CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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REP12/CF

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

35th Session
Rome, Italy, 2-7 July 2012

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

Maastricht, The Netherlands,
26 – 30 March 2012

NOTE: This report includes Codex Circular Letter CL 2012/7-CF

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To: Codex Contact Points
Interested International Organizations

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Subject: DISTRIBUTION OF THE REPORT OF THE SIXTH SESSION OF THE CODEX COMMITTEE ON CONTAMINANTS IN FOODS (REP12/CF)

The Report of the Sixth Session of the Codex Committee on Contaminants in Foods is attached. It will be considered by the Thirty-fifth Session of the Codex Alimentarius Commission (Rome, Italy, 2-7 July 2012).

PART I: MATTERS FOR ADOPTION BY THE 35TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION

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

1. Draft Maximum Levels for Melamine in Food (*Liquid infant formula)* (para. 58, Appendix V); and
2. Proposed Draft Maximum Levels for Total Aflatoxins in Dried Figs and Associated Sampling Plan (para. 82, Appendix VI).

Other matters for adoption

3. Risk Analysis Principles Applied by the Codex Committee on Contaminants in Foods (para. 22, Appendix II);
4. Revision of the *Code of Practice for Source Directed Measures to Reduce Contamination of Food with Chemicals* (CAC/RCP 49-2001) (para. 33, Appendix III); and
5. Revised Definiton of Contaminant (para. 33, Appendix IV)

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 2012.

PART II: REQUEST FOR COMMENTS AND INFORMATION

6. Priority List of Contaminants and Naturally Occurring Toxicants for Evaluation by JECFA (para. 163, Appendix IX)

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. 163 and presented in Appendix XI 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 XII 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 2013.

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SUMMARY AND CONCLUSIONS

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

MATTERS FOR ADOPTION/CONSIDERATION BY THE 35TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION

Proposed Draft Standards and Related Texts for Adoption

The Committee agreed to forward:

- Risk Analysis Principles Applied by the Codex Committee on Contaminants in Foods (para. 22, Appendix II);
- Revision of the *Code of Practice for Source Directed Measures to Reduce Contamination of Food with Chemicals* (CAC/RCP 49-2001) (para. 38, Appendix III);
- Revised Definition of Contaminant (para. 38, Appendix IV);
- Draft Maximum Levels for Melamine in Food (*Liquid Infant Formula)* (para. 58, Appendix V);
- Proposed Draft Maximum Level for Total Aflatoxins in Dried Figs (including sampling plan) (para. 82, Appendix VI)

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:

- Code of Practice for Weed Control to Prevent and Reduce Pyrrolizidine Alkaloid Contamination in Food and Feed (para. 114, Appendix VII);
- Revision of the Maximum levels for lead in fruit juices, milk and secondary milk products, infant formula, canned fruits and vegetables, fruits and cereal grains (except buckwheat, cañihua and quinoa) in the *General Standard for Contaminants and Toxins in Food and Feed* (para. 127, Appendix VIII);
- Annex for Prevention and Reduction of Afatoxins and Ochratoxin A in Sorghum to the *Code of Practice for Prevention and Reduction of Mycotoxin Contamination in Cereals* (CAC/RCP 51-2003) (para. 136, Appendix IX);
- Code of Practice for the Prevention and Reduction of Ochratoxin A contamination in Cocoa (para. 141, Appendix X);
- Code of Practice to Reduce the Presence of Hydrocyanic Acid in Cassava (para. 165);
- Proposed Draft Maximum Levels for Cassava and Cassava Products (para. 165);
- Proposed Draft Levels for Radionuclides in Food (para. 169).

Revocation of Standards

- The Committee agreed to recommend the revocation of Guideline Levels for Vinyl Chloride Monomer and Acrylonitrile in Food and Packaging Material (CAC/GL 6-1991) (para. 106).

Matters of Interest to the Codex Alimentarius Commission

The Committee:

- Agreed to hold at Step 4 the Proposed Draft Maximum Levels for Arsenic in Rice until further data became available and to explore through a discussion paper the development of a code of practice for arsenic in rice (para. 65);
- agreed to return the Proposed Draft Maximum Levels for DON in cereals and cereal-based products and associated sampling plans to Step 2 for redrafting, comments and consideration at its next session (para. 77);
- agreed to suspend work on fumonisins in maize and maize-products and to explore through a discussion paper whether there were gaps in the *Code of Practice for Prevention and Reduction of Mycotoxin Contamination in Cereals* and the need for a separate code of practice for fumonisins in maize and any other measures to control fumonisins in maize (paras. 92 – 96).
- agreed to continue discussion on editorial amendments to the GSCTFF to the next session (para. 105);
- agreed to develop discussion papers on risk management options for pyrrolizidine alkaloids in foods (para. 115), methylmercury in fish and predatory fish (para. 174), and aflatoxins in cereals (para. 175); and
- 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. 163, Appendix XI).

Matters of Referred to Codex Committees and Task Forces

Executive Committee of the Codex Alimentarius CommissionCommittee on Methods of Analysis and Sampling (CCMAS)

– The Comittee agreed to request CCMAS to identify suitable methods of analysis for the determination of inorganic arsenic in rice in order to assist the CCCF to establish MLs for arsenic in rice (para. 63).

Committee on General Principles (CCGP)

– The Committee agreed to inform CCGP of the Revision of Risk Analysis Principles Applied by the Codex Committee on Contaminants in Foods and the revision of the definition of contaminant, respectively (paras 22 and 38).

– The Committee agreed to request CCGP to explore ways to make information and other similar documents available in the Codex system (para. 157).

INTRODUCTION

1. The Codex Committee on Contaminants in Foods (CCCF) held its 6th session in Maastricht (the Netherlands) from 26 to 30 March 2012, at the kind invitation of the Government of the Netherlands. Mr. Martijn Weijtens, Head of Unit, Department for Animal Supply Chain and Animal Welfare, Ministry of Economic Affairs, Agriculture and Innovation, the Netherlands, chaired the meeting. The Session was attended by 183 delegates representing 58 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. Mr. Kees Lever, Director Plant Supply Chain and Food Quality Department of the Ministry of Economic Affairs, Agriculture and Innovation, welcomed the participants and opened the session on behalf of the Minister of Agriculture.

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 fumonisins after finalizing Item 7.

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 United States of America (Item 10) and to establish an in-session Working Group on follow-up on the results of JECFA evaluations and on new work under the chairmanship of the European Union with the understanding that the report would be discussed under Item 11.

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

6. The Committee noted the information provided in the working document.

REVISION OF THE RISK ANALYSIS PRINCIPLES APPLIED BY THE CODEX COMMITTEE ON FOOD ADDITIVES AND THE CODEX COMMITTEE ON CONTAMINANTS IN FOODS AS TO THEIR SEPARATION FROM THE CODEX COMMITTEE ON FOOD ADDITIVES AND THEIR APPLICABILITY TO FEED (Agenda Item 2b)[4]

7. The Delegation of the Netherlands, as Chair of the Electronic Working on the revision of the Risk Analysis Principles applied by the Committee on Food Additives and the Committee on Contaminants, introduced the item and recalled that the work focused on the separation of the risk analysis principles for CCCF from those of CCFA and the consideration of the proposals to make the principles more explicit with regard to feed as per the recommendations contained in Annex 1 of CX/CF 11/5/2 including updating of the terminology which were considered to be of editorial nature.

8. The Delegation further explained that some key discussion points needed further consideration by the Committee, namely whether adulteration should be dealt with in the Principles and whether there were different approaches for levels of contaminants in animal products originating from feed as to their consideration in human exposure assessments or for the establishment of MLs in feed, which needed to be specified in the Principles.

9. The Committee decided to first focus its discussion on the editorial amendments and took the following decisions:

Section 1 Scope

10. The Committee noting that in some instances where urgent risk management decisions were necessary e.g., in the case of melamine, scientific advice was not necessarily only from JECFA, but also from other sources, and therefore amended paragraph 1 accordingly and consequentially, paragraph 17.

11. For consistency with the General Standard for Contaminants and Toxins in Food and Feed, the Committee agreed to refer also to toxins in addition to contaminants in paragraph 3. The paragraph was further amended to specify the applicability of the risk analysis principles to feed and reference to “food-producing animals” was deleted as this was already covered by the footnote.

12. In paragraph 8, the Committee considered a proposal to retain the original provision as it related to the minimum quality criteria for data and not to requirements for data availability which were two different aspects. The JECFA Secretariat clarified that the important point related to data requirement and that quality criteria were part of the requirements. In view of this clarification, the Committee agreed to leave the paragraph as proposed by the working group.

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1 CRD 1 (Annotated Agenda – Division of competence between the European Union and its Member States).
2 CX/CF 12/6/1.
3 CX/CF 12/6/2.
4 CX/CF 12/6/3. CRD 7 (Comments of the USA); CRD 8 (Comments of the EU); CRD 11 (Comments of Ghana); CRD 12rev (Comments of Japan); CRD 21 (Comments of India); and CRD 25 (Comments of Cameroon).

13. The Committee considered whether to refer to risk assessment policy at the end of the first sentence in paragraph 11. The JECFA Secretariat clarified that defining the scope of the risk assessment and defining risk assessment policies were not the same, but when defining the scope of risk assessment policy guidance should be included. Based on this clarification the Committee agreed to retain the proposed revision.

14. The Committee agreed to not refer to impact assessment in paragraph 12 and to retain the original text. The Committee noted that impact assessment refers to a task of a risk manager where all potential impacts of a proposed risk management measure have to be evaluated not only in relation to reduction of health risks, but also to economic impact. By giving a task of impact assessment to JECFA, it could create the impression that JECFA should evaluate non public health consequences which was not their role. Consequential amendment was therefore also made to paragraph 30.

15. The Committee agreed to re-insert "independence" as this was an important attribute that contributed to the credibility and transparency of the JECFA risk assessment methodology, and noted that the rest of the proposed changes were in line with the procedures followed by JECFA when selecting experts.

16. In paragraph 26, the Committee agreed to insert "constraints, uncertainties and assumptions" for consistency with similar provisions in the Working Principles for Risk Analysis applied within the Framework of Codex.

Adulteration and its relation to the work of the Committee

17. The Committee discussed how to approach the issue of adulteration and whether this should be included in the principles.

18. It was noted that adulteration was a rather broad term, but that it could be understood in the context of the Committee where adulteration may lead to a level of a contaminants that may endanger human health.

19. It was also noted that the Committee had previously dealt with adulteration in the case of melamine which was to establish maximum levels for melamine in food and feed products to distinguish adulterated product from levels resulting from non-intentional and unavoidable presence from different sources.

20. The Committee agreed that adulteration in cases similar to those of melamine were adequately covered by its terms of reference however, in order to make it more explicit in the Principles, it agreed to include a separate paragraph with relevant provisions following paragraph 17.

Different approaches for contaminants in animal products originating from feed

21. The Committee agreed that there was no need to address this issue in the Principles.

Conclusion

22. The Committee agreed to forward the proposed revised Risk Analysis Principles Applied by the Codex Committee on Contaminants in Foods to the 35th Session of the Codex Alimentarius Commission for adoption and to inform the Codex Committee on General Principles accordingly (Appendix II).

REVISION OF THE CODE OF PRACTICE FOR SOURCE DIRECTED MEASURES TO REDUCE CONTAMINATION OF FOOD WITH CHEMICALS AS TO THEIR APPLICABILITY TO FEED (Agenda Item 2c)[5]

23. The Delegation of the Netherlands, as lead country of the electronic working on the revision of the Code of Practice for Source Directed Measures to Reduce Contamination of Food with Chemicals as per their applicability to feed, informed the Committee that the inclusion of references to feed were in line with the proposals recommended in Annex 2 of CX/CF 11/5/2 were considered to be of editorial nature. The Delegation further informed the Committee that, in addition to the editorial changes, there were some additional questions related to the responsibility for feed additives within Codex and the need for a direct relation to scientific proof for food safety impact of contaminants in feed and whether this should be addressed in the Code of Practice.

24. The Committee first focused its discussion on the editorial amendments and made the following decisions:

25. The Committee agreed to refer to "food" and "feed" as opposed to "foodstuff" and "feedingstuff" for consistency.

26. In paragraph 4, the Committee agreed to replace "never" with "not" as more achievable since practical approaches would not always be able to ensure levels of chemical contaminants were below the maximum levels considered tolerable to ensure food safety. A consequential amendment was done along these lines in the first sentence of paragraph 5.

27. The Committee further agreed to introduce two separate entries to differentiate between measures to identify and separate contaminated food and feed that may ultimately enter the human food/feed chain from food/feed fit for human/livestock consumption/feeding. In view of this, the paragraph following the last bullet was rephrased for clarity.

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5 CX/CF 12/6/4. CRD 7 (Comments of the USA); CRD 8 (Comments of the EU); CRD 10 (Comments of Thailand); CRD 19 (Comments of Indonesia); CRD 20 (Comments of Malaysia); CRD 21 (Comments of India); and CRD 25 (Comments of Cameroon).

28. In addition, the Committee considered a proposal to delete the reference to "feed" as it would imply that contaminant levels in food as well as feed should be as low as reasonably achievable whereas the ALARA Principle was not applicable to feed and could result in a non-tariff trade barrier. The Committee however agreed to retain the applicability of the ALARA to feed as the General Standard for Contaminants and Toxins in Food and Feed already limited the application of ALARA to contaminants in feed that can be transferred to food of animal origin and can relevant for public health.

29. In order to reinforce the fact that consideration of feed in the code was in relation to their relevance to food safety the Committee agreed to include the word "in respect of food safety" where appropriate.

30. In paragraph 5, the Committee agreed to refer to "food batch" to differentiate from "feed batch".

31. In paragraph 6, the Committee agreed to rephrase the last sentence to strengthen that food quality and safety should be maintained throughout the food chain.

32. In paragraph 7, the Committee agreed to amend the last bullet point to provide for flexibility in the application of this provision.

Codex responsibility for feed additives

33. The Committee considered the question on whether it should be the responsibility of the CCCF to deal with the issues related to feed additives/feed additive residues.

34. In this regard, the Committee considered a revised definition of contaminant as proposed by the working group which includes a reference to feed to make more clear that the definition of contaminant applies to food and feed for consistency with the terms of reference and the scope of the GSCTFF.

35. In this regard, the Committee noted that the terms of reference of the Committee on Residues of Veterinary Drugs in Foods covered feed additives when establishing maximum residue limits for veterinary drugs in food of animal origin arising from the addition of veterinary drugs to feed (i.e. medicated feed) and that the same applied when establishing maximum residue limits for pesticides as a result of phytosanitary treatments. In addition, the Committee noted the view of several delegations that any feed additive/feed additive residues that may result in its unavoidable / unintentional presence in food due to the carry over of the substance from the feed into food being relevant to food safety was already covered by the definition of contaminant. Based on these considerations, the Committee agreed with the revised definition of contaminant as proposed by the working group.

36. The Delegation of Japan indicated that the inclusion of "or feed" in the revised definition of contaminant, which referred to "contaminant" as any substance "not intentionally" added to food "or feed", introduced a discrepancy between the definition and section 1.2.2 of the General Standard for Contaminants and Toxins in Food and Feed which did not explicitly exclude feed additives (intentionally added to feed) from the indicated application of the term "contaminant" as opposed to compounds governed by other Codex committees such as pesticide or veterinary drugs residues. The Delegation further noted that, if the definition of contaminant would be limited to the "unintentional/unavoidable" presence of substance in foods and "feed", the scope of the preamble in the GSCTFF would still allow for interpretation that feed additives "intentionally" added to feed are covered by the definition of contaminant as not explicitly excluded in the list as other substances like veterinary drugs and pesticide residues.

Specification of the need for a direct relation and scientific proof of food safety impact for feed in the Code of Practice

37. Based on the above considerations, in particular those related to the application of ALARA to feed in paragraph 4, the Committee agreed that there was no need to specify the direct relation and scientific proof of food safety impact for feed in the Code of Practice.

Conclusion

38. The Committee agreed to forward the proposed revised Code of Practice for Source Directed Measures to Reduce Contamination of Food with Chemicals (applicability to feed) and the proposed revised definition of contaminant to the 35th Session of the Codex Alimentarius Commission for adoption and to inform the Codex Committee on General Principles accordingly (Appendices III and IV).

MATTERS OF INTEREST ARISING FROM FAO AND WHO: FAO AND WHO ACTIVITIES IN THE AREA OF PROVISION OF SCIENTIFIC ADVICE INCLUDING CAPACITY BUILDING ACTIVITIES RELEVANT TO THE WORK OF THE CODEX COMMITTEE ON CONTAMINANTS IN FOODS (Agenda Item 3a)[6]

39. The JECFA Secretariat summarized the information provided in the working paper as follows:

6 CX/CF 12/6/5; and CX/CF 12/6/5-Add.1.

74TH JECFA MEETING

Cyanogenic glycosides

40. Cyanogenic glycosides, compounds naturally occurring in plants such as cassava, in particular, when underprocessed can form cyanide at levels that are of health concern. Acute poisoning in humans as well as several chronic diseases associated with underprocessed cassava consumption have been reported. Hence JECFA identified the need to set an acute reference dose and a chronic health-based guidance value. An ARfD of 0.09 mg/kg of body weight was established, expressed as cyanide and applicable to foods containing cyanogenic glycosides as the main source of cyanide. A PMTDI of 0.02 mg/kg of body weight, as cyanide, was also established. Estimates of dietary exposure, assuming total conversion to cyanide, resulted in a possible exceedance of the acute ARfD by 2 to 10-fold, depending on the food and age group considered. For the chronic consumption, the PMTDI could be exceeded by 1 to 5-fold, depending on food and age-group considered. These estimates do not take into consideration any reduction in concentration of total HCN as a result of food preparation or processing. The ML for sweet cassava is for the raw product. If the starting level of HCN in the raw sweet cassava were 50 mg/kg as HCN, the minimum effective processing would result in a concentration of 15 mg/kg as HCN, and the most effective processing would give a HCN concentration of 2 mg/kg.

Fumonisins

41. In the re-evaluation of fumonisins JECFA considered all new data since the last evaluation in 2001. A PMTDI of 2 ug/kg of body weight was derived from new data. As this was the same value as the previously established group PMTDI for FB1, FB2 and FB3, alone or in combination, this group PMTDI was retained. Dietary exposure estimates indicate an exceedance of this value at the population level in certain regions within some countries representing high maize consumption and highly contaminated maize. Since adverse effects from fumonisin exposure may occur, reduction of exposure is highly desirable, particularly in areas of the world where maize is a major dietary staple food and where high contamination can occur. As fumonisins do not carry over from feed to animal products in significant amounts, occurrence of fumonisins in feed was not a human health concern. Implementation of proposed Codex MLs could significantly reduce exposure.

CAPACITY BUILDING ACTIVITIES RELEVANT TO THE WORK OF THE CCCF

Mycotoxin in Sorghum

42. The WHO representative informed the Committee on the project funded through the Codex Trust Fund on the data collection on mycotoxins in sorghum. The representative reiterated the background to the project, to fill in data gaps identified in previous discussion papers on the subject, and reiterated the three objectives of the project as described in document CX/CF 12/6/5-Add.1. The four African countries selected for the project were selected on the basis of being major sorghum producing and consuming countries as well as having the infrastructure and accessibility to perform the project. WHO and FAO regional officers are in contact with respective countries to set up the project, which is intended to provide a final report in 2013. The funds for the project, provided by the EU to the Codex Trust Fund are limited and hence selections with respect to countries, number of samples, and number of mycotoxins to be analysed are limited. The discussion paper on mycotoxins and mycotoxin producing fungi in sorghum prepared for this session, as well as previous discussion papers on the topic, provide important information to guide the project. It was emphasized that the project is intended to fill some data gaps, and in combination with all the information already compiled should enable the Committee to take decisions on the appropriate course of action.

Tool to guide sampling plans for mycotoxin detection

43. FAO is investigating the feasibility of developing a tool to assist in the design and characterization of performance of sampling plans for mycotoxin detection. The first step will be the collection of existing mycotoxin contamination data (including specific mycotoxin-commodity combinations, seasonal and regional variations, etc.) to set up a database that will serve as the basis for the development of the tool. FAO in collaboration with various research institutes and other international organizations has started collecting mycotoxin contamination data.

OTHER MATTERS

44. Reference was made to a list of recent publications of JECFA evaluations[7] as listed in document CX/CF 12/6/5, including the publication of the full report on the FAO/WHO Expert Consultation on the Risks and Benefits of Fish Consumption[8].

45. The Committee recalled that at its last session it agreed to consider the need to review the existing guideline levels (GLs) for methylmercury in fish and predatory fish in the General Standard for Contaminants and Toxins in Food and Feed when the full report of the Joint FAO/WHO Expert Consultation on the Risks and Benefits of Fish Consumption became available. In view of the information provided by the JECFA Secretariat, the Committee agreed that the in-session Working Group on follow-up on the results of JECFA evaluations and on new work would take up this matter in order to make recommendations for consideration by the Committee under Item 11.

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7 http://www.who.int/foodsafety/chem/jecfa/publications/en/index.html.

8 http://www.fao.org/docrep/014/ba0136e/ba00.pdf

46. The JECFA Secretariat informed the Committee on the recent publication of guidance for application of risk analysis during food safety emergencies[9]. This guidance contains the essential elements for establishing procedures for assessing and managing risks within the framework of national food safety emergency response plans, and forms part of a series to be compiled within the work of INFOSAN (International Food Safety Authorities Network) to assist countries in food safety emergencies.

47. The JECFA Secretariat then drew the attention to the very difficult financial situation that FAO and WHO are facing for the program on the provision of scientific advice. She emphasized that this scientific advice forms the basis for the work of Codex, and FAO and WHO are no longer in a position to respond to all requests for scientific advice to support the work of Codex. Efforts need to be undertaken by Member States to provide increased support to this program.

MATTERS OF INTEREST ARISING FROM OTHER INTERNATIONAL ORGANIZATIONS – International Atomic Energy Agency (Agenda Item 3b)[10]

48. The Committee noted the information contained in the working document, in particular, information on the 16th Meeting of the Interagency Committee on Radiation Safety (IACRS) which related to the low values for iodine in the guideline levels for radionuclides in foods could justify their revision in the General Standard for Contaminants and Toxins in Food and Feed.

49. The WHO Representative informed the Committee of the efforts undertaken by WHO to perform a preliminary health risk assessment following the Fukushima Daiichi nuclear power plant accident. Preliminary exposure assessments for populations in Japan as well as the rest of the world have been undertaken by an international expert panel, these assessments are now used by a second expert panel to perform health risk assessments. This work is undertaken in collaboration with other international organization.

50. The WHO representative also noted that after this accident several countries struggled with the interpretation and application of the guideline levels for radionuclides in foods contaminated following a nuclear or radiological emergency in the General Standard for Contaminants and Toxins in Food and Feed and that there may be some merit in looking into these guideline levels for possible revision and/or clarification.

51. In view of the above, the Committee agreed that the in-session Working Group on follow-up on the results of JECFA evaluations and on new work would take up this matter in order to make recommendations for consideration by the Committee under Item 11.

DRAFT MAXIMUM LEVELS FOR MELAMINE IN FOOD (*LIQUID INFANT FORMULA)* (Agenda Item 4)[11]

52. The Committee at its last session had agreed to forward to the Commission for adoption at Step 5/8, the ML of 0.15mg/kg for liquid infant formula with a 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 national authorized migration limit".* However, due to countries reservations and concerns with the note, the 34th Session of the Commission agreed to adopt the ML at Step 5, to advance it to Step 6 for comments and consideration by the Committee.

53. The Committee noted that there was wide support for the proposed ML. It was of the view of the Committee that the proposed draft ML was based on the good scientific background.

54. However the Committee did not support the inclusion of the note. Some delegations expressed concern with the note pointing out that migration of melamine from food contact materials was not regulated in their countries, and that if the note on exemption was included it would create problems determining whether or not the melamine came from the packaging.

55. Other delegations emphasized that liquid infant formula should not be packaged in melamine-based packaging materials taking into account that the product was for vulnerable infants. The concern was also expressed that keeping the note might favour the use of packages that contain melamine.

56. Some other delegations pointed out that many country data show that levels above proposed ML have not been found, and therefore considered the note not necessary.

57. In view of the discussion, the Committee agreed to set a level of 0.15 mg/kg for melamine in liquid infant formula as consumed without the note on the exemption from the ML.

STATUS OF THE PROPOSED DRAFT MAXIMUM LEVELS FOR MELAMINE IN FOOD (*LIQUID INFANT FORMULA*)

58. The Committee agreed to forward the proposed draft maximum level for liquid infant formula to the 35th Session of the Codex Alimentarius Commission for adoption at Step 8 (Appendix V).

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9 http://www.fao.org/docrep/014/ba0092e/ba0092e00.pdf.

10 CX/CF 12/6/6; and CRD 23 (comments of Japan).

11 REP11/CF, Appendix III; CX/CF 12/6/7 (comments at Step 6 in reply to CL 2011/16 from Australia, Brazil, Chile, Colombia, Costa Rica, Dominican Republic, New Zealand, Sri Lanka and Uruguay); CX/CF 12/6/7-Add.1 (additional comments at Step 6 of Benin, Egypt, EU, Ghana, Iran, Kenya, Mali, Nicaragua and USA); CRD 14 (comments of NHF); CRD 16 (comments of Costa Rica); CRD 17 (comments of Vietnam); CRD 18 (comments of Nigeria); CRD 19 (comments of Indonesia); CRD 20 (comments of Malaysia); CRD 21 (comments of India); CRD 22 (comments of Nicaragua); CRD 24 (comments of Philippines); and CRD 25 (comments of Cameroon).

PROPOSED DRAFT MAXIMUM LEVELS FOR ARSENIC IN RICE (Agenda Item 5)[12]

59. The Delegation of China, as lead country of the Electronic Working Group on Arsenic, introduced the document highlighting the main issues associated with the establishment of maximum levels for arsenic in rice as follows: Current data available allow for the establishment of maximum levels for arsenic in rice (raw) at 0.3 mg/kg for inorganic or total arsenic and rice (polished) 0.2 mg/kg for inorganic arsenic. If maximum levels for inorganic arsenic were to be set further data needed to be sourced as there is currently insufficient robust occurrence data to establish maximum levels for inorganic arsenic in rice (raw and processed). Validated analytical methods should also be identified in case maximum levels for inorganic arsenic were to be established and the Committee may wish to request the Committee on Methods of Analysis and Sampling to identify such methods. Consideration may also be given to the development of a code of practice identifying factors that may reduce inorganic arsenic contamination in rice and rice-based products.

60. Several delegations expressed the following views: maximum levels for arsenic in rice were necessary however more comprehensive occurrence data from different rice varieties and additional major producing countries were needed in particular for the most toxic form, i.e. inorganic arsenic, before proceeding with the establishment of MLs; the lack of internationally validated methods of analysis for the determination of inorganic arsenic was also a limiting factor to generate data on inorganic arsenic in rice; the JECFA PTWI for inorganic arsenic had been withdrawn therefore there is no health reference to estimate the risk for consumers' health. The uncertainties surrounding the estimation of the risk based on the allowance of a benchmark dose lower confidence limit (BMDL) did not provide for an adequate estimate of the risk to consumers health. Further, in terms of the principles for the establishment of MLs as set out in the Risk Analysis Principles and the Preamble of the General Standard for Contaminants and Toxins in Food and Feed, the lack of availability of data and methods of analysis for the determination and enforcement of MLs to complete the risk assessment did not provide enough grounds for the establishment of inorganic MLs at this point. These delegations favoured the collection of more data before proceeding with the elaboration of MLs, to request the CCMAS to identify internationally validated methods of analysis for inorganic arsenic in rice and the development of a code of practice that would identify good agricultural and manufacturing practices available for the reduction of inorganic arsenic contamination in rice (raw and processed).

61. Other delegations considered that there was sufficient robust data available at this moment to establish MLs for arsenic in rice and that, if further data collection would be considered necessary, it should focus on occurrence data for inorganic arsenic in rice (raw and processed). It was noted that the MLs proposed in the working document could be set for inorganic arsenic and that total arsenic could be measured as a screening method and that exceedance from the MLs be confirmed by determining the level of inorganic arsenic. It was further noted that a similar approach was already taken to establish MLs for methylmercury in fish. In this regard, it was noted that the JECFA report already made available suitable methods of analysis for the determination of inorganic arsenic although validation studies were still ongoing at international level.

62. The JECFA Secretariat clarified that a detailed risk assessment has in fact been completed, and the PTWI withdrawn because it was no longer considered to be health protective. Arsenic causes cancer in humans, and the risk assessment, based on human data, resulted in the conclusion that the previous PTWI is in the range of potential low effect levels in humans. She noted that arsenic is a public health problem and therefore measures need to be taken to reduce arsenic exposure. JECFA had identified rice, in areas where this is a staple food, as one of the main contributors to dietary exposure together with drinking water. JECFA considered about 1800 results for total arsenic and about 900 results for inorganic arsenic in rice. Regarding analytical methods, she noted that a number of validated methods for inorganic arsenic are available, however these are complex and may not be available for routine monitoring in some countries. In analogy to approaches taken for mercury, the possibility to measure total arsenic for routine monitoring, and in case where it exceeds the proposed MLs a follow up with specific methods for inorganic arsenic could be considered.

63. Based on the above considerations, the Committee agreed that CCMAS should be requested to identify suitable methods of analysis for the determination of inorganic arsenic in rice in order to assist the Committee in the establishment of MLs; that a discussion paper considering the possibility to develop a Code of Practice to Control for the Prevention and Reduction of Arsenic Contamination in Rice should be prepared for consideration by the next session of the Committee; and that member countries, especially rice-producing countries, should provide occurrence data on inorganic arsenic contamination of rice to GEMS/Food[13] in order to allow the Committee to resume the discussion on the MLs at its 8th Session (2014). In this regard, the Committee recalled that work on the establishment of MLs for arsenic in rice had already been approved by the 34th Session of the Commission (2011) and that the timeline for completion of work was the 7th Session of the Committee (2013).

64. The Committee further agreed that an electronic working group chaired by China and co-chaired by Japan, working in English only and open to all Codex members and observers, would prepare a discussion paper on the possibility to develop a code of practice. In addition, China would prepare proposals for maximum levels for inorganic arsenic in rice (raw and processed) for consideration by the 8th Session of the Committee based on additional data provided by that time to GEMS Food.

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12 CX/CF 12/6/8; CX/CF 12/6/8-Add.1 (comments of Benin, Colombia, Costa Rica, Cuba, Egypt, EU, Indonesia, Japan, Kenya, Mali, Thailand and USA); CRD 13 (comments of China); CRD 15 (comments of Republic of Korea); CRD 17 (comments of Vietnam); CRD 18 (comments of Nigeria); CRD 21 (comments of India); CRD 24 (comments of Philippines); and CRD 25 (comments of Cameroon).

13 For information please contact vergerp@who.int

STATUS OF THE PROPOSED DRAFT MAXIMUM LEVELS FOR ARSENIC IN RICE

65. The Committee agreed to retain at Step 4 the proposed draft maximum levels for inorganic or total arsenic in rice (raw) at 0.3 mg/kg and inorganic arsenic in rice (polished) at 0.2 mg/kg until the Committee resumed the consideration of this matter at its 8th Session based on the outcome of proposals to be prepared by China and to inform the Executive Committee accordingly.

PROPOSED DRAFT MAXIMUM LEVELS FOR DEOXYNIVALENOL (DON) IN CEREALS AND CEREAL-BASED PRODUCTS AND ASSOCIATED SAMPLING PLANS (Agenda Item 6)[14]

66. The Delegation of Canada, as lead country of the electronic Working Group, introduced item and highlighted the recommendations of the working group, in particular, the MLs for raw cereal grains, semi-processed products and cereal-based foods for infants and young children and associated sampling plans, as presented in the CX/CF 12/6/9. The Delegation further informed the Committee that it had been tasked with assessing the possibility of revising the *Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals* (CAC/RCP 51-2003), that very few comments had been received in this regard and that no proposal was being made for its revision at this point.

67. The Committee recalled its earlier decision to establish MLs for DON in cereals and cereal-based products and considered whether the three categories and their MLs as recommended by the working group were appropriate.

68. Many delegations supported the establishment of MLs for raw cereal grain, although a delegation requested clarification on what was understood by wheat and whether it included common and durum wheat or only common wheat. In supporting the establishment of an ML for raw cereal grain, delegations pointed out that establishing MLs for the unprocessed product was necessary to achieve the desired ML of semi-processed products. Many of those delegations that supported establishing an ML for this category also supported the proposed level of 2 mg/kg. Some other delegations and an observer questioned the need to establish an ML for raw cereal grains, pointing out that milling could substantially reduce DON levels and that setting of MLs could be trade restrictive. It was also noted that occurrence levels varied from variety to variety and showed seasonal and regional variation.

69. There was general support for establishing MLs for semi-processed products. However, taking into account the significant differences as regards the presence of DON in different semi-processed products, it was questioned whether one general ML could apply to all semi-processed products or whether there was a need to further categorize semi-processed products and to set separate MLs for each of these categories. With regard to the proposed ML, many delegations supported the level of 1 mg/kg.

70. Some delegations supported establishment of an ML for cereal-based infant foods noting that infants were a particularly vulnerable group. Other delegations questioned the need for cereal-based infant foods to be included, pointing out that the JECFA evaluation had not considered cereal-based infant foods and some questioned their relevance from a trade perspective. For those delegations who supported the establishment of an ML for this category, there was general agreement that a lower level should be established. Some delegations supported the ML of 0.5 mg/kg while some proposed levels ranging from 0.2 mg/kg to 0.3 mg/kg. It was noted that with GMP, lower levels were achievable.

71. A delegation proposed that more time be given for the implementation of the COP to allow further more data collection on the occurrence of DON in cereals before MLs for DON could be elaborated.

Sampling plan

72. The Committee agreed that the same sampling format as the sampling plan for tree nuts should be followed and that it should consequently include operational characteristics curves.

Conclusion

73. In view of the discussion, the Committee agreed to re-establish the electronic working group, led by Canada and co-chaired by the European Union, working in English only, to redraft the proposals for ML for DON and its associated sampling plan, taking into account the discussions and decisions above, for circulation for comments and consideration by the next session.

Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals

74. The Committee noted that there was no need to revise this Code at this stage as it was still valid and relevant.

MLs for Acetylated derivatives of DON in cereals

75. A delegate proposed that the work of the electronic Working Group should also include establishment of MLs for acetylated derivatives of DON, since the 33rd Session of CCMAS had noted that it was impossible to identify methods for acetylated derivatives of DON because no fully validated method of analysis was available and that for a maximum level it was necessary to identify an appropriate method of analysis. This reply from CCMAS was in response to the request of the 5th Session of the Committee to identify methods for acetylated derivatives of DON. The Committee however recalled its previous decision that work should proceed on MLs for DON and that it would at the 8th Session of the Committee consider the extension of the ML to acetylated derivatives of DON.

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[14] CX/CF 12/6/9; CX/CF 12/6/9-Add.1 (comments of Costa Rica, EU, Japan, Kenya and USA); CX/CF 12/6/9-Add.2 (comments of Egypt); CRD 12rev (comments of Japan); CRD 13 (comments of China); CRD 15 (comments of Republic of Korea); CRD 18 (comments of Nigeria); CRD 19 (comments of Indonesia); CRD 24 (comments of Philippines); and CRD 25 (comments of Cameroon).

76. In this regard, the Committee recalled that work on the establishment of MLs for DON in cereals and cereal-based products had already been approved by the 33rd Session of the Commission (2010) and that the timeline for completion of work was this Session of the Committee.

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

77. 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.

78. The Committee agreed to inform the Executive Committee accordingly.

PROPOSED DRAFT MAXIMUM LEVELS FOR TOTAL AFLATOXINS IN DRIED FIGS INCLUDING SAMPLING PLANS (Agenda Item 7)[15]

79. The Committee recalled that at its last session there was wide support for the proposed Maximum Level of 10 µg/kg but that it was not possible to agree with the proposed ML without having full clarity about the sampling plan and had agreed to return the Proposed Draft ML for Dried Figs to Step 2/3 so that the sampling plans according to the proposed ML could be developed for consideration by this session of the Committee.

80. The Delegation of Turkey, as Chair of the electronic Working Group on Dried Figs, introduced the proposed revised sampling plan for the proposed draft ML for total aflatoxins in dried figs, as presented in CRD 26.

81. The Committee agreed on the proposed draft ML of 10 µg/kg and associated revised sampling plan with a deletion of the reference to "edible portion" in paragraph 44 of the sampling plan as all portions of dried figs were edible.

STATUS OF THE PROPOSED DRAFT MAXIMUM LEVELS FOR TOTAL AFLATOXINS IN DRIED FIGS INCLUDING SAMPLING PLANS

82. The Committee agreed to forward the Proposed Draft ML of 10 µg/kg for Dried Figs including the sampling plan to the 35th Session of the Codex Alimentarius Commission for adoption at Step 5/8 (with omission of Steps 6 and 7) (Appendix VI).

PROPOSED DRAFT MAXIMUM LEVELS FOR FUMONISINS IN MAIZE AND MAIZE-PRODUCTS AND ASSOCIATED SAMPLING PLANS (Agenda Item 7bis)[16]

83. The Committee recalled that its 4th Session agreed to hold the proposed draft MLs for fumonisins in maize and maize products at Step 4 until advice was provided by JECFA. In view of the evaluation of fumonisins by the 74th meeting of JECFA (see Item 3a), the Committee was now in a position to determine how to proceed with the MLs. The Committee noted that Brazil had prepared a discussion paper to facilitate the discussion.

84. The Delegation of Brazil introduced the proposals in CX/CF 12/6/18 and informed the Committee that it had updated the previous paper presented to the Committee (CX/CF 10/4/8) and had included the information and recommendations of the evaluation of JECFA. In developing the paper, comments provided to the 4th CCCF were also considered. The Delegation therefore proposed that the Committee consider the recommendations, in particular the MLs and associated sampling plans, as presented in the discussion paper.

85. Several delegations expressed their support for the proposed MLs of 5000 µg/kg for corn/maize, unprocessed and 2000 µg/kg for corn/maize flour/meal. A delegation however required clarification on whether reference to maize grain unprocessed was equivalent to raw maize grain as in the proposal for DON (*see* Agenda Item 6); and whether the corn/maize flour also included grits or flakes, as the presence of fumonisins varies in different maize milling products. It was clarified that corn/maize flour did not include flakes or grits. A delegation pointed out that it could support the ML as proposed for raw maize grain, but questioned whether such an ML was necessary since further processing, such as milling could significantly reduce fumonisins levels.

86. Another delegation supported a level of 5000 µg/kg for both the raw and the corn/maize flour as there was no need to differentiate between the different commodities.

87. The Delegation of Tanzania, supported by many other African delegations indicated that maize was a staple food in their countries and that consumption could be as high as 500 g/person/day and that in such cases, the PMTDI of fumonisins of 2 µg/kg/bw/day would be exceeded when maize containing 2000 µg/kg or more was consumed. These delegations further indicated that JECFA has noted that exceedance of the PMTDI could occur in some regions with high consumption. These delegations therefore could not support the proposed MLs and expressed the view that if it was not possible to establish levels that could provide equal protection globally, then establishment of levels should be left to each country to develop based on their consumption patterns. Some of these delegations proposed as an alternative, the development of a code of practice specifically for fumonisins in maize.

88. Some other delegations expressed the need for further data collection before deciding on development of the MLs.

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15 CX/CF 12/6/10; CX/CF 12/6/10-Add.1 (Comments at Step 3: Costa Rica, EU, Kenya, and the USA); CX/CF 12/6/10-Add.2 (Additional comments at Step 3: Egypt); CRD 20 (comments of Malaysia); CRD 25 (comments of Cameroon); and CRD 26 (Proposed revision of sampling plan for the proposed draft maximum levels for total aflatoxins in dried figs (including sampling plans) prepared by Turkey).

16 CX/CF 12/6/18 (discussion paper prepared by Brazil); CRD 4 (comments of Egypt); CRD 8 (comments of the EU); CRD 13 (comments of China); CRD 18 (comments of Nigeria); CRD 19 (comments of Indonesia); and CRD 25 (comments of Cameroon).

89. The JECFA Secretariat clarified that about 12% of the more than 10 000 analytical data used in its exposure assessment came from the Africa region. It was further clarified that JECFA had undertaken an impact assessment as requested by the Committee including the proposed MLs presented at the 4th Session and had concluded that the levels could result in reduced exposure. The Representative also clarified that exceedance of the PMTDI in many regions was not only due to high consumption, but a combination of high consumption and high contamination levels. In view of the findings of JECFA there is therefore clear merit to establish MLs. One delegation stated that the difference in contamination in maize is not as large as is the difference in maize consumption and recommended that MLs be based on consumption levels of the highest maize consuming regions.

90. With regard to the development of a code of practice, it was noted that although there was already a *Code of Practice for Prevention and Reduction of Mycotoxin Contamination in Cereals* that the current code of practice covered all cereals, but that something more specific for the prevention and reduction of fumonisins in maize was necessary.

Sampling plans

91. The Committee noted the same sampling plan for similar toxins, e.g. DON in the same commodity could be used and that there might be need for small changes in the sample plan with respect to the sample sizes.

Conclusion

92. In view of the discussion, noting that there was agreement for the need for MLs on raw maize/corn grains and corn/maize flour, but that there was no agreement on the actual MLs and the further proposal to develop a code of practice for fumonisins in maize, the Committee agreed on the following decisions:

- To develop a discussion paper to identify the gaps in the *Code of Practice for Prevention and Reduction of Mycotoxin Contamination in Cereals* and the need for a separate code of practice for fumonisins in maize and whether there are any other measures to control fumonisins in maize; and
- To suspend work on MLs for fumonisins in maize and its associated sampling plans for 1 year until the outputs of the discussion paper are considered.

93. The Committee agreed to establish an electronic working group lead by Brazil and co-chaired by the United States of America and working in English only to develop the discussion paper for consideration by the next session. African countries were encouraged to participate in this working group.

94. In this regard, the Committee recalled that work on the establishment of MLs for fumonisins in maize had already been approved by the 32nd Session of the Commission (2009) and that the timeline for completion of work was this Session of the Committee.

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

95. The Committee agreed to suspend development of the proposed draft MLs for fumonisins until the consideration of the discussion paper by the electronic working group (see para. 92) at the 7th Session.

96. The Committee agreed to inform the Executive Committee accordingly.

EDITORIAL AMENDMENTS TO THE CODEX GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOOD AND FEED (Agenda Item 8)[17]

97. The Delegation of the European Union, as lead of the Electronic Working Group on the Editorial Revision of the GSCTFF, introduced the document highlighting the editorial changes and main issues associated with the revision of the General Standard.

98. The Delegation recalled that in 2009 the Committee had agreed to discontinue work on the food categorization system to be used for the purpose of the GSCTFF, but to instead provide a clear description of the food/feed for which a maximum level applies and to screen the existing MLs provided for in Schedule I of the GSCTFF to provide where necessary a clearer description of the food/feed to which the ML applies. The Delegation indicated that following this decision, all code numbers in the GSCTFF were deleted and instead a column providing for the portion of the commodity to which the ML apply and additional notes were included to provide further clarification of the products covered by the ML.

99. Based on the above, the Delegation drew the attention of the Committee to the following issues: The Codex Classification for Food and Feed established within the framework of the Committee on Pesticide Residues has primarily been developed for the establishment of maximum residue limits for pesticides in foods and therefore mainly refer to raw agricultural commodities. This Classification did not fully meet the needs of the GSCTFF as several MLs and GLs also apply to processed commodities and may not also entirely apply to MLs for agricultural commodities in view of the nature of the Classification. In addition, there was ongoing work in CCPR to revise the Classification that may introduce further changes in the commodity groups which might not be suitable for the purposes of setting MLs for contaminants in food and feed.

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17 CX/CF 12/611; and CRD 12rev (comments of Japan).

100. In this regard, the Delegation indicated a number of questions in relation to the description of the commodities vis-à-vis the Classification e.g. the GSCTFF refers to "raw wheat" and the Classification refers to "wheat" and establishes different code numbers for "durum wheat" "emmer" and "spelt" but refers all of them in turn to "wheat" therefore it was not clear whether the term "raw wheat" in the GSCTFF could be equated to "wheat" in the Classification and if so whether the term "wheat" also applied to the other aforesaid commodities. Similarly this discrepancy also applied to other commodities as explained in the working document CX/CF 12/6/11.

101. The Delegation also drew the attention of the Committee that MLs listed in the GSCTFF arose from the work of the CCCF but also from standards developed by commodity committees. In this regard, it was not clear when commodity standards were revoked or superseded by more general standards whether the MLs listed in the "old" individual commodity standards were consequentially revoked and therefore should be removed from the GSCTFF as the corresponding "new" general standards do not contain such MLs anymore but instead a general statement on contaminants as set out in the Procedural Manual. In this regard, it was neither quite clear whether the intention of the commodity committee was to insert the general statement on contaminants in the "new" general standards because the MLs from the "old" individual standards were already listed in the GSCTFF and were therefore still valid for the purposes of the "new" general standards. It might then be advisable to keep the MLs listed in the GSCTFF and to further consider this matter to make before making a final decision.

102. The Delegation further drew the attention of the Committee that the Codex Alimentarius Commission had adopted *Guideline Levels for Vinyl Chloride Monomer and Acrylonitrile in Food and Packaging Material* (CAC/GL 6-1991). The Guidelines were adopted when the GSCTFF was not yet adopted. When all MLs for contaminants were transferred into the GSCTFF some associated individual standards and related texts like CAC-GL 6/1991 were not revoked. The Delegation therefore recommended revocation of CAC/GL 6-1991 as the GLs for these compounds were already included in the GSCTFF.

103. Several delegations noted that some editorial changes were not necessarily editorial and that due to the late distribution of the document they had not had an opportunity to consider all the changes proposed and to ascertain their implications on the MLs listed in the GSCTFF and therefore proposed the document be referred back to the working group for further development and comments.

104. The JECFA Secretariat informed the Committee that the GEMS Food follows the Classification of Food and Feed in particular for agricultural products however processed products were developed separately as not fully available in the Classification. The Secretariat noted that it would be important to keep consistency on between the description of the commodities in the GSCTFF and the Classification to the extent possible to facilitate submission of data to GEMS Foods.

Conclusion

105. In view of the above discussion and taking in account the decision of the 3rd Session of the Committee (2009) in relation to the categorization of commodities in the GSCTFF, the Committee agreed to re-establish the electronic working group led by the European Union to work on the above-mentioned issues including those indicated in working document CX/CF 12/6/11 in order to present a revised proposal for consideration by the next session of the Committee.

106. The Committee also agreed to recommend to the 35th Session of the Codex Alimentarius Commission revocation of CAC/GL 6-1991 *Guideline Levels for Vinyl Chloride Monomer and Acrylonitrile in Food and Packaging Material* as the GLs for these compounds were already transferred into the GSCTFF.

DISCUSSION PAPER ON MANAGEMENT PRACTICES FOR THE PREVENTION AND REDUCTION OF CONTAMINATION OF FOOD AND FEED WITH PYRROLIZIDINE ALKALOIDS (PAs) (Agenda Item 9a)[18]

107. The Delegation of the Netherlands, as lead of the electronic Working Group on PAs, introduced the report of the working group, as presented in CX/CF 12/6/12.

108. It was reported that there were a number of data gaps and uncertainties regarding the risk of PAs to humans, including: the relative toxicity of different PAs; the major PA contributors in the human diet in different geographical areas; the extent to which animal consumption of PAs contributes to human health effects; the overall risk to humans from PAs; and the efficacy of different management practices. However, due to the potential health-threatening effects that can be caused by ingestion of these toxins in feed or food, the Working Group concluded that it is desirable to reduce exposure of both human and animals to PAs as much as possible. The Working Group therefore recommended development of a code of practice (COP) for the prevention and reduction of contamination of food and feed with PA, in particular with regard to weed control as there was useful information available in this regard.

109. In addition, further recommendations were proposed for discussion:

[18] CX/CF 12/6/12; CRD 4 (comments of Egypt); CRD 7 (comments of the USA); CRD 8 (comments of EU); CRD 10 (comments of Thailand); CRD 13 (comments of China); CRD 25 (comments of Cameroon); and CRD 29 (Project Document for a "Code of Practice for the Prevention and Reduction of Pyrrolizidine Alkaloid Contamination of Food and Feed from Weeds" prepared by the Netherlands).

- whether information could be gathered during the development of a COP or as a separate activity on the topics 'Management practices to reduce exposure of food-producing animals to PA-containing plants – livestock and bees' and 'Management practices to reduce presence of PAs in commodities – raw and processed' which in principle should be included in the proposed COP, but where there was currently too little information available on existing practices and their efficacy;
- if non-agricultural management methods such as education, dietary advice or labelling, could potentially reduce PA exposure and could be developed further in the COP; and
- whether the development of a methodology which could be used to evaluate if a particular measure is relevant/effective for their own situation could be done as part of the work on a COP or as a separate activity.

110. The Committee agreed on the elaboration of a COP including 'Management practices for weed removal/reduction' and made an amendment in the title of the project document to read "Code of Practice for weed control to prevent and reduce pyrrolizidine alkaloid contamination in food and feed".

111. However on the topics of 'Management practices to reduce exposure of animals to PAs', 'Management practices to reduce exposure of food-producing animals to PA-containing plants – livestock and bees' and 'Management practices to reduce presence of PAs in commodities – raw and processed', the Committee noted that a number of data gaps had been identified and quite a lot of uncertainties existed and that it was premature to include in the COP; that more data collection was necessary and that a discussion paper could be prepared on this matter.

112. With regard to non-agricultural management methods, some delegations pointed out that non-agricultural management methods could significantly contribute to reduction of PAs exposure but that inclusion of this topic in the COP could wait until the outcome of the JECFA assessment.

113. With regard to the development of a methodology, the Committee agreed that it was premature to undertake this work as the efficacy of many methods had not yet been evaluated.

Conclusion

114. The Committee agreed to initiate new work on the development of a Code of Practice for weed control to prevent and reduce pyrrolizidine alkaloid contamination in food and feed, as presented in the project document (Appendix VII). Subject to approval by the Commission, the Committee agreed that the proposed code of practice would be developed by an electronic Working Group led by the Netherlands, working in English only, and open to all Codex members and observers, for comments at Step 3 and consideration at the next session.

115. The Committee also agreed that this electronic Working Group would prepare a discussion paper for consideration by the next session on the topics 'Management practices to reduce exposure of animals to PAs', 'Management practices to reduce exposure of food-producing animals to PA-containing plants – livestock and bees' and 'Management practices to reduce presence of PAs in commodities – raw and processed' to explore their possible inclusion in the proposed Code of Practice.

DISCUSSION PAPER ON 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 CHEMICAL (Agenda Item 9b)[19]

116. The Delegation of United States of America, as lead of the working group, introduced the discussion paper and reminded the Committee that the working group had been asked to reconsider existing maximum levels for lead with a focus on foods important for infants and children and also on canned fruits and vegetables, in view of the withdrawal of the PTWI by JECFA. In addition the working group had been asked to determine if there was a need for revision of the *Codes of Practice for the Prevention and Reduction of Lead Contamination in Foods* and *for Source Directed Measures to Reduce Contamination of Foods with Chemicals*, respectively. The Delegation informed the Committee that in undertaking its task, it had evaluated MLs for lead in groups of similar foods in the GSCTFF, by comparing them with lead occurrence data from JECFA. In some cases the MLs were also compared to non-JECFA data, such as data from total diet studies of the United States of America or Australia. It was acknowledged that more global data would be needed to determine whether lower MLs are appropriate and achievable.

117. The Delegation informed the Committee that in most cases, the working group recommended re-evaluating MLs when the JECFA mean or range of means fell below the Codex MLs. The Working group had also considered whether children were high consumers of the food or had significant lead exposure from the food, since lead is of particular concern for children.

118. The Delegation then highlighted the recommendations of the working group to:

- Not re-evaluate MLs for vegetables other than root and tubers; meat of cattle, pigs, sheep and poultry; and natural mineral waters;

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19 CX/CF 12/6/13; CRD 3 (comments of Kenya); CRD 4 (comments of Egypt); CRD 6 (comments of Mali); CRD 7 (comments of the USA); CRD 8 (comments of the EU); CRD 9 (comments of FoodDrinkEurope); CRD 13 (comments of China); CRD 18 (comments of Nigeria); CRD 19 (comments of Indonesia); CRD 21 (comments of India); CRD 25 (comments of Cameroon); and CRD 28 (Project Document for the revision of maximum levels for lead prepared by the USA).

- re-evaluate MLs for fruit, pulses, root and tuber vegetables; canned fruit and vegetables products; fruit juices; cereal grains, except buckwheat, cañihua and quinoa; edible offal of cattle, pigs and poultry; assorted fats, oils and spreads; fish; milk and secondary milk products; infant formula; wine; and food grade salt; and
- consolidate the MLs for canned fruit and vegetable products.

119. The working group did not indentify any need for revision of the codes of practices.

120. There was general support for the re-evaluation and revision of the MLs for the commodities proposed, although some delegations proposed that some other commodities also be considered:

- in addition to roots and tubers, that other vegetables, such as bulb vegetables, fruiting vegetables, amongst others;
- in addition to edible offal, meat; and
- in addition to infant formulae, follow-up formula and also weaning foods.

121. However, some other delegations noted that the recommendation to re-evaluate the MLs for milk and its secondary products were based on limited data and expressed the view that the Committee should base its decision on the re-evaluation of the MLs for these commodities on global data. These Delegations therefore proposed that more global data be submitted before the Committee could take a decision on the re-evaluation of the MLs for these products.

122. The Committee was reminded that this was an initial exercise to identify commodities for which the MLs could be re-evaluated and that global data was necessary and would be taken into account when re-evaluating the actual MLs. The Committee was also further reminded in regard to the addition of other commodities, that the work was limited to those commodities for which MLs already existed in the GSCTFF.

123. The JECFA Secretariat informed the Committee that in total over 110 000 occurrence data from all regions of the world have been considered, covering a broad range of foods. Only from the African region no data have been submitted. All data will be made available to the working group.

124. Since there was general agreement on most of the commodities proposed by the working group, the Committee agreed that it would not be possible to undertake the re-evaluation of all the commodities at the same time and that this work would need to be undertaken in phases. The Committee, taking into account its earlier request to focus on foods for infants and also on canned fruits and vegetables, agreed to prioritize fruit juices, milk and secondary milk products, infant formula, canned fruits and vegetables, fruits and cereal grains (except buckwheat, cañihua and quinoa).

125. Countries were encouraged to submit occurrence data to GEMS/Food[i] which would need to be considered in the re-evaluation and possible revision of the MLs for lead in the identified commodities.

Conclusion

126. In view of the discussion, the Committee agreed to start new work on the revision of the MLs for lead in fruit juices, milk and secondary milk products, infant formula, canned fruits and vegetables, fruits and cereal grains (except buckwheat, cañihua, and quinoa) as presented in the project document (Appendix VIII), pending approval by the 35th Session of the Commission. It was noted that where possible follow-up formula could be taken into account during this work because the data that was used for infant formula could also apply to this product.

127. The Committee agreed to establish an electronic working group lead by the United States of America, and working in English only, and open to all members and observers, to revise the MLs for lead for comments at Step 3 and consideration at the next session.

DISCUSSION PAPER ON MYCOTOXINS IN SORGHUM (Agenda Item 9c)[20]

128. The Delegation of Nigeria, as the lead of the electronic Working Group on Mycotoxins in Sorghum, introduced the report of the working group, as presented in CX/CF 12/6/14. The Delegation recalled that the electronic working group had been tasked to update the discussion paper and to scrutinize the *Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals* (CAC/RCP 51-2003) in order to ascertain whether it was relevant and feasible for the production of sorghum or whether a specific annex on mycotoxins in sorghum was needed.

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20 CX/CF 12/16/14; CRD 3 (comments of Kenya); CRD 4 (comments of Egypt); CRD 5 (comments of Benin); CRD 6 (comments of Mali); CRD 7 (comments of the USA); CRD 8 (comments of the EU); CRD 10 (comments of Thailand); CRD 13 (comments of China); CRD 25 (comments of Cameroon); and CRD 27 (Project Document for an additional annex for "Prevention and Reduction of Aflatoxins and Ochratoxin A in sorghum" prepared by Nigeria).

129. It was reported that based on the toxigenic fungi isolated from the grain around the globe, there were over thirty potential mycotoxins that could contaminate sorghum including the commonest mycotoxins such as aflatoxins, zearalenone and ochratoxins A, fumonisins, moniliformin, deoxynivalenol and ergot alkaloids. Based on the predominance of aflatoxin-producing fungi and *Alternaria* spp in sorghum, the working group concluded although that the *Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals* (CAC/RCP 51-2003) was relevant to some mycotoxins in sorghum, it was silent on aflatoxins which were the commonest contaminant of sorghum worldwide. The Working group had therefore recommended that a specific annex to the COP for the management of aflatoxins and *Alternaria* spp. in sorghum be developed.

130. The Committee was further informed that the working group had recommended that the FAO/WHO project on mycotoxins in sorghum sponsored by Codex Trust Fund (*see* Agenda Item 3) be diversified and extended in order to include as many of the potential toxins associated with the toxigenic fungi found in the grain and to involve researchers on mycotoxins from significant sorghum producing and exporting countries of the world.

131. Some delegations were of the opinion that development of the annex was premature as more work should be undertaken as regards the prevention of the presence of aflatoxins and ochratoxin A with a view to future development of an annex on these mycotoxins. These delegations were also of the view that further information was necessary to provide a better understanding of the occurrence and toxicological relevance of some of the other mycotoxins, e.g., sterigmatocystin, moniliformin and ergot alkaloids). It was noted that the FAO/WHO project could provide some further information on these matters and it was suggested that the project collect more data on agricultural practices and mycotoxin levels in sorghum growing countries and that the project be extended beyond the four sub-Saharan African countries.

132. Several other delegations noted that sorghum was a cereal of increasing international importance and a staple in many regions; that mycotoxins in sorghum had a long history in the Committee and that it was timely to start the development of an annex specific for mycotoxins in sorghum, in particular on aflatoxins and ochratoxin A, as there was sufficient information to support this.

133. The Representative of WHO clarified that there already existed quite a substantial amount of valuable information on the occurrence of mycotoxin types and levels related to the sorghum production world wide, however information on the occurrence of mycotoxins in sorghum in many countries was incomplete. Therefore a project has been implemented to collect data in four selected countries in Africa (Burkina Faso, Ethiopia, Mali and Sudan). The FAO/WHO project supported by the Codex Trust Fund with funding from the EU was intended to focus on mycotoxin data collection and analysis and to compare data between the countries selected, and to the extent possible, also information on agricultural practices (*see* Agenda Item 3a). The Representative further informed that due to limited funds available it was difficult to expand the project to other countries in Africa.

134. The Representative proposed that the Committee proceed with the development of the COP as there were sufficient information on agricultural practices in sorghum-producing countries and therefore there was no need not wait on the conclusion of the project.

135. The Committee, noting the increasing consumption of sorghum in the world and existence of information available on aflatoxins and ochratoxins A in sorghum, agreed on developing an annex to the CAC/RCP 51-2003. The Committee made an amendment in the Section on Purpose and Scope of the new work in the project document to clarify that the purpose of the work was also intended to provide guidance to small-scale producers.

Conclusion

136. The Committee agreed to initiate new work on the development of an annex for the management of aflatoxins and ochratoxin A in sorghum to the *Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals* (CAC/RCP 51-2003), as presented in the project document (Appendix IX), subject to approval by the 35th Session of the Commission. The Committee agreed to establish an electronic Working Group led by Nigeria and co-chaired by Sudan, working in English only and open to all members and observers, to prepare the proposed draft annex for comments at Step 3 and consideration at the next session.

DISCUSSION PAPER ON OCHRATOXIN A IN COCOA (Agenda Item 9d)[21]

137. The Committee recalled that its last session had agreed that an electronic Working Group led by Ghana would update the discussion paper on Ochratoxin A (OTA) in Cocoa taking into account new available data with a view to developing a code of practice, for consideration by this session of the Committee.

138. The Delegation of Ghana, as lead of the electronic Working Group on OTA in Cocoa, introduced the document and highlighted the recommendations of the working group in particular to commence new work for the development of a code of practice for the prevention and reduction of OTA in cocoa along similar lines as the current *Code of Practice for the Prevention and Reduction of Ochratoxin A Contamination in Coffee* (CAC/RCP 69-2009). The Delegation further explained that setting a maximum level for OTA in cocoa could be considered only after the development and implementation of this code.

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21 CX/CF 12/6/15; CRD 3 (comments of Kenya); CRD 5 (comments of Benin); CRD 7 (comments of the USA); CRD 8 (comments of the EU); CRD 10 (comments of Thailand); CRD 13 (comments of China); CRD 24 (comments of Philippines); and CRD 25 (comments of Cameroon).

139. The Committee generally supported the development of the code of practice and made minor amendments in the sections on Purpose and Scope of the new work and on Main aspects of the Project Document to clarify that the new work would cover the stages of primary production of cocoa bean.

140. With regard to the issue of ML, the Committee agreed that setting a ML could be considered in future once the code of practice had been finalized and countries had implemented it.

Conclusion

141. The Committee agreed to initiate new work on the development of a code of practice for the prevention and reduction of OTA in cocoa, as presented in the project document (Appendix X). Subject to approval by the Commission, the Committee agreed that the proposed code of practice would be developed by an electronic Working Group led by Ghana, working in English, for comments at Step 3 and consideration at the next session.

DISCUSSION PAPER ON GUIDANCE FOR RISK MANAGEMENT OPTIONS IN LIGHT OF DIFFERENT RISK ASSESSMENT OPTIONS (Item 9e)[22]

142. The Delegation of United States of America, as lead of the working group, introduced the discussion paper and explained that the paper contained a brief description of risk assessment steps and outcomes and provided a description of the risk management options by the Committee as well as that for national governments. The document further outlined other measures that national governments could use.

143. The Delegation noted that the document provided very useful information for the Committee and for national governments and that it could also be of value to other Codex Committees. The Delegation therefore proposed that the Committee consider ways to give the document a more official status to ensure that it was not lost and available for use.

144. There was general agreement that the document contained very useful information and should be maintained for use by the Committee and by national governments. Some delegations were of the view that the document should be given a more formal status and proposed that it be appended to the *Risk Analysis Principles Applied by the Codex Committee on Contaminants* in the Procedural Manual. Some other delegations however did not support appending the document to the risk analysis principles as no gap had been identified in these principles. These delegations were of the opinion that the document should be maintained in a more informal way and had been written with this in mind.

145. Other delegations noted that the document provided very useful information on the risk assessment approach and the interpretation of risk assessment outcomes which could be of valuable to risk managers especially in developing countries and therefore proposed that it be developed into a guidance for national governments.

146. The Codex Secretariat clarified that that if the Committee were to agree to append the document to the risk analysis principles that only information for use by the Committee or Codex should be maintained in the document. It was further pointed out that if the document were to be developed as a guidance to governments that it should focus on those sections of the documents of relevance to governments and that this work would be considered as new work for the Committee and would require a project document and approval by the Commission.

147. It was noted that more informal ways could be sought to maintain the document, by either making it available as an information document prior to each session of the Committee or that a better location of the document, which would ensure their easy accessibility and visibility, could be explored in future, including their posting on the new Codex website, which offered improved features for presenting the work of Codex.

148. Noting the clarification by the Secretariat and the implications if the document were to be made official, it was agreed that the document should be maintained as a whole as all the information was relevant and interrelated.

149. It was noted that similar issues of how to make information documents more accessible and available had arisen in other committees and that a more general question should be put to CCGP to explore ways on how to deal with such documents in the Codex system.

150. The Committee therefore noted that a request be put to CCGP to explore ways on making information documents available and accessible in the Codex system could be made and to append the document to the report of the Committee in the interim until advice was received from CCGP.

151. Having agreed on this approach, the Committee proceeded with a section by section consideration of the document. In addition to editorial amendments, amendments to avoid ambiguity and to provide more clarity, the Committee also made the following changes.

152. The Committee agreed to amend the title to read “Guidance for Risk Management Options in Light of Different Risk Assessment Outcomes”.

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22 CX/CF 12/6/16 , CRD 3 (comments of Kenya), CRD 8 (comments of the EU), CRD 9 (comments of FoodDrinkEurope), CRD 10 (comments of Thailand), CRD 13 (comments of China); CRD 25 (comments of Cameroon); and CRD 30 (Discussion paper on guidance for risk management options in light of different risk assessment options prepared by the USA).

153. The definition of risk management in paragraph 8, second bullet point, was aligned with the definition in the Procedural Manual for consistency.

154. The title of section IV was amended to "Risk Assessment Tools and Outcomes" to more accurately reflect the contents of this section.

155. A new paragraph 15 bis was added to provide a better understanding of the threshold of toxicological concern (TTC) approach.

156. Paragraph 24 was amended to better align with the official definition of the PTWI (see glossary of terms Environmental Health Criteria 240[23]) and to avoid the impression that "provisional" implied "interim" value.

Conclusion

157. The Committee agreed, as an interim measure, to append the document to the report for future reference (Appendix XIII) and to explore placing document on the Codex Website. Further, the Committee agreed request CCGP to explore ways to make information and other similar documents available in the Codex system.

PRIORITY LIST OF CONTAMINANTS AND NATURALLY OCCURRING TOXICANTS PROPOSED FOR EVALUATION BY JECFA (Agenda Item 10)[24]

158. The Delegation of the United States America, 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 2A).

159. The Committee was informed that four substances remained on the priority list: 3-MCPD esters, glycidyl esters, pyrrolizidine alkaloids, non-dioxin like PCBs, and that two new proposals for inclusion in the list had been made: re-evaluation of dioxins and dioxin-like PCBs and exposure assessment of cadmium from cocoa and cocoa products.

160. With regard to the request for re-evaluation of dioxins and dioxin-like PCBs, the JECFA Secretariat stated that dioxins were a known public health problem and that it might not be the best use of JECFA resources to perform a re-evaluation, but that it would be important for countries to implement source directed measures to reduce formation and release of dioxins into the environment, thereby reducing human exposure. One delegation supported the view expressed by the JECFA Secretariat. The Republic of Korea clarified that there were difficulties in communicating with consumers in light of different risk assessment outcomes by different organizations. The JECFA Secretariat noted that this was an issue not limited to dioxins and it might be useful to consider work on this on a more general basis.

161. With regard to the request for an exposure assessment of cadmium from cocoa and cocoa product the Committee agreed to include the proposal in the list and noted that relevant data would be needed to undertake the assessment.

162. 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 cadmium and to not request a re-evaluation of dioxins and dioxin-like PCBs at this point.

Conclusion

163. The Committee endorsed the priority list of contaminants and naturally occurring toxicants for JECFA evaluation as proposed by the working group (Appendix XI) 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 11)[25]

164. 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 2B. The Committee endorsed the recommendations as proposed by the working group:

Cyanogenic glycosides

165. The Committee agreed to establish an electronic Working Group to start new work on a code of practice and MLs for hydrocyanic acid in cassava and cassava products for comments at Step 3 and consideration by the next session, pending approval by the 35th Session of the Commission.

166. The Committee agreed that the electronic Working Group would:

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23 http://whqlibdoc.who.int/ehc/WHO_EHC_240_6_eng_Chapter3.pdf

24 REP11/CF, Appendix V; CL 2011/6-CF; CX/CF 12/6/17; CRD 2A (Report of the in-session Working Group on Priorities for evaluation by JECFA); and CRD 25 (comments of Cameroon).

25 CRD 2B (Report of the in-session Working Group on the follow-up on recent JECFA assessments and identification of topics for future work).

- undertake a review of the MLs for hydrocyanic acid in existing Codex commodity standards for bitter cassava and sweet cassava with a view of the possible revision of these MLs and the establishment of new MLs for additional commodities, such as ready-to-eat cassava chips;
- develop a code of practice to reduce the presence of hydrocyanic acid in cassava in which the agricultural aspects and the methods of processing are addressed; and
- identify methods of analysis suitable for analysis of hydrocyanic acid in foods.

167. The electronic Working Group will be led by Australia and co-chaired by Nigeria, will work in English only and be open to all Codex members and observers.

168. The Committee agreed that Australia and Nigeria would prepare a project document for submission to the 67th Session of the Executive Committee through the Codex Secretariat.

Radionuclides in food

169. The Committee agreed to establish an electronic Working Group to start new work on levels for radionuclides in food for comment at Step 3 and further consideration by the next session, subject to approval by the 35th Session of the Commission.

170. The Working Group would:

- review the current guideline levels for radionuclides in food; and
- develop in connection with the review of the guideline levels, a clear guidance on the interpretation and application of the guideline levels.

171. The Committee agreed that the electronic Working Group would be led by the Netherlands and co-chaired by Japan, working in English only and open to all members and observers.

172. The Netherlands and Japan will prepare a project document for submission to the 67th Session of the Executive Committee through the Codex Secretariat.

173. The Committee noted the importance of involving the IAEA and other relevant organizations in this work.

Methylmercury

174. The Committee agreed to the development of a discussion paper on the review of the guideline level for methylmercury in fish and predatory fish through an electronic Working Group led by Norway and co-chaired by Japan for consideration and discussion at the next session with the view of identification of possible actions or new work on this issue.

Aflatoxins in cereals

175. The Committee agreed to the development of a discussion paper on aflatoxins in cereals through an electronic Working Group led by Brazil and co-chaired by the United States of America for consideration and discussion at the next session with the view of identification of possible actions or new work on this issue.

Other Matters

176. The Committee reiterated the need to be more proactive in the collection and generation of data once the need to request a JECFA risk assessment within CCCF is identified in order to have sufficient data in time available for the JECFA risk assessment and for the subsequent risk management discussions in the Committee once the JECFA assessment is available. The Committee noted that the information document contained useful information and will be made available again at the next session.

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

177. The Committee was informed that its seventh session would be co-hosted by the Netherlands and Russian Federation and that it was tentatively scheduled to be held in Moscow, Russian Federation in April 2013. The exact venue and date would be determined by the host Governments in consultation with the Codex Secretariat.

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[i] For information please contact vergerp@who.int

SUMMARY STATUS OF WORK

SUBJECT MATTERS	STEP	ACTION BY:	DOCUMENT REFERENCE (REP12/CF)
Risk Analysis Principles Applied by the Codex Committee on Contaminants in Foods	-	Governments 35th CAC Governments Turkey Governments 7th CCCF	para. 22, Appendix II
Revision of the *Code of Practice for Source Directed Measures to Reduce Contamination of Food with Chemicals* (CAC/RCP 49-2001)	-		para. 38, Appendix III
Revised Definition of Contaminant	-		para. 38, Appendix IV
Draft Maximum Levels for Melamine in Food (*Liquid Infant Formula)*	8		para. 58, Appendix V
Proposed Draft Maximum Level for Total Aflatoxins in Dried Figs including Sampling Plan	5/8		para. 82, Appendix VI
Proposed Draft Maximum Levels for Arsenic In Rice	Held at Step 4	8th CCCF	para. 65
Proposed Draft Maximum Levels for Deoxynivalenol (DON) in Cereals and Cereal-based Products and Associated Sampling Plans	2/3	Electronic Working Group (Canada/EU) 7th CCCF	para. 77
Editorial Amendments to the General Standard for Contaminants and Toxins in Food and Feed	-	Electronic Working Group (European Union) 7th CCCF	para. 105
New Work			
Proposed Draft Code of Practice for Weed Control to Prevent and Reduce Pyrrolizidine Alkaloid Contamination in Food and Feed	1/2/3	35th CAC Electronic Working Group (The Netherlands) 7th CCCF	para. 114, Appendix VII
Proposed Draft Revision of the Maximum Levels for Lead in Fruit Juices, Milks and Secondary Milk Products, Infant Formula, Canned Fruits and Vegetables, Fruits and Cereal Grains (except buckwheat, cañihua and quinoa) in the *General Standard for Contaminants and Toxins in Food and Feed*	1/2/3	35th CAC Electronic Working Group (USA) 7th CCCF	para. 127, Appendix VIII
Proposed Draft Annex for Prevention and Reduction of Aflatoxins and Ochratoxin A in Sorghum to the *Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals* (CAC/RCP 51-2003)	1/2/3	35th CAC Electronic Working Group (Nigeria/Sudan) 7th CCCF	para. 136, Appendix IX
Proposed Draft Code of Practice for the Prevention and Reduction of Ochratoxin A contamination in Cocoa	1/2/3	35th CAC Electronic Working Group (Ghana) 7th CCCF	para. 141, Appendix X
Proposed Draft Code of Practice to Reduce the Presence of Hydrocyanic Acid in Cassava	1/2/3	35th CAC Electronic Working Group (Australia/Nigeria) 7th CCCF	para. 165
Proposed Draft Maximum Levels for cassava and cassava products	1/2/3	35th CAC Electronic Working Group (Australia/Nigeria) 7th CCCF	para. 165

SUBJECT MATTERS	STEP	ACTION BY:	DOCUMENT REFERENCE (REP12/CF)
Proposed Draft levels for radionuclides in food	1/2/3	35th CAC Electronic Working Group (The Netherlands/Japan) 7th CCCF	para. 169
Discussion Papers			
Discussion paper on the development of a code of practice for arsenic in rice	-	Electronic Working Group (China/Japan)	paras 64
Discussion Paper on control measures for fumonisins in maize	-	Electronic Working Group (Brazil/USA)	para. 92
Discussion paper on management practices to reduce exposure of animals to pyrrolizidine alkaloids; to reduce exposure of food-producing animals (livestock and bees) to PA-containing plants; and to reduce presence of PAs in commodities (raw and processed)	-	Electronic Working Group (The Netherlands)	para. 115
Discussion paper on the review of the guideline level for methylmercury in fish and predatory fish	-	Electronic Working Group (Norway/Japan)	para. 174
Discussion paper on aflatoxins in cereals	-	Electronic Working Group (Brazil/USA)	para. 175
Priority List of Contaminants and Naturally Occurring Toxicants proposed for evaluation by JECFA	-	Governments 7th CCCF	para. 163, Appendix XI

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APPENDIX II

PROPOSED RISK ANALYSIS PRINCIPLES APPLIED BY THE CODEX COMMITTEE ON CONTAMINANTS IN FOODS

SECTION 1. SCOPE

1. This document addresses the applications of risk analysis principles by the Codex Committee on Contaminants in Foods (CCCF) and the Joint FAO/WHO Expert Committee on Food Additives (JECFA). For urgent matters that may pose human health risk and for matters that are not in the terms of reference of JECFA, this document does not preclude the possible consideration of recommendations arising from other internationally recognized expert bodies, or FAO/WHO *ad hoc* consultations..

2. This document should be read in conjunction with the *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius*.

3. This document also applies to contaminants and toxins in feed in cases where the contaminant in feed can be transferred to food of animal origin and can be relevant for public health. This excludes feed[1] additives, processing aids and agricultural and veterinary chemical residues that are the responsibility of other relevant Codex committees.

SECTION 2. GENERAL PRINCIPLES OF CCCF AND JECFA

4. CCCF is primarily responsible for recommending risk management proposals for adoption by the CAC.

5. JECFA is primarily responsible for performing the risk assessments upon which CCCF and ultimately the CAC base their risk management recommendations.

6. CCCF and JECFA recognize that interaction between risk assessors and risk managers is critical to the success of their risk analysis activities. CCCF and JECFA should continue to develop procedures to enhance interaction between the two bodies.

7. CCCF and JECFA should ensure that their contributions to the risk analysis process involve all interested parties, 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.

8. JECFA, in consultation with CCCF, should continue to explore developing minimum quality criteria for data requirements necessary for JECFA to perform risk assessments. These criteria should be used by CCCF in preparing its Priority List for JECFA. The JECFA Secretariat should consider whether these minimum requirements for data availability have been met when preparing the draft agendas for meetings of JECFA.

SECTION 3. CCCF

COMMUNICATION WITH JECFA

9. CCCF's risk communication with JECFA includes prioritizing substances for JECFA assessment with a view to obtaining the best quality risk assessment for contaminants and toxins in food and feed.

10. CCCF shall consider the following when preparing its priority list of substances for JECFA review:

- Consumer protection from the point of view of health and prevention of unfair trade practices;
- 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.

11. When referring substances to JECFA, CCCF shall provide a clearly defined scope for the risk assessment request, background information and explain the reasons for the request when chemicals are nominated for evaluation.

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[1] The terms "feed" refer to both "feed (feedingstuffs)" and "feed ingredients" as defined in the Code of Practice on Good Animal Feeding (CAC/RCP 54/2004). For the purposes of these principles, feed refers only to food producing animals and does not cover feed for pet animals.

12. 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.

13. CCCF may request JECFA to review any methods and guidelines being considered by CCCF for assessing maximum levels for contaminants and toxins. CCCF would make such request in order to obtain JECFA's guidance on the limitations, applicability and appropriate means for implementation of a particular method or guideline.

14. In cases where JECFA has performed a risk assessment and CCCF and ultimately CAC determines that additional scientific guidance is necessary, CCCF or CAC may make a more specific request to JECFA to obtain the scientific guidance necessary for a decision on a risk management recommendation.

RISK MANAGEMENT

15. CCCF's risk management recommendations to the CAC with respect to contaminants and toxins shall be guided by the principles described in the Preamble and relevant annexes of the Codex General Standard for Contaminants and Toxins in Food and Feed (GSCTFF).

16. CCCF's risk management recommendations to the CAC that involve safety aspects of food and feed standards for human health shall be based on JECFA's risk assessments, and shall take into account the relevant uncertainties and safety factors in the risk assessment and recommendations described by JECFA. When establishing its standards, codes of practice, and guidelines, CCCF shall clearly state when it applies any other legitimate factors, in addition to JECFA's risk assessment, in accordance with the *Statements of Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to which other Factors are taken into Account*, and specify its reasons for doing so.

17. CCCF shall endorse maximum levels only for those contaminants for which 1) JECFA or other FAO/WHO expert consultations have performed a quantitative risk assessment, 2) meets the criteria established as a significant contributor to total dietary exposure for consumers (*as per the Codex Policy for Exposure of Contaminants and Toxins in Foods*) and 3) the level of the contaminant in food or feed can be determined through appropriate sampling plans and analytical methods, as adopted by Codex. CCCF should take into consideration the analytical capabilities of developing countries unless public health considerations require otherwise.

17bis CCCF may also set MLs in order to address and distinguish the justifiable presence of the substances from intentional unauthorized use in food and feed which may give rise to a human health concern.

18. CCCF shall take into account differences in regional and national food consumption patterns and dietary exposure as assessed by JECFA when recommending maximum levels for contaminants and toxins in food and feed.

19. Before finalising proposals for maximum levels for contaminants and toxins, 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 toxins in food or feed and about other relevant technical and scientific aspects, as necessary to provide for a suitable scientific basis for its risk management proposals to CAC.

SECTION 4. JECFA

PREPARATION OF RISK ASSESSMENT

20. When establishing the agenda for a JECFA meeting, the JECFA Secretariat work closely with CCCF and the Codex Secretariat to ensure that CCCF's work priorities are addressed in a timely manner. The JECFA Secretariat should give first priority to substances that present an emergency or imminent public health risk and then to substances that are known or expected problems in international trade.

RISK ASSESSMENT

21. The selection of JECFA experts to participate in any specific meeting should be made after a careful consideration of the necessary scientific competence and experience required for the assessment of the substances on the agenda and independence, taking into account gender and geographical representation to ensure that all regions are represented.

22. JECFA should provide CCCF with science-based risk assessments that include the four components of risk assessment as defined by CAC. JECFA should determine, to the extent possible, the risks associated with various levels of dietary exposure to contaminants and toxins. Because of the lack of appropriate information, however, this may be possible only on a case by case basis.

23. 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.

24. When evaluating dietary exposure to contaminants and toxins during its risk assessment, JECFA should take into account regional differences in food consumption patterns.

COMMUNICATION WITH CCCF

25. JECFA should strive to provide CCCF with science-based quantitative risk assessments in a transparent manner.

26. JECFA should provide CCCF with information on the applicability and any constraints, uncertainties and assumptions of the risk assessment to the general population, to particular subpopulations and should as far as possible identify potential risks to populations of potentially enhanced vulnerability (e.g. children, women of childbearing age and the elderly).

27. JECFA should provide to CCCF its scientific views on the validity and the distribution aspects of the available data regarding contaminants and toxins in food and feed, which have been used for exposure assessments, and should give details on the magnitude of the contribution to the exposure from specific foods and feeds as may be relevant for the risk management recommendations of CCCF.

28. JECFA should communicate to CCCF the magnitude and source of uncertainties in its risk assessments. When communicating this information, JECFA should provide CCCF with a description of the methodology and procedures by which JECFA estimated any uncertainty in its risk assessment.

29. JECFA should communicate to CCCF the basis for all assumptions used in its risk assessments including default assumptions used to account for uncertainties.

30. JECFA's risk assessment output to CCCF is limited to presenting its deliberations and the conclusions of its risk 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.

APPENDIX III

PROPOSED REVISED CODE OF PRACTICE FOR SOURCE DIRECTED MEASURES TO REDUCE CONTAMINATION OF FOOD AND FEED[1] WITH CHEMICALS

(CAC/RCP 49-2001)

1. This document deals with the major sources of environmental chemicals which may contaminate food or feed for food producing animals and constitute a hazard to human health and therefore, have been considered for regulation by CCCF/CAC. Apart from environmental contaminants, foods may contain chemicals used as pesticides, veterinary drugs, food additives or processing aids. However, since such substances are dealt with elsewhere in the Codex system, they are not included here.

2. The main objective of this document is to increase awareness of sources of chemical contamination of food and feed, and of source-directed measures to prevent such contamination. This means that measures recommended in the document may lie outside the direct responsibility of the food or feed control authorities and Codex.

3. National food or feed control authorities should inform relevant national authorities and international organizations of potential or actual food or feed contamination problems and encourage them to take appropriate preventive action. This should result in decreased levels of chemical contamination and, in the long term, could result in a decreasing need to establish and maintain Codex Maximum Levels for chemicals in food or feed.

4. Different approaches may be used to try and ensure that the levels of chemical contaminants in food and feed are as low as reasonably achievable and not above the maximum levels considered tolerable from a human health view.

Essentially, these approaches consist of

(a) measures to eliminate or control the source of contamination,

(b) processing to reduce contaminant levels, and

(c) measures to identify and separate contaminated (levels above ML) food that may ultimately enter the human food chain from food fit for human consumption.

(d) measures to identify and separate contaminated (levels above ML) feed that may ultimately enter the feed chain from feed fit for livestock feeding.

The contaminated food should be assessed as to its acceptability for human consumption.

By analogy, contaminated feed exceeding MLs should also be rejected for feed use unless the feed is treated to make it fit for animal consumption. In some cases, a combination of the above approaches must be used, for example, if emissions from a previously uncontrolled source have resulted in environmental pollution with a persistent substance, such as PCBs or mercury. When fishing waters or agricultural land become heavily polluted due to local emissions, it may be necessary to blacklist the areas concerned, i.e. to prohibit the sale of foods and feeds derived from these polluted areas and to advise against the consumption of such foods or use of such feeds.

5. Control of final products is unlikely to be enough to guarantee contaminant levels below established Maximum Levels. In most cases, chemical contaminants cannot be removed from food or feed and there is no feasible way in which a contaminated food batch can be made fit for human consumption or a contaminated feed batch can be made fit for animal consumption in respect of food safety. The advantages of eliminating or controlling food or feed contamination at source, i.e. the preventive approach, are that this approach is usually more effective in reducing or eliminating the risk of untoward health effects, requires smaller resources for food or feed control and avoids the rejection of food or feed.

6. Food and feed production, processing and preparation operations should be analysed with a view to identifying hazards and assessing the associated risks. This should lead to a determination of critical control points and the establishment of a system to monitor production at these points (i.e. the Hazard Analysis Critical Control Point or “HACCP” approach). It is important that care is exercised throughout the whole production-processing and distribution chain to ensure food safety and quality are maintained throughout..

7. Pollution of air, water and arable land can result in the contamination of crops grown for food or feed, food producing animals and surface and ground waters used as sources of water for drinking and food production and processing. The relevant national authorities and international organisations should be informed about actual and potential food or feed contamination problems and encouraged to take measures to:

- control emissions of pollutants from industry, e.g. the chemical, mining, metal and paper industries, and also from weapons testing.
- control emissions from energy generation (including nuclear plants) and means of transportation.

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1 The term “feed” refers to both “feed” and “feed ingredients” as defined in the Code of Practice on Good Animal Feeding (CAC/RCP 054 2004). For the purposes of this Code of Practice, feed refers only to food producing animals, and does not cover feed for pet animals.

- control the disposal of solid and liquid domestic and industrial waste, including its deposition on land, disposal of sewage sludge and incineration of municipal waste.
- control the production, sale, use and disposal of certain toxic, environmentally-persistent substances, e.g. organohalogen compounds (PCBs, brominated flame retardants, etc.), lead, cadmium and mercury compounds.
- ensure that before new chemicals are introduced onto the market, and especially if they may eventually be released into the environment in significant amounts, they have undergone appropriate testing to show their acceptability from the health and environmental points of view.
- where possible, replace toxic environmentally-persistent substances by products which are more acceptable from the health and environmental points of view.

8. This Code should be read in connection with the *Code of Practice for Good Animal Feeding* (CAC/RCP 54-2004).

APPENDIX IV

PROPOSED REVISED DEFINITION FOR CONTAMINANT

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

APPENDIX V

DRAFT MAXIMUM LEVELS FOR MELAMINE IN FOOD:

LIQUID INFANT FORMULA (as consumed)

(At Step 8)

Product Name	ML (mg/kg)
Liquid infant formula (as consumed)	0.15

APPENDIX VI

PROPOSED DRAFT MAXIMUM LEVELS FOR TOTAL AFLATOXINS IN DRIED FIGS
(INCLUDING SAMPLING PLAN)

(At Step 5/8)

Product Name	ML (µg/kg)
Dried Figs	10

Annex

SAMPLING PLAN FOR AFLATOXIN CONTAMINATION IN DRIED FIGS

DEFINITION

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

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

Sampling plan - is defined by an aflatoxin test procedure and an accept/reject level. An aflatoxin test procedure consists of three steps: sample selection of sample(s) of a given size, sample preparation and aflatoxin quantification. The accept/reject level is a tolerance usually equal to the Codex maximum level.

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

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

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

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

Ready-to-eat dried figs – dried figs, which are not intended to undergo an additional processing/treatment that have proven to reduce levels of aflatoxin.

Operating Characteristic (OC) Curve – a plot of the probability of accepting a lot versus lot concentration when using a specific sampling plan design. The OC curve also provides an estimate of good lots rejected (exporter's risk) and bad lots accepted (importer's risk) by a specific aflatoxin sampling plan design.

SAMPLING PLAN DESIGN CONSIDERATIONS

1. Importers commercially classify dried figs mostly as "ready-to-eat" (RTE). As a result, maximum levels and sampling plans are proposed for only ready-to-eat dried figs.
2. The performance of the proposed draft sampling plan was computed using the variability and aflatoxin distribution among laboratory samples of dried figs taken from contaminated lots. Because the dried fig count per kg is different for different varieties of dried figs, the laboratory sample size is expressed in number of dried figs for statistical purposes. However, the dried fig count per kg for each variety of dried figs can be used to convert laboratory sample size from number of dried figs to mass and vice versa.
3. Uncertainty estimates (variances) associated with sampling, sample preparation, and analysis and the negative binomial distribution[1] are used to calculate operating characteristic (OC) curves that describe the performance of the proposed aflatoxin-sampling plans for dried figs.

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

4. The analytical variance measured in the sampling study reflects within laboratory variance and was replaced with an estimate of analytical variance that reflects a reproducibility relative standard deviation of 22%, which is suggested by Thompson and is based upon Food Analysis Performance Assessment Scheme (FAPAS) data[2]. A relative standard deviation of 22% is considered by FAPAS as an appropriate measure of the best agreement that can be reliably obtained between laboratories. An analytical uncertainty of 22% is larger than the within laboratory variation measured in the sampling studies for dried figs.

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

AFLATOXIN TEST PROCEDURE AND MAXIMUM LEVELS

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

7. The maximum level for "ready-to-eat" dried figs is 10 μg/kg total aflatoxins.

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

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

   Maximum level – 10 μg/kg total aflatoxins

   Number of laboratory samples – 3

   Laboratory sample size - 10 kg

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

   Analytical method – performance based (see Table 2)

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

   The operating characteristic curve describing the performance of the sampling plan for the ready-to-eat dried figs is shown in paragraph 46 at the end of this Annex.

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

SAMPLE SELECTION

Material to be sampled

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

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

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

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

Incremental Sample Selection

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

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

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

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

Number and Size of Incremental Samples for Lots of varying weight

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

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

Lot or Sublot Weight [b] (T in Tonnes)	Minimum Number of Incremental Samples	Minimum Incremental Sample Size [c] (g)	Minimum Aggregate Sample Size (kg)	Laboratory Sample Size (kg)	Number of Laboratory Samples
15.0 ≥ T > 10.0	100	300	30	10	3
10.0 ≥ T > 5.0	80	300	24	8	3
5.0 ≥ T > 2.0	60	300	18	9	2
2.0 ≥ T > 1.0	40	300	12	6	2
1.0 ≥ T > 0.5	30	300	9	9	1
0.5 ≥ T > 0.2	20	300	6	6	1
0.2 ≥ T > 0.1	15	300	4.5	4.5	1
0.1 ≥ T	10	300	3	3	1

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

b/ 1 Tonne = 1000 kg

c/ Minimum incremental sample size = laboratory sample size (30 kg)/minimum number of incremental samples, i.e. for 10 < T ≤ 15 tonne, 300 g = 30000 g/100

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

Static Lots

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

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

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

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

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

Dynamic Lots

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

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

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

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

    Equation 2: $S = (D \times LT) / (T \times V)$,

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

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

    Equation 3: $SF = (S \times V) / (D \times MR)$.

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

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

30. If the lot is moving at 500 kg per minute, the entire lot will pass through the sampler in 40 minutes (2400 sec) and only 14.4 cuts (14 incremental samples) will be made by the cup through the lot (Equation 3). This may be considered too infrequent, in that too much product (1,388.9 kg) passes through the sampler between the time the cup cuts through the stream.

Packaging and Transportation of Samples

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

Sealing and Labelling of Samples

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

SAMPLE PREPARATION

Precautions

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

Homogenization - Grinding

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

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

36. The use of vertical cutter mixer type grinders that mix and comminute the laboratory sample into a paste represent a compromise in terms of cost and fineness of grind or particle size reduction[3]. A better homogenization (finer grind), such as a liquid slurry, can be obtained by more sophisticated equipment and should provide the lowest sample preparation variance[4].

Test portion

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

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

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

ANALYTICAL METHODS

Background

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

Performance Criteria for Methods of Analysis

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

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

Criterion	Concentration Range (ng/g)	Recommended Value	Maximum Permitted Value
Blanks	All	Negligible	n/a
Recovery	1 to 15	70 to 110%	n/a
	>15	80 to 110%	n/a
Precision or Relative Standard Deviation RSD_R (Reproducibility)	1 to 120	Equation 4 by Thompson	2 x value derived from Equation 4
	>120	Equation 5 by Horwitz	2 x value derived from Equation 5
Precision or Relative Standard Deviation RSD_r (Repeatability)	1 to 120	Calculated as 0.66 times Precision RSD_R	n/a
	>120	Calculated as 0.66 times Precision RSD_r	n/a

n/a = not applicable

42. The detection limits of the methods used are not stated. Only the precision values are given at the concentrations of interest. The precision values (expressed as a %) are calculated from equations 4 and 5 developed by Thompson[2] and Horwitz and Albert[5], respectively.

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

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

Equation 4: $RSD_R = 22.0$

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

where:

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

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

44. Results should be reported on the sample.

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

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

Table 3.Variances[a] associated with the aflatoxin test procedure for each dried figs

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

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

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

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

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

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

OPERATING CHARACTERISTIC CURVE DESCRIBING THE PERFORMANCE OF THE DRAFT AFLATOXIN SAMPLING PLAN FOR READY-TO-EAT DRIED FIGS

46. The operating characteristic curve describing the performance of draft aflatoxin sampling plan for ready-to-eat dried figs is shown in Figure 1.

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

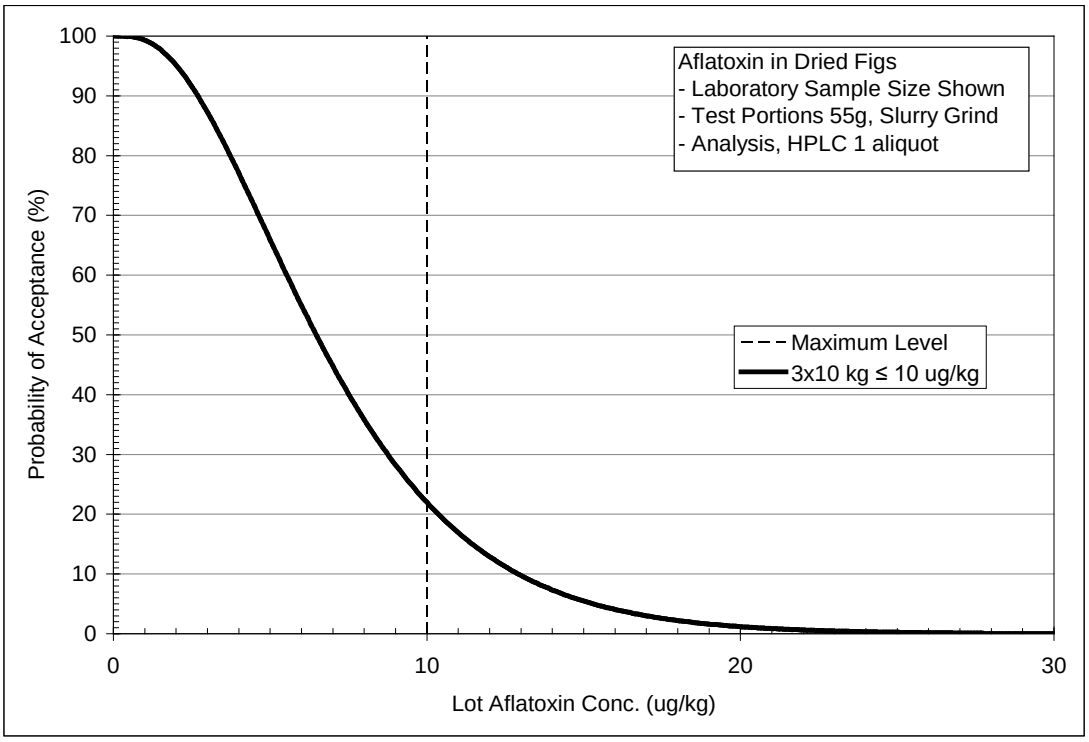

Figure 1. Operating characteristic (OC) curve describing the performance of the aflatoxin sampling plan for ready-to-eat dried figs using three laboratory samples of 10 kg each and a maximum level of 10 µg/kg total aflatoxins, water-slurry comminution method, test portion that reflects 55 g fig mass, and quantification of aflatoxin in a the test portion by HPLC.

APPENDIX VII

PROJECT DOCUMENT

PROPOSAL FOR A "CODE OF PRACTICE FOR WEED CONTROL TO PREVENT AND REDUCE PYRROLIZIDINE ALKALOID CONTAMINATION IN FOOD AND FEED"

1- Purpose and Scope of the new work

The purpose of the proposed new work is to provide to member countries and the food and feed producing industries a guidance to prevent and reduce pyrrolizidine alkaloid (PA) contamination of food and feed. The Code will cover different types of management practices for control of PA-containing weeds.

2- Relevance and timeliness

Several PAs have been evaluated by the International Agency for Research on Cancer (IARC). Lasiocarpine, monocrotaline and riddelliine have been classified as Group 2B (possibly carcinogenic to humans) while hydroxysenkirkine, isatidine, jacobine, retrorsine, seneciphylline, senkirkine and symphytine have been classified as Group 3 (not classifiable as to its carcinogenicity to humans, IARC, 1976, 1983, 2002).

Pyrrolizidine alkaloids (PAs) are toxins found naturally in a wide variety of plant species. PAs are probably the most widely distributed natural toxins and affect wildlife, livestock and humans. Outbreaks of toxicity in farm animals cause severe economic losses to farmers and rural communities and there is the possibility of risk to humans from the intake of PA contaminated food of botanical or animal origin. There have been cases reported where salads have been contaminated with PA containing weeds. Also consumption of grain or grain products (flour or bread) contaminated with PA-containing seeds has been involved in outbreaks of poisonings affecting rural populations in Afghanistan, India, South Africa and the former USSR. It was recognized by FAO that the principal control measure for PA contamination of food and feed is weed control in accordance with Good Agricultural Practices.

3- Main aspects to be covered

The proposed new work will focus on good practices that will prevent of reduce contamination of food and weed with PAs from weeds. The code will cover control measures for eradication of weed as well as measures for control of plant release and spread.

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

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

The code will provide additional guidance for countries in order to preventing and reducing PA contamination of food and feed and consequently minimize consumer dietary exposure to PAs.

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

The code would provide internationally recognized scientific and technical guidance in order to improve the enhancement of international trade.

c) Work already undertaken by other organizations in this field

FAO as produced a Consumer Protection Fact Sheet in which shortly some weed control measures have been described. This Code will provide more detailed information for control measures for PA-containing weeds.

5- Relevance to Codex Strategic Goals

The work proposed falls under all five Codex Strategic Goals:

Goal 1: Promoting Sound Regulatory Frameworks

The result of this work will assist in promoting sound regulatory frameworks in international trade by using scientific knowledge and practical experience for prevention and reduction of PA contamination of food and feed.

This work will harmonize procedures for developed and developing countries with a view to promoting maximum application of Codex Standards for fair trade.

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

This work will help in establishing risk management options and strategies to control PAs in food and feed.

Goal 3: Strengthening Codex work-management capabilities

By establishing a general framework for the management of food safety risks associated with the prevention and reduction of PA contamination of food and feed will provide a general document that can be referenced by CCCF and it can be used by many countries.

Goal 4: Promoting cooperation between seamless linkages between Codex and other multilateral bodies.

The work will supplement the information already provided by FAO on PA control measures and thus contribute to FAO's work.

Goal 5: Promoting maximum application of codex standards

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

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

This new work is recommended in the Discussion Paper on Management Practices for the Prevention and Reduction of Contamination of Food and Feed with Pyrrolizidine Alkaloids (CX/CF 12/6/12).

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

PAs are on the Priority List for Evaluation by JECFA. The outcome will give further evidence on the effectivity of management practices for the control of PA contamination of food and feed.

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

Currently, there is no need for additional technical input from external bodies.

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

If the Commission approves, the draft Code of Practice will be circulated for comments at Step 3 and consideration by the 7th session of CCCF at Step 4 in 2013. Adoption at Step 5 by the Commission is planned for 2014 and adoption at Step 8 by the Commission is foreseen for 2015.

APPENDIX VIII

PROJECT DOCUMENT

PROPOSAL TO REVISE MAXIMUM LEVELS FOR LEAD IN FRUIT JUICES, MILK AND SECONDARY MILK PRODUCTS, INFANT FORMULA, CANNED FRUITS AND VEGETABLES, FRUITS, AND CEREAL GRAINS (EXCEPT BUCKWHEAT, CAÑIHUA, AND QUINOA) IN THE GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOOD AND FEED

1. Purpose and Scope of the new work

The purpose of the proposed new work is to revise the maximum levels (MLs) for lead in various foods in light of the decision by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) to withdraw the provisional tolerable weekly intake (PTWI) for lead. The scope of the new work encompasses the establishment of revised MLs for lead in fruit juices, milk and secondary milk products, infant formula, canned fruits and vegetables, fruits, and cereal grains (except buckwheat, cañihua, and quinoa).

2. Relevance and timeliness

At its 73rd session, JECFA conducted a new toxicological evaluation of lead in food. In the evaluation, JECFA stated that exposure to lead is associated with a wide range of effects, including various neurodevelopmental effects, impaired renal function, hypertension, impaired fertility, and adverse pregnancy outcomes. Because of the neurodevelopmental effects, fetuses, infants, and children are the subgroups that are most sensitive to lead. JECFA estimated that the previously established PTWI of 25 μg/kg-body weight is associated with a decrease of at least 3 intelligence quotient points in children and an increase in systolic blood pressure of approximately 3 mmHg (0.4 kPa) in adults. JECFA therefore concluded that this PTWI could no longer be considered health protective, and it was withdrawn. Because dose-response analyses do not indicate a threshold for neurodevelopmental and blood pressure effects, JECFA concluded that it was not possible to establish a new PTWI that would be considered to be health protective.

Given the health impact of lead, it is important to reduce exposure to lead from food, particularly for infants and children, as they constitute the most sensitive subpopulation in terms of neurodevelopmental effects. The new work aims to reduce exposure by revising MLs for lead in various foods in the General Standard for Contaminants and Toxins in Food and Feed (GSCTFF). It is also worth noting that some of the existing MLs for lead in food in the GSCTFF, such as MLs ≥ 1 ppm for various canned fruit and vegetable products, are outdated and appear to reflect the historic use of lead soldered cans.

3. Main aspects to be covered

The proposed new work will focus on revising MLs for lead in fruit juices, milk and secondary milk products, infant formula, canned fruits and vegetables, fruits, and cereal grains (except buckwheat, cañihua, and quinoa), taking into consideration global data on prevalence levels of lead in these foods.

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

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

Revision of the MLs for lead will protect consumers by potentially lowering exposure to lead from food.

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

For countries interested in reexamining their own lead standards in light of the JECFA report, this new work will provide international standards on which to draw, and may thus provide a more consistent international approach to standard setting for lead in food.

c. Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body(ies)

JECFA's conclusion that it is not possible to establish a health protective PTWI for lead indicates the importance of new work on revising MLs for lead in food.

5. Relevance to Codex Strategic Goals

Goal 1: Promoting sound regulatory frameworks

This work will assist in promoting sound regulatory frameworks by using scientific information and data analysis to develop MLs.

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

This work will assist in promoting widest and consistent application of scientific principles and risk analysis by using scientific information and data analysis to develop MLs. This work will draw heavily on work previously done by JECFA in keeping with scientific principles and risk analysis.

Goal 3: Strengthening Codex work-management capabilities

This work will assist Codex in its goal of strengthening its work-management capabilities, specifically to respond quickly and efficiently to international developments, by providing new MLs in response to the conclusions of the 73rd JECFA on lead in food.

Goal 4: Promoting cooperation between Codex and relevant international organizations

The work done by JECFA is the groundwork for this new effort by the CCCF. CCFC will continue to work with JECFA on this project, particularly as new data on lead in food are submitted to the GEMS database.

Goal 5: Promoting maximum and effective participation of members

As exposure to lead from food appears to be a global phenomenon, this work will support and embrace all aspects of this objective by requiring participation of both developed and developing countries to conduct the work.

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

This new work is discussed in CX/CF 12/6/13 (Discussion Paper on 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), which was presented at the 6th Session of CCCF in March 2012.

Identification of any requirement for and availability of expert scientific advice

The JECFA Secretariat will provide needed expert scientific advice.

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

Currently, there is no identified need for additional technical input from external bodies.

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

The work will commence after the Codex Alimentarius Commission approves the new work in July 2012. The proposed draft revised MLs will be circulated for comments at Step 3 and consideration by the 7th Session of CCCF at Step 4 in 2013. Adoption at Step 5 by the Commission is planned for 2014 and adoption at Step 8 by the Commission can be expected by 2015.

APPENDIX IX

PROJECT DOCUMENT

PROPOSAL FOR AN ADDITIONAL ANNEX FOR "PREVENTION AND REDUCTION OF AFLATOXINS AND OCHRATOXIN A (OTA) IN SORGHUM" IN THE EXISTING CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF MYCOTOXIN CONTAMINATION IN CEREALS (CAC/RCP 51-2003)

1. Purpose and Scope of the new work

The purpose of the proposed new work is to provide member countries and sorghum industry, including small scale producers, a guidance to prevent and reduce Aflatoxins and Ochratoxin A (OTA) contamination in sorghum. The scope of the new work encompasses the development of draft annex for the prevention and reduction of Aflatoxins and OTA Contamination in sorghum, which will cover the stages of primary production, storage and distribution to the point of usage of sorghum.

2. Relevance and timeliness

Aflatoxins have been documented as naturally occurring carcinogens and are primarily associated with high incidence of liver cancer in some parts of the world. Aflatoxins are known hepatotoxins and hepacarcinogens causing the death of people that ate highly contaminated cereals. Aflatoxin B1 has particularly been identified as causative factor in the development of hepatocellular carcinoma, an emerging chronic disease of global concern.

The toxicity of Ochratoxin A (OTA) has been reviewed by the International Agency for Research on Cancer (IARC), that has classified OTA as a possible human carcinogen (group 2B), and by the Joint FAO/WHO Expert Committee on Food Additives (JECFA). Ochratoxin A is a mycotoxin that occurs naturally worldwide in food commodities including sorghum and sorghum products. In sorghum, OTA is field and storage mycotoxins.

Sorghum is fast gaining prominence as food, feed and industrial cereal in the world. The demand for it is fast growing; this is evident in the fact that while only 59 countries export sorghum, 110 countries import sorghum for their need. Whichever use the cereal is put, it is of public health interest to be safe for use; and good agricultural practices will help in achieving this goal.

3. Main aspects to be covered

The proposed new work will focus on good practices that will control contamination of sorghum with Aflatoxins and OTA producing fungi, growth of the fungi and production of aflatoxins and ochratoxin A. The code will cover the value chain stages of land preparation, cultivation, pre-harvest, post harvest handling, storage and transportation practices) to develop strategies to prevent and reduce aflatoxins and OTA contamination of sorghum.

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

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

The annex will provide additional guidance for countries in order to improve sorghum quality, preventing and reducing aflatoxins and OTA contamination and consequently minimize consumer dietary exposure to aflatoxins and OTA from sorghum and sorghum products.

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

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

c) Work already undertaken by other organizations in this field

This is an extension of the contents of COP to cater for the particular needs for good production practices of sorghum. Some work has been done by International Crop Research Institute for the Semi Arid Tropics (ICRISAT) on management of aflatoxins and fumonisins in sorghum. However there is a grave scarcity of report of work done in respect of OTA and other mycotoxins in sorghum. This informed the on going pilot project work of the WHO/FAO on fungi and mycotoxins in sorghum funded by Codex Trust Fund.

5. Relevance to Codex Strategic Goals

The work proposed falls under all five Codex Strategic Goals:

Goal 1: Promoting Sound Regulatory Frameworks

The result of this work will assist in promoting sound regulatory frameworks in international trade by using scientific knowledge and practical experience for prevention and reduction of Aflatoxins and OTA contamination in sorghum.

This work will harmonize procedures for developed and developing countries with a view to promoting maximum application of Codex Standards for fair trade.

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

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

Goal 3: Strengthening Codex work-management capabilities

By establishing a general framework for the management of food safety risks associated with the prevention and reduction of aflatoxins and OTA contamination in sorghum will provide a general document that can be referenced by CCCF and it can be used by many countries

Goal 4: Promoting cooperation between Codex and relevant international organizations..

The involvement of FAO and WHO in Codex activities in general and in the pilot project on sorghum in particular is an evidence of seamless linkages of these bodies and Codex.

Goal 5: Promoting maximum application of codex standards

This work will support and embrace all aspects of this objective by requiring participation of both developed and developing countries to execute the work.

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

This new work is a recommendation in the Discussion Paper on fungi and mycotoxin in sorghum which was adopted at the 6th Session of Codex Committee on Contaminants in Foods.

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

There is sufficient scientific information in the Discussion Paper and also with JECFA for this stage of the work.

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

Currently, there is no need for additional technical input from external bodies

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

If the Commission approves, the proposed draft annex will be circulated for comments at Step 3 and consideration by the 7th session of CCCF at Step 4 in 2013. Adoption at Step 5 by the Commission is planned for 2013 and adoption at Step 8 by the Commission can be expected by 2014.

APPENDIX X

PROJECT DOCUMENT

PROPOSAL FOR NEW WORK ON CODE OF PRACTICE FOR
THE PREVENTION AND REDUCTION OF OCHRATOXIN A CONTAMINATION IN COCOA

1. Purpose and Scope of the new work

The purpose of the proposed new work is to provide to member countries and the cocoa industry a guidance to prevent and reduce Ochratoxin A (OTA) contamination in cocoa. The scope of the new work encompasses the development of a draft Code of Practice for the prevention and reduction of OTA Contamination in Cocoa, which will cover the stages of primary production of cocoa. It is anticipated that this new work would be undertaken based on FAO Guidelines for the Prevention of Mould Formation in Coffee and in line with the current Code of Practice elaborated for Coffee.

2. Relevance and timeliness

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

Ochratoxin A is a mycotoxin that occurs naturally worldwide in food commodities including cocoa beans and cocoa products. In cocoa, OTA is mostly associated with cocoa bean shells and fat free cocoa solids (cocoa powder). The cocoa beans are not eaten as such; they undergo industrial conversion into cocoa products before consumption. Cocoa products are very important ingredients in pharmaceuticals, cakes, biscuits and chocolate confectionery. Around 71% of the world supply of cocoa beans comes from West Africa. Cocoa beans are also produced in Asia and Latin America. Being a crop produced by smallholders, cocoa is a valuable cash crop for hundreds of thousands of farmers in the cocoa producing countries, and it is also of great importance to the economies of these countries.

The most effective way to prevent and reduce OTA in cocoa beans and cocoa products is the use of Good Agricultural Practices (GAP) along the cocoa value chain.

3. Main aspects to be covered

The proposed new work will focus on good practices that will control infection of cocoa with OTA producing fungi, growth of the fungi and OTA production. The code will cover the stages of cocoa bean production (pre-harvest, primary processing, storage and transportation practices) to develop strategies to prevent and reduce OTA contamination in cocoa.

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

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

b) The code will provide additional guidance for countries in order to improve cocoa quality, preventing and reducing OTA contamination and consequently minimize consumer dietary exposure to OTA from cocoa products.

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

d) The code would provide internationally recognized scientific guidance in order to improve the enhancement of international trade.

e) Work already undertaken by other organizations in this field

Not much work has been done by other international organizations on OTA in cocoa; however, FAO has produced some guidelines for the Prevention of mould formation in coffee. Codex has also developed Code of Practice for the prevention and reduction of Ochratoxin A contamination in coffee (CAC/RCP 69-2009).

5. Relevance to Codex Strategic Goals

The work proposed falls under all five Codex Strategic Goals:

Goal 1: Promoting Sound Regulatory Frameworks

The result of this work will assist in promoting sound regulatory frameworks in international trade by using scientific knowledge and practical experience for prevention and reduction of OTA contamination in cocoa.

This work will harmonize procedures for developed and developing countries with a view to promoting maximum application of Codex Standards for fair trade.

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

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

Goal 3: Strengthening Codex work-management capabilities

By establishing a general framework for the management of food safety risks associated with the prevention and reduction of OTA contamination in cocoa will provide a general document that can be referenced by CCCF and it can be used by many countries

Goal 4: Promoting cooperation between seamless linkages between Codex and other multilateral bodies.

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

Goal 5: Promoting maximum application of codex standards

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

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

This new work is recommended in the Discussion Paper on OTA in cocoa to be presented and discussed at the 6th Session of Codex Committee on Contaminants in Foods.

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

Additional scientific advice is not necessary at this moment, as FAO has already published the Guidelines for the Prevention of Mould Formation in Coffee. Mould formation in coffee and cocoa is caused by similar mycoflora.

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

Currently, there is no need for additional technical input from external bodies

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

If the Commission approves, the draft Code of Practice will be circulated for comments at Step 3 and consideration by the 7th session of CCCF at Step 4 in 2013. Adoption at Step 5 by the Commission is planned for 2013 and adoption at Step 8 by the Commission can be expected by 2014.

APPENDIX XI

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: occurrence data available Japan: subchronic toxicity test and occurrence end 2013 Surveillance data by summer 2013 (new method being developed) China: Total Diet Study on 3-MCPD esters available Canada: surveillance data available	Germany, supported by EC, Canada, Japan
Glycidyl ester	Full evaluation (toxicological assessment and exposure assessment) Bioavailability of free compounds	Japan: (analytical method under development) Surveillance in fats and oils Summer 2013 Subchronic tox studies summer 2013 USA: end 2012 as planned	Germany; USA
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 2013 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 - available Netherlands: provides monitoring data to EFSA database Rep of Korea: monitoring data - available EU: to assure that EFSA data will be made available Belgium: total diet study available end 2012 Tunisia: monitoring data - available	Rep of Korea Canada
Cadmium	exposure assessment from cocoa and cocoa-product		Colombia

APPENDIX XII

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).

APPENDIX XIII

GUIDANCE FOR RISK MANAGEMENT OPTIONS IN LIGHT OF DIFFERENT RISK ASSESSMENT OUTCOMES

Contents

I. Background

1. The 4th Session of the Codex Committee on Contaminants in Foods (CCCF) agreed to establish an electronic Working Group to develop guidance on risk management options to consider when dealing with the results from risk assessment approaches used by the Joint FAO/WHO Committee on Food Additives (JECFA) (ALINORM 10/33/41; paragraph 111). The resulting discussion paper was discussed at CCCF's 5th Session.

2. 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
        - Implications of different risk assessment outcomes and description of possible risk management options.

3. An electronic Working Group was established and the members are listed in the Appendix. Comments to the working drafts were provided by many members of the workgroup and incorporated into the present document for presentation at the CCCF 6th Session.

II. Discussion and Conclusions

4. Traditionally in the food area, risk assessment is based on deterministic endpoints, i.e., use of the no observed adverse effect level (NOAEL) or no observed effect level (NOEL) and the mean or high level of exposure. Methods to assess the dose responses of toxicity assays have evolved beyond just determination of a NOAEL. Further, as the available data allow, probabilistic and distributional methods can be used to characterize the hazard(s) as well as the exposure(s). These approaches allow for more description of variability in the population and uncertainty in the risk estimates. Additional risk assessment outcomes are also used and reported, such as the margin of exposure (MOE), which gives a relative indication of the level of health concern without actually quantifying the risk. These expansions of risk assessment tools and the information they provide may require additional consideration on the part of risk managers as they evaluate risk management options.

5. Further, in many instances, exposure information has greatly improved which has improved the risk assessment of food borne chemicals. This in turn, has allowed for the consideration of different exposure scenarios (e.g., for different susceptible populations) and better and more precise estimates of risks in these populations. This more detailed information needs greater scrutiny by risk management as well as considerations for what fraction of the population will be affected by different measures (though not discussed in this discussion paper).

6. The purpose of this discussion paper is to discuss options for how the different risk assessment outputs may be considered in the choice for risk management options. CCCF explored whether it is possible to link specific risk management options to specific risk assessment outcomes. However, in the area of contaminants, such a one-to-one association does not seem feasible as the origin and characteristics of these compounds, and thus the risk assessment outcomes, vary greatly. In addition, it was recognized during the plenary of the 5th CCCF that there is no fundamental difference in available risk management options for the different risk assessment outcomes. Therefore, the choice was made for this discussion paper to include an extensive discussion on the factors of a risk assessment outcome which could be taken into account in the choice for a relevant risk management option.

   To this purpose, the heart of the document is found in three sections:

   i. Risk assessment outcomes (a discussion of principles and techniques used)

   ii. Interpretation of the risk assessment outcomes (a discussion of which factors to consider and options on how to do this)

   iii. Risk management options (a discussion of different options and their possible use)

7. This document aims at risk communication and is intended to be an informal overview. It is not aimed to prepare or change any standards..

III. Introduction

8. This discussion paper elaborates on the guidance to CCCF found in the "Working Principles for Risk Analysis For Application in the Framework of the Codex Alimentarius" found in the Codex Alimentarius Commission (Codex) Procedural Manual. Codex embraces the use of risk analysis in the development of risk-based approaches for the management of public health hazards in food. Risk analysis is made up of three interactive components:

   - Risk Assessment: itself comprised of four components, hazard identification, hazard characterization (including dose response analysis), exposure assessment, and risk characterization. While these are recognized as separate components, in reality, these risk assessment components are not performed in a series of four subsequent steps (i.e., one component following the other), but are usually performed interactively and iteratively.

   - Risk Management: The process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options.. Usual risk management components consist of preliminary risk management activities, recognizing and evaluating possible risk management options (based on the risk assessment outcome), implementation of management decisions, and monitoring and review of subsequent actions to see if the risk management options implemented are working to protect public health.

   - Risk Communication: is the interactive exchange of information and opinions throughout the risk analysis process about risk and related issues. It includes all stakeholders involved in the risk analysis process.

9. Although it is desirable to have a clear separation of the functional activities and roles of risk assessment and risk management in order to ensure scientific independence as well as transparency, it is acknowledged that risk managers should communicate and interact with risk assessors throughout the process, particularly during the problem formulation and planning and scoping phases at the beginning of the risk analysis process. This will help focus and direct the risk assessment on the appropriate risk management issue(s) and question(s). Thus, the relationship between risk assessment and risk management is an interactive, often iterative and complementary, process.

10. Although risk communication encompasses communication among all stakeholders all through the risk analysis process, there is a critical discussion between risk assessors and risk managers at the end of the risk assessment when communicating the outcomes to the risk managers. These outcomes will help the risk managers determine what food safety decisions may or may not be needed.

11. As detailed in the Codex Procedural Manual (Section IV: Risk Analysis, Sections 2, 3, CCFA/CCCF and 4, JECFA), there is an interrelationship between CCCF and JECFA which requires comprehensible and transparent communication. JECFA is primarily responsible for providing CCCF with science-based risk assessments, comprised of the four components mentioned above. This serves as the basis for CCCF's food safety discussions and recommendations for risk management options, such as maximum limits (MLs) in foods.

12. For further discussion and detail on the risk analysis process/framework and the components of risk analysis, refer to the Codex Procedural Manual, the Environmental Health Criteria document 240: Principles and Methods for the Risk Assessment of Chemicals in Food (EHC 240 (FAO/WHO, 2009)), and the FAO Food and Nutrition Paper 87: Food Safety Risk Analysis – A Guide for National Food Safety Authorities (WHO/FAO, 2006), among many possible references.

13. The definitions to the terms relevant to this paper (i.e., glossary), and detailed descriptions and considerations of the risk assessment techniques used in this discussion paper can be found in:

FAO/WHO (Food and Agriculture Organization of the United Nations/World Health Organization). 2009. Environmental Health Criteria 240: Principles and methods for the risk assessment of chemicals in food.

At: http://www.who.int/foodsafety/chem/principles/en/index1.html

IV. Risk Assessment Tools and Outcomes

14. Risk assessment is a process intended to estimate the risk to a given target organism, system, or (sub)population, including the identification of attendant uncertainties, following exposure to a particular agent, taking into account the inherent characteristics of the agent of concern as well as the characteristics of the specific target system (IPCS Risk Assessment Terminology; WHO, 2004). There are several outcomes that are possible from a risk assessment, e.g. a quantitative estimation of the risk at specified exposure levels, a Health Based Guidance Value (HBGV), a Margin of Exposure (MOE), a qualitative description of a possible prioritization of risks.

15. Probabilistic approaches to describe the range of responses and exposures can also be used when appropriate data are available. Since modeling with probabilities and distributions requires more intensive effort and resources, a decision on whether it is worthwhile to engage in such modeling over the deterministic approaches needs to be made, i.e., does the increased transparency of the uncertainty and variability addressed in these models make a significant difference in public health safety over the deterministic approaches. For exposure analyses, probabilistic approaches are increasingly being utilized as they help better characterize the variability and variety of possible exposures. For hazard characterization, JECFA currently relies more extensively on dose response modeling which is described below.

16. The Threshold of Toxicological Concern (TTC) approach is a screening tool that has been developed in order to assess substances of unknown toxicity present at low levels in the diet. Application of the TTC approach requires knowledge of the chemical structure and adequate information for a conservative estimate of human exposure. This information is compared to structurally related chemicals of known toxicity. In this respect, the TTC approach has the potential to be used both for qualitative risk assessment and for priority setting, to enable efficient use of available resources.

Point of Departure (POD)

17. The POD serves as the basis for the hazard characterization, i.e., for the derivation of the HBGV or MOE. The POD, or reference point, is the appropriate (i.e., low- or no-effect) dose associated with the critical endpoint(s) and critical study(ies) (i.e., based on the most sensitive species; most sensitive endpoint of relevance to humans). The POD can be based on the NOAEL (no observed adverse effect level) or LOAEL (lowest observed adverse effect level). However, if the data allow a benchmark dose (BMD) or benchmark dose lower confidence limit (BMDL) to be derived from dose-response modeling, these can be used as the POD (EHC 240).

18. The NOAEL is the highest experimental dose level for which the response is not statistically significantly different compared with the response in the control group. If a NOAEL could not be identified from the most relevant study, then the LOAEL can be selected as the POD.

19. The BMD method involves fitting a series of dose response models to the data, and a BMD is estimated from each model as the dose corresponding to a specified change in effect over background (i.e., the benchmark response, BMR; this could be the 5 or 10% effect level for instance). The lower bound 95% confidence limit on the BMD is calculated, i.e. the BMDL, to account for uncertainty in the data (e.g., the BMDL10 would be the lower confidence bound on the BMR at the 10% effect level). For those models that provide an acceptable fit to the data, the BMDLs are calculated and the range of BMDLs expressed. As a conservative approach,, the lower end of the range of BMDLs is often used as a POD. JECFA has proceeded with this approach, but there are other approaches, e.g., model averaging, that can be used if so decided. Also, a more or less conservative approach (e.g., smaller or larger effect level for the BMR) might be considered in some cases if more statistically or biologically appropriate models are selected, or more reliable data sets are used for modeling.

20. The BMD method has a number of advantages over the use of a NOAEL or LOAEL for deriving a POD. Whereas the NOAEL/LOAEL are discrete doses used in a study(ies), the BMD approach involves modeling the dose-response curve in the range of all the relevant observable data, and then using that model to estimate a dose that corresponds to a particular level of response. The BMD method therefore makes use of the full dose response data in the statistical analysis, which also allows for the quantification of the uncertainty in the data. Higher uncertainty in the data, for example due to small group sizes or high variation within a group, would be reflected in a lower POD (EHC 240).

Uncertainty/Safety Factors

21. Uncertainty, or safety, factors are used to address the uncertainty and variability surrounding the data being used to estimate risk. An uncertainty/safety factor is usually a composite factor by which the selected POD is divided to derive a HBGV. Critical in the application of uncertainty/safety factors is always the transparent description and explanation for the selection of all factors applied.

22. A default uncertainty/safety factor of 10 or 100 is used depending on whether human or animal studies are used in deriving the POD. If a human study is used then a factor of 10 is usually used to account for the variability in responses between average humans and those who are highly sensitive. If an animal study is used then an additional 10-fold factor is used to account for differences between the average responses in the experimental animals used in the study identified to derive the POD and those in average humans. Additional uncertainty/safety factors can be used "case-by-case," mainly to account for deficiencies in the database, to extrapolate from sub-chronic to chronic exposure, or to extrapolate from a LOAEL to a NOAEL.

23. In some cases a chemical specific adjustment factor (CSAF) can be used (EHC 240). CSAFs enable the incorporation in risk assessment of specific quantitative data on species differences or human variability in either toxicokinetics or toxicodynamics to replace part of the default uncertainty factor described above (IPCS, 2005).

Health-Based Guidance Values (HBGVs)

24. HBGVs are the quantitative expression of an oral exposure (either acute or chronic) that would be expected to be without appreciable health risk. They are established for compounds that produce adverse effects via a mechanism that demonstrate a non-linear dose-response relationship, i.e., an exposure level is observed where an adverse effect cannot be discerned above background. HBGVs are derived by dividing the POD by suitable uncertainty factors to result in a tolerable or acceptable daily or weekly intake. Expressed on a per kg body weight basis, it is applicable to the whole population, but derived attempting to also protect the most sensitive part of the population.

25. For some contaminants, it may be useful to establish more than one reference value (e.g., for acute and chronic exposures). There are occassionswhere a provisional HBGV is determined (e.g., a provisional tolerable weekly intake, PTWI). The tolerable intake is generally referred to as "provisional" as there is often a paucity of data on the consequences of human exposure at low levels.

Margin of Exposure (MOE)

25. The MOE is the ratio between a POD and an estimate of human exposure. For genotoxiccarcinogens, the traditional assumption is that there is a linear dose response down to zero dose and that some degree of risk may exist at any level of exposure. Thus, JECFA does not establish HBGVs for substances that are known to be genotoxic. In these cases, a MOE is derived. However, the MOE approach can also be used for substances with a non-linear dose response, particularly for which the database is not sufficient to set a health-based guidance value.

26. This approach provides advice to inform risk managers of how close estimates of human exposure are to those that produce a measurable effect in laboratory animals or humans. In addition, MOEs for different substances derived by the same methodology can be compared to assist risk managers in prioritizing risk management actions for various chemical substances.

Quantitative Risk Estimates

27. If sufficient data are available, JECFA can also perform a fully quantitative risk assessment, describing the quantitative risk estimated at defined levels of exposure. This has been done for contaminants like aflatoxins, cadmium, and lead, where the risk (i.e., number of estimated cases per year) per ingested dose was estimated for different populations at risk. Quantitative risk assessment outcomes allow for other subsequent analyses such as a quantitative health impact assessment and cost-benefit analysis. However, detailed quantitative risk assessments require a considerable amount of data that are often not available.

V. Interpretation of Risk Assessment Outcomes

Uncertainty and Variability

28. Uncertainty in risk assessment is due to lack of knowledge and it increases when data are of poor quality or inadequate. It is not the same as variability. Variability refers to true heterogeneity or diversity. For example, a risk assessor may be very certain that different people drink different amounts of water, but may be uncertain about how much variability there is in water intakes within the population. Uncertainty can often be reduced by collecting more and better data, whereas variability is an inherent property of the population being evaluated. Variability can also be better characterized with more data, but it cannot be reduced or eliminated. Distinguishing between variability and uncertainty is important in characterizing risk.

29. Predictions of hazard estimated from a given deterministic model are only point estimates and, to a larger or smaller extent, uncertain. This uncertainty arises from at least three sources:

    - the sampling error arising from inferences about a larger population from a single experiment;
    - the reality that dose response estimates often differ among experiments with different experimental design, protocol or uncontrolled circumstances; and
    - the fact that the "true" model is not known, which results in additional uncertainty when interpolating between doses, but even more so when extrapolating outside the dose range containing observations.

    These uncertainties may all be represented in a dose response assessment through the use of probability distributions or probability trees. The latter technique involves using multiple alternative plausible assumptions about what data sets or models are to be used to produce an estimate, which results in a range of plausible estimates.

30. Efforts to clearly distinguish between variability and uncertainty and how they impact the hazard assessment outcomes are important when characterizing risk. Sensitivity analysis can provide some insight to the quantitative impact of either uncertainty or variability on estimates of risk. This analysis helps determine how changes in various inputs (data or assumptions) affect the outcomes of a risk assessment.

31. In addition to the hazard assessment, uncertainties in the risk assessment can also arrive from the exposure estimation, which uses chemical concentration and food consumption data. Uncertainties concerning the chemical concentration within the exposure estimation are related, among others, to the data source (legal limits or laboratory data), the food analyzed (raw commodity or ready-to-eat food), sampling protocols (if the sample is representative of the population sampled), the number of samples analyzed, and the analytical method used (sensitivity, precision and accuracy). Uncertainties in food consumption data are related, among others, to the type of data (e.g., GEMS Food diets or individual data), the number of individuals surveyed, the age of the data (as dietary patterns can vary over time), and whether the surveyed population can be extrapolated to the rest of the population.

HBGV

32. HBGVs such as the ADI, TDI, and RfD are deterministic values which imply a demarcation between what is assumed to be a "safe" level of exposure (i.e., exposures below the HBGV) versus a "non-safe" level (i.e., exposures above the HBGV). However, it should be kept in mind that due to uncertainty and variability, these apparent "bright lines" in reality are not as precise (i.e., not as sharp a boundary between safe and non-safe) as they appear to indicate. Moreover these are levels for chronic, life-time exposures, and are often based on conservative assumptions. Hence, short term exceedance may not be of health consequence. However, this needs to be determined on a case-by-case basis, since it is dependent on the characteristics of the compound.

Margin of Exposure

33. There is no general guideline for the interpretation of the MOE. The acceptability of a MOE depends on its magnitude and is ultimately a risk management decision. To aid that decision, the risk assessment should provide information on the nature, magnitude, and possible consequences of the inherent uncertainties and variability in both the toxicological and exposure data. The following are some points regarding the acceptability of a MOE that can be considered.

    - When comparisons between the linear low dose extrapolation, used by some risk assessment authorities for genotoxic carcinogens, are made to MOE estimates, the risk of one in a million cancer risk from a linear extrapolation of a BMDL10 is equivalent of dividing the BMDL by 100,000 (see 64th JECFA report (WHO, 2006)). This might be considered an upper value for which greater MOE values would be considered of low risk for contaminants without data to establish a mode of action. When there are adequate data to determine a genotoxic mode of action, a MOE of 10,000 may be considered low concern from a public health point of view and might be considered as a low priority for risk management actions if it is based on a BMDL10 from an animal study (WHO, 2006). If the BMDL is based on a reliable human study, the appropriate MOE will need to be considered on a case by case basis.

    - For compounds with other endpoints, particularly non-genotoxic ones, consideration of whether the identified MOE presents a concern for human health could follow a process similar to selection of appropriate uncertainty factors to be used in establishing a reference value (e.g., factor of 10 for interspecies differences, 10 for human variability and additional factors for important gaps in the database). Therefore, a MOE of 100 might be considered a lower value for some non-genotoxic contaminants. In case of higher or lower uncertainty, a higher or lower guidance value for the MOE can be recommended.

    - Decisions on the acceptability of an MOE are made on a case by case basis depending on the level of public health protection needed or desired and the extent and nature of the population of people being exposed. Again, when the uncertainties and variability are clearly and transparently described, this will assist the decision on what is an acceptable MOE for that contaminant. Some considerations can assist the risk manager regarding an appropriate MOE level:

        - *POD from animal or human studies.* A smaller MOE may be acceptable when a MOE is derived from a human study, depending on the quality of the study.

        - *The number of assumptions and amount of uncertainty*. Greater uncertainty in the data, and consequently, the need to use a greater number of assumptions in the risk assessment, suggest the need for a larger acceptable MOE.

        - *The number of responses (adverse effects)*. A smaller MOE may be appropriate when a compound induces only one type of response. If a compound induces several different types of adverse effects, a larger MOE may be advised.

        - *The nature of the response(s)*. The severity of the effect (e.g., non-specific weight change versus tumor), whether the response is a precursor effect in the mode of action or a frank apical effect, and the slope of the dose response curve (e.g., steep versus shallow rise; over what range of doses it rises) help discern an acceptable MOE.

- *Persistence of compound*. Information about the contaminant's persistence in the body would suggest a larger MOE for those compounds that persist longer in the body.
- *Size of affected population.* If a great number of people are exposed versus a very small number, a larger MOE may be necessary for the first case to take larger variability of exposure level into account.
- *Sensitive populations/lifestages*. The risk manager may decide that sensitive populations (e.g., children at risk) need to be considered and a larger MOE may be appropriate to take their sensitivities into account.

VI. Risk Management Options

General Considerations

34. CCCF has a number of risk management options it can recommend that could achieve a desired level of protection of public health. There are risk management options that national authorities can directly adopt from CCCF and implement, e.g., adoption of a ML for contaminants in specific foods into a national standard. CCCF guidance can be used by national authorities to issue guidance to industry, e.g., providing guidance for good manufacturing practices (GMPs) during processing to minimize contamination.

35. In some cases, a single option may have the potential to successfully manage the risks associated with a particular food contaminant. In most cases, a combination of options may be necessary. For example, the setting and enforcement of MLs by national authorities may stimulate good practices by food business operators. Also, where a high level of uncertainty is indicated by the risk assessment, national authorities may need to consider whether a graduated implementation is warranted, e.g., introduction of guidance to reduce exposure whilst commissioning further work to refine the estimates.

36. The choice of a risk management option will depend on a number of factors, including the severity of the health risk, the probability of its occurrence, the number of individuals potentially affected, the level of protection required or desired, and the anticipated effectiveness of the proposed risk management option(s) on the reduction of health risk.

37. Risk management options are implemented by a variety of parties, including government, the food industry, and consumers, each of which has different responsibilities depending on the risk management option being used. The Codex Alimentarius assists national authorities with its development of food standards, guidelines, and related texts. While risk management options recommended by CCCF can relate directly to actions national authorities may adopt or adapt and then implement, there is not always a one-to-one correspondence between a particular risk management option and a subsequent action by the implementing body (be it a national authority, industry, or consumers). In the section hereunder, a distinction is made between activities for CCCF and those for national authorities.

CCCF

Maximum Level (ML)

38. The Codex ML for a contaminant in a food or feed commodity is the maximum concentration of that contaminant recommended by Codex to be permitted in that commodity. The Codex Procedural Manual states that CCCF shall endorse MLs only for those contaminants for which:

    a. JECFA, or *ad hoc* FAO/WHO expert meetings, has completed a safety assessment or has performed a quantitative risk assessment, and

    b. The level of the contaminant in food can be determined through appropriate sampling plans and analysis methods. The setting of an ML for a contaminant may be considered where the risk is high and when it occurs in foods which make a significant contribution to total exposure.

39. The Principles for establishing MLs in food and feed for CCCF are described in the Preamble of the General Standard for Contaminants and Toxins in Food and Feed (CODEX STAN 193-1995). CCCF generally refers to the HBGV or MOE level recommended by JECFA when considering an ML.

40. Although MLs are mainly set for primary commodities, it may be appropriate to set an ML for processed foods where the setting of an ML for the primary commodity is judged to be ineffective or where the contaminant arises as a result of processing (e.g., chloropropanols) or where appropriate processing may result in the removal of a toxin. In cases where the source of the contamination is sporadic, such as with biotoxins in bivalve mollusks, setting an ML can serve as an effective control against occasional poisoning outbreaks if regular monitoring is undertaken.

41. For a contaminant that has a chronic toxic effect and a lognormal exposure distribution among the population, the setting of an ML for that chemical in the food in which it occurs often has little impact on the mean exposure of the population. If a reduction in exposure is desired, a significant proportion of the food would have to be removed or recalled from the market in order to shift the mean value. However, it should be kept in mind that the setting of a well chosen ML can put pressure on preventive measures by food business operators, and these measures might result in a shift of the distribution curve as a whole, depending on the possibilities of prevention. In cases where the exposure of all consumers to a chemical is well below the HBGV, establishing an ML in the food is unlikely to have any impact in terms of public health. However, in case the low exposure is due to the existence and enforcement of a ML and effective preventive practices by food business operators, it can not be concluded that the ML has no impact on public health.

42. In order to evaluate their potential effectiveness, different hypothetical MLs can be examined for a contaminant under its exposure scenarios and help provide insights to risk management options and the ultimate ML established (e.g., aflatoxin in tree nuts).

43. There may be instances where JECFA concludes that a contaminant may produce adverse effects under a given exposure scenario, but due to the nature of the dose response relationship a HBGV cannot be established (e.g., lead). In these instances, JECFA may provide a qualitative description of its findings to CCCF so the Committee and national authorities understand the complexity of the situation. A national authority can take this information in account when deciding what course of action for their country to take.

Guidelines/Guidances/Codes of Practice

44. When the development of an ML is not warranted or is unlikely to be effective, other products can be developed. This may be in the form of a best practice guideline document or a code of practice.

45. Codex guidelines provide principles that set out policy in certain key areas; and guidelines for the interpretation of these principles or for the interpretation of the provisions of the Codex general standards. Guidances describe the current science-based thinking on a topic and should be viewed as recommendations for national authorities or those implementing such measures (such as industry), unless specific regulatory requirements are cited.

46. Codex Codes of Practice (CoP) can be useful measures to reduce occurrence levels and therefore exposure. Also, CoP can be developed when specific guidance is needed to facilitate compliance with a (future) ML, or where establishing an ML is not feasible. Codex CoP define the production, processing, manufacturing, transport, and storage practices for individual foods or groups of foods that are considered essential to ensure the safety and suitability of food for consumption.

National Authorities

Establish Regulatory Requirements

47. One of the major risk management options for a national authority is to establish regulatory requirements, such as regulatory levels. A regulatory level is usually based on the Codex ML for a contaminant in a food or feed commodity.

48. The national authority establishes the regulatory level through legislation and/or rule making (the process usually entails proposing the new level in a policy statement and then soliciting stakeholder/public input on the proposed new policy before instituting the regulatory level). Codex member countries usually adopt or adapt the Commission's adopted standard. Members can establish or maintain a different standard if there is a scientific/public health -basis for their national situation and trade. When a ML is not recommended by the Codex, national governments can establish a ML based on national data available or on data from other countries, if relevant. It should be kept in mind that the rationale for setting of a national ML is transparent to other member countries.

Guidelines/Guidances

49. The national authorities, the food industry, or a 3rd party expert body can draft more specific guidances based on those from Codex to further explain how industry can implement these good practices. For example, these documents could identify those points between production and consumption where food safety measures could be implemented to prevent or limit initial levels of contaminants in raw materials (e.g., select ingredients that do not contain a known contaminant), reduce potential for environmental contamination or cross contamination (e.g., mandate food processing controls), and/or reduce contaminant levels in foods (e.g., physical inspection processes). As a specific example, food additive/ processing aids that reduce the formation of a specific contaminant can be applied, e.g., the approved addition of asparaginase to reduce the formation of acrylamide. Industry-led quality assurance programs at the producer level are other examples of good practices.

50. National authorities can utilize Codex guidelines to publish guidances, notices, or directives to address food safety issues (these can be new or updated policies that are not regulations). For example, notices and directives can be written instructions for government personnel, but serve as information sources to industry and the public since these guidances generally are publicly available. Furthermore, national authorities can develop (or encourage the development of) specific documents and guides on good practices, e.g., good agricultural practices (GAPs), good manufacturing practices (GMPs), good hygienic practices (GHPs), and Hazard Analysis and Critical Control Point (HACCP) plans.

VII. Other Possible Actions by National Authorities

51. In addition to adopting or adapting specific risk management options from CCCF (i.e., MLs, guidances, codes of practice), national authorities can take a variety of other actions that can be based on the options provided by CCCF.

Dietary advice/Labeling

52. National authorities can issue advisory documents on safe intake levels (for instance, quantity/portion of specific foods, in the context of the trade-off of risk of consuming the contaminant and nutritional benefits in food consumption (e.g., methylmercury in fish versus omega-3 fatty acids)) for certain food products across specific demographics (e.g., pregnant women, children, elderly, immunocompromised).

53. Authorities can require labeling to inform consumers how to avoid specific contaminant levels (e.g., provide specific cooking directions to minimize acrylamide formation). Pregnant women exposed to methylmercury in fish can be advised through education campaigns to decrease the consumption of fish with high contamination levels (e.g., predatory fish). This provides information to consumers so that they can voluntarily limit exposure.

54. Proper labeling includes information that instructs the consumer regarding safe handling practices and, where appropriate, briefly informs the consumer of the food safety issue.

Mitigation strategies

55. National authorities may work with industry to reduce human exposure to contaminants by setting appropriate targets and establishing strategies to promote reaching such targets. Risk-based inspection of establishments, collection and analysis of samples, and/or monitoring of products can be implemented to ensure mitigation of any potentially harmful exposures to contaminants (e.g., monitoring of dioxin in foods so dioxin sources could be tracked and identified and then targeted for reduction). This may likely require extensive advocacy and awareness creation.

56. National authorities may also ensure mitigation of risk via sampling and monitoring for enforcement of HACCP, GMP, GAP, and compliance with MLs.

Recalls/Public Health Alerts

57. National authorities (where they have the authority and sufficient evidence) and industry can invoke recalls of commodities when they are determined to be unsafe food products. Monitoring of adverse event reports and consumer complaints help determine if there are exposures to potentially unsafe food products.

Education/Training

58. An important risk management action is education and training for all stakeholders involved in food safety. Education can occur for those in national authorities, industry, public health or consumer interest groups, agriculture, trade and the public at large. Appropriate training for those in food safety should be a priority for national authorities and industry to institutionalize. Extension services, including provisions for practical educational training at colleges and universities, could be mobilized to support education of relevant groups. Every possible avenue for reaching out to stakeholders should be considered to maximize the education message(s), e.g., on-line capabilities and networks, public meetings, advisories.

59. Consumer education can provide guidance in terms of dietary advice for avoiding or limiting exposure to certain foods (e.g., methylmercury in fish; educating local fish eating communities), advice on cooking practices (e.g., correct preparation of kidney beans to break down phytohaemagglutinin or cassava to avoid hydrogen cyanide), and consumer education for handling foods in the home. For acrylamide, approaches could include educational campaigns among the population aimed at controlling the degree of cooking of home-made fried or roasted potatoes (lighter colored potatoes have lower acrylamide levels) and at decreasing the consumption of fried potatoes.

60. Technical training on proper food safety practices is paramount in ensuring safe food. Again, every possible avenue of reaching out to technical personnel should be considered to maximize training, e.g., webinars, on-line modules, on-site training, front line supervisor training, stakeholder meetings.

61. Just as industry training and/or education by national authorities can be done, industry's input and/or contribution to authorities also is important as a source of information to evaluate existing risk in food processing-related processes.

Research

62. Laboratory research can provide additional data for refining risk assessments and contribute to better risk management decision(s) for determining food safety and can provide education and training opportunities. Research can develop/improve methods for detecting contaminants in food, determine toxicological effects of food contaminants, determine effects of processing techniques on food composition, help elucidate factors that influence contamination, and elaborate preventive measures and mitigation strategies.

VIII. Risk Communication Considerations

63. An important risk management action is to ensure good communication with all stakeholders and impacted parties regarding the food safety measure(s) being taken. Communication can take many guises, through advisories, public meetings (often to inform and also to solicit input), technical meetings (with industry, other agencies, consumer groups; usually to solicit input), and constituent updates. This is also an opportunity for the constituents to become educated about new expectations.

64. Public meetings may be structured as simply informative, e.g., the national authority announces a new policy and invites written and oral comment. Public meetings can be also in the form of break-out groups as experts from all sectors are invited to participate in deliberative exchanges or sessions with the outcome in the form of proposed action items for one or all parties to take or a revised policy. The national authority can solicit input from a neutral 3rd party expert group where risk management options to deal with a particular food safety issue are discussed and technical experts from academia/ research/ industry/ government are brought together to consider all relevant scientific information presented and provide recommendations.

65. National authorities can hold regular meetings with constituent groups for the purpose of allowing them to ask specific questions to the authority relative to a new or change in policy or regulation. This is an opportunity for the constituents to become informed about new risk management options/policies.

66. Because of international trade, communication is also important between authorities of different countries. One of the aims of Codex Alimentarius is to promote coordination of food standards.

67. An important aspect of communications is to assess if it is effective or not. The conduct of impact studies to evaluate the effects of risk communication on consumers, for example, would be very useful to see if the message(s) had any impact.

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