# CODEX ALIMENTARIUS COMMISSION





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REP21/CF

# JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX ALIMENTARIUS COMMISSION

44<sup>th</sup> Session Geneva, Switzerland 8 – 13 November 2021

REPORT OF THE 14<sup>th</sup> SESSION OF THE CODEX COMMITTEE ON CONTAMINANTS IN FOODS

(virtual) 3-7 and 13 May 2021 REP21/CF i

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Discussion Comments Consideration	MLs for total aflatoxins in cereals and cereal-based products including foods for infants and young children	CXS 193-1995	2/3/4	para. 137
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Responsible					Appendices &
Party	Purpose	Text/Topic	Code	Step	Paragraphs
CCEXEC81 CAC44 JECFA EWG (New Zealand and Canada) Members and Observers CCCF15	Critical Review Approval Discussion Comments Consideration	MLs for methylmercury in orange roughy and pink cusk eel	CXS 193-1995	1/2/3/4	Appendix VI para. 166
CCEXEC81 CAC44 EWG (Nigeria and Ghana) Members and Observers CCCF15	Critical Review Approval Discussion Comments Consideration	Code of practice for the prevention and reduction of mycotoxins contamination in cassava and cassava-based products		1/2/3/4	Appendix VII para. 169
CCCF14		MLs for HCN in cassava and cassava- based products	CXS 193-1995	Discontinued	para. 172
JECFA CCCF15	Discussion Consideration	MLs for cadmium and lead in quinoa	CXS 193-1995		para. 180
CCCF14		Radioactivity in food, feed and drinking water in normal circumstances		Discontinued	Para. 185
EWG (EU, Japan, Netherlands and USA) CCCF15	Discussion Consideration	Guidance on data analysis for development of MLs and for improved data collection			para. 208
Codex Secretariat Members/observers In-session WG (Canada) CCCF15	Comments Discussion Consideration	Approach to identify the need for revision of standards and related texts for contaminants in food and feed			para. 218
Codex/JECFA/ Host Country Secretariats CCCF15	Discussion Consideration	Forward work plan for CCCF		1	paras. 223 and 228
JECFA Members and Observers In-session WG (USA) CCCF15 CCNASWP16	Evaluation Comments Discussion Consideration	Priority list of contaminants for evaluation by JECFA		-	Appendix VIII para. 231
Members and Observers EWG and In-session WG (EU) CCCF15	Comments Discussion Consideration	Follow-up work to the outcomes of JECFA evaluations and FAO/WHO expert consultations		-	para. 235

# LIST OF ABBREVIATIONS

AF(s)	Aflatoxin(s)	
AFT 1	Total aflatoxins	
ALARA A	As Low As Reasonable Achievable	
CAC (	Codex Alimentarius Commission	
CCASIA F	FAO/WHO Coordinating Committee for Asia	
CCCF (	Committee on Contaminants in Foods	
CCEXEC E	Executive Committee	
CCFA (	Codex Committee on Food Additives	
CCFH (	Codex Committee on Food Hygiene	
CCLAC F	FAO/WHO Coordinating Committee for Latin America and the Caribbean	
CCMAS (	Codex Committee on Methods of Analysis and Sampling	
CCNASWP F	FAO/WHO Coordinating Committee for North America and South West Pacific	
CCRVDF (	Codex Committee on Residues of Veterinary Drugs in Foods	
CCSCH (	Codex Committee on Spices and Culinary Herbs	
CL (	Circular Letter	
COP (	Code of Practice	
CRD (	Conference Room Document	
DON [	Deoxynivalenol	
EU E	European Union	
EFSA E	European Food Safety Authority	
EWG E	Electronic Working Group	
FAO F	Food and Agriculture Organization	
GEMS/Food (	Global Environment Monitoring System	
GMP(s)	Good Manufacturing Practice(s)	
GSCFF (	General Standard for Contaminants in Food and Feed	
HBGV(s)	Health Based Guidance Value(s)	
HCN I	Hydrocyanic acid/hydrogen cyanide	
IAEA I	International Atomic Energy Agency	
	Intergovernmental Oceanographic Commission of the United Nations Educational, Scientific and Cultural Organization	
JECFA J	Joint FAO/WHO Expert Committee on Food Additives	
LAC L	Latin America and the Caribbean	
LOQ I	Limit of Quantification	
ML(s)	Maximum Level(s)	
OTA (	Ochratoxin A	
PAs F	Pyrrolizidine alkaloids	
PTMI F	Provisional Tolerable Monthly Intake	
RTE F	Ready-To-Eat	
PCBs F	Polychlorinated biphenyls	
TEF 1	Toxicity equivalent factor	
	Toxicity equivalent factor  Tolerable weekly intake	

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UNSCEAR	United Nations Scientific Committee on the Effects of Atomic Radiation	
USA	United States of America	
WG	Working Group	
WHA	World Health Assembly	
WHO	World Health Organization	
WFP	World Food Program	

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# LIST OF CONFERENCE ROOM DOCUMENTS

CRD No.	Agenda Item	Submitted by
01	Division of Competence	EU (Division of Competence between EU and its Member States)
02	5, 6, 7, 8, 9, 10(a), 11, 12, 13, 14, 18, 20	Tanzania
03	2, 5, 7, 10(a), 10(b), 11, 12, 13, 14, 18	EU
04	2, 7, 9, 14, 15	Nigeria
05	5, 11	International Confectionery Association (ICA)
06	5, 6, 7, 8, 10a, 10b, 13, 14	Uganda
07	13	Japan
08	7, 8, 10(b), 13, 14, 15	Thailand
09	2, 8, 10(a), 14, 15	India
10	5, 6, 7, 8, 9, 10 (a), 10 (b), 13, 14, 15, 18	Republic of Korea
11	2, 11, 12, 13, 14, 16, 18, 19, 20	USA
12	2, 7, 8, 9, 14	Indonesia
13	5, 6, 7, 8, 9	Dominican Republic
14	5, 6, 10(a)	El Salvador
15	2, 5, 6, 7, 8, 9, 10(a), 10(b), 11, 12, 13, 18, 20	African Union (AU)
16	5, 6, 7, 8, 9, 10(a), 10(b), 11, 13, 14	Senegal
17	8	China
18	6, 7, 8, 9, 10(a), 15	Ecuador
19	8	Turkey
20	8, 9, 10(a), 10(b), 15	Mali
21	10(a)	World Food Program (WFP)
22	9 (Revised COP/Lead)	USA

#### INTRODUCTION

1. The Codex Committee on Contaminants in Foods (CCCF) held its 14<sup>th</sup> Session virtually, from 3 to 7 and 13 May 2021, at the kind invitation of the Government the Netherlands. The session was chaired by Dr. Sally Hoffer, Manager, Food Safety and Sustainable Food, Directorate Plant Agro Food Chains, Ministry of Agriculture, Nature and Food Quality, The Netherlands. The session was attended by 92 Member Countries, one Member Organization, and 32 observer organizations. The list of participants is contained in Appendix I.

#### **OPENING OF THE SESSION**

2. The session was opened by Ms Marije Beens, Director General for Agriculture and Food Quality of the Ministry of Agriculture, Nature and Food Quality in the Netherlands. Mr Steve Wearne, vice-Chairperson of the Codex Alimentarius Commission, also addressed the meeting.

#### **Division of Competence**

3. CCCF noted the division of competence between the European Union and its Member States, according to paragraph 5, Rule II of the Rules of Procedure of the Commission.

#### ADOPTION OF THE AGENDA (Agenda Item 1)1

- 4. CCCF:
  - i) noted that Agenda Items 17 and 19 would be discussed subject to availability of time and that no issues would be considered under Agenda Item 21 and
  - ii) adopted the provisional agenda as its Agenda for the session.

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

- 5. CCCF noted that some matters were for information only, and that certain issues would be considered under the relevant agenda items as follows:
  - Cadmium (Agenda Item 5 and 6).
  - Ciguatera toxins (Agenda Items 3 and 20).
  - Periodic review of Codex standards for contaminants (Agenda Item 18).
  - Scopoletin (Agenda Item 20).

#### **Executive Committee of the Codex Alimentarius Commission (CCEXEC78)**

### **Timeliness of Codex working documents**

6. CCCF noted that the Codex Secretariat would continue to work closely with the Chair of CCCF, Chairs of EWGs and the Host Country Secretariat on ways to improve work management of the Committee.

### Committee on Methods of Analysis and Sampling (CCMAS40)

Review of methods in the General Standard for Methods of Analysis and Sampling (CXS 234-1999)

7. A delegation noted that conversion to performance criteria was already contained in the *Guidelines for Establishing Numeric Values for Method Criteria* in the Procedural Manual but that some examples might need updating. The Codex Secretariat confirmed that the Guidelines in the PM should be followed, and if there were any need for amendments, this should be brought to the attention of CCMAS for their consideration.

- 8. CCCF acknowledged the *General Standard for Methods of Analysis and Sampling* (CXS 234-1999) as the single reference point for methods of analysis and sampling under the remit of CCMAS.
- 9. CCCF agreed:
  - i) to review the methods in the Standard for General Methods of Analysis for Contaminants (CXS 228-2001) with the view to transfer them to the General Standard for Methods of Analysis and Sampling (CXS 234-1999) if applicable and subsequent revocation of the Standard for General Methods of Analysis for Contaminants and

<sup>&</sup>lt;sup>1</sup> CX/CF 21/14/1

<sup>2</sup> CX/CF 21/14/2

ii) that Brazil with the assistance of the United States of America and Japan would review the methods in the *General Standard for Methods of Analysis for Contaminants* (CXS 228-2001) with the aim of assessing their appropriateness or replacement by other more appropriate methods and possible conversion to performance criteria for consideration by CCCF15 (2022). The work would focus only on those methods related to compounds in CXS 228-2001 that fall within the definition of contaminant.

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

- 10. The Representative of FAO summarized the information in the working document and highlighted the activities by JECFA90 (2020) and JECFA91 (2021), including the evaluation of some mycotoxins such as certain trichothecenes and ergot alkaloids, a group of substances evaluated for their potential presence in oils and fats when transported as a previous cargo as well as exposure assessment of cadmium. He further highlighted expert meetings convened by FAO and WHO that aimed to provide scientific advice on tropane alkaloids in food as well as ciguatera fish poisoning, and the FAO's publication on climate change that covered several food safety hazards including heavy metals, mycotoxins and marine toxins; he also presented other FAO work including the recent report on food safety aspects of edible insects, as well the ongoing reviews on microplastics and seaweed.
- 11. The Representative of WHO introduced progress of the work on dioxin and dioxin-like compounds, aiming to provide refined TEFs later in 2022. He further introduced microplastic issues, concerning implication on public health, stating that the report for the assessment of health risks of microplastics would be published in 2021, and drew the attention of CCCF14 to the WHO Global Strategy for Food Safety which was requested by a resolution of the World Health Assembly.
- 12. Several delegations expressed support for the new FAO report on edible insects<sup>4</sup>, stating that edible insects were a popular source of food in certain areas of the world. They reminded CCCF that CCASIA in the past had discussed the establishment of standards for edible insects and suggested CCCF take into consideration food safety aspects of edible insects.
- 13. With respect to how CCCF could consider food safety aspects of edible insects, the Codex Secretariat suggested considering it as a part of follow-up work to outcomes of FAO, WHO and JECFA under Agenda Item 20.

#### Conclusion

- 14. CCCF:
  - i) welcomed the report provided by FAO and WHO and
  - ii) agreed that any issues around edible insects, as well as the other issues raised in the working paper, such as ciguatera fish poisoning, tropane alkaloids, etc., would be considered under Agenda Item 20.

# MATTERS ARISING FROM OTHER INTERNATIONAL ORGANIZATIONS (Agenda Item 4)<sup>5</sup>

#### The Joint FAO/IAEA Center of Nuclear Techniques in Food and Agriculture

- 15. The Representative of the Joint FAO/IAEA Centre introduced the item and summarized the information provided in the working paper related to technical cooperation projects in the area of food safety and control, international research projects and research laboratories.
- 16. The Representative drew the attention of CCCF to the ongoing work in IAEA on radionuclides in food, feed and drinking water and the linkages with the information presented in the discussion paper for consideration by CCCF under Agenda Item 16. He mentioned that work at the international level in this area is currently developing methodologies that can be used to produce criteria to assess these radionuclides in food. This work involved FAO, IAEA and WHO. An updated summary<sup>6</sup> of this is given in the aforesaid discussion paper. He further noted that naturally occurring radionuclides in food, feed and water do not seem to be an issue for food safety and trade. The IAEA could also commit to producing any necessary information or documents that might be helpful to food authorities, in this regard and thanked the EWG, the Chairs of the EWG and the Codex Secretariat for the excellent discussion paper.

#### **Conclusion**

17. CCCF welcomed the information provided by the Representative of the Joint FAO/IAEA Center.

<sup>3</sup> CX/CF 21/14/3

Looking at edible insects from a food safety perspective. Challenges and opportunities for the sector, FAO (2021) http://www.fao.org/3/cb4094en/cb4094en.pdf

<sup>&</sup>lt;sup>5</sup> CX/CF 21/14/4

<sup>6</sup> CX/CF 21/14/14, paras. 27-31

# MAXIMUM LEVELS FOR CADMIUM IN CHOCOLATES CONTAINING OR DECLARING <30% TOTAL COCOA SOLIDS ON A DRY MATTER BASIS (Agenda Item 5)<sup>7</sup>

- 18. Ecuador, as Chair of the EWG, introduced the item and recalled that CCCF13 (2019) had advanced the ML to Step 5/8 for adoption by CAC42 (2019). The Commission had adopted the ML at Step 5 only, for comments at Step 6 and further consideration by CCCF14. The EWG Chair drew attention to the decision of CAC42 that the concept of proportionality as agreed by CCCF13 with respect to the adopted MLs by CAC41 (2018) should be maintained. If new additional information provided did not justify a change to the ML, CCCF14 would recommend the adoption of the ML of 0.3 mg/kg by CAC at its next session. CAC42 confirmed that upon such recommendation by CCCF14, CAC shall adopt the ML without further discussion.<sup>8</sup>
- 19. The EWG Chair further recalled that JECFA91 had performed a new exposure assessment of cadmium in all food sources and the conclusions were that the major foodstuffs that contribute to dietary cadmium exposure continue to be the same, i.e., cereals or cereal-based foodstuffs, vegetables and seafood. None of the evaluations carried out by JECFA73 (2010), JECFA77 (2013) and JECFA91 (2021) had identified cocoa products as major contributors to dietary cadmium exposure. There was also no new additional information received to justify a change to the ML proposed, given that the worldwide rejection rate for these products at that ML would be 3.2% and the rejection rate for the LAC region would be 12%. The recommendation would thus be to adopt an ML of 0.3 mg/ kg for chocolates that contain or declare less than 30% of total cocoa solids on a dry matter basis.
- 20. The JECFA Secretariat confirmed that JECFA91 had undertaken a new exposure assessment for cadmium from all food sources, taking into account all new submitted data and dietary cadmium exposure estimates from 44 national studies. JECFA91 had confirmed the conclusions of previous JECFA meetings that cadmium in cocoa does not constitute a significant source of exposure within the human diet on a global level. However, one specific exception had been noted by JECFA91, for children of the GEMS/Food cluster G07 (mainly European countries) that consume only cocoa sources from cluster G05 (mainly South America) cocoa products do constitute a more significant source of exposure to cadmium. The Secretariat further added that on the global level, however, the contribution of the total cadmium intake that is caused by cocoa is minor in comparison to the commodities mentioned above.
- 21. The Secretariat also explained that after any JECFA meeting on food contaminants, a summary is published containing the highlights on the final outcome, the final statement and brief explanation on how JECFA derived their conclusion. This is followed by the JECFA report containing more detailed information on how the key data were collected and considered and how JECFA derived its conclusion. Finally, a monograph containing detailed information on all the data submitted and assessed by JECFA is published. Recognizing the needs of CCCF14 and on an exceptional basis, for the summary report of JECFA91 a more comprehensive summary report was published containing all the information that will be part of the report, which includes the JECFA deliberations and key data elements that went into the evaluation and how the conclusions were reached in order to assist CCCF in its discussion on this item. Therefore, the publication of the report of JECFA91 would not provide any additional information on this issue and it was unlikely that the monograph would provide further information to enable a different conclusion on this item at a future session of CCCF.
- 22. The Chair also reminded CCCF that two MLs were already adopted for the chocolate categories with the higher cocoa content and according to the decision taken at CCCF13, if no consensus were reached at CCCF14, the work would be discontinued until the Code of practice for the prevention and reduction of cadmium contamination in cocoa beans was finalized and implemented. In light of the latest JECFA evaluation and the fact that no new information had been brought forward to justify a change in the ML, she proposed to advance the ML to Step 8 for adoption by CAC44 (2021) and asked the plenary for any objections.

#### **Discussion**

23. The European Union, supported by Norway, reiterated their view and reservation as also expressed at CCCF13 and CAC42<sup>9</sup>. The EU further noted that this was confirmed in 2021 by the JECFA91 exposure assessment of cadmium from all sources, which indicated that chocolate and cocoa products with high cadmium concentrations can contribute up to 9.4% of the exposure of European children of 3-9 years old and for Europeans consuming only cocoa products from one particular region, cocoa products could even be the main contributors to the cadmium exposure (39.4% of the cadmium exposure). This justified the need for a lower cadmium ML for this category of chocolates of 0.1 mg/kg.

REP19/CF-Appendix III; CX/CF 21/14/5 (Australia, Canada, Colombia, EU, Kazakhstan, Morocco, Saint Kitts and Nevis, Switzerland, USA, ECA and FIA); CX/CF 21/1/4/5-Add.1 (Australia, Canada, Brazil, Chile, Colombia, Cuba, Ecuador, Egypt, El Salvador, EU, Malaysia, Peru, Trinidad and Tobago, Uganda, USA, ECA and ICA)

<sup>8</sup> REP19/CAC, paras 65-66

<sup>9</sup> REP19/CF, para. 53, REP19/CAC, para. 57

24. The Delegation also indicated that the concept of proportionality applicable to the two MLs adopted by CAC41 was not justified for this category of chocolates because milk chocolates are consumed by children, while dark chocolates usually are not consumed by this population group. In order to adequately protect children, a stricter ML would be more appropriate for chocolates containing or declaring less than 30% of cocoa solids, even if this ML was not proportionate to the previously agreed MLs for dark chocolates. An extensive explanation had been provided in writing in the relevant comment papers <sup>10</sup>in support of this reservation.

25. Egypt also expressed a reservation on the proposed ML as it enforced a lower ML of 0.1 mg/kg as more protective for consumers, especially children.

#### Conclusion

- 26. CCCF agreed to advance the ML of 0.3mg/kg for chocolates containing or declaring <30% total cocoa solids to Step 8 for adoption by CAC44 (Appendix II), noting the reservations of the European Union, Norway and Egypt to this decision.
- 27. The Chair reminded CCCF that all technical issues had been thoroughly discussed and urged Codex members to respect the decision made at this session and not to reopen such discussions at CAC44.

MAXIMUM LEVELS FOR CADMIUM IN CHOCOLATES CONTAINING OR DECLARING ≥30% TO <50% TOTAL COCOA SOLIDS ON A DRY MATTER BASIS AND COCOA POWDER CONTAINING OR DECLARING 100% TOTAL COCOA SOLIDS ON A DRY MATTER BASIS READY FOR CONSUMPTION (Agenda Item 6)<sup>11</sup>

<u>Chocolates containing or declaring ≥30% to <50% total cocoa solids</u>

- 28. Ecuador, as Chair of the EWG, introduced the item and focused on the conclusions and recommendations that led to the proposed MLs for consideration by CCCF. The EWG Chair recalled the decision of CCCF13 for the EWG to continue work on MLs for the categories in question using a proportional approach; recognizing the need for some flexibility in the proportionality between the MLs for the different chocolate categories to avoid very high rejection rates.
- 29. At the time of preparing the MLs, the report of JECFA91 was not yet available, but the EWG did consider all the data available in GEMS/Food, including the data available to JECFA91 (2021), for the development of the MLs proposals for the categories under consideration.
- 30. For this category two scenarios were presented, one following the proportional approach and the other based on analysis of data from GEMS/Food and that based on the two considerations, this evaluation resulted in a range of MLs with some overlap, namely:
  - <u>Scenario (1) GEMS/Food data</u>: A range of 0.6 0.7 mg/kg, for which the ML of 0.6 mg/kg accounts for rejection rates of 10.39% (worldwide basis) and 13.16% (regional basis, Latin America and the Caribbean) and the ML of 0.7 mg/kg accounts for rejection rates of 5.74% (worldwide basis) and 7.33% (regional basis, Latin America and the Caribbean).
  - <u>Scenario (2) Proportional approach</u>: A range of 0.5 0.6 mg/kg, for which the ML of 0.5 mg/kg accounts for rejection rates of 16.23% (worldwide basis) and 20.53% (regional basis, Latin America and the Caribbean).
- 31. The EWG Chair reminded CCCF on the outcomes of JECFA evaluations on cadmium in chocolates and cocoa-derived products as stated in previous sessions of CCCF and also under Agenda Item 5, and noted that the range of MLs proposed were all protective of consumers' health on a global basis and therefore the focus of the discussion should remain on considering an ML with a minimum negative impact on trade that could best accommodate all regions concerned.
- 32. The CCCF Chair reminded the Committee that an agreement had been reached on the ML for chocolates containing or declaring <30% total cocoa solids on a dry matter basis; that two MLs for chocolates containing or declaring ≥50% to <70% and ≥ 70% of total cocoa solids on a dry matter basis had been already adopted by CAC; therefore, there was a need to also agree on the remaining chocolate category. She also reminded CCCF that the EWG had shown the rejection rates for the 2 scenarios based on the proportionality approach and on GEMS/Food data and that the recommendation of the EWG was in light of the JECFA evaluations, which showed that implementing the proposed MLs would have little impact on exposure and to choose an ML which has lesser impacts on trade.

#### **Discussion**

33. A number of delegations expressed support either for Scenario 1, and an ML of 0.7 mg/kg, or for Scenario 2 and an ML of 0.6 or 0.5 mg/kg.

<sup>&</sup>lt;sup>10</sup> CX/CF 21/14/5, CX/CF 21/14/5-Add.1 and CRD03

CL 2021/11/OCS-CF; CX/CF 21/14/6; CX/CF 21/14/6-Add.1 (Australia, Canada, Chile, Cuba, Ecuador, Egypt, El Salvador, EU, Iraq, USA, FoodDrinkEurope, IAEA and ICA)

34. Delegations supporting the higher ML of 0.7 mg/kg highlighted that JECFA91 had confirmed that the presence of cadmium in chocolate was not a significant public health concern and the proposed MLs would have limited practical benefit in reducing dietary exposure to cadmium. However, it was necessary to balance the JECFA outcome with the potential adverse impact on international trade to ensure globally safe levels with minimum negative impact on trade, and the level of 0.7 mg/kg would ensure a balance between globally acceptable safe levels while still promoting fair practices in trade and helping to prevent competitive advantage and unnecessary food waste. The delegations noted that these MLs had been discussed since 2013, that a pragmatic solution needed to be found and that data submitted so far to GEMS/Food had supported the outcomes of the different JECFA evaluations.

- 35. Delegations supporting Scenario 2 (0.5 or 0.6 mg/kg) noted that this option was in line with the proportionality approach as agreed by CCCF13.
- 36. The European Union could not support either of the two proposals for the reasons previously expressed at CCCF13 and under Agenda Item 5, and as explained in their written comments in CX/CF 21/14/6-Add.1. The EU drew attention to the outcomes of JECFA91 evaluation. Even though JECFA concluded that for most consumers the exposure remains below the PTMI, the EU's assessment concluded differently, because in the EU a TWI is established which is 50% lower than the toxicological value established by JECFA. Furthermore, JECFA confirmed that children are the consumer groups which undergo the highest exposure to cadmium in the EU in particular for the categories of chocolates of less than 30% and between 30-50% of cocoa solids. As already commented under Agenda Item 5, the EU did not agree to apply the proportional approach for the MLs in chocolates containing less than 50% of cocoa solids, as these products are regularly consumed by children, while the darker chocolates are not, due to their bitter taste. The EU further noted that the conclusions taken for the worldwide data were driven by a large proportion of data from the LAC region and that data from other cocoa producing regions such as Africa and Asia were much underrepresented. It was also not clear whether the data originated from recent years and whether mitigation practices were applied to limit the cadmium concentrations in the crops. This justified the need for a lower cadmium ML for this category of chocolates of 0.3 mg/kg.
- 37. The European Union, supported by Switzerland and Norway expressed its reservation to setting the MLs at any of the levels proposed.
- 38. Egypt also expressed its reservation to the proposed ML as they enforced a lower ML of 0.3 mg/kg as more protective for consumers, especially children.

#### **Conclusion**

- 39. CCCF agreed to advance the ML of 0.7mg/kg for chocolates containing or declaring ≥30% to <50% total cocoa solids to Step 5/8 for adoption by CAC44 (Appendix II), noting the reservations of the European Union, Switzerland, Norway and Egypt.
- 40. The Chair reminded CCCF that all technical issues had been thoroughly discussed and urged Codex members to respect the decision made at this session and not to reopen such discussions at CAC44.
  - Cocoa powder containing or declaring 100% total cocoa solids on a dry matter basis ready for consumption
- 41. The EWG Chair explained that the category had been agreed by CCCF, but when analysing the data in the GEMS/Food database it was not always clear if the cocoa powder was (i) 100% total cocoa solids, (ii) natural cocoa powder, or (iii) pure cocoa powder and no information was provided on the intended use of the product (e.g. final consumption). The EWG had therefore decided to use all data to propose an ML.
- 42. Two scenarios were presented similar to the approach for chocolates containing or declaring ≥30% to <50% total cocoa solids on a dry matter basis namely:
  - Scenario (1) GEMS/Food data: A range of 2.0 3.0 mg/kg, for which the ML of 2.0 mg/kg accounts for rejection rates of 5.39% (worldwide basis) and 13.42% (regional basis, Latin America and the Caribbean) and the ML of 3.0 mg/kg accounts for rejection rates of 2.49% (worldwide basis) and 6.33% (regional basis, Latin America and the Caribbean).
  - Scenario (2) Proportional approach: A range of 1.3 1.5 mg/kg, for which the ML of 1.3 mg/kg accounts for rejection rates of 11.48% (worldwide basis) and 27.64% (regional basis, Latin America and the Caribbean) and the ML of 1.5 mg/kg accounts for rejection rates of 8.26% (worldwide basis) and 20.37% (regional basis, Latin America and the Caribbean).
- 43. The EWG Chair however noted that since more than 80% of the available data in GEMS/Food did not show the declared percentage of cocoa in the analyzed samples, neither did they indicate whether they were the intermediate product or final product, CCCF should consider changing the name of the category to better reflect the products especially since all available data were considered to determine the proposals for MLs under the two scenarios.

Renaming the category

- 44. CCCF considered firstly whether to rename the category as follows:
  - There was little support to rename the category.
  - Most delegations agreed that it was appropriate to incorporate all GEMS/Food data for cocoa powder into the
    analysis irrespective of whether or not the declared percent of total cocoa solids was given, or whether or not
    they were intermediate or final products.

MLs for cocoa powder

- 45. CCCF proceeded to consider the two scenarios and noted that a number of delegations expressed support of either Scenario 1 or Scenario 2 for the same reasons expressed for the category of chocolates containing or declaring less than 30% and ≥30% to <50% total cocoa solids on a dry matter basis. In addition, it was noted that this category was not usually consumed directly as food but as an ingredient.
- 46. Other delegations noted the following:
  - The decision on the ML could await implementation of the COP so as to assess its impact on cadmium levels, and to allow further generation and submission of data to GEMS/Food.
  - There was limited data from the African region for the analysis and derivation of the proposed MLs which also support generation and submission of data to GEMS/Food in order to increase better representativeness of data at the global level.
- 47. One observer noted that if there were no global ML, that non-science-based levels were being taken up by default by other countries in the absence of having a Codex standard. It was therefore very important to have a Codex ML set for this category.
- 48. Similarly to the points raised for the previous categories of chocolates, the European Union, supported by Norway and Switzerland, expressed their support for a lower ML of 0.60 mg/kg in order to sufficiently protect all EU consumers, in particular the younger and more vulnerable consumer groups for the same reasons expressed previously (paragraph 36). Alternatively, as cocoa powder was a commodity which is of lesser significance for international trade, these delegations could also support to not set an ML for this commodity.
- 49. Egypt could not support the proposed MLs in both scenarios as it enforced a lower ML of 0.6 mg/kg as more protective for consumers, especially children.
- 50. An observer highlighted a technical issue regarding Scenario 2. He explained that there was a big difference between chocolates and 100% cocoa powder. The non-fat component was the key component that could contain cadmium and this should be used for the proportional calculation. Chocolate would typically have about 45% non-fat solids, which is where the cadmium could be present, whereas in 100% cocoa powder, typically there would be about 90% non-fat solids. This tended to be twice the amount of non-fat solids in 100% cocoa powder compared to chocolate. Therefore, it was necessary to double a proposed ML derived using the proportionality approach for 100% cocoa powder. The proportional approach calculated in Scenario 2 did not take this into account, so if the proportional calculation were done appropriately, it would align with the GEMS/Food data scenario. He noted that further information was presented in their comments in CX/CF 21/14/6-Add.1.
- 51. The JECFA Secretariat, noting that members alleged several times the importance of an ML to protect the children, clarified that the JECFA exposure assessment/evaluation had not revealed that such a need existed on a global level. He noted the European Union pointed out correctly that a subcategory of European children may face a more significant contribution from exposure to cadmium through cocoa products, and if the EU intended to protect that particular subsegment of its children, it was their prerogative. However, at a global level, there was no health benefit (i.e. a reduction in dietary exposure to cadmium) gained from putting up an ML on any cocoa containing products.

- 52. CCCF agreed:
  - i) to postpone discussion on the MLs by one year to allow for more data submission and proposals for MLs;
  - ii) to re-establish the EWG chaired by Ecuador, and co-chaired by Ghana, working in English and Spanish to:
    - a. continue working on the ML for cocoa powder containing or declaring 100% total cocoa solids on a
      dry matter basis ready for consumption taking into consideration submitted written comments and
      comments made at this session; and to present the analysis in more detail at the next session and
    - b. collaborate closely with the EWG on data analysis (see Agenda Item 17).
  - iii) to request JECFA to issue a call for data specific to cocoa powder containing or declaring 100% total cocoa solids ready for consumption;

- iv) to encourage Members to submit data and actively participate in the EWG and
- v) that if no new data were submitted, the current data set would be used to derive the ML.

# CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF CADMIUM CONTAMINATION IN COCOA BEANS (Agenda Item 7)<sup>12</sup>

- 53. Peru, as Chair of the EWG, introduced the item and recalled that the aim of the COP was to provide Codex members and other stakeholders with risk management measures to prevent/reduce cadmium contamination in cocoa beans and to support implementation of the MLs for cadmium in chocolates and cocoa products. The scope was limited to risk management measures applicable to primary production, post-harvest processing (fermentation, drying and storage) and transport. These practices had been identified as currently available and proven to be practical, cost-effective and applicable worldwide by large, medium and small-scale producers with medium- and long-term impact on reduction of cadmium contamination in these products. Other measures applicable to the rest of the food chain could be included in the COP when they become available and could be part of the revision of the COP. The EWG Chair further emphasized that a comprehensive approach should be taken in order to efficiently manage cadmium contamination in the production of cocoa beans. He also encouraged Codex members and observers to continue providing internationally validated risk mitigation measures for the further development of the COP.
- 54. The Chair called for general comments on the format and content of the COP, and whether such comments would support the adoption of the COP at Step 5, and indicated that specific comments submitted in writing to this session would be forwarded to the EWG for their consideration in the further development of the COP.
- 55. CCCF noted general support for the development of the COP but that further work needed to be done in the EWG to bring the COP for finalization at the next session of the Committee.
- 56. Delegations provided the following general comments:
  - There is sufficient information on mitigation measures available for field production and post-harvest processes that could assist in the further development of the COP in the EWG.
  - The COP should address agricultural realities and recommend mitigation measures that are practical for all the
    options given in the COP as opposed to theoretical options that are currently described in the document,
    therefore there needs to be more work to ensure that these measures will be achievable for farmers and
    producers.
  - The COP should identify mitigation measures that are also applicable in the short-term and so more readily available to producers for implementation, but should also look into more medium and long-term measures.
  - While, some short-term measures could be achieved more readily, long-term mitigation measures identified in the COP might need to be looked into in more detail to avoid committing to measures that might be difficult for farmers or producers to comply with in future.
- 57. A delegation noted that the COP addressed mitigation measures to reduce cadmium contamination mainly for the medium-long term.
- 58. Ecuador, as Coordinator of CCLAC, also referred to the support of the region <sup>13</sup> in developing this COP.

#### Conclusion

59. CCCF agreed to:

- i) advance the Code of Practice for the Prevention and Reduction of Cadmium Contamination in Cocoa Beans for adoption at Step 5 by CAC44, on the understanding that the COP will be further revised by the EWG as per the general comments provided by CCCF and the specific written comments submitted to this session and
- ii) re-establish the EWG, chaired by Peru and co-chaired by Ecuador and Ghana, working in English and Spanish, to work further on the COP taking into account the general comments provided by the Committee and the specific written comments submitted to this session.

CL 2021/12/OCS-CF; CX/CF 21/14/7; CX/CF 21/14/7-Add.1 (Australia, Canada, Cuba, Ecuador, EU, Iraq, Japan, Philippines, USA, FoodDrinkEurope and ICA)

<sup>13</sup> CX/CF 21/14/2, para. 10

### MAXIMUM LEVELS FOR LEAD IN CERTAIN FOOD CATEGORIES (Agenda Item 8)14

60. Brazil, as Chair of the EWG, introduced the item, and highlighted the issues which needed to be addressed, viz. data management issues and clarity on certain categories for which MLs should be established; and that MLs were proposed for consideration by CCCF.

61. CCCF had a short discussion on the general issues related to data management noting that these general views would be considered under Agenda Item 17; followed by a discussion on the questions raised in points (b) – (f) (CX/CF 21/14/8, paragraph 12.1) and consideration of the proposed MLs (CX/CF 21/14/8, Appendix I).

Recommendation (a): Issues on the data analysis for the ML development

Rejection rates

- 62. There was general support for a cut-off of 5% (ranging either from 0 5% or 2 5%), and that rejection rates should be determined on a case-by-case basis.
- 63. Several delegations noted that rejection rates would depend on the availability and amount of data, concentration and distribution of the occurrence data, consumption volumes and patterns, mitigation measures, impact on exports and trade, consumer groups, whether the ML would be set for public health or trade harmonization, amongst others, but that MLs should always be based on the ALARA principle.

Extremes in data sets

64. Views were expressed that attention should be paid to extremes in data and that such data should be carefully evaluated to determine whether they should be retained in or removed from the dataset, as there could be different reasons for such extremes in data, for example due to climatic changes in some years or adulteration. Other views were expressed, that such extremes should not be cut out of the data set *per se* if no information was available, as it would be difficult to know the reasons for these outliers. It was therefore important for submitters of data to indicate what the outliers were and to review their data set for any outliers, and determine whether or not these should be remain in the dataset (i.e. are valid), prior to submission.

Geographic representative data

65. CCCF reiterated the importance of using geographically representative data for the establishment of global MLs and noted that the data used for the current proposals for MLs for lead in certain food categories did not include for example data from the African region, yet such data existed for commodities such as sugars, eggs, spices. Not taking into account geographically representative data could result in MLs that could be a barrier to trade.

#### **Conclusion**

66. CCCF noted the views expressed and that the issues raised under Recommendation a) would be further considered under Agenda Item 17.

Recommendation (b): Establish MLs for dried culinary herbs and spices or use the already established MLs for fresh leafy, root and tuber vegetable and apply concentration factors

- 67. There was general support to establish MLs for dried spices and culinary herbs as these were the commodities most widely traded and also in line with the standards being developed in CCSCH and the *General Standard for Contaminants in Food and Feed* (CXS 193-1995) which indicates that MLs should be established for food moving in international trade. However, views varied on whether to establish a single ML for dried spices and culinary herbs or to establish separate MLs for the different dried spices and culinary herbs based on available data. It was noted that different factors, such as processing and storage conditions, could impact on MLs for these products.
- 68. However, there was also support for setting separate MLs for fresh and dried culinary herbs, as culinary herbs were either traded as fresh or in dried form, but that applying an ML for leafy vegetables to fresh culinary herbs would not be appropriate. In case that an ML for fresh culinary herbs would be considered, the data would need to be checked carefully for the specific species of culinary herbs to ensure that the ML is appropriate for all species of fresh culinary herbs in order to avoid situations where the ML would be too low or high for certain species within the group to which the ML applies.
- 69. Limited support was expressed for the use of concentration factors in this case. MLs to be set for dried culinary herbs and spices should be set on available data and not based on concentration factors apply to the corresponding fresh product.

<sup>&</sup>lt;sup>14</sup> CX/CF 21/14/8; CX/CF 21/14/8-Add.1 (Australia, Canada, Chile, Cuba, Ecuador, Egypt, EU, Iraq, Japan, USA, FoodDrinkEurope, ICBA, ICA, ISDI and THIE)

70. While there was support to establish MLs for dried spices and culinary herbs, views were expressed that this work should be postponed to allow the submission of more geographically representative data and to allow for the implementation of the newly revised *Code of Practice for the Prevention and Reduction of Lead Contamination in Foods* (CXC 56-2004).

#### Conclusion

#### 71. CCCF:

- supported the establishment of MLs for dried spices and culinary herbs and that consideration could be given to establishing MLs also for certain fresh culinary herbs;
- did not support the use of concentration factors to derive an ML for dried culinary herbs;
- did not support applying the ML for fresh leafy vegetables to fresh culinary herbs and
- noted that the dried commodities were important in international trade.

#### 72. CCCF agreed:

- to postpone discussion on MLs for one year to allow submission of new data to GEMS/Food;
- that if no new data were submitted that CCCF15 would take a decision based on the current data set.

#### Recommendation (c): To establish an ML of 2.0 mg/kg for dried rhizomes, bulbs and roots

- 73. In view of the decision to postpone discussion on MLs for dried spices and culinary herbs, CCCF agreed to postpone the discussion on this ML, but noted the following views:
  - The data used was not sufficient and did not reflect all the categories within this group for the establishment of an ML at this stage, and that data from primary producers were needed.
  - It was not appropriate to exclude turmeric data from the data set for the establishment of the ML as not all turmeric was necessarily adulterated and that the intentional addition of adulterants should not be considered while establishing MLs for contaminants.
  - The turmeric data should be excluded to derive the ML for this group but that the ML should also apply to turmeric.
  - The adulteration of turmeric was food fraud and such products should be eliminated from the food trade.
  - The current data set was dominated by data on turmeric and that it would be difficult to determine whether turmeric should be analyzed separately or be included with other rhizomes, bulbs and roots and the further work should consider data with and without turmeric for the establishment of an ML. This would help to determine whether the levels for turmeric were normal or due to adulteration and whether a single ML for dried rhizomes, bulbs and roots including or excluding turmeric could be set.
- 74. CCCF further noted there was general support to establish a single ML for dried rhizomes, bulbs and roots but there were divergent views as to the ML equal to or lower than 2.0 mg/kg.

#### **Conclusion**

75. CCCF agreed to postpone discussion by a year to allow for further data submission through GEMS/Food and that the EWG would look at MLs for this category with and without data for turmeric and to try to determine what tumeric samples are adulterated so these samples could be excluded in the data set., Both analyses would be presented for consideration by CCCF.

Recommendation (d): To establish an ML of 0.1 mg/kg for eggs only, in view of the lack of occurrence data for egg products and that there is no harmonized definition for preserved eggs

- 76. CCCF noted the following views:
  - Before a decision could be taken, consideration should be given to whether MLs still should be established for
    fresh eggs if preserved eggs were excluded from the dataset, since the initial proposal for establishing MLs for
    eggs and egg products had been based on data including processed eggs and that consideration should be given
    to trade and health implications if an ML for eggs were established.
  - MLs should be established for fresh eggs and that consideration could be given to establishing separate MLs
    for chicken eggs and duck eggs, in view of the lower concentration of lead in chicken eggs compared to duck
    eggs and also in view of the higher consumption volume of chicken eggs.
  - A single ML should be established for fresh eggs with no further differentiation between chicken eggs and duck eggs.

77. Those delegations who supported the establishment of an ML for eggs only, also expressed support either for the ML of 0.1 mg/kg or for lower levels for chicken eggs, , or that more data should be obtained to derive the ML.

#### **Conclusion**

- 78. CCCF agreed that the EWG would consider the feasibility of establishing MLs for fresh eggs, either as a single ML or separate MLs for chicken and duck eggs, based on submission of additional data specific for fresh eggs.
  - Recommendation (f): To set an ML for cereal-based foods for infants and young children "as is" or "as consumed"
- 79. There was little support to express the ML "as consumed".
- 80. A proposal was made to express the ML on a "dry matter basis" similar to the ML for DON in cereal-based foods for infants and young children in the GSCFF since these products were widely traded as dried products and for which data was available and that reconstitution would require diluent which could also be a source of lead adding to variability and lead concentrations in products on an "as consumed" basis. Other delegations supported this proposal as the closest to "as is" products and also referred to the term "as sold" as an alternative descriptor.
- 81. Delegations in favour of setting the ML for cereal-based foods for infants and young children "as is" indicated the following:
  - "as consumed": the product "as consumed" was not appropriate as they come in different formulations and preparation instructions which make their analysis and enforcement difficult. Therefore:
  - "as is": this term was more practical from a regulatory point of view and easier to analyze if the ML was set on "as is" basis as it did not require the product to be prepared before being analyzed which could be difficult especially if there are no clear preparation instructions. In addition, there are also no standard procedures available for the preparation of the different cereal-based foods. Therefore, setting an ML for a product "as consumed" might lead to legal uncertainties and problems for the laboratories and law enforcement. On the contrary:
  - "on a dry matter basis": the "dry matter basis" would need adjustment of the data by correcting for the moisture content, and data available on GEMS/Food do not always report information on the moisture content of the samples.
- 82. It was also pointed out that it was important to be clear on how the data was analyzed to determine whether to express the ML on a "dry matter basis" or "as is".

- 83. CCCF agreed to consider this matter at the next session and that the EWG should consider the data and evaluate the possibilities for either expressing the ML on a "dry matter basis" or "as is".
  - Recommendation (f): To establish an ML for lead in herbal tea specific for infant and young children or for lead in teas and herbal teas (solid, dried)
- 84. CCCF noted varying views expressed on this issue.
- 85. Delegations not supporting establishing an ML for lead for herbal tea specific for infants and young children questioned whether an ML was justified due to the limited dataset; noted information on international trade was unclear and there was a lack of consumption data.
- 86. Delegations in favour of establishing an ML for lead in herbal teas for infants and young children, expressed the view that:
  - Such products were traded internationally.
  - It could contribute to reducing exposure of lead in infants and young children.
  - If work were to proceed with an ML that it should be based on data for dried herbal teas.
  - It would not be appropriate to set MLs for herbal teas and apply it to infants and young children and it was possible to achieve lower levels than the MLs proposed.
  - It would not be appropriate to set MLs for herbal teas and apply it to infants but to rather set MLs specifically for herbal teas for infants and young children because through careful sourcing of the raw material it was possible to reduce the concentrations of lead in these products which was important for reducing the exposure of the young consumer groups therefore it was possible to achieve lower levels than the MLs proposed.
  - If an ML for herbal teas for infants and young children would be considered, then the data for the dried teas that are prepared by infusion or decoction should be considered apart from data for herbal teas that are sold as liquid.

87. It was also noted that herbal tea, depending on the types of herbs in the tea, may not be classified as a food product so the EWG should provide a definition and a scope of herbal tea meant for infants and children which the ML would apply to

88. Views were also expressed to consider establishing an ML for teas and herbal teas not specifically for infants and young children, but that more data was needed for this.

#### Conclusion

89. CCCF agreed not to set an ML for lead in herbal teas specific for infants and young children at this time.

#### Other categories

Sugars and sugar-based candies

- 90. CCCF noted that for the MLs for sugars:
  - It would be difficult to discuss the proposed MLs for sugars since rejection rates up to and about 5% were not provided.
  - Sugar was a major food commodity traded internationally and the proposed lower MLs were not appropriate and thus a broader range of MLs should be presented with corresponding rejection rates.
  - The proposed MLs were trade restrictive and more data should be requested on which to base the ML.
  - If no new data was submitted, then rejection rates should be presented for higher levels to see what the most appropriate MLs would be.
  - More transparency was needed on where the data originated from so that geographic representivity could be assessed.
  - Nomenclature should be aligned with the Standard for Sugars (CXS 212-1999).
- 91. Brazil expressed the view that the approach followed previously for the review of MLs for lead should be followed, if no new data were provided by producer countries, the proposed ML would be acceptable as it showed a low rejection rate.
- 92. CCCF did not consider the other commodities in this category as the approaches for the derivation of the MLs, the presentation of the MLs and their respective rejection rates were similar.
- 93. An observer noted that there had been no specific call for data for sugar-based confectionary and that the ML should be based on data specific for this category.

#### **Conclusion**

94. CCCF agreed to postpone decisions on MLs for a year to allow more time for submission of data to GEMS/Food for analysis by the EWG and that the EWG present data on a broader range of rejection rates and more information on the regions of origin of the data, and thus a wider range of MLs. Producing countries were encouraged to submit data.

#### Food for infants and young children

Fruit juices

- 95. The USA, who led the previous work on revision of ML for lead in different food categories in GSCFF, clarified that the data for that review had included juices labelled for infants and young children for all juices and grape juice. For juices exclusively from berries and small fruit, no juices exclusively labelled for young infants were present in the data set.
- 96. The European Union expressed support for a lower ML of 0.02 mg/kg which could be achieved with the global data set.
- 97. An observer noted that there were different MLs for fruit juices in the GSCFF and one for fruit juices obtained exclusively from berries and other small fruits. When these levels were set, there were higher rejection rates for the fruit juices from berries. While there are steps to achieve lower levels, there were cost implications and therefore CCCF needed to be careful with establishing lower MLs.

- 98. CCCF:
  - agreed that the MLs for fruit juices in the GSCFF already included juices for infants and young children and noted the reservations of the European Union and Norway to this decision and
  - agreed to include a note in the notes/remarks of the GSCFF for the MLs for fruit juices and grape juices as follows: "the ML also applies to fruit juices for infants and young children".

Ready-to-eat meals

99. CCCF agreed to postpone decision on this category by one year to allow submission of additional data to support the establishment of an ML.

Other foods

100. CCCF confirmed that it was not feasible to set MLs for yoghurt, cheese and milk-based products as these products were complex mixtures.

#### **General Conclusion**

- 101. CCCF agreed to:
  - clarify the MLs for fruit juices and grape juices in the GSCFF also apply to infants and young children and to advance this ML to CAC44 for adoption (Appendix IV) noting the reservations of the European Union and Norway;
  - ii) discontinue work on an ML for herbal teas, yoghurt, cheese and milk-based products for infants and young children at this time;
  - iii) re-establish the EWG, chaired by Brazil, working in English to:
    - a. continue working on MLs for lead in dried spices and culinary herbs, including dried bulbs, rhizomes and roots; fresh culinary herbs; eggs; sugars and sugar-based candies; cereal-based products for infants and young children and ready-to-eat meals for infants and young children taking into account the written comments submitted, comments and decisions made at the session and new data from GEMS/Food; and to describe in more detail the data analysis and present a broader range of MLs and rejections rates and
    - b. work in close collaboration with the EWG on data management (see Agenda Item 17).
  - iv) request JECFA to issue a call for data to get more (geographically representative) data available to the EWG, with the aim to finalize the MLs next year.
- 102. CCCF encouraged all countries with an interest in the categories discussed to submit data on GEMS/Food and to actively participate in the EWG.

# REVISION OF THE CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF LEAD CONTAMINATION IN FOODS (CXS 56-2004) (Agenda Item 9)<sup>15</sup>

- 103. The United States of America, as Chair of the EWG, introduced the item and indicated that the COP had been reviewed extensively over the past 2 years. The revised COP had been improved from the previous version by incorporating additional information on sources of lead and practices for reducing lead during agricultural production and food processing. Written comments submitted to this session were of editorial nature for consistency with terminology used in Codex or to improve the clarity of the text and have been already incorporated in the COP to facilitate its consideration by CCCF.
- 104. CCCF noted general support for the final adoption of the COP with the additional revisions made by the EWG Chair as highlighted in CRD22.
- 105. CCCF also agreed that, besides reviewing the lead specifications for diatomaceous earth and charcoal (activated carbon), CCCF further recommended CCFA to request JECFA to review bentonite given its importance for food processing.

- 106. CCCF agreed to:
  - i) forward the revised *Code of Practice for the Prevention and Reduction of Lead Contamination in Foods* (CXS 56-2004) (Appendix V) to CAC44 for adoption at Step 5/8 and
  - ii) recommend to CCFA to request JECFA to:
    - review the lead specifications for diatomaceous earth and charcoal (activated carbon) and
    - b. evaluate available data to support development of a lead specification for bentonite.

<sup>&</sup>lt;sup>15</sup> CL 2021/14/OCS-CF; CX/CF 21/14/9; CX/CF 21/14/9-Add.1 (Australia, Canada, Chile, Cuba, Ecuador, Egypt, EU), Iraq, Japan, USA, Thailand and IUFOST)

# MAXIMUM LEVELS FOR TOTAL AFLATOXINS IN CEREALS AND CEREAL-BASED PRODUCTS INCLUDING FOODS FOR INFANTS AND YOUNG CHILDREN (At Step 4) (Agenda Item 10a)<sup>16</sup>

- 107. Brazil, as Chair of the EWG, introduced the item, and highlighted the key issues related to data management and the recommendations for MLs for the different categories of cereals and cereal-based foods.
- 108. CCCF noted that the data management issues (i.e. rejection rates, outliers, etc.) were similar to those discussed under Agenda Item 8 and that further discussion would be held on these issues under Agenda Item 17.
- 109. CCCF proceeded to consider the recommendations as outlined.

Discussion

110. Views were expressed as follows

Maize grain, destined for further processing

How should maize data be evaluated

Geographical representation of data

111. More data should be requested to ensure better geographic representation and that an entry on country of origin should be included in the data submission template to better assess regional representation of the data.

Outliers

- 112. Data should be examined in more detail as regards outliers. As aflatoxins are very heterogeneously distributed in a lot, it was therefore important to consider whether the data are based on samples representative of the lot or whether they are samples from hotspots within a lot and so they can be considered as outliers.
- 113. If outliers do not affect the 95<sup>th</sup> percentile, there would be no need to exclude them for the consideration of the ML proposals.

Year to year variations and geographical variations

114. The year to year variations, due to climatic conditions, and regional variations should be further examined to assess their impact on the ability to meet the proposed ML/to come to a rejection rate acceptable for the different years and regions.

Food aid/food security

115. The current ML proposals could have a negative impact on food security and the ability to purchase and provide food aid to vulnerable populations particularly cereal products for infants and young children. It was therefore important to consider higher MLs to ensure availability of food for food aid and that consideration be given to the possible impact on availability of food for food aid if lower MLs are established.

Segregation of data: Maize destined for human consumption/animal feed

- 116. There were divergent views on whether to set a single ML for maize grain for further processing (including all types of maize grains) or maize for direct consumption/ready-to-eat and whether the ML should be set on data exclusively from maize destined for human consumption or on the whole data set.
- 117. However, it was generally accepted that it would be difficult to segregate data for maize for human consumption from data for maize intended for animal feed, as its intended purpose was not always indicated on the lot. One delegation was of the view that higher rejection rates could be applied when considering data that does not differentiate between maize intended for food and feed.
- 118. Consideration should be given to establish an ML only for ready-to-eat maize based on the whole dataset. This was more suitable for human health protection especially in the African region where maize was a staple food and was traded as maize regardless of whether it would be going for further processing or was meant for direct human consumption. In this case, the ML for the whole category of maize should be 10 µg/kg in line with already existing standards in many African countries.
- 119. It would be useful to consider the impact of segregating the data or using the whole data set when proposing MLs/rejection rates for maize, as it was also important to limit aflatoxins in feed for livestock especially when there is a possibility for carry-over from feed to food (e.g. dairy cattle/milk)..

CX/CF 21/14/10-Part I; CX/CF 21/14/10-Add.1 (Australia, Canada, Chile, Cuba, Ecuador, Egypt, Iraq, Kazakstan, Philippines, Thailand, Uganda, USA, Venezuela, ACF, IAEA, ISDI, MSF, UNICEF and WFP)

120. It would assist to issue another call for data that consider the points raised by delegations e.g. country of origin, whether the maize is destined for food or feed, etc. and to consult with the JECFA Secretariat on the possibility to segregate data, and if possible, to go back to the data submitters to get more details on the data uploaded onto GEMS/Food. If this would not be possible, the EWG may propose an ML based on the full data set for consideration by CCCF. Countries were encouraged to submit available data to GEMS/Food to ensure geographical distribution, if no new data were received, then the current data set would be used as the basis for the ML.

- 121. The JECFA Secretariat explained that the optimal option would be to find a way to separate the data, so only data on aflatoxin in actual food commodities are used in the assessment. This would require a lot of double-checking by the data submitters and probably only help CCCF part of the way. There is, however, no way to ensure that what is intended for feed does not end up as food. One way forward for JECFA is to consider a couple of scenarios in a future assessment. One scenario is that only data on aflatoxin in clearly stated food commodities are used in the assessment. Another scenario could be that all data, also data which might refer to aflatoxin levels in commodities that might end up being used as feed are used in the assessment which then would give us a kind of upper bound.
- 122. Brazil indicated that further assessment of the existing and additional data would be possible but would require timely submission of the new data so that the EWG can give due consideration to the different scenarios suggested by delegations including wider ranges for MLs. Therefore, depending on how much data would be available, and when it would be available, it would be possible to have more rounds of consultation amongst the members of the EWG.

#### Consideration of the MLs

- 123. The following specific views were provided, ranging from:
  - To support a higher ML of 20 μg/kg with a rejection rate of 4.5% or
  - To support a lower ML of 10 μg/kg for maize grain destined for direct human consumption or maize grain for further processing which would result in a similar rejection rate of 5.4% that currently applies to the proposed ML of 15 μg/kg for maize for further processing (CX/CF 21/14/10-Part I, Annex, Proposal 2).

#### **Conclusion**

- 124. CCCF agreed that the EWG would assess the data to:
  - verify the outliers and whether they should be excluded or not;
  - analyse year to year and regional variations;
  - consider whether the ML would be set for maize for further processing or maize for direct human consumption and
  - assess the impact of lower MLs on food aid/food security particularly cereal products for infants and young children.
- 125. CCCF further agreed that the EWG should:
  - try to gather more geographically representative data, including details on food and feed, request JECFA to issue a call for data and
  - liaise with the WHO JECFA Secretariat whether it would be possible to further segregate data available on GEMS/Food to differentiate between maize grain for food or feed.

Other food categories: Flour, meal, semolina and flakes derived from maize; husked/polished rice; sorghum grain, destined for further processing; cereal-based food for infants and young children

126. For the other categories for which MLs were proposed, CCCF noted that further work was needed by the EWG and noted general and specific views as follows:

#### <u>General comments</u>

- 127. There was general support for the categories other than maize grain but divergent views on the MLs that should apply to these categories.
- 128. In addition, the following was noted:
  - How the considerations given for maize grain would impact on processed products e.g. geographical distribution of data, year to year variations, regional variation, treatment of outliers, etc.
  - How processing, including cleaning and sorting, could help to reduce aflatoxin contamination in processed products to allow lower MLs with acceptable rejection rates.
  - MLs for processed products should be supported by data and information on the expected aflatoxin reductions due to processing.

#### Specific comments

129. <u>Flour, meal, semolina and flakes derived from maize</u>: wider ranges of MLs and rejection rates, up to and about 5% should be presented and consideration should be given to processes that could reduce contamination in this category, including polished rice, similar to the considerations taken for DON in flour, meal, semolina and flakes derived from wheat, maize or barley, and arsenic in rice, respectively.

130. For cereal-based food for infants and young children: data should be analyzed to determine if the ML should be set for the product "as is" or "on a dry matter basis". A comment was made to set the ML on "as is" basis as the most straightforward method that would not require an adjustment of the moisture content in the products.

#### Conclusion

131. CCCF agreed that the EWG should further the work on these categories, with the aim to finalize the MLs at CCCF15, taking into account the comments made during this session. This would include presentation of a wider range of MLs and rejection rates, especially up to and about 5%, which would also apply to maize grain, and to include considerations on the effect of processing on the reduction of aflatoxins contamination.

#### **Methods**

132. CCCF noted while there were several internationally validated methods available that could be used for the MLs proposed and even for lower MLs, consideration should be given when setting MLs to ensure that the methods were widely available for use, that they could meet the LOQ and LOD recommendations of CCMAS when measuring each isomer in the sum of components, and should also consider whether MLs allow rapid field methods for rapid screening and routine use.

#### JECFA dietary exposure assessment

133. CCCF noted that there was no need for a JECFA dietary exposure assessment at this point, in view of further work on the MLs and that such a request could be reconsidered at CCCF15.

#### **General Conclusion**

134. See Agenda Item 10(b).

# SAMPLING PLANS AND PERFORMANCE CRITERIA FOR TOTAL AFLATOXINS IN CERTAIN CEREALS AND CEREAL-BASED PRODUCTS INCLUDING FOODS FOR INFANTS AND YOUNG CHILDREN (Agenda Item 10b)<sup>17</sup>

- 135. Brazil introduced the item and referred to the recommendations concerning sampling plans and performance criteria for the establishment of MLs for total aflatoxins in these products.
- 136. CCCF confirmed:
  - The need for sampling plans and agreed that they should be developed simultaneously as the MLs were developed to ensure that when the MLs were finalized, the corresponding sampling plans would be available to support these MLs.
  - Consideration could be given to aligning with existing sampling plans in GSCFF, but also to consider other approaches such as ISO 24333:2009.
  - There was no need to request advice from CCMAS on establishment of performance criteria on "sum of components" at this time. The reply from CCMAS36 (2015) on the same question for fumonisins might be equally applicable to aflatoxins. However, the EWG chair noted this question had been discussed in the WG and Members had expressed concerns.

### General Conclusion: Agenda Items 10(a)/10(b)

#### 137. CCCF agreed:

- i) to re-establish the EWG, chaired by Brazil and co-chaired by India, working in English to:
  - a. continue working on MLs for total aflatoxins in maize grain; flour, meal, semolina and flakes derived from maize; husked and polished rice; sorghum grain destined for further processing and cerealbased food for infants and young children, as well as associated sampling plans, taking into account the written comments submitted, comments, conclusions and decisions made at the session and new data from GEMS/Food and
  - b. work in close collaboration with the EWG on data management (see Agenda Item 17).

<sup>&</sup>lt;sup>17</sup> CX/CF 21/1/4/10-Part II, CX/CF 21/14/10-Add.2 (Argentina, Canada, Cuba, Chile, Egypt, Iran, Kenya, Mexico, Republic of Korea, USA, AOCS and EURACHEM)

ii) to request the JECFA Secretariat to issue a call for data on all the categories under discussion with a view to obtaining more geographically representative data and to include a request for country of origin and if possible to differentiate between maize for food or feed with the aim to finalize the MLs next year and

- iii) if no data are submitted, the MLs would be finalized on the existing data set by the next session of CCCF.
- 138. CCCF urged all countries with an interest in the categories discussed to submit data onto GEMS/Food and to actively participate in the EWG.

MAXIMUM LEVEL FOR TOTAL AFLATOXINS IN READY-TO-EAT PEANUTS AND ASSOCIATED SAMPLING PLAN (Agenda Item 11)<sup>18</sup>

MAXIMUM LEVELS FOR TOTAL AFLATOXINS AND OCHRATOXIN A IN NUTMEG, DRIED CHILI AND PAPRIKA, GINGER, PEPPER AND TURMERIC AND ASSOCIATED SAMPLING PLANS (Agenda Item 12)<sup>19</sup>

139. The Codex Secretariat reminded CCCF that consideration of these items was suspended in 2018 to ensure implementation of the respective codes of practice for the prevention and reduction of aflatoxin contamination in peanuts (CXC 55-2004) and mycotoxins in spices (CXC 17-2017) and to resume discussion in 3 years' time to reconsider the MLs based on new/additional data submitted to GEMS/Food. The Secretariat further recalled that the JECFA Secretariat would issue a call for data in 3 years' time to assist the work of the EWGs following their re-establishment by CCCF.

#### Ready-to-Eat Peanuts

- 140. Delegations emphasized the following:
  - The importance of accelerating the finalization of the ML and sampling plan to ensure public health and fair practices in trade.
  - The COP (CXC55) has been available for implementation by member countries for many years now.
  - The GEMS/Food should be the reference source of data to derive MLs for contaminants in Codex.
  - The impact assessment conducted by JECFA83 should be taken into account when considering proposals for MLs for AFTs in ready-to-eat peanuts.
  - The new dataset (data from 2018 onward) should be utilized in addition to the old dataset when considering
    proposals for MLs to enable identifying possible differences between the old and new ML proposals due to the
    implementation of the COP.
  - The ML should take into consideration the previous ML set for peanuts intended for further processing.

Certain spices: Nutmeg, dried chili and paprika, ginger, pepper and turmeric

- 141. Delegations generally supported to resume work on the establishment of MLs for nutmeg, dried chili and paprika, ginger, pepper and turmeric and associated sampling plans.
- 142. India expressed its willingness to continue chairing both EWGs.

# Conclusion

#### Ready-to-Eat Peanuts

- 143. CCCF agreed to:
  - i) re-establish the EWG, chaired by India, working in English, to:
    - a. consider new or additional data available on GEMS/Food only and take into account old and new data for comparison;
    - b. update the working paper that was last presented at CCCF12 (2018) (CX/CF 18/12/10) and
    - c. prepare revised proposals for MLs for total aflatoxins in Ready-To-Eat Peanuts and associated sampling plan for comments and consideration by CCCF15 (2022), taking into consideration the outcome of the impact assessment conducted by JECFA83 and the new and old datasets available on GEMS/Food.
  - ii) request the JECFA Secretariat to issue a call for data to collect data for further consideration by the EWG.

<sup>&</sup>lt;sup>18</sup> REP18/CF, para. 115, Appendix VII; REP19/CF, paras. 16, 80; REP18/EXEC2-Rev.1, para.23

<sup>19</sup> REP18/CF, para. 119, Appendix VIII; REP19/CF, para. 81

Certain spices: Nutmeg, dried chili and paprika, ginger, pepper and turmeric

144. India also requested that, following the assessment of the new data available on GEMS/Food and proposals for MLs, that the EWG would put forward for consideration by CCCF15, JECFA could do an impact assessment of the different proposals if needed.

#### 145. CCCF agreed to:

- i) re-establish the EWG, chaired by India, working in English, to:
  - a. consider new or additional data available on GEMS/Food;
  - b. update the working paper that was last presented at CCCF12 (2018) (CX/CF 18/12/11) and
  - c. prepare revised proposals for MLs for total aflatoxins and ochratoxin A in spices: nutmeg, chili and paprika, ginger, pepper and turmeric, respectively, for comments and consideration by CCCF15 (2022) and associated sampling plans taking into account the new and old datasets available on GEMS/Food.
- ii) request the JECFA Secretariat to issue a call for data to collect data for further consideration by the EWG.

#### METHYLMERCURY IN FISH (Agenda item 13)<sup>20</sup>

146. New Zealand, as Chair of the EWG, introduced the item and provided key points in relation to the proposals for the establishment of MLs for methylmercury in additional fish species, sampling plans and the background to the work, summarized the process followed by the EWG, the conclusions and recommendations for consideration by CCCF.

#### Selection of species for ML setting

- 147. The EWG Chair explained the selection of species for ML setting was clear exceedance of the agreed selection criterion of 0.3 mg/kg methylmercury. He further explained that there were questions around a trade criterion to select species for ML setting. The EWG had discussed various options, but the majority view was to benchmark trade significance from species that currently have MLs and as a result, Marlin, which is the species with the lowest export volume out of the species, had been used as a reference species.
- 148. Setting group MLs for the taxonomic groupings that would include pink cusk eel and Patagonian toothfish was not supported by the EWG because of lack of or insufficient data for some of the species therein or because some of them were below the 0.3 mg/kg criterion e.g. an ML for all toothfish species in the taxonomic grouping was not supported because there was no methylmercury data for Antarctic toothfish and also that the total mercury data was below the selection criteria for this species.
- 149. The three species (orange roughy, pink cusk eel and Patagonian toothfish) for which new work was proposed, had all met the selection criterion with or without consideration of trade, but that in order to proceed with developing the ML for Patagonian toothfish, more data would be needed to set a robust ML.
- 150. With the three species identified for ML setting and 48 taxonomic groups of fish in total reviewed (summarized in Appendix II of CX/CF 14/21/11), the review of MLs for any other additional fish species could be discontinued.

#### Sampling plans/literature review

- 151. The EWG Chair confirmed that there was a potential for large variation of methylmercury in fish and a lot, and this differed mainly along weight or length of fish. There was limited data on the variation of methylmercury between different tissues in an individual fish. One of the difficulties is then relating any tissue variation in methylmercury back to the data sets in GEMS/Food because the sampling location on fish was not generally recorded. An initial proposal was to address these issues with species specific sampling parameters and appendices, but this approach was not favoured. Consequently, the proposed approach and format for a sampling plan is presented in Appendix IV of CX/CF 21/14/11 so that work can progress with an approach where the provisions for sampling are on different weight and value classes of the fish. This could be further refined through consideration of commercial weights for those species with MLs, to ensure the correct weight classes, and also by reviewing national sampling plans where sampling tissue is undertaken.
- 152. CCCF was informed that in identification of the literature around the above questions and consideration of the risk management measures, it was identified that there was not a consolidated source of advice on risk management measures for managing methylmercury in fish. It was therefore proposed to undertake a literature review to understand if there is sufficient literature available to develop such advice.

<sup>&</sup>lt;sup>20</sup> CX/CF 21/14/11

#### **Discussion**

#### Consideration of the MLs

153. There was general support to start new work for orange roughy and pink cusk eel, but in view of the lack of sufficient data for Patagonian toothfish, it was felt that further review was needed on the feasibility for setting an ML for this species.

- 154. An observer, while supporting the new work, expressed the view that when setting MLs for methylmercury, consideration should also be given to selenium content in fish as research, which it had consulted, had reported that mercury is toxic because it binds to selenium enzymes, thereby preventing the enzymes' proper function, so it is the ratio of selenium to mercury in fish that determines methylmercury's toxicity and not its absolute level in fish..
- 155. The JECFA Secretariat announced that FAO/WHO would be convening another expert meeting to update the risk/benefit of fish consumption which had been done around 10 years ago, and would consider the claims around selenium and if there were sufficient clinical evidence to support this, then it would be taken into account.

#### Trade criterion

- 156. On a question to clarify how to address a trade criterion to select species for ML setting, the Codex Secretariat clarified that there was no specific trade criterion defined on which to base ML setting and that CCCF should be guided overall by the dual mandate of Codex and more specifically by the rules/principles established by CCCF, especially in the Preamble to the GSCFF.
- 157. She drew attention of CCCF to the dual mandate of Codex, viz. "protecting the health of the consumers and ensuring fair practices in the food trade;" and stated that normally the Committee fulfilled this mandate by setting MLs for contaminants of public health concern or importance for commodities that are moving in international trade.
- 158. She furthermore drew attention to the general principles for establishing MLs in the Preamble of the GSCFF, specifically that:

"MLs should be set only for those contaminants that present <u>both a significant risk to public health and a known or expected problem in international trade."</u>

"Maximum levels shall be based on sound scientific principles leading to levels, which are acceptable worldwide, so that there is no unjustified barrier to international trade."

"MLs shall only be set for food in which the contaminant may be found in amounts that <u>are significant for the total exposure of the consumer</u>, taking into consideration the Policy of the Committee on Contaminants in Foods for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups (Section IV of the Procedural Manual)."

- 159. Noting the above, it was noted that the extent of trade was not touched upon, but rather whether there was a known or expected trade problem, and thus one could argue that not having harmonized MLs could lead to such a problem in trade. The role of Codex was to develop internationally agreed MLs informed by scientific risk assessment and having the least impact on trade. To ensure no unjustified barrier to international trade, and having no negative impact on food security, CCCF established MLs based on ALARA with a reasonable rejection rate.
- 160. She also noted that while there were trade criteria in the "Criteria for the establishment of work priorities (criteria applicable for commodities)" which touched on volume of production and consumption in individual countries and volume and pattern of trade between countries, it was understood that that this was applicable to new work proposals for commodity standards which were normally quality related, rather than safety standards. These criteria were also not applicable to horizontal standards and such criteria were never developed as was noted in a paper prepared by the Secretariat in the review of the Critical Review<sup>21</sup>.
- 161. Thus, guided by the Preamble of GSCFF, it would appear that there was no basis to weigh the amount of trade/trade significance in the setting of MLs. It was also questionable if it would be feasible to define a trade criterion (such as looking at trade volumes or value) as it would not necessarily be the case that if a commodity is traded in lower volumes, that there wouldn't be a public health concern where a commodity is highly consumed. In addition, lower volumes could still have large economic relevance.
- 162. In the case of safety standards, and when looking at the dual mandate of Codex, consumer health protection would in many ways "have greater importance than" the issue of trade. When taking risk management decisions, CCCF would need to ensure that such measures have the least trade disruptive effect while guaranteeing that public health is not unduly affected. Such efforts can be assisted at times if an assessment of the impact of a hypothetical MLs on dietary exposure is requested as needed from JECFA.

<sup>&</sup>lt;sup>21</sup> CX/EXEC 20/78/4

# **Conclusio**n

163. CCCF agreed to start new work on MLs for methylmercury in orange roughy and pink cusk eel and to amend the project document accordingly.

#### Sampling plans

164. CCCF noted the support for further work on the sampling plan following the approach proposed in Appendix III of CX/CF 21/14/11 and that further work should ensure the practicality of the sampling plan.

#### Literature review on risk management measures

165. There was general support for undertaking a literature review to identify the feasibility of developing guidance for the management of methylmercury levels in fish. The EWG Chair clarified that the literature review aimed to identify practical measures for the management of methylmercury in fish (e.g. at the catch, sorting and processing level).

#### **General Conclusion**

- 166. CCCF agreed to:
  - i) submit the project document for new work on MLs for methylmercury in orange roughy and pink cusk eel (Appendix VI) to CAC44 for approval;
  - ii) discontinue the review of MLs for any other additional species;
  - iii) establish an EWG chaired by New Zealand, and co-chaired by Canada, working in English, to:
    - a. develop MLs for orange roughy and pink cusk eel;
    - b. consider further data to establish the feasibility of setting an ML for Patagonian toothfish;
    - c. develop the sampling plan and
    - d. conduct a literature review to assess the feasibility of developing guidance for the management of methylmercury in fish.
  - iv) request the JECFA Secretariat to issue a call for data specific for orange roughy, pink cusk eel and all toothfish.

# HYDROCYANIC ACID AND MYCOTOXIN CONTAMINATION IN CASSAVA AND CASSAVA-BASED PRODUCTS (Agenda Item 14)<sup>22</sup>

#### Mycotoxins in cassava and cassava-based products

- 167. Nigeria, as Chair of the EWG, introduced this item, and highlighted that, based on the replies to CL 2019/74-CF and CL 2020/51-CF, as well as data and information provided by members of the EWG, it was possible to identify risk mitigation measures available to date that have proven to be cost-effective and applicable worldwide by large, medium and small-scale farmers and producers. The replies also provided the scope of the COP as to the relevant mycotoxins (i.e. aflatoxins and ochratoxin A) and the stages of the production chain to be covered by the COP (i.e. pre-planting, planting, post-harvest processing including fermentation, drying, storing and distribution). The EWG Chair further informed CCCF that based on these facts, there was general support for the development of a code of practice to prevent and reduce mycotoxins contamination in these products as presented in the Appendix I to CX/CF 21/14/12.
- 168. CCCF agreed with the development of the COP and to include a few amendments in the project document to improve clarity as proposed in CRD03.

- 169. CCCF agreed to:
  - submit the project document on the development of a Code of Practice for the prevention and reduction of mycotoxins contamination in cassava and cassava-based products to CAC44 for approval as new work (Appendix VII) and
  - ii) establish an EWG, chaired by Nigeria and co-chaired by Ghana, working in English, to work on the development of a Code of Practice for the prevention and reduction of mycotoxins contamination in cassava and cassava-based products, with focus on aflatoxins and OTA, and the stages of production as identified in the project document, based on the data and information provided in Appendix II to CX/CF 21/14/12.

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#### Hydrogen cyanide in cassava and cassava-based products

170. Nigeria, as Chair of the EWG, stated that data and information on HCN in cassava and cassava-based products as reported in Appendix III to CX/CF 21/14/12 indicated that it would be advisable to await new/additional data/information to become available in future, especially from ongoing studies in this field, to reassess the need and feasibility to establish MLs for these products.

171. CCCF concurred with this recommendation and recalled that the MLs for HCN in gari and cassava flour as contained in the GSCFF remain unchanged.

#### **Conclusion**

172. CCCF agreed to discontinue the discussion on the establishment of MLs for HCN in cassava/cassava-based products and to await new/additional data to become available in the future, especially from ongoing studies in this field, to reassess the need and feasibility to establish new MLs for HCN in cassava and cassava-based products.

# CADMIUM AND LEAD IN QUINOA (Agenda Item 15)<sup>23</sup>

- 173. The JECFA Secretariat presented the paper, focusing on the analysis undertaken, the key findings and recommendations.
- 174. CCCF first considered whether it was necessary to establish MLs for cadmium and lead in quinoa, followed by a discussion on whether to extend the MLs for these contaminants in cereal grains to quinoa as presented in GSCFF or whether separate MLs for cadmium and lead in quinoa should be established.
- 175. While there was wide support for the establishment of MLs for cadmium and lead in quinoa, there were however divergent views on whether to extend the MLs for cereal grains in GSCFF to quinoa or to develop separate MLs.
- 176. Delegations in favour of extending the MLs for cereal grains to quinoa pointed out that MLs were needed in view of the growing trade and consumption of quinoa.
- 177. Delegations in favour of separate MLs pointed out that:
  - Quinoa is a pseudocereal and the conditions for growing were different from other cereals and therefore the establishment of MLs for quinoa should be based on quinoa-specific data.
  - It was not possible to extrapolate the MLs for cereals to quinoa due to differences in uptake for example of cadmium, which depends on the cultivar and the soil.
  - The data set used for the JECFA Secretariat analysis was very limited and further data were needed which should be more geographically representative. That data generation was ongoing in certain countries and could be submitted to GEMS/Food to support establishment of MLs specific for quinoa.
- 178. Other delegations questioned the appropriateness to establish MLs at this time, as:
  - There was no basis for MLs from a public health perspective since the analysis by the JECFA Secretariat showed
    that the extension of the current MLs for cadmium and lead in cereals to quinoa in CXS193 or the
    establishment of separate MLs at the levels proposed in the analysis, i.e. 0.1 or 0.2 mg/kg for cadmium and
    0.1 or 0.2 mg/kg for lead, would have little impact on exposure from these contaminants for the general
    population.
  - Setting such MLs would have cost and trade implications without any further benefit to public health.
  - No information had been provided that MLs were needed for trade harmonization. However, if CCCF were to proceed with the setting of MLs, that it should be clear that that would not be on the basis of public health protection.
- 179. Noting the diverse views expressed on whether or not to establish MLs, and if MLs were to be established, whether to extend the MLs for cadmium and lead in cereals to quinoa in CXS193 or whether to have separate MLs for quinoa, the limited data available, the need to consider the different cultivars and growing conditions, and ongoing work on data generation, the Chair proposed to postpone the discussion on MLs for cadmium and lead in quinoa for 3 years to allow data generation and submission to GEMS/Food. CCCF supported this proposal.

- 180. CCCF agreed:
  - to request the 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, in two-years' time;

<sup>23</sup> CX/CF 21/14/13; CX/CF 21/14/13-Add.1 (Australia, Canada, Chile, Cuba, Ecuador, Egypt, EU, Iraq, Japan, USA and IAEA)

ii) that the call for data should include a request for data on occurrence of lead and cadmium, and in addition consumption data, and country of origin should be indicated in the remarks field in order to help assess the geographic representativity of the data and

iii) the JECFA Secretariat would prepare an analysis of the new data and prepare a paper for consideration by CCCF17.

#### RADIOACTIVITY IN FEED, FOOD AND DRINKING WATER IN NORMAL CIRCUMSTANCES (Agenda Item 16)<sup>24</sup>

- 181. The European Union, as Chair of the EWG, introduced the item and recalled that, following information provided by the Representative of the Joint FAO/IAEA Division, CCCF13 had agreed that explorative work should be undertaken on food safety and trade issues associated with radionuclides in food (including drinking water) and feed in non-emergency situations. An EWG, chaired by the EU, and co-chaired by Japan was established to produce a discussion paper to increase the understanding of the presence of radioactivity in food and feed in non-emergency situations and to enable CCCF to take an informed decision on possible follow-up actions at this session.
- 182. The EWG Chair indicated that in the EWG comments were made as regards the need to have a stronger case made to CCCF to work further on this issue, to clarify the relation between the work to be possibly undertaken by CCCF and work already and planned to be undertaken by FAO, IAEA, WHO and UNSCEAR, and to clarify the terms used and to ensure consistent use of these terms. The discussion paper as presented in the Appendix I of CX/CF 21/14/14 took into account these comments.
- 183. The EWG Chair further noted that in the discussion paper it was concluded that naturally occurring radionuclides (i.e. mainly <sup>40</sup>K, <sup>210</sup>Po, <sup>228</sup>Ra and <sup>226</sup>Ra) are found in many different foods and tend to give radiation doses higher than those provided by artificially produced radionuclides (such as <sup>134</sup>Cs, <sup>137</sup>Cs, <sup>131</sup>I and <sup>90</sup>Sr) in situations not affected by a nuclear emergency situation in the past, but no specific safety problem for food, feed or drinking water due to the presence of naturally occurring radionuclides had been identified. Furthermore, no international trade issues had been identified due to the presence of naturally occurring radionuclides in food, feed and drinking water.

#### **Discussion**

184. Following comments, the Representative of the Joint FAO/IAEA Centre clarified that the informative document would be presented to CCCF before publication. The EWG Chair further clarified that the informative document would focus on naturally occurring radionuclides, shall inform on regional variations in presence of naturally occurring radionuclides in food (including drinking water) and feed, uptake variations depending on the type of food, and that the regular update on any development in the field of radioactivity will relate to naturally occurring and artificially produced radionuclides.

#### **Conclusion**

#### 185. CCCF agreed:

- i) that no further work was required to be done by CCCF at this time given that naturally occurring radionuclides in food, feed and water did not seem to be an issue for food safety and trade;
- ii) to welcome the offer of 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/water, thereby also reflecting regional variations and
- iii) to request IAEA to keep CCCF informed of any development in the field of naturally occurring and artificially produced radioactivity, in particular on the FAO/IAEA/WHO work to develop methodologies that could be used to produce criteria with which to assess radionuclides in food.

# GUIDANCE ON DATA ANALYSIS FOR DEVELOPMENT OF MAXIMUM LEVELS AND FOR IMPROVED DATA COLLECTION (Agenda Item 17)<sup>25</sup>

186. The European Union, as Chair of the EWG, introduced the item and recalled that CCCF12 (2018) considered the proposal of the JECFA Secretariat to develop a general guidance on data analysis for ML development that would help EWGs to take consistent approaches for data analysis. CCCF12 agreed to establish an EWG chaired by EU, co-chaired by Japan, the Netherlands and USA to prepare a discussion paper. In 2019, the EWG Chair informed CCCF13 that it had not been possible to prepare the discussion paper in time for consideration by the established EWG and instead, the EWG Chair prepared a paper containing a non-exhaustive list of topics for consideration by CCCF, and it was agreed to extend the scope of the work to address improved data collection. CCCF13 agreed to re-establish the EWG chaired by EU, co-chaired by Japan, the Netherlands and USA, to further develop the discussion paper based on the discussion at that session.

<sup>&</sup>lt;sup>24</sup> CX/CF 21/14/14

<sup>&</sup>lt;sup>25</sup> CX/CF 21/14/15

187. At the present session, CCCF was informed that the discussion paper in the Annex to CX/CF 21/14/15 was prepared by the EWG Chair and that due to the very late availability of the paper, no consultation with the Co-Chairs and EWG members had taken place.

#### Discussion

- 188. The discussion paper was presented with more details provided on application of rejection rates, identification and handling of outliers (extreme values) and presentation of data in EWG reports to CCCF.
- 189. CCCF was invited to provide views on the appropriateness of the identified topics and other possible topics for inclusion in a guidance for data analysis for ML development and improved data collection, and in particular on the suggestion to include discussion on elements to take into account when determining an appropriate rejection rate.

#### General comments

- 190. The general view was that the appropriate rejection rate, deviating from the 5% rejection rate which is regularly used as reference, is to be determined on a case by case basis. A possible guidance should only provide elements for consideration with sufficient flexibility for the choice of the rejection rate when setting MLs in CCCF.
- 191. There was general support to the topics identified in the discussion paper. Several delegations indicated that the guidance should focus first on data submission (collection), data analysis and data presentation as this had priority and were not in favour of including discussion on elements for choosing appropriate rejection rates while others indicated that such guidance would be helpful.
- 192. As regards the issue of identification and handling of outliers, the JECFA Secretariat expressed their support for the work of the EWG and indicated that they could provide information on how outliers and extreme values, as well as other issues of data analysis as indicated in the paper, are handled by JECFA when evaluating available occurrence data for exposure assessments. It was welcomed that JECFA would supply such information to the EWG.

#### Additional comments

193. The following additional topics/issues were raised during the exchange of views:

Reporting LOQs

194. The importance of reporting the LOQ and to provide guidance on how to report levels of contaminants which are a sum of components and for which certain components are not quantified (lowerbound versus upperbound).

Reporting occurrence data on GEMS/Food

- 195. The important elements to be provided when reporting occurrence data should be specified in the call for data for submission to the GEMS/Food database.
- 196. The EWG Chair indicated that data can be submitted to the GEMS/food database not only in response to a specific call for data and therefore general guidance on what information is important to be provided when submitting occurrence data to GEMS/Food database would be appropriate.

Availability of data on GEMS/Food Handling of data not submitted to GEMS/Food

- 197. The handling of data not submitted to the GEMS/Food database noting there is an obligation for data to be submitted to the GEMS/Food database for it to be considered in the data analysis..
- 198. For the data analysis of large datasets, it is important that all relevant information is provided in specific fields (for sorting/filtering of data) and not in the "comment field".
- 199. In addition, guidance on how the EWG should deal with specific situations would be appropriate, e.g. no data available in GEMS/Food database, or if additional information on origin or purpose of food was not provided.

Data from imports

200. Data from imports are biased as they have to comply with specifications of the importing country and are not necessarily geographically representative for the presence of a contaminant in food commodities. Therefore, consideration should be given to exclude such data sets from the data analysis.

FAO/WHO inputs into the guidance

- 201. The importance of input from FAO, WHO and GEMS/Food database managers into the development of this guidance. Step-wise approach to the development of the guidance
- 202. Given the extensive scope of the document, consideration could be given to break down the work and to determine topics for discussions in a first phase, with the understanding that the other topics will be discussed at a later stage.

Handling of outliers

203. The importance of guidance on how to identify and deal with outliers.

Availability of calls for data in all UN languages

204. The need to have calls for data in all UN languages to ensure better participation of non-English speaking countries into the data submission.

- 205. In order to facilitate the participation of certain countries in the work of the EWG, the importance to be able to work in other languages than English was highlighted. The EWG Chair noted that this was not feasible in view of the extensive work ahead and the commitment to present the outcome of the discussions of the EWG at CCCF15 but indicated that comments could be submitted in French and Spanish in the EWG, but that the working document (i.e. the guidance) would be presented in English only.
- 206. The Codex Secretariat informed that all Codex documents, in particular circular letters (CLs), are available in English, French and Spanish.
- 207. The JECFA Secretariat indicated that they would consider to provide calls for data and other JECFA documents in UN languages other than English but stressed that this would require additional resources which are not currently available, and as such, would require consultation on a case by case basis. The Secretariat encouraged Codex members to consider provision of extra-budgetary resources to JECFA to cover the expenses of providing calls for data and other JECFA documents in UN languages other than English.

#### Conclusion

#### 208. CCCF agreed:

- i) that the work should be focused on data collection, data analysis and data presentation as a priority in the coming year and that discussion on elements for consideration such as appropriate rejection rates would not be taken up for now;
- ii) that a CL will be issued requesting Codex members and observers to submit comments on the topics identified in the Annex to CX/CF 21/14/15, for consideration by the EWG in addition to the comments made at this session and
- iii) to re-establish the EWG chaired by European Union, co-chaired by Japan, the Netherlands and USA, working in English only, to prepare guidance on data analysis for development of MLs and for improved data collection based on the comments provided at this session and those in reply to the CL.
- 209. The Chair urged the EWG Chair to start work within the EWG without any further delays and to regularly report on its progress to the Codex Secretariat and the Chair of CCCF to ensure a timely completion of the guidance for discussion at CCCF15, given the importance of this work for future discussions on MLs within CCCF.
- 210. The Chair encouraged Codex members and observers to actively participate in this EWG. She also reiterated that the EWG Chairs dealing with MLs, i.e. Ecuador, Brazil, India and New Zealand, should work in close collaboration with the EWG on data analysis in order to take into account, to the extent possible, the outcomes of the discussions in this EWG when proposing MLs for consideration at CCCF15.

# APPROACH TO IDENTIFY THE NEED FOR REVISION OF STANDARDS AND RELATED TEXTS DEVELOPED BY THE CODEX COMMITTEE ON CONTAMINANTS IN FOODS (Agenda Item 18)<sup>26</sup>

- 211. Canada, as Chair of the EWG, introduced this item, reminding that there was no structured approach to review existing standards and related texts for contaminants in food and feed including maximum levels (MLs), guideline levels (GLs) and codes of practice (COP) to determine the need for their revision. The EWG had been tasked to propose a practical approach to identify the need for revision of existing standards and related texts developed by CCCF for consideration at this session.
- 212. Three options had been proposed by the EWG as described in paragraph 2 of CX/CF 21/14/16. A circular letter, CL 2020/53-CF, had been issued recommending consideration of the available options for a 3 year trial period and based on the broad support for Option 2 the EWG was presenting a systematic approach for how CCCF would implement and operationalize this option on a 3-year trial basis.
- 213. The EWG Chair clarified that this option would provide flexibility and place the least administrative burden on CCCF. Furthermore, she emphasized that this structured approach would not preclude the continued ad hoc review of existing Codex standards and related texts upon nomination by a Codex member, consistent with the guidance provided in the Preamble to the GSCFF and the Procedural Manual.

<sup>&</sup>lt;sup>26</sup> CX/CF 21/14/16;

214. The EWG Chair also informed that proposed prioritization criteria for identifying standards and related texts for review had been developed which took into account both potential human health impact and possible trade disruptions.

#### Discussion

- 215. CCCF expressed general support to implement Option 2 on a 3-year trial basis as outlined in paragraph 9 13 of CX/CF 21/14/16.
- 216. A view was expressed that in a case that an ML was established for a certain contaminant due to health concerns, the ML should not be increased by the review, unless i) there was a trade disruption caused by a change of the Codex Classification of Food and Feed or commodity standard (and consequently additional commodities are covered by the ML for which no occurrence data were assessed for the establishment of the ML) and/or ii) if a better description of the commodity covered by the ML could mitigate to a certain extent the observed trade disruptions (e.g. by adding "intended for further processing" or by specifying the portion of the commodity /product to which the ML applies).
- 217. The EWG Chair clarified that the prioritization criteria were flexible and based on the results of the 3-year trial further consideration could be given to the criteria.

#### **Conclusion**

- 218. CCCF agreed to:
  - i) implement the pilot on the review of Codex standards for contaminants in food and feed (Option 2) on a threeyear basis as outlined in paragraphs 9-13 of CX/CF 21/14/16 using the prioritization criteria as presented in Appendix I of CX/CF 21/14/16;
  - ii) request the Codex Secretariat to circulate the tracking lists for comments, in the form of a CL, in advance of CCCF15 (2022) based on input provided by Canada;
  - iii) consider the comments in reply to the CL in an in-session WG to be established at CCCF15 (2022), chaired by Canada, in order to make recommendations to CCCF on the need to revise Codex standards and related texts for contaminants in food and feed and
  - iv) note that the pilot (Option 2) could be evaluated as outlined in paragraphs 14-16 of CX/CF 21/14/16 to further improve the procedures for review on a needed basis.

### FORWARD WORK-PLAN FOR THE CODEX COMMITTEE ON CONTAMINANTS IN FODDS (Agenda Item 19)27

#### Review of contaminant/staple food combinations for future work of CCCF

- 219. The Host Country Secretariat introduced the item and noted that the paper was developed in collaboration with the Codex and JECFA Secretariats. Referring to CX/21/14/17, and noting that the paper had been issued just prior to the session, she explained that it would be circulated for comments and thus was presented at this session for information only.
- 220. She recalled the intent of the forward plan, which was to identify food contaminants of public health and trade concern in staple foods moving in international trade which might need to be addressed by CCCF in future. She recalled that this paper was developed as a result of the discussion on the forward plan at CCCF13, that it was agreed to focus on staple foods as contamination in these foods could have a significant impact on exposure and thus be a health risk to populations, and that the intent of the document was to provide an approach/methodology (screening method) so that a list of contaminant/staple food combinations could be identified for further follow-up by CCCF.
- 221. The approach was illustrated by three examples, which could be expanded if there was agreement on the approach presented. The choice to take up work from the list of interest that would be developed should take account of the workload of CCCF and form part of a prioritization process for CCCF together with, the follow-up to JECFA/FAO/WHO evaluations/expert meetings, the review of existing standards for contaminants in food and feed and possible other proposed new work.
- 222. She further explained that if there were agreement on this approach, based on comments received to the CL, the approach/methodology could be further refined, such as refining the list of staple foods which had now a varying level of detail, and identifying further contaminant/staple food combinations beyond the three examples of staple foods. The intent was that, once the framework is finalized and agreed by CCCF, a mechanism for taking the work further could be identified by CCCF15, e.g. for an EWG to take the work forward.

<sup>27</sup> 

#### **Conclusion**

#### 223. CCCF agreed that:

- i) the Codex Secretariat would issue a CL requesting comments on the approach/methodology proposed and
- ii) the Host Country Secretariat, JECFA and Codex Secretariats would consider the comments received and further develop the paper for consideration by CCCF15.

#### <u>Project plan for the evaluation of implementation of COPs of CCCF</u>

- 224. The Codex Secretariat introduced the item, and recalled that at CCCF13, the Host Country Secretariat introduced a proposal on developing a pilot project to evaluate the implementation of COPs in the context of the forward workplan discussion. CCCF13 had agreed with the approach to launch a pilot project and that a more detailed proposal would be prepared and presented to this session.
- 225. She however reported that a more detailed proposal had not been prepared in light of ongoing discussions among the Host Country Secretariat, FAO, WHO and the Codex Secretariat on how to approach the pilot. The project fell within the purview of FAO and WHO in terms of its technical assistance programmes and also with the Codex Secretariat especially in light of the ongoing discussion on the monitoring of use of standards in Codex as one of the objectives of the Codex Strategic Plan 2020-2025.
- 226. In view of the above, the Codex Secretariat, in consultation with FAO and WHO, and also with the Host Country Secretariat, will continue looking at ways of taking this project forward in the context of monitoring the use of Codex standards and would keep CCCF informed on progress.
- 227. The Representative of FAO informed CCCF that FAO continued to be available to provide technical assistance and capacity building on a needs basis.

#### **Conclusion**

228. CCCF agreed with the recommendation of the Codex Secretariat as stated in paragraph 226.

# JECFA EVALUATIONS (Agenda Item 20)<sup>28</sup>

#### Priority list of contaminants for evaluation by JECFA

- 229. The Codex Secretariat recalled that due to the virtual nature of CCCF14, the usual in-session of the WG on Priorities chaired by USA could not be held and instead, the Codex Secretariat prepared a working document CX/CF 21/14/18 to update the priority list as shown in the Annex to this document, based on the outcomes of the JECFA evaluations on ergot alkaloids (removed) and trichothecenes (T2 and HT2) (add information related to the status of the JECFA evaluation), the issues raised under Agenda Item 2 on scopoletin, and the replies to CL 2020/24-CF by which no new compounds had been added and only an additional note were made in relation to data availability on arsenic.
- 230. With regard to scopoletin, the Codex Secretariat recalled that this compound had been included in the priority list at the request of CCNASWP13 (2014) and retained in the list at the request of CCNASWP14 (2016) and CCNASWP15 (2019). She drew attention to a consultant's report on the findings of the toxicological data review available in the Annex of CX/CF 21/14/2-Add.1 which was not for discussion by CCCF but for consideration by CCNASWP16 (2022). The Secretariat proposed to keep scopoletin in the priority list awaiting feedback from CCNASWP16 on whether countries from the south-west Pacific region could provide the data and studies required to support the evaluation of scopoletin by JECFA and their subsequent consideration by CCCF. She further advised that Codex members and observers interested in noni products/scopoletin, besides those from the south-west Pacific region, were encouraged to generate/provide relevant data/information to GEMS/Food to enable the evaluation of scopoletin by JECFA and their subsequent consideration by the Committee. CCCF concurred with these recommendations.

# <u>Conclusion</u>

#### 231. CCCF agreed to:

- endorse the priority list as amended (Appendix VIII);
- ii) keep scopoletin in the priority list awaiting feedback from CCNASWP16 on the provision of necessary data and studies to perform evaluation of scopoletin and to encourage Codex members to generate and submit data to GEMS/Food;
- iii) continue to request comments and/or information on the priority list for consideration by CCCF15 and
- iv) re-convene the in-session WG at CCCF15 chaired by USA.

<sup>&</sup>lt;sup>28</sup> CL 2020/24-CF; CX/CF 21/14/18; CX/CF 21/14/18-Add.1 (Canada, Chile and Ecuador); CX/CF 21/14/2-Add.1; CX/CF 21/14/3

#### Follow-up work to the outcomes of JECFA evaluations and FAO/WHO expert consultations

232. The Codex Secretariat further recalled that due to the virtual nature of CCCF14, the in-session WG on the Follow-Up to JECFA Evaluations and FAO/WHO Expert Consultations led by the European Union could not be held and that instead, the Secretariat prepare a working document CX/CF 21/14/18 highlighting the recently concluded JECFA evaluations and FAO/WHO expert consultations relevant to the work of CCCF.

- 233. The European Union provided further information on the compounds listed in CX/CF 21/14/18 as follows:
  - Pyrrolizidine alkaloids: JECFA80 (2015) had evaluated PAs on request of CCCF05 (2011), and CCCF10 (2016) agreed to discuss PAs once the full JECFA evaluation became available. He drew attention to the key outcomes of the JECFA evaluation and noted that now that the report had been published CCCF should consider follow-up actions which could include possible revisions to the Code of Practice for Weed Control to Prevent and Reduce Pyrrolizidine Alkaloid Contamination in Food and Feed (CXC 74-2014) or consider the feasibility of other risk management measures (i.e. MLs).
  - Ciguatera Poisoning: The report of the FAO/WHO Expert Meeting on Ciguatera Fish Poisoning (2018) was published in 2020. He noted that the expert meeting was convened at the request of CCCF11 (2017) to request scientific advice from FAO and WHO to allow CCCF to develop appropriate risk management options to address this matter. The Expert Meeting concluded that there are many gaps in the available information about ciguatera poisoning, and there were some needs that require urgent attention regarding both risk management and research and drew attention to the FAO/IAEA/IOC-UNESCO initiatives as highlighted in CX/CF 21/14/3.
  - Trichothecenes: JECFA90 (2020) updated the risk assessment including an exposure assessment on T-2 and HT-2, at the request of CCCF11 (2017). The full evaluation was not yet complete and was still on the priority list for JECFA evaluations, thus follow-up actions could be considered once the full evaluation became available.
  - Ergot alkaloids: JECFA91 (2021) evaluated ergot alkaloids at the request of CCCF13 (2019). JECFA91 noted that some exposure estimates exceeded the group health-based guidance value (HBGV) established for ergot alkaloids, and that this may indicate a human health concern. However, the full JECFA evaluation was not yet available, and proposed that follow-up actions be considered once the full evaluation became available.
  - (-) scopolamine and (±) hyoscyamine (tropane alkaloids): The FAO/WHO Expert Meeting (2020) was convened
    to respond to a request for scientific advice from the World Food Program (WFP) after poisoning incidents
    from the distributed food aids. The Expert Meeting had proposed operational limits that should be health
    protective for adults and children for WFP products, but that these limits could be extended also to other
    cereals and grain products when consumed in comparable quantities.

#### Edible insects

234. The Codex Secretariat recalled that this issue was brought to the attention of the Committee under Agenda Item 3 and referred for consideration under this Agenda Item. The Secretariat noted that there was an interest from Codex members to consider work in CCCF on edible insects. However, this was a cross-cutting issue that might need action in other committees in Codex, such as CCFH and CCRVDF. Therefore, it would not be advisable to consider this issue in isolation in each committee. The Secretariat therefore proposed that guidance should be sought from CCEXEC on how best to proceed in a more cohesive way on risk management measures to ensure safety of edible insects. She further noted that edible insects could be considered as an emerging food safety issue where Codex should give a timely response in line with Goal 1 of the Codex Strategic Plan 2020-2025. CCCF concurred with this recommendation.

#### **Conclusion**

#### 235. CCCF agreed to:

- establish an EWG chaired by European Union, working in English, to prepare a discussion paper on pyrrolizidine alkaloids to look into the feasibility of possible follow-up actions for consideration by CCCF15;
- ii) issue a CL requesting comments on possible follow-up actions to the outcomes of the JECFA evaluations and FAO/WHO expert consultations in particular those for which the full report was already available, such as ciguatera poisoning and tropane alkaloids, for consideration by the in-session WG to be convened at CCCF15;
- iii) re-convene the in-session WG at CCCF15 chaired by European Union and
- iv) request guidance from CCEXEC on the best approach to address the safety of edible insects in Codex.

# OTHER BUSINESS AND FUTURE WORK (Agenda Item 21)

236. CCCF noted that no other business had been proposed.

# DATE AND PLACE OF THE NEXT SESSION (Agenda Item 22)

237. CCCF was informed that CCCF15 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.

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#### **APPENDIX I**

# LIST OF PARTICIPANTS LISTE DES PARTICIPANTS LISTA DE PARTICIPANTES

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### **APPENDIX II**

### MAXIMUM LEVELS FOR CADMIUM IN CERTAIN CATEGORIES OF CHOCOLATES

### (For adoption at Step 8)

Commodity / Product Name	Maximum Level (mg/kg)	Notes/Remarks
Chocolates containing or declaring <30% total cocoa solids on a dry matter basis	0.3	Including milk chocolate, family milk chocolate, milk chocolate couverture, Gianduja milk chocolate, table chocolate, milk chocolate Vermicelli/milk chocolate flakes

### (For adoption at Step 5/8)

Commodity/Product Name	Maximum Level (mg/kg)	Notes/ Remarks
Chocolate containing or declaring ≥30% to <50% total cocoa solids on a dry matter basis,	0.7	Including sweet chocolate, Gianduja chocolate, semi – bitter table chocolate, Vermicelli chocolate/chocolate flakes, bitter table chocolate, couverture chocolate

APPENDIX III

# CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF CADMIUM CONTAMINATION IN COCOA BEANS (For adoption at Step 5)

### 1. INTRODUCTION

- 1. The objective of this proposed draft Code of Practice (COP) is to provide guidance to member states and the cocoa production industry on the prevention and reduction of cadmium (Cd) contamination in cocoa beans during production and postharvest processing: fermentation, drying and storage; including during any transportation that might be involved.
- 2. Cd is a heavy metal that predominantly enters the environment through anthropogenic activities such as processing ores, burning fuels, and waste, and the application of phosphate and sewage-containing fertilizers. Cd can also enter the soil naturally by volcanic activity, from marine shale soils, erosion or by sea-salt aerosols.
- 3. Cd is toxic and persistent in soil (estimated half-life for Cd in soils varying between 15 to 1100 years). Cd is absorbed and bioaccumulated by cocoa trees (*Theobroma cacao* L), which in some cases results in unacceptably high levels in cocoa beans, so measures may be needed to prevent Cd presence in the soil and reduce Cd absorption.
- 4. Cd is not found in nature in its pure state. Its most common oxidation state is +2 and it is usually found associated with iron (Fe), zinc (Zn), lead (Pb), phosphorus (P), magnesium (Mg), calcium (Ca), or copper (Cu) through its "cation exchange capacity". The concentrations of Cd in soil solution depend mainly on soil pH, which affects Cd solubility and mobility. Most metals in the soil tend to be more available at acidic pH, which increases the availability for plants.
- 5. Greater adsorption of Cd on the surface of soil particles is desirable, considering that this reduces the mobility of this contaminant in the soil profile and, consequently, its environmental impact. The concentration of heavy metals (Cd) in soil solution and, consequently, its bioavailability and mobility are mainly controlled by adsorption and desorption reactions on the surface of the soil colloids. Soil factors that affect the accumulation and availability of heavy metals include pH, texture, organic material, Fe and manganese (Mn) oxides and hydroxides, Zn, carbonates, chlorinity and cation exchange capacity.
- 6. Elevated chloride content in soils tend to enhance chloride complex formation, which decreases the adsorption of Cd on soil particles, thereby increasing Cd mobility and bioavailability.
- 7. Over time, the development in our understanding of how various cropping systems contribute or alleviate cadmium contamination in cocoa beans could be used to develop integrated systems for the management of cadmium levels in cocoa beans.
- 8. The grafting tool as a genetic strategy with low cadmium accumulation varieties is a viable option in various soil types and different Cd levels, but has only been tried experimentally for reducing Cd in cacao tress. Personal information obtained in field production areas of Peru showed that cocoa beans exported to Europe are crossed varieties with "Chuncho" Cacao". Leyva, C. 2019.
- 9. To mitigate Cd levels in cocoa beans it is crucial to identify cocoa-growing areas with high Cd and develop specific and general strategies to address this problem.

### 2. **SCOPE**

10. The scope of this Code of Practice is to provide guidance on recommended practices to prevent and reduce Cd contamination in cocoa beans before planting or for new plantations and during the production stage through the harvest and post-harvest phase including during any transportation phase that might be involved or existing plantations of cocoa trees that can produce beans for up to 25 years.

### 3. **DEFINITIONS**

**Biochar – biocarbon** is a byproduct of the pyrolysis of residual biomass.

Cocoa bean: The seed of the cocoa fruit composed of episperm (integument), embryo and cotyledon.

**Pulp or mucilage**: Aqueous, mucilaginous and acidic substance in which the seeds are embedded.

**Harvesting and opening the fruits**: Fruits are manually harvested and opened using a sickle, machete or wooden baton.

**Bioremediation**: The use of living organisms, primarily microorganisms, to degrade environmental contaminants into less toxic forms.

**Phytoremediation**: A type of bioremediation process that uses plants to remove, transfer, stabilize, and/or destroy contaminants in the soil and groundwater.

**Air emissions**: They are defined as unwanted gaseous or particulate materials (Cadmium) released to the atmosphere as a direct result of production, accumulation or consumption activities in the economy.

**Bioavailability**: Bioavailability of a mineral in nutrition to plants and soils can be defined as its accessibility to normal metabolic and physiological processes as influenced by many factors including total concentration and speciation of metals, pH, redox potential, temperature, total organic content (both particulate and dissolved fractions), and suspended particulate content.

**Adsorption, Absorption and Desorption**: Physical, chemical or exchange adsorption of cadmium to soil particles is a concept that refers to the attraction and retention that a body makes on its surface of ions, atoms or molecules that belong to a different body. Absorption is a term that refers to the damping exerted by a body before a radiation that passes through it; to the attraction developed by a solid on a liquid with the intention that its molecules penetrate into its substance; to the ability of a tissue or a cell to receive a material that comes from its outside. Desorption is the process of removing an absorbed or adsorbed substance.

Cachaza: by-product of sugar cane.

**Cation Exchange Capacity (CEC)**: A measure of the soil's ability to hold positively charged ions. It is a very important soil property influencing soil structure stability, nutrient availability, soil pH and the soil's reaction to fertilizers and other ameliorants. The clay mineral and organic matter components of soil have negatively charged sites on their surfaces which adsorb and hold positively charged ions (cations). This electrical charge is critical to the supply of nutrients to plants because many nutrients exist as Mg, K and Ca cations by electrostatic force.

**Electrical conductivity**: Electrical conductivity in metals is a result of the movement of electrically charged particles. The atoms of metal elements are characterized by the presence of valence electrons, which are electrons in the outer shell of an atom that are free to move about. In addition, it is denoted by the symbol  $\sigma$  and has SI units of siemens per meter (S/m). Electrical conductivity of water samples is used as an indicator of how salt-free, ion-free, or impurity-free the sample is; the purer the water, the lower the conductivity (the higher the resistivity). Conductivity measurements in water are often reported as specific conductance, relative to the conductivity of pure water at 25 °C.

**Drying process**: Drying of cocoa beans either under sunlight or in mechanical/solar dryers (or a combination of both) in order to reduce the moisture content (less than 8 %) to make them stable for storage.

**Fermentation**: process designed to degrade the pulp or mucilage and initiate biochemical changes in the cotyledon by enzymes and microorganisms inherent in the environment of the farm.

**Humus:** refers to compost that is obtained of artificial manner when organic waste is decomposed by organisms and beneficial microorganisms

**Soil Amendments**: Any material added to the soil to improve its physical and chemical properties. The application of amendment depends on the characteristics of the soils, and may include compost, magnesium carbonate, vinasse, zeolite (minerals that hydrate and dehydrate reversibly, adsorbents); charcoal or biochar; calcium sulphate, lime, cachaza, zinc sulphate, dolomite (calcium magnesium carbonate), vermicompost, sugar cane, palm kernel cake, phosphate rock, and other organic matter.

**Validation**: Obtaining evidence that a control measure or combination of control measures, if properly implemented, is capable of controlling the hazard to a specified outcome.

**Sampling**: Procedure used to draw or constitute a sample. Empirical or punctual sampling procedures are not statistically-based procedures that are used to make a decision on the inspected lot.

Pruning: annually removal from shade trees and cocoa plants of branches that are dry, diseased or un-balanced.

**Shading**: Growing cocoa plants with shade trees to reduce the amount of radiation and wind that reaches the crop. Shading is usually more or less 50% during the first 4 years of plant life after which percentage of shade can be reduced to 25 or 30%.

Vinasse: A byproduct of the production of alcohol from sugarcane.

### 4. RECOMMENDED PRACTICES TO PREVENT AND REDUCE Cd CONTAMINATION IN COCOA BEANS

### 4.1 Contamination before sowing – new plantations

11. The prevention and reduction of Cd in cocoa should begin with the physical-chemical analysis of the soil and be an integral part of the practices before sowing or establishment of a new plantation. Physical analysis parameters are: Sand %, clay %, silt %, textural class. Chemical analysis should consider: pH, organic matter %, Total N %; Available ppm of P, K, Pb, Fe oxides and hydroxides, Mn carbonates, Cd and Zn; Changeable (cmol (+) /kg) of Ca, Mg, K, Na, Al and, H; CEC, Bas. Camb %, Ac. Camb. %, and Sat. Al. suitable for farmers, and it should be kept in mind as a control measure CXC 49-2001: Code of practice concerning source directed measures to reduce contamination of foods with chemicals.

- 12. No specific recommendation on Cd levels in cocoa growing areas has been identified, but 1.4 mg/kg¹ has been identified as an upper level for Cd in soil for growth of other crops, and could be applied for new cocoa plantations. Water levels can be monitored to determine if they are a potential source of Cd, e.g. higher than background levels due to point source contamination; as an upper limit for Cd in water could be 0,005 mg/lt. Nonetheless, a largest nationwide published survey in Ecuador of Cd in cacao in terms of number of trees collected (n=560) allows to estimate soil Cd concentrations, which correspond to specific concentrations in cocoa beans. The data show, that for example, for ensuring that the mean Cd concentration in cocoa beans do not significantly exceed 1 mg Cd/kg, the soil Cd should not exceed 0.4 mg Cd/kg if the soil pH=5.0. If the soil pH = 7, the Cd concentration in the soil should not exceed 1.0 mg Cd/kg.
- 13. Although there are known benefits to agroforestry, data on the impact of agroforestry vs. monoculture on Cd levels, they are preliminary. Studies that have systematically or statistically compared agroforestry with monoculture found no statistically significant difference in Cd uptake in cacao beans.
- 14. The most commonly used species are musaceae (bananas, moles and cambures) for temporary shadows and legumes such as the pore or bucare (Erythrina sp.) and guabas (Ingas) for permanent shades. Other shading species are being used that provide greater economic benefits such as timber species (laurel, cedar, Colombian mahogany (*Cariniana pyriformis*), cenizaro or rain tree and terminalia) and / or fruit trees (citrus, avocado, sapote, breadfruit, date palm etc.). It is advisable to sow short trees and use citrus or fruit trees for the borders of cocoa plantations.
- 15. Install plantations in areas far from roads or take measures to reduce the exposure of the cacao plantations to gases emitted by the combustion of vehicles because they may contain Cd. Likewise, they should be located in areas separated from dumps in cities, mining areas, smelting areas, industrial wastes, sewage and household waste water because these could be a source of Cd.
- 16. Avoid flooded soils if the water sources are an increased source of Cd.
- 17. In new plantations, the use of cover crops of perennial legumes should be considered. Cover crops improve soil organic matter and they can protect soil from erosion and reduce the loss of nutrients, improving soil productivity through greater availability of essential nutrients and reducing the bioavailability of metals.

### 4.2 From production to the harvesting phase

- 18. Knowledge of the sources and the distribution of Cd in the soil is important. In general, it should be noted that any organic or inorganic amendment applied to the crop should be previously Cd analyzed, because depending on its source may contain levels of Cd and become a source to for the entry into the crop. Sewage sludges, fly ashes have high concentrations of Cd. The fertilizers applied should meet the specified criteria in relation to Cd levels.
- 19. Data suggest that there is a positive correlation between higher levels of Cd in soil (as measured by soil tests) and elevated levels of Cd in plant tissues and cocoa beans. Furthermore, multivariate regression analysis showed that bean Cd concentrations increased with increasing total soil Cd.
- 20. Soil characterization analysis laboratories for cocoa plantations should be conducted by laboratories that are accredited with the worldwide recognized ISO/IEC 17025:2017 standard; using validated methods which include the use of certified reference materials, standards and associated uncertainties. In addition, it is very important to carry out soil analyses with internationally recognized methods (e.g. endorsed by Codex Alimentarius) such as Flame Atomic Absorption Spectrometry (F-AAS), Inductively Coupled Plasma Optical Emission Spectrometry (ICP-OES), Graphite Furnace with Atomic Absorption Spectrometry (GF-AAS) and Inductively Coupled Plasma Mass Spectrometry (ICP-MS). These methods include appropriate ones for local farmers trying to export cocoa. These analyses not only include Cd but other nutrients too. It is important to clearly state here that soils well supplied with nutrients are less likely to bioaccumulate Cd.

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21. The soil sampling protocol should consider obtaining samples representative of each farm because Cd content could be variable in the same production area of cocoa. The protocol should take into account international standards for taking samples in soils specifically contaminated with metals.

22. In areas where cocoa beans have relatively higher levels of Cd it is important to determine soil and irrigation water salinity (Cd chloride salts) since the absorption of Cd by plants increases with chloride. Therefore, it is important to determine the electrical conductivity of soil and water which should be less than 2mS/cm. It seems that these measures would not be needed if there are no concerns regarding Cd levels in cocoa beans.

### 4.2.1 Strategies to immobilize cadmium in the soil

- 23. When there is a deficiency of Zn in the soil, soil Zn levels should be increased. Cd competes with Zn, and Cd is more likely to enter the plant and accumulate in cocoa beans when Zn soil concentration is low. Moreover, it is recommended to specify critical levels of Zn for cocoa, taking as a reference various methods of sample analysis, for example: DTPA, Olsen modified; with the aim of making the strategy more applicable.
- 24. The application of zinc sulphate is carried out with the balanced fertilization that is conducted annually at the cocoa plantation, according to the requirements of the crop and the soil. However, with the addition of zinc sulfate, soil acidification occurs, requiring addition of limestone.
- 25. Liming is an agronomic management practice that reduces Cd uptake by cocoa trees cultivated on highly acidic soils, and its addition also might improve nutrition and production of cocoa trees. However, it is important to know the content of Cd in these limes as they come from mines and are highly variable so everything depends on the origin of the raw materials used.
- 26. The most effective methods developed to date to decrease Cd bioavailability is through liming the soil when soil pH is below 5.5. When the pH is higher than 5.5 it should be known how to be managed.
- 27. Apply liming levels in low doses (3 t/ha/year) and preferably dolomite CaMg (CO<sub>3</sub>)<sub>2</sub> to gradually increase the pH and incorporate Ca and Mg that are essential for the growth of cocoa and can precipitate Cd decreasing its bioavailability. Over liming should be avoided.
- 28. A greater amount of soil organic matter causes a lower absorption of Cd and may help decrease Cd in cocoa beans, based on experimental studies. The use of organic fertilizers such as treated manure from stabled livestock, compost, etc. increases the organic matter content of the soil and improves its microbiological activity. Levels of 3 to 4 % of organic matter in cocoa plantations decreases cadmium in cocoa beans.
- 29. Phosphate fertilizers and sedimentary phosphoric rock may contain Cd as an impurity. Nonetheless, for successful cocoa production it is vital to add phosphate fertilizers because tropical soils have very limited native phosphorus content. However, producers should control the amount of Cd in phosphate fertilizers they use or comply with any national limits given by governments. In addition, by using organic fertilizers the phosphorus content of the soil can be improved, while these fertilizers show a high phosphorus bioavailability.
- 30. In general, the formula for the doses of nitrogen, phosphorus and potassium (NPK) in fertilizers to be applied to cocoa crop vary according to the age of the plant and the characteristics of the soil. Verify the heavy metal analysis prior of application to ensure that Cd content is low. Soils well supplied with nutrients are less likely to bioaccumulate Cd.
- 31. The application of soil amendments (magnesium carbonate (MgCO<sub>3</sub>), vinasse, zeolite, humus, charcoal, calcium sulfate (CaSO<sub>4</sub>), cachaza and zinc sulfate (ZnSO<sub>4</sub>), which vary depending on the characteristics of the soils, can help decrease Cd concentrations in cocoa beans.
- 32. Vinasse is a source of K that promotes the installation of fungi that form mycorrhizas in the roots of the cacao tree, increasing the efficiency of P nutrition and immobilizing Cd.
- 33. Lime and sugarcane cake can reduce the flow of Cd in the soil profile. Zeolite is another option in soils with high sand content in clay-textured soils. Also, Apatite (rock phosphate) would be very expensive compared to use of dolomitic limestone to raise pH and reduce soil Cd Phyto availability.
- 34. Biochar has been shown to reduce the bioavailability of Cd in cocoa beans. The reduction rates are comparable to liming and have an additive influence on liming. However, biochar is an expensive soil amendment and may not be cost effective for farmers who grow cocoa.
- 35. Biochar, compost and their combinations have significant effects on soil physicochemical features, metals (Cd) availability and enzyme activities in heavy metal-polluted soil. Therefore, they mitigate Cd concentration in soil.

36. The genotypes identified with low bioaccumulation of Cd have the potential to be used as rootstocks in the production of propagation material to reduce the absorption of Cd from soil; Moreover, Cd mitigation could be done by grafting plants with rootstocks with low cadmium content and obtaining new varieties that are not as prone to the absorption of Cd and modify soils to reduce Cd absorption by plants. Eleven cultivars of the "Chuncho" Cacao variety from Cusco – Peru had a range concentration of Cd (mg/kg) from <0.05 to 0.11, so the "Chuncho" Cacao variety could be used for grafting. Furthermore, when planting new plantations, it should be recommended to plant varieties of cocoa trees, which are less prone to cadmium uptake.

- 37. The Streptomyces sp. strain has bioremediation activity as it reduces Cd uptake in cocoa plants. This has been demonstrated on an experimental basis.
- 38. The legumes coinoculated with plant growth promoting bacteria Cd resistant such Streptomyces of the family Streptomycetaceae could be useful in phytoremediation of Cd-contaminated soils and biofertilization.

### 4.2.2. Avoiding further cadmium contamination of the soil

- 39. In areas where soil levels of Cd are high, remove pruned material from the ground as they could contain Cd, which will be released into the top layers of the soil after decay. The practice should be to remove pruned material from the crop field.
- 40. To avoid the application of sewage sludge
- 41. To avoid burial or incineration of household waste, as approximately 10% of garbage is made up of metals, including Cd. Their burial can contaminate the groundwater, while incineration can contaminate the atmosphere by releasing volatile metals and consequently polluting soils
- 42. To take action at the level of national or regional authorities to limit main polluting industrial activities near cocoa plantations, such as non-ferrous mining and smelting, metal using industry, coal combustion and phosphate fertilizer manufactures.

### 4.3 Post-harvest phase

- 43. Mucilage draining improves the sensorial quality of cocoa beans in the process of fermentation reducing its acidity. The time bean draining effect in a thesis of 0, 2, 4 and 6 hours of creole cocoa from Peru, concluded that the best one with fermentation above 80 % was 4 hours of drainage, while another thesis studying the effect of draining time in the clon CCN51 (cocoa beans which contain more water) including 0, 12, 24, 36 hours concluded that 36 hours was the best one with 86.00 ± 9.63 of fermentation and the draining of 12 hours had a fermentation percentage of 83.83 ± 1.48. An experimental study demonstrated that the draining of pulp or mucilage for 12 hours (longer time than normal) significantly reduced the content of Cd in cocoa beans in one variety without affecting the physical or organoleptic quality of the cocoa at the time of the evaluation. An experimental study demonstrated that the draining of the pulp or mucilage for 12 hours (longer time than normal) significantly reduced the content of Cd in cocoa beans of the clonal hybrid (cultivar) CCN-51 without affecting physical or organoleptic quality of the cocoa at the time of the evaluation.
- 44. After fermentation, cocoa beans should be dried on clean solid surfaces to avoid contamination by soil.
- 45. It is a recommended practice to make sure that during the fermentation of cocoa beans they are not contaminated with smoke, or with gases coming from dryers or vehicles.
- 46. The process of fermentation of cocoa beans should be an important practice that any export organization should carry out to reduce the levels of Cd of their cocoa beans.
- 47. During storage, contamination of cocoa beans due to spills of fuels, exhaust gases or fumes should be prevented.
- 48. The longer the fermentation process (80 %), the less Cd in cocoa beans. This statement is confirmed by a reliable cited scientific publication which indicates that Cd concentrations decrease as the fermentation proceeds. Cd beans can be reduced if pH is sufficiently acidified during fermentation.
- 49. The strain of Saccharomyces cerevisiae is one of the strains that intervenes in cocoa fermentation, therefore by increasing its population in such process could improve the absorption of Cd and the safety of cocoa.

### 4.4 Transport phase

Protect cocoa from becoming wet and contaminated from other materials:

- 50. Cover loading/unloading areas to protect from rain.
- 51. Ensure vehicles are well maintained and thoroughly cleaned.
- 52. Ensure tarpaulins/covers are clean and free from damage.
- 53. Ensure containers have not been used for chemicals or noxious substances, are well-maintained and clean.
- 54. Ensure humidity levels are as low as possible by using ventilated containers if available and cardboard/kraft paper lining, with silica gel bags.
- 55. For bagged cocoa: load bags carefully and cover with materials to absorb condensation.
- 56. For cocoa in bulk: use a sealable plastic liner if possible and ensure it is kept clear of the roof of the container.
- 57. Ensure ventilation holes in containers are free from clogging.
- 58. Try to ensure cocoa is not exposed to temperature fluctuations or stored near noxious materials.

### **APPENDIX IV**

# AMENDMENT TO THE MAXIMUM LEVEL FOR LEAD IN FRUIT JUICES IN THE GENERAL STANDARD FOR CONTAMINANTS IN FOOD AND FEED (CXS 193-1995) (For adoption as consequential amendment to the MLs for fruit juices)

Commodity/Product Name	Maximum Level (mg/kg)	Portion of the Commodity/Product to which the ML applies	Notes/Remarks
Fruit juices	0.03	Whole commodity (not concentrated) or commodity reconstituted to the original juice concentration, ready to drink.  The ML applies also to nectars, ready to drink.	The ML does not apply to juices exclusively from berries and other small fruit.  Relevant Codex commodity standard is CXS 247-2005  The ML also applies to fruit juices for infants and young children
Grape juice	0.04	Whole commodity (not concentrated) or commodity reconstituted to the original juice concentration, ready to drink. The ML applies also to nectars, ready to drink.	Relevant Codex commodity standard is CXS 247-2005.  The ML also applies to fruit juices for infants and young children

APPENDIX V

### **REVISION OF THE CODE OF PRACTICE FOR THE** PREVENTION AND REDUCTION OF LEAD CONTAMINATION IN FOODS (CXC 56-2004)

(For adoption at Step 5/8)

### **INTRODUCTION**

- 1. Lead is a toxic heavy metal that occurs in the environment both naturally, and to a greater extent from anthropogenic sources, because of its widespread industrial uses. The toxic effects of lead in food have been reviewed several times by the FAO/WHO Joint Expert Committee on Food Additives (JECFA). Lead exposure is associated with neurodevelopmental effects, mortality (mainly due to cardiovascular diseases), impaired renal function, hypertension, impaired fertility, and adverse pregnancy outcomes. Because of neurodevelopmental effects, fetuses, infants, and children are the most sensitive to lead exposures.
- 2. At its 73<sup>rd</sup> session (June 2010), JECFA concluded that in populations with prolonged dietary exposures to higher levels of lead, measures should be taken to identify major contributing sources, and if appropriate, to identify methods for reducing dietary exposure that are commensurate with the level of risk reduction.
- 3. Lead exposure can occur through food and water, and through use of cosmetics, dietary supplements, traditional medicines, and materials used in religious practices. Lead exposure also occurs in the workplace, through hobbies, from lead paint, in toys for children, and generally through exposure to lead-contaminated soil and air.
- 4. Lead contamination of food arises from numerous sources, including air and soil. Atmospheric lead from industrial pollution or leaded gasoline can contaminate food through deposition on agricultural crops. Agricultural crops can also take up lead from contaminated soil or contaminated soil may be deposited on plant surfaces. Lead contamination in soil may result from industrial pollution (e.g. mining); past use or inappropriate application of pesticides, fertilizers (including sewage sludge and biosolids); improperly disposed waste (e.g., batteries, construction materials); and lead-containing ordnance stored on former munitions sites and from ammunition used in rifle or military firing. Contaminated plants and soil are, in turn, a source of contamination of livestock.
- 5. Water is also a source of lead contamination of food. Surface water sources can be contaminated through runoff (drainage), atmospheric deposition, and, on a local level, by leaching of lead from game shot or fishing sinkers. Contaminated surface waters are a potential source of contamination of aquatic food producing animals. For drinking water and water for food preparation, corrosion of lead pipes or lead-containing fittings in water distribution systems and building plumbing systems is a primary source of lead contamination.
- 6. Lead contamination of food can also arise from food processing, food handling, and food packaging. Sources of lead in food processing areas include lead paint and lead-containing equipment, such as piping and lead-soldered machinery. In the packaging area, lead-soldered cans have been identified as an important source of lead contamination of food. Other packaging items that are potential sources of lead contamination include colored plastic bags and wrapping papers, cardboard containers that contain lead or are colored with lead-containing dyes, lead foil capsules on wine bottles, and lead-glazed ceramics, lead crystal, or lead-containing metal vessels used for packaging or storing foods.
- 7. There have been worldwide efforts to reduce lead exposure from food. Such efforts have focused on implementing standards for maximum or allowable lead levels in food, food additives, and food contact materials; ending the use of lead-soldered cans; controlling lead levels in drinking water; reducing leaching from lead-containing vessels or restricting their use for decorative purposes; and identifying and reacting to additional sources of lead contamination in foods or dietary supplements. Although not targeted specifically at food, efforts to reduce environmental sources of lead, including restrictions on industrial emissions and restricted use of leaded gasoline, have also contributed to declining lead levels in food. Despite efforts to reduce lead exposure, lead contamination of foods may still result from lingering environmental contamination (e.g. from leaded gasoline), continued use of lead-containing products (e.g. lead-glazed ceramic vessels erroneously used for food), and consumption of products remaining on the market (like older vintage wines).
- 8. The Codex Alimentarius Commission and national authorities (GSCTFF CXS 193-1995) have established or recommended standards for maximum levels of lead in various foods. Low levels of lead in foods may be unavoidable, because of the ubiquitous presence of lead in the modern industrial world. However, following good agricultural and manufacturing practices can minimize lead contamination of foods. Because many useful interventions for reducing lead rely on actions by consumers, including educating consumers about certain foods known to contain elevated levels of lead, a section with suggestions on consumer practices has also been included in this Code.

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

### 1.1 Source directed measures

9. National or relevant food control authorities should consider implementation of source directed measures in the Code of Practice for Source Directed Measures to Reduce Contamination in Foods with Chemicals (CXC 49-2011).

### 1.2 Agricultural

- 10. Leaded gasoline is a major contributor to atmospheric lead. National or local authorities should reduce or eliminate the use of leaded gasoline in agricultural areas.
- 11. Agricultural lands near industrial facilities, roadways, and ordnance depots, outdoor shooting ranges and military firing ranges may have higher lead levels in soils than more isolated lands. Sources of lead on agricultural lands should be removed, including vehicle batteries; damaged or unused electric fencing batteries; and old, discarded vehicles and machinery.
- 12. Use of lead solder and other lead materials for repairing farming equipment should be avoided. Land near buildings with weathered exterior paint also may have high lead levels, and there is a particular concern when such buildings are situated near livestock or small gardens.
- 13. Where possible, farmers should test lead levels in soils, particularly for farms that are near lead sources or that are suspected of having elevated lead levels to determine if lead levels exceed recommended maximums for planting by national or local authorities. If lead soil levels exceed these recommended maximums, farmers should avoid farming food crops without prior consultation with the national or local authorities.
- 14. Livestock should be prevented from grazing in areas with lead sources, including peeling paint, bonfire ash, metal roofing material, and contaminated surface waters. In addition, livestock soil consumption should be minimized, through a balanced feed diet (including mineral mixes).
- 15. In general, where there are potential sources of lead exposure to livestock, secure fencing and housing for livestock is a good practice to help minimize lead contamination.
- 16. Animal feed should meet lead standards established by national or local authorities, where available, as contaminants in feed can be transferred to food of animal origin and can be relevant for public health.
- 17. Dairy cows and other dairy animals found to have elevated lead levels should not be used as a source of milk until lead decreases to levels deemed appropriate by national authorities.
- 18. Farmers should avoid using lands that have been treated with lead arsenate pesticide, such as former orchards, to grow crops that may accumulate lead internally (e.g. root crops) or on their surface (e.g. leafy vegetables).
- 19. Fertilizers (including sewage sludge and biosolids) should adhere to standards set by national or local authorities, and farmers should avoid growing crops on lands that have been treated with fertilizers that do not adhere to maximum allowable lead levels set by national or local authorities.
- 20. Farmers should avoid using compounds that contain lead (such as lead arsenate pesticide) or may be contaminated with lead (e.g. improperly prepared copper fungicide or lead-containing phosphate fertilizer) in agricultural areas.
- 21. Leafy vegetables are more vulnerable than non-leafy vegetables or root vegetables to deposition from airborne lead. Cereal grains also have been reported to absorb lead from the air at a significant rate. In areas where atmospheric lead levels are high, farmers should choose crops that are less vulnerable to airborne deposition.
- 22. In areas known to have higher lead levels in soil, consider planting certain types of garden plants and trees that may be less susceptible to lead contamination from soil including fruiting vegetables, vegetables that grow on vines, and fruit trees. It may be helpful to decrease the planting of leafy and root vegetables, or to relocate these crops to fields with lower lead levels.
- 23. Water for irrigation, livestock farming, and aquaculture should be protected from sources of lead contamination and, where possible, monitored for lead levels to prevent or reduce lead contamination of crops, livestock, and aquaculture products. For example, well water used for irrigation and livestock farming should be properly protected to prevent contamination and the water should be routinely monitored.
- 24. Dryers powered with leaded gasoline have been found to contaminate drying crops with lead. Farmers and processors should avoid using dryers or other equipment powered by leaded gasoline on harvested crops.
- 25. Crops should be protected from lead contamination (e.g. exposure to atmospheric lead, soil, dust) during transport to processing facilities.

26. Home, community, or small-scale commercial gardeners should also take steps to reduce lead contamination. Avoid planting near roadways and buildings painted with lead-based paint. Consider testing soil, where practical, particularly if gardens are located in an area with potentially high lead soil levels. Good gardening practices for soils with mildly elevated lead levels include mixing organic matter into the soil, increasing the soil pH through liming to reduce availability of lead to plants, choosing plants that are less vulnerable to lead contamination, using liners to reduce contact deposition of soil on plants, and applying mulch to reduce dust and soil splashing on plants. Some lead levels may be considered too high for gardening. It may be possible to build up gardening beds with lead-free soil in such areas and add phosphate amendments (not fertilizers) that promote formation of insoluble lead compounds to reduce availability of lead to plants. Contaminated soil can be physically removed and replaced with clean soil. Home and community gardeners should consult with local agricultural services, where available, for advice on what lead levels are too high for gardening, advice on how to garden safely in lead-contaminated soils, and recommended practices for disposal of removed soil.

27. Local and national authorities should make farmers aware of appropriate practices for preventing lead contamination of farmlands and aquaculture farms.

### 1.3 Drinking water

- 28. National or local authorities should consider establishing allowable lead levels or appropriate treatment techniques for controlling lead levels in drinking water. The WHO has established a guideline value for maximum lead levels in drinking water of 0.01 mg/L, but some national authorities may have set lower target levels.
- 29. Administrators of water systems with high lead levels should recommend treatment techniques, such as increasing the pH of acidic waters, to minimize corrosion and reduce leaching of lead in the distribution system. Detailed recommendations for managing high lead levels can be found in other resources, including the WHO Guidelines for Drinking-Water Quality. <sup>1</sup> Because changes in water treatment practices (e.g. addition of chloramines or use of corrosion control treatment) can influence the levels of lead in drinking water, lead levels should be monitored during any system changes.
- 30. Given the number of potential lead sources in drinking water systems, including brass faucets, lead solder on copper pipes, lead pipes, and lead service lines, administrators of water systems should replace, where appropriate, problematic lead piping and other lead-containing fixtures.
- 31. National or local authorities should monitor lead levels in drinking water in schools and childcare centres and apply mitigation measures to reduce elevated lead levels.

### 1.4 Food ingredients and processing

- 32. Food producers should limit lead in foods to levels below recommended MLs in the *General Standard for Contaminants and Toxins in Food and Feed* (CXS 193-1995) or standards established by national or local authorities for foods and food additives; this is particularly important for foods intended for infants and children.
- 33. Where standards are not available, national or local authorities should consider establishing standards limiting the concentration of lead allowed in foods, including the traditional foods of their countries. In the absence of standards, national or local authorities or industry should monitor selected foods, including dietary supplements, to ensure that lead levels do not rise above normal background levels or are as low as reasonably achievable.
- 34. Food processors should choose food and food ingredients, including ingredients used for dietary supplements, that are below the recommended MLs, or where no MLs are available, that are as low as reasonably achievable. Where feasible, they should also consider whether the land used to produce crops has been treated with lead-containing pesticides and fertilizers (including sewage sludge and biosolids).
- 35. Food processors should consider having control measures in place to monitor incoming ingredients or verify that suppliers are providing ingredients that are below the recommended MLs or where there are no MLs available, that levels are as low as reasonably achievable. Food processors should consider occasional testing of incoming raw materials and finished products for lead to verify that their control measures are functioning effectively.
- 36. More focused testing should be considered for ingredients or products known to contain high lead levels or that are intended for infants and children. This is particularly important for ingredients or products that may have a history of economic adulteration.
- 37. For foods for infants and children, consideration should be given to sourcing of raw materials and ingredients used in the manufacture of finished products to ensure levels of lead are as low as reasonably achievable.

World Health Organization. Guidelines for drinking-water quality (latest edition) incorporating the 1st addendum.

38. During processing, maximum removal of surface lead from plants should be practiced, e.g. by thoroughly washing vegetables, particularly leafy vegetables; removing the outer leaves of leafy vegetables; and peeling root vegetables, where appropriate. Home gardeners should also follow such steps if their soil has elevated lead levels.

- 39. Food processors should ensure that the water supply for food processing complies with MLs for lead established by the national or local authorities.
- 40. Food processors should examine piping within facilities to ensure that older piping is not adding lead to water supplies inside the facility, and should replace, where appropriate, outdated piping, fittings, and old containers as they may contain brass alloys and lead soldering.
- 41. Food processors should use food-grade metals for all metal surfaces that come into contact with food and beverages.
- 42. Food processors should not use lead solder to repair broken equipment in food processing facilities. They also should not substitute non-food-grade equipment that may be present in a food processing facility for broken food-grade equipment.
- 43. Food processors should ensure that lead paint peelings do not become a source of lead contamination in processing facilities. If food processors carry out lead paint abatement in their facilities, they should also ensure that appropriate cleanup procedures are followed to prevent further dispersion of lead paint and dust, which could create a greater hazard.
- 44. Because filtration aids (specifically diatomaceous earth, bentonite, and charcoal filtration) used in processing fruit juices, wines, and beer can contain lead, selecting filtration aids with lower lead levels or washing filtration aids with solutions such as ethylenediamine tetraacetic acid (EDTA) or hydrochloric acid solution, can reduce lead levels in the beverages. Alternative filtration methods also may be used, for example, ultrafiltration. Filtration aids used for processing beverages should comply with *Guidelines on Substances Used as Processing Aids* (CXG 75-2010).
- 45. Metal detectors and X-rays are commonly used in food facilities for detecting physical hazards. Metal detectors or X-rays can be used in food establishments such as slaughterhouses and fish processing facilities to detect and facilitate removal of lead shot (pellets) or fishing sinkers in wild game and fish.

### 1.5 Production and use of packaging and storage products

- 46. To provide maximum protection against lead contamination, food processors should not use lead-soldered cans. Alternatives to lead-soldered cans are discussed in the Guidelines for can manufacturers and food canners. Prevention of metal contamination of canned foods, FAO Food and Nutrition Paper No. 36 (Rome, 1986) as well as JECFA Monograph 622. These alternatives include using two-piece cans (which lack side seams) rather than three-piece cans, using cementing and welding to bond seams instead of soldering, using lead-free (tin) solders, and using alternative containers, such as lead-free glass.
- 47. Where it is not feasible to avoid the use of lead-soldered cans, methods for reducing lead exposure from lead-soldered cans are discussed in depth in FAO Food and Nutrition Paper 36. Lead can be released from the solder surface itself, or from solder dust or solder splashes deposited inside the can during the can-making process. Methods for reducing splashing and dust formation include avoiding the use of excess flux, controlling exhaust over the work area to minimize dust deposition, controlling the temperature of the fluxed can body and solder, post-solder lacquering of the interior surface or interior side seams of cans, careful wiping of excess solder from finished cans, and washing soldered cans before use. For a detailed description of proper manufacturing practices with lead-soldered cans, the FAO paper should be consulted.
- 48. Tinplate used for food cans should meet international standards for maximum allowable lead concentration. ASTM International has set a maximum concentration of 0.010 percent lead for "Grade A" tinplate.
- 49. Lead dyes or lead-based printing inks should not be used for food packaging, such as for brightly colored candy wrappers. Even if such wrapping does not come in direct contact with foods, children may be tempted to put the brightly colored wrappers in their mouths.
- 50. Plastic bags or boxes with exteriors treated with lead-based dyes or lead-based printing inks should not be used for packaging food. Handling of these items during cooking or reuse by consumers for storing other food items can cause lead contamination.
- 51. Packaging foods for sale in traditional lead-glazed ceramics should be avoided because these ceramics may leach significant quantities of lead into the foods.

52. Lead foil capsules should not be used on wine bottles because this practice may leave lead residues around the mouth of the bottle that can contaminate wine upon pouring.

- 53. National and local authorities should consider setting standards for lead migration from lead-glazed ceramic ware, lead crystal, and other lead-containing items that might potentially be used for food storage or preparation by consumers.
- 54. As one regulatory option, national and local authorities could consider setting standards for lead migration and lead composition in food contact materials used in food processing or manufacturing.
- 55. Decorative ceramic ware that has the potential to leach unacceptable quantities of lead should be clearly labeled as not for food use.
- 56. Ceramic ware producers should use manufacturing procedures and quality control mechanisms that minimize lead leaching.

### 1.6 Consumer practices and consideration of certain foods

- 57. National and local authorities should consider educating consumers about the hazards of lead, particularly to children; sources of lead; and appropriate practices to reduce lead contamination from food prepared in the home or grown in the garden.
- 58. Consumers should wash vegetables and fruit thoroughly to remove dust and soil that may contain lead. Removing outer leaves from leafy greens and peeling root crops can reduce lead levels. Washing hands before preparing food will also help remove any lead-contaminated dust or soil from hands.
- 59. Consumers should store food and eating/cooking utensils in sealed containers or closed cabinets to protect them from falling dust. Consumers should avoid storing foods, particularly acidic foods or foods for infants and children, in decorative ceramic ware, lead crystal, or other containers that can leach lead. Foods should not be stored in opened lead-soldered cans or stored in reused lead-dyed bags and containers. Consumers should avoid frequent use of ceramic mugs when drinking hot beverages such as coffee or tea, unless the mugs are known to have been made with a lead glaze that is properly fired or fired with a non-lead glaze.
- 60. Where lead in water distribution systems is a problem, consumers should let water run from faucets before use to allow corroded lead from piping to be flushed out of the system, particularly if they are preparing foods for infants or children. Hot water from the faucet should not be used for drinking, cooking or food preparation. If filters are used, consumers should ensure they are properly installed and replaced regularly according to manufacturer specifications. Another option is to use an alternative water source for food preparation.
- 61. Consumers should be educated about the concerns surrounding geophagia (the practice of consuming clay or soil) that is practiced mainly by children and pregnant and lactating women. Various clay products, known by names such as calabash chalk, mabele, sikor, and pimbpa, have been found to contain elevated lead levels. Pregnant and lactating women, and children who frequently engage in geophagia, should be discouraged from this practice.
- 62. Consumers should be educated that foods sold as traditional medicines, including herbs and spices, may be sources of lead exposure.
- 63. Meat from game killed with lead shot (pellets) or from waterfowl that have ingested lead shot may be a source of lead exposure. Therefore, children and women of childbearing age should reduce or avoid consumption of game killed with and containing lead shot. When hunting game intended for consumption, consider using a rifle or using a slug rather than buckshot in a shotgun, as this may reduce lead contamination of the meat; although there is the potential for lead fragments to remain in the game meat. Meat containing lead fragments or shot should be excised and discarded.
- 64. National or local authorities should educate people about the potential risks of consuming local specialty foods or collected wild foods (e.g. mushrooms) that could contain elevated lead levels.

**APPENDIX VI** 

# PROJECT DOCUMENT PROPOSAL FOR NEW WORK ESTABLISHMENT OF MAXIMUM LEVELS FOR METHYLMERCURY IN ORANGE ROUGHY AND PINK CUSK-EEL (For approval)

### 1. Purpose and Scope of the new work

This work aims to establish Maximum Levels (MLs) for methylmercury in orange roughy and pink cusk-eel.

### 2. Relevance and timeliness

The current MLs for methylmercury in fish (tuna: 1.2 mg/kg, alfonsino: 1.5 mg/kg, marlin: 1.7 mg/kg and shark: 1.6 mg/kg) were adopted in 2018<sup>1</sup>. These MLs replaced Guideline Levels (GLs) encompassing all predatory and non-predatory fish species, with the decision of the CAC that consideration should be given to establishment of MLs rather than GLs (REP18/CF, paragraph 81). A recommendation had been previously made that discussion could be commenced on considering MLs for other species in the GEMS/Food database, with a preliminary analysis presented in the supporting discussion paper (CX/CF 17/11/12, paragraph 15). With the establishment of an agreed upon framework at CCCF12 to apply the "as low as reasonably achievable" (ALARA) principle in the establishment of MLs for methylmercury in fish, it is timely to undertake work to derive MLs for additional fish species.

### 3. Main aspects to be covered

ML(s) for methylmercury in additional fish species, taking into account the following:

- a. Results of discussions of the CCCF
- Risk assessments by JECFA
- c. Conclusions of the Joint FAO/WHO Expert Consultation on the Risks and Benefits of Fish Consumption
- d. Achievability of the MLs

The following species of fish have been identified as having average levels of methylmercury sufficient to exceed the selection criterion of 0.3 mg/kg.

Orange roughy	
Pink cusk-eel	

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

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

The new work will derive ML(s) for methylmercury in fish species identified as having average levels of methylmercury sufficient to exceed the selection criterion of 0.3 mg/kg.

Diversification of national legislation and actual or potential impediments to international trade.

The international trade of fish and fishery products is increasing, and the new work will provide internationally-harmonized standards. The three fish species are of equivalent or grater trade value to species presently with MLs

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

The proposed work to establish MLs for methylmercury in the identified fish species globally has not been undertaken by any other international organizations nor suggested by any relevant international intergovernmental bodies.

### Consideration of the global magnitude of the problem or issue

The consumption and international trade of fish and fishery products are increasing globally, thus this work is of worldwide interest and becoming increasingly significant.

### 5. Relevance to Codex Strategic Goals

The proposed work falls under the following Codex Strategic Goals of the Codex Strategic Plan 2020-25

General Standard for Contaminants in Food and Feed (CXS 193-1995)

### Strategic Goal 1: Address current, emerging and critical issues in a timely manner

This work was proposed in response to needs identified by Members in relation to food safety, nutrition and fair practices in the food trade. There is already significant trade in fish species which potentially have methylmercury levels that exceed the selection criterion of 0.3 mg/kg.

### Strategic Goal 2: Develop standards based on science and Codex risk-analysis principles

This work will use the scientific advice of the joint FAO/WHO expert bodies to the fullest extent possible. Also, all relevant factors will be fully considered in exploring risk management options.

### Strategic Goal 4: Facilitate the participation of all Codex Members throughout the standard setting process

Due to the international interest in the trade and consumption of fish, this work will support and embrace all aspects of this objective by requiring participation of both developed and developing countries to conduct the work.

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

This new work is recommended following the criteria for establishing MLs in food and feed as outlined in the *Standard for Contaminants in Food and Feed* (CXS 193-1995).

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

Expert scientific advice has been already provided by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and the Joint FAO/WHO Expert Consultation on the Risks and Benefits of Fish Consumption.

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

A need for additional technical input from external bodies has not been identified.

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

Identified species	Timeframe
Pink cusk-eel	Final adoption by CAC in 2024
Orange roughy	or earlier

**APPENDIX VII** 

### PROJECT DOCUMENT PROPOSAL FOR NEW WORK

Development of a Code of practice for the prevention and reduction of mycotoxins contamination in cassava and cassava-based products (For approval)

### 1. Purpose and scope of the new work

The purpose of the proposed new work is to develop a Code of Practice (CoP) that will provide risk management guidance to Codex member countries and relevant stakeholders, e.g. farmers, cassava-based industries (including small-scale producers), national/regional technical/regulatory agencies, etc., for the prevention/reduction of mycotoxins, i.e. aflatoxins and ochratoxin A (OTA), contamination in cassava and cassava-based products during pre-planting, post-harvest processing including fermentation, drying, storing and distribution.

### 2. Relevance and timeliness

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

The toxicity of OTA has been reviewed by the International Agency for Research on Cancer (IARC), which classified OTA as a possible human carcinogen (Group 2B) and also by the Joint FAO/WHO Expert Committee on Food Additives (JECFA). OTA is a mycotoxin that occurs naturally worldwide in food commodities including roots and tubers and their products. In roots and tubers, fusarium species have been implicated as pre-harvest contaminants mycotoxins, while aspergillus and peniccilium species have been implicated as post-harvest mycotoxins.

Discussion papers considered by the Codex Committee on Contaminants in Foods (CCCF) have described the fast growing global profile of cassava, a root crop commodity commonly used as food, raw material for human foods, animal feeds, pharmaceutical and confectionary industries. The obvious significance in export trade, especially in regional trade such as amongst members of the FAO/WHO Coordinating Committee for Africa (CCAFRICA) is worthy to note. The health impact of aflatoxins and OTA in cassava and cassava-based products was considered by CCCF13 (2019) (CX/CF 19/13/14). Summary of data from a WTO/FAO/WHO supported regional total diet study involving four sub-Sahara African countries amongst others, showed that aflatoxins and OTA contamination in cassava is of public health concern.

The CoP will assist countries to comply with measures and protocols to prevent/reduce aflatoxins and OTA contamination in cassava and cassava-based products which will in turn facilitate trade. Given the health concerns, there is need for cassava to be safe for use and consumpiton; and good practices in agriculture, processing and distribution will help in achieving this goal.

### 3. Main aspects to be covered

The CoP will cover the value chain stages of:

- 1. land preparation,
- 2. cultivation,
- 3. pre-harvest.
- 4. post-harvest handling,
- 5. storage
- 6. transportation practices

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

### **General criterion**

This is for consumer health protection and to prevent/reduce post-harvest losses though best practices from the point of view of food safety and food security. This is also to ensure fair practices in trade while taking into account the identified needs of developing countries.

The CoP will provide risk management guidance for countries and relevant stakeholders to improve the overall safety and quality of cassava and cassava-based products, by preventing/reducing aflatoxins and OTA contamination, and so to minimize consumer dietary exposure to aflatoxins and OTA from roots/tubers and their products and to enhance trade in these products.

### Specific criteria

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

The CoP will provide internationally harmonized risk management practices to Codex members and stakeholders for the prevention/reduction of aflatoxins and OTA contamination in cassava and cassava-based products to ensure public health and fair practices in trade.

b. Scope of work and establishment of priorities between the various sections of the work

See points 1 and 3.

c. Work already undertaken by other organizations in this field

CCCF is the subsidiary body of the Codex Alimentarius Commission (CAC) having competence on the provision of risk management practices along the food chain to contain contamination of food and food products with chemicals and toxins. A way to do this is through the development of codes of practice. There is already in existence a *Code of practice* for the reduction of hydrocyanic acid (HCN) in cassava and cassava products (CXC 73-2013) to assist in keeping the quality and safety of these products.

As per mycotoxins, some work has also been done by organizations or agencies, for instance, the International Institute of Tropical Agriculture, National Root Crops Research Institute Umudike South-East, Nigeria and Universities in the rain forest belts in Nigeria on management of mycotoxins in roots and tubers. The African Union (AU), through its Partnership for Aflatoxin Control in Africa (PACA platform), is driving eradication of adverse human health effects by aflatoxins from the continent.

However, there is currently no international document that assemble relevant risk management practices available to date into a single document which best reflect effective measures applicable worldwide to contain mycotoxin contamination in fresh and processed cassava for application by Codex members and relevant stakeholders. This CoP will so build on work of recognized organizations, agencies and technical programs/platforms across the world to provide such a unique single internationally harmonized guidance document for use by countries and other stakeholders.

### 5. Relevance to Codex Strategic Goals

The new work falls under the following Codex Strategic Goals of the Codex Strategic Plan 2020-2025:

Goal 1: Address current, emerging and critical issues in a timely manner

Aflatoxin and OTA contamination in cassava and cassava-based products is a public health concern. Given that cassava or cassava-based products are considered staple food in certain regions and countries, there is need for cassava to be safe for use and consumption. In addition, trade in cassava and its products are growing and therefore, there is also need to ensure safe and fair practices in trade.

This work will harmonize risk management practices across regions/countries to promote maximum application of Codex standards to protect consumers' health and to ensure fair practices in trade. The result of this work will also assist in promoting sound regulatory frameworks in international trade by using good management practices that are proven to be effective and applicable worldwide to prevent/reduce aflatoxins and OTA contamination in these products.

Goal 2: Develop standards based on science and Codex risk analysis principles

This work will help in identifying risk management options and developing strategies to prevent/reduce aflatoxins and OTA in cassava production and processing based on science and risk-based principles.

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

Currently there is no Codex document addressing mytocoxin contamination in cassava and cassava-based products. The development of the CoP will support implementation of commodity standards available for fresh and processed cassava e.g. Codex Standards for Sweet Cassava (CXS 238-2003), Bitter Cassava (CXS 300-2010), Cassava Flour (CXS 176-1989), Gari (CXS 151-1985), etc. as well as will complement the CoP to contain HCN in cassava and cassava-based products.

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

At this moment, expert advice from scientific advisory bodies, e.g. JECFA, is not necessary. There are several publications on management of mycotoxins published by FAO and other organizations/agencies that are available for consultation.

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

Currently, there is no need for technical input from external bodies. However, if the need arises, such identified bodies shall be contacted.

9. The proposed timeline for completion of the new work, including the starting date and the proposed date for the adoption by the Codex Alimentarius Commission

Subjec to approval by CAC (2021), the CoP will be circulated for comments and consideration by CCCF15 (2022). Adoption by CAC is planned for 2024 or earlier.

### **APPENDIX VIII**

### 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  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. NOTE: Needs to be put in context to cancer risk assessment. Organic: (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.  EU: Inorganic arsenic occurrence data  India: Occurrence data in rice  Japan and China: Occurrence data on rice and rice products  Turkey: Occurrence data in rice  USA: Occurrence data on rice cereals, and rice and non-rice products; 2016 risk assessment; 2016 draft action level for inorganic arsenic in rice cereal.  USA: Studies  Pilot neurodevelopmental study of inorganic arsenic impacts on rat behavior (2019); follow-up study expected in 2020  Toxicokinetic studies on metabolism and disposition of inorganic and organic arsenic and metabolites in mice (various life stages) (2018-19)  Developmental toxicity test in C. elegans on inorganic arsenic (2018) and ongoing study on organic arsenic.  Non-governmental report, Effects of Inorganic Arsenic in Infant Rice Cereal on Children's Neurodevelopment (2017)	USA
Scopoletin	Full evaluation (toxicological assessment and exposure assessment) in fermented noni juice	CCNASWP still working on standard for noni juice and data availability.  CCNASWP15 agreed¹ 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.	CCNASWP

<sup>&</sup>lt;sup>1</sup> REP20/NASWP, paras. 74, 83, Appendix II

Contaminants	Background and question(s) to be answered	Data availability (when, what)	Proposed by
		ccnaswp15 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.	
		A consultant was hired by the Codex Secretariad to undertake a toxicological review of scopoletin as presented in the Annex <sup>2</sup> to CX/CF 21/14/2-Add.1.	
Trichothecenes (T2 and HT2)	Update of risk assessment, including exposure assessment (T2, HT2, DAS)	Brazil: occurrence data in cereals  Canada: occurrence data (commodity specific and unprocessed cereal grains)  EU: Report by EFSA on dietary exposure, including an HBGV; occurrence data.  Japan: occurrence data in raw cereals	JECFA83 (2016), recommendation supported by CCCF11 (2017). JECFA90 (2020) Completion of risk assessment including toxicological evaluation following JECFA90 exposure assessment