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ANALYSIS OF AGENDA ITEMS IN PREPARATION FOR THE 18TH SESSION OF THE CODEX COMMITTEE ON CONTAMINANTS IN FOODS (CCCF18)

Prepared to Support the Participation of Codex Communities of Practice Supported by GFoRSS

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Disclaimer and Disclosure of Interest

It is important to note that the proposed analysis and associated conclusions and recommendations stem from the work of independent food regulatory experts. The analysis and associated recommendations or positions are presented as mere suggestions and should not be considered as a direction or final recommendation to the competent authority empowered to develop and endorse Codex positions.

Disclosure of Interest: *Experts involved in the development of this analysis contribute to various food safety and nutrition regulatory capacity building initiatives funded by other Governments, aid agencies, industry and international organizations.*

OBJECTIVES

This document offers an analysis of agenda items to support participation in the 18th session of the **Codex Committee on Contaminants in Foods (CCCF18)**, scheduled to take place in Bangkok, Thailand from **23** to **27 June 2025**.

The document is intended for possible use by the Codex communities of practice promoted by the Global Food Regulatory Science Society (GFoRSS), as part of their contribution to enhancing awareness and supporting effective participation in international standard setting meetings (Codex meetings), by representatives from member countries and observers.

This document will offer an analysis of select key agenda items to support the development of positions at the national and regional level. This analysis is indicative in nature and does not represent an official position of the organization, its membership or its management.

The analysis provided in this document offers a factual review of key agenda items of CCCF18, pertaining to:

A. Agenda Item 5.1: Maximum levels for lead in certain food categories

Document Number: CX/CF 25/18/5

Status in Codex Process: NA

Background

Lead is a naturally occurring toxic metal found in the environment and in different products. Its widespread use has resulted in extensive environmental contamination, human exposure and significant public health problems in many parts of the world. Considering the conclusions of JECFA73 (2011) about dietary lead exposure stating that there **is no safe level of lead**, international organizations include the reduction of risks of exposure to lead among the priority themes in terms of environmental health.

CCCF started working since its 6th session on the revision of Maximum Levels (MLs) for lead established in the General Standard for Contaminants and Toxins in Food and Feed (CXS 193-1995) to reduce dietary exposure to lead.

The key decisions reached by the committee are presented below:

At CCCF11 (2017), the Committee agreed to expand the work on Lead beyond the food categories listed in CXS 193, with the consideration of new Maximum Levels (MLs) for a range of food commodities.

Since then, an Electronic Working Group (EWG) led by Brazil has been working on proposals for new MLs for lead in selected food commodities.

At the CCCF12 (2018) and CCCF13 (2019), the committee discussed the criteria to select new food categories for ML elaboration, considering international trade and potential exposure. CCCF13 agreed to focus on **MLs proposals for Lead in food for infants and young children**, except those for which MLs have already been established in CXS 193, spices and aromatic herbs; eggs and sugars and confectionery, excluding cocoa.

The EWG established at CCCF13 worked on lead data extracted from the GEMS/Food Database considering results from 2008 – 2019. MLs were proposed for eggs, preserved eggs, fresh and dried culinary herbs and spices (fruits and berries; fresh and dried rhizomes, bulbs and roots; bark; floral parts; seed).

At the CCCF14 (**2021)**, CCCF agreed to:

- Clarify that the MLs for **fruit juices and grape juices** in CXS 193 also apply to infants and young children. These MLs were adopted at CAC44.
- Discontinue work on MLs for **herbal teas, yoghurt, cheese and milk-based** products for infants and young children.

At CCCF15 (**2022)**, CCCF agreed to:

- **Discontinue work on fresh eggs,** given its low relevance for international trade and the low occurrence levels observed.
- **Discontinue work on ML for dried garlic,** given that there is already an ML of 0.1 mg/kg for fresh garlic on the General Standard for Contaminants and Toxins in Food and Feed (GSCTFF).
- **Discontinue work on molasses** as there was not sufficient data to establish an ML.
- Recommend the adoption by CAC45 the following MLs at Step 5/8:
    - Cereal-based foods for infants and young children at **0.02 mg/kg**
    - White and refined sugar, corn and maple syrup and honey at **0.1 mg/kg**
    - Sugar-based candies at **0.1 mg/kg**,
- To consider a separate ML for brown and raw sugar due to the high value of these commodities in international trade and because they are likely to contain more lead than white or refined sugar.
- Forward the ML for lead at 0.02 mg/kg at Step 5 for ready-to-eat meals for infants and young children and to further consider by the EWG as per the possible exclusion of certain foods that may not be able to achieve this ML for consideration at CCCF16 (2023).
- Re-establish the EWG, led by Brazil, to consider MLs for **ready-to-eat meals for infants and young children**

(exclusion of certain foods) and brown and raw cane sugars based on data currently available in GEMS/Food for consideration by **CCCF16 (2023)** and MLs for **culinary herbs** (fresh/dried) and **spices** (dried) following a JECFA call for data in 2022 for consideration by **CCCF17 (2024).**

At CCCF16 (2023), delegates discussed MLs proposed by the EWG chaired by Brazil, for certain sugar food categories (soft brown, raw and non-centrifuged), and for ready-to-eat meals for infants and young children (exclusion of certain foods) (at Steps 4 and 7).

CCCF16 agreed to:

- Forward to CAC46 the following MLs for adoption:
  - For soft brown sugar, raw sugar and non-centrifuged sugar (including Panela and Mascavo): a single ML at 0.15 mg/kg at step 5/8. and
  - For ready-to-eat meals for infants and young children, a single ML of 0.02 mg/kg at step 8.
- To continue the work on MLs for lead for culinary herbs (fresh/dried) and spices; and to present the proposals for these commodities at CCCF17 for consideration.
- To encourage Codex members to submit data with clear identification of the dried/fresh state of the samples of culinary herbs and spices to GEMS/Food database and if no agreement is reached at CCCF17, to discontinue work on this category.

At CCCF17 (2024), delegates discussed EWG's proposals within the establishment of MLs for culinary herbs (fresh/dried) and spices. CCCF17 agreed to:

1. **Forward to CAC47 for adoption the following proposed MLs:**

Commodity	Proposed ML (mg/kg)	Step	Reservations Noted
Spices, dried aril	0.9	5/8	India
Dried seeds (excluding celery seeds)	0.9	5/8	India
Dried celery seeds	1.5	5/8	European Union, India
Dried rhizomes and roots	2.0	5/8	EU, Indonesia, Egypt, India
Dried floral parts	2.5	5/8	EU, Egypt, Türkiye, India
Spices, dried fruit and berries (excl. Sichuan pepper, star anise, paprika, sumac)	0.6	5/8	India
Spices, dried paprika and sumac	0.8	5/8	-
Dried Sichuan pepper and dried star anise	3.0	5/8	European Union
Dried culinary herbs	2.5	5	The EU suggested lowering the ML to **1.5 mg/kg** based on EFSA data. Concerns were raised that this data wasn't reflected in GEMS/Food, and a **call for data** may be needed. One Member also proposed using **"moisture content"** instead of "humidity."
Dried bark	2.5	5	- ML of **2.0 mg/kg** would be better to protect children. - One Member requested a delay in adoption to allow analysis of **new data**. - Concerns about **economic adulteration** affecting data quality, with a call to exclude such data and assign this task to the **EWG** rather than relying on the GEMS/Food database.

2. **Discontinue** work on MLs for:
   - Spices, dried flowers spices, as chamomile is mainly used in **herbal infusions** in most countries.
   - Fresh culinary herbs, pending the development of an ML for **dried herbs**, and to reconsider the **relevance of the note on using moisture content**.
3. **Re-establish** EWG (chaired by Brazil) to:
   - Continue work on MLs for lead in **dried bark** and **dried culinary herbs**
   - Consider moisture content note relevance for fresh culinary herbs
4. **Request JECFA to:**
   - Issue a call for lead data in spices, dried bark (excluding data related to economic adulteration), and dried culinary herbs
   - Analyze available data for spice mixtures
5. **Request the Secretariat** to issue a CL for comments on the application of MLs to multi-ingredient products.

At CAC47 (2024), the commission adopted the proposed MLs:

At Step 5/8	dried aril (0.9 mg/kg); dried seeds, excluding celery seed (0.9 mg/kg); dried celery seeds (1.5 mg/kg); dried rhizomes and roots (2.0 mg/kg); dried floral parts (2.5 mg/kg), dried fruit and berries, excluding Sichuan pepper, star anise, paprika and sumac (0.6 mg/kg); dried paprika and sumac (0.8 mg/kg) and dried Sichuan pepper and star anise (3.0 mg/kg)
At Step 5	dried bark and dried culinary herbs, advancing to Step 6 for comments and further consideration by CCCF18.

At CCCF18 (2025), delegates will discuss EWG's proposals within the establishment of MLs for culinary herbs (fresh/dried) and dried bark spices,

Based on the conclusions and supporting updated GEMS/Food data (including 2024 JECFA submissions), CCCF is invited to consider:

1. Reviewing whether to discontinue previously adopted MLs (CCCF17/CAC47) **(Step 7)**.
2. Advancing the new MLs proposed by the EWG for adoption by CAC48 (2025) **(Step 4)**.

Commodity/Product Name	Maximum Level (ML) mg/kg (as adopted by CAC47 at Step 5) For comments at Step 6	Maximum Level (ML) mg/kg (new proposals by the EWG) For comments at Step 3	Portion of the Commodity/Product to which the ML applies	Notes/Remarks
Spices, dried bark	2.5	3.0	whole, ground, powder, crushed	-
Dried culinary herbs	2.5	2.0	whole, ground, powder, crushed	Relevant Codex commodity standards are CXS 328-2017, CXS 342-2021, CXS 345-2021.

Analysis

ANALYSIS OF THE METHODOLOGY FOLLOWED BY THE EWG

Participation and organization

23 countries and one organization, participated to the EWG's work led by Brazil, to consider MLs of lead for culinary herbs and spices based on data currently available on GEMS/Food for consideration by CCCF18 (2025). One draft was circulated to the EWG's members; comments were received from Canada, Japan, Mexico, Thailand, Uruguay, and the United States of America (USA).

Used data collection

A new call for data was conducted in 2024 to consider maximum levels (MLs) by CCCF18.

Data on lead in dried bark and culinary herbs collected from 2014 to 2025 were extracted by the WHO administrator of the GEMS/Food database.

Data that did not meet basic criteria, and results from samples collected before 2014 were not considered.

To handle left-censored data, the EWG chose to present results using both lower bound (LB) and upper bound (UB) approaches, standardizing all data to mg/kg, considering that the CCCF guidance didn't give recommendation on specific guidelines for the outlined methods: lower bound (LB), middle bound (MB), and upper bound (UB).

NB: In this method, at the LB, results below the limit of detection (LOD) are replaced by zero and those below the limit of quantification (LOQ) by the numerical value of the LOD; at the UB, the results below the limit of detection (LOD) are replaced by the numerical value of the LOD, and those below the limit of quantification (LOQ) are replaced by the numerical value of the LOQ.

Food categories were grouped by food similarity, considering the classification of spices and culinary herbs established by the Codex Committee on Spices and Culinary Herbs (CCSCH).

Regional comparisons and full statistical details were mentioned in the report.

Classification	Food examples
Culinary herbs	Apple mint, basil, bay leaves, celery, chervil, chives, cilantro, coriander, dill, dillweed, fennel, herbs NES, herb of grace, hyssop, kaffir lime leaves, lemon balm, lemongrass, lemon thyme, lovage leaves, mint, oregano, parsley, peppermint, pimpernel, rosemary, sage, savoury, stevia, tarragon, thyme, spearmint, wormwoods
Spices, dried, bark	Cinnamon, bark, canella bark, cassia bark

ANALYSIS OF FOOD CATEGORIES

For bark spices

Data were submitted by 4 regions and spanned 2016–2024 from the **EURO** region (European Union), the **PAHO** region (Brazil, Canada, Uruguay, USA), the **SEARO** region (India, Indonesia, Sri Lanka, Thailand), and the **WPRO** region (China, Malaysia, New Zealand, Singapore, Vietnam).

The 2024 data call excluded economically adulterated samples, aiming to reflect natural lead occurrence. Slightly higher mean levels in recent data suggest natural variability. Due to broader geographic coverage, the full dataset was used to evaluate the impact of hypothetical maximum levels (MLs) on dietary intake.

The impact of implementing hypothetical MLs for lead on dried bark (n= **768)** was generally analyzed across five regions based on the UB approach (Intake at the worst-case consumption scenario: Bark (0.4 g/day G12); theoretical body weight value = 70 kg.) and in the PAHO region (P95 values are higher in the PAHO region, with a P95 of 2.88 mg/kg that is higher than the ML of 2.5 mg/kg).

Lead levels in dried bark were analyzed in 768 samples (717 positive), with concentrations ranging from 0.001 to 5.71 mg/kg. The overall mean was 0.68 mg/kg, and the P95 value was 2.32 mg/kg. A subset of data from 2024–2025 (284 samples) showed a slightly higher mean of 0.86 mg/kg, with similar P95 and P97.5 values.

The impact of implementing hypothetical maximum levels (MLs) for lead was assessed using the upper bound (UB) approach. At an ML of 2.5 mg/kg, 4.0% of samples would be rejected, and dietary lead intake could be reduced by 16%. Stricter MLs (e.g., 1.0 mg/kg) would lead to higher rejection rates (up to 23.7%) and greater intake reductions (55%).

In the PAHO region (**301 samples**), the P95 was 2.88 mg/kg, above the proposed ML of 2.5 mg/kg. Applying an ML of 2.5 mg/kg would lead to a 7% rejection rate and a 23% reduction in intake.

An ML of 3.0 mg/kg is considered more appropriate for this region, balancing safety and sample retention.

For Dried culinary herbs

Following concerns expressed at CCCF17 over the exclusion of more than 1,500 EU herb samples, the EWG decided to use raw data submitted directly by the EU, due to incomplete data in the GEMS/Food system.

After filtering, a final dataset of **2,222 samples** of dried and non-identified culinary herbs was analyzed.

This dataset excluded 75 dry-weight-only samples, 23 samples with high LOQs (3.0–4.0 mg/kg), one outlier (28.3 mg/kg), and 14 Stevia samples not commonly considered culinary herbs. These exclusions did not affect the overall mean or P95 values.

Across all regions, the **mean lead level** was **0.40–0.41 mg/kg** and **P95 was 1.20 mg/kg** (LB and UB). Lead concentrations ranged from **0.005 to 7.7 mg/kg**, with LOQs between **0.003 and 0.395 mg/kg**.

Regionally, the **PAHO region** (Brazil, Canada, Peru, Uruguay, USA) had the **highest P95 (1.83 mg/kg)** and mean (0.58 mg/kg), while EMRO and WPRO had the lowest averages.

For herbs with at least 59 samples, P95 values remained **at or below 2.0 mg/kg**, supporting the proposal to set a **single ML** for all culinary herbs.

A summary of lead levels in **dried culinary herbs**, including cinnamon and cassia is provided in the report. Cinnamon had a higher mean (0.78 mg/kg) and P95 (2.4 mg/kg), while cassia showed lower values (mean 0.33 mg/kg, P95 1.5 mg/kg).

To assess dietary risk, lead exposure was evaluated using the **GEMS/Food Cluster Diet G09** (worst-case scenario: **8.89 g/person/day** for herbs). Hypothetical MLs from 3.0 to 1.0 mg/kg were tested:

An ML of **2.0 mg/kg** (revised from the previous 2.5 mg/kg) would reduce intake by **12% globally** and **23% in the PAHO region**, with **sample rejection rates below 5%**, thus balancing safety and trade impact.

ANALYSIS OF THE EWG'S PROPOSALS

The proposals for new MLs for lead in dried bark and dried culinary herbs appear well-founded scientifically and practically balanced, aiming to protect public health while minimizing trade impact. The recommended stepwise process ensures opportunities for further data collection and refinement before final adoption:

Commodity / Product Name	ML (mg/kg) (As adopted by CAC47 – Step 5)	ML Proposed (mg/kg) (by the EWG – Step 3)	Portion of the Commodity / Product to Which the ML Applies
Spices, dried bark	2.5	3.0	Whole, ground, powder, crushed
Dried culinary herbs	2.5	2.0	Whole, ground, powder, crushed

Category	Details
1. Scientific Basis and Data Robustness	- Based on the ALARA principle balancing health protection and trade feasibility. - Uses comprehensive GEMS/Food database and new data from 2024 JECFA call. - Excludes outliers and compares datasets to reduce the influence of adulterated or erroneous data.
2. Public Health Protection	- Aims to reduce lead exposure from dried bark and culinary herbs, common in foods. - Limits set with rejection rate <5%, protecting consumers while being feasible for industry.
3. Trade and Practicality Considerations	- Limits maintain low rejection rates to avoid trade disruption and economic impact. - Updated data ensures limits reflect current contamination and market realities.
4. Alignment with Previous Work and Flexibility	- Builds on CCCF previous discussions, addressing missing data and adulteration. - Stepwise adoption (Step 4 and Step 7) allows further data submission and review for flexibility.
5. Potential Challenges and Considerations	- Geographic data coverage may still be uneven, limiting global applicability. - Continuous monitoring and data calls needed for emerging risks. - Smaller producers may need support to comply, especially in high-lead regions.

POTENTIAL IMPACT OF THE PROPOSED MLs

While the proposed MLs offer important health protections and align with international standards, countries will need to balance trade impacts, enhance monitoring capacity, and potentially support producers through the transition to meet these limits. Regional collaboration and capacity building will be key to maximizing benefits and minimizing challenges.

Aspect	Potential Impact	Comments
Trade and Export	- Potential increase in export rejections if local contamination exceeds MLs- MLs designed to keep rejection rates below 5%	Compliance is crucial to maintaining access to international markets
Public Health	- Reduction in dietary lead exposure- Protection of vulnerable groups, especially children	Expected positive impact on public health and food safety
Data Collection & Monitoring	- Possible challenges due to limited local data and testing capacity- Need to strengthen analytical and surveillance capabilities	Investment in infrastructure and expertise required
Economic & Regulatory Impact	- Additional costs for testing and compliance- Possible burden on small producers- Improved market reputation and access potential	Importance of support measures and regulatory alignment
Regional Cooperation	- Opportunities for data sharing and standards harmonization- Capacity building through collaboration	Encourages regional participation in JECFA data calls and CCCF

Conclusion and Recommendations

Member countries are encouraged to support the adoption of the new Maximum Levels (MLs) for lead in dried bark and dried culinary herbs. These MLs are scientifically grounded, based on updated and robust data applying the ALARA principle, and designed to protect public health by reducing dietary lead exposure. They also balance health concerns with trade practicality by maintaining rejection rates below 5%, minimizing economic disruptions for producers and exporters.

To ensure effective implementation, it is recommended that member countries promote ongoing data collection and regional data sharing to improve the representativeness of the MLs. Additionally, capacity building and technical support should be provided to small-scale producers, particularly in areas with naturally higher lead levels, to help them comply with the new limits. Regional cooperation in harmonizing standards and enforcement will be crucial, along with continuous monitoring and timely reporting of new data to CCCF for future ML reviews.

B. Agenda Item 7: Sampling plans for total aflatoxins and ochratoxin A in certain spices (at Step 7)

Document Number: CX/CF 25/18/7

Status in Codex Process: Step 7

Background

Entity	Year	Key Actions and Decisions
CCCF16	2023	- Noted the need for further work on sampling plans for total aflatoxins and ochratoxin A in certain spices. - Agreed to continue working via the Electronic Working Group (EWG) for presentation at CCCF17. - Used the EU sampling plan as the discussion starting point. - Decided to reconvene the EWG, chaired by India, to develop sampling plans considering all written comments.
CCCF17	2024	- Recognized the need for specific sampling plans and method performance criteria for total aflatoxins and ochratoxin A in nutmeg, dried chilli, and paprika. - Re-established the EWG to finalize the sampling plan. - Mandated the EWG to ensure alignment with Codex guidance and the General Standard for Contaminants in Food and Feed (CXS 193-1995). - Agreed to forward the sampling plans to CAC47 for adoption at Step 5.
EWG, chaired by India	2023–2025	- Developed and refined sampling plans for the agreed MLs. - Reviewed comments and aligned plans with commodity value, practicality, and performance criteria. - Circulated revised drafts for comments and CCCF consideration.
CAC47	2024	- Adopted the sampling plans at Step 5 as proposed by CCCF17.

At CCCF18, (2025), delegates will consider the EWG's proposals, notably the following elements to advance the development of the sampling plan:

Sampling Plans

- Finalize the sampling plan structure, subdivision logic, and sample size criteria as outlined in Appendix I, including unresolved items noted in square brackets, aiming for completion by CCCF18.
- Reject the proposed change to ≤20% precision and mandatory 200 g incremental sample size due to lack of scientific and operational feasibility.
- Correct table notation errors (e.g., change ">10–≤15" to ">10–<15") to prevent misinterpretation.

Numeric Performance Criteria for Methods of Analysis

- Retain current method performance criteria:
  - Precision at ≤44%.
  - Recovery between 60–115%.

Other Matters

- Consider adopting a separate maximum level (ML) of 15 µg/kg for AFB1 in future discussions, reflecting its toxicological importance and alignment with international standards.

Analysis

Seventeen countries participated in the Electronic Working Group (EWG), which conducted two rounds of virtual consultations from October 2024 to February 2025. Key contributors included Indonesia, Thailand, the USA, and Brazil. The group reviewed aflatoxin research, compared sampling methods, and evaluated analytical standards, emphasizing practicality for developing countries. The revised draft clarified sublot structures, aligned sample weights by particle size, and updated performance criteria according to Codex guidelines.

The EWG has developed a harmonized sampling plan for spices across different forms (whole, crushed, powdered), improving the structure, clarity, and scientific robustness of the text.

Key features of the updated draft include:

- Differentiated sampling approaches based on particle size.
- Clear guidance via detailed tables for incremental and aggregate sampling.
- Method performance criteria aligned with international standards.

Key Points Of Discussion

- **Sample Weight**: Proposal to increase incremental sample weight to 200 g was rejected; 100 g retained due to spice value.
- **Editorial Fixes**: Table notations corrected for clarity (e.g., ">10–≤15" to ">10–<15").
- **Powdered Spices**: Sampling values ([40 g], [80 g]; [0.1–4 kg]) remain unresolved.
- **Method Criteria**: Stricter limits (≤20% precision, 70–120% recovery) not accepted. Current criteria (≤44% precision, 60–115% recovery) maintained.
- **Table Format**: Headers improved; sublot columns kept for completeness.
- **AFB1 ML**: Separate ML of 15 µg/kg for AFB1 added, aligned with international norms.

Key Decisions

- Maintain **100 g** incremental sample weight.
- Retain **precision at ≤44%** and **recovery at 60–115%** for analytical methods.
- Consider establishing a separate ML for **aflatoxin B1 (AFB1)**, pending a broader CCCF agreement.

Outstanding Issues

- Sampling parameters for **powdered spices** (incremental and aggregate sample sizes) remain in square brackets for further discussion and resolution at CCCF18.

Conclusion and Recommendations

Member countries may support the ongoing Codex work to develop harmonized sampling plans for total aflatoxins and ochratoxin A in spices, commodities of important relevance to several regions' trade and food safety systems.

Progress was made at CCCF, including agreed definitions for particle sizes, a 10 kg aggregate sample weight, and alignment of the decision rule with other Codex sampling plans. However, key issues remain, particularly regarding sampling of powdered spices and numeric performance criteria for analysis.

Recommendations:

1. Participate in the EWG chaired by India to help address outstanding technical issues.
2. Submit regional data on spice handling and sampling, especially for powdered spices.
3. Coordinate regionally to present unified positions through Codex structures.
4. Align national standards with Codex and ISO definitions for consistency.
5. Engage in upcoming sessions (CCCF18, CAC48) to ensure regional interests are reflected.

C. Agenda Item 8: Maximum level and associated sampling plan for total aflatoxins in ready-to-eat peanuts (at Step 4)

Document Number: CX/CF 25/18/8 and CX/CF 25/18/8-Add.1 (At the time of conducting this analysis, these working documents had not yet been made accessible).

Status in Codex Process: Step 4

Background

CCCF Session	Key Actions / Discussions	Recommendations / Outcomes
2013 (CCCF07)	India proposed new work to establish an ML for AFT in RTE peanuts. EWG led by India was established.	Prepare discussion paper for CCCF08.
2014 (CCCF08)	Discussion paper considered. Work formally initiated. EWG re-established. CAC37 approved the new work.	Develop proposal for CCCF09.
2015 (CCCF09)	EWG proposed ML of 10 µg/kg. Requested JECFA exposure assessment for MLs of 4, 8, 10, and 15 µg/kg.	Await JECFA results before advancing ML.
2016 (CCCF10)	Work held at Step 4 pending JECFA results.	--
JECFA83	Concluded little additional health benefit at ML <15 µg/kg; rejection rates at 4 µg/kg were ~20% vs ~10% at 15.	--
2017 (CCCF11)	ML of 15 µg/kg proposed; faced opposition due to ALARA principle and inconsistency with MLs for other nuts.	Seek comments on MLs of 10 and 15 µg/kg (Step 3).
2018 (CCCF12)	No consensus on 10, 12, or 15 µg/kg.	Hold ML of 10 µg/kg at Step 4; JECFA to issue data call in 3 years.
2019 (CCCF13)	Item not discussed; held at Step 4.	Reminder status only.
2021 (CCCF14)	The Secretariat recalled suspension in 2018 to allow COP implementation; reconsider in 3 years.	--
2022 (CCCF15)	New data reviewed, still no consensus. Concerns over ALARA, rejection rates, and lack of RTE-specific data.	Return ML and sampling plan to Step 2/3.
2023 (CCCF16)	Data analysis improved; ~11,500 data points identified as likely RTE peanuts. Need to define "RTE peanuts."	Prepare RTE definition and categorize data for CCCF17; develop ML and sampling plan for CCCF18.
2024 (CCCF17)	- Applied existing RTE tree nut definition (CXS 193) to RTE peanuts - Established EWG (India chair, USA co-chair) - Requested JECFA to issue data call distinguishing RTE and FFP - Requested GEMS/Food to verify "unknown" data origin	EWG to develop ML and sampling plan for CCCF18; data clarification and call initiated.

At CCCF18 (2025), the EWG will present their proposal related to Maximum level and associated sampling plan for total aflatoxins in ready-to-eat peanuts considering the comments at Step 3 in reply to CL2024/12-CF.

D. Agenda Item 9: Revision of the code of practice for the prevention and reduction of aflatoxin contamination in peanuts

Document Number: CX/CF 25/18/9

Status in Codex Process: NA

Background

At JECFA49 (1998), the Joint FAO/WHO Expert Committee on Food Additives evaluated AFs (B1, B2, G1 and G2; AFT) and it was concluded that aflatoxins are human liver carcinogens with AFB1 as the most potent one. No tolerable daily intake was proposed since aflatoxins were considered genotoxic carcinogens. Thus, adoption of the ALARA (as low as reasonably achievable) principle was recommended to reduce the potential risk.

At JECFA83 (2017), the Joint FAO/WHO Expert Committee on Food Additives re-evaluated toxicological data and dietary exposure to AFs and reaffirmed the conclusions of the 49th JECFA meeting (FAO/WHO, 1998).

At CCCF16 (2023), the Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Peanuts (CXC 55-2004) was identified for possible review and agreed to establish an Electronic Working Group (EWG) chaired by Brazil to develop a discussion paper to explore whether there are new measures supporting revision of the CoP.

At CCCF16 (2023), the committee identified this code of practice (CoP) for revision as part of an overall work on the review of Codex standards for contaminants, knowing that there is already a maximum level (ML) of 15 µg/kg for peanuts for further processing adopted by the Codex Alimentarius Commission (CAC) and a proposed ML for ready-to-eat (RTE) peanuts under consideration by CCCF.

At CCCF17(2024), Brazil, as Chair of the EWG, introduced the agenda item, provided background, summarized the EWG's discussions and recommendations, and noted that new practices had been identified to prevent/reduce aflatoxin contamination in peanuts. These support the revision of CXC 55.

Discussion Highlights

- CCCF expressed general support for initiating the revision of CXC 55.
- The project document was slightly amended to clarify that the revision aims to support the implementation of maximum levels (MLs) for aflatoxins in peanuts.
- In response to a comment on including feed and merging the work with CXC 45-1997 (on aflatoxin B1 in feed for dairy animals), CCCF noted:
    - CXC 55 is currently limited to peanuts for human consumption.
    - The EWG may consider expanding the scope to animal feed.
    - Merging with CXC 45 could be considered under a separate agenda item.

Conclusion

CCCF agreed to:

- Start new work on the revision of CXC 55-2004.
- Forward the project document to CAC47 for approval.
- Establish an EWG, chaired by Brazil and co-chaired by India (working in English), to draft the proposed revision for CCCF18.

At CAC47 (2024), this new work was Approved.

At CCCF18, the EWG will invite Codex members to consider the revised Code of practice for the prevention and reduction of aflatoxin contamination in peanuts prepared by the EWG (CXC 55-2004) and to advance the COP in the Step Procedure for adoption by CAC48.

Work process and key points of discussion

- Two drafts of the revised CoP were shared within the EWG via the Codex Forum.
- 24 countries and 3 organizations participated in the EWG.

- Comments received from Australia, Cabo Verde, Canada, Costa Rica, Indonesia, Iran, Japan, the Netherlands, Nigeria, and the USA, were considered during the document's revision.
- The EWG revised different sections of the document notably: the scope, definitions, recommended practices based on good agricultural practices (GAP) and on good manufacturing practices (GMP), risk management for aflatoxin control in the peanut chain. Additional sections were introduced such as the introduction, related Codex texts, general recommendations.

The main changes proposed for the Code of Practice (CoP) are presented in the following table summarizing the key points from the revised CoP draft:

Topic	Details
Modification of Existing Practices	No changes to practices from CXC 55-2004 unless supported by new literature. Editorial changes made.
New Sections Added	- **Introduction and General Recommendations**: Summarizes aflatoxin formation and related practices. - **Related Codex Texts**: References Codex texts to be considered with the CoP. ● *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 feeding stuff for milk producing animals (CXC 45-1997)*
Revised Definitions	Definitions aligned with Codex texts and additional relevant definitions included.
Feed Included in Scope	Peanut by-products considered for feed, addressing aflatoxin contamination concerns.
Literature-Based Measures	Measures identified by Codex members to prevent/reduce aflatoxin contamination were included.
Removal of Irrelevant Information	Removed content unrelated to aflatoxin production, such as soil erosion and irrigation water quality.
Separation of Post-Harvest and Pre-Harvest Practices	Post-harvesting subsections were placed under Good Manufacturing Practices (GMP), while Good Agricultural Practices (GAP) focused on pre-harvesting and harvesting.
Peanut Growth Stages Table	A table added to clarify peanut reproductive growth stages and optimal harvesting maturity to minimize aflatoxin risk.
Moisture Content Disagreement	Debate occurred regarding the appropriate moisture content for peanuts after drying; the revised CoP recognizes divergent views on acceptable moisture content in peanuts post-drying. One member proposed aligning with CXS 200-1995's moisture levels of 10% for in-pod peanuts and 9% for kernels. However, the Standard acknowledges that lower limits may be necessary in relation to climatic conditions, transport duration, and storage environments—especially in tropical and hot regions where aflatoxin formation remains a risk even below 9% moisture.
Roasting as Aflatoxin Control	A new section added on the effect of roasting in reducing aflatoxin contamination.
Revised Risk Management Section	Replaced “Complementary Management System” with “Risk Management for Aflatoxin Control in Peanut Chain,” with clearer text and examples.

Analysis

The proposed revision of the Code of Practice (CoP) for aflatoxin management in peanuts aims to incorporate recent scientific data and effective risk management measures to reduce the Aflatoxin contamination in peanuts, addressing aflatoxigenic species identification and critical stages of peanut growth where contamination risks are heightened.

The table below highlights key factors that countries should consider in adopting the revised CoP principles, including local contexts, challenges, and perspectives.

Topic	Context	Recommendation
Existing Practices	Several countries mostly Arab countries (MENA) are involved in peanut production and trade, particularly Egypt and Sudan.	Ensure that the new version of the CoP is clearly communicated and adapted for local contexts, considering varying peanut production levels and aflatoxin management practices in different countries.
Inclusion of New Sections	The **Introduction** and **General Recommendations** sections may need to be tailored to reflect local knowledge and challenges, such as peanut cultivation practices.	Countries may benefit from more specific examples of aflatoxin-producing species and stages in peanut production that are prevalent in their regions. These details help tailor the best practices to regional needs.
Related Codex Texts	Codex guidelines are referenced, but countries should ensure they align with local regulatory measures.	Countries should ensure Codex texts align with local regulatory dispositions. Adapt recommendations to regional standards where necessary.
Revised Definitions	Revised definitions are essential, but countries may have variations in agricultural terminology and aflatoxin-related standards.	Conduct a review of the revised definitions to ensure compatibility with regional agricultural definitions and ensure alignment with updated CoP.
Feed Included in Scope	Peanut by-products are used for livestock feed, and aflatoxin contamination in feed is a growing concern.	Emphasize aflatoxin control in feed products. Launch awareness campaigns about aflatoxin risks in peanut-based animal feeds.
Literature-Based Measures	Some countries may lack resources to apply all literature-based measures identified.	Tailor the document to include practical, region-specific measures that can be implemented with limited resources. Focus on low-cost, effective practices suitable for small-scale farmers.
Post-Harvest and Pre-Harvest Practices	Many countries may lack post-harvest infrastructure.	Prioritize **GAP** (Good Agricultural Practices), focusing on pre-harvest stages like drying and moisture control. Provide simplified guidance for regions with limited post-harvest infrastructure and more detailed guidance for advanced processing facilities.
Peanut Growth Stages Table	The growth stages table is crucial, but climate in some areas may result in different peanut growth patterns.	Adapt the peanut growth stages table to reflect regional climatic conditions. Address aflatoxin risks in the context of local climates and provide guidance for handling peanuts in hot, dry regions.
Moisture Content Disagreement	Moisture content is a key issue linked to aflatoxin development, especially in hot, dry climates where drying can be challenging. Many countries, particularly in the Middle East and North Africa (MENA), are characterized by: High ambient temperatures, extended dry seasons, limited access to climate-controlled storage and varying humidity levels (coastal vs. desert areas). These conditions create a favorable environment for aflatoxin production, even when peanuts are dried to the Codex-recommended 9.0% moisture level.	Given the regional climate and infrastructure limitations, a stricter moisture limit (8.0%) is justified and recommended to effectively reduce the risk of aflatoxin contamination in peanuts. This adjustment would support food safety, enhance marketability (especially for export), and protect public health across the region. To consider practical drying solutions, such as drying facilities or low-tech methods suitable for small farmers.
Roasting as Aflatoxin Control	Roasting peanuts is widely practiced in several countries, especially for local snack production.	Highlight roasting as an effective aflatoxin reduction method. Provide clear guidelines on roasting temperatures and times for small and medium-scale processors.
Revised Risk Management Section	Risk management in the peanut supply chain may not be as formalized in many countries.	Provide clear examples of risk management practices in the peanut supply chain. Focus on practical steps for smaller farmers and processors. Offer examples of how countries can implement these practices within their own regulatory frameworks.

Conclusion and Recommendations

Given the importance of reducing aflatoxin exposure from peanuts, codex delegations might support advancing the revised CoP presented by the EWG in the step procedure for adoption by CAC48, reflecting the advancement in research and to integrate new practical applications across regions.

For the Adoption of the Revised CoP by countries and considering their national context, additional considerations should be considered related to the application of the revised CoP principals, such as:

- **Encourage the adoption of the COP**: countries should adopt the revised CoP as a foundational framework for managing aflatoxin contamination in peanuts. This adoption will help align national standards with international Codex recommendations, ensuring consistent food safety and quality practices across the region.
- **Develop National Aflatoxin Control Programs**: countries should establish or update national aflatoxin control programs based on the revised CoP. This includes introducing specific regulations for aflatoxin monitoring, early detection, and contamination control, particularly in high-risk production areas.
- **Develop and adopt risk management practices** within the peanut supply chain, with a focus on actionable steps tailored to small-scale farmers and processors. Highlight how these practices can be adapted and applied within the regulatory frameworks of countries.
- **Capacity Building and Training**: countries should invest in capacity building by organizing training programs, workshops, and seminars for farmers, food processors, and regulatory bodies. These programs should focus on the principles of the revised CoP, aflatoxin risks, control measures, and how to implement best practices in local contexts.
- **Regional Collaboration and Knowledge Sharing**: Encourage collaboration between countries to share knowledge, experiences, and best practices related to aflatoxin control. Regional forums or working groups could be established to facilitate discussions and create harmonized versions of the CoP approach for managing aflatoxin contamination.
- **Promote Research and Innovation**: Encourage local research institutions to conduct studies on aflatoxin contamination specific to regional peanut production. This can lead to the development of innovative solutions, such as new peanut varieties resistant to aflatoxin-producing molds, or more efficient drying and storage technologies suitable for local conditions.
- **Provide Support for Infrastructure Development**: Invest in the necessary infrastructure, such as improved drying and storage facilities, to ensure proper aflatoxin management in peanuts. This is particularly important for regions with high humidity or temperature fluctuations that make it difficult to control moisture levels during harvest and storage.

By addressing these considerations and implementing the revised CoP's principles, countries can enhance their food safety systems, reduce aflatoxin risks, and improve the overall quality and safety of peanuts in the region.

E. Agenda Item 11: Review of the Code of practice for the reduction of acrylamide in foods (CXC 67-2009)

Document Number: CX/CF 25/18/12 (At the time of conducting this analysis, the working document had not yet been made accessible)

Status in Codex Process: NA

Background

- Acrylamide, a potentially carcinogenic compound found in various foods, poses health concerns, especially for infants and children, who have higher exposure levels than adults.
- The Codex Committee on Contaminants in Foods (CCCF) has initiated work to address concerns about acrylamide, a potential carcinogen found in foods.
- An Electronic Working Group (EWG) was established to develop a Code of Practice (CoP) for reducing acrylamide in food.
- Building on scientific assessments from bodies like JECFA and EFSA, the CCCF aims to harmonize risk management strategies to protect consumer health and facilitate global trade.

The main decisions made by CCCF are:

CCCF Session (Year)	Conclusions and Recommendations
CCCF16 (2023)	Established EWG chaired by India and co-chaired by Saudi Arabia to prepare a discussion paper on acrylamide in foods for CCCF17.
CCCF17 (2024)	CCCF expressed general support for revising the Code of Practice (CXC 67), contingent on further assessment of new mitigation measures. It was agreed that issuing a Codex Circular Letter (CL) to collect information on risk management practices would better support the Electronic Working Group (EWG) than requesting occurrence data at this stage. CCCF decided to: - Re-established the EWG (India/Saudi Arabia) to develop a discussion paper including a proposal for a revised Code of Practice. - To issue a Circular Letter (CL) to collect information on new risk management measures for acrylamide reduction.

At CCCF18 (2025), the EWG will present a proposal related to the development of a discussion paper including a proposal for a revised Code of Practice.

At the time of conducting this analysis, the report of the EWG had not yet been made accessible.

Analysis

Key points

Acrylamide is considered genotoxic and carcinogenic, with health risks dependent on exposure levels. The 2004 JIFSAN Workshop found that existing epidemiological studies lacked sufficient statistical power to confirm cancer risks at dietary exposure levels.

Both the European Commission and JECFA have emphasized the need for more systematic and comprehensive studies on acrylamide exposure and its risks. Reported average exposure levels vary by country, with infants and children identified as the most vulnerable group, at least twice those of adults.

According to JECFA, average dietary intakes result in margins of exposure (MOEs) that are generally of low concern, but MOEs for high consumers, especially related to neurotoxicity and carcinogenicity, are significantly lower, indicating potential health risks.

JECFA and other bodies (e.g., WHO, EU) recommend continued efforts to reduce acrylamide in food and water, highlight the need for updated toxicological data, and emphasize the importance of improved exposure assessment, *particularly in developing countries*.

In its final report (CX/CF 24/17/12, 2024), based on the scientific documentation studied, the EWG summarized the following key information related to Acrylamide (AA) in Foods:

Topic	Main Findings
Toxicology & Toxicokinetics	AA is rapidly absorbed and metabolized mainly to glycidamide via CYP2E1; distributed widely including fetus; neurotoxicity, reproductive toxicity, genotoxicity reported in animals; human variability in metabolism exists.
Toxico-dynamics	Neurotoxicity (peripheral and central nervous system), developmental and reproductive toxicity in rodents; morphological nerve changes at dietary levels.
Analytical Methods	LC-MS/MS and GC-MS are most reliable; methods provide sensitive, reproducible detection; emerging tools include immunoassays, NIR, image analysis for process control.
Occurrence Data	Acrylamide levels vary with food type and processing; highest in fried/baked potato products and coffee; low/none in fruits, chicken meat, herbal tea.
Dietary Exposure	Average human exposure low (~0.2–0.5 µg/kg bw/day); infants and children more exposed; epidemiological studies inconclusive on cancer risk. Despite existing studies, both international organizations (e.g., EFSA, JECFA, European Commission) and researchers agree that current data are insufficient to fully assess the risks, highlighting the need for more robust and comprehensive research on acrylamide exposure and its health effects.
Risk Assessment	MOEs suggest low risk at average intake; nerve effects possible in high consumers; ongoing need for long-term studies and pharmacologically based pharmacokinetic (PBPK) modelling recommended.
Risk Management	Complete elimination impossible; mitigation includes process changes (storage, enzyme use, fermentation); monitoring ongoing in EU, Canada, USA; continuous risk management recommended.
Conclusion & Recommendations	Continue efforts on occurrence and exposure data collection; update toxicity data; promote mitigation strategies; encourage data sharing among countries.

Conclusion and Recommendations

Member countries are encouraged to actively support and contribute to the EWG's work on revising the Code of Practice for acrylamide reduction. To effectively contribute to the global efforts on acrylamide risk management, member countries are encouraged to support and actively participate in the ongoing work of the EWG. Their involvement can be enhanced through the following actions:

- **Provide region-specific data** on acrylamide occurrence and dietary exposure, reflecting local food consumption patterns and processing methods.
- **Lead or collaborate on regional research** to better understand acrylamide levels in traditional and staple foods unique to national/regional diets.
- **Develop culturally appropriate mitigation strategies**, such as adapting cooking methods or ingredient substitutions that align with local culinary practices.
- **Establish national or regional monitoring programs** to track acrylamide levels in food products and assess the effectiveness of mitigation measures.
- **Organize capacity-building initiatives and training workshops** to strengthen expertise in acrylamide risk assessment, monitoring, and control.
- **Engage in international collaboration** to share data, experiences, and benefit from best practices with other countries.

F. Agenda Item 12: 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)

Document: CX/CF 25/18/13

Status in Codex Process: NA

Background

- **CCCF13 (2019)** agreed to establish an electronic working group (EWG) chaired by Canada and co-chaired by Japan and the United States of America to develop an approach for reviewing existing Codex standards developed by CCCF.
- **CCCF14 (2021)** agreed to establish tracking lists of Codex standards, an approach and prioritization criteria for recommending existing Codex contaminant standards for review, and to implement this approach for a three-year trial period (2022-24).
- **CCCF15 (2022)** agreed to maintain, without further prioritization, tracking Lists A and B and to create an Ov**erall Highest Priority List** of Codex Standards and Related Texts for Contaminants in Food and Feed (the "OHPL"),
- **CCCF16 (2023)** agreed to establish an electronic working group (EWG) chaired by Canada to develop a discussion paper on the 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)
- **CCCF17(2024)** agreed to re-establish the EWG, chaired by Canada and co-chaired by Saudi Arabia to: (i) revise the discussion paper; (ii) propose revisions to CXC 45-1997; (iii) consider how other related Codex CoPs of practice could be integrated or merged to avoid overlap, inconsistencies, and redundancies; and (iv) prepare a project document for new work.
- **At CCCF18**, the EWG will invite CCCF to consider initiating a revision of the *Code of Practice for the Reduction of Aflatoxin B1 (CXC 45-1997)*. If agreed, CCCF should:
  - Review and adjust the project document for submission to CAC48 (2025).
  - Assess the proposed outline, especially:
    - Integration with related Codex Codes to avoid overlaps.
    - Appropriateness of revisions and availability of supporting data.
  - Consider issuing a circular letter to gather relevant risk management practices and data.
  - Re-establish the EWG to further develop the Code for review at CCCF19 (2026).

Work process and key points of discussion

- (27) Codex Members and one (1) Codex Observer participated in the EWG.
- Two rounds of comments on the proposed edits to CXC 45-1997 and its associated appendices, notably on the new technical information proposed for inclusion in the CoP, as well as the document's structure and approach to integrating related Codex texts.
- Two Codex Members provided comments during the first round, and four (4) Codex Members commented in the second round and revision of The CoP were done accordingly.

The key points discussed by the EWG members, regarding the proposed changes to the (CoP), including updates to technical content, structure, and guidance integration, are presented in the following table.

Point	Details
General Consensus	There was overall agreement among EWG members on the technical content, structure, and integration approach for the proposed revisions.
Support for Revision	The EWG supports revising CXC 45-1997 due to the significant amount of new and updated information available since its drafting 28 years ago.

Improved Practical Guidance	An updated CoP would more accurately and comprehensively provide practical aflatoxin B1 control measures in feed for milk-producing animals.
Alignment with Other Codex Texts	The revised CoP aims to align with recently updated Codex CoPs on aflatoxins in cereals and other feed ingredients, avoiding overlap, inconsistencies, and redundancy.
Integration of Relevant Measures	Measures from CXC 51-2003 applicable to non-cereal crops (e.g., legumes, oilseeds) have been incorporated, along with a new 'Related Guidance' section listing relevant Codex texts.
Concerns About Document Length	Some members commented on the lengthiness of the revised CoP and recommended internal streamlining where possible.
Streamlining and Redundancy	Efforts will continue to reduce redundancy within and between Codex texts if the revision is approved as new work.
Need for More Data and Participation	Broader input, especially from tropical regions, is needed to enhance the CoP. ***A circular letter (CL) requesting additional aflatoxin management information may be necessary.***

Analysis

The EWG has proposed a **revision of the Codex Code of Practice (CXC 45-1997)**, which addresses the **reduction of aflatoxin B1 contamination in raw materials and supplemental feedstuffs for milk-producing animals**.

Several documents support this proposal for new work and are presented in the proposal as an annex:

Appendix	Content
Appendix I	Project document proposing new work to revise CXC 45-1997
Appendix II	Proposed revisions to the CoP: a new text is underlined; deletions shown in strikethrough. Yellow highlights show integrated text from CXC 51-2003.
Appendix III	Key references used in drafting the updated CoP
Appendix IV	Voluntarily submitted national control strategies
Appendix V	National regulations for aflatoxin B1 in animal feed

Points of Interest

- **Climate Risks:** Many countries face **hot and humid** or **semi-arid climates**, conditions that significantly increase the risk of aflatoxin B1 contamination.
- **Agricultural Relevance:** Feed materials like maize, sorghum, and oilseeds are either locally produced or imported in large quantities across several regions.
- **Livestock Industry:** Aflatoxin-contaminated feed can harm the **dairy and livestock sector**, affecting milk safety and public health.

Opportunities

- **Participate in the Circular Letter (CL):** By providing **risk management practices and national standards**, countries can shape the final CoP to better fit their realities.
- **Support Regional Harmonization:** regional contributions can promote **coherent policies** across regions, reducing trade barriers and enhancing food safety compliance.

Challenges to Address

- **Data Gaps:** Limited published data from some countries may hinder full regional representation in the revision process.
- **Resource Constraints:** Smaller feed producers may require technical support to comply with updated Codex guidance.

Conclusion and Recommendations

Several member countries have strong reason to engage in the proposed revision of CoP CXC 45-1997 due to their climatic, agricultural, and food safety realities:

Several regions are characterized by semi-arid to humid climates, which make crops and feed more susceptible to aflatoxin B1 contamination, a major concern for public health and trade. Additionally, many countries have growing dairy and livestock sectors, where contaminated feed can directly affect milk safety and consumer health.

Member countries might give their support to the EWG's proposal. The revised CoP presents an opportunity to shape international guidance that reflects regional conditions and supports harmonized food safety standards:

By contributing through locally representative data submission, countries can ensure the updated CoP is both **effective and relevant** for their context.

Member countries are encouraged to:

- Participate in the Electronic Working Group (EWG) and to respond to the upcoming **Circular Letter (CL)** with national data on aflatoxin B1 in feed, including: Surveillance data, risk management strategies and national regulations.
- Promote Regional Coordination and develop joint Codex positions to strengthen impact and foster regional policy alignment.
- Support Implementation of the CoP locally:
  - Invest in **capacity-building and training** for feed producers, especially small and medium-scale operations.
  - Strengthen national surveillance and regulatory systems for aflatoxin control.

G. Agenda Item 13: Development of a Code of practice for the prevention and reduction of tropane alkaloids in food and feed

Document Number: CX/CF 25/18/14

Status in Codex Process: NA

Background

Year	Committee/ Organization	Action / Outcome
2020	FAO/WHO Expert Meeting	Provided scientific advice on the risks of Tropane Alkaloids (TAs) in foods.
2022	(CCCF15)	Noted the need for follow-up actions based on the FAO/WHO Expert Meeting's advice.
2023	(CCCF16)	Established an Electronic Working Group (EWG), chaired by China and co-chaired by Saudi Arabia, to prepare a discussion paper on the need and feasibility of actions on TAs.
2024	(CCCF17)	Reviewed the first discussion paper (CX/CF 24/17/11) prepared by the EWG. Re-established the EWG (same chairs) to develop a revised discussion paper including: A proposed Code of Practice A project document for CCCF18. Requested JECFA to issue a call for data on TA contamination in food and feed, with guidance on sampling stages.

At CCCF18 (2025): CCCF is invited to decide whether the current data and information provided are sufficient to support new work on a Code of Practice (CoP) for preventing and reducing TA contamination in food and feed.

If yes, CCCF should:

- Review and adjust the project document and forward it to CAC48 (2025) for approval as new work.
- Assess the draft CoP outline for structure, content, and areas needing improvement following approval of new work by CAC48,
- Re-establish the EWG to further develop the CoP for CCCF19 (2026), based on the guidance provided by CCCF18.

If not and the discussion paper needs further development:

CCCF is invited to identify gaps and needed data/information to guide the EWG's future work.

Analysis

Work Process and Key Point Discussed by the EWG

23 countries and 3 organizations participated in the EWG. The draft CoP was circulated twice. Comments were received from Brazil, China, France, Japan, Mexico, and the USA.

A summary of the key elements and modifications considered during the development of the draft Code of Practice (CoP) on Tropane Alkaloids and the related rationale are presented are presented below:

1. **Retention of Original Title**
   The original title was retained to reflect the broad scope of the CoP, covering field-level to consumer-level measures, and to allow future inclusion of other TA-producing plants.
2. **Inclusion of Animal Feed in Scope**
   Although initially excluded, animal feed was reintroduced to address direct health effects in animals and align with the One Health approach.
3. **Reference to Codex Feed Guidance (CXC 54-2004)**
   This ensures consistency with existing Codex feed standards, improving global applicability and ease of implementation.

4. **Conditional Future Inclusion of Other TA Plants**
Expansion to other species such as *Atropa belladonna* was considered, especially for equine health, but deferred pending further scientific data.

5. **Emphasis on Processing Stage Data Needs**
More information is needed on TA levels during processing to assess effectiveness of mitigation strategies. Current data lack traceability and representativeness.

6. **Field Management as Primary Control Strategy**
Weed control in the field remains the most effective method to reduce TA contamination, despite gaps in processing-stage data.

In the EWG's report, supporting Appendices were provided notably:

- Appendix I: related to the new work proposal.
- Appendix II: Draft CoP.
- Appendix III: Data analysis on TA occurrence in food and feed.

Key points of discussion are presented in the table below:

Modification	Rationale
1. Retention of Original Title	The broader title reflects the CoP's comprehensive scope, including field, processing, and consumer-level measures. It also allows future inclusion of other TA-producing plants (e.g., Atropa belladonna).
2. Inclusion of Animal Feed in Scope	Although initially excluded due to minimal human health risks (EFSA, 2008), it was reintroduced to address direct animal health impacts and protect farm productivity under the One Health approach.
3. Reference to Codex Feed Guidance (CXC 54-2004)	Ensures alignment with existing Codex standards for animal feed, supporting global consistency and ease of implementation.
4. Conditional Future Inclusion of Other TA Plants	Suggested expansion to include species like Atropa belladonna, especially due to equine sensitivity, was postponed pending further scientific evidence.
5. Emphasis on Processing Stage Data Needs	More data is needed on TA levels during post-harvest and processing to assess mitigation effectiveness; current data lack sampling context and traceability.
6. Field Management as Primary Control Strategy	Despite data gaps in processing, strong weed control at the field level remains the most effective and proven method to reduce TA contamination.

The main sections and information provided in the discussion paper:

Section	Key Points / Content Summary
Introduction	Presents updated data from GEMS/Food and EWG input. Builds on previous work (CCCF17, CX/CF 24/17/11).
Information available to Develop CoP	Focus shifts from toxicology and risk (covered previously) to strategies for controlling TA contamination in food and feed.
Key TAs & Risk Focus	Atropine and scopolamine are primary toxins, causing acute health risks requiring proactive risk management to prevent spikes.

Exposure Sources	1) Unintentional contamination from Datura and other TA plants mixed with staple crops during processing/storage. 2) Misidentification by consumers ingesting toxic plant parts.
CoP Control Focus	1) Supply-chain interventions: phytosanitary monitoring, mechanical sorting to exclude contaminated material. 2) Public awareness via education, visual ID tools, and workshops.
TA-Containing Plants	Widespread in several plant families; main concern is Datura species causing sporadic high contamination events in food/feed.
Occurrence Data in food and feed	Extensive GEMS/Food data (2006-2023) analyzed; contamination mostly sporadic, highest in cereals, spices, herbs, feeds.
Processing Impact	Lack of processing-stage data; current evidence shows limited effect of food processing on TA reduction; prevention critical.
Feasible Mitigation Measures	Effective control through: - Weed management (herbicides, integrated approaches)- Crop rotation, soil management, seed purity- Monitoring, removal, cleaning, traceability- Training and consumer awareness campaigns.
Key Recommendations	Emphasize field management and supply-chain controls, complemented by consumer education for effective TA contamination mitigation.

Conclusion and Recommendations

Tropane alkaloids (TAs), particularly atropine and scopolamine, are naturally occurring plant toxins that may contaminate food and feed through co-harvesting with TA-producing weeds (e.g. Datura species). The risk is especially relevant for herbal infusions, cereals, legumes, and spices, which are widely consumed and traded in several countries. The lack of national/regional-specific occurrence data limits the ability to assess and manage risks effectively at the national and regional levels.

Member countries are encouraged to actively support and contribute to the ongoing work in Codex (CCCF18) to revise the Code of Practice for the Prevention and Reduction of Contamination by TAs considering the opportunity to strengthen preventive measures globally and in a regional context.

Member countries are encouraged to:

1. Actively participate in the Electronic Working Group (EWG) on TAs, providing feedback on draft documents and sharing relevant national data.
2. Initiate or strengthen monitoring programs to generate occurrence data on TAs in locally consumed food commodities; considering that current used data and proposed mitigation strategies are largely based on European contexts, which may not fully reflect the practices or risks in other regions.
3. Identify and document existing mitigation practices used in the region to prevent TA contamination, especially during harvesting and processing.
4. Advocate for inclusive and geographically representative data during CCCF discussions to ensure Codex guidance reflects global realities.
5. Promote capacity-building in analytical methods for detecting TAs in national food safety laboratories.

These actions will reinforce the contribution of countries to Codex work and help ensure that the revised Code of Practice is globally applicable, risk-based, and implementable at national levels.

H. Agenda Item 15: Review of numeric performance criteria for methods of analysis for total aflatoxins utilizing the sum of components concept in relevant sampling plan

Document Number: CX/CF 25/18/16

Status in Codex Process: NA

Background

At CCCF16 (2024), the Codex Committee considered a request from CCMAS42 (2023) to:

- Revise numeric performance criteria for aflatoxin methods using the sum of components approach across all relevant commodities.
- Evaluate all sampling plans in CXS 193-1995 to ensure alignment with the updated General Guidelines on Sampling (CXG 50-2004).

At CCCF18 (2025), delegates will discuss EWG's proposals. Brazil volunteered to review and propose revised numeric performance criteria for aflatoxins for CCCF18 (2025).

CCCF is invited to consider the following actions:

- **Review the revised method performance criteria** proposed in the Appendix for:
  - Peanuts intended for further processing
  - Ready-to-eat tree nuts
  - Tree nuts for further processing (almonds, hazelnuts, pistachios, and shelled Brazil nuts)
  - Dried figs
    These revisions aim to replace the current performance criteria in the respective sampling plans under the *General Standard for Contaminants and Toxins in Food and Feed (CXS 193-1995)*.
- **Submit the revised criteria to CCMAS** for endorsement and for subsequent adoption by CAC48.
- **Note:** Once endorsed by CCMAS and adopted by CAC, the numeric performance criteria for the methods of analysis in these sampling plans will be replaced by a reference to the *Recommended Methods of Analysis and Sampling (CXS 234-1999)*, which will house the updated criteria.

Analysis

METHODOLOGY FOLLOWED BY THE EWG

The methodology adopted for establishing the method performance criteria for total aflatoxins in specified commodities is designed to ensure analytical methods intended to meet rigorous, harmonized standards for sensitivity, accuracy, and reliability.

Key elements and considerations of this approach are summarized below:

Point element	Description
Scope	This work excludes the broader review of sampling plans, which remains pending.
New Approach	A new approach based on AFB1:AFB2:AFG1:AFG2 = 1:1:1:1 is proposed for certain nuts and dried figs, differing from CAC46 (2023) criteria for cereals.
Focus of Methodology	Establishes clear, measurable criteria for methods to reliably detect and quantify total aflatoxins (AFB1, AFB2, AFG1, AFG2) in peanuts, tree nuts, and dried figs.
Maximum Level (ML)	The regulatory aflatoxin concentration limit (µg/kg) allowed in the commodity.
Limit of Detection (LOD)	Lowest concentration at which aflatoxins can be reliably detected (not necessarily quantified).

Limit of Quantification (LOQ)	Lowest concentration at which aflatoxins can be quantitatively measured with acceptable precision.
Precision (%)	Acceptable variability in repeated measurements to ensure repeatable/ reproducible results.
Minimal Applicable Range	The validated concentration range over which method performance is guaranteed.
Recovery (%)	Efficiency of aflatoxin extraction and detection from the commodity, expressed as a percentage of known value.
Tailored Methodology	Criteria differentiated for commodities intended for further processing vs. ready-to-eat, reflecting contamination risks and consumption patterns.
Objective	Harmonize testing methods globally to facilitate consistent enforcement, improve monitoring reliability, and protect public health.

ANALYSIS OF THE METHODOLOGY FOLLOWED BY THE EWG

The proposed methodology is technically sound, internationally harmonized, and aligned with Codex updates. It supports reliable monitoring and enforcement of MLs for aflatoxins, with appropriate sensitivity and applicability across different commodity types.

The analysis of the proposed method performance criteria for total aflatoxins in various commodities is summarized in the table presenting the evaluation of each parameter:

Parameter	Description	Evaluation
Target Commodities	Peanuts (processing), Tree nuts (processing & ready-to-eat), Dried figs	Key high-risk foods for aflatoxin contamination
Analyte	Total aflatoxins (AFB1 + AFB2 + AFG1 + AFG2), and individual components	Aligned with Codex's 1:1:1:1 sum-of-components approach
Maximum Level (ML)	15 µg/kg (processing), 10 µg/kg (ready-to-eat and figs)	Reflects current Codex MLs
Limit of Detection (LOD)	≤3 µg/kg for ML = 15 µg/kg; ≤2 µg/kg for ML = 10 µg/kg	Enables detection well below ML thresholds
Limit of Quantification (LOQ)	≤6 µg/kg (ML = 15); ≤4 µg/kg (ML = 10)	Ensures quantifiable results at or below ML
Precision	Coefficient of variation < 44%	Acceptable for complex food matrices, but relatively high
Applicable Range	Total AFs: 8.4–21.6 µg/kg (ML = 15); 5.6–14.4 µg/kg (ML = 10)	Suitable dynamic range for accurate quantification near ML
Recovery (%)	Total AFs: 60–115%; Individual AFs: 40–120%	Meets Codex validation guidance; wide range could affect accuracy for individual components
Harmonization with Codex	Based on 2023 CCMAS/CAC decisions; reference to CXS 234 expected	Supports standardization and future referencing under Codex Methods (CXS 234-1999)
Implementation Considerations	May require high-end instrumentation; feasibility in some countries could be challenging	Implementation support or capacity building may be needed

POTENTIAL IMPACT OF THE PROPOSED MLs

Analysis and recommendation regarding the proposed method performance criteria for total aflatoxins in peanuts, tree nuts, and dried figs:

Aspect	Implication for Countries
Relevance of Commodities	Peanuts, almonds, pistachios, and dried figs are widely produced, imported, or consumed in many countries.
Analytical Sensitivity (LOD/LOQ)	The low LODs and LOQs (down to 0.5 µg/kg) require advanced analytical equipment, such as HPLC with fluorescence detection or LC-MS/MS.
Precision & Recovery Requirements	Achieving <44% precision and 60–115% recovery for total AFs may be challenging for under-equipped labs but still reasonably achievable.
Regulatory Alignment	Adoption of these criteria would align national standards with Codex and support international recognition of results.
Laboratory Capacity Gaps	Not all countries may have the infrastructure, trained personnel, or budget to implement the proposed methods fully.
Trade and Compliance	Harmonizing with Codex will facilitate exports and reduce rejection risks in international markets.

Conclusion and Recommendations

Member countries are encouraged to adopt the proposed method performance criteria to align with Codex standards, ensuring consistency in aflatoxin monitoring globally. To support this, member countries should first assess their national laboratory capacities through a gap analysis to identify areas requiring improvement.

Where gaps exist, investment in analytical equipment and training is essential, potentially facilitated through regional cooperation or international support from organizations such as FAO, IAEA, and AOAD. Implementation may be phased, focusing initially on high-risk commodities and key import/export sectors to optimize resources.

Strengthening regional collaboration by establishing reference laboratories as centers of excellence will enhance method validation and training.

Finally, active participation in Codex forums like CCCF and CCMAS is vital to represent national/regional interests and share experiences throughout the implementation process.

I. Agenda Item 16: Application of maximum levels to multi-ingredient products CL 2025/03-CF

Document Number: CX/CF 25/18/17

Status in Codex Process: NA

Background

At CCCF17 (2024), questions were raised about maximum levels (MLs) for mycotoxins in spice mixtures.

- A proposal was made by the Codex and host Secretariats (CRD37) to include a note in the General Standard for contaminants (CXS 193-1995) suggesting the application of individual MLs to the whole mixture based on the relative proportions of ingredients.
- Several views were expressed on this proposal, noting that the issue extends beyond spices to other mixtures, and the General Standard already offers guidance for handling mixtures.
- CCCF17 suggested that the Codex Secretariat issue a circular letter (CL) to request comments on the need for further guidance for multi-ingredient products.
- The circular letter invites Codex members and observers to comment on the following points:

  (a) The necessity for further guidance on multi-ingredient products, and

  (b) If such guidance is needed, to propose:

  - An amendment to the current guidance in the General Standard (CXS 193-1995), particularly regarding the establishment of MLs for mixtures, or
  - Adding a note to the MLs in question, or
  - Any other suitable proposals.

  The Annex to the CL provides further background, including possible scenarios involving MLs for mixtures, and encourages members to suggest additional scenarios and feedback on the issues raised.

Analysis

Scientific summary of the document

This document outlines the principles and methods for establishing and applying maximum levels (MLs) of contaminants in food and feed, specifically for processed, multi-ingredient, and derived products. It underscores the importance of scientifically validated approaches to ensure food safety while addressing the practical challenges of applying these standards.

The framework provided is based on the Criteria for Establishing Maximum Levels in the General Standard for Contaminants in Food and Feed (CXS 193-1995), offering an approach for the application of MLs to processed and multi-ingredient products. The document also identifies practical issues, such as unknown ingredient proportions in mixtures, and proposes solutions for determining MLs in these situations.

Following concerns raised at CCCF17 about the lack of knowledge regarding the composition of multi-ingredient products like spice mixtures, the document suggests applying the lowest ML of individual ingredients to the entire mixture when proportions are unknown. If the contaminant level exceeds this ML, further investigations would be needed to determine the ingredient proportions and assess compliance.

Additionally, the document proposes the inclusion of a footnote in the Codex Standard (CXS 193-1995) to provide clarification on how to handle cases with uncertain ingredient proportions. It also suggests that further provisions may be required to ensure the effective application of MLs in multi-ingredient and processed products.

To support the implementation of these guidelines, practical examples are provided, demonstrating how MLs for spice mixtures can be calculated in scenarios with known and unknown ingredient proportions.

Summary of the key points

Current Codex Provision (CXS 193-1995, Annex 1):

- MLs are primarily established for raw agricultural products.

- For processed and multi-ingredient foods, MLs can be applied using concentration or dilution factors based on product composition and contaminant behavior during processing.
- Separate MLs may be established for processed products if contamination patterns differ consistently or if contamination occurs during processing.
- This approach relies on knowing the composition and contaminant behavior in processed or multi-ingredient foods.

Limitations Identified:

- In many cases, especially with products like spice mixtures, the relative proportions of ingredients are unknown or difficult to determine.
- This lack of compositional data challenges the practical application of MLs using the current standard's approach.
- Without ingredient proportion data, enforcement and compliance assessment become complex and inconsistent.

Proposed New Work / Practical Approach:

- As discussed at CCCF17, a pragmatic solution is to apply the lowest ML of any individual ingredient as a screening level to the entire multi-ingredient mixture when proportions are unknown.
- If contaminant levels are below or equal to this lowest ML, the product is considered compliant with no further testing needed.
- If levels exceed this threshold, further investigation into ingredient proportions is required to assess compliance accurately.
- The Committee is considering adding this approach as additional guidance or a footnote to the existing standard for clarity and practical use.
- This new work aims to balance enforceability, consumer protection, and feasibility in cases where compositional data are unavailable.

PROPOSED CALCULATION OF MLs:

When ingredient proportions are known, the ML for the mixture is calculated as a weighted average of the MLs of individual ingredients.

When the proportions of ingredients in a mixture are unknown, the lowest ML is applied. If the contaminant concentration exceeds that ML, the relative proportions must be determined and the ML recalculated accordingly.

Here's a clearer explanation of the examples and calculations:

Example 1: Mixture of Spices A, B, C, and D with Unknown Proportions

Spices involved	**A, B, C, D**
MLs	Spice A has an ML of 2 mg/kg, while spices B, C, and D have no MLs
Step 1	Apply the ML of 2 mg/kg to the entire mixture, as the proportions of each ingredient are unknown.
Compliance conditions	• **Compliant condition**: If the concentration of the contaminant in the mixture is ≤ 2 mg/kg, the mixture is compliant. • **Non-compliant condition**: If the concentration exceeds 2 mg/kg, you must determine the proportions of each spice in the mixture.
Step 2	If the proportion of spice A in the mixture is 1/3 (i.e., 33% of the mixture), you calculate the new ML for the mixture. **New ML calculation**: 3 * 2 mg/kg (ML of Spice A) = 6 mg/kg
Conclusion	**The new ML for the mixture is 6 mg/kg, so if the contaminant concentration is below 6 mg/kg, the mixture is compliant.**

Example 2: Mixture of Spices A, B, and C with Known MLs

Spices involved	**A, B, C**
MLs	Spice A has an ML of 3 mg/kg, Spice B has an ML of 6 mg/kg, and Spice C has an ML of 9 mg/kg.
Step 1	Apply the ML of 3 mg/kg (the lowest ML) to the entire mixture.
Compliance	• Compliant condition: If the concentration of the contaminant is ≤ 3 mg/kg, the mixture is compliant. • Non-compliant condition: If the concentration exceeds 3 mg/kg, you must determine the proportions of each spice in the mixture.
Step 2	If the spices are in equal proportions (1/3 each), the ML for the mixture is calculated by averaging the MLs weighted by the proportion of each spice. **New ML calculation: (1/3 * 3 mg/kg) + (1/3 * 6 mg/kg) + (1/3 * 9 mg/kg) = 6 mg/kg**
Conclusion	If the concentration is ≤ 6 mg/kg, the mixture is compliant.
Step 3	If the proportion of spice A is 1/2 of the mixture (50%), and the other spices (B and C) each make up 1/4 (25% each), the ML is recalculated based on these proportions. **New ML calculation**: (1/2 * 3 mg/kg) + (1/4 * 6 mg/kg) + (1/4 * 9 mg/kg) = 5.25 mg/kg
Conclusion	**If the concentration is ≤ 5.25 mg/kg, the mixture is compliant.**

SUMMARY OF COMMENTS RECEIVED FROM CODEX MEMBERS AS A RESPONSE TO THE CL

Most Codex members support **further guidance** for applying **MLs** to **multi-ingredient products**, especially spice mixtures. Key issues include the **unknown proportions** of components, **lack of specific MLs** for composite products, and **analytical or enforcement difficulties**.

(a) Necessity for Further Guidance

- **Broad support** from members such as **Argentina, Brazil, Canada, Ghana, Kenya, Egypt, EU, Indonesia, Iran, Iraq, Japan, New Zealand, Philippines, Senegal, Singapore, Thailand, Turkey** for enhanced clarity, enforcement consistency, and risk management.
- **Ghana, Kenya, Philippines, Thailand, Senegal** emphasize the **limitations of current guidance** and the need for **harmonized international standards**.
- **Chile and USA** urge caution or oppose adding new text to the standard, focusing instead on primary products or existing ML enforcement.
- **Singapore, Philippines, and Japan** stress the **complexity and limited health benefit** of strict ML enforcement in spices due to low consumption and data limitations.

(b) Proposed Approaches to Guidance

- **Annex I Amendment (preferred by Canada, Ghana, Kenya, New Zealand, Philippines, EU)** to include:
  - **Weighted average methods** where ingredient proportions are known.
  - **Default to lowest ML** when proportions are unknown (e.g., Brazil, EU, Egypt, Indonesia, Iran).
  - **Examples and scenarios** to support practical enforcement (Ghana, EU, Senegal).
- **Footnotes or clarifying notes** (supported by Canada, Indonesia, Singapore, Japan, EU, Ghana) attached to relevant MLs (e.g., for spices) to provide interim flexibility.
- **Alternative or pragmatic solutions**:
  - **Use predominant ingredient's ML** (Singapore).
  - **Estimate average mixture ML from typical spice ratios** (Singapore, Turkey).

    - **Exclude example (i)** due to error and misleading guidance (Thailand, Canada, EU).
    - **Avoid broad application** and restrict to cases like **lead in spice mixtures** (Japan, USA).
- **U.S., FIA, ISDI** express concerns that:
    - Applying the **lowest ML to the full mixture** is overly conservative, **may distort exposure assessments**, and **could lead to trade barriers or economic adulteration**.
    - Suggest focusing on **risk-based, targeted MLs** for specific mixtures rather than blanket rules.

(c) Other Recommendations

- **Ghana, Kenya, EU** propose **collaboration with CCMAS**, development of **case studies**, and alignment with **existing Codex precedents**.
- **USA, Philippines** suggest waiting for **data review (e.g., GEMS/Food)** before adopting new MLs for spice mixtures.
- **UAE** emphasizes **full ingredient disclosure** for mixtures.
- **Industry groups (FIA, ISDI)** support **science-based, risk-proportionate frameworks** and caution against overly rigid, impractical methodologies.

Conclusion and Recommendations

Multi-ingredient products, particularly spice mixtures, present challenges for applying contaminant Maximum Levels (MLs) due to often unknown or variable ingredient proportions.

International discussions under Codex have explored options to clarify and harmonize ML applications to these products.

Recommendations:

1. **Support Development of Clear, Harmonized Guidance**
   Member countries are encouraged to align with the international trend toward establishing clear, harmonized guidance within Codex frameworks that address ML application for multi-ingredient foods.
2. **Emphasize Practicality and Trade Facilitation**

- Recognize the **complexity and difficulty in obtaining exact ingredient proportions**, especially for small-scale importers and local producers.
- Encourage flexibility in enforcement to avoid unnecessary trade barriers, particularly for spices with low consumption and minor contribution to overall contaminant exposure.

3. **Develop National or Regional Databases and Case Studies**

- Collect and analyze data on typical ingredient proportions in common spice mixtures or multi-ingredient products within the region to support science-based ML applications.
- Use this data to inform regulatory decisions and possible development of **specific MLs for common mixtures**.

4. **Coordinate Regional Capacity Building and Regulatory Cooperation**

- Facilitate information exchange and harmonized enforcement practices among countries to improve regulatory consistency and consumer protection.
- Support training for analytical and enforcement authorities on the application of multi-ingredient ML guidance.

5. **Monitor Codex Developments and Participate Actively**

- Follow ongoing Codex discussions, especially the outcomes of CCCF18 and subsequent sessions regarding spice mixtures and multi-ingredient MLs.
- Provide inputs reflecting regional needs and priorities and consider incorporating Codex-adopted guidance into national standards.

J. Agenda Item 17: Analysis of the occurrence data of lead in spice mixtures

Document Number: CX/CF 25/18/18

Status in Codex Process: NA

Background

Year	Entity	Decision/Action
2024	**CCCF17**	Reviewed discussion paper on MLs for lead in spices, including spice mixtures. Concluded no MLs for spice mixtures in the general standard d for contaminants in food and feed (CXS 193-1995) (GSCFF) due to lack of guidance for multi-ingredient products. Recommended issuing **Circular Letter 2024/03-CF** to gather comments on applying MLs to multi-ingredient products (discussed in item 16). Requested **JECFA** to analyze GEMS/Food database for lead in spice mixtures for CCCF18 discussion.
2024	**CAC47**	**Adopted maximum levels (MLs)** for lead in **spices**, including **dried seeds** (excluding celery seeds), based on CCCF17 proposals.

SUMMARY OF THE WORK PRESENTED BY JECFA

In response to a request from the Codex Committee on Contaminants in Foods (CCCF) to support discussions on setting Codex maximum levels (MLs) for lead in multi-ingredient products, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) presented a detailed analysis of lead contamination in spice mixtures using data retrieved from the GEMS/Food database.

- The analysis focused on over 14,000 sample results collected between 2014 and 2024, of which 5,250 were considered most relevant to spice mixtures.
- JECFA applied two approaches to characterize contamination levels: one based on GEMS/Food group names and another using keyword text searches (e.g., "mix", "masala", "seasoning") to better isolate likely spice mixtures.
- The findings indicated that these mixtures tend to have higher mean lead concentrations (up to 0.60 mg/kg) than individual spices (0.24 mg/kg), and that exposure was particularly significant for children.

JECFA's lead exposure assessment for spice mixtures used consumption data from the GEMS/Food cluster diet and the FAO/WHO CIFOCOss database.

- While GEMS/Food provided broad per capita spice availability (average 2.6 g/day), CIFOCOss offered more detailed individual intake data from 14 countries, with the Netherlands providing the most reliable figures.
- However, limitations include lack of specificity for spice mixtures, limited data from many regions, and small sample sizes, underscoring the need for better, targeted consumption data.

Consumption Data used in JECFA assessment is presented in the table below:

Source	Type of Data	Key Findings	Limitations
GEMS/Food Cluster Diet Data	Per capita food availability	✓ Average: 2.6 g/day/person across clusters ✓ Range: 0.5 – 7.0 g/day	✓ Not specific to spice mixtures ✓ Includes condiments and individual spices
FAO/WHO Chronic Individual Food Consumption database (CIFOCOss) Database	Individual dietary intake data	✓ Data from 14 countries for "mixed herbs and spices" ✓ Most countries: <1 g/day consumption	✓ Limited countries and small sample sizes ✓ Most countries lacked reliable P95 data
Netherlands (CIFOCOss)	Reliable individual intake (P95)	- Children: Mean = 3.8 g/day, P95 = 10.4 g/day- Adults: Mean = 5.3 g/day, P95 = 11.0 g/day	Only country with >60 individuals, enabling statistically valid estimates
Other Data (FAOSTAT)	National supply/utilization	- Yemen and Saint Vincent: up to 18 g/day per capita for spices and aromatics (broad category)	Category includes other stimulants, not just spices or spice mixtures

JECFA proposed two potential MLs for lead in spice mixtures and evaluated their effectiveness in reducing dietary exposure and their enforcement implications, as summarized below:

Proposed Maximum Levels (MLs) for Lead in Spice Mixtures

JECFA's work provides a scientific foundation for CCCF discussions on the feasibility and public health benefit of adopting a Codex ML for lead in spice mixtures, while recognizing the need to manage both health risks and enforcement challenges.

PROPOSED MAXIMUM LEVELS (MLS) AND RISK CHARACTERIZATION METHODOLOGY

As part of its assessment, the **Joint FAO/WHO Expert Committee on Food Additives (JECFA)** evaluated the need for setting Codex Maximum Levels (MLs) for **lead in spice mixtures**, using an evidence-based, quantitative **risk assessment framework**. This framework involved:

1. Exposure Assessment

JECFA combined:

- **Occurrence data** from the **GEMS/Food database**, focusing on six food categories that may include spice mixtures.
- **Consumption data** from the **FAO/WHO Chronic Individual Food Consumption Database (CIFOCOss)**, especially for countries where data on **"mixed herbs and spices"** were available.

Two population groups were considered:

- **Adults** (average weight: 84 kg)
- **Children** (average weight: 20 kg)

Mean and **95th percentile (P95)** consumption levels were used to estimate daily lead intake from spice mixtures in µg/kg body weight/day.

2. Endpoints for Risk Characterization

JECFA used **health-based guidance values** (Points of Departure (PoDs)) established in its **73rd meeting (JECFA73, 2011)** for lead toxicity:

- **Neurodevelopmental effects in children**:
  ➤ PoD = **0.6 µg/kg bw/day** (associated with a 1 intelligence quotient IQ point loss)
- **Increased systolic blood pressure in adults**:
  ➤ PoD = **1.3 µg/kg bw/day** (associated with a 1 mmHg increase in blood pressure)

These endpoints were selected because lead is a **non-threshold contaminant**, meaning **no safe exposure level** can be definitively established, particularly for children.

3. Risk Characterization Results

Using the above methodology, JECFA estimated the contribution of **spice mixtures** to total lead exposure and evaluated the impact of different ML scenarios:

Scenario	Children (P95)	Adults (P95)	% of PoD Used (Children)	% of PoD Used (Adults)
No ML	0.31 µg/kg bw/day	0.08 µg/kg bw/day	**52%**	**6%**
ML = 2 mg/kg	0.11 µg/kg bw/day	0.04 µg/kg bw/day	**18%**	**3%**
ML = 1 mg/kg	0.09 µg/kg bw/day	0.04 µg/kg bw/day	**15%**	**3%**

Interpretation:

While both ML scenarios reduce exposure, **ML = 1 mg/kg** offers a **marginal additional benefit** over 2 mg/kg but results in higher product rejection.

The **greatest public health concern** is for **children**, where exposure to lead from spice mixtures alone could approach half of the neurotoxicity threshold without regulation.

CONCLUSION ON PROPOSED MLs

ML Option	Rationale	Estimated Impact	Trade-Off
2 mg/kg	Balances protection and feasibility	~15% reduction in exposure-Rejection rate: 1.9%	Moderate stringency; widely implementable
1 mg/kg	Greater protection for children	~18% reduction in exposure-Rejection rate: 5.1%	Higher rejection rate; stricter control needed

JECFA RECOMMENDATION

JECFA recommends that Codex consider adopting an ML for lead in spice mixtures of **1 or 2 mg/kg**, recognizing:

- The importance of protecting children from neurodevelopmental risks.
- The absence of a clear threshold for lead toxicity.
- The practicality of enforcement and trade implications, particularly for high-volume spice producers and importers.

JECFA recommends that CCCF18 consider the establishment of maximum levels (MLs) for spice mixtures within the broader context of setting MLs for multi-ingredient foods. A consistent and coordinated approach is needed, aligning JECFA's technical risk assessments with Codex's procedural guidance. This should include consideration of Agenda Item 16 and the feedback provided by member countries in response to Circular Letter CL 2024/03-CF. Such alignment would ensure clarity and coherence in how MLs are applied to complex food products.

Conclusion and Recommendations

JECFA applied an internationally accepted risk assessment framework, combining global occurrence data from the GEMS/Food database with individual consumption data (CIFOCOss), focusing on both average and high consumers (95th percentile) among adults and children. Risk characterization was based on JECFA's 2011 health-based guidance values: 0.6 µg/kg bw/day for children (linked to IQ loss) and 1.3 µg/kg bw/day for adults (linked to blood pressure). Spice mixtures alone may contribute up to 52% of the PoD in children at high intake levels, indicating a significant concern.

Two MLs were considered:

- ❖ **2 mg/kg** → exposure reduced to 18% of PoD in children, with 1.9% sample rejection.
- ❖ **1 mg/kg** → exposure reduced to 15%, but with 5.1% rejection.

The methodology applied by JECFA includes available international occurrence data and use of high-percentile exposure estimates. However, **uncertainties remain**, particularly due to:

- ❖ Limited and non-specific consumption data for spice mixtures,
- ❖ Inconsistent product naming in the GEMS/Food database,
- ❖ Sparse regional data from underrepresented countries.

These uncertainties suggest a need for improved data collection to refine future risk estimates and ensure regionally appropriate decisions.

Given the significant use of **spice mixtures for several countries** and **limited regional data on consumption and contamination**, member countries should:

1. **Support the establishment of an ML** for lead in spice mixtures within the proposed range (1–2 mg/kg), recognizing the health protection benefits, especially for children.
2. **Advocate for a flexible, risk-based approach**:
    - Prefer an ML of **2 mg/kg** as a pragmatic first step to allow compliance and trade continuity and reduce exposure.
3. **Encourage improved geographically representative data collection**:
    - Invest in **national dietary surveys** and contamination testing specific to spice mixtures.
    - Collaborate regionally to fill current **data gaps**, which limit precise exposure estimates.

4. **Call for Codex guidance on multi-ingredient products**:
   - Request clearer criteria on applying MLs to mixed foods, to ensure **consistency and enforceability**.
5. **Balance public health protection with trade interests**, particularly for countries that are major importers or exporters of spices.

K. Agenda Item 18: Analysis of the occurrence data of aflatoxins In cereals

Document Number: CX/CF 25/18/19

Status in Codex Process: NA

Background

Entity	Year	Action/Decision
CCCF15	2022	Finalized MLs for total aflatoxins in certain cereals and cereal-based products, including foods for infants and young children.
CAC45	2022	Adopted MLs but requested CCCF to review them within 3–5 years, contingent on sufficient data submission via GEMS/Food.
Codex (General Standard)	2022	Published the MLs for total aflatoxins in CXS 193-1995.
CAC46	2023	Noted CCCF Chair's intention to outline an approach for reviewing or setting new MLs, depending on data availability.
CCCF17	2024	-Chair clarified review depends on data; suggested JECFA issue a call for data to facilitate review decision at CCCF18. -Agreed to request JECFA to issue a data call and prepare an overview to support decision-making at CCCF18.
JECFA Secretariat	2024	Issued a call for data on 31 July 2024, with a submission deadline of 31 October 2024, to support possible review of MLs at CCCF18.

At CCCF18, based on the assessment done by JECFA, delegates are invited to give their comments on the conclusion and recommendations presented by JECFA notably:

- ❖ Whether there is a need to establish a specific ML for total aflatoxins in cereals, other than maize and rice, for example, of 5 µg/kg, as is currently the case for polished rice.
- ❖ Whether the current ML for husked rice (20 µg/kg) could be reduced to, for example, 15 µg/kg without jeopardizing the food supply and major trade interests.
- ❖ Whether further investigation of the evidence is required for consideration by CCCF18 (2025).

Analysis

Work process

- ❖ In 2024, the **JECFA Secretariat** retrieved a total of **8,196 results** on aflatoxin occurrence in cereals from the **GEMS/Food database**. These data were derived from samples of **raw cereal commodities**, not prepared food products.
- ❖ The dataset spanned a **sampling period from 2014 to 2024**, with **64%** of the data submitted specifically for the 2024 call for data.
- ❖ The analysis focused on a wide range of cereals, with the largest number of samples coming from **polished rice (n=4,425)**, followed by **maize (n=839)** and **maize flour (n=718)**. Other cereals included husked rice, wheat and wheat flour, barley, sorghum, rye, oats, millet, spelt, buckwheat, and quinoa. Categories with fewer than 200 samples were grouped under "other cereals" (n=605).
- ❖ The data reflected contributions from **over 25 countries**, with the largest submissions coming from **Kenya (n=3,887)**, the **USA (n=1,039)**, and **Thailand (n=920)**. Other notable contributors included the **EU**, **Saudi Arabia**, **Singapore**, **Canada**, **Indonesia**, **Japan**, **Mali**, and **Montenegro**, with 16 additional countries providing smaller datasets (fewer than 10 results each).

- In terms of analytical results, **aflatoxins were not detected in 92% of the samples**, indicating a generally low occurrence. The **limits of detection (LOD)** for the analytical methods used ranged from **0.001 to 1.12 µg/kg**, and **limits of quantification (LOQ)** ranged from **0.003 to 3.36 µg/kg**.
- To accommodate non-detects and non-quantified results, the data were interpreted using two scenarios: the **lower-bound (LB)** scenario, which assumes a value of zero for non-detects and the LOD for non-quantified results; and the **upper-bound (UB)** scenario, which assumes the LOD for non-detects and the LOQ for non-quantified results.

Analysis

The analysis of aflatoxin concentrations in cereals, based on over 8,000 samples from the GEMS/Food database (2014–2024), provides important insights for reviewing Codex Maximum Levels (MLs). Most cereals, except maize, had aflatoxin levels **below the strictest Codex ML of 5 µg/kg**, which is set for infant and young child foods. However, maize and maize flour showed higher concentrations, often exceeding the ML for ready-to-eat products, though still within limits for products destined for further processing.

The data support continued confidence in existing MLs for most cereals but suggest a need to review limits for maize-based products, especially in regions with higher contamination. Rejection rate projections under different ML scenarios help estimate the practical impact of regulatory changes. For example, stricter MLs could improve food safety but would increase rejection rates slightly up to 6% for maize flour at a 10 µg/kg threshold.

Key Ideas

- Right-skewed distribution of aflatoxin levels: Most samples are low, but a few are significantly higher.
- Low contamination for most cereals: Polished rice, wheat, and other grains typically meet current Codex MLs.
- Maize and maize flour exceed the 10 µg/kg ML in many cases but align with the 15 µg/kg ML for further processing.
- Stricter MLs (e.g., 5 µg/kg for all cereals) would increase food safety but lead to modest increases in rejection rates.
- Husked rice has slightly elevated levels but remains within acceptable safety limits under current standards.

- Projected **rejection rates** based on various ML scenarios were calculated and presented in Table 2. If an ML of **5 µg/kg** were applied:
  - **0.25%** of polished rice samples,
  - **0.13%** of wheat and wheat flour, and
  - **2.3%** of other cereals would be rejected.
- For **husked rice**, using the **current ML of 20 µg/kg** results in a **1.8% rejection rate**. Lowering the ML to **15 µg/kg** would increase this to **2.4%** and **reduce average contamination by 26%**.
- In the case of **maize and maize flour**, both show similar contamination patterns. Applying a **15 µg/kg ML** would lead to **4.5%** and **5.2%** rejection rates respectively, while reducing the **mean aflatoxin levels by 93%**. A stricter ML of **10 µg/kg** would increase rejection rates to **5.5% (maize)** and **6.0% (maize flour)**, with a further **15–22% reduction** in mean contamination.

Cereal	ML Scenario (µg/kg)	Data points	Mean AFT concentration (µg/kg)	High AFT concentration 95th Percentile (µg/kg)	Rejection rate (%)
Maize flour	**No ML**	**718**	**9.80**	**15.42**	**0**
	ML: 15	681	0.69	2.84	5.2
	ML: 10 (CXS-193-1995)	675	0.59	2.39	6.0
Maize	**No ML**	**839**	**10.25**	**12.22**	**0**
	ML: 15 (CXS-193-1995)	801	0.54	1.74	4.5
	ML: 10	793	0.42	1.14	5.5
Polished rice	**No ML**	**4425**	**0.67**	**0.80**	**0**
	ML: 5 (CXS-193-1995)	4414	0.64	0.80	0.25
Husked rice	**No ML**	**340**	**1.41**	**1.52**	**0**
	ML: 20 (CXS-193-1995)	334	0.38	0.75	1.8
	ML: 15	332	0.28	0.70	2.4
Wheat	**No ML**	**794**	**0.86**	**1.00**	**0**
	ML: 5	793	0.85	1.00	0.13
Wheat flour	**No ML**	**475**	**1.63**	**1.00**	**0**
	ML: 5	469	0.33	1.00	0.13
Other cereals	**No ML**	**605**	**2.78**	**1.00**	**0**
	ML: 5	591	0.50	1.00	2.3

GENERAL OVERVIEW OF THE ASSESSMENT, INCLUDING THE METHODOLOGY AND KEY CONCLUSIONS

Aflatoxin Risk Assessment in Cereals

The assessment aimed at:

- Assessing the public health risks associated with dietary exposure to aflatoxins, primarily aflatoxin B1 (AFB1), from cereals, especially maize and rice.
- Evaluating how different maximum level (ML) scenarios affect dietary exposure and liver cancer risk.
- Informing Codex Alimentarius Commission (CAC) deliberations on potential revisions of MLs for total aflatoxins in cereal products.

Methodology

Work Process (Methodological Steps)

- Data Sources: Aflatoxin concentration data were retrieved from the GEMS/Food database, and food availability was based on per capita cereal consumption patterns.
- Diet Simulation: Modeled dietary intake scenarios using:
  - Average consumption of all cereals,
  - Plus 95th percentile consumption of one key cereal (either maize or rice) to simulate high exposure.
- Contamination Scenarios: Considered three ML regulatory options:
  - No ML
  - Current Codex MLs (15–20 µg/kg for some cereals)
  - Stricter MLs (10–15 µg/kg for maize/rice; 5 µg/kg for others)

Assumptions for Risk Assessment

- Toxicological Basis: Applied the JECFA 83 (2016) dose-response model for AFB1, assuming it represents total aflatoxins due to its potency. This approach reflects scientific consensus that AFB1 accounts for ~80% of total aflatoxins and poses the greatest carcinogenic risk.
- Exposure Units: Exposure measured in ng/kg body weight/day.
- Cancer Risk Factor: Liver cancer risk modeled based on hepatitis B virus (HBV) status:

- 0.3 for HBV-positive population
- 0.01 for HBV-negative population

❖ HBV Prevalence: Varies by region (e.g., <2% in high-income countries; >6% in Sub-Saharan Africa and Southeast Asia)

N.B.

Hepatitis B Virus (HBV) is included in the aflatoxin risk assessment for the reason that **people with chronic HBV infection are far more susceptible to liver cancer** when exposed to aflatoxin B1 (AFB1). The risk is **multiplicative**, not just additive. Since **HBV prevalence varies by region**, factoring it in allows for **more accurate, region-specific estimates of cancer risk** from aflatoxin exposure. This is essential for setting **realistic and protective maximum levels (MLs)** in food safety standards.

Analysis of Results

Maize-Dominant Diets (High Risk Regions)

Scenario	Exposure Estimate	Liver Cancer Risk	Risk Reduction
Case 1 – No ML	**50 ng/kg bw/day**	**0.66–1.60/100,000/year**	**–**
Case 2 – Moderate MLs	**↓ ~72%**	**Reduced risk**	**72% vs. Case 1**
Case 3 – Stricter MLs	**↓ ~90%**	**Minimal risk**	**90% vs. Case 1, 66% vs. Case 2**

Rice-Dominant Diets

Scenario	Exposure Estimate	Liver Cancer Risk	Risk Reduction
Case 4 – No ML	**31 ng/kg bw/day**	**0.41–0.99/100,000/year**	**–**
Case 5 – Moderate MLs	**↓ ~54%**	**Reduced risk**	**54% vs. Case 4**
Case 6 – Stricter MLs	**↓ ~84%**	**Minimal risk**	**84% vs. Case 4, 64% vs. Case 5**

JECFA's conclusions and proposals

❖ Aflatoxins in cereals pose a measurable risk of liver cancer, especially in HBV-prevalent regions and among populations with high maize or rice consumption.

❖ Implementing or tightening Codex MLs can lead to substantial reductions in dietary exposure and cancer risk.

❖ The most stringent ML scenario evaluated (10 µg/kg for maize, 15 µg/kg for husked rice, 5 µg/kg for other cereals) provides the greatest public health protection—up to 90% risk reduction.

Maize-based Diets

❖ Without MLs (Case 1):
- Exposure: ~50 ng/kg body weight/day
- Liver cancer risk: 0.66 to 1.60 cases/100,000/year depending on region

❖ With ML of 15 µg/kg (Case 2):
- Exposure and risk reduced by 72%

❖ With stricter MLs (10 µg/kg for maize, 5 µg/kg for others — Case 3):
- Exposure and risk reduced by 90% vs. Case 1, and 66% vs. Case 2

Rice-based Diets

❖ Without MLs (Case 4):
- Exposure: ~31 ng/kg body weight/day
- Liver cancer risk: 0.41 to 0.99 cases/100,000/year

- With ML of 20 µg/kg for rice (Case 5):
  - Risk reduced by 54%
- With stricter MLs (Case 6):
  - Risk reduced by 84% vs. Case 4, and 64% vs. Case 5

- Current Codex MLs (e.g., 15 µg/kg for maize, 20 µg/kg for rice) still provide meaningful protection (54–72% reduction) but are less effective than stricter scenarios.
- Policy Implication: Stricter MLs across all cereals could be justified based on public health benefits, but must be balanced against food availability, compliance capacity, and trade implications.

Conclusion and Recommendations

The issue of aflatoxin contamination in cereals is a serious public health concern, particularly due to its well-established link to liver cancer, especially in populations with high Hepatitis B Virus (HBV) prevalence. This is highly relevant for many countries, where cereals like maize and rice are dietary staples, and food safety control systems may face challenges.

The recent conclusions from JECFA confirm that even moderate reductions in aflatoxin maximum levels (MLs) can significantly reduce cancer risk. In this context, it is essential that member countries engage actively in Codex discussions and take strategic steps to update and implement aflatoxin MLs that reflect both scientific evidence and regional realities.

Member countries might support the Codex initiative to review maximum levels (MLs) for total aflatoxins in cereals, beginning with a maximum level of **15 µg/kg for maize and husked rice**, while maintaining **5 µg/kg for cereal-based foods intended for infants and young children**, in accordance with Codex's most stringent protection levels.

At the same time, it's important to align future MLs with regional realities, including consumption patterns, national food security priorities, and the current capacity of national food control and testing systems. The following recommendations are proposed:

- Advocate for regional flexibility and staged enforcement, allowing for differences in national capacity, exposure levels, and food security priorities.
- Enhance national testing, surveillance, and data reporting systems, including contributions to international databases like GEMS/Food.
- Strength international and regional support for laboratory infrastructure, data generation, and risk assessment capacity.
- Increased investment in technical cooperation and access to analytical tools is essential for enabling countries to effectively monitor aflatoxin levels, contribute data to platforms such as GEMS/Food, and fully participate in future ML reviews and Codex decision-making processes.