

CODEX ALIMENTARIUS COMMISSION

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Food and Agriculture
Organization of the
United Nations



World Health
Organization

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

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REPORT OF THE 13rd SESSION OF THE CODEX COMMITTEE ON CONTAMINANTS IN FOODS

Yogyakarta, Indonesia

29 April – 3 May 2019

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Responsible Party	Purpose	Text/Topic	Code	Step	Appendices & Paragraphs
Members and Observers CCEXEC76 CAC42	Comments Critical Review Adoption Amendment Revocation	Proposed draft revised MLs for lead in selected commodities in the GSCTFF	CXS 193-1995	5/8	Appendix II para. 44
		Amendment of the ML for wine		---	
		Revocation of corresponding MLs for lead in selected commodities in the GSCTFF		---	
Members and Observers CCEXEC76 CAC42	Comments Critical Review Adoption	Proposed draft ML for cadmium in certain categories of chocolates	CXS 193-1995	5/8	Appendix III para. 56
Members and Observers CCEXEC76 CAC42	Comments Critical Review Adoption	Draft Code of practice for the reduction of 3-MCPDEs and GEs in refined oils and food products made with refined oils	-	8	Appendix IV para. 79
Members and Observers CCEXEC76 CAC42	Comments Critical Review Adoption	Draft Guidelines for rapid risk analysis following instances of detection of contaminants in food where there is no regulatory level	-	8	Appendix V para. 87
Members and Observers CCCF14	---	Proposed draft ML for AFT in RTE peanuts and associated sampling plan	CXS 193-1995	4	para. 80
Members and Observers CCCF14	---	Proposed draft MLs for AFT and OTA in nutmeg, dried chili and paprika, ginger, pepper and turmeric and associated sampling plans	CXS 193-1995	4	para. 81
EWG (Ecuador and Ghana) Members and Observers CCCF14	Discussion Comments Consideration	MLs for cadmium in chocolates and cocoa-derived products	CXS 193-1995	2/3	para. 56
CCEXEC76 CAC42 EWG (Brazil) Members and Observers CCCF14	Critical Review Approval Discussion Comments Consideration	MLs for AFT in certain cereals and cereal-based products including foods for infants and young children	CXS 193-1995	1/2/3	Appendix IX para. 155
CCEXEC76 CAC42 EWG (Brazil) Members and Observers CCCF14	Critical Review Approval Discussion Comments Consideration	MLs for lead in certain food categories	CXS 193-1995	1/2/3	Appendix VI para. 96
CCEXEC76 CAC42 EWG (USA, UK and Japan) Members and Observers CCCF14	Critical Review Approval Discussion Comments Consideration	Revision of the <i>Code of practice for the prevention and reduction of lead contamination in foods</i> (CXC 56-2004)	CXC 56-2004	1/2/3	Appendix VII para. 107

Responsible Party	Purpose	Text/Topic	Code	Step	Appendices & Paragraphs
CCEXEC76 CAC42 EWG (Peru, Ghana and Ecuador) Members and Observers CCCCF14	Critical Review Approval Discussion Comments Consideration	Development of a Code of practice for the prevention and reduction of cadmium contamination in cocoa beans	---	1/2/3	Appendix VIII para. 112
EWG (New Zealand and Canada) CCCCF14	Discussion Consideration	MLs for methylmercury in additional fish species	---	---	para. 127
EWG (Nigeria and Ghana) CCCCF14	Discussion Consideration	MLs for HCN in cassava and cassava-based products and COP for the reduction of mycotoxin contamination in cassava and cassava-based products	---	-	para. 144
EWG (EU, Japan, Netherlands and USA) CCCCF14	Discussion Consideration	Guidance on data analysis for ML development and for improved data collection	---	-	para. 165
EWG (Canada, Japan and USA) CCCCF14	Discussion Consideration	Approach to identify the need for revision of standards and related texts developed by CCCF	---	-	para. 178
Codex / JECFA Secretariats CCCCF14	Discussion Consideration	MLs for cadmium and lead for quinoa	---	-	para. 103
Codex / JECFA / Host Country Secretariats CCCCF14	Discussion Consideration	Forward work plan for CCCF	---	-	paras. 175 and 181,
JECFA Members CCCCF14	Evaluation Comments Consideration	Priority list of contaminants and naturally occurring toxicants proposed for evaluation by JECFA and follow-up to the outcome of JECFA evaluations	---	-	paras. 168 - 169

LIST OF ABBREVIATIONS

AF(s)	Aflatoxin(s)
AFT	Total aflatoxins
ALARA	As Low As Reasonable Achievable
ARfD	Acute reference dose
CAC	Codex Alimentarius Commission
CCAFRICA	FAO/WHO Coordinating Committee for Africa
CCCF	Committee on Contaminants in Foods
CCEXEC	Executive Committee
CCFH	Committee on Food Hygiene
CCNASWP	FAO/WHO Coordinating Committee for North America and South West Pacific
CCPR	Committee on Pesticide Residues
CCRVDf	Committee on Residues of Veterinary Drugs in Foods
CL	Circular Letter
COP	Code of Practice
CRD	Conference Room Document
CTX(s)	Ciguatoxin(s)
DAG(s)	Diacylglycerol(s)
ECA	European Cocoa Association
EFSA	European Food Safety Authority
EU	European Union
EWG	Electronic Working Group
FAO	Food and Agriculture Organisation
FEDIOL	The EU Vegetable Oil and Proteinmeal Federation
FIVS	Fédération internationale des vins et spiritueux
GAP(s)	Good agricultural practice(s)
GE(s)	Glycidyl ester(s)
GEMS/Food	Global Environment Monitoring System
GMP(s)	Good Manufacturing Practice(s)
GSCTFF	General Standard for Contaminants and Toxins in Food and Feed
HBGV(s)	Health Based Guidance Value(s)
HCN	Hydrocyanic acid
IAEA	International Atomic Energy Agency
ICA	International Confectionary Association
ICBA	International Council of Beverages Associations
ICGA	International Chewing Gum Association
IDF	International Dairy Federation
IFT	Institute of Food Technologists
ISDI	International Special Dietary Foods Industries
JECFA	Joint FAO/WHO Expert Committee on Food Additives
LOQ	Limit of Quantification
MAG(s)	Monoacylglycerol(s)
3-MCPD	3-monochloropropane-1,2-diol or 3-chloropropane-1,2-diol
3-MCPDE(s)	3-monochloropropane-1,2-diol or 3-chloropropane-1,2-diol ester(s)
MCT(s)	Medium-chain triacylglycerol(s)

ML(s)	Maximum Level(s)
OIV	Organisation internationale de la vigne et du vin
OTA	Ochratoxin A
PA(s)	Pyrrolizidine Alkaloid(s)
PCB(s)	Polychlorinated biphenyl(s)
PTWI	Provisional Tolerable Weekly Intake
PWG	Physical Working Group
RTE	Ready-To-Eat
STDF	Standards and Trade Development Facility
TDI	Tolerable Daily Intake
TEF	Toxicity equivalent factor
TTC	Threshold of Toxicological Concern
UK	United Kingdom
USA	United States of America
WG	Working Group
WHO	World Health Organization

LIST OF CRDs

CRD No.	Agenda Item	Submitted by
01	Division of Competence	EU (Division of Competence between EU and its Member States)
02	19(a)	USA as Chair of the in-session WG (Report of the in-session WG on the Priority List of Contaminants and Naturally Occurring Toxicants for Evaluation by JECFA)
03	10	New Zealand as Chair of the PWG (Report of the PWG on the consideration of the Guidelines for risk analysis of instances of contaminants in food where there is no regulatory level or risk management framework)
04	2	EU, Japan, Kenya, USA
05	4	EU, USA
06	11	EU, Kenya, Malaysia, USA, ICBA
07	12	EU
08	13	EU, Kenya, USA
09	14	EU, Switzerland, USA
10	15	EU, Japan, Kenya, USA
11	16	EU, Kenya, USA
12	17	EU, Kenya, USA
13	20	EU
14	10	New Zealand as Chair of the EWG (Guidelines for risk analysis of instances of contaminants in food where there is no regulatory level or risk management framework established - Arabic and Chinese courtesy version of CX/CF 19/13/8)
15	2, 15	Codex Secretariat (Proposed revision of the sampling plan for methylmercury in fish for consideration by CCCF)
16	15	Japan
17	5,6,11,13,14,16,17	Indonesia
18	2,5,7,8	India
19	7,11,17	Thailand
20	6	Malaysia
21	2,5,6,8,9,10,11,13	Nigeria
22	5,6,7,10	Egypt
23	4,11,12,13,15,16,17	Republic of Korea
24	5,6,7,10,11,13,14,15,17,19a	Ghana
25	5,6,7,8,9	Uganda
26	7	USA as Chair of the EWG (Revised draft COP for the reduction of 3-MCPDEs and GEs in refined oils and food products made with refined oils based on comments submitted in reply to CL 2019/09-CF)
27	2,4,5,6,7,10,11,13,14,15,16,17,20	Dominican Republic
28	2,5,7,10,15,17,18	Senegal
29	6	Cuba
30	6	ICA
31	3,5,6,10,13,14	Ecuador

CRD No.	Agenda Item	Submitted by
32	6,14	El Salvador
33	14	Nicaragua
34	5,6,7,10,11,13,14,15,17,18	African Union
35	2	New Zealand as Chair of the EWG on Methylmercury in Fish (Outcomes of the informal meeting to address the sampling plan for methylmercury in fish based on CRD15 and comments submitted in CRDs)
36	5, 10, 11,15, 16, 17	Philippines
37	11	ICGA
38	Opening Session	Opening remarks, Purwiyatho Hariyadi (On behalf of Chair and Vice-Chairs of CAC)

INTRODUCTION

1. The Codex Committee on Contaminants in Foods (CCCF) held its 13th Session in Yogyakarta, Indonesia, from 29 April to 3 May 2019, at the kind invitation of the Governments of Indonesia and The Netherlands. The session was chaired by Dr Wieke Tas, Ministry of Agriculture, Nature and Food Quality, The Netherlands, and co-chaired by Dr Roy Sparringa, Senior Advisor, Agency for the Assessment and Application of Technology, Centre for Technology Services, Indonesia. The session was attended by 45 member countries, one Member Organization, and 18 observer organizations. The list of participants is contained in Appendix I.

OPENING OF THE SESSION

2. Dr Penny K. Lukito, Chairperson for the Indonesian Food and Drug Authority, opened the session and extended her warmest welcome to all participants. She emphasized the importance of the mandate of Codex to protect the health of consumers and ensure fair practices in the food trade and demonstrated the strong commitment of the Indonesian government on active participation in Codex activities. Mr Louis Beijer, Netherlands Embassy, Agricultural Counsellor, highest representative of the Ministry of Agriculture in Indonesia, addressed the Committee and expressed his great appreciation to Indonesia for its willingness to co-host and co-chair the session and wished CCCF successful deliberations.
3. Dr Markus Lipp and Dr Kim Petersen, welcomed the attendees on behalf of FAO and WHO respectively. Professor Purwiyatno Hariyadi, the vice-Chair of the Codex Alimentarius Commission, also addressed the meeting.

Division of Competence

4. 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 Codex Alimentarius Commission.

ADOPTION OF THE AGENDA (Agenda Item 1)¹

5. CCCF adopted the provisional agenda as its Agenda for the Session.
6. CCCF agreed to establish an in-session Working Group on the Priority List of Contaminants and Naturally Occurring Toxicants for Evaluation by JECFA, chaired by USA, and to discuss the outcomes under Agenda Item 19.

MATTERS REFERRED TO CCCF BY CAC AND/OR ITS SUBSIDIARY BODIES (Agenda Item 2)²

7. CCCF noted that some matters were presented for information only and matters from CCMAS39 (2018) regarding sampling plans for MLs for methylmercury in fish would be discussed under Agenda Item 15.

Committee on Spices and Culinary Herbs

Dried oregano and dried basil leaves

8. CCCF noted that, from a procedural point of view, there was nothing that prevented a reference to the *Code of Practice for Weed Control to Prevent and Reduce Pyrrolizidine Alkaloid Contamination in Food and Feed* (CXC 74–2014) under the section on contaminants in the standards for dried oregano and dried basil leaves.

All commodity committees

9. CCCF agreed to inform all commodity committees that in the absence of MLs in the GSCTFF, documents such as codes of practice could be referenced in the sections of contaminants or hygiene or other appropriate sections.

Guidelines for the management of (micro)biological foodborne crises/outbreaks

10. CCCF noted the interests of members to develop a similar guidance covering outbreaks caused by contaminants, but agreed to consider this matter once the work in CCFH had been completed.

ML for total aflatoxins in ready-to-eat peanuts and associated sampling plans

11. CCCF was informed that this matter referred to Agenda Item 8 that had been included in the agenda to serve as a reminder that it was held at Step 4 pending further implementation on the COP. CCCF further noted that the same applied to Agenda Item 9.

¹ CX/CF 19/13/1

² CX/CF 19/13/2; CX/CF 19/13/2-Add.1

12. India pointed out that at CCCF10, the decision on setting ML for AFT in RTE peanuts at 10 µg/kg could not be agreed upon and JECFA was therefore asked to perform an impact assessment on hypothetical MLs; at CCCF12, the proposal had again been put on hold due to the lack of implementation of the *Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Peanuts* (CXC 55-2004) even after the JECFA evaluation. India highlighted that: (i) the COP had already been adopted in 2004; (ii) risk assessment carried out by JECFA in 2016 had concluded that enforcing an ML of 4, 8 or 10 µg/kg for RTE peanuts would have little further impact on dietary exposure of aflatoxins to the general population, compared with an ML of 15 µg/kg; (iii) additional data for AFT in RTE peanuts for 8802 samples from April 2018 to March 2019 had been generated and submitted to GEMS/Food which did not support the ML below 10 µg/kg; and (iv) postponing the adoption of the ML might have further trade impediments for RTE peanuts for developing countries which were the main peanut producers and exporters. India further questioned how CCCF had decided that the COP had not been implemented.
13. However, CCCF noted there was support for maintaining the decisions taken by CCCF12 i.e. to hold the ML of 10 µg/kg for AFT in RTE peanuts at Step 4 to ensure the effective implementation of the COP since there were no new elements to justify changing the decision of CCCF12 while Codex standards should be established based on scientific evidence.
14. In response to one question on whether there had been any mechanisms to monitor the implementation of the COP, the Codex Secretariat clarified that this subject would be considered under Agenda Item 20 and a discussion paper on monitoring the use of Codex standards would be considered at CCGP32 (2020).
15. Two delegations informed CCCF that they had started the implementation of the COP in their countries and new data were being prepared for submission.

Conclusion

16. CCCF agreed to:
 - i. urge members to extensively implement the COP, collect and submit new data for further consideration; and
 - ii. re-establish an EWG at CCCF14 (2020), to work on the new data and prepare a proposal for consideration by CCCF15 (2021).
17. CCCF noted the reservation of India on the decision of this session i.e. not accelerating of the finalization the ML as recommended by CCEXEC75 (2018).

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

18. The JECFA Secretariat informed CCCF that the JECFA86 (2018) meeting had been held since the last CCCF focused on food additives, and therefore no new JECFA evaluations on contaminants could be reported to the current session. The Secretariat further informed that the monograph on pyrrolizidine alkaloids, evaluated at JECFA80 (2015) would be available by June 2019.
19. In addition the JECFA Secretariat informed CCCF that:
 - the *Ad-hoc* FAO/WHO Expert Meeting on Ciguatera Food Poisoning, which was held in 2018 in responding to a request by CCCF11 (2017), evaluated known CTXs (toxicological and exposure assessments) including geographic distribution, rate of illness and guidance for the development of risk management options and the report would be available by third quarter of 2019.
 - JECFA was engaged in updating various risk assessment methodologies including; harmonization of chronic dietary exposure assessment for different food chemicals and combined exposure from dual uses compounds (pesticides and veterinary drugs); more detailed guidance on the interpretation and evaluation of genotoxicity studies; guidance on dose-response modelling and application of the benchmark-dose approach; and finally guidance for the evaluation of enzyme preparations.
20. A member noted the GEMS/Food database expressed appreciation to FAO and WHO for their support to the GEMS/Food which contributes greatly to the work of CCCF, such as the work on the MLs for cadmium in chocolate and cocoa-derived products, and encouraged members and observers to continue submitting data to GEMS/Food.

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

21. The Representative of the Joint FAO/IAEA Division introduced the item and summarized the information provided in CX/CF 19/13/4 on radionuclides in food and drinking water in non-emergency situations; technical cooperation and capacity building; coordinated research initiatives; networking and contributions; and nuclear and radiological emergency preparedness.
22. In relation to IAEA's work on radioactivity in food, the two Representatives from IAEA and the Joint FAO/IAEA Division respectively provided two presentations covering the background to and timeline for its ongoing work on radionuclides in food in non-emergency situations. Historically, IAEA safety standards addressed radionuclides in food only in the context of responding to a nuclear or national emergency, however this had now been extended to address radionuclides in food in non-emergency situations. IAEA also discussed the difference between naturally-occurring and human-made radionuclides in food, the variability observed in the concentrations of the different radionuclides in different foods and the general approach to dose assessments.
23. The Representatives explained that this work had been carried out in collaboration with FAO and WHO and would also require careful consideration regarding any impact on food standards, food safety and trade aspects for which feedback from Codex members was very important and could be gathered through CCCF. The Representative further noted that such work would not entail the establishment of MLs for radionuclides in food in normal situations but providing guidance to food safety authorities for increased understanding of radioactivity in food and related food safety and trade issues.
24. Delegations in general supported an explorative work on food safety and trade issues associated with radionuclides in food (including drinking water) in non-emergency situations. They mentioned that radioactivity in feed should be included as there were few guidance on feed at national / international levels in order to ensure safety of food of animal origin.
25. A delegation noted that there was no definition for normal situations as compared to emergency situations.

Conclusion

26. CCCF agreed to establish a EWG on radioactivity in feed and food to produce a discussion paper for consideration at its next session, chaired by EU, co-chaired by Japan, working in English with the following TOR:
 - (i) Provide factual information on the radioactivity of both human-made and natural origin that can be found in feed and food (including drinking water) in normal circumstances (i.e. not in an emergency exposure situation following a nuclear or radiological emergency).
 - (ii) Identify the issues related to the presence in normal circumstances of radioactivity in feed and food (including drinking water) of both human-made and natural origin, such as feed and food safety, transfer of radioactivity from feed to food of animal origin, possible public health risks via intake of food, trade issues, etc.
27. CCCF noted that this discussion paper would:
 - (i) result in an increased understanding of the presence of radioactivity in feed and food (including drinking water) in normal circumstances and related issues, and
 - (ii) provide the Committee with the appropriate information enabling CCCF14 to take an informed decision in 2020 on possible follow-up actions.

PROPOSED DRAFT MAXIMUM LEVELS FOR LEAD IN SELECTED COMMODITIES IN THE GSCTFF (Agenda Item 5)⁵

28. The USA, as Chair of the EWG, introduced the item and recalled the purpose of this work and the work process followed in the review of the MLs in the GSCTFF as described in Appendix II of CX/CF 19/13/5 and previous sessions of CCCF. USA further recalled that CCCF12 had decided to develop MLs for wine and fortified wines made from grapes harvested after the date of the adoption of the MLs by CAC and on edible offal of cattle, pig and poultry.
29. CCCF agreed to consider the proposed MLs as follows:

⁴ CX/CF 19/13/4

⁵ CL 2019/07-CF; CX/CF 19/13/5; CX/CF 19/13/5-Add.1 (Australia, Canada, Cuba, EU, Japan, Kazakhstan, Kenya, Mexico, Peru, Republic of Korea, USA, FIVS, OIV)

Wine

30. The EWG Chair, explained that for wine, 100% of samples in the 2019 LOQ-limited dataset met the current ML of 0.2 mg/kg. In addition, 100% of samples may meet a hypothetical ML of 0.15 mg/kg; 99% of samples may meet a hypothetical ML of 0.1 mg/kg; 97% of samples may meet a hypothetical ML of 0.05 mg/kg. Although the total dataset for wine may meet a hypothetical ML of 0.05 mg/kg, individual categories of wine (e.g. dessert, white, etc.) may not be able to achieve this lower ML. While most types of wine would meet the proposed ML of 0.05 mg/kg, some types of wine had a rejection rate that would approach 5%. Based on these observations, the EWG recommended two MLs for consideration by CCCF i.e. 0.1 and 0.05 mg/kg respectively.
31. Delegations in support of lowering the ML to 0.1 mg/kg indicated the following:
- This ML was preferred given the reduced impact on trade (1% of wine in trade would be non-compliant rather than 3% with an ML of 0.05 mg/kg);
 - At a hypothetical ML of 0.05 mg/kg, violation rates would be 5-11% for subcategories of “dessert wine” and “white wine”. The high violation rates would have significant impact on the availability of wine as well as on the economic interests of the wine industry.
 - As wines were not consumed by children, there was no need to establish for wine an ML as strict as the one for grape juice which was consumed significantly by adults and children.
 - The ML of 0.1 mg/kg for lead in wine did not contradict the OIV proposal to revise their current ML for lead in wine to 0.10 mg/L.
32. Other delegations in favor of a ML of 0.05 mg/kg indicated that they could support the ML of 0.1 mg/kg in view of the considerations given in support of a ML of 0.1 mg/kg.
33. A delegation noted that it could support the ML of 0.1 mg/L, even though it had submitted occurrence data for lead in wines to GEMS/Food which was supportive of a ML of 0.15 mg/kg (4.2 % trade rejection) or higher; and indicated that at an ML of 0.1 mg/kg and 0.05 mg/kg there would be 12.5% and 50% trade rejections, respectively, based on their country data.
34. Based on the above, CCCF agreed to lower the ML from 0.2 mg/kg to 0.1 mg/kg for wines made from grapes harvested after the date of the adoption of the ML by CAC42.
35. CCCF further agreed to retain the ML of 0.2 mg/kg for wines made from grapes harvested before the date of the adoption of the revised ML of 0.1 mg/kg by CAC42 to continue to provide for an international reference for the trade of these wines.

Fortified / liqueur wines

36. CCCF agreed to establish a ML of 0.15 mg/kg for fortified / liqueur wines made from grapes harvested after the adoption of the ML by CAC42.

General comments on wines

37. The Observer of OIV noted that OIV was an intergovernmental organization representing 85% of the world wine production and 65% of consumption respectively. The Observer further noted that after CCCF12, OIV member countries had decided to revise the current OIV ML for lead with a view to lowering the ML to 0.10 mg/L for wines and 0.15 mg/L for fortified / liqueur wines made both from grapes harvested after the date of adoption of the MLs that would be considered for adoption by the OIV General Assembly in July 2019 immediately after CAC42. The Observer strongly supported harmonization between Codex and OIV and the distinction between wines and fortified / liqueur wines at the proposed MLs.

Edible offal

38. The EWG Chair introduced the recommendations of the EWG as follows:
- **Cattle:** Consider lowering the ML for lead in edible offal of cattle from **0.5 mg/kg to 0.15 mg/kg**.
 - **Pig:** Consider lowering the ML for lead in edible offal of pig from **0.5 mg/kg to 0.15 mg/kg**.
 - **Poultry:** Consider lowering the ML for lead in edible offal of poultry from **0.5 mg/kg to 0.1 mg/kg**.
39. A delegation indicated that they were unable to support the recommendations for the revised (lower) MLs in edible offal without considering data more representative of international production and trade. In addition, clearer justification for these reductions were needed as offal was a very minor and sporadic contributor to total lead exposure.

40. In view of the fact that the MLs for the three food categories were quite close, CCCF considered a proposal to have a single ML for edible offal at 0.15 mg/kg. It was however noted that the *Classification of Food and Feed* (CXM 4-2989) considered separate definitions for edible offal (mammal) and edible offal (poultry) and on this basis it would not be advisable to merge the three categories.
41. CCCF also considered a proposal to establish a higher ML for edible offal for cattle at 0.2 mg/kg considering that the lifespan of cattle was greater than that of pigs and poultry and that cattle for dairy/meat production usually move more often during their lifespan to different farms and grazing areas as compared to pigs and poultry which could result in higher levels of lead in the relevant organs (tissues). In addition, an ML of 0.2 mg/kg would eliminate 2% of the samples in international trade as opposed to 4% in the case of an ML of 0.15 mg/kg while still allowing for reduction to lead exposure from the consumption of edible offal from cattle.
42. CCCF further considered a proposal that edible offal should include intestines for cattle, pig and poultry because intestines were consumed in large quantities in certain countries. CCCF recalled that the current definition for edible offal (mammal) in the *Classification of Food and Feed* did not include intestines. In addition, the Codex Secretariat informed CCCF of the ongoing discussions between CCPR and CCRVDF on a harmonized definition of edible offal and that until such a time a harmonized definition could be agreed, the product definition contained in the Classification may serve as a guidance for the definition of edible offal for the purposes of the GSCTFF and to specify in the remarks to the MLs the tissues of which the data were used to derive the new MLs.
43. Based on the above considerations, CCCF agreed to lower the MLs for edible offal as follows:
- Cattle: From 0.5 mg/kg to 0.2 mg/kg.
 - Pig: From 0.5 mg/kg to 0.15 mg/kg.
 - Poultry: From 0.5 mg/kg to 0.1 mg/kg.

Conclusion

44. CCCF agreed to:
- (i) advance the revised (lower) MLs for wines (from grapes harvested after the adoption of the ML by CAC) at 0.1 mg/kg; fortified / liqueur wines (from grapes harvested after the adoption of the ML by CAC) at 0.15 mg/kg; edible offal (cattle, pig and poultry) at 0.2, 0.15 and 0.1 mg/kg respectively to Step 5/8 for adoption by CAC42 (Appendix II), specifying the tissues used for deriving the MLs.
 - (ii) propose that CAC42 revoke the existing MLs for lead in edible offals (cattle, pig and poultry).
 - (iii) forward a consequential amendment to the current ML of 0.2 mg/kg for lead for wine, including fortified / liqueur wine and to specify that this ML applies to wine made from grapes harvested before the adoption of the new MLs by CAC42.

PROPOSED DRAFT MAXIMUM LEVELS FOR CADMIUM IN CHOCOLATES AND COCOA-DERIVED PRODUCTS (Agenda Item 6)⁶

45. Ecuador, as Chair of the EWG, also on behalf of the co-chairs, Brazil and Ghana, introduced the item and explained the work process followed and presented the conclusions and recommendations to CCCF as presented in CX/CF 19/13/6. The EWG Chair highlighted that, based on additional data submitted to GEMS/Food, the proposed ML of 0.9 mg/kg for the category of chocolates with $\geq 30\%$ to $< 50\%$ total cocoa solids on a dry matter basis, was the same as or similar to the MLs which were adopted in 2018 for chocolates containing or declaring $\geq 50\%$ to $< 70\%$ (0.8 mg/kg) and $\geq 70\%$ (0.9 mg/kg) which was problematic as it was expected that chocolate with lower percentages of total cocoa solids should also have lower MLs for cadmium. In the case of cocoa powder (100% total cocoa solids on a dry matter basis, sold for final consumption), there were wide variations in occurrence of cadmium and that at the levels proposed, the rejection rates for the Latin American and Caribbean region would result in a significant impact on trade in this region.
46. The EWG Chair noted that there was a lack of consensus on the proposed MLs (CX/CF 19/13/6, Appendix I) in the EWG, that it might be difficult to also achieve consensus in CCCF. He had therefore prepared four scenarios based on comments received, for consideration by the plenary as a possible way forward as follows:

⁶ CL 2019/08-CF; CX/CF 19/13/6; CX/CF 19/13/6-Add.1 (Brazil, Canada, Colombia, EU, Peru, Republic of Korea, USA and ICA)

- Postpone the proposal for MLs for the remaining chocolate categories and collect more data for both categories above 50% total cocoa solids on a dry matter basis;
 - Establish an ML of 0.8 mg/kg by pooling both categories $\geq 30\%$ to $< 70\%$ cocoa solids;
 - Establish MLs for the remaining chocolate and cocoa powder categories with the current data and values presented in the conclusions; and
 - Discontinue work on cocoa powder (100% total cocoa solids on a dry matter basis, sold for final consumption)
47. Ecuador noted that there was a need to collect more data for the categories for which MLs had already been established, i.e. chocolates that contain or declare $\geq 50\%$ to $< 70\%$ total cocoa solids on a dry matter basis and $\geq 70\%$ total cocoa solids on a dry matter basis, as the already established MLs might be inconsistent with the MLs proposed by the EWG for the remaining two categories, i.e. chocolate products containing or declaring $< 30\%$ total cocoa solids on a dry matter basis and chocolate and chocolate products containing or declaring $\geq 30\%$ to $< 50\%$ total cocoa solids on a dry matter basis would be in conflict with these MLs.

48. In response to one of the alternative options to the establishment of MLs from the EWG, which was to request a new evaluation by JECFA, the JECFA Secretariat clarified that while it stood ready to serve CCCF's need for scientific advice, he was not aware of sufficient new data regarding the toxicological effects to warrant a new risk assessment for cadmium. The results of such an assessment was unlikely to help CCCF in its decision-making progress any more than the existing JECFA risk assessment had helped CCCF to come to a consensus to date.

Discussion

49. CCCF considered the four scenarios put forward by the EWG Chair.
50. Delegations who spoke expressed the following views:
- It would not be appropriate to look at the review of the recently adopted MLs as this could undermine the Codex standard-setting process and the credibility of Codex.
 - Before any other scenarios could be considered, CCCF should try to reach consensus as this matter had been before CCCF for several years and consideration should be given to set MLs for the remaining categories proportional to the existing MLs for the chocolates that contain or declare $\geq 50\%$ to $< 70\%$ total cocoa solids on a dry matter basis and $\geq 70\%$ total cocoa solids on a dry matter basis.
 - The issue of cadmium was a trade issue rather than a public health issue and that work was being undertaken to monitor the effect of MLs on exports. Several mitigation measures had been identified, were being implemented and would assist to minimize cadmium in cocoa and cocoa products. These mitigation measures would be taken up in the COP for the prevention and reduction of cadmium contamination in cocoa under consideration in Agenda Item 14.
 - As Codex had already adopted MLs for two categories of chocolates, it was necessary to have MLs for the other categories as some regions had already set strict MLs not reasonably achievable based on global data collected by the EWG and not consistent with global ALARA. Without Codex MLs, such regional precedents might become default reference points for other countries to follow, despite significant challenges for achievability in regions that are prone to higher cadmium in soils, particularly in volcanic regions.
 - Work on an ML for cocoa powder (100% total cocoa solids on a dry matter basis, sold for final consumption) should continue. This ML could always be reviewed in future should new data indicate such a need.
 - For the manufacturing industry, a single global, reasonably achievable ML for cadmium in cocoa powder would help simplify compliance standards. There was no cocoa butter in this category and so greater flexibility on proportional achievability was necessary. To discontinue work would leave open the possibility of multiple and/or overly strict regional or national MLs that could unfairly impact certain cocoa-producing origins and complicate the supply chain.
 - Work should be discontinued as it had been on the agenda for some time.
51. Noting the lack of consensus to postpone discussion on the remaining categories, CCCF considered the proposal of the CCCF Chair to consider the MLs on a proportional basis to the existing MLs as follows:

- for chocolate products containing or declaring <30% total cocoa solids on a dry matter basis: 0.3 mg/kg
- chocolate and chocolate products containing or declaring ≥30% to <50% total cocoa solids on a dry matter basis: 0.5 mg/kg; and
- cocoa powder (100% total cocoa solids on a dry matter basis): 1.5 mg/kg

52. There was general agreement with this approach while recognizing the need for some flexibility in the proportionality between the MLs for the different chocolate categories to avoid very high rejection rates.

53. The EU however noted that even if this approach were followed, they could not support the proposed MLs as in the EU a more conservative HBGV was in place. For the EU risk assessment, it had been shown that for certain vulnerable groups the HBGV could be exceeded up to six-fold; and that in terms of exposure of children to cadmium, strict levels had been set in the EU for chocolate products containing less than 50% total cocoa solids on a dry matter basis and for cocoa powder which was used as an ingredient in chocolate milks consumed by children.

Chocolates containing or declaring <30% total cocoa solids on a dry matter basis

54. There was general support for the proposed ML of 0.3 mg/kg recognizing that there was a good proportional distribution of geographic data with a relatively low rejection rate on a worldwide basis (3.2%) although it was noted that this would result in higher rejection rates of 12% in particularly the Latin American and Caribbean region. The EU, supported by Norway and another delegation, were not in a position to support this ML for the reasons expressed above (see paragraph 53). Ecuador also could not support this level because of the high rejection rates for the Latin American and Caribbean region.

Chocolates containing or declaring ≥30% to <50% total cocoa solids on a dry matter basis and cocoa powder (100% total cocoa solids on a dry matter basis, sold for final consumption)

55. While there was some support for the levels proposed, it was recognized that more time was needed to consider the levels for these two categories and that further data should be submitted to assist in this discussion. Likewise, it was pointed out that the proposed ML of 0.5 mg/kg would generate a rejection rate of 22.1% for the Latin American and Caribbean region.

Conclusion

56. CCCF agreed:

- (i) to advance the ML of 0.3 mg/kg for chocolates containing or declaring <30% total cocoa solids on a dry matter basis for adoption at Step 5/8 by CAC42, and noted the reservations of the EU, Norway and Ecuador to this decision;
- (ii) to re-establish the EWG chaired by Ecuador and co-chaired by Ghana, working in English and Spanish to continue work on MLs for the categories for chocolate and chocolate products containing or declaring ≥30% to <50% total cocoa solids on a dry matter basis; and cocoa powder (100% total cocoa solids on a dry matter basis) for consideration by CCCF14, using a proportional approach;
- (iii) to encourage continued data submission for use by the EWG in view of the need for balance between proportionality and rejection rates;
- (iv) to not revise the existing MLs for chocolates that contain or declare ≥50% to <70%, and ≥70% total cocoa solids on a dry matter basis; and
- (v) if no consensus were reached at CCCF14, the work would be discontinued until the COP for the prevention and reduction of cadmium contamination in cocoa was finalized and implemented (Agenda Item 14).

DRAFT CODE OF PRACTICE FOR THE REDUCTION OF 3-MCPDEs AND GEs IN REFINED OILS AND FOOD PRODUCTS MADE WITH REFINED OILS (Agenda Item 7)⁷

57. The USA, as Chair of the EWG, also on behalf of the co-chairs, Malaysia and EU, introduced the item, and explained that based on all written comments submitted in reply to CL 2019/09, a revised document (CRD26) had been prepared and proposed to use this as a basis for discussion.

⁷ CL 2019/09-CF; CX/CF 19/13/7; CX/CF 19/13/7-Add.1 (Australia, Canada, Colombia, Costa Rica, EU, Japan, Indonesia, Kenya, Republic of Korea, Malaysia, USA and FEDIOL)

58. The EWG Chair informed CCCF that, in addition to editorial amendments, modifications on various aspects (e.g. clarifying the process of glycidol ester formation, stating that physical refining occurs at higher temperatures than chemical refining, adding explanatory texts on the handling/disposal of water/alcohol mixtures as well as deodorization, etc.) had been incorporated in CRD26. The EWG Chair highlighted there were two statements remaining in square brackets (paragraphs 2 and 5 of CRD26) for further examination in the plenary.
59. CCCF considered the COP (as revised in CRD26) section by section, and in addition to editorial changes, noted the following comments and took the following decisions:

Introduction

Paragraph 2

60. Some delegations proposed to delete the sentence in square brackets listing products that could contribute to (i) the exposure of 3-MCPDEs and GEs as the scope of the COP was intended for refined oils and food products made with refined oils and exposure to 3-MCPDEs and GEs was not limited to the listed products (i.e. infant formula, dietary supplements, fried potato products, and fine bakery wares) and (ii) it was not necessary to mention them; others were of the view that from those commodities, at least infant formula, should be retained since the JECFA assessment focused on this food category.
61. CCCF agreed to maintain the product list and rephrased the sentence to make it clear that these were non-exhaustive examples.

Paragraph 3

62. The JECFA Secretariat confirmed that GE and glycidol had been identified as genotoxic carcinogens while conversely 3-MCPD and 3-MCPDE had been identified to be non-genotoxic carcinogens.
63. Delegations considered whether this paragraph was relevant to the COP. A delegation indicated that this paragraph exactly explained the reason to develop the COP and necessity to implement the provisions therein and thus was of importance.
64. CCCF therefore agreed to maintain this paragraph in the introduction and to revise it as to clarify that 3-MCPD and 3-MCPDE were non-genotoxic carcinogens.

Paragraph 5

65. Delegations in favor of the deletion of the sentence in square brackets referring specifically to palm oil noted that (i) 3-MCPDE and GE contents were not only related to oil type, but also to environmental conditions, genotypes, factors relating to processing or refinery processes, and post-harvest handling; and (ii) the example on refined palm oil was a historical information which might lead to unnecessary discrimination against palm oil, and with the advancement of technologies, refined palm oil with lower 3-MCPDE and GE could be produced nowadays.
66. The EWG Chair pointed out the work had been initiated due to the concern with palm oil; therefore it seemed to be necessary to include the example on refined palm oil in this paragraph.
67. CCCF agreed to: (i) delete the sentence in square brackets; and (ii) retain the reason for starting the work in the report (i.e. refined palm oil had historically been reported to have higher concentrations of these esters than other refined edible oils) for reference.

Scope

Paragraph 18

68. A delegation suggested removing reference to national and local authorities, producers, manufacturers, and other relevant bodies as Codex standards were developed for all interested parties and there was no need to specify the stakeholders.
69. CCCF however, agreed to keep the text unchanged as this followed the approach taken for other COPs developed by CCCF and that measures in the COP should be implemented by not only governments, but also other stakeholders.

Agriculture Practice for Vegetable Oils

Paragraph 23

70. CCCF noted that "oil seeds" included in this paragraph meant seeds for milling and agreed to revise this paragraph accordingly and move it to the section on Oil Milling and Refining as more appropriate.

71. In response to the question that the temperature requirement e.g. cool temperatures (e.g. < 25°C) in this paragraph might not be applicable to tropical countries, it was clarified that the temperature given was only as an example and as such the application of such value was flexible.

Oil Milling and Refining

Paragraph 28

72. CCCF agreed with the deletion of the reference to polar solvent / alcohol (ethanol mixtures) and make the provision more general to provide for flexibility in the application of such substances. With this change, the last sentence was deleted as it was redundant.

Treatment Post Refining

Paragraph 45

73. CCCF agreed to revised the paragraph related to treatment of refined MCT oil with ones or more bases in order to improve the accuracy and for easy readability.

Selection and Uses of Refined Oils in Food Products made from these Oils:

Paragraph 47

74. A delegation expressed their view that the recommendation to decrease 3-MCPDE and GE by reducing the amount of refined edible oils in finished product contained in this paragraph could be expressed in a more flexible way. CCCF thus agreed to refer to this recommendations as an alternative option.

Other matters

75. A delegation pointed out that there was a risk identified at household level due to the repeated use and heating of oils, however no any advice was included in the draft COP. Another delegation expressed the view that (i) it would be more appropriate for national or local authorities to provide such advice; and (ii) at the current stage, it was unnecessary to include such advice in the COP in order to avoid the impression that only the occurrence of 3-MCPD, 3-MCPDE and GE was linked to household practice.
76. The Representative of FAO informed CCCF that the development and implementation of appropriate protective measures applicable at the household and consumer level should be the responsibility and opportunity of regional, national or local governments. In order to ensure its effectiveness, such measures needed adapting to national and local environments, reflecting among others, dietary habits, languages spoken and food preparation practices.
77. CCCF agreed to not include advice to consumers in this COP, and noted that provision of such advice could be provided by national or local governments taking into account conditions at local level.

Annex I

78. CCCF made consequential changes to be aligned with those amendments made in the main text of the COP.

Conclusion

79. CCCF agreed to advance the Code of practice for the reduction of 3-MCPDEs and GEs in refined oils and food products made with refined oils to Step 8 for adoption by CAC42 (Appendix IV).

PROPOSED DRAFT MAXIMUM LEVEL FOR TOTAL AFLATOXINS IN READY-TO-EAT PEANUTS AND ASSOCIATED SAMPLING PLANS (Agenda Item 8)⁸

80. CCCF noted that this agenda item was not for discussion and recalled its discussion on this matter under Agenda Item 2.

PROPOSED DRAFT MAXIMUM LEVEL FOR TOTAL AFLATOXINS AND OCHRATOXIN A IN NUTMEG, DRIED CHILI AND PAPRIKA, GINGER, PEPPER AND TURMERIC AND ASSOCIATED SAMPLING PLANS (Agenda Item 9)⁹

81. CCCF noted that this agenda item was not for discussion according to the decision of CCCF12 to hold these MLs at Step 4 to ensure the implementation of the *Code of Practice for the Prevention and Reduction of Mycotoxins in Spices* (CXC 78-2017) and to generate data to enable progress in the consideration of the MLs for mycotoxin in spices by a future CCCF.

⁸ REP18/CF para. 115, Appendix VII

⁹ REP18/CF para. 119, Appendix VIII

DRAFT GUIDELINES FOR RISK ANALYSIS OF INSTANCES OF CONTAMINANTS IN FOOD WHERE THERE IS NO REGULATORY LEVEL OR RISK MANAGEMENT FRAMEWORK (Agenda Item 10)¹⁰

82. New Zealand, as Chair of the EWG and PWG, also on behalf of the Co-Chair, The Netherlands, presented the report of the PWG (CRD3) and explained that the PWG had broad agreement on the guidelines' principles and noted that discussion had focused on four technical themes: title, scope, terminology and characteristics of the cut-off value, and ordering the process steps in the decision tree. In addition several other minor amendments had been made to the text to improve clarity. He proposed that CCCF focus on the key themes for its discussion.
83. CCCF agreed with the revised text in CRD03, made editorial amendments and made the following comments and additional decisions:
- agreed to reflect in the body text the change in the title;
 - agreed to correct footnote 1 by inserting the text from the report of CRD03 and agreed to replace footnotes 2 and 6 with references to WHO or JECFA reports, as more appropriate and without losing important reference information forming the basis for the application of the Guidelines;
 - reordered the scope for better flow and agreed to revise the introductory text on examples of contaminants included in the scope to clearly explain that the listed contaminants were merely examples and a non-exhaustive list;
 - included the *General Guidelines on Sampling* (CXG 50 – 2004) as additional Codex text relevant to the Guidelines (Section 2 - Purpose) in view of the extensive guidance on sampling in Section 6 - Reporting on detections; and deleted reference to “quantified uncertainty with sampling and analysis” in Section 6, noting that uncertainty would not be calculated in cases addressed by the Guidelines, that it would be difficult to know the distribution of the contaminant in a lot and that it was unlikely to have the uncertainty of sampling to report;
 - amended Section 7.7 to indicate that the risk assessor could consider exposure from other foods if data were available when undertaking a rapid exposure assessment of the contaminant of interest;
 - clarified that the points raised in Section 7.9 Decision by the risk manager were options for consideration providing flexibility to risk management and was therefore not necessary to provide a specific time frame for the holding of a consignment; that after application of the TTC decision tree it might be necessary to acquire further information, but that it was not a routine requirement; and
 - aligned the decision tree for rapid risk analysis with the corresponding texts in the Guidelines.
84. CCCF noted that the Guidelines had been thoroughly discussed and was ready to be advanced in the Step process.
85. A member, however, noted that in their view the Guidelines could potentially cause disruption to international trade, especially due to the differences in understanding and technical capacity to apply the principles, especially related to laboratory capacity. The delegation therefore proposed to have another round of comment on the Guidelines and also expressed the need for a global effort sponsored by FAO or WHO to assist with the implementation of the Guidelines in particular related to the TTC concept.
86. The Representative of FAO explained that normative work in form of MLs, guidance documents, COPs and similar texts was the main task of CCCF. Capacity building, the strengthening of technical and institutional capabilities to implement Codex texts in the national context was the prime objective of development agencies, amongst which FAO, IAEA and WHO. He encouraged interested member states to contact the local representative of those agencies and express their desire for assistance in designing development activities tailored to the specific national or regional needs in improving the technical and institutional capabilities to improve the implementation of and the compliance with applicable Codex texts.

Conclusion

87. CCCF agreed to advance the Guidelines for rapid risk analysis following instances of detection of contaminants in food where there is no regulatory level to Step 8 for adoption by CAC42 (Appendix V).

¹⁰ CL 2019/10-CF; CX/CF 19/13/8; CX/CF 19/13/8-Add.1 (Australia, Canada, Costa Rica, Colombia, EU, Indonesia, Japan, Kenya, Republic of Korea, Switzerland, USA, ICBA, IDF, IFT and ISDI)

DISCUSSION PAPER ON THE ESTABLISHMENT OF NEW MAXIMUM LEVELS FOR LEAD IN COMMODITIES ACCORDING TO A PRIORITIZATION APPROACH (Agenda Item 11)¹¹

88. Brazil, as Chair of the EWG, introduced the item and explained that the aim of the work was to identify for which food categories that did not have MLs in the GSCTFF, MLs should be established for. The EWG Chair explained the work process that was followed for the selection¹² and prioritization¹³ of commodities for which MLs for lead should be established and drew attention of CCCF to the recommendations for discussion.
89. The EWG Chair further explained that the process entailed a three-step procedure: identification of food categories; prioritization of the identified food categories based on exposure assessment and consideration on trade volumes. She also noted that the new proposal was for a staggered approach to address three work packages and that foods for infants and young children should be considered a high priority with the exception of infant formula for which an ML was already established.

Discussion

90. CCCF agree with the selection and prioritization criteria used and focused its discussion on the food categories proposed for the establishment of MLs.
91. The following views were expressed by delegations:
- The new work proposal was ambitious and that a certain degree of flexibility should be allowed for the order of food categories listed to accommodate new data that might become available.
 - The workload of CCCF and the principles in the GSCTFF should be taken into account when deciding on the priority food categories. Highest priority should be given to primary products that contributed most to the exposure of lead and those traded in significant amounts.
 - A step-wise approach would be more practical and that immediate new work should focus either only on work package 1 or on both packages 1 and 2.
 - Consideration should be given to the inclusion of coffee and coffee products.
 - Sugars and confectionary, excluding cocoa should be moved to work package 1 as these products were widely consumed by children.
 - When work was done on spices and aromatic herbs, the focus should be on those that contribute the most to exposure; and for teas and herbal teas, a transfer factor should be included.
 - The prioritization criteria should not only take into account exposure and international trade, but also the complexity of the food category.
92. In view of the huge workload, and the comments made, CCCF agreed to focus on:
- Food for infants and young children (except those for which an ML has already been established in the GSCTFF)
 - Spices and aromatic herbs
 - Eggs
 - Sugars and confectionary, excluding cocoa
93. CCCF noted that the food categories were broad, but that an analysis of further available data would assist in determining the sub-categories for which the MLs should be established.
94. CCCF further agreed that once the work on the identified food categories was finalized, CCCF could consider follow-up action on the other food categories and possibly any other issues that would be identified through the new work.
95. Based on the above considerations, CCCF revised the project document accordingly.

Conclusion

96. CCCF agreed to:
- (i) submit the revised project document (Appendix VI) to CAC42 for approval as new work; and
 - (ii) establish an EWG, chaired by the Brazil, working in English, to prepare, subject to approval of CAC42, proposed draft MLs for comments and consideration at CCCF14; and
 - (iii) issue a call for data on the agreed categories in order to identify sub-categories for which MLs could be proposed for consideration by CCCF14.

¹¹ CX/CF 19/13/9

¹² CX/CF 19/13/9, Appendix II, para. 3

¹³ CX/CF 19/13/9, paras. 8-16

DISCUSSION PAPER ON LEAD AND CADMIUM IN QUINOA (Agenda Item 12)¹⁴

97. The JECFA Secretariat introduced the item and explained that even though it was not possible to complete the paper in time for this meeting, a literature search and gathering of data in GEMS/Food prior to the meeting indicated that available occurrence data on cadmium and lead in quinoa or other pseudo-cereals were limited.
98. As a way forward the JECFA Secretariat proposed that CCCF could consider to request occurrence data for inclusion for a future analysis to be included in a discussion paper. This paper could then be presented at the next meeting. It was also proposed that CCCF could consider to use data from other plants and use extrapolation as a tool to establish measures for quinoa and other relevant pseudo-cereals.
99. The Codex Secretariat explained that the extrapolation tool currently used in CCPR allow the establishment of group MRLs by extrapolating data from a representative commodity (or representative commodities) to other crops based on the *Classification of Food and Feed (CXG 4-1989)* and the *Principle and Guidance on the Selection of Representative Commodities for the Extrapolation of MRLs for Pesticides to Commodity Groups (CXG 84-2012)*. She also explained that in the Classification, cereal grains also cover similar grains and pseudo-cereals such as cañihua, buckwheat, quinoa, etc., and the Principles and Guidance identify cereals such as wheat and maize as representative commodities to extrapolate data to establish group MRLs to cover these similar grains and pseudo-cereals.
100. The Secretariat further informed that CCRVDF was also discussing the possible option of extrapolation and CCCF might wish to explore the possibility to refer to the experiences from CCPR and CCRVDF on this aspect. She also noted that extrapolation to establish group MLs was also mentioned in the GSCTFF.

Discussion

101. Regarding the use of the extrapolation tool, delegations expressed the following views:
- Extrapolation could be done for chemicals applied for specific purposes while contaminants occurred unintentionally and were unavoidable which could make extrapolation difficult.
 - In CCPR, extrapolation was based on GAP data which was not applicable for contaminants.
 - Variability in geographic and crop growth conditions, including soil chemistry and other environmental parameters, would be expected to have significant influences on contaminants uptake by different plant species possibly negating the applicability or effectiveness of extrapolation.
 - The nature of routes of contamination varied between contaminants, i.e. lead came from deposition from the air, which might lead to similar concentrations in grains while cadmium came from the soil which might result in different concentrations.
 - Quinoa was not a cereal and the growing conditions, characteristics and uptake of contaminants would be different from cereals.
102. Noting that a project for collection of data of heavy metals in quinoa was underway in the EU, it was generally agreed that it might be appropriate to consider quinoa separately and an ML for lead and cadmium in this commodity could be based on data specific to quinoa.

Conclusion

103. CCCF agreed that JECFA would issue a call for data on occurrence data for cadmium and lead in quinoa through GEMS/Food; and based on the information collected, the JECFA secretariat, with the assistance of the Codex Secretariat, would finalize the paper for consideration by CCCF¹⁴.

DISCUSSION PAPER ON REVISION OF THE CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF LEAD CONTAMINATION IN FOODS (CXC 56-2004) (Agenda Item 13)¹⁵

104. The USA, as Chair of the EWG, also on behalf of the co-Chair, the United Kingdom, introduced the item and stressed that the aim of this discussion paper was to provide additional information on sources of lead in food and updated measures for reducing lead in food that had become available since the publication of the COP to support its revision.

Discussion

105. CCCF generally agreed with the proposal noting there was sufficient additional information available on lead sources and mitigation measures to justify revisions to the COP.

¹⁴ CX/CF 19/13/10

¹⁵ CX/CF 19/13/11

106. In replying to one question on whether setting standards for lead migration and lead composition in food contact materials used in food processing or manufacturing was within the scope of this work, it was clarified that it was not the intention to establish such standards, but to provide this as an option for consideration by regulatory bodies.

Conclusion

107. CCCF agreed to
- (i) submit the project document (Appendix VII) to CAC42 for approval as new work; and
 - (ii) establish an EWG, chaired by USA and co-chaired by UK and Japan, working in English, to prepare, subject to approval of CAC42, a revised version of the COP, based on the document provided in Appendix II of CX/CF 19/13/11, for comments and consideration at CCCF14.

DISCUSSION PAPER ON THE DEVELOPMENT OF A CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF CADMIUM CONTAMINATION IN COCOA (Agenda Item 14)¹⁶

108. Peru, as Chair of the EWG, also on behalf of the co-chairs, Ghana and Ecuador, introduced the item and recalled that CCCF12 agreed to consider a discussion paper on the feasibility to develop a COP to reduce cadmium contamination in cocoa beans by determining if mitigation measures available at present supported the development of the COP and if so whether such measures covered the entire production chain or part of it (e.g. primary production only) and whether such measures were proven to be cost-effective and applicable regionally or worldwide by large, medium and small-scaled producers.
109. The EWG Chair indicated that risk management measures available to-date support the development of a COP during primary production and post-harvest (i.e. fermentation, drying and storage processes). Such measures were validated to be feasible, cost-effective and applicable worldwide by large, medium and small farmers. Manufacturing / processing practices that could effectively reduce cadmium levels in processed products (e.g. chocolates) would not be included in the scope of the COP as they were not yet readily available. However, there was ongoing studies to reduce cadmium contamination at different stages of the processing chain that were being carried out in different countries that could be incorporated in the COP in future.
110. The EWG Chair stressed that this COP would help to reduce cadmium contamination in cocoa beans and their products and would facilitate the application and compliance with the MLs for cadmium in chocolates and chocolate products.
111. Noting that there was wide support for the development of the COP, CCCF considered the project document and made some editorial amendments.

Conclusion

112. CCCF agreed to:
- (i) submit the project document (Appendix VIII) to CAC42 for approval as new work; and
 - (ii) establish an EWG, chaired by Peru and co-chaired by Ghana and Ecuador, working in English and Spanish, to prepare, subject to the approval of CAC42, a draft COP based on the document provided in Appendix II to CX/CF 19/13/12, for comments and consideration at CCCF14.

DISCUSSION PAPER ON THE ESTABLISHMENT OF MAXIMUM LEVELS FOR METHYLMERCURY IN ADDITIONAL FISH SPECIES (Agenda Item 15)¹⁷

113. New Zealand, as Chair of the EWG, also on behalf of the co-Chair Canada, introduced the item and summarized the work process of the EWG as well as the data and information considered by the EWG to arrive at the recommendations for consideration by CCCF.
114. The EWG Chair reminded CCCF that with the agreement on MLs for tuna, alfonsino, marlin and shark, there was an established framework to apply an ALARA approach in setting MLs for methylmercury in fish. He further emphasized the decision of CCCF12 that for future ML development, data on both methylmercury and total mercury would need to be available, as it was shown that for certain fish species the ratio of methylmercury to total mercury was very low and for the data analysis it could not always be assumed that total mercury would be mostly present as methylmercury. He noted that it would not be possible to propose MLs for further taxonomic groupings or individual fish species based on the current methylmercury data in GEMS/Food, but that based on total mercury, species for future ML development could be identified.

¹⁶ CX/CF 19/13/12

¹⁷ CX/CF 19/13/13

115. The EWG Chair further informed CCCF that the EWG was recommending a work programme for derivation of MLs based on prioritized fish species / taxonomic grouping, but that the work was contingent on submission of further data on total mercury and methylmercury concentrations into GEMS/Food.
116. Recognizing that the recommended program was quite ambitious and contingent on data submission, the EWG Chair proposed that the work be postponed until new data became available and that a further discussion paper on the feasibility of developing MLs could be prepared for consideration by CCCF.

Discussion

117. CCCF considered the recommendations of the EWG and the proposal of the EWG Chair to postpone starting of the work and to develop a further discussion paper.
118. There was general agreement that it might be premature to proceed with new work at this time and that a further discussion paper should be prepared given the lack of methylmercury data, and members should be encouraged to submit data on methylmercury in fish.
119. CCCF further noted that data, should amongst others:
- be submitted for both methylmercury and total mercury and preferably from paired analysis;
 - be from ideally at least two locations in a maritime zone;
 - should be from ideally samples from representative fishery areas; and
 - give consideration to request binomial names of fish species or FAO taxonomic coding as an entry field to improve the consistency of data grouping.
120. Noting that there might be several other aspects to the types of data needed, it was agreed that the chairs of the EWG and JECFA Secretariat would discuss all the necessary elements for the call for data.
121. A delegation while agreeing with the importance of data, noted the cost for testing for methylmercury compared with testing for total mercury and the need to improve laboratory capacity.
122. Questions were raised on the threshold to evaluate international trade and it was explained that the selection criteria in trade was based on the average catch of alfonso for which CCCF12 had established an ML. A delegation expressed the view that for additional fish species for which MLs for methylmercury should be set, it was necessary to take into consideration the trade volume of fish species and drew the attention of CCCF to CRD16 which provided a table containing trade volumes of 14 species identified and comparison with marlin for which an ML was already established.
123. CCCF also noted a general comment that while the cut-off level of 0.3 mg/kg methylmercury for selection of fish species for which MLs should be set, was not contested, it was not appropriate to state that only species with an average of methylmercury greater than 0.3 mg/kg presented a risk of exposures exceeding the PTWI, because also species with lower concentrations could contribute to overall exposure.

Other related matters

Sampling plan for methylmercury in fish

124. The EWG Chair, referring to CRD35, informed CCCF on the outcomes on the informal group discussion to address the comments submitted on the sampling plan for methylmercury in fish and to also address the two questions that CCMAS was unable to address (see Agenda Item 2).
125. The EWG Chair informed CCCF that a revised sampling plan would not be presented at this session as areas of inconsistency with other sampling plans in the GSCTFF were identified and needed to be addressed; and noted that the two following remaining questions, i.e. (i) whether there is evidence that methylmercury can vary widely between individual fish sampled at the same time and (ii) whether the whole fish should be analyzed or only specific fractions of edible portions, could be addressed through the consideration of contemporary scientific literature and national monitoring data. Both these issues could be addressed through the EWG on MLs for methylmercury in fish and the findings presented for consideration at CCCF14.
126. CCCF agreed to this proposal.

Conclusion

127. CCCF agreed to:
- (i) request JECFA to issue a call for data;
 - (ii) re-establish the EWG chaired by New Zealand and co-chaired by Canada to revise the discussion paper based on new data to be submitted to GEMS/Food to consider whether it is feasible to proceed with establishment of MLs for additional fish species. The paper should clearly identify the fish species for which MLs should be established; and
 - (iii) To consider issues related to sampling plans for methylmercury in fish.

DISCUSSION PAPER ON THE ESTABLISHMENT OF MAXIMUM LEVELS FOR HYDROCYANIC ACID IN CASSAVA AND CASSAVA-BASED PRODUCTS AND OCCURRENCE OF MYCOTOXINS IN THESE PRODUCTS (Agenda Item 16)¹⁸

128. Nigeria, as Chair of the EWG, introduced the item and highlighted that this issue was based on the request from CCAFRICA wanting to know if it was appropriate to extend the existing ML for HCN of 2 mg/kg in gari to fermented cassava products, and whether mycotoxins were of public health concern in these products.

The harmonization of the expression of HCN levels i.e. free or total HCN

129. The EWG Chair explained that based on the data available for the preparation of the paper it was not possible to conclude whether harmonizing of the expression of HCN levels could be done i.e. free or total HCN current appearing in the MLs for gari (free HCN) and cassava flour (total HCN).

The appropriateness to extend the existing ML for free HCN of 2 mg/kg in gari to fermented cassava products

130. The EWG Chair explained that an ML 2 mg/kg was already established for gari and it had been demonstrated to be protective enough over the years and it could be extended to the fermented cassava as consumed, especially fufu, as also demonstrated by the data presented.

Discussion

131. A delegation expressed the view that before the extension of the ML could be considered, the harmonization of the expression of HCN needed to be addressed. It was not clear from the data provided whether it was free or total HCN. The delegation also questioned the high rejection rate if the ML of gari were to be applied to the fermented cassava products identified in the paper.
132. In response to the question on the high rejection rate of 87% of fufu when it applied to existing ML of gari, it was clarified that fermented cassava with high rejection rate in the document was for further processing and when further process through cooking (heat treatment) for human consumption, the level of HCN would be decreased dramatically and would have a reasonable rejection rate.
133. CCCF noted that there was no data presented in the paper to demonstrate the effect of further processing (e.g. heat treatment to reduce the content of HCN in the final product).
134. The EWG Chair further clarified that, in response to the question on the expression of HCN levels, i.e. free or total, only 5% of data were expressed as total HCN while others were not specified.
135. The Codex secretariat reminded CCCF that while the initial request was from CCAFRICA, CCCF was a global committee setting international standards in accordance with the principles in the GSCTFF. CCCF11 had agreed to look at all fermented cassava products and if CCCF agreed to extend the ML for gari to other fermented cassava products, it would apply to all fermented cassava products traded worldwide. It was important to also look into the data to see if it supported extension to all fermented cassava products.
136. In response to a proposal to issue a call for data for HCN in cassava to further this work, and to a request to modify the GEMS/Food database as to allow submission of data on free versus total HCN and fermented versus non-fermented cassava, the JECFA Secretariat noted that it was not sufficiently clear to the JECFA Secretariat exactly what data are requested in order to help CCCF in its decision making process. The Secretariat proposed that CCCF should first consider requesting a background document which should address details about the varieties of cassava (bitter or sweet) used, the names of the products (semi-processed and for final consumption), the production process applied to produce the food in commerce and the production steps performed in the households. The background paper also needed to include details about the fate of total and free cyanides during the production process, including at household level.
137. Noting it was premature to proceed with a call for data, CCCF agreed that an EWG should first prepare a background informative discussion paper to provide a global picture of fermented cassava products and address amongst others, which are the cassava varieties grown in different regions; which are the cassava fermented products traded worldwide; what are the consumption patterns, whether semi-process or RTE and to consider data preferably of paired samples (free/bound) to better understand the relationship between these two forms of HCN; what the effects cooking / heat treatment are on HCN in semi-processed (for further processing) and processed products (destined for the final consumer); and other relevant elements that could become clearer as the paper is developed.
138. Based on the findings of this paper, CCCF14 may decide on the further steps e.g. identify fermented cassava products on which data could be gathered through a call for data to consider the feasibility to establish MLs for HCN on a global basis.

Mycotoxins in fermented cassava product

139. Nigeria, as Chair of the EWG, explained that mycotoxins, particular aflatoxin and ochratoxin were of public health concern in both fermented and unfermented cassava products. Since fungal contamination of cassava products occurs mainly after processing due to poor handling and storage practices and also to some extent at pre-harvest stage due to proliferation of *Fusarium* species in the field amongst others, due to poor GAPs / GMPs, he recommended CCCF considering the development of a COP for reduction and prevention of mycotoxins in cassava and cassava fermented products.

Discussion

140. CCCF generally agreed with the proposal also in recognition that CCCF had already developed a *Code of Practice for the Reduction of Hydrocyanic Acid (HCN) in Cassava and Cassava Products* (CXC 73-2013) and noted the following views:
141. It would be helpful to target on reduction and prevention of aflatoxins and OTA, which could be beneficial for the reduction of other mycotoxins in cassava and cassava fermented products
- (i) More information was needed to start new work
 - Which phase is the most critical in terms of reduction and prevention of mycotoxins in cassava and cassava fermented products
 - What analyte should be measured
 - What kind of information of mitigation technologies or practices are available worldwide that could be applicable at all scale of productions (specially a medium and small businesses)
142. The Codex secretariat reminded CCCF that the current approach for the development of COPs was to first see whether there was enough information (i.e. mitigation measures that can be applied across regions at different scales of production that are proven to be cost-effective) for the development of a COP. She further suggested issuing a CL to collect relevant information that could assist to identify information available to support the development of a COP.
143. CCCF agreed that a discussion paper should be prepared that would address whether there were sufficient mitigation measures to support the development of a COP. Information to support the development of the paper would be collected through a circular letter.

Conclusion

144. CCCF agreed to:
- (i) establish an EWG, chaired by Nigeria and co-chaired by Ghana, working in English only, to prepare discussion papers for consideration at CCCF14 as follows:
 - background information paper to provide a global picture of fermented cassava products taking into account the issues raised in written comments and the points raised in this session; and
 - discussion paper identifying mitigation measures to support development of a COP for prevention and reduction of mycotoxins in cassava and cassava products taking into account the points raised in this session.
 - (ii) inform CCAFRICA of the discussions on MLs of HCN in fermented cassava products and the possible development of COP for prevention and reduction of mycotoxin contamination in cassava and cassava products
145. Nigeria encouraged members from other regions to support and provide the relevant data to EWG. Brazil offered to provide available information.

DISCUSSION PAPER ON THE ESTABLISHMENT OF MAXIMUM LEVELS FOR TOTAL AFLATOXINS IN CEREALS (WHEAT, MAIZE, SORGHUM AND RICE), FLOUR AND CEREAL-BASED FOODS FOR INFANTS AND YOUNG CHILDREN (Agenda Item 17)¹⁹

146. Brazil as Chair of the EWG, also on behalf of the co-Chair India, introduced the item and recalled that maize, rice, wheat and their derived products contributed the most to total dietary aflatoxins (AFs) exposure; that as recommended by JECFA it was necessary to reduce exposure to AFs, and that establishment of MLs could contribute significantly to reduce exposure to AFs. The EWG Chair noted that the *Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals* (CXC 51-2003) was adopted in 2003 and revised in 2017 and the logical next step for the CCCF was to establish MLs.

147. The EWG Chair explained that the paper aimed to demonstrate that establishment of MLs could reduce intake worldwide and would help to protect consumer health, the EWG had taken into account data from 2008 to 2018 and was recommending to start new work on the food categories identified in paragraph 17 of CX/CF 19/13/15. In addition, CCCF should address whether to include rice flour and sorghum in the new work and whether to issue a call for data on whole wheat flour to determine whether this food category should also be included in this new work.

Discussion

148. While there was general support for the establishment of MLs, observations were made that the work should be based on more geographically representative data. It was noted that occurrence data in cereals used for the analysis by the EWG and the subsequent proposal for new work, relied heavily on data from a few countries and regions.
149. A delegation noted that careful data analysis was required to prevent the erroneous inclusion of outliers, which may result in overestimation of percentiles, which in turn would result in overly conservative MLs, such as was the case for some of the data for rice presented in the paper.
150. CCCF agreed to include sorghum in the list noting that it was a staple food in many parts of the world and encouraged countries to submit data to support this work.
151. On the inclusion of rice flour or not, it was noted that there were many different kinds of products on the market as rice flour could originate from different sources, e.g. intact polished rice, broken rice, husked rice, mixtures with starch, and could therefore have different contamination patterns. In the absence of a Codex definition for rice flour it would be more appropriate to first issue a call for data which should clearly specify the source of the rice flour. Based on the submitted data a more informed decision on an ML for this commodity could be reached. Two delegations also proposed that rice flour should be considered as a lower priority as the commodity had a low impact on exposure.
152. There was also agreement that a further call for data should be issued on whole wheat flour and parboiled rice to better assess whether these food categories should be added later.
153. A delegation expressed the view that wheat grain should not be included in the new work at this stage. CCCF noted that for the agreed on commodities, it would be important to use geographically representative data to undertake an assessment of the health impact of hypothetical MLs before proceeding, including to determine if similar health impacts could be achieved at lower sample rejection rates, also that when undertaking the establishment of MLs consideration should be given to year-to-year variation, whether the MLs would take into account use of rapid field tests using higher LOQ than laboratory testing; and its impact on food security.
154. CCCF noted that the work would be quite extensive and agreed to (i) delete the wheat grain, destined for further processing and flour, meal, semolina, and flakes derived from wheat, excluding whole wheat flour from the list and to amend the project document accordingly and to (ii) follow a similar approach to the work on lead by first working on the MLs for the agreed categories and only once this work was completed to consider the remaining food categories.

Conclusion

155. CCCF agreed:
- (i) To submit the project document (Appendix IX) to CAC42 for approval as new work;
 - (ii) to establish an EWG chaired by Brazil and co-chaired by India, working in English, to prepare, subject to the approval of CAC, the proposed draft MLs for circulation for comments at Step 3 and consideration at CCCF14; and
 - (iii) to issue for a call for data for all discussed food categories for submission to GEMS/Food.
 - (iv) that once the work on the MLs for the current set of commodities were completed, to consider other cereals and cereal-based products.

GENERAL GUIDANCE ON DATA ANALYSIS FOR DEVELOPMENT OF MAXIMUM LEVELS (Agenda Item 18)²⁰

156. The EU, as Chair of the EWG, introduced the item and informed CCCF that it had not been possible to prepare in time a discussion paper for consideration by the established EWG rather it was prepared by the EU as Chair of the EWG. CCCF further informed that this document contains a non-exhaustive list of topics that could be considered by the general guidance on data analysis for ML development.

²⁰ CX/CF 19/13/16

157. The EWG Chair explained that, in addition to the possible topics mentioned in CX/CF 19/13/16, the following topics could be included for further consideration by CCCF:
- Importance that food and feed for which data are provided are correctly identified and reported, with detailed information on the food or feed concerned (correct identification, state of the food/feed (fresh, dried, ready-to-eat, etc.).
 - Handling of data not provided to the GEMS/Food.
 - Handling of outliers.
 - Handling of data for which it can be reasonably assumed that the unit of the data provided or the basis on which the data are expressed (e.g. fat basis vs whole weight) is not correct.
 - Lack of information on data provided.

Discussion

158. CCCF focused its discussion on whether the various topics identified as possible criteria would be relevant and if not to remove them from the list and whether there were other topics than those mentioned by the EWG Chair (EU) that could be included as pertinent criterion to provide guidance on data analysis for the development of MLs.

Title

159. CCCF noted comments that additional detailed information was needed on the occurrence data (e.g. country of origin, dried or fresh, etc.) and to ensure that this information could be provided in detail to the GEMS/Food. Given the importance of this, it was proposed to extend the scope of the work and to change the title into "General Guidance on data analysis for ML development and guidance for improved data collection" to better reflect the scope of the document.

Proposed criteria

Removal of criteria

160. CCCF agreed that it would be difficult for chairs of EWGs to determine whether data provided were based on the application of relevant COPs developed by Codex/CCCF or application of GAPs/GMPs and that this work was outside the scope of the guidance document. It was therefore agreed to delete the criterion 7 which indicated that it should be evaluated if the provided occurrence data reflect the application of Codex/CCCF COPs or GAPs/GMPs.

Topics for further consideration

161. CCCF noted the following topics for further consideration:
- Information on the methods of analysis and their validation used for generating the occurrence data.
 - Handling datasets with a different contamination pattern (e.g. as consequence of originating from different regions, different production years).
 - Providing guidance on when to combine or keep separate such datasets for assessment.
 - Re-iteration of importance of providing sufficient detail of provided data to allow correct grouping. This correct grouping is also of major importance for correct use of these data for exposure assessment.
 - Include guidance on how best to present data in EWG reports to CCCF.

Other matters

162. The EWG Chair clarified that the scope of the work was to give guidance for improvement of data analysis and data collection therefore, questions around the basis on which the MLs should be proposed (i.e. rejection rate, occurrence data and reduction risk) was outside the scope of this document.
163. In response on questions whether the GEMS/Food database could accommodate additional details required for data analysis, the JECFA secretariat clarified that the GEMS/Food database could be adapted to ensure that the additional required detailed information could be correctly introduced/reported into the GEMS/Food database.
164. A delegation noted that for developing countries it is often difficult to generate the data requested and to actively participate in the technical discussions on data in CCCF which may prevent an adequate consideration of the needs and the full participation of these countries in the standard-setting process.

Conclusion

165. CCCF:

- (i) agreed on the relevance of this work for the improved data collection and establishment of MLs;
- (ii) agreed to re-establish the EWG, chaired by EU and co-chaired by Japan, The Netherlands and USA, working in English only, to prepare a paper on a general guidance on data analysis for ML development and improved data collection for consideration at CCCF14; and
- (iii) noted that the guidance shall take into account the capacity of the different regions to generate the necessary data.

PRIORITY LIST OF CONTAMINANTS AND NATURALLY OCCURRING TOXICANTS FOR EVALUATION BY JECFA (Agenda Item 19(a))²¹

166. The USA, as Chair of the in-session WG, presented the report on the outcomes of the discussion on the priority list.

167. CCCF revised the priority list based on comments provided by Codex members for accuracy. CCCF also agreed to delete the reference to JECFA to perform an impact assessment of aflatoxins in RTE peanuts from the priority list in light of the outcomes of the impact assessment on hypothetical MLs and related violation rates carried out by JECFA83 (2016), the decision taken at CCCF12 (2018) and the discussion held under Agenda Item 2 of this session.

Conclusion

168. CCCF:

- agreed to request the Codex Secretariat to ask CCNASWP whether (a) they wish to retain scopoletin on the priority list and, if so, (b) when suitable data would be forthcoming.
- accepted the recommendations of the in-session WG and endorsed the priority list of contaminants and naturally occurring toxicants for JECFA evaluation as revised (Appendix X);
- agreed to the prioritization exercise performed by the in-session WG, which identified ergot alkaloids, arsenic (inorganic and organic) and dioxin and dioxin-like PCBs as top priorities for future JECFA evaluations;
- agreed to re-convene the in-session WG at its next session; and
- agreed to continue to request comments and/or information on the priority list for consideration by CCCF14.

FOLLOW-UP WORK TO THE OUTCOME OF JECFA EVALUATIONS (Agenda Item 19(b))²²

169. CCCF noted that there was no follow-up work to the outcome of JECFA evaluations for consideration at this session.

FORWARD WORK PLAN FOR THE COMMITTEE ON CONTAMINANTS IN FOODS (Agenda Item 20)²³

170. The Host Country Secretariat (The Netherlands) introduced the item, also on behalf of the Codex and JECFA Secretariats, and recalled that, due to the heavy workload of CCCF, planning of work had been discussed several times by CCCF, and CCCF12 had decided not to apply a criteria approach for work management but that there was merit in a longer term forward planning, by systematically identifying areas for food contamination of concern for public health and with trade implications, e.g. focusing on contamination in key staple foods including the need for review of existing standards, COPs and related texts. She explained that to broadly address all areas of work of CCCF a proposed forward work plan consisting of four appendices had been prepared.

171. CCCF considered the proposed forward work plan and made the following comments and decisions:

Appendix A: Identification of key staple food / contaminant combinations

172. The Host Country Secretariat introduced the approach (i.e. to have a systematic exploration of possible contamination of the identified staple foods and identify if there were key staple food - contaminant combinations that could be of health concern but had not been considered by CCCF) and made the following clarifications to the appendix:

²¹ CL 2019/11-CF; REP18/CF-Appendix X; CX/CF 19/13/17 (Australia, Canada, Costa Rica, USA)

²² CX/CF 19/13/3

²³ CX/CF 19/13/18

- Millet and sorghum should be included in the list of the most important staple food; and
- The inventory in the table more referred to “cereal grains” rather than “raw grains”.

173. CCCF agreed that the approach could provide an adequate framework to identify important topics of work for CCCF.
174. A delegation pointed out that, although in agreement with the framework, it should not be too strictly applied, as from a public health perspective, some foods not being identified as major staple foods were also of importance e.g. foods for infants and young children and, due to their broad use as food ingredients, edible oils.

Conclusion

175. CCCF agreed that the host country, JECFA and the Codex Secretariats would continue work on this matter taking into account comments received during and after the meeting and report back to CCCF14.

Appendix B: Review of existing CCCF standards that may need revision

176. CCCF considered whether a structured approach to identify the need to review existing standards should be developed and if yes, what this approach should entail.
177. CCCF noted the following views:
- updating the existing standards was very important to keep them up to date with possible changed situations and a work plan in this regard would be needed;
 - the proposed approach should not lead to too much administrative burden. An option could be to periodically issue a CL with existing standards (e.g. those over 10 years old) requesting members to indicate which standards should be considered by CCCF for review and the corresponding justifications should be provided; and
 - the proposed approach should not preclude ad hoc decisions to revise the existing standards.

Conclusion

178. CCCF agreed to establish an EWG, chaired by Canada and co-chaired by Japan and USA, working in English, to prepare a proposal for an approach to identify the need for review of existing CCCF standards for consideration at CCCF14.

Appendix C: Evaluation of implementation of COPs

179. The Host Country Secretariat introduced the proposal on developing a pilot project through organizations providing technical assistance such as STDF or other organizations to evaluate the implementation of the COPs.
180. The following views were observed:
- to develop criteria on revised COPs to facilitate their implementation should be within the mandate of CCCF rather than the pilot project while the pilot project could only make proposals for consideration by CCCF;
 - the ongoing work on the monitoring of the use of Codex standards conducted at CCGP should be duly considered; and
 - in view of the wide variety of existing COPs and their applicability to different countries, the project should be further developed into a more detailed work plan.

Conclusion

181. CCCF agreed with the approach to launch a pilot project on the evaluations of the implementation of COPs and that a more detailed project proposal would be developed by the Host Country, Codex and JECFA Secretariats with the assistance of EU, Kenya, Senegal and USA for consideration at CCCF14.

Appendix D: Possible other future topics for CCCF

182. CCCF considered that whether the topics contained in Appendix D should be the subjects of new work, and if so, if these should be done on a short- or longer term.
183. A delegation emphasized the importance on the topic of identification of key feed commodity – contaminant combinations. The delegation also expressed the view that it was not possible to include packaging materials or in general food contact materials in the work of CCCF in a comprehensive way in the light of the wide range of this area of work, but as it could be important from a public health point of view, some typical topics e.g. mineral oils could be addressed if needed.

Conclusion

184. CCCF noted that the appendix had been prepared for the purpose of inventory and no immediate actions would be taken at this time.

OTHER BUSINESS AND FUTURE WORK (Agenda Item 21)

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

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

186. CCCF was informed that CCCF14 was scheduled to be held in Utrecht, the Netherlands in approximately one year's time, the final arrangements being subject to confirmation by the Host Country and the Codex Secretariats.

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APPENDIX II

**PROPOSED DRAFT REVISED MLs FOR LEAD IN SELECTED COMMODITIES IN THE GSCTFF (CXS 193-1995)
(AT STEP 5/8)**

Commodity/Product Name	Maximum Level (ML) mg/kg (For adoption at Step 5/8)	Portion of the Commodity/Product to which the ML applies	Notes/Remarks
Cattle, edible offal of	0.2	Whole commodity	Edible offal means such offal as have been passed as fit for human consumption, but not including lungs, ears, scalp, snout (including lips and muzzle), mucous membranes, sinews, genital system, udders, intestines and urinary bladder (CXM 4-1989) The ML applies to the following edible offal: Brain, head, heart, kidney, liver, tongue and stomach
Pig, edible offal of	0.15	Whole commodity	Edible offal means such offal as have been passed as fit for human consumption, but not including lungs, ears, scalp, snout (including lips and muzzle), mucous membranes, sinews, genital system, udders, intestines and urinary bladder (CXM 4-1989) The ML applies to the following edible offal: Blood, heart, kidney, liver and tongue
Poultry, edible offal of	0.1	Whole commodity	Poultry edible offal are such edible tissues and organs, other than poultry meat and poultry fat, from slaughtered poultry as have been passed fit for human consumption (CXM 4-1989) The ML applies to the following edible offal: Heart, kidney, liver, stomach and thymus
Wine	0.1	<u>Whole commodity</u>	The ML applies to wine made from grapes harvested after the date of adoption (CAC42, July 2019)
Fortified / Liqueur wine	0.15	<u>Whole commodity</u>	The ML applies to wine made from grapes harvested after the date of adoption (CAC42, July 2019)

**CONSEQUENTIAL AMENDMENT TO THE ML FOR LEAD IN WINE IN THE GSCTFF (CXS 193-1995)
(FOR ADOPTION)**

Commodity/Product Name	Maximum Level (ML) mg/kg (For adoption as consequential amendment)	Portion of the Commodity/Product to which the ML applies	Notes/Remarks
<u>Wine (wine and fortified / liqueur wine)</u>	0.2	<u>Whole commodity</u>	<u>The ML applies to wines and fortified / liqueur wines made from grapes harvested before (CAC42, July 2019)</u>

**REVOCAION OF MLs FOR LEAD IN CORRESPONDING SELECTED COMMODITIES IN THE GSCTFF (CXS 195-1993)
(FOR REVOCATION)**

Commodity/Product Name	Maximum Level (ML) mg/kg (For revocation)	Portion of the Commodity/Product to which the ML applies	Notes/Remarks
Cattle, edible offal of	0.5	Whole commodity.	
Pig, edible offal of	0.5	Whole commodity.	
Poultry, edible offal of	0.5	Whole commodity.	

APPENDIX III

**PROPOSED DRAFT MAXIMUM LEVEL FOR CADMIUM
IN CERTAIN CATEGORIES OF CHOCOLATES**

(AT STEP 5/8)

Commodity / Product Name	Maximum Level (ML) (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

APPENDIX IV**DRAFT CODE OF PRACTICE FOR THE REDUCTION OF 3-MONOCHLOROPROPANE-1,2- DIOL ESTERS (3-MCPDEs) AND GLYCIDYL ESTERS (GEs) IN REFINED OILS AND FOOD PRODUCTS MADE WITH REFINED OILS
(AT STEP 8)****INTRODUCTION**

1. Edible oils, which include vegetable oils and fish oils, are produced from various commodities, including fruits, seeds, nuts, and fish. Refining of edible oils (at temperatures of about 200°C or higher) can produce 3-monochloropropane-1,2-diol (MCPD) esters (3-MCPDEs) and glycidyl esters (GEs).
2. Exposure to 3-MCPDE and GE can occur through consumption of refined oils and various food products containing refined oils, for example, infant formula, dietary supplements, fried potato products, and fine bakery wares.
3. Toxicology studies show that 3-MCPDE and 3-MCPD have effects on the kidney and male reproductive organs, and are non-genotoxic carcinogens. GE and glycidol are genotoxic carcinogens.¹
4. The 83rd JECFA Meeting evaluated 3-MCPD, 3-MCPDE, GE and glycidol and recommended that efforts to reduce 3-MCPDE and 3-MCPD in infant formula be implemented and that measures to reduce GE and glycidol in fats and oils continue, particularly when used in infant formula.
5. Different types of unrefined oils have different capacities to form 3-MCPDE and GE during deodorization (part of the refining process).
6. Processing conditions during refining have an important effect on formation of 3-MCPDE and GE for all oil types. Most unrefined oils do not contain detectable levels of 3-MCPDE or GE.
7. For vegetable oils, factors that contribute to capacity to form 3-MCPDE and GE during refining include climate, soil and growth conditions of source plants or trees, their genotype, and harvesting techniques. These factors all affect the levels of precursors of 3-MCPDE and GE (e.g. acylglycerols, chlorine-containing compounds).
8. 3-MCPDE forms primarily from the reaction between chlorine containing-compounds and acylglycerols like triacylglycerols (TAGs), diacylglycerols (DAGs), and monoacylglycerols (MAGs). GE forms primarily from DAGs or MAGs.
9. Some chlorinated compounds are precursors for 3-MCPDE formation. Oil producing plants or trees absorb chloride ions (in the form of chlorinated compounds) during plant or tree growth from soil (including from fertilizers and pesticides) and from water, and these chloride ions are converted into reactive chlorinated compounds, leading to formation of 3-MCPDE during oil refining.
10. Oil fruits and seeds contain the enzyme lipase; lipase activity increases with fruit maturation, while the lipase activity in seeds remains stable. Lipase interacts with oil from mature fruits to rapidly degrade TAGs into free fatty acids (FFAs), DAGs, and MAGs, while the effect of lipase in seeds that are appropriately stored is negligible.
11. GE formation begins at about 200°C. GE formation increases exponentially with increasing temperature. When DAGs exceed 3-4% of total lipids, the potential for GE formation increases. Formation of 3-MCPDE occurs at temperatures as low as 160-200°C, and formation does not increase with higher temperatures.
12. Because 3-MCPDE and GE are formed via different mechanisms, different mitigation strategies are needed to control their formation. Due to the different formation mechanisms, there generally is no relationship between relative levels of 3-MCPDE and GE in individual oil samples.
13. GE is generally easier to mitigate than 3-MCPDE, because its formation is directly associated with elevated temperatures (with formation beginning at about 200°C and becoming more significant at temperatures >230°C). GE is formed primarily from DAGs and does not require the presence of chlorinated compounds. Oils can be deodorized at temperatures below 230°C to avoid significant GE formation. However, it is not practical to decrease deodorization temperatures below the threshold that would lead to 3-MCPDE formation (160-200°C), as that could affect the quality and safety of the oil.

¹ 3-MCPDE and GE, following consumption, are broken down in the body to 3-MCPD and glycidol, respectively.

14. Although 3-MCPDE and GE are primarily produced during deodorization, mitigation measures can be applied across the edible oil production chain, from agricultural practices for vegetable oils (e.g. cultivation, harvesting, transporting, and storing of fruits and seeds), to oil milling and refining (e.g. crude oil production and treatment, degumming/bleaching, and deodorization), as well as to post-refining measures (e.g. additional bleaching and deodorization and use of activated bleaching earth). Where possible, it may be best to remove precursors at the earlier stages of processing, to minimize the formation of 3-MCPDE and GE.
15. There are a wide range of methods to mitigate 3-MCPDE and GE, and the applicable methods used will vary depending on different conditions (including the oil source, the refining process, and the type of equipment in use). In addition, multiple methods may need to be combined to reduce 3-MCPDE and GE in oils. Manufacturers should select and apply those techniques that are appropriate to their own processes and products.
16. In concert with mitigation of 3-MCPDE and GE, it is important to also consider the overall impacts on the quality of refined oils and oil-based products, including product properties such as smell and taste, FFA profiles, stability attributes, levels of nutrients, and removal of contaminants such as pesticides and mycotoxins. In addition, environmental impacts of the recommended mitigation practices should be considered.
17. Although most work on mitigation of 3-MCPDE and GE in refined oils has focused on palm oil, some of the information and experience on mitigation of 3-MCPDE and GE in palm oil may be applicable to mitigation of 3-MCPDE and GE in other refined oils. Therefore, where data are available, this document specifies when the mitigation approach is specific to palm oil, and when it may be more widely applicable to other refined oils, including fish oils.

SCOPE

18. This Code of Practice intends to provide national and local authorities, producers, manufacturers, and other relevant bodies with guidance to prevent and reduce formation of 3-MCPDE and GE in refined oils and food products made with refined oils. This guidance covers three strategies (where information is available) for reducing 3-MCPDE and GE formation:
 - (i) Good agricultural practices,
 - (ii) Good manufacturing practices, and
 - (iii) Selection and uses of refined oils in food products made from these oils.

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

19. Producing edible vegetable oils involves several major steps: cultivating, harvesting, transporting, and storing the fruits and seeds for further processing; palm oil milling where fruit is sterilized and crude oil is extracted; oilseed crushing where oilseeds are cleaned, ground, and steamed and crude oil is extracted; and refining of the crude oils.
20. Producing edible fish oils involves several major steps: harvesting the fish, steam cooking, de-watering/wet reduction (which involves pressing the liquor, separating the oil and water, and optionally, water washing the oil), and refining of the crude oils.
21. Refining edible oils consists of two main types; chemical or physical refining. Chemical refining consists of degumming (removal of phospholipids); neutralization (addition of hydroxide solution to remove FFAs through formation of soaps); bleaching (using clays) to reduce colors and remove remaining soaps and gums, trace metals, and degradation products; and deodorization (i.e. a steam-distillation process carried out at low pressures, 1.5-6.0 mbar, and elevated temperatures, 180 - 270°C) to remove FFA, colors, and volatile compounds, including certain contaminants. Physical refining involves degumming, bleaching, and deodorization (which occurs at higher temperatures than chemical refining), as it does not have a neutralization step. While several factors influence the selection of physical refining, it is typically conducted on oils containing low levels of phospholipids.

AGRICULTURAL PRACTICES FOR VEGETABLE OILS

22. When planting new trees, farmers should consider selecting oil palm plant varieties with low lipase activity in oil fruits, if available, as low lipase activity is one factor that can reduce formation of FFAs and acylglycerol precursors.
23. During cultivation of oil plants or trees, farmers should minimize use of substances such as fertilizers, pesticides, and water that have excessive amounts of chlorine-containing compounds, in order to reduce chlorine uptake by the fruits and seeds. Non-chlorinated sulfate fertilizers could serve as an alternative to chlorine-containing fertilizers.

24. Farmers should harvest oil palm fruits when they are at optimal ripeness, minimize handling of the fruits to reduce bruising and prevent formation of FFAs, and avoid using damaged or overripe fruits, which may be associated with higher 3-MCPDE and GE formation.
25. Farmers should transport oil palm fruits to oil mills as soon as possible.

OIL MILLING AND REFINING

Crude Oil Production and Treatment

26. Processors should consider storing oil seeds for milling at cool temperatures (e.g. < 25°C) and dry conditions (optimally <7% moisture content) to help ensure low levels of lipase.
27. Following receipt of oil palm fruits at the mill, processors should sterilize the fruits immediately (preferably within less than 2 days of harvesting) at temperatures at or below 140°C to inactivate lipases (with temperatures varying depending on the sterilization method). (Fruits may be washed prior to sterilization to remove chlorine precursors.) For oilseeds, processors should clean, grind, and heat to inactivate lipases.
28. Processors should consider washing crude vegetable oil with chlorine-free water to remove chlorine-containing compounds.
29. Processors should avoid using residual vegetable oil recovered from solvents or additional extractions, as this oil tends to have higher levels of precursors (e.g. DAGs, chlorine-containing compounds).
30. Processors should assess precursors in batches of crude vegetable oils or fish oils (e.g. DAGs, FFAs, chlorine-containing compounds) to adjust refining parameters and target appropriate mitigation strategies depending on the type of vegetable oil or fish oil being processed and processing conditions.
31. Preferentially refining crude vegetable oil or fish oil with low concentrations of precursors can produce finished oils with lower levels of 3-MCPDE and GE.

Degumming

32. Processors should use milder and less acidic conditions (e.g. either degumming with a low concentration of phosphoric, citric, or other acids or water degumming) to decrease 3-MCPDE in vegetable oils or fish oils. The concentration of acid needed depends on the quality of the crude vegetable oil or fish oil. Care should be taken to remove sufficient concentrations of phospholipids and acid to ensure quality.
33. Lowering the degumming temperature may help to reduce formation of 3-MCPDE precursors in vegetable oils; however, the degumming temperature will depend on numerous factors including the type of vegetable oil.

Neutralization

34. Using chemical refining (i.e., neutralization) as an alternative to physical refining can help remove precursors (e.g. chloride) and reduce FFAs, which may allow for lower deodorization temperatures in vegetable oils or fish oils. However, chemical refining can lead to excessive oil loss (especially for palm oil due to higher FFA levels) and may have a greater environmental impact than physical refining.

Bleaching

35. Use of greater amounts of bleaching clay may reduce formation of 3-MCPDE and GE in all vegetable oils and fish oils. However, bleaching clays that contain significant amounts of chlorine-containing compounds should be avoided.
36. Use of more pH-neutral clays reduces the acidity and potential to form 3-MCPDE in palm oil, some seed oils, and fish oil.

Deodorization

37. Processors should consider conducting deodorization of vegetable oils and fish oils at reduced temperatures to decrease formation of GE. For example, it has been suggested to conduct deodorization at 190-230°C for vegetable oils and less than 190°C for fish oils. The temperature will vary depending on the residence time of oil. Processors can determine the optimal conditions for their processes.
38. As an alternative to traditional deodorization, processors can conduct dual deodorization of vegetable oils and fish oils (2-stage deodorization) to reduce thermal load in oil and to decrease formation of GE, with a smaller reduction in 3-MCPDE. This includes both a shorter deodorization period at a higher temperature and a longer deodorization period at a lower temperature. Consideration needs to be given to parameters such as temperature, vacuum pressure, and time, and variations in equipment design and capability. Also, additional post processing may be required to reduce levels of GE.

39. Use of a stronger vacuum facilitates evaporation of volatile compounds due to the increased steam volume and rate of stripping, contributing to decreased deodorization temperatures and reduced formation of GE, and to a lesser extent 3-MCPDE, in vegetable and fish oils.
40. Short-path distillation² (in place of deodorization) has been shown to reduce the thermal load and formation of esters in fish oil, contributing to lower amounts of 3-MCPDE and GE in comparison to conventional deodorization. However, additional post processing using mild deodorization is needed to address sensory considerations.

TREATMENT POST REFINING

41. The following recommended practices can be used for reducing levels of 3-MCPDE and GE in refined oils. These practices may be most appropriate for oils with 3-MCPDE and GE levels that are higher than desired for their intended use.
42. Additional bleaching and deodorization following initial bleaching and deodorization has been shown to achieve lower levels of GE in refined palm oil. (The second deodorization should occur at a lower temperature than the first deodorization.)
43. Application of activated bleaching earth during post refining has been shown to reduce GE in refined vegetable oils.
44. Use of short-path distillation (pressure: <1 mbar and temperature: 120 to 270°C) on bleached and deodorized vegetable oil can reduce acylglycerol components and levels of 3-MCPDE and GE.
45. Treatment of refined MCT (medium-chain triacylglycerols) oil with fatty acids and a cation counterion, such as an alkali metal, as well as one or more bases converts 3-MCPDE to MAGs, DAGs and TAGs, and GEs to DAGs.

SELECTION AND USES OF REFINED OILS IN FOOD PRODUCTS MADE FROM THESE OILS

Oil selection

46. Selecting refined vegetable oils and fish oils with low levels of 3-MCPDE and GE (e.g. either through natural occurrence or through application of mitigation measures) results in lower levels of 3-MCPDE and GE in finished products containing these oils. For example, variation in levels of 3-MCPDE and GE in infant formula has been observed, which may be due to the use of oils with different levels of 3-MCPDE and GE; therefore, selection of oils low in 3-MCPDE and GE can result in infant formulas with lower 3-MCPDE and GE levels. However, manufacturers also may have to consider quality or compositional factors. For example, for infant formula, refined oils are selected by manufacturers to ensure these products meet compositional criteria, e.g. national criteria or those established in the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CXS 72-1981).

Processing modifications

47. Reducing the amount of refined vegetable oils and fish oils used in finished products may be an alternative to reduce the levels of 3-MCPDE and GE in the finished product. However, this could impact the organoleptic or nutritional qualities of the finished products.
48. Use of refined vegetable oils themselves during frying does not contribute to formation of additional 3-MCPDE and GE, but rather the formation of additional 3-MCPDE during frying may result from the type of food that is fried (e.g., meat and fish products).

² Short-path distillation enables gentle removal of volatile compounds at relatively low temperatures. This is accomplished through reduced pressure, where the boiling point of the compound to be separated is lowered and there is increased efficiency due to the short distance between the evaporator and the condenser surface.

POTENTIAL MITIGATION MEASURES FOR REDUCING 3-MCPDEs AND GEs

The mitigation measures are not listed in order of priority.
 It is recommended that reduction measures be tested to identify the most successful for your own product.

Production Stage	Mitigation measures
AGRICULTURAL PRACTICES FOR VEGETABLE OILS	<ul style="list-style-type: none"> • Select oil palm plant varieties with low lipase activity, if available. • Minimize use of substances such as fertilizers, pesticides, and irrigation water that contain excessive amounts of chlorine-containing compounds during oil plant/tree cultivation. • Harvest oil palm fruits when they are at optimal ripeness. Minimize handling of the fruit. Avoid using damaged or overripe fruit. • Transport oil palm fruits to oil mills as soon as possible.
OIL MILLING AND REFINING	<div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;"> <p>Crude Oil Production and Treatment</p> <ul style="list-style-type: none"> • Store oil seeds at cool temperatures and dry conditions. • Sterilize oil palm fruit at temperatures at or below 140°C. Clean, dry, and heat oilseeds to inactivate lipases. • Wash crude vegetable oil with chlorine-free water. • Avoid using residual vegetable oil recovered from solvents or extractions. • Assess precursors (e.g. DAGs, FFAs, and chlorine compounds) in batches of crude vegetable oil or fish oil to adjust refining parameters. • Preferentially refine crude vegetable oil or fish oil with low concentrations of precursors. </div> <div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;"> <p>Degumming</p> <ul style="list-style-type: none"> • Use milder and less acidic conditions (e.g. either degumming with a low concentration of acid or water degumming) in vegetable oils or fish oils. • Lower the degumming temperature in vegetable oils. </div> <div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;"> <p>Neutralization</p> <ul style="list-style-type: none"> • Use chemical refining (i.e. neutralization) as an alternative to physical refining in vegetable oils or fish oils. </div> <div style="border: 1px solid black; padding: 5px;"> <p>Bleaching</p> <ul style="list-style-type: none"> • Use greater amounts of bleaching clay in vegetable oils and fish oils. • Use more pH-neutral clays to reduce acidity in palm oils, some seed oils, and fish oils. </div>

POTENTIAL MITIGATION MEASURES FOR REDUCING 3-MCPDE AND GE

The mitigation measures are not listed in order of priority.

It is recommended that reduction measures be tested to identify the most successful for your own product.

Production Stage	Mitigation measures
OIL MILLING AND REFINING	<p>Deodorization</p> <ul style="list-style-type: none"> • Conduct deodorization of vegetable oils or fish oils at reduced temperatures. The temperatures will vary depending on residence time of oil. • Conduct dual deodorization of vegetable oils and fish oils (2-stage deodorization) as an alternative to traditional deodorization. • Use a stronger vacuum to facilitate evaporation of volatile compounds and to contribute to decreased deodorization temperatures in vegetable oils and fish oils. • Use short-path distillation (in place of deodorization) to reduce the thermal load in fish oil.
TREATMENT POST REFINING	<ul style="list-style-type: none"> • Conduct additional bleaching and deodorization following initial bleaching and deodorization of refined palm oil. • Apply activated bleaching clay to refined vegetable oils. • Use short-path distillation on bleached and deodorized vegetable oils. • Treat refined MCT (medium-chain triglyceride) oil with fatty acids and a cation counterion, such as an alkali metal, as well as one or more bases to convert 3-MCPDE to MAGs, DAGs and TAGs and GE to DAGs.
SELECTION AND USES OF REFINED OILS	<p>OIL SELECTION</p> <ul style="list-style-type: none"> • Select refined vegetable oils or fish oils with lower levels of 3-MCPDE and GE. <p>PROCESS MODIFICATIONS</p> <ul style="list-style-type: none"> • Reduce the amount of refined vegetable oils or fish oils in finished products.

APPENDIX V**DRAFT GUIDELINES FOR RAPID RISK ANALYSIS FOLLOWING INSTANCES OF DETECTION OF CONTAMINANTS IN FOOD WHERE THERE IS NO REGULATORY LEVEL (AT STEP 8)****1. INTRODUCTION**

The detection of chemical contaminants in foods where there is no regulatory level is increasing due to both the diversity of the food supply and the continuing advancement of analytical capabilities. Risk managers must respond to such detections in a manner that is adequately protective of public health but that at the same time also takes account of the practicalities of import admissibility processes.

Where detection of a chemical contaminant in food where there is no regulatory level necessitates a rapid risk management response, e.g. to consider import admissibility a pragmatic risk-based approach should be applied. This approach:

- Should accommodate situations where there is limited or no toxicological data available;
- Should be able to be applied within the competence of the importing country;
- Should be rapid, where rapid means that it is able to be applied within a restricted timeframe in scenarios where a full risk assessment is neither a practicable, nor feasible, option.

The draft guideline incorporate a rapid risk analysis approach using a cut-off value¹ and the Threshold of Toxicological Concern (TTC), to assess low levels of chemical exposures, and to identify if further data are required to assess human health risk.^{2,3}

2. PURPOSE

The guidelines provide an approach to assist governments in the rapid risk analysis of instances of detection of chemical contaminants in food where there is no regulatory level .

The guidelines should be read in conjunction with the following relevant texts: Working Principles for Risk Analysis for Food Safety for Application by Governments (CXG 62-2007);

- *The Agreement on the Application of Sanitary and Phytosanitary Measures of the World Trade Organization* (WTO/SPS Agreement);
- *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* (Codex Alimentarius Commission Procedural Manual.);
- *Principles and Guidelines for National Food Control Systems* (CXG 82-2013);
- *Principles for Food Import and Export Inspection and Certification* (CXG 20-1995);
- *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification* (CXG 26-1997);
- *Guidelines for Food Import Control Systems* (CXG 47-2003);
- *Guidelines for the Exchange of Information between Countries on Rejections of Imported Foods* (CXG 25-1997);
- *Principles and Guidelines for the Exchange of Information in Food Safety Emergency Situations* (CXG 19-1995);
- *Guidelines for Settling Disputes over Analytical (Test) Results* (CXG 70-2009);
- *Principles and Guidelines for the Exchange of Information between Importing and Exporting Countries to support the Trade in Food* (CXG 89-2016);
- *Principles for Traceability / Product Tracing as a Tool Within a Food Inspection and Certification System* (CXG 60-2006);
- *Guidelines on the Application of Risk Assessment to Feed* (CXG 80-2013);
- *Guidance for Governments on Prioritizing Hazards in Feed* (CXG 81-2013);
- *General Guidelines on Sampling* (CXG 50-2004)

¹ The cut-off value is a guideline indicating whether or not a specific risk management action might be taken on the basis of the concentration of the contaminant in the consignment tested. For values above the cut-off, application of these guidelines would result in the risk manager deciding to progress with a rapid risk analysis

² Principles and methods for the risk assessment of chemicals in food. Environmental Health Criteria 240. Chapter 9.

³ These guidelines do not preclude other methods which may be considered in the future

3. SCOPE

Contaminants subject to these guidelines are:

- Those detected in food where there is no regulatory level; and,
- Those meeting the definitions within the *General Standard for Contaminants and Toxins in Food and Feed* (CXS 193-1995) for which there are no specific Codex, regional or national standards, recommendations or guidelines; and,
- Those where the detections have not been previously reported in the food and are unexpected (i.e. not a recurring or an intermittent occurrence); and,
- Those found within a specific lot or consignment of food or food ingredient,

Contaminants detected in situations where the risk manager is investigating the possibility of intentional adulteration of food are excluded.

Examples of (groups of) contaminants included in the scope of these guidelines

- Contaminants that may occur in materials used or created during processing of food and that may be inadvertently present in the food (e.g. printing inks, oils/lubricants/resins used as manufacturing maintenance compounds, cleaning compounds, traces of chemicals used in the manufacturing facility);
- Chemicals used to mitigate specific environmental, sustainability and climate change issues, (e.g. nitrification and urease inhibitors), which have not been anticipated to be present in food;

4. PRINCIPLES

The following principles apply:

- These guidelines apply to food for human consumption that is currently in trade;
- Contaminant detection information used in this scheme should satisfy the requirements of the relevant official food control programs for sampling and analysis;
- Where there is an instance of the detection of a contaminant in a traded consignment of food where there is no regulatory level the competent authority in the exporting country can be notified and any relevant food safety information shared;
- The risk assessment and risk management decisions, including data and information used to support the decision, should be documented in a transparent and systematic manner and made available upon request;
- Where there are continuing or frequent detections of a contaminant in food where there is no regulatory level, targeted surveillance activities should be undertaken to determine the extent of potential human exposure and the source(s) of contamination.

5. ROLES

The provisions in this section are without prejudice to existing national or regional provisions already in place.

In many cases the risk manager will be the competent authority performing the official control/surveillance programs or import controls, including sampling, and who subsequently will receive the results from the accredited or equivalent level laboratory. Decisions on the safety or otherwise of the food consignment in question will be made under national food safety legislation.

When carrying out the risk assessment, the competent authority should ensure that relevant stakeholders are notified of the detection of the contaminant in food where there is no regulatory level as soon as possible and that a risk assessment is carried out in a timely manner. This is particularly important in the case of food in international trade.

Stakeholders other than the competent authority may also carry out non-regulatory monitoring programs for a range of reasons e.g. satisfying provisions of supplier contracts. If the detection of the contaminant in food is reported by other stakeholders, the competent authority can consider such results in a preliminary assessment but should ensure that the reported results are confirmed in an accredited or equivalent level laboratory before doing a final assessment.

6. REPORTING OF DETECTION(S)

The laboratory, with accreditation or equivalent level recognition for food contaminant analysis, should report all detections and measured contaminant levels from official / officially recognized food monitoring and surveillance programs as prescribed by risk managers, including those contaminants for which no regulatory level is established. As such, the presence of the contaminant should have been confirmed by the accredited or equivalent level laboratory and the samples should have been subject to quality assurance provisions as required by an official regulatory program. Sample source for reported detections should be unambiguous.

Information provided by the analytical laboratory to the risk manager should include:

- Type of sampling program e.g. cross-sectional, longitudinal, random surveillance, targeted surveillance and sampling procedures;
- Sample preparation protocol;
- Test method, its analytical performance, mode of quantification and standards used for quantification and whether it is a confirmatory method that provides identifying information regarding the chemical structure of the analyte;
- Total number of samples tested, type of samples and number of detections, type of samples and;
- If available, summary statistics of occurrence data;
- Identification of chemical class / chemical type of the analyte;
- If available, assessment of the homogeneity of distribution for the contaminant in the lot.

7. APPLICATION OF THE DECISION TREE FOR RAPID RISK ANALYSIS

On confirmation of an instance of the detection of a contaminant in food where there is no regulatory level the risk manager should, in a timely manner, apply the rapid risk analysis approach in the accompanying decision tree (see Annex). The rapid risk analysis approach allows for prioritization of only those instances where further in-depth investigations are warranted.

7.1. Contaminants with established HBGVs, PODs or BMDLs (Step 1 of the Decision Tree for Rapid Risk Analysis)

Contaminants for which there are established health-based guidance values (HBGVs), toxicological points of departure (POD) or benchmark dose levels (BMDLs) can progress directly to rapid exposure assessment (Step 9)⁴ as these values enable risk characterization.

7.2. Exclusionary contaminant categories (Step 2 of the Decision Tree for Rapid Risk Analysis)

As identified in the TTC approach certain contaminant categories may not be suitable for rapid risk assessment given their chemical or toxicological properties. Unless there is prior experience with rapid risk analysis of these groupings, a risk manager, seeking expert advice where required, should not apply the decision tree to the following categories of contaminants:

- High potency carcinogens (i.e. aflatoxin-like, azoxy- or N-nitroso-compounds, benzidines),
- Chemicals of unknown or unique structure,
- Inorganic chemicals,
- Metals and organometallics,
- Proteins,
- Steroids,
- Nanomaterials,
- Radioactive substances
- Organo-silicon compounds, and
- Chemicals that are known or predicted to be persistent and bioaccumulate.

In cases when contaminants falling into the exclusionary categories are detected, risk managers need to follow existing regulatory frameworks, standards, recommendations and guidance where these are available.

⁴ Taking note of the appropriate assessment factors

7.3. Application of the cut-off-value (Step 3 of the Decision Tree for Rapid Risk Analysis)

If quantitative measurement of the contaminant in food where there is no regulatory level exceeds the cut-off value of 1 µg/kg, the risk manager should inform relevant stakeholders of such measurements and request that all available information be shared for rapid risk assessment as soon as possible.

A premise for the application of the cut-off value is that within a population the consignment will form only a tenth of the standard adult daily diet, based on access to a varied diet that may contain the same food from other sources and a range of other food groups. For certain sub-populations where a consignment could represent more than a tenth of the daily diet intake, for example with foods for infants or sole source nutrition products, the cut-off values may not be appropriate. Such instances should be considered on a case-by-case basis and progressed for full risk assessment when there is uncertainty over the proportion of the diet for which a food consignment may represent for these sub-populations.

Where measured levels do not exceed the cut-off value of 1 µg/kg a risk management decision can be made that the consignment does not require a specific risk management response. The cut-off value does not necessitate the analytical laboratory achieving a limit of detection of 1 µg/kg.

7.4. Information sharing from the competent authorities of exporting country (Step 4 of the Decision Tree for Rapid Risk Analysis)

Beyond notifying relevant stakeholders about the instance of detection of the contaminant in food where there is no regulatory level, the risk manager should request any relevant food safety information, if available, from the competent authorities of the exporting country. Relevant food safety information may include, but is not limited to, toxicological datasets, prior occurrence in food, food processing information and any history of use.

7.5. Request for rapid risk assessment (Step 5 of the Decision Tree for Rapid Risk Analysis)

The risk manager should seek completion of a rapid risk assessment of the detected contaminant in food where there is no regulatory level, as soon as practicable. The risk manager should provide any toxicological and occurrence data obtained from the exporting country to the risk assessor.

7.6. Toxicological data collection (Step 6 of the Decision Tree for Rapid Risk Analysis)

The risk assessor should access any additional toxicological data on the contaminant or chemically/structurally related compounds that could further inform the choice of the rapid risk assessment approach (i.e. TTC vs HBGV/POD/BMDL approach).

7.7. Selection of the TTC value / Establishment of a HBGV/POD/BMDL, exposure assessment and risk characterisation (Steps 7-10 of the Decision Tree for Rapid Risk Analysis)

If sufficient toxicological data are available for the contaminant in food where there is no regulatory level, it should be determined if establishment of an ad-hoc HBGV/POD/BMDL is feasible in the agreed timeframe⁵. If a HBGV/POD/BMDL can be established the risk characterization should be undertaken using this value.

In the absence of sufficient toxicological data to establish a HBGV/POD/BMDL for the contaminant in food where there is no regulatory level, dietary intake against an appropriate threshold of no concern or reference value for any outcome whether genotoxic or non-genotoxic, should be selected for the contaminant based on its structural properties (Step 7).⁶

With the available dataset the risk assessor should undertake an exposure assessment⁷ of the contaminant in the food of interest, possibly considering exposure from other foods if data are available, and characterize the risk in relation to the TTC or HBGV/POD/BMDL selected through the Decision Tree for Rapid Risk Analysis (Steps 9 and 10). Any assumptions and uncertainties in the rapid risk assessment should be recorded.

⁵ HBGVs are the quantitative expression of an oral exposure (either acute or chronic) in the form of a dose that would be expected to be without appreciable health risk. (Principles and methods for the risk assessment of chemicals in food (EHC 240, 2009))

⁶ Evaluation of certain food additives. 82nd report of the Joint FAO/WHO Expert Committee on Food Additives. <https://apps.who.int/iris/handle/10665/250277>

⁷ Principles and methods for the risk assessment of chemicals in food (EHC 240, 2009). In the absence of domestic consumption data for the food of interest an exposure assessment could refer to alternative data sources such as the relevant, or alternatively highest overall, consumption value in the WHO Global Environment Monitoring System (GEMS) food cluster diets. A further approach could be to assess whether the intakes of the food of interest for the exposure to match the selected TTC value are sufficiently exaggerated over normal patterns (e.g. > 1 kg/day) to make such an exposure scenario unrealistic.

7.8. Reporting (Steps 11 and 12 of the Decision Tree for Rapid Risk Analysis)

The risk assessor should provide the results, including information on assumption and uncertainties to the risk manager in a clear, consistent and standardized manner, within an agreed upon time frame.⁸

7.9. Decision by the risk manager

The risk manager should take into account the results of the rapid risk assessment provided by the risk assessor and decide whether a risk management response is warranted. This includes for example:

- Judging the food consignment / lot as fit for human consumption on the basis of negligible risk to human health,
- Judging the food consignment / lot as unfit for human consumption on the basis of a potential risk to human health,
- Placing the food consignment on hold while seeking further information on the possible levels of the contaminant in other lots and consignments to better understand the potential public health concern and whether a full risk assessment may be required.

The risk manager should communicate the risk management option taken and any decision on safety or otherwise of the consignment / lot as soon as practicable. *The Principles and Guidelines for the Exchange of Information between Importing and Exporting Countries to Support the Trade in Food* (CXG 89-2016) provide guidance on exchange of food safety information between competent authorities.

Ultimately, when dietary exposure in comparison with a HBGV or other hazard characterization value would pose a public health concern and possible risk management measures that would result in reductions to the dietary exposure are identified then steps should be taken to implement appropriate risk management measures.

8. FURTHER RISK MANAGEMENT ACTIVITIES

One risk management option may be targeted surveillance to gain more information on recurrence of instances of detection of the contaminant in food and to more closely evaluate the level of dietary exposure over time.

Where the detection of the contaminant in food where there is no regulatory level occurs on one or more occasions but its presence is below a level of toxicological concern, subsequent surveillance or undertaking toxicological studies is unlikely to be required.

Where the detection of the contaminant in food where there is no regulatory level becomes a repeated occurrence in food, and new information may become available on the toxicity of the contaminant, or when there are indications that dietary exposure may be at a level that constitutes a potential risk to human health, then consideration should be given to undertaking toxicological studies and/or initiating a full risk assessment.

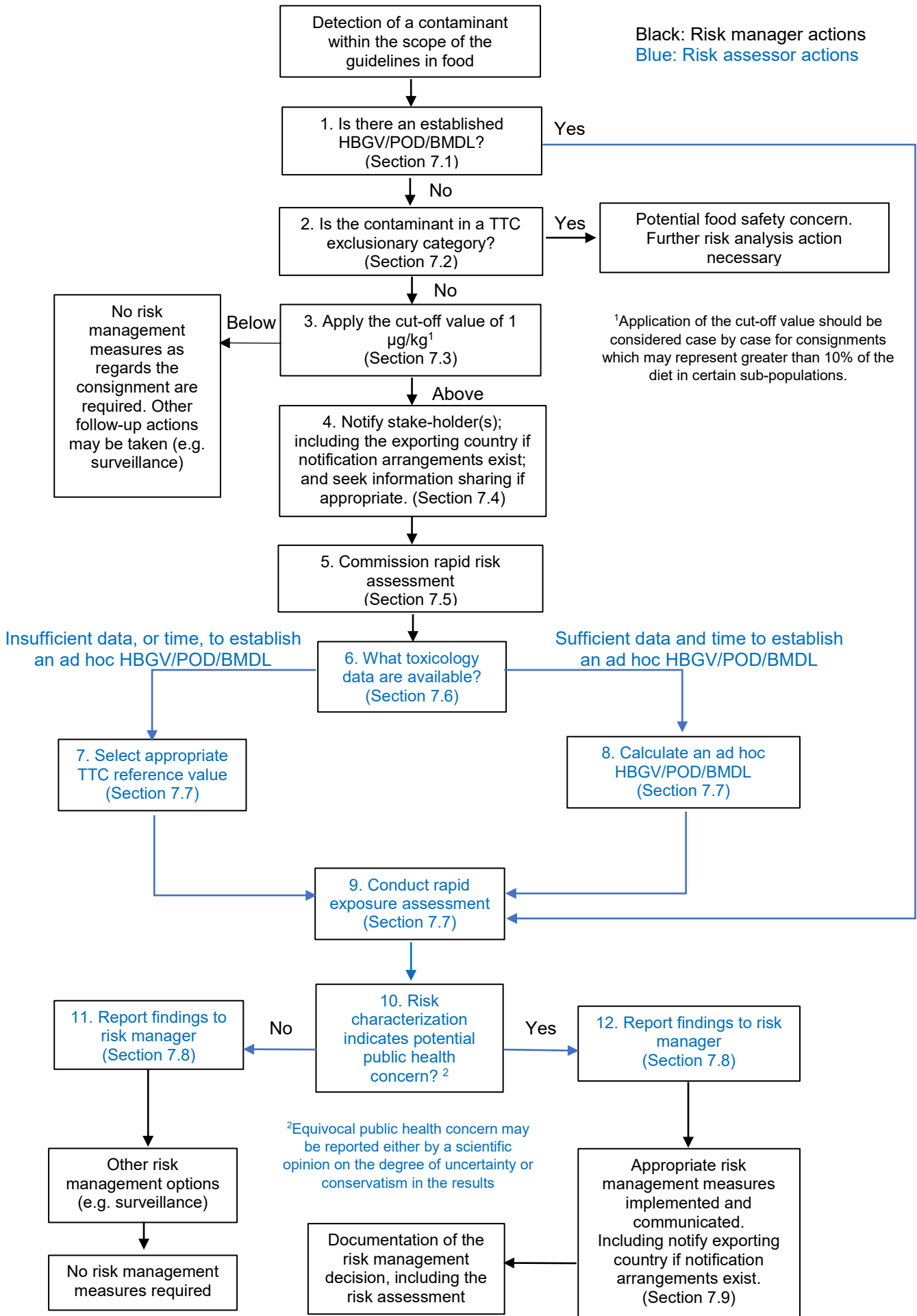
Gathering and sharing data through the WHO Global Environmental Monitoring System Food Consumption Database (GEMS/Food) would support any international consideration for development of standards.

9. RISK COMMUNICATION

Consumers and other stakeholders have a high level of interest in information on the presence of contaminants in food and the outcomes of the risk assessment and risk management activities of competent authorities. Thus, appropriate risk communication is recommended when risk management measures are implemented for contaminants in food where there are no regulatory levels.

⁸ The risk assessor should provide a scientific opinion on any assumptions and the degree of uncertainty in the results of the rapid risk assessment.

Annex - Decision Tree for Rapid Risk Analysis



APPENDIX VI**PROJECT DOCUMENT FOR NEW WORK
ESTABLISHMENT OF MAXIMUM LEVELS FOR LEAD IN CERTAIN FOOD CATEGORIES****1. Purpose and scope**

The purpose of this work is to protect public health by harmonizing the level of lead in food categories not included in the *General Standard for Contaminants and Toxins in Food and Feed* (CXS 193-1995) (GSCTFF) and ensure fair practices in international food trade.

2. Its relevance and timeliness

Lead was evaluated by the JECFA at its 16th, 22nd, 30th, 41st, 53rd and 73rd meetings. At the JECFA73 meeting a new toxicological evaluation of lead in food was conducted, at the request of Codex Committee on Contaminants in Food (CCCF). In the evaluation¹ JECFA73 stated that exposure to lead is associated with a wide range of effects, including various neurodevelopmental effects, impaired renal function, hypertension, impaired fertility and adverse pregnancy outcomes. Because of the neurodevelopmental effects, fetuses, infants and children are the subgroups that are most sensitive to lead. JECFA withdrew the previously established provisional tolerable weekly intake (PTWI) of 25 µg/kg bw and concluded that since there is no indication for a threshold of effect it was not able to establish a new tolerable intake level. JECFA also 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 of reducing dietary exposure that are commensurate with the level of risk reduction.

Food is the major source of exposure to lead. The GSCTFF does not have MLs for lead established for several food categories that impact more in the dietary exposure than several current ML for categories such as mango chutney, pickled cucumbers, etc. Nevertheless, some food categories are broadly consumed and/or may contain high levels of lead and can significantly contribute to the intake of lead.

In this context, a new work for MLs for lead in different food categories which are not covered by the GSCTFF should be developed aiming lower lead exposure.

3. The main aspects to be covered

New MLs for lead in the following food categories:

- Food for infants and young children
(except those for which an ML has already been established in the GSCTFF)
- Spices and aromatic herbs
- Eggs
- Sugars and confectionary, excluding cocoa

As the food categories above are broad, an analysis of further available data will assist in determining the sub-categories for which the MLs should be established.

An assessment against the criteria for the establishment of work priorities

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

The new work will establish Maximum Level(s) for lead in several categories.

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

The new work will provide harmonized international maximum levels.

- c) *Work already undertaken by other organizations in this field*

The risk assessment has already been done for lead by JECFA.

4. Relevance to the Codex Strategic Objectives

The work proposed falls under the following Codex Strategic Goals of the Codex Strategic Plan 2014-2019:

¹ JECFA. Evaluation of Certain Food Additives and Contaminants. Seventy-third report of the joint FAO/WHO Expert Committee on Food Additives. WHO Technical Report Series 960.

Strategic goal 1 Establish international food standards that address current and emerging food issues

This work was proposed in response to needs identified by JECFA to decrease lead dietary exposure.

Strategic goal 2 Ensure the application of risk analysis principles in the development of Codex standards

The establishment of MLs shall take into account the exposure assessment proposed by JECFA.

5. Information on the relation between the proposal and other existing Codex documents

This work follows-up on the ongoing work on the revision of existing MLs for lead in the GSCTFF.

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

Expert scientific advice has been already provided by JECFA.

7. Identification of any need for technical input to the standard from external bodies so that this can be planned for the proposed timeline for completion of the new work

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

8. Proposed timeline for completion of work

Subject to the approval by the 42nd Session of the Codex Alimentarius Commission in 2019 and depending on the availability of further occurrence data, MLs for the food categories (or their possible sub-categories) identified in section 3 will be finalized by 2021 or earlier.

APPENDIX VII

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

1. The purpose and scope of the project

The purpose of the proposed new work is to revise the *Code of Practice for the Prevention and Reduction of Lead Contamination in Foods* (CXC 56-2004) (COP) adopted in 2004 to reflect new information available on measures to reduce lead during agricultural production and food processing. A revised COP would complement ongoing work by CCCF on lead, including revision of maximum levels (MLs) for lead in selected commodities in the *General Standard for Contaminants and Toxins in Food and Feed* (GSCTFF) and a discussion paper on future work on MLs for lead for inclusion in the GSCTFF.

The scope of the work encompasses updating the existing lead COP to add new information on lead reduction in the areas of agricultural production (e.g., techniques to address lead contamination in soil and water) and food processing (e.g., filtration aids for juice manufacture, measures to reduce lead in foods during cooking, and minimizing introduction of lead from food processing equipment).

2. Relevance and timeliness

At its 73rd session (2010), JECFA conducted a new evaluation of lead. JECFA stated that exposure to lead is associated with a wide range of effects, including various neurodevelopmental effects, mortality (mainly due to cardiovascular diseases), impaired renal function, hypertension, impaired fertility, and adverse pregnancy outcomes. Fetuses, infants, and children are the most sensitive to lead exposures due to neurodevelopmental effects. JECFA withdrew the provisional tolerable weekly intake (PTWI) for lead and concluded that it was not possible to establish a new PTWI that would be health protective. 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 of reducing dietary exposure that are commensurate with the level of risk reduction.

Given the health concerns associated with lead exposures, the new work aims to continue to reduce exposures by updating the existing COP.

3. Main aspects to be covered

The work will address measures, supported by scientific data that have become available since adoption of the COP in 2004. Measures to be addressed may include remediation of agricultural soil contaminated with lead (e.g., soil amendments), removal of lead from water used for irrigation and washing, and food processing modifications (e.g. evaluation of filtration aids).

4. Assessment against the criteria for the establishment of work priorities**General criterion**

To protect consumers' health (particularly infants and young children), exposures to lead should be reduced through best practices. A revised COP compiling agricultural and food processing and preparation measures to reduce lead will identify additional measures that can be taken to reduce exposures. A revised COP will facilitate fair trade by making this updated information on recommended practices available to all member countries.

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

Development of a revised COP is needed to ensure that information on recommended practices for preventing and reducing lead exposures is available to all member countries. It will also provide the means to enable exporters to ensure reduced lead levels and to assist in compliance with any current MLs and those that may be established in the future.

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

The revised COP will provide measures to reduce lead in food, as it will address all aspects of food production from agricultural production to processing to packaging and distribution.

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

Codes of practice or toolboxes that address lead exposures have been developed for workplaces, for water sanitation (e.g., WHO) and for agriculture, and can be used in the revision of the COP.

5. Relevance to Codex Strategic Goals**Goal 1: Establish international food standards that address current and emerging food issues**

Updating the COP for the prevention and reduction of lead contamination in foods will address a current need to continue to reduce lead exposures, using updated measures.

Goal 2: Ensure the application of risk analysis principles in the development of Codex standards

This work will assist in applying risk analysis principles in the development of Codex standards by using scientific data and results from the JECFA assessment to support the continued reduction of lead in foods.

Goal 3: Facilitate the effective participation of all Codex members

The proposed draft revision to the COP will make additional information on recommended practices to prevent and reduce lead available to all member countries.

Goal 4: Implement effective and efficient work management systems and practices

A revised COP will help ensure development and implementation of effective and efficient work management systems and practices by agricultural producers, food processors, and consumers to produce foods with lower levels of lead.

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

In 2004, the Codex Alimentarius Commission adopted the Code of Practice for the Prevention and Reduction of Lead Contamination in Foods (CXC 56-2004). In addition, MLs for a variety of foods (e.g., fruit juices, canned fruits, canned vegetables, infant formula) have been updated over the past several years in the GSCTFF and completion of this work is anticipated in 2019. There is also a proposal for new work on the development of MLs for lead for additional foods for inclusion in the GSCTFF. This revised COP supports the ongoing ML work.

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

The JECFA Secretariat has already provided needed expert scientific advice (JECFA, 73rd report).

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

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

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

Work will commence following approval by CAC42 in 2019. Completion of work is expected by 2021 or earlier.

APPENDIX VIII**PROJECT DOCUMENT FOR NEW WORK****DEVELOPMENT OF A CODE OF PRACTICE FOR THE REDUCTION AND PREVENTION OF CADMIUM CONTAMINATION IN COCOA BEANS****1. The purpose and scope of the project**

The purpose of the new proposal is to develop a Code of Practice (COP) that will provide guidance to Member States and the cocoa production industry on the prevention and reduction of cadmium contamination in cocoa beans during production and post-harvest processing: fermentation, drying and storing.

The scope of the work intends to provide guidance on recommended measures to prevent and reduce cadmium contamination in cocoa: Before planting or in new plantations, during the production stage until harvest and in the post-harvest stage. This COP applies to the cocoa beans marketed internationally.

2. Relevance and timeliness

At its 77th Session (2013), the Joint FAO/WHO Expert Committee on Food Additives (JECFA) determined that the estimates of mean population dietary exposure to cadmium from products containing cocoa and its derivatives for the 17 GEMS/Food Cluster Diets ranged from 0.005 to 0.39 µg/kg bw (body weight) per month, which equated to 0.02 – 1.6% of the Provisional Tolerable Monthly Intake (PTMI) of 25 µg/kg bw. JECFA's conclusion that intake of cadmium from cocoa and cocoa derived products is not a health concern.

CCCF establishing MLs for cadmium in chocolate and cocoa derived products makes it necessary a COP that outlines measures to prevent and reduce cadmium in cocoa contamination to levels as low as reasonably achievable (ALARA) in order to mitigate cadmium exposures and support fair trade.

The COP will assist countries to comply the MLs for cadmium in chocolates established by CAC and in general will assist to reduce cadmium contamination in cocoa beans to facilitate international trade.

3. Main aspects to be covered

Code of practice for the prevention and reduction of cadmium contamination in cocoa beans taking into consideration the following:

- a) Production system (conventional, organic, mixed plantations with agroforestry).
- b) Cocoa crop factors that determine cadmium absorption by plants.
- c) Strategies to immobilize cadmium and decrease its availability in soil
- d) Phyto-extraction of heavy metals cadmium: Agronomic management of the cocoa crop, cocoa physiology, cadmium bioaccumulation in cocoa beans.
- e) Growing and plantation areas, soil amendments and its cost efficiency, especially for small cocoa farmers, pruning, optimal time of harvest.
- f) Cocoa genetics (germplasm, clones)
- g) Post-harvest technology (fermentation, drying, storing),

4. An assessment with regard to the criteria for setting priorities for work.**General criterion**

To protect consumers' health exposures to cadmium should be reduced through best practices. The COP will introduce agricultural and post-harvest practices to reduce cadmium and through this COP will facilitate fair trade by making this information on recommended practices available to all member countries.

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

This COP will provide a consistent source of guidance to cocoa producers and post-harvest processors in all of Member countries to prevent and reduce cadmium contamination in cocoa beans. It will thus provide assurance to exporters that levels of cadmium in cocoa and cocoa products meet the ALARA principle, and also Codex Maximum Levels (ML) of cadmium in chocolates and cocoa derived products that are under development.

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

The scope of work involves developing a COP that will provide technical guidance on the reduction of cadmium contamination in cocoa beans in agricultural and post-harvest production level. The development of this COP will help to reduce exposures to cadmium and support international trade of cocoa beans and their products.

c. Work already undertaken by other international organizations in this field and/or suggested by relevant international intergovernmental bodies

None.

5. Relevance to Codex Alimentarius Strategic Goals (Plan 2014 – 2019)**Goal 1: Establish international food standards that address current and emerging food issues****Objective**

1.2 Proactively identify emerging issues and Member needs and, where appropriate, develop relevant food standards.

1.2.2 Develop and revise international and regional standards as needed, in response to needs identified by Members and in response to factors that affect food safety, nutrition and fair practices in the food trade.

Goal 3: Facilitate the effective participation of all Codex Members**Objective**

3.1 Increase the effective participation of developing countries in Codex.

3.1.1 Encourage Members to develop sustainable national institutional arrangements to promote effective contribution to the Codex standard setting processes

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

GSCTFF (MLs for cadmium in chocolate products)

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

None.

8. Identification of any need for technical input to the standard from external bodies so that this can be planned for the proposed timeline for completion of the new work

There is no need for additional technical input from external bodies besides available risk mitigation practices from validated field researches from this and next year.

9. Proposed timeline for completion of work

Subject to the approval by the 42nd Session of the Codex Alimentarius Commission in 2019, the Code of practice for the prevention and reduction of cadmium contamination in cocoa beans will be considered at CCCF14 and CCCF15 with a view to its completion in 2021 or earlier.

PROJECT DOCUMENT FOR NEW WORK**ESTABLISHMENT OF MAXIMUM LEVELS FOR AFLATOXINS IN CERTAIN CEREALS AND CEREAL-BASED PRODUCTS, INCLUDING FOOD FOR INFANTS AND YOUNG CHILDREN****1. Purpose and scope**

The purpose of this work is to protect public health and to ensure fair practices in the international food trade by establishing MLs for aflatoxins in cereal and cereal-based products.

2. Its relevance and timeliness

Toxicological data and human dietary exposure to aflatoxins (AFs) were evaluated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) at its 49th and 83rd meetings. The findings showed that AFs are genotoxic human liver carcinogens, being among the most potent mutagenic and carcinogenic substances known so far. Hepatitis B virus was shown to be a critical contributor to the potency of aflatoxins in inducing liver cancer, AFs potency being 30 times higher in carriers of hepatitis B virus than in non-carrier of hepatitis B virus. No tolerable daily intake was proposed for AFs, as is typical for genotoxic carcinogens. At its last evaluation, JECFA83 also noted that rice, maize, wheat and sorghum needed to be considered in future risk management activities for aflatoxins, considering their great contribution to aflatoxin exposure in some parts of the world.

Cereal and cereal-based products are highly consumed worldwide and thus any level of AFs contamination in these products could significantly contribute to total AFs exposure. Currently, there is no maximum level (ML) for AFs in cereal and cereal-based products, thus, a new work on the establishment of MLs for the categories listed below, could greatly contribute to AFs dietary exposure reduction.

- Maize grain destined for further processing and flour, meal, semolina and flakes derived from maize
- Husked and Polished Rice
- Cereal-based Food for infants and young children
- Sorghum

3. The main aspects to be covered

MLs for aflatoxins in cereal and cereal-based products, considering the following:

- the Policy of the Codex Committee on Contaminants in Foods for exposure Assessment of Contaminants and Toxins in Foods or Food Groups (Procedural Manual Section IV); and
- the criteria for the establishment of maximum levels in food and feed established in Annex I of General Standard for Contaminants and Toxins in Food and Feed (CXS 193-1995) (GSCTFF).

4. An assessment against the criteria for the establishment of work priorities

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

The new work will establish MLs for AFs in cereal and cereal-based products.

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

The new work will provide harmonized international maximum levels.

- c) *Work already undertaken by other organizations in this field*

The risk assessment has already been done for AFs by JECFA83.

5. Relevance to the Codex Strategic Objectives

The work proposed falls under the following Codex Strategic Goals of the Codex Strategic Plan 2014-2019:

Strategic goal 1 Establish international food standards that address current and emerging food issues

This work was proposed in accordance to the JECFA recommendation to reduce AFs dietary exposure.

Strategic goal 2 Ensure the application of risk analysis principles in the development of Codex standards

JECFA recommended that efforts continue to reduce aflatoxin exposure using valid intervention strategies, including the development of effective, sustainable and universally applicable pre-harvest prevention strategies. The establishment of MLs for AFs in cereal and cereal products will contribute to the protection of consumers' health.

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

This new work is recommended following the Procedural Manual and the GSCTFF.

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

Expert scientific advice has been already provided by JECFA.

8. Identification of any need for technical input to the standard from external bodies so that this can be planned for the proposed timeline for completion of the new work

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

9. Proposed timeline for completion of work

Subject to the approval by the 42nd Session of the Codex Alimentarius Commission in 2019, the MLs for AFs in cereal and cereal-based products including food for infants and young children will be finalized in 2022 or earlier.

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

Contaminants and Naturally Occurring Toxicants	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 Canada: occurrence data on foods of animal origin Brazil: occurrence data on milk, raw eggs, fish, and fat (poultry and mammals)	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)	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 <ul style="list-style-type: none"> • 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 <i>C. elegans</i> on inorganic arsenic (2018) and ongoing study on organic arsenic. • Non-governmental report, Effects of Inorganic Arsenic in Infant Rice Cereal on Children's Neurodevelopment (2017) Brazil: occurrence data on total arsenic in rice, poultry, pork, fish, and cattle meat, inorganic arsenic occurrence data in rice Japan and China: occurrence data on rice and rice products Australia/New Zealand: total diet study; inorganic arsenic occurrence data in rice India: occurrence data in rice Turkey: occurrence data in rice EU: inorganic arsenic occurrence data	USA
Scopoletin	Full evaluation (toxicological assessment and exposure assessment) in fermented noni juice	CCNASWP still working on standard for noni juice and data availability	CCNASWP

Contaminants and Naturally Occurring Toxicants	Background and Question(s) to be Answered	Data Availability (When, What)	Proposed By
Ergot alkaloids ¹	Full evaluation (toxicological assessment and exposure assessment)	EFSA (2012) report EU: occurrence data; assessment on exposures to ergot alkaloids (EFSA report published in May 2017) Canada: occurrence data (commodity specific and unprocessed cereal grains), and data on processing factors through production chain NZ: occurrence data on cereals (1 year of data) Japan: occurrence data in wheat, barley, and wheat products	EU; Canada
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).

¹Ergot is mentioned in quality chapter, suggestion for integration into GSCTFF.