49th Joint Coordination Meeting of Arab and CCNE Codex Contact Points

PREPARATION FOR THE 49th SESSION OF THE CODEX ALIMENTARIUS COMMITTEE ON FOOD LABELLING (CCFL)

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Context and challenges : Agenda Item 5

ANNEX TO THE GENERAL STANDARD FOR THE LABELLING OF PRE-PACKAGED FOODS (CXS 1-1985):
GUIDELINES ON THE USE OF PRECAUTIONARY ALLERGEN LABELLING (STEP 7)

Shift from the paradigm of "legal precaution" to **"scientific risk management"** .

Three pillars: Protection of sensitive consumers, harmonization of global trade, and reduction of unjustified claims.

Scope: Exclusive focus on unintentional presence (cross-contamination) without affecting mandatory ingredient declaration.

Transition to a risk-based approach

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Background

…….Before 2020:

- Lack of a harmonized framework for the EPA

2020:

- Adoption of the Code of Practice for Allergens (CXC 80-2020)

CCFL47–48:

- Development of EPA guidelines
- Validation of general principles

CCFL48 (2024) : Finalization of revisions to the General Standard on Prepackaged Food Labelling (GSFFL)

- The draft guidelines on the EPA have moved to stage 5 for adoption
- Adoption by the Commission and granting of an additional period to complete the work by the end of CCFL49 (2026)
- FAO/WHO Request for Scientific Advice

Background (Suite)

After adoption at step 5:

EWG : Reinstated in March 2025 under the joint presidency of the United States, Australia, and the United Kingdom. **Current Mandate:** Finalizing the texts by incorporating the scientific data from 2025.

Methodology : Use of two consultation documents (DC1 and DC2) to reach a consensus on the critical sections (**4.3, 4.3.1 and 5**):

- Section 4.3 (when to use EPA)
- Reference doses (Rd), Check the relevance of the proposed thresholds, Examine the structure of the table and its notes.
- Labeling presentation: Evaluate:

  - the new provision for products without an ingredients list,
  - the use of expressions such as "may contain",
  - the rules relating to gluten labelling.

CCFL49 (2026):

Objective: finalization (Step 8)?

Issues for discussion at the 49th session of Codex of food Labelling

- **(Section 4. 1)**: Use of the term **"should"** to indicate recommendations rather than strict obligations.
- Adoption of the **Reference Intakes Table (Section 4.3.1)**:
  - Inclusion of numerical values for all allergens.
  - New reference intake for gluten set at **4 mg**.
  - Recognition of wheat as both:
    - An allergen (IgE-mediated)
    - A trigger for celiac disease
  - Requirement for dual reference intakes (total protein and gluten).
- **Flexibility for National Authorities (Section 4.3.2)**:
  Allowing countries/regions to establish reference doses for additional hazards.
  Must follow recognized scientific principles.
- Activation of **Training Programs (Section 4.4)**:
  - Encouragement for authorities to organize training and awareness programs.
  - Target groups: manufacturers, health professionals, and consumers.
- Adoption of **Presentation and Display Rules (Section 5)**:
  - Inclusion of Section 5.2 bis for products without an ingredient list.
  - Ensuring precautionary labeling remains clearly visible.
  - Recommendation to place precautionary labeling directly below or close to the ingredients list.

Analysis

1. Risk-Based Framework for Use of PAL (Section 4.3)

The draft provides that:

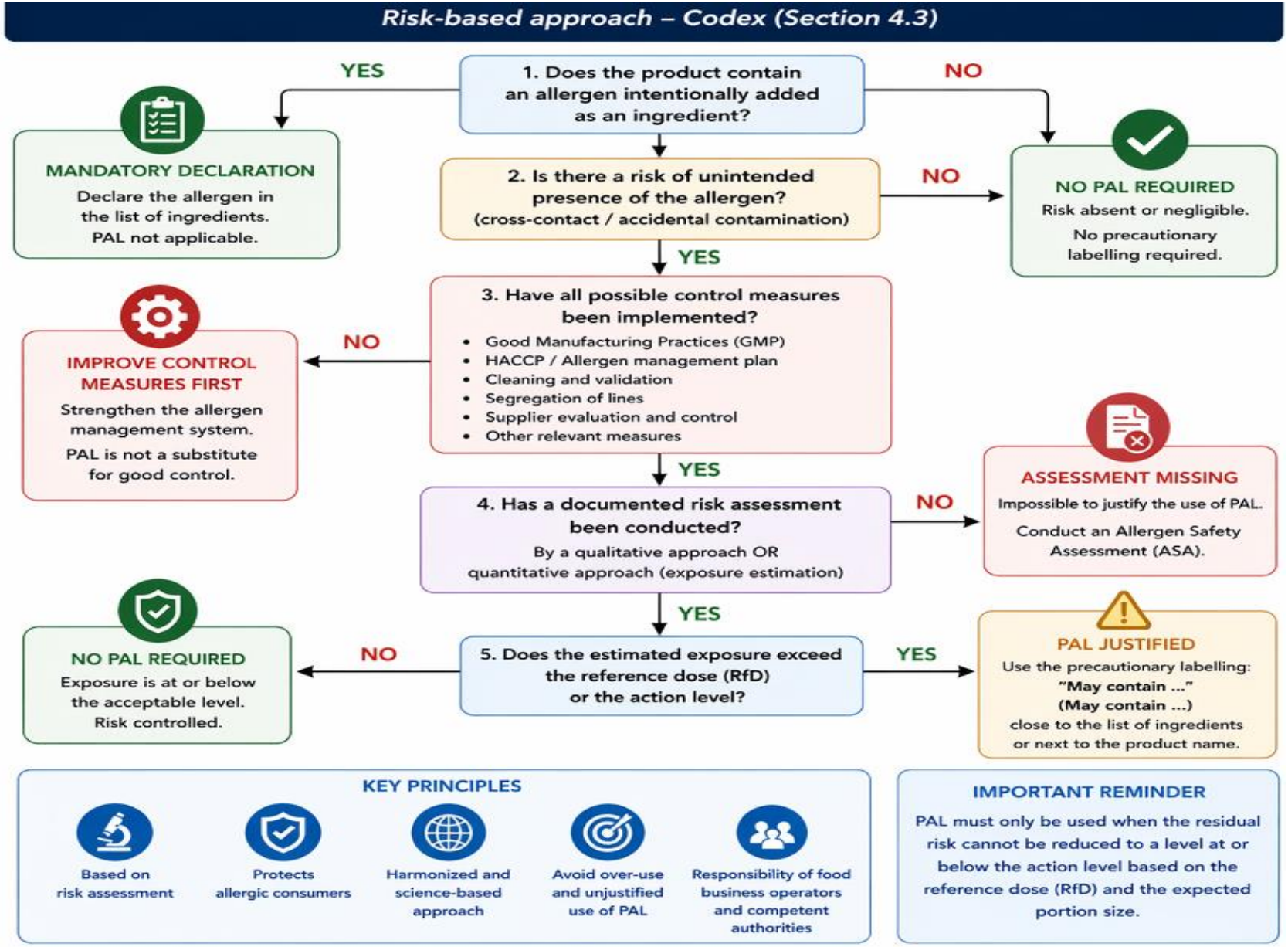
> "PAL should only be used when it is demonstrated that unintended allergen presence cannot be mitigated to a level at or below the action level based on the reference doses…"

Key points:

- ❑ PAL must be based on **risk assessment**
- ❑ It cannot substitute for good allergen management practices (CXC 80-2020)
- ❑ Overuse of PAL should be avoided
- ❑ Action levels are derived from RfDs and expected portion size

Policy significance:

- Establishes a science-based, globally harmonized threshold approach.
- Shifts PAL from voluntary, precautionary disclaimers to a structured risk-management tool.
- Enhances consumer trust by limiting indiscriminate use of "may contain".



Analysis

1. Risk-Based Framework for Use of PAL (Section 4.3)

Critical points and divergences on section 4.3

- **Major debate: "must" vs. "should"**
- **Difficulty of practical application**
- **Uncertainties around the thresholds (Dr)**
- **Risk of variable interpretation**
- **Fear of increased liability for operators**

Recommendations (Applicability by Operators) :

Support / Not support ?

- Ensure that Section 4.3 is **operational and implementable** by food business operators of all sizes.
- Develop **clear, practical guidance** (step-by-step approach) for applying reference doses in real production settings.
- Provide **simple decision-making tools** (e.g., thresholds, flowcharts, examples).
- Take into account **SMEs constraints** (limited technical and analytical capacity).
- Promote **capacity building and technical support** to facilitate compliance.
- Encourage **gradual implementation** with a transition period where needed.

2. Reference Doses (RfDs) – Section 4.3.1

Table structure: The table classifies priority allergens (almonds, eggs, milk, etc.) with values ranging from **1.0 mg** (nuts, celery) to **200 mg** (crustaceans).

Case of Gluten: A distinction is made for cereals containing gluten. Wheat has two reference values (RdRs) : one for total protein (**5.0 mg) related to** IgE allergies , and one for gluten (**4.0 mg**) related to celiac disease. Barley and rye are assigned only the RdR of **4.0 mg for gluten** .

	Dose de référence (DdR) (mg de protéines totales provenant de l'~~allergène~~ **aliment allergénique**)	**Dose de référence (DdR) Total de gluten (mg)[3bis] provenant de céréales contenant du gluten**
Arachides	2,0	
Œuf	2,0	
Lait	2,0	
Sésame	2,0	
Noisette	3,0	
Blé[3bis]	**5,0**	**4,0**
Orge[3bis] Seigle[3bis]	–	
Poisson	5,0	
Sarrasin	10	
Lupin	10	
Soja	10	
Crustacés	200	

Relevance of thresholds

Scientific basis: The thresholds are based on FAO/WHO expert recommendations (2022-2025) using the **ED05 exposure level** (dose triggering a reaction in 5% of the sensitive population).

Criticism: ED05 was chosen because it allows for a more feasible risk assessment for companies than ED01, for which the analytical methods sometimes lack sensitivity. However, some members and observers are concerned that these thresholds may not adequately protect infants and young children.

2. Reference Doses (RfDs) – Section 4.3.1

Recommendations:

Support / Not support ?

- **Clarification of conversions:** Although conversion factors have been removed to simplify the text, it is crucial that operators have separate technical guides to convert analytical results to mg of total protein in order to compare them to the Dr.

- Single RfD of 4 mg gluten for wheat, barley, and rye?

Justification : More conservative approach for wheat (compared to 5 mg total protein), avoids dual values (protein vs gluten), and reduces confusion while supporting a harmonized, risk-based framework.

3. Section 4.3.2: National Flexibility in Establishing Reference Intakes

- Provides **flexibility to national and regional authorities**.
- Allows them to **establish reference doses** for allergens or hazards **not included in the global Codex list**.
- Requires that such decisions be based on **recognized scientific principles** and **risk assessment**.
- Ensures adaptability to **local consumption patterns and specific public health needs**.

Recommendation:
Support / Not support

- **Harmonisation:** Maintain the use of internationally harmonised DdRs to avoid trade barriers, while allowing national authorities the possibility of establishing DdRs for local allergens not listed

4. Section 4.3.3

Prohibition of combination: If a product uses precautionary labeling for gluten (e.g., *"May contain gluten"*), it **must not** bear the statement *"Gluten-free"* .

Recommendations:
Support / not support

Retain wording: "If a PAL statement for cereal(s) containing gluten is used on the label, then the term 'gluten free' shall not be used on the label or in labelling."
Justification : Avoids contradictory labelling; supports risk-based consumer protection.

5. Section 4.4

- Focuses on **training and awareness programs**.
- Encourages competent authorities to **build capacity** among stakeholders.
- Targets **manufacturers, health professionals, and consumers**.
- Aims to ensure **correct understanding and proper application** of allergen labeling standards. Supports **consistent implementation** and reduces misinterpretation of precautionary labeling.

Recommendations:

Support / not support

Requirement that PAL is complemented by education/information programs led by competent authorities.

- Establish **structured and continuous training programs** at the national level.
- Develop **harmonized guidance materials and practical tools** for stakeholders.
- Promote **public awareness campaigns** to improve consumer understanding.
- Encourage **collaboration between authorities, industry, and health experts**.

Justification : Ensures correct understanding and appropriate use of PAL.

6. Presentation of PAL (Section 5)

Standardized Terminology: Use of the phrase **"May contain [allergen]"** . Rejection of ambiguous terms such as "Traces of".

Strategic Placement: The statement must be placed immediately after or below the list of ingredients.

Readability: The contrast, font size and style must be identical to those of the ingredients list to ensure optimal visibility.
Absence of ingredients list: If the product is free of them, the mention EPA must appear near the name of the food.

Section 5.2 bis

- Addresses **products exempt from an ingredients list**.
- Requires that **precautionary allergen labeling (PAL)** remains **clearly visible and prominent**.
- Ensures that the absence of an ingredients list **does not reduce consumer protection**.
- Specifies that the precautionary statement should be **placed in a noticeable location on the label**.
- Aims to maintain **clarity, transparency, and consistency** in allergen communication.

Recommendations:

Support / not support

Retain requirement for prominent placement of PAL and same field of vision as allergen statements.
Justification : Improves visibility and consumer awareness.

6. Footnotes 4 bis et 4ter

- Provide **additional clarification** to support the interpretation of allergen reference doses.
- Ensure **scientific consistency** in how values are applied and understood.
- Clarify specific **technical aspects or exceptions** related to certain allergens or thresholds.
- Help avoid **misinterpretation or misuse** of reference values in risk management and labeling decisions.
- Strengthen the overall **credibility and robustness** of the guidance.

Recommendations:

Support / not support

Footnote 4bis

Support inclusion of all cereals containing gluten (wheat, barley, rye) when source is unknown.
Justification : Ensures transparency and consumer protection.

Footnote 4ter

Support use of the term "gluten" in addition to cereal names.
Justification : Enhances consumer understanding.

CONCLUSION AND RECOMMENDATIONS

This draft guideline represents a major step forward in modernizing allergen labelling by moving from a **general precautionary approach** toward a **science-based risk assessment framework**.

This document offers several important advantages:

- it strengthens the protection of allergic consumers through more justified and reliable precautionary allergen labelling;
- it reduces the excessive and unjustified use of "may contain" statements, thereby improving consumer confidence;
- it promotes international harmonization of practices and facilitates trade;
- it clarifies the responsibility of food business operators in allergen risk management.

However, its immediate implementation may create significant challenges for developing countries, particularly for small and medium-sized enterprises (SMEs), due to:

- limited analytical and technical capacities;
- lack of reliable food consumption data;
- difficulties in conducting quantitative risk assessments;
- high costs associated with cleaning validation and control systems;
- and the need for capacity building for both competent authorities and food operators.

CONCLUSION AND RECOMMENDATIONS

Therefore, we can support the adoption of the draft, provided that implementation remains progressive, pragmatic, and adapted to national realities.

It specifically recommends:

- development of simplified technical guidance and operational models;
- maintenance of reasonable flexibility for developing countries;
- stronger support for SMEs;
- and clear clarification of responsibilities between food business operators and competent authorities.
- The principle should be supported, but its practical applicability must be ensured.

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