CODEX ALIMENTARIUS COMMISSION



Food and Agriculture Organization of the United Nations



Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: codex@fao.org - www.codexalimentarius.org

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

46th Session 27 November and 2 December 2023

REPORT OF THE 16th SESSION OF THE CODEX COMMITTEE ON CONTAMINANTS IN FOODS Utrecht, Netherlands (Kingdom of the) 18-21 and 26 April 2023 E

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SUMMARY AND STATUS OF WORK

Responsible Party	Purpose	Text/Topic	Code	Step(s)	Appendices & Paragraphs
Members and Observers CCEXEC84 CAC46	Critical Review Adoption	MLs for lead for soft brown, raw, and non-centrifugal sugars	CXS 193-1995	5/8	Appendix II para. 28 (i)
Members and Observers CCEXEC84 CAC46	Critical Review Adoption	MLs for lead for ready-to-eat meals for infants and young children	CXS 193-1995	8	Appendix II para. 28 (ii)
EWG (Brazil) Members and Observers CCCF17	Discussion Comments Consideration	MLs for lead in culinary herbs (fresh/dried) and spices (dried)	CXS 193-1995	2/3	para. 29
Members and Observers CCEXEC84 CAC46	Critical Review Adoption	Code of practice for the prevention and reduction of mycotoxin contamination in cassava and cassava-based products	-	8	Appendix III para. 36
Members and Observers CCMAS42 CCEXEC84 CAC46	Endorsement Critical Review Adoption	Sampling plans for total aflatoxins in certain cereals and cereal-based products including foods for infants and young children	CXS 193-1995	5/8	Appendix IV para. 41
EWG (India) Members and Observers CCCF17	Discussion Comments Consideration	ML for total aflatoxins in ready- to-eat peanuts and associated sampling plan (Definition of RTE peanuts)	CXS 193-1995	2/3	para. 52
CCEVEC94	Critical Boviou	 <u>Adoption</u> MLs for: Ochratoxin A in chili pepper, paprika and nutmeg; and Total aflatoxins in chili pepper and nutmeg 	CXS 193-1995	5/8	
CCEXEC84 CAC46 EWG (India) Members and Observers CCCF17	Critical Review Adoption/ Discontinuation Discussion Comments Consideration	 <u>Discontinuation</u> MLs for: Ochratoxin A in ginger, pepper (black and white) and turmeric; and Total aflatoxins in paprika, ginger, pepper (black and white) and turmeric 	-	-	Appendix V para. 69
		Sampling plans for OTA and AFT (chili pepper, paprika and nutmeg)	-	2/3	
CCEXEC84 CAC46 EWG (USA, France, Spain, and Panama) Members and Observers CCCF17	Critical Review Approval Discussion Comments Consideration	New work on Code of Practice/Guidelines for the prevention or reduction of ciguatera poisoning	-	1/2/3	Appendix VI, para. 81

Responsible Party	Purpose	Text/Topic	Code	Step(s)	Appendices & Paragraphs
EWG (EU) Members and Observers CCCF17	Discussion Consideration	Discussion paper on pyrrolizidine alkaloids	-	-	para. 84
EWG (Brazil) Members and Observers CCCF17	Discussion Consideration	Discussion paper on new measures supporting the revision of the Code of practice for the prevention and reduction of aflatoxin contamination in peanuts	CXC 55-2004		para. 105 (iv)(a)
EWG (Canada) Members and Observers CCCF17	Discussion Consideration	Discussion paper on new measures supporting the revision of the Code of practice for the reduction of aflatoxin B1 in raw materials and supplemental feedingstuffs for milk-producing animals	CXC 45-1997		para. 105 (iv)(b)
EWG (China and Saudi Arabia) CCCF17	Discussion Consideration	Discussion paper on the need and feasibility of possible follow- up actions on tropane alkaloids	-	-	para. 113 (i)
EWG (India and Saudi Arabia) CCCF17	Discussion Consideration	Discussion paper on possible risk management measure(s) for acrylamide in foods taking into account the most recent JECFA evaluations	-	-	para. 133 (iv)
USA CCCF17	Discussion Consideration	Discussion paper on the development of a Code of practice for the prevention and reduction of cadmium contamination in foods	-	-	para. 139
EWG (EU, Japan, the Netherlands, and USA) Members and Observers CCCF17	Discussion Consideration	General guidance on data analysis for development of maximum levels and improved data collection	-	-	para. 98 (xi)
CCCF19	Suspended	Identification of staple food- contaminant combinations of relevance to public health and international trade that have not yet been addressed by CCCF	-	-	para. 101
Members and Observers WG (Canada) CCCF17	Comments Discussion Consideration	Review of Codex standards for contaminants	-	-	para. 105 (iv)(c)
JECFA, FAO, WHO, etc. Members and Observers WG (EU) CCCF17	Evaluation Comments Discussion Consideration	Follow-up work to the outcomes of JECFA evaluations and FAO/WHO expert consultations	-	-	para. 113 (iii)

Responsible Party	Purpose	Text/Topic	Code	Step(s)	Appendices & Paragraphs
CCCF17	Discussion Consideration	Reconsider the opportunity to develop discussion papers on the need and feasibility of possible follow-up actions on ergot alkaloids and trichothecenes (T-2, HT-2 and DAS)	-	-	para. 113 (ii)
Members and Observers WG (USA) CCCF17	Comments Discussion Consideration	Priority list of contaminants for evaluation by JECFA	-	-	Appendix VII para. 133 (i-iii)
CCNASWP17 Members and Observers	Information Data submission	 CCCF to retain scopoletin in the priority list. Codex members concerned to generate and submit data to support the conduct of the safety evaluation by JECFA. 	-	-	para. 133 (v)
CCPR54 CCFA54	Request for advice Information	 CCPR to clarify: whether ethylene oxide (EtO) and 2-chloroethanol (2-CE) meet the Codex definition of pesticide, and whether coordination of risk assessment between JECFA and JMPR would be required to evaluate EtO and 2-CE as a contaminant CCFA to be informed of this decision as EtO and 2-CE can potentially be found as an impurity in certain food additives 	-	-	para. 133 (vi)
JECFA Secretariat CCCF17	Call for Data Review/Analysis Consideration	 JECFA Secretariat to: issue a call for data on cadmium and lead in quinoa and quinoa-based products, including foods for infants and young children and review/analyze the new data and prepare a discussion paper for consideration by CCCF 	-	-	para. 133 (vii)
Members and Observers CCFA54	Data submission Information	 Members and Observers to submit data on lead in bentonite, diatomaceous earth, and charcoal (activated carbon). CCCFA54 to confirm data availability to proceed with the review or establishment of the new specification. 	-	-	para. 133 (viii)

Responsible

Responsible Party	Purpose	Text/Topic	Code	Step(s)	Appendices & Paragraphs
Codex Members and Observers IAEA/FAO/WHO CCCF17	Comments Review Information	Codex members and observers to provide comments on the information document on natural radionuclides in food, feed and drinking water for review by IAEA/FAO/WHO and consideration by CCCF	-	_	paras. 19, 20 (iii)
CCCF17	Discussion Information	Foresight on emerging issues in food and feed safety relevant to contaminants	-	-	paras. 135, 138

A 57	
AFT	Total aflatoxins
AHPA	American Herbal Products Association
2-CE	2-chloroethanol
CAC	Codex Alimentarius Commission
CCCF	Committee on Contaminants in Foods
CEFAS	Reference Centre for Bivalve Mollusc Sanitation, the Centre for Environment, Fisheries, and Aquaculture Science
CCEXEC	Executive Committee of the Codex Alimentarius Commission
CCFA	Codex Committee on Food Additives
CCLAC	FAO/WHO Coordinating Committee for Latin America and the Caribbean
CCMAS	Codex Committee on Methods of Analysis and Sampling
CCNASWP	FAO/WHO Coordinating Committee for North America and South-West Pacific
CCPR	Codex Committee on Pesticide Residues
CCSCH	Codex Committee on Spices and Culinary Herbs
CL	Circular Letter
СоР	Code of Practice
CRD	Conference Room Document
CTF	Codex Trust Fund
DAS	Diacetoxyscirpenol (DAS)
EAC	East African Community
EtO	Ethylene Oxide
EU	European Union
EWG	Electronic Working Group
FAO	Food and Agriculture Organization
FERG	Foodborne Disease Burden Epidemiology Reference Group
GEMS/Food	Global Environment Monitoring System
GSCFF	General Standard for Contaminants in Food and Feed
HBGV	Health-Based Guidance Value
HCN	Hydrocyanic Acid
IAEA	International Atomic Energy Agency
ICUMSA	International Commission for Uniform Methods of Sugar Analysis
ICA	International Confectionery Association
IFT	Institute of Food Technologists
JECFA	Joint FAO/WHO Expert Committee on Food Additives
JMPR	Joint FAO/WHO Meetings on Pesticide Residues
LOD	Limit of Detection
LOQ	Limit of Quantification
ML(s)	Maximum Level(s)
MOE	Margin of Exposure
NFPS	New Food Sources and Production Systems
NFS	WHO Nutrition and Food Safety department
OHPL	Overall Highest Priority List
J	

074	
OTA	Ochratoxin A
PCBs	Polychlorinated biphenyls
PFAS	Polyfluoroalkyl Substances
PRRI	Public Research and Regulation Initiative
PWG	Physical Working Group
RTE	Ready-To-Eat
SFC	Staple Food-contaminant Combinations
SOP	Statements of principle concerning the role of science in the Codex decision-making process and the extent to which other factors are taken into
UAE	United Arab Emirates
UNICEF	United Nations International Children's Emergency Fund
USA	United States of America
USAID	United States Agency for International Development
VWG	Virtual Working Group
WG	Working Group
WHA	World Health Assembly
WHO	World Health Organization
WFP	World Food Programme

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LIST OF CONFERENCE ROOM DOCUMENTS (CRDs)

INTRODUCTION

1. The Codex Committee on Contaminants in Foods (CCCF) held its 16th Session, in Utrecht, Netherlands (Kingdom of the), from 18 to 21 April 2023, with online adoption of the report on 26 April 2023, at the kind invitation of the Government of the Kingdom of the Netherlands. Dr Sally Hoffer, Manager Safe and Sustainable Food, Ministry of Agriculture, Nature and Food Quality, Plant Agro Chains and Food Quality, Netherlands (Kingdom of the) chaired the Session which was attended by 51 Member countries, one Member organization and 10 Observer organizations. The list of participants is contained in Appendix I.

OPENING OF THE SESSION

- 2. H. E. Ernst Kuipers, Minister of Health, Welfare and Sport, opened the Session and extended his warmest welcome to all participants. The Minister highlighted that, considering the current global political and environmental problems, the work of the Members of the Codex Alimentarius Commission (CAC) on ensuring the safety of food was more relevant than ever. The Minister further stressed that contamination in food was an important issue that affected all parties within the Codex Alimentarius system in the same way and that should therefore be tackled jointly by governments, industry, and NGOs.
- 3. Mr Victor Sannes, Director of the Department of Nutrition, Health Protection and Prevention of the Dutch Ministry of Health, Welfare and Sport also addressed the Committee, recalling that the Kingdom of the Netherlands had hosted discussions on contaminants in food since 1964. He further stressed that, codes of practice or maximum levels established by Codex were a success for the protection of public health.
- 4. Mr Tom Heilandt, Codex Secretary, Dr Markus Lipp and Mr Kim Petersen, on behalf of FAO and WHO respectively, also addressed the Committee.

Division of Competence¹

5. CCCF noted the division of competence between the European Union (EU) and its Member States, according to paragraph 5, Rule II of the Procedure of the CAC.

ADOPTION OF THE AGENDA (Agenda Item 1)²

- 6. CCCF:
 - (i) adopted the Provisional Agenda as the Agenda for the Session; and
 - (ii) agreed to consider the development of a discussion paper for a code of practice to prevent or reduce cadmium contamination in foods under Agenda Item 17 (Other Business).
- 7. CCCF noted that items scheduled for discussion under other business were subject to availability of time.

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

- 8. The Codex Secretariat introduced the item and presented the crosscutting activities taking place at the Executive Committee (CCEXEC) and CAC, including the guidance on the application of the *Statements of principle concerning the role of science in the Codex decision-making process and the extent to which other factors are taken into account* (SoP), New food sources and production systems (NFPS), future of Codex, monitoring the use and impact of Codex standards and the 60th Anniversary of Codex. The Secretariat also invited Codex Members and Observers to submit their comments on the relevant circular letters (CLs) requesting comments on the SoP and NFPS for consideration by CAC46 (2023).
- 9. The Codex Secretariat further highlighted that, within the framework of monitoring the use and impact of Codex standards, the Secretariat is working on a case study on the use and impact of the *Code of practice for the prevention and reduction of mycotoxin contamination in cereals* (CXC 51-2003) which was linked to the discussion in CCCF on the forward plan and the implementation of codes of practice (CoPs) vis-à-vis the development and enforcement of maximum levels (MLs)⁴. The Secretariat also noted that requests pertaining to arsenic and scopoletin, from the FAO/WHO Coordinating Committee for Latin America and the Caribbean (CCLAC) and the FAO/WHO Coordinating Committee for North America and the South-West Pacific (CCNASWP) respectively, would be discussed under Agenda Item 16 (Priority List).

¹ CRD01

² CX/CF 23/26/1(REV1)

³ CX/CF 23/26/2(REV1)

⁴ REP19/CF13, paras. 179-181; REP21/CF14, paras. 224-228; REP22/CF15, paras. 12-14

- 10. The Codex Secretariat also recalled a request from CAC40 (2017) on whether MLs for lead and cadmium for cereals in the *General Standard for Contaminants in Food and Feed* (CXS 193-1995), which currently excluded quinoa and other pseudo-cereals, could be extended to cover such commodities or whether separate MLs could be established for quinoa for these contaminants. She recalled that CCCF14 (2021)⁵ agreed to postpone the discussion on this matter for three years to allow data generation and submission to GEMS/Food and that the Joint FAO/WHO Expert Committee on Food Additives(JECFA) Secretariat would prepare an analysis of the new data for consideration by CCCF17 (2024).
- 11. In relation to the "future of Codex", a Member supported face-to-face report adoption in case of a physical Codex meeting wherever possible and practical as this was more conducive to achieving consensus and more equitable for countries in different time zones who otherwise had to attend the virtual report adoption at inconvenient times soon after travel.

- 12. CCCF:
 - (i) noted the information provided; and
 - (ii) agreed that matters concerning the evaluation of arsenic and scopoletin and the issuance of a JECFA call for data on cadmium and lead in quinoa would be further considered under Agenda Item 16.

MATTERS OF INTEREST ARISING FROM FAO AND WHO INCLUDING JECFA (Agenda Item 3)⁶

- 13. The FAO JECFA Secretariat introduced the item and provided an update regarding the FAO activities of relevance to CCCF, including the following:
 - FAO published "Thinking about the future of food safety A foresight report"⁷ which outlined how major global drivers and trends would shape food safety in tomorrow's world. In particular the publication discussed some of the most important emerging issues in food and agriculture with a focus on food safety implications, including climate change, changing consumer behaviour and food consumption patterns, new food sources and food production systems, technological innovations and scientific advances, microbiome science, circular economy, food contact materials, etc. The FAO JECFA Secretariat referred to the foresight side event that was held prior to CCCF16 and thanked all the members for the active participation and discussion⁸.
 - FAO continued to collaborate with the World Food Programme (WFP), the United Nations Children's Fund (UNICEF), Doctors without Borders and the United States Agency for International Development (USAID) to develop a roadmap to manage the specific risks food aid agencies are facing in ensuring safe and nutritious foods for humanitarian aid, taking into account food security, sustainability, and nutrition. FAO was also providing risk assessment advice to these agencies on selected contaminants (e.g., tropane alkaloids), as previously reported, and others.
 - FAO developed a report compiling information on the occurrence of microplastics in all commodities, microplastic contamination along food value chains, plastic migration from food contact materials and packaging, and a review of the existing literature on the toxicity of the most common plastic monomers, polymers, and additives. The report, titled "*Microplastics in food commodities*"⁹ could set up the basis for risk assessment and for the formulation of risk management options.
 - FAO in collaboration with its Reference Centre for Bivalve Mollusc Sanitation, the Centre for Environment, Fisheries, and Aquaculture Science (CEFAS), had developed guidance on bivalve mollusc sanitation and has delivered a number of capacity building activities on relevant laboratory protocols, accreditation, and use of methods for bivalve mollusc testing.
 - FAO and WHO were making preparations to convene an expert consultation on risk-benefit of fish consumption to review the new evidence and update the conclusions and recommendations of the 2010 report as needed. The expert consultation would be held in October 2023.
 - FAO elaborated the FAO Strategic Priorities for Food Safety within the FAO Strategic Framework 2022-31 which described FAO's work on food safety and how it would contribute to the 2030 Agenda. FAO's food safety priorities belonged to four main strategic areas: strong multi-stakeholder governance for food safety, strong science to support food safety decisions, strong national food control systems and strong public-private cooperation for food safety.

⁵ REP21/CF14, para. 180

⁶ CX/CF 23/26/3

^{7 &}lt;u>https://www.fao.org/documents/card/en/c/cb8667en</u>

^{8 &}lt;u>https://www.fao.org/fao-who-codexalimentarius/news-and-events/news-details/en/c/1637298/</u>

⁹ <u>https://www.fao.org/3/cc2392en/cc2392en.pdf</u>

- 14. The WHO JECFA Secretariat, reporting on the activities of WHO, informed CCCF that under the Codex Trust Fund (CTF), WHO was preparing a series of workshops entitled *Evidence-informed decision on food safety risk management* -*Establishment of maximum levels of chemical contaminants in food*. The WHO JECFA Secretariat explained that these workshops were part of the WHO Nutrition and Food Safety department (NFS) activities to better deliver scientific knowledge, technical tools, and messages to Member States, industries, and consumers. He also added that these workshops would address Member States with different levels of advancement of their national Codex systems, including available capacity on risk management.
- 15. The WHO JECFA Secretariat further mentioned that the NFS was committed to helping Member States to make more evidence-informed decisions on food safety and nutrition risk management. This included understanding the risk analysis components: risk assessment, risk management, and risk communication as defined by the Codex Alimentarius. He further stressed that the role of science was critical in maintaining food safety by understanding the causes and mechanisms of foodborne illness and by developing evidence-based guidelines, control measures, and regulations.
- 16. The WHO JECFA Secretariat recalled that the CTF provided capacity strengthening support to developing and transition economy countries to effectively participate in Codex work. The CTF also facilitated the participation of eligible countries in Codex activities and initiatives, which included institutional capacity-building for national Codex structures and the development of national standards or regulations, following good Codex practice.
- 17. The WHO JECFA Secretariat also mentioned the following:
 - WHO held an ad-hoc expert consultation in Lisbon, Portugal during which the 2005 WHO toxic equivalency factors (TEFs) for dioxin-like compounds, including some polychlorinated biphenyls (PCBs), were re-evaluated. The outcome and details of this expert consultation would be published in a peer-reviewed paper in first half of 2023.
 - WHO reviewed the state of evidence on microplastic in drinking-water and published a report assessing the risks to human health in August 2019. Working with a group of international experts, WHO has also assessed human health risks arising from exposure to microplastic particles from the environment, identified research needs and outlined the scope of future work needed on microplastic particles.
 - The WHO Global Strategy for Food Safety 2022-2030 was adopted by the World Health Assembly (WHA75) in May 2022. This document updated the last strategy on food safety in order to address current and emerging challenges, incorporate new technologies, and include innovative approaches for strengthening national food safety systems.
 - WHO advanced a process to estimate the global, regional, and national burden of foodborne diseases given a new WHO mandate under the resolution WHA73.5 and under the support provided by "Foodborne Disease Burden Epidemiology Reference Group (FERG)". Along with a guidance entitled "*Estimating the burden of foodborne diseases: A practical handbook for countries*", WHO was also establishing a programme to support countries to strengthen national capacity towards estimating the burden of foodborne diseases.

18. CCCF thanked FAO and WHO, and noted the information provided.

MATTERS OF INTEREST ARISING FROM OTHER INTERNATIONAL ORGANIZATIONS The Joint FAO/IAEA Centre of Nuclear Techniques in Food and Agriculture (Agenda Item 4)¹⁰

19. In addition to the information provided in the working document, the Codex Secretariat recalled the discussion related to the presence of natural radionuclides in food, feed, and water, and that CCCF14 (2021) had agreed¹¹ that no action was needed at Codex level for the time being. However, CCCF14 welcomed the offer by IAEA to elaborate, with the collaboration of FAO and WHO, an informative document for the food safety regulators community, providing the state of the art of natural radioactivity in food, feed, and water. This document was being circulated for comments by Codex members in CL 2023/17-CF¹², available in English, French, and Spanish, with a deadline for comments of 30 June 2023. The Secretariat encouraged Members and Observers to send their comments as indicated in the CL so that IAEA, FAO, and WHO can review the document and present it to CCCF17 for consideration.

¹⁰ CX/CF 23/26/4

¹¹ REP21/CF14, paras. 15-17, 181-185

¹² https://www.fao.org/fao-who-codexalimentarius/committees/committee/related-circular-letters/en/?committee=CCCE

20. CCCF:

- (i) expressed its appreciation to the Joint FAO/IAEA Centre;
- (ii) noted the information provided; and
- (iii) encouraged Members and Observers to submit comments in reply to CL 2023/17-CF.

MAXIMUM LEVELS FOR LEAD IN CERTAIN FOOD CATEGORIES (at Steps 4 and 7) (Agenda Item 5)¹³

- 21. Brazil, as Chair of the Electronic Working Group (EWG), introduced the item and provided a summary of key points of discussions that took place in the EWG and during the virtual meeting of the working group (VWG), including proposals for MLs for soft brown, raw, and non–centrifugal sugars and ready-to-eat meals for infants and young children.
- 22. CCCF considered the two proposals put forward by the VWG in CRD07 as follows:

Soft brown, raw, and non-centrifugal sugars

- 23. The Chairperson noted general support for an ML of 0.15 mg/kg for this food category.
- 24. It was noted that this ML was consistent with the ML for white and refined sugars of 0.1 mg/kg adopted by CAC45 (2022), as these sugars are less refined.

Ready-to-eat meals for infants and young children

- 25. Brazil, as Chair of the EWG, explained that there was general support for a single ML of 0.02 mg/kg, the same ML which was adopted at Step 5 in 2022. Two members indicated their preference for an ML of 0.03 mg/kg as proposed by the EWG. Another member noted that, considering the analytical capacities of countries, an ML of 0.04 mg/kg could be considered based on the discussion that took place at the VWG.
- 26. The EWG Chair explained that an ML of 0.02 mg/kg would have a rejection rate higher than the cut-off level of 5% and would require, following the guidance provided in the Procedural Manual for method performance criteria, an analytical method with a Limit of Quantification (LOQ) of 0.008 mg/kg, which only a few countries would be able to apply based on data from GEMS/Food. The mean lead occurrence for higher MLs scenarios would not change very much i.e., 0.008 mg/kg for MLs of 0.05 mg/kg or 0.04 mg/kg and 0.007 mg/kg for MLs of 0.03 and 0.02 mg/kg, hence, a more restrictive ML may not impact much on exposure. In view of this, higher MLs could still provide health protection, with rejection rates below 5%, and would accommodate analytical capacities of countries especially considering that Ready-To-Eat (RTE) foods cannot be further processed to meet a lower ML.
- 27. CCCF noted general support for an ML of 0.02 mg/kg considering: the same ML was adopted¹⁴ by CAC45 for cerealbased products for infants and young children, thus the ML was achievable; the need for a high level of protection for infants and young children; the rejection rate was only slightly higher than 5%; the ML was already adopted by CAC45 at Step 5.

Conclusion

- 28. CCCF agreed to forward to CAC46 the following (Appendix II):
 - (i) An ML of 0.15 mg/kg for soft brown, raw, and non-centrifugal sugars for adoption at Step 5/8; and
 - (ii) An ML of 0.02 mg/kg for ready-to-eat meals for infants and young children for adoption at Step 8.
- 29. CCCF recalled that the EWG chaired by Brazil, working in English only, would continue to work on MLs for lead in culinary herbs (fresh/dried) and spices (dried) for consideration by CCCF17¹⁵ and that a JECFA call for data had already been issued.

CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF MYCOTOXIN CONTAMINATION IN CASSAVA AND CASSAVA-BASED PRODUCTS (at Step 7) (Agenda Item 6)¹⁶

30. Nigeria, as Chair of the EWG, speaking also on behalf of the co-Chair, Ghana, introduced the item and provided a summary of discussions at the EWG noting that the EWG had revised the CoP based on the recommendations provided by CCCF15 and additional comments submitted by members of the EWG.

¹³ CL 2023/18-CF; CX/CF 23/16/5; CX/CF 23/16/5-Add.1 (Comments of Argentina, Canada, Chile, Cuba, Egypt, Indonesia, Iraq, Japan, Kenya, New Zealand, Peru, Republic of Korea, Singapore, USA, AHPA, ICUMSA and ICA)

¹⁴ REP22/CAC45, para. 65, App. II

¹⁵ REP22/CF15, paras. 90, 92 and 102(iv)

¹⁶ CL 2023/19-CF; CX/CF 23/16/6; CX/CF 23/16/6-Add.1 (Comments of Argentina, Canada, Chile, Cuba, Egypt, Iraq, Kenya, New Zealand, Peru, Republic of Korea, USA, ICUMSA and PRRI)

31. The EWG Chair noted that a revised CoP was available in CRD35 incorporating comments submitted to this Session in reply to CL 2022/91-CF, which were mainly of editorial nature to improve the accuracy and/or clarity of the provisions in the CoP.

Discussion

Section 3 - Risk management measures related to planting/pre-harvest stages

- 32. An Observer noted that risk management practices concerning the application of rotational crops should clearly distinguish between those instances where such practices were applicable (e.g., for soil fertility/erosion prevention) and those where such practices should be avoided or be more carefully implemented to prevent/reduce the possibility of mycotoxin contamination. CCCF therefore agreed to revise paragraph 13 to provide for consistency and flexibility in the application of rotational measures between cassava and crops susceptible to mycotoxin contamination.
- 33. A Member also recommended the inclusion of preventive measures that would reduce the risk of soil-borne pathogens and the subsequent mycotoxin contamination. CCCF agreed to add an additional paragraph to include provisions for treatment of planting material with fungicide/insecticide/nutrient solutions as per label instructions and the subsequent steps before field planting.

Section 5 - Risk management related to post-harvest stages

34. CCCF agreed that other heat treatments such as "steaming" could also be applied and thus amended the title of section 5.1.3 and text under this section accordingly.

Other comments

35. CCCF noted that other risk management practices proposed for inclusion in the CoP, which were not intended to reduce mycotoxin contamination in cassava and cassava-based products, should not be included in the CoP.

Conclusion

36. CCCF agreed to forward the Code of practice for the prevention and reduction of mycotoxin contamination in cassava and cassava-based products to CAC46 for adoption at Step 8 (Appendix III).

SAMPLING PLANS FOR TOTAL AFLATOXINS IN CERTAIN CEREALS AND CEREAL-BASED PRODUCTS INCLUDING FOODS FOR INFANTS AND YOUNG CHILDREN (at Step 4) (Agenda Item 7)¹⁷

- 37. Brazil, as Chair of the EWG and Physical Working Group (PWG), introduced the item and provided a summary of key points of discussion that took place in the EWG and PWG that met immediately prior to the Session. These included that data from all countries supported an isomer ratio > 50:50 AFB1: AFB2+AFG1+AFG2, that AFB1 was the most toxic isomer, and that using a 50:50 ratio would allow an achievable LOQ for the minor isomers.
- 38. The EWG Chair noted that there had been general support in the PWG:
 - to align sampling plans for flour meal, semolina and flakes derived from maize and cereal-based foods for infant and young children with the deoxynivalenol (DON) and fumonisins sampling plans in the same commodities; and
 - for a laboratory sample weight of 5 kg or higher for maize grain, rice (husked and polished) and sorghum.
- 39. With regard to methods performance criteria for total aflatoxins (AFT) considering a 50:50 ratio of AFB1:AFB2+AFG1+AFG2, the EWG Chair drew the attention of CCCF to concerns raised during the PWG as highlighted in paragraphs 13–14 of CRD08. To address the concerns a footnote was added in the Limit of Detection (LOD) and LOQ for AFB2, AFG1 and AFG2 in Table 3. She noted that such approach should be evaluated by the Codex Committee on Methods of Analysis and Sampling (CCMAS) and recalled that the Note 2 to the *Working instructions for the implementation of the criteria approach in Codex* (Procedural Manual) acknowledged that approaches described for developing method performance criteria are intended for single-analyte provisions and may not be suitable for provisions involving sum of components. There are numerous ways in which methods and limits that involve a sum of components can be converted into method performance criteria, but this should be taken with care on a case-by-case basis.

Discussion

40. CCCF agreed with the proposals of the PWG on the points raised above and, in addition to editorial corrections, made the following decisions:

¹⁷ CL 2023/20-CF; CX/CF 23/16/7; CX/CF 23/16/7-Add.1 (Comments of Argentina, Canada, Chile, Egypt, Iraq, Japan, Kazakhstan, Kenya, Peru, UAE, USA, ICUMSA and WFP)

- amended the note to LOD and LOQ (Table 3) to more accurately indicate that if values for AFB2, AFG1 and AFG2 could not be validated, the LOD and LOQ for AFB2, AFG1 and AFG2 could be up to parameters for AFB1;
- for the definition of laboratory sample for the sampling plans and performance criteria that it also referred to cereal grains and not only shelled cereal grains to cover also maize and rice in the sampling plan; and
- for the laboratory sample weight for maize grain, rice (husked and polished) and sorghum to be equal or larger than 5 kg.

- 41. CCCF agreed to forward the sampling plan (Appendix IV) to:
 - (i) CCMAS42 for endorsement; and
 - (ii) CAC46 for adoption at Step 5/8 and inclusion in the *General Standard for Contaminants in Food and Feed* (CXS 193-1995).

MAXIMUM LEVELS FOR TOTAL AFLATOXINS IN READY-TO-EAT PEANUTS AND ASSOCIATED SAMPLING PLANS (at Step 4) (Agenda Item 8)¹⁸

- 42. India, as Chair of the EWG, introduced the item and provided background to the work, a summary of key points of discussion and recommendations for consideration by CCCF.
- 43. The EWG Chair in particular highlighted the key points in relation to the data analysis, the limited data points (250 data points) available without corresponding occurrence in the respective member country/geographic region-wise breakup and that there was insufficient time for the EWG to obtain information for analysis to address the request of CCCF14 and CCCF15 and present a paper that clearly presents the data analysis for consideration by CCC16. The Chairperson proposed that the Committee consider the recommendations presented in the working document.
- 44. The GEMS/Food Administrator provided a video presentation of the work undertaken to support the EWG. He explained that the EWG was provided a preliminary analysis of 440 local food names applicable to nearly 86 000 data points, corresponding to occurrence of aflatoxins in peanuts and submitted to the database since 2012. The analysis suggested that 250 of the local food names, applicable to approximately 11 500 data points for AFT and 14 000 data points for AFB1, correspond to Ready-to-Eat (RTE) peanuts and could possibly serve with the ML setting process, pending assessment by the EWG. In addition, all datapoints were provided with country/region information.

Discussion

- 45. CCCF considered the recommendations as presented in the working document as follows.
- 46. There was general agreement that work should continue on developing MLs for AFT in RTE peanuts. However, comments were made requesting the precise meaning to RTE peanuts in the context of this work before proceeding on the development of MLs in order to clarify which data be considered by the EWG.
- 47. CCCF noted the offer of members who were mainly importers of peanuts to submit recent data on AFT in RTE peanuts once there was clarity on a definition for RTE peanuts, also providing the country of origin so that it could be useful for looking into regional differences by the EWG.
- 48. CCCF therefore considered a proposal that work on the MLs could be undertaken in two stages over two years, first to address the definition of RTE peanuts, followed by the work on an ML for RTE peanuts based on an agreed definition, and associated sampling plans. It was also pointed out that there were already definitions for RTE dried figs and tree nuts in CXS 193-1995 and that if the definition for RTE peanuts would differ from the current definition in the CXS 193, then clear rationale or justification should be provided.
- 49. CCCF also recalled that the EWG, in its further deliberations, should also take into account the decision of CCCF15 as highlighted in REP22/CF15, paragraph 180(iii), that practical examples should be provided of how samples from GEMS/Food would be classified.
- 50. CCCF noted the offer of the GEMS/Food Administrator to support the EWG by assisting with advice on the identification and segregation of data specific for RTE peanuts.
- 51. With regard to the recommendation (iii) in the report of the EWG, it was noted that it should refer to a LOD of above $4 \mu g/kg$.

¹⁸ CL 2023/23-CF; CX/CF 23/16/8; CX/CF 23/16/8-Add.1 (Comments of Canada, Chile, Kenya, Peru, Singapore, USA and AHPA)

- 52. CCCF agreed:
 - (i) to re-convene the EWG, chaired by India, working in English, to work over the next two years on the ML for AFT in RTE peanuts and the associated sampling plan, as follows:
 - (a) to prepare a proposal on a clear definition for RTE peanuts for the establishment of an ML for AFT in RTE peanuts and categorization of the occurrence data for consideration by CCCF17, working in close collaboration with the GEMS Administrator;
 - (b) following discussion and agreement on the definition for RTE peanuts at CCCF17 and working closely with the EWG on data analysis to propose an ML for RTE peanuts and associated sampling plans for consideration by CCCF18.
 - the EWG should take into account the decision of CCCF15 as highlighted in REP22/CF15, paragraph 180(iii) in particular in relation to the data analysis and the need to have at least two rounds of comments each year in the EWG (REP22/CF15, paragraphs 170 and 177); and
 - (iii) to inform CCEXEC of the decision and request extension of the timeline for completion of work to 2025.

MAXIMUM LEVELS FOR TOTAL AFLATOXINS AND OCHRATOXIN A IN NUTMEG, DRIED CHILI AND PAPRIKA, GINGER, PEPPER AND TURMERIC AND ASSOCIATED SAMPLING PLAN (at Step 4) (Agenda Item 9)¹⁹

- 53. India, as Chair of the EWG, introduced the item and provided background to the work, a summary of key points of discussion in the EWG and recommendations for consideration by CCCF16.
- 54. The EWG Chair reminded CCCF of the rationale for MLs for AFT and Ochratoxin A (OTA) for the spices in question, viz. for public health protection and trade facilitation; and that based on the data analysis the EWG was proposing single MLs of 20 µg/kg for AFT in dried chili pepper and nutmeg; and for OTA in dried chili pepper, paprika and nutmeg. Furthermore, it was proposed that no MLs be established for the remaining spices, i.e., ginger, pepper and turmeric, and paprika in the case of AFT and ginger, pepper, turmeric in the case of OTA, since the majority of the samples were reported ND and percentage of rejections were also not a major concern.
- 55. With respect to the sampling plan, the EWG Chair explained that comments had been sought through CL 2022/45-CF on the sampling plan from CRD16 presented to CCCF15 and that a revised plan was presented for comments. He however recommended that the sampling plan should be further considered in the EWG for presentation to CCCF17.
- 56. He proposed that CCCF16 focus discussion on the two MLs proposed for AFT and OTA in the selected spices and clarified that the ML for OTA was also for paprika in addition to dried chili pepper and nutmeg.

Discussion

General

57. The Chairperson noted that a number of African countries had, through CRDs, requested that work on the MLs be postponed allowing further time for submission of data. It had been reported to the Chair that a number of east African countries had generated data which were ready for submission. However, noting that this work had already been previously extended to allow implementation of the *Code of practice for prevention and reduction of mycotoxins in spices* (CXC 78-2017) and that the deadline for completion of work was 2024, the Chairperson proposed to continue discussion on the MLs proposed by the EWG and to keep open the possibility to review these MLs within 3 – 5 years' time provided sufficient data were submitted through GEMS/Food. The Chair of the EWG also explained that it would be difficult to agree to a postponement unless there was clarity whether the data were for both AFT and OTA and for which spices currently under discussion in the Committee and proposed that CCCF continue consideration of the proposals of the EWG.

OTA in dried chili pepper, paprika and nutmeg

58. There was general agreement with the ML of 20 μg/kg for OTA in dried chili pepper, paprika and nutmeg, while a proposal was made for a higher ML of 30 μg/kg due to a rejection rate of higher than 20% for an ML of 20 μg/kg and for a lower ML of 15 μg/kg for nutmeg giving the health concern related to the presence of OTA in food.

¹⁹

CL 2023/24-CF; CX/CF 23/16/9; CX/CF 23/16/9-Add.1 (Comments of Argentina, Canada, Chile, Egypt, Iraq, Japan, Peru, Republic of Korea, USA, AHPA and ICUMSA)

REP23/CF16

59. Clarification was requested on how to define dried chili pepper and paprika and different proposals were made for naming dried chili pepper. It could either be named by its botanical (scientific) name, explaining that it included chilies, chili powder, cayenne and paprika, or it could be aligned with the definitions in the *Standard for Dried and Dehydrated Chili Peppers and Paprika* (CXS 353-2022) recently developed by the Codex Committee on Spices and Culinary Herbs (CCSCH) and adopted by CAC45. India clarified that, while dried chili pepper and paprika were from the same botanical species, they were traded and labelled as dried chili pepper and paprika due to difference in chemical properties such as pungency (in line also with the *Standard for Dried and Dehydrated Chili Peppers and Paprika in press*). CCCF therefore agreed to refer to each commodity separately in CXS193, consistent with the approach taken in CCSCH.

Conclusion

60. CCCF agreed to set an ML of 20 μg/kg for OTA in chili pepper, paprika and nutmeg (dry, dried) and to apply the ML to whole/powder/crushed/ground portion of the aforementioned spices.

OTA in ginger, pepper (black and white) and turmeric

61. While there was general agreement to not establish an ML for this group of spices as proposed by the EWG, given that the available data did not indicate significant presence of OTA in these spices, CCCF noted a proposal to continue work on MLs due to the diverse MLs worldwide for the commodities in question, and to also apply an ML of 20 μg/kg for these spices.

Conclusion

62. CCCF agreed to discontinue work on MLs for OTA in ginger, pepper (black and white) and turmeric given that the available data did not indicate significant presence of OTA in these spices.

AFT in dried chili pepper and nutmeg

- 63. While there was general support for the proposed MLs, the EU expressed concern with the proposed ML noting that aflatoxins are genotoxic carcinogens and a public health issue and therefore levels should be set as low as reasonably achievable and, in their opinion, applying good practices, lower levels were achievable.
- 64. The EWG Chair explained that these commodities were consumed in greatly lesser amounts as compared to staple foods and that with respect to public health, it was understood that these particular commodities at lower levels might not have a greater public health impact. However, an impact assessment had not been done for the different MLs for these commodities, but it was important for Codex to set a harmonized ML as MLs varied across the world.
- 65. The JECFA Secretariat clarified that it was unlikely that different MLs would have a noticeable impact on public health, but more likely an impact on trade. An impact assessment was always possible, but in the case of spices, it might not be a good use of resources required to do such an assessment as the difference in public health impact among the various MLs can reasonably expected to be negligible.

Conclusion

Maximum levels

- 66. CCCF agreed to set an ML of 20 μg/kg for AFT in chili pepper and nutmeg (dry, dried) and to apply the ML to whole/powder/crushed/ground portion of the aforementioned spices.
- 67. CCCF agreed to discontinue work on MLs for ginger, paprika, pepper (black and white) and turmeric given that the available data did not indicate significant presence of AFT in these spices.

Sampling plans

68. CCCF noted that further work was needed on the sampling plans and agreed that further work could be undertaken in the EWG for presentation to CCCF17. The Committee noted the offer of the EU to provide clarification on aspects of the sampling plan (e.g., particle size) as the starting point for discussion is the EU sampling plan.

General Conclusion

- 69. CCCF agreed:
 - to forward the ML of 20 μg/kg for AFT in chili pepper and nutmeg (dry/dried) and the ML 20 μg/kg for OTA in chili pepper, paprika and nutmeg (dry/dried) to CAC46 for adoption at Step 5/8 (Appendix V), noting the reservations of the European Union, Norway, and Switzerland for the MLs for AFT for the reasons explained in paragraph 63;
 - (ii) that the MLs could be reviewed in 3 years' time if sufficient data are submitted through GEMS/Food;

- (iii) to discontinue work on MLs for AFT in paprika, ginger, pepper (black and white) and turmeric and MLs for OTA in ginger, pepper (black and white) and turmeric; and to inform CCEXEC and CAC46 accordingly; and
- (iv) to re-convene the EWG, chaired by India, working in English, to develop sampling plans for the agreed MLs taking into account all written comments submitted to CCCF16; for comments and consideration by CCCF17.

PREVENTION OR REDUCTION OF CIGUATERA POISONING (Agenda Item 10)²⁰

- 70. The United States of America (USA), as Chair of the EWG, speaking also on behalf of the co-Chair, the European Union, introduced the item and provided background to the work, a summary of key points of discussion that took place in the EWG, including the key challenges and gaps in knowledge, conclusions, and recommendations for consideration by CCCF.
- 71. The EWG Chair pointed out that while there were still key challenges and knowledge gaps that there was wide support to start developing a CoP and outlined some of the topics that could be covered in the CoP.
- 72. CCCF considered the recommendations of the EWG to either request the EWG to revise the discussion paper or to proceed with new work on a CoP/Guidelines.

Discussion

- 73. There was general support to start work on a CoP as ciguatera poisoning was of major public health concern even though there were still some knowledge gaps/challenges. It was noted that these knowledge gaps/challenges could be addressed during further discussion in the CoP development process, or the CoP could always be updated in future as more information would become available, and that this approach had been taken in the past for the development of a CoP to prevent and reduce arsenic contamination in rice.
- 74. A Member questioned the appropriateness of a CoP noting the knowledge gaps and whether it would be more appropriate to work on Guidelines in view of these knowledge gaps.
- 75. The EWG Chair explained that there was wide support and preference for a CoP, but that Guidelines, which are normally higher-level principles and less prescriptive, could be considered. But that further clarity was needed on the difference between a CoP and Guidelines.
- 76. The Codex Secretariat explained that while there was reference to CoPs as texts developed by Committees in the Procedural Manual, there was no definition nor other guidance on what constitutes a CoP, and neither was there mention of Guidelines or what constitutes a Guideline and the difference with a CoP. However, it had become common practice that CoPs were developed to provide more practical guidance/measures to reduce or prevent a particular hazard in food, whereas a guideline is developed to provide higher level principles and approaches/frameworks to address a particular issue. Generally, in CCCF, the approach has been to develop CoPs. The Secretariat proposed that, for the moment, the project document could refer to either a CoP/Guidelines and to leave it open for further discussion in the EWG. What needed to be clear was what would be addressed in the work, i.e., reduction and prevention of ciguatera poisoning and the main aspects to be covered by the text.
- 77. Noting the explanation from the Codex Secretariat, CCCF agreed to be flexible on this matter for developing either a CoP or Guidelines.
- 78. CCCF further noted a comment of the importance to gather and collect information of the effectiveness and feasibility of recommended practices, including the data of analytical methods used for confirmation of effectiveness to ensure smooth discussion and development of a CoP/Guidelines.
- 79. The FAO Representative thanked the EWG Chairs for their work and recalled that ciguatera poisoning (CP) remains a topic of active engagement for FAO. The Representative noted the comments made by FAO on CRD22 and he also informed CCCF of the e-learning course²¹: "Monitoring and preventing ciguatera poisoning" that was jointly developed by FAO, IAEA, WHO, and the Intergovernmental Oceanographic Commission of UNESCO.
- 80. The WHO Representative mentioned that they had recently published a paper²² titled *Ciguatera poisoning Ciguatera poisoning is a consequence of eating contaminated seafood,* which describes to the public how ciguatera poisoning could be detected, and which possible mitigation measures intended for local food safety authorities and the food sector were available. He indicated that the paper could be an input to the development of the CoP/Guidelines.

²⁰ CL 2023/21-CF; CX/CF 23/16/10; CX/CF 23/16/10-Add.1 (Comments of Argentina, Canada, Chile, Cuba, Iraq, Japan, Kenya, New Zealand, Peru, Philippines, Singapore, USA and ICUMSA)

²¹ https://elearning.fao.org/course/view.php?id=648

²² Ciguatera poisoning (who.int)

- 81. CCCF agreed to:
 - (i) start new work on a CoP/Guidelines for the prevention or reduction of ciguatera poisoning;
 - (ii) forward the project document (Appendix VI) to CAC46 for approval; and
 - (iii) establish an EWG, chaired by the United States of America and co-chaired by France, Spain, and Panama, working in English, to prepare a proposed CoP/Guidelines for comments and consideration by CCCF17.

PYRROLIZIDINE ALKALOIDS (Agenda Item 11)²³

- 82. The Chairperson recalled that the discussion paper prepared by the EU had been submitted late, which did not allow delegates to review it, and requested CCCF to focus on the next steps to be taken on this work. The Chairperson therefore proposed to circulate the paper for comments and for the EWG to revise the paper for consideration by CCCF17.
- 83. CCCF concurred with the above proposals.

Conclusion

- 84. CCCF agreed to request that:
 - (i) the Codex Secretariat issue a CL requesting comments on the recommendations in the discussion paper CX/CF 23/16/11; and
 - (ii) the EWG chaired by the European Union, working in English only, prepare a revised paper based on the comments received in response to the CL for consideration by CCCF17.

GUIDANCE ON DATA ANALYSIS FOR DEVELOPMENT OF MAXIMUM LEVELS AND FOR IMPROVED DATA COLLECTION (Agenda Item 12)²⁴

85. The European Union, as Chair of the WG, and also on behalf of the Co-Chairs Japan, the Netherlands, and the United States of America, introduced the item and summarized key points of discussion in the VWG and PWG meetings of the WG held prior to the Session. The EWG Chair presented the recommendations of both meetings as contained in CRD06. CCCF agreed to most recommendations as presented, but some recommendations were discussed in more detail.

Discussion

Recommendation 1

- 86. It was clarified that the recommended changes in the GEMS/Food database were not final, but the workplan was to provide the recommendations to the GEMS/Food administrator for review.
- 87. A Member requested to change the field "methods of analysis" to "method of analysis principle" as this field would not list all methods of analysis but the principle of the method of analysis. The EWG Chair indicated that CRD06 paragraph 15(f) and Part B of the Annex indicated that analytical methods should be limited to method principles/approaches and not to provide a list of all possible variants of methods of analysis.
- 88. An Observer raised the following questions:
 - Field O (LOD) Data submitters might upload data to GEMS/Food incorrectly in situations where, the LOQ being mandatory and the LOD not, but the dataset only contains an LOD value, there might be a possibility to misplace the LOD value in the LOQ field: The EWG Chair indicated that there had been extensive discussion on whether both LOQ and LOD should be mandatory in the pre-meetings of the WG and that the discussion and proposed revisions to GEMS/Food were summarized in CRD06 paragraph 14(c) and Part A of the Annex on how to handle datasets in relation to LOQ and LOD fields. He further noted that data submitters should be careful when uploading data on GEMS/Food to avoid placing data in the wrong fields.
 - Fields P (LOQ) and T (Results) With the LOQ being mandatory, whether the remarks on "numeric result is mandatory if LOD or LOQ are not provided" under the "results" field is redundant/not necessary: The EWG Chair explained that the new proposed flag was a clarification and not absolutely necessary with reporting LOQ mandatory but it also provides clarification for previously submitted data currently available in GEMS/Food as reporting of the LOQ is not yet mandatory. Should the revisions be accepted, for new submissions, the flag would not be applicable, but the "results" field shall remain mandatory.

²³ CX/CF 23/16/11

²⁴ CX/CF 23/16/12

- New field on "Product Type and the usability of data to make risk management decisions decisions and therefore
 to make the field mandatory: Referring to the ongoing discussion on MLs for aflatoxins in peanuts and the
 difficulty to differentiate data between "destined for further processing" and "ready-to-eat", whether the new
 field with the inclusion in the menu of the option "not applicable" should not be mandatory to assist CCCF in
 making risk management decisions for setting MLs. The EWG Chair indicated that, following discussion in the
 pre-meetings of the WG, there is first the need to clearly define the terms "for further processing" and "readyto-eat" as this might not always be as such applicable across all commodities, it would therefore be appropriate
 to maintain this field as optional for the time-being.
- 89. Another Observer noted that the changes proposed to GEMS/Food should be carefully considered by the GEMS/Food Administrator so that the database remains compatible with other similar databases to facilitate communication and exchange of data between different existing occurrence data databases. The Representative of WHO indicated that the GEMS/Food Administrator was closely following the work of the EWG and collaborating with the EWG Chairs in addressing questions on and proposals for changes to GEMS/Food particularly those related to data submission and communication with other databases.

Recommendation 6

- 90. The EWG Chair introduced the recommendation regarding minimum number of samples, combined or individual datasets, and dietary exposure reduction rates calculations. A member stated that the calculation of dietary exposure reduction rates was a risk assessment function and should be undertaken by JECFA. It was further stated that JECFA provides the scientific advice on which the risk management decisions of the Committee are based, as outlined in section 4 of the Procedural Manual. This issue was important to clarify the roles of JECFA and CCCF as risk assessor and risk managers respectively.
- 91. CCCF agreed to amend the Recommendation 6(iii) arising from the WG to "Further consider the role of the Committee in calculating dietary exposure reduction rates when considering MLs."
- 92. An observer also indicated that paragraph 26 of CRD06 did not accurately reflect the discussion on minimum number of samples and that other options were proposed that would still be open to discussion in the EWG and were not reflected in CRD06.
- 93. The EWG Chair clarified that the bullets under this recommendation would be further discussed in the EWG. In particular for other options to be considered on the minimum number of samples, this would be part of further work after CCCF17. The Observer noted that this would be inconsistent with Recommendation 3 in paragraph 39 of CRD06. A member therefore proposed to refer to "provisional minimum number of samples" as opposed to "minimum number of samples".
- 94. CCCF agreed with the proposal to refer to "provisional minimum number of samples" to address the concerns expressed by the observer.

Recommendation 9

95. The EWG Chair noted that this recommendation would be captured in the preamble of the guidance.

Other considerations

- 96. The EWG Chair clarified that changes proposed to GEMS/Food under Recommendation 1 as summarized in CRD06 and illustrated in Parts A and B of the Annex of CRD06 would be further considered by the GEMS/Food Administrator in terms of their feasibility for implementation over a period of time as some changes would be easier to implement than others, e.g., certain changes might not yet be feasible due to compatibility of historical data with newly submitted data. In any case, all proposed changes to existing fields and proposed new fields were only applicable for data submitted after the implementation of the changes. Based on the feedback provided by the GEMS/Food Administrator, there would be an opportunity for further discussion in the EWG with a view to present a document for finalization by CCCF17. He further noted that, as regards the proposed additional fields, there was a need to make a clear balance between the burden of submission of data in view of the addition of new fields and the added value from having additional fields.
- 97. On the request for sending out the sections data selection, data clean-up, generating overview of data and statistical analysis for comments with a CL, the EWG Chair further clarified that following the workplan for the further development of the guidance document, it was foreseen to elaborate a new version of section 2 and 3 in line with Recommendation 3 and there would be ample opportunity to provide comments in the EWG for the further revisions of and/or simplification of the sections under consideration by the EWG. The document as finalized by the EWG would be then submitted to the Codex Secretariat for comments and consideration by CCCF17.

- 98. CCCF agreed:
 - (i) on the proposed changes to the GEMS/Food database as presented in the Annex, part A and B of CRD06, and with changes agreed in this Session (paragraph 87);
 - (ii) on the workplan for the coming year for the section "Data collection, data submission and data extraction" provided for in paragraph 17 of CRD06;
 - (iii) on the topics to be addressed in the sections "Data selection/clean-up generating overview of data" and "statistical analysis " as listed in paragraph 20 of this CRD06;
 - (iv) on the proposed workplan for the coming year on the sections "Data selection/clean-up generating overview of data" and "statistical analysis" as provided in paragraph 23 of CRD06;
 - (v) that a list of topics of sections "Data selection/clean-up generating overview of data" and "statistical analysis" shall be elaborated for consideration and agreement by CCCF17 for further discussion after CCCF17;
 - (vi) on the conclusions as regards:
 - (a) the provisional minimum number samples as provided in paragraph 26 of CRD06 and referred to in paragraph 94 of the report;
 - (b) whether a combined dataset or individual datasets should be used for developing MLs, as provided in paragraph 29 of CRD06;
 - (c) further consider the role of the Committee in calculating dietary exposure reduction rates when considering MLs as provided in paragraph 91 of the report.
 - (vii) to recommend to WHO the development of additional training materials and opportunities for the data submission to and data extraction from the GEMS/Food database and to recommend the Codex Member countries to provide the necessary funds for this;
 - (viii) on a more structured process for elaborating calls for data;
 - (ix) on the consideration of data availability and quality before deciding on new work;
 - (x) to holding of a physical meeting of the WG immediately prior to CCCF17 to discuss the guidance document; and
 - (xi) to re-convene the EWG chaired by the European Union, co-chaired by Japan, the Netherlands, and the United States of America, working in English, to continue the work on a proposal for a general guidance on data analysis for ML development and improved data collection.

FORWARD WORK-PLAN FOR CCCF: REVIEW OF STAPLE FOOD-CONTAMINANT COMBINATIONS FOR FUTURE WORK OF CCCF (Agenda Item 13)²⁵

- 99. The Host Country Secretariat, speaking also on behalf of the Codex and JECFA Secretariats, introduced the item and provided a summary of the discussion that took place in a physical meeting prior to the Session. She recalled that this item was the result of the discussion on the forward plan at CCCF13 (2019), where it was agreed to develop an approach for the systematic exploration of key staple food-contaminant combinations (SFC) that could be of public health concern with potential trade implications which had not yet been considered by CCCF. She recalled that, in the discussion paper²⁶ submitted to CCCF14, a possible approach was introduced to identify staple food-contaminant combinations that might be of relevance to explore further in CCCF and that could be taken up in the regular work process of CCCF. For this Session, a discussion paper had been prepared, with an analysis of the comments received in reply to CL 2021/87-CF, and which provided several ways forward to continue with the consideration of this item in CCCF.
- 100. She further explained that the physical meeting discussed the options available and concluded that there was general support for the work presented in the current discussion paper, including the establishment of an EWG, to further develop the approach on the identification of staple food-contaminant combinations for exploration by CCCF, with flexibility on which methodology to use. However, if no Chair could be identified for such EWG, that there were no objections to postponing the discussion and revisiting this topic in 3 to 5 years' time. The meeting further noted that staple foods were already considered in the framework of the review of Codex standards for contaminants as a prioritization criterion (Agenda Item 14) and that new work on SFC combinations could still be proposed following the existing procedures in CCCF.

²⁵ CX/CF 23/16/13

²⁶ CX/CF 21/14/17

- 101. CCCF agreed to:
 - (i) postpone the discussion on the identification of staple food-contaminant combinations for further exploration by CCCF; and
 - (ii) revisit this topic in 3 years' time.

REVIEW OF CODEX STANDARDS FOR CONTAMINANTS (Agenda Item 14)²⁷

102. Canada, as Chair of the VWG, introduced the item and summarized key points of discussion in the virtual meeting held prior to the Session. The VWG Chair presented several recommendations set out in response to the eight charge questions in paragraphs 8 to 15 of CRD03, including recommendations for editorial amendments, annual updates of Lists A, B and Overall Highest Priority List (OHPL) and the revision or creation of prioritization criteria. The VWG noted that further details in support of the recommendations were presented in CRD02(Rev.1) and CRD03.

Discussion

- 103. The VWG Chair clarified that List A dealt with the age of existing standards while list B recommended standards for reevaluation based on information available in CAC and CCCF reports, while the overall highest priority list (OHPL) presented the priorities for review for Codex Members based on the prioritization criteria agreed by CCCF. The VWG Chair explained that this was the second of the three-year pilot with the review exercise and that the development of the lists, including the prioritization criteria, was still subject to improvements as the pilot was being tested. A Member recalled a suggestion in the PWG to consider a more selective review of standards in List B to focus on items specifically recommended for re-review. The VWG Chair reflected that this would be reviewed as part of the process improvements during the trial period. As priorities were identified, and subsequent work was carried out through EWGs, it would be expected that Lists A and B would be kept within a manageable size and would remain under constant review to keep Codex standards for contaminants up to date.
- 104. CCCF noted the interests of Brazil and Canada to develop discussion papers to review the codes of practice for aflatoxins in peanuts and raw materials and supplemental feedingstuffs for milk-producing animals, respectively, to determine the need and feasibility for revision, such as if there are new measures for aflatoxin control in peanuts.

Conclusion

105. CCCF agreed to endorse the recommendations of the VWG as follows:

Editorial amendments to Lists A, B and OHPL

(i) CCCF agreed with the editorial amendments to Lists A, B and OHPL.

Revisions to the Prioritization Criteria

(ii) CCCF agreed with revisions to the prioritization criteria as follows:

Revised criteria

- (a) Recommended for re-evaluation: CCCF, CAC or a member country recommended the standard for reevaluation within a certain period or at an unspecified future date. <u>Codex Alimentarius Commission (CAC)</u> (Priority 1); CCCF (Priority 2); Member country only (Priority 3).
- (b) New occurrence data are available: Occurrence data identified by CCCF or its member countries and/or submitted to the GEMS/Food database are significantly different across two or more regions or markets than those used to establish the existing ML or GL. <u>Or significant new data are available from regions of concern</u> <u>and/or regions where data were previously lacking</u> (Priority 1 - high).

<u>New criteria</u>

- (c) Health-based guidance value (HBGV) cannot be established: Either JECFA, upon request by CCCF, or other relevant joint FAO/WHO expert consultations recognized by CCCF cannot establish a HBGV due to genotoxicity and carcinogenicity, for which the margin of exposure (MOE) indicates a potential health concern, or other rationale that does not support establishment of a threshold for the critical effect. (Priority 1 moderate - high)
- (d) The CoP be available for at least 3 to 5 years since ML(s) established for the relevant contaminant-food combination(s) (priority not applicable).

²⁷ REP22/CF15, para. 218; CL 2022/85-CF; CX/CF 23/16/14 (Comments of Canada, Ecuador, Egypt, Japan, Kenya, Iran, New Zealand, Peru, Republic of Korea, USA and AOCS)

Annual updates to Lists A, B and OHLP

- (iii) CCCF agreed:
 - (a) to not add any additional standards to the OHPL at this time;
 - (b) that all standards in List B could be reviewed by Canada in advance of the next CL being issued to ensure that each was clearly recommended for re-evaluation by a member country, CCCF or CAC; and
 - (c) to continue with the annual case-by-case evaluation of standards in the OHPL to propose for possible review.

Other matters

- (iv) CCCF agreed with the following for consideration by CCCF17:
 - (a) to establish an EWG chaired by Brazil, working in English, to develop a discussion paper to explore whether there are new measures supporting revision of the *Code of practice for the prevention and reduction of aflatoxin contamination in peanuts* (CXC 55-2004);
 - (b) to establish an EWG chaired by Canada, working in English, to develop a discussion paper to explore whether there are new measures supporting revision of the *Code of practice for the reduction of aflatoxin B1 in raw materials and supplemental feedingstuffs for milk-producing animals* (CXC 45-1997); and
 - (c) to reconvene the WG, chaired by Canada, to meet prior to CCCF17 to consider the comments in reply to the CL on priorities for review of existing Codex standards for contaminants that would be distributed by the Codex Secretariat and to make recommendations for consideration by CCCF.

FOLLOW-UP WORK TO THE OUTCOMES OF JECFA EVALUATIONS AND FAO/WHO EXPERT CONSULTATIONS (Agenda Item 15)²⁸

- 106. The European Union, as Chair of the VWG, introduced the item and summarized key points of discussions in the virtual meeting held prior to the Session, as contained in CRD04. The VWG Chair presented recommendations on possible follow-up actions to the outcomes of JECFA evaluations and FAO/WHO expert consultations which were on tropane alkaloids, ergot alkaloids and T-2 and HT-2 toxin and diacetoxyscirpenol (DAS).
- 107. The VWG Chair recalled that for the three topics, the VWG reiterated the recommendations made at CCCF15 i.e., to develop a discussion paper to look into the need and feasibility of possible follow-up actions for consideration by CCCF and that, to this purpose, leading countries to carry out the work needed to be identified.

Ergot alkaloids

- 108. The VWG Chair noted that the JECFA full report and toxicological monograph were now available for consultation. He reiterated that consideration of ergot alkaloids would cover the 12 ergot alkaloids (including their -inine epimers) evaluated by JECFA which may pose challenges from the analytical perspective. Data availability was still limited in terms of geographical spread and were quite diverse (e.g., for individual, group, or total ergot alkaloids). There would be a need to issue a call for data on the occurrence of these ergot alkaloids and to define in the discussion paper the minimum requirements for submission of data to GEMS/Food database that could support work on these toxins in future.
- 109. The VWG Chair informed CCCF that a number of member countries were in the process of generating data but work on validation of methods was needed to clarify what methods could be used to generate the data.

Trichothecenes - T-2, HT-2 and diacetoxyscirpenol (DAS)

110. The VWG Chair noted that the JECFA full report was now available, and the toxicological monograph would be available shortly for consultation. There would be a need to issue a call for data on the occurrence of these trichothecenes and to define the minimum requirements for submission of data in food and feed to GEMS/Food that could support work on these toxins in future.

Discussion

111. In response to a request on future follow-up work on the upcoming FAO/WHO expert consultation on risk/benefits of fish consumption, the VWG Chair clarified that this issue could be taken up in the framework of the review of Codex standards for contaminants (methylmercury in fish) or the priority lists of contaminants for evaluation by JECFA (dioxins and dioxins-like PCBs). The Representative of WHO further explained that the consultation was scheduled for October 2023 and that the report might not be available in time for CCCF17.

²⁸ REP22/CF15, paras. 222-224; CX/CF 23/16/3

112. China expressed its interest in developing a discussion paper on the need and feasibility of possible follow-up actions on tropane alkaloids by CCCF.

Conclusion

- 113. CCCF agreed to:
 - (i) establish an EWG, chaired by China and co-chaired by Saudi Arabia, working in English, to prepare a discussion paper on tropane alkaloids to look into the need and feasibility of possible follow-up actions for consideration by CCCF17;
 - (ii) reconsider the elaboration of a discussion paper on the need and feasibility of possible follow-up actions on ergot alkaloids and trichothecenes (T-2, HT-2, and DAS) at CCCF17; and
 - (iii) reconvene, as necessary, the in-session WG at CCCF17, chaired by the European Union.

PRIORITY LIST OF CONTAMINANTS FOR EVALUATION BY JECFA (Agenda Item 16)²⁹

114. The United States of America (USA), as Chair of the VWG, introduced the item and summarized key points of discussion in the virtual meeting of the WG held prior to the Session. The VWG Chair presented recommendations on amendments to the priority list based on comments in reply to CL 2022/84-CF and explained that for the compounds currently sitting in the list, information was updated as provided by members and the JECFA Secretariat. In addition, two compounds were included in the priority list namely thallium (USA) and perfluoroalkyl substances (namely, PFOS, PFOA, PFNA, PFHxS) (Singapore).

Discussion

Acrylamide

- 115. India requested the inclusion of acrylamide in the priority list and noted that excessive consumption of food containing acrylamides, particularly fried foods, as well as bakery and confectionery products, could cause human health concerns. The Delegation indicated they could submit data to GEMS/Food within a year. They also indicated that, as the last evaluation took place more than 10 years ago, it might help if JECFA could re-evaluate this compound in a future evaluation.
- 116. The JECFA Secretariat indicated that acrylamide was evaluated by JECFA twice, in 2005 and 2011, and was identified as a genotoxic carcinogen therefore a health-based guidance value could not be established, and it was unlikely that new data that might have become available since the last evaluation could change this outcome. The Secretariat further noted that as a result of these evaluations, CCCF did not establish any MLs but developed a *Code of practice for the reduction of acrylamide in foods* (CXC 67-2009). In view of this, there might not be sufficient rationale to spend the limited JECFA resources on evaluating acrylamide for the third time.
- 117. Based on the above considerations, India expressed its interest in developing a discussion paper on acrylamide in foods for consideration by CCCF.

Cadmium and lead in quinoa

- 118. The Codex Secretariat recalled the decision taken at CCCF14 on cadmium and lead in quinoa (see Agenda Item 2).
- 119. CCCF agreed that a call for data should be issued taking into account the points raised at CCCF14 and comments made at this Session.
- 120. The JECFA Secretariat requested that a table listing Calls for Data be added to the Priority List in the future to support JECFA's work.

Ethylene Oxide and 2-chloroethanol

121. The VWG Chair indicated that Indonesia had proposed addition of ethylene oxide (EtO) and 2-chloroethanol (2-CE) to the priority list, noting that EtO and 2-CE could result from use as a fumigant pesticide, from use of food additives where EtO and 2-CE are impurities, or potentially from environmental releases. Also, EtO and 2-CE have become a trade issue with varying national regulatory frameworks. The VWG Chair noted there were questions about whether EtO and 2-CE should be viewed as a contaminant, pesticide, or impurity in a food additive and how to proceed and therefore, consultation would be helpful.

²⁹ REP22/CF15, Appendix IX; CL 2022/84-CF; CX/CF 23/16/15 (Comments of Canada, Indonesia, Kenya, Mexico, New Zealand, and Peru)

122. The VWG recommended that Indonesia's proposal for addition of EtO and 2-CE to the priority list be deferred for consideration until CCCF17 in order to request input from the Codex Committee on Pesticide Residues (CCPR), on whether EtO and 2-CE meets the definition of a pesticide under Codex, and if not, whether some coordination with regards to a risk assessment would be required between the Joint FAO/WHO Meetings on Pesticide Residues (JMPR) and JECFA to evaluate this compound as a contaminant. The VWG also recommended that CCFA be informed of CCCF decisions, as EtO and 2-CE could potentially be found as an impurity in certain food additives.

Lead in bentonite, diatomaceous earth and activated carbon

- 123. A member recalled that, when finalizing the revision of the *Code of practice for the prevention and reduction of lead contamination in foods* (CXC 56-2004), CCCF14 had recommended CCFA to (i) review the lead specifications for diatomaceous earth and charcoal (activated carbon) and (ii) evaluate available data to support development of a lead specification for bentonite.³⁰
- 124. CCCF noted that CCFA53 (2023) had emphasized that, should confirmation of data availability not be provided at CCFA54 (2024), a reply to CCCF would be put forward, noting the lack of a data sponsor, and that CCFA may not be able to respond to CCCF's request for bentonite, activated carbon, and diatomaceous earth³¹.
- 125. CCCF noted that alternative data sources may be acceptable, such as a compilation of enforcement data.
- 126. Another member questioned whether data could be added to GEMS/Food and the WHO Representative stated that he would need to consult with the GEMS/Food database Administrator.
- 127. The Codex Secretariat indicated that this request belonged to the remit of CCFA as it related to the revision of an existing specification or the establishment of a new specification and as such it should be dealt with in CCFA and that no further action was required from CCCF in this regard. However, delegations at CCCF should coordinate with their delegations at CCFA in order to provide the required information to CCFA54.

Scopoletin

- 128. A Member noted that scopoletin had been retained in the priority list at the request of CCNASWP16 (2023) (see Agenda Item 2) and questioned whether the final adoption of the Regional Standard for Fermented Noni Fruit Juice developed by CCNASWP could be delayed until JECFA performed the safety evaluation of scopoletin. The Delegation further referred to the possibility of using historic data on the safe use of the product to assist speeding up the evaluation of this compound. The Delegation also noted that it would not be appropriate to adopt a standard with a pending risk assessment by JECFA.
- 129. The JECFA Secretariat indicated that CCNASWP continued to be very interested in having a standard for fermented noni fruit juice. However, it had not yet been possible for the members of CCNASWP to fully develop all the toxicological data that would be necessary for a JECFA evaluation. The Secretariat further noted that the toxicological profile of scopoletin was not known yet and that scopoletin was used as an identity marker in noni products.
- 130. The Codex Secretariat noted that this was a regional standard and adoption of such a standard was discretional to Members of that region present at CAC. The Secretariat further noted that if there were members concerned with the adoption of this standard, they had to convey their concerns to CCEXEC, under the Critical Review, through their regional coordinators or express their concerns at CAC when this standard would be considered for adoption. She further noted that there were several Codex commodity standards which refer to CXS 193-1995 but did not necessarily have corresponding MLs for the products covered by the scope of these standards in CXS 193. In addition, some Codex quality standards did have specific provisions under the contaminants section to cover situations where an ML for a contaminant was not available in CXS 193 such as the standards for bitter and sweet cassava vis-à-vis MLs for cyanogenic glycosides/hydrocyanic acid (HCN) and that the Regional Standard for Fermented Noni Fruit Juice had a similar caveat to cover the concern on the potential toxicity of scopoletin.

Other considerations

- 131. Canada indicated their support for the evaluation of dioxins and dioxin-like PCBs and arsenic (inorganic and organic) as they have regulatory MLs for inorganic and total arsenic in certain foods and were in the process of updating their MLs for dioxins and dioxin-like PCBs. They also indicated their support for the evaluation of thallium.
- 132. Singapore reaffirmed their support for the evaluation of per- and polyfluoroalkyl substances (PFAS) and committed to provide additional occurrence data for additional PFAS classes should these be identified by JECFA to support the risk assessment and indicated their intention to take up work on PFAS after the JECFA risk assessment. The Delegation encouraged Members and Observers to submit data on toxicology and epidemiology studies which Singapore was unable to provide.

³⁰ REP21/CF14, paras. 105, 105(ii)

³¹ REP23/FA53, para. 134

- 133. CCCF agreed to:
 - (i) endorse the priority list as amended (Appendix IX);
 - (ii) continue to request comments and/or information on the priority list for consideration by CCCF17;
 - (iii) re-convene the in-session WG at CCCF17 chaired by the United States of America;
 - (iv) establish an EWG, chaired by India and co-chaired by Saudi Arabia, working in English, to develop a discussion paper on acrylamide in foods taking into account the most recent JECFA evaluations, to look into the feasibility of risk management measure(s) for consideration by CCCF17;
 - (v) retain scopoletin in the priority list and to call upon Codex members concerned to generate and submit data to support the conduct of the safety evaluation by JECFA;
 - (vi) defer the addition of ethylene oxide (EtO) and 2-chloroethanol (2-CE) to the priority list until next year and to request clarification from CCPR on whether EtO and 2-CE meet the Codex definition of pesticide and whether coordination of risk assessment between JECFA and JMPR would be required to evaluate EtO and 2-CE as a contaminant and to inform CCFA of this decision as EtO and 2-CE could potentially be found as an impurity in certain food additives;
 - (vii) request the JECFA Secretariat:
 - (a) to issue a call for data on cadmium and lead in quinoa and quinoa-based products, including foods for infants and young children;
 - that the call for data should include a request for data on occurrence of lead and cadmium for the last 10 years, consumption data, and country of origin (if known) should be indicated in the remarks field in order to help assess the geographic representativity of the data;
 - 2) data collected with methods with a LOQ of 0.4 mg/kg or below, would be helpful but not required, given the current MLs in CXS193 for lead and cadmium in grains of up to 0.4 mg/kg.
 - (b) to prepare an analysis of the new data and prepare a paper for consideration by CCCF17.
 - (viii) encourage Members and Observers to submit data on lead in bentonite, diatomaceous earth, and charcoal (activated carbon) so that data availability could be confirmed at CCFA54 in order to proceed with the review or establishment of the new specification.

OTHER BUSINESS (Agenda Item 17)

Review of proposed agenda for CCCF17

134. The Chairperson did a stock take of all decisions taken at the Session to provide an overview of the agenda for the next Session. CCCF confirmed the decisions taken under the relevant agenda items for inclusion in the agenda for CCCF17.

Foresight on emerging issues in food and feed safety relevant to contaminants

- 135. CCCF noted that during the side event on *Foresight on Emerging Issues in Food and Feed Safety*, the Codex Secretariat provided different options that could be used to bring emerging issues in food safety relevant to contaminants to the attention of CCCF including the possibility of having an agenda item where members could bring issues for discussion in addition to matters that could be brought by FAO and WHO under Agenda Item 3.
- 136. The FAO Representative, in welcoming the idea of having an agenda item on emerging issues, noted that while FAO would report on relevant work carried out by the foresight programme, it would also be important to use this agenda item as an opportunity for Members and Observers to exchange information and knowledge on new trends and emerging issues that could be of significance to CCCF.
- 137. CCCF noted comments in relation to the possibility to expand on some of the topics discussed during the side event on foresight such as novel foods or technologies being developed/applied and the potential associated hazards and risks e.g., edible insects, hydroponic technologies, specific contamination patterns observed in novel foods vis-à-vis conventional foods, etc.
- 138. The Chairperson noted that a way to bring issues to the attention of CCCF could be by issuing a CL with selected topics for comments by Codex Members and Observers. CCCF agreed to bring emerging issues in food safety relevant to contaminants to the attention of CCCF by having an agenda item for this topic.

Code of practice for the prevention and reduction of cadmium contamination in foods

139. CCCF agreed that the United States of America would prepare a discussion paper to consider the development a CoP to prevent or reduce cadmium contamination in foods.

DATE AND PLACE OF NEXT SESSION (Agenda Item 18)

140. CCCF was informed that CCCF17 was scheduled to be held in approximately one year's time, the final arrangement subject to confirmation by the Host Country and the Codex Secretariats.

APPENDIX I

LIST OF PARTICIPANTS LISTE DES PARTICIPANTS LISTA DE PARTICIPANTES

CHAIRPERSON – PRÉSIDENTE - PRESIDENTA

Dr Sally Hoffer Chair of CCCF Ministry of Agriculture, Nature and Food Quality PO Box 20401 The Hague Netherlands

CHAIR'S ASSISTANT – ASSISTANTE DE LA PRÉSIDENTE – ASISTENTA DE LA PRESIDENTA

Ms Astrid Bulder Senior Risk Assessor National Institute for Public Health and the Environment (RIVM) PO Box 1 Bilthoven Netherlands

MEMBERS NATIONS AND MEMBER ORGANIZATIONS ÉTATS MEMBRES ET ORGANISATIONS MEMBRES ESTADOS MIEMBROS Y ORGANIZACIONES MIEMBROS

ARGENTINA - ARGENTINE

Lourdes D'Esposito Directora INAL -Administración Nacional de Medicamentos Alimentos y Tecnología Medica Buenos Aires

AUSTRALIA - AUSTRALIE

Mr Steve Crossley Director – International Affairs and Dietary Exposure Assessment Food Standards Australia New Zealand Canberra

AUSTRIA - AUTRICHE

Dr Daniela Hofstaedter Senior Expert AGES - Austrian Agency for Health and Food Safety Vienna

AZERBAIJAN - AZERBAÏDJAN - AZERBAIYÁN

Ms Irade Huseynli Head of Division Food Safety Agency of the Republic of Azerbaijan Baku Ms Arzu Yusubova leading advisor Food Safety Agency of The Republic of Azerbaijan Baku

BELGIUM - BELGIQUE - BÉLGICA

Dr Christine Vinkx Food safety Expert FPS Health, Food Chain Safety and Environment Brussels

Mr Andrea Carletta Expert Contaminant FPS Public Health Bruxelles

Ms Vromman Valérie Attaché Belgian Food Safety Agency Bruxelles

BRAZIL - BRÉSIL - BRASIL

Ms Larissa Bertollo Gomes Pôrto Health Regulation Specialist Brazilian Health Regulatory Agency – ANVISA Brasília Ms Patricia Diniz Andrade Professor University of Brasilia Brasília

Ms Deise Baggio Ribeiro Professor Federal University of Santa Catarina (UFSC) Florianópolis

Ms Flávia Beatriz Custódio Ph.D of Food Science Universidade Federal de Minas Gerais Belo Horizonte

Mr Milton Cabral De Vasconcelos Neto Health and Technology Analyst Ezequiel Dias Foundation - FUNED Belo Horizonte

Mr Wilkson Oliveira Rezende Official Inspector Ministry of Agriculture and Livestock - MAPA Brasília

Mr Rafael Ribeiro Goncalves Barrocas Federal Food Inspector Ministry of Agriculture and Livestock - MAPA Brasília

Mrs Lígia Schreiner Food risk assessment manager Brazilian Health Surveillance Agency - ANVISA Brasília

CABO VERDE - CAP-VERT

Mrs Alice Rodrigues Técnico de Regulação da ERIS ERIS Praia

Mrs Verena Furtado Técnico de Regulação da ERIS ERIS Praia

CANADA - CANADÁ

Mr John Field Chief, Chemical Health Hazard Assessment Division Food Directorate Ottawa

Dr Rosalie Awad Section Head, Food Contaminants Section Health Canada Ottawa

Mr Jason Glencross International Policy Analyst Canadian Food Inspection Agency Ottawa Dr Beata Kolakowski Science Leader Canadian Food Inspection Agency Ottawa

CHILE - CHILI

Mrs Lorena Delgado Rivera Encargada Laboratorio Biotoxinas Ministerio de Salud Santiago

CHINA - CHINE

Prof Yongning Wu Chief Scientist China National Center for Food Safety Risk Assessment Beijing Dr Huihui Bao

Doctor China National Center for Food Safety Risk Assessment Beijing

Dr Xiaoxia Ding Professor Oil Crops Research Institute, Chinese Academy of Agricultural Sciences Wuhan

Mrs Bing Lyu Associate Professor China National Center for Food Safety Risk Assessment Beijing

Ms Jiongqian Pang Investigator Department of Food Safety Standards, Risk Surveillance and Assessment, National Health Commission of the People's Republic of China Beijing

Dr Yi Shao Professor China National Center for Food Safety Risk Assessment Beijing

Mr Jin Ye Associate Professor Academy of National Food and Strategic Reserves Administration, China Beijing

Mr Qinghua Zhang Professor Research Center for Eco-Environmental Sciences, Chinese Academy of Sciences Beijing

COLOMBIA - COLOMBIE

Eng Ivan Dario Vargas Mendoza Profesional especializada Instituto Nacional de Vigilancia de Medicamentos y Ali mentos - INVIMA Bogotá

CROATIA - CROATIE - CROACIA

Mrs Marija Pašalić Senior Expert Advisor Ministry of Health Zagreb

CUBA

Mr Osvaldo Vladimir Puñales Sosa Funcionario Especialista en Higiene, Epidemiología y Nutrición, Jefe de programa de Prevención y Control de las Enfermedades Transmitidas por los Alimentos Ministerio de Salud Pública La Habana

CZECH REPUBLIC - TCHÈQUE, RÉPUBLIQUE -CHECA, REPÚBLICA

Mr Jakub Fisnar Expert Ministry of Agriculture of the Czech Republic Prague 1

DOMINICA - DOMINIQUE

Dr Al-Mario Casimir Agriculture Officer I (DRM Coordinator) Ministry of Agriculture Fisheries Blue and Green Economy Roseau

Ms Colita Nation Technical Officer-Laboratory Services Dominica Bureau of Standards Roseau

ECUADOR - ÉQUATEUR

Eng Saul Flores Secretaría del Comité Coordinador FAO/OMS para América Latina y El Caribe CCLAC Agencia de Regulación y Control Fito y Zoosanitario-AGROCALIDAD Quito

EL SALVADOR

Mrs Claudia Patricia Guzmán Jefe del Punto de Contacto Codex Organismo Salvadoreño de Reglamentación Técnica San Salvador

ESTONIA - ESTONIE

Ms Maia Radin Head of Unit Ministry of Rural Affairs Tallinn

ESWATINI - SWAZILANDIA

Mr Nelson Mavuso Director of Agriculture Ministry of Agriculture Mbabane

EUROPEAN UNION - UNION EUROPÉENNE -UNIÓN EUROPEA

Mr Frans Verstraete Deputy Head of Unit European Commission Brussels

Ms Judit Krommer Administrator European Commission BRUSSELS

Ms Veerle Vanheusden Administrator European Commission Brussels

FINLAND - FINLANDE - FINLANDIA

Ms Elina Pahkala Chief Specialist Ministry of Agriculture and Forestry

FRANCE - FRANCIA

Mrs Karine Bertholon Chargée de mission Ministère de l'agriculture et de la souveraineté alimentaire Paris

Mrs Patricia Dillmann Chargée de mission Ministère de l'agriculture et de la souveraineté alimentaire Paris

GERMANY - ALLEMAGNE - ALEMANIA

Mrs Annette Rexroth Senior Officer Federal Ministry for Food and Agriculture Bonn

GRENADA - GRENADE - GRANADA

Ms Dilly-Ann Bartholomew-date Produce Chemist Ministry of Agriculture St. George's

HONDURAS

Ms Maria Eugenia Sevilla Gerente Técnico de Inocuidad Agroalimentaria SENASA Tegucigalpa

INDIA - INDE

Ms Reeba Abraham Deputy General Manager Agricultural and Processed Food Products Export Development Authority (APEDA)

Dr Dinesh Singh Bisht Scientist C Spices Board India

Mr Manoj Kumar Gupta Deputy Director (Technical) Ministry of Commerce & Industry

Mr Praveen Kumar Director Ministry of Commerce & Industry

Mr Pushp Vanam Joint Director Food Safety and Standards Authority of India (FSSAI) New Delhi

INDONESIA - INDONÉSIE

Mr Nugroho Indrotristanto Pharmacy and Food Supervisor Indonesian Food and Drug Authority Jakarta

Mrs Sulistiyorini Sulistiyorini Food Security Analyst National Food Agency Jakarta

Mr Dasep Wahidin Deputy Director/Food Inspector Indonesian Food and Drug Authority Jakarta

Dr Raphaella Widiastuti Researcher National Research and Innovation Agency (BRIN) Bogor

IRELAND - IRLANDE - IRLANDA

Dr Joe Hannon Senior Technical Executive Food Safety Authority of Ireland

ITALY - ITALIE - ITALIA

Mr Giulio Cardini officer Ministry of Agriculture, Food Sovereignty and Forests Rome

JAPAN - JAPON - JAPÓN

Mr Tetsuo Urushiyama Associate Director Ministry of Agriculture, Forestry and Fisheries Tokyo Mr Fumimasa Ichinose Deputy Director Ministry of Health, Labour and Welfare Tokyo

Mr Naofumi lizuka Deputy Director Ministry of Health, Labour and Welfare Tokyo

Mr Tomoaki Miura Associate Director Ministry of Agriculture, Forestry and Fisheries Tokyo

Dr Hiroyuki Noda Director, Office of International Food Safety Ministry of Health, Labour and Welfare Tokyo

Ms Kanako Sasaki Deputy Director, Office of International Food Safety Ministry of Health, Labour and Welfare Tokyo

Mr Yoshiyuki Takagishi Associate Director Ministry of Agriculture, Forestry and Fisheries Tokyo

Dr Yukiko Yamada President International Food Safety Consultant Tokyo

JORDAN - JORDANIE - JORDANIA

Eng Rafat Alhalaki Head of Imported Food Safety and Quality Compliance Jordan Food and Drug Administration Amman

MOROCCO - MAROC - MARRUECOS

Mrs Keltoum Darrag Représentante régionale Nouacer- Settat MOROCCO FOODEX

Ms Arif Khadija Ingénieur en Chef Office National de Sécurité Sanitaire des Produits Alimentaires Rabat

NETHERLANDS - PAYS-BAS - PAÍSES BAJOS

Mrs Nikki Emmerik Senior Policy Officer Ministry of Health, Welfare and Sport The Hague

Mrs Weiluan Chen Science Officer National Institute for Public Health and the Environment Bilthoven

NEW ZEALAND - NOUVELLE-ZÉLANDE – NUEVA ZELANDIA

Ms Jeane Nicolas Senior Adviser Toxicology Min Primary Industry Wellington

NIGERIA - NIGÉRIA

Dr Abimbola Opeyemi Adegboye Director National Agency for Food and Drug Administration and Control ABUJA

NORWAY - NORVÈGE - NORUEGA

Ms Julie Tesdal Håland Senior Adviser Norwegian Food Safety Authority Oslo

PAKISTAN - PAKISTÁN

Mr Muhammad Ismail Chughtai Principal Scientist Nuclear Institute for Agriculture & Biology (NIAB), Pakistan Atomic Energy Commission (PAEC) Faisalabad

PANAMA - PANAMÁ

Eng Joseph Gallardo Ingeniero de Alimentos / Punto de Contacto Codex Ministerio de Comercio e Industrias Panama

PHILIPPINES - FILIPINAS

Mr Phelan Apostol Chair, NCO Sub-Committee on Contaminants in Food Food and Drug Administration-Department of Health

Dr Karen Kristine Roscom Member, SCCF Bureau Agricultural Fisheries Standards-Department of Agriculture Quezon City

REPUBLIC OF KOREA - RÉPUBLIQUE DE CORÉE - REPÚBLICA DE COREA

Dr Hyung Wook Chung Senior Scientific Officer Residues and Contaminants Standard Division Ministry of Food and Drug Safety

Ms Eun Ryong Park Scientific officer Residues and Contaminants Standard Division Ministry of Food and Drug Safety

Ms Jooyeon Kim Researcher Food Standard Division Ministry of Food and Drug Safety Dr Young-Suk Kim Professor Dept. of Food Science & biotechnology Ewha Woman's University

Dr Yong Kyoung Kim Scientific officer Safety analysis division Experiment research institute National Agricultural products quality management service Ministry of agriculture, food and rural affairs

RUSSIAN FEDERATION – FÉDÉRATION DE RUSSIE – FEDERACIÓN DE RUSIA

Ms Kseniia Bokovaia Head of the Division Federal Service for Surveillance on Consumer Rights Protection and Human Well-being Moscow

SAUDI ARABIA - ARABIE SAOUDITE – ARABIA SAUDITA

Mr Yasir Alaqil Specifications and Regulations Expert Saudi Food and Drug Authority Riyadh

Mr Mohammed Al Mutairi Head of the Inorganic Chemistry Department Saudi Food and Drug Authority Riyadh

Ms Lama Almaiman Senior risk assessment specialist I Saudi Food and Drug Authority Riyadh

SINGAPORE - SINGAPOUR - SINGAPUR

Dr Jun Cheng Er Specialist Team Lead (Exposure Assessment) Singapore Food Agency Singapore

Dr How Chee Ong Scientist Singapore Food Agency Singapore

SPAIN - ESPAGNE - ESPAÑA

Ms Violeta García Henche Jefa de Sección del Servicio de Gestión de Contaminantes Organismo Autónomo Agencia Española de Seguridad Alimentaria y Nutrición (AESAN OA)-Ministerio de Consumo Madrid

SRI LANKA

Dr B Ruchika Fernando Senior lecturer University of Peradeniya Peradeniya

STATE OF LIBYA - L'ÉTAT DE LIBYE – ESTADO DE LIBIA

Dr Jamal Ben Zeglam Lecturer Faculty of Veterinary Medicine, University of Tripoli Tripoli

SWEDEN - SUÈDE - SUECIA

Mrs Carmina Ionescu Codex Coordinator National Food Agency Uppsala

Mrs Sofia Ardell Head of department Swedish Food Agency Uppsala

Dr Nurun Nahar Principal Regulatory Officer Swedish Food Agency Uppsala

SWITZERLAND - SUISSE - SUIZA

Mr Mark Stauber Head, Food Hygiene Federal Food Safety and Veterinary Office FSVO Bern

SYRIAN ARAB REPUBLIC -RÉPUBLIQUE ARABE SYRIENNE -REPÚBLICA ÁRABE SIRIA

Dr Moutaz Zarkawi Deputy Head Department of Agriculture/Head of Animal Reproduction Section Atomic Enery Commission Syria

THAILAND - THAÏLANDE - TAILANDIA

Ms Chutiwan Jatupornpong Standards Officer, Senior Professional Level National Bureau of Agricultural Commodity and Food Standards, Ministry of Agriculture and Cooperatives Bangkok

Ms Nitzachon Khacharin Trade and Technical Manager of Fisheries Products Thai Food Processors' Association Bangkok

Mr Sompop Lapviboonsuk Scientist, Senior Professional Level Ministry of Higher Education, Science, Research and Innovation Bangkok Dr Kwantawee Paukatong Federation of Thai Industries The Federation of Thai Industries Bangkok

Ms Savarin Sinaviwat Scientist, Professional Level Ministry of Higher Education, Science, Research and Innovation Bangkok

Ms Wiphada Sirisomphobchai Scientist, Expert Level Department of Livestock Development, Ministry of Agriculture and Cooperatives Pathum Thani

Dr Nanthiya Unprasert Advisor Thai Frozen Foods Association Bangkok

UNITED KINGDOM - ROYAUME-UNI – REINO UNIDO

Mr Craig Jones Senior Policy Advisor Food Standards Agency

Ms Monica Mann Senior Policy Advisor Food Standards Agency

Ms Helen Twyble Senior Policy Advisor Food Standards Agency

UNITED REPUBLIC OF TANZANIA – RÉPUBLIQUE-UNIE DE TANZANIE – REPÚBLICA UNIDA DE TANZANÍA

Mr John Wanjala Faustine Officer Government Chemist Laboratory Authority Dar Es Salaam

UNITED STATES OF AMERICA – ÉTATS-UNIS D'AMÉRIQUE – ESTADOSUNIDOS DE AMÉRICA

Dr Lauren Robin Chief Center for Food Safety and Applied Nutrition College Park, MD

Dr Eileen Abt Chemist, Plant Products Branch Center for Food Safety and Applied Nutrition College Park, MD

Dr Anthony Adeuya Chemist Center for Food Safety and Applied Nutrition College Park, MD Mrs Doreen Chen-Moulec International Issues Analyst U.S. Department of Agriculture Washington, DC

Mr Alexander Domesle Senior Advisor for Chemistry, Toxicology, and Related Sciences Food Safety and Inspection Service, USDA Washington, DC

OBSERVERS - OBSERVATEURS -OBSERVADORES

INTERNATIONAL GOVERNMENTAL ORGANIZATIONS – ORGANISATIONS GOUVERNEMENTALES INTERNATIONALES – ORGANIZACIONES GUBERNAMENTALES INTERNACIONALES

INTER-AMERICAN INSTITUTE FOR COOPERATION ON AGRICULTURE (IICA)

Mrs Alejandra Díaz Agricultural Health and Food Safety Specialist IICA Coronado

NON-GOVERNMENTAL ORGANIZATIONS – ORGANISATIONS NON GOUVERNEMENTALES – ORGANIZACIONES NO GUBERNAMENTALES

EUROPEAN FOOD EMULSIFIER MANUFACTURERS' ASSOCIATION (EFEMA)

Mrs Anja Andersen Regulatory Affairs Strategy Lead EFEMA Brabrand

EUROPEAN VEGETABLE PROTEIN ASSOCIATION (EUVEPRO)

Dr Huub Scheres Scientific & Regulatory Advocacy, Director IFF

FOODDRINKEUROPE

Ms Mette Blauenfeldt EMEA Regulatory Affairs and SHE Manager, Animal Nutrition & Health, Human Nutrition & Health | DSM Nutritional Products FoodDrinkEurope

INTERNATIONAL CO-OPERATIVE ALLIANCE (ICA)

Mr Kazuo Onitake Senior Scientist Japanese Consumers' Co-operative Union Tokyo Ms Maria R. Dorsett International Trade Specialist Foreign Agriculture Service, U.S. Department of Agriculture Washington, D.C.

Mr Richard White Consultant Corn Refiners Association Bradenton, FL

Mr Yuji Gejo Officer International Co-operative Alliance Tokyo

INTERNATIONAL CONFECTIONERY ASSOCIATION (ICA/IOCCC)

Ms Liz Colebrook Director, Food Safety International Confectionery Association

INTERNATIONAL COUNCIL OF BEVERAGES ASSOCIATIONS (ICBA)

Dr Maia Jack Chief Science & Regulatory Officer American Beverage Association Washington, DC

Mr Stefan Ronsmans Director The Coca-Cola Company Brussels

INSTITUTE OF FOOD TECHNOLOGISTS (IFT)

Dr. Martin Slayne Ingredion Incorporated Bridgewater, NJ

INTERNATIONAL FRUIT AND VEGETABLE JUICE ASSOCIATION (IFU)

Dr David Hammond Chair Legislation Commission International Fruit and Vegetable Juice Association Paris

INTERNATIONAL LIFE SCIENCES INSTITUTE (ILSI)

Dr Konrad Korzeniowski Scientific Project Manager ILSI Brussels

INTERNATIONAL SPECIAL DIETARY FOODS INDUSTRIES (ISDI)

Ms Evangelia Mavromichali Regulatory Affairs Officer ISDI Brussels

Dr Angelika Tritscher Global Food Safety Director ISDI Brussels

WORLD FOOD PROGRAMME (WFP)

Mr Francesco Mascherpa Food specification/regulatory consultant World Food Programme

FAO PERSONNEL PERSONNEL DE LA FAO PERSONAL DE LA FAO

Mr Markus Lipp Senior Food Safety Officer Food and Agriculture Organization of the U.N. Rome

Mr Vittorio Fattori Food Safety Officer Food and Agriculture Organization of the U.N. Rome

WHO PERSONNEL PERSONNEL DE L'OMS PERSONAL DE LA OMS

Mr Kim Petersen Scientist World Health Organisation

CCCF SECRETARIAT

Dr Marie-Ange Delen Coordinator Codex Alimentarius Netherlands Ministry of Agriculture, Nature and Food Quality The Hague

Mrs Judith Amatkarijo Conference Organiser Ministry of Economic Affairs & Climate THE HAGUE

Ms Sheela Khoesial Officer Codex Alimentarius Netherlands Ministry of Agriculture, Nature and Food Quality The Hague

CODEX SECRETARIAT

Ms Gracia Brisco Food Standards Officer Joint FAO/WHO Food Standards Programme Food and Agriculture Organization of the U.N. Rome

Ms Verna Carolissen Mackay Food Standards Officer Joint FAO/WHO Food Standards Programme Food and Agriculture Organization of the U.N. Rome

Mr Giuseppe Di Chiera Programme Specialist Joint FAO/WHO Food Standards Programme Food and Agriculture Organization of the U.N. Rome

Mr David Massey Special Advisor Food Standards Officer Joint FAO/WHO Food Standards Programme Food and Agriculture Organization of the U.N. Rome

APPENDIX II

MAXIMUM LEVELS FOR LEAD IN CERTAIN FOOD CATEGORIES

Commodity/ Product Name	Maximum Level (ML) mg/kg	Portion of the Commodity/Product to which the ML applies	Notes/Remarks
Soft brown, raw and non–centrifugal sugars	0.15	Whole commodity	The ML applies to soft brown sugar, raw sugar and non-centrifugal sugar. Relevant Codex commodity standard is CXS 212-1999.

(For adoption at Step 5/8)

(For adoption at Step 8)

Commodity/ Product Name	Maximum Level (ML) mg/kg	Portion of the Commodity/Product to which the ML applies	Notes/Remarks
Ready-to-eat meals for infants and young children	0.02	Whole commodity	The ML applies to all ready-to-eat meals intended for infants (up to 12 months) and young children (12 to 36 months). Relevant Codex commodity standard is CXS 73-1981.

APPENDIX III

CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF MYCOTOXINS CONTAMINATION IN CASSAVA AND CASSAVA-BASED PRODUCTS

(FOR ADOPTION AT STEP 8)

1. INTRODUCTION

- 1. Mycotoxins are fungal toxins that have been reported in a wide variety of agricultural products. They can pose health and economic consequences. The most frequently occurring mycotoxins in cassava and cassava-based products are aflatoxins and ochratoxin A. The aflatoxins are mainly produced by *Aspergillus flavus*, *A. parasiticus and A. minisclerotigenes*; while Ochratoxin A is mainly produced by *Penicillium verrucosum and Aspergillus ochraceus* as well as *A. carbonarius* and *A. niger*. Aflatoxins are among the most potent carcinogenic, teratogenic, and mutagenic compounds known. Depending on the affected species, these mycotoxins can act as nephrotoxins, hepatotoxins, immunotoxins, neurotoxins, teratogens, or carcinogens, however, the liver is the primary target for toxicity. The major aflatoxins commonly found in agricultural commodities are aflatoxin B1, B2, G1, and G2, of which aflatoxin B1 is the most potent. Ochratoxin A may cause nephrotoxic, teratogenic, immunosuppressive, and carcinogenic effects, depending on the affected species. Ochratoxin A is one of the most potent renal carcinogens, inducing cancer in rats at very low doses. The International Agency for Research on Cancer (IARC) has classified the aflatoxins as carcinogenic to humans (Group 1) and Ochratoxin A as *possibly* carcinogenic to humans (Group 2B).
- 2. The prevalence of several species of fungi that are implicated in mycotoxin production usually differs from one region to another. The fungi, which can be found in soil and dust, residues of cultivated crops, stored cassava and cassava-based products at processing or storage facilities are usually associated with pre-harvest and/or post-harvest contamination of cassava and cassava-based products in regions having climate and soil conditions that permit both small or large scale cassava cultivation.
- 3. The severity of pre-harvest fungal infection and propagation largely depends on the prevailing environmental and climatic factors, which may differ from year to year and from region to region. It also depends on the presence of innocula, and the farming practices that are employed. The degree of damage to the roots made during harvest or by rodents, insects and other organisms also influences the severity of contamination. Good agricultural practices (GAP) and good manufacturing practices (GMP) could play a major role in reducing the severity of contamination. Storage duration may play a role in mycotoxin production, as it is known that the risk of postharvest fungal infection and production of mycotoxins in stored grain increases with the storage duration as indicated in the *Code of practice for the prevention and reduction of mycotoxin contamination in cereals* (CXC 51-2003).
- 4. There are many species and cultivars of cassava. Edible types are classified into one of two categories, bitter and sweet, depending on the cyanogenic glycoside levels. The bitter and sweet varieties have high (≥ 100 mg/kg) and low (≤ 50 mg/kg) hydrocyanic acid (HCN) content, respectively as indicated in the *Code of practice for the reduction of hydrocyanic acid in cassava and cassava products* (CXC 73-2013). Cassava roots are usually processed and consumed in various forms, which may differ across countries. However, the primary reason for processing cassava root is to reduce the cyanogenic glycoside content. The presence of certain mycotoxins in cassava and cassava-based products destined for human food and animal feed use is not unexpected. Therefore, it is important to diligently monitor products and processes for indications of the various conditions that promote fungal contamination and mycotoxin accumulation.
- 5. This Code of Practice provides science-based information for all countries to contemplate in their efforts to prevent and reduce mycotoxin contamination in cassava and cassava-based products.
- 6. The effectiveness of this Code of Practice will be determined by regulatory authorities, extension educators, farmers, producers, processors, distributors, and food business owners in each country by considering the general principles and examples of GAP and GMP provided in the Code. Additionally, other local crops, climate, and agronomic practices should be examined to facilitate implementation of these practices where applicable. This Code of Practice is expected to apply to all cassava and cassava-based products relevant to human dietary intake and health, as well as international trade.
- 7. This Code of Practice provides information on general principles for the reduction of various mycotoxins in cassava and cassava-based products. In addition, it provides a basis for training and education of farmers, agricultural workers, processors, manufacturers, and distributors.

2. SCOPE

8. This Code of Practice covers cassava and cassava-based products meant for human consumption and intends to provide national and local authorities, farmers, producers, manufacturers, distributors and other relevant bodies with information and guidance to aid in the prevention and reduction of mycotoxin contamination in cassava and cassava-based products. This guidance covers: Good Agricultural Practices (GAP), Good Manufacturing Practices (GMP), Good Storage Practices (GSP) and Good Distribution Practices (GDP).

3. RECOMMENDED PRACTICES APPLICABLE TO PRE-PLANTING STAGE

Site Selection

9. The farmer should avoid planting in valleys, to avoid pooling water and flooding. Water can transport fungal innoculums. Where possible, ensure proper planning for crop rotation in successive seasons. This will help in reducing innocula in the farm which may be present from post-harvest waste that harbours toxigenic fungal spores. Particular crops (e.g., groundnuts, maize and sugarcane) have been found to be susceptible to certain species of toxigenic fungi and rotating planting with these crops should be monitored and evaluated. Crops that are said to be of low susceptibility to toxigenic fungi should be used in rotation to reduce the cross contamination from inoculum.

Farmland clearing and preparation

10. After selecting appropriate sites for planting, the land should be cleared, and waste properly disposed of to avoid contamination of the cassava roots with innocula from infected weed or other crops. The soil should be loosened by tilling using clean (sanitized) and suitable farm tools and equipment to reduce stress to cassava roots. This is particularly critical during the root growth and maturation period and also to promote healthy root development. Farmers are encouraged to adopt good agricultural practices.

Cassava variety (cultivar) and seed selection

11. Selection and use of healthy, pest- and disease-free cassava stems are important for good planting. The ability to resist fungi and other plant pathogens should be considered when selecting cassava varieties. Cassava cuttings that are free of fungi should be planted.

4. RECOMMENDED PRACTICES APPLICABLE TO PLANTING AND PRE-HARVEST STAGE

Planting

- 12. To prevent fungal growth no infected (having rotting spots) stem should be planted. Planting practices that have been reported to prevent rot could be adopted including *vertical planting* which involves placing the cassava cuttings vertically to avoid rot, especially during the rainy season.
- 13. In addition, planting material may be dipped in a fungicide/insecticide/nutrient solution in an attempt to reduce soil-borne pathogens and are recommended for pre-planting treatment. Planting stakes should be dipped for 5 minutes in prophylactic fungicide/insecticides/nutrient solutions as guided by label instructions. The dipped stake should then be allowed to dry, and be placed in a shaded, well-ventilated area before field planting.
- para. 13 bis Where possible, planting cassava on any land where groundnut, maize, sugarcane, or other highly susceptible crops were cultivated the previous year is not recommended or would need to ensure the soil has not been contaminated with *A. flavus*, *A. parasiticus* and other related species.

4.2 Weed control

- 14. Certain weeds can harbour toxigenic fungi and compete for moisture, light and nutrients thereby stifling cassava plant development. Either manual or mechanical approaches can be used for weed control, approved herbicides could also be used.
- 15. The use of post emergence herbicide could be recommended immediately once weeds are spotted on the field. In some cases, pre-emergence herbicides could be used before planting to minimize weed growth. Small-scale farms could use hoes and cutlasses to remove weeds, however, care should be taken to prevent mechanical injury of the cassava plants. Note that land preparation needs to be done properly to control the weeds, at least for the first 3 months.

4.3 Pesticide use

16. Approved pesticides could be used to minimize insect damage and fungal infection in the soil or around the crop. Weather models could be used to plan the best pesticide type and application timing. When applying pesticides, users should follow all label instructions to ensure the safe and proper use of the pesticide product. Where needed, ensure access to agrochemicals authorized for use.

4.4 Irrigation

17. Where 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 root maturation provides favourable condition for fungal infections, thus, sprinkle irrigation during anthesis and the maturation of the roots should be avoided.

5. RECOMMENDED PRACTICES APPLICABLE TO HARVEST STAGE

5.1 Harvesting

- 18. Harvesting should involve adequate planning in order to maintain quality and prevent crop wastage and possible rot. The amount of roots to be harvested should be determined based on market needs and demand.
- 19. Cassava should be harvested when the soil is slightly soft and not overly saturated, in order to easily remove soil from the roots and avoid fungal contamination during peeling.
- 20. However, to meet market demand, cassava roots may be harvested all through the different climatic seasons. As such, it is necessary that measures be taken to prevent or reduce damages to harvested cassava roots, especially for hard soils, to prevent fungal growth after damage.

5.2 Conveyance tools

21. Containers and conveyances (e.g., trucks) used for collecting and transporting the harvested roots from the field to processing and storage facilities, should prevent mechanical damage to cassava roots and be cleaned, sanitized, and dried.

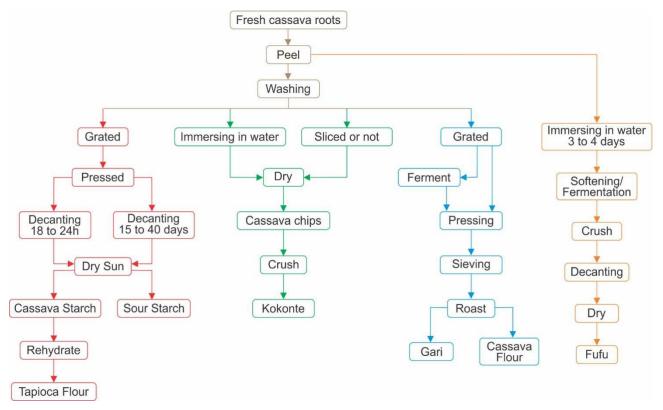
5.3 Holding conditions

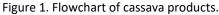
- 22. Prior to the processing step and while being held for use, cassava roots should not be exposed to the sun, high temperatures, mechanical damage, or other conditions that could promote fungal contamination, since the roots still have a high-water activity suitable for microbial development. Water activity (a_w), is commonly defined in foods as the water that is not bound to food molecules and that can support the growth of bacteria, yeasts, and fungi. A continuous progression from harvest to final product should be planned, so that the roots will not be stored for a long period. The ideal time is 2 to 3 days without enhanced storage methods.
- 23. Cassava roots should be stored in a suitable storage room. Enhanced storage methods of fresh cassava roots, such as storing in low temperatures in combination with fungicide treatment or waxing, can help extend shelf life of fresh roots by 2 to 6 weeks. This practice is suitable for storing or exporting large amounts of roots. Food handlers that can afford specialized equipment with the necessary technical skills may use improved storage methods to store fresh roots for preservation.

6. RECOMMENDED PRACTICES APPLICABLE TO POST-HARVEST STAGES

6.1 Cassava-based products

24. Cassava roots can be processed into various fermented or non-fermented cassava-based products. These products, which may be specific to certain regions, have a wide range of applications including food for humans. The processing steps by which these various products are obtained differ and can be found in the *Code of practice for the reduction of hydrocyanic acid in cassava and cassava products* (CXC 73-2013). The approach here is to mention some of the various steps that may potentially influence fungal contamination but not for any specific product type (for some product types see Figure 1). Processing of cassava should be initiated within 8-12 hours of receiving cassava roots as a raw material to avoid spoilage.





6.1.1 Washing

25. After harvest if cassava root is to be processed immediately it should be washed to remove the surface dirt and soil thus reducing innoculums of toxigenic fungal species. The source of water is an important factor to be considered, also. Either potable water or water treated such in a way that it makes it fit for its intended purpose should be used for washing to avoid potential contamination. Proper washing is vital to ensure sand or mud is removed from all parts of the root, especially the contours.

6.1.2 Peeling

26. Immediately after washing, peeled cassava roots should be processed and should not be stored unprocessed. Peeling is either done manually using a knife or is done mechanically. It is done to remove the outer inedible portion of the cassava roots. Peeling should be carried out in a clean environment, and not in one where other crops have been stored, otherwise, it may serve as a source of contamination for the cassava.

6.1.3 Boiling / steaming

27. For the processing of roots of sweet cassava varieties, it is recommended to boil or steam the roots immediately after peeling and washing. This will expose any fungus to temperatures they cannot survive. If not used, immediately, adequate care should be taken to prevent fungal re-contamination.

6.2 Size reduction: Grating, pulping and slicing or chipping

- 28. Where further processing of washed cassava roots includes size reduction activities, regardless of the size of the roots to be further processed, cassava variety, or type of available equipment, adequate care must be taken to ensure such unit processing does not lead to fungal contamination.
- 29. Where cassava chips or slices are dried at farm level or in a processing facility, the chips or slices should be dried on a cleaned, dry, raised platforms and at appropriate distance away from probable sources of contamination, such as refuse dumps. When sun-drying is carried out, it should be done on raised platforms that would ensure good hygienic practice.
- 30. If chips or slices are dried artificially, the dryers' thermostat should be optimally maintained to achieve the acceptable moisture content of the cassava and cassava-based products at the right time to prevent mould growth.
- 31. Unhygienic practices at this stage could serve as potential sources of fungal innoculum. Therefore, the environment and all tools used should be kept clean in all steps of processing.

6.2.1 Fermentation

32. The fermentation of cassava roots is primarily used for further cyanide elimination, flavour development and product stability. All containers and equipment used in fermentation should remain clean at all times to ensure they do not become a natural source of innoculum. Fermentation typically takes place over 2 to 5 days.

6.2.2 Dewatering

33. This process involves removing water from grated cassava roots and it is usually done by pressing. The dewatering process could last up to two days. Dewatering could be done before or after fermentation. Water removal should be optimal, and care should be taken not to use contaminated processing materials such as contaminated sacks as they may become sources of fungi innoculums. Food grade sacks should be used. Adequate cleaning and sterilization of the sacks should be done frequently.

6.3 Cake breaking / granulating

34. The process involves feeding the cassava cake into a cassava grater that will break it into granules. Wet cakes can be sifted to remove lumps. Where a cassava grater is not available, a manual sifter is most often used to break the cake and sift the granules at the same time. The grater should be clean and the sacks containing cake or granules should not be placed on dirty surfaces (such as floors). Clean containers should be used to hold the wet granules to ensure product is not contaminated. Clean pans, bowls or sacks should be used in emptying the cakes.

6.4 Drying

35. Cassava should be dried to acceptable moisture content to prevent fungal growth and subsequent mycotoxins production. High microbial loads may be caused by use of unclean drying surfaces and materials, so care must be taken to clean surfaces. Granules or chips should be properly spread per square meter of drying surface and should not be overloaded to allow for air circulation. Platforms for drying should be raised to prevent contamination such as dust, animals, and pests. Batches of granules not adequately dried should be spread out in a ventilated room until the products are dried. Drying surfaces and materials should be clean.

6.5 Milling

36. The environment should be monitored to prevent cross contamination from dust. The dried flour should be stored in a clean moisture-proof container. The milling machine should be cleaned and dried after use.

6.6 Sieving

37. The sieve to be used in further processing steps should be stored properly and cleaned with potable water and completely dried before use.

6.7 Frying

38. Frying of gari among other fermented cassava products should be done at high temperatures and monitored in order to discourage fungal proliferation.

7. STORAGE

- 39. Storage facilities should be cleaned and can be disinfected with approved fumigants and pesticides before materials are brought in, to remove dust, fungal spores, crop residues, animal and insects' droppings, soil, insects and foreign materials (e.g., stones, metal and broken glass, and other sources of contamination). Sheds, silos, bins, and other building materials intended for cassava and cassava-based product storage should be dried and well ventilated. Contamination from the ground water, moisture condensation, rain, entry of rodents, and insect activities can make the commodities more susceptible to fungal infection. Ideally, storage areas should be able to prevent wide temperature fluctuations. Temperature and humidity can be monitored and controlled where possible
- 40. Packaged cassava and cassava-based products should be stored in dry and cool conditions. Prevent direct contact with the floor or walls.
- 41. Determine moisture content of the lot, and if necessary, dry the product to the suitable moisture content recommended prior to storage. Fungal growth is closely related with water activity (a_w), and it is recognized that fungal growth is inhibited at a_w of less than 0.60. In addition, safe storage guidance may be provided to reflect the environmental situation in each region.

8. PACKAGING

42. Moisture content of cassava-based products mainly in form of flour and granules shall be monitored before packaging to avoid packing a product that will favour the growth of micro-organisms. Cassava and cassava-based products should be packaged in food grade materials. Packaging materials should be made of materials, which should not absorb moisture when packed and sealed. Where necessary, packaging technologies such as vacuum and modified atmosphere packaging can be applied.

9. TRANSPORTATION

- 43. Transport containers, including vehicles such as trucks and railway vessels, boats and ships should be dry and free of old crop dust, visible fungal growth, musty odour, insects, and any contaminated material that could contribute to mycotoxin levels in lots and cargoes of cassava and cassava-based products. As necessary, transport containers should be cleaned and disinfected with appropriate substances (which should not cause off-odours, off-flavour or contaminate the cassava and cassava-based products) before use and re-use and be suitable for the intended cargo. At unloading, the transport container should be emptied of all cargo and cleaned as appropriate.
- 44. Shipments of cassava and cassava-based products 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 cassava and cassava-based products, which could lead to local moisture build-up and consequent fungal growth and mycotoxin formation.
- 45. Avoid pest infestation during transport by the use of pest proof containers

10. PRODUCT INFORMATION AND CONSUMER AWARENESS

46. Specific storage instructions for the cassava and cassava-based products should be provided on the packaging to ensure protection from unfavourable conditions, which may promote fungi growth and contamination. The instructions for storage before (e.g., store in a cool, dry, well-ventilated area) and after the product is opened should be legible and in clear language, in order to maintain product quality.

APPENDIX IV

SAMPLING PLANS FOR TOTAL AFLATOXINS IN CERTAIN CEREALS AND CEREAL-BASED PRODUCTS INCLUDING FOODS FOR INFANTS AND YOUNG CHILDREN (For adoption at Step 5/8)

Sampling plans and performance criteria for aflatoxin (AFB1+AFB2+AFG1+AFG2) in maize grain, destined for further processing.

Maximum level	15 μg/kg AFB1+AFB2+AFG1+AFG2	
Increments	Increments of 100 g, depending on the lot weight (\geq 0.5 tons)	
Sample preparation	dry grind with a suitable mill (particles smaller than 0.85 mm – 20 mesh)	
Laboratory sample weight	≥5 kg	
Number of laboratory samples	1	
Test portion	25 g	
Method	Selected according to the established performance criteria in Table 3	
Decision rule	If the sum of test results of AFB1, AFB2, AFG1 and AFG2 for the laboratory sample is equal to or less than 15 μ g/kg, accept the lot. Otherwise, reject the lot.	

Sampling plans and performance criteria for aflatoxin (AFB1+AFB2+AFG1+AFG2) in flour meal, semolina and flakes derived from maize

Maximum level	10 μg/kg AFB1+AFB2+AFG1+AFG2
Increments	10 x 100 g
Sample preparation	dry grind with a suitable mill (particles smaller than 0.85 mm – 20 mesh), if necessary for coarse samples
Laboratory sample weight	1 kg
Number of laboratory samples	1
Test portion	25g
Method	Selected according to the established performance criteria in Table 3
Decision rule	If the sum of test results of AFB1, AFB2, AFG1 and AFG2 for the laboratory sample is equal to or less than 10 μ g/kg, accept the lot. Otherwise, reject the lot

Sampling plans and performance criteria for aflatoxin (AFB1+AFB2+AFG1+AFG2) in husked rice

Maximum level	20 μg/kg AFB1+AFB2+AFG1+AFG2	
Increments	Increments of 100 g, depending on the lot weight (<u>></u> 0.5 tons)	
Sample preparation	dry grind with a suitable mill (particles smaller than 0.85 mm – 20 mesh)	
Laboratory sample weight	≥5 kg	
Number of laboratory samples	1	
Test portion	25 g	
Method	Selected according to the established performance criteria in Table 3	
Decision rule	If the sum of test results of AFB1, AFB2, AFG1 and AFG2 for the laboratory sample is equal to or less than 20 μ g/kg, accept the lot. Otherwise, reject the lot	

Sampling plans and performance criteria for aflatoxin (AFB1+AFB2+AFG1+AFG2) in polished rice

Maximum level	5 μg/kg AFB1+AFB2+AFG1+AFG2	
Increments	Increments of 100 g, depending on the lot weight (<u>></u> 0.5 tons)	
Sample preparation	dry grind with a suitable mill (particles smaller than 0.85 mm – 20 mesh)	
Laboratory sample weight	≥5 kg	
Number of laboratory samples	1	
Test portion	25g	
Method	Selected according to the established performance criteria in Table 3	
Decision rule	If the sum of test results of AFB1, AFB2, AFG1 and AFG2 for the laboratory sample is equal to or less than 5 μ g/kg, accept the lot. Otherwise, reject the lot	

Sampling plans and performance criteria for aflatoxin (AFB1+AFB2+AFG1+AFG2) in sorghum

Maximum level	10 μg/kg AFB1+AFB2+AFG1+AFG2
Increments	Increments of 100 g, depending on the lot weight (<u>></u> 0.5 tons)
Sample preparation	dry grind with a suitable mill (particles smaller than 0.85 mm – 20 mesh)
Laboratory sample size	≥5 kg
Number of laboratory weight	1
Test portion	25 g
Method	Selected according to the established performance criteria in Table 3
Decision rule	If the sum of test results of AFB1, AFB2, AFG1 and AFG2 for the laboratory sample is equal to or less than 10 $\mu g/kg$, accept the lot. Otherwise, reject the lot

Sampling plans and performance criteria for aflatoxin (AFB1+AFB2+AFG1+AFG2) in cereal-based food for infants and young children

Maximum level	5 μg/kg AFB1+AFB2+AFG1+AFG2
Increments	10 x 100 g
Sample preparation	dry grind with a suitable mill (particles smaller than 0.85 mm – 20 mesh), if necessary for coarse samples
Laboratory sample weight	1 kg
Number of laboratory samples	1
Test portion	25g
Method	Selected according to the established performance criteria in Table 3
Decision rule	If the sum of test results of AFB1, AFB2, AFG1 and AFG2 for the laboratory sample is equal to or less than 5 μ g/kg, accept the lot. Otherwise, reject the lot

Sampling plans and performance criteria for aflatoxin (AFB1+AFB2+AFG1+AFG2) in cereal-based food for infants and
young children destined for food aid programs

Maximum level	10 μg/kg AFB1+AFB2+AFG1+AFG2	
Increments	10 x 100 g	
Sample preparation	dry grind with a suitable mill (particles smaller than 0.85 mm – 20 mesh), if necessary for coarse samples	
Laboratory sample size	1 kg	
Number of laboratory weight	1	
Test portion	25g	
Method	Selected according to the established performance criteria in Table 3	
Decision rule	If the sum of test results of AFB1, AFB2, AFG1 and AFG2 for the laboratory sample is equal to or less than 10 μ g/kg, accept the lot. Otherwise, reject the lot	

Definitions:

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	It is defined by an aflatoxin test procedure and an accept/reject level. An aflatoxin test procedure consists of three steps: sample selection, sample preparation and analysis or aflatoxin 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 cereal grains, shelled cereal grains and cereal-based products 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 aflatoxin for chemical analysis.

SAMPLING PLAN DESIGN CONSIDERATIONS

MATERIAL TO BE SAMPLED

 Each lot of cereal grains and cereal-based products, which is to be examined for AFs, must be sampled separately. Lots larger than 50 tons should be subdivided into sublots to be sampled separately. If a lot is greater than 50 tons, the lot should be subdivided into sublots according to Table 1.

Table 1. Subdivision of cereal grains sublots according to lot weight: Maize grain, sorghum, polished rice and husked rice

Lot weight (t)	Maximum weight or minimum number of sublots	Number of incremental samples	Minimum laboratory sample weight (kg)
<u>≥</u> 1500	500 tons	100	5
> 300 and < 1500	3 sublots	100	5
<u>></u> 100 and ≤ 300	100 tons	100	5
<u>></u> 50 and < 100	2 sublots	100	5
< 50	-	3 - 100*	5

*see Table 2

2. Considering 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 size by a maximum of 20%.

INCREMENTAL SAMPLE

- 3. The suggested minimum size of the incremental sample of cereal grains and cereal-based products should be 100 g for lots \geq 0.5 tons.
- 4. For lots less than 50 tons of cereal grains and cereal-based products, the sampling plan must be used with 3 to 100 incremental samples, depending on the lot weight. For very small lots (< 0.5 tons) 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 5 kg. Table 2 may be used to determine the number of incremental samples to be taken.

Table 2. Number of incremental samples of cereal grains to be taken depending on the weight of the lot: Maize grain, sorghum, polished rice, and husked rice

Lot weight (t)	Number of incremental samples	Minimum laboratory sample weight (kg)
<u>≤</u> 0.05	3	5
> 0.05 - <u><</u> 0.5	5	5
> 0.5 - <u><</u> 1	10	5
> 1 - < 3	20	5
> 3 - <u><</u> 10	40	5
> 10 - <u><</u> 20	60	5
> 20 - < 50	100	5

STATIC LOTS

- 5. A static lot can be defined as a large mass cereal grains and cereal-based products 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 grains and cereal-based products 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 sublot 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 size (LT), incremental sample size (IS), aggregate sample size (AS) and the individual packing size (IP), as follows:

 $SF = (LT \times IS)/(AS \times IP).$

8. The sampling frequency (SF) is the number of packages sampled. All sizes 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 cereal grains and cereal-based products 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.

SEALING AND LABELLING OF SAMPLES

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 PRECAUTIONS

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

HOMOGENIZATION - GRINDING

- 17. As the distribution of aflatoxin is extremely non-homogeneous, laboratory samples should be homogenized by grinding the entire laboratory sample received by the laboratory. Homogenization is a procedure that reduces particle size and disperses the contaminated particles evenly throughout the comminuted laboratory sample.
- 18. The laboratory sample should be finely ground and mixed thoroughly using a process that approaches as complete homogenization as possible. Complete homogenization implies that particle size is extremely small, and the variability associated with sample preparation is minimized. After grinding, the grinder should be cleaned to prevent aflatoxin cross-contamination.

TEST PORTION

- 19. The suggested weight of the test portion taken from the comminuted laboratory sample should be approximately 25 g. If the laboratory sample is prepared using a liquid slurry, the slurry should contain 25 g.
- 20. Procedures for selecting the 25 g test portion from the comminuted laboratory sample should be a random process. If mixing occurred during or after the comminution process, the 25 g test portion can be selected from any location throughout the comminuted laboratory sample. Otherwise, the 25 g test portion should be the accumulation of several small portions selected throughout the laboratory sample.

ANALYTICAL METHODS

21. 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 is shown in Table 3. Utilizing this approach, laboratories would be free to use the analytical method most appropriate for their facilities.

Commodity	Analyte	ML (µg/kg)	LOD (µg/kg)	LOQ (µg/kg)	Precision (%)	Minimal applicable range (µg/kg)	Recovery (%)
Maize grain	AF B1+B2+G1+G2	15	≤ 3	≤ 6	<u><</u> 44	8.4 - 21.6	60 - 115
	AFB1	-	≤ 1.5	≤ 3.0	<u>< 44</u>	4.2 - 10.8	60 - 115
	AFB2	-	≤ 0.5*	≤ 1*	<u><</u> 44	1.4 - 3.6	40 - 120
	AFG1	-	≤ 0.5*	≤ 1*	<u><</u> 44	1.4 - 3.6	40 - 120
	AFG2	-	≤ 0.5*	≤ 1*	<u><</u> 44	1.4 - 3.6	40 - 120
Maize flour, meal, semolina, and flakes derived from maize; Sorghum grain; cereal- based foods for infants and young children for food aid programs	AF B1+B2+G1+G2	10	≤ 2	≤ 4	<u><</u> 44	5.6 - 14.4	60 - 115
	AFB1	-	≤ 1.0	≤ 2.0	<u><</u> 44	2.8 - 7.2	60 - 115
	AFB2	-	≤ 0.33*	≤ 0.67*	<u><</u> 44	0.9 - 2.4	40 - 120
	AFG1	-	≤ 0.33*	≤ 0.67*	<u>< 44</u>	0.9 - 2.4	40 - 120
	AFG2	-	≤ 0.33*	≤ 0.67*	<u>< 44</u>	0.9 - 2.4	40 - 120
Husked Rice	AF B1+B2+G1+G2	20	≤ 4	≤ 8	<u>< 44</u>	11.2 - 28.8	60 - 115
	AFB1	-	≤ 2.0	≤ 4.0	<u>< 44</u>	5.6 - 14.4	60 - 115
	AFB2	-	≤ 0.67*	≤ 1.33*	<u><</u> 44	1.9 - 4.8	60 - 115
	AFG1	-	≤0.67*	≤1.33*	<u><</u> 44	1.9 - 4.8	60 - 115
	AFG2	-	≤ 0.67*	≤ 1.33*	<u>< 44</u>	1.9 - 4.8	60 - 115
Polished Rice; Cereal-based food for infants and young children	AF B1+B2+G1+G2	5	≤1	≤ 2	<u><</u> 44	2.8 - 7.2	40 - 120
	AFB1	-	≤ 0.5	≤ 1	<u><</u> 44	1.4 - 3.6	40 - 120
	AFB2	-	≤ 0.17*	≤ 0.33*	<u><</u> 44	0.5 - 1.2	40 - 120
	AFG1	-	≤ 0.17*	≤ 0.33*	<u><</u> 44	0.5 - 1.2	40 - 120
	AFG2	-	≤ 0.17*	≤ 0.33*	< 44	0.5 - 1.2	40 - 120

*If those values could not be validated, LOD and LOQ for AFB2, AFG1 and AFG2 could be up to parameters for AFB1.

APPENDIX V

MAXIMUM LEVELS FOR TOTAL AFLATOXINS AND OCHRATOXIN A IN CERTAIN SPICES

(For adoption at Step 5/8)

Ochratoxin A

Commodity/ Product Name	Maximum Level (ML) µg/kg	Portion of the Commodity/Product to which the ML applies	Notes/Remarks
Chili pepper, paprika, nutmeg	20	Whole/Powder/Crushed/Ground	Spices (dried/dry)

Total Aflatoxins

Commodity/ Product Name	Maximum Level (ML) µg/kg	Portion of the Commodity/Product to which the ML applies	Notes/Remarks
Chili pepper, nutmeg	20	Whole/Powder/Crushed/Ground	Spices (dried/dry)

APPENDIX VI

PROPOSAL FOR A NEW WORK ON A CODE OF PRACTICE/GUIDELINES FOR THE PREVENTION OR REDUCTION OF CIGUATERA POISONING PROJECT DOCUMENT (For approval)

1) Purpose and scope of the project

The purpose of the proposed new work is to develop a code of practice (COP) or guidelines to prevent or reduce ciguatera poisoning based upon work already undertaken by the Food and Agriculture Organization of the United Nations (FAO) in collaboration with the World Health Organization (WHO), the International Atomic Energy Association (IAEA) and the Intergovernmental Oceanographic Commission of the United Nations Educational, Scientific and Cultural Organization (IOC-UNESCO). Ciguatera poisoning (CP) has become a global health issue and is increasing in prevalence due to factors that include climate change. Coastal communities that rely on local fishing as a food supply and as a source of income are particularly at risk from increasing occurrences of ciguatera poisoning.

The scope of the work is to complete a CoP/guidelines to prevent or reduce ciguatera poisoning based on a discussion paper developed by an electronic Working Group (EWG) established in 2022.

2) Relevance and timeliness

In 2016, at the 32nd Session of the Codex Committee on Fisheries and Fishery Products, the Pacific Nations raised ciguatera poisoning as an issue that is increasingly affecting the tropical and subtropical regions of the Pacific Ocean, Indian Ocean, and Caribbean Sea between the latitudes of 35°N and 35°S. The issue of CP was raised at the 11th Session of the Codex Committee on Contaminants in Food (CCCF11, 2017). CCCF agreed to request scientific advice from FAO/WHO to enable the development of appropriate risk management options, resulting in the *FAO/WHO Report of the Expert Meeting on Ciguatera Poisoning*, published in 2020. CCCF15 (2022) agreed to establish an EWG chaired by the United States and co-chaired by the European Union to prepare a discussion paper on the development of a code of practice or guidelines to prevent or reduce ciguatera poisoning. The EWG was asked to build upon the work already undertaken by the FAO in collaboration with the International Atomic Energy Association (IAEA) and the Intergovernmental Oceanographic Commission of the United Nations Educational, Scientific and Cultural Organization (IOC-UNESCO).

3) Main aspects to be covered

This work will address measures for prevention or reduction of ciguatera poisoning including surveillance and monitoring programs, food safety management systems, data sharing, and consumer advice directed at various stakeholders such as competent authorities, fish sector operators (harvesters and producers), healthcare professionals, and consumers.

4) Assessment against the criteria for establishment of work priorities

- (a) Consumer protection from the point of view of health and fraudulent practices. To protect consumer health, exposure to ciguatera poisoning through consumption of contaminated seafood (e.g., fish) should be avoided. A CoP/guidelines providing recommendations to governments, fish sector operators (harvesters and producers), healthcare professionals, and consumers will help prevent contaminated seafood from entering the marketplace and enable consumers to avoid contaminated products.
- (b) Diversification of national legislations and apparent resultant or potential impediments to international trade. Currently, best practices and legislations. Development of a CoP/guidelines is needed to ensure that information on recommended practices for preventing and reducing ciguatera exposure is available to all member countries. It also will provide the means to enable exporters to ensure reduced risk of ciguatera poisoning and to assist in compliance with any MLs that may be established in the future.

(c) Scope of work and establishment of priorities between the various sections of the work.

The CoP/guidelines will address environmental measures, harvesting practices, safe production principles, government guidance and oversight, and consumer advice.

(d) Work already undertaken by other international organizations in this field. Work on ciguatera poisoning has been undertaken by several international organizations and public health agencies such as FAO, WHO, IOC-UNESCO, IAEA, EuroCigua, and the North Pacific Marine Science Organization ("PICES"), and who can be consulted in development of a CoP/guidelines. These organizations have made recommendations but have not offered a CoP/guidelines.

5) Relevance to Codex Strategic Goals

- (a) Goal 1 Address current, emerging and critical issues in a timely manner. Establishing a CoP/guidelines for prevention or reduction of ciguatera poisoning will address the current need for guidance to ensure the health of consumers.
- (b) Goal 2 Develop standards based on science and Codex risk-analysis principles. This work will apply risk analysis principles in the development of a CoP/guidelines by using scientific data and recommendations from FAO/WHO and other recognized expert bodies to support a reduction in exposure of consumers to ciguatera poisoning.
- (c) Goal 3 Increase impact through the recognition and use of Codex standards. The proposed CoP/guidelines ensure that information on recommended practices to prevent and reduce ciguatera poisoning consist of current best practices and are available to all member countries, especially those with fewer resources to devote to this topic.
- (d) Goal 4 Facilitate the participation of all Codex Members throughout the standard setting process. Developing a CoP/guidelines through the Codex Step process will make information on recommended practices to prevent and reduce ciguatera poisoning available to all Codex members.
- (e) Goal 5 Enhance work management systems and practices that support the efficient and effective achievement of all strategic plan goals. A CoP/guidelines will help ensure development and implementation of effective and efficient work management systems and practices by providing basic guidance for countries and producers to keep ciguatoxin-contaminated seafood out of the marketplace.

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

The *Code of Practice for Fish and Fishery Products* (CXC 52-2003) provides comprehensive technical guidance on the harvesting, processing, transport and sale of fish and fishery products. It does not give specific guidance as to the reduction or avoidance of CP but serves as a useful reference for further work on a CoP/guidelines.

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

The FAO has already provided needed expert scientific advice in the form of the FAO/WHO Report of the Expert Meeting on Ciguatera Poisoning, published in 2020. Additional scientific advice may be required as the work progresses.

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

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

9) Timeline for completion of the new work

Work will commence following recommendation by CCCF and approval by CAC in 2023. Completion of work is expected by 2027 or earlier.

APPENDIX VII

PRIORITY LIST OF CONTAMINANTS FOR EVALUATION BY JECFA

SECTION A: PRIORITY LIST OF CONTAMINANTS FOR EVALUATION BY JECFA

Contaminants	Background and question(s) to be answered	Data availability (when, what)	Proposed by
Dioxins and dioxin-like PCBs	Full evaluation (toxicological assessment and exposure assessment) to update 2001 JECFA assessment and incorporate data on developmental effects from in utero exposures.	EFSA: Assessment available September 2018 WHO: Expert consultation to develop TEFs held in October 2022; report expected in 2023. Brazil: Occurrence data on milk, raw eggs, fish, and fat (poultry and mammals) Canada: Occurrence data on foods of animal origin	Canada
Arsenic (inorganic and organic)	Inorganic: 2011 JECFA evaluation based on cancer effects. This evaluation would focus on non-cancer effects (neurodevelopmental, immunological and cardiovascular) and could inform future risk management needs. <u>NOTE</u> : Needs to be put in context to cancer risk assessment. <u>Organic</u> : (exploratory)	Australia/New Zealand: Total diet study; inorganic arsenic occurrence data in rice Brazil: Occurrence data on total arsenic in rice, poultry, pork, fish, and cattle meat, inorganic arsenic occurrence data in rice Canada: Occurrence data on inorganic and total arsenic in a variety of commercial foods. Chile: Occurrence data on inorganic and total arsenic in algae, crustaceans, gastropods, bivalve molluscs and small fish. EU: Inorganic arsenic occurrence data India: Occurrence data in rice Japan and China: Occurrence data on rice and rice products New Zealand: Inorganic arsenic occurrence data in seafood Turkey: Occurrence data in rice USA: Occurrence data in rice USA: Occurrence data in rice products; 2016 risk assessment. USA: Studies: Neurodevelopmental studies of inorganic arsenic impacts on rat behavior (2019, 2022) Toxicokinetic studies on metabolism and disposition of inorganic and organic arsenic and metabolites in mice (various life stages) (2018-20)	USA

Contaminants	Background and question(s) to be answered	Data availability (when, what)	Proposed by
		 Developmental toxicity test in <i>C. elegans</i> on inorganic arsenic (2018) and ongoing study on organic arsenic. Non-governmental report, Effects of Inorganic Arsenic in Infant Rice Cereal on Children's 	
Scopoletin	Full evaluation (toxicological assessment and exposure assessment) in fermented noni juice	Neurodevelopment (2017) CCNASWP16 finalized the regional standard for fermented noni juice. and agreed to request CCCF to retain scopoletin on the priority list and to call upon Codex members to generate and submit data to support the conduct of the safety evaluation by JECFA. CCNASWP15 has also requested FAO and WHO to organize a new call for data for the safety evaluation of scopoletin. FAO reminded that a full dataset including exposure and toxicity is required.	CCNASWP
		A consultant was hired by the Codex Secretariat to undertake a toxicological review of scopoletin as presented in the Annex to CX/CF 21/14/2-Add.1.	
Thallium	Full evaluation (toxicological assessment and exposure assessment)	<u>EU</u> : Two EFSA assessments, occurrence data <u>New Zealand</u> : Total Diet Study data <u>USA:</u> Occurrence data on brassica- containing foods, in baby foods, and in Total Diet Study results. U.S. National Toxicology Program is conducting studies on thallium (I) sulfate.	United States
Perfluoroalkyl substances (e.g., PFOS, PFOA, PFNA, PFHxS)	Full evaluation (toxicological assessment and exposure assessment)	<u>EU</u> : Occurrence data <u>Japan</u> : Occurrence data <u>Singapore</u> : Occurrence data <u>USA</u> : Occurrence data from FDA Total Diet Study and targeted surveys (seafood, bottled water, and milk). Occurrence data in meat and poultry from the USDA National Residue Program. Toxicology/risk assessments from US Agency for Toxic Substances Disease Registry and Environmental Protection Agency.	Singapore

Contaminant/ Commodity	Background and question(s) to be answered	Data call	Output
MLs for Cadmium and lead in quinoa	CCCF14 upon request from CAC agreed to request the JECFA Secretariat to consider whether the MLs for cadmium and lead in CXS193 for cereal grains could be extended to quinoa (pseudo-cereal) or whether new / separate MLs for quinoa should be established	JECFA Secretariat to issue call for data on Cd and Pb in quinoa and quinoa-based products, including foods for infants and young children. See REP23/CF16, para 133(vii)	JECFA Secretariat to prepare an analysis of the data and a discussion paper for for CCCF17.

SECTION B: OTHER MATTERS FOR ACTION BY JECFA SECRETARIAT