CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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REP25/CF18

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Forty-eighth Session
10-14 November 2025

REPORT OF THE 18th SESSION OF THE CODEX COMMITTEE ON CONTAMINANTS IN FOODS

Bangkok, Thailand

23-27 June 2025

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SUMMARY AND STATUS OF WORK

Responsible Party	Purpose	Text/Topic	Code	Step(s)	Appendices & Paragraphs
Members and Observers CCEXEC89 CAC48 Codex Secretariat	Critical Review Adoption Publication	ML for lead in spices, dried bark	CXS 193-1995	8	Appendix III Para 47 (i) (a)
Members and Observers CCEXEC89 CAC48 Codex Secretariat	Critical Review Adoption Publication	ML for lead in culinary herbs, dried	CXS 193-1995	5/8	Appendix III Para 47 (i) (b)
CCEXEC89 CAC48	Critical Review Discontinuation	ML for lead in culinary herbs, dried	CXS 193-1995	7	Appendix III Para 47 (ii)
CCMAS45 Members and Observers CCEXEC90 CAC49 Codex Secretariat	Endorsement Critical Review Adoption Publication	Sampling plans and numeric performance criteria for total aflatoxins and ochratoxin A in certain spices	CXS 193-1995	8	Appendix IV Para 62
CCMAS45 Members and Observers CCEXEC90 CAC49 Codex Secretariat	Endorsement/ Advice Critical Review Adoption Publication	Revised numeric performance criteria for methods of analysis for total aflatoxins utilizing the sum of components concept in relevant sampling plans. Amendment to the relevant sampling plans in the *General Standard for contaminants in food and feed* (CXS 193-1995) by replacing the current NPC and related texts with a reference to the *Recommended methods of analysis and sampling* (CXS 234-1999) once CCMAS45 has endorsed the revised numeric performance criteria.	CXS 193-1995 CXS 234-1999	-	Appendix X Para 133 (i)-(iii)
Members and Observers CCEXEC89 CAC48 Codex Secretariat	Critical Review Adoption Publication	*Code of practice for the prevention and reduction of aflatoxin contamination in peanuts* (revision)	CXC 55-2004	5/8	Appendix V Para 80 (i)
CCEXEC89 CAC48	Critical Review Discontinuation	Maximum level and associated sampling plan for total aflatoxins in ready-to-eat peanuts	CXS 193-1995	4	Para 72 (i)
CCEXEC89 CAC48 EWG (Türkiye, United Kingdom, and Netherlands) Members and Observers CCCF19	Critical Review Approval Discussion Comments Consideration	New work on the revision of the *Code of practice for weed control to prevent and reduce pyrrolizidine alkaloid contamination in food and feed*	CXC 74-2014	1/2/3	Appendix VI-Part I Para 90 (ii)

Responsible Party	Purpose	Text/Topic	Code	Step(s)	Appendices & Paragraphs
CCEXEC89 CAC48 EWG (Canada and Saudi Arabia) Members and Observers CCCF19	Critical Review Approval Discussion Comments Consideration	New work on the revision of the *Code of practice for the reduction of Aflatoxin B1 in raw materials and supplemental feedingstuffs for milk-producing animals*	CXC 45-1997	1/2/3	Appendix VII Para 102 (ii)
CCEXEC89 CAC48 EWG (China and Saudi Arabia) Members and Observers CCCF19	Critical Review Approval Discussion Comments Consideration	New work on the development of a code of practice for the prevention and reduction of tropane alkaloids in food and feed	-	1/2/3	Appendix VIII Para 106 (ii)
CCEXEC89 CAC48	Critical Review Adoption	Editorial amendments to CXS 193-1995: • Removal of outdated content from Annex X - *Scientific justification for the guideline levels for radionuclides in foods contaminated following a nuclear or radiological emergency* of CXS193 • Inclusion of maximum levels for marine biotoxins (Section 1.5 of the *Standard for live and raw bivalve molluscs* (CXS 292-2008)) in CXS193	-	-	Appendix II Para 17 (v) Para 198
CCEXEC89/CAC48 Codex Secretariat	Information Publication	• Link to the IAEA document on *Natural radioactivity in food, feed, and drinking-water* on the Codex website, once available. • Guidance on data analysis for the development of maximum levels and for improved data collection (main text) (Information document)	-	-	Para 28 (iii) Appendix IX Para 123 (i)
EWG (USA) Members and Observers CCCF19	Discussion Comments Consideration	Code of practice for the prevention and reduction of cadmium contamination in foods	-	2/3	Para 52 (i)
EWG (India, Qatar, and Saudi Arabia) Members and Observers CCCF19	Discussion Consideration	Discussion paper on the review of the *Code of practice for the reduction of acrylamide in foods*	CXC 67-2009	-	Para 97 (i)

Responsible Party	Purpose	Text/Topic	Code	Step(s)	Appendices & Paragraphs
EWG (European Union, Japan, the Netherlands, and the USA) Members and Observers CCCF19	Discussion Comments Consideration	Guidance on data analysis for the development of maximum levels and for improved data collection (Annexes I-VI)	-	-	Para 123 (ii)-(iii)
EWG (Japan, India, Panama, and the USA) Members and Observers CCCF19	Discussion Consideration	Discussion paper on options for guidance on the application of maximum levels to spice mixtures	-	-	Para 143
EWG (Brazil and Thailand) JECFA Secretariat Members and Observers CCCF19 CCCF20	Discussion Consideration	Call for data for aflatoxins in cereal grains and cereal-derived products (Brazil/JECFA Secretariat for consideration by CCCF19) Discussion paper on the review of data in the GEMS/Food database to assess the need for: • revising maximum levels for aflatoxins in cereal grains and cereal-derived products in CXS 193-1995; • considering the development of new maximum levels for specific cereals; and • evaluate the necessity to revise CXC 51-2003 (EWG for consideration by CCCF20)	-	-	Para 161 (i)-(ii)
EWG (New Zealand and Canada) CCCF19	Discussion Consideration	Discussion paper on reviewing the maximum level for methylmercury in tuna and the associated sampling plan	-	-	Para 166 (vi)
EWG (European Union) CCCF19	Discussion Consideration	Discussion paper on T-2, HT-2, DAS and ergot alkaloids	-	-	Para 172 (i)
EWG (Türkiye and the United Kingdom) CCCF19	Discussion Consideration	Discussion paper on the development of a code of practice for the prevention and reduction of ochratoxin A contamination in dried fruits	-	-	Para 192

Responsible Party	Purpose	Text/Topic	Code	Step(s)	Appendices & Paragraphs
The USA, with the assistance of Canada, the European Union, Japan, and other interested countries CCCF19	Discussion Consideration	Discussion paper on developing guidance related to food safety aspects of recycled plastics in food packaging	-	-	Para 189
Brazil, with the assistance of Costa Rica CCCF19	Discussion Consideration	Discussion paper to identify methods or numeric performance criteria for maximum levels in CXS 193-1995 for which there are no methods in CXS 234-1999	-	-	Para 194
Members and Observers WG (Canada) CCCF19	Comments Discussion Consideration	Review of Codex standards for contaminants	-	-	Para 166 (v)
Members and Observers WG (USA) CCCF19	Comments Discussion Consideration	Follow-up work on the outcomes of JECFA evaluations and FAO/WHO expert consultations	-	-	Para 172 (ii)
Members and Observers WG (USA) CCCF19	Comments Discussion Consideration	Priority list of contaminants for evaluation by JECFA	-	-	Appendix XI Para 183 (ii)
Codex Secretariat Members and Observers WGs	Distribution Comments Discussion	Circular Letters: • Code of practice for the prevention and reduction of cadmium contamination in foods: General and commodity-specific mitigation measures, including for cereal and cereal products, vegetables, pulses and legumes, fruits, and shellfish • *Code of practice to prevent acrylamide in foods* (CXC 67-2009): Mitigation measures that have been proven to be feasible and effective for application for local and/or regional conditions to reduce acrylamide contamination in foods.	-	-	Paras 52 (iii), 97 (ii), 102 (iv), 106 (iv), 166 (iv), 183

Responsible Party	Purpose	Text/Topic	Code	Step(s)	Appendices & Paragraphs
		• *Code of practice for the reduction of aflatoxin B1 in raw materials and supplemental feedingstuffs for milk-producing animals* (CXC 45-1997): Risk management practices and other data or information that can support the further development of the CoP. • Code of practice for the prevention and reduction of tropane alkaloids contamination in food and feed: Additional risk management practices and other data/information that could support the further development of the CoP. • Review of Codex standards for contaminants • Priority list of contaminants for evaluation by JECFA			

LIST OF ABBREVIATIONS

2-CE	2-chloroethanol
3-MCPDE	3-monochloropropane-1,2-diol ester
AFB1	Aflatoxin B1
AFB2	Aflatoxin B2
AFG1	Aflatoxin G1
AFG2	Aflatoxin G2
AFT	Total Aflatoxins
ALARA	As Low as Reasonably Achievable
BPA	Bisphenol A
CAC	Codex Alimentarius Commission
CCCF	Codex Committee on Contaminants in Foods
CCEXEC	Executive Committee of the Codex Alimentarius Commission
CCFA	Codex Committee on Food Additives
CCFFP	Codex Committee on Fish and Fishery Products
CCMAS	Codex Committee on Methods of Analysis and Sampling
CIFOCOss	FAO/WHO Chronic Individual Food Consumption Data summary statistics
CL	Circular Letter
CoP	Code of Practice
CRD	Conference Room Document
CXC	Codex Code of Practice
CXG	Codex Guideline
CXS	Codex Standard
DAS	4,15-diacetoxyscirpenol
EHC	Environmental Health Criteria
EI	Environmental Inhibitor
EtO	Ethylene Oxide
EU	European Union
EWG	Electronic Working Group
FAO	Food and Agriculture Organization of the United Nations
FAORAP	Food and Agriculture Organization of the United Nations Regional Office for Asia and the Pacific
FFP	For Further Processing
GEMS/Food	Global Environment Monitoring System - Food Contamination Monitoring and Assessment Programme
GE	Glycidyl Ester
GL	Guideline Level
IAEA	International Atomic Energy Agency
IOC-UNESCO	Intergovernmental Oceanographic Commission of the United Nations Educational, Scientific, and Cultural Organization

ISWG	In-session working group
JECFA	Joint FAO/WHO Expert Committee on Food Additives
LOD	Limit of Detection
LOQ	Limit of Quantification
ML	Maximum Level
ND	Not Detectable
NPC	Numeric Performance Criteria
OHPL	Overall Highest Priority List
P95	95th percentile
PA	Pyrrolizidine Alkaloid
PAH	Polycyclic Aromatic Hydrocarbon
PAHO	Pan-American Health Organisation
PWG	Physical working group
RTE	Ready-To-Eat
SEARO	South-East Asia Region
UK	United Kingdom
USA	United States of America
VWG	Virtual working group
WHO	World Health Organization
WPRO	Western Pacific Region

LIST OF CONFERENCE ROOM DOCUMENTS (CRDs)

CRD No.	Agenda Item	Submitted by
1	Division of Competence	European Union
2	13	Chair (China)
3	21	Chair (USA)
4	20	Chair (USA)
5	12	Chair (Canada)
6	19	Chair (Canada)
7	22	Host country Secretariat
8	22	Türkiye
9	9	Chair (Brazil)
10	10	Chair (Türkiye)
11	7, 8, 11, 12, 18	Singapore
12	2, 3, 9	Rwanda
13 Rev.1	6, 16, 21	Food Industry Asia (FIA)
14	7, 10, 14	Thailand
15	7, 8, 11, 14, 17, 18	United States of America (USA)
16	5, 6, 8, 11, 14, 16, 17	China
17	2, 3, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 17, 18	European Union (EU)
18 Rev.1	2, 3, 5, 6, 7, 8, 9, 10, 12, 13, 14, 15, 19, 21	United Republic of Tanzania
19	6, 9, 10, 13	Republic of Korea
20	2, 3, 5, 6, 7, 8, 9, 10, 12, 13, 14, 15, 19, 21	Uganda
21	2, 5, 6, 8, 9, 12, 15, 17, 18	Senegal
22	3, 9, 10, 12, 13	Nigeria
23	5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 19	India
24	2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 20, 21	Panama
25	6, 9, 10, 11, 12	El Salvador
26	6	Chair (USA)
27	17	Japan
28	2, 3, 7, 8, 12, 14	Kenya
29	2, 3, 5, 6, 7, 8, 9, 10, 12, 13, 14, 15, 19, 21	Burundi
30	6, 11, 16	Institute of Food Technologists (IFT)
31	9	Chair (Brazil)
32	7	Chair (India)
33	5, 6, 9, 10, 12, 13, 15	Ghana
34	2, 3, 5, 6, 7, 8, 9, 10, 12, 13, 14, 15, 19, 21	East African Community (EAC)
35	5, 6, 9, 10, 12, 13, 15, 16	Egypt
36	5, 7, 8, 9, 11, 12, 13, 15, 16, 17, 18	International Union of Food Science and Technology (IUFOST)
37	6, 8, 9, 10, 12, 14	Zambia
38	5, 6, 8, 9, 10, 12, 14, 15	African Union (AU)
39	14	Chair (European Union)

INTRODUCTION

1. The Codex Committee on Contaminants in Foods (CCCF) held its 18th Session in Bangkok, Thailand, from 23 to 27 June 2025, in a hybrid format, at the kind invitation of the Governments of the Kingdoms of Thailand and the Netherlands. Dr. Sally Hoffer, Manager Safe and Sustainable Food, Ministry of Agriculture, Nature and Food Quality, Plant Agro Chains and Food Quality, Netherlands (Kingdom of the), chaired the Session, which was attended by 71 Member countries, one Member organization, and 23 Observer organizations. The list of participants is contained in Appendix I.

OPENING OF THE SESSION

2. Ms Anongnat Jakaeo, Secretary to the Minister of Agriculture and Cooperatives, Thailand, opened the meeting and underscored its critical role as an international platform for enhancing food safety standards and consumer health globally. The Secretary further highlighted the increasing challenge posed by emerging contaminants, emphasizing the urgent need for robust risk assessment and management approaches within the international food system. Reaffirming the commitment of Thailand to Codex and CCCF, she expressed confidence that the Committee would be instrumental in fostering scientific advancements, promoting food safety technologies, and developing effective, long-term measures for food safety risk management and public health protection.

3. Ms Miriam Otto, Deputy Ambassador of the Netherlands in Thailand, also addressed the meeting and emphasised the paramount importance of food safety amidst rapid global expansion in food production and trade. The Deputy Ambassador highlighted that unsafe food not only jeopardised public health but also undermined food security, as it failed to provide healthy nourishment. She concluded by describing the meeting as a crucial opportunity for participants to achieve tangible progress toward a safer global food production and supply chain.

4. The following representatives also addressed CCCF:

- Dr Betul Vazgecer, Vice-Chairperson of the Codex Alimentarius Commission
- Dr Jos Vandelaer, the World Health Organization (WHO) Representative to Thailand
- Mr Robert Simpson, Deputy Regional Representative, Food and Agriculture Organization of the United Nations Regional Office for Asia and the Pacific (FAORAP)
- Dr Sally Hoffer, Chairperson of CCCF

Division of Competence

5. CCCF18 noted the division of competence between the European Union (EU) and its Member States, according to paragraph 5, Rule II of the Procedure of the Codex Alimentarius Commission (CAC).

ADOPTION OF THE AGENDA (Agenda item 1)[1]

6. CCCF18 adopted the Provisional Agenda as the Agenda for the Session, and agreed to discuss the following topics under Agenda item 22, Other business, subject to the availability of time:

(i) An update to a new work proposal on guidance related to food safety aspects of the use of recycled plastics in food packaging (United States of America (USA)).

(ii) A proposal for the development of a code of practice for the prevention and reduction of ochratoxin A (OTA) contamination in dried fruits (Türkiye, CRD08).

(iii) A proposal to identify maximum levels (MLs) in the *General standard for contaminants in food and feed* (CXS 193-1995) that do not have corresponding methods of analysis or numeric performance criteria (NPC) in the *Recommended methods of analysis and sampling* (CXS 234-1999), and the identification of appropriate analytical methods or NPC for these MLs (Brazil).

(iv) The evaluation of CCCF between 2020 and 2023 (The Netherlands as Host Country Secretariat, CRD07).

7. CCCF18 also agreed to establish the following in-session working groups (ISWGs), open to all Members and Observers, and working in English to review:

(i) the project document on new work on the development of a code of practice for the prevention and reduction of tropane alkaloids (TAs) in food and feed, as presented in Appendix II of CX/CF 25/18/14, chaired by China (Agenda item 13); and

(ii) the Guidance on data analysis for development of MLs and improved data collection, as presented in Appendix I of CX/CF 25/18/15, chaired by the European Union (Agenda item 14).

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1 CX/CF 25/18/1

MATTERS REFERRED TO THE COMMITTEE BY THE CODEX ALIMENTARIUS COMMISSION AND/OR ITS SUBSIDIARY BODIES (Agenda item 2)[2]

8. CCCF noted that, while most items were for information purposes, there were matters for action arising from the Codex Committee on Methods of Analysis and Sampling (CCMAS), and a matter for action relating to an editorial amendment to Annex X - *Scientific justification for the guideline levels for radionuclides in foods contaminated following a nuclear or radiological emergency* of CXS193.

43rd Session of CCMAS (2024)

9. CCCF recalled that CCMAS43 had requested the Committee to consider:

- adding example methods for determining total aflatoxins (AFT) in cereals in CXS193, which would also incorporate the listing of EN 17641 as an example method for certain cereals and cereal-based products, including foods for infants and young children; and
- transferring all NPC from CXS193 to CXS234.

10. CCCF18 agreed to consider these requests at a future session, at such a time when work on the review of sampling plans and/or updating of NPC in CXS193 becomes more advanced.

44th Session of CCMAS (2025)

11. The Committee was informed that CCMAS44 had agreed to develop a discussion paper on sampling plans for bulk materials/heterogeneous lots, including for mycotoxins, and that CCCF would be kept informed of this work and consulted as necessary.

12. A Member, recalling that sampling plans in CXS193 are developed by CCCF, requested clarification on the extent to which the Committee should take into account the discussion paper and work on sampling plans for bulk materials/ heterogeneous lots when reviewing sampling plans.

13. The Codex Secretariat explained that the CCMAS decision to develop the discussion paper was in response to questions raised when the *General guidelines on sampling* (CXG 50-2004) were being revised and its related information document for the general guidelines was being developed. The Secretariat provided further reassurance that CCMAS would only look at approaches for sampling plans and that it remained the remit of CCCF to develop sampling plans. CCMAS would ensure that there was communication with the Committee once the CCMAS discussion paper was more advanced.

Editorial amendment to Annex X of CXS193

14. The Codex Secretariat explained that the paragraph referencing the adoption of the *Guideline levels for radionuclides in foods following accidental nuclear contamination for use in international trade* (CXG 5-1989) in Annex X of CXS193 and its associated footnote were no longer relevant due to the revocation of CXG5 by CAC29 (2006) following the revision and transfer of the guideline levels (GLs) to CXS193.

15. Noting that this paragraph and the associated footnote did not provide any technical information, but rather contained outdated historical data on the GLs, CCCF agreed to delete them to keep the Annex up to date.

The model for future Codex work

16. CCCF noted the "CCCF Chair's Activity: Inspiration from EWG Chairs", organised by the Chairperson during the pre-session meeting on 22 June 2025, which shared experiences by Electronic Working Group (EWG) chairs, lessons learned, and practical tips for future EWG chairs.

Conclusion

17. CCCF18:

(i) noted the matters for information referred to by CAC, the Executive Committee, and other subsidiary bodies;

(ii) encouraged:

(a) more Members to take leadership roles in electronic working groups; and

(b) Members and Observers to provide input to the monitoring framework for the Codex Strategic Plan 2026-2031

[2] CX/CF 25/18/2; CX/CF 25/18/2-Add.1

(iii) agreed to take into account the ongoing work on sampling plans for bulk materials/heterogeneous lots by the Codex Committee on Methods of Analysis and Sampling, including mycotoxins, when reviewing sampling plans in CXS193 in the future, and noted that CCMAS would consult with CCCF as the work progresses;

(iv) considered the addition of example methods for numeric performance criteria at a later stage, as work continues updating NPC and reviewing sampling plans; and

(v) forwarded the editorial amendments in Annex X - *Scientific justification for the guideline levels for radionuclides in foods contaminated following a nuclear or radiological emergency* of CXS193 to CAC48 (2025) for adoption (Appendix II).

MATTERS OF INTEREST ARISING FROM FAO AND WHO, INCLUDING JECFA (Agenda item 3)[3]

18. The WHO Secretariat of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) provided an update regarding the FAO and WHO activities of relevance to CCCF, including the following:

- Since CCCF17 (2024), JECFA convened two meetings in 2024 (98th on veterinary drug residues and 99th on food additives). The 100th meeting (June 2025) addressed food additives, while the 101st (October 2025) would assess arsenic only, due to WHO budgetary constraints. The WHO JECFA Secretariat further mentioned that the originally planned evaluation of dioxins had been deferred, noting that financial limitations led to the postponement of the veterinary drug residue meeting and a possible reduction in the scope of future JECFA sessions.
- The Global Environment Monitoring System - Food Contamination Monitoring and Assessment Programme (GEMS/Food) database continued to actively support the work of CCCF by supporting several Codex EWGs in the collection and analysis of global food contamination data to derive recommendations for MLs. The FAO/WHO Global Individual Food Consumption Data Tool and the FAO/WHO Chronic Individual Food Consumption Data summary statistics (CIFOCOss) provided useful food-based statistics for the work of Codex Members.

19. The WHO JECFA Secretariat, reporting on the activities of WHO, also informed CCCF about the current activities carried out by WHO at the global and regional level, including work on New Approach Methodologies, particularly in the context of food safety risk assessment, as well as a project that aims to fill in knowledge gaps in terms of chemical water safety and emerging contaminants, which can serve as the basis for future work by relevant Codex committees.

20. The FAO JECFA Secretariat, reporting on the activities of FAO, informed CCCF of the following:

- FAO and WHO continued to prioritise scientific advice based on Codex criteria and resource availability. The increasing demands for JECFA evaluations and the impact of reduced donor funding on meeting these needs were noted. Ongoing work addressed chemical contaminants in water used throughout the agrifood system, with an expert meeting evaluating emerging and known contaminants, including pharmaceuticals, agrochemicals, and fluorinated compounds.
- Work was undertaken on food safety risks in circular economy practices, focusing on chemical safety and regulatory gaps in emerging food packaging materials. The report on FAO's foresight on New Food Sources and Production Systems, which identified novel and traditional hazards and stressed the need for collaborative safety assessments and proactive measures, was also mentioned. Reports on environmental inhibitors (EIs) and risks in therapeutic foods for contexts of limited food availability, as well as personalised nutrition, particularly food supplements and functional foods, were also highlighted.
- Updates were presented, including on the risks and benefits of fish consumption, new guidance for bivalve mollusc sanitation, and formalised collaboration on Harmful Algal Blooms between FAO and the Intergovernmental Oceanographic Commission of the United Nations Educational, Scientific and Cultural Organization (IOC-UNESCO). Consideration was being given to reviewing the role of food contaminants in antimicrobial resistance and the published guidance on integrating artificial intelligence, big data, and Internet of Things into early warning systems. An international workshop reviewed advances in the risk assessment of chemical contaminants in animal feed, with FAO preparing a manual for harmonised methodologies.

Discussion

21. Members thanked FAO and WHO for their presentations and noted that:

[3] CX/CF 25/18/3; CX/CF 25/18/3-Add.1

- In the context of the report *Food safety in the context of limited food availability*, and in addition to the *Code of practice for the reduction of 3-monochloropropane-1,2- diol esters (3-MCPDE) and glycidyl esters (GEs) in refined oils and food products made with refined oils* (CXC 79-2019), consideration could be given to the establishment of MLs for specific food items; and
- An online tutorial on the GEMS/Food database would further increase its use and aid Members' understanding.

22. A Member noted its willingness to contribute to the work on food packaging waste and recycling, and microplastics and further noted its interest in the work developed by WHO and the United Nations Environment Programme to update the report "*State of the Science of Endocrine Disrupting Chemicals, 2012*", recalling relevant previous discussion on endocrine disruptors in Codex.

23. In response to a request for information regarding foresight on emerging issues in food and feed safety relevant to contaminants, it was recalled that, following decisions by CCCF17, the standing agenda item concerning foresight was removed from the agenda of the Committee, with provisions made for the organisation of side events for further information exchange as required. In this context, CCCF noted the side events held on mineral oil hydrocarbons and environmental inhibitors (EIs).

24. The FAO JECFA Secretariat noted the issuance of the circular letter CL 2025/06-CF, to gather information on emerging issues relevant to the Committee's work, and that, based on these replies and future information shared by Members, interest in convening a side event on foresight at CCCF19 (2025) was under evaluation.

Conclusion

25. CCCF18 thanked FAO and WHO for their work and noted the information provided.

MATTERS OF INTEREST ARISING FROM OTHER INTERNATIONAL ORGANIZATIONS (Agenda item 4)[4]

26. The Representative of the Joint FAO/IAEA Centre provided an update on their activities relevant to CCCF's work. The Representative further informed the Committee that the document on natural radionuclides in food, feed, and drinking water had been reviewed by IAEA/FAO/WHO, and comments submitted by Codex Members and Observers in response to CL 2023/17-CF had been considered in the updated information document. The Representative noted that the International Atomic Energy Agency (IAEA) would keep CCCF informed about the publication of this document on the IAEA website and thanked all Codex Members who provided replies to the circular letter (CL).

27. The Codex Secretariat clarified that, although IAEA would publish the aforementioned document, it would not be a Codex publication; however, a link to it could be made available on the Codex website to facilitate consultation by the Codex membership.

Conclusion

28. CCCF18:

(i) expressed its appreciation to the Joint FAO/IAEA Centre;

(ii) noted the information provided by the IAEA Representative; and

(iii) agreed to publish a link to the information document *Natural radioactivity in food, feed and drinking-water* on the Codex website once this document becomes available.

MAXIMUM LEVELS FOR LEAD IN CERTAIN FOOD CATEGORIES (at Steps 4 and 7) (Agenda item 5)[5]

29. Brazil, as Chair of the EWG, introduced the item and recalled that the JECFA Secretariat had issued a new call for data, specifically requesting the exclusion of submissions potentially linked to economic adulteration. The submitted data had been processed in early 2025, with contributions received from several Members.

30. The EWG Chair also provided the background of the work, summarised the work process to develop the MLs, as well as the responses to CL 2025/09-CF, and highlighted the key points of discussions in the EWG, which included sensitivity analyses comparing complete data sets with those expressed on a dry weight basis and comparing data submitted after the 2024 JECFA call for data with older data available in the GEMS/Food database. The EWG evaluated whether the newly submitted data warranted a revision of the MLs proposed at CCCF17.

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4 CX/CF 25/18/4

5 CL 2025/09-CF; CX/CF 25/18/5; CX/CF 25/18/5-Add.1 (Comments of Argentina, Canada, Chile, Egypt, Ghana, Indonesia, Japan, Kenya, New Zealand, Philippines, Singapore, Thailand, the United Arab Emirates (UAE), the United States of America (USA), and the International Commission for Uniform Methods of Sugar Analysis (ICUMSA))

31. The EWG Chair informed CCCF that, for spices, dried bark, the new data did not indicate a reduction in lead levels, and so there was no evidence that the older data were from adulterated samples. Therefore, the entire dataset, including data submitted to both JECFA calls for data, was considered in establishing the ML for lead in spices, dried bark. For culinary herbs, dried samples with high limits of quantification (LOQs) had been excluded, as it is not possible to evaluate if the non-detects with those LOQs could comply with the ML under consideration. Global and regional 95th percentile (P95) values were examined in relation to the hypothetical MLs.

32. The EWG Chair also informed CCCF that the EWG proposed MLs of 3.0 mg/kg for lead in spices, dried bark, and 2.0 mg/kg for lead in culinary herbs, dried. Nevertheless, all scenarios were presented to the Committee to decide on the best approach. The EWG was of the view that extrapolation of MLs from dried to fresh culinary herbs was unnecessary, and accordingly, the related Note had been removed.

Discussion

Procedural matters

33. Before considering the proposals of the EWG, the Chairperson noted that there were some procedural issues raised in the comments submitted in reply to CL 2025/09-CF on the status of the MLs previously adopted at Step 5, and the need to discontinue these should CCCF agree with the new MLs proposed for discussion at Step 4.

34. The Codex Secretariat clarified that while commodity standards or other texts could be amended at Step 7 and advanced to Step 8, this procedure generally did not apply to MLs or other single numerical standards. When new data is introduced, it would be necessary to reconsider the MLs in full, necessitating discontinuation of the existing ML adopted at Step 5 if a new numerical value is agreed upon. This was because the new value constituted a complete revision based on a new or different set of data, rather than a partial amendment. The Secretariat noted that this practice was well established in the Codex Committee on Pesticide Residues and the Codex Committee on Residues of Veterinary Drugs in Foods, but less commonly applied in CCCF, as MLs that were advanced to Step 5/8 (with the omission of Steps 6 and 7) were generally adopted as such by CAC.

35. The Codex Secretariat further recommended that CCCF should avoid advancing MLs to Step 5 if there were remaining issues to be resolved or pending new data submission and should instead return such MLs to Step 2/3 for consideration based on the updated dataset. This approach would avoid any procedural inconsistencies. The Secretariat finally noted that, yet, both MLs were for consideration by the Committee, and CCCF, as a risk manager, could decide the best course of action concerning these MLs.

36. CCCF noted the explanations provided by the Codex Secretariat and proceeded to consider the recommendations of the EWG.

MLs for lead in spices, dried bark, and culinary herbs, dried

37. India expressed support for the EWG's proposed ML of 3.0 mg/kg for lead in spices, dried bark, but did not support the proposed ML of 2.5 mg/kg for all culinary herbs, dried, because some of the individual herbs reviewed in the paper did not have 59 or more data points. India proposed that the ML be determined based on the P95 value only for individual culinary herbs with 59 or more data points, in line with the guidance on data analysis for ML development (Agenda item 14).

38. A Member expressed concerns regarding the adequacy of the available data for certain specific herbs to support the establishment of MLs and highlighted the importance of a robust evidence base for such decisions. The EWG Chair emphasised that there had been several calls for data over the years (in 2019, 2020, 2021, 2022, and 2024) and that these calls for data included occurrence data of lead in spices, dried bark, and culinary herbs, dried, and that the MLs were therefore based on the best data available. It was up to CCCF to consider whether to proceed with the establishment of MLs if there were questions around the sufficiency of the data used to derive the MLs.

39. China supported the proposed ML of 3.0 mg/kg for lead in spices, dried bark, as it corresponded to an acceptable rejection rate, with no regional rejection rate exceeding 5%. China informed that it had submitted 235 data points to GEMS/Food in 2022, and analysis of those specific data showed that an ML of 2.5 mg/kg would result in a rejection rate of 19.57%; thus, the ML of 3.0 mg/kg is more appropriate. Regarding culinary herbs, dried, China supported an ML of 2.5 mg/kg, citing general support during the previous session and new data from developed countries.

40. Another Member did not support the proposed ML for culinary herbs, dried, as their preference was for an ML of 1.5 mg/kg.

41. A Member Organization noted that the global dataset had been divided into five regions and that the proposed MLs were based solely on the Pan-American Health Organisation (PAHO) data. The approach for setting Codex MLs should be based on the global data set, and only in cases where the distribution patterns of the data would significantly differ among regions, a case-by-case analysis based on regional data could be considered. As no significant statistical differences were observed across regions, it was recommended to use the global data set. The Member Organization supported an ML of 2.5 mg/kg for spices, dried bark, based on a 4% global rejection rate, and questioned the emphasis on PAHO, especially given lower lead levels in major producing regions such as the WHO South-East Asia Region (SEARO) and Western Pacific Region (WPRO). For culinary herbs, dried, the Member Organization supported an ML of 2.0 mg/kg.

42. Other Members who supported MLs of 2.5 mg/kg for spices, dried bark, and 2.0 mg/kg for culinary herbs, dried, emphasised the importance of using global data while also considering regional variations, and noted that the proposed MLs were both achievable and representative of the available data. In this regard, a Member noted that for some culinary herbs, dried (e.g., bay leaf and wormwoods), the P95 concentrations were not estimated due to low sample sizes; yet, the maximum lead concentration exceeded 2.0 mg/kg. The Member asked if the proposed ML of 2.0 mg/kg could therefore be achieved, to which the EWG Chair explained that the specific culinary herbs for which P95 were calculated could comply with the ML of 2.0 mg/kg separately.

43. CCCF noted that the issues related to which data set (global versus regional) was most relevant for deriving MLs would be further considered under Agenda item 14 and that further guidance on this matter would therefore be forthcoming.

44. CCCF agreed to advance the ML of 2.5 mg/kg for lead in spices, dried bark, which had been adopted at Step 5 by CAC47 (2024), as well as the new ML of 2.0 mg/kg for lead in culinary herbs, dried, at Step 3 proposed by the EWG.

Explanatory notes on the extrapolation of MLs for fresh culinary herbs

45. A Member noted that while the Preamble of CXS193 provided guidance on extrapolating MLs from fresh to dried products, it did not offer guidance for the reverse. The Committee should thus consider re-inserting the note agreed by CCCF17 to the ML for culinary herbs, dried.

46. CCCF therefore agreed to retain the explanatory note in the ML for lead in culinary herbs, dried as follows: "*MLs for fresh culinary herbs may be derived based on the moisture content of the fresh herb in relation to the dry herb.*".

Conclusion

47. CCCF18 agreed to:

(i) forward to CAC48 the following (Appendix III):

(a) an ML of 2.5 mg/kg for lead in spices, dried bark for adoption at Step 8, noting the reservations of China and India as expressed in paragraphs 37 and 39; and

(b) an ML of 2.0 mg/kg for lead in culinary herbs, dried for adoption at Step 5/8 (with the omission of Steps 6 and 7), with the explanatory note for fresh culinary herbs as indicated in paragraph 46, noting the reservations of China and India as expressed in paragraphs 37 and 39.

(ii) discontinue work on the ML of 2.5 mg/kg for lead in culinary herbs, dried (at Step 7), and to inform CAC48 accordingly.

CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF CADMIUM CONTAMINATION IN FOODS (at Step 4) (Agenda item 6)[6]

48. The United States of America, as Chair of the EWG and the Physical Working Group (PWG) that took place before the Session, introduced the item, provided the background of the work, summarised the work process to develop the code of practice (CoP), as well as the responses to CL 2025/10-CF, highlighted the key points of discussions in the EWG and the PWG, and presented the conclusions and recommendations for consideration by CCCF. The findings of the PWG are presented in Conference Room Document CRD26.

49. The EWG/PWG Chair noted general support for the overall structure and content of the CoP, and majority support for incorporating the *Code of practice for the prevention and reduction of cadmium contamination in cocoa beans* (CXC 81-2022) as an annex to the code of practice. There were also some specific proposed edits to the code of practice and suggestions for additional commodities to be addressed in the annexes to the CoP.

6 CL 2025/10-CF; CX/CF 25/18/6; CX/CF 25/18/6-Add.1 (Comments of Argentina, Australia, Brazil, Chile, Ecuador, Egypt, Ghana, Honduras, Indonesia, Iran (Islamic Republic of), Japan, Kenya, New Zealand, Republic of Korea, Singapore, Thailand, UAE, USA, the International Confectionery Association (ICA), and ICUMSA)

Discussion

50. There was general agreement to develop further the code of practice, including the annexes on seaweed and rice, and to incorporate CXC81 as an annex to the CoP once the general provisions applicable to all foods in the main body of the code of practice are more complete. It was clarified that discussions on CXC81 would not be reopened during this work, but that incorporation of CXC81 as an annex could result in some practices being removed from the annex, as the general provisions of the CoP would cover them.

51. Furthermore, Members agreed that a CL could be issued to gather more information on general mitigation practices and mitigation for additional commodities to determine the need to develop annexes for them. The additional commodities include cereal and cereal products (e.g., wheat and its derivatives, maize), vegetables (including leafy vegetables), pulses and legumes, fruits, and shellfish.

Conclusion

52. CCCF18 agreed to:

(i) return the Code of practice for the prevention and reduction of cadmium contamination in foods to Step 2/3 for redrafting and circulation for comments with the intent to achieve advancement to Step 5 at CCCF19 based on available data/information;

(ii) re-establish the EWG, chaired by the United States of America, working in English, to:

(a) further develop the code of practice, taking into account discussions and written comments submitted during the Session; and

(b) further develop the annexes on seaweed and rice, and additional annexes for commodities for which there are specific mitigation measures not covered under general provisions applicable to all foods.

(iii) request the Codex Secretariat to issue a circular letter on general and commodity-specific mitigation measures, including for cereal and cereal products (e.g., wheat and its derivatives, maize), vegetables (including leafy vegetables), pulses and legumes, fruits, and shellfish; and

(iv) integrate the *Code of practice for the prevention and reduction of cadmium contamination in cocoa beans* (CXC 81-2022) into the Code of practice for the prevention and reduction of cadmium contamination in foods when the general provisions applicable to all foods in the main body of the CoP are completed or near completion.

SAMPLING PLANS FOR TOTAL AFLATOXINS AND OCHRATOXIN A IN CERTAIN SPICES (at Step 7) (Agenda item 7)[7]

53. India, as Chair of the EWG and the PWG that took place before the Session, introduced the item, provided the background of the work, summarised the work process to develop the sampling plans further, including numeric performance criteria, recalled the decisions of CCCF17, highlighted key points of discussion in the EWG and the PWG, and presented the conclusions and recommendations for consideration by CCCF.

54. The EWG/PWG Chair, drawing attention to CRD32, highlighted the changes made to the sampling plans, in particular:

- The incremental sample weights for large particle spices (100 g) are due to the high spice trade value.
- The editorial corrections to avoid overlapping definitions in lot weight ranges, accept an incremental sample size of 80 g for powdered spices (Table 5), and amend relative values for aggregate sample weights (Table 6) accordingly.
- The alignment of the method NPC with international standards, consistent with normal practice in Codex, allowing for achievability by competent laboratories worldwide.
- The removal of a separate ML for aflatoxin B1 (AFB1) (proposed in the EWG) as per the decision of CCCF11 (2017) to establish only ML for AFT.

55. The EWG/PWG Chair proposed that CCCF consider the revised sampling plans as presented in Appendix I to CRD32 and send them to CCMAS for endorsement and adoption by CAC.

Discussion

56. CCCF noted the general support for the sampling plan, as revised in Appendix I to CRD32, noted the following comments, and made the subsequent decisions:

[7] CX/CF 25/18/7

57. A Member Organization, supported by another Member, while acknowledging the outcome of the discussion in the PWG and accepting the decision to forward the sampling plans to CCMAS for endorsement, expressed its preference for an incremental sample size of 200 g instead of 100 g. This was in line with previously agreed sampling plans for AFT in tree nuts, given that the particle size and pattern of heterogeneity of contamination were the same for whole large particle spices (e.g., nutmeg) as for tree nuts.

58. Another Member emphasised that samples taken must be representative of the sample lot or batch, thereby ensuring minimal consumer risk while not resulting in an unacceptable level of risk to producers or exporters (high rejection rates). Considering that mycotoxins were not evenly distributed in foods, it was important to ensure maximum consumer health protection; therefore, the Member also supported a sample size of 200 g.

59. CCCF agreed to retain the 100 g incremental size due to the high value of spices.

60. CCCF also agreed to replace the note to Table 2 with the following: *"if the test result is ≤ to the Codex ML, then accept the lot, otherwise, reject the lot"* for consistency with the approach for the decision rule currently used in sampling plans in CXS193, and to apply this change also in Section B and C.

61. Noting the general support for the sampling plans with the additional changes, CCCF agreed that they were ready for endorsement by CCMAS45 (2026), subsequent adoption by CAC49 (2026), and inclusion in CXS193.

Conclusion

62. CCCF18 agreed to advance the sampling plans and the numeric performance criteria for total aflatoxins and ochratoxin A in certain spices (i.e., nutmeg, dried chilli and paprika) to Step 8 for adoption by CAC49 after endorsement by CCMAS45 (Appendix IV).

MAXIMUM LEVEL AND ASSOCIATED SAMPLING PLAN FOR TOTAL AFLATOXINS IN READY-TO-EAT PEANUTS (at Step 4) (Agenda item 8)[8]

63. India, as Chair of the EWG, introduced the item, provided the background of the work, summarised the work process to develop the ML, recalled the decisions of CCCF17, highlighted key points of discussion in the EWG, and presented the conclusions and recommendations for consideration by CCCF.

64. The EWG Chair explained that the GEMS/Food Administrator had provided data, and that data was available only for seven countries, only three of which were listed as top 10 producer countries, indicating inadequate geographical representation of the data. The EWG Chair explained that based on the mean occurrence data calculated for four countries (Brazil, India, Thailand, USA), which demonstrated a range of 6.06/8.33 – 44.275 µg/kg, an ML of 10 µg/kg was proposed for consideration by CCCF18. This ML was similar to that already established for ready-to-eat (RTE) tree nuts, taking into account that the same definition was used for RTE peanuts and that the ML should be lower than the one established for peanuts intended for further processing (FFP) (15 µg/kg).

Discussion

65. CCCF noted that there were several concerns regarding the data assessed and the approach taken for the establishment of the proposed ML, which included but were not limited to the following:

- The data assessed was between 2014 and 2016, and no more recent data (between 2017 and 2024) had been considered, yet there had been calls for data and submission of data to the GEMS/Food database.
- Members, such as Brazil, Canada, and Kenya, had submitted data, of which some did not appear to have been considered.
- The ML had been proposed based on mean occurrence values rather than the P95, which was the normal approach for the setting of MLs. A Member also observed that if the P95 were indeed used to derive a proposed ML for RTE peanuts, the value would be well above the ML of 15 µg/kg for peanuts intended for further processing.
- The criteria to derive a proposed ML (e.g., rejection rates, exposure assessment), as well as the number of samples used, were either not provided or were unclear.
- The JECFA83 (2016) impact assessment had shown that there would be no additional public health benefit in relation to setting the ML at 10 µg/kg versus 15 µg/kg, but the lower ML would result in higher rejection rates.
- It was unclear if the GEMS/Food Administrator had worked with the EWG to sort previously submitted data into RTE and FFP, as had been agreed by CCCF17.

[8] CX/CF 25/18/8

66. A Member noted that the mean occurrence calculated by the EWG of 44 µg/kg was inconsistent with calculations using data submitted by Brazil. Much of the data submitted by Brazil indicated levels as 'not detectable (ND)'; the Member thus sought clarification on how such data (ND) was considered in the EWG.

67. The EWG Chair clarified that the GEMS/Food Administrator provided the data assessed and that the calculation of the ML was based on the mean occurrence. Two approaches had been taken to derive the ML, which were (a) based on data excluding products such as ground peanut, peanut butter, and peanut with butter; and (b) including such data (e.g., for peanut butter, ground peanut, and peanut with butter). The proposed ML of 10 µg/kg was also based on the fact that an ML for RTE peanuts should be lower than the existing ML for peanuts intended for further processing (currently 15 µg/kg) and that it was in line with the ML for RTE tree nuts.

68. The Chairperson confirmed that an incomplete data set may have been sent to the EWG, and, due to this, she proposed to suspend discussion and request the JECFA Secretariat to do a full analysis of all the data, including recently submitted data, to look at the feasibility of setting an ML for RTE peanuts. The findings of the JECFA Secretariat could be presented to CCCF19 to help it decide on the way forward.

69. However, this proposal had limited support among members who proposed that work on the ML and associated sampling plan be discontinued, noting that the establishment of an ML for RTE peanuts had been discussed over a long period in CCCF without much progress. They indicated that time could be given to first finalise the revision of the *Code of practice for the prevention and reduction of aflatoxin contamination in peanuts* (CXC 55-2004) (see Agenda item 9) and enable its implementation, after which new work could be reconsidered. This additional time could also allow more geographically representative data to be submitted in accordance with the definition for RTE peanuts. It was also noted that with the possible restructuring of the GEMS/Food database, there would be a clearer separation of the data for RTE peanuts and peanuts intended for further processing, which would facilitate assessment of the data.

70. Another Member expressed its view that the issue of data and other concerns raised could have been addressed in the EWG if its terms of reference had been followed and if there had been two rounds of discussion and consultation with members of the EWG. One more Member noted that due to the late availability of the paper, there was a limited opportunity to review it.

71. An Observer indicated that, at the very lowest, they would have been prepared to support 15 µg/kg as an ML and that it was important that any future decision on an ML be made based on scientific information and a full data set, including representative data from producer countries and data for at least 10 years. It was also noted that providing several hypothetical ML scenarios, along with their associated rejection rates, would help facilitate the discussion and support the establishment of appropriate MLs.

Conclusion

72. CCCF18 agreed:

    (i) to discontinue work on the maximum level and the associated sampling plan for total aflatoxins in ready-to-eat peanuts and inform CAC48 accordingly; and

    (ii) that more time should be given for the implementation of the revised *Code of practice for the prevention and reduction of aflatoxin contamination in peanuts* (CXC 55-2004), and for data generation and submission to the GEMS/Food database in relation to ready-to-eat peanuts, which could support a possible consideration of new work on establishing an ML for RTE peanuts in the future.

REVISION OF THE *CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF AFLATOXIN CONTAMINATION IN PEANUTS* (CXC 55-2004) (at Step 4) (Agenda item 9)[9]

73. Brazil, as Chair of the EWG and the PWG that took place before the Session, speaking also on behalf of the co-Chair, India, introduced the item. The EWG/PWG Chair provided the background of the work, summarised the work process to revise the CoP, as well as the responses to CL 2025/13-CF, highlighted key points of discussion in the EWG and the PWG, and presented the conclusions and recommendations for consideration by CCCF.

74. The EWG/PWG Chair sought the agreement of CCCF to delete the provision for roasting in Section 7.6, paragraph 65, from the revised CoP, noting concerns that roasting was not recognised as a step that could reduce aflatoxin in peanuts in some member countries, and that aflatoxin could bind to components of the peanut matrix, making them less detectable during routine analytical testing of the "free" mycotoxin. Further elaboration was provided in paragraphs 3-5 of CRD31.

[9] CL 2025/13-CF; CX/CF 25/18/9; CX/CF 25/18/9-Add.1 (Comments of Canada, Chile, Ecuador, Egypt, Ghana, Indonesia, Iran (Islamic Republic of), Japan, Kenya, Philippines, Singapore, Thailand, UAE, USA, and ICUMSA)

75. CCCF agreed to use CRD31 as the basis for discussion to advance the CoP in the Step Procedure.

Discussion

76. CCCF noted the general support for the changes made to the CoP in Appendix I to CRD31, including the deletion of Section 7.6, paragraph 65 on roasting, and for its advancement in the Step Procedure.

77. In addition to some editorial corrections, CCCF made additional amendments to the text.

78. A Member, in referring to paragraph 34bis[10], indicated that peanuts are not a vining plant, so using the term "vines" may cause misunderstanding. The term "pegs" is more appropriate, and it was further explained by the EWG/PWG Chair that 'pegs' referred to the mature part of the plant, while 'vines' referred to the whole plant. Another Member suggested that in paragraph 34bis, windrow drying should be correctly referenced to align with paragraph 34.

79. In this context, there was general agreement to amend paragraph 34bis so that "once the ***windrow*** *drying is done, the separation of the pods from the* ***vines pegs*** *must be carried out….*"

Conclusion

80. CCCF18:

(i) agreed to forward the revised *Code of practice for the prevention and reduction of aflatoxin contamination in peanuts* (CXC 55-2004) to CAC48 for adoption at Step 5/8 (with the omission of Steps 6 and 7) (Appendix V); and

(ii) noted the importance of implementing the CoP to support data collection to enable further risk management measures to be considered in the future.

REVIEW OF THE *CODE OF PRACTICE FOR WEED CONTROL TO PREVENT AND REDUCE PYRROLIZIDINE ALKALOID CONTAMINATION IN FOOD AND FEED* (CXC 74-2014) AND DEVELOPMENT OF GUIDANCE ON SAMPLING AND ANALYSIS PERFORMANCE CHARACTERISTICS FOR THE COLLECTION OF DATA FOR SUBMISSION TO THE GEMS/FOOD DATABASE (Agenda item 10)[11]

81. Türkiye, as Chair of the EWG and the Virtual Working Group (VWG) that was held before the Session, also speaking on behalf of the co-Chairs, the United Kingdom and the Netherlands, introduced the item, provided the background of the work, and summarised the work process to review the CoP and to develop the guidance, as well as the responses to CL 2025/27-CF. The EWG/VWG Chair recalled the key points of the discussion held at the EWG, noting that it was agreed that the new work proposal in the project document would focus solely on the revision of the CoP, excluding sampling and analysis methods. The EWG/VWG Chair further noted that the guidance on sampling and analysis performance characteristics would offer recommendations on LOQs, pyrrolizidine alkaloid isomers, and data collection, and would clarify data requests (individual/total PAs) and identify at-risk foods.

82. The EWG/VWG Chair, recalling the discussions in the VWG, concluded by noting the agreement to support the revision of the *Code of practice for weed control to prevent and reduce pyrrolizidine alkaloid contamination in food and feed* (CXC 74-2014), and that additionally, a guidance document on sampling and analysis performance characteristics had been developed for use by the Committee to complement the CoP and facilitate data collection for future CCCF work. The revised project document and the revised guidance are presented in CRD10.

83. It was further noted that climate change increased the production of alkaloids in plants as a way for them to cope with various environmental stressors. Therefore, the work was timely and of relevance.

84. CCCF agreed to use CRD10 as the basis for the discussion and noted the general support for the new work proposal.

Discussion

Review of the *Code of practice for weed control to prevent and reduce pyrrolizidine alkaloid contamination in food and feed* (CXC 74-2014) – Project document for new work on the revision of the Code of practice

85. Members suggested the following points to be considered during the future revision of the CoP:

- The CoP should include achievable measures that small and medium enterprises could adopt.
- Regarding grazing animals and pasture management, it would be appropriate to check the scientific literature regarding new findings on the sensitivity of different animal species to PAs, to provide accurate recommendations for pasture management based on up-to-date information.

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10 This paragraph number corresponds to that in CRD31 and is reflected as paragraph 32 in Appendix V.

11 CL 2025/27-CF; CX/CF 25/18/10; CX/CF 25/18/11; CX/CF 25/18/10-Add.1 (Comments of Canada, Chile, Egypt, Japan, Kenya, New Zealand, Singapore, and the USA)

- Attention should be directed towards crops that inherently contain PAs to facilitate the differentiation of their associated risks.
- The need for clarity on the categorisation of ayurvedic/herbal products, where they were consumed as food or used in nutraceutical/health supplements globally.

86. CCCF agreed to delete the words "testing strategies" under the section "Main aspects to be covered" of the project document, to align the language with the defined objectives and scope of the CoP.

Guidance document on sampling and analysis performance characteristics for the collection of data to be submitted to the GEMS/Food database for pyrrolizidine alkaloids in foods

87. CCCF noted the general support for the guidance document.

88. A Member Organization noted that while the reference to the CXG50 for the sampling for PAs analysis was accurate, it would have been appropriate to supplement the general guidelines with specific guidance on the number of incremental samples, size of incremental samples and size of aggregate samples based on lot size and variability to guarantee representativeness of the sample for the sampled lot. Nevertheless, the Member Organization could support the guidance in its current form and availability as an appendix to the report of the Session for future reference.

89. In response to a request for clarification on the status of the guidance document, the Chairperson noted that the work had been completed and that the guidance would be included in an appendix to the report, for reference in any future calls for data.

Conclusion

90. CCCF18 agreed to:

(i) start new work on the revision of the *Code of practice for weed control to prevent and reduce pyrrolizidine alkaloid contamination in food and feed* (CXC 74-2014), subject to approval by CAC48;

(ii) forward the project document to CAC48 for approval as new work (Appendix VI, Part I) ;

(iii) include the guidance in Appendix VI, Part II of the report, for reference in any future calls for data;

(iv) re-establish the EWG, chaired by Türkiye, and co-chaired by the United Kingdom and the Netherlands, working in English, to revise CXC74 for consideration by CCCF19, that will address the following:

(a) Additional foods affected by PAs, such as grains and grain-based products, teas, herbal infusions, herbal and pollen-based food supplements, salad plants, culinary herbs, spices, honey, and pollen.

(b) Specific practices for beekeeping not covered under the measures for weed control mentioned in the current CoP.

(c) New approaches to weed control in primary production and recommendations for food and feed establishments on good manufacturing/hygiene practices.

(d) Measures that are practicable and feasible for small and medium enterprises.

(e) Pasture management taking into account the sensitivity of different animal species to PAs based on new findings in recent scientific literature.

(f) Measures on how to deal with supplements (ayurvedic/herbal products) when they are regulated as foods.

(g) The inherent levels of PAs in plants and the risks associated with different species.

REVIEW OF THE *CODE OF PRACTICE FOR THE REDUCTION OF ACRYLAMIDE IN FOODS* (CXC 67-2009) (Agenda item 11)[12]

91. India, as Chair of the EWG, speaking also on behalf of the co-Chair, Saudi Arabia, introduced the item. The EWG Chair provided the background of the work, summarised the work process to review the CoP, highlighted key points of discussion, and presented the conclusions and recommendations for consideration by CCCF.

Discussion

92. The Chairperson recalled that in accordance with the working practice in CCCF, which was already applied several times in the Committee, when proposing new work, a discussion paper should first be developed, which should contain a proposal for the new or revised CoP and the project document. This approach would allow CCCF to determine the feasibility of finalising the work in a timely manner.[13]

12 CX/CF 25/18/12

13 REP24/CF17, para 129

93. Members expressed general support for the revision of the CoP, noting that the technical advancements of acrylamide mitigation strategies and existing information in the literature could be sufficient to support such a revision.

94. However, in line with the Chairperson's comments on the working practice in CCCF, delegations agreed that more time was needed to develop the discussion paper and project document further, to understand better the scope of the work and the revisions needed, the proposed organisation of the revised CoP, and to identify more information on existing mitigation strategies since the adoption of the CoP in 2009 that could be included in the code of practice. A more extensive and well-developed discussion paper could better inform the terms of reference for the EWG when it undertakes the new work following its approval by CAC, which could lead to a smoother completion of the work. The additional time would also allow a draft revision of the CoP to be proposed.

95. CCCF agreed with the Chairperson's suggestion to request the Codex Secretariat to issue another CL to gather more information (in addition to the comments in response to CL 2024/79-CF) on mitigation measures that have been proven to be feasible and effective for application for local and/or regional conditions to reduce acrylamide in foods. The EWG Chair requested that the CL and responses to it be circulated at the earliest opportunity, so that improvements to the discussion paper and project document can take into account the comments to the CL, and the discussion paper and project document could be made available in good time before CCCF19.

96. An Observer informed CCCF that it was in the process of updating a toolbox for the reduction of acrylamide in foods and indicated that it would like to contribute to the review of the CoP.

Conclusion

97. CCCF18 agreed to:

(i) re-establish the EWG, chaired by India, co-chaired by Qatar and Saudi Arabia, working in English, to further develop the discussion paper and the project document, as well as the proposed revisions to the *Code of practice for the reduction of acrylamide in foods* (CXC 67-2009) for consideration by CCCF19; and

(ii) request the Codex Secretariat to issue a circular letter to gather more information (in addition to the comments in response to CL 2024/79-CF) on mitigation measures that have been proven to be feasible and effective for application for local and/or regional conditions to reduce acrylamide contamination in foods.

REVIEW OF THE *CODE OF PRACTICE FOR THE REDUCTION OF AFLATOXIN B1 IN RAW MATERIALS AND SUPPLEMENTAL FEEDING STUFFS FOR MILK-PRODUCING ANIMALS* (CXC 45-1997) (Agenda item 12)[14]

98. Canada, as Chair of the EWG and the VWG that was held before the Session, also speaking on behalf of the co-Chair of Saudi Arabia, introduced the item, provided the background of the work, summarised the work process to review the CoP, as well as the responses to CL 2025/23-CF, highlighted key points of discussion in the EWG and the VWG, and presented the conclusions and recommendations for consideration by CCCF. The EWG/VWG Chair explained that comments provided during the VWG had been taken into account, and CRD05 had been prepared accordingly. The Committee agreed to use this document as the basis for discussions.

99. The EWG/VWG Chair also noted that new control measures for AFB1, particularly concerning forage crops, silage, hay, oilseeds, pulses, and legumes, were integrated in the text, aiming for applicability across temperate and tropical climates. Structural changes proposed included new subsections for purpose/scope, definitions, related guidance, general recommendations, and preparation for storage and animal feeding. In addition, following consultation with the Codex Secretariat, it was decided to cross-reference relevant Codex texts to avoid duplication of information.

100. The EWG/VWG Chair concluded by noting that the project document had been further updated to acknowledge climate change impacts and the increasing detection of aflatoxin M1 in milk in African regions.

Discussion

101. CCCF noted the general support for the proposal in CRD05 and further stated that, in addition to comments already received, the issuance of a CL requesting risk management practices and other data/information would further support the development of the CoP.

Conclusion

102. CCCF18 agreed to:

(i) start new work to revise the *Code of practice for the reduction of Aflatoxin B1 in raw materials and supplemental feedingstuffs for milk-producing animals* (CXC 45-1997), subject to approval by CAC;

[14] CL 2025/23-CF; CX/CF 25/18/13; CX/CF 25/18/13-Add.1 (Comments of Argentina, Brazil, Canada, Chile, Ecuador, Egypt, Ghana, Thailand, Uruguay, USA, ICUMSA, and the International Dairy Federation (IDF/FIL))

(ii) forward the project document to CAC48 for approval as new work (Appendix VII);

(iii) re-establish the EWG, chaired by Canada, co-chaired by Saudi Arabia, working in English, to further revise the code of practice for comments and consideration by CCCF19; and

(iv) to request the Codex Secretariat to issue a circular letter requesting risk management practices and other data or information that can support the further development of the CoP.

DEVELOPMENT OF A CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF TROPANE ALKALOIDS CONTAMINATION IN FOOD AND FEED (Agenda item 13)[15]

103. China, as Chair of the EWG and the ISWG that took place in the margins of the plenary session, speaking also on behalf of the co-Chair of Saudi Arabia, presented the item. The EWG/ISWG Chair provided the background of the work, summarised the work process to develop the discussion paper further, as well as the responses to CL 2025/41-CF, highlighted key points of discussions in the EWG and the ISWG, and presented the conclusions and recommendations for consideration by CCCF. In particular, the EWG/ISWG Chair highlighted that references to animal health were removed from the project document as animal health was not within the mandate of Codex. The revised project document (for consideration) and the revised CoP (for information) are presented in CRD02.

104. CCCF agreed to use CRD02 as the basis for discussion and decided that the project document contained in Appendix I, with an editorial correction to the spelling of 'consumers', could be submitted to CAC for approval as new work.

105. The EWG/ISWG Chair agreed with the Chairperson that a CL could be issued to request information on risk management practices and other data/information that could support the further development of the CoP.

Conclusion

106. CCCF18 agreed to:

(i) start new work to develop a code of practice for the prevention and reduction of tropane alkaloids contamination in food and feed, subject to approval by CAC48;

(ii) forward the project document to CAC48 for approval as new work (Appendix VIII);

(iii) re-establish the EWG, chaired by China and co-chaired by Saudi Arabia, working in English, to develop the code of practice further, taking into account the written comments submitted to CCCF18, for comments and consideration by CCCF19; and

(iv) request the Codex Secretariat to issue a circular letter requesting risk management practices and other data/ information that could support the further development of the CoP, in addition to those contained in the information presented to CCCF18.

GUIDANCE ON DATA ANALYSIS FOR THE DEVELOPMENT OF MAXIMUM LEVELS AND FOR IMPROVED DATA COLLECTION (Agenda item 14)[16]

107. The European Union, as Chair of the EWG and the ISWG that took place in the margins of the plenary session, speaking also on behalf of the co-Chairs Japan, the Netherlands, and the United States of America, introduced the item, provided the background of the work, summarised the work process to develop the guidance, highlighted key points of discussion in the working groups held before CCCF18 and in the ISWG, and presented the conclusions and recommendations for consideration by CCCF.

108. The EWG/ISWG Chair recalled that CCCF17 agreed to produce a document that would provide practical guidance to EWGs performing data analysis for the development of MLs, and that the more complex issues would be addressed in separate annexes for further development and discussion after CCCF18, together with issues identified for future discussion.

109. The EWG/ISWG Chair further recalled that, based on the information received by the GEMS/Food Database Administrator, the requested changes to the GEMS/Food database template could not be implemented before CCCF18. Recalling the work process, he noted that the document would be updated following the implementation of the agreed changes to the GEMS/Food database template and experience gained in EWGs in applying the guidance.

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15 CL 2025/41-CF; CX/CF 25/18/14; CX/CF 25/18/14-Add.1 (Comments of Canada, Cuba, Egypt, Ghana, Iraq, Iran (Islamic Republic of), Japan, Kenya, Singapore, USA, FoodDrinkEurope, and the Institute of Food Technologists (IFT))

16 CX/CF 25/18/15

110. The EWG/ISWG Chair concluded by presenting the discussion held at the ISWG, which focused on the main text of the "Guidance on data analysis for the development of maximum levels and for improved data collection" (Guidance). These comments included, *inter alia*, the submission of paired samples (before and after processing) to the GEMS/Food database to better assess the efficacy of a CoP and processing in reducing contaminant levels, along with the appropriateness of the GEMS/Food database template for this purpose; the requirement for LOQ reporting to become mandatory, with Limit of Detection (LOD) reporting being optional; the use of datasets with (nearly) all quantified results without reporting LOD/LOQ; the guarantees to be provided on the implementation of a CoP and the exclusion of datasets by the EWG related to the non-implementation of a CoP; and the reference to both parametric and non-parametric statistical methods.

111. CCCF agreed to use CRD39 as the basis for the discussion and noted the following comments.

Discussion

General comments

112. CCCF endorsed the decision that preliminary exposure assessments, derived from the target commodity, could be conducted to estimate the impact of hypothetical MLs on reducing dietary exposure. This information would serve as a reference for EWGs tasked with recommending MLs, provided resources were available. Should a more detailed or complex evaluation, such as an overall exposure assessment, be deemed necessary, the Committee could formally request JECFA to evaluate the effects of hypothetical MLs on dietary risk reduction. This was based on the fact that the calculation of dietary exposure was considered a risk assessment function, appropriately undertaken by JECFA.

Main text of the Guidance

Footnote 2

113. A new sentence was added under footnote 2, i.e. "in agreement with the rules at the time the data were submitted". This addition aimed to ensure that data, which were correctly submitted initially, would not be disparaged in the working group's output document.

Paragraphs 109 and 110

114. The EWG/ISWG Chair presented proposed edits in paragraphs 109 and 110. A proposal was made to replace "such practices" with "good agricultural and manufacturing practices" for clarity. CCCF agreed to use the phrase "good practices along the production chain".

115. In response to a request for clarification regarding paragraphs 109 and 110, on how the guidance would help to confirm or indicate the implementation of a CoP, the EWG/ISWG Chair clarified that when a call for data would be issued, it would indicate submissions reflecting the implementation of a CoP, if available. Alternatively, data would clearly indicate that they pertained to good practices adopted at the national level. The EWG/ISWG Chair noted that this would ensure that MLs were based on data reflecting the application of good practices.

Paragraphs 152 and 163

116. CCCF supported the replacement of "recommending MLs" with "proposing MLs" in paragraphs 152 and 163 as more appropriate.

Paragraph 157

117. New language was included under paragraph 157 to provide further clarity to the text as follows, in quotation marks: If a detailed or more complex evaluation is necessary, "(e.g. overall exposure assessment)" CCCF can request JECFA to evaluate the effects of hypothetical MLs on the reduction of "the risk from the" dietary exposure, as calculation of dietary exposure is a risk assessment function that JECFA should undertake.

Other comments

118. The WHO JECFA Secretariat highlighted the importance of the GEMS/Food database for the work of CCCF and confirmed the feasibility of the changes proposed to the GEMS/Food database template. The WHO JECFA Secretariat further noted that the changes could not yet be implemented due to a lack of resources and called upon the member countries to support the work on the further development of the GEMS/Food database, as it would also benefit the work of the Committee.

119. In reply to a request for clarification on the modality by which the Guidance would remain a living document, the Chairperson clarified that the EWG would continue its work, particularly on revising the annexes, for consideration by CCCF. This ongoing work would further ensure that the document remained relevant, noting that, at the same time, should the EWG dissolve, any Member could propose modifications or additions if new information emerged, for consideration by the Committee.

Annexes

120. As regards future work on the annexes to the Guidance and possible topics for future discussion, there was general support to:

- carry out further work on Annex III "Drawing charts/graphs and plots on distribution of occurrence data", V "Presentation of data analysis/statistical analysis", and Annex VI "Glossary of terms"; and
- prepare a discussion paper on Annex I "Determination of outliers/extreme values and handling them", II "Minimum number of data points for estimating high percentile values" and Annex IV "Preliminary calculation of dietary exposure and its reduction rate to the contaminants from target commodity(ies) at the hypothetical MLs" and possible topics for future discussion (see CX/CF 25/18/15, Appendix II) for decision on further work at CCCF19.

121. The FAO JECFA Secretariat, noting the extensive work accomplished by the EWG, observed that several issues currently being addressed by the EWG, and in particular in the annexes, were already detailed in existing documents, such as the Environmental Health Criteria (EHC) 240, published jointly by FAO/WHO. The FAO JECFA Secretariat suggested that the EWG could review such documents to avoid duplication of effort and ensure efficiency.

122. In response to this intervention, the EWG/ISWG Chair noted that, as an internal solution, a discussion paper or similar document could be developed to elaborate on the annexes and topics for further discussion, including a reference to what has already been covered by EHC 240, to avoid duplication or contradiction of existing information. This approach would provide a more robust foundation for consideration at CCCF19, allowing for a better basis to determine which aspects would require further development.

Conclusion

123. CCCF18 agreed to:

(i) endorse the main text of the "Guidance on data analysis for the development of maximum levels and for improved data collection" and to publish it as an information document on the Codex website, with the understanding that the document would be updated following the implementation of the agreed changes to the GEMS/Food database template and the experience gained in EWGs in applying the Guidance (Appendix IX);

(ii) further work on Annex III "Drawing charts/graphs and plots on distribution of occurrence data", V "Presentation of data analysis/statistical analysis", and Annex VI "Glossary of terms" for consideration by CCCF19;

(iii) prepare a discussion paper on Annex I "Determination of outliers/extreme values and handling them", Annex II "Minimum number of data points for estimating high percentile values and" and Annex IV "Preliminary calculation of dietary exposure and its reduction rate to the contaminants from target commodity(ies) at the hypothetical MLs", and possible topics for future discussion considering existing publications like the Environmental Health Criteria EHC 240, for consideration by CCCF19; and

(iv) re-establish the EWG, chaired by the European Union, and co-chaired by Japan, the Netherlands, and the United States of America, to continue the work on the Guidance on data analysis for the development of maximum levels and for improved data collection (point ii) and to prepare the aforementioned discussion paper (point iii).

REVIEW OF NUMERIC PERFORMANCE CRITERIA FOR METHODS OF ANALYSIS FOR TOTAL AFLATOXINS UTILIZING THE SUM OF COMPONENTS CONCEPT IN RELEVANT SAMPLING PLANS (Agenda item 15)[17]

124. Brazil introduced the item and recalled that CCMAS42 (2023) had requested CCCF to provide numeric performance criteria for aflatoxin methods utilizing the sum of components concept for all relevant commodities to replace the existing NPC contained in sampling plans in CXS193. Proposals for NPC for methods of analysis contained in sampling plans for AFT in peanuts intended for further processing, ready-to-eat tree nuts and tree nuts destined for further processing: almonds, hazelnuts, pistachios and shelled Brazil nuts, and dried figs had been made following the approach proposed by CCMAS for AFTs for certain cereals and cereal-based products, including foods for infants and young children based on AFB1: AFB2:AFG1:AFG2 of 1:1:1:1.

125. Brazil explained in detail the approach followed as advised by CCMAS, as well as taking into account the *Guidelines for establishing the numeric values for criteria,* Table. 1 to the *Working instructions for the implementation of the criteria approach in Codex* (Codex Procedural Manual).

126. Brazil proposed that CCCF consider the proposals in the appendix to CX/CF 25/18/16 and send them to CCMAS for endorsement and inclusion in CXS234.

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17 CL 2025/15-CF; CX/CF 25/18/16; CX/CF 25/18/16-Add.1 (Comments of Canada, Chile, Egypt, Ghana, Indonesia, Japan, Kenya, Singapore, Thailand, Türkiye, USA, and ICUMSA)

Discussion

127. CCCF noted concerns raised with respect to the approach for developing the NPC, noting that AFTs were usually measured by summing up the four individual aflatoxins, as AFT was not an analyte, but that the different individual aflatoxins B1, B2, G1 and G2 were, and determination of validation parameters such as LOQ for AFT could lead to reporting quantified results lower than the LOQ for AFT.

128. A Member requested clarification on how these analytical parameters were developed for AFTs.

129. Brazil reiterated that the approach followed was the same as the approach used by CCMAS for AFT for certain cereals and cereal-based products, including foods for infants and young children. In addition, it was noted that establishing NPC for the sum of components was a complex issue. While there was guidance provided in an information document titled "Approaches which use a 'sum of components'" published on the Codex website, this guidance, however, stated that NPC should be set on a case-by-case basis. Requesting clarification on the approach from CCMAS would be useful for future development/review of NPC for the sum of components.

130. While there was general agreement to forward the NPC to CCMAS for consideration and endorsement, CCCF, noting the concerns raised, agreed that advice should be sought from CCMAS on the need to establish NPC for AFT or the individual aflatoxins, and, if the NPC should be set for AFT, how to report the results.

131. CCCF further noted that clarification and advice were important because the approach taken could have an impact on data submission, i.e., one of the mandatory fields in the GEMS/Food database is for LOQs to be provided (see Agenda item 14). A consistent and clear approach would be needed for data submission, as there would be questions about which LOQ to fill in for AFT.

132. CCCF also noted the explanation by the Codex Secretariat that the NPC, once endorsed by CCMAS, would be included in CXS234, the single reference for methods of analysis. The Codex Secretariat further noted that, as a consequence, the relevant sampling plans in CXS193 would be amended by replacing the current NPC and related texts with a reference to CXS234.

Conclusion

133. CCCF18 agreed to:

(i) forward the numeric performance criteria to CCMAS45 for endorsement and inclusion in CXS234 (Appendix X);

(ii) request the Codex Secretariat to amend the relevant sampling plans in CXS193 by replacing the current NPC and related texts with a reference to CXS234 once the Codex Committee on Methods of Analysis and Sampling has endorsed the new NPC, and to inform CAC48 accordingly; and

(iii) request advice from CCMAS45 as per paragraphs 129-130.

APPLICATION OF MAXIMUM LEVELS TO MULTI-INGREDIENT PRODUCTS (Agenda item 16)[18]
ANALYSIS OF OCCURRENCE DATA OF LEAD IN SPICE MIXTURES (Agenda item 17)[19]

134. CCCF agreed to consider the two agenda items jointly due to their related nature. The Chairperson provided background information and recalled that CCCF17 had considered proposed MLs for lead in spices (excluding dried celery seed), noting the absence of MLs for multi-ingredient products in CXS193. CCCF17 had recognised that MLs for spice mixtures could be derived based on the proportional contribution of each ingredient, considering their varying contamination profiles.

135. The Chairperson further recalled that CCCF17 had reviewed a proposal to insert a note with guidance on the application of ingredient-specific MLs to mixtures. Diverging views had been expressed: while some Members supported the most conservative ML when ingredient proportions were unknown, others considered the note unnecessary given the guidance already provided in Annex I to CXS193. Additional concerns had been raised regarding deficiencies in labelling and the potential use of spices non-compliant to Codex MLs in mixtures.

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18 CL 2025/03-CF; CX/CF 25/18/17 (Comments of Argentina, Brazil, Canada, Chile, Egypt, EU, Ghana, Indonesia, Iran (Islamic Republic of), Iraq, Japan, Kenya, New Zealand, Philippines, Senegal, Singapore, Thailand, Türkiye, UAE, USA, Food Industry Asia (FIA), ICUMSA, and the International Special Dietary Food Industries (ISDI))

19 CX/CF 25/18/18

136. Consequently, CCCF17 had requested that the Codex Secretariat issue a CL to solicit comments on the need for further guidance on the application of MLs to multi-ingredient products, including illustrative calculations, and had invited the JECFA Secretariat to analyse the occurrence data of lead in spice mixtures in the GEMS/Food database. CL 2025/03-CF, prepared by the Codex Secretariat in collaboration with the Chairperson's assistant, had presented several options, and comments received had remained divided on both the necessity and format of such guidance. Errors in one illustrative calculation had been noted.

137. The JECFA Secretariat had analysed the GEMS/Food data and concluded that:

- setting an ML of 2 mg/kg for lead in spice mixtures would reduce dietary lead exposure in the general population by ~15% relative to the current situation with no Codex ML;
- lowering the ML to 1 mg/kg would achieve an ~18% reduction but would increase the rejection rate of spice mixtures from 1.9% to 5.1%; and
- other dietary and environmental sources contributed significantly to total lead exposure, underscoring the need to consider cumulative exposure.

138. The Chairperson invited CCCF to consider, firstly, in light of the JECFA Secretariat's conclusions and the comments received, whether MLs for lead in spice mixtures should be established, whereafter consideration could be given to the need for further guidance on the application of MLs to multi-ingredient products.

Discussion

139. A Member Organization stated that Annex I of CXS193 already explained that MLs were primarily established for raw agricultural commodities and permitted the calculation of MLs for multi-ingredient foods based on ingredient composition. The Member Organization suggested that any additional guidance for cases where ingredient proportions were unknown could be incorporated into Annex I. It was further noted that individual MLs had been, or would be, established for most spices and were applicable to spice mixtures. Therefore, setting a separate ML for spice mixtures would not further reduce lead exposure. The Member Organization observed that the proposed MLs of 1 or 2 mg/kg were higher than those for certain individual spices and could facilitate the undetectable blending of non-compliant spices, which would be contrary to the As Low As Reasonably Achievable (ALARA) principle and existing prohibitions on such practices. Consequently, the Member Organization did not support the establishment of a distinct ML for spice mixtures.

140. A Member highlighted the complexity of relying on guidance versus establishing MLs for lead in spice mixtures and proposed that further work proceed through a discussion paper and an EWG, including a second review of spice mixtures data in the GEMS/Food database. This view was supported by other Members, who also emphasised the need for clear guidance to address information gaps and prevent potential trade barriers.

141. In addition, Members expressed the following views:

- The establishment of a single ML for spice mixtures should be supported, as enough data on possible spice mixtures were available in the GEMS/Food database.
- While current provisions in CXS193 remained relevant, the frequent unavailability of ingredient proportions in spice mixtures complicated the application of ingredient-specific MLs. Should a single ML approach not be adopted, alternative guidance would be necessary.
- Such guidance could address two scenarios: (a) where ingredient proportions are known, MLs would be calculated; accordingly, and (b) where proportions are unknown, fixed MLs such as the 1–2 mg/kg levels recommended by JECFA could be considered.
- Pragmatic guidance on evaluating compliance with MLs for lead in spice mixtures had been prepared (CRD27) and could serve as a starting point for the work of the EWG.

142. CCCF noted the broad support for the development of a discussion paper to explore further the different options for guidance on the application of MLs and to restrict this guidance to spice mixtures rather than all multi-ingredient products. The Committee further noted that there was limited support to establish a single ML for lead in spice mixtures based solely on the JECFA Secretariat's analysis at CCCF18.

Conclusion

143. CCCF18 agreed to establish an EWG, chaired by Japan and co-chaired by India, Panama, and the United States of America, working in English, to prepare a discussion paper exploring options for guidance on the application of MLs to spice mixtures, using CX/CF 25/18/18 and CRD27 as a starting point, and the further data analysis of spice mixtures. The discussion paper will be submitted for consideration at CCCF19.

ANALYSIS OF OCCURRENCE DATA OF AFLATOXINS IN CEREALS (Agenda item 18)[20]

144. The Chairperson recalled that CAC45 (2022) had adopted MLs for AFTs in certain cereals and cereal-based products, including foods for infants and young children, but had requested CCCF to review these MLs within five years, due to several Members' reservations. CCCF17 had requested the JECFA Secretariat to issue a call for data to support this review. The JECFA Secretariat's analysis identified public health concerns in the absence of risk management measures and found that the current MLs for maize and rice reduced risk by a factor of three, with rejection rates of 5.2% and 1.8%, respectively. Stricter MLs could achieve up to a nine-fold risk reduction but may increase rejection rates. The Chairperson drew attention to the proposal to move the review of MLs for aflatoxins in cereals to the Overall Highest Priority List (OHPL) (see Agenda item 19), and proposed that, as a way forward, the Committee could consider the preparation of a discussion paper to assess the need for revising MLs for aflatoxins in cereals and cereal-based products.

Discussion

145. A Member expressed the view that this item could be revisited in two years. As previously noted, the CCCF decision was to review the matter within five years following adoption of the MLs in 2022. Therefore, the Member expressed its willingness to prepare a discussion paper as proposed by the Chairperson. The Member, however, suggested that a discussion paper first be prepared to evaluate the need for revision of the current MLs for presentation to CCCF20 (2027). To support the development of this paper, a call for data could be issued following CCCF19. Such an approach would allow seasonal variations influenced by year-to-year climatic changes to be taken into account.

146. Members expressed support for this proposal and provided comments on the following matters.

Review of MLs for cereal-based foods for infants and young children and sorghum

147. A Member Organization noted that cereal-based foods for infants and young children, for which MLs of 5 µg/kg and 10 µg/kg (destined for food aid programmes), respectively, had been adopted, were not included in the review by the JECFA Secretariat. The Member Organization emphasised that these products should be included in the scope of the future review. In response, the JECFA Secretariat clarified that the discussion paper had been prepared based on the data currently available in the GEMS/Food database, and that an analysis of AFTs in cereal-based foods for infants and young children could be undertaken once additional data became available.

148. A Member recalled that although a specific ML for sorghum had been established, the JECFA Secretariat's analysis had grouped sorghum with other grains subject to a single ML. Therefore, any future review of the sorghum ML would need to be conducted separately. It was further noted that the adopted ML had been based primarily on data provided by that Member, and additional data from other Members would be important to support the review. The Member also referred to discussions held during CCCF13 (2019) to CCCF15 (2022), which had underscored the importance of conducting impact assessments to determine whether significant reductions in exposure could be achieved with lower rejection rates. The need to consider year-to-year variability in contamination levels was also highlighted.

149. The Chairperson clarified that impact assessments could be conducted at a later stage following consideration of the discussion paper.

The scope for further review

150. A Member noted that aflatoxin levels were heavily influenced by agro-climatic conditions and good practices implemented throughout the supply chain. The Member did not consider an immediate review of the MLs necessary at this stage. It was also emphasised that cereals constituted a major part of international food aid, and any revision of MLs should take this aspect into account if considered. The Member further highlighted that the *Code of practice for the prevention and reduction of mycotoxin contamination in cereals* (CXC 51-2003) already addressed multifactorial aspects affecting mycotoxin levels and remained the priority instrument to ensure food safety. The scope of CXC51 was last amended in 2017, and that consideration should rather be given to reviewing CXC51. The Member expressed interest in being part of such work.

151. In response, the Chairperson proposed that the discussion paper could also examine the relevance and application of CXC51. It was clarified that the discussion paper would outline possible options for the way forward, while any decision on the matter will be taken at CCCF20.

152. The Chairperson also clarified that the paper would consider specific cereals illustrated in CX/CF 25/18/19, while addressing all other cereals in more general terms.

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Consideration of separate MLs for husked rice

153. A Member, referring to CRD11, proposed that the forthcoming call for data include metadata distinguishing between husked rice destined for further processing and husked rice RTE. While acknowledging the classification challenges previously encountered with peanuts, the Member emphasised that such differentiation was important, as global health initiatives actively promoted the consumption of whole grains, including husked rice, over polished white rice. The Member further requested that, should such data become available, the working group consider the feasibility of establishing separate MLs for these two categories.

154. In response to the above proposal, a Member expressed interest but also raised concerns. Another Member acknowledged the relevance of the proposal but emphasised the practical difficulties involved. Drawing on the experience with peanuts, the Member noted the challenges associated with clearly defining and classifying products as either for further processing or RTE. It was highlighted that such distinctions might be even more difficult to apply to husked rice, as Members typically did not separate their data in this manner. Therefore, the Member suggested that, should this approach be pursued, consideration would need to be given to developing clear definitions and guidelines to assist Members in preparing and submitting appropriate data.

155. The JECFA Secretariat noted that existing data often lacked such identifiers, and separating product streams could be difficult. However, the Secretariat agreed to include this request in the next call for data, and the necessity for setting separate MLs for these two categories could be further assessed.

The requirements for the forthcoming call for data

156. In response to a question on whether the forthcoming call should request data generated only after the implementation of CXC51, the Chairperson clarified that the year of data generation must be specified to assess its relation to the Code's application. It was further confirmed that the CoP had already been adopted in 2003.

157. A Member noted that the GEMS/Food database largely captured data on traded cereals only, and the upper and lower bounds in the GEMS/Food database, including the 97.5th percentile, might not accurately represent global production or aflatoxin levels under realistic domestic conditions. This aspect required careful consideration, as the traded portion could be very small compared to the overall global production. The Member further expressed the view that the EWG should also consider published literature and independent research in their review to get a better global picture of the situation on the ground.

158. The JECFA Secretariat encouraged Members to upload all relevant data to GEMS/Food, including those pertaining to their domestic markets, for use in the analysis. The Secretariat added that published literature seldom contained the level of detail required for assessment and urged Members to submit data that accurately represented current conditions to the GEMS/Food database.

159. An Observer suggested that data from 2023 and onwards, including up to 2026, be considered as a subset for analysis in light of the MLs adopted by CAC45 (2022).

160. The Chairperson reiterated that the GEMS/Food database included specific data fields that needed to be completed upon submission, emphasizing that only with such detail could reliable MLs be derived. The Chairperson also proposed that the detailed requirements for the call for data be further considered at CCCF19.

Conclusion

161. CCCF18 agreed:

(i) that Brazil, in conjunction with the JECFA Secretariat, would prepare a text for a call for data for consideration by CCCF19; and

(ii) to establish an EWG chaired by Brazil, co-chaired by Thailand, working in English, to prepare a discussion paper for CCCF20. The paper would review all data in GEMS/Food to assess the need for revising MLs for AFTs for cereal grains and cereal-derived products in CXS193, consider the derivation of new MLs for specific cereals, and evaluate the necessity to revise CXC51.

REVIEW OF CODEX STANDARDS FOR CONTAMINANTS (Agenda item 19)[21]

162. Canada, as Chair of the VWG that was held before the Session, introduced the item, provided the background of the work and summarised the work process, recalling that CCCF17 agreed to maintain the prioritisation of existing Codex contaminant standards for review as an annual CCCF agenda item and to solicit information annually via a CL before presenting recommendations to plenary.

[21] REP24/CF17, para 153; CL 2025/08-CF; CX/CF 25/18/20 (Comments of Canada, Chile, Egypt, Ghana, Japan, Kenya, Senegal, Singapore, and the USA)

163. The VWG Chair summarised the comments received in response to CL 2025/08-CF and highlighted the key points of discussions in the VWG, as presented in CRD06, including: the additional standards from List A: Codex standards for contaminants established or reviewed ≥25 or ≥15 and >25 years ago, and List B: Codex standards for contaminants recommended for re-evaluation for inclusion in the OHPL; standards already in the OHPL that could be considered overall highest priority for review; volunteers to lead or co-lead items in the OHPL; and whether the "Review of Codex standards for contaminants" was the most appropriate place to address the request from CCMAS42 to evaluate the sampling plans in CXS193, ensuring their alignment with the revised CXG50.

164. Concerning the last point, the VWG Chair noted that the VWG confirmed that this agenda item was suitable to track the review of sampling plans to ensure their alignment with the revised CXG50. It was recommended to conduct the review of sampling plans concurrently with updates to the associated MLs. The VWG Chair also informed CCCF that "Initiate concurrent review of sampling plan" was added to the "Other comments and information" column and that it was suggested to incorporate a tracking table as an annex to the annual CL for this agenda item.

165. The VWG Chair concluded by drawing the attention of CCCF to Agenda item 18, "Analysis of occurrence data of aflatoxins in cereals" recalling its relevance to List B, and proposed to investigate whether volunteers from member countries could perform analysis from the GEMS/Food database, to determine whether there was sufficient new information to initiate a re-evaluation. Volunteers could commit to conducting the data analysis only, and not necessarily to act as chair or co-chair of an EWG to re-evaluate the standard. The Committee noted that related consideration would be further discussed under Agenda item 18 (as this agenda item was discussed after Agenda item 19).

Conclusion

166. CCCF18 agreed to:

(i) add the following standards from Lists A and B to the OHPL:

(a) Cadmium, cereal grains - ML;

(b) OTA in coffee (*Code of practice for the prevention and reduction of Ochratoxin A contamination in coffee* (CXC 69-2009));

(c) Aflatoxins, various cereals and cereal-based foods MLs (x7); and

(d) Polycyclic aromatic hydrocarbons in smoked and dried foods (*Code of practice for the reduction of contamination of food with polycyclic aromatic hydrocarbons (PAH) from smoking and direct drying processes* (CXC 68-2009)).

(ii) add prioritisation criteria, rationale, and other information to indicated entries in the OHPL;

(iii) track sampling plan re-evaluation in the OHPL, for alignment with CXG50 when relevant, and in a new annex that will be circulated as part of the annual CL;

(iv) issue a CL in advance of CCCF19;

(v) re-convene the WG chaired by Canada before CCCF19; and

(vi) review the ML for methylmercury in tuna and the associated sampling plan through an EWG, chaired by New Zealand and co-chaired by Canada, working in English.

FOLLOW-UP WORK ON THE OUTCOMES OF JECFA EVALUATIONS AND FAO/WHO EXPERT CONSULTATIONS (Agenda item 20)[22]

167. The United States of America, as Chair of the VWG that was held before the Session, introduced the item, provided the background of the work, highlighted the key points of discussion in the VWG, as contained in CRD04, and presented summary tables detailing recent JECFA evaluations and FAO/WHO expert consultations, along with corresponding CCCF follow-up activities. The VWG Chair also highlighted progress made at CCCF18 on some of the elements included in the table, including, *inter alia*, PAs and TAs.

168. Conversely, the VWG Chair further noted that no CCCF follow-up had been reported for the JECFA93 (2022) and JECFA90 (2020) evaluations on T-2, HT-2, and 4,15-diacetoxyscirpenol (DAS), nor the JECFA91 (2021) evaluation on ergot alkaloids; and neither had any Member volunteered to take up work on preparing discussion papers on these topics at the VWG. The VWG Chair requested CCCF18 to consider whether there was interest in conducting work on these items.

22 REP24/CF17, para 164; CX/CF 25/18/3

Discussion

169. The Chairperson reminded CCCF that initiating consultations and evaluations that were not subsequently acted upon was not an efficient use of valuable resources and stressed the importance of utilizing the outcomes of the JECFA evaluations and FAO/WHO expert consultations. The Chairperson encouraged Members to volunteer to carry out follow-up work as identified by the VWG.

170. A Member Organization expressed interest in developing a discussion paper focusing on T-2, HT-2, DAS, and ergot alkaloids. They noted that such a paper would thoroughly examine the relevant issues on these toxins and assess whether updates were needed for the annexes in the CXC51, consequently. They further clarified that this work would not duplicate the one to be carried out by Brazil, which concentrated on aflatoxins (Agenda item 18); instead, their discussion paper would exclusively address T-2, HT-2, DAS, and ergot alkaloids as outlined in the annexes of CXC51. The Member Organization concluded by noting that the paper would aim to determine the necessity of initiating discussions on establishing MLs for certain commodities, determine the need for submitting additional available data to GEMS/Food, and the terms of reference for such a call for data.

171. Recalling that JECFA101 (2025) would evaluate arsenic, the VWG Chair highlighted the appropriateness of reconvening the WG before CCCF19 to consider the corresponding follow-up activities.

Conclusion

172. CCCF18 agreed to:

(i) establish an EWG, chaired by the European Union, working in English, to prepare a discussion paper on T-2, HT-2, DAS, and ergot alkaloids for consideration by CCCF19; and

(ii) reconvene the WG, chaired by the United States of America, to consider the follow-up work on the outcomes of JECFA evaluations and FAO/WHO expert consultations before CCCF19.

PRIORITY LIST OF CONTAMINANTS FOR EVALUATION BY JECFA (Agenda item 21)[23]

173. The USA, as Chair of the VWG that was held before the Session, introduced the item, provided the background of the work, and highlighted the key points of discussion in the VWG. The VWG Chair presented recommendations on amendments to the priority list based on comments in reply to CL 2025/04-CF and those received during the VWG, as included in CRD03, *inter alia*, updates on data availability for dioxins and dioxin-like polychlorinated biphenyls, arsenic (inorganic and organic), thallium, and per- and polyfluoroalkyl substances.

174. In addition, the VWG Chair also recalled that CCCF17 had considered a proposal to change the term "perfluoroalkyl substances" to "per- and polyfluoroalkyl substances" and that the VWG had agreed to discuss this proposal again at CCCF18. The VWG Chair clarified that, based on input received from the FAO JECFA Secretariat, the VWG agreed to maintain the name as listed.

175. The VWG Chair concluded by recalling that the VWG recommended that OTA be added to the priority list for a full evaluation (toxicological assessment and exposure assessment) and that an impact assessment be added for cadmium and lead MLs in yerba mate (under discussion in MERCOSUR[24]).

176. The VWG Chair also drew attention to proposals for including bisphenol A (BPA), copper and chromium, and iron filings in green tea on the priority list. The VWG Chair noted that the VWG had agreed not to add BPA, copper, or chromium to the priority list at this time. However, further consideration could be given to their inclusion in the priority list pending further information at CCCF19. In the case of iron filings, the VWG agreed not to include this in the priority list for the reasons explained in CRD03.

Discussion

Bisphenol A

177. A Member expressed concerns regarding the postponement of BPA consideration to CCCF19, noting that delays in JECFA guidance could impede timely responses to emerging issues, potentially disrupting global food trade and leaving countries that do not have their own national risk assessment agencies without international scientific guidance. The Member also noted that regulatory decisions based on their existing national risk assessments for BPA, which led to different conclusions, would be enforced as early as of January 2027. The Member further noted that many countries were monitoring BPA and that data would be available for a JECFA evaluation and proposed that it would also be worthwhile to include other bisphenols, such as bisphenol S and bisphenol F, in the evaluation, in addition to BPA. Other Members also supported this position.

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23 REP24/CF17, para 168, and Appendix X; CL 2025/04-CF; CX/CF 25/18/21 (Comments of Brazil, Canada, Chile, Ghana, Indonesia, Kenya, Mexico, Qatar, Singapore, Türkiye, and the USA)

24 MERCOSUR (Mercado Común del Sur - *Southern Common Market*)

178. The Chairperson clarified that Members could submit additional information on BPA and other contaminants via the annual CL for priority consideration, and that, even if added to the priority list, JECFA's evaluation depended on expert availability and capacity.

Ethylene Oxide and 2-Chloroethanol (EtO and 2-CE)

179. A Member noted that the comprehensive evaluation of EtO and 2-CE by JECFA was of great importance and a crucial element in protecting consumer health and facilitating fair practices in the food trade. The Member further acknowledged that generating new and primary data to support JECFA evaluation of these compounds was challenging, noting at the same time that they were gathering occurrence data on these substances to support the evaluation. Considering these constraints, the Member proposed to request JECFA to perform a risk assessment for EtO and 2-CE, separately, based on existing scientific literature, while, at the same time, inviting other Members to provide data to JECFA.

180. The FAO JECFA Secretariat clarified that the Joint JECFA Secretariat considered and coordinated requests and priority lists not only from CCCF but also those from other committees. The Secretariat further mentioned that FAO and WHO would jointly determine what could be accomplished from the overall work program, considering available resources, the suitability of experts, and existing data, and would report to CCCF19 accordingly.

181. The FAO JECFA Secretariat also informed the Committee that JECFA's work was currently resource-limited, primarily financially, and expressed its willingness to collaborate with member countries eager to provide support, aiming to expedite JECFA's work and address requests as promptly as possible. The Secretariat invited Members willing to support the work of JECFA for CCCF to contact jecfa@fao.org or jecfa@who.int.

182. Paraguay and Uruguay supported the request for a risk evaluation of cadmium and lead in yerba mate and informed CCCF that they would provide occurrence data for cadmium and lead in yerba mate and infusions. In response to this information, the Chairperson clarified that both Members would then be directly included in the table under Section A of the priority list.

Conclusion

183. CCCF18 agreed to:

(i) endorse the priority list as amended (Appendix XI); and

(ii) reconvene the WG, chaired by the United States of America, on the priority list of contaminants for evaluation by JECFA before CCCF19.

OTHER BUSINESS (Agenda item 22)

Guidance related to food safety aspects of recycled plastics in food packaging (USA)

184. The USA, in recalling the general support of CAC47 to initiate work on this topic[25], reiterated its intention to submit a discussion paper and a potential project document on developing a guidance document related to food safety aspects of recycled plastics in food packaging at CCCF19.

Discussion

185. A Member indicated that at this time, there was no clear evidence confirming a link between the use of recycled plastics and food safety or fair trade. The Member noted that FAO and WHO should first establish a more robust scientific foundation before new work could be considered. The Member also questioned whether CCCF was the appropriate committee to undertake this task, suggesting that it might fell more suitably under the mandate of the Codex Committee on Food Additives (CCFA).

186. It was, however, clarified that the discussion paper would only compile all information and views relevant to the topic. CCCF19 would then be invited to consider the discussion paper and decide on the suitable step(s) forward. It was therefore premature to contemplate new work or to consider the establishment of an EWG at CCCF18. Nevertheless, Members wishing to participate in the development of the discussion paper could indicate their interest to the USA. A Member Organization expressed its willingness to contribute actively to the elaboration of the discussion paper.

187. An Observer expressed its support for the development of the discussion paper, noting that matters on food contact applications have attracted much innovation within the food science and technology, and food production communities. The Observer noted that a discussion paper would allow wider perspectives on how international standardisation and harmonisation of practices could be achieved in food contact applications within Codex.

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25 REP24/CAC47, para 21

188. CCCF noted that this topic would fall under its remit, rather than CCFA.

Conclusion

189. CCCF18 agreed to request the United States of America, with assistance from Canada, the European Union, Japan, and other interested member countries, to prepare and submit a discussion paper on developing guidance related to food safety aspects of recycled plastics in food packaging for consideration by CCCF19.

Development of a Code of practice for the prevention and reduction of ochratoxin A contamination in dried fruits (Türkiye, CRD08)

190. Türkiye sought CCCF's consideration to submit the project document (Appendix II of CRD08) to CAC for approval as new work, highlighting that there were already Codex MLs and CoPs for the prevention and reduction of OTA contamination for various food groups, and that literature was available on the prevention and reduction of OTA in dried fruits.

191. The Chairperson proposed to revise the discussion paper and project document further, for consideration at CCCF19, in line with current CCCF approaches for consideration of new work proposals.

Conclusion

192. CCCF18 agreed to establish an EWG, chaired by Türkiye and co-chaired by the United Kingdom, working in English, to refine the discussion paper and project document for the development of a code of practice for the prevention and reduction of OTA contamination in dried fruits, for consideration by CCCF19.

Identification of methods for MLs in CXS193 for which there are no methods in CXS234 (Brazil)

193. Brazil expressed its intent to prepare a discussion paper to identify methods or NPC for MLs in CXS193, for which there are no methods in CXS234.

194. CCCF18 expressed appreciation to Brazil for its offer to prepare this discussion paper for consideration by CCCF19. The Committee noted the offer of Costa Rica to assist Brazil in the preparation of the discussion paper.

Issues identified under Agenda item 19

(i) Inclusion of MLs for marine biotoxins in CXS193 (Canada)

Discussion

195. Canada sought clarification from the Codex Secretariat on how the MLs for saxitoxin group, okadaic acid group, domoic acid group, brevetoxin group, and azaspiracid group in Section 1.5 of the *Standard for live and raw bivalve molluscs* (CXS 292-2008) could be reflected in CXS193, as they are currently found only in CXS292.

196. The Codex Secretariat explained that the Committee could request the Secretariat to copy these MLs in CXS193 while retaining the MLs in CXS292 and to inform CAC accordingly. She indicated that this approach would ensure that CCCF does not lose sight of these MLs when it considers the need to review MLs in the future under the standing agenda item "Review of Codex standards for contaminants".

197. The Codex Secretariat indicated that a request could be sent to the Codex Committee on Fish and Fishery Products (CCFFP) in the future to consider removing the MLs from CXS292 to avoid possible inconsistencies, pending a decision by CAC on the status of CCFFP.

Conclusion

198. CCCF18 agreed to request the Codex Secretariat to include in CXS193, the MLs in Section 1.5 of CXS292, and to inform CAC48 accordingly.

(ii) Harmonisation of the terminology "destined for further processing" and "intended for further processing" in CXS193

199. CCCF18 noted that the terms "destined for further processing" and "intended for further processing" were used interchangeably and agreed to discuss this topic again should there be further issues in the future.

Evaluation of the Codex Committee on Contaminants in Foods 2020-2023 - (Host Country Secretariat, CRD07)

200. The Chairperson explained that CRD07 aimed to solicit feedback from delegates on their experience in attending CCCF sessions, acknowledged the responses provided by delegates to post-meeting surveys over several years, and explained the follow-up to issues that have been identified in these responses. The Chairperson invited delegates to provide any further comments to CRD07 by emailing the Host Secretariat within 2 weeks after CCCF18.

Review of proposed agenda for CCCF19

201. The Chairperson presented a stock take of all decisions taken at the Session to provide an overview of the agenda for the next Session. CCCF confirmed the decisions taken under the relevant agenda items for inclusion in the agenda for CCCF19.

DATE AND PLACE OF NEXT SESSION (Agenda item 23)

202. CCCF was informed that CCCF19 was tentatively scheduled from 19 to 23 October 2026, the final arrangement subject to confirmation by the Host Country and the Codex Secretariats. The Committee noted the offer of Egypt to co-host CCCF19.

APPENDIX I

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APPENDIX II

EDITORIAL AMENDMENTS TO ANNEX X OF CXS 193-1995

(For adoption by CAC48)

Note: Deletions are indicated in **bold** and ~~strikethrough~~.

Annex X

SCIENTIFIC JUSTIFICATION FOR THE GUIDELINE LEVELS FOR RADIONUCLIDES IN FOODS CONTAMINATED FOLLOWING A NUCLEAR OR RADIOLOGICAL EMERGENCY

The guideline levels for radionuclides in foods, and specifically the values presented in Table 1 above, are based on the following general radiological considerations and experience of application of the existing international and national standards for control of radionuclides in food.

~~**Significant improvements in the assessment of radiation doses resulting from the human intake of radioactive substances have become available since the guideline levels were issued by the Codex Alimentarius Commission in 1989[1] (CXG 5-1989).**~~

Infants and adults: The levels of human exposure resulting from consumption of foods containing radionuclides listed in Table 1 at the suggested guideline levels have been assessed both for infants and adults and checked for compliance with the appropriate dose criterion.

In order to assess public exposure and the associated health risks from intake of radionuclides in food, estimates of food consumption rates and ingestion dose coefficients are needed. It is assumed that 550 kg of food is consumed by an adult in a year. The value of infant food and milk consumption during the first year of life used for infant dose calculation, equal to 200 kg, is based on contemporary human habit assessments. The most conservative values of the radionuclide-specific and age-specific ingestion dose coefficients, i.e. relevant to the chemical forms of radionuclides which are most absorbed from the gastro-intestinal tract and retained in body tissues, are taken from the IAEA.

Radiological criterion: The appropriate radiological criterion, which has been used for comparison with the dose assessment data below, is a generic intervention exemption level of around 1 mSv for individual annual dose from radionuclides in major commodities, e.g. food, recommended by the International Commission on Radiological Protection as safe for members of the public.

Naturally-occurring radionuclides: Radionuclides of natural origin are ubiquitous and, as a consequence, are present in all foodstuffs to varying degrees. Radiation doses from the consumption of foodstuffs typically range from a few tens to a few hundreds of microsieverts in a year. In essence, the doses from these radionuclides when naturally present in the diet are unamenable to control; the resources that would be required to affect exposures would be out of proportion to the benefits achieved for health. These radionuclides are excluded from consideration in this document as they are not associated with emergencies.

One-year exposure assessment: It is conservatively assumed that during the first year after major environmental radioactive contamination caused by a nuclear or radiological emergency, it might be difficult to readily replace foods imported from contaminated regions with foods imported from unaffected areas. According to FAO statistical data, the mean fraction of major foodstuff quantities imported by all the countries worldwide is 0.1. The values in Table 1 as regards foods consumed by infants and the general population have been derived to ensure that if a country continues to import major foods from areas contaminated with radionuclides, the mean annual internal dose of its inhabitants will not exceed around 1 mSv (see Annex XI). This conclusion might not apply for some radionuclides if the fraction of contaminated food is found to be higher than 0.1, as might be the case for infants who have a diet essentially based on milk with little variety.

Long-term exposure assessment: Beyond one year after the emergency, the fraction of contaminated food placed on the market will generally decrease as a result of national restrictions (withdrawal from the market), changes to other produce, agricultural countermeasures, and decay.

Experience has shown that in the long term, the fraction of imported contaminated food will decrease by a factor of a hundred or more. Specific food categories, e.g. wild forest products, may show persistent or even increasing levels of contamination. Other categories of food may gradually be exempted from controls. Nevertheless, it must be anticipated that it may take many years before levels of individual exposure as a result of contaminated food could be qualified as negligible.

~~[1] The Codex Alimentarius Commission at its 18th Session (Geneva 1989) adopted *Guideline Levels for Radionuclides in Foods Following Accidental Nuclear Contamination for Use in International Trade* (CXG 5-1989) applicable for six radionuclides (^{90}Sr, ^{131}I, ^{137}Cs, ^{134}Cs, ^{239}Pu and ^{241}Am) during one year after the nuclear accident.~~

APPENDIX III

MAXIMUM LEVELS FOR LEAD IN SPICES, DRIED BARK, AND CULINARY HERBS, DRIED

(For adoption at Step 8)

Commodity/ Product name	Maximum level (ML) mg/kg	Portion of the commodity/ product to which the ML applies	Notes/Remarks
Spices, dried bark	2.5	Whole, ground, powder, crushed	-

(For adoption by CAC48 at Step 5/8 (with the omission of Steps 6 and 7))

Commodity/ Product name	Maximum level (ML) mg/kg	Portion of the commodity/ product to which the ML applies	Notes/Remarks
Culinary herbs, dried	2.0	Whole commodity	The relevant Codex commodity standards are CXS 328-2017, CXS 342-2021, and CXS 345-2021. MLs for fresh culinary herbs may be derived based on the moisture content of the fresh herb in relation to the dry herb.

(For discontinuation at Step 7)

Commodity/ Product name	Maximum level (ML) mg/kg	Portion of the commodity/ product to which the ML applies	Notes/Remarks
Culinary herbs, dried	2.5	Whole commodity	MLs for fresh culinary herbs may be derived based on the moisture content of the fresh herb in relation to the dry herb.

APPENDIX IV

SAMPLING PLANS FOR TOTAL AFLATOXINS AND OCHRATOXIN A IN NUTMEG, DRIED CHILLI AND PAPRIKA

(For adoption at Step 8 after endorsement by CCMAS)

A) Spices with large particle size (Whole nutmeg, whole dried chilli and whole paprika)

In case of large lots and on condition that the sublot can be separated physically, each lot shall be subdivided into sublots following Table 1. 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 sublot may exceed the mentioned weight in Table 1 by a maximum of 20%.

Table 1: Subdivision of Spices sublots according to lot weight – Whole nutmeg, whole dried chilli and whole paprika –

Lot weight (tonne)	Weight or number of sublots	No incremental samples	Aggregate sample weight (kg)
≥ 500	100 tonnes	100	10
> 125 and < 500	5 sublots	100	10
≥ 25 and ≤ 125	25 tonnes	100	10
< 25	—	10 – 100 (*)	1 - 10
(*) Depending on the lot weight — see Table 2			

Each sub-lot shall be sampled separately. The number of incremental samples of 100 g to be taken depends on the weight of the lot, with a minimum of 10 and a maximum of 100. The figures in the following Table 2 shall be used to determine the number of incremental samples to be taken and the subsequent division of the aggregate sample.

Table 2: Number of incremental samples to be taken according to lot weight – Whole nutmeg, whole dried chilli and whole paprika – (for lots < 25 tonnes)

Lot weight (tonnes)	No of incremental samples	Aggregate sample weight (kg)
≤ 0.1	10	1
> 0.1 – ≤ 0.2	15	1.5
> 0.2 – ≤ 0.5	20	2
> 0.5 – ≤ 1.0	30	3
> 1.0 – ≤ 2.0	40	4
> 2.0 – ≤ 5.0	60	6
> 5.0 – ≤ 10.0	80	8
> 10.0 – <25.0	100	10

If the test result is ≤ Codex ML, then accept the lot; otherwise, reject the lot.

B) Spices with small particle size (crushed/cracked/broken/flakes of nutmeg, dried chilli and paprika)

In the case of large lots and on condition that the sublot can be separated physically, each lot shall be subdivided into sublots following Table 3. 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 sublot may exceed the mentioned weight in Table 3 by a maximum of 20%.

Table 3: Subdivision of spices sublots according to lot weight
- crushed/cracked/broken/flakes of nutmeg, dried chilli and paprika -

Lot weight (tonnes)	Weight or number of sublots	Number of incremental samples	Aggregate sample weight (kg)
≥ 25	25 tonnes	100	10
< 25	—	5 – 100 (*)	0.5 – 10
(*) Depending on the lot weight — see Table 4			

Each sublot shall be sampled separately. The number of incremental samples of 100 g to be taken depends on the lot weight, with a minimum of 5 and a maximum of 100. resulting in an aggregate sample of 0.5 to 10 kg. Table 4 can be used to determine the number of incremental samples to be taken from lots of various sizes.

Table 4: Number of incremental samples to be taken according to lot weight
- crushed/cracked/broken/flakes of nutmeg, dried chilli and paprika –
(for lots < 25 tonnes)

Lot weight (tonnes)	Number of incremental samples	Aggregate sample weight (kg)
≤ 0.01	5	0.5
> 0.01 – ≤ 0.1	10	1
> 0.1 – ≤ 0.2	15	1.5
> 0.2 – ≤ 0,5	20	2
> 0.5 – ≤ 1.0	30	3
> 1.0 – ≤ 2.0	40	4
> 2.0 – ≤ 5.0	60	6
> 5.0 – ≤ 10.0	80	8
> 10.0 – < 25.0	100	10

If the test result is ≤ Codex ML, then accept the lot; otherwise, reject the lot.

C) Powdered spices (obtained by grinding nutmeg, dried chilli and paprika)

In the case of large lots and on condition that the sublot can be separated physically, each lot shall be subdivided into sublots following Table 5. 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 sublot may exceed the mentioned weight in Table 5 by a maximum of 20%.

Table 5: Subdivision of spices sublots according to lot weight
- Powdered spices (nutmeg, dried chilli and paprika) -

Lot weight (tonnes)	Weight or number of sublots	Number of incremental samples	Aggregate sample weight (kg)
≥ 25	25 tonnes	50	4
< 25	—	3 – 50 (*)	0.24 – 4.0
(*) Depending on the lot weight — see Table 6			

Each sublot shall be sampled separately. The number of incremental samples of 80 g to be taken depends on the lot weight, with a minimum of 3 and a maximum of 50 incremental samples. Table 6 can be used to determine the number of incremental samples to be taken from lots of various sizes.

Table 6: Number of incremental samples of powdered spices to be taken depending on the weight of the lot - (for lots < 25 tonnes) -

Lot weight (tonnes)	Minimum number of incremental samples	Minimum aggregate sample weight (kg)
≤ 0.1	3	0.24
> 0.1 – ≤ 0.5	10	0.8
> 0.5 – ≤ 5.0	25	2
> 5.0 – ≤ 10.0	35	2.8
> 10.0 – < 25.0	50	4

If the test result is ≤ Codex ML, then accept the lot; otherwise, reject the lot.

Method performance criteria[1]

Table 7: Method performance criteria for the analysis of total aflatoxins and ochratoxin A in spices

Commodity	Analyte	ML (µg/kg)	LOD (µg/kg)	LOQ (µg/kg)	Precision (%)	Minimal applicable range (µg/kg)	Recovery (%)
Chilli pepper, nutmeg	AFT B1+B2+G1+G2	20	≤ 4	≤ 8	≤ 44	11.2 – 28.8	60 – 115
	AFB1	-	≤ 1	≤ 2	≤ 44	2.8 – 7.2	40 – 120
	AFB2	-	≤ 1	≤ 2	≤ 44	2.8 – 7.2	40 – 120
	AFG1	-	≤ 1	≤ 2	≤ 44	2.8 – 7.2	40 – 120
	AFG2	-	≤ 1	≤ 2	≤ 44	2.8 – 7.2	40 – 120
Chilli pepper, paprika, nutmeg	OTA	20	≤ 4	≤ 8	≤ 44	11.2 – 28.8	60 – 115

[1] Upon endorsement by the Codex Committee on Methods of Analysis and Sampling and adoption by the Codex Alimentarius Commission, the numeric performance criteria will be transferred to the *Recommended methods of analysis and sampling* (CXS 234-1999), and this section will be replaced with a general reference to CXS234.

APPENDIX V

REVISED *CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF AFLATOXIN CONTAMINATION IN PEANUTS* (CXC 55-2004)

(For adoption at Step 5/8
(with the omission of Steps 6 and 7))

1. INTRODUCTION

1. Research has demonstrated that aflatoxins (AF) are among the most potent liver carcinogens. This classification was established by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) at its forty-ninth meeting and reaffirmed at its eighty-third meeting, based on studies in test species and human epidemiological studies. In addition to their carcinogenic properties, aflatoxins exhibit acute and chronic toxicity and genotoxic, carcinogenic, and immunosuppressive effects. Aflatoxins can be found in several food commodities, including peanuts, tree nuts, dried figs, cereals, spices, and derived products.

2. Several species of the *Aspergillus* section *Flavi* are known to produce aflatoxins, with *Aspergillus flavus, A. parasiticus,* and related species commonly isolated from peanuts. These fungi are usually found in soils where peanuts grow and can infect them under favourable conditions. The interaction of the host plants, the fungus, and the environment determines the infection of the peanut and the subsequent aflatoxin production. Pre-harvest conditions such as drought stress, elevated temperatures, and humidity during seed filling and plant development are among the most important factors that influence aflatoxigenic fungal infection and aflatoxin production.

3. After harvest, peanuts are cured, often sun-dried, stored, and traded. To prevent aflatoxigenic species growth and toxin formation, the water activity and/or moisture content of peanuts can be monitored and maintained. Colour sorting, blanching, and roasting are processing techniques that are used for aflatoxin reduction in peanuts.

2. SCOPE

4. This document is intended to provide guidance for all parties involved in producing/processing, and handling of peanuts intended for food and feed. Peanuts and peanut products should be prepared and handled in accordance with the *General principles of food hygiene* (CXC 1-1969, which apply to all foods prepared for human consumption, and the *Code of hygienic practice for groundnuts (peanuts)* (CXC 22-1979). These outline the measures that should be implemented by those responsible for ensuring that food is safe and suitable for consumption.

3. RELATED CODEX TEXTS

- *General standard for contaminants and toxins in food and feed* (CXS 193-1995)
- *Recommended methods of analysis and sampling* (CXS 234-1999)
- *General principles of food hygiene* (CXC 1-1969)
- *Code of hygienic practice for groundnuts (peanuts)* (CXC 22-1979)
- *Standard for peanuts* (CXS 200-1995)
- *Code of practice for the reduction of aflatoxin B1 in raw materials and supplemental feedingstuffs for milk-producing animals* (CXC 45-1997)

4. DEFINITIONS

- **Density flotation** is a physical separation process used to remove damaged, immature, or potentially aflatoxin-contaminated peanut kernels based on differences in their density.
- **Blows (Pops)**: In-shell peanuts, which are unusually light in weight due to extensive damage from physiological, mould, insect, or other causes and which can be removed, for example, by an air-separation process.
- **Curing**: Drying of the in-shell peanuts to a safe moisture level.
- **Farmers' stock peanuts**: In-shell peanuts as they come from farms.
- **Moisture content**: total amount of water present in a product.
- **Loose shelled kernels:** peanut kernels or any portion of kernels completely free from shells when found in farmers' stock peanuts.
- **Peg**: An ovary stalk that goes underground and from where the pods originate.
- **Water activity (a_w)**: A measure of free moisture in a product.
- **Xerophilic fungi:** Fungi that can grow at low water activity, below 0.85, under at least one set of environmental conditions.

- **Winnowing** is a physical separation process that removes lighter materials such as husks, shells, or dust from edible kernels by using airflow or mechanical agitation.

5. GENERAL RECOMMENDATIONS

5. Document the harvesting, drying, cleaning, and storage procedures and conditions (e.g. temperature, moisture, humidity) each season to help identify causes of fungal growth and prevent future occurrences. Validated predictive models can be useful in helping make management decisions.

6. Ensure all vehicles (e.g. wagons, trucks), equipment, and materials used for planting, harvesting, transporting, drying, cleaning, and storage are:

   - cleaned of potential sources of contamination (e.g. crop residues, dust, insects, fungal growth, broken glass, animal excrement) and dried. Use approved cleaners and disinfectants that do not cause off-odours, flavour, or contaminate the crop.
   - intact and able to provide protection from water (e.g. precipitation, groundwater seepage, condensation) as well as rodents, birds, and insects that can contaminate the crop and cause physical damage, making it more susceptible to mould infection. Use registered fumigants or insecticides as needed.

7. Ensure all equipment and materials used for planting, harvesting, transporting, drying, cleaning, and storage are in good working order and calibrated to relevant conditions (e.g. moisture sensors), where applicable. Have spare parts available to minimize time loss for equipment repairs.

8. Aim to minimize mechanical damage to crops during cultivation, irrigation, pest management practices, harvest, and cleaning.

9. Contact product or equipment manufacturers, competent authorities, and/or extension services for supplementary information about the practices noted in this code of practice.

10. Extension services can advise about aflatoxin mitigation measures relevant to regional conditions and situations.

11. Products used in the production of food and animal feed that may indirectly prevent or control aflatoxin-producing species (e.g. insecticides, additives used to support fermentation, biofungicides, and biopesticides) or directly reduce aflatoxin levels post-harvest (e.g. additives and mycotoxin detoxifying agents (MDAs)) should be approved/registered and used within the parameters set by competent authorities. In approving /registering the use of *Aspergillus* strains as biopesticides, competent authorities should take into account that research has shown that *A. flavus* can undergo sexual recombination, generating new, aflatoxin-producing genotypes.

12. Aflatoxin concentrations in food and feed may be heterogeneous. Therefore, it is important that any sampling and testing follow Codex sampling plans or those of competent authorities to provide accurate and representative results. The sampling plan for total aflatoxins in peanuts is established in the *General standard for contaminants and toxins in food and feed* (CXS 193-1995).

6. RECOMMENDED PRACTICES BASED ON GOOD AGRICULTURAL PRACTICES (GAP)

6.1 Pre-planting preparation and planting

13. For effective pre-harvest control of aflatoxin contamination in peanuts, it is essential to consider all the environmental and agronomical factors that influence pod and seed infection by the aflatoxigenic fungi and aflatoxin production. These factors can vary considerably from one location to another and between seasons in the same location. Some conditions may be particularly favourable to fungal infection and subsequent aflatoxin contamination of peanuts. In these circumstances, appropriate planning and agricultural practices should be employed to reduce aflatoxin contamination in peanuts.

14. The cultivation of peanuts on the same land for several cycles may lead to a build-up of high populations of aflatoxigenic fungi, particularly *A. flavus* and/or *A. parasiticus,* in the soil, increasing the probability of infection and aflatoxin contamination. Some studies have been carried out on the effect of crop rotation on aflatoxin contamination. In semi-arid environments, populations of aflatoxigenic fungi may be very high, and crop rotations have little influence on the activity of these species. Cropping systems in some regions involve diverse cultivation and fertilizer practices that, individually or taken together, may affect the survival or build-up of populations of the aflatoxigenic fungi. There is evidence that peanuts grown in different soil types may have significantly different infection levels by the fungi. Light sandy soils, for example, favour rapid proliferation of the fungi, particularly under dry conditions. In contrast, heavier soils have a higher water-holding capacity and, therefore, there is less likelihood of drought stress, which may partly explain the lower-than-average levels of aflatoxin contamination in peanuts grown on such soils.

15. Use soil test results to determine if fertilizer and/or soil conditioners are needed to maintain appropriate soil pH and plant nutrition. This helps prevent plant stress, especially during seed development, when peanuts are more susceptible to fungal infection. Utilizing soil amendments such as composting manure and gypsum/lime at sowing time is shown to reduce *A. flavus* seed infection and aflatoxin formation. Lime and gypsum are sources of calcium that enhance cell thickness and pod filling and decrease fungal infection while also altering soil pH. Organic supplements, such as composting manure and non-contaminated crop residues, improve the soil's water-holding capacity, minimizing the effect of drought during plant development and reducing fungal infection and aflatoxin accumulation in the peanut seeds.

16. The choice of peanut variety is important, so before planting, farmers should consult with the national or relevant competent authorities or extension services to identify the cultivars most suitable for their region. They should also consider the availability of varieties resistant to various factors, such as insect infestation and fungal and other microbial infections, which can affect the safety and quality of the peanuts. A cultivar that is suitable for a particular growing season and matures at the end of the rainy season should be selected, allowing post-harvest field drying under favourable conditions. It is undesirable that a variety suffers from drought stress during pod maturation; therefore, some adjustments may have to be implemented to avoid such stress. Cultivation strategies may be considered, that maximize harvest during dry conditions while preventing drought stress as much as possible (e.g. the use of early ripening cultivars that mature before the rainy season has ended).

17. It is essential to prevent the overcrowding of plants by adhering to the recommended spacing between rows and within plants for the specific species or varieties being cultivated. Establishing optimal plant populations is crucial, as excessively high densities can result in drought stress, particularly in seasons where rainfall is not at ideal levels needed for growth.

6.2 Pre-harvest

18. When necessary, irrigation may be used as a strategy to mitigate the impact of heat and drought stress. Water stress affects plants in three ways: first, by wilting the plant and reducing its metabolic activity, which inhibits the plant's natural defences against fungal infection; second, by lowering the water activity in the soil, which reduces growth and activity of competing microorganisms; and third, by promoting the growth of *A. flavus* or *A. parasiticus*, which are xerophilic fungi.

19. Irrigation to ensure adequate soil moisture during the pod/seed filling and before harvest should minimize pre-harvest aflatoxin contamination of peanuts. This may be achieved by growing a thoroughly irrigated crop or applying supplementary irrigation to a rain-fed crop. If irrigation is used, ensure that it is applied evenly and that all plants in the plot have an adequate water supply.

20. Excessive weed growth may affect available soil moisture. Effective weed control by the use of registered herbicides or cultivation is therefore advisable. During weed cultivation, care should be taken to avoid damaging pegs and pods.

21. Cultivation and crop protection practices that lower the incidence of soil insects, mites, and nematodes can help reduce aflatoxin contamination. Minimizing insect damage and fungal infection in the vicinity of the crop can be achieved by the proper use of registered insecticides, insect-resistant cultivars, fungicides, and other appropriate practices within an integrated pest management program. Growers should consult local or national authorities and extension services to identify the insects and pests commonly found in their region that may attack peanuts, making them more susceptible to fungal infections and aflatoxin production.

22. No fungicide, combinations of fungicides, or other chemical treatments appear to have been widely adopted for the practical control of infection and subsequent aflatoxin contamination of peanuts pre-harvest. The results of studies on the application of fungicides on freshly harvested or windrowed peanuts are equivocal.

23. Biological methods could be used, like biofungicides and biopesticides. For example, the deliberate introduction of competitive, non-aflatoxigenic *A. flavus* and *A. parasiticus* into the agricultural environment can suppress the natural occurrence of the aflatoxigenic fungi.

6.3 Harvest

24. Local and national authorities, as well as trade associations, should take the lead in informing growers of the hazards associated with aflatoxin contamination of peanuts and how they may practice safe harvesting procedures to reduce the risk of contamination.

25. Peanuts must be harvested at full maturity (R8, as shown in Table 1) unless there are chances of extreme heat, rainfall, or drought conditions. It is very important to harvest the crop at optimal maturity, as excessive numbers of over-mature pods at harvest can be reflected in high levels of aflatoxin in the product, and immature pods are more likely to be contaminated by aflatoxins due to lower phytoalexin levels, which give natural resistance to fungal infection. Delayed harvest of peanuts may cause a significant increase in the aflatoxin content of infected plants (or peanuts). Monitoring crop maturity, precipitation, and soil temperature, as well as the use of predictive models, if available, may be very useful in helping target optimal harvest periods.

26. Table 1 represents the stages of peanut reproductive growth. The following stages correspond to the beginning of pod formation (R3), pod expansion (R4), and seed formation (R5). Once it reaches the ground, the peg with its swollen ovary doubles its width, and the expansion of the pod begins. With the pod fully expanded, the growth of the seed's cotyledon begins. Seed formation begins approximately 60 days after planting. When the pod cavity is completely filled with seed, the plant reaches the R6 stage around 74 days after planting. When 50% of the plants have at least one pod that shows colour on the inner part of the pericarp, the plantation reaches the R7 stage, indicating the beginning of maturation. Complete maturation (R8), indicating the moment of harvest, occurs when 70 to 75% of the pods are placed in the inner part of the pericarp. Stages R7 and R8 occur approximately in the last 30 days of the peanut planting cycle. Maturation can be observed by the colour of the cotyledons, which varies from white (immature kernels) to pink (more mature kernels).

Table 1. Stages of peanut reproductive growth.

Stage	Reproductive stages	Description	Figure
R1	Beginning bloom	One open flower at any node on the plant.	
R2	Beginning peg	One elongated peg (gynophore).	
R3	Beginning pod	One peg in the soil with turned swollen ovary at least twice the width of the peg.	
R4	Full pod	One fully expanded pod, to dimensions characteristic of the cultivar.	
R5	Beginning seed	One fully expanded pod in which seed cotyledon growth is visible when the fruit is cut in cross-section.	
R6	Full seed	One pod with cavity apparently filled by the seeds when fresh.	

Stage	Reproductive stages	Description	Figure
R7	Beginning maturity	One pod sharing visible natural coloration or blotching of inner pericarp or testa.	
R8	Harvest maturity	66-75% of all developed pods have testa or pericarp coloration.	
R9	Over-mature pod	One undamaged pod showing orange-tan coloration of the testa and/or natural peg deterioration	

27. Individual plants that die due to damage from pests, pathogens, such as *Sclerotium rolfsii* or *Fusarium* spp., and diseases, like rosette virus, or insects, such as termites, earwigs, and false wireworms that cause damage to the pods, should be harvested separately, if possible, as peanuts from these plants are likely to be contaminated with aflatoxins.

28. If irrigation systems are used, care should be taken to harvest peanuts beyond the reach of irrigation systems separately to avoid mixing peanuts from irrigated sections with those from unirrigated sections.

29. Damage to peanut pods at the time of harvest should be avoided as much as possible since this can lead to rapid invasion of the pods by aflatoxigenic fungi.

30. After harvest, peanut pods should be exposed to the sun and wind for maximum drying rate. This may be accomplished by turning the plants to leave the pods uppermost, away from the ground, and exposed to sun and wind. Curing should be completed as soon as possible to a safe water activity to prevent the growth of microorganisms, particularly aflatoxigenic fungi. However, curing too rapidly may cause skin slippage and off-flavours of the peanut kernels. When curing by supplemental heat, excessive heat should be avoided since this impairs the general quality of the peanuts, e.g., causing the splitting of kernels after shelling. Close checks of the moisture content/water activity of lots of farmers' stock peanuts should be maintained.

31. Peanuts should be dried so that damage to the peanuts is minimized and moisture levels are lower than those required to support fungal growth during storage. The ideal combination of moisture level and maximum allowed drying period will vary with peanut variety and agricultural zone. It is envisaged that the preliminary windrow drying should achieve a moisture level of <12%, whereas the second drying phase, on a flat surface or by other suitable methods, should attain a moisture level of <10% for peanuts in-pod and <9% for peanut kernels. Lower moisture levels may be required for certain destinations in relation to the climate, duration of transport, and storage.

32. Once the windrow drying is done, the separation of the pods from the pegs must be carried out. This can be done manually or mechanically, being careful not to damage the fruit with rough handling and the use of poorly adjusted machinery, which would allow moisture to enter the pod and increase the risk of fungal contamination and spoilage of the seed.

33. Peanuts should be cleaned and sorted to remove damaged peanuts and other foreign matter. Cleaning procedures, such as density separators or air legs to remove light pods and slotted screens to eliminate pre-shelled kernels, may remove some infected peanuts.

7. RECOMMENDED PRACTICES BASED ON GOOD MANUFACTURING PRACTICE (GMP)

7.1 Transport to Processing Facilities

34. Harvest peanuts (farmers' stock peanuts) should be transported to a suitable storage facility or the processing area for processing as soon as possible after harvesting or drying.

35. Consignments of farmers' stock peanuts should be protected from additional moisture by using covered or airtight containers or tarpaulins, but remove them promptly after transportation to avoid moisture trapping, which could make the consignment more conducive to mould growth and aflatoxin contamination. Avoid temperature fluctuations that may cause condensation on the farmers' stock peanuts, which could lead to local moisture build-up and consequent fungal growth and aflatoxin formation.

36. Avoid insect, bird, and rodent infestation during transportation using pest-proof containers or insect and rodent-repellent chemical treatments if they are approved for the intended use.

7.2 Segregation of aflatoxin-contaminated lots

Farmers' stock peanuts should be screened for aflatoxin contamination using appropriate sampling and analytical techniques to segregate peanut loads for proper storage. Aflatoxin-free loads should be segregated from loads with low levels of aflatoxin contamination, loads destined for subsequent processing and clean-up, and loads that are highly contaminated.

37. Research results indicate that quality sorting removes a large part of the aflatoxins present at harvest.

7.3 Storage of in-shell peanuts

38. The post-harvest storage phase is crucial for controlling aflatoxin contamination in peanuts.

39. A properly ventilated warehouse with a roof of suitable material and a concrete floor is required to prevent the rewetting of peanuts and mould development. Ensure that the storage facilities include dry, well-ventilated structures that protect from rain, allow water to drain away from the facility, protect from entry of insects, rodents, and birds, and minimize temperature fluctuations. Also, the following are examples of warehouse improvements proven to be effective: (1) To reduce solar heat load, warehouse roofs with white paint can be used instead of conventional galvanized roof material, and (2) The double roofing concept of installing a new roof over a defective, existing roof, with an air space in-between the two roofs, has proven effective in controlling warehouse condensation.

40. Storage temperature and relative humidity should be carefully monitored during storage. Storage temperature and relative humidity should not be above 30°C and 85%, respectively. Ideally, relative humidity below 70% and temperatures between 0°C and 10°C are optimal for minimizing spoilage and fungal growth during long-time storage.

41. Uniform loading in the warehouse allows excessive heat and moisture to escape and reduces areas favourable for insect infestation. Stockpiling of peanuts can cause heat build-up and moisture accumulation, causing mould growth and aflatoxin contamination.

42. The increase in aflatoxin contamination during storage and transportation depends on water activity and moisture content, the temperature in the environment, and the hygienic conditions. Aflatoxigenic fungi such as *A. flavus* and *A. parasiticus* cannot grow or produce aflatoxins at water activities less than 0.7 and moisture content less than 9%.

43. Store at the lowest temperature possible, consistent with ambient conditions, but avoid near-freezing temperatures. Where possible, aerate the peanuts by circulating air through the storage area to maintain proper and uniform temperature levels throughout the storage area.

44. When necessary, aflatoxin levels in farmers' stock peanuts coming into and out of storage should be monitored for aflatoxins using appropriate sampling and screening techniques, such as rapid tests that report acceptable/not acceptable results.

45. For bagged peanuts, ensure that the bags are clean and dry and stacked on pallets, or incorporate a water-impermeable layer between the bags and the floor. When low-temperature storage is not available, the use of hermetic storage bags is recommended. These bags create airtight and moisture-proof conditions, reducing aflatoxin contamination during long-term storage. To further improve their effectiveness, hermetic storage can be combined with oxygen absorbers or CO_2 injection, particularly to prevent fungal growth during the critical early phase of storage.

46. Measure the temperature, when possible, of the stored peanuts at scheduled intervals during storage. Increasing temperature is likely a good indicator of microbial growth as well as insect infestation. Visually check peanuts for evidence of mould growth and insect damage. Separate the apparently infected peanuts and send samples for analysis if possible. When separated, lower the temperature of the remaining peanuts and aerate. Avoid using visually infected peanuts for food or feed production.

47. Use good 'housekeeping' procedures to minimize the levels of insects and fungi in storage facilities. This may include the use of suitable traps, registered insecticides, fungicides, and fumigants.

48. Record the harvesting and storage procedures employed each season and document measurements of temperature, moisture levels, water activity, and humidity, along with any deviations or alterations from conventional practices. This information may be very useful for explaining the causes of fungal growth and aflatoxin contamination during a particular crop year and help to avoid similar issues in the future.

7.4 Receiving and shelling

49. A buyer for a shelling plant, whether located at the plant or an outlying buying point, should monitor the quality of peanuts. Buyers should encourage farmers' stock peanuts suppliers to follow Good Agricultural Practices (GAP) as described herein, including application and documentation of good agricultural practices, quality assurance, and quality control measures.

50. Farmers' stock peanuts received at the shelling plant should be inspected on arrival. It is advisable to know the origin and history of each lot of peanuts. The transport vehicle should be examined. If the vehicle is not fully enclosed, it should have a covering such as tarpaulin to keep out rain or other forms of water. The general appearance of the peanuts should be observed during the process of unloading. If the peanuts are wet to the touch, they should not be mixed with peanuts in a bulk warehouse. The vehicle that contains the peanuts should be set aside until a decision is made for their disposal. If possible, remove a sample from each lot, separate the "loose shelled" kernels, and shell the remainder for peanut grade observation before an acceptance decision is made.

51. Specifications for the purchase of peanuts intended for further processing should include a maximum level for aflatoxins based on appropriate sampling and analysis methods.

52. Peanuts showing signs of insect damage or mould growth must be rejected because of the higher risk of aflatoxin contamination. Aflatoxin test results should be known before allowing lots of raw peanuts to be processed. Any lot of raw peanuts with unacceptable levels of aflatoxins, which cannot be reduced to permitted levels by the available sorting equipment, should not be accepted.

53. Suppliers of shelled peanuts should comply with the processor requirements to ensure that the finished product meets all specifications, including the maximum limit for aflatoxins.

54. Examine all loose-shelled, damaged "blows" and undersized kernels for possible presence of mould. If no external mould is visible, split the kernels to disclose possible hidden mould growth. Excessive mould or the presence of mould resembling aflatoxigenic fungi, such as A. flavus, warrants a chemical test for aflatoxin or rejection of the lot.

7.5 Sorting

55. Several peanut processing procedures, such as sorting, density flotation, blanching, and roasting, have been shown to reduce aflatoxin levels by up to 99%. Aflatoxins can be reduced at any stage of production by removing defective peanuts and foreign matter by sorting (electronically or manually), winnowing, separating by gravity, or other methods. Sorting is the final step for removing defective kernels.

56. In electronic or laser sorting, each shelled peanut is inspected, and discoloured peanuts are removed, as discoloration often indicates fungal growth and potential aflatoxin contamination. Sorting can reduce up to 70% of aflatoxin. Utilizing equipment that can remove kernels with internal defects through differences in near-infrared transmittance has been shown to be an effective method for reducing aflatoxin levels.

57. In the case of manual sorting, belts should be well-lit, with peanuts passing through no more than one layer deep and operated at a speed that enables hand sorters to ensure effective removal of foreign material and defective kernels. Sorting machines should be adjusted as often as practicable against standards to ensure the removal of all defective kernels. Adjustments should be checked frequently and regularly.

58. To remove mould-contaminated peanuts effectively, sorting should be performed before and after blanching and roasting. Where splitting is part of the processing operation, kernels that resist splitting should be removed. The effectiveness of sorting techniques should be checked by regular aflatoxin analyses of the sorted peanuts, or in the finished product, or both. This should be done frequently enough to ensure the product is completely acceptable.

59. Defective kernels (mouldy, discoloured, rancid, decayed, shrivelled, insect, or otherwise damaged) should be bagged separately and tagged as unsuitable for human consumption. Containers of defective peanuts should be removed from the processing area as soon as possible. Peanuts possibly contaminated or contaminated with aflatoxins exceeding food standards, based on previous analysis, could be redirected to oil production, non-food, or feed uses, given that any existing standard is met.

7.6 Blanching

60. Blanching is a process that involves the partial drying of raw shelled peanuts with the aim of loosening skins/testa for easy removal by blanching rollers. The blanched kernels are then sorted for discoloration manually or using electronic colour sorters. As much as a 90% reduction in aflatoxin can be achieved when blanching is used in conjunction with gravity tables and manual or electronic sorting. If the colour sorting process is ineffective for blanched peanuts, as can occur when severe drought stress causes peanuts to dry in the soil before harvest, it is common practice to roast the blanched peanuts and perform the colour sorting process again. This accentuates the darkening process and facilitates colour sorting.

7.7 Packaging and storage of the end product

61. Peanuts should be packed in appropriate packages, such as clean jute bags, cartons, or food-grade plastic bags, such as polypropylene bags. Hermetic storage bags are also recommended for specific conditions such as room temperature storage, long-term storage, and high-humidity environments. Ensure food-contact materials comply with the safety standards set by regulatory authorities. All bags/cartons should be lot-identified to facilitate traceability before being moved to controlled storage facilities or transported.

62. Peanuts that have been processed should be stored and transported under such conditions as to maintain the integrity of the container and the product within it. Carriers should be clean, dry, weatherproof, free from infestation, and sealed to prevent water, rodents, or insects from reaching the peanuts. Peanuts should be loaded, held, and unloaded in a manner that protects them from damage or water. Well-insulated carriers or refrigerated vehicles are recommended for transport when climatic conditions indicate such a need. Extreme care should be taken to prevent condensation when unloading peanuts from cold storage or a refrigerated vehicle. In warm, humid weather, the peanuts should be allowed to reach room temperature before exposure to external conditions. This may require 1 to 2 days. Peanuts that have been spilled are vulnerable to contamination and should not be used for edible products.

63. Export-grade peanuts should be clearly labelled as either "ready-to-eat" (or equivalent name) or "destined for further processing," indicating that additional processing is required before they are used as an ingredient in foodstuffs, otherwise processed, or offered for human consumption.

8. RISK MANAGEMENT FOR AFLATOXIN CONTROL IN THE PEANUT CHAIN

64. The Hazard Analysis Critical Control Point (HACCP) system is an all-encompassing integrated food safety management system that is used to identify and control hazards within the production and processing system. The general principles of HACCP are described in the *General principles of food hygiene* (CXC 1-1969).

65. Aflatoxins in peanuts are both of microbial origin (due to fungal contamination) and present a chemical hazard. Therefore, integrated control measures are needed. When properly implemented, this system should result in a reduction of the levels of aflatoxins in peanuts. The use of HACCP as a food safety management system has many benefits over management control systems in some segments of the food industry. Control of aflatoxin contamination during agricultural production is mainly achieved through minimizing insect infestation and controlling irrigation. Particular attention should be paid to the soil population of the fungi, the health of the seed material, soil moisture deficit stress during pod formation and pod maturity stages, and rainfall at harvest. After harvesting, the critical control points may be identified for aflatoxins produced by fungi during drying and storage. For example, aflatoxins can be formed while peanuts are being dried, which is usually carried out in the field, and can also continue to form during farm storage if drying has been inadequate or when storage is carried out at high relative humidity and/or temperature. During manufacturing, sorting, and roasting are the main steps in the reduction of aflatoxin, making them critical control points.

66. It is recommended that resources be directed to promoting GAPs and GMPs at pre-harvest, harvest, drying, storage, processing, and distribution of various products. A HACCP system should be built on sound GAPs and GMPs.

67. Integrated aflatoxin control programs may incorporate HACCP principles to control risks associated with aflatoxin contamination of foods and feeds. Implementing HACCP principles can minimize aflatoxin contamination of peanuts through the application of preventive controls to the extent feasible in the production, handling, storage, and processing of each peanut crop.

APPENDIX VI

PART I: PROPOSAL FOR NEW WORK ON THE REVISION OF THE *CODE OF PRACTICE FOR WEED CONTROL TO PREVENT AND REDUCE PYRROLIZIDINE ALKALOID CONTAMINATION IN FOOD AND FEED* (CXC 74-2014)

PROJECT DOCUMENT

(For approval)

1) Purpose and scope of the project

The proposed revision aims to update the *Code of practice for weed control to prevent and reduce pyrrolizidine alkaloid contamination in food and feed (*CXC 74-2014).

Based on limited occurrence data on pyrrolizidine alkaloids (PAs), the 80th JECFA meeting noted that the calculated margin of exposures (MOEs) for honey (high consumers) and tea (mean and high consumers) indicated a potential concern.

The current code of practice (CoP) focuses on weed control to prevent and reduce PAs. The updates will address the following additions: Additional foods affected by PAs, such as grains and grain-based products, teas, herbal infusions, herbal and pollen-based food supplements, salad plants, culinary herbs, spices, honey, and pollen. Specific practices for beekeeping not covered under the measures for weed control mentioned in the current CoP. New approaches to weed control in primary production and recommendations for food and feed establishments on good manufacturing/hygiene practices.

The title of the CoP will be revised as *Code of practice to prevent and reduce pyrrolizidine alkaloids contamination in food and feed.*

2) Relevance and timeliness

PAs were assessed by the Joint Food and Agriculture Organization of the United Nations (FAO)/World Health Organization (WHO) Expert Committee on Food Additives (JECFA) at its eightieth meeting, which took place in Rome, Italy, from 16 to 25 June 2015. Details of the assessment can be found in WHO Food Additives Series: 71-S2, Safety evaluation of certain food additives and contaminants, Supplement 2: Pyrrolizidine alkaloids. Available at https://apps.who.int/iris/rest/bitstreams/1318952/retrieve. JECFA concluded that the presence of PAs in certain foods is of concern.

3) Main aspects to be covered

The revision will review the organization of the CoP to determine whether its structure should align with recently adopted CoPs. This revision will focus on expanding measures for weed control in primary production, including foods not covered in the existing CoP, and developing recommendations for bee products. It will also develop recommendations for food and feed processors, including primary production, good manufacturing, and hygiene practices. The EWG revision will also consider whether annexes are needed or if the material can be covered in one document.

4) Assessment against the criteria for the establishment of work priorities

(a) **Consumer protection from the point of view of health and fraudulent practices**. To protect consumer health, exposure to PAs should be prevented or reduced. An update of the existing CoP providing recommendations to governments and feed and food business operators will help to prevent contaminated food from entering the market.

(b) **Diversification of national legislations and apparent resultant or potential impediments to international trade.** An update of the existing CoP is needed to ensure that the most recent information on recommended practices for preventing and reducing PAs contamination is available to all member countries. It will also provide exporters with the means to ensure reduced levels of PAs and to assist in compliance with any maximum levels (MLs) that may be established in the future.

(c) **Scope of work and establishment of priorities between the various sections of the work.** The update of the existing CoP will address all relevant measures for preventing or reducing PAs contamination at the different steps in the food and feed chain: production, harvest, storage, processing, and distribution.

(d) **Work already undertaken by other international organizations in this field.** Codes of practice and/or guidelines and recommendations to reduce the presence of PAs have been developed by sector organisations for specific foods (such as tea and herbal infusions, food supplements, and herbs).

5) Relevance to Codex Strategic Goals

(a) **Goal 1: Address current, emerging, and critical issues in a timely manner.** Updating the CoP for the prevention or reduction of PAs in food and feed will address the current need for guidance to ensure consumers' health.

(b) **Goal 2: Develop standards based on science and Codex risk-analysis principles.** This work will apply risk analysis principles in updating the CoP by using scientific data and recommendations from FAO/WHO and other recognized expert bodies to support a reduction in consumers' exposure to PAs.

(c) **Goal 3: Increase impact through the recognition and use of Codex standards.** The proposed update of the CoP ensures that information on recommended practices to prevent and reduce the presence of PAs consists of current best practices and will be available to all member countries, especially those with fewer resources to devote to this topic.

(d) **Goal 4: Facilitate the participation of all Codex Members throughout the standard-setting process.** The update of the CoP will inform all Codex Members and Observers through the Codex Step process.

(e) **Goal 5: Enhance work management systems and practices that support the efficient and effective achievement of all strategic plan goals.** An update of the CoP will help ensure the development and implementation of effective and efficient work management systems and practices by providing basic guidance for countries and producers to keep foods and feeds highly contaminated with PAs out of the marketplace.

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

This proposal concerns an update of the existing *Code of practice for weed control to prevent and reduce pyrrolizidine alkaloid contamination in food and feed* (CXC 74-2014).

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

JECFA assessed PAs at its 80th meeting, which took place in Rome, Italy, from 16 to 25 June 2015.

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

There is no identified need for additional technical input from external bodies.

9) Timeline for completion of the new work

Work will commence following the recommendation by the Codex Committee on Contaminants in Foods and approval by the Codex Alimentarius Commission in 2025. Completion of work is expected by 2028.

PART II: GUIDANCE ON SAMPLING AND ANALYSIS PERFORMANCE CHARACTERISTICS FOR THE COLLECTION OF DATA TO BE SUBMITTED TO THE GEMS/FOOD DATABASE FOR PYRROLIZIDINE ALKALOIDS IN FOODS

(For reference for future calls for data)

OBJECTIVE

1. The purpose of this guidance is to establish sampling and analytical method performance criteria used to collect data on pyrrolizidine alkaloids (PAs) in food, intended for submission to the GEMS/Food database.

PAs WHOSE DATA WILL BE COLLECTED

2. The primary focus of data collection should be 1,2-unsaturated PAs (the term "1,2-unsaturated PAs" refers to all 1,2-unsaturated PAs and their associated N-oxides) in foods, as most studies on the toxicity and occurrence of PAs in foods have focused on 1,2-unsaturated PAs. Data on other PAs can be submitted as well.

3. It is recommended that all 21 of the 1,2-unsaturated PAs in Table 1 be analysed in foods and the corresponding data be submitted. If suitable analytical methods are available, it is also recommended to analyse the additional 14 PAs in Table 2, as these are PAs known to co-elute with one or more of the 21 PAs in Table 1.

Table 1. Most frequently detected 1,2-unsaturated PAs in food.

1,2-unsaturated PAs	CAS Number	1,2-unsaturated PAs-N-oxide	CAS Number
Intermedine	10285-06-0	Intermedine-N-oxide	95462-14-9
Lycopsamine	10285-07-1	Lycopsamine-N-oxide	95462-15-0
Senecionine	130-01-8	Senecionine-N-oxide	13268-67-2
Senecivernine	72755-25-0	Senecivernine-N-oxide	101687-28-9
Seneciphylline	480-81-9	Seneciphylline-N-oxide	38710-26-8
Retrorsine	480-54-6	Retrorsine-N-oxide	15503-86-3
Echimidine	520-68-3	Echimidine-N-oxide	41093-89-4
Lasiocarpine	303-34-4	Lasiocarpine-N-oxide	127-30-0
Senkirkine	2318-18-5		
Europine	570-19-4	Europine-N-oxide	65582-53-8
Heliotrine	303-33-3	Heliotrine-N-oxide	6209-65-0

Table 2. PAs to co-elute with PAs given in Table 1

1,2-unsaturated PAs	CAS Number	Co-elution
- Indicine - Echinatine - Rinderine	480-82-0 480-83-1 6029-84-1	Possible co-elution with lycopsamine/intermedine
- Indicine-N-oxide - Echinatine-N-oxide - Rinderine-N-oxide	41708-76-3 20267-93-0 137821-16-0	Possible co-elution with lycopsamine-N-oxide/intermedine-N-oxide
- Integerrimine	480-79-5	Possible co-elution with senecivernine/senecionine
- Integerrimine-N-oxide	85955-28-8	Possible co-elution with senecivernine-N-oxide/ senecionine-N-oxide
- Heliosupine	32728-78-2	Possible co-elution with echimidine
- Heliosupine-N-oxide	31701-88-9	Possible co-elution with echimidine-N-oxide
- Spartioidine	520-59-2	Possible co-elution with seneciphylline
- Spartioidine-N-oxide	121123-61-3	Possible co-elution with seneciphylline-N-oxide
- Usaramine	15503-87-4	Possible co-elution with retrorsine
- Usaramine N-oxide	117020-54-9	Possible co-elution with retrorsine N-oxide

4. Ideally, data should be collected for individual PAs and not as the sum of the PAs given in Table 1 and Table 2. Results below the limit of quantification (LOQ) should be recorded as non-detect.

5. It is important to note that Table 1 and Table 2 are not exhaustive. Data for additional 1,2-unsaturated PAs beyond those listed in Table 1 and Table 2, and additional PAs may also be submitted.

FOODS FOR WHICH TO COLLECT DATA

6. Considering occurrence data and regional representation presented in the Joint FAO/WHO Expert Committee on Food Additives (JECFA) 2020 evaluation and other sources[1], it may be recommended to collect data on the food categories in Table 3.

Table 3. Food category and examples of foods of concern for contamination

Food category[a]	**Examples**[b] **of foods of concern for contamination**
Cereals and cereal products	Grain flour[c], bread[c]
Teas (tea and other herbal teas)	Black tea, green tea, chamomile, rooibos, raspberry leaves, blackberry leaves, nettle, marshmallow, lemon verbena, sage
Culinary herbs	Lovage, oregano, marjoram, parsley, thyme, savory, borage mint, lemon balm, anise, basil, curry, chive, peppermint, fennel
Salad plants	Rocket
Spices	Cumin, anise seed
Food supplements	Herbal supplements, pollen-based supplements
Bee products	Honey, pollen, royal jelly
Foods of animal origin	Eggs[d], milk[d], meat[d]

a) There is a lack of regional data for all food categories.
b) Foods were selected based on the frequency or levels of PAs reported in the literature. The available occurrence data indicate that teas, herbal and pollen-based food supplements, salad plants, culinary herbs, spices, honey, and pollen are representative foods in terms of the frequency and level of detection of PAs.
c) There is a lack of data, and the frequency of PA detection is low.
d) In the JECFA 2020 safety evaluation, it is recommended to provide occurrence data, especially in foods of animal origin. The data show that the frequency and level of PA detection are low.

SAMPLING AND SAMPLE PREPARATION

7. Sampling for PA analysis should follow the *General guidelines on sampling* (CXG 50-2004) developed by the Codex Committee on Methods of Analysis and Sampling (CCMAS). Contamination due to the presence of PA-producing plants in foods, such as culinary herbs, salad plants, spices, teas, and pollen, occurs sporadically and is therefore non-homogeneous. Therefore, proper sampling is critical.

8. To ensure representative sampling, the number or quantity of incremental samples should be adjusted based on lot size and variability. For large lots that can be physically separated, dividing them into smaller, homogeneous sub-lots is recommended to enhance sample representativeness.

9. As the distribution of PAs is extremely non-homogeneous, excluding liquid samples, samples should be prepared—and especially homogenized—with extreme care. The whole aggregate sample or portions of it should be used for homogenization/grinding to ensure representativeness.

10. Aggregate samples of liquid foods and solid foods with small particle size (particles smaller than 0.85 mm[2]) are homogenized by thorough mixing. To ensure homogenization, mixing of honey should occur at appropriately high enough temperatures that crystallization does not occur (≥ 20°C) but low enough that degradation does not occur (≤ 45°C).

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1 Patrick P. et al. 2018. Occurrence of pyrrolizidine alkaloids in animal- and plant-derived food: result of a survey across Europe. https://doi.org/10.1080/19440049.2017.138272
Florian K. et al. 2020. Occurrence and Risk Assessment of Pyrrolizidine Alkaloids in Spices and Culinary Herbs from Various Geographical Origins. https://doi.org/10.3390/toxins12030155
Picron J,F. et al. 2018. Analytical strategies for the determination of pyrrolizidine alkaloids in plant-based food and examination of the transfer rate during the infusion process. https://www.sciencedirect.com/science/article/abs/pii/S0308814618310288?via%3Dihub

2 *General standard for contaminants and toxins in food and feed* (CXS 193-1995)

ANALYSIS OF PERFORMANCE CHARACTERISTICS

11. Data should be obtained using quantitative analysis methods validated in accordance with the principles for the establishment of analysis methods in the Procedural Manual of the Codex Alimentarius Commission. Analytical methods recommended are those that meet the specific criteria[1] in Table 4.

Table 4. Specific criteria for individual 1,2-unsaturated PAs

Commodity	LOQ	Precision (% RSD)	Recovery (%)
Solid foods and honey	≤ 10 µg/kg	≤ 44	60 - 115
Liquid foods, excluding honey	≤ 0.15 µg/L	≤ 44	40 - 120

APPENDIX VII

PROPOSAL FOR NEW WORK ON THE REVISION OF THE *CODE OF PRACTICE FOR THE REDUCTION OF AFLATOXIN B1 IN RAW MATERIALS AND SUPPLEMENTAL FEEDINGSTUFFS FOR MILK-PRODUCING ANIMALS* (CXC 45-1997)

PROJECT DOCUMENT

(For approval)

1) Purpose and scope

The purpose of the proposed new work is to provide competent authorities, producers, marketers, processors and farmers with updated guidance to prevent and reduce aflatoxin contamination in animal feeds intended for milk-producing animals.

The scope of the new work will focus on reviewing and updating the *Code of practice for the reduction of aflatoxin B1 in raw materials and supplemental feedingstuffs for milk-producing animals* (CXC 45-1997).

2) Relevance and timeline

Aflatoxin M1 can be found in milk as a result of aflatoxin B1 contamination in animal feed. The *Code of practice for the reduction of aflatoxin B1 in raw materials and supplemental feedingstuffs for milk-producing animals* (CXC 45-1997) has not been revised or amended since it was first elaborated in 1997. New information has become available since 1997 on aflatoxin management in the feedingstuffs of milk-producing animals. Updates will broaden the scope of the document to recognize its application to milk from animals in addition to bovine species. It is important to update this CoP as milk and milk products continue to be staple foods worldwide, and milk is used as a main ingredient of dairy-based infant formula. Aflatoxin M1 is increasingly being detected in milk in Africa, and the growing climate variability is a contributing factor to increased aflatoxins in crops. Small-scale farmers who often rely on home-mixed or unregulated feeds are particularly vulnerable to aflatoxin contamination. Furthermore, JECFA concluded at its 56th meeting in 2002 that aflatoxin M1 is a genotoxic carcinogen.

3) Main aspects to be covered

This work will address measures to prevent or reduce aflatoxin B1 contamination in animal feed and feed ingredients to mitigate aflatoxin M1 contamination of milk. All revisions will be supported by scientific data that have become available since CXC45 was elaborated in 1997.

Updates will expand upon or add new information about aflatoxin management approaches in feed and feed ingredients. It will also include current information on the use of preservatives, mycotoxin detoxifying agents, and other emerging physical, biological, and chemical control strategies for aflatoxins in feed. Conditions that are required for aflatoxin B1 formation will be explained to help ensure that control and mitigation measures are understood in the context of different geographic regions, feedstuffs, etc., in order to be adequately applied.

As well, updates to CXC45 will consider how information in the Codex CoPs on aflatoxin prevention and control in cereals and, to a lesser extent, nuts, can be leveraged to limit redundancies between Codex texts, if possible (refer to Section 6 for more information).

4) Assessment against the criteria for the establishment of work priorities

General criterion

a) **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**. Milk and milk products are staple foods in many countries worldwide, including developing countries. The updated CoP will provide additional guidance for member countries and the feed industry to reduce or prevent aflatoxin contamination in feed intended for milk-producing animals, thus minimizing dietary exposure to aflatoxin M1.

   A revised CoP will facilitate fair trade by making updated information on recommended practices to reduce aflatoxin contamination in the feedingstuffs of milk-producing animals available to all member countries and the feed industry. This, in turn, will support efforts to meet the Codex maximum level (ML) for aflatoxin M1 in milks which will also facilitate trade.

Specific criteria

a) **Diversification of national legislations and apparent resultant or potential impediments to international trade.** The CoP would provide internationally available and recognized scientific and technical guidance that will assist in ensuring compliance with Codex and national MLs for aflatoxin M1 in milk.

b) Work already undertaken by other organisations in this field. The Joint FAO/WHO Expert Committee on Food Additives (JECFA) completed a risk assessment for aflatoxin M1 in 2002 at its 56th meeting.

5) Relevance of the Codex strategic goals

a) Goal 1: Address current, emerging, and critical issues in a timely manner. Updating the CoP on the reduction of aflatoxin contamination in feeds intended for milk-producing animals will address the need for up-to-date guidance that will help ensure the health of consumers, particularly for globally relevant staple foods such as milk and milk products.

b) Goal 2: Develop standards based on science and Codex risk-analysis principles. This work will involve reviewing peer-reviewed scientific data and information that supports reducing aflatoxins in animal feed. Recommended strategies will help reduce consumer exposure to and risks posed by aflatoxin M1 in milk to meet the Codex ML for aflatoxin M1 in milks, which was supported by JECFA56's 2002 assessment of aflatoxin M1.

c) Goal 3: Increase impact through the recognition and use of Codex standards. The proposed CoP will present a variety of recommended and scientifically proven strategies to control aflatoxin contamination in the feed of milk-producing animals that are based on current best practices and are globally available. The warm climate of many geographic regions worldwide and high humidity during storage lends itself to aflatoxin formation in feedingstuffs, making the updates to this CoP relevant to many member countries.

d) Goal 4: Facilitate the participation of all Codex Members throughout the standard-setting process. Updates to the CoP would be conducted by an electronic working group in which all member countries will be invited to participate in. Updating an existing CoP through the Codex Step procedure will make the information on the best practices included in the CoP available to all members at each step of the process. The warm climates of many regions worldwide lend itself to aflatoxin formation in feedingstuffs. As such, this work will benefit from the participation and expertise of both developed and developing countries.

e) Goal 5: Enhance work management systems and practices that support the efficient and effective achievement of all strategic plan goals. An updated CoP will support the development and implementation of effective and efficient work management systems and practices by providing basic guidance for member countries and feed producers to reduce aflatoxin contamination in the feeds for milk-producing animals.

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

The Codex ML for aflatoxin M1 in milks was adopted in 2001. Revisions to CXC45 will support the achievement of the Codex ML for aflatoxin M1 in milks.

In 2003, the Codex Alimentarius Commission (CAC) approved the adoption of the *Code of practice for the prevention and reduction of mycotoxin contamination in cereals* (CXC 51-2003; amended 2014, 2017; revised 2016); this CoP includes aflatoxins and clearly indicates that it applies to mycotoxin prevention and reduction measures for cereal grains intended for both human and animal consumption. When first elaborated, CXC51 largely mirrored CXC45, although CXC51 has since been amended (2014, 2017) and revised (2016).

There are also Codex CoPs for aflatoxins in nuts, which could be used as feed:

- *Code of practice for the prevention and reduction of aflatoxin contamination in tree nuts* (CXC 59-2005)
- *Code of practice for the prevention and reduction of aflatoxin contamination in peanuts* (CXC 55-2004)

Any future updates to CXC45 will consider if and how the other Codex CoPs for aflatoxins in other agricultural commodities could be leveraged, to reduce redundancy between Codex texts, when possible.

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

JECFA56 completed a risk assessment for aflatoxin M1 in 2002. Additional expert scientific advice is not required.

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

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

9) Proposed timeline for completion of the work

Subject to approval by CAC, work would commence in 2025, and proposed revisions to CXC45 would be presented to the Codex Committee on Contaminants in Foods in 2026. The revised CoP is expected to be finalized for adoption by 2027.

APPENDIX VIII

PROPOSAL FOR NEW WORK ON THE DEVELOPMENT OF A CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF TROPANE ALKALOIDS CONTAMINATION IN FOOD AND FEED

PROJECT DOCUMENT

(For approval)

1) Purpose and scope of the project

The purpose of the proposed new work is to develop a code of practice (CoP) to prevent and reduce tropane alkaloids contamination in food and feed. The scope of the work is to complete a CoP to prevent and reduce tropane alkaloids (TAs) contamination in food (e.g. cereal grains, dried legumes, herbs and spices, herbal teas, baby foods and leafy green vegetables such as spinach) and feed, particularly derived from *Datura*, for various stakeholders including farmers, food and feed manufacturers, competent authorities, and consumers.

2) Relevance and timeliness

Food aid contaminated with TAs was determined to cause food poisoning outbreaks in the Republic of Uganda and the Republic of South Sudan in 2019. These events affected more than 300 people and even resulted in deaths. The *Joint FAO/WHO expert meeting on tropane alkaloids* [1] (FAO/WHO, 2020) provided expert scientific advice on TAs in processed and unprocessed food products. To develop appropriate risk management measures in the United Nations World Food Programme (WFP) supply chains, it was recognized that limits expressed as physical toxic *Datura stramonium* seed contamination of cereals and grains will be beneficial for screening purposes at the field level. An *FAO/WHO guidance document on physical Datura stramonium seed contamination*[2] was developed and published in 2020 to address this. Since then, global reports of TA contamination and poisoning in plant-based foods have continued to emerge (e.g. Reports of tropane alkaloid poisonings and analytical techniques for their determination in food crops and products from 2013 to 2023[3]).

The 17th Session of the Codex Committee on Contaminants in Foods (CCCF17, 2024) agreed to follow up on the findings of these documents and consider the development of a code of practice and project document for consideration by CCCF18.

3) Main aspects to be covered

This work will address measures for preventing TA contamination in food and feed, including pre-harvest agricultural mitigation strategies related to *Datura* weeds control. It will also address post-harvest measures such as sorting grains and seeds to remove *Datura* seeds, sorting *Datura* plants from leafy green vegetables, and extra precautions for processed food (including cereal-based food for infants and young children). Furthermore, since foodborne illnesses caused by TA can also occur at the household level, the CoP would also include some consumer practices.

4) Assessment against the criteria for the establishment of work priorities

(a) Consumer protection from the point of view of health and fraudulent practices. To protect consumer health, exposure to TAs should be prevented or reduced. A CoP providing recommendations to farmers, food and feed manufacturers, competent authorities, and consumers will help prevent contaminated food and feed from entering the market.

(b) Diversification of national legislation and apparent resultant or potential impediments to international trade. The development of a CoP is needed to ensure that information on recommended practices for preventing and reducing TA exposure is available to all member countries. It will also provide the means to enable exporters to minimize the risk of TAs and assist in compliance with any MLs that may be established in the future.

(c) Scope of work and establishment of priorities between the various sections of the work. The CoP will address all relevant measures for preventing or reducing TAs at the different steps in the food and feed chain.

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1 https://cdn.who.int/media/docs/default-source/food-safety/jecfa/summary-and-conclusions/tropane-alkaloids-expert-meeting_30-march-3-april-2020_executive-summary.pdf?sfvrsn=f6c51fc1_5
https://openknowledge.fao.org/server/api/core/bitstreams/6f846395-4481-46ca-850d-8953ae8ccb38/content

2 https://openknowledge.fao.org/server/api/core/bitstreams/cdcafea7-63dd-4c7c-a767-34b168a3904c/content

3 Gravador, R. S., Haughey, S., Meneely, J., Greer, B., Nugent, A., Daniel, C. S., & Elliott, C. (2024). Reports of tropane alkaloid poisonings and analytical techniques for their determination in food crops and products from 2013 to 2023. Comprehensive Reviews in Food Science and Food Safety, 23, e70047. https://doi.org/10.1111/1541-4337.70047

(d) Work already undertaken by other international organizations in this field. Several bodies and organizations, such as Joint FAO/WHO Expert Committee on Food Additives (JECFA), Food and Agriculture Organization (FAO), World Health Organization (WHO), and World Food Programme (WFP), have undertaken work on TAs and can be consulted in developing a CoP. These organizations have made recommendations but have not offered a CoP.

5) Relevance to Codex Strategic Goals

(a) Goal 1: Address current, emerging, and critical issues in a timely manner. Establishing a CoP to prevent or reduce TAs in food and feed will address the current need for guidance to ensure consumers' health.

(b) Goal 2: Develop standards based on science and Codex risk-analysis principles. This work will apply risk analysis principles in developing a CoP, using scientific data and recommendations from FAO/WHO and other recognized expert bodies to support a reduction in consumers' and animals' exposure to TAs (to control levels in feed).

(c) Goal 3: Increase impact through the recognition and use of Codex standards. The proposed CoP ensures that information on recommended practices to avoid and prevent TAs consists of current best practices and is available to all member countries, especially those with fewer resources to devote to this topic.

(d) Goal 4: Facilitate the participation of all Codex Members throughout the standard-setting process. Developing a CoP through the Codex Step process will inform all Codex members and observers about recommended practices to prevent and reduce TAs.

(e) Goal 5: Enhance work management systems and practices that support the efficient and effective achievement of all strategic plan goals. A CoP will help develop and implement effective and efficient work management systems and practices by providing basic guidance for countries and producers to keep highly TA-contaminated food out of the marketplace.

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

Standard for certain pulses (CXS 171-1989), *Standard for sorghum grains* (CXS 172-1989), *Standard for maize* (corn) (CXS 153-1985), *Standard for wheat and durum wheat* (CXS 199-1995) and *Standard for oats* (CXS 201-1995) include a provision that the products "shall be free from the following toxic or noxious seeds in amounts which may represent a hazard to human health", including *Datura* species. The weed control measures in the *Code of practice for weed control to prevent and reduce pyrrolizidine alkaloid contamination in food and* feed (CXC 74-2014) are also relevant.

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

The Joint FAO/WHO Expert Meeting (FAO/WHO, 2020) and other risk assessment bodies, such as the European Food Safety Authority (EFSA) (EFSA CONTAM Panel, 2008, 2013, 2016, 2018, and 2022), have already provided expert scientific advice.

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

There is no identified need for additional technical input from external bodies.

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

Work will commence in 2025 following CCCF18's recommendation and approval by the 48th Session of the Codex Alimentarius Commission in 2025. Completion is expected by 2028.

APPENDIX IX

GUIDANCE ON DATA ANALYSIS FOR THE DEVELOPMENT OF MAXIMUM LEVELS AND FOR IMPROVED DATA COLLECTION

Blue text in single brackets indicates edits based on changes that could be implemented in a first phase.
Purple text in double brackets indicates edits that could potentially be made at a later stage.

(For publication as an information document on the Codex webpage)

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ANNEXES[1]

[1] To be developed.

PREAMBLE

1. The steps in the development of a maximum level (ML) can include:

   - Identification of a new health or trade issue relevant to a contaminant – commodity/food combination
   - Development of a discussion paper that explores preliminary occurrence data, exposure data, and global significance of the contaminant-commodity/food combination.
   - Agreement by the Codex Committee on Contaminants in Foods (CCCF) to begin a new work, including discussion of Terms of Reference (ToR) of a working group, and submission of a proposal for new work to the CAC
   - Development of a document recommending MLs in the Codex step procedure and a more in-depth analysis of occurrence data, exposure data, global significance of the contaminant-commodity/food combination, and impact of proposed MLs.
   - Recommendation to send MLs to the Codex Alimentarius Commission (CAC) for adoption.

2. The primary data source for CCCF is GEMS/Food, an international database run by the World Health Organization, containing data on contaminant levels in different foods. Member countries are encouraged to submit data from their national monitoring programs either on a routine basis or in response to calls for data from CCCF; the data must meet certain criteria for submission (such as including a limit of quantification (LOQ) or limit of detection (LOD) for non-quantified data). External data, such as data from scientific literature, may be referenced, but are typically not used in setting MLs.

3. Prior to starting work on a discussion paper or ML document, CCCF shall establish ToR for the working group and may request the Codex Secretariat to issue a Call for Data. As outlined in the CAC Procedural Manual, 30th Ed., the ToR shall clearly state the objective(s) to be achieved by the establishment of the working group, the language(s) to be used, and the time frame by which the work is expected to be completed. The Call for Data typically identifies the contaminant and food/commodities of interest and the date range of requested data. Previous Calls for Data have also asked for information such as the LOQ and LOD of the analytical method and specific sample names; they have also identified fields in the GEMS/Food database where information should be entered and identified the appropriate basis of results.

4. Establishing ToR and planning the scope of a Call for Data is an important step in the data collection process. Careful attention to the ToR and Call for Data will result in better quality data for use in establishing MLs.

5. The management of data plays a key role in the work of elaborating MLs, and it is of common interest to have data of good quality (such as data that reflect an accurate picture of the contamination of food presented with statistical analysis). Occurrence data should ideally be obtained through statistically based sampling (ref. *General Guidelines on Sampling* (CXG 50-2004)), and analysis should be conducted using validated methods with appropriate LOQ and LOD in laboratories that have quality assurance systems. Ideally, data submitted by member countries should be nationally representative.

6. The aim of this guidance document is to provide the elements for ensuring good quality data and to ensure a harmonised use and analysis of the available occurrence data by different electronic working groups (EWGs) for the development/ elaboration of Codex MLs.

7. This guidance is for internal use in CCCF, but national/regional authorities may use the relevant information contained in this guidance document for the development/elaboration of national/regional MLs.

DATA COLLECTION AND SUBMISSION

8. The introductory page for the WHO GEMS/Food database is Global Environment Monitoring System (GEMS) / Food Contamination Monitoring and Assessment Programme. The data submission (upload) and data extraction (download) process begins at the website, GEMS/Food Contaminants Database.

9. The database page opens to a Welcome page with two tabs, a Home Page tab and a Search tab. For full functionality, members must register and log in to their accounts. After logging in, the data submitter will have access to an Upload tab, in addition to the Home Page tab and Search tab. The submitter will also be able to access regular and bulk templates for uploading data, the GEMS/Food e-learning tool, and useful links such as Frequently Asked Questions.

10. Prior to submitting data, submitters should review materials on the GEMS/Food internet site (Nutrition and Food Safety (who.int)) or linked GEMS/Food pages. Detailed instructions are found in the document, INSTRUCTIONS FOR ELECTRONIC SUBMISSION OF DATA ON CHEMICALS IN FOOD AND THE DIET (hereafter referred to as INSTRUCTIONS) on the GEMS/Food internet site. This document provides instructions on registering an account, logging into the GEMS/Food database, inserting data into the Excel template, and uploading the Excel template. Familiarity with Excel is very helpful.

11. Data can be submitted to the GEMS/Food database on any food at any time, not just in response to a Call for Data specifying specific foods or time periods of interest. If data are submitted in response to a specific Call for Data, consider noting this information in the Remarks field. Data that falls outside the date frame referenced in a Call for Data can also be submitted. These data may be informative for the study of contaminant levels over time.

12. If questions arise about technical aspects of data submissions, the submitter should contact the GEMS/Food database administrator. Questions could include error messages on upload, registration problems, how to name samples, what fields are mandatory, the definition of fields, problems with mapping, etc.

13. If questions arise about whether data align with a specific Call for Data, the submitter should consult the EWG Chair and, if needed, the Codex or JECFA Secretariats. Questions could include whether the samples correspond to the definitions provided in the Call for Data or the ToR of the EWG.

14. Data submitters should develop and retain metadata associated with data submissions. The metadata will help answer questions that might arise from the EWG. Metadata could include the year of production, the overall LOD and LOQ range associated with a dataset, information on product labels, information on the location of collection (e.g. import or retail), names of staff who submitted the data, and when the data were submitted, the batch ID associated with the submitted dataset, etc.

15. Data quality should be assessed by the submitter before data are uploaded to GEMS/Food. If serious questions arise about data quality (missing information, suspect analyses), do not submit the data until these questions can be addressed.

16. If the submitter identifies a problem with a dataset after submission, consult with the GEMS/Food database administrator on withdrawing or correcting the dataset, which should be identifiable by batch ID.

Filling out the GEMS/Food template

17. The template worksheet for regular (non-bulk) submissions[2] contains five tabs, which include (1) a checklist for submitting institutions, (2) Food Mapping of the sample, (3) a template for Individual Analysis results, (4) the WHO and FoodEx2 classification system, and (5) chemicals currently listed as options for submission in a drop-down menu.

18. The first step when submitting data is to fill out Tab "1. Start", which contains a checklist for the Institution preparing a dataset for submission, including identification of the chemical of interest. (Note that an option is outlined in the INSTRUCTIONS for chemicals that are not available in the drop-down menu.)

19. The second step is to review the food/feed/product names in the dataset and map the national food classification with the WHO and FoodEx2 classification. Tab "2. Food Mapping" contains the mapping tool: the Local Food Identifier (column A, free text) and two levels of classification in drop-down menus, i.e., Level 1: WHO Food Group (Column B) and Level 2: WHO Food Identifier (Column C). After the Local Food Identifier, WHO Food Group, and WHO Food Identifier fields are filled in, the WHO Food Code, FoodEx2 code, and the FoodEx2 name are generated automatically in columns E, F, and G of Tab 2.

20. One source of confusion in data submissions is how often each food needs to be mapped on the food mapping template. For example, if the submitter is uploading three foods with the following "Local Food Identifiers" -- Ginger, crystallized; Ginger powder, dried; and Ginger slices, dried -- all three would be entered separately on the food mapping template, Tab 2, and mapped to WHO "Herbs, spices, and condiments" (Column B) and "Ginger, root" (Column C). However, if the submitter is uploading 100 additional data points for "Ginger, crystallized," the mapping only needs to be done once for all the "Ginger, crystallized" samples.

[2] See INSTRUCTIONS FOR ELECTRONIC SUBMISSION OF DATA ON CHEMICALS IN FOOD AND THE DIET for discussion of bulk template submissions.

21. The INSTRUCTIONS also state that mapping should be done only once if the national classification is stable. While some countries or regions may have centralized data submission, in other countries, different institutions or parts of institutions may have accounts and submit data separately. If this is the case, institutions should attempt to coordinate how they are mapping food in order to have consistency across submissions.

22. The third step in filling out the GEMS/Food template is to enter Individual Analysis results in Tab "3. Individual Analysis Results." Fields include the Local Food Identifier (previously mapped to codes in Tab 2), chemical concentration, units of measurement, LOD, LOQ, etc. Because the Local Food Identifiers have been mapped in Tab 2, columns B, C, and D on Tab 3 will be filled automatically with the information from the mapping exercise. Column A will automatically indicate an error if any of the fields on this Tab are incorrectly filled out. The remaining columns should be filled following the detailed instructions in INSTRUCTIONS.

23. Note that columns with blue headings in the GEMS/Food template are mandatory. Columns with white headings are optional (can be left blank) if the information is not available.

24. The current fields for Individual Analysis Results in the GEMS/Food database are listed in Guidance Table 1. Bracketed text (whether single or double brackets) indicates changes that have been agreed on, but not yet implemented. Blue text in single brackets indicates edits based on changes that could be implemented in a first phase (timing to be made available at CCCF18). Purple text in double brackets indicates edits that could potentially be made at a later stage.

25. Paragraphs 26 to 52, below Guidance Table 1, provide additional guidance on fields to data submitters.

Guidance Table 1: Current fields in GEMS/Food template

Column	Field	Field type /Drop-down menu	Mandatory or Optional	Flag language (proposed new or revised)
E	Local Food Identifier	Free text	Mandatory	[Provide a *brief but descriptive* name of the food, such as "Orange roughy" (versus "Fish") or "Polished/white rice" (versus "rice.")]
F	Serial no of the Record	Free text	Mandatory	[One serial number is used for each sample. Data on different contaminants in the same sample should have the same serial number. National institutions should coordinate serial number selection to ensure numbers are informative and non-duplicative.]
G	[Submitting] Country/Region/Observer	Drop-down menu • (List of countries, regions, observers) • Unspecified	[Mandatory]	[Identifies country, region, or observer (region unspecified) submitting the data; this is not the country of production. If the observer is not listed in the dropdown menu, choose Unspecified and note the name of the Observer in the Remarks.]
H	Contaminant	Drop-down menu • (List of contaminants)	Optional	[Please select a contaminant from the list. A contaminant is required, but manual entry in "Column H: Contaminant" is optional if a contaminant has been added on Worksheet 1: Start. If "multiple" is selected in Worksheet 1: Start, manual entry of contaminants in Field H is required.]
I	Food Origin	Drop-down menu • Domestic • Imported • Mixed origin • Unknown	Optional	
J	Sampling Date	Free text (YYYY)	Mandatory	
K	Sample representative-ness ~~[/reliability]~~	Drop-down menu • Random [(routine)] sampling • Targeted sampling • Unknown	Mandatory	[Targeted sampling refers to the targeted follow-up of specific findings of contamination. Random (routine) sampling refers to sampling that is not targeted and can include routine surveillance or sampling specific food types or importing countries.]
L	Laboratory Identification	Free text	Optional	[Laboratory that completed the analysis.]

Column	Field	Field type /Drop-down menu	Mandatory or Optional	Flag language (proposed new or revised)
M	Analytical Quality Assurance	Drop-down menu • Internal quality assurance and reference standards only. • Successful participation in relevant proficiency tests / [interlaboratory comparisons] during the sampling and analysis period. • Official accreditation for the relevant methods during the sampling and analysis period. • Unknown quality assurance of the lab.	Optional	
N	Measurement units for Contaminant Levels	Drop-down menu [• mg/kg • µg/kg • ng/kg • pg/kg • Bq/kg]	Mandatory	[Check units carefully. Make sure units chosen from the dropdown menu align with the sample results.]
O	LOD	Free text	Mandatory for results not quantified [(i.e., non-detect)] if LOQ is not provided. ([[Optional]])	Enter a numeric value greater than 0 and less than LOQ. This field contains the limit of detection reported by the laboratory. [LOD ~~and~~ or LOQ are mandatory if the ~~Result is not provided~~ non-detect is entered in Results (T).]
P	LOQ	Free text	Mandatory for results not quantified if LOD is not provided. ([[Mandatory)]]	Enter a numeric value greater than 0 and LOD. This field contains the limit of quantification reported by [the] laboratory.[LOD and or LOQ are mandatory if ~~Result is not provided~~ non-detect is entered in Results (T).]

Column	Field	Field type /Drop-down menu	Mandatory or Optional	Flag language (proposed new or revised)
Q	Results based on	Drop-down menu • Fat content • Dry weight • As is (raw, fresh [, as sold]) • As consumed	Mandatory	
R	Portion analyzed	Drop-down menu • Edible only • [Whole food (edible + inedible)]	Mandatory	[Example: shelled nut (edible) versus unshelled nut (whole food)]
S	State of food analyzed ([Cooked/Raw])	Drop-down menu • Cooked • Raw • Unknown	Optional	[Example: raw fish versus cooked fish]
T	Results	Free text	Mandatory	[Entering a result is mandatory: either a zero, non-detect, or a numeric result. Zero or non-detect can be entered only if LOQ or LOD are provided.]
U	Individual vs Aggregated data	Drop-down menu • Individual • Aggregated	[[Mandatory]]	
V	Confidentiality of Data	Drop-down menu • Yes • Blank	Optional	[All data for which "blank" is chosen or no option is selected will be considered as non-confidential in data handling and analysis.]
W	Remarks/References	Free text	Optional	
X	[[Year of production/harvest]]	[[Free text (YYYY)]]	[[Optional]]	
Y	[[Compositional information]]	[[Free text]]	[[Optional]]	[[Information from labels or as determined analytically such as major ingredients, fat content, water content, or percent total cocoa solids.]]
Z-1	[[Country/Region of Production of Finished Product]]	[[Menu • Unknown • Countries/Regions (A-Z)]]	[[Optional]]	

Column	Field	Field type /Drop-down menu	Mandatory or Optional	Flag language (proposed new or revised)
Z-2	Country/Region of Origin of Raw Materials	[[Menu • Unknown • Countries/Regions (A-Z)]]	[[Optional]]	
AA	[[Product type]]	[[Menu: • Destined for further processing • Ready to eat • Not applicable • Unknown]]	[[Optional]]	[[“Destined for further processing” and “ready to eat” are defined for certain contaminants and commodities in the *Codex General Standard for Contaminants and Toxins in Food and Feed*, CXS-193. See paragraph 48 below.]]
BB	[[Sampling location in production chain]]	[[Menu: • Unknown • Production site • Bulk lot transport • Border (import/export) • Market/Retail • Other]]	[[Mandatory]]	[[Provides information on where the sample was obtained in the production chain.]]
CC	[[Principle of method of analysis]]	[[Menu • Method A • Method B • Method Z • Other • Unknown]]	[[Optional]]	

26. **E. Local food identifier**. Mandatory field. When possible, the data submitter should provide names in English. Adding details to the name can help the data analyst with sample classification (e.g., "pineapple-orange juice" versus "juice. On the other hand, an overly long sample name (e.g., listing all ingredients in a multi-ingredient food) can complicate the work of analysts. Supplemental name information can also be added to the Remarks column.

27. **F. Serial No.** Mandatory field. One serial number (sample ID) should be used for each sample. If information on multiple contaminants is submitted for one sample, the same serial number should be used. National institutions are responsible for coordinating the use of the same serial number for all submissions of analyte data for the same food sample. National institutions should coordinate serial number selection to ensure numbers are informative and non-duplicative. The numbering conventions should provide information that is traceable to the submitter/time of submission/monitoring program. Avoid numbering with uninformative serial numbers like 1, 2, 3, etc. If submissions are made in response to two different data calls, the submitter of the second dataset should ensure that the new data has not replaced the previous data, checking with the GEMS/Food database administrator as needed.

28. **G. [Submitting] Country/Region/Observer. [**Mandatory field. Identifies country, region, or observer (region unspecified) submitting the data; this is not the country of production. If the observer is not listed in the dropdown menu, choose Unspecified and note the name of the Observer in the Remarks.]

29. **H. Contaminant.** [Optional field. A contaminant can be added on "Worksheet 1: Start" or by manual entry in "Column H: Contaminant. A contaminant must be identified, but entering the contaminant name in Column H is optional if a contaminant has been added on Worksheet 1. However, if "multiple" is selected in Worksheet 1: Start, manual entry of contaminants in Field H is required.]]

30. **I. Food origin.** [Optional field. Identifies samples as domestic, imported, mixed origin, or unknown.]

31. **J. Sampling date.** [Mandatory field. Identifies the sampling date.]

32. **K. Sample representativeness.** [Mandatory field. The term "random (routine) sampling" refers to sampling that is not targeted and can include routine surveillance or sampling specific food types or specific importing countries. For example, testing a wide range of imported samples of a certain food category for the presence of a certain contaminant is "random." The term "targeted sampling" should be chosen for follow-up sampling after specific findings of contamination. For example, if a country identifies a sample from a particular manufacturer as having high levels of a contaminant, additional sampling of the same lot or lots produced at the same time by the same manufacturer would be "targeted."]

33. **L. [Laboratory Identification**. Optional field. Identifies the laboratory that completed the analysis.]

34. **M. [Analytical Quality Assurance**. Optional field. Provides analytical quality assurance information on analysing laboratory.]

35. **N. Measurement Units for Contaminant Levels**. [Mandatory field. Provides units for contaminant results. Check units carefully. Make sure units chosen from the dropdown menu align with the sample results. Ensure that the reporting unit is the same for results, LOD, and LOQ. Ideally, the data submitter should provide both the LOQ and LOD, even though these fields are currently only mandatory for non-quantified results.]

36. **O. LOD**. [LOD field contains the limit of detection reported by the laboratory. Enter a numeric value greater than 0 and less than LOQ. Note that LOD or LOQ are mandatory if non-detect is entered in Results (T).] [[Reporting LOD is optional but encouraged.]] (Comment: Fields O. LOD and P. LOQ to be switched so that the mandatory filed P. LOQ comes first).

37. **P. LOQ**. [LOQ field contains the limit of quantification reported by the laboratory. Enter a numeric value greater than 0 and the LOD. Note that LOD or LOQ are mandatory if non-detect is entered in Results (T).] [[LOQ is mandatory for samples submitted after XX/XX/XXXX. Prior to XX/XX/XXXX, LOQ was only mandatory for results not quantified if LOD was not provided.]] (Comment: Fields O. LOD and P. LOQ to be switched so that the mandatory filed P. LOQ comes first).

38. **Q. Results based on**. Mandatory field. Provides information on whether results are based on analysis "as is (raw, fresh, as sold)"; "as consumed"; or based on fat content or dry weight. Examples include (1) "fat content": results for lipid (fat)-soluble contaminants in animal meat tissue, based on fat content, (2) "dry weight": results for contaminants in animal tissue, when sample is dried in laboratory until moisture is removed before analysis, (3) "as is (raw, fresh, as sold)": dried vegetables and fruits sold at retail; also, results for powdered infant formula, unreconstituted with water and (4) "as consumed": results for diluted powdered infant formula.

39. **R. Portion analysed**. Mandatory field. Provides information on whether the whole food is analysed or only the edible portion (e.g. shelled nut (edible) versus unshelled nut (whole food)).

40. **S. State of food analysed**. [Optional field. Provides information on whether the food sample is cooked or raw (e.g. raw fish versus cooked fish).]

41. **T. Results.** [Entering a result is mandatory: either a zero, non-detect, or a numeric result. Zero or non-detect can be entered only if LOQ or LOD are provided.]

42. **U. Aggregated sample**. Optional [[Mandatory.]] Aggregated data refers to results based on pooled samples, such as samples from Total Diet Studies. Aggregated data are often excluded from violation rate analyses conducted to determine appropriate MLs, which are based on observing the distribution of the data and upper percentiles exceeding proposed MLs. However, aggregated data can be included in the GEMS/Food database, and limited data have been included in CCCF analyses in the past. The GEMS/Food database administrator or a statistician should be consulted before including aggregated data. If aggregated data are included in an ML analysis, this fact should be noted in the EWG paper.

43. **V. Confidential data**. [Optional field. Note that all data for which "blank" is chosen or no option is selected will be considered as non-confidential in data handling and analysis.] Countries can submit data as "Confidential" if they wish to limit access to use by FAO, WHO, and related technical bodies, such as Codex. The GEMS/Food database administrator can provide records marked "Confidential" to EWG Chairs; therefore, EWG Chairs should always consult with the GEMS/Food database administrator on data extraction before downloading data. If a country submitted data as "Confidential" in response to a Call for Data, the submitting country should also make the EWG Chair aware of this fact during the data extraction/analysis phase.

44. **W**. **Remarks/References**. [Optional field that can be used to add relevant information for which there is not a defined field. Examples of information that have been included in this column are information on product labels (such as ingredients or detailed product names) or detailed information on the method of analysis. Other information that may be entered in this column is a reference to a specific Call for Data.]

45. **[[X. Year of production/harvest.** Optional field**.** Provides information on year of production, e.g for food of animal origin, or year of harvest, e.g for food of plant origin, if information is available.**]]**

46. **[[Y. Compositional information**. Optional. Information **from labels** such as major ingredients, fat content, water content, or percent total cocoa solids for chocolate.]]

47. **[[Z. Country/Region of Origin/production**. Optional. Provides information on the Country or Region of Origin/Production of the [food or raw material or sampled lot or consignment]. If this information is not known, Unknown can be selected.]]

48. **[[AA. Product type**. Optional. Provides information on whether the sample is "Destined for Further Processing" or "Ready to Eat," or whether this information is "Not applicable" or "Unknown." "Destined for Further Processing (FFP)" and "Ready to Eat" are defined in several places in the Codex General Standard for Contaminants and Toxins in Food and Feed (CXS-193-1995). For aflatoxin in maize, sorghum, tree nuts, peanuts, and dried figs or deoxynivalenol in cereal grains, "destined for further processing" means intended to undergo an additional processing/treatment that has proven to reduce levels of aflatoxin or deoxynivalenol before being used as an ingredient in foodstuffs, otherwise processed or offered for human consumption. For aflatoxin in tree nuts and dried figs, "Ready to Eat" means not intended to undergo an additional processing/treatment that has proven to reduce levels of aflatoxins before being used as an ingredient in foodstuffs, otherwise processed or offered for human consumption. For the commodities mentioned above, "For Further Processing" and "Ready to Eat" or "Unknown" can be selected; for other commodities, "Not Applicable" should be selected.

49. CXS-193-1995 also refers in several places to "ready to eat" infant meals and liquid milk "for further processing." Field AA does not apply to these uses of "ready to eat" and "for further processing."]]

50. **[[BB. Sampling location in the production chain**. Mandatory. Provides information on where the sample was obtained in the production chain, i.e., Production site (e.g firm, food plant), Bulk lot transport, Border (e.g testing at import or export), Market/Retail, or Other. If this information is not known, Unknown can be selected. If Other is selected, information can be added to Remarks.]]

51. **[CC. Principle of the method of analysis**. Optional. The method of analysis, such as ICPMS or GC-MS, can be selected from a pull-down menu.]]

52. **Errors**. Prior to upload, the data submitter should review the file carefully for errors. During upload, the data file is scanned to identify problems before writing data into the database. The data submitter is responsible for correcting errors and re-submitting the template. Datasets can be rejected for a variety of reasons, some of which are listed below. The GEMS/Food database administrator can be contacted for assistance.

    a. Reported result < LOD, missing LOQ or LOD when result is non-detect [[-missing LOQ-]], reported LOD > LOQ

    b. Dates entered in the wrong format

    c. Mandatory fields incomplete

    d. Duplicate entries in the current worksheet or in the database

DATA EXTRACTION

53. The data extraction process begins at the database website: GEMS/Food Contaminants Database. As noted above, for full functionality, analysts must register and log in to their accounts. After logging in, analysts will see a Welcome page with two tabs, a Home Page tab, and a Search tab. The Home Page tab contains a limited number of prepared extracted datasets by region and contaminant. For specific searches, the analyst selects the Search tab. The Search function allows the analyst to filter data by WHO Region, Contaminant, Food Category, Food Name, and Sampling Period. These filters will allow the analyst to identify data responsive to a particular Call for Data or ToR.

54. To identify the most accurate dataset for extraction for the development of ML proposals, it is best to consult with the GEMS/Food database administrator. Data submitters may make choices when submitting data that could result in data being missed during extraction. For example, data uploaded as "food for infants and children" may be missed in a search limited to "fruit and vegetable juices." Another example is that juice data may be mistakenly mapped as "fruit and fruit products" although the Local Food Identifier or Remarks field clearly identifies the samples as juice. Consultation with the GEMS/Food database administrator before extraction may help the EWG ensure they have extracted all the relevant data for the ML analysis from GEMS/Food.

55. Confidential data is another reason EWG Chairs should always consult with the GEMS/Food database administrator on data extraction before downloading data. The GEMS/Food database administrator can provide records marked "Confidential" to EWG Chairs. These records will not show up in a routine search as described above. EWG members who are interested in a more detailed analysis of confidential data can consult with the EWG Chair.

56. It is important to maintain a record of all filters and search terms for the EWG report.

57. [[Changes were made in the GEMS/Food database in 2025/6 to make LOQ mandatory and to introduce new fields such as X, Y, Z1, Z2, AA, BB, CC. Legacy data submitted before these changes should be considered valid and be used in ML development.]]

DATA SELECTION /CLEAN-UP OF DATA

General considerations

58. This section provides guidance on the selection and clean-up of data for submission and analysis in the context of CCCF work. It is intended to support consistent and transparent handling of data across different sources, while acknowledging that key decisions—e.g. if MLs need to be developed— fall within the remit of the CCCF. The procedures outlined here aim to facilitate high-quality data analysis while promoting harmonization among contributors.

Origin of data

59. For the development of MLs based on occurrence data, only data in the GEMS/Food database should be used. Non-GEMS/Food data can only be used to support a complementary analysis to inform understanding of the data, e.g. when only limited data are available in the GEMS/Food database for certain time periods or regions, particularly limited data from primary producing countries.

60. Non-GEMS/Food data, such as data directly submitted to the EWG by Codex Member Country(ies)/Organization or Observer(s) or obtained through a literature search, are also subject to clean-up procedures, as necessary.

Clean-up of data

61. The purpose of data clean-up is to remove non-relevant or inappropriate samples from the dataset before analysing the dataset to recommend MLs.

62. Examples of samples that should be removed from a dataset include:

    a. Samples that are clearly outside the ToR of the work e.g. ketchup samples for work on tomato sauce.

    b. Samples that are outside the date range of the ToR of the work, e.g. samples that are 20 years old and the ToR refers to data from 10 years previously. This is particularly important if a Code of Practice (COP) for the prevention and reduction of contamination of relevant contaminants in foods has been adopted since older data were generated.

    c. Samples missing crucial information (see paragraphs 66-73 below).

    d. Samples with unacceptably high LOQs (see paragraphs 93-96 below).

63. Clean-up of data refers only to the extracted dataset. The original data in the GEMS/Food database will not be modified and will remain unaffected by the steps indicated below, unless the data submitter requests corrections or other changes from the GEMS/Food database administrator.

64. For the clean-up of data, it is recommended to involve an expert on the specific contaminant who may have insight in which patterns in data are irregular or not.

65. All steps taken in the clean-up of data should be recorded and described in the final Codex working document presented by the EWG to the Plenary of CCCF, e.g. detailed information on the reason for data exclusions (e.g. LOD/LOQ specified is higher than hypothetical MLs being considered, questionable outliers, etc.), number of data points excluded during the clean-up process, if possible, also including a breakdown of how many were excluded at each step, etc.

Handling of data

Missing information

66. Once all non-relevant or inappropriate data are removed from the dataset, then data should not be excluded if all mandatory fields are completed (see section data collection and submission) and the data meet the criteria for uploading in the GEMS/Food database. It should be noted that even if all mandatory fields are filled in and the data meet the criteria, the data may still be incomplete for deriving MLs.

67. In cases where sample information in the GEMS/Food database is needed but incomplete, (e.g. missing or unclear), the first step should be to reach out to the contact point for the data-submitting country/organization or observer to allow for missing information to be obtained. This is particularly important if the missing information was requested in a Call for Data. The GEMS/Food database administrator can also be asked to conduct this outreach.

68. If missing information is available, a corrected data file should be provided by the submitting country/organization or observer to the EWG and the GEMS/Food database administrator. Analysis using the corrected samples may continue. The request and corrections should be noted in the EWG working document.

69. If missing information cannot be obtained and the EWG chair concludes that the data should be excluded in the analysis due to missing information, the EWG should note the exclusion of the data and possible impacts of exclusion in their working document.

70. Examples of missing information indicating that data should possibly be excluded from further data analysis:

- the state of the food analysed is missing (e.g. cooked versus raw, and the analysis is intended to be based on raw food only)
- inadequate product description in the local food identifier field (e.g. the analysis is being performed on “mackerel”, but the product is described as “fish,” and the analysis depends on identifying fish species)
- and others

71. Examples of missing information that would not prevent further data analysis (depending on case-by-case review):

- sampling information: type of sampling, location of sampling in production chain
- state of the product, for example, raw or cooked, is not identified in Field ‘S’ but information can be deduced from other information provided, e.g. the sample is described as cooked fish.
- principle of method of analysis used
- when ML is based on a sum-of-components and data are not reported for all the components but for those that contribute significantly to the sum or in case the occurrence is reported as sum.

72. The EWG chair should not exclude all data that is missing any optional field but should consider what details are needed for the development/elaboration of MLs. For example, some commodities may require additional information to develop MLs, e.g. for raw grains, information on the processing stage may be important to propose MLs, but this information would not be needed for finished foods.

73. As noted above, non-GEMS data considered as part of a complementary analysis may be missing crucial information. The EWG Chair should apply the same criteria and questions (e.g. is the missing information critical to inclusion) to the non-GEMS data.

Incorrect information

74. In cases where there are clear indications that the unit of the data or the basis on which the data are reported are incorrect, the first step should be to reach out to the contact point for the country/organization or observer that submitted the data and request that they review the entries for possible corrections. The GEMS/Food database administrator can also be asked to conduct this outreach.

75. If the submitting country/organization or observer agrees that a correction is needed, a corrected datafile should be provided to the EWG and the GEMS/Food database administrator by the submitting country or observer. Analysis using these samples may continue. The request and corrections should be noted in the EWG working document.

76. If the accuracy of the data cannot be confirmed and corrections cannot be made, these data should be excluded from further data analysis.

77. Examples of apparent errors that should lead to contacting submitters for possible correction and resubmission:

- All data in a 200-sample dataset are expressed as µg/kg, except 5 quantified data points expressed as mg/kg. When plotting these data in a frequency distribution curve, after having converted them to the same unit, the five data points in mg/kg would be identified as possible outliers (see paragraphs 82-92 and Annex I).
- 195 results in a 200-sample dataset of samples of food with a typical fat content of 5% fall in the range of 0-20 mg/kg; however, 5 data points fall within in the range of 100–400 mg/kg, suggesting they were reported on a fat basis rather than the designated whole weight basis. When plotting these data in a frequency distribution curve, they would be identified as possible outliers (see paragraphs 82-92 and Annex I).

Data for which the information on the portion analysed is not clear.

78. For some foods (e.g. fruits, rice), if the portion analysed is not clear (e.g. peeled vs whole fruit, or husked rice vs polished rice), the point of contact for the country/organization or observer that submitted the data can be contacted for clarification. In case no clarification is provided, it should be reflected whether the unclear information is important for the contaminant in question and the final concentration found in the product. In addition, for some foods, it may be assumed that the portion was analysed in the state that it is usually sold/consumed, e.g. citrus fruit is usually fresh unless it is clearly identified as canned. Any such assumptions should be recorded and presented in the final document presented by the EWG to the plenary of CCCF. If no reasonable assumption can be made, these data should be excluded from further data analysis unless the necessary information was obtained.

Data originating from suspected fraudulent/economically adulterated samples

79. In assessing whether contaminated samples are the result of fraudulent/economic adulteration, the nature of the contaminant must be taken into account first (e.g. lead versus mycotoxin). Wide differences from year-to-year may be the result of natural variability (e.g. high level of mycotoxins due to specific climate conditions in a certain region/production year). In other instances, wide differences may be the result of poor practices (e.g. lead). Possible signs of fraudulent/economically adulterated samples are:

- certain samples are orders of magnitude higher than others, e.g. 0.1 mg/kg versus 100 mg/kg, or
- temporal variability in data (depending on contaminant), e.g. data are much higher in one year of the dataset.

Data that are clearly related to fraudulent/economically adulterated samples should be excluded from the analysis, and the exclusion must be documented.

Data from targeted sampling and bias

80. Targeted sampling differs from random sampling in that targeted sampling refers to targeted follow-up of specific findings of contamination. In principle, these data should not be used in the derivation of MLs as they are not representative of the general population and may not reflect achievable levels in regular situations.

81. It should also be noted that some bias could be introduced in random sampling as there might be reasons for more extensive sampling in specific regions or types of products. Such data could include higher or lower levels than the normal range and should not be excluded without further consideration, as these reflect natural variation in the occurrence data.

Determination and handling of outliers/extreme values

82. The EWG Chair should review the dataset to determine if there are outliers/extreme values that should be removed. This section provides guidance on different approaches to identifying outliers/extreme values and protocols for removing them, if appropriate.

83. As a general rule, it is important that outliers/extreme values not be discarded unless there is a valid reason to do so.

84. Extreme values can be valid values, e.g. due to the heterogeneity of contaminant distribution (such as hotspots for mycotoxins) or due to natural variation of measured contaminants (e.g. resulting from weather conditions, soil condition, etc.). Other extreme values can be erroneous, e.g. errors in measuring and processing data, including incorrect calculation or using the incorrect unit of measurement, or result from fraudulent behaviour (economic adulteration).

85. Erroneous values or values resulting from economic adulteration should always be removed from the final dataset before determining MLs. Valid extreme values will have to be reviewed on a case-by-case basis, using visual inspection of the data (see Annex III for examples) first, followed by statistical methods (Annex I).

86. The presence of outliers in datasets has a significant impact on the arithmetic mean and extreme values, but not on the median. However, consideration should be given to the percentage of any potential outliers present in the whole dataset. Since the high percentile values, rather than maximum values, are used as a basis for the development of MLs based on rejection rates, the impact of outliers on derived MLs will usually be small. However, in cases where a notable percentage of data points (e.g. 2–5%) are excluded from the dataset as outliers, this could affect the high percentile values (see also paragraph 92). In these cases, it is appropriate to provide a comment regarding the effect of the exclusion of the outliers on the achievability of MLs (i.e. rejection rate) under consideration.

87. Annex I to this guidance document provides more details on statistical approaches to identify outliers.

88. "Outlier" defined in the *Guideline on Analytical Terminology* (CXG 72-2009) assumes a normal distribution in a dataset comprised of results from repeated analysis of the same sample. It states, "*the statistical outliers are discarded unless the statistician for good reason decides to retain them*". In contrast, the datasets addressed in this guidance document are analytical results from a variety of samples and from different analytical methods. Because the distribution of these data is unknown (in many cases, it will not follow a normal distribution), and the data may be combined from multiple sources, it is difficult to predict the range of variation within a dataset. Therefore, this Guidance recommends that the statistical outliers not be discarded unless a good reason to exclude them is identified and scientifically explained.

89. Extreme values that are identified as errors should be addressed as described in paragraphs 74-77. However, extreme values that lack a clear explanation should be retained and evaluated to determine if they should be handled as outliers in the final dataset. A sensitivity analysis can be performed to understand the impact that the inclusion of outliers has on the overall assessment.

90. As there can be many causes for extreme values and some of these values may not be regarded as extreme if combined with data from other sources (countries/regions, different years, etc.), the possible exclusion of an extreme value as an outlier should be determined based on the combined, cleaned-up dataset. If individual datasets are analysed separately, more careful consideration should be given to the exclusion of extreme values as outliers.

91. There may be cases where extreme values are scientifically valid depending on production and weather conditions and/or other potential factors such as volcanic eruptions, etc. Considering the characteristics of the contaminant distribution of occurrence data in food, it is not recommended to simply exclude extreme values based on the results of statistical outlier tests or other methods such as visual inspection. Since the range of the concentration distribution that can be empirically or theoretically assumed varies significantly depending on the type of contaminant (heavy metals, mycotoxins, etc.), the handling of extreme values must be determined on a case-by-case basis. For example, special consideration should be given to mycotoxins whose concentrations can vary significantly depending on the sampling methods utilized due to the heterogeneous distribution in a lot, as well as very large annual variations.

92. If outliers are excluded, it is recommended that the reason for exclusion be clearly reported in the final document presented by the EWG to the plenary of CCCF. Sensitivity analyses can be performed to show how the exclusion or non-exclusion of outliers may or may not affect the calculation of high percentile values. It should be reiterated that a few extreme values remaining in the dataset will have little effect on the calculation of the high percentile values, provided that the total number of data points in the dataset is sufficiently larger than the minimum number of data points required to calculate high percentile values.

Limit of Quantification (LOQ) and Limit of Detection (LOD)

Exclusion based on LOQ

93. Different methods of analysis provide different LODs and LOQs. A high LOQ does not automatically mean that the data should be excluded.

94. Guidance for data inclusion/exclusion in different LOQ/LOD scenarios

- In the case where no LOQ/LOD is provided for a specific dataset
  - The submitting country/organization or observer should be contacted as a first step to obtain such information (i.e. LOD and/or LOQ).
  - In the case where the dataset contains (nearly) only quantified results: the dataset could be used[3] .
  - In the case where the dataset contains a significant amount of left-censored data (individual data without quantified (finite) values, generally referred to as data below the reported LOQs/LODs): the dataset should not be used.
- In the case where an LOQ is provided:
  - Identify a cut-off level for the LOQ in the analysis depending on the MLs being considered (examples: LOQ < ML under discussion, LOQ < 1/2 ML under discussion).
  - In the case where the dataset contains a significant amount of left-censored data: further contextual information should be considered (e.g. are data from an importing country or producing country).

95. If almost all data in the dataset are below the LOQ or reported as non-detects (NDs, <LOD), it is not possible to estimate high percentile values to establish proposed MLs. When there are only a small number of quantitative values, the dataset should be handled on a case-by-case basis following the guidance provided in the section on "Handling of datasets with a large proportion of left-censored data". In this case, when proposing MLs, it is not appropriate to calculate high percentile values using only quantitative values, as this may result in unnecessarily high MLs.

96. The EWG working document should clearly outline the criteria by which certain data were excluded from the dataset due to high LOD/LOQs (e.g. the reported LOD/LOQ for some samples is higher than the proposed ML, or the reported LOD/LOQ for some samples is 'x' orders of magnitude greater than the lowest LOD/LOQ of the vast majority of other samples in the dataset, suggesting an error) or if the whole dataset should be excluded from the analysis, as removing individual data can introduce bias.

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[3] In the current GEMS/Food database template, the reporting of the LOD or LOQ is not mandatory in case of quantified results. Therefore, these data, reported with this template could be used, in particular in case of insufficient other data, with the clear indication in the document presented by the EWG to the plenary of CCCF that no LOQ/LOD was provided for these data, in agreement with the rules at the time the data were submitted.

Sum of components and LOQ

97. In the case of levels of contaminants that are a sum of components (e.g., total aflatoxins), the following should be considered.

- The general rule is that levels of contaminants that are a sum of components are reported as the lower bound, i.e., for non-quantified levels of components, the values are set to 0.
- The LODs or LOQs for the individual components are required to be provided for the non-quantified components below the LOD or LOQ.
- When only data on individual components are reported, the individual data can be summed into a total result.
- In specific cases, it may be appropriate to report levels of contaminants that are a sum of components using a middle bound approach (i.e. non-quantified levels of components are set equal to ½ of LOQ (or the LOD in case the LOQ is not provided) or upper bound approach (i.e. non-quantified results are set equal to LOQ (or the LOD in case the LOQ is not provided); however, these cases should be clearly identified in advance before data submission in the instructions for the Call for data.

DATA ANALYSIS: GENERATING OVERVIEW OF DATA

Overview of countries, number of data points, period of data coverage

98. After clean-up of the dataset, the remaining data are considered to be of sufficient quality for the analysis. An overview of these remaining data with details (e.g. country of production of finished product, production/harvest year, amount of data included and excluded) should be provided in a table and described in the working document. All steps taken in the data clean-up and the rationale and assumptions made should be provided with the overview. In addition, it could be useful to provide information (e.g. from FAO) on the major production regions for the commodity under discussion. Based on this overview, the EWG can also present a more focused analysis of specific geographical areas and time periods.

Geographical coverage of the provided occurrence data

99. When evaluating an ML for a particular commodity, the dataset should include representation of production regions that are important to international trade. Therefore, it is helpful (and may be required in the future) that the country/region that produces the finished products is reported in the GEMS/Food database (see Section Data Collection and Submission). Also, major production regions for certain commodities may be geographically limited; if this is the case, the EWG Chair can report this information in the working document. In that context, data from producing regions should be considered, as the data from countries importing the food might be biased if the food has to comply with the requirements of the importing country, such as an ML already established in that country. If a region has very restrictive MLs such that contamination levels of imported foods are skewed to the left, this may not be an accurate representation of the variability in contamination from producing regions. However, data from importing countries also reflect foods (ingredients) traded internationally and as consumed, and should be considered to some degree. Indeed, additional contamination could take place during transport from the producing country (e.g. mycotoxin production).

100. In some cases, it could be appropriate to give priority to datasets from producing countries over datasets from importing countries. However, in that case, the datasets from producing countries should reflect the implementation of good agricultural and manufacturing practices (GAPs, GMPs) as provided in Codex CoPs, if available, and be representative of products that would be traded internationally.

101. Another option is to provide separate analyses for producing and importing country datasets. If possible, a sensitivity analysis on using data from producing versus importing countries should be performed to guide the selection of data used to set MLs.

102. Only if there are enough data that show an indication of large differences in reported levels between regions or between countries in a region, analysis could be performed by region or country. It should be noted that for a country approach, this should be done for major producing countries in the region, and sufficient data should be available. (See Section on Statistical analysis of occurrence data/Handling of datasets for ML development).

103. In summary, although there are different approaches possible to look at data from importing countries versus producing countries or regional data, it is important to keep in mind that Codex MLs are global standards, so the default approach for data processing should be to analyse data globally.

104. Guidance for datasets that lack geographic coverage:

- If the region(s) for which data are lacking is/are important production region(s) and on the condition of a clear commitment from the region(s) to provide additional data, some additional years (e.g. 2-3 years) typically are allowed for data collection before continuing the discussion on ML proposals, provided that there is no urgency and CCCF agrees. After expiry of the granted additional years, the discussion on MLs would be continued based on available data, regardless of whether geographic coverage has been reached or not.
- If there is no commitment from the important producing region(s) to provide the additional data or if collecting additional data within the agreed timeframe (e.g. 2-3 years) is not feasible, the consideration on MLs will be continued based on available data or be discontinued.
- If the region(s) for which data are lacking is/are not important production region(s): the consideration on MLs will be continued based on available data.
- If there is an urgent need to establish an ML for consumer health protection, a compromise needs to be reached in CCCF to set an ML based on available data. In these cases, the ML can be reviewed within 3–5 years to assess whether adjustments are necessary when more data are available.

Time period coverage of the provided occurrence data

105. It is appropriate that the provided occurrence data relate to multiple production years for ML development. Requirements may be different for different types of contaminants (e.g. mycotoxins, plant toxins, marine biotoxins, processing and environmental contaminants) and is a function of the assumed year-to-year variation or evolution of contamination in time.

106. For contaminants such as mycotoxins which are known to have year-to-year variation, data from the last 10 years may provide a very good representation of the year-to-year variation; however, there may be cases where more than 10 years of data should be considered (e.g. sampling effort reduced in recent years or fewer higher quality datasets are available). For other contaminants, year-to-year variation is less relevant, and possibly more recent data (or a smaller time range) can be selected. In any case, it should be discussed whether data older than 10 years are relevant for the analysis.

107. Further, it could be relevant to investigate/include older data to learn whether certain species/subgroups from a food group/category tend to have higher levels.

108. It may be appropriate in certain cases to perform a time trend analysis. In these cases, data from more than 10 years are to be considered to determine if concentrations have changed/are changing with time and this could be used to determine whether a certain number of years of data should be used for ML elaboration to represent current concentrations.

109. If a Codex CoP has been established and implemented, the data under consideration should be from the years after the implementation of that CoP to reflect good agricultural and manufacturing practices.

110. If the EWG excludes data on the basis of data being collected before implementation of the CoP and without an indication by a country that good practices along the production chain had already been implemented before the establishment of the CoP, the exclusions and rationale should be clearly documented in the final document presented by the EWG to the Plenary of CCCF.

STATISTICAL ANALYSIS OF OCCURRENCE DATA /HANDLING OF DATASETS FOR ML DEVELOPMENT

General considerations

111. The following sections explain considerations before conducting a statistical analysis of the extracted data/cleaned-up data and how the results of the statistical analysis should be presented in the EWGs for developing globally applicable MLs.

112. Statistical analysis should be conducted on the extracted/cleaned-up data. When assessing the data, the first step should be analysing the distribution of the dataset. In general, the distribution of contaminant data in food tends to be right-skewed, e.g. a log-normal distribution (See Figure 1). For such non-normal distributions, the use of parametric statistical methods, which are based on the normal distribution, is not appropriate.

113. CXS193 states in Annex I, "*MLs should be set at a level which is (slightly) higher than the normal range of variation in levels in food and feed.*" This means that to develop an ML, there is a need to estimate high percentile values (generally 95th percentile values) with a high confidence level. In food safety, a confidence level of 95% is usually used. The figure below (Figure 1) explains, using a modelled distribution, the relationship among a high percentile value, hypothetical ML (usually a rounded value of the percentile value), and percentage of data points that exceed the hypothetical ML when the ML is the same as the 98th percentile value.

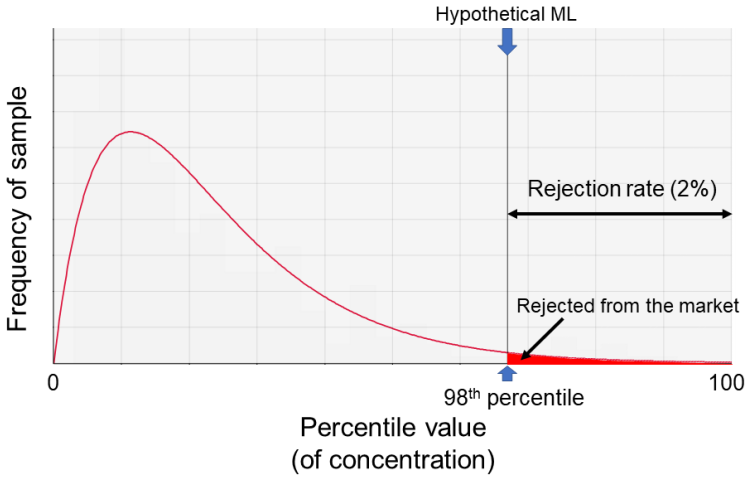

Figure 1. Simplified depiction of the relationship among a high percentile value, hypothetical ML, rejection rate, and percentage of samples exceeding the hypothetical ML.

Note: In the above, it is assumed that the hypothetical ML is the same as the 98th percentile value. The choice of the 98th percentile for hypothetical ML in this figure is for example only.

Minimum number of data points for estimating high percentile values

114. For the development of an ML, it is necessary to estimate high percentile values (generally 95th percentile values) of a dataset. A minimum number of 59 data points is required for a 95th percentile estimation with 95% confidence (see Option 1, Annex II). Annex II provides additional details on alternative options for calculating the minimum number of data points required in relation to estimating high percentile values.

Handling datasets

Handling datasets with a low number of data points

115. When the evaluation of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) suggests that a health risk from exposure to a contaminant is significant, a smaller number of data points than the minimum number of data points (i.e. 59 data points, refer paragraph 114 and Annex II) would be considered adequate for developing an ML, provided the confidence level of the estimated high percentile values is only slightly lower than the expected high confidence level, such as 95%. (See Annex II for an example of how to calculate the confidence level.) For example, when an ML is urgently needed for consumer health protection, the EWG tasked with recommending MLs should consider recommending to the CCCF the development of MLs even if only a small number of data points are available. If sufficient data becomes available in the future, revision of the previously established ML can be considered.

116. If there is not an immediate health risk, and the number of data points is insufficient for developing an ML, additional data calls could be requested. However, if after repeated data calls, the available number of data points is still much lower than the required minimum number of data points, a decision should be recommended to the CCCF on a case-by-case basis about whether to develop an ML using the limited dataset or to discontinue the work. Another option may be to expand the ML to a larger food group, if an ML for the larger group is justified.

117. For commodities that are not routinely consumed and/or not traded internationally, the availability of occurrence data may be insufficient. In such cases, the EWG tasked with recommending MLs should consider recommending to the CCCF that the ML requested for the commodity/contaminant combination may not meet the criteria described in CXS193 and the Procedural Manual (Section 4.5 "Policy of the Codex Committee on Contaminants in Foods for Exposure Assessment of Contaminants and Toxins in Foods or Feed Groups") for developing MLs.

118. If the number of data points is significantly less than the required minimum number of data points (i.e. 59, refer paragraph 114 and Annex II), and there is no strong reason for developing an ML immediately, there is no need to perform further statistical analyses. If additional data are needed to establish a statistically robust ML, further data calls may be necessary.

119. In reviewing existing MLs, even if only a small number of data points from limited regions are available and/or no new data will be generated, the EWG tasked with recommending MLs should not automatically recommend revoking the ML due to the small number of data points unless the ML is inconsistent with current good agricultural and manufacturing practices or current toxicological data. If a potentially significant risk exists from consuming the commodity, an option would be to recommend to CCCF to maintain the existing ML, or if there is no longer a significant health risk or there is no known trade barrier, an option would be to recommend to CCCF to revoke the ML. In some cases, when reviewing an ML, if there are only a small number of datapoints for a particular commodity, it may be possible to consider merging the commodity under the food group from which the commodity was originally excluded (e.g. removing an exclusion for canned *Brassica* from a canned vegetables ML (ref. REP18/CF12, paragraph 32)).

Handling datasets where available data on individual commodity(ies)/food(s) are insufficient, but data for the food group are sufficient.

120. Even when the data points are sufficient for a whole food group, if the data are separated according to individual foods in that food group, the data points may be too small for the development of MLs for individual foods. In general, the analysis of currently available data should begin with the development of a discussion paper. Based on available data, the EWG should recommend a preliminary approach to setting MLs for individual foods versus food groups, as well as recommending language for a new data call. If, after the data call and data collection, it is found that there are fewer data points available than initially expected, the food(s) that the ML should target may need to be changed to a broader range of foods, e.g. individual food(s) to food subgroups or food subgroups to food group.

121. The appropriateness of developing an ML for a food group depends on whether the distribution of contaminant concentration values in the individual foods within the food group is similar. Non-parametric statistical tests, such as the Mann-Whitney U test (for 2 datasets) or the Kruskal-Wallis H-test (for 2 or more datasets), can be used to determine if the distribution of those foods in the group can be considered to have a similar distribution, even when the number of data points is relatively small. However, as contamination levels among commodities within a food group may vary significantly, it is important to be flexible in the choice of methods and interpretation of statistical testing. If the number of data points is relatively small, comparison of datasets by box-and-whisker plots is also useful, provided the percentage of left-censored data is less than 25% of the respective dataset.

122. If an individual food shows a different distribution of contaminant concentrations from the other foods in the food group, two different MLs may need to be established, one for the food group excluding the individual food and the other for the individual food. Similar approaches can be taken for subgroup(s) in the food group. If there are insufficient data for individual food(s) to meet the required minimum number of data points, additional data calls can be issued for those foods for which it is considered necessary to develop MLs. If the consumption of an individual food that shows a different distribution pattern from the food group does not contribute significantly to the total exposure to the contaminant of concern, it may be considered negligible from a consumer health protection point of view. In such cases, no additional data call is required, and its exclusion from ML development for the food group may be considered (e.g. ML for lead in salt, food grade excluding salt from marshes (REP18/CF paragraphs 39-41). As for food groups and their sub-groups, reference can be made to the commodity covered by relevant Codex commodity standards, the *Classification of Foods and Animal Feeds* (CXA 4-1989) developed by the Codex Committee on Pesticide Residues (CCPR), and the food categorization system used by Codex Committee on Food Additives (CCFA) on processed foods.

123. When developing an ML for a broader food group due to limited data availability for individual foods or subgroups, some foods (or subgroups) might show different distribution patterns from others in the same food group. If there is not sufficient data to develop a separate ML for these foods, the EWG tasked with recommending MLs could recommend to the CCCF whether these foods should be excluded from the ML development until sufficient data becomes available.

Handling of datasets (including use of substitution methods) with a large proportion of left-censored data points

124. The "dataset" in this section refers to a dataset or datasets which is (are) among the dataset(s) selected to be used for ML development. This section is particularly relevant when the datasets used for ML development contain a high ratio of non-quantified data points (e.g. due to low sensitivity of available analytical methods for the concentration in the samples; extremely low frequency of occurrence; etc.) after data clean-up.

125. Though no official definition of the term "left-censored" is found in any of the Codex documents, in statistics, individual data without quantified (finite) values are called left-censored data, generally referred to as data below the reported LOQs/LODs.

126. For statistical analysis of datasets containing left-censored data, conventional substitution methods should be considered, particularly when calculating statistics such as the 95th percentile, or when estimating sample rejection rates and reductions in exposure for target commodities under hypothetical MLs. If the dataset contains a high ratio of left-censored data, statistical analysis using only quantified values is not recommended because this practice introduces bias into the results of the statistical analysis.

Substitution methods for datasets with a large proportion of left-censored data

127. The conventional approach to dealing with left-censored data for statistical analysis is the use of one or more of the following substitution scenarios:

- Lower-bound (LB) scenario: results below the LOQ are replaced by zero, or by LOD if the LOD is known (results <LOD are replaced by zero);
- Upper-bound (UB) scenario: results below the LOQ are replaced by the reported LOQ value; and
- The middle-bound (MB) scenario: A point estimate between the two extreme scenarios (LB and UB); assigning a value of LOQ/2, the square root of the LOQ, or (LOD +LOQ)/2 if the LOD is known for analytical results below the reported LOQ. In general, LOQ/2 is the most widely used.

For each of these scenarios, if the LOQ is not reported and only the LOD is reported, use the LOD as an alternative.

128. In general, depending on the distribution of data, these substitution methods may be used for calculating measures of central tendency such as the arithmetic mean when estimating dietary exposure (See EHC 240[4]). If the EWG tasked with recommending MLs is to perform preliminary calculations for the reduction of exposure, the choice of LB, MB or UB scenarios may affect the calculated arithmetic mean and the estimated exposure from target commodities based on the arithmetic mean. However, for ML development, the effect of left-censored values on the empirical estimation of high percentile values may be negligible, and there may be little impact on the ML regardless of which scenario is chosen, unless a large majority of data points are left-censored (i.e., <LOD).

129. The datasets with a large proportion of left-censored data should be handled on a case-by-case basis, depending on the result of the JECFA risk assessment on the contaminant and the consumption of the food concerned. Ideally, the LB, MB, and UB estimates should be calculated and presented. It is very important to know the distribution of quantified values in case of a high percentage of left-censored data when estimating high percentile values using a modelled distribution for developing MLs.

130. When the dispersion of quantified values is within a narrow range (values close to each other) and close to the reported LOQ, developing an ML may be unnecessary unless the contaminant is highly toxic. The EWG can make a recommendation to the CCCF on the appropriateness of an ML in this situation.

Handling of multiple datasets

Analysis of individual and combined datasets and making decision on the necessity of comparing individual datasets before combining, especially when distribution patterns are significantly different.

131. As Codex MLs are for global application, they should ideally be based on global datasets. While a default approach for ML development is to use the combined global dataset, individual datasets per year or per region are provided for additional consideration. Whether an ML should be based on a global dataset or a dataset from a specific region/year should be decided by the CCCF on a case-by-case basis, following statistical analysis as described in this section.

4 ENVIRONMENTAL HEALTH CRITERIA 240, Principles and methods for the risk assessment of chemicals in food (WHO, 2009)

132. Parametric statistical methods are available for comparing distribution patterns of individual datasets per region/country or per year. The null hypothesis is that all datasets are assumed to follow the same distribution. Such tests include the t-test (for 2 datasets) or ANOVA (for 2 or more datasets).

133. Many templates for non-parametric statistical methods are available on the Internet. Among them, MS Excel templates for performing Mann-Whitney U tests (for 2 datasets) and Kruskal-Wallis H-tests (for 2 or more datasets) are available for download from the FAO's JMPR website[5].

134. In addition, it is helpful to draw box-and-whisker plots or histograms of each dataset to compare if there are visual differences in the distributions before combining the datasets. It is preferable to draw a histogram only when the dataset contains a sufficient number of data points (see paragraph 114 and Annex II). For a dataset with a smaller number of datapoints, it is difficult to know the shape of the distribution by a histogram, and a box-and-whisker plot is more helpful (See Annex III).

135. Proposing an ML(s) using combined dataset(s) (global datasets) has been done conventionally in EWGs. When there is no significant difference between the distributions of multiple datasets from different sources, it is considered of little importance to perform additional data analysis and comparison for each individual dataset (although it would be ideal to do so if resources and time permit).

136. When the number of data points is significantly different between individual datasets from different regions/ countries, the resulting combined dataset reflects primarily the conditions of a country/region with the larger number of datapoints, rather than that of all countries/regions submitting the data. To address this problem, it would be theoretically feasible, although requiring a complex process, to balance the datasets by weighting them by the production or trade volume or on any other reasonable factors. However, the methodology and justification for the use of data weighting have not been considered in the past in CCCF, and because of its complexity and related workload, this is not envisaged to be done until workable guidance is elaborated in the future for this. If there are concerns about distortion in the distribution of the combined dataset due to the presence of a very large dataset, it should be considered on a case-by-case basis. For the time being, it may be recommended to also conduct analyses for each individual dataset, as presented in the following sections or to seek advice from JECFA on data analysis.

Cases where the analysis of individual datasets is recommended

137. If a statistical test indicates a significant difference between the distribution of multiple datasets, and the difference is substantial, it is recommended to analyse individual datasets alongside the combined dataset for ML development. However, this should be decided on a case-by-case basis as the extent of differences in distribution is typically dependent on the combination of commodity and contaminants being examined. A rationale for analysing the specific datasets separately alongside the combined dataset should be provided, and if no rationale can be found, the combined dataset should be used as a default.

138. When considering the use of individual datasets, it is recommended to compare the statistical results, such as high percentile values of the separate datasets, to those of the combined dataset. It should be noted that robust high percentile values cannot be obtained for individual or combined datasets whose sample sizes are lower than the minimum required number of data points (see paragraph 114 and Table 1 in Annex II).

139. It should be noted that when multiple datasets are considered individually, multiple possible MLs may be identified. It is outside the scope of this Guidance to provide guidance on which possible ML to be selected as it is the CCCF that decides on the appropriate ML, taking into account elements that can differ case-by-case.

140. If the datasets from different regions/countries are analysed separately through the statistical methods recommended in this Guidance, the EWG tasked with recommending MLs could provide elements for the choice of the dataset on which to base the ML for consideration and decision by CCCF. For example, if there is assurance that the datasets with high concentrations are for commodities produced under good practices (Codex CoP or GAP, GMP, etc.), then the focus could be on the high concentration datasets to consider globally applicable MLs.

Conducting data analysis by visualization

141. There are different methods of illustrating the chart/graph and plots to show the distribution of occurrence data and statistical values for evaluating the appropriateness of the proposed draft ML. Annex III presents examples of exploratory data analyses and statistics. Depending on the contaminant, the number of data points and distribution of occurrence data (parametric vs non-parametric), exploratory data analyses by visualization may be performed on a case-by-case basis.

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5 "Appendix XIV Electronic Attachments (2020_Nov)" and open "XIV 12 Spreadsheet for Kruskal_Wallis 20 group.xls" to carry out Mann-Whitney U test and Kruskal-Wallis H-test.
https://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/jmpr/jmpr-docs/en/

Data aggregation and calculation of descriptive statistics

142. The following information and summary statistics can be presented for occurrence datasets, meeting the minimum requirements:
   - Number of total data points.
   - Number of data points lower than the reported LOQs (or LODs), and/or ratio of the number of data <LOQ (or < LOD) among the total number of data points.
   - Range of LOQs (LODs) among data excluded or included in the final dataset used to recommend MLs.
   - Mean (arithmetic mean), if the dataset contains datapoints below LOQ (LOD), three arithmetic means based on three substitutional scenarios of LB, MB, and UB could be prepared (if the distribution is or close to normal and symmetric).
   - If the distribution is highly skewed, a geometric mean using the same approach as above could be an option, but has not been used yet within CCCF.
   - Median (50th percentile values), but if more than 50% of datapoints are below LOQ, the median could be reported as "<LOQ" (or <LOQ).
   - High percentile values (e.g. 95th, 97th, and 98th percentile values, as necessary, depending on discussions in the EWG on appropriate rejection rate(s)); if more than 95%, 97% etc. of data points are below the LOQ, then the associated percentiles could be reported as "<LOQ" (or <LOD).
   - Minimum.
   - Maximum: in cases where the maximum was identified as a potential outlier, and the maximum value was not excluded from the dataset, it may be worth reporting the 2nd highest value, 3rd highest value, etc., for additional context.
   - Range of quantified data.
   - Standard deviation, which is a measure of the amount of variation of a parametric distribution.
   - Interquartile values (see Annex III), which are a measure of the amount of variation of a non-parametric distribution.

143. Many of these statistics can be easily obtained by using Excel Functions, by using a menu of Descriptive Statistics in Data Analysis tools in MS Excel, or from any other statistical application. Different statistical applications use different calculation protocols and, as such, return different percentile values for the same dataset. Therefore, when calculating percentile values using computer applications, the values obtained should be carefully checked against the functions used and state the name and, if appropriate, details of the application used for the calculation.

144. When left-censored data comprise most of the dataset, it may not be possible to calculate high percentile values. In such cases, it is recommended to use the substitution method with LB, MB, or UB scenarios. Although this should be done on a case-by-case basis, depending on the number of quantified values and the contaminant distribution, methods such as estimating high percentile values from probability density functions by modelling the distribution of occurrence data can be used.

Calculation of rejection rates at hypothetical MLs

Estimation of hypothetical MLs

145. From a high percentile value (usually slightly higher than the 95th percentile) of the target dataset, a candidate value for an ML is identified, which takes into consideration the precision of the current analytical method and the significant figures of the analytical results. Numerical values for MLs should preferably be regular figures in a geometric scale (0.01, 0.02, 0.05, 0.1, 0.2, 0.5, 1, 2, 5, etc.), unless this may pose problems in the acceptability of the MLs (Annex I to CXS 193-1995)

146. Once the numerical candidate value of an ML has been determined, the next higher and lower values can also be suggested as hypothetical MLs. (For example, for a candidate ML of 0.5 mg/kg, additional hypothetical MLs could be 0.4 and 0.6 mg/kg). In the case of revision to existing MLs, the existing ML should also be added as one of the hypothetical MLs. Further, values obtained from the high percentile values (e.g. 95th, 97th, and 98th percentile values) can also be used directly as hypothetical MLs.

147. When the decision is made to analyse multiple datasets with different distribution patterns separately, hypothetical MLs are determined from the high percentile values of each dataset. If the distribution patterns are significantly different, hypothetical MLs of individual datasets may be significantly different (see paragraph 139).

148. There is no rule for the number of hypothetical MLs to be proposed, but it is preferable to have more than 2 hypothetical MLs (to be considered case-by-case), for consideration of their impacts on dietary exposure from target commodities and economics arising from rejection rates to be further discussed in the EWG tasked with recommending MLs to the CCCF.

149. The rationale for choosing an ML must be explained clearly in the document prepared for CCCF. The rationale should be based clearly on the analysis, not a pre-chosen value.

Calculation of rejection rates at the hypothetical MLs

150. The rejection rate is defined as the equation below. It can be easily obtained using MS Excel functions (such as the COUNTIF function) directly or using statistical or modelling/simulation applications after modelling each dataset. If a different method is used to calculate the rejection rate, the method should be clearly stated in the working document.

Rejection rate (%) = (number of data points > hypothetical ML) / (total number of data points) ×100

151. It should be noted that the rejection rate may be different from that anticipated from the high percentile due to rounding. The smaller the number of data points used to calculate rejection rates, the greater the uncertainty in estimating the rejection rate. In the calculation of rejection rate, it is assumed that samples that exceed the hypothetical ML are excluded from the market with 100% probability by the enforcement of the ML.

Assessment of the impact of an ML on the rejection rate

152. To assess the impact on international trade of the commodity, the combined global dataset should be used, and if necessary, datasets for each region. Calculating rejection rates on a country-by-country basis is not recommended to be done by the EWG tasked with proposing ML but a Codex Member might bring to the attention of the EWG/CCCF the economic impact certain hypothetical MLs have for their country for consideration, in case this is not sufficiently reflected in the assessment of impact of the hypothetical ML on rejection rate for their region/country.

153. For contaminants known to have large annual variation in concentrations, the rejection rate should be calculated for the dataset of each year, if possible, for year-to-year comparison of rejection rates.

Improvement of the calculation of rejection rates

154. At different hypothetical MLs, the calculated rejection rates may not change significantly, depending on the contaminant distribution. Given the skewed nature of contaminant data, the number of data points in the high percentile range is often much lower than that in the low percentile range, which affects the estimation of hypothetical MLs and rejection rates (See Figure 1 for the shape of the distribution).

155. If the distribution pattern of the combined (potentially global) dataset shows a single peak, modelling/simulation application (such as @Risk, Crystal Ball, R, etc.) can be used to model the distribution to continuously estimate the distribution near the high percentile values from the distribution function and more refined and improved estimates of the rejection rate may be possible.

156. If a more detailed or improved impact assessment regarding rejection rates is needed, requesting an evaluation from JECFA is an option.

Preliminary calculation of the effects of MLs on the reduction of dietary exposure to the contaminant from the target commodity at hypothetical MLs

Calculation of dietary exposure and reduction from the target commodity at hypothetical MLs

157. To ensure that the proposed ML is protective of consumers' health, it might be appropriate to quantitatively evaluate the effect of a hypothetical ML in reducing dietary exposure from the target commodity by comparing the exposure without an ML and hypothetical MLs under consideration. In the case of a revision of an existing ML, the dietary exposure from the target commodity under the already established ML is compared with the exposure under the new hypothetical MLs (revised ML).

Preliminary exposure assessment from the target commodity can be conducted as reference information in EWGs tasked with recommending MLs if resources are available.

If a detailed or more complex evaluation is necessary (e.g. overall exposure assessment), CCCF can request JECFA to conduct an evaluation of the effects of hypothetical MLs on the reduction of the risk from dietary exposure, as calculation of dietary exposure is a risk assessment function that JECFA should undertake. For examples of how to calculate the reduction rate of dietary exposure from the target commodity, please refer to Annex IV.]

Improvement of the calculation of the reduction of dietary exposure reduction rates

158. If a more detailed or improved impact assessment regarding dietary exposure is needed, an evaluation from JECFA might be requested.

Preparing final recommendations to CCCF

159. When finalizing an analysis, the EWG tasked with recommending ML may face challenging questions such as whether an ML is needed based on a preliminary exposure assessment, whether multiple draft proposed MLs are needed, which dataset should be used, or which rejection rate is appropriate. Different perspectives may arise than were envisioned when the ToR for the work was developed. The EWG should not make a final decision but prepare questions and recommendations to be put forward to the CCCF as a whole.

160. If the estimated UB dietary exposure is well below the health-based guidance value (HBGV) even without an ML, and a proposed ML is at or about the LOQ value, the ML would have little impact on reducing dietary exposure and would be unnecessary. For contaminants where an HBGV has not been established, if all the data are left-censored, it could be recommended to CCCF to establish the ML(s) at the LOQ value for the time being if there is a potential health concern. However, if most of the data are left-censored and there is no or little health concern, it could be recommended to CCCF that there is no need to establish ML(s). For example, a combined dataset of lead in fresh chicken eggs after data clean-up contained 99% left-censored data points, ranging from 0.001 to 0.257 mg/kg. The calculated exposure reduction at the hypothetical ML was low, and the proposed ML was within the range of reported LOQs. Therefore, development of ML for lead in chicken eggs was discontinued (ref. CX/CF 22/15/7).

161. If the estimated UB dietary exposure is close to or above the HBGV or the margin of exposure is low, the development of an ML could be recommended to the CCCF, even if a proposed ML is close to the reported LOQs, provided that there is a validated analytical method(s) with appropriate LOQ. If necessary, additional calls for data using more sensitive analytical methods (lower LOQs) may be recommended.

162. When quantified values show a large variation and reach significantly high value(s), it could be recommended to CCCF to develop an ML in order to eliminate highly contaminated foods from the international market. If the contaminant is highly toxic or genotoxic/carcinogenic and found in foods that are consumed in high volumes, it could be recommended to CCCF that the establishment of an ML would protect consumer health, even if the rejection rate is low. For example, the combined dataset of total aflatoxins in sorghum grains after clean-up contained 94% of left-censored data, and the upper range of quantified concentrations in this dataset exceeded 200 µg/kg. This indicates that an ML based on a low rejection rate would still have a large impact on reducing dietary exposure to aflatoxins from sorghum grains. A draft ML was recommended to CCCF for aflatoxins in sorghum with a rejection rate of 0.9% and an intake reduction of 46.5% (ref. CX/CF 22/15/9).

163. Overall, if dietary exposure is assessed, EWGs tasked with proposing MLs to CCCF should evaluate the balance between the rejection rate and the reduction of dietary exposure from the target commodity at each hypothetical ML and determine which level is as low as reasonably achievable or offer options to CCCF to inform the Committee's decision.

164. While it is out of the scope of this Guidance to determine what rejection rate is the most appropriate, the EWG tasked with recommending MLs to the CCCF should also consider regional and international consumption patterns to determine a proposed draft ML among the hypothetical MLs with respect to protecting consumer health and ensuring food security and fair trade.

165. It is the responsibility of Codex Members to check the impact of the draft ML (or hypothetical ML(s)) against their own national/regional data and to provide comments on the results of their statistical analysis to the EWG or to the plenary.

DATA PRESENTATION IN EWG REPORTS TO CCCF

Presentation of data analysis: statistical analysis

166. It is important that the data are presented in such a way in the EWG report to CCCF as a working document that they enable an informed discussion on appropriate MLs for deliberation through the Codex Step procedure. This means that the data are reported with inclusion of all assumptions e.g. how many data were excluded and the reasons thereof, how left-censored data were managed, whether data outside the GEMS/Food database were considered, etc.

167. Annex V provides the elements and examples of templates that can be used by the EWG when presenting the results of statistical analyses of occurrence data for ML development. The EWG may use the templates or modify them on a case-by-case basis, as the details reported will depend on the amount of data available and the nature of the contaminant.

APPENDIX X

NUMERIC PERFORMANCE CRITERIA FOR TOTAL AFLATOXINS IN CERTAIN FOOD MATRICES

(For endorsement by CCMAS, adoption by CAC, and inclusion in CXS 234-1999)

Commodity	Analyte	ML (µg/kg)	LOD (µg/kg)	LOQ (µg/kg)	Precision (%)	Minimal applicable range (µg/kg)	Recovery (%)
Peanuts intended for further processing	AF B1+B2+G1+G2	15	≤ 3	≤ 6	< 44	8.4 - 21.6	60 - 115
	AFB1	-	≤ 0.75	≤ 1.5	< 44	2.1 - 5.4	40 - 120
	AFB2	-	≤ 0.75	≤ 1.5	< 44	2.1 - 5.4	40 - 120
	AFG1	-	≤ 0.75	≤ 1.5	< 44	2.1 - 5.4	40 - 120
	AFG2	-	≤ 0.75	≤ 1.5	< 44	2.1 - 5.4	40 - 120
Tree nuts destined for further processing: almonds, hazelnuts, pistachios, and shelled Brazil nuts	AF B1+B2+G1+G2	15	≤ 3	≤ 6	< 44	8.4 - 21.6	60 - 115
	AFB1	-	≤ 0.75	≤ 1.5	< 44	2.1 - 5.4	40 - 120
	AFB2	-	≤ 0.75	≤ 1.5	< 44	2.1 - 5.4	40 - 120
	AFG1	-	≤ 0.75	≤ 1.5	< 44	2.1 - 5.4	40 - 120
	AFG2	-	≤ 0.75	≤ 1.5	< 44	2.1 - 5.4	40 - 120
Ready-to-eat tree nuts: almonds, hazelnuts, pistachios and shelled Brazil nuts	AF B1+B2+G1+G2	10	≤ 2	≤ 4	< 44	5.6 - 14.4	60 - 115
	AFB1	-	≤ 0.5	≤ 1.0	< 44	1.4 - 3.6	40 - 120
	AFB2	-	≤ 0.5	≤ 1.0	< 44	1.4 - 3.6	40 - 120
	AFG1	-	≤ 0.5	≤ 1.0	< 44	1.4 - 3.6	40 - 120
	AFG2	-	≤ 0.5	≤ 1.0	< 44	1.4 - 3.6	40 - 120

Commodity	Analyte	ML (µg/kg)	LOD (µg/kg)	LOQ (µg/kg)	Precision (%)	Minimal applicable range (µg/kg)	Recovery (%)
Dried figs	AF B1+B2+G1+G2	10	≤ 2	≤ 4	< 44	5.6 - 14.4	60 - 115
	AFB1	-	≤ 0.5	≤ 1.0	< 44	1.4 - 3.6	40 - 120
	AFB2	-	≤ 0.5	≤ 1.0	< 44	1.4 - 3.6	40 - 120
	AFG1	-	≤ 0.5	≤ 1.0	< 44	1.4 - 3.6	40 - 120
	AFG2	-	≤ 0.5	≤ 1.0	< 44	1.4 - 3.6	40 - 120

APPENDIX XI

PRIORITY LIST OF CONTAMINANTS FOR EVALUATION BY JECFA

Contaminants	Background and question(s) to be answered	Data availability (when, what)	Proposed by
Dioxins and dioxin-like PCBs	Full evaluation (toxicological assessment and exposure assessment) to update the JECFA57 (2001) assessment and incorporate data on developmental effects from in utero exposures.	EFSA: Updated assessment anticipated 2026; EU yearly collection of occurrence data in feed and food WHO: Expert consultation to develop TEFs held in October 2022; publication in 2024 (https://www.sciencedirect.com/science/article/pii/S027323002 3001939) Brazil: Occurrence data on milk, raw eggs, fish, and fat (poultry and mammals) Canada: Occurrence data on foods of animal origin USA: FDA occurrence data from the previous 10 years for milk, eggs, meat, and seafood, and TDS data from 2018-2022 for dairy products, eggs, meat, poultry, seafood, and other foods. USDA occurrence data from 2012-2013, 2018-2019, and 2023-2024 for meat, poultry, and Siluriformes fish. Singapore: TDS data New Zealand: Occurrence data	Canada

Contaminants	Background and question(s) to be answered	Data availability (when, what)	Proposed by
Arsenic (inorganic and organic)	Inorganic: The JECFA73 (2011) evaluation based on cancer effects. This evaluation would focus on non-cancer effects (neurodevelopmental, immunological, and cardiovascular) and could inform future risk management needs. NOTE: Needs to be put in context to cancer risk assessment. Organic: (exploratory)	Australia/New Zealand: TDS; inorganic and organic arsenic occurrence data Brazil: Occurrence data on total arsenic in rice, poultry, pork, fish, and cattle meat, and inorganic arsenic occurrence data in rice and fish. Canada: Occurrence data on inorganic and total arsenic in a variety of commercial foods. Chile: Occurrence data on inorganic and total arsenic in algae, crustaceans, gastropods, bivalve molluscs, and small fish. EU: Inorganic and organic arsenic occurrence data India: Occurrence data in rice Japan and China: Occurrence data on rice and rice products Türkiye: Occurrence data in rice USA: FDA occurrence data from various foods for the past 10 years. FDA 2016 risk assessment. USDA occurrence data in meat, poultry, and Siluriformes fish for the past 10 years. USA: Studies: • Neurodevelopmental studies of inorganic arsenic impacts on rat behaviour (2019, 2022) • Toxicokinetic studies on metabolism and disposition of inorganic and organic arsenic and metabolites in mice (various life stages) (2018-20) • Developmental toxicity test in *C. elegans* on inorganic arsenic (2018) and an ongoing study on organic arsenic. • Non-governmental report, Effects of Inorganic Arsenic in Infant Rice Cereal on Children's Neurodevelopment (2017) Singapore: TDS data on inorganic and total arsenic	United States of America
Scopoletin	Full evaluation (toxicological assessment and exposure assessment) in fermented noni juice	CCNASWP16 (2023) has finalised the standard for fermented noni fruit juice and requested CCCF to keep scopoletin in the priority list and provide data as it becomes available. CCNASWP15 (2019) agreed to request CCCF to retain scopoletin on the priority list and to call upon Codex members to generate and submit data to support the conduct of the safety evaluation by JECFA. CCNASWP15 also requested FAO and WHO to organize a new call for data for the safety evaluation of scopoletin. FAO reminded that a full dataset, including exposure and toxicity, is required. The Codex Secretariat hired a consultant to undertake a toxicological review of scopoletin as presented in the Annex to CX/CF 21/14/2-Add.1.	FAO/WHO Coordinating Committee for North America and Southwest Pacific

Contaminants	Background and question(s) to be answered	Data availability (when, what)	Proposed by
Thallium	Full evaluation (toxicological assessment and exposure assessment)	EU: Two EFSA assessments, occurrence data New Zealand: TDS data USA: Occurrence data on brassica-containing foods, in baby foods, and in TDS results. U.S. National Toxicology Program is conducting studies on thallium (I) sulphate. USDA occurrence data for meat, poultry, and Siluriformes fish for the past 10 years. Canada: TDS data Singapore: TDS data available in 2028 Japan: Survey on cereals and vegetables, data available in 2026	United States of America
Perfluoroalkyl substances (e.g. PFOS, PFOA, PFNA, PFHxS)	Full evaluation (toxicological assessment and exposure assessment)	EU: Occurrence data Japan: Occurrence data; risk assessment report (2025). Singapore: Occurrence data USA: Occurrence data from FDA TDS and targeted surveys (seafood, bottled water, milk, clams). Occurrence data in meat and poultry from the USDA National Residue Program. Toxicology/risk assessments from the US Agency for Toxic Substances Disease Registry and the Environmental Protection Agency. Canada: TDS data for dairy, fish, meat, fruits, vegetables, and prepared foods, and targeted survey data in flour, cereal, popcorn, and root vegetables China: TDS data New Zealand: Occurrence data	Singapore
Ethylene oxide (EtO) and 2- chloroethanol	Full evaluation (toxicological assessment and exposure assessment)		Indonesia
Ochratoxin A (OTA)	Full evaluation (toxicological assessment and exposure assessment)	Türkiye: Occurrence data in dried fruits	Türkiye
Cadmium and lead in yerba mate	Impact assessment of maximum levels	Brazil: consumption data for yerba mate and occurrence data on cadmium and lead Paraguay: occurrence data on cadmium and lead Uruguay: occurrence data on cadmium and lead	Brazil, Paraguay, and Uruguay