



**Food and Agriculture  
Organization of  
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**World Health  
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**REP15/CF**

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME  
CODEX ALIMENTARIUS COMMISSION  
38<sup>th</sup> Session  
Geneva, Switzerland, 6 - 11 July 2015**

**REPORT OF THE NINTH SESSION OF THE  
CODEX COMMITTEE ON CONTAMINANTS IN FOODS  
New Delhi, India  
16 - 20 March 2015**

**NOTE:** This report includes Codex Circular Letter CL 2015/8-CF.



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**CX 4/35.2**

**CL 2015/8-CF  
March 2015**

**To:** Codex Contact Points  
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**Subject: DISTRIBUTION OF THE REPORT OF THE NINTH SESSION OF THE CODEX COMMITTEE ON CONTAMINANTS IN FOODS (REP15/CF)**

The Report of the Ninth Session of the Codex Committee on Contaminants in Foods is attached. It will be considered by the Thirty-eighth Session of the Codex Alimentarius Commission (Geneva, Switzerland, 6 - 11 July 2015).

**PART I: MATTERS FOR ADOPTION BY THE 38<sup>TH</sup> SESSION OF THE CODEX ALIMENTARIUS COMMISSION**

**Proposed draft and draft standards and related texts at Step 5, 5/8 and 8 of the Procedure**

1. **Proposed draft and draft maximum levels for lead in fruit juices and nectars (excluding juices exclusively from berries and other small fruits), ready-to-drink; canned fruits (excluding berries and other small fruits); canned vegetables (excluding canned brassica, canned leafy vegetables and canned legume vegetables); berries and other small fruits (excluding cranberry, currant and elderberry); cranberry; currant; elderberry; brassica vegetables; legume vegetables; fruiting vegetables, cucurbits; fruiting vegetables, other than cucurbits (excluding fungi and mushrooms) at Steps 8 and 5/8 (paras 49-50, Appendix IV);**
2. **Draft maximum levels for deoxynivalenol (DON) in cereal-based foods for infants and young children; in flour, meal, semolina and flakes derived from wheat, maize or barley; and in cereal grains (wheat, maize and barley) destined for further processing including sampling plans and performance criteria for methods of analysis at Step 8 (para 91, Appendix VI);**
3. **Proposed draft maximum level for inorganic arsenic in husked rice (para 69, Appendix V);**
4. **Proposed draft revision of the Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals (CAC/RCP 51-2003) (general provisions applicable to mycotoxins in cereals) at Step 5 (para 104, Appendix VII).**

Governments and international organisations wishing to submit comments on the above documents should do so in writing, in conformity with the *Procedures for the Elaboration of Codex Standards and Related Texts* (Part 3 – *Uniform Procedure for the Elaboration of Codex Standards and Related Texts, Procedural Manual of the Codex Alimentarius Commission*) **by e-mail**, to the above address, **before 31 May 2015**.

**PART II: REQUEST FOR COMMENTS AND INFORMATION**

5. **Priority list of contaminants and naturally occurring toxicants for evaluation by JECFA (paras 152-153, 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 Committee on Contaminants in Foods as indicated in para 152 and presented in Appendix IX 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 X of this Report.

Governments and international organisations 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, **by e-mail**, to the above address, **before 15 January 2016**.

## SUMMARY AND CONCLUSIONS

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

### MATTERS FOR ADOPTION/CONSIDERATION BY THE 38<sup>TH</sup> SESSION OF THE CODEX ALIMENTARIUS COMMISSION

#### Proposed draft standards and related texts for adoption

The Committee agreed to forward:

- maximum levels for lead in fruit juices and nectars (excluding juices exclusively from berries and other small fruits), ready-to-drink; canned fruits (excluding berries and other small fruits); canned vegetables (excluding canned brassica, canned leafy vegetables and canned legume vegetables); berries and other small fruits (excluding cranberry, currant and elderberry); cranberry; currant; elderberry; brassica vegetables; legume vegetables; fruiting vegetables, cucurbits; fruiting vegetables, other than cucurbits (excluding fungi and mushrooms) at Steps 8 and 5/8 (paras 49-50, Appendix IV);
- maximum levels for deoxynivalenol (DON) in cereal-based foods for infants and young children; in flour, meal, semolina and flakes derived from wheat, maize or barley; and in cereal grains (wheat, maize and barley) destined for further processing including sampling plans and performance criteria for methods of analysis at Step 8 (para 91, Appendix VI);
- maximum level for inorganic arsenic in husked rice at Step 5 (para 69, Appendix V);
- revision of the Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals (CAC/RCP 51-2003) (general provisions applicable to mycotoxins in cereals) at Step 5 (para 104, Appendix VII).

#### New work

The Committee agreed to submit to the Commission, through the Executive Committee, a proposal for new work on a Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Spices (para 143, Appendix VIII).

#### Revocation of standards

The Committee agreed to recommend the revocation of maximum levels in the General Standard for Contaminants and Toxins in Food and Feed (CODEX STAN 193-1995) as follows: canned grapefruit, canned mandarin oranges, canned mangoes, canned pineapples, canned fruit cocktail, canned tropical fruit salad, canned asparagus, canned carrots, canned mature processed peas, canned mushrooms, canned palmito (palm hearts) and canned sweet corn (para 51, Appendix IV).

#### Matters of interest to the Codex Alimentarius Commission

The Committee:

- noted matters referred to the Committee by the Commission and its subsidiary bodies and provided replies when appropriate in particular as to the monitoring of the implementation of the Codex Strategic Plan 2014-2019 (para 10, Appendix II);
- agreed to continue to work on outstanding issues related to the review of MLs for lead in fruits and vegetables (fresh and processed) in the GSCTFF (para 48);
- agreed to return maximum levels for cadmium in chocolate and cocoa-derived products for further revision, comments and consideration at its next session (para 55);
- agreed to return the Code of Practice for the Prevention and Reduction of Arsenic Contamination in Rice for further development, comments and consideration at its next session (para 74);
- agreed to hold the ML for total aflatoxins in peanuts, ready-to-eat, pending the outcome of the JECFA exposure assessment for health impact (para 100);
- agreed to return the annexes of the Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals for further development, comments and consideration at its next session and to consider an additional annex on ergot alkaloid for possible inclusion in the Code (paras 103-104);
- agreed to use the GEMS/Food platform for data submission and analysis for the development of MLs and to develop specific templates for submission of additional data in consultation with the GEMS/Food Secretariat; supported the publication of the guidance document for the submission and analysis of data on the GEMS/Food website, linked also from the Codex website (para 108);
- could not come to a consensus on the approach for phasing-in lower maximum levels for contaminants but agreed that the approach would be considered in future as appropriate (para 117);
- agreed to further consider the development of maximum levels for methylmercury in fish including the expansion of the ML proposals to fish species other than tuna that can accumulate high methylmercury concentrations and the conduct of an exposure assessment based on the different ML proposals (para 125);

- agreed to consider in future any work on guideline levels for radionuclides in food in the General Standard for Contaminants and Toxins in Food and Feed pending the outcome of the work of the International Commission on Radiological Protection on the review of dose coefficients for ingestion of radionuclides to assess public exposure and associated health risk due to intake of radionuclides in food (para 134);
- agreed to further consider the development of MLs for mycotoxins in spices including further prioritisation of work and clarification as to the mycotoxin(s)/spice(s) combination for which MLs should be established (para 138)
- endorsed the Priority list of contaminants and naturally occurring toxicants for JECFA evaluation (para 152, Appendix IX).

#### **Matters of interest to Codex committees and task forces**

##### **Committee on Methods of Analysis and Sampling**

The Committee agreed to forward sampling plans, including performance criteria for methods of analysis, to CCMAS for endorsement for:

- fumonisins (B<sub>1</sub>+B<sub>2</sub>) in maize (grain) and maize products (flour and meal) (para 13, Appendix III) and
- deoxynivalenol (DON) in cereal-based foods for infants and young children; in flour, meal, semolina and flakes derived from wheat, maize or barley; and in cereal grains (wheat, maize and barley) destined for further processing (para 91, Appendix VI) to CCMAS for endorsement.

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**LIST OF ABBREVIATIONS**

ALARA	As Low As Reasonable Achievable
AU	African Union
CAC	Codex Alimentarius Commission
CCCF	Committee on Contaminants in Foods
CCEXEC	Executive Committee
CCFA	Committee on Food Additives
CCFFV	Committee on Fresh Fruits and Vegetables
CCFH	Committee on Food Hygiene
CCMAS	Committee on Methods of Analysis
CCNASWP	FAO/WHO Coordinating Committee for North America and South West Pacific
CCPFV	Committee on Processed Fruits and Vegetables
CCPR	Committee on Pesticide Residues
CCSCH	Committee on Spices and Culinary Herbs
COP	Code of practice
CRD	Conference Room Document
CTF	Codex Trust Fund
DON	Deoxynivalenol
EU	European Union
EWG	Electronic Working Group
FAO	Food and Agriculture Organisation
GL	Guideline Level
GEMS/Food	Global Environment Monitoring System
GSCTFF	General Standard for Contaminants and Toxins in Food and Feed
IAEA	International Atomic Energy Agency
ICPR	International Commission on Radiological Protection
LOD	Limit of Detection
LOQ	Limit of Quantification
JECFA	Joint FAO/WHO Expert Committee on Food Additives
3-MCPD	3-monochloropropane-1,2-diol or 3-chloropropane-1,2-diol
ML	Maximum Level
OTA	Ochratoxin A
PCBs	Polychlorinated Biphenyls
PTWI	Provisional Tolerable Weekly Intake
RTE	Ready-To-Eat
SDOs	Standards Developing Organisations
TECDOC	Technical Document
USA	United States of America
WG	Working Group
WHO	World Health Organisation
WTO	World Trade Organisation
WTO/SPS Agreement	Agreement on the Application of Sanitary and Phytosanitary Measures of the World Trade Organisation

## INTRODUCTION

1. The Codex Committee on Contaminants in Foods (CCCF) held its 9<sup>th</sup> Session in New Delhi, India, from 16 to 20 March 2015, at the kind invitation of the Government of India. The Session was chaired by Dr Wieke Tas, Department of Animal Health and Market Access, Ministry of Economic Affairs, The Netherlands. The Session was attended by 55 Member countries, 1 Member Organisation, and Observers from 13 international organisations. The list of participants is given in Appendix I.

## OPENING OF THE SESSION

2. The Session was opened by Mr Alphonsus Stoelinga, Ambassador of the Kingdom of The Netherlands, Mr Yudhvir Singh Malik, CEO of the Food Safety and Standards Authority of India (FSSAI), and Ms Nata Menabde, Representative of the WHO, on behalf of WHO and FAO.

### Division of Competence<sup>1</sup>

3. The Committee noted the division of competence between the European Union and its Member States, according to paragraph 5, Rule II of the Rules of Procedure of the Codex Alimentarius Commission, as presented in CRD1.

## ADOPTION OF THE AGENDA (Agenda Item 1)<sup>2</sup>

4. The Committee adopted the Provisional Agenda as its Agenda for the Session.
5. The Committee agreed to establish the following in-session working groups:
  - Revision of the *Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals* (CAC/RCP 51-2003), chaired by Brazil (Agenda Item 11); and
  - Priority list of contaminants and naturally occurring toxicants for evaluation by JECFA, chaired by United States of America (Agenda Item 18).

## MATTERS REFERRED TO THE COMMITTEE BY THE CODEX ALIMENTARIUS COMMISSION AND/OR ITS SUBSIDIARY BODIES (Agenda Item 2)<sup>3</sup>

6. The Committee noted the information presented in the working documents and agreed that:
  - the request for safe intake levels for scopoletin in fermented noni juice would be discussed in the in-session working group on a priority list of contaminants and naturally occurring toxicants for evaluation by JECFA;
  - matters related to sampling plans and performance criteria for fumonisins would be considered in an in-session working group on the revision of the *Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals*, led by Brazil; and
  - matters related to the sampling plans and performance criteria for methods of analysis for DON in cereals and cereal-based products, would be considered under Agenda Item 9.

### Guidance on information documents

7. The Committee agreed to request the Codex Secretariat to make available on the Codex website the "Guidance for Risk Management Options in Light of Different Risk Assessment Outcomes" as an Information Document of CCCF.
8. It was also clarified that the current information document (CF/9 INF/1) for use in discussions related to contaminants and toxins in the GSCTFF was not an information document in terms of the Guidance developed by CCGP, but was a document for internal use by the Committee and would continue to be made available prior to each session of the Committee.

### Monitoring of the Codex Strategic Plan 2014 – 2020

9. The Committee noted that the Strategic Plan 2014 – 2019 had been adopted by the 36<sup>th</sup> Session of the Commission and that a template for monitoring the implementation of selected activities relevant to all committees had been prepared by the Codex Secretariat (Appendix II of CX/CF 15/9/2).
10. The Committee agreed that all selected activities were relevant to CCCF. Specific replies were presented in Appendix II for consideration by the 70<sup>th</sup> Session of CCEXEC and the 38<sup>th</sup> Session of CAC in 2015.

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<sup>1</sup> [CRD1](#)

<sup>2</sup> [CX/CF 15/9/1](#)

<sup>3</sup> [CX/CF 15/9/2](#); [CX/CF 15/9/2-Add.1](#); [CRD3](#) (Comments of EU, Kenya, Mali and AU); [CRD20](#) (Revised sampling plans for fumonisins in maize grain, maize flour and maize meal prepared by Brazil); [CRD23](#) (Revised sampling plans for fumonisins in maize grain, maize flour and maize meal prepared by the in-Session WG on Fumonisin led by Brazil)



### **Sampling Plans for Fumonisin in Maize Grain, Maize Flour and Maize Meal**

11. The Delegation of Brazil, as chair of the in-session WG, introduced the revised sampling plans and performance criteria for methods of analysis. The sampling plans had been revised to remove inconsistencies as requested by CCMAS. Adjustments to the performance criteria had been made and were in accordance with the "Guidelines for establishing numeric values for criteria."
12. The Committee agreed with the proposals and made some minor editorial corrections.

### **Conclusion**

13. The Committee agreed to send the sampling plans and performance criteria for methods of analysis to CCMAS for endorsement (Appendix III). The Committee noted that the 37<sup>th</sup> Session of CAC had adopted the sampling plans subject to endorsement by CCMAS and there was no need to re-submit the sampling plans to the Commission.

### **MATTERS OF INTEREST ARISING FROM FAO AND WHO, INCLUDING JECFA (Agenda Item 3)<sup>4</sup>**

14. The FAO and WHO Representatives introduced the item. The Committee was informed of the following:
  15. The 80<sup>th</sup> Meeting of JECFA (16 - 25 June 2015) would evaluate (besides several food additives) two classes of contaminants: non-dioxin-like PCBs and pyrrolizidine alkaloids. In preparation for the meeting an extensive systematic review was being conducted to collect and evaluate all available relevant data/information in a structured way.
  16. In scheduling the JECFA meetings and developing the agenda, the FAO/WHO Joint Secretariat has to take into account the priorities requested by three different committees (i.e. CCFA, CCCF and CCRVDF), and due to the increasing requests for scientific advice by JECFA, not all requests can be addressed in the subsequent meeting. In scheduling the work the JECFA Secretariat takes into account existing priority criteria, on-going Codex work and available resources. To ensure that the process efficiency is optimised, it is very important to have clear commitments and timelines by member countries to provide the data needed for the JECFA evaluation.
  17. The FAO Mycotoxin Sampling Tool 5, had been further expanded by adding two new mycotoxin/commodity combinations (i.e. OTA in oats and OTA in wheat) for a total of 26 combinations for which the tool could provide guidance on the design of the sampling plans. FAO encouraged CCCF members to use it and to send their feedback to further expand and improve it.
  18. The WHO Representative updated the Committee on various activities that were being undertaken by FAO and WHO to improve the global database for exposure assessments, and on several projects in countries and sub-regions to undertake total diet studies as a comprehensive and cost effective tool to assess food chemical contamination.

### **Status report on mycotoxin in Sorghum project**

19. The WHO Representative informed the Committee that the project had been finalised and that the final report was under preparation, and only some of the key results were summarised in CX/CF 15/9/3-Add.1. The Representative reminded the Committee of the goals of this project and the key outcomes. In the 1 532 samples analysed, 16 different mycotoxins had been detected with a proportion of positive samples between 31.5 and 36%. Of note was the detection with high prevalence of two mycotoxins, sterigmatocystin and diacetoxyscirpenol, that had not previously been reported in Africa. Moreover, about half of the positive samples contained more than two mycotoxins, and this important aspect of co-occurrence was being further analysed.
20. With respect to the value chain studies, results show that sorghum production was an important factor for the livelihood of farmers, but there seemed to be a certain lack of awareness of the relationship of mould infestation and mycotoxin contamination. While each country had specific challenges, some common trends regarding agricultural high and low risk practices along the production chain could be identified. Some aspects were presented in Table 2 of CX/CF 15/9/3-Add.1 and this information could inform the ongoing revision of the *Code of Practice for the Reduction and Prevention of Mycotoxin Contamination in Cereals*, in particular in relation to sorghum.
21. The WHO Representative acknowledged the important work of the national teams in the implementation of this project, as well as the support of the project coordinator and the technical input of staff from FAO and WHO. The financial support of the EC through the Codex Trust Fund for this project was also acknowledged. A meeting between the four participating countries to share experience would be held in May, kindly hosted by the Partnership for Aflatoxin in Africa (PACA).

<sup>4</sup> [CX/CF 15/9/3](#); [CX/CF 15/9/3-Add.1](#); [CRD4](#) (Comments of Mali, Nigeria and AU)

<sup>5</sup> <http://www.fstools.org/mycotoxins/>

22. Several delegations expressed their appreciation for this project and for the presentation of summary data. Comments were made on:
- the need for further clarity on some of the data presented, especially in Table 2 summarizing information of the value chain studies where some so-called 'practices' were actually 'situations';
  - the need to analyse the fungal profile e.g. to develop biocontrol measures;
  - why ergot alkaloids were not included in the project; and
23. A request to continue the project for one further year was made, as well as a request for the draft report of project to be shared with participating countries before finalisation.
24. The WHO Representative clarified that the data were being further analysed and clarified, and that the draft report could be shared with the participating countries. When planning the project, decisions had to be made on what could be achieved with the resources available and within the time frame planned, therefore it had been decided to not include analysis of the fungal profile nor other mycotoxins that could not be covered with the same sampling and analytical run. Since the CTF would come to an end in 2015 and because there were no further resources available, the CTF was not in the position to extend the project for another year.
25. The Committee agreed to ask FAO and WHO to analyse the data and provide recommendations to the Committee at its next session as regards the mycotoxins of importance and the feasibility to establish MLs for these mycotoxins and to propose changes to the *Code of Practice for the Reduction and Prevention of Mycotoxin Contamination in Cereals*.

**MATTERS OF INTEREST ARISING FROM OTHER INTERNATIONAL ORGANISATIONS (Agenda Item 4)<sup>6</sup>**

26. The Committee noted the information provided by the Observer of IAEA and that the issues related to radionuclides would be discussed under Agenda Item 15.

**DRAFT AND PROPOSED DRAFT REVISION OF MAXIMUM LEVELS FOR LEAD IN SELECTED COMMODITIES IN THE GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOOD AND FEED (Agenda Item 5)<sup>7</sup>**

27. The Delegation of the USA, as Chair of the EWG on the revision of the MLs for lead in the GSCTFF, introduced the matter and reminded the Committee that this work followed previous work on the revision of MLs started in 2012 following the outcome of the 73<sup>rd</sup> JECFA safety evaluation of lead where the PTWI of 25 µg/kg had been withdrawn and a new PTWI that would be considered health protective had not been possible to establish. As no safe levels were identified by JECFA, the Delegation explained that the focus of the review was to assess the occurrence data of lead in those commodities for which MLs were allocated in the GSCTFF, to determine what percentage of samples could meet the revised (lower) MLs. The Delegation therefore confirmed that the proposals were not based on levels of exposure or consumption.
28. As regards the data procedure, the Delegation explained that occurrence data for the past 10-15 years had been taken from the GEMS/Food Database and processed in two steps to produce two data-sets namely: (1) a raw data set which excluded samples not meeting the basic criteria e.g. cooked or otherwise processed fruits and vegetables were removed and (2) a LOQ-limited data set based on the limit of quantification of the analytical method associated with each sample which excluded samples with no reported LOQ or with a LOQ higher than the Codex ML for the particular food. The final step in the analysis was to prepare tables showing the percentage of lead level results in the LOQ-limited dataset that met the current and hypothetical (lower) ML and to make recommendations to reduce or maintain the ML based on those percentages. The percentage value would be consistent with the current occurrence data and would provide some reduction in the lead level but without having too significant impact on international trade. There was no specific rule to identify the appropriate cut-off value but in general the approach was to recommend reduction in MLs when the percentage of excluded samples was less than 5%.
29. The Delegation concluded that the above approach had consistently been applied in the review of the MLs for lead to ensure coherence in the recommendations made on the MLs for lead in the GSCTFF.

<sup>6</sup> [CX/CF 15/9/4](#); [CRD5](#) (Comments of AU)

<sup>7</sup> [CX/CF 15/9/5](#); [CX/CF 15/9/5-Add.1](#) (Comments of Argentina, Chile, Egypt, Ghana, Thailand, USA, AU and ICBA); [CRD6](#) (Comments of EU, India, Indonesia, Mali and Nigeria)

30. The Chair of CCCF reminded the Committee that the 36<sup>th</sup> Session of the Commission (2013) had adopted the MLs for lead in fruit juices and nectars (ready-to-drink), canned fruits and canned vegetables at Step 5 on the understanding that countries concerned would submit relevant data to GEMS/Food within 1 year to allow the 9<sup>th</sup> Session of CCCF (2015) to reconsider these MLs for submission to the 38<sup>th</sup> Session of the Commission (2015).<sup>8</sup> In addition, the 8<sup>th</sup> Session of CCCF (2014) had agreed to postpone the discussion on MLs for lead in several fruits and vegetables until the 9<sup>th</sup> Session of CCCF to allow interested countries to submit new or additional data to GEMS/Food and that if no data were made available, the Committee would agree on the revised (lower) MLs at its 9<sup>th</sup> Session.<sup>9</sup> This approach was consistent with the decision of 7<sup>th</sup> Session of CCCF (2013) on the revised (lower) ML for infant formula.<sup>10</sup>
31. The Committee considered the recommendations of the EWG as follows:
- Fruit juices and nectars (excluding juices from berries and other small fruits), ready-to-drink**
32. Delegations against the reduction of the ML requested to postpone the finalisation of the revised (lower) ML in view of the lack of geographically representative occurrence data, in particular the lack of data from African countries, and the approach taken to derive the revised (lower) ML. These delegations argued that countries should be given more time to provide data to GEMS/Food to allow the establishment of global-based MLs. They felt that the approach was not based on consumption and exposure rates, but on the reduction of the ML on the basis of the LOQ of the analytical method and a cut-off value for rejection of samples not complying with the revised (lower) ML falling within the LOQ-limited dataset with no scientific rationale for the selection of the values. The application of this approach could leave aside samples that otherwise could be accepted and so have an impact on the final proposal for a reduction of the ML i.e. a revised (higher) ML that would still provide a reduction of the ML and have less negative impact on international trade.
33. Delegations in favour of the reduction of the ML acknowledged the work of the EWG on the fruit and vegetable groups for the past 2 sessions of CCCF and indicated that sufficient time had been given by CAC and CCCF to submit data to finalize the ML at this session and so the Committee should proceed with the finalisation of this ML. They stated that the implementation of the *Code of Practice for the Prevention and Reduction of Lead Contamination in Foods* (CAC/RCP 56-2004) could also aid in reducing levels of lead in food. An analysis of the impact of not excluding samples associated with LOQs above the cut-off value had not been done to keep the consistency in the approach taken with the review of the MLs for lead in the GSCTFF.
34. A Delegation questioned exclusion of a number of samples for fruit juices from the review. The Chair of the EWG explained that the samples excluded were juice drinks which were not covered by the ML in the GSCTFF.
35. Another Delegation requested exclusion of passion fruit juice from the ML as data showed that around 30% of samples would not comply with the revised (lower) ML. The study was being finalised at the time the EWG carried out the review but the results would now be made available in GEMS/Food. The EWG could then analyse the data and make a proposal to the 10<sup>th</sup> Session of CCCF (2016) for final decision, which was consistent with the approach taken by CCCF in the revision of MLs in the GSCTFF. The Chair of the EWG confirmed that this matter had been raised in the EWG but could not be addressed as data were not yet available on GEMS/Food at the time of the review of the ML and therefore supported the suggested approach.
36. In view of above, the Committee agreed to exclude passion fruit juice from the ML for fruit juices and nectars and wait until the 10<sup>th</sup> Session of CCCF to make a final decision on this matter based on the recommendation of the EWG.
37. The Committee further agreed that exclusion for juices from berries and other small fruits should be limited to juices that were “exclusively” prepared from berries and other small fruits.
38. The Committee therefore agreed to reduce the ML for lead in fruit juices and nectars (excluding juices exclusively from berries and other small fruits and passion fruit), ready-to-drink from 0.05 to 0.03 mg/kg. The Committee also agreed to retain the ML of 0.05 mg/kg for juices and nectars from berries and other small fruit at 0.05 mg/kg.
- Canned fruits (excluding berries and other small fruits)**
39. The Committee agreed to reduce the ML from 1mg/kg to 0.1 mg/kg. The Committee noted that the ML also applied to canned mixed fruits.

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<sup>8</sup> [REP13/CAC, para 79](#)

<sup>9</sup> [REP14/CF, para 22](#)

<sup>10</sup> [REP13/CF, para 37](#)

40. Following this decision, the Committee agreed to make the following consequential amendments to the MLs for lead in the GSCTFF: (i) recommend revocation of the MLs for canned grapefruit, canned mandarin oranges, canned mangoes and canned pineapples, canned fruit cocktail and canned tropical fruit salad and (ii) retain the MLs for canned raspberries and canned strawberries at 1mg/kg for consideration at the 10<sup>th</sup> CCCF based on the recommendation of the EWG.

**Berries and other small fruits**

41. The Committee agreed to reduce the ML from 0.2 mg/kg to 0.1 mg/kg and to exclude certain types of berries i.e. cranberry, currant, elderberry and to retain the existing ML of 0.2 mg/kg for these fruits.

**Canned vegetables (excluding canned brassica, leafy and legume vegetables)**

42. The Committee agreed to reduce the ML from 1mg/kg to 0.1 mg/kg. The Committee noted that the ML also applied to canned mixed vegetables.
43. Following this decision, the Committee agreed to recommend revocation of the following MLs for canned asparagus, canned carrots, canned mature processed peas, canned mushrooms, canned palmito (palm hearts) and canned sweet corn.
44. The Committee noted that MLs for canned brassica vegetables, canned leafy vegetables and canned legume vegetables would be considered by the EWG.

**Vegetables**

45. The Committee agreed with the following: (i) reduce the ML for brassica vegetables from 0.3 mg/kg to 0.1 mg/kg; (ii) reduce the ML for legume vegetables from 0.2 mg/kg to 0.1 mg/kg; (iii) reduce the ML for fruiting vegetables, cucurbits from 0.1 mg/kg to 0.05 mg/kg; and (iv) reduce the ML for fruiting vegetables, other than cucurbits from 0.1 mg/kg to 0.05 mg/kg (excluding fungi and mushrooms).
46. The Committee noted a proposal to exclude sweet corn from the ML for fruiting vegetables, other than cucurbits, however data in support of this reduction came mainly from one region while global GEMS/Food data supported inclusion of canned sweet corn under the ML for fruiting vegetables, other than cucurbits.
47. The Committee also noted that in view of the exclusion of fungi and mushrooms from the ML for fruiting vegetables, other than cucurbits, MLs for these commodities would be considered by the EWG.

**Other matters**

48. The Committee agreed to re-establish the EWG, chaired by USA, working in English only, to continue to work on outstanding issues related to the review of MLs for lead in fruits and vegetables in the GSCTFF namely review of MLs for passion fruit juice; juices and nectars from berries and other small fruits; canned berries and other small fruits; jams (fruit preserves) and jellies; mango chutney; canned chestnuts and canned chestnuts puree; canned brassica vegetables; canned leafy vegetables; canned legume vegetables; pickled cucumbers (cucumber pickles); preserved tomatoes; processed tomato concentrates; table olives; fungi and mushrooms.

**STATUS OF THE DRAFT AND PROPOSED DRAFT MAXIMUM LEVELS FOR LEAD IN SELECTED COMMODITIES IN THE GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOOD AND FEED**

49. The Committee agreed to forward draft MLs for fruit juices and nectars (excluding juices exclusively from berries and other small fruits and passion fruit), ready-to-drink at 0.03 mg/kg, canned fruits (excluding berries and other small fruits) at 0.1 mg/kg and canned vegetables (excluding canned brassica, leafy and legume vegetables) at 0.1 mg/kg to the 38<sup>th</sup> Session of the Commission for adoption at Step 8.
50. The Committee agreed to forward proposed draft MLs for berries and other small fruits (excluding cranberry, currant and elderberry) at 0.1 mg/kg; cranberries at 0.2 mg/kg; currant at 0.2 mg/kg; elderberry at 0.2 mg/kg; brassica vegetables at 0.1 mg/kg; legume vegetables at 0.1 mg/kg; fruiting vegetables, cucurbits at 0.05 mg/kg; and fruiting vegetables, other than cucurbits at 0.05 mg/kg (excluding fungi and mushrooms) to the 38<sup>th</sup> Session of the Commission for adoption at Step 5/8.
51. The Committee agreed to recommend revocation of the following MLs by the 38<sup>th</sup> Session of the Commission: canned grapefruit, canned mandarin oranges, canned mangoes, canned pineapples, canned fruit cocktail, canned tropical fruit salad, canned asparagus, canned carrots, canned mature processed peas, canned mushrooms, canned palmito (palm hearts) and canned sweet corn.

### **PROPOSED DRAFT MAXIMUM LEVELS FOR CADMIUM IN CHOCOLATE AND COCOA-DERIVED PRODUCTS (Agenda Item 6)<sup>11</sup>**

52. The Delegation of Ecuador, as chair of the EWG, introduced the item and informed the Committee that in view of the diverse comments received, it would be difficult to reach agreement and that the EWG should continue to develop the proposal for consideration at the next session.

#### **Conclusion**

53. The Committee agreed to re-establish the EWG, chaired by Ecuador and co-chaired by Brazil and Ghana, working in English and Spanish, to reconsider the proposed draft MLs taking into account the comments submitted to this session.
54. The EWG should clearly identify the products for which the MLs were being established and provide the rationale for the MLs.

### **STATUS OF THE PROPOSED DRAFT MAXIMUM LEVELS FOR CADMIUM IN CHOCOLATE AND COCOA-DERIVED PRODUCTS**

55. The Committee agreed to return the proposed draft MLs to Step 2/3 for further consideration by the EWG, circulation for comments and further consideration by the next session of CCCF.

### **PROPOSED DRAFT MAXIMUM LEVEL FOR INORGANIC ARSENIC IN HUSKED RICE (Agenda Item 7)<sup>12</sup>**

56. The Delegation of China, as Chair of the EWG, introduced the item and referred to the recommendations of the EWG in regard to the establishment of MLs and the ways forward if the Committee could not agree on a ML for inorganic arsenic in husked rice (CX/CF 15/9/9 paragraphs 6-8).
57. The Chair reminded the Committee that the 8<sup>th</sup> session of CCCF (2014) had agreed to defer the final decision on the feasibility to set an ML for inorganic arsenic in husked rice until the current session in view of the relevance of this matter for many Codex members. She had encouraged countries, especially rice-producing countries, to submit data to GEMS/Food that could then be considered by the EWG in order to facilitate the discussion at this session.
58. The Chair invited delegates to express their views on the need for an ML for inorganic arsenic in husked rice considering that the Commission had already adopted an ML for polished rice which was the major component of the rice trade (79%); international trade in husked rice was 10% of the rice trade; husked rice was not the major component in the consumption of cereals.
59. Delegations, while not opposed to the establishment of an ML for inorganic arsenic in husked rice, provided the following views: if no consensus could be reached on a numerical value, work on this matter should be discontinued; CCCF could revisit the possibility to establish an ML for inorganic arsenic in husked rice in light of new/additional data generated following the finalisation and implementation of the Code of Practice for the Prevention and Reduction of Arsenic Contamination in Rice.
60. Delegations that supported the establishment of an ML for inorganic arsenic in husked rice provided the following views:
- there was a need to protect consumers' health as husked rice was a staple food in some countries and regions (e.g. Africa, Asia);
  - there was a growing demand for husked rice in view of its additional nutritional value;
  - there was a need to ensure fair trade practices as the absence of an ML for inorganic arsenic in husked rice could allow rice that might not comply with the ML for polished rice to be distributed in the form of husked rice;
  - there might be a need for some mechanism to check the compliance of husked rice, such as a polishing procedure or conversion factor;
  - the polishing procedure in laboratories was difficult to conduct;
  - finalisation of the COP was scheduled for 2017 and the impact on the reduction of arsenic concentration in rice following the implementation of the COP would require some years.

<sup>11</sup> [CX/CF 15/9/6](#); [CX/CF 15/9/6-Add.1](#) (Comments of Colombia, Costa Rica, Cuba, Egypt, Kenya, Malaysia and Nicaragua); [CX/CF 15/9/6-Add.2](#) (Comments of Argentina, El Salvador, Ghana, Republic of Korea, Thailand, USA and AU); [CRD7](#) (Comments of Costa Rica, Dominican Republic, Ecuador, EU, India, Indonesia, Mali, Nigeria and Peru); [CRD24](#) (Comments of the Republic of Korea)

<sup>12</sup> [CX/CF 15/9/7](#); [CX/CF 15/9/7-Add.1](#) (Comments of Argentina, Egypt, El Salvador, Ghana, Japan, Kenya, Republic of Korea, Thailand, Uruguay, USA and AU); [CRD8](#) (Comments of EU, India, Mali, Nigeria and Philippines); [CRD24](#) (Comments of the Republic of Korea)

61. The Committee noted general support for the establishment of an ML for inorganic arsenic in husked rice and proceeded with the discussion of the possible levels.
62. The following proposals for MLs with the corresponding reduction in intake of inorganic arsenic and violation rates were presented for consideration by the Committee: 0.25, 0.3, 0.35 and 0.4 the violation rates and relative reduction being 11.7% and 12%; 4.9% and 6.3%; 1.9% and 2.5%; and 0.7% and 1.3% respectively. If an ML was agreed, a note on analysis of total arsenic as a screening tool similar to the one agreed upon for polished rice should be included.
63. Delegations in favour of an ML of 0.4 mg/kg indicated that this ML was technologically achievable by most countries concerned, provide a reduction in the intake of inorganic arsenic through rice by eliminating husked rice with extremely high concentration of inorganic arsenic. and would have a minimum negative impact on trade of husked rice. Delegations in favour of a lower level indicated they would prefer an ML of 0.25 mg/kg but could compromise on an ML of 0.3 mg/kg in order to facilitate the establishment of an ML for inorganic arsenic in husked rice. Other delegations, while preferring an ML of 0.4 mg/kg, expressed their willingness to compromise on an ML of 0.3 or 0.35 mg/kg, which provided further reduction in the intake of inorganic arsenic while still keeping the violation rates at an acceptable percentage.
64. Views were also expressed in relation to the need to collect more geographically representative data, and that the analysis presented in CX/CF 15/9/7 in relation to the reduction in inorganic arsenic intake and violation rates across the GEMS/Food cluster diets missed data from major rice-producing countries from Asia (e.g. India, Indonesia, Bangladesh, etc.) and other countries where husked rice was a major staple food (e.g. some African countries).
65. In view of the proposal for an ML of 0.35 mg/kg, the Committee discussed whether CCMAS should be asked to consider whether available methods of analysis for inorganic arsenic in rice were of sufficient precision to support the implementation of an ML with two significant figures. The Committee agreed that this question should be considered by the EWG.

#### **Conclusion**

66. As a compromise solution, the Committee agreed on an ML for husked rice at 0.35 mg/kg and to send this proposal to the Commission for adoption at Step 5. The delegations of the EU, Japan and Norway expressed their reservation to this decision.
67. The Committee agreed that the ML for inorganic arsenic in husked rice should be accompanied by a note on analysis of total arsenic as a screening method.
68. However, in view of the opinions expressed in relation to the need for more geographically representative data, the Committee agreed to re-establish the EWG, chaired by Japan and co-chaired by China, to further consider new/additional data provided by countries especially main rice-producing countries and countries where husked rice was a major staple food. The Committee should then consider the outcome of the analysis performed by the EWG based on the current and new/additional data to confirm or change the ML of 0.35 mg/kg at its next session. The Committee encouraged countries concerned to submit data to GEMS/Food so that the ML could be finalised at the next session of CCCF. The Delegation of India and EU committed to submit data to GEMS/Food in time for consideration by the EWG. The EWG will work in English only.

#### **STATUS OF THE PROPOSED DRAFT MAXIMUM LEVEL FOR INORGANIC ARSENIC IN HUSKED RICE**

69. The Committee agreed to forward the proposed draft ML of 0.35 mg/kg of inorganic arsenic in husked rice with the note for total arsenic as a screening method to the 38<sup>th</sup> Session of the Commission for adoption at Step 5 (Appendix V).

#### **PROPOSED DRAFT CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF ARSENIC CONTAMINATION IN RICE (Agenda Item 8)<sup>13</sup>**

70. The Delegation of Japan, as Chair of the EWG, introduced the item. The Delegation drew the attention of the Committee to sections 1 (Introduction) and 2 (Scope) as they contained certain terms that had to be clarified to continue the development of the remaining provisions, in particular those concerning mitigation measures to prevent and reduce arsenic contamination in rice. In this regard, the Delegation informed the Committee that several practices to prevent and reduce arsenic contamination in rice had been identified and included in the COP. In addition, studies on mitigation measures were ongoing, the results of which would become available soon and would assist to improve the COP. The Delegation encouraged Codex members to provide information on mitigation measures applied in their countries and proven to be effective for inclusion in the COP.

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<sup>13</sup> [CX/CF 15/9/8](#); [CX/CF 15/9/8-Add.1](#) (Comments of Argentina, Chile, Egypt, El Salvador, Kenya, Nicaragua, Thailand, USA, AU and FoodDrinkEurope); [CRD9](#) (Comments of EU, India, Indonesia, Mali and Philippines)

71. The Committee focused its discussion on sections 1 and 2. In section 1, the Committee noted that all field studies regardless of their scale were important and should be conducted to identify measures that were feasible and effective for local or regional conditions. To this aim, the Committee made the following amendment: “*Field studies should be conducted to identify measures that are feasible and effective for local or regional conditions*”. In section 2, the Committee agreed that the scope should be limited to source directed measures and agricultural measures to reduce and prevent arsenic contamination in rice and that guidance for consumers should be included under risk communication (section 6).
72. The Committee noted that comments submitted on the remaining sections of the COP would be considered by the EWG.

### **Conclusion**

73. The Committee agreed to re-establish the EWG, led by Japan and co-chaired by China to further develop the COP in light of comments submitted and decisions taken at this session. The EWG would work in English only.

### **STATUS OF THE PROPOSED DRAFT CODE OF PRACTICE TO FOR THE PREVENTION AND REDUCTION OF ARSENIC CONTAMINATION IN RICE**

74. The Committee agreed to return the COP to Step 2/3 for further development, comments and consideration by the 10<sup>th</sup> Session of CCCF.

### **DRAFT MAXIMUM LEVELS FOR DEOXYNIVALENOL (DON) IN CEREAL-BASED FOODS FOR INFANTS AND YOUNG CHILDREN; IN FLOUR, MEAL, SEMOLINA AND FLAKES DERIVED FROM WHEAT, MAIZE OR BARLEY; AND IN RAW CEREAL GRAINS (WHEAT, MAIZE AND BARLEY) INCLUDING SAMPLING PLANS FOR RAW CEREAL GRAINS (Agenda Item 9)<sup>14</sup>**

75. The Committee recalled that the MLs for cereal-based foods for infants and young children; for flour, meal, semolina and flakes derived from wheat, maize or barley; and for raw cereal grains (wheat, maize and barley) had been held at Step 7 as no agreement could be reached at the last session; and that the sampling plans for raw cereal grains had not been endorsed by CCMAS subject to questions raised and proposals made for consideration by the Committee (see CX/MAS 15/9/2 Add.1). The Committee also recalled that for cereal-based foods, the ML should apply to cereal-based foods on a dry matter basis.

### **MLs for raw cereal grains (wheat, maize and barley) and flour, meal, semolina and flakes derived from wheat, maize or barley**

76. There were varying views on the commodities for which MLs should be established, as well as diverse views on the levels for these commodities, in particular for the flour, meal, semolina and flakes derived from wheat, maize or barley.
77. Those delegations in favour of only one ML, i.e. for the flour, meal, semolina and flakes derived from wheat, maize or barley reiterated their views, previously expressed that, if an ML was established for flour, meal, semolina and flakes from wheat, maize or barley, there was no need for an ML for the raw cereal grains as many processes were available to reduce DON levels in the “semi-processed” products that would be health protective. They also stated that MLs for raw cereal grains could be trade restrictive and negatively affect global food supply especially in years where climatic conditions were favourable for high prevalence of DON. It was noted that raw cereals prior to sorting and removal of damaged kernels, were not traded internationally as this designation referred to commodities as harvested at the farm and did not take into account processes the harvest is subjected to before export. An observation was also made that data had shown that there were several mitigation techniques being applied at many stages of the supply chain to most efficiently and effectively combat a naturally variable and sporadically occurring contaminant like DON and assure end products were still safe.

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<sup>14</sup> [REP14/CF, Appendix XII](#); [CRD10](#) (Comments of EU, Ghana, India, Mali, Nigeria, Norway, Thailand, USA, AACCI and AU); [CRD21](#) (Comments of IBFAN)

78. Those delegations in favour of establishing levels for both sets of commodities, i.e. for raw cereal grains and for flour, meal, semolina and flakes from wheat, maize or barley, reiterated the view that a level for raw cereal grains was necessary as these were the commodities most widely traded and was in line with the principles for establishing MLs in the GSCTFF. The view was also expressed that the level was particularly needed for some countries, in particular African countries, where there were no sophisticated milling processes available, and where sorting or cleaning was not necessarily done prior to processing. Therefore the ML for the raw cereal grains was necessary to assist in achieving the required ML for DON in the 'semi-processed' products. There was general agreement among these delegations for a level of 2 mg/kg. The Delegation of the Russian Federation did not support this level, as it would not be sufficient to achieve the level flour, meal, semolina and flakes derived from wheat, maize or barley.
79. There were however varying views on whether the level should apply before or after sorting. A delegation also proposed to delete the note as it could cause confusion, because sorting or cleaning applied to many commodities as traded and in some years where there were higher levels of DON due to climatic conditions, more sorting and other measures would be required. Another proposal was for an alternative note that could be considered similar to the note for aflatoxins in commodities "destined for further processing" and to clearly indicate those measures, such as sorting, cleaning and colour sorting that were proven to reduce levels of DON.
80. There were varying views on the ML of 1 mg/kg for the flour, meal, semolina and flakes derived from wheat, maize or barley. Several delegations supported the level of 1 mg/kg, while the Delegation of the Russian Federation supported an ML of 1 mg/kg for barley and maize flour only, as the other levels proposed would not be health protective taking into account the high consumption of particularly wheat products in their country. The delegations of EU and Norway did not support this level as consultation with their risk assessment body indicated that the level of 1 mg/kg would lead to increased exposure and exceedances of the group Health Based Guidance Values.
81. On a question for clarification whether lower levels would provide any further health protection, the JECFA secretariat clarified that the JECFA evaluation had not reported any exceedances except for foods for infants in Germany and in France for all age groups. No specific impact assessments on different hypothetical levels had been conducted.
82. Noting the wide support for the ML for the raw cereal grains, a delegation, in the spirit of compromise, agreed that a level for DON in cereal grains could be agreed to, but that the note should be re-considered. A proposal was made to use the note initially proposed at the 5<sup>th</sup> session of the Committee. Noting the earlier proposal on the note (paragraph 79), the Committee agreed to refer to cereal grains "destined for further processing" and to qualify that it meant that additional processing or treatments proven to reduce levels of DON could be applied and that Codex members could define the processes that have been shown to reduce levels.

#### **Conclusion**

83. Noting the wide support for the MLs for cereal grains (wheat, maize and barley) for further processing and for flour, meal, semolina and flakes derived from wheat, maize or barley, the Committee agreed that the MLs, 2 mg/kg and 1 mg/kg, respectively, could be sent for adoption.
84. The Delegation of the Russian Federation expressed their reservation to the ML for both the cereal grains intended for further processing and to the ML for flour, meal, semolina and flakes from wheat, maize or barley, while the Delegations of EU and Norway expressed their reservations to the ML for flour, meal, semolina and flakes for the reasons expressed above.

#### **Cereal-based foods for infants and young children**

85. Several delegations and an observer supported the ML of 0.2 mg/kg on a dry matter basis, as it was necessary to have levels as low as possible in line with the ALARA principle to protect infants and young children, a vulnerable group of the population. Data has shown that this level was achievable. The Delegations in favour of a level of 0.5 mg/kg on a dry matter basis or 0.2 mg/kg on an "as consumed basis" pointed out that the higher level was more achievable, and would still be health protective.
86. The Delegation of the Russian Federation proposed that a lower level should be set as the level of 0.2 mg/kg would not give adequate health protection.

#### **Conclusion**

87. Noting the wide support for the ML of 0.2 mg/kg on a dry matter basis, the Committee agreed that this ML could be sent for adoption.
88. The Delegation Russian Federation expressed their reservation to this decision.



### Sampling Plans and Performance Criteria

89. The Committee noted its earlier discussion to have the same sampling plans for all cereals. Therefore, in view of the agreement on the sampling plan for fumonisins (Agenda Item 2), the Committee agreed to align the sampling plan for DON in cereal grains with that for fumonisins. The Committee noted that with the amendments to the sampling plan, i.e. deletion of the aggregate sample, the request for clarification from CCMAS was no longer applicable. The sampling plan was also extended to cereal-based foods for infants and young children and to flour, semolina, meal and flakes derived from wheat, maize or barley.

### Conclusion

90. The Committee agreed to the sampling plans and performance criteria for methods of analysis as amended and to submit these to CCMAS for endorsement.

### **STATUS OF THE DRAFT MAXIMUM LEVELS FOR DEOXYNIVALENOL (DON) IN CEREAL-BASED FOODS FOR INFANTS AND YOUNG CHILDREN; IN FLOUR, MEAL, SEMOLINA AND FLAKES DERIVED FROM WHEAT, MAIZE OR BARLEY; AND IN RAW CEREAL GRAINS (WHEAT, MAIZE AND BARLEY) INCLUDING SAMPLING PLANS FOR RAW CEREAL GRAINS**

91. The Committee agreed to advance the MLs and the associated sampling plans to the Commission for adoption at Step 8. The sampling plans and performance criteria for methods of analysis being subject to endorsement by CCMAS. (Appendix VI).

### **PROPOSED DRAFT MAXIMUM LEVEL FOR TOTAL AFLATOXINS IN READY-TO-EAT PEANUTS AND ASSOCIATE SAMPLING PLAN (Agenda Item 10)<sup>15</sup>**

92. The Delegation of India, as Chair of the EWG, introduced the item and highlighted the conclusions and recommendations of the EWG (CX/CF 15/9/9, paragraphs 4-6). The Delegation recommended that the Committee consider the level of 10 µg/kg for total aflatoxins in RTE peanuts, but also consider requesting JECFA to perform an exposure assessment for health impact on proposed MLs for total aflatoxins in RTE peanuts.
93. The following views were expressed: support for the ML of 10 µg/kg for RTE peanuts; support for the ML and the recommendation to request JECFA to perform an exposure assessment; that the level for total aflatoxins in RTE peanuts should only be considered after the JECFA impact assessment; that this assessment could be performed using four different hypothetical levels, 4, 8, 10, and 15 µg/kg.
94. With regard to the definition of RTE, views were expressed for a clearer definition for RTE peanuts, as it was difficult to distinguish between ready-to-eat raw in-shell or raw shell peanuts and those ready-to-eat raw in-shell or raw shell peanuts destined for further processing. The only way in which a distinction could be made, was through a declaration by the trader or through labelling. Concern was also expressed on the inclusion of multi-ingredient foods.
95. The JECFA Secretariat noted that there is a pending request from CCCF to JECFA to update the aflatoxins risk assessment. This work would also include an updated exposure assessment. The additional request now discussed was for an impact assessment of different hypothetical MLs for RTE peanuts, effect on exposure and health, and assessment of violation rates with these different MLs. For this a clear definition of the product to be considered was required.
96. The Delegation of India, as a chair of the EWG, recalled the discussion of the previous session and clarified that the RTE peanuts include several categories of peanuts, such as raw shelled peanuts, raw-in-shell peanuts, roasted in shell peanuts, roasted/blanched shelled peanuts, fried shelled peanuts with or without skin, coated peanuts in all types of packing (consumer or bulk), and any other products having preparation of more than 20% of peanuts. The Committee noted that the definition for RTE peanuts had been included in the GSCTFF.
97. However, noting that the ML should be established for RTE peanuts, the Committee agreed to remove mixed preparations from the list of RTE peanuts.

### Conclusion

98. The Committee agreed to request JECFA to conduct an exposure assessment for health impact and calculate violation rates based on the hypothetical MLs of 4, 8, 10 and 15 µg/kg for total aflatoxins in RTE peanuts.
99. The Committee agreed that work on the ML for aflatoxins in RTE would be undertaken when the results of the JECFA impact assessment became available.

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<sup>15</sup> [CX/CF 15/9/9](#); [CX/CF 15/9/9-Add.1](#) (Comments of Chile, Egypt, El Salvador, Ghana, Nicaragua, Thailand, USA and AU); [CRD11](#) (Comments of EU, Mali, Nigeria and Philippines)

**STATUS OF THE PROPOSED DRAFT MAXIMUM LEVEL FOR TOTAL AFLATOXINS IN READY-TO-EAT PEANUTS AND ASSOCIATED SAMPLING PLAN**

100. The Committee agreed to hold the proposed draft ML and sampling plan at Step 4 pending the outcome of the JECFA exposure assessment for health impact.

**PROPOSED DRAFT REVISION OF THE CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF MYCOTOXIN CONTAMINATION IN CEREALS (CAC/RCP 51-2003) (Agenda Item 11)<sup>16</sup>**

101. The Delegation of Brazil, as Chair of the EWG, introduced the revised the *Code of Practice For the Prevention and Reduction Of Mycotoxin Contamination in Cereals* as prepared by the in-session working group. The Delegation explained that the EWG had revised the Code as requested by the last session of the Committee; that all comments received for this session had been taken up by the in-session working group; and that a revised Code was being presented for consideration and advancement in the Step process. The Delegation also explained that the in-session Working Group had agreed to delete the proposed draft annex for ergot alkaloids as further discussion was needed on this. A delegation had also informed the working group that several practices for prevention and control of DON in cereal grains had become available and that the annex related to these mycotoxins should be further developed.

**General discussion**

102. There was general agreement that the Code could be advanced in the Step process. A few issues that needed to be considered or revised were highlighted e.g. the use of certain terminology such as “infection” and “contamination”; and the need to more correctly refer to toxigenic species of *Aspergillus*. The Delegation of Brazil noted that the Code could refer to toxigenic species of *Aspergillus*, but that the issue of terminology had been discussed previously; that the terms were not being used synonymously and as such were correct in the document. With regard to other concerns, these could be addressed in the next round of comments.

**Ergot alkaloids**

103. The Committee noted that a proposal had been made for an additional annex on ergot alkaloids, but that further information was needed on which the Committee could take a decision on the inclusion of such an annex. The Delegation of Germany agreed to develop a discussion paper.

**STATUS OF THE PROPOSED DRAFT REVISION OF THE CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF MYCOTOXIN CONTAMINATION IN CEREALS**

104. The Committee agreed to forward the main text of the proposed draft revision to the 38<sup>th</sup> Session of the Commission for adoption at Step 5 (Appendix VII) and returned the annexes to Step 2/3 for further consideration by the EWG, chaired by Brazil and co-chaired by Canada and USA, circulation for comments and further consideration by the next session of the Committee.

**DISCUSSION PAPER ON SUBMISSION AND USE OF DATA FROM GEMS/FOOD (Agenda Item 12)<sup>17</sup>**

105. The WHO Representative introduced the discussion paper and highlighted the rationale for this paper and the recommendations made.
106. The Representative encouraged Member countries to submit data through the web-based platform, so that all contaminants data would be available through one global database. This is a very important source for the work of CCCF, and restricted access to all detailed data could be made available upon request to CCCF working group leaders. Public access is to aggregated data only.
107. A request was made to organize a workshop to demonstrate to delegates how to submit and use data, and the WHO representative agreed that this could be done during the next session of CCCF in a side-event. It was pointed out that currently not all commodities for which the Committee had developed standards were covered in the GEMS/Food database and that the relevant information would be provided for inclusion in the database.

<sup>16</sup> [CX/CF 15/9/10](#); [CX/CF 15/9/10-Add.1](#) (Comments of Egypt, Kenya, Sudan and BIO); [CX/CF 15/9/10-Add.2](#) (Comments of Canada, El Salvador, Ghana, Republic of Korea and AU); [CRD12](#) (Comments of EU, India, Japan, Mali and Nigeria); [CRD19](#) (Revised COP for the Prevention and Reduction of Mycotoxin Contamination in Cereals prepared by Brazil); [CRD22](#) (Revised COP for the Prevention and Reduction of Mycotoxin Contamination in Cereals prepared by the in-session WG on the COP led by Brazil); [CRD24](#) (Comments of the Republic of Korea)

<sup>17</sup> [CX/CF 15/9/11](#); [CRD13](#) (Comments of EU, India, Indonesia, USA and AU)

## Conclusion

108. The Committee agreed to use the GEMS/Food platform for data submission and analysis for its work in the development of MLs to the extent possible, and supported the publication of the guidance document on the GEMS/food website, linked also from the Codex website. Comments on the guidance document should be provided directly to the GEMS/Food programme. If future work of the Committee required data collection the GEMS/Food template would be followed, and should additional information need to be collected that was not part of the database, WG Chairs should consult with the GEMS/Food secretariat when developing templates for the collection of data.

## **DISCUSSION PAPER ON APPROACHES FOR PHASING IN OF LOWER MAXIMUM LEVELS FOR CONTAMINANTS (Agenda Item 13)<sup>18</sup>**

109. The WHO Representative introduced the document and explained the background to the discussion paper and the proposed approach for the phasing in of lower levels for contaminants. The Representative emphasised that the approach would be applicable only in those cases as explained in paragraph 9 of the document. The Representative further emphasised that the proposed approach was within the normal rules and procedures for establishing MLs and would have no implications with regard to the WTO/SPS Agreement. The only difference to the current practice was that the ML would be set with the explicit recognition that a lower ML was the target to be reached within an agreed timeframe and a commitment that risk mitigation measures would be implemented to reach the target. The Representative proposed that the Committee consider the approach and also consider whether it could be used for certain MLs on a trial basis at the Session.
110. The Committee considered the recommendations as presented in the discussion paper.
111. There was general support for the use of such an approach in situations where it was difficult to find agreement and a clear commitment was needed, especially in conjunction with implementation of risk mitigation measures, such as development and implementation of codes of practice, but further details need to be worked out. Concerns were expressed in relation to:
- use of the term “slightly higher ML”. Clarification was needed to the meaning of the term and whether it was something different from the ALARA principle as stated in the GSCTFF;
  - the decision on the target ML. The setting of such a target should take into account what is achievable at current practices within the defined time frame;
  - the establishment of a time frame. The process should provide for some flexibility as periods for implementation of risk mitigation measures and their impact would differ, especially in the case of environmental contaminants which may take longer to clear from the environment;
  - the establishment of a time frame should be defined on a case-by-case basis and may require trend studies to be undertaken to define the needed time frame.
  - concern was raised about the lack of commitment to implement risk mitigation measures and a commitment would be required by FAO and WHO to support data collection to allow the review of the MLs after a defined period. There would be a need also to determine how long after the implementation of a code of practice data should be collected, and whether there should be a comparison of data before or after the implementation of a code of practice.
112. It was also noted that while the approach could be supported, it would not necessarily be appropriate for use in the establishment of MLs for DON, as it was not clear whether it would fit the criteria. An observer also expressed concern if the approach were used for the establishment of MLs for cereal-based foods for infants and young children, as infants and young children, would continue to be exposed to high levels of DON. The observer stated that prolonged exposure to DON in infants and young children could have serious health effects.
113. The Delegations of the EU and Norway also expressed the view that they could agree to the approach, provided a note was made to the agreed “higher” ML that would allow countries with existing lower MLs to continue to be allowed to use their lower MLs for the defined time period.
114. The Codex Secretariat confirmed that Codex standards, including MLs were voluntary in nature and as such, it was up to countries, whether or not to accept the Codex standard (ML) into their national legislation. The Secretariat also noted however that if trade concerns or disputes arose, these would be matters for WTO and not for Codex and as such, the proposed note would not be appropriate.
115. The WHO Representative informed the Committee that neither WHO nor FAO could commit to assist with data generation and implementation of risk mitigation measures but would provide support where possible.

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<sup>18</sup> [CX/CF 15/9/12](#); [CRD14](#) (Comments of El Salvador, India and AU); [CRD21](#) (Comments of IBFAN)

116. In view of the concerns expressed, a proposal was made for the further development of the paper to address the concerns and provide a more detailed procedure and the principles for the implementation of the procedure for consideration at the next session. However, other delegations pointed out that there was no need for further development of the paper, but that the Committee should consider the approach for the phasing in of lower MLs under other agenda items relating to establishment of MLs if consensus is not reached.

#### **Conclusion**

117. The Committee could not come to a consensus on the discussion paper, but agreed that revision of the discussion paper was not needed. The approach would be considered under relevant agenda items, as appropriate and in the future.

#### **DISCUSSION PAPER ON MAXIMUM LEVELS FOR METHYLMERCURY IN FISH (Agenda Item 14)<sup>19</sup>**

118. The Delegation of Japan presented the discussion paper (CX/CF 15/9/13). The Delegation highlighted the issues addressed, viz. the species to which an ML could apply and the criteria for identifying these species; MLs for methylmercury in the identified fish species; and analytical methods for enforcement. He informed the Committee that the paper presented different ML scenarios, and gave clear indication of the reduction rate of exposure for each of the MLs in the different diet clusters, as well as the violation rates for each of the MLs. The main species for which MLs could be established were Albacore and Bigeye tuna, but it might be difficult to distinguish these tunas from other tuna species. Another option could be to establish ML for all tuna species, with the exception of skipjack tuna. In the case of methods of analysis, it was pointed out that although there were methods available, many of the older methods would have problems complying with method criteria concerning sufficient sensitivity (i.e. LOD and LOQ) and that standards developing organisations (SDOs) should be encouraged to develop and validate methods with larger applicable range covering higher MLs.
119. The Delegation informed the Committee that the EWG could not come to a consensus on an ML and that the Committee should consider the recommendations made in the paper.

#### **General discussion**

120. Those delegations and observers in favour of establishing MLs for methylmercury (total mercury for screening purposes) expressed the view that the MLs were necessary to protect consumers, in particular those most vulnerable, like pregnant women and lactating mothers and children and that the ML would also facilitate trade. These delegations were of the opinion that species, other than tuna, which can accumulate high concentrations of methylmercury should also be included, such as shark, sword fish and blue marlin. It was also acknowledged that consumer advisories at the national or regional levels should be used in conjunction with an ML.
121. Those against the establishment of an ML were of the view that: consumer advisories were more appropriate and that the benefits of fish consumption should be taken into account; the establishment of an ML could result in limiting consumption; the establishment of an ML could set up a costly testing programme, which might not be justified from a public health perspective; the establishment of an ML at international level was likely to be problematic due to different types of fish and different consumption patterns in different regions. It was noted that there would be a low impact on exposure even compared to a situation when no levels were established. Delegations also pointed out the data indicated that the foods for which the ML is intended would not meet the criteria for selecting foods or food groups as established in the Procedural Manual and GSCTFF.
122. Some delegations, both those for and those opposed to the establishment of MLs also proposed to revoke the current GLs.
123. A proposal was also made for JECFA to conduct an updated assessment to take into account all new data. It was suggested that FAO and WHO should also consider development of guidance to assist governments in addressing the risk from methylmercury.
124. The WHO Representative reiterated that fish consumption as well as occurrence of methylmercury in certain fish species was highly variable, and looking at averages would not give the correct picture. She added that while fish was an important source of nutrition in many parts of the world and fish consumption had clear health benefits, there were also clear health concerns for exposure to methylmercury with child neurodevelopment being affected. Certain fish species can contain high levels of methylmercury and were the main source of exposure. She stated that from a public health perspective it was important to limit exposure and prevent highly contaminated fish entering the market place so as to protect the most sensitive part of the population. However any measures to limit exposure of sensitive populations needed to be accompanied by fish consumption advisory to balance the risks and benefits of fish consumption.

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<sup>19</sup> [CX/CF 15/9/13](#); [CRD15](#) (Comments of EU, Ghana, Mali, Nigeria, Norway, Thailand, USA, AU and IACFO)

## Conclusion

125. Noting the continued support for an ML for methylmercury, the Committee agreed that further work on this should continue through the development of another discussion paper to consider expanding the ML to fish species that can accumulate high methylmercury concentrations, other than tuna and that consideration should be given to narrowing down the ML ranges. It was recognised that development of this paper would require additional data and that an exposure assessment based on different MLs should be conducted.
126. The Committee agreed to re-establish the EWG, chaired by Japan and co-chaired by New Zealand to prepare a discussion paper with proposals for ML for methylmercury, including a project document for consideration by the next session.
127. WHO and FAO agreed to participate in the working group, to provide information on fish consumption and assist the working group in performing exposure assessments as needed.

## DISCUSSION PAPER ON RADIONUCLIDES (Agenda Item 15)<sup>20</sup>

128. The Delegation of the Netherlands, as Chair of the EWG, introduced the item. The Delegation drew the attention of the Committee to the 5 issues that constituted the mandate given by CCCF to the EWG namely: (i) Stage of food production to which the Codex Guideline Levels in the GSCTFF apply; (ii) Period of time these GLs should apply in food trade following a nuclear or radiological emergency; (iii) Identification of internationally validated methods of analysis for radionuclides in foods; (iv) Development of sampling plans to enhance the implementation of the Codex GLs; and (v) need for additional guidance for the interpretation and implementation of the Codex GLs.
129. The Representative from IAEA informed the Committee on the activities of the InterAgency Working Group on Radionuclides led by IAEA as contained in CX/CF 15/9/4. As regards the first four questions considered by the EWG:
  - i. the Joint Division considers that Codex GLs relate to food in international trade and that when comparing the GLs to radionuclide concentrations in food, it is necessary to take into account any change in radionuclide concentrations when the food is ready to eat (e.g. what the radionuclide concentrations would be in the food after reconstitution or as otherwise prepared for consumption);
  - ii. the Joint Division also does not consider that it is possible to define a fixed time frame for the application of the GLs, and a practical approach is needed, for example, until the underlying assumptions contained in the GSCTFF (e.g. fraction of contaminated food, and minor crops) are no longer valid;
  - iii. it is also considered that the identification of internationally validated methods of analysis for radionuclides in foods would be useful to include in Codex Standards, especially as different analytical methodologies are necessary for different types of radionuclide (i.e. alpha-, beta- and gamma-emitters), and,
  - iv. it is agreed that the General Guidelines on Sampling (CAC/GL 50-2004) are sufficient for radionuclide testing and allow users enough flexibility.
130. The Representative also informed the Committee on the elaboration of a technical document (TECDOC) on the control of foodstuffs and drinking water contaminated as a result of nuclear or radiological emergency. The TECDOC aimed to assist food control officials in understanding which international standards relating to radionuclides in food and drinking (potable) water they should apply following a nuclear or radiological emergency (post-accident/emergency). It would also provide a framework for the derivation of appropriate national dose criteria and corresponding derived criteria (activity concentrations) for radionuclides in food and drinking water once the nuclear or radiological emergency had been declared over.
131. The Representative added that this document would complement work at the international level i.e. Codex on GLs for food moving in international trade contaminated with radionuclides following a nuclear or radiological emergency. He informed the Committee that the TECDOC would be available soon and should be made available in time for the next session of CCCF for information/consideration.
132. The Committee welcomed the activities of IAEA in support of member countries to better deal with nuclear/radiological contamination at the national level and noted that the information contained in the TECDOC could be useful for future work on radionuclides within CCCF.
133. The Committee further noted that the International Commission on Radiological Protection (ICRP) was reviewing dose coefficients for ingestion of radionuclides to assess public exposure and the associated health risk from intake of radionuclides in food. The review was expected to be finalised within 2-3 years.

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[CX/CF 15/9/14](#); [CRD16](#) (Comments of EU, India, Mali, USA and AU)

### Conclusion

134. In view of the ongoing work of ICRP on radionuclides, the Committee agreed that any possible new work should be delayed until such time as the outcome of the review became available, which might lead to the revision of the Codex GLs in the GSCTFF.

### **DISCUSSION PAPER ON MYCOTOXIN CONTAMINATION IN SPICES (Agenda Item 16)<sup>21</sup>**

135. The Delegation of India, as Chair of the EWG, introduced the item and provided a summary of the work and the approach taken to understand which mycotoxins should be addressed and for which spices, to aid in the development of a priority list of spices. The Delegation indicated that MLs should be set for total aflatoxins, aflatoxin B1 and OTA and that the priority list of spices was presented in the paper.
136. The Committee generally supported the priority list of spices proposed by EWG and noted some proposals to remove sesame seeds from the list as these were considered to be oil seeds and were used as flavours and not spices; to add cinnamon as it was an important commodity for some regions; and to move nutmeg as a first priority. It was noted that the prioritisation of spices should also take into account the work of the Committee on Spices and Culinary Herbs (CCSCH), and the classification of food and feed developed by CCPR. Concerns were also expressed on classification of some commodities as spices that could be considered as fresh or processed fruits or vegetables, e.g. garlic.
137. The Codex Secretariat clarified that in regard to commodities that (depending on the degree of processing), could fall into more than one category, i.e. fresh, processed or spices, there was very good communication between CCFFV, CCPFV and CCSCH. Also while it might be useful to consider the CCPR classification for food and feed, it was important to note that work on the revision of the classification was ongoing, but in principle the work on spices was complete.

### Conclusion

138. In view of the interest to continue with work on MLs in spices, but the need for further clarity on which mycotoxin/spice(s) combination to establish MLs and the rationale for this, as well as further need for prioritisation of the work, the Committee agreed to re-establish the EWG, led by India and co-chaired by Indonesia and EU, working in English to prepare a new discussion paper and project document for establishment of ML for spices. The discussion paper should also include proposals for possible MLs to assist the next session of the Committee to take a decision on new work.
139. The Delegation of India informed the Committee that it had already started some work on MLs for the first four spices in the priority list and that this would be used to inform the EWG.

### **DISCUSSION PAPER ON FEASIBILITY TO DEVELOP A CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF MYCOTOXIN CONTAMINATION IN SPICES (Agenda Item 17)<sup>22</sup>**

140. The Delegation of Spain, as Chair of EWG, introduced the item. The Delegation explained that the main mycotoxins identified in spices were OTA and aflatoxins and that the working group had identified several measures that could be used to reduce the risk for mycotoxin production. There was therefore sufficient information to proceed with the development of a code of practice and a proposal for its structure was presented in the paper. The Delegation explained that the structure consisted of a main body with general recommended practices and specific annexes classified by mycotoxin and groups of spices, but that further work was necessary to identify for which mycotoxin(s) /spice or group of spices combination annexes should be developed. The Delegation noted that work on the COP should take into account all other codes of practice in Codex, as well as the work of the CCSCH.

### Discussion

141. The Committee considered the recommendations of the Working Group and agreed to start new work on the code of practice for the prevention of mycotoxin contamination in spices, using the structure as outlined in the EWG report, i.e. general guidance applying to all spices and annexes to address mycotoxin/spices or groups of spices combinations.
142. The Committee also agreed to inform CCFH of its decision to start new work on a COP. The Committee agreed that it would not request CCFH to remove any mycotoxin-related measures from the Code of Hygienic Practice for Spices and Dried Aromatic Herbs at this time, until the work in CCCF had been completed.

<sup>21</sup> [CX/CF 15/9/15](#); [CRD17](#) (Comments of El Salvador, EU, Mali, Nigeria, Thailand, Philippines, USA and AU)

<sup>22</sup> [CX/CF 15/9/16](#); [CRD18](#) (Comments of El Salvador, EU, India, Republic of Korea, USA and AU); [CRD24](#) (Comments of the Republic of Korea)

### Conclusion

143. The Committee agreed to request the Commission to approve new work on the Code of Practice for the Prevention and Reduction of mycotoxin contamination in spices and to forward the project document to the Executive Committee for critical review (Appendix VIII).
144. The Committee also agreed to establish the EWG, chaired by Spain and co-chaired by India and The Netherlands working in English only, to prepare, subject to approval by the Commission, a proposed draft of Code of Practice for circulation for comments at Step 3 and consideration at its next session. The EWG would also prepare a discussion paper to outline the development of possible annexes for mycotoxin/individual spices or groups of spices combinations.

### PRIORITY LIST OF CONTAMINANTS AND NATURALLY OCCURRING TOXICANTS PROPOSED FOR EVALUATION BY JECFA (Agenda Item 18)<sup>23</sup>

145. The Delegation of the USA, as Chair of the in-session WG, presented the report on the outcome of the discussion on the priority list.
146. The Committee was informed that six substances remain on the priority list, viz. 3-MCPD esters, glycidyl esters, sterigmatocystin, diacetoxyscirpenol, fumonisins, and aflatoxins. The Committee was further informed that pyrrolizidine alkaloids and non-dioxin like PCBs had been removed from the list since they were scheduled for evaluation by 80<sup>th</sup> JECFA in June 2015.
147. The Committee noted the following new proposals for inclusion in the list from the WG:
- Aflatoxins - exposure assessment and impact assessment of different MLs for RTE peanuts;
  - Scopoletin - full risk assessment with a view to advise CCNASWP in their development of a standard for noni juice;
  - Inorganic arsenic for evaluation of non-cancer effects (neurodevelopmental, immunological and cardiovascular); and
  - Dioxins - update of the risk assessment.
148. Regarding the request to include dioxins, the Committee noted that this would not be a high priority, considering that extensive re-assessment was being undertaken by national and regional agencies, and as such the JECFA assessment could build on this work once completed.
149. Regarding the request for full risk assessment of scopoletin, the JECFA Secretariat noted that availability of data appeared limited. This was also confirmed by some countries. Information on this compound should also be requested from CCNASWP members and other countries.
150. On the four mycotoxins in the priority list (i.e. sterigmatocystin, diacetoxyscirpenol, fumonisins and aflatoxins), the JECFA Secretariat informed the Committee that these should be evaluated together and that a JECFA meeting dedicated to mycotoxins was tentatively planned for 2016.
151. The Committee agreed with the recommendations of the WG, with some editorial amendments to the priority list.

### Conclusion

152. The Committee endorsed the priority list of contaminants and naturally occurring toxicants for JECFA evaluation as proposed by the WG (Appendix IX) and agreed to re-convene the in-session Working Group at its next session.
153. 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 19)

154. The Committee noted that there was no other business and future work to consider.

### DATE AND PLACE OF THE NEXT SESSION (Agenda Item 20)

155. The Committee was informed that the 10<sup>th</sup> Session was tentatively scheduled to be held in The Netherlands in approximately one year's time, the final arrangements being subject to confirmation by the Host Country and the Codex Secretariat.

<sup>23</sup> [REP14/CF, Appendix XIII](#); [CX/CF 15/9/17](#) (Comments of AU); [CRD2](#) (Report of the in-session WG on Priorities led by USA)

## SUMMARY STATUS OF WORK

SUBJECT MATTER	STEP	ACTION BY	DOCUMENT REFERENCE (REP15/CF)
Draft and proposed draft maximum levels for lead in fruit juices and nectars (excluding juices exclusively from berries and other small fruits), ready-to-drink; canned fruits (excluding berries and other small fruits); canned vegetables (excluding canned brassica, canned leafy vegetables and canned legume vegetables); berries and other small fruits (excluding cranberry, currant and elderberry); cranberry; currant; elderberry; brassica vegetables; legume vegetables; fruiting vegetables, cucurbits; fruiting vegetables, other than cucurbits (excluding fungi and mushrooms)	8 and 5/8	38 <sup>th</sup> CAC	paras 49-50, Appendix IV
Draft maximum levels for deoxynivalenol (DON) in cereal-based foods for infants and young children; in flour, meal, semolina and flakes derived from wheat, maize or barley; and in cereal grains (wheat, maize and barley) destined for further processing including sampling plans and performance criteria for methods of analysis	8	38 <sup>th</sup> CAC 37 <sup>th</sup> CCMAS	para 91, Appendix VI
Proposed draft maximum level for inorganic arsenic in husked rice	5	38 <sup>th</sup> CAC EWG (Japan / China) 10 <sup>th</sup> CCCF	para 69, Appendix V
Proposed draft revision of the Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals (CAC/RCP 51-2003)	5	38 <sup>th</sup> CAC EWG (Brazil / Nigeria / USA) 10 <sup>th</sup> CCCF	para 104, Appendix VII
Proposed draft maximum level for total aflatoxins in ready-to-eat peanuts including sampling plan	4	---	para 100
Proposed draft maximum levels for lead in selected fruits and vegetables (fresh and processed)	2/3	EWG (USA) 10 <sup>th</sup> CCCF	Para 48
Proposed draft maximum level for cadmium in chocolate and cocoa-derived products	2/3	EWG (Ecuador / Brazil / Ghana) 10 <sup>th</sup> CCCF	para 55
Proposed draft Code of Practice for the Prevention and Reduction of Arsenic Contamination in Rice	2/3	EWG (Japan / China) 10 <sup>th</sup> CCCF	para 74
Proposed draft Annexes to the Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals (CAC/RCP 51-2003)	2/3	EWG (Brazil / Canada / USA)	para 104
Proposed draft Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Spices	1/2/3	38 <sup>th</sup> CAC EWG (Spain / The Netherlands) 10 <sup>th</sup> CCCF	paras 143-144, Appendix VIII
Revocation of maximum levels for lead in the GSCTFF namely: canned grapefruit, canned mandarin oranges, canned mangoes, canned pineapples, canned fruit cocktail, canned tropical fruit salad, canned asparagus, canned carrots, canned mature processed peas, canned mushrooms, canned palmito (palm hearts) and canned sweet corn.	---	38 <sup>th</sup> CAC	para 51, Appendix IV



SUBJECT MATTER	STEP	ACTION BY	DOCUMENT REFERENCE (REP15/CF)
Sampling plans for fumonisins (B <sub>1</sub> +B <sub>2</sub> ) in maize (grain) and maize products (flour and meal)	---	37 <sup>th</sup> CCMAS	para 13, Appendix III
Ergot alkaloids	---	Germany	para 103
Maximum levels for methylmercury in fish	---	EWG (Japan / New Zealand) 10 <sup>th</sup> CCCF	para 125
Maximum levels for mycotoxins in spices	---	EWG (India / EU / Indonesia) 10 <sup>th</sup> CCCF	para 138
Priority list of contaminants and naturally occurring toxicants proposed for evaluation by JECFA	---	10 <sup>th</sup> CCCF	para 152, Appendices IX and X
Submission and use of data from GEMS/Food	---	---	para 108
Approaches for phasing-in of lower maximum levels for contaminants	---	---	para 117
Radionuclides in foods	---	---	para 134

**APPENDIX I**

**LIST OF PARTICIPANTS  
LISTE DES PARTICIPANTS  
LISTA DE PARTICIPANTES**

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**APPENDIX II**

**RESPONSES OF CCCF9 TO THE STRATEGIC PLAN IMPLEMENTATION**

Replies of CCCF9 is shown in **and Underlined** font.

Strategic Goal	Objective	Activity	Expected Outcome	Measurable Indicators/Outputs
1: Establish international food standards that address current and emerging food issues.	1.1: Establish new and review existing Codex standards, based on priorities of the CAC.	1.1.1: Consistently apply decision-making and priority-setting criteria across Committees to ensure that the standards and work areas of highest priority are progressed in a timely manner.	New or updated standards are developed in a timely manner.	- Priority setting criteria are reviewed, revised as required and applied. - # of standards revised and # of new standards developed based on these criteria.
<p><b>Question to the Committee:</b>                      Is this activity relevant to the work of the Committee? <b>Yes.</b>                      Does the Committee use any specific criteria for standards development?  <b>Yes, the Committee has specific criteria to develop standards that are laid down in the Procedural Manual and in the Preamble and Annex I to the GSCTFF.</b>                      Does the Committee intend to develop such criteria?  <b>No. The current criteria are sufficient.</b></p>				
	1.2: Proactively identify emerging issues and Member needs and, where appropriate, develop relevant food standards.	1.2.1: Develop a systematic approach to promote identification of emerging issues related to food safety, nutrition, and fair practices in the food trade.	Timely Codex response to emerging issues and to the needs of Members.	- Committees implement systematic approaches for identification of emerging issues. - Regular reports on systematic approach and emerging issues made to the CCEXEC through the Codex Secretariat.
<p><b>Question to the Committee:</b>                      Is this activity relevant to the work of the Committee? <b>Yes.</b>                      How does the Committee identify emerging issues and members needs? Is there a systematic approach? Is it necessary to develop such an approach?  <b>Emerging issues can be reported by the members directly to the CCCF or by other committees. This process may lead to the revision or the development of Standards where necessary.</b>  <b>No, current procedures are sufficient.</b></p>				
		1.2.2: Develop and revise international and regional standards as needed, in response to needs identified by Members and in response to factors that affect food safety, nutrition and fair practices in the food trade.	Improved ability of Codex to develop standards relevant to the needs of its Members.	- Input from committees identifying and prioritising needs of Members. - Report to CCEXEC from committees on how standards developed address the needs of the Members as part of critical review process.
<p><b>Included in question to 1.2</b></p>				

Strategic Goal	Objective	Activity	Expected Outcome	Measurable Indicators/Outputs
2: Ensure the application of risk analysis principles in the development of Codex standards.	2.1: Ensure consistent use of risk analysis principles and scientific advice.	2.1.1: Use the scientific advice of the joint FAO/WHO expert bodies to the fullest extent possible in food safety and nutrition standards development based on the <i>“Working Principles of Risk Analysis for Application in the Framework of the Codex Alimentarius”</i> .	Scientific advice consistently taken into account by all relevant committees during the standard setting process.	<ul style="list-style-type: none"> <li>- # of times the need for scientific advice is:</li> <li>- identified,</li> <li>- requested and,</li> <li>- utilised in a timely manner.</li> </ul>
<p><b>Question to the Committee:</b></p> <p>Is this activity relevant to the work of the Committee? <b>Yes.</b></p> <p>Does the Committee request scientific advice in course of its work, how often does it request such advice? <b>Yes, when necessary.</b></p> <p>Does the Committee always use the scientific advice, if not, why not?</p> <p><b><u>The Committee uses systematically the scientific advice that it has requested.</u></b></p>				
		2.1.2: Encourage engagement of scientific and technical expertise of Members and their representatives in the development of Codex standards.	Increase in scientific and technical experts at the national level contributing to the development of Codex standards.	<ul style="list-style-type: none"> <li>- # of scientists and technical experts as part of Member delegations.</li> <li>- # of scientists and technical experts providing appropriate input to country positions.</li> </ul>
<p><b>Question to the Committee:</b></p> <p>Is this activity relevant to the work of the Committee?</p> <p><b><u>Yes. Scientific and technical expertise is required to develop draft standards and to justify positions supported by the Members.</u></b></p> <p>How do members make sure that the necessary scientific input is given into country positions and that the composition of the national delegation allows to adequately present and discuss this position?</p> <p><b><u>Prior to developing and advancing a country’s position, Members typically seek and engage national scientific and technical expertise from within their government and from those outside of government.</u></b></p> <p>What guidance could be given by the Committee or FAO and WHO?</p> <p><b><u>The Committee does not believe that a specific guidance is needed on this point.</u></b></p>				
		2.1.3: Ensure that all relevant factors are fully considered in exploring risk management options in the context of Codex standard development.	Enhanced identification, and documentation of all relevant factors considered by committees during the development of Codex standards.	<ul style="list-style-type: none"> <li>- # of Committee documents identifying all relevant factors guiding risk management recommendations.</li> <li>- # of Committee documents clearly reflecting how those relevant factors were considered in the context of standards development.</li> </ul>

Strategic Goal	Objective	Activity	Expected Outcome	Measurable Indicators/Outputs
<p><b>Question to the Committee:</b> Is this activity relevant to the work of the Committee? <b>Yes. In its capacity of risk manager, the Committee ensures that all relevant factors in exploring risk management options are considered.</b> How does the Committee ensure that all relevant factors have been taken into account when developing a standard and how are these documented? <b>The Committee follows the Working Principles for Risk Analysis in the Procedural Manual and the specific criteria for setting MLs for contaminants in the GSCTFF.</b></p>				
		2.1.4: Communicate the risk management recommendations to all interested parties.	Risk management recommendations are effectively communicated and disseminated to all interested parties.	- # of web publication/communications relaying Codex standards. - # of media releases disseminating Codex standards.
<p><b>Question to the Committee:</b> Is this activity relevant to the work of the Committee? <b>Yes. currently this is mainly done through the publication of standards and related texts on the Codex website. The development of the Codex communication strategy would have a positive impact on this activity.</b> When taking a risk management decision, does the Committee give guidance to members how to communicate this decision? Would more consideration of this be helpful to members? <b>No. Once the Codex general communication strategy will be developed, more consideration could be given to this issue.</b></p>				
3: Facilitate the effective participation of all Codex Members.	3.1: Increase the effective participation of developing countries in Codex.	3.1.5: To the extent possible, promote the use of the official languages of the Commission in committees and working groups.	Active participation of Members in committees and working groups.	- Report on number of committees and working groups using the languages of the Commission.
<p><b>Question to the Committee:</b> Is this activity relevant to the work of the Committee? <b>Yes.</b> Is the use of official languages in working groups of the Committee sufficient? <b>The Committee uses English as common language in the Working Groups, and uses other official languages when possible.</b> What are the factors determining the choice of languages? <b>This depends on the Members chairing and co-chairing the working groups.</b> How could the situation be improved? <b>A suggestion could be to promote co-chairing arrangements by countries with different languages.</b></p>				
	3.2: Promote capacity development programmes that assist countries in creating sustainable national Codex structures.	3.2.3: Where practical, the use of Codex meetings as a forum to effectively conduct educational and technical capacity building activities.	Enhancement of the opportunities to conduct concurrent activities to maximise use of the resources of Codex and Members.	- # of activities hosted on the margins of Codex meetings.

Strategic Goal	Objective	Activity	Expected Outcome	Measurable Indicators/Outputs
<p><b>Question to the Committee:</b> Is this activity relevant to the work of the Committee? <b><u>Yes, the promotion of such capacity development programs is of interest for all committees, including CCCF.</u></b> Does the Committee organise technical capacity activities or other activities in the margins of Committee sessions? If yes – how many and with which topics have been organised in the past. If no – could this be useful and what topics could be addressed? <b><u>The Committee previously had a Workshop on Risk Analysis organised by JECFA during the 4<sup>th</sup> Session of CCCF, Workshop on the International Workshop on Feed Risk Assessment for Chemicals at the last session. The Committee intends to have a side event on the use of the GEMS/Food data base at the next session.</u></b></p>				
<p>4: Implement effective and efficient work management systems and practices.</p>	<p>4.1: Strive for an effective, efficient, transparent, and consensus based standard setting process.</p>	<p>4.1.4: Ensure timely distribution of all Codex working documents in the working languages of the Committee / Commission.</p>	<p>Codex documents distributed in a more timely manner consistent with timelines in the Procedural Manual.</p>	<ul style="list-style-type: none"> <li>- Baseline Ratio (%) established for documents distributed at least 2 months prior to versus less than 2 months prior to a scheduled meeting.</li> <li>- Factors that potentially delay the circulation of documents identified and addressed.</li> <li>- An increase in the ratio (%) of documents circulated 2 months or more prior to meetings.</li> </ul>
<p><b>Question to the Committee:</b> Is this activity relevant to the work of the Committee? <b><u>Yes.</u></b> Does the Committee have a mechanism in place to ensure timely distribution of documents? What could be done to further improve the situation? <b><u>The requirement for timely distribution of documents already exists and is included in the Procedural Manual. However, all members should be more disciplined in ensuring its implementation.</u></b></p>				
		<p>4.1.5: Increase the scheduling of Work Group meetings in conjunction with Committee meetings.</p>	<p>Improved efficiency in use of resources by Codex committees and Members.</p>	<p>- # of physical working group meetings in conjunction with Committee meetings, where appropriate.</p>
<p><b>Question to the Committee:</b> Is this activity relevant to the work of the Committee? <b><u>Yes. CCCF schedules Working Group meetings in conjunction with Committee meetings, if necessary.</u></b> Does the Committee hold physical working groups independent of Committee sessions? If yes – why is this necessary? <b><u>The Committee believes that in general the system in place today, i.e. EWG preparing the draft documents for the Committee, is sufficient to ensure the efficiency of the work of the Committee. Currently there does not seem to be any added value in CCCF to organise working group meetings independent of Committee sessions, however the Committee may look into the opportunity as necessary.</u></b></p>				

Strategic Goal	Objective	Activity	Expected Outcome	Measurable Indicators/Outputs
	4.2: Enhance capacity to arrive at consensus in standards setting process.	4.2.1: Improve the understanding of Codex Members and delegates of the importance of and approach to consensus building of Codex work.	Members and delegates awareness of the importance of consensus in the Codex standard setting process improved.	<ul style="list-style-type: none"> <li>- Training material on guidance to achieve consensus developed and made available in the languages of the Commission to delegates.</li> <li>- Regular dissemination of existing material to Members through Codex Contact Points.</li> <li>- Delegate training programs held in association with Codex meetings.</li> <li>- Impediments to consensus being achieved in Codex identified and analysed and additional guidance developed to address such impediments, if necessary.</li> </ul>

**Question to the Committee:**

Is this activity relevant to the work of the Committee?

**Yes. The Committee strongly believes that it is essential to maintain consensus-based decision making in the framework of Codex Alimentarius. This is necessary to ensure the legitimacy, credibility and worldwide acceptance of Codex standards. The obligation to strive for consensus-based decision making is clearly spelled out in Rule XII of the Rules of Procedure of the CAC. It is the role of the chair to explore all possible means to reach consensus. Efforts are also required from Members to achieve consensus.**

Are there problems with finding consensus in the Committee? If yes – what are the impediments to consensus? What has been attempted and what more could be done?

**Problems may arise in this Committee, as well as in any other Committees. All efforts should be made to ensure that all decisions of the Committee are taken on the basis of consensus, or the standard should not be forwarded to the CAC.**

**APPENDIX III****SAMPLING PLAN FOR  
FUMONISINS (FB1 + FB2) IN MAIZE GRAIN AND MAIZE FLOUR AND MAIZE MEAL****(for endorsement by CCMAS)****ANNEX I****SAMPLING PLANS FOR FUMONISINS IN MAIZE GRAIN AND MAIZE FLOUR AND MAIZE MEAL****Maize grain, unprocessed**

Maximum level	4 000 µg/kg FB1 + FB2
Increments	increments of 100 g, depending on the lot weight (≥ 0.5 tonnes)
Sample preparation	dry grind with a suitable mill (particles smaller than 0.85 mm - 20 mesh)
Laboratory sample weight	≥ 1 kg
Number of laboratory samples	1
Test portion	25 g test portion
Method	HPLC
Decision rule	If the fumonisin-sample test result for the laboratory samples is equal or less than 4 000 µg/kg, accept the lot. Otherwise, reject the lot.

**Maize flour and maize meal**

Maximum level	2 000 µg/kg FB1 + FB2
Increments	10 x 100 g
Sample preparation	None
Laboratory sample weight	≥ 1 kg
Number of laboratory samples	1
Test portion	25 g test portion
Method	HPLC
Decision rule	If the fumonisin-sample test result is equal or less than 2000 µg/kg, accept the lot. Otherwise, reject the lot.

**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 a fumonisin test procedure and an accept/reject level. A fumonisin test procedure consists of three steps: sample selection, sample preparation and analysis or fumonisin quantification. The accept/reject level is a tolerance usually equal to the Codex maximum level (ML).

**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 shelled maize 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 in such a way to ensure that the laboratory sample is still representative of the subplot sampled.

**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 fumonisin for chemical analysis.

### SAMPLING PLAN DESIGN CONSIDERATIONS

#### *Material to be sampled*

1. Each lot of maize, which is to be examined for fumonisin, must be sampled separately. Lots larger than 50 tonnes should be subdivided into sublots to be sampled separately. If a lot is greater than 50 tonnes, the lot should be subdivided into sublots according to Table 1.

**Table 1.** Subdivision of maize sublots according to lot weight

Lot weight (t)	Maximum Weight or minimum number of sub lots	Number of incremental sample	Minimum laboratory Sample Weight (kg)
≥ 1500	500 tonnes	100	1
> 300 and < 1500	3 sublots	100	1
≥ 100 and ≤ 300	100 tonnes	100	1
≥ 50 and < 100	2 sublots	100	1
< 50	-	3-100*	1

\* see table 2

2. Taking into account that the weight of the lot is not always an exact multiple of the weight of sublots, the weight of the subplot may exceed the mentioned weight by a maximum of 20%.

#### *Incremental Sample*

3. The suggested minimum weight of the incremental sample should be 100 grams for lots ≥0.5 tonnes.
4. For lots less than 50 tonnes, the sampling plan must be used with 3 to 100 incremental samples, depending on the lot weight. For very small lots (≤ 0.5 tonnes) a lower number of incremental samples may be taken, but the aggregate sample uniting all incremental samples shall be also in that case at least 1 kg. Table 2 may be used to determine the number of incremental samples to be taken.

**Table 2.** Number of incremental samples to be taken depending on the weight of the lot

Lot weight (t)	Number of incremental sample	Minimum Laboratory Sample Weight (kg)
≤ 0.05	3	1
> 0.05 - ≤ 0.5	5	1
> 0.5 - ≤ 1	10	1
> 1 - ≤ 3	20	1
> 3 - ≤ 10	40	1
> 10 - ≤ 20	60	1
> 20 - < 50	100	1

**Static Lots**

5. A static lot can be defined as a large mass of shelled maize 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 maize is stationary at the time a sample is selected. Selecting a truly random sample from a static lot can be difficult because all containers in the lot or subplot may not be accessible.
6. 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.
7. 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:  

$$SF = (LT \times IS) / (AS \times IP).$$
8. The sampling frequency (SF) is the number of packages sampled. All weights should be in the same mass units such as kg.

**Dynamic Lots**

9. Representative aggregate samples can be more easily produced when selecting incremental samples from a moving stream of shelled maize 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).
10. 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 maize flow past the sampling point.
11. 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.
12. The size of the aggregate sample (S) in kg, taken from a lot by a cross cut sampler is:  

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

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).
13. 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 as a function of S, V, D, and MR.  

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

**Packaging and Transportation of Samples**

14. 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.
15. 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**

16. Sunlight should be excluded as much as possible during sample preparation, since fumonisin may gradually break down under the influence of ultra-violet light. Also, environmental temperature and relative humidity should be controlled and not favor mold growth and fumonisin formation.
17. As the distribution of fumonisin is extremely non-homogeneous, laboratory samples should be homogenised by grinding the entire laboratory sample received by the laboratory. Homogenisation is a procedure that reduces particle size and disperses the contaminated particles evenly throughout the comminuted laboratory sample.
18. The laboratory sample should be finely ground and mixed thoroughly using a process that approaches as complete homogenisation as possible. Complete homogenisation 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 fumonisin cross-contamination.

**Test portion**

19. The suggested weight of the test portion taken from the comminuted laboratory sample should be approximately 25 g
20. Procedures for selecting the test portion from the comminuted laboratory sample should be a random process. If mixing occurred during or after the comminuting process, the test portion can be selected from any location throughout the comminuted laboratory sample. Otherwise, the test portion should be the accumulation of several small portions selected throughout the laboratory sample.
21. 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**

22. A criteria-based approach, whereby a set of performance criteria is established with which the analytical method used should comply, is appropriate. The criteria-based approach has the advantage that, by avoiding setting down specific details of the method used, developments in methodology can be exploited without having to reconsider or modify the specific method. A list of possible criteria and performance levels are shown in Table 3). Utilising this approach, laboratories would be free to use the analytical method most appropriate for their facilities.

**Table 3.** Performance criteria for Fumonisin B1+ B2.**Maize Grain**

Analyte	ML (mg/Kg)	LOD (mg/Kg)	LOQ (mg/Kg)	RSD <sub>R</sub>	Recovery (%)
FB1 + FB2	4.0	-	-	-	-
FB1		≤ 0.3*	≤ 0.6*	HorRat ≤ 2 ( < 27%)	80 - 110
FB2		≤ 0.15*	≤ 0.3*	HorRat ≤ 2 ( < 32%)	80 - 110

\* - The LOD and LOQ were derived based upon typical B1:B2 ratio of 5:2 in naturally-contaminated samples

**Maize Flour/Meal**

Analyte	ML (mg/Kg)	LOD (mg/Kg)	LOQ (mg/Kg)	RSD <sub>R</sub>	Recovery (%)
FB1 + FB2	2.0	-	-	-	-
FB1		≤ 0.15*	≤ 0.3*	HorRat ≤ 2 ( < 30%)	80 – 110
FB2		≤ 0.06*	≤ 0.15*	HorRat ≤ 2 ( < 34%)	80 – 110

\* - The LOD and LOQ were derived based upon typical B1:B2 ratio of 5:2 in naturally-contaminated samples

**APPENDIX IV****DRAFT MAXIMUM LEVELS FOR LEAD****(Step 8)**

<b>Product name</b>	<b>Maximum level (mg/kg)</b>	<b>Portion of the Commodity/Product to which the ML Applies</b>	<b>Notes/Remarks</b>
Canned fruits	0.1	The ML applies to the product as consumed.	The ML does not apply to canned berries and other small fruits. Relevant Codex commodity standards are CODEX STAN 242-2003, CODEX STAN 254-2007, CODEX STAN 78-1981, CODEX STAN 159-1987, CODEX STAN 42-1981, CODEX STAN 99-1981.
Canned vegetables	0.1	The ML applies to the product as consumed.	The ML does not apply to canned brassica vegetables, canned leafy vegetables and canned legume vegetables. Relevant Codex commodity standard is CODEX STAN 297-2009 (except annexes on canned green beans and canned wax beans and canned green peas).
Fruit juices	0.03	Whole commodity (not concentrated) or commodity reconstituted to the original juice concentration, ready to drink. The ML applies also to nectars, ready to drink.	The ML does not apply to juices exclusively from berries and other small fruit. The ML does not apply to passion fruit juice and nectar. Relevant Codex commodity standard is CODEX STAN 247-2005.
Fruit juices exclusively from berries and other small fruits	0.05	Whole commodity (not concentrated) or commodity reconstituted to the original juice concentration, ready to drink. The ML applies also to nectars, ready to drink.	Relevant Codex commodity standard is CODEX STAN 247-2005.

**PROPOSED DRAFT MAXIMUM LEVELS FOR LEAD**

(Step 5/8)

<b>Product name</b>	<b>Maximum level (mg/kg)</b>	<b>Portion of the Commodity/Product to which the ML Applies</b>	<b>Notes/Remarks</b>
Berries and other small fruits	0.1	Whole commodity after removal of caps and stems.	The ML does not apply to cranberry, currant and elderberry.
Elderberry	0.2	Whole commodity after removal of caps and stems.	
Cranberry	0.2	Whole commodity after removal of caps and stems.	
Currants	0.2	Fruit with stem.	
Brassica vegetables	0.1	Head cabbages and kohlrabi: whole commodity as marketed, after removal of obviously decomposed or withered leaves. Cauliflower and broccoli: flower heads (immature inflorescence only). Brussels sprouts: "buttons" only.	The ML does not apply to kale and leafy Brassica vegetables.
Fruiting vegetables	0.05	Whole commodity after removal of stems Sweet corn and fresh corn: kernels plus cob without husk.	The ML does not apply to fungi and mushrooms.
Legume vegetables	0.1	Whole commodity as consumed. The succulent forms may be consumed as whole pods or as the shelled product.	

**REVOCAION OF MAXIMUM LEVELS FOR LEAD FOR INDIVIDUAL STANDARDS FOR CANNED  
FRUITS AND VEGETABLES  
IN THE GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOOD AND FEED**  
(following the establishment of maximum levels for lead in in the above-mentioned commodities)  
**(for adoption by CAC)**

<b>Product name</b>	<b>Maximum level (mg/kg)</b>	<b>Notes/Remarks</b>
Canned fruit cocktail	1	Relevant Codex commodity standard is CODEX STAN 78-1981.
Canned grapefruit	1	Relevant Codex commodity standard is CODEX STAN 254-2007.
Canned mandarin oranges	1	Relevant Codex commodity standard is CODEX STAN 254-2007.
Canned mangoes	1	Relevant Codex commodity standard is CODEX STAN 159-1987.
Canned pineapples	1	Relevant Codex commodity standard is CODEX STAN 42-1981.
Canned tropical fruit salad	1	Relevant Codex commodity standard is CODEX STAN 99-1981.
Canned asparagus	1	Relevant Codex commodity standard is CODEX STAN 297-2009.
Canned carrots	1	Relevant Codex commodity standard is CODEX STAN 297-2009.
Canned mature processed peas	1	Relevant Codex commodity standard is CODEX STAN 297-2009.
Canned mushrooms	1	Relevant Codex commodity standard is CODEX STAN 297-2009.
Canned palmito (palm hearts)	1	Relevant Codex commodity standard is CODEX STAN 297-2009.
Canned sweet corn	1	Relevant Codex commodity standard is CODEX STAN 297-2009.

**APPENDIX V**

**PROPOSED DRAFT MAXIMUM LEVEL FOR INORGANIC ARSENIC IN HUSKED RICE**

**(Step 5)**

**ARSENIC**

<b>Commodity / Product Name</b>	<b>Maximum Level (ML) mg/kg</b>	<b>Portion of the commodity to which the ML applies</b>	<b>Notes/remarks</b>
Rice, husked	0.35	Whole commodity	<p>The ML is for inorganic arsenic (As-in).</p> <p>Countries or importers may decide to use their own screening when applying the ML for As-in in rice by analysing total arsenic (As-tot) in rice. If the As-tot concentration is below the ML for As-in, no further testing is required and the sample is determined to be compliant with the ML. If the As-tot concentration is above the ML for As-in, follow-up testing shall be conducted to determine if the As-in concentration is above the ML.</p>

**APPENDIX VI**

**DRAFT MAXIMUM LEVELS FOR DEOXYNIVALENOL (DON) IN CEREAL-BASED FOODS FOR  
INFANTS AND YOUNG CHILDREN;  
IN FLOUR, MEAL, SEMOLINA AND FLAKES DERIVED FROM WHEAT, MAIZE OR BARLEY;  
AND IN CEREAL GRAINS (WHEAT, MAIZE AND BARLEY) DESTINED FOR FURTHER PROCESSING**

**(Step 8)**

**DEOXYNIVALENOL (DON)**

<b>Commodity / Product Name</b>	<b>Maximum Level (ML) mg/kg</b>	<b>Portion of the commodity to which the ML applies</b>	<b>Notes/remarks</b>
Cereal-based foods for infants and young children	0.2	ML applies to the commodity on a dry matter basis.	For sampling plan, see Annex below.  All cereal-based foods intended for infants (up to 12 months) and young children (12 to 36 months)
Flour, meal, semolina and flakes derived from wheat, maize or barley	1		For sampling plan, see Annex below.
Cereal grains (wheat, maize and barley) destined for further processing	2		For sampling plan, see Annex below.  “Destined for further processing” means intended to undergo an additional processing/treatment that has proven to reduce levels of DON before being used as an ingredient in foodstuffs, otherwise processed or offered for human consumption. Codex members may define the processes that have been shown to reduce levels



**DRAFT SAMPLING PLANS FOR DEOXYNIVALENOL (DON) IN CEREALS****(Step 8)****Cereal grains (wheat, cereal and barley) destined for further processing**

Maximum level	2000 µg/kg DON
Increments	increments of 100 g, depending on the lot weight (≥ 0.5 tonnes)
Sample preparation	dry grind with a suitable mill (particles smaller than 0.85 mm - 20 mesh)
Laboratory sample weight	≥ 1 kg
Number of laboratory samples	1
Test portion	25 g test portion
Method	HPLC
Decision rule	If the DON-sample test result for the laboratory samples is equal or less than 2000 µg/kg, accept the lot. Otherwise, reject the lot.

**Cereal-based foods for infants and young children**

Maximum level	200 µg/kg DON
Increments	10 x 100 g
Sample preparation	None
Laboratory sample weight	1 kg
Number of laboratory samples	1
Test portion	25 g test portion
Method	HPLC
Decision rule	If the DON sample test result is equal or less than 200 µg/kg, accept the lot. Otherwise, reject the lot.

**Flour, semolina, meal and flakes derived from wheat, cereal or barley**

Maximum level	1000 µg/kg DON
Increments	10 x 100 g
Sample preparation	None
Laboratory sample weight	1 kg
Number of laboratory samples	1
Test portion	25 g test portion
Method	HPLC
Decision rule	If the DON sample test result is equal or less than 1000 µg/kg, accept the lot. Otherwise, reject the lot.

**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 a DON test procedure and an accept/reject level. A DON test procedure consists of three steps: sample selection, sample preparation and analysis or DON quantification. The accept/reject level is a tolerance usually equal to the Codex maximum level (ML).

**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 shelled cereal 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 in such a way to ensure that the laboratory sample is still representative of the sublot sampled.

**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 DON for chemical analysis.

**SAMPLING PLAN DESIGN CONSIDERATIONS*****Material to be sampled***

1. Each lot of cereal, which is to be examined for DON, must be sampled separately. Lots larger than 50 tonnes should be subdivided into sublots to be sampled separately. If a lot is greater than 50 tonnes, the lot should be subdivided into sublots according to Table 1.

**Table 1.** Subdivision of cereal sublots according to lot weight

Lot weight (t)	Maximum Weight or minimum number of sub lots	Number of incremental sample	Minimum laboratory Sample Weight (kg)
≥ 1500	500 tonnes	100	1
> 300 and < 1500	3 sublots	100	1
≥ 100 and ≤ 300	100 tonnes	100	1
≥ 50 and < 100	2 sublots	100	1
< 50	-	3-100*	1

\* see table 2

2. Taking into account that the weight of the lot is not always an exact multiple of the weight of sublots, the weight of the sublot may exceed the mentioned weight by a maximum of 20%.

***Incremental Sample***

3. The suggested minimum weight of the incremental sample should be 100 grams for lots ≥ 0.5 tonnes.
4. For lots less than 50 tonnes, the sampling plan must be used with 3 to 100 incremental samples, depending on the lot weight. For very small lots (≤ 0.5 tonnes) a lower number of incremental samples may be taken, but the aggregate sample uniting all incremental samples shall be also in that case at least 1 kg. Table 2 may be used to determine the number of incremental samples to be taken.

**Table 2.** Number of incremental samples to be taken depending on the weight of the lot of

Lot weight (t)	Number of incremental sample	Minimum Laboratory Sample Weight (kg)
≤ 0.05	3	1
> 0.05 - ≤ 0.5	5	1
> 0.5 - ≤ 1	10	1
> 1 - ≤ 3	20	1
> 3 - ≤ 10	40	1
> 10 - ≤ 20	60	1
> 20 - < 50	100	1

**Static Lots**

5. A static lot can be defined as a large mass of shelled cereal 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 cereal is stationary at the time a sample is selected. Selecting a truly random sample from a static lot can be difficult because all containers in the lot or subplot may not be accessible.
6. 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.
7. 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:  

$$SF = (LT \times IS) / (AS \times IP).$$
8. The sampling frequency (SF) is the number of packages sampled. All weights should be in the same mass units such as kg.

**Dynamic Lots**

9. Representative aggregate samples can be more easily produced when selecting incremental samples from a moving stream of shelled cereal 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).
10. 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 cereal flow past the sampling point.
11. 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.

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

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

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).

13. 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 as a function of S, V, D, and MR.

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

### **Packaging and Transportation of Samples**

14. 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.
15. 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**

16. Sunlight should be excluded as much as possible during sample preparation, since DON may gradually break down under the influence of ultra-violet light. Also, environmental temperature and relative humidity should be controlled and not favour mould growth and DON formation.
17. As the distribution of DON is extremely non-homogeneous, laboratory samples should be homogenised by grinding the entire laboratory sample received by the laboratory. Homogenisation is a procedure that reduces particle size and disperses the contaminated particles evenly throughout the comminuted laboratory sample.
18. The laboratory sample should be finely ground and mixed thoroughly using a process that approaches as complete homogenisation as possible. Complete homogenisation 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 DON cross-contamination.

### **Test portion**

19. The suggested weight of the test portion taken from the comminuted laboratory sample should be approximately 25 g
20. Procedures for selecting the test portion from the comminuted laboratory sample should be a random process. If mixing occurred during or after the comminuting process, the test portion can be selected from any location throughout the comminuted laboratory sample. Otherwise, the test portion should be the accumulation of several small portions selected throughout the laboratory sample.
21. 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**

22. A criteria-based approach, whereby a set of performance criteria is established with which the analytical method used should comply, is appropriate. The criteria-based approach has the advantage that, by avoiding setting down specific details of the method used, developments in methodology can be exploited without having to reconsider or modify the specific method. A list of possible criteria and performance levels are shown in Table 3). Utilising this approach, laboratories would be free to use the analytical method most appropriate for their facilities.

**Table 3.** Proposed method criteria for DON in cereals.

<b>Commodity</b>	<b>ML (mg/kg)</b>	<b>LOD (mg/kg)</b>	<b>LOQ (mg/kg)</b>	<b>Precision on HorRat</b>	<b>Minimum applicable range (mg/kg)</b>	<b>Recovery</b>
Cereal grains (wheat, cereal and barley) destined for further processing	2.0	≤ 0.2	≤ 0.4	≤ 2	1-3	80 - 110%
Cereal-based foods for infants and young children	0.2	≤ 0.02	≤ 0.04	≤ 2	0.1 – 0.3	80 – 110%
Flour, semolina, meal and flakes derived from wheat, cereal or barley	1.0	≤ 0.1	≤ 0.2	≤ 2	0.5 – 1.5	80 – 110%

**APPENDIX VII****PROPOSED DRAFT REVISION OF THE CODE OF PRACTICE FOR THE  
PREVENTION AND REDUCTION OF  
MYCOTOXIN CONTAMINATION IN CEREALS (CAC/RCP 51-2003)****(Step 5)****INTRODUCTION**

1. Mycotoxigenic fungi are prevalent in regions in climatic zones which allow for small and large scale cereal grain production. Although the species and strains may differ among grain producing regions, these fungi are present in soils, in wild host plant species, in the residues of cultivated crops and stored grains and in the dust in drying and/or storage facilities. The fungi are associated with both pre-harvest and post-harvest mycotoxin contamination in cereals.
2. The severity of pre-harvest fungal propagation is highly dependent upon weather conditions varying greatly from year to year in grain-producing regions. The severity of pre-harvest infection and propagation of toxigenic fungi can also vary with the degree of damage caused by insects and other non-toxigenic fungi. Because of these factors, mycotoxin concentrations observed in grains at harvest vary widely from year to year. Reliable prevention of pre-harvest fungal infection has proven to be elusive, even with application of good agricultural practices (GAP) and commercially available fungicides. Cereal breeding has resulted in only modest gains in genetic resistance to the *Fusarium* ear blight (*Fusarium* head blight) of cereals in cultivars with acceptable quality, yield and tolerance to other important cereal diseases.
3. The severity of post-harvest fungal infection and propagation during prolonged periods of grain storage can be managed more predictably through GAP and good manufacturing practices (GMP) that ensure that moisture levels in stored grain remain below levels that are conducive to germination of spores of common post-harvest fungal species specific to the environmental conditions present in the region. However, research has confirmed that spores of such species are ubiquitous in soils, equipment, and storage structures despite diligent cleaning. Consequently, germination of mycotoxigenic species can occur within certain temperature ranges if even a small amount of stored grain develops elevated moisture levels from exposure to precipitation or insect infestation. The size and design of large grain storage structures and the limited availability of technology often make precise monitoring of moisture and temperature impractical.
4. Risk of post-harvest fungal infection and production of mycotoxins in stored grain increases with the duration of storage. However, for reasons of food security and a continuous supply of cereal grains for direct consumption, processing and/or animal feed, long term storage, generally throughout an entire crop year or for even longer periods, may be a necessity depending on the grain needs of the specific production region where the commodity is being stored.
5. The complete prevention of dissemination by pre-harvest and post-harvest mycotoxigenic fungal species is not practically achievable, even when GAP and GMP are followed. Therefore, the intermittent presence of mycotoxins in cereal grains destined for food and animal feed use is to be expected.
6. The General Code of Practice by Codex provides current and relevant information for all countries to consider in their efforts to control and reduce mycotoxin contamination in cereal grains, grain-derived foods and animal feeds. In order for this Code of Practice to be effective, it will be necessary for the national authorities, producers, marketers, and processors in each country to consider the general principles and examples of GAP and GMP provided in the Code, taking into account their local crops, climate, and agronomic practices to enable and facilitate adoption of these practices where relevant and feasible. This Code of Practice applies to all cereal grains and cereal products relevant to human dietary intake and health as well as international trade.
7. It is important for grain producers to realise that GAP, including storage and handling methods, represent the primary line of defence against contamination of cereals with mycotoxins, followed by the implementation of GMP during the handling, storage, processing and distribution of cereals for human food and animal feed. Processing industries also have a role to implement GMP where required, mainly during grain sorting, cleaning and processing.
8. Cereal grain producers should be trained to follow GAP and maintain a close relationship with agricultural advisors, extension services and national authorities to obtain information and advice regarding the choice of appropriate cereal grain cultivars and plant protection products suitable for use in their respective production regions so as to reduce incidence and levels of mycotoxins.
9. This General Code of Practice contains general principles for the reduction of various mycotoxins in cereals. For the education of producers and providing information on testing to relevant parties, the following should be observed:

a) National authorities and/or other organisations should educate producers regarding the environmental factors that cause infection and growth of the mycotoxigenic fungi, and mycotoxin production in cereal crops at the farm level. Emphasis should be placed on the fact that the planting, preharvest and postharvest strategies for a particular crop will depend on the climatic conditions of that particular region and year, taking into account the local crops, and traditional production methods for that particular country or region. National authorities should support scientific research on methods and techniques to prevent fungal growth in the field and during harvest and storage.

b) It is necessary to make available affordable and accurate test kits and associated sampling plan for producers/handlers/processors to quickly access the mycotoxins levels to allow testing of grain shipments without undue disruption of operations plans. The proper use and implementation of any such test kits or tools is critical to their provision of accurate information and data. Procedures should be in place to properly handle, through segregation, reconditioning, recall or diversion, cereal crops that may pose a threat to human and/or animal health.

10. This Code for the prevention and reduction of mycotoxins in cereal grains and grain-derived foods and feeds recommends practices based on GAP and GMP and are generally consistent with Hazard Analysis Critical Control Points (HACCP) principles which are incorporated into current food safety practices and certification schemes now in global use in production, storage, handling, transportation, processing, distribution and trade. The implementation of HACCP principles will minimise mycotoxin contamination through applications of preventive control measures to the extent feasible mainly during storage and processing of cereals.

## I. RECOMMENDED PRACTICES BASED ON GOOD AGRICULTURAL PRACTICES (GAP) AND GOOD MANUFACTURING PRACTICES (GMP)

### Planting

11. Consider developing and maintaining a crop rotation/sequence schedule appropriate to avoid planting the same crop in the same field, for two consecutive seasons in order to reduce the inoculum in the field. Some crops have been found to be particularly susceptible to certain species of mycotoxigenic fungi and the use in rotation with each other should be evaluated. Table 1 shows the most susceptible crops to mycotoxigenic fungi and the mycotoxins that can be produced. Some of these crops are infected after harvest, but the seeds can carry mycotoxigenic fungal spores. Crops of low susceptibility to mycotoxigenic fungi such as clover, alfalfa, beans and other legumes can be used in rotation to reduce the inoculums in the field. Wheat and maize have been found to be particularly susceptible to *Fusarium* species and they should not be used at very close positions in rotation with each other if possible. When used in the same rotation, inclusion of soybeans, oilseeds and pulses may reduce the incidence and severity of pre-harvest infection.

Table 1. Susceptible rotation crops to mycotoxigenic fungi associated with production of mycotoxins (not exhaustive).

Crops	Fungi	Potential of Mycotoxins
Peanuts	<i>Aspergillus flavus</i> <i>A. parasiticus</i> <i>A. nomius</i> And other related species	Aflatoxins
Maize	<i>A. flavus</i> <i>A. parasiticus</i> and other related species	Aflatoxins
	<i>Fusarium graminearum</i> <i>F. culmorum</i>	deoxynivalenol, nivalenol, zearalenone
	<i>F.verticillioides</i> , <i>F. proliferatum</i>	<i>fumonisin</i>

Crops	Fungi	Potential of Mycotoxins
Sorghum	<i>Fusarium graminearum</i>	deoxynivalenol, nivalenol, zearalenone
	<i>Alternaria</i> spp.	alternariol, methyl ether alternariol, tenuazonic acid
	<i>F.verticillioides</i> , <i>F. proliferatum</i>	<i>fumonisin</i> s
	<i>A. flavus</i> <i>A. parasiticus</i> and related species	<i>aflatoxins</i>
	<i>P.verrucosum</i> <i>Aspergillus ochraceus</i> and related species <i>A. carbonarius</i> <i>A. niger</i>	<i>ochratoxin A</i>
	<i>Claviceps purpurea</i> <i>C. Africana</i> <i>C. sorghi</i> and related species	ergot alkaloids
Wheat	<i>Alternaria</i> spp.	alternariol, methyl ether alternariol, tenuazonic acid
	<i>F. graminearum</i> <i>F. culmorum</i> <i>F.asiaticum</i>	deoxynivalenol, nivalenol, zearalenone
Barley	<i>F. graminearum</i> <i>F. culmorum</i> <i>F.asiaticum</i>	deoxynivalenol, nivalenol, zearalenone
Oats	<i>F. graminearum</i> <i>F. culmorum</i> <i>F. langsethii</i>	deoxynivalenol, nivalenol, zearalenone, T-2 and HT-2 toxin
Rye	<i>F. graminearum</i> <i>Claviceps purpurea</i>	deoxynivalenol, ergot alkaloids
Cotton	<i>A. flavus</i> <i>A. parasticus</i>	aflatoxins
Millet	<i>F. graminearum</i>	deoxynivalenol
Triticale	<i>F. graminearum</i>	deoxynivalenol

#### Tillage and Preparation for Seeding (Planting)

12. When possible and practical, use certified seeds as free from mycotoxin, prepare the seed bed for each new crop by plowing under or by destroying or removing old seed heads, stalks, and other debris that may have served, or may potentially serve as substrates for the growth of mycotoxin-producing fungi. However, tilling may not be appropriate with respect to other economic and environmental benefits, such as moisture conservation, maintenance of soil organic matter, reduced erosion, and lower fuel and water use, hence its costs and benefits should be considered prior to application.

13. Utilise the results of soil tests to determine if there is need to apply fertilizer and/or soil conditioners to assure adequate soil pH and plant nutrition to avoid plant stress, especially during seed development stage of crop growth.

14. When available, grow varieties (cultivars) developed and selected for their traits of providing at least partial resistance to both non-toxigenic and toxigenic fungi and insect pests and for lower mycotoxin accumulation. It is important to plant only those varieties recommended for use in a particular area of a country by virtue of their specific physiological and agronomic traits.



15. As far as practical, crop planting should be timed to avoid high temperature and drought stress during the period of seed development and maturation. Predictive models, when available, could be used as a tool to plan for the best planting period.

16. Ensure appropriate density of planting by maintaining the recommended row and intra- plant spacing for the species/varieties grown. Information concerning plant- spacing may be provided by seed companies, national authorities or extension services.

### **Pre-harvest**

17. Where possible, minimise insect damage and fungal infection in the vicinity of the crop by proper use of registered and approved insecticides and fungicides and other appropriate practices within an integrated pest management program. Predictive models could be used to plan the best application timing and mode of pesticide application.

18. As certain weed species can be host plant for toxigenic fungi and competition of weed species during crop development can increase plant stress, it is important to control weeds in the crop by using mechanical methods, registered herbicides or other safe and suitable weed eradication practices utilising an integrated pest management program.

19. Minimise mechanical damage to plants during cultivation, irrigation and pest management practices. Minimise lodging of plants to prevent contact of the aerial parts of the plants with soil, particularly at the flowering stage of the crop. Soil and soil water are sources of inoculum (spores) of toxigenic fungal species.

20. If irrigation is used, ensure that it is applied evenly and that all plants in the field have an adequate supply of water. Irrigation is a valuable method of reducing plant stress in some growing situations. Excess precipitation during anthesis (flowering) makes conditions favourable for dissemination and infection by *Fusarium spp.*; thus irrigation during anthesis and during the ripening of the crops, specifically wheat, barley, and rye, should be avoided.

21. Plan to harvest grain at low moisture content and full maturity, unless allowing the crop to continue to full maturity would subject it to extreme heat, rainfall or drought conditions. Delayed harvest of grain already infected by *Fusarium* species may cause a significant increase in the mycotoxin content of the crop. If mechanical drying equipment is available, earlier harvest may be helpful in limiting mycotoxin production during the final stages of crop maturation. Models could be used to predict the mycotoxin production based on environmental conditions, such as climate conditions and agricultural production conditions, being a guide to timely monitoring and surveying of mycotoxin levels.

22. Before harvest ensure that all equipment, to be used for harvesting, drying, cleaning and storage of crops, is in a good working order and cleaned of crop residues, grain and dust as much as possible. A breakdown of equipment during this critical period may cause grain quality losses and enhance mycotoxin formation. Keep important spare parts available on the farm to minimise time loss from repairs. Make sure that the equipment needed for moisture content measurements is available and calibrated.

### **Harvest**

23. Containers and conveyances (e.g. wagons, trucks) to be used for collecting and transporting the harvested grain from the field to drying facilities, and to storage facilities after drying, should be clean, dry and free of crop residues, old grain, grain dust, insects and visible fungal growth before use and re-use.

24. As far as possible, avoid mechanical damage to the grain and avoid contact with soil during the harvesting operation. Steps should be taken to minimise the spread of infected seed heads, chaff, stalks, and debris (crop residues) onto the ground where spores may inoculate future crops. Mechanised harvest methods such as the use of combines result in large amounts of this crop residue being left in the field. Where crop rotation/ sequence and related tillage practices permit, it is preferable to incorporate this crop residue into the soil by ploughing or cultivation by other means.

25. During the harvesting operation, the moisture content should be determined in several spots of each load of the harvested grain since the moisture content may vary considerably within the same field. As far as possible, avoid harvesting grain with high moisture contents due to precipitation or morning dew and late afternoon as it takes a longer time to dry. If possible, harvest grain in such field(s) as shown to have a higher infection rate by *Fusarium* ear blight through preharvest monitoring or surveying of grain separate from fields with a lower infection rate.

26. Harvested grain that has not been dried to a safe storage moisture level should not be stored or transported in bins, wagons or trucks for prolonged periods of time. Transit time for movement from field to drying facility should be minimised unless the grain is already at acceptable storage moisture levels before harvest. When necessary it is recommended that the trucks and containers to be opened, to increase aeration and minimise the condensation effects.

## Drying and cleaning

27. Avoid piling or heaping high-moisture, freshly harvested commodities for more than a few hours prior to drying or threshing to lessen the risk of fungal growth. If it is not possible to dry the commodities immediately, aerate them by forced air circulation.

28. When necessary pre-cleaning before drying can be carried out to remove large amounts of straw or other plant material that can carry mould or mould spores. Sorting and washing methods can be utilised to clean the grain. However it is important that the grain is not damaged during the procedure and that it is dried thoroughly if washing is used.

29. It is very important to ensure that moisture levels in harvested grains are low enough to permit safe storage for even relatively short periods of time ranging from a few days to a few months. A maximum level of 15% moisture is generally considered to be low enough to prevent further growth of pre-harvest fungi and germination of spores of fungi that typically infected grain and impart mycotoxins during storage, such as *Penicillium* and similar toxigenic moulds

30. Freshly harvested cereals should be dried immediately in such a manner that damage to the grain is minimised and moisture levels are lower than those needed for fungal growth during storage. It is preferable to reduce grain moisture content to an acceptable level prior to transfer to storage bins and other storage structures. If it is not possible dry the commodities immediately, aerate them by forced air circulation and kept the period before drying as short as possible. Mechanical drying is preferred. Flat bed and re-circulating batch driers are adequate for small scale operations while using a continuous flow-dryer is preferred for large scale drying for long storage periods. Grains should not be excessively dried or at excessively high temperatures to avoid deterioration in nutritional quality and suitability for milling or other processing. Avoid accumulating too much grain in the pre-drier storage or "wet tank", especially when field conditions are warm. Store only enough that can be easily dried in a suitable time period.

31. If mechanical means of drying are not available, sun and open air drying should be done on clean surfaces; grains should be protected from rain, dew, soil, pests, droppings from birds during this process. For even and faster drying, mix or stir grains frequently in thin layers to dry evenly and quickly.

32. After drying, cereal grain should be cleaned to remove damaged and immature kernels and other foreign matter. Kernels containing symptomless infections cannot be removed by standard cleaning methods. Seed cleaning procedures, such as gravity tables and optical sorting, may remove broken kernels that are susceptible to infection

## Storage after drying and cleaning

33. It is important that bins, silos, sheds and other buildings intended for grain storage are dry, well-vented structures that provide protection from rain, snow, ground water, moisture condensation, and the entry of rodents, birds and insects that can not only contaminate grain but damage grain kernels to make them susceptible to mould infection. Ideally, storage structures should be designed so as to minimise wide fluctuations in the temperature of the stored grain.

34. Storage facilities should be cleaned prior to receiving grain to remove dust, grain, crop residues, animal and insect excreta, insects, foreign material and other source of contamination.

35. For bagged commodities, ensure that bags are clean, dry and stacked on pallets or incorporate a water impermeable layer between the bags and the floor. The bags should facilitate aeration and be made of non-toxic food-grade materials, that do not attract insects and rodents and are sufficiently strong to resist storage for longer periods. When stored by the conventional system bagged grains should enter storage with moisture content less than 1% of the reference moisture held by the bulk storage system.

36. Determine moisture content of the lot, and if necessary, dry the crop to the moisture content recommended for storage. Fungal growth in grain is closely related with water activity ( $a_w$ ). Although the appropriate moisture content for fungal growth on various grains is different, the  $a_w$  is basically the same. Researchers have shown that recommended  $a_w$  to avoid fungal growth is generally less than 0.70. In general, the moisture content of grains during storage should not be higher than 15%. Appropriate level of moisture content of grain should be determined based on cereal variety, kernel size, grain quality, storage period and storage condition (e.g. temperature). In addition, safe storage guidance may be provided to reflect the environmental situation in each region. Table 2 shows values of moisture content in relation to different water activities at 25°C for some cereals.

Table 2. Values of grain moisture content in relation to water activities at 25°C for some cereals.

Cereal	Moisture content (%) at various water activity			
	0.60	0.65	0.70	0.75
Rice	13.2	13.8	14.2	15.0
Oat	11.2	12.2	13.0	14.0
Rye	12.2	12.8	13.6	14.6
Barley	12.2	13.0	14.0	15.0
Maize	12.8	13.4	14.2	15.2
Sorghum	12.0	13.0	13.8	14.8
Wheat	13.0	13.6	14.6	15.8

37. The mycotoxin level in in-bound and out-bound grain should be monitored when relevant, using appropriate sampling and testing programs that are appropriate to the mycotoxin system.

38. To more effectively monitor the condition of stored grain, it is advisable, if possible, to measure the temperature and humidity of the storage facilities and the stored grain at regular time intervals during storage. A grain temperature rise of 2-3°C may indicate microbial growth and/or insect infestation. If temperature or moisture becomes unacceptably high, where possible, aerate the grain by circulation of air through the storage area to maintain proper and uniform temperature levels. Aeration should be conducted, if possible, during periods of low ambient relative humidity of air being forced through the mass of stored grain. Aeration during periods of high relative humidity can actually increase condensation and water activity in stored grain whose temperature is below ambient air temperature. Grain can also be transferred from one storage container to another to promote aeration and disruption of potential hot spots during storage. If grain spoilage or mould growth in grain is observed, separate the apparently infected portions of the grain and send samples for analysis for the presence of mycotoxins. When spoiled grain is removed, it is extremely important to minimise the mixing of the spoiled grain with the remaining portion of grain that appears to be in good condition. Small quantities of highly contaminated grain can greatly increase mycotoxin levels in grain that is otherwise in good condition. When spoiled grain has been removed, it may be necessary to aerate the remaining grains to lower the temperature to acceptable levels.

39. For cold climate countries, it is important to note that reduction of grain temperature below 15 degrees Celsius that can occur during colder months of temperate grain producing regions will contribute to safe storage and prevention of mould growth and mycotoxin production. Extremely cold temperatures will also inhibit insect growth and reproduction, reducing risk of insect damage in turn facilitating mould growth.

40. Use good housekeeping procedures to minimise the levels of rodent pests, insects and fungi in storage facilities. This may include the use of suitable, registered insecticides and fungicides or appropriate alternative methods within an integrated pest management program. Care should be taken to select and use only those pest control products that will not create a safety concern based on the intended end use of the grains and the maximum levels of pesticide residue dictated by regulation or buyer specifications. Since rodent pests can damage the crop during storage, the storage facility must be kept free of rodents such as rats and mice to the extent possible.

41. The use of a suitable, approved preservative (e.g. organic acids such as propionic acid) may be beneficial. These acids are effective in killing various fungi and thus prevent the production of mycotoxins in grains intended only for animal feed. The salts of the acids are usually more effective for long-term storage. Care must be taken because these compounds can negatively affect the taste and odour of the grain.

42. Document the harvesting, drying, cleaning and storage procedures implemented each season by making notes of measurements (e.g. temperature, moisture, and humidity) and any deviation or changes from traditional practices. This information may be very useful for explaining the cause(s) of fungal growth and mycotoxin formation during a particular crop year and help to avoid similar occurrences in the future. Validated predictive models, when available, could be used to control fungal growth and mycotoxin production during these procedures.

### Transport from storage

43. Transport containers, vehicles such as trucks and railway cars and vessels (boats and ships) should be dry and free of old grain, grain dust, visible fungal growth, insects and any contaminated material that could contribute to mycotoxin levels in lots and cargoes of grain. As necessary, transport containers should be cleaned and disinfected with appropriate substances (which should not cause off-odours, flavour or contaminate the grain) before use and re-use and be suitable for the intended cargo. The use of registered fumigants or insecticides may be useful. At unloading, the transport container should be emptied of all cargo and cleaned as appropriate.

44. Shipments of grain should be protected from additional moisture by using covered or airtight containers or tarpaulins. Minimise temperature fluctuations and measures that may cause condensation to form on the grain, which could lead to local moisture build-up and consequent fungal growth and mycotoxin formation.

45. Avoid insect, bird and rodent infestation during transport by the use of insect-and rodent proof containers or insect and rodent repellent chemical treatments if they are approved for the intended end use of the grain.

### **Processing**

46. Sorting and cleaning are effective processes to remove contaminated grains and reduce mycotoxin content in cereals. Visibly mouldy infected and/or damaged kernels should be discarded in order to prevent their entry into the food and livestock feed supply chains. This is particularly important if the grain is intended for direct human consumption rather than industrial processing.

47. Analytical testing can be used as a tool to monitor mycotoxin concentrations in cereal grains. It is important that the cereal grains removed from storage for transport are tested at loading or unloading for mycotoxin concentrations before going into storage at grain processing facilities, especially when the risk of mycotoxin contamination is high. Lots containing higher levels of mycotoxin should undergo processing that significantly decreases mycotoxin levels to guarantee a safe product to consumers.

48. Brushing, scouring and peeling to remove hulls and bran layers of the grain can significantly reduce mycotoxin content as the outer parts of the kernel of most cereal grains typically contains higher mycotoxin levels or adhering contaminated dust. Such redistribution of the mycotoxins present in unprocessed grains can result in unacceptably high levels of mycotoxins such as DON in the separated hulls and seed coat (bran layers) fractions. Where these fractions are to be used for food use rather than being discarded, it is also important to monitor mycotoxin levels to ensure food safety in the products as consumed.

49. Industrial dry milling of grain to produce whole grain products containing all portions of the unprocessed kernels in their naturally occurring relative proportions will not reduce mycotoxin levels from those observed in the unprocessed grain. Dry milling processes that segregate some or all of the hull and bran layers of the grain can significantly reduce the mycotoxin content of milled products derived from grain endosperm (inner portions of kernels) used as food ingredients to levels below those present in the unprocessed grain. Wet milling of maize grain isolates most mycotoxins from the starch fraction used as food ingredients.

50. Milled grain products that are stored for long periods of time are also susceptible to mould growth and increased in mycotoxin levels imparted by the mould species. It is therefore important to avoid storing flour and other milled grain products for long periods of time, but if it is unavoidable then the products should be stored in proper storage containers and conditions at safe moisture levels with minimum temperatures changes. Such containers must deter insect and rodent infestation and should be subject to integrated pest control measures.

51. For grain products and grain-derived foods that pass through a fermentation step, poorly preserved starter cultures are significant sources of mycotoxin contamination. The starter cultures should be maintained pure, viable and sealed to prevent water entrance and other contamination.

52. The beer steeping process (soaking and germination phases) raises the seed moisture level to about 45% which is favourable for fungal growth and mycotoxin production. The situation is problematic if the process is done under open, poor sanitary conditions. Therefore, steeping should be carried out in weatherproof containers under controlled atmosphere.

53. All grain processing activities should follow good hygiene practices and HACCP-based (Hazard Analysis and Critical Control Points) good manufacturing practices.

**APPENDIX VIII****PROJECT DOCUMENT****PROPOSAL FOR NEW WORK ON “CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF MYCOTOXIN CONTAMINATION IN SPICES”****(for approval by CAC)****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 mycotoxin contamination of spices. The Code and annexes will cover different types of management practices for control mycotoxins in different spices.

**2- Relevance and timeliness**

Several mycotoxins have been evaluated by the International Agency for Research on Cancer (IARC). Aflatoxins have been classified as Group 1 (carcinogenic to humans) while OTA has been classified as Group 2B (possible human carcinogen).

Mycotoxins are fungal secondary metabolites that have been associated with severe toxic effects to vertebrates. They are produced by many important phytopathogenic and food spoilage fungi including *Aspergillus*, *Penicillium*, *Fusarium*, and *Alternaria* species. The contamination of foods and animal feeds with mycotoxins is a worldwide problem.

Human exposure to mycotoxins may can be high due to the fact that they are present in a wide variety of foodstuffs, such as spices, cereals, oilseeds, some fruits and vegetables, nuts, coffee, wine, etc. Besides their presence in food, they are stable compounds and therefore they cannot be removed completely from those foodstuffs. Thus, it is important to maintain the level contamination of mycotoxins in food at the lowest achievable level (ALARA principle).

It was recognised by FAO that the most efficient way to approach the problem of mycotoxins contamination in foodstuffs is the prevention or minimising their concentrations by means of following a code of good practices

**3- Main aspects to be covered**

The proposed new work will focus on good practices that will prevent or reduce contamination of spices with mycotoxins. The Code will cover Good Agricultural Practices, Good Manufacturing Practices and Good Storage practices, since mycotoxin contamination can develop during any of this steps.

**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 mycotoxins contamination of spices and consequently minimise consumer dietary exposure to mycotoxins.

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

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

*c) Work already undertaken by other organisations in this field*

There are some practical recommendations to avoid mycotoxin producing moulds during harvest and processing of several spices in the FAO Diversification Booklet 20 on Spices and herbs for home and market.

**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 mycotoxins contamination of spices.

This work will harmonise 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 mycotoxins in spices.

*Goal 3: Strengthening Codex work-management capabilities*

The Code will provide a general framework for the management of food safety risks associated with the prevention and reduction of mycotoxins contamination of spices that can be used by countries to prevent and reduce mycotoxin contamination in spices.

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

The work will supplement the information already provided by FAO on moulds 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 by the Committee following discussion on the feasibility to develop a Code of practice for the prevention and reduction of mycotoxin contamination in spices based on a discussion paper (CX/CF 15/9/16) presented at its 9<sup>th</sup> Session (2015).

The Code of hygienic practice for spices and dried aromatic plants (CAC/RCP 42-1995) contains general provisions to prevent mycotoxin contamination in spices, such as certain precautions to be utilised during the drying process and the inclusion of the mycotoxin control of the raw material. This COP has been amended recently by the Committee on Food Hygiene (CCFH, 2013) and adopted by the Codex Alimentarius Commission (CAC, 2014).

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

Mycotoxins have been assessed by JECFA on several occasions and aflatoxins is currently present on the Priority List for Evaluation by JECFA. The outcome will give further evidence on the effectivity of management practices for the control of mycotoxins 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.**

Subject to approval by the Commission in 2015, the Code will be submitted for consideration by CCCF in 2016. Final adoption by the Commission is foreseen for 2018.

**APPENDIX IX****PRIORITY LIST OF CONTAMINANTS AND NATURALLY OCCURRING TOXICANTS  
FOR EVALUATION BY JECFA**

<b>Contaminants and Naturally Occurring Toxicants</b>	<b>Background and Question(s) to be Answered</b>	<b>Data Availability (When, What)</b>
Sterigmatocystin	Safety assessment	EU: Survey data 2014 -2015 EFSA risk assessment
Diacetoxyscirpenol	Safety assessment	Unknown
Fumonisin	Update exposure assessment	After new occurrence data have been collected
Aflatoxins	(1) Update the risk assessment (2) Impact assessment of different MLs in RTE peanuts, effect on exposure and health, and assessment of violation rates with these different MLs <sup>1</sup>	New data available in public literature and occurrence data in GEMS/Food
3-MCPD esters	Full evaluation (toxicological assessment and exposure assessment)	Germany: occurrence data and data on hydrolysis (humans – in vivo) available, additional occurrence data using new methods; study to improve analytical methods on-going Japan: sub-chronic toxicity data and occurrence data available; China: Total Diet Study on 3-MCPD esters available Canada: surveillance data including recent surveillance in infant formula, temporal trend data EU: occurrence data USA: occurrence data for oils used in infant formula, study on data gaps Netherlands: occurrence data
Glycidyl ester	Full evaluation (toxicological assessment and exposure assessment) Bioavailability of free compounds	Japan: Surveillance in fats and oils, and sub-chronic toxicity studies available; risk assessment with exposure assessment and MoE USA: occurrence data for oils used in infant formula, study on data gaps EU: occurrence data available Canada: occurrence data, trend data
Scopoletin <sup>1</sup>	Full evaluation (toxicological assessment and exposure assessment) in fermented Noni juice	
Inorganic arsenic <sup>1,2</sup>	Evaluation of non-cancer effects (neurodevelopmental, immunological and cardiovascular)	
Dioxins <sup>1,3</sup>	Full evaluation (toxicological assessment and exposure assessment)	EFSA evaluation and other assessments

<sup>1</sup> Proposals from CCCF9 for new contaminants and naturally occurring toxicants for JECFA Priority List.

<sup>2</sup> Request to be addressed by FAO/WHO in the most appropriate way.

<sup>3</sup> Lower priority: JECFA evaluation to build on the ongoing work at national and regional re-assessment of dioxins.

**APPENDIX X****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 prioritisation criteria<sup>1</sup>
  - 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 organisations.

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<sup>1</sup> Section 3, para.10 of the Risk Analysis Principles Applied by the Codex Committee on Contaminants in Foods (See Procedural Manual of the Codex Alimentarius Commission).