

CODEX ALIMENTARIUS COMMISSION

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Food and Agriculture
Organization of the
United Nations



World Health
Organization

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REP18/CF

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

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**REPORT OF THE 12th SESSION OF THE
CODEX COMMITTEE ON CONTAMINANTS IN FOODS**

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SUMMARY AND STATUS OF WORK

Responsible Party	Purpose	Text/Topic	Code	Step	Para(s).
Members CCEXEC76 CAC41	Adoption Revocation Amendment	MLs for lead in selected commodities (revision of MLs / revocation of corresponding MLs / amendments to MLs)	CXS 193 - 1995	5/8	45
Members CCEXEC76 CAC41	Adoption	MLs for cadmium in chocolate containing or declaring $\geq 50\%$ to $< 70\%$ total cocoa solids on a dry matter basis; and chocolate containing or declaring $\geq 70\%$ total cocoa solids on a dry matter basis	-	5/8	67 (i) and (ii)
Members CCEXEC76 CAC41	Adoption / revocation	MLs for tuna, alfoncino, marlin and shark; and the GLs for methylmercury in predatory and non-predatory fish Amendment to the note for the ML on inorganic arsenic in rice (consequential amendment)	CXS 193 - 1995	5/8	91 (i) and (iii) 84
Members CCEXEC76 CAC41	Adoption	<i>COP for the prevention and reduction of dioxins, dioxin-like PCBs and non dioxin-like PCB contamination in food and feed</i>	CXC 62 - 2006	5/8	98
Members CCEXEC73 CAC40 EWG (USA, EU, Malaysia) CCCF13	Adoption / further drafting / comments	COP for the reduction of 3-MCPDE and GE in refined oils and products made with refined oils	-	5	102 (ii) and (iii)
Members CCEXEC76 CAC41 EWG/PWG (New Zealand and the Netherlands) CCCF13	Adoption / further drafting / comments	Guidelines for risk analysis of instances of contaminants in food where there is no regulatory level or risk management framework established	-	5	124 (i) - (iii)
CAC41	Discontinue	Establishment of MLs for cadmium in dry mixtures of cocoa and sugars sold for final consumption; and ML for methylmercury in amberjack and sword fish	-	-	67(iv) and 91(ii)
CCEXEC76 CAC41	Retain	MLs for total aflatoxins in ready-to-eat peanuts (establishment of MLs); and MLs for total aflatoxins and ochratoxin A in nutmeg, chili and paprika, ginger, pepper and turmeric	CXS 193 - 1995	4	115 (i); and 119 (i)
Members EWG (USA) CCCF13	Review / Revision Comments	MLs for lead in wine and edible offals	CXS 193 - 1995	2/3	46

SUMMARY AND STATUS OF WORK

Responsible Party	Purpose	Text/Topic	Code	Step	Para(s).
Members EWG (Ecuador Brazil, and Ghana) CCCCF13	Review / Revision Comments	MLs for cadmium in chocolate and cocoa-derived products (category of chocolate and chocolate products containing or declaring (1) < 30% and (2) ≥ 30% to < 50% total cocoa solids on a dry matter basis)	-	2/3	67 (iii) and (v)
Codex and JECFA Secretariats	Discussion	Lead and cadmium in quinoa	-	-	14
EWG (New Zealand and Canada) CCCCF13	Discussion	MLs for methyl mercury in additional fish species	CXS 193 - 1995		93
CCCCF13	Discussion	Establishment of ML for HCN in cassava and cassava-based products and occurrence of mycotoxins in these products	-	-	125
EWG (Brazil) CCCCF13	Discussion	Structured approach to prioritize commodities for which new MLs for lead could be established for inclusion in the GSCTFF	-	-	131 (i)
EWG (Brazil and India) CCCCF13	Discussion	Aflatoxins in cereals (establishment of MLs for total aflatoxins in wheat, maize, sorghum and rice (specifying the categories)	-	-	138
EWG (Peru, Ghana and Ecuador) CCCCF13	Discussion	Development of a Code of practice for the prevention and reduction of cadmium contamination in cocoa	-	-	144
Codex Secretariat/ Host Secretariat / JECFA Secretariat CCCCF13	Discussion	Forward workplan for CCCF	-	-	154
EWG (EU, USA, The Netherlands, Japan)	Discussion	General guidance on data analysis for ML development	-		158
EWG (USA, UK) CCCCF13	Discussion	Revision of the <i>Code of Practice for the Prevention and Reduction of Lead Contamination in Foods</i> (CXC 56-2004)	-		160
CCMAS	Endorsement /Information	Sampling plan for MLs for methylmercury in fish; and Need for internationally validated method of analysis for STC	CXS 193 - 1995	5/8 -	91 (iv); and 139
JECFA	Call for data	Occurrence: of total aflatoxins in RTE peanuts; total aflatoxins and OTA in spices (nutmeg, chili and paprika, ginger, pepper and turmeric); Lead in specific food categories		-	115 (ii); 119 (ii); and 131 (ii)

SUMMARY AND STATUS OF WORK

Responsible Party	Purpose	Text/Topic	Code	Step	Para(s).
CCCF13	Prioritisation	Priority list of contaminants and naturally occurring toxicants for evaluation by JECFA	-	-	148

LIST OF ABBREVIATIONS

AFT	Total aflatoxins
ALARA	As Low As Reasonable Achievable
CAC	Codex Alimentarius Commission
CCASIA	FAO/WHO Coordinating Committee for Asia
CCCF	Committee on Contaminants in Foods
CCEXEC	Executive Committee
CCFICS	Committee on Food Import and Export Certification and Inspection Systems
CCMAS	Committee on Methods of Analysis and Sampling
CFP	Ciguatera fish poisoning
CL	Circular Letter
COP	Code of Practice
CRD	Conference Room Document
EFSA	European Food Safety Authority
EU	European Union
EWG	Electronic Working Group
FAO	Food and Agriculture Organisation
GAP	Good agricultural practice
GE	Glycidyl esters
GEMS/Food	Global Environment Monitoring System
GL	Guideline level
GSCTFF	General Standard for Contaminants and Toxins in Food and Feed
HCN	Hydrocyanic acid
IAEA	International Atomic Energy Agency
JECFA	Joint FAO/WHO Expert Committee on Food Additives
LOQ	Limit of quantification
3-MCPD	3-monochloropropane-1,2-diol or 3-chloropropane-1,2-diol
ML	Maximum Level
NDL-PCBs	Non-dioxin-like PCBs
OECD	Organization for Economic Cooperation and Development
OIV	International Organisation of Vine and Wine
OTA	Ochratoxin A
PCBs	Polychlorinated Biphenyls
PWG	Physical working group
RTE	Ready-To-Eat
SDOs	Standards development organizations
STC	Sterigmatocystin
TTC	Threshold of toxicological concern
USA	United States of America
WG	Working Group
WHO	World Health Organisation

INTRODUCTION

1. The Codex Committee on Contaminants in Foods (CCCF) held its 12th Session in Utrecht, the Netherlands, from 12 to 16 March 2018, at the kind invitation of the Government of the Netherlands. The Session was chaired by Dr Wieke Tas, Department of Animal Health and Market Access, Ministry of Economic Affairs, The Netherlands. The Session was attended by 59 Member countries, one Member Organization, and Observers from 18 international organizations. The list of participants is provided in Appendix I.

OPENING OF THE SESSION

2. The Session was opened by Ms Marjolijn Sonnema, Director General of the Ministry of Agriculture, Nature and Food Quality. Mr Purwiyatno Hariyadi, the vice Chair of the Codex Alimentarius Commission also addressed the meeting.

Division of Competence¹

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

ADOPTION OF THE AGENDA (Agenda Item 1)²

4. CCCF adopted the Provisional Agenda with amendments in the order to discuss Agenda Item 14 immediately after Agenda Item 5 and Agenda Item 16 immediately after Agenda Item 6.
5. CCCF agreed:
 - i. to establish an in-session Working Group on the priority list of contaminants and naturally occurring toxicants for evaluation by JECFA, chaired by the United States of America, and to discuss the outcome of the in-session WG under Agenda Item 17;
 - ii. to discuss the development of a general guidance on how to handle occurrence data to derive MLs under Agenda Item 18; and
 - iii. to discuss new work to revise the *Code of Practice for the Prevention and Reduction of Lead Contamination in Foods* (CXC 56-2004), proposed by the United States of America, under Agenda Item 19.
6. CCCF agreed that consideration of matters under Agenda Item 19 are subject to availability of time.

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

7. CCCF noted matters for information and agreed to address the request of CCEXEC73 to provide a reasonable deadline for the completion of the ongoing work under the relevant agenda items.
8. In particular, CCCF considered the following matters:

Biopesticides, biofertilizers, biostimulants

9. Chile stated that the most appropriate way to approach this matter was to first start working on biopesticides and present the proposal at CCPR50, leaving biofertilizers and biostimulants for future work.
10. CCCF noted this information.

Standard for quinoa

11. The JECFA Secretariat proposed as a way forward that the Codex Secretariat examine the history as to why the MLs for lead and cadmium in cereals in the GSCTFF (CXS 193-1995) exclude explicitly quinoa, while the JECFA Secretariat prepare a review of existing scientific data on lead and cadmium in quinoa. Both would report back to the next session of CCCF.
12. CCCF noted the view that since quinoa was a pseudo-cereal and the growing conditions were different, 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.
13. CCCF also noted the view that aside from quinoa, the MLs for lead and cadmium in the GSCTFF also do not apply to buckwheat and cañihua. It was further noted that the revised *Classification of Food and Feed* (CXM 4-1989) included pseudo-cereals in the group of cereal grains and that this revision should be taken into account when considering MLs for quinoa.

¹ CRD01

² CX/CF 18/12/1

³ CX/CF 18/12/2; CRD06 (EU, India, Kenya); CRD23 (Nigeria); CRD31 (Ecuador)

Conclusion

14. CCCF agreed to discuss this matter at CCCF13 based on the paper from the Codex and JECFA Secretariats.

MATTERS OF INTEREST ARISING FROM FAO AND WHO (including JECFA) – (Agenda Item 3)⁴

15. The JECFA Secretariat informed CCCF that the 84th and 85th JECFA meetings held since the last CCCF focused on food additives and residues of veterinary drugs in foods, respectively, and therefore no new JECFA evaluations on contaminants could be reported to the current session.
16. In addition the JECFA Secretariat:
- highlighted the upcoming meeting of the FAO/WHO joint scientific advice program on Ciguatera Fish Poisoning scheduled for November 2018 and urged countries to explore all opportunities to submit suitable responses to the call for data and call for experts⁵.
 - encouraged countries to contact FAO and WHO regarding any discussion on mobilizing extra-budgetary resources for the joint scientific advice program, and the recent commitment for financial support by the EU was gratefully acknowledged.
 - provided an update on the on-going efforts to improve the data collection on food contamination and consumption data to further strengthen the exposure assessment side of the risk assessment work.
 - highlighted the recently published call for data for national food consumption data⁶ and on-going work to update risk assessment methods and principles, including an update of the exposure assessment chapter of the Environmental Health Criteria document 240.

MATTERS OF INTEREST ARISING FROM OTHER INTERNATIONAL ORGANIZATIONS (Agenda Item 4)⁷

International Atomic Energy Agency

17. The Representative of IAEA highlighted the following items: a new research project on the analysis of mixtures of contaminants; a joint FAO/IAEA/WHO initiative to develop technical guidance on radionuclide activity concentration values in food and drinking water in non-emergency situations; capacity development activities, and two new safety guides that include food restrictions as part of nuclear emergency planning.

Organization for Economic Cooperation and Development

18. The Representative of the OECD Nuclear Energy Agency noted that the post-nuclear-accident food management framework presented during CCCF11 is being considered for acceptance by OECD member country governments. It was stated that this framework is felt to be consistent with Codex.

PROPOSED DRAFT AND DRAFT MAXIMUM LEVELS FOR LEAD IN SELECTED COMMODITIES IN THE GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOOD AND FEED (CXS 193-1995) (Agenda Item 5)⁸

19. The United States of America, as Chair of the EWG, introduced the item and recalled that this work was a follow-up of the JECFA73 evaluation of lead and was particularly focused on the prevention of adverse health effects due to exposure to lead in foods relevant to vulnerable groups such as infants and young children. The work process used in the revision of the MLs had consistently been applied since the approval of the new work in 2012 to ensure coherence in the recommendations made for the revised (lower) MLs. This approach ensured that the revised MLs have a minimum negative impact on trade (violation rate < 5%) while remaining health protective for all population groups. The approach this year was slightly revised to include datasets with quantified results but with no reported LOQ, since these samples constituted a significant portion of some datasets for the commodities reviewed available from the GEMS/Foods database.
20. The Chair of the EWG introduced the 9 recommendations as follows:

⁴ CX/CF 18/12/3

⁵ http://www.who.int/foodsafety/areas_work/chemical-risks/CFP/en/ or <http://www.fao.org/food/food-safety-quality/scientific-advice/calls-data-experts/en/>

⁶ http://www.who.int/foodsafety/Food_Consumption_Data.pdf

⁷ CX/CF 18/12/4; CX/CF 18/12/4-Add.1; CRD22 (Dominican Republic)

⁸ CL 2018/1-CF; CX/CF 18/12/5; CX/CF 18/12/5-Add1 (Argentina, Australia, Canada, Colombia, Costa Rica, Egypt, India, Japan, Kenya, Republic of Korea, Turkey, Uruguay, FIVS, OIV and WPTC); CRD07 (China, EU, Uganda and AU); CRD19 (Thailand); CRD21 (Mali); CRD23 (Nigeria); CRD24 (Senegal); CRD28 (Ghana); CRD31 (Ecuador); CRD32 (Cuba)

Grape Juice

21. CCCF11 agreed to retain the ML of 0.05 mg/kg for juices obtained exclusively from berries and small fruits and to work on a positive list of these fruits that could achieve lower levels (e.g. 0.03 or 0.04 mg/kg) as more data became available. The Chair of the EWG noted that data available supported a separate lower ML for grape juice of 0.04 mg/kg.
22. CCCF noted the view that juices were traded in concentrated form and that the establishment of an ML of 0.04 mg/kg would eliminate 15% of the grape juice concentrates from the international trade if applied directly to the concentrate and could create problems when inspecting the product at the import control point. It would therefore be preferable to retain grape juice under the current ML of 0.05 mg/kg for juices obtained exclusively from berries and small fruits.
23. CCCF however noted general support for setting a single lower ML for grape juice at 0.04 mg/kg and recalled that the ML for fruit juices and nectars (including those obtained from berries and small fruits) applied to ready-to-drink juices / nectars.
24. CCCF thus agreed to lower the ML for grape juice from 0.05 mg/kg to 0.04 mg/kg.

Processed tomato concentrates

25. CCCF11 agreed to forward an ML of 0.05 mg/kg for adoption by CAC40 at Step 5. The Chair of the EWG noted that additional data submitted to the EWG supported a higher ML of 0.08 mg/kg, which was based on the analysis of additional samples of tomato concentrates with different concentration ratios.
26. CCCF noted the following comments: an ML of 0.08 mg/kg was more representative of the lead contamination in these products while still ensuring protection of consumer health and minimum negative impact on trade; an ML of 0.08 mg/kg would eliminate 11% of the samples in international trade especially for those tomato concentrates with high natural soluble solids content (e.g. TSS = 28 – 38%); that the data did not yet represent a good geographical distribution, the ML for processed commodities should be consistent with the ML for fresh tomatoes and therefore concentration factors should be applied in accordance with industry practices which would provide for flexibility in the application of MLs for the different tomato concentrates on the market.
27. CCCF noted that the current ML for fruiting vegetables (which includes fresh tomatoes) of 0.05 mg/kg could be used to derive, with concentration factors, an ML for tomato concentrates, and that such an approach would be in line with the desire of CCCF to consolidate MLs where possible, and would provide for flexibility in the application of MLs for this food category. Consequently, the existing ML for this food category would be revoked.

Mango chutney

28. CCCF noted that all available data uploaded to GEMS/Food had been considered in proposing the ML and that additional submitted data had improved geographical distribution and supported an ML of 0.3 mg/kg. CCCF further noted that although simplification of categories was desirable, maintaining a category for mango chutney as opposed to including the commodity in jams, jellies and marmalades had already been agreed by CCCF11.
29. India indicated that the proposed revised ML of 0.3 mg/kg was not representative of the actual occurrence data considered by the EWG as it also included data from non-producing countries and would introduce a rejection rate of 4%, which was considered too high. The Delegation noted that the composition of this product introduced ingredients such as salt and vinegar that could add to the presence of lead in the final product hence an ML of 0.5 mg/kg with a violation rate of 2-3% would be more appropriate.
30. Other delegations supported an ML of 0.5 mg/kg or alternatively to extend the ML of 0.4 mg/kg for jams, jellies and marmalades to mango chutney.
31. As a compromise, CCCF agreed to lower the ML for lead in mango chutney from 1 mg/kg to 0.4 mg/kg.

Canned brassica vegetables

32. CCCF agreed to include canned brassica vegetables in the canned vegetables category with an ML of 0.1 mg/kg.

Fresh-farmed mushrooms

33. The Chair of the EWG noted that available data supported an ML of 0.2 mg/kg. CCCF noted comments that an ML of 0.2 mg/kg with a violation rate of 4% was too restrictive considering that mushrooms were not a major contributor to lead exposure. An ML of 0.3 mg/kg with a violation rate of 2% would be more appropriate and would be consistent with approach for the ML for inorganic arsenic in rice. This higher ML would still ensure the removal of highly contaminated mushrooms from international trade and would assist to reduce lead exposure of consumers (under the current situation of not having a Codex ML).

34. CCCF therefore agreed to establish an ML of 0.3 mg/kg for fresh farmed mushrooms, common mushrooms (*Agaricus bisporous*), shiitake mushrooms (*Lentinula edodes*), and oyster mushrooms (*Pleurotus ostreatus*).

Wine

35. CCCF considered the proposed ML of 0.05 mg/kg and noted the view that when setting MLs for wine, the specific characteristics of certain types of wines should be considered, such as the fruit which was used, and whether the wine was a fortified or liqueur wine. It was also noted that the ML should only be set for wine produced from grapes harvested after the date of the modification of the ML due to the ageing period and shelf life of wine (e.g. old vintage with high added value). It was further noted that an ML of 0.05 mg/kg was too restrictive considering wines were not aimed at infants and young children.
36. The Observer of OIV indicated that the proposed ML would exclude a significant portion of the wine production especially fortified wines from the international market. OIV had set an ML of 0.15 mg/kg in 2006 and continued to work on the reduction of lead contamination in wines that might lead to the further reduction of the OIV ML in future. Collaboration between Codex and OIV was important to avoid duplication of work or inconsistent standards that may be trade disruptive. The Observer supported the view that any revised Codex ML should apply to wines from grapes harvested after the date of adoption of the ML.
37. CCCF recognized the value of gathering additional data in developing the ML to enhance geographical distribution to better assess the appropriate lower ML, welcoming data that could also be contributed by OIV through GEMS/Food and, also of adopting an approach that categorized different types of grape wine clearly.
38. CCCF agreed that the EWG would continue to develop an ML for wine made from grapes and for fortified wines, made from grapes harvested after the date of the establishment of the ML.

Salt

39. CCCF noted the view that an ML of 1.5 mg/kg with a compliance rate of 98% (2% violation rate) was a more appropriate value than the proposed 1 mg/kg, as the commodity is consumed in small daily amounts and often produced in developing countries by small and medium sized manufacturers.
40. CCCF also recognized that salt from marshes should be excluded from the ML as the value proposed would not be high enough for this niche product.
41. CCCF therefore agreed to lower the ML for lead in salt (excluding salt from marshes) from 2 mg/kg to 1 mg/kg.

Fat spreads and blended spreads

42. CCCF agreed to lower the ML for lead in fat spreads and blended spreads from 0.1 mg/kg to 0.04 mg/kg.

Edible fats and oils

43. CCCF noted the view that the proposed ML of 0.07 mg/kg (with 4% violation rate) would cause excessive impact on international trade and that the ML should be lowered from 0.1 mg/kg to 0.08 mg/kg with a compliance rate of 97% (3% violation rate).
44. CCCF agreed to lower the ML for lead in edible fats and oils from 0.1 mg/kg to 0.08 mg/kg.

Conclusion

45. CCCF agreed:
- i. to advance the MLs for grape juice, mango chutney, canned brassica vegetables, fresh farmed mushrooms, salt (excluding salt from marshes), fat spreads and blended spreads, edible fats and oils to CAC41 for adoption at Step 5/8 (with omission of Steps 6/7); and
 - ii. to propose that CAC41 revoke the existing MLs for the mango chutney, salt, fat spreads and blended spreads, edible fats and oils in view of the adoption of revised MLs, and the ML for processed tomato concentrates categories.
46. CCCF further agreed:
- iii. to establish an EWG chaired by the United States of America, working in English, to work on MLs for wine (as described in paragraph 38) and on edible offals as previously agreed; and
 - iv. to communicate to CCEXEC that the work could be expected to be concluded at CCCF13.

PROPOSED DRAFT MAXIMUM LEVELS FOR CADMIUM IN CHOCOLATE AND COCOA-DERIVED PRODUCTS (Agenda Item 6)⁹

47. Ecuador, as Chair of the EWG, also on behalf of the co-chairs, Brazil and Ghana, introduced the item and presented their recommendations to CCCF as shown in CX/CF 18/12/6, Appendix I, Tables 1, 2 and 3. They also informed CCCF of a typographical error in Tables 1 to 3, where the unit for the ML should be “mg/kg” instead of “µg/kg”.

Table 1

Proposal for MLs for cadmium in chocolates

48. CCCF agreed to round the proposed MLs for chocolates to one decimal place for consistency and to facilitate sample analysis and reporting.

Chocolate containing or declaring $\geq 50\%$ to $< 70\%$ total cocoa solids on a dry matter basis

49. There was wide support for the proposed ML of 0.8 mg/kg, while one delegation proposed the ML of 0.6 mg/kg, which would increase the rejection rate to 4.3%.
50. CCCF agreed to advance the ML of 0.8 mg/kg for final adoption by CAC41.

Chocolate containing or declaring $\geq 70\%$ total cocoa solids on a dry matter basis

51. CCCF widely supported the ML of 1.0 mg/kg as proposed by the EWG, while one delegation and one observer organization supported a lower ML of 0.8 mg/kg. It was recalled that chocolates with high content of total cocoa solids were not usually consumed by children, and therefore a higher ML could be allocated taking into account the outcome of the JECFA77 evaluation which would also be consistent with the MLs proposed for the remaining categories of chocolates.
52. CCCF agreed to compromise on an ML of 0.9 mg/kg and to advance the ML for final adoption by CAC41.

Chocolate products containing or declaring $< 30\%$ total cocoa solids on a dry matter basis

53. Delegations in support of the proposed ML of 0.4 mg/kg were of the opinion that there was no health concern associated with the exposure to cadmium through the consumption of cocoa-derived products (e.g. chocolates) and therefore there was no added health benefit in setting lower MLs. This was also in line with the outcome of the JECFA77 evaluation. CCCF noted the view that since there were a number of countries who had challenges in achieving lower levels in view of the naturally higher cadmium content in the environment (e.g. volcanic areas), that the production of cocoa was important for the socio-economic development of small-scale farmers in some countries, and the absence of effective mitigation strategies for such natural conditions, it was sensible at this point in time to set the ML at 0.4 mg/kg in order to be globally ALARA.
54. Other delegations in favour of 0.1 mg/kg or 0.2 mg/kg expressed concern for the adverse impact on vulnerable populations at the proposed ML of 0.4 mg/kg.
55. In light of the diverging views, CCCF was not able to reach an agreement and decided to leave this category for discussion at the next session.

Chocolate and chocolate products containing or declaring $\geq 30\%$ to $< 50\%$ total cocoa solids on a dry matter basis

56. In addition to the ML of 0.5 mg/kg proposed by the EWG, there were views to support MLs of 0.3 mg/kg or 0.7 mg/kg as an alternative to provide effective health protection especially to vulnerable groups and to consider trade impacts. Views in support of an ML of 0.5 mg/kg indicated that this was consistent with the ML of 0.4 mg/kg for chocolates with a total cocoa solids $< 30\%$, that based on the JECFA77 evaluation this ML had a minimum impact on the daily intake of cadmium from the diet and this category of chocolate was not usually consumed by children.
57. CCCF noted that the ML for this category was derived in a different manner than for other categories. Moreover, since views were too far apart for a compromise to be achieved during the session, the Chair proposed that the EWG continue working on this category to assess if it was feasible to merge the first two categories in Table 1 to derive one ML for chocolate and chocolate products containing or declaring $< 50\%$ total cocoa solids on a dry matter basis. It was noted however that the small dataset for this category in comparison with the datasets for the chocolates $< 30\%$ should be taken into account when exploring the possibility to merge the two categories.

⁹ CL 2018/2-CF; CX/CF 18/12/6; CX/CF 18/12/6-Add.1 (Australia, Brazil, Canada, Colombia, Egypt, Japan, Kenya, Republic of Korea, USA, ECA and ICGMA); CRD08 (EU, Uganda and AU); CRD21 (Mali); CRD22 (Dominican Republic); CRD28 (Ghana); CRD29 (El Salvador); CRD31 (Ecuador); CRD32 (Cuba)

58. Ecuador, as Chair of the EWG, noted that the ML proposed for this category was derived from the relevant datasets available.
59. An Observer noted that although exposure to cadmium through consumption of these products might not pose a health concern, when considering MLs for contaminants, the total intake of cadmium through the contribution of relevant foods should be taken into account to protect consumers especially those vulnerable groups.

Table 2 - Dry mixtures of cocoa and sugars sold for final consumption

60. Ecuador, as the EWG Chair explained that there were very few samples with information on the percentages of total cocoa solids for these categories. In view of this data limitation, the EWG recommended to discontinue work on these categories or to merge them.
61. Views not in support of the discontinuation emphasized the importance to continue the discussion in the Codex arena for establishing global ALARA-based MLs to protect the health of vulnerable populations like young children. The absence of an international reference would lead countries to establish national MLs which might be trade disruptive.
62. Views in support of the discontinuation pointed out the low significance of this product category in the international trade and the absence of MLs established elsewhere outside of Codex.
63. In light of the data limitation, CCCF agreed to discontinue work on dry mixtures of cocoa and sugars sold for final consumption in Table 2 but to continue work on cocoa powder (100% total cocoa solids on a dry matter basis) in Table 3, as it would be possible in the future to derive values for the products in Table 2 from the value in Table 3.

Table 3 - Cocoa powder (100% total cocoa solids on a dry matter basis)

64. Initially, there were varying views regarding the need to set a Codex ML also for this category. However, since CCCF chose this category over that in Table 2 for setting an ML, it decided to continue its discussion on the ML of 1.5 mg/kg proposed by the EWG.
65. While there was general support for the ML of 1.5 mg/kg, CCCF was reminded that based on total cocoa solids, the ML for cocoa powder should be consistent with the ML of 0.9 mg/kg established for chocolate containing or declaring 70% total cocoa solids on a dry matter basis.
66. CCCF agreed to continue its work on cocoa powder (100%) taking into consideration MLs established for the chocolate categories to be consistent across categories of cocoa-derived products.

Conclusion

67. CCCF agreed:
- i. to advance the ML of 0.8 mg/kg for adoption at Step 5/8 by CAC41 for chocolate containing or declaring $\geq 50\%$ to $< 70\%$ total cocoa solids on a dry matter basis;
 - ii. to advance the ML of 0.9 mg/kg for adoption at Step 5/8 by CAC41 for chocolate containing or declaring $\geq 70\%$ total cocoa solids on a dry matter basis;
 - iii. to continue work on the category of chocolate and chocolate products containing or declaring (1) $< 30\%$ and (2) $\geq 30\%$ to $< 50\%$ total cocoa solids on a dry matter basis and to assess if it is feasible to merge these two categories to derive one ML for chocolate containing or declaring $< 50\%$ total cocoa solids on a dry matter basis;
 - iv. to discontinue work on dry mixtures of cocoa and sugars sold for final consumption; and
 - v. to continue work on cocoa powder (100% total cocoa solids on a dry matter basis) taking into consideration MLs established for other product categories.
68. CCCF further agreed to re-establish an EWG chaired by Ecuador, co-chaired by Brazil and Ghana, working in English and Spanish reporting to CCCF13, to work on points (iii) and (v) of paragraph 67.

PROPOSED DRAFT MAXIMUM LEVEL FOR METHYLMERCURY IN FISH INCLUDING ASSOCIATED SAMPLING PLANS (Agenda Item 7)¹⁰

69. The Netherlands, as chair of the EWG, also on behalf of the co-chairs, Canada and New Zealand, introduced the item and highlighted the work of the EWG which consisted of development of MLs, determining the associated notes to the MLs and development of an associated sampling plan.

¹⁰ CL 2018/3-CF; CX/CF 18/12/7; CX/CF 18/12/7-Add.1 (Australia, Canada, Colombia, Cuba, EU, Japan, Kenya, Malaysia, Republic of Korea, Uganda, USA, AU, ICGMA and ISDI); CRD19 (Thailand); CRD21 (Mali); CRD22 (Dominican Republic); CRD24 (Senegal); CRD28 (Ghana); CRD31 (Ecuador)

70. The EWG Chair also reminded CCCF of previous decisions not to establish a level for canned tuna, to continue with the approach to establish MLs for methylmercury, while screening for total; to develop a footnote to the higher MLs to indicate the need for additional risk management measures, namely consumer advice, to protect health, amongst others.
71. The EWG Chair noted that for the development of the MLs, the newly submitted data were merged with those from the CCCF11 dataset and analyzed for new proposals based on ALARA. She further informed that while the EWG developed MLs based on the P95 of the data (5% rejection rate), which was the approach taken in the discussion paper preparing this work, comments were also received in the EWG that lower rejection rates should be considered. Following the approach taken for the establishment of MLs for lead, alternative proposals based on the next higher ML resulting in lower rejection rate than 5% were also included for consideration.
72. The EU expressed the view that it could not agree for the time being with any of the MLs proposed as the levels were higher than those currently in force in the EU and would result in higher exposure to mercury which was a public health concern. This view was supported by Switzerland and Norway.
73. CCCF considered the recommendations of the EWG, considered the views expressed and took the following decisions:

ML for tuna

74. CCCF first considered the ML based on P95 (1.1 mg/kg) and noted that while there was some support for this ML because it would be more protective for health, that many delegations believed the rejection rate of 5% was too high, and that the ML of 1.2 mg/kg or other higher MLs such as 1.7 mg/kg should be considered which would result in lower rejection rates. Views were also expressed that the ML for tuna should be set based on the species of tuna with high mercury content, such as Bigeye or Bluefin tuna. The ML of 1.2 mg/kg was proposed as a compromise as this was based on the data of all tuna species but with a next lower rejection rate than 5%.

Conclusion

75. CCCF agreed on an ML of 1.2 mg/kg.
76. EU, Switzerland and Norway expressed their reservation to this decision for the reasons given in paragraph 72.

ML for Alfonsino, marlin and shark

77. CCCF agreed with an ML of 1.5 mg/kg for alfonsino, 1.7 mg/kg for marlin and 1.6 mg/kg for shark which were the proposed MLs based on a next lower rejection rate than 5% and noted the reservation of the EU, Switzerland and Norway for the reasons given in paragraph 72.

Amberjack

78. CCCF noted that based on the new dataset used by the EWG, the average and median concentration of total mercury and methylmercury fall below the 0.3 mg/kg used as selection criterion for selecting fish species for setting MLs and therefore agreed to discontinue work on the ML for Amberjack.

Swordfish

79. CCCF noted that the proposed draft ML for swordfish was high and considered whether it should proceed with establishing an ML for this species. An observer noted that it would be unacceptable to establish such a high ML only taking into account rejection rates as a determining factor, especially since swordfish contained limited selenium which has been suggested to have a protective effect against methylmercury unlike the situation for the other fish species for which MLs had been set.
80. Noting that once MLs for the fish species were agreed, the GLs would be revoked, a proposal was made to develop a new GL for certain species including swordfish.
81. The Codex Secretariat clarified that the current work on MLs in fish was undertaken to replace the current GLs following the decision of CAC that consideration should be given to establishment of MLs rather than GLs, and that when scientific advice became available, GL levels should be reviewed with the view of converting them to MLs. She also recalled the difficulty to develop a list of predatory fish to which the GL apply in the past and that it would not be appropriate to have a GL in view of the CAC decision.
82. CCCF noted that although the methylmercury concentrations in swordfish were high which was of health concern when consuming this fish, no consensus could be reached on an appropriate ML.

Conclusion

83. CCCF agreed to discontinue work on the ML for swordfish.

Notes to the MLs

Note on mercury for screening purposes

84. CCCF agreed with the proposal of the EWG with an amendment to indicate that no further testing was needed when the total mercury was equal to or less than the ML for methylmercury. As this note was based on the note for inorganic arsenic in rice, CCCF agreed to similarly amend the note for arsenic in rice.

Existing note attached to the current Guideline levels

85. CCCF agreed to retain the note attached to the current GLs, but to amend the text to indicate that the ML applied also to fresh or frozen fish intended for further processing to ensure that fish not complying with the ML would not be used for canning. CCCF noted that with this amendment, the footnote would not make the ML applicable to canned tuna which was in line with the decision made at the previous session not to set an ML for canned tuna.

Consumer advice supplemental to ML

86. CCCF agreed to the option c proposed by the EWG amended to refer to “women of child-bearing age” noting the clarification from the JECFA Secretariat that the most sensitive period for negative health impacts of methylmercury is very early in foetal development and that JECFA uses the term women of child-bearing age rather than pregnant women.

Sampling plan

87. CCCF made editorial amendments to the sampling plan, including deletion of the references to analytical methods as the preference was to use performance criteria in Codex sampling plans, deletion of references to canned fish and revision of the performance criteria for methods of analysis following the decisions on the MLs and agreed to send the sampling plan to CCMAS for endorsement and to request CCMAS advice on the following:
- The necessary performance criteria for the MLs;
 - Whether there is evidence that methyl mercury can vary widely between individual fish sampled at the same time. How this would apply to large fish sold as individual units and whether the sampling plan provides enough basis to deal with this; and
 - Whether the whole fish should be analyzed or only specific fractions of edible portions. Currently only mention is made that the mid-section should be sampled for some large fish.

Other matters

88. CCCF noted 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.
89. Brazil noted that sampling plans in the GSCTFF should be harmonized and that this should be considered in future.
90. The Representative of WHO informed CCCF that discussions are ongoing in the context of the Minamata Convention on Mercury on methods for monitoring for baseline data and effectiveness monitoring. For signatories to the Convention human biomonitoring is mandatory, fish monitoring has been acknowledged as an important tool and this topic would be discussed at the Conference of the Parties (COP2) in June. WHO encouraged delegates to engage with their colleagues from the environment sector and delegates to the Minamata Convention in order to make them aware of the Codex sampling plan to coordinate fish monitoring for food safety with the monitoring for effectiveness within the Minamata Convention.

Conclusion

91. CCCF agreed to:
- i. advance the MLs for tuna, alfonsino, marlin and shark to CAC41 for adoption at Step 5/8 (Appendix IV, part A)
 - ii. inform the Commission of discontinuation of work on ML for amberjack and swordfish;
 - iii. request revocation of the GLs for methylmercury; and
 - iv. send the sampling plan (Appendix IV, part B) to CCMAS for endorsement together with specific questions in paragraph 87.

Further work on MLs for other fish species

92. New Zealand noted that with the agreement of the MLs for tuna, alfonsino, marlin and shark, there was an agreeable framework to apply ALARA in the establishment of MLs for methylmercury in fish. He noted that in the paper presented to CCCF11, further fish species were identified for which data could be gathered to establish MLs and that New Zealand had started gathering data for some of these species. The delegation proposed that CCCF consider work on MLs for the additional species.
93. CCCF agreed to establish an EWG chaired by New Zealand and co-chaired by Canada and working in English only to prepare a discussion paper on the establishment of MLs for additional fish species. The paper should clearly identify the fish species for which MLs should be established and include a project document with proposals for MLs for consideration by CCCF13.

PROPOSED DRAFT REVISION OF THE CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF DIOXINS AND DIOXIN-LIKE PCBS IN FOOD AND FEED (CXC 62-2006) (Agenda Item 8)¹¹

94. The European Union, as Chair of the EWG introduced the item and recalled that CCCF11 had agreed that the revised COP would include mitigation measures for NDL-PCBs and additional measures for containment of dioxins and dioxin-like PCBs.
95. The EWG Chair noted that all comments submitted to this Session had, to the extent possible, been incorporated into the revised text. The EWG Chair noted in particular that extensive scientific explanations (e.g. reference to the JECFA evaluations, the transfer mechanisms of dioxins and PCBs in food producing animals, etc.) had been removed from the introduction to better reflect the requirements of a COP.
96. In response to an observation that more time be given to consult on the proposed changes to the COP, the EWG Chair emphasized that the majority of the changes were of an editorial nature, deletions or to complement existing provisions and that CCCF should explore if it were possible to advance the work for final adoption by CAC41.
97. CCCF considered the revised COP, and aside from editorial amendments, noted that pentachlorophenol may be allowed in fence treatment by national authorities (paragraph 63 of the COP) and that the COP dealt with PCBs specifically in food and feed and that situations where, for example, animals were put out to grass would be covered by source directed measures up front in the COP.

Conclusion

98. CCCF agreed to advance the proposed draft *COP for the Prevention and Reduction of dioxins, and dioxin-like PCBs and non dioxin-like PCB Contamination in Food and Feed* to CAC41 for adoption at Step 5/8 (Appendix V).

PROPOSED DRAFT CODE OF PRACTICE FOR THE REDUCTION OF 3-MONOCHLOROPROPANE-1,2-DIOL ESTERS (3-MCPDE) AND GLYCIDYL ESTERS (GE) IN REFINED VEGETABLE OILS AND FOOD PRODUCTS MADE WITH REFINED VEGETABLE OILS, ESPECIALLY INFANT FORMULA (Agenda Item 9)¹²

99. The United States, as Chair of the EWG, also on behalf of the co-chairs, EU and Malaysia, introduced the item, reminding delegates of the background to the COP and highlighting the comments received that had led to a proposed revision of the text. The EWG Chair noted that the title had been amended to better reflect the scope of the COP covering all foods made with refined vegetable oils. The introduction had been edited to better reflect the format of a COP (and to avoid duplication of scientific information already available that is not of direct relevance to the COP), whilst retaining information that was helpful in understanding the context and application of the COP. In addition, experimental mitigation measures had been removed from the COP, so that it only reflected those practices currently in use.
100. CCCF discussed the revised text and noted the following issues:
- removing the term “vegetable” from the title would broaden the scope of the COP and allow for the inclusion of non-vegetable oils, e.g. fish oils, since these are also refined oils used in food (including infant formula) and prone to formation of these contaminants;

¹¹ CL 2018/4-CF; CX/CF 18/12/8; CX/CF 18/12/8-Add.1 (Brazil, Canada, Cuba, Egypt, EU, Kenya, USA and AU); CRD18 (Japan); CRD19 (Thailand); CRD21 (Mali); CRD22 (Dominican Republic); CRD25 (revised COP - EWG Chair proposal); CRD28 (Ghana)

¹² CL 2018/5-CF; CX/CF 18/12/9; CX/CF 18/12/9-Add.1 (Australia, Canada, Costa Rica, Egypt, Japan, Kenya, Republic of Korea, FoodDrinkEurope, GOED, ICGMA, ISDI and SNE); CRD09 (EU and AU); CRD19 (Thailand); CRD20 (Indonesia); CRD21 (Mali); CRD22 (Dominican Republic); CRD28 (Ghana); CRD30 (revised COP - EWG Chair proposal); CRD31 (Ecuador)

- a new paragraph could be added to the introduction of the COP explaining that the text could also be applicable to fish oils and subsequent additional references to fish oils could also be added elsewhere in the text as appropriate; and
- discussions on proposed revisions to the text regarding specific practices on matters such as: low lipase activity, irrigation water, polar solvents, degumming, bleaching clay, or the inclusion of specific references to fish oils would be kept in square brackets and deferred to a re-established EWG for further discussion.

101. In order to cover all edible oils in the COP, the Chair advised that if examples of practices or information were missing from the proposed COP, then Codex members and observers interested in this matter should provide this information to the EWG.

Conclusion

102. CCCF agreed:

- that the scope of the COP covers refined oils and food products made with refined oils;
- to forward the COP (with the sections in square brackets related to the points raised in 2nd and 3rd bullet points of paragraph 100) to CAC41 for adoption at Step 5 (Appendix VI); and
- to establish an EWG chaired by the United States of America, co-chaired by EU and Malaysia, working in English, to revise the COP based on the comments and information submitted by Codex members and observers and to resolve all outstanding issues in order to submit a new draft for consideration by CCCF13.

PROPOSED DRAFT MAXIMUM LEVEL FOR AFLATOXINS IN READY-TO-EAT PEANUTS AND ASSOCIATED SAMPLING PLANS (Agenda Item 10)¹³

103. India, as chair of the EWG, introduced the item and informed CCCF that the aim of the EWG was to consider comments on the MLs of 10 and 15 µg/kg in order to prepare a revised proposal for consideration by CCCF12 as agreed at CCCF11. The EWG Chair informed CCCF that there had been general consensus for the ML of 10 µg/kg for AFT in RTE peanuts considering carcinogenicity of AFT and consistency with the approach taken for the establishment of MLs for AFT in tree nuts.

Discussion

104. CCCF considered the proposal of 10 µg/kg.

105. Those in favour expressed the view that the level matched what was achievable in their countries or in their national legislation; that it was consistent with the ML established for tree nuts and that it was important to have a separate ML different from peanuts for further processing which would encourage better practices and better RTE peanuts in the market.

106. Those opposed to the 10 µg/kg expressed preference for a higher level of 15 µg /kg or 12.5 µg /kg or for lower levels of 8 µg /kg or 4 µg/kg.

107. Those in favour of an ML of 4 µg/kg expressed the following views:

- that an ML of 4 µg/kg was in force in their national or regional legislation and that introducing a higher level would not be acceptable to their consumers and would result in higher exposures especially since the introduction of consumption/dietary advice on the benefits of nuts consumption, including peanuts in the diet;
- EFSA had looked at the impact of introducing a higher level and had concluded that for consumers of peanuts, based on estimates of current exposure to AF, the cancer risk is higher than the excess lifetime cancer risk of 10⁻⁵. A level of 10 µg/kg would result in further increase in the cancer risk by a factor of 1.6 to 1.8 based on a simulation of the possible dietary exposure to AF;
- the ML of 4 µg/kg had been in place since 2004 in the EU and that there was no evidence of difficulty to achieve this level, nor was there a problem with supply to their markets; and that the lower level was essential for consumer protection.

¹³ CL 2018/6-CF; CX/CF 18/12/10; CX/CF 18/12/10-Add.1 (Canada, Colombia, Costa Rica, Egypt, India, Kenya, Malaysia, Paraguay, Philippines, USA and ICGMA); CRD10 (EU, Uganda and AU); CRD19 (Thailand); CRD20 (Indonesia); CRD21 (Mali); CRD22 (Dominican Republic); CRD23 (Nigeria); CRD24 (Senegal); CRD27 (Nicaragua); CRD28 (Ghana); CRD31 (Ecuador)

108. Those in favour of an ML of 15 µg/kg expressed the following views:
- The impact assessment by JECFA, the risk assessment body for CCCF, indicated there would be no additional public health benefit at 10 µg /kg versus 15 µg /kg while resulting in higher rejection of RTE peanuts;
 - the assessment of achievability was dominated by data from EU where an ML of 4 µg/kg was in place for many years thus skewing downwards achievability and that if more representative data were applied, the rejection rate would increase;
 - that lower levels could result in higher rejections leading to food waste; that it should be borne in mind that peanuts were mainly produced in developing countries, was an important crop from a nutritional as well as economic perspective; and that with the implementation of good agricultural practices could be revised in future.
109. The Representative of FAO reminded CCCF about the importance of Codex standards for international trade which are designed to be simultaneously health-protective and trade-inclusive at a global level and noted that consumption patterns of peanuts vary greatly globally. In this regard, he urged CCCF to focus on the need to find a compromise as the absence of an international standard would not be facilitating trade and might put public health at risk. The Representative emphasized that for the goal of alleviating poverty and eradicating hunger the work of Codex and suitable international food safety standards were critical.
110. Noting the lack of consensus, CCCF considered as a compromise an ML of 12 µg/kg, however, CCCF could not reach consensus for the same reasons expressed above. A view was also expressed that if the level of 12 µg/kg were agreed to, the MLs for other tree nuts would need to be revised since the MLs of these nuts are based on a JECFA evaluation with an outcome similar to the one for peanuts.
111. CCCF then considered a proposal from the JECFA Secretariat to hold an ML for aflatoxins in RTE peanuts, while producing countries would make clear efforts to implement the *Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Peanuts* (CXC 55-2004) and collect occurrence data. The work could then be taken up again in 3 to 5 years once new data were made available and assessed by JECFA.
112. India, noted that only the MLs of 10 or 15 µg/kg should have been considered by CCCF as agreed by CCCF11. They drew the attention of CCCF to the criteria for work priorities in the Procedural Manual which included the general criterion “consumer protection from the point of view of health, food safety, ensuring fair practices in the food trade and taking into account the identified needs of developing countries.” and the Statements of principle concerning the role of science in the Codex decision-making process and the extent to which other factors are taken into account, in particular bullet point 8 which stated “The integration of other legitimate factors in risk management should not create unjustified barriers to trade¹⁴; particular attention should be given to the impact on developing countries of the inclusion of such other factors.” In view of these provisions and the fact that most countries who supported the ML of 10 µg/kg were developing countries, proposed that this ML should be forwarded to CAC for adoption.
113. India also pointed out that the COP had been available since 2004 and might already be implemented by countries, and that if work were suspended that one year should be given for submission of additional data.
114. However, CCCF noted there was general support for the proposal of the JECFA Secretariat. It was clarified that data should be specifically for RTE peanuts and as moved in trade and that the data should clearly indicate if they referred to RTE or for further processing such as oil production or for feed.

Conclusion

115. CCCF agreed:
- i. to hold the ML of 10 µg/kg at Step 4 (Appendix VII) to ensure implementation of the COP (CXC 55-2004);
 - ii. that JECFA would issue a call for data in three-years' time; and
 - iii. that an EWG would be re-established, once the data were submitted, to prepare a proposal for consideration by CCCF15.

¹⁴ According to the WTO principles, and taking into account the particular provisions of the SPS and TBT Agreements.

PROPOSED DRAFT MAXIMUM LEVEL FOR TOTAL AFLATOXINS AND OCHRATOXIN A IN NUTMEG, CHILI AND PAPRIKA, GINGER, PEPPER AND TURMERIC AND ASSOCIATED SAMPLING PLANS (Agenda Item 11)¹⁵

116. India, as chair of the EWG, introduced the item and informed CCCF that although there was a lack of consensus in the EWG on the MLs for AFT and OTA in the said spices, CCCF could consider, based on low consumption of spices setting an ML of either 30 or 20 µg/kg for AFT and 20 µg/kg for OTA in all spices. Noting the high occurrence levels presented to the EWG, there was a need to reduce mycotoxin levels in spices by implementing the recently adopted *Code of practice for the prevention and reduction of mycotoxins in spices* (CXC 78-2017) and that the MLs, if agreed, could be revised based on new occurrence data following implementation of the COP.

Discussion

117. CCCF considered the proposals and noted the following views:
- support for a level of 20 µg/kg for OTA in the specified spices;
 - support for setting an ML of 20 µg/kg for OTA for chili and paprika, but to set a lower ML for the other spices; or to set MLs only for chili of 30 µg/kg for AFT and 20 µg/kg for OTA;
 - a preference for a level of 15 µg/kg for OTA in the specified spices;
 - a proposal to set MLs for chili for AFT at 30 µg/kg and OTA at 20 µg/kg considering the high contamination rates and that this is a highly international traded commodity;
 - a proposal to set MLs for ginger, pepper and turmeric for AFT and OTA at 20 µg/kg as for the other spices this would result in too much rejection;
 - consideration should be given to MLs for both OTA and AFT with lower rejection rates;
 - the proposals were based on data collected before the implementation of the COP; and
 - a proposal to hold the ML at Step 4 to first allow countries to implement the COP and collect data after implementation of the COP.
118. In view of the range of views, CCCF could not agree on a single figure for the MLs for AFT and OTA in the specified spices.

Conclusion

119. CCCF agreed:
- i. to suspend work and to hold the ML of 20/30 µg/kg for AFT and 20 µg/kg for OTA in nutmeg, chili and paprika, ginger, pepper and turmeric, respectively, at Step 4 (Appendix VIII) to give time to countries to implement the *Code of Practice for the prevention and reduction of mycotoxins in spices* (CXC 78-2017);
 - ii. that JECFA would issue a call for data in three-years' time; and
 - iii. that an EWG would be re-established once the data were submitted to prepare a proposal for consideration by a future CCCF.

PROPOSED DRAFT GUIDELINES FOR RISK ANALYSIS OF CHEMICALS INADVERTENTLY PRESENT IN FOOD AT LOW LEVELS (Agenda Item 12)¹⁶

120. New Zealand, as chair of the EWG, also on behalf of the co-chairs The Netherlands, introduced the item and highlighted the key issues discussed in the EWG. The EWG Chair explained that an informal meeting had taken place prior to the session to address some of the key questions, namely on the scope of the document; whether there was a need for definitions, clarification on the cut-off value(s); the availability of rapid risk assessment methodologies, amongst others, which resulted in a revised Guidelines prepared for discussion which contained proposals for:
- a revised title to clearly illustrate the primary application of the Guidelines and to avoid different interpretations of "emerging contaminants" or "inadvertently present";
 - more concise introduction;

¹⁵ CL 2018/7-CF; CX/CF 18/12/11; CX/CF 18/12/11-Add.1 (Canada, Colombia, Egypt, India, Japan, Kenya, Republic of Korea, Uruguay and USA); CRD11 (EU, Uganda and AU); CRD20 (Indonesia); CRD21 (Mali); CRD22 (Dominican Republic); CRD23 (Nigeria); CRD24 (Senegal); CRD28 (Ghana)

¹⁶ CL 2018/8-CF; CX/CF 18/12/12; CX/CF 18/12/12-Add.1 (Australia, Canada, Colombia, Costa Rica, Egypt, India, Japan, Kenya, Republic of Korea, USA, FoodDrinkEurope, ICGMA, IDF, IOFI and ISDI); CRD04 (CX/CF 18/12/12 in Arabic and Chinese); CRD05 (JECFA Secretariat); CRD12 (EU and AU); CRD21 (Mali); CRD22 (Dominican Republic); CRD26 (revised guidelines - New Zealand proposal); CRD28 (Ghana); CRD31 (Ecuador)

- a clearer scope to illustrate that the Guidelines was aimed at contaminants which fell outside the normal regulatory framework including narrative from the definition section and deletion of the definition; and
- a new section on derivation of cut-off values to better explain how cut-off values should be derived. This section included general considerations as well as criteria for establishment of a cut-off value. An example cut-off value was included for illustrative purposes only.

121. New Zealand further explained that no other rapid risk assessment methods could be identified and the document therefore focused on the TTC methodology only. They also explained that the example for derivation of cut-off value (Annex 2 of Appendix IX) was there for illustrative purposes for the development of the document only, but would not be included in the final document.
122. In view of the changes made and clarifications provided, CCCF agreed to consider the revised proposal as proposed by New Zealand.

Discussion

123. CCCF agreed with the proposals in the revised guidelines, made some editorial and other amendments and made the following comments and additional decisions:
- that the scope needed further refining to clearly indicate that the contaminants under discussion fall outside the scope of contaminants for which a regulatory framework already existed, i.e. for which there was a Codex standard and if not, a national standard. The JECFA Secretariat confirmed that compounds for which there are regulatory requirements, e.g. food additives, pesticides, veterinary drugs, etc. would be excluded from the Guidelines as well as compounds for which there may be health-based guidance value (such a tolerable daily intake) established, and that this should be clearly indicated in the scope.
 - the entry for a cut-off value(s) in section 4 Principles was kept in square brackets as further discussion was needed on the feasibility of establishing a single cut-off value or whether more than one cut-off value would be needed taking into account that different contaminants may have different toxicity levels and foods containing the contaminant may be consumed at significantly different levels in different countries or regions. Also the issue of acute toxicity would need to be considered as the TTC classes were based on chronic toxicity studies. A proposal was also made to consider whether a cut-off value should be mandatory.
 - Clarification was also provided by the JECFA Secretariat that the exclusion categories listed in section 8.1 Exclusion categories are excluded from the TTC approach since they were not covered in the databases from which the exposure class thresholds, the TTC values, were derived.
 - As the Guidelines are intended for application by governments, reference to relevant Codex texts, rather than specific Codex committees (e.g. CCCF, CCFICS) would be more appropriate. In this regard, the reference to the mandate of CCCF was not appropriate and text should rather be developed to explain the meaning of contaminants excluded from these Guidelines (section 3 Scope). Along the same lines, texts developed by CCFICS should be included as references instead of the current formulation of the text in section 8.9 decision by the risk manager.

Conclusion

124. CCCF agreed:
- i. to advance the Guidelines to Step 5 for adoption by CAC41 (Appendix IX);
 - ii. to re-establish the EWG, chaired by New Zealand and co-chaired by The Netherlands, working in English only, to further develop the Guidelines especially those parts remaining in square brackets for consideration at the next session; and
 - iii. to keep open the possibility of a PWG, chaired by New Zealand and The Netherlands, to meet immediately before the next session of CCCF, to consider written comments submitted and prepare a revised proposal for consideration by CCCF13.

DISCUSSION PAPER ON MAXIMUM LEVEL(S) FOR HYDROCYANIC ACID IN CASSAVA AND CASSAVA-BASED PRODUCTS AND MYCOTOXIN CONTAMINATION IN THESE PRODUCTS (Agenda Item 13)¹⁷

125. CCCF:

- recalled that CCCF11 agreed to establish a EWG chaired by Nigeria to address HCN and mycotoxin contamination in cassava and cassava-based products.
- deferred the discussion until next year in the absence of the EWG Chair to present the item at the current session and encouraged Codex members to continue submitting data to GEMS/Food.

DISCUSSION PAPER ON FUTURE WORK ON MAXIMUM LEVELS FOR LEAD FOR INCLUSION IN THE GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOOD AND FEED (CXS 193-1995) (Agenda Item 14)¹⁸

126. Brazil, as Chair of the EWG, introduced the item and drew the attention of CCCF to the recommendations in paragraph 25 of the document for consideration by CCCF namely: (i) to agree on the prioritization criteria, (ii) to decide on the prioritized list of commodities and (iii) to provide comments on additional food categories (for which there are data in support of the establishment of an ML) or transfer of food categories within the identified high, intermediate and low priority commodities.
127. CCCF recalled the decision of CCEXEC73¹⁹ that CCCF not propose further work on the development of new MLs for lead for inclusion in the GSCTFF until work on the revision of existing MLs in the general standard was completed.

Prioritization criteria

128. CCCF agreed the prioritization criteria outlined in paragraphs 14-17 of CX/CF 18/12/14 were helpful, but in examining the proposed prioritization of categories as identified in Table 4 of CX/CF 18/12/14, noted the need to take exposure data into account when establishing priorities as occurrence and trade data alone did not fully capture those commodities with high contribution to the exposure.
129. The JECFA Secretariat confirmed that JECFA would publish a call for occurrence data for lead in the categories listed and encouraged Member countries to submit such data.

Prioritized commodities

130. CCCF discussed the list of commodities prioritized in high, intermediate and low categories and made proposals for additions or relocation of commodities taking into account their contribution to lead exposure and relevance in international trade. In this regard, the following views were provided by delegations:
- Algae and seaweeds was prioritized in intermediate priority list with high occurrence level without any trade information. In recognition of the growing trade of these products on the international market, CCASIA is currently developing a standard for laver products. There are trade data available in support to place it in the high priority commodities.
 - The limited contribution of cocoa and cocoa products and tea and herbs/fruits for infusions would not justify their inclusion in the high priority list. Furthermore, MLs for dried fruits and vegetables can be derived from the corresponding fresh fruits / vegetables by applying processing factors, therefore there is no need to set separate MLs for fresh and dried fruits.
 - Confectionary products should be considered for inclusion in the high priority list based on relevance to international trade and consumption patterns from sensitive groups such as children.

Conclusion

131. CCCF:

- agreed to establish an EWG led by Brazil, working in English, to prepare for CCCF13 a revised discussion paper and project document which also took into consideration exposure data (in addition to other criteria for prioritization of commodities) in establishing the prioritization categories for MLs, and to propose, if feasible, MLs for the categories indicated with a focus on commodities identified as high in the priority list; and

¹⁷ CX/CF 18/12/13; CRD13 (EU, Uganda and USA); CRD20 (Indonesia); CRD22 (Dominican Republic); CRD23 (Nigeria)

¹⁸ CX/CF 18/12/14; CRD14 (EU, Kenya, Malaysia, Republic of Korea, Uganda, USA and AU); CRD19 (Thailand); CRD20 (Indonesia); CRD21 (Mali); CRD22 (Dominican Republic); CRD28 (Ghana)

¹⁹ REP17/EXEC2 para. 56(ii)

- ii. noted that the JECFA Secretariat would issue a call for occurrence data for lead in the categories listed (CX/CF 18/12/14, Table 4) and encouraged Member countries to submit data to GEMS/Foods to assist in the development of the discussion paper and decision at CCCF13 on new work on MLs for lead for the categories identified as high priority.

DISCUSSION PAPER ON AFLATOXINS AND STERIGMATOCYSTIN CONTAMINATION IN CEREALS (Agenda Item 15)²⁰

132. Brazil as Chair of the EWG introduced the item and highlighted the work of the EWG and the three recommendations presented in the document. Due to the toxicity and occurrence of aflatoxins in widely consumed foods, a proposal was made to set MLs for aflatoxins in cereals and cereal-based foods including foods for infants and young children; it was premature to set MLs for STC due to the lack of an internationally validated analytical method and reference material for this mycotoxin; and consideration could be given to development of an annex to *Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals* (CXC 51 - 2003) if there are specific management practices available for STC in cereals.

Recommendation 1 – new work on ML(s) for aflatoxins in cereals and cereal-based foods including foods for infants and young children

133. CCCF noted the views CXC 51 - 2003 had been revised, including a specific annex for aflatoxins in 2016. It was therefore appropriate that the revised COP should be implemented for some period of time and updated occurrence data collected before beginning work on new MLs, also considering the workload of CCCF and that there were no current concerns for international trade.
134. CCCF noted that it was necessary to distinguish the categories of cereals for which MLs were to be set, to be specific in the commodities²¹ and what data were representative of which commodity. It was also necessary to be clear in the scope of the proposed new work that the focus would be on total aflatoxins for grains or on products made from grains, for human consumption and that the impact of proposed MLs on grain availability also be considered. Some Delegations stressed the need to define the types of rice (grain, husked or polished rice) and that aflatoxins were rarely found on white or polished rice.
135. The JECFA Secretariat noted concerns from a public health point of view when dealing with such potent contaminants in staple foods. CCCF had specifically requested the work and the call for data had been targeted to these commodities and a large number of occurrence data received from all over the world. It would be appropriate to develop MLs for the key cereals listed for which sufficient data are available and indicating higher levels of contamination.
136. The JECFA Secretariat suggested that work should first focus on maize, rice, sorghum and wheat, and propose MLs at CCCF13, both for the commodity itself and for the products derived from them, such as flour as well as cereal-based foods for infants and young children.
137. CCCF noted the view that the work should examine flour and grains and then cereal-based foods for infants and young children, both for public health and trade concerns.

Conclusion

138. CCCF agreed to establish an EWG, chaired by Brazil and co-chaired by India, working in English, reporting to CCCF13, to further develop the discussion paper and provide proposed MLs for total aflatoxins in wheat, maize, sorghum and rice (specifying the categories) for grains for human consumption. The EWG should also propose MLs for flour and cereal-based foods for infants and young children.

Validated method of analysis for STC

139. CCCF agreed to inform the SDOs of the need for an internationally validated method of analysis for STC through CCMAS.

Annex on STC in the *Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals* (CXC 51 - 2003)

140. CCCF agreed that there was insufficient information for the development of an annex and that no action was needed at this stage.

²⁰ CX/CF 18/12/15; CRD15 (EU, Kenya, Republic of Korea, Uganda, USA and AU); CRD19 (Thailand); CRD20 (Indonesia); CRD21 (Mali); CRD28 (Ghana)

²¹ e.g. distinct types of rice

DISCUSSION PAPER ON THE DEVELOPMENT OF A CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF CADMIUM CONTAMINATION IN COCOA (Agenda Item 16)²²

141. Peru, as Chair of the EWG, presented the item and stressed the usefulness of administering a survey to gather information on validated practices throughout the food chain for the prevention and reduction of cadmium contamination in cocoa prior to starting new work on the development of a COP. To gather this information, CCCF agreed that a circular letter would be prepared for the survey and distributed by the Codex Secretariat.
142. The view was expressed that in the conclusions the only points that should be listed are those which are relevant for the development of the COP and that the statement that 'human intake of cocoa is low, so health risks from exposure to cadmium through cocoa consumption are low and not considered to be a health concern' should not be counted in the conclusions.
143. The JECFA Secretariat requested CCCF to pay a particular attention to mitigation measures that would be feasible even for small-scale farmers to apply since they were the ones affected most by this issue.

Conclusion

144. CCCF agreed to re-establish an EWG chaired by Peru, co-chaired by Ghana and Ecuador, working in English and Spanish, to further elaborate the discussion paper to:
- i. determine whether mitigation measures available at present would support the development of the COP; and
 - ii. identify the scope of the COP (e.g. whether the COP will cover the whole production chain or only primary production) based on the replies provided to the survey.
145. If the conditions under i) and ii) above are met, then the EWG should provide a project document and a first draft of a COP.
146. The EWG should focus its work on mitigation measures that are proven to be cost-effective and applicable worldwide by large and small-scale producers.

PRIORITY LIST OF CONTAMINANTS AND NATURALLY OCCURRING TOXICANTS FOR EVALUATION BY JECFA (Agenda Item 17)²³

147. The United States of America, as Chair of the in-session WG, presented the report on the outcome of the discussion on the priority list.

Conclusion

148. CCCF:
- i. accepted the recommendations of the in-session WG and endorsed the priority list of contaminants and naturally occurring toxicants for JECFA evaluation as amended (Appendix X) and agreed to reconvene the in-session WG at its next session; and
 - ii. agreed to continue to request comments and/or information on the priority list for consideration by CCCF13.

FORWARD WORK PLAN FOR THE COMMITTEE ON CONTAMINANTS IN FOODS (Agenda Item 18)²⁴

149. The Codex Secretariat introduced the item and recalled that CCCF11 agreed to consider a forward work plan to manage (prioritize) its overall work in order to address increase requests for new work from Codex members in reasonable time. The Secretariat noted that the paper summarizes good practices in place applied by CCCF in prioritizing different aspects of their work (e.g. ongoing work in the Step Procedure, follow-up to JECFA evaluations, request for JECFA safety evaluation of contaminants, etc.).
150. The Secretariat underlined the importance for CCCF to operate strategically by prioritizing items within its workload, and explained that CCCF might benefit from applying an approach that looks at the overall workload of CCCF, including the ability of CCCF to complete the work within a reasonable timeframe, taking into account the data needs, data gaps, availability of missing data in a reasonable timeframe, and the need for scientific advice (JECFA priorities). In this way, CCCF would be able to keep a balance between ongoing work and proposals for new work within the time available for plenary sessions and to strategize the agenda for future meetings. The plan was not intended to leave out work, but to prioritize work so that all work had the same opportunity for discussion and completion with a reasonable timeframe.

²² CX/CF 18/12/16; CRD16 (EU, Kenya, Uganda, USA and AU); CRD21 (Mali); CRD28 (Ghana); CRD29 (El Salvador)

²³ REP17/CF Appendix XII; CX/CF 18/12/17 (Brazil and Canada); CRD02 (report of the in-session WG on priorities); CRD17 (Philippines); CRD21 (Mali); CRD28 (Ghana)

²⁴ CX/CF 18/12/18

151. The Secretariat highlighted that the work plan would also avoid the need of additional physical meetings prior to the plenary (with the subsequent extension of the duration of the meeting and associated costs for Codex members and observers) and would address the recommendations of CCEXEC as to the management of the overall work of CCCF. The Secretariat further noted that the Critical Review performed by CCEXEC looked at the overall work of Codex committees, which includes work in the Step Procedure and other additional work such as consideration of discussion papers.
152. Views were expressed that more time was needed for reflection on how to proceed with a forward work plan for CCCF; that this matter had been previously addressed in response to a request from CCEXEC and that no further action was needed since CCCF already had sufficient processes in place to manage its work. Developing a scoring system to prioritise work could prove difficult especially when trying to determine what was important for public health. There was more benefit in having well-developed discussion papers and project documents on which decisions for new work could be based.
153. The Representative of WHO proposed that there might be real value in longer term forward planning, by systematically identifying areas for food contamination of concern for public health and with trade implications, e.g. starting with key staple foods and known contamination problems. This would allow delegates to work within their countries on information and data gathering well in advance before topics come on the agenda of CCCF.

Conclusion

154. CCCF agreed that a further discussion paper would be prepared by the Codex, JECFA and the Host Country Secretariats with assistance of EU. The paper would focus on whether CCCF covered the main staple foods moving in international trade and the related presence of contaminants being of public health concern.

Proposal for the development of a general guidance on data analysis for ML development

155. CCCF considered the proposal of the JECFA Secretariat to develop a general guidance on data analysis for ML development as it was observed that different approaches were taken by the EWGs for the current session. These differences concerned for example the handling of occurrence data without information on LOQ. A general guidance would help future EWGs to take consistent approaches for data analysis.

Conclusion

156. CCCF agreed to establish an EWG chaired by EU, co-chaired by the United States of America, the Netherlands and Japan, working in English, to prepare a discussion paper.

OTHER BUSINESS AND FUTURE WORK (Agenda Item 19)

Proposal for new work on the revision of the *Code of Practice for the Prevention and Reduction of Lead Contamination in Foods (CXC 56-2004)*

157. The United States of America introduced their proposal for new work.
158. The purpose of the proposed new work is 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 MLs for lead in selected commodities in the GSCTFF and future work on MLs for lead for inclusion in the GSCTFF.
159. The scope of the work would encompass the updating of the existing 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).

Conclusion

160. CCCF agreed to establish an EWG chaired by the United States of America, co-chaired by the United Kingdom, working in English, to prepare a discussion paper including a project document for a proposal for new work on the revision of the COP for consideration by CCCF13.

Timely availability of working papers and translation of comment papers

161. The Chair drew the attention of CCCF to the late availability of working documents and the subsequent very limited time for comments and increase in translation costs. The Chair indicated that for those working documents submitted after the deadline established by the Codex Secretariat, the comments would be distributed in original language only. She further noted that timely submission of working documents would ensure ample time for providing comments and their translation and would limit proliferation of CRDs.

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

162. CCCF was informed that CCCF13 was scheduled to be held in Yogyakarta, Indonesia in approximately one year's time, the final arrangements being subject to confirmation by the Host Country and the Codex Secretariats.
163. Indonesia thanked the Host Country for the opportunity to provide the co-hosting of CCCF and invited all delegates to attend the upcoming session of CCCF.

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APPENDIX II**REVISION OF THE GSCTFF (CXC 193-1995)****MLs FOR LEAD IN SELECTED COMMODITIES FOR ACTION BY CAC41:
ADOPTION AT STEP 5/8, REVOCATION AND AMEDMENTS**

Commodity / Product Name	MLs (mg/kg) at Step 5/8 (with omission of Steps 6/7) for adoption by CAC41 are shown in bold and underline	MLs for revocation by CAC41 are shown strikethrough	Portion of the Commodity / Product to which the ML applies	Notes/Remarks Text for amendment by CAC41 are either in bold and underline (additions – fruit juices) or strikethrough (removal – canned vegetables)
Fruit juices obtained exclusively from berries and other small fruits	---	0.05	Whole commodity (not concentrated) or commodity reconstituted to the original juice concentration, ready to drink. The ML applies also to nectars, ready to drink.	FOR AMENDMENT BY CAC41 <u>The ML does not apply to grape juice</u> Relevant Codex commodity standard is CXS 247-2005.
<u>Grape juice</u>	<u>0.04</u>	---	<u>Whole commodity (not concentrated) or commodity reconstituted to the original juice concentration, ready to drink. The ML applies also to nectars, ready to drink.</u>	<u>Relevant Codex commodity standard is CXS 247-2005.</u>
<u>Processed tomato concentrates</u>		1.5		<u>Relevant Codex commodity standard is CXS 57-1981.</u>
Mango chutney	<u>0.4</u>	4		Relevant Codex commodity standard is CXS 160-1987.
Canned vegetables	---	0.1	The ML applies to the product as consumed.	FOR AMENDMENT BY CAC41 <u>The ML does not apply to canned brassica vegetables</u> Relevant Codex commodity standard is CXS 297-2009.
<u>Fresh farmed mushrooms (common mushrooms (<i>Agaricus bisporus</i>), shiitake mushrooms (<i>Lentinula edodes</i>), and oyster mushrooms (<i>Pleurotus ostreatus</i>))</u>	<u>0.3</u>	---	<u>Whole commodity</u>	<u>Relevant Codex commodity standard is CXS 38-1981</u>
Salt, food grade	<u>1</u>	2	Whole commodity as prepared for wholesale or retail distribution	Relevant Codex commodity standard is CXS 150-1985. <u>Excluding salt from marshes</u>
Fat spreads and blended spreads	<u>0.04</u>	0.4	Whole commodity as prepared for wholesale or retail distribution	Relevant Codex commodity standard is CXS 256-2007.
Edible fats and oils	<u>0.08</u>	0.4	Whole commodity as prepared for wholesale or retail distribution.	Relevant Codex commodity standards are CXS 19-1981, CXS 33-1981, CXS 210-1999, CXS 211-1999 and CXS 329-2017

APPENDIX III**PROPOSED DRAFT MAXIMUM LEVELS FOR CADMIUM
IN CHOCOLATES AND COCOA-DERIVED PRODUCTS****(AT STEP 5/8)****Proposal for maximum levels for cadmium in chocolates**

Commodity / Product Name	Maximum Level (ML) mg/kg	Portion of the Commodity / Product to which the ML applies	Notes / Remarks
Chocolate containing or declaring $\geq 50\%$ to $< 70\%$ total cocoa solids on a dry matter basis	0.8	Whole commodity as prepared for wholesale or retail distribution	Including sweet chocolate, Gianduja chocolate, semi – bitter table chocolate, Vermicelli chocolate / chocolate flakes, and bitter table chocolate.
Chocolate containing or declaring $\geq 70\%$ total cocoa solids on a dry matter basis	0.9	Whole commodity as prepared for wholesale or retail distribution	

APPENDIX IV-PART A

**PROPOSED DRAFT MAXIMUM LEVELS FOR METHYLMERCURY IN FISH
INCLUDING ASSOCIATED SAMPLING PLANS**

(AT STEP 5/8)

MLs FOR METHYLMERCURY IN THE FOLLOWING SPECIES OF FISH

Commodity / Product Name	Maximum Level (ML) (mg/kg)	Portion of the Commodity/Product to which the ML Applies	Notes/Remarks
Tuna	1.2	Whole commodity fresh or frozen (in general after removing the digestive tract)	<p>Countries or importers may decide to use their own screening when applying the ML for methylmercury in fish by analysing total mercury in fish. If the total mercury concentration is below or equal to the ML for methylmercury, no further testing is required and the sample is determined to be compliant with the ML. If the total mercury concentration is above the ML for methylmercury, follow-up testing shall be conducted to determine if the methylmercury concentration is above the ML.</p> <p>The ML also applies to fresh or frozen fish intended for further processing.</p> <p>Countries should consider developing nationally relevant consumer advice for women of childbearing age and young children to supplement the ML.</p>
Alfonsino	1.5		
Marlin	1.7		
Shark	1.6		

APPENDIX IV-PART B**PROPOSED DRAFT SAMPLING PLAN FOR METHYLMERCURY CONTAMINATION IN FISH**

(for endorsement by CCMAS)

DEFINITIONS

The following definitions should apply:

Lot	An identifiable quantity of a food commodity delivered at one time and determined by the official to have common characteristics, such as origin, variety, type of packing, packer, consignor, or markings.
Sublot	Designated part of a larger lot in order to apply the sampling method on that designated part. Each sublot must be physically separate and identifiable.
Incremental sample	The quantity of material taken from a single random place in the lot or sublot.
Aggregate sample	The combined total of all the incremental samples that is taken from the lot or sublot. The aggregate sample has to be at least as large as the laboratory sample or samples combined.
Laboratory sample	A sample intended for a laboratory.

SAMPLING METHODS**GENERAL PROVISIONS****Personnel**

Sampling should be performed by an authorised person as designated by the national authority.

Material to be sampled

Each lot or sublot which is to be examined should be sampled separately.

Precautions to be taken

In the course of sampling, precautions should be taken to avoid any changes which would affect the levels of contaminants, adversely affect the analytical determination or make the aggregate samples unrepresentative.

Incremental samples

As far as possible, incremental samples should be taken at various places distributed throughout the lot or sublot.

Preparation of the aggregate sample

The aggregate sample should be made up by combining the incremental samples.

Samples for enforcement, defence and referee purposes

The samples for enforcement, defence and referee purposes should be taken from the homogenised aggregate sample unless this conflicts with the rules of the national authority as regards the rights of the food business operator.

Packaging and transmission of samples

Each sample should be placed in a clean, inert container offering adequate protection from contamination, from loss of analytes by adsorption to the internal wall of the container and against damage in transit. All necessary precautions should be taken to avoid any change in composition of the sample which might arise during transportation or storage.

Sealing and labelling of samples

Each sample taken for official use should be sealed at the place of sampling and identified following the locally applicable rules.

A record should be kept of each sampling, permitting each lot or sublot to be identified unambiguously (reference to the lot number should be given) and giving the date and place of sampling together with any additional information likely to be of assistance to the analyst.

SAMPLING PLAN

Division of lots into sublots

Large lots should be divided into sublots on condition that the subplot may be separated physically. For products traded in bulk consignments Table 1 should apply. For other products Table 2 should apply. Taking into account that the weight of the lot is not always an exact multiple of the weight of the sublots, the weight of the subplot may exceed the mentioned weight by a maximum of 20%.

Number of incremental samples

The aggregate sample should be at least 1 kg except where it is not possible, e.g. when the sample consists of 1 package or unit.

The minimum number of incremental samples to be taken from the lot or subplot should be as given in Table 3.

The incremental samples should be of similar weight/volume. The weight/ volume of an incremental sample should be at least 100 grams, resulting in an aggregate sample of at least about 1 kg. Departure from this method should be recorded.

Table 1 Subdivision of lots into sublots for products traded in bulk consignments

Lot weight (ton)	Weight or number of sublots
$\geq 1\ 500$	500 tonnes
> 300 and $< 1\ 500$	3 sublots
≥ 100 and ≤ 300	100 tonnes
< 100	—

Table 2 Subdivision of lots into sublots for other products

Lot weight (ton)	Weight or number of sublots
≥ 15	15-30 tonnes
< 15	—

Table 3 Minimum number of incremental samples to be taken from the lot or subplot

Weight or volume of lot/sublot (in kg)	Minimum number of incremental samples to be taken
< 50	3
≥ 50 and ≤ 500	5
> 500	10

If the lot or subplot consists of individual packages or units, then the number of packages or units which should be taken to form the aggregate sample is given in Table 4.

Table 4 Number of packages or units (incremental samples) which should be taken to form the aggregate sample if the lot or subplot consists of individual packages or units

Number of packages or units in the lot/ subplot	Number of packages or units to be taken
≤ 25	at least 1 package or unit
26-100	about 5%, at least 2 packages or units
> 100	about 5%, at maximum 10 packages or units

Specific provisions for the sampling of large fish arriving in large lots

In case the lot or subplot to be sampled contains large fish (individual fish weighing more than about 1 kg) and the lot or subplot weighs more than 500 kg, the incremental sample should consist of the middle part of the fish. Each incremental sample should weigh at least 100 g.

SAMPLING AT RETAIL STAGE

Sampling of foodstuffs at retail stage should be done where possible in accordance with the sampling provisions set out in this sampling plan.

Where it is not possible to carry out the method of sampling set out above because of the unacceptable commercial consequences (e.g. because of packaging forms, damage to the lot, etc.) or where it is practically impossible to apply the abovementioned method of sampling, an alternative method of sampling may be applied provided that it is sufficiently representative for the sampled lot or subplot and is fully documented.

SAMPLE PREPARATION AND ANALYSIS

LABORATORY QUALITY STANDARDS

Laboratories should be able to demonstrate that they have internal quality control procedures in place. Examples of these are the 'ISO/ AOAC/IUPAC Guidelines on Internal Quality Control in Analytical Chemistry Laboratories'¹.

Wherever possible the trueness of analysis should be estimated by including suitable certified reference materials in the analysis.

Precautions and general considerations

The basic requirement is to obtain a representative and homogeneous laboratory sample without introducing secondary contamination.

All of the sample material received by the laboratory should be used for the preparation of the laboratory sample.

Compliance with maximum levels laid down in the General Standard for Contaminants and toxins in Food and Feed should be established on the basis of the levels determined in the laboratory samples.

Specific sample preparation procedures

The analyst should ensure that samples do not become contaminated during sample preparation. Wherever possible, apparatus and equipment coming into contact with the sample should not contain mercury and be made of inert materials, e.g. plastics such as polypropylene, polytetrafluoroethylene (PTFE) etc. These should be acid cleaned to minimise the risk of contamination. High quality stainless steel may be used for cutting edges.

There are many satisfactory specific sample preparation procedures which may be used for the products under consideration. For those aspects not specifically covered by this sampling plan, the CEN Standard 'Foodstuffs. Determination of elements and their chemical species. General considerations and specific requirements'² has been found to be satisfactory but other sample preparation methods may be equally valid.

¹ Edited by M. Thompson and R. Wood, Pure Appl. Chem., 1995, 67, 649-666.

² Standard EN 13804:2013, 'Foodstuffs. Determination of elements and their chemical species. General considerations and specific requirements', CEN, Rue de Stassart 36, B-1050 Brussels.

Treatment of the sample as received in the laboratory

The complete aggregate sample should be finely ground (where relevant) and thoroughly mixed using a process that has been demonstrated to achieve complete homogenisation.

Samples for enforcement, defence and referee purposes

The samples for enforcement, defence and referee purposes should be taken from the homogenised material unless this conflicts with the applicable rules at the national level on sampling as regards the rights of the food business operator.

METHODS OF ANALYSIS

Definitions

r	Repeatability the value below which the absolute difference between single test results obtained under repeatability conditions (i.e., same sample, same operator, same apparatus, same laboratory, and short interval of time) may be expected to lie within a specific probability (typically 95%) and hence $r = 2,8 \times s r$.
s r	Standard deviation calculated from results generated under repeatability conditions.
RSD r	Relative standard deviation calculated from results generated under repeatability conditions $[(s r /) \times 100]$.
R	Reproducibility the value below which the absolute difference between single test results obtained under reproducibility conditions (i.e., on identical material obtained by operators in different laboratories, using the standardised test method), may be expected to lie within a certain probability (typically 95%); $R = 2,8 \times s R$.
s R	Standard deviation, calculated from results under reproducibility conditions. 'RSD R' = Relative standard deviation calculated from results generated under reproducibility conditions $[(s R /) \times 100]$.
LOD	Limit of detection, smallest measured content, from which it is possible to deduce the presence of the analyte with reasonable statistical certainty. The limit of detection is numerically equal to three times the standard deviation of the mean of blank determinations ($n > 20$).
LOQ	Limit of quantification, lowest content of the analyte which can be measured with reasonable statistical certainty. If both accuracy and precision are constant over a concentration range around the limit of detection, then the limit of quantification is numerically equal to 10 times the standard deviation of the mean of blank matrix determinations ($n \geq 20$).
HORRAT³ r	The observed RSD r divided by the RSD r value estimated from the (modified) Horwitz equation (2) (cf. point C.3.3.1 ('Notes to the performance criteria')) using the assumption $r = 0,66 R$.
HORRAT⁴ R	The observed RSD R divided by the RSD R value estimated from the (modified) Horwitz equation ⁵ (cf. point 'Notes to the performance criteria').
u	Combined standard measurement uncertainty obtained using the individual standard measurement uncertainties associated with the input quantities in a measurement model ⁶
U	The expanded measurement uncertainty, using a coverage factor of 2 which gives a level of confidence of approximately 95% ($U = 2u$).
Uf	Maximum standard measurement uncertainty.

³ Horwitz W. and Albert, R., 2006, The Horwitz Ratio (HorRat): A useful Index of Method Performance with respect to Precision, Journal of AOAC International, Vol. 89, 1095-1109. (2) M. Thompson, Analyst, 2000, p. 125 and 385-386.

⁴ Horwitz W. and Albert, R., 2006, The Horwitz Ratio (HorRat): A useful Index of Method Performance with respect to Precision, Journal of AOAC International, Vol. 89, 1095-1109.

⁶ International vocabulary of metrology – Basic and general concepts and associated terms (VIM), JCGM 200:2008.

General requirements

Methods for analysis for total mercury are appropriate for screening purpose for control on methylmercury levels. If the total mercury concentration is below or equal to the maximum level for methylmercury, no further testing is required and the sample is considered to be compliant with the maximum level for methylmercury. If the total mercury concentration is at or above the maximum level for methylmercury, follow-up testing should be conducted to determine if the methylmercury concentration is above the maximum level for methylmercury.

Specific requirements

Performance criteria

Where no specific methods for the determination of contaminants in foodstuffs are prescribed at the Codex level, laboratories may select any validated method of analysis for the respective matrix provided that the selected method meets the specific performance criteria set out in Table 5.

It is recommended that fully validated methods (i.e. methods validated by collaborative trial for the respective matrix) are used where appropriate and available. Other suitable validated methods (e.g. in-house validated methods for the respective matrix) may also be used provided that they fulfil the performance criteria set out in Tables 5.

Where possible, the validation of in-house validated methods should include a certified reference material.

Table 5 Performance criteria for methods of analysis of mercury and methylmercury

Parameter	Criterion		
Applicability	Fish specified in the General Standard for Contaminants and Toxins in Food and Feed (GSCTFF, CXS 193-1995)		
Specificity	Free from matrix or spectral interferences		
Repeatability (RSD _r)	HORRAT _r less than 2		
Reproducibility (RSD _R)	HORRAT _R less than 2		
Recovery	The provisions of 'Recovery calculations' apply		
LOD	= three tenths of LOQ		
LOQ	Methylmercury	ML is < 0,100mg/kg	ML is ≥ 0,100 mg/kg
		≤ two fifths of the ML	≤ one fifth of the ML

Notes to the performance criteria:

The Horwitz equation⁷ (for concentrations $1,2 \times 10^{-7} \leq C \leq 0,138$) and the modified Horwitz equation⁸ (for concentrations $C < 1,2 \times 10^{-7}$) are generalised precision equations which are independent of analyte and matrix but solely dependent on concentration for most routine methods of analysis.

Modified Horwitz equation for concentrations $C < 1,2 \times 10^{-7}$:

$$RSD R = 22\%$$

where:

- RSD R is the relative standard deviation calculated from results generated under reproducibility conditions $[(s R /) \times 100]$
- C is the concentration ratio (i.e. 1 = 100 g/100 g, 0,001 = 1 000 mg/kg). The modified Horwitz equation applies to concentrations $C < 1,2 \times 10^{-7}$.

⁷ W. Horwitz, L.R. Kamps, K.W. Boyer, J.Assoc.Off.Analy.Chem.,1980, 63, 1344.

⁸ M. Thompson, Analyst, 2000, p. 125 and 385-386.

Horwitz equation for concentrations $1,2 \times 10^{-7} \leq C \leq 0,138$:

$$\text{RSD R} = 2C^{(-0,15)}$$

where:

- RSD R is the relative standard deviation calculated from results generated under reproducibility conditions $[(s R /) \times 100]$
- C is the concentration ratio (i.e. 1 = 100 g/100 g, 0,001 = 1 000 mg/kg). The Horwitz equation applies to concentrations $1,2 \times 10^{-7} \leq C \leq 0,138$.

Fitness-for-purpose' approach

For in-house validated methods, as an alternative a 'fitness-for-purpose' approach⁹ may be used to assess their suitability for official control. Methods suitable for official control must produce results with a combined standard measurement uncertainty (u) less than the maximum standard measurement uncertainty calculated using the formula below:

$$U_f = \sqrt{(\text{LOD}/2)^2 + (\alpha C)^2}$$

where:

- U_f is the maximum standard measurement uncertainty ($\mu\text{g}/\text{kg}$).
- LOD is the limit of detection of the method ($\mu\text{g}/\text{kg}$). The LOD must meet the performance criteria set in point C.3.3.1 for the concentration of interest.
- C is the concentration of interest ($\mu\text{g}/\text{kg}$);
- α is a numeric factor to be used depending on the value of C. The values to be used are given in Table 6.

Table 6 Numeric values to be used for α as constant in formula set out in this point, depending on the concentration of interest

C ($\mu\text{g}/\text{kg}$)	α
≤ 50	0,2
51-500	0,18
501-1 000	0,15
1 001-10 000	0,12
$> 10 000$	0,1

Table 7: Calculated performance criteria for $ML \geq 0.1 \text{ mg}/\text{kg}$

	ML mg/kg	LOD mg/kg	LOQ mg/kg	Min. applicable range		Precision RSDR (%)
				From mg/kg	To mg/kg	
All Tuna	1.2	0.12	0.24	0.64	1.76	31.1
Alfonsino	1.5	0.15	0.3	0.823	2.177	30.1
All Marlin	1.7	0.17	0.34	0.947	2.453	29.5
Shark	1.6	0.16	0.32	0.885	2.315	29.8

⁹ M. Thompson and R. Wood, *Accred. Qual. Assur.*, 2006, p. 10 and 471-478.

REPORTING AND INTERPRETATION OF RESULTS

Expression of results

The results should be expressed in the same units and with the same number of significant figures as the maximum levels laid down in the *General Standard for Contaminants and Toxins in Food and Feed* (GSCTFF) (CXS 193-1995).

Recovery calculations

If an extraction step is applied in the analytical method, the analytical result should be corrected for recovery. In this case the level of recovery must be reported.

In case no extraction step is applied in the analytical method, the result may be reported uncorrected for recovery if evidence is provided by ideally making use of suitable certified reference material that the certified concentration allowing for the measurement uncertainty is achieved (i.e. high accuracy of the measurement), and thus that the method is not biased. In case the result is reported uncorrected for recovery this should be mentioned.

Measurement uncertainty

The analytical result should be reported as $x \pm U$ whereby x is the analytical result and U is the expanded measurement uncertainty, using a coverage factor of 2 which gives a level of confidence of approximately 95% ($U = 2u$).

INTERPRETATION OF RESULTS

Acceptance of a lot/sublot

The lot or subplot is accepted if the analytical result of the laboratory sample does not exceed the respective maximum level as laid down in the *General Standard for Contaminants and Toxins in Food and Feed* (GSCTFF, CXS 193-1995), taking into account the expanded measurement uncertainty and correction of the result for recovery if an extraction step has been applied in the analytical method used.

Rejection of a lot/sublot

The lot or subplot is rejected if the analytical result of the laboratory sample exceeds beyond reasonable doubt the respective maximum level as laid down in the *General Standard for Contaminants and Toxins in Food and Feed* (GSCTFF, CXS 193-1995), taking into account the expanded measurement uncertainty and correction of the result for recovery if an extraction step has been applied in the analytical method used.

Applicability

The present interpretation rules should apply for the analytical result obtained on the sample for enforcement. In case of analysis for defence or reference purposes, the locally applicable rules should apply.

APPENDIX V**PROPOSED DRAFT REVISION OF THE CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF DIOXINS, DIOXIN-LIKE PCBs AND NON-DIOXIN-LIKE PCBs IN FOOD AND FEED (CXC 62-2006)****(AT STEP 5/8)****INTRODUCTION****General remarks**

1. Dioxins, including polychlorinated dibenzo-p-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs) and dioxin-like polychlorinated biphenyls (DL-PCBs) and non-dioxin-like PCBs (NDL-PCBs) are persistent organic pollutants (POPs) in the environment. Although dioxins and DL-PCBs show similarities in their toxicological and chemical behaviour, their sources are different. On the other hand while DL-PCBs and NDL-PCBs show a different toxicological behaviour, their sources are similar or the same. The NDL-PCBs account for the majority of the total PCB contamination, the remainder being DL-PCBs.
2. Current sources of dioxins and PCBs entering the food chain include new emissions and remobilisation of deposits or reservoirs in the environment. New emissions are mainly via the air route. Dioxins and PCBs decompose very slowly in the environment and remain there for very long periods of time. Therefore, a large part of current exposure is due to releases of dioxins and PCBs that occurred in the past.
3. PCBs were produced intentionally and in considerable amounts between the 1930s and 1970s and were used in a wide range of applications. PCBs are still in use in existing closed systems in certain countries and contained in solid matrices (e.g. sealing materials and electrical capacitors). Certain commercial PCBs are known to be contaminated with PCDFs and could therefore be regarded as a potential source for dioxin contamination.
4. Today, release of PCBs occurs from leakages, accidental spills and illegal disposal and through emissions via air from thermal processes. The emission of PCBs from paints and/or sealants into the environment e. g. during demolition and reconstruction of older buildings appears to be of some importance as a source.
5. Dioxins are formed as unwanted by-products from a number of human activities including certain industrial processes (e.g. production of chemicals, metallurgical industry) and combustion processes (e.g. waste incineration). Accidents at chemical factories have been shown to result in high emissions and contamination of local areas. Other dioxin sources include domestic furnaces as well as agricultural burning of harvest residues and backyard burning of household wastes. Natural processes such as volcanic eruptions and forest fires can also produce dioxins.
6. When released into the air, dioxins can deposit locally on plants and on soil, consequently contaminating both food and feed. Dioxins can also be widely distributed by long-range atmospheric transport. The amount of deposition varies with proximity to the source, plant species, weather conditions and other specific conditions (e.g. altitude, latitude, temperature).
7. Sources of dioxins in soil include deposition from atmospheric dioxins, application of contaminated sewage sludge to farm land, flooding of pastures with contaminated sludge, and prior use of contaminated pesticides (e.g., 2,4,5-trichlorophenoxy acetic acid) and fertilizers (e.g. certain composts). Other sources of dioxins in soil may be of natural origin (e.g. ball clay).
8. Dioxins and PCBs are poorly soluble in water. However, they are adsorbed onto mineral and organic particles suspended in water. The surfaces of oceans, lakes and rivers are exposed to aerial deposition of these compounds which are consequently concentrated along the aquatic food chain. The entry of waste water or contaminated effluents from certain processes, such as chlorine bleaching of paper or pulp and metallurgical processes, can lead to contamination of water and sediment of coastal ocean areas, lakes and rivers.
9. The uptake of dioxins and PCBs by fish occurs via gills and diet. Fish accumulate dioxins and PCBs predominantly in their fatty tissue and liver. Bottom dwelling/bottom feeding fish species are more exposed to contaminated sediments than pelagic fish species. However, levels of dioxins and PCBs in bottom dwelling/bottom feeding fish are not always higher than those in pelagic fish depending on the size, diet and physiological characteristics of the fish. Other factors that may affect accumulation of dioxins and PCBs in fish include age, weight, lipid content or environmental status of their environment.
10. Food of animal origin is the predominant route of human exposure to dioxins and PCBs with approximately 80–90% of the total exposure via fats in fish, meat and dairy products. Levels of dioxins and PCBs in animal fat may be related to contamination of the local environment and to contamination of feed (e.g. fish-oil and fish-meal) or to certain production processes (e.g. artificial drying).

11. The Joint FAO/WHO Expert Committee on Food Additives (JECFA) assessed at its 57th meeting in 2002 the toxicity of dioxins and DL-PCBs. The long half-lives of dioxins and DL-PCBs mean that each daily ingestion has a small or even a negligible effect on overall body burden. In order to assess long- or short-term risks to health due to these substances, total or average intake should be assessed over months, and tolerable intake should be assessed over a period of at least 1 month. To encourage this view, the JECFA decided to express the tolerable intake as a monthly value in the form of a provisional tolerable monthly intake (PTMI). A PTMI of 70 pg/kg bw per month for dioxins and DL-PCBs expressed as Toxic Equivalent Factors (TEFs) was derived. JECFA concluded that despite the uncertainties, the intake estimates suggest that a considerable fraction of the population has a long-term mean intake above the PTMI.

12. JECFA assessed at its 80th meeting in 2015 the toxicity of NDL-PCBs. JECFA concluded that none of the available studies on the six indicator PCBs (PCB 28, PCB 52, PCB 101, PCB 138, PCB 153 and PCB 180) and PCB 128 were suitable for derivation of health-based guidance values or for assessment of the relative potency of the NDL-PCBs compared with a reference compound. Therefore, a comparative approach using the minimal effect doses was developed in order to estimate Margins of Exposure (MOEs) to provide guidance on human health risk.

JECFA concluded that dietary exposures to NDL-PCBs are unlikely to be of health concern for adults and children, based on the available data. Although the MOEs are lower for breastfed infants, based on current knowledge, the benefits of breastfeeding are considered to outweigh the potential disadvantages that may be associated with the presence of NDL-PCBs in breast milk.

13. In order to reduce the contamination of food from animal origin, control measures at the feed level should be considered. These may involve developing Good Agricultural Practice, Good Animal Feeding Practice (see Codex Alimentarius Commission: Code of Practice on Good Animal Feeding), and Good Manufacturing Practice guidance and measures to effectively reduce dioxins and PCBs in feed, including:

- Identification of agricultural areas with increased dioxin and PCB contamination due to local emission, accidents or illegal disposal of contaminated materials, and monitoring of feed and feed ingredients derived from these areas,
- Monitoring of dioxin and PCB content of sewage sludge and compost used as fertilizers in agriculture, as well as its compliance with nationally established guideline or maximum levels.
- Establishing recommendations for special agricultural use (e.g. limitation of grazing or use of appropriate agricultural techniques),
- Identification of possibly contaminated feed and feed ingredients,
- Monitoring compliance with nationally-established guideline levels or maximum levels, if available, and minimizing or decontaminating (e.g., refining of fish oil) non-complying feed and feed ingredients, and
- Identification and control of critical feed manufacturing processes (e.g. artificial drying by direct heating).

14. Similar control measures, where applicable, should be considered for reducing dioxins and PCBs in food.

Transfer of dioxins and PCBs in food producing animals

15. Dioxins and PCBs accumulate in tissues of food-producing animals, including fish. In addition, they can be excreted in fat-containing products such as milk and eggs. There are clear differences in toxicokinetic behaviour between the various dioxin and PCB congeners.

16. For most farm animal species existing studies have shown that dioxins and PCBs are accumulated in body fat and liver, but also excreted into eggs and milk. This excretion contributes to lower accumulation in the body, and decreased levels after termination of the exposure. In growing animals the increase in body fat mass is also an important factor in the tissue levels obtained during exposure, which decreases after termination of the exposure.

17. Factors related to the kinetics of contaminants in the animal may be described by factors like the

- transfer rates (TRs) describing the percentage of the ingested contaminant that is excreted in milk or eggs or
- bioconcentration factor (BCF), describing the ratio between the level in tissues, milk or eggs, and that in the feed. BCFs are more suitable for tissues, since it is more difficult to obtain the information on the total weight of muscle or adipose tissues in the animal required to calculate the TRs.

18. TRs and BCFs differ for each congener but in practice those for the lower chlorinated and more persistent congeners are more relevant because they contribute most to the TEQ, like PeCDD, 2,3,4,7,8-PeCDF, TCDD, TCDF (in the case of chickens) and to a lesser extent the hexachlorinated PCDD/Fs. Only in some cases, like where pentachlorophenol (PCP) is the contamination source, will higher chlorinated congeners like HpCDD make a significant contribution to the TEQ level. In the case of DL-PCBs, PCB-126 and to some extent PCB-169 are the most relevant congeners in terms of contribution to the Toxic Equivalency (TEQ) levels.

19. PCDD/Fs and PCBs are accumulated to a greater extent in fillet of oily fish (such as salmon and trout) than leaner fish, the latter having higher concentrations of these compounds in the liver tissue. The main feed-related sources of dioxins and DL-PCBs in farmed fish are often fish oil and fishmeal. In addition to the feed composition, the transfer of dioxins and PCBs to fillets depends on other factors such as species, and animal growth and levels of dioxins and DL-PCBs in the environment (water and sediment).

Source directed measures

20. Reducing sources of dioxins and PCBs is an essential prerequisite for reduction of contamination. Measures to reduce dioxin emission sources should be directed to reducing the formation of dioxin during thermal processes as well as the application of destruction techniques. Measures to reduce PCBs emission sources should be directed to minimizing releases from existing equipment (e.g. transformers, capacitors), prevention of accidents and better control of the disposal and destruction of PCBs containing oils and wastes.

21. The Stockholm Convention on Persistent Organic Pollutants (Stockholm Convention) is a global treaty to protect human health and the environment from POPs including dioxins and PCBs. It includes a number of possible source-directed measures that national authorities can consider.

22. Part II of Annex A of the Stockholm Convention lists the following priority measures:

- (a) with regard to the elimination of the use of PCBs in equipment (e.g. transformers, capacitors or other receptacles containing liquid stocks) by 2025:
 - (i) identify, label and remove from use equipment containing greater than 10 % PCBs and volumes greater than 5 litres;
 - (ii) identify, label and remove from use equipment containing greater than 0.05 % PCBs and volumes greater than 5 litres;
 - (iii) Endeavour to identify and remove from use equipment containing greater than 0.005 % PCBs and volumes greater than 0.05 litres;
- (b) consistent with the priority measures under a), to reduce exposures and risk to control the use of PCBs:
 - (i) Use only with intact and non-leaking equipment and only in areas where the risk from environmental release can be minimised and quickly remediated;
 - (ii) Do not use in equipment in areas associated with the production or processing of food or feed;
 - (iii) When used in populated areas, including schools and hospitals, all reasonable measures to protect from electrical failure which could result in a fire, and regular inspection of equipment for leaks;
- (c) that equipment containing PCBs, as described under a) shall not be exported or imported except for the purpose of environmentally sound waste management;
- (d) Except for maintenance and servicing operations, not allow recovery for the purpose of reuse in other equipment of liquids with polychlorinated biphenyls content above 0.005 %
- (e) Ensure environmentally sound waste management of liquids containing PCBs and equipment contaminated with PCBs having a PCB content above 0.005 %, as soon as possible but no later than 2028.
- (f) Identify other articles containing more than 0.005 % PCBs (e.g. cable-sheaths, cured caulk and painted objects) and manage them in an environmentally sound manner.

23. Part II of Annex C of the Stockholm Convention lists the following industrial source categories, that have the potential for comparatively high formation and release of dioxins and PCBs to the environment.

- (a) Waste incinerators, including co-incinerators of municipal, hazardous or medical waste or of sewage sludge;
- (b) Cement kilns firing hazardous waste;
- (c) Production of pulp using elemental chlorine or chemicals generating elemental chlorine for bleaching;

- (d) Thermal processes in the metallurgical industry, i.e. secondary copper production; sinter plants in the iron and steel industry; secondary aluminium production; secondary zinc production.

24. Part III of Annex C also lists the following source categories that may unintentionally form and release dioxins and PCBs to the environment:

- (a) Open burning of waste, including burning of landfill sites;
- (b) Thermal processes in the metallurgic industry not mentioned in Part II, Annex C;
- (c) Residential combustion sources;
- (d) Fossil fuel-fired utility and industrial boilers;
- (e) Firing installations for wood and other biomass fuels;
- (f) Specific chemical production processes releasing unintentionally formed POPs, especially production of chlorophenols and chloranil;
- (g) Crematoria;
- (h) Motor vehicles, particularly those burning leaded gasoline;
- (i) Destruction of animal carcasses by burning;
- (j) Textile and leather dyeing (with chloranil) and finishing (with alkaline extraction);
- (k) Shredder plants for the treatment of end of life vehicles;
- (l) Smouldering of copper cables;
- (m) Waste of oil refineries.

Adopting technologies to minimize formation and release of dioxins and PCBs from these source categories can be considered by national authorities when developing national measures to reduce dioxins, DL-PCBs and NDL PCBs.

25. Other possible sources of PCB contamination in food and feed that authorities may consider addressing include intake of contaminated soil (free ranging laying hens, flooded land, burned areas), waste oil (transmission oil leakage, using waste oil in paints), sisal (bags, binding twine), tyres used as feeding troughs or plaything in animal enclosures, applications of PCB-containing paints or coatings and releases from caulk.

Scope

26. This Code of Practice focuses on measures (e.g. Good Agricultural Practices, Good Manufacturing Practices, Good Storage Practices, Good Animal Feeding Practices, and Good Laboratory Practices) for national authorities, farmers, feed and food manufacturers as well as consumers to prevent or reduce dioxin and PCB contamination in foods and feeds.

27. This Code of Practice applies to the production and use of all materials destined for feed (including grazing or free-range feeding, forage crop production and aquaculture) and food at all levels whether produced industrially, on farms or in households.

28. Since the global limitation and reduction of dioxins and PCBs from non food / feed related industrial and environmental sources may lie outside of the responsibility of CCCF, these measures will not be considered within this Code of Practice.

RECOMMENDED PRACTICES BASED ON GOOD AGRICULTURAL PRACTICES (GAPS), GOOD MANUFACTURING PRACTICES (GMPS), GOOD STORAGE PRACTICES (GSPS), GOOD ANIMAL FEEDING PRACTICES (GAFPS), AND GOOD LABORATORY PRACTICES (GLPS)

Control measures within the food chain

Air, Soil, Water

29. To reduce dioxin and PCB contamination in the air, national food authorities should consider recommending to their national authorities responsible for air pollution measures to restrict uncontrolled burning of wastes, including the burning of landfill sites or backyard burning, and the use of PCP treated wood for domestic heaters.

30. Control measures to prevent or reduce contamination of the environment by dioxins and PCBs are important. To reduce possible contamination of feed or food, agricultural land with unacceptable dioxin and PCB contamination due to local emission, accidents, or illegal disposal of contaminated materials should be identified.

31. Agricultural production on contaminated areas should be avoided or should be restricted if a significant transfer of dioxins and PCBs to feed or food produced on these areas is anticipated.

32. The spreading of sewage sludge contaminated with dioxins and PCBs can lead to dioxins and PCBs adhering to vegetation which can increase livestock exposure. Sewage sludge used in agriculture should be monitored, as necessary, for dioxins and PCBs and treated, as necessary. National guidelines should be adhered to where applicable.

33. Livestock, game, and poultry exposed to contaminated soil may accumulate dioxins and PCBs by consumption of contaminated soil or plants. These areas should be identified and access by certain food producing animals controlled. If necessary, the outdoor production in these areas should be restricted.

34. Source-reduction measures may take many years to reduce contamination levels in wild fish due to the long half-lives of dioxins and PCBs in the environment. To reduce exposure to dioxins and PCBs, highly contaminated areas (e.g. lakes, rivers or contaminated marine catching areas) and relevant fish species should be identified and fishing in these areas should be controlled and, if necessary, restricted.

Feed

35. The bulk of human dietary intake of dioxins and PCBs is due to the concentration of these substances in the lipid component of animal derived foods (e.g., poultry, fish, eggs, meat and milk). In lactating animals dioxins and PCBs can be excreted with milk fat, and in laying hens they may concentrate in the fat content of the egg yolk. To reduce this transfer, control measures at the feed and feed ingredients level should be considered. Measures to reduce dioxin and PCB levels in feed would have a rapid effect on their concentrations in food of animal origin originating from farm animals, including farmed fish. Such measures may include:

- identification of possibly contaminated areas in the feed supply ecosystem,
- identification of the origin of frequently contaminated feed or feed ingredients, and
- monitoring the compliance of feed and feed ingredients with nationally-established guideline levels or maximum levels, if available.

36. National authorities should periodically sample and analyse suspect feed and feed ingredients using recognized international methods to verify dioxin and PCB levels. This information will determine actions, if needed, to minimize dioxin and PCB levels and allow alternative feed and feed ingredients to be located, if necessary.

37. The purchaser and user should pay attention to and request guarantees from their supplier as regards

- origin of feed and feed ingredients to ensure that producers and/or companies have certified production facilities, production processes and quality assurance programs (e.g. HACCP-like principles);
- accompanying documents confirming compliance with nationally-established guideline levels or maximum levels, if available, according to national requirements.

Feed of animal origin

38. Due to the position of their precursors in the food chain, animal derived feed has a higher risk for dioxin and PCB contamination compared to plant derived feed. Attention should be paid to avoid dioxins and PCBs from entering the food chain through the feeding of animal derived feed to food producing animals. Animal derived feed should be monitored, as necessary, for dioxins and PCBs. Feed of animal origin that exceeds nationally established guideline levels or maximum levels, if available, or contains elevated levels of dioxins or PCBs should not be fed to animals unless the fat has been removed.

39. If intended for use in feed, fish-oil and other products derived from fish or animal fats should be monitored to the extent practicable for dioxins and PCBs. If there are nationally established guideline levels or maximum levels for animal feeds, the feed manufacturer should ensure that the products are in compliance with these provisions.

Feed of plant origin

40. If potential sources of dioxins and PCBs are anticipated in the vicinity of fields, attention should be paid to monitor these areas, as necessary.

41. Cultivation sites irrigated with water or treated with sewage sludge or municipal compost that may contain elevated dioxin and PCB levels should be monitored, as necessary, for contamination.

42. Prior treatment of fields with herbicides from the chlorinated phenoxyalkanoic acid type or chlorinated products like pentachlorophenol should be considered as a potential source for dioxin contamination. Dioxin levels in soil and forage plants from sites treated previously with dioxin-contaminated herbicides should be monitored as necessary. This will enable national authorities to take appropriate management measures in order to prevent the transfer of dioxins (and PCBs) to the food chain.

43. Typically, oilseeds and vegetable oil are not significantly contaminated with dioxins and PCBs. This also applies to other by-products of oilseed processing (e.g. oilseed cakes) used as feed ingredients. However, certain vegetable and animal oil refining by-products (e.g. fatty acid distillates and deodistillates) and spent products used in oil refining (e.g. bleaching clays) may contain increased levels of dioxins and PCBs and should be analysed, as necessary, if used for feed.

Feed and food processing

Drying processes

44. Certain processes for the artificial drying of feed and food (and feed or food ingredients) and the heating of indoor growing facilities (e.g. greenhouses) require a flow of heated gases, either a flue gas-air mix (direct drying or heating) or heated air alone (indirect drying or heating). Accordingly, fuels not expected to generate dioxins and dioxin-like compounds should be used. Feed, food and feed or food ingredients that are dried or subjected to heated air should be monitored as necessary to ensure that drying or heating processes do not result in elevated levels of dioxins and PCBs.

45. The quality of commercial dried feed materials, in particular green fodder, and commercially dried foods depends on the selection of the raw material and the drying process. The purchaser should consider requiring a certificate from the manufacturer/supplier, confirming that the dried goods are produced applying Good Manufacturing Practice, particularly in the choice of the fuel used for drying or heating and are in compliance with nationally-established guideline levels or maximum levels, if available.

Smoking

46. Depending on the technology used, smoking can be a critical processing step for increased dioxin content in foods, especially if the products show a very dark surface with particles of soot. Such processed products should be monitored for dioxins and PCBs, as necessary, by the manufacturer.

Milling / Disposal of contaminated milling fractions

47. Airborne external deposition of dioxins and PCBs on the surface of all parts of the grain plants as well as the adherent dust fraction from the standing crop is widely removed during the milling process and before the final grinding process. If present, most particle-bound contamination is removed in the loading chute with the remaining dust. Further external dioxins and PCB contaminations are significantly reduced during aspiration and sieving. Certain grain fractions, especially dust, chaff and mixed screenings, can have increased dioxin and PCB levels and should be monitored, as necessary. If there is evidence of elevated contamination, such fractions should not be used in food or feed and should be treated as waste.

Food preparation

48. Food selection and preparation can reduce exposure to dioxins and PCBs

49. Food preparation such as skinning, trimming the fat, in addition to the disposing of pan drippings and poaching/boiling liquids) are practical approaches to reduce exposure to dioxins and PCBs. Although removal of fat can reduce dioxin and PCB levels significantly, such practices also reduce fat-soluble nutrients and other beneficial compounds (such as the long-chain-3 polyunsaturated fatty acid). Therefore, it is essential to carefully consider both risks and benefits in any public health message regarding food consumption.

Substances added to feed and food

Minerals and trace elements

50. Some minerals and trace elements are obtained from natural sources. However, experience has shown that geogenic dioxins may be present in certain prehistoric sediments. Therefore, dioxin levels in minerals and trace elements added to feed or food should be monitored as necessary.

51. Reclaimed mineral products or by-products from certain industrial processes may contain elevated levels of dioxins and PCBs. The user of such feed ingredients should verify that dioxin and PCBs are within nationally established guideline levels or maximum levels, if available, through certification by the manufacturer or supplier.

52. Elevated levels of dioxins have been found in ball clay used as an anticaking agent in soybean meal in feed. Attention should be paid to minerals used as binders or anticaking agents (e.g. bentonite, montmorillonite, kaolinitic clay, diatomaceous earth) and carriers (e.g. calcium carbonate) used as feed ingredients. As assurance to the user that these substances do not contain minerals with elevated levels (e.g. exceeding nationally- established guideline levels or maximum levels, if available) of dioxins and PCBs, the distributor should provide appropriate certification to the user of such feed ingredients.

53. Feed of some food producing animals is supplemented with trace elements (e.g. copper or zinc). Minerals, including trace elements, which are by-products or co-products of industrial metal production have been shown to contain elevated levels of dioxins. Such products should be monitored for dioxins and PCBs, as necessary.

Ingredients

54. Feed and food manufacturers should ensure that all ingredients in feed and food comply with nationally established guideline levels or maximum levels of dioxins and PCBs, if available.

Harvesting, transport, storage of feed and food

55. To the extent feasible, it should be ensured that minimal contamination with dioxins and PCBs occurs during the harvest of feed and food. This can be achieved in possibly contaminated areas by minimizing soil deposition on feed and food during harvest by using appropriate techniques and tools according to Good Agricultural Practice. Roots and tubers, grown on contaminated soil, should be washed to reduce soil contamination. If roots and tubers are washed, they should be sufficiently dried before storage or be stored following techniques (e.g. ensilage) aiming to prevent mould formation.

56. After flooding, crops harvested for feed and food should be monitored for dioxins and PCBs, if there is evidence of dioxin and/or PCB contamination in the flood water.

57. To avoid cross-contamination, the transport of feed and food should only be performed in vehicles (including ships) and in containers that are free of dioxins and PCBs. Storage containers for feed and food should be painted only with dioxin and PCB-free paint.

58. Storage sites for feed or food should be free from dioxins and PCB contamination. Surfaces (e.g. walls, floors) treated with tar-based paints may result in transfer of dioxins and PCBs to food and feed. Surfaces that come in contact with smoke and soot from fires always bear a risk of contamination with dioxins and PCBs. These sites should be monitored as necessary for contamination before use for storage of feed and food.

Special problems of animal keeping (Housing)

59. Food producing animals may be exposed to dioxins and PCBs found in certain treated wood used in buildings, farm equipment and bedding material. To reduce exposure, animal contact with treated wood containing dioxins and PCBs should be minimized. In addition, sawdust from treated wood containing dioxins and PCBs should not be used as bedding material.

60. Due to the potential for soil contamination, eggs from free living or free-range hens (e.g. organic farming) may have higher levels of dioxins and PCBs compared to eggs from caged hens and should be monitored, as necessary.

61. Attention should be paid to older buildings as they may have building materials and varnishes that may contain dioxins and PCBs. If they have caught fire, measures should be taken to avoid contamination of the feed and feed chain by dioxins and PCBs.

62. In housings without a floor covering, the animals may take up soil particles from the ground. If there are indications of increased levels of dioxins and PCBs, contamination of the soil should be controlled as necessary. If needed, the soil should be exchanged.

63. Pentachlorophenol-treated wood in animal facilities has been associated with elevated levels of dioxins in beef. Wood (e.g. railroad ties, utility poles) treated with chemicals such as pentachlorophenol or other unsuitable substances should not be used as fence posts for enclosures of free-range animals, unless allowed by national authorities, or feed lines. Hay racks should not be constructed from such treated wood. The preservation of wood with waste oils should also be avoided.

Monitoring

64. Farmers and industrial feed and food manufacturers have the primary responsibility for feed and food safety. Testing could be conducted within the framework of a food safety program (e.g. Good Manufacturing Practices, On-Farm Safety programmes, Hazard Analysis and Critical Control Point programs, etc.) In previous sections of this Code, it is mentioned where it could be appropriate to perform monitoring. Competent authorities should enforce the primary responsibility of farmers, feed and food manufacturers for feed and food safety through the operation of surveillance and control systems at appropriate points throughout the food chain, from the primary production to the retail level. In addition competent authorities should establish their own monitoring programs.

65. As analyses for dioxins are relatively expensive, periodic tests should be performed to the extent feasible at least by industrial feed and food manufacturers including both incoming raw materials and final products and data should be kept (see paragraph 75). The frequency of sampling should be considered by the results from previous analyses (by individual companies and/or via a pool of industry results within the same sector). If there are indications of elevated levels of dioxins and PCBs, farmers and other primary producers should be informed about the contamination and the source should be identified and the necessary measures taken to remediate the situation and reduce or prevent further contamination.

66. Monitoring programs dealing with contaminations originating from the environment, accidents or illegal disposals should be organized by operators in the feed and food chain and by competent national authorities in order to obtain additional information on food and feed contamination. Products or ingredients at risk or found with elevated concentrations should be monitored more intensively. For example, monitoring programs may include major fish species used in food or feed that have been shown to contain elevated levels of dioxins and PCBs.

Sampling, analytical methods, data reporting and laboratories

67. Advice concerning analytical requirements and qualification of laboratories is given in the literature.

68. Traditional methods for the analysis of dioxin and DL-PCBs rely on gas chromatography coupled to high-resolution mass spectrometry (GC-HRMS) which is time-consuming and expensive. Methods based on gas chromatography coupled to tandem mass spectrometry (GC-MS/MS) can also be used to quantify dioxins and DL-PCBs. Alternatively, bioassay techniques have been developed as high throughput screening methods which can be less expensive than traditional methods. However, the cost of analysis remains an impediment to data collection thus research priority should be given to the development of less costly analytical methods for the analysis of dioxin and DL-PCBs.

69. Gas chromatography (GC) coupled to Electron Capture Detection (ECD) and mass spectrometers (including ion trap, low-resolution (LRMS), high-resolution (HRMS) and tandem mass (MS/MS) spectrometers) are used in the analysis of NDL-PCBs. The analysis of NDL-PCBs generally does not require as extensive a clean-up procedure as the DL-PCBs or dioxins. For screening purposes, GC-ECD is often used. GC/MS may also be used for screening purposes.

Sampling

70. Important aspects of sampling for dioxin and PCB analysis are collecting representative samples, avoiding cross contamination and deterioration of samples and unambiguously identifying and tracing back samples. To avoid cross-contamination, samples should be put in containers or other receptacles that are not reactive and that have been chemically cleaned or certified to be free of contaminants. All relevant information on sampling, sample preparation and sample description (e.g. sampling period, geographic origin, fish species, fat content, size of fish) should be recorded.

Analytical methods and data reporting

71. Analytical methods should be applied only if they are fit for purpose meeting a minimum of requirements. If nationally-established maximum levels are available, the limit of quantification (LOQ) of the method of analysis should be in the range of one fifth of this level of interest. For adequate time trend measurements, the limit of quantification of the method of analysis should be clearly below the mean of the present background ranges for the different matrices.

72. Performance of a method of analysis should be demonstrated in the range of the level of interest, e.g. 0.5 x, 1 x and 2 x level of maximum level with an acceptable coefficient of variation for repeated analysis. The difference between upper bound and lower bound levels (see next para.) should not exceed 20% for feed and food with a dioxin concentration of about 1 pg WHO-PCDD/PCDF-TEQ/g fat. If needed, another calculation based on fresh weight or dry matter could be considered.

73. Except for bioassay techniques, the results of total dioxin and DL-PCB levels in a given sample should be reported as lower bound, medium bound and upper bound concentration by multiplying each congener by their respective WHO Toxic Equivalency Factor (TEF) and subsequently summing them up to give the total concentration expressed as Toxic Equivalency (TEQ). The three different TEQ values should be generated reflecting assignment of zero (lower bound), half the limit of quantification (medium bound), and limit of quantification (upper bound) values to each non-quantified dioxin and DL-PCB congener. For the analysis of NDL-PCBs the analytical result should also be reported as lower-bound, medium bound and upper-bound and indicate clearly to what the analytical result refers to (sum of six indicator PCBs, total PCBs, etc.)

74. Depending on the sample type, the reported information may also include the lipid or dry matter content of the sample as well as the method used for lipid extraction and for the determination of dry matter. This report should also include a specific description of the procedure used to determine the LOQ.

75. A high throughput screening method of analysis with proven acceptable validation could be used to screen the samples with significant levels of dioxins and PCBs. Screening methods should have less than 1% false-negative results in the relevant range of interest for a particular matrix. Use of ¹³C-labelled internal standards for dioxins or PCBs allows for specific control of possible losses of the analytes in each sample. As such,, false-negative results can be avoided thus preventing contaminated food or feed from being used or marketed. For confirmatory methods, use of these internal standards is mandatory. For screening methods without control of losses during the analytical procedure, information on correction of losses of compounds and the possible variability of results should be given. Levels of dioxins and PCBs in positive samples (above the level of interest) should be determined by a confirmatory method.

Laboratories

76. Laboratories involved in the analysis of dioxins and PCBs using screening as well as confirmatory methods of analysis should be accredited by a recognized body operating in accordance with ISO/IEC Guide 58:1993 as revised by ISO/IEC 17011:2004 or have quality assurance programs that address all critical elements of accrediting agencies to ensure that they are applying analytical quality assurance. Accredited laboratories should follow the ISO/IEC/17025 standard "General requirements for the competence of testing and calibration laboratories" or other equivalent standards.

77. Regular participation in interlaboratory studies or proficiency tests for the determination of dioxins and PCBs in the relevant feed and food matrices is highly recommended according to ISO/IEC/17025 standard.

QUALITY MANAGEMENT AND EDUCATION

78. Good Agricultural Practices, Good Manufacturing Practices, Good Storage Practices, and Good Animal Feeding Practices are valuable systems for further reduction of dioxin and PCB contamination in the food chain. Farmers as well as feed and food manufacturers should consider informing their employees on how to prevent contamination by the implementation of control measures. Good Laboratory Practices is a valuable system to ensure high quality of the analytical outcome.

ANNEX
GLOSSARY OF TERMS
(for the purpose of this code of practice)

Term	Explanation
anticaking agent	Substance that reduces the tendency of particles of a feed or food to stick
binder	Substance that increases the tendency of individual particles of a feed or food to stick
coefficient of variation	Statistical parameter expressing: 100 x standard deviation of a set of values/mean value of set
confirmatory method of analysis	Method of analysis with high quality parameters capable of confirming analytical results produced from screening methods with lower quality parameters
congener	One of two or more compounds of similar chemical structures with respect to classification
dioxins (PCDD/PCDF)	Include 7 polychlorinated dibenzo-p-dioxins (PCDDs) and 10 dibenzofurans (PCDFs) with similar toxicological properties and belong to a group of lipophilic and persistent organic substances. Depending on the degree of chlorination (1–8 chlorine atoms) and the substitution patterns, 75 different PCDDs and 135 different PCDFs (“congeners”), can be distinguished.
dioxin-like PCBs (DL-PCBs)	Include 12 non-ortho and mono-ortho substituted polychlorinated biphenyls (PCBs) showing toxicological properties (dioxin-like activity) that are similar to dioxins
fish	Poikilothermic vertebrate animals including Pisces, Elasmobranches and Cyclostomes. For the purpose of this code of practice, molluscs and crustaceans are also included
feed	Any single or multiple materials, whether processed, semi-processed or raw which is intended to be fed directly to food producing animals
food	Any substance, whether processed, semi-processed or raw which is intended for direct human consumption, and includes drink, chewing gum and any substance which has been used in the manufacture, preparation or treatment of “food” but does not include cosmetics, tobacco, medicinal products, narcotic or psychotropic substances, residues and contaminants
feed or food ingredient	A component or constituent of any combination or mixture making up a feed or food, whether or not it has a nutritional value in the diet, including additives. Ingredients are of plant, animal or aquatic origin, or may originate from other organic or inorganic substances.
guideline levels	The maximum concentration of a substance which is recommended by a national or international authority to be acceptable in feed or food, however not legally binding
HACCP	Hazard Analysis Critical Control Point (HACCP) is a system that identifies, evaluates and controls hazards which are significant for food safety

Term	Explanation
limit of quantification (LOQ) (valid for dioxins and PCBs only)	The limit of quantification of an individual congener means the lowest concentration of the analyte that can be measured with reasonable statistical certainty, fulfilling the identification criteria as described in internationally recognised standards such as in EN 16215:2012 and/or EPA methods 1613 and 1668 as revised. The limit of quantification of an individual congener may be identified as the concentration of an analyte in the extract of a sample which produces an instrumental response at two different ions to be monitored with an S/N (signal/noise) ratio of 3:1 for the less sensitive signal and fulfilment of the basic requirements such as e.g. retention time, isotope ratio according to the determination procedure as described in EPA method 1613 as revised.
maximum levels	Legally binding maximum concentration of a substance in feed or food, established by a national or international authority
minerals	Inorganic compounds used in food and feed being required for normal nutrition or used as processing aids.
Non dioxin-like PCBs (NDL-PCBs)	Includes the 197 PCB congeners other than the 12 non-ortho and mono-ortho substituted PCBs. The NDL-PCBs account for the majority of the total PCB contamination, the remainder being DL-PCBs. The Stockholm Convention on POPs recommends the measurement of six indicator PCBs (PCB 28, PCB52, PCB 101, PCB, 138, PCB 153 and PCB 180) to characterise contamination by NDL-PCBs.
PCBs	Polychlorinated biphenyls belonging to a group of chlorinated hydrocarbons, formed by direct chlorination of biphenyl. Depending on the number of chlorine atoms (1 – 10) and their position at the two rings, 209 different compounds (“congeners”) are theoretically possible. The 209 congeners of PCBs include the dioxin-like PCBs (12 congeners) and the non-dioxin-like PCBs (197 congeners).
PCP Pelagic fish species	Pentachlorophenol Fish species living in free water (e.g., ocean, lake) without contact to the sediment
Persistent organic pollutant (POP)	Chemical substance that persists in the environment, bioaccumulates through the food web, and poses a risk of causing adverse effects to human health and the environment
Stockholm Convention (POPs Convention)	The Stockholm Convention on Persistent Organic Pollutants is a global treaty to protect human health and the environment from persistent organic pollutants (POPs) including dioxins and dioxin-like PCBs. It entered into force on 17th May 2004. In implementing the Stockholm Convention governments will take measures to eliminate or reduce the release of POPs into the environment.
Screening method of analysis	Method of analysis with lower quality parameters to select samples with significant levels of an analyte
Trace elements	Chemical elements essential for plant, animal and/or human nutrition in small amounts
Toxic Equivalency Factor (TEF)	Estimates of the toxicity of dioxin-like compounds relative to the toxicity of 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD), which is assigned a TEF of 1.0. WHO-TEFs for human risk assessment are based on the conclusions of the World Health Organization (WHO) – International Programme on Chemical Safety (IPCS) expert meeting (Geneva, June 2005)
Toxic Equivalency (TEQ)	Relative toxicity value calculated by multiplying the concentration of a congener by its toxic equivalency factor (TEF)
WHO-TEQ	TEQ value for dioxins furans and dioxin-like PCBs, established by WHO and based on established Toxic Equivalency Factors (TEFs)

APPENDIX VI**PROPOSED DRAFT CODE OF PRACTICE FOR THE REDUCTION OF 3-MONOCHLOROPROPANE-1,2-DIOL ESTERS (3-MCPDE) AND GLYCIDYL ESTERS (GE) IN REFINED OILS AND FOOD PRODUCTS MADE WITH REFINED OILS****(AT STEP 5)****INTRODUCTION**

1. Edible vegetable oils are produced from fruits, seeds, and nuts. Refining of edible vegetable oils (at temperatures of about 200°C or higher) can produce 3-monochloropropane-1,2-diol (MCPD) esters (3-MCPDE) and glycidyl esters (GE). Refined palm oil has been reported to have the highest concentrations of these esters and the greatest consumption rate worldwide, in comparison to other refined oils (e.g. grapeseed, olive, soya bean, rapeseed, sunflower, walnut, hazelnut).
2. Exposure to 3-MCPDE and GE can occur through consumption of refined vegetable oils and food products containing refined vegetable oils, including infant formula, fried potato products (e.g. french fries and potato crisps), and fine bakery wares (e.g. cookies, croissants, and donuts).
3. 3-MCPDE and 3-MCPD have toxic effects on the kidney and male reproductive organs, and 3-MCPD is a non-genotoxic carcinogen. GE and glycidol are genotoxic carcinogens.¹
4. The JECFA evaluation 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 vegetable oils have different capacities to form 3-MCPDE and GE during deodorization (part of the refining process). Factors contributing to this variation include climate, soil and growth conditions of the plants, their genotype, harvesting techniques, and processing conditions—all of which affect the levels of precursors of 3-MCPDE and GE (e.g. acylglycerols, chlorine-containing compounds). Most unrefined oils do not contain detectable levels of 3-MCPDE or GE.
6. 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 monoacylglycerols.
7. Some chlorinated compounds are precursors for 3-MCPDE formation. Research studies in oil palm trees have shown that chloride ions (in the form of chlorinated compounds) are absorbed during tree growth from the soil (including from fertilizers and pesticides) and water, and are converted into lipophilic chlorinated compounds that may generate hydrochloric acid during oil refining, leading to formation of 3-MCPDE.
8. Oil seeds and fruits contain the enzyme lipase; lipase activity increases with fruit maturation, while the activity in lipase seeds remains stable. Lipase interacts with oil from mature fruits to rapidly degrade TAGs into free fatty acids (FFAs) and DAGs and MAGs, while the effect of lipase in seeds that are appropriately stored is negligible.

GE formation begins at about >200°C, and increases exponentially with increasing temperature when DAGs exceed 3-4% of total lipids, while 3-MCPDE formation occurs at temperatures as low as 160-200°C, and formation does not increase with higher temperatures.
9. 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 not a relationship between relative levels of 3-MCPDE and GE in individual oil samples.
10. 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, 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.

11. Although 3-MCPDE and GE are primarily produced during deodorization, mitigation measures can be applied across the edible oil production chain beginning with agricultural practices (e.g. cultivation, harvesting and storage of fruits) to oil milling and refining (e.g. fruit and seed selection and processing, degumming/bleaching, and deodorization) as well as to post-refining measures (e.g. additional bleaching and deodorization, 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. For example, efforts to mitigate 3-MCPDE should also focus on cultivation, harvesting, and milling, not just refining.
12. Although most work on mitigation of 3-MCPDE and GE in refined oils has focused on palm oil because of its greater capacity to form 3-MCPDE and GE and its importance economically, 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 vegetable oils.
13. 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 oilseed or fruit being processed, the refining process, and the type of equipment installed). 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.
14. 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, FFAs, and other 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.
15. [Although this COP was developed for refined vegetable oils, some measures may be applicable to fish oils.]

SCOPE

16. 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, including infant formula. 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, including infant formula

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

17. Producing edible oils involves several major steps: cultivating, harvesting, and transporting the fruits and seeds for further processing; oil milling, where palm fruit is sterilized, while oilseeds are cleaned, ground, and steamed; extracting oil from the fruits and seeds; and refining.
18. Refining 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. Physical refining involves degumming, bleaching, and deodorization, but 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

19. [Consider selecting oil plant varieties with low lipase activity as being one factor (e.g. for palm oil, <10 µmole fatty acid released per minute/gram dry mesocarp) in reducing formation of FFAs and acylglycerol precursors.]
20. Minimize use of substances such as fertilizers, pesticides, [and irrigation] water that have excessive amounts of chlorine-containing compounds during cultivation to reduce chlorine absorption by the oil trees and ultimately the palm fruits.

21. Harvest oil palm fruit when they are at optimal ripeness. Minimize handling of the fresh fruit bunches to reduce bruising and prevent formation of FFAs. Avoid using damaged or overripe fruits, which may be associated with higher 3-MCPDE and GE formation.
22. Transport oil palm fruits to oil mills as soon as possible.

OIL MILLING AND REFINING

Crude Oil Production and Treatment

23. Following receipt of the oil palm fruits at the mill, sterilize the fruits immediately (preferably within a few hours to less than 2 days of harvesting) at temperatures at or below 120°C to inactivate lipases (with temperatures varying depending on the sterilization method).
24. [Wash crude vegetable oil with polar solvents like chlorine-free water or water/alcohol (ethanol) mixtures to remove chlorine-containing compounds.]
25. Avoid recycling residual oil recovered from solvents or additional extractions, as this oil tends to have higher levels of precursors (e.g. chlorine-containing compounds, DAGs).
26. Assess precursors in batches of crude vegetable oils (e.g. DAGs, chlorine-containing compounds) to adjust refining parameters and target appropriate mitigation strategies depending on the type of vegetable oil being processed and processing conditions.
27. Preferentially refining crude vegetable oil with low concentrations of precursors can produce finished oils with lower levels of 3-MCPDE and GE.

Degumming

28. [Use milder and less acidic conditions (e.g. either degumming with a low concentration of phosphoric acid (0.02%) or water degumming) to decrease 3-MCPDE in vegetable oils. The concentration of phosphoric acid needed depends on the quality of the crude vegetable oil. Care should be taken to remove sufficient concentrations of phospholipids and phosphoric acid to ensure quality.]
29. 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 type of vegetable oil.

Neutralization

30. Using chemical refining (i.e., neutralization) in place of physical refining can help remove precursors (e.g. chloride) and reduce FFAs, which may allow for lower deodorization temperatures in vegetable 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

31. [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.
32. Use of more pH-neutral clays reduces the acidity, and potential to form 3-MCPDE in palm oil and some seed oils.

Deodorization

33. 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 or even lower temperatures for fish oils.]
34. As an alternative to traditional deodorization, conduct dual deodorization of vegetable oils (2-stage deodorization) to reduce thermal load in oil. This includes both a shorter (e.g. 5 minutes at 250°C) and a longer (e.g. 120 minutes at 200°C) deodorization period. 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.
35. 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 oils.

TREATMENT POST REFINING

36. [The following recommended practices are for reducing levels of 3-MCPDE and GE in refined oils with high levels of these esters.]
37. Conduct additional bleaching and deodorization steps following initial bleaching and deodorization of the refined palm oil, to achieve lower levels of GE in the refined palm oil. (The second deodorization should occur at a lower temperature than the first deodorization.)
38. Application of activated bleaching earth during post refining has been shown on an industrial scale to reduce GE in refined vegetable oils.
39. Use of short-path distillation² (pressure: <1 mbar and temperature: 120 to 270°C) on bleached and deodorized vegetable oils can reduce acylglycerol components and levels of 3-MCPDE and GE.
40. Treatment of refined MCT (medium-chain triglyceride) oil with one or more bases (including, carbonate, bicarbonate, hydroxide, oxide, alkoxide, amine bases, hydrides, and phosphines) converts 3-MCPDE and GE to TAGs. This method is being tested using other vegetable oils.

SELECTION AND USES OF REFINED OILS IN FOOD PRODUCTS MADE FROM THESE OILS, INCLUDING INFANT FORMULA

Oil selection

41. [In case refined oils with low levels of 3-MCPDE and GE is needed for food such as infant formula, the following recommended practices should be followed.]
42. Selecting refined vegetable oils with lower 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 types of oils used in these formulas. However, in some cases, it may be difficult to replace particular oils in the finished products due to desired 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

43. Reducing the amount of refined vegetable oils in finished products is expected 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.
44. 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 and GE 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.

RECOMMENDED MITIGATION MEASURES FOR REDUCING 3-MCPDE AND GE

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

Production Stage	Mitigation measures
AGRICULTURAL PRACTICES	<ul style="list-style-type: none"> • Select oil plant varieties with low lipase activity. • Minimize use of substances such as fertilizers, pesticides, and irrigation water that contain excessive amounts of chlorine during oil palm cultivation. • Harvest oil palm fruits when they are at optimal ripeness. Minimize handling of fresh fruit bunches. Avoid using damaged or overripe fruit. • Transport oil palm fruits to oil mills as soon as possible.
OIL MILLING AND REFINING	<p>CRUDE OIL PRODUCTION AND TREATMENT</p> <ul style="list-style-type: none"> • Sterilize oil palm fruits at temperatures at or below 120°C. • Wash crude vegetable oil with polar solvents (e.g. chlorine-free water or water/alcohol mixtures). • Avoid recycling residual oil recovered from solvents or extractions. • Assess precursors (e.g., DAGs and chlorine compounds) in batches of crude vegetable oil to adjust refining parameters. • Preferentially refine crude vegetable oil with low concentrations of precursors. <p>Degumming</p> <ul style="list-style-type: none"> • Use milder and less acidic conditions, e.g. either degumming with a low concentration of phosphoric acid (0.02%) or water degumming for vegetable oils. • Lowering the degumming temperature in vegetable oils may reduce formation of 3-MCPDE precursors. <p>Neutralization</p> <ul style="list-style-type: none"> • Use of chemical refining (i.e. neutralization) in place of physical refining can help remove precursors (e.g. chloride) and reduce FFA, which may allow for lower deodorization temperatures in some vegetable oils. <p>Bleaching</p> <ul style="list-style-type: none"> • Use greater amounts of bleaching clay in vegetable oils. • Use more pH-neutral clays to reduce acidity in palm oils and some seed oils.

RECOMMENDED MITIGATION MEASURES FOR REDUCING 3-MCPDE AND GE

The mitigation measures are not listed in order of priority.
 It is recommended that all 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"> • Consider conducting deodorization of vegetable oils at reduced temperatures. • An alternative to traditional deodorization is dual deodorization (2-stage deodorization) of vegetable oils which includes a shorter (e.g. 5 minutes at 250°C) and a longer (e.g. 120 minutes at 200°C) deodorization period. • Use of a stronger vacuum facilitates evaporation of volatile compounds and contributes to decreased deodorization temperatures in vegetable oils.
TREATMENT POST REFINING	<ul style="list-style-type: none"> • Conduct additional bleaching and deodorization following initial bleaching and deodorization of refined palm oil. • Application of activated bleaching clay to refined vegetable oils has been shown to reduce GE. • Use short-path distillation on bleached and deodorized vegetable oils. • Treatment of refined MCT (medium-chain triglyceride) oil with bases converts 3-MCPDE and GE to triacylglycerols.
SELECTION AND USES OF REFINED OILS	<p>OIL SELECTION</p> <ul style="list-style-type: none"> • Select refined vegetable oils with lower levels of 3-MCPDE and GE as this can reduce levels of 3-MCPDE and GE in the finished product. <p>PROCESS MODIFICATIONS</p> <ul style="list-style-type: none"> • Reduce the amount of refined vegetable oils in finished products as this may reduce the levels 3-MCPDE and GE in finished products. • Use of refined vegetable oils themselves during frying does not contribute to the formation of additional 3-MCPDE and GE, but rather the formation of additional 3-MCPDE and GE may result from the type of food that is fried (e.g. meat and fish products).

*

APPENDIX VII

**PROPOSED DRAFT MAXIMUM LEVEL FOR TOTAL AFLATOXINS IN READY-TO-EAT PEANUTS
(HELD AT STEP 4)**

AFLATOXINS, TOTAL

Commodity / Product Name	Maximum Level (ML) µg/kg	Portion of the Commodity / Product to which the ML applies	Notes / Remarks
Peanuts	10		The ML applies to peanuts "ready to eat"

APPENDIX VIII

PROPOSED DRAFT MAXIMUM LEVELS FOR TOTAL AFLATOXINS AND OCHRATOXIN A IN NUTMEG, DRIED CHILLI AND PAPRIKA, GINGER, PEPPER AND TURMERIC

(HELD AT STEP 4)

AFLATOXINS, TOTAL (AFT)

Commodity / Product Name	Maximum Level (ML) $\mu\text{g}/\text{kg}$	Portion of the Commodity / Product to which the ML applies	Notes / Remarks
Nutmeg, Chili and Paprika, Ginger, Pepper and Turmeric	[30] [20]		

OCHRATOXIN A (OTA)

Commodity / Product Name	Maximum Level (ML) $\mu\text{g}/\text{kg}$	Portion of the Commodity / Product to which the ML applies	Notes / Remarks
Nutmeg, Chili and Paprika, Ginger, Pepper and Turmeric	20		

APPENDIX IX**PROPOSED DRAFT GUIDELINES FOR RISK ANALYSIS OF INSTANCES OF CONTAMINANTS IN FOOD WHERE THERE IS NO REGULATORY LEVEL OR RISK MANAGEMENT FRAMEWORK ESTABLISHED****(AT STEP 5)****1. INTRODUCTION**

The detection of contaminants in foods that are not already subject to a regulatory framework 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 protective of public health but also takes account of the practicalities of initial detections.

Many such contaminants will not be regulated at either a Codex or national level. There may be a number of reasons why a contaminant is not regulated, including a novel or recent emergence as a food contaminant, or lack of resources to support regulatory intervention on non-priority contaminants.

Where detection of a contaminant in food necessitates a rapid risk management response, a *pragmatic risk-based approach* should be applied. In situations where there is limited or no toxicological data available the risk analysis process must accommodate this limitation, and ensure protection of public health while any unjustified effects on trade are minimised. Further the risk analysis process should be able to be applied within the competence of most countries and within a restricted timeframe. Given this scenario under time constraints a full risk assessment is neither a practicable or feasible option. The Threshold of Toxicological Concern *decision tree* is a valid screening tool, based on scientific risk assessment principles, to assess low dose chemical exposures, and to distinguish those for which further data are required to assess the human health risk from those with no appreciable risk.

A rapid risk analysis approach will protect public health while ensuring food security and minimising food wastage.

2. PURPOSE OF THIS GUIDELINES

These guidelines provide an approach to assist governments in the rapid risk analysis *instances of contaminants in food where there is no regulatory level or risk management framework established*.

These guidelines should be read in conjunction with the following relevant texts:

1. Working Principles for Risk Analysis for Food Safety for Application by Governments (CXG 62-2007)
2. The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement);
3. Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius (Codex Alimentarius Commission Procedural Manual.);
4. Principle and Guidelines for National Food Control Systems (CXG 82-2013);
5. Principles for Food Import and Export Inspection and Certification (CXG 20-1995);
6. Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification (CXG 26-1997);
7. Guidelines for Food Import Control Systems (CXG 47-2003);
8. Guidelines for the Exchange of Information between countries on rejections of imported foods (CXG 25-1997);
9. Principles and Guidelines for the Exchange of Information in Food Safety Emergency Situations (CXG 19-1995);
10. Guidelines for Setting Disputes over Analytical (Test) Results (CXG 70-2009);
11. Principles and guidelines for the exchange of information between importing and exporting countries to support the trade in food (CXG 89-2016); and
12. Principles for Traceability / Product Tracing as a Tool Within a Food Inspection and Certification System (CXG 60-2006)

3. SCOPE

Contaminants subject to these guidelines are:

- *Those falling within the mandate of the Codex Committee on Contaminants in Foods and for which there are no specific Codex standards, recommendations or guidelines¹;*
- *Those where the detections are a novel or recently emerged occurrence, or have not been previously reported in the food;*
- *Those found within a specific lot or consignment of food ;*

[Where there are continuing detections of a contaminant in food, targeted surveillance activities should be undertaken to determine the extent of potential human exposure and the source of contamination. In conjunction, exploration of risk management options, such as maximum levels, might be necessary, e.g. commissioning of a full risk assessment to characterise the potential hazard and risk]

The following examples are groups of contaminants that would fall under the scope of this document if present in food:

- Greenhouse gas mitigation technology e.g. chemicals used to address specific environmental and climate change-related issues, including within agriculture nitrification and urease inhibitors, which have not been anticipated to be present in food
- contaminants from materials used during processing of food e.g. non-regulated packaging materials and printing inks, oils/lubricants/resins used as manufacturing maintenance compounds
- natural toxins e.g. newly characterised mycotoxins or phytotoxins
- Environmental contaminants e.g. flame retardants and musks/fragrances

Chemicals identified to have a role in economically motivated adulteration of food, and present at a level reflective of adulteration, are not covered by these guidelines.

4. PRINCIPLES

- Detection information acted upon by risk managers should satisfy the requirements of official food control programmes for sampling and validation
- [A cut-off value(s)] of no public health concern should be established for application as a first step
- Where there is a detection of the contaminant in a traded consignment the competent authority in the exporting country should be notified and any relevant food safety information shared
- Risk assessors carrying out the rapid evaluation method should have appropriate competency and experience
- The risk assessment and risk management decision should be documented in a transparent and systematic manner

5. ROLES

In most cases, it will be the competent authority that is the risk manager and decisions on the safety or otherwise of the food consignment in question will be taken under food safety legislation

When carrying out risk management activities, the competent authority should ensure that relevant stakeholders are notified of the detection of *the* contaminant in food as soon as possible and evaluation *is* carried out in a timely manner. This is particularly important in the case of food in trade.

Stakeholders other than the competent authority may carry out non-regulatory monitoring activities for a range of reasons e.g. satisfying provisions of supplier contracts. If the detection in food of *the* contaminant is reported by other stakeholders, the competent authority should ensure that such results as reported are validated in an officially approved / recognised laboratory before *doing* a risk *analysis*

REPORTING OF DETECTION(S)

Risk managers should be informed of detections of concentrations of contaminants found in official / officially recognised food monitoring and surveillance programmes as a routine procedure. As such, the presence of the contaminant will have been validated in an approved / recognised laboratory and the samples will have been subject to quality assurance provisions as required by an official regulatory programme. Sample provenance should be unambiguous.

Information provided by the analyst to the risk manager should include:

¹ Note that some countries may have national standards in the absence of Codex standards

- Type of sampling programme e.g. cross-sectional, longitudinal, targeted surveillance
- Test method and its analytical performance
- Number of detections and total number of samples tested
- Summary statistics of occurrence data
- Identification of chemical class / chemical type.

In supplying this information, the officially recognised laboratory may provide a scientific/technical opinion on the possible source(s) of the chemical substance detected

6. [DERVIATION OF THE CUT-OFF VALUE

7.1 General considerations

A pragmatic step in the establishment of a rapid screening methodology is the derivation of a cut-off value for the test result or cluster of results below which the consignment or lot of food does not constitute a public health concern. Establishing this cut-off value should take into account the very limited exposure scenario and the need to apply any risk management measures proportional to risks to human health.

The cut-off value must be sufficiently conservative so that any chemical exposure that could be a food safety concern is flagged for further rapid evaluation, the TTC decision tree genotoxicity threshold provides a benchmark for this. A fit for purpose cut-off value should cater for foods for infant consumption as well as foods for the general population. Tests below the cut-off value should indicate to risk managers that no expert risk assessment is required and safe food is not unduly wasted.

7.2 Criteria for establishment of a cut-off value

The cut-off should represent a conservative estimate of negligible risk for all chemicals, excepting categories that are excluded from appropriate consideration within the TTC decision tree.

The cut-off should be based on a realistic estimate for dietary intake for the general population, for the consignment in question. Therefore the average daily portion size should be adjusted for the likely proportion of the total daily dietary intake resulting from the affected consignment or batch.

Where relevant to the contaminant finding, the cut-off value should account for infant body weight and consumption patterns.

The cut-off value should be easily applied by risk managers without recourse to specialist advice.

7.3 Example cut-off value

The application of the above criteria can be realised by cut-off values of [0.3 / 1 µg/kg] as presented in the example in Appendix 2.]

7. APPLICATION OF THE DECISION TREE FOR RISK MANAGEMENT DECISION MAKING

On confirmation of the presence of *the* contaminant in food the risk manager should apply the decision tree in a timely manner. See Appendix 1

7.1. Exclusionary categories (Step 1 of the Decision Tree)

As identified in the Threshold of Toxicological Concern (TTC) *decision tree* certain chemical groupings may not be suitable for rapid evaluation given chemical or toxicological properties. Unless there is prior experience with rapid evaluation of the chemical grouping, a risk manager should exclude applying the decision tree to the following categories of contaminants:

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

7.2. Application of the cut-off value (Step 2 of the Decision Tree)

The risk manager should apply the cut-off value to the detected concentration of the contaminants in the food under investigation.

If the detection of the emerging contaminant exceeds the cut-off value:

- then rapid evaluation should be sought.
- the risk manager should inform relevant stakeholders of the detections and their intention to submit all available information for rapid evaluation as soon as possible².

Where the detection does not exceed the cut-off value a risk management decision can be made that the consignment does not present a food safety concern. Informing the relevant stakeholders of the detection may still be of value

7.3. Country of origin information sharing (Step 3 of the Decision Tree)

In the case of food in trade, in addition to notifying of the detection of *the* contaminant in food, the risk manager should request any relevant food safety information from the competent authorities of the exporting country. Relevant food safety information may include, but is not limited to, toxicological datasets, prior occurrence in the food of interest and any history of use.

7.4. Request for rapid evaluation (Step 4 of the Decision Tree)

The risk manager should seek rapid evaluation of the detection in the first instance, for completion as soon as possible and practicable. The risk manager will provide any country of origin information obtained to the risk assessor

7.5. Toxicological data collection (Step 5 of the Decision Tree)

The risk assessor will access any readily available toxicology data on the contaminant that will inform the choice of the rapid evaluation method.

7.6. Other relevant food safety information

The risk assessor will access any other readily available food safety data on the contaminant that will inform the choice of the rapid evaluation method. This may include, but is not limited to, prior occurrence, exposure data and processing information.

7.7. Rapid evaluation: *Application of the TTC decision tree, exposure assessment and risk characterisation* (Steps 6-9 of the Decision Tree)

If a health based guidance value for the emerging contaminant is available, or sufficient toxicological data is available to establish one, hazard characterisation should be undertaken using the health based guidance value. (Step 7)

In the absence of a health based guidance value, or sufficient toxicological data to establish one, the TTC decision tree should be applied to arrive at an appropriate threshold of no concern for the contaminant (Step 6).

With the dataset available the risk assessor should undertake an exposure assessment of the contaminant in the food of interest and characterise the risk in relation to the *threshold of no concern established through the TTC decision tree*(Steps 8 and 9). Any assumptions and uncertainties in the exposure assessment should be recorded.

7.8. Reporting (Steps 10 and 11 of the decision tree)

The risk assessor should provide the results to the risk manager in a clear and standardised manner, in an agreed time frame.

The risk assessor may provide a scientific opinion on the degree of uncertainty in the results of the rapid evaluation.

7.9. Decision by the risk manager

The risk manager should take into account the scientific opinion provided by the risk assessor and decide on the risk management response. This includes:

² In the case of food in trade, The Codex Committee on Food Import and Export Inspection and Certification systems (CCFICS) provides guidance on exchange of food safety information between Competent Authorities

- (i) Judging the food consignment / lot as fit for human consumption on the basis of negligible risk to human health
- (ii) Judging the food consignment / lot as unfit for human consumption on the basis of a potential risk to human health
- (iii) Seeking further information on the possible level of the contamination in further consignments / lots so as to better establish whether there is a potential public health concern and a formal risk assessment may be required

The risk manager should communicate the option taken and any decision on fitness or otherwise of the consignment / lot as soon as possible and practicable. In the case of food in trade, The Codex Committee on Food Import and Export Inspection and Certification systems (CCFICS) provides guidance on exchange of food safety information between competent authorities (Principles and guidelines for the exchange of information between importing and exporting countries to support the trade in food (CXG 89-2016)).

8. FURTHER RISK MANAGEMENT ACTIVITIES

The risk management scenario may result in targeted surveillance to gain more information on the possibility of further events and more closely evaluate the level of dietary exposure over time.

Where a detection of *the* contaminant becomes a frequent or consistent occurrence in food, new information becomes available on the toxicity of the contaminant, or there are indications that dietary exposure may be at a level that constitutes a potential risk to human health; consideration should be given to undertaking toxicological studies and/or planning for a formal risk assessment.

9. RISK COMMUNICATION

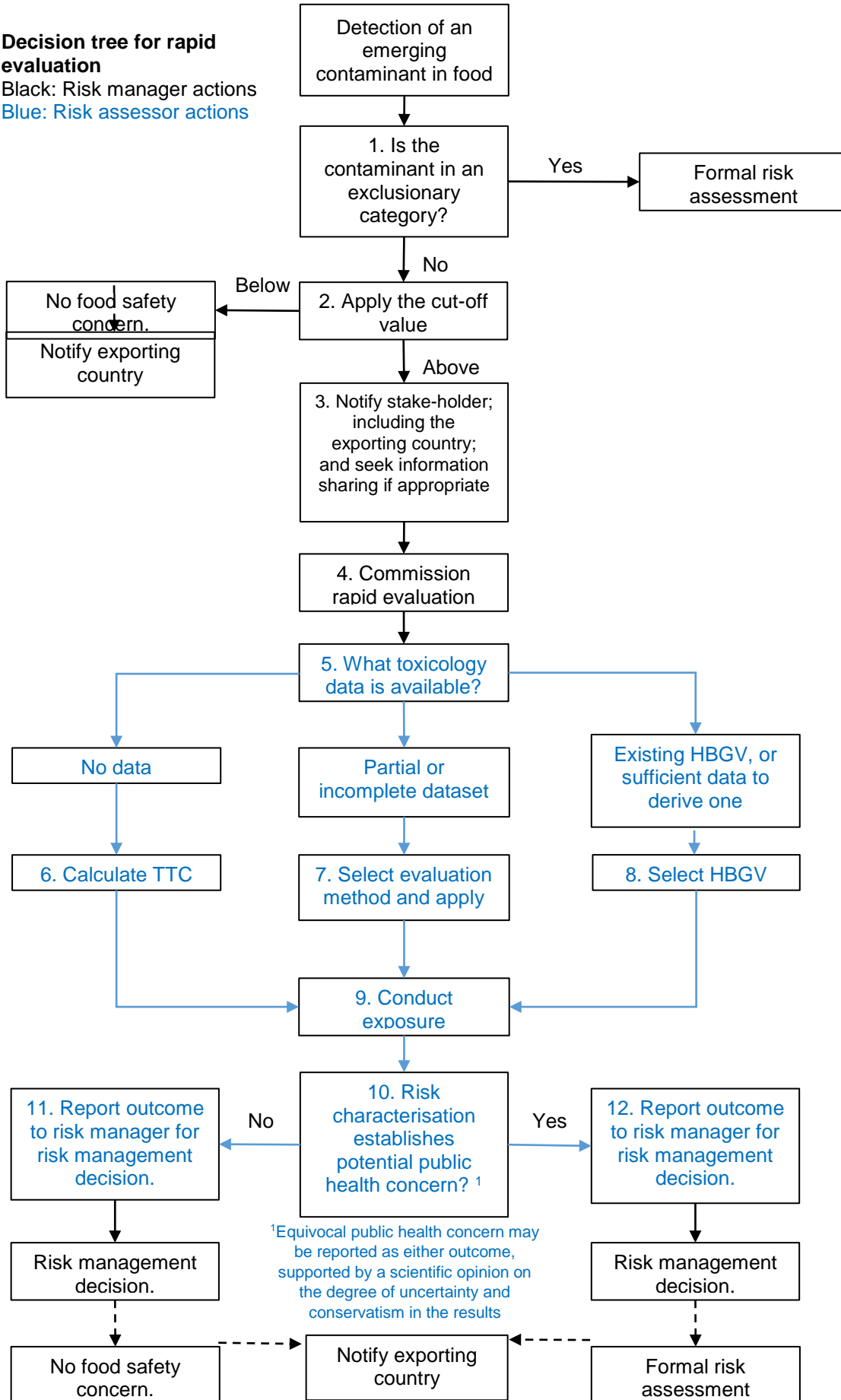
Consumers and other stakeholders have a high level of interest in the presence of contaminants in food and the outcomes of the risk assessment and risk management activities of competent authorities. Thus the communication of risk management decisions for contaminants that might be found in foods should be appropriately addressed in broader risk communication plans.

10. TRAINING

The competency and experience of risk assessors applying the rapid evaluation methodology within the decision tree is a key input to consistent and transparent scientific advice being provided to risk managers. It is likely that the risk assessors will be employees of the competent authority or government body/agency but in the case that non-government personnel are contracted to provide risk assessment advice, they should be subject to competency and experience requirements as specified by the competent authority.

Decision tree for rapid evaluation

Black: Risk manager actions
Blue: Risk assessor actions

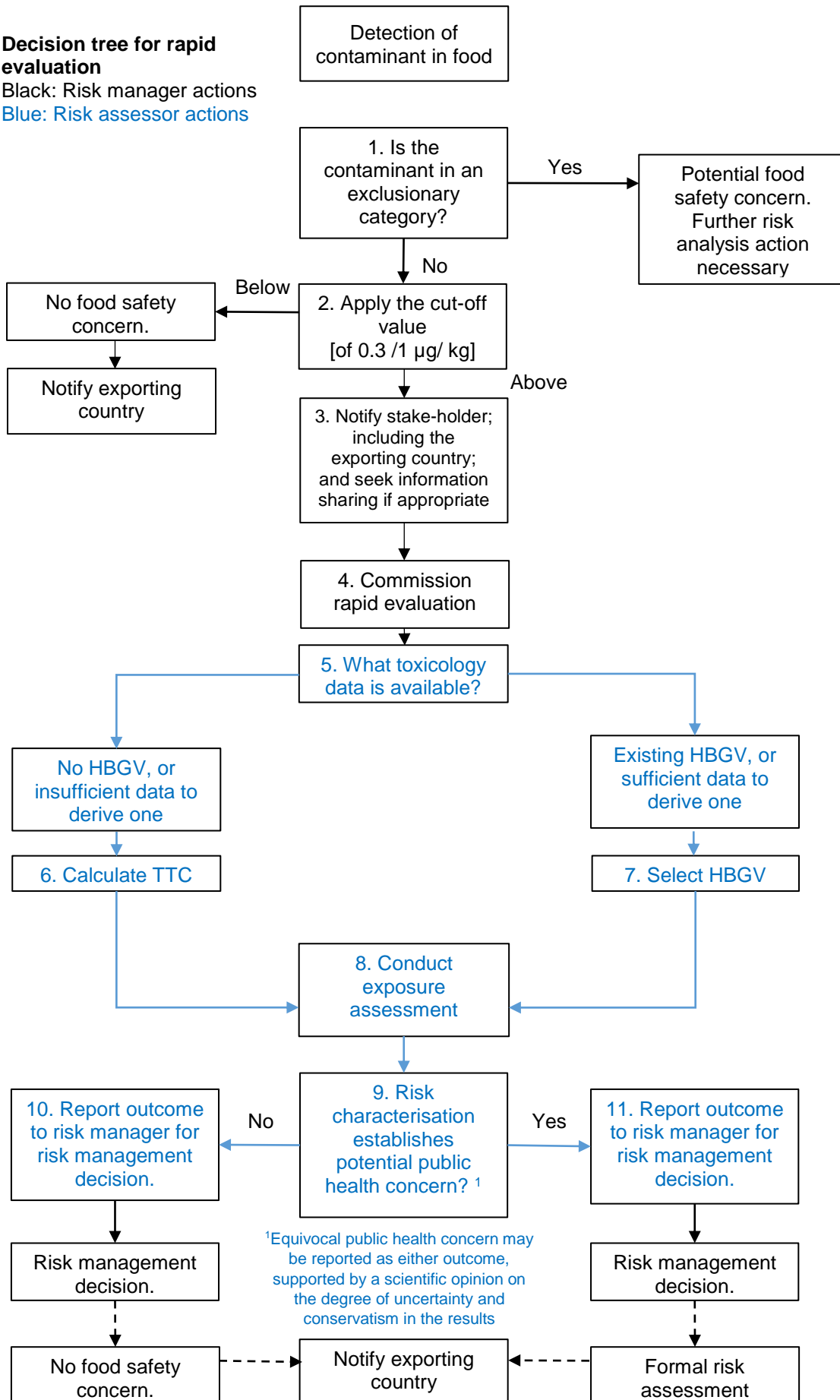


[Annex 1] Decision tree

Decision tree for rapid evaluation

Black: Risk manager actions

Blue: Risk assessor actions



[Annex 2] Example of derivation of cut-off value

A cut-off value can be calculated using the following formula:

$$\text{Cut-off value} = (\text{TNC} / (\text{BWM} * \text{CAF})) * \text{CF}$$

Where:

TNC is the Threshold of No concern ($\mu\text{g}/\text{kg}$ bw/day)

BWM is the Body Weight adjusted mass of food consumed per day (g/ kg bodyweight /day)

CAF is the Consignment adjustment factor ¹ (dimensionless).

CF is the unit conversion factor (1000)

¹ The consignment adjustment factor (CAF) is defined as the ratio of the maximum mass of the daily diet that would be impacted through the instance of a detection of a contaminant in a consignment or lot to the total daily mass of foodstuffs consumed.

Example cut-off value calculations:

Foods for infant consumption

$$\text{Cut-off value} = 0.3 \mu\text{g}/\text{kg} = (0.0025 \mu\text{g}/\text{kg} \text{ bw}/\text{day} / (72 * 0.1)) * 1000$$

TNC = TTC decision tree genotoxicity threshold: 0.0025 $\mu\text{g}/\text{kg}$ bw/day

BWM = 72 g/kg bodyweight/ day = total daily diet intake: 550g/day* / bodyweight: 7.64 kg[#]

* A rounded daily intake value calculated from the annual mass of foodstuffs consumed by an infant in the first year of life, as reported in Annex 1 of the Radionuclide Guidelines in CXS 193-1995.

[#] Average of median bodyweights for male and female 5-6 month old infants, reported according to the Joint FAO/WHO/UNU expert report on human energy requirements (FAO/WHO/UNU, 2004).

CAF = 0.1

CF = 1000

Foods for consumption by the general population

$$\text{Cut-off value} = 1 \mu\text{g}/\text{kg} = (0.0025 \mu\text{g}/\text{kg} \text{ bw}/\text{day} / (25 * 0.1)) * 1000$$

TNC = TTC decision tree genotoxicity threshold: 0.0025 $\mu\text{g}/\text{kg}$ bw/day

BWM = 25 g/kg bodyweight/ day = total daily diet intake: 1500g/day* / bodyweight: 60 kg[#]

* A rounded daily intake value calculated from the annual mass of foodstuffs consumed by an adult, as reported in Annex 1 of the Radionuclide Guidelines in CXS 193-1995.

[#] Assumed average adult bodyweights (EHC 240, 2009).

CAF = 0.1

CF = 1000]

Annex [3] Case studies

United Kingdom Food Standards Authority interim assessment for tetrodotoxin:

<https://www.food.gov.uk/sites/default/files/uk-provisional-risk-assessment-july-2016.pdf>

New Zealand Ministry for Primary Industries occurrence and risk characterisation of migration of packaging chemicals in New Zealand Foods:

<http://www.mpi.govt.nz/dmsdocument/21871-occurrence-and-risk-characterisation-of-migration-of-packaging-chemicals-in-new-zealand-foods>

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 ¹	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 and Brazil: occurrence data on foods of animal origin.	Canada
Inorganic Arsenic	2001 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.	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: conducting neurodevelopmental study in rats to assess impact of arsenic on behavior; study to be completed in 2019, results expected in 2020 Brazil: iAs occurrence data in rice; submitted total As data on poultry, pork, fish, and cattle meat Japan and China: occurrence data on rice and rice products (already submitted to GEMS/Food) AU/NZ: total diet study; occurrence data in rice products. India: occurrence data in rice Turkey: occurrence data in rice	USA
Scopoletin	Full evaluation (toxicological assessment and exposure assessment) in fermented Noni juice	CCNASWP still working on standard for noni juice and data availability	FAO/WHO Coordinating Committee for North America and South-West Pacific (CCNASWP)
Ergot alkaloids ²	Full evaluation (toxicological assessment and exposure assessment)	EFSA (2012) report EU: occurrence data (collecting); assessment on exposures to ergot alkaloids (EFSA report published in May 2017) Canada: occurrence data (commodity specific and unprocessed cereal grains) NZ: occurrence data on cereals (2-year collection, will provide data from first year)	EU; Canada

Ciguatoxins ³	Full evaluation (toxicological assessment and exposure assessment), including geographic distribution and rate of illness; congeners; methods of detection	India EU: Eurocigua project, RASFF US: occurrence data (outbreak management) Australia: illness data Cuba: epidemiological data Japan: Data available and will reach out to FAO secretariat regarding submission. Japan can provide information on methods. FAO/WHO scientific meeting scheduled for November 2018. To support this meeting, there has been a call for data and experts.	CCCF
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) Cuba: epidemiological data EU: Report by EFSA on dietary exposure published in July 2017. Data will be made available to GEMS/food database.	83 rd JECFA, recommendation supported by CCCF11.

¹ Lower priority: JECFA evaluation to build on the ongoing work at national and regional re-assessment of dioxins.

² Ergot is mentioned in quality chapter, suggestion for integration into GSCTFF.

³ The calls for data and for experts for the meeting on Ciguatoxins will be made available in time on the respective FAO and WHO websites:

FAO: www.fao.org/food/food-safety-quality/scientific-advice/calls-data-experts/en/

WHO: <http://www.who.int/entity/foodsafety/call-data-expert/en/index.html>