

CODEx ALIMENTARIUS COMMISSION



Food and Agriculture
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World Health
Organization

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Agenda Item 2.1, 4, 5, 6, 7, 8.2

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CODEx COMMITTEE ON FOOD LABELLING

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COMMENTS FROM IRAN

Agenda item 2.1: The use of “country of harvest” in addition to the mandatory declaration of country of origin in food labelling of spices

The requirement to state both the **harvesting country** and the **Country Of Origin** for agricultural products is not limited to cases involving a substantial transformation of the product. In many instances, a product is purchased from the country where it was originally harvested, then repackaged in a second country and distributed under the name of that second country. If the harvesting country is not clearly declared, consumer rights are not adequately protected and such practices cannot be regarded as fair trade. This issue is particularly relevant in the case of spices. Most spices do not undergo substantial industrial or chemical processing after harvest. Spices are derived from plant sources, and the post-harvest processes are generally limited to simple operations such as drying. Therefore, the criterion of “substantial transformation” alone does not sufficiently justify the requirement to indicate both the **Country Of Harvest** and the **Country Of Origin** for spices.

A more plausible justification for requiring both declarations is the widespread practice of repackaging in intermediary countries during the stages between production and large-scale distribution. In such cases, transparent labeling is essential to ensure traceability, protect consumer rights, and maintain fair trade practices. It is recommended that no new terminology, such as “region,” be introduced into the documents. Throughout all meetings and discussions, the terms **COO (Country Of Origin)** and **COH (Country Of Harvest)** were consistently used, referring respectively to the **country of origin** and the **country of harvest**. Therefore, there is no need to introduce a new term such as “region”.

In summary, while the “**Country Of Harvest**” refers to the location where the product is harvested (as first material), the “**Country Of Origin**” refers to the location where it is produced or processed (as final product). These two concepts hold particular significance in legal and commercial contexts.

So, it is recommended to make both mandatory for agricultural products and saffron as well, while removing the inserted footnote.

Agenda item 4: Consideration of labelling provisions in draft Codex standards (endorsement) (CCFO)

Iran appreciates the work undertaken by CCFO in developing the Draft Standard for Microbial Omega-3 Oils and generally supports the proposed labelling provisions contained in Section 7.

Iran agrees that declaring EPA and DHA content is important for consumer information and transparency. Iran also supports the requirement to identify the microbial source by including the genus name in the product designation.

However, regarding Section 7.3, Iran considers that the phrase “other labelling requirements specified in the country of authorisation” may benefit from further clarification to avoid inconsistent interpretation and implementation among Codex Members.

Iran suggests considering more precise wording or additional guidance to ensure harmonized application of labelling requirements in international trade while maintaining flexibility for national regulatory frameworks.

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 (PAL) (Step 7)

General Comment

The draft guidelines are comprehensive, scientifically robust, and represent a significant step toward harmonizing global approaches to precautionary allergen labelling (PAL). The document provides a strong

foundation for consistent, risk-based application of PAL and appropriately balances consumer protection with the facilitation of international trade.

The Islamic Republic of Iran supports the overall direction of the draft and offers the following comments to further enhance clarity, harmonization, and practical implementation across Member countries.

1. Establishing Reference Doses (RfDs) for Allergens Not Yet Covered

(Relevant to paragraph 51 – Need for clarity and consistency in RfD development)

Comment

Section 4.3.2 allows national or regional authorities to establish their own Reference Doses (RfDs) when one is not provided in the guidelines. While such flexibility is important, the absence of a defined methodological framework may lead to divergent RfDs for the same allergen across jurisdictions. This could create inconsistencies in risk management, regulatory expectations, and international trade.

Recommendations

- **Provide methodological guidance:** Include an annex or dedicated section outlining recommended scientific approaches for deriving new RfDs. This may reference acceptable data sources (e.g., double-blind placebo-controlled food challenge studies, population threshold modelling such as ED01/ED05), statistical approaches, uncertainty factors where applicable, and expectations regarding peer review and transparency.
- **Encourage harmonization:** Establish a mechanism for sharing newly derived RfDs among Codex Members, such as a voluntary notification system or centralized repository. This would promote convergence and reduce the risk of regulatory divergence.
- **Include an illustrative example:** A worked example demonstrating how an authority might derive an RfD for a less common allergen would enhance transparency and promote harmonized scientific approaches.
- **Introduce a periodic review mechanism:** Include a provision for the periodic review of established RfDs in light of emerging clinical evidence, improved population data, advances in threshold modelling, and developments in analytical science. This would ensure that reference doses remain scientifically current and globally aligned.
- **Clarify analytical feasibility considerations:** Provide guidance on how analytical limits of detection (LOD) and limits of quantification (LOQ) should be considered when establishing and applying RfDs. Alignment between toxicological thresholds and practical laboratory capabilities is essential to ensure enforceability, regulatory certainty, and consistent implementation across jurisdictions.

2. Clarifying the Distinction between Allergen Types and Reaction Mechanisms

(Relevant to paragraph 51 – Ensuring clear differentiation of allergenic hazards)

Comment

The draft refers to the need to distinguish IgE-mediated wheat allergy from gluten intolerance (coeliac disease). Further clarification in this area would strengthen the appropriate application of PAL. These conditions differ significantly in immunological mechanism, clinical presentation, severity, and threshold sensitivity. Without clearer differentiation, there is a risk that PAL may be inconsistently applied or misinterpreted by regulators, food business operators, and consumers.

Recommendations

- **Categorize allergen types:** Consider including a section or table distinguishing allergens according to reaction mechanism (e.g., IgE-mediated allergy, non-IgE-mediated allergy, T-cell-mediated conditions such as coeliac disease). This would support alignment of RfDs and PAL decisions with physiological and clinical realities.
- **Provide specific guidance for wheat and gluten:**
 - Clarify how to address wheat allergens that cause IgE-mediated reactions separately from gluten, which is relevant to coeliac disease.
 - Provide guidance on how gluten thresholds established for “gluten-free” claims may interact with PAL considerations for wheat as an allergen.

- **Ensure consistency with existing Codex texts:** Any differentiation between allergenic conditions should remain fully aligned with the General Standard for the Labelling of Prepackaged Foods (CXS 1-1985) and other relevant Codex standards to avoid regulatory fragmentation and ensure coherent global implementation.

These clarifications would contribute to more accurate risk assessment and consistent labelling practices.

3. Implementation Timeline and Transition Expectations

(Relevant to paragraph 51 – Enhancing clarity on implementation and compliance)

Comment

While the scientific and technical content of the guidelines is strong, explicit guidance regarding implementation timelines and transition expectations would facilitate smooth and coordinated adoption. Food business operators and national authorities require clarity on anticipated timelines to align regulatory amendments, label revisions, reformulation activities, and staff training.

Recommendations

- **Phased implementation:** Consider recommending a staged implementation approach, for example beginning with major allergens or priority food categories before expanding to additional allergens.
- **Defined transition period:** Suggest a reasonable transition period (e.g., 12–24 months after adoption) to allow for label updates, risk assessments, supply chain adjustments, and education of relevant stakeholders.
- **Compliance considerations:** Acknowledge that monitoring and enforcement may be conducted within existing national food safety and labelling frameworks, while allowing flexibility for country-specific regulatory systems.
- **Capacity-building considerations:** Recognize that some Member countries may require technical assistance, laboratory strengthening, and training to effectively implement risk-based PAL approaches. Encouraging international cooperation and knowledge-sharing would support equitable and consistent global implementation.

4. Consistency and Clarity of Precautionary Allergen Labelling Statements

Comment

While the draft appropriately emphasizes risk assessment and the establishment of reference doses, additional clarity regarding the wording of precautionary allergen labelling statements would further enhance consumer understanding and prevent inconsistent market practices.

Recommendations

- **Encourage standardized PAL phrasing:** Promote the use of clearly defined and limited expressions (e.g., “may contain [allergen]”) to reduce variability and consumer confusion.
- **Discourage non-specific or unjustified statements:** Avoid overly broad or precautionary statements that are not supported by documented risk assessment and validated allergen control measures.
- **Reinforce risk-based use of PAL:** Emphasize that PAL should only be applied when a residual risk remains after implementation of Good Manufacturing Practices (GMP), allergen management plans, and preventive controls.

Standardization of wording would improve consumer confidence, enhance clarity in international markets, and support fair trade.

Agenda item 6: Amendments to the General standard for the labelling of pre-packaged foods (CXS 1-1985): Provisions relevant to joint presentation and multipack formats (Step 4)

General Comment

The proposed amendments provide useful clarification for joint presentation and multipack formats and help modernize the General Standard for the Labelling of Prepackaged Foods (CXS 1-1985) in response to evolving packaging practices. The work of the EWG is appreciated, and the draft generally enhances consistency and consumer understanding. The following comments highlight areas where further clarity or final decisions would support interpretation and implementation.

1. Bracketed Text in Section 8.1.3.1

Comment:

Appendix I notes that CCFL49 must decide on the inclusion or removal of bracketed text in Section 8.1.3.1, which concerns the mandatory labelling information required on the outer packaging when it differs from that of the individually packaged items. A final decision on this bracketed text is essential, as its presence or absence directly affects:

- clarity regarding producer and distributor responsibility
- consistency in mandatory information between outer and inner packaging
- the transparency of information for consumers purchasing multipacks

Recommendation:

Codex should finalize whether the bracketed provisions remain or are removed, and provide a brief rationale in the final text to guide national authorities and industry in applying the requirement consistently.

2. Greater Detail on the Resolution of Differing Views (Ingredients, Net Contents, Dates)

Comment:

The draft notes that the EWG addressed differing views on how ingredients, net contents, and date marking should appear on joint or multipack formats. However, Appendix I and the main document give limited explanation of the nature of the initial disagreements or how the final compromise was reached. Without this context, the rationale behind the selected approach may be unclear, particularly for:

- determining which information must appear on both inner and outer packaging
- interpreting when outer packaging declarations supersede or complement inner declarations
- aligning national regulations with Codex requirements

Recommendation:

Provide a concise explanation (either in the report or as a footnote) of the key differing views and how the EWG resolved them. This would improve transparency and help ensure uniform application across Member countries.

3. Clarification of the Term “Container” and Its Relationship to Inner Packaging

Comment:

Appendix I acknowledges differing views regarding whether the definition of “container” in the GSLPF applies strictly to outer packaging. Although the group reached agreement that inner packaging not intended for individual sale is out of scope, the underlying ambiguity in terminology could still cause practical confusion.

For example, situations involving:

- sealed inner units that are not sold individually but contain essential consumer information
- inner packaging that might reasonably be separated from the outer packaging by consumers
- multipacks in which both inner and outer units carry partial labelling information

Recommendation:

Clarify or restate the definition of “container” as it applies within these amendments, ensuring it is clearly limited to outer packaging for the purpose of Sections 8.1.3.1–8.1.3.3. Alternatively, include a short explanatory note within the guideline text. This would minimize inconsistencies across jurisdictions.

Overall Conclusion

The proposed amendments move the General Standard toward greater clarity in the context of modern packaging formats. Finalizing the bracketed text, providing more detail on how differing views were resolved, and clarifying the use of “container” would strengthen the document and enhance consistent, global application.

Agenda item 7: Guidelines on application of food labelling provisions in emergencies (Step 4)

General Comment

Across the highlighted sections, a recurring challenge is balancing clarity, flexibility, and scope.

Iran recommends ensuring that each key concept, ingredient substitution, unsafe product, and illustrative examples, is framed with:

- clear guiding principles,
- flexibility suited to crisis conditions, and
- safeguards to maintain consumer protection and regulatory coherence.

These refinements would support consistent implementation across Codex Members during emergency situations.

1. Ingredient Substitution

Iran notes the reference to the “**lack of consensus on ingredient substitution**” and the proposal to include only a high-level reference with brief clarification on communication to consumers.

To support effective implementation during emergencies, additional clarification is still required on the following points:

- **Conditions under which substitutions may occur** (e.g., supply chain disruption, shortages, emergency authorization).
- **Minimum information that must be communicated to consumers**, even under simplified emergency labeling.
- **Acceptable communication channels** (e.g., on-pack statements, digital notices, point-of-sale information, public advisories).
- **Expectations for transparency** regarding potential allergen risks or nutritional changes due to substitutions.

A high-level reference alone may not sufficiently guide national authorities or food business operators. A brief but clear specification of the communication principles would strengthen consumer protection while maintaining necessary flexibility.

2. Definition and Description of “Unsafe Product”

The document indicates that refinements were needed to make the description of an “**unsafe product**” both flexible and clear.

Iran recommends further clarification to ensure that the guidelines:

- Provide a functional definition that can be applied across diverse emergency scenarios.
- Distinguish between products that become unsafe because of the emergency, and products already unsafe due to contamination, spoilage, mislabeling, or other risks.
- Clearly outline the criteria or indicators that competent authorities should use to identify and classify a product as unsafe under emergency conditions.
- Clarify how emergency labeling provisions interact with existing Codex food safety standards, so as not to weaken established protections.

A refined description is necessary to ensure consistent application and avoid misinterpretation during urgent decision-making.

3. Use of Examples

The concern that examples may be misunderstood as exhaustive is valid.

However, examples, when properly framed, can enhance clarity, especially in a complex domain such as emergency food labeling.

Iran recommends:

- Including illustrative examples only if they are clearly labeled as *non-exhaustive, for guidance purposes only*, and *not prescriptive*.
- Ensuring that the examples demonstrate principles, not specific product categories.
- Providing examples that show a variety of emergency situations to illustrate the intended flexibility of the guidelines.

This approach helps avoid misinterpretation while supporting food business operators and authorities with practical guidance.

Agenda item 8.2: Proposal for new work on a guiding definition for a more uniform application of labelling provisions to “small packages” and their related exemptions set in existing Codex texts

- **Scope Clarification**

-Exclusion of "Small Units": The document clearly states that "small units" are outside the scope of this proposal. This exclusion should be prominently placed in the introduction or purpose statement for immediate clarity.

-Consequences of Undefined "Small Packaging": The proposal correctly identifies that "small packaging" lacks a harmonized Codex definition. Further detail on the practical implications of this gap (e.g., for enforcement, trade) would strengthen the justification for new work.

- **Measurement Criteria Consistency**

-Area vs. Volume/Weight: The document notes that "small units" are defined by surface area, while "small packaging" sometimes uses volume or weight thresholds. The proposal should:

- Explain the historical or practical reasons for these differing measurement bases.
- Clarify if the new work aims to harmonize these criteria or delineate their distinct applications.

- **Impact of Technology and E-Commerce**

- Evolving Commercial Environments: The proposal acknowledges that technology and e-commerce influence packaging and labeling. To enhance this point:

- Provide specific examples of how digital information access interacts with small-pack exemptions.
- Explicitly state whether the proposed guidance will address digital labeling contexts.

- **Supporting Evidence of Divergence**

-International Provisions: The document refers to a table and list of national/regional provisions to demonstrate a lack of harmonization. This comparative evidence is crucial.

- Ensure this information is clearly presented and accessible within the document to fully support the need for Codex action.
