

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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Agenda Item 5, 7

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD LABELLING

Forty-ninth Session

Ottawa, Canada

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COMMENTS FROM ISDI

Agenda item 5:

Precautionary Allergen Labelling (PAL) (*Agenda Item 5 – CX/FL 26/49/5, Step 7*)

ISDI appreciates the work and conclusions of physical working group related to the draft *Guidelines on the Use of Precautionary Allergen Labelling* held on 10 May 2026 ahead of the committee.

Suggested Footnote to specifically address food for infant and young children for section 4.3

During the physical Working Group discussion, FAO clarified that infants and young children were explicitly considered in the FAO/WHO risk assessment, including evaluation of age-related sensitivity. While evidence suggests increased sensitivity in this group, particularly for cow's milk protein, a population-based ED05 was applied as an allergen-specific judgement for cow's milk protein, but this approach was not extended to other allergens.

For other allergens, available data do not support the scientific applicability of population-based ED05 values to infants, young children and individuals with particular dietary requirements. Overall, reference doses are derived from heterogeneous populations and have not been specifically validated for these subgroups and ISDI questions if these reference points are sufficiently protective for them.

In this context, ISDI proposes to add a footnote at the end of section 4.3:

4.3 PAL [shall be used when / should be limited to cases where] it is demonstrated that unintended presence of a food allergen(s) cannot be mitigated to a level at or below the action level 3 for the allergenic food based on the reference doses in tables at 4.3.1 for IgE-mediated food allergy and 4.3.2 for coeliac disease (FOOTNOTE).

This footnote should read:

FOOTNOTE: "Where relevant, for foods for special dietary use (as defined in Codex Standard 146-1985), stricter reference values may be applied based on the general principles established by these guidelines."

Presentation of PAL: Section 5.2.3

When gluten is present and the source is not known or cannot be verified using current analytical methods, ISDI is of the opinion that PAL statements should read 'may contain gluten'. Noting that, where the presence of wheat is known, it could be explicitly declared in accordance with applicable allergen labelling requirements.

Agenda item 7:

Guidelines on the Application of Food Labelling Provisions in Emergencies

(*Agenda Item 7 – CX/FL 26/49/7, Step 4*)

Codex Alimentarius seeks to define the contexts in which flexible labelling may be permissible (i.e. instances of significant supply chain disruptions or food shortages). The Codex guidelines provide guidance on how to mitigate disruptions to supply chains and food shortages caused by emergency situations for all populations.

Manufacturers of infant formula (and other foods for infants and young children) work within established humanitarian frameworks and have clear policies governing the donation and/or provision of low-cost supplies during emergencies. They also comply with all applicable laws and regulations. We particularly refer to the Operational Guidance on Infant Feeding in Emergencies (OG-IFE) version 3.0 (Oct 2017). The draft Codex guidelines do not change this in any way.

As speed and flexibility are key requirements under an emergency where the supply of ingredients is highly variable, a flexible approach to declaring ingredients (e.g., declaring 'vegetable oils/fats' instead of specific oils of origin) shall be considered to ensure that labelling information of a prepackaged food is truthful, transparent and non-misleading while ensuring the safety of the food.

Therefore, ISDI supports the inclusion of foods for special dietary uses in the scope of the guidance with specific consideration as suggested by section 3.1.11 with the following amendment to be aligned with the definition of FSDU (CXS 146/1985):

3.1.11 Address where relevant ~~Consider and mitigate~~**Consider and mitigate** ~~any specific risks for~~ ~~populations with particular dietary requirements~~ ~~for vulnerable populations~~ **any specific risks for populations with particular dietary requirements** within the country where the food will be consumed (e.g. infants, young children, persons with special dietary needs).

However, ISDI is of the opinion that the section may be a better fit within section 3.2 (Implementing and Monitoring Authorized Flexibilities).