment was not possible (see Agenda Item 11); and to start work on a code of practice for the prevention/reduction of contamination of food with PA including a compilation of existing effective management/mitigation practices to prevent/reduce PAs contamination of food. In view of these considerations, the Committee also agreed with the recommendation of the working group not to start work on an ML for PA in food and feed for the time being.

Conclusion

82. The Committee agreed to re-establish the electronic Working Group on PA, led by the Netherlands, working in English only and open to all Codex members and observers, to update the discussion paper based on the above considerations, in particular to undertake further compilation of existing management practices and to evaluate the possibility to develop a code of practice for consideration by the next session of the Committee.

83. The Committee also encouraged Codex members and observer to develop more analytical reference standards for PA and to gather more information on the occurrence of PA in food and feed.

OTHER MATTERS

Preparation of discussion papers and other working documents

84. The Committee noted that discussion papers should be focused on the questions/issues put forward by the Committee and should present succinct supportive information necessary to provide the rationale for the recommendations. Additional background scientific information that may be useful for further consultation by Codex members and observers could be retained in Annexes in original language. This will also facilitate discussion at plenary by focusing on the issue at hand and not deviating the attention by also commenting on the background information. The Committee also noted that when available, scientific information should preferably be cross referenced instead of reproducing it in the discussion paper and that, if JECFA monographs were not yet available, the drafts could be obtained from the JECFA Secretariat. The Committee further noted that long documents could add to additional printing and translation costs that might be sometimes cumbersome for the host country. It was noted that the Codex Secretariat may provide examples or guidelines on how to prepare discussion papers in order to have a uniform presentation of these documents.

ENDORSEMENT OF PROVISIONS FOR HEALTH-RELATED LIMITS FOR CERTAIN SUBSTANCES IN THE STANDARD FOR NATURAL MINERAL WATER (Agenda Item 10)[19]

85. The Committee recalled that its last session had considered the removal of the temporary endorsement of sections 3.2.17 to 3.2.20 of the *Standard for Natural Mineral Waters* (CODEX STAN

[18] CX/CF 11/5/14. CRD 7 (comments of the European Union); CRD 9 (comments of Thailand); CRD 12 (comments of Tanzania); and CRD 20 (comments of Republic of Korea).

[19] CX/CF 11/5/15; CRD 3 (comments of Kenya); CRD 4 (comments of Mali); CRD 7 (comments of the European Union); CRD 9 (comments of Thailand); CRD 13 (comments of Indonesia); and CRD 14 (comments of Japan).

108-1981) following the identification of methods of analysis by the Committee on Methods of Analysis and Sampling (CCMAS) based on the LOD and LOQ for the compounds[20] and to endorse these sections. In addition the Committee had considered whether the compounds in sections 3.2.1 to 3.2.16 could be integrated into the General Standard for Contaminants and Toxins in Food and Feed (GSCTFF) previously endorsed by the 2nd Session of the Committee. To consider these matters, the Committee had agreed to establish an electronic Working Group led by the United States of America and co-chaired by The Netherlands to develop criteria to differentiate between safety and quality parameters and based on these criteria to determine which of the compounds in section 3.2 of the Standard were safety parameters and whether these could be integrated into the GSCTFF. In addition, the electronic Working Group was tasked with determining more appropriate maximum levels for the compounds in sections 3.2.17 to 3.2.20 if these were considered safety parameters.

86. The Delegation of the United States of America, as Chair of the electronic Working Group on the endorsement of provisions for health-related limits for certain substances in the Standard for Natural Mineral Waters, introduced the report and recommendations as presented in CX/CF 11/5/15.

87. The Delegation explained that definitions had been proposed for safety and quality parameters and that according to the definition for safety, all compounds in sections 3.2.1 to 3.2.16 were defined as safety parameters, with the exception of copper. In relation to sections 3.2.17 to 3.2.20, it was reported that there were two schools of thought on whether to define these compounds as safety or quality parameters as the working group could not agree on the definition of a quality parameter. Some were of the opinion that mineral oil and surface-active agents were quality parameters and PAHs, PCBs and pesticides could be considered safety parameters, while others were of the opinion that all should be considered quality parameters. There was however agreement in the working group that safety and quality parameters should be maintained in the Standard, but listed separately.

88. The Committee had an exchange of views on the compounds in sections 3.2.17 to 3.2.20. The following was considered:

- natural mineral waters were clearly distinguishable from drinking water as laid down in the definition for natural mineral water in section 2.1 of the Standard and this should be taken into consideration when considering the quality and safety parameters under section 3.2.
- in view of the definition of natural mineral water, safety and quality parameters applicable to drinking water are not applicable to natural mineral waters, especially in the case of environmental contaminants of anthropogenic origin in sections 3.2.17 to 3.2.20, for which limits for natural mineral water should be stricter than the limits applicable to drinking water, not for safety reasons, but as specific quality parameters.
- the title of section 3.2 “Health-related limits for certain substances” should be changed to “substances for quality parameters” if the compounds were considered quality parameters and that a new section on contaminants should be added in line with the Format of Commodity Standard as prescribed in the Procedural Manual.
- respective MLs for pesticides and PCBs (section 3.2.18) and PAHs (3.2.20) should be added in the section on Contaminants in the Standard if MLs were set in future; or if PCBs and pesticides were to be considered as safety parameters, that maximum levels needed to be established and integrated into the GSCTFF and that the Committee on Natural Mineral Waters (CCNMW) could be requested to consider appropriate MLs for these compounds.
- refer the sections 3.2.17 – 3.2.20 back to the CCNMW to establish levels as quality parameters or to delete these two subsections as there was no value to maintain them without any numerical value.
- the compounds in sections 3.2.17 to 3.2.20 could have an impact on human health. However, these compounds are not expected to occur in natural mineral waters according to the Standard and that the levels set at the LOD and LOQ were below the level at which they

[20] ALINORM 11/33/23, paras 57 – 82 and Appendix II.

could be a safety concern as they were actually quality levels to maintain the purity of natural mineral waters as defined in the Standard.

- there was no need to set levels in sections 3.2.17 to 3.2.20, as the LOD and LOQ were de facto levels to ensure the quality and safety of the natural mineral waters.
- Endorsement of quality parameters was outside the remit of the Committee.

Conclusion

89. Noting that according to the Standard the compounds in sections 3.2.17 to 3.2.20 should not be present in natural mineral waters but permitted at levels below the LOQ, and the general sense of the Committee that the compounds in sections 3.2.17 to 3.2.20 should therefore be considered quality parameters, it was agreed to inform the Commission to remove footnote 3 in the *Standard on Natural Mineral Waters* (CODEX STAN 108-1981) as there was no need for the endorsement of these sections since there was no safety concern associated with these compounds at the proposed levels[20].

90. The Committee took no further action on the integration of the safety parameters in sections 3.2.1 to 3.2.16 into the *General Standard on Contaminants and Toxins in Food and Feed*.

PRIORITY LIST OF CONTAMINANTS AND NATURALLY OCCURRING TOXICANTS PROPOSED FOR EVALUATION BY JECFA (Agenda Item 11)[21]

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

92. The Committee noted that fumonisins and cyanogenic glycosides were scheduled for evaluation by the 74th JECFA Meeting (June 2011) and therefore removed these compounds from the priority list. The Committee agreed with the recommendations of the working group in regard to 3-MCPD esters, glycidyl esters, pyrrolizidine alkaloids (PAs) and non dioxin-like PCBs, and to not request a re-evaluation of dioxins at this point in time.

Conclusion

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

OTHER BUSINESS AND FUTURE WORK (Agenda Item 12)[22]

REPORT OF THE IN-SESSION WORKING GROUP ON THE FOLLOW-UP BY CCCF ON RECENT JECFA EVALUATIONS

94. The Delegation of the European Union, as the Chair of the in-session Working Group presented the report on the discussion and recommendations of the working group. The full explanation and rationale of the discussion and recommendations of the working group can be found in CRD 23. The Committee endorsed the recommendations as proposed by the working group:

Maximum levels for cadmium in various foods in the *General Standard for Contaminants and Toxins in Food and Feed* and the related *Code of Practice for Source Directed Measures to Reduce Contamination of Foods with Chemicals*

95. The Committee agreed that no follow-up was necessary.

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21 CL 2010/13-CF; ALINORM 10/33/41, Appendix VII; CX/CF 11/5/16, CRD 2 (Report of the in-session Working Group on Priorities).

22 CRD 23 (Report of the informal ad-hoc working group on the follow-up CCCF on recent JECFA evaluations).

Maximum levels for lead in various foods in the *General Standard for Contaminants and Toxins in Food and Feed* and the related *Code of Practice for the Prevention and Reduction of Lead Contamination in Foods* and the *Code of Practice for Source Directed Measures to Reduce Contamination of Foods with Chemicals*

96. The Committee agreed to establish an electronic Working Group to: (i) reconsider the existing maximum levels with a focus on foods important for infants and children and also on the canned fruits and vegetables and (ii) reconsider if other existing maximum levels should be addressed.

97. The electronic Working Group will be led by the United States of America, will work in English only and be open to all Codex members and observers.

Maximum levels for mercury in natural mineral water and salt (food grade) and guideline levels for methylmercury in fish and predatory fish in the *General Standard for Contaminants and Toxins in Food and Feed* and the related *Code of Practice for Source Directed Measures to Reduce Contamination of Foods with Chemicals*

98. The Committee agreed that no follow-up as regards the existing MLs for mercury was necessary. The Committee also agreed to consider the need to review the existing GLs for methylmercury in fish and predatory fish when the full report of the Joint FAO/WHO Expert Consultation on the Risks and Benefits of Fish Consumption becomes available.

Perchlorate

99. The Committee agreed that no follow-up was necessary since no health concern was identified at current estimated levels of exposure from food and drinking water.

Chlorine-containing disinfectants in food production and processing

100. The Committee took note of the report of the Joint FAO/WHO Expert Meeting on the Benefits and Risks of the Use of Chlorine-containing Disinfectants in Food Production and Processing and agreed that no further action was necessary.

Other Matters

101. The Committee noted that the JECFA Secretariat and the Chair of the CCCF would explore the possibility to organize in conjunction with the next session of the Committee a half day seminar on the methodologies followed by JECFA evaluations.

102. The JECFA Secretariat informed the Committee that WHO was finalizing the update on the new web-based system for data submission to the GEMS/Food Programme and that all submission of data (should be done to the GEMS/Food Programme. The JECFA Secretariat also indicated that training on how to submit such data will be provided by WHO. Further questions in this regard should be addressed to Philippe Verger, GEMS/Food Programme, e-mail: vergerp@who.int.

DATE AND PLACE OF THE NEXT SESSION (Agenda Item 13)

103. The Committee was informed that its sixth session was tentatively scheduled to be held in The Netherlands in March 2012. The exact venue and date would be determined by the host Government in consultation with the Codex Secretariat.

SUMMARY STATUS OF WORK

SUBJECT MATTERS	STEP	ACTION BY:	DOCUMENT REFERENCE (REP11/CF)
Proposed Draft Code of Practice for the Prevention and Reduction of Ethyl Carbamate Contamination in Stone Fruit Distillates	5/8	Governments 34th CAC	para. 26, Appendix II
Proposed Draft Maximum Levels for Melamine in Food (*Liquid Infant Formula)*	5/8		para. 33, Appendix III
Proposed Draft Maximum Levels for DON and its Acetylated Derivatives in Cereals and Cereal-based Products	2/3	Electronic Working Group (Canada) Governments 6th CCCF	para. 43
Proposed Draft Maximum Level for Total Aflatoxins in Dried Figs	2/3	Turkey Governments 6th CCCF	para. 50
Proposed Draft Maximum Levels for Arsenic In Rice (New Work)	1/2/3	Electronic Working Group (China) 34th CAC Governments 6th CCCF	para. 64, Appendix IV
Risk Analysis Principles for contaminants and natural toxins in food and feed	-	Electronic Working Group (The Netherlands) 6th CCCF	para. 9
Editorial Amendments to the General Standard on Contaminants and Toxins in Food and Feed	-	Electronic Working Group (European Union) 6th CCCF	para. 51
Discussion Paper on Mycotoxins in Sorghum	-	Electronic Working Group (Nigeria)	para. 58
Discussion Paper on Risk Management Options in light of Different Risk Assessment Outcomes	-	Electronic Working Group (USA/The Netherlands) 6th CCCF	para. 70
Discussion Paper on Ochratoxin in Cocoa	-	Electronic Working Group (Ghana) 6th CCCF	para. 75
Discussion Paper on Pyrrolizidine Alkaloids	-	Electronic Working Group (The Netherlands) 6th CCCF	para. 82
Priority List of Contaminants and Naturally Occurring Toxicants proposed for evaluation by JECFA	-	Governments 6th CCCF	para. 93, Appendix V
Maximum Levels for Lead in various foods in the GSCTFF and the Code of Practice for the Prevention and Reduction of Lead Contamination in Foods and Code of Practice for Source Directed Measures to Reduce Contamination of Foods with Chemicals	-	Electronic Working Group (United States of America) 6th CCCF	paras 96-97

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APPENDIX II

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

(FOR ADOPTION AT STEP 5/8)

INTRODUCTION

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

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

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

4. Stone fruit distillates, in particular, contain ethyl carbamate in manyfold higher concentrations than other fermented foods and beverages. In stone fruit distillates ethyl carbamate can be formed from cyanogenic glycosides that are natural constituents of the stones. When mashing the fruit, the stones may be damaged and cyanogenic glycosides from the stones may come into contact with enzymes in the fruit mash. Cyanogenic glycosides are then degraded to hydrocyanic acid/cyanides. Hydrocyanic acid may also be released from intact stones during a prolonged storage of the fermented mash. During the distillation process hydrocyanic acid may be enriched in all fractions. Cyanide in the distillates may be oxidized to cyanate, which can react with ethanol to form ethyl carbamate. Certain environmental conditions such as exposure to light, high temperatures and the presence of copper ions promote the formation of ethyl carbamate in the distillate.

5. Although no strong correlation between the level of hydrocyanic acid and ethyl carbamate has been established so far, it is evident that under certain conditions high concentrations of hydrocyanic acid lead to higher levels of ethyl carbamate. A potential increase in ethyl carbamate formation has been associated with levels at or above 1 mg/l hydrocyanic acid in the final distillate. Based on practical experiences it can be assumed that from 1 mg of hydrocyanic acid up to 0.4 mg ethyl carbamate potentially can be formed in a non-equimolar relationship.

SCOPE AND DEFINITIONS

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

7. The definitions below apply to this Code:

(a) **Stone Fruit** means for the purpose of this Code of Practice certain edible fruit of trees belonging to the genus Prunus of the rose family (Rosaceae), i.e. cherry, plum, peach and apricot.

(b) **Distillates** means, for the purpose of this Code of Practice, alcohol-rich products obtained after the distillation process and ready for consumption.

(c) **Stone Fruit distillates** means, for the purpose of this Code of Practice, the distillates for consumption, obtained after the distillation:

- of the mash prepared by fermentation of crushed stone fruits
- of fermented stone fruit marc (pomace).
- of mash obtained by fermentation and/or maceration of crushed and/or whole stone fruit in ethyl alcohol or alcoholic beverages.

GENERAL REMARKS

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

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

TYPICAL PRODUCTION PROCESS

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

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

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

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

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

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

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

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

(h) dilution to the final alcoholic grade.

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

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

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

RECOMMENDED PRACTICES BASED ON GMP’s

RAW MATERIALS AND PREPARATION OF FRUIT MASH

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

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

16. The fruit should preferably be de-stoned.

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

FERMENTATION

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

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

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

DISTILLATION EQUIPMENT

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

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

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

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

(d) When copper catalytic converters or other dedicated cyanide separators are not available, copper (I) chloride preparations can be added to the fermented fruit mash before distillation. The purpose of these preparations containing copper (I) ions is to bind hydrocyanic acid before it passes into the distillate. Copper (II) ions are without effect and should not be used.

22. While copper ions can inhibit formation of ethyl carbamate precursors in the mash and in the still, they can promote formation of ethyl carbamate in the distillate. Therefore, use of a stainless steel condenser at the end of the distillation device rather than a copper condenser will limit presence of copper in the distillate and reduce the rate of ethyl carbamate formation.

DISTILLATION PROCESS

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

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

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

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

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

CHECKS ON THE DISTILLATE, RE-DISTILLATION AND STORAGE

Hydrocyanic acid

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

29. If the concentration of hydrocyanic acid in the distillate exceeds a level of 1 mg/l, re-distillation with catalytic converters or copper preparations is recommended.

30. Distillates should be stored in bottles that are lightproof (or filter ultraviolet light) or in covering boxes and not at higher temperatures.

Ethyl carbamate

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

32. Additional distillation is effective in order to reduce ethyl carbamate in distillates.

GENERAL RECOMMENDATIONS

33. The national, state and local governments as well as the non-governmental organizations (NGOs, commercial associations and cooperatives) should provide their own basic training and update the information on mitigating ethyl carbamate in stone fruit distillates.

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

APPENDIX III

PROPOSED DRAFT MAXIMUM LEVELS FOR MELAMINE IN FOOD

(LIQUID INFANT FORMULA)

(FOR ADOPTION AT STEP 5/8)

Product Name	ML (mg/kg)
Liquid infant formula (as consumed)	0.15 **Note** The maximum level does not apply to liquid infant formula for which it can be proven that the level of melamine higher than 0.15 mg/kg is the consequence of migration from food contact materials taking into account any nationally authorized migration limit

APPENDIX IV

PROJECT DOCUMENT

PROPOSAL FOR NEW WORK ON A MAXIMUM LEVEL FOR ARSENIC IN RICE

1. The purpose and scope of the project

This project aims to establish a maximum level for arsenic in rice.

2. Relevance and timeliness

Arsenic was evaluated by JECFA at its 10th, 27th, 33rd and 72nd meetings. Arsenic has organic and inorganic species, of which the inorganic form is the most toxic. Inorganic arsenic has been evaluated on a number of occasions by IARC (1973, 1978, 1980, and 2004).

At its 33rd meeting in 1988, JECFA assigned a provisional tolerable weekly intake (PTWI) of 15 μg/kg bw for inorganic arsenic. In 2010, the 72th meeting of JECFA assessed the levels and patterns of arsenic contamination in food commodities, including in rice, on the basis of occurrence data from the literature and from data submitted by Australia, Brazil, France, Japan, New Zealand and Singapore. An inorganic arsenic exposure assessment conducted by JECFA indicated that the PTWI of 15 μg/kg bw (equivalent to 2.1 μg/kg bw per day) is in the region of the BMDL0.5 (3.0 μg/kg bw per day with the range of 2–7 μg/kg bw per day) from lung cancer epidemiological studies and therefore was no longer appropriate. The Committee withdrew the previous PTWI.

Therefore, there is a need for an international regulatory level, based upon scientific evidence, having as its goal the protection of human health with a minimum of economic impact on international trade.

3. The main aspects to be covered

It is proposed to establish a maximum level for arsenic in rice, considering the following:

a) Toxicological evaluations of arsenic by JECFA

b) The availability of sufficient occurrence and exposure data in rice

c) Consumption in g/day for rice as given by 13 GEMS/Food Consumption Cluster Diets and additional information on national consumption data for rice

d) New data from Codex members.

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

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

The new work will establish a maximum level for arsenic in rice.

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

The new work will provide an internationally-harmonized standard.

Rice is a staple food in many countries, and international market potential has been increasing.

5. Relevance to Codex Strategic Goals

The proposed work falls under the following Codex Strategic Goals:

Goal 1. Promoting sound regulatory frameworks

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

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

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

Goal 3. Strengthening Codex work-management capabilities

The establishment of a maximum level for arsenic in rice is a way to manage risks associated with the consumption of highly-contaminated staple food.

Goal 4. Promoting maximum application of Codex standards

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

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

This new work is recommended in the Discussion Paper on a Maximum Level for Arsenic in rice presented and discussed at the 5th Session of Codex Committee on Contaminants in Foods.

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

It is not foreseen.

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

None

9. The proposed time line for completion of the new work, including the starting date, proposed date for adoption at Step 5 and the proposed date for adoption by the Commission

1. Subject to approval by the Commission, the proposed draft Maximum Level for Arsenic in rice will be considered by the 6th Session of the CCCF with a view to its finalization in 2013.

APPENDIX V

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

Contaminants and naturally occurring toxicants	*Background and Question(s) to be answered*	*Data availability (when, what)*	*Proposed by*
3-MCPD esters	Full evaluation (toxicological assessment and exposure assessment)	Germany: end 2011 (occurrence) Japan: subchronic toxicity test and occurrence end 2013 China: Total Diet Study on 3-MCPD esters+glycidyl ester available Canada planned surveillance study, by end 2011	Germany, supported by EC, Canada, Japan
Glycidyl esters	Full evaluation (toxicological assessment and exposure assessment) Bioavailability of free compounds	Bioavailability studies on-going Limited occurrence data available Germany: no data yet, analytical method under development, data not before end 2012 Canada planned surveillance study, by end 2011 United States of America: data will be available before end of 2012	Germany, USA,

Contaminants and naturally occurring toxicants	*Background and Question(s) to be answered*	*Data availability (when, what)*	*Proposed by*
Pyrrolizidine alkaloids (PAs)	Identify most relevant PAs (occurrence and toxicity) for human health Full risk assessment Identify of data gaps Consideration of PAs in feed as it carries over from feed to animal products	All data collected by the eWG Australia additional toxicological data end of 2011 EU: on-going occurrence data collection (DATEX unit of EFSA	CCCF
Non dioxin-like PCBs	Full risk assessment	Canada, data from total diet studies, monitoring data	Republic of Korea; Canada

APPENDIX VI

Nomination of new substances for the Priority List of Contaminants and Naturally Occurring Toxicants for evaluation by JECFA

1. Basic information

1) Proposal for inclusion submitted by:

2) Name of compound; chemical name(s):

3) Identification of (additional) data (toxicology, metabolism, occurrence, food consumption) which could be provided to JECFA:

4) List of countries where surveillance data are likely to be available, and if possible list of contact person who could provide such data, including quality assurance information on the data.

5) Timeline for data availability:

2. Detail information

1) Whether or not the occurrence of the compound in commodities will have potential to cause public health and/or trade problems;

2) Whether or not commodities containing the compound are in international trade and represent a significant portion of the diet; and,

3) Commitment that a dossier (as complete as possible) will be available for evaluation by the JECFA.

4) Relevant justification and information on the following prioritization criteria[1]

- Consumer protection from the point of view of health and prevention of unfair trade practices;
- Compliance with CCCF's Terms of Reference;
- Compliance with JECFA's Terms of Reference;
- Compliance with the Codex Alimentarius Commission's Strategic Plan, its relevant plans of work and Criteria for the Establishment of Work Priorities;
- The quality, quantity, adequacy, and availability of data pertinent to performing a risk assessment, including data from developing countries;
- The prospect of completing the work in a reasonable period of time;
- The diversity of national legislation and any apparent impediments to international trade;
- The impact on international trade (i.e., magnitude of the problem in international trade);
- The needs and concerns of developing countries; and,
- Work already undertaken by other international organizations.

[1] Section 3, para.20 of the Risk Analysis Principles Applied by the Codex Committee on Food Additives and the Codex Committee on Contaminants in Foods (See Procedural Manual of the Codex Alimentarius Commission).