46th Joint Coordination Meeting of Arab and CCNE Codex Contact Points

ANALYSIS OF AGENDA ITEMS 6 AND 8 IN PREPARATION FOR THE 45TH SESSION OF THE CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING (CCMAS45)

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Agenda Item 6:
Methods of Analysis for Precautionary Allergen Labelling
Document Number: CX/MAS 26/45/9

Status in Codex Process: N/A

Background:

- The Codex Committee on Food Labelling updated the General Standard for the Labelling of Prepackaged Foods (CXS 1-1985) to include a list of priority allergens.
- These allergens include cereals containing gluten, crustacea, eggs, fish, peanuts, milk, sesame, and certain tree nuts.
- The Codex Committee on Methods of Analysis and Sampling (CCMAS) was asked to identify analytical methods capable of detecting unintended allergen presence in food.
- An Electronic Working Group (EWG) compiled currently used methods and assessed their validation status according to international guidelines such as AOAC and EN standards.

Objective of the Work:

- Provide technical input to CCFL on available analytical methods for allergen detection.

- Evaluate whether these methods are fit for purpose relative to established action levels (ALs).

- Review validation status and analytical performance of currently used methods.

CCMAS45 is invited to consider a draft response to CCFL, including tables summarizing available methods and their validation status, and to determine whether further development of numeric performance criteria for allergen detection methods should be explored in the future.

Key Technical Considerations:

- Extensive reliance on proprietary ELISA kits.
- Differences in validation quality among methods.
- Matrix effects affecting analytical performance.
- Need to convert results into total allergenic protein units.
- Importance of aligning analytical ranges with allergen threshold levels.
- Clarification that listing methods does not mean endorsement.

Tables 1 & 2 – Overview of Available Methods:

Table 1 – Methods with Stronger Validation

Key Observations

- Generally low Limits of Quantification (LOQs).
- LOQs appear suitable relative to FAO/WHO reference doses and action levels.
- Examples:
  - Peanut, egg, milk: LOQs around 0.31–1 mg/kg.
  - Gluten ELISA methods: LOQs around **1–5 mg/kg**.
  - Crustacea: approximately **0.31–0.66 mg/kg**.

Important Consideration:
LOQ should ideally be significantly below the action level (recommended safety margin about 3× lower).

Tables 1 & 2 – Overview of Available Methods:

Table 2 – Methods with Limited Validation

Key Observations

•Many methods still show adequate analytical sensitivity.

•However, most rely on:

- Manufacturer validation
- In-house validation only

•Lack of multi-laboratory validation increases uncertainty in reproducibility and comparability.

Main Limitation: Variability in:

- LOQs
- Reporting units
- Method robustness across different laboratories and food matrices.

Key Analytical Challenges:

- Standardization of reporting units (protein vs whole food vs specific proteins).
- Matrix and processing effects in different food products.
- Differences between allergen detection methods across countries.
- Trade implications due to proprietary analytical kits.

Recommendations:

- Support forwarding the draft response to CCFL, recognizing that it appropriately clarifies that listed methods are provided for information and are not endorsed, and that suitability must be demonstrated case-by-case.
- Emphasize fitness-for-purpose relative to action levels (ALs), ensuring that selected methods have LOQs sufficiently below the relevant AL and analytical ranges that cover the required concentration levels.
- Encourage harmonized reporting units, preferably expressed as mg total protein from the allergenic source per kg food, to facilitate consistent interpretation and trade.
- Highlight matrix and processing effects, stressing the need for laboratories in the region to verify method performance in locally relevant food matrices.
- Acknowledge trade and accessibility implications, particularly the reliance on proprietary ELISA kits and the importance of ensuring method availability across regions.
- Encourage CCMAS to remain open to future discussion on performance-based criteria, should CCFL request further work in this area.

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Agenda Item 8:
Harmonization of Names and Format for Principles and Provisions Identified in CXS 234 (2025)
Document Number: CX/MAS 26/45/12

Status in Codex Process: N/A

Background:CCMAS44

- the need to harmonize the names and format of analytical method principles in CXS 234-1999.

- (EWG) led by Brazil and Chile was formed to continue the work Due to the technical complexity.

- Consultations between July 2025 and January 2026 was conducted and the EWG proposed improvements and a harmonized structure.

Objective of the Work:

- Harmonize terminology used for analytical method principles.
- Standardize the format of provisions listed in CXS 234.
- Improve clarity, consistency, and alignment with international scientific terminology.

The EWG completed its TORs and submitted outcomes in Appendix I (Annexes A–D).

Annex A – Principles of Methods of Analysis (Establish a standardized list of analytical principles based on the analytical technique used)

Key Improvements

- Alignment with international terminology (IUPAC, ISO, VIM, ASTM).
- Removal of unnecessary procedural steps from principles.
- Consistent expression of analytical techniques (e.g., Technique + Detector).

Key Issues for Discussion

- Whether to include only currently used principles or also future techniques.
- Need for clearer structure between:
  - Techniques
  - Variants
  - Historical methods
  - Sample preparation steps.
- Clarification between spectrometry and spectroscopy terms.

Annex B – Acronyms and Abbreviations (Provide standardized acronyms for analytical techniques.)

Benefits

- Improves clarity in Codex standards.
- Ensures consistent use of acronyms such as HPLC, GC, ICP, and MS/MS.

Issues to Address

- Possible redundancy among some acronyms.
- Distinction between detectors and analytical systems.
- Decision on including advanced technologies for future use.

Annex C – Acronyms for Standard Method References (Standardize abbreviations of recognized organizations and reference bodies.)

Advantages

- Enhances transparency in citing analytical methods.
- Supports consistent referencing across Codex standards.

Points for Consideration

- Whether the list should include only standard organizations.
- Need for a mechanism to periodically update the list.
- Harmonization of formatting across entries.

Annex D – Harmonization of Provisions

Proposed Approach

- Introduce a structured method to harmonize provision names in CXS 234 without changing scientific requirements.
- Use mapping tables to identify inconsistencies across commodities.

Important Considerations

- Distinguishing editorial harmonization from substantive changes.
- Avoiding scientific confusion between similar terms.
- Standardizing how commodity forms are described.
- Reviewing the proposal to remove “sample preparation” as a separate provision.

Recommendations:

- General Position

- Support harmonization of terminology and format in CXS 234-1999.
- Emphasize that harmonization should be editorial and clarity-enhancing, not a reopening of scientific or policy decisions.

- Annexes A & B (Principles & Acronyms)

Member countries may:

- Support clearer definitions aligned with international terminology (IUPAC, ISO, VIM).
- Support using a consistent format: Technique + detector (if applicable).
- Encourage removing unnecessary procedural details from "principle".
- Key point: Request clarification whether Annex A should include:
  - Only principles currently used in CXS 234; or
  - Also, additional techniques for future use.

Recommendations:

- Annex C (Standard Method References)
  - Inclusion of journals (e.g., Analytica Chimica Acta) differs from standard-setting bodies.
  - Clarification may be needed whether Annex C is limited to standard organizations or broader references.
- Annex D (Harmonization of Provisions)

Member countries may:

- Support harmonizing provision names (e.g., single standardized terms).
- Support splitting combined provisions (e.g., “calcium and magnesium”).
- Support deleting “sample preparation” as a provision, provided no normative requirement is lost.
- Emphasize that substantive changes must be referred to the responsible commodity committee.

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