

# CODEX ALIMENTARIUS COMMISSION



Food and Agriculture  
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World Health  
Organization

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Agenda Item 5

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## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON FOOD LABELLING

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#### 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)

*Comments by Burundi, El Salvador, India, Japan, Kenya, Nigeria, the Philippines, Republic of Korea, Senegal, United Republic of Tanzania, Zambia, and Institute of Food Technologists (IFT)*

#### Burundi

Burundi welcomes the progress made by CCFL48 on both the revision of the General Standard for the Labelling of Prepackaged Foods (CXS 1-1985) and the Draft Guidelines on the Use of Precautionary Allergen Labelling (PAL). Burundi supports the advancement of the PAL guidelines to Step 8, recognizing their critical role in protecting consumers from allergen-related health risks through clear, prominent, and consistent labelling.

Burundi notes that PAL should be grounded in a science-based and risk-proportionate approach, supported by internationally validated analytical methods, harmonized reporting units, and clear guidance on equivalent wording, gluten declarations, and allergen thresholds. Burundi also underscores the importance of accessible, non-proprietary methods and practical implementation considerations to support effective enforcement, particularly in developing countries.

#### El Salvador

#### TEMA 5: Anexo a la Norma General para el etiquetado de los alimentos preenvasados (CXS 1-1985): Directrices para el uso del etiquetado precautorio de alérgenos (trámite 7)

##### Comentarios generales:

El Salvador agradece el documento CCFL preparado por el Grupo de Trabajo Electrónico, presidido por Estados Unidos de América, Australia y El Reino Unido.

El Comité Espejo del Codex sobre Etiquetado de los Alimentos (CCFL) ha revisado el Informe del Grupo de Trabajo Electrónico (GTE).

El Salvador apoya que el proyecto avance al Trámite 8 del Procedimiento de Elaboración de Normas del Codex, siempre y cuando se consideren los comentarios realizados por El Salvador en las secciones específicas del proyecto de norma.

##### Comentarios específicos:

A continuación, se presentan los comentarios específicos, según Apéndice 1, del documento CX/FL 26/49/5: Proyecto de anexo a la Norma General para el Etiquetado de los Alimentos Preenvasados (CXS 1-1985): Directrices para el Uso del Etiquetado Precautorio de Alérgenos. En el trámite 7.

- Sobre los **Principios generales en el numeral 4.3**, se propone añadir el texto subrayado en negrita y cursiva, después del texto entre corchetes:

[El EPA **solo debería** utilizarse cuando se demuestre que la presencia involuntaria de un alérgeno alimentario no puede reducirse a un nivel igual o inferior al nivel de acción correspondiente a dicho alérgeno alimentario en función de las dosis de referencia que figuran en el Cuadro 4.3.1.] **No obstante, el EPA podrá utilizarse en función de los resultados de una evaluación cualitativa en la cual se determine la posibilidad de la presencia del alérgeno.**

##### Justificación:

El Salvador considera que al establecer que el EPA “solo debería” utilizarse bajo la condición indicada podría generar retos técnicos y económicos para los fabricantes, especialmente cuando no se dispone de estudios cuantitativos o de la capacidad analítica para demostrar el cumplimiento de los niveles de acción.

Por ello, El Salvador considera pertinente mantener un enfoque flexible en la redacción, de manera que no se restrinja el uso del EPA únicamente a escenarios donde exista verificación cuantitativa, sino que también pueda sustentarse en evaluaciones y controles de carácter cualitativo, siempre que estos se desarrollen en el marco de la implementación de las prácticas establecidas en el “Código de prácticas sobre la gestión de los alérgenos alimentarios por parte de los operadores de empresas de alimentos (CXC 80-2020)”. Este enfoque permitiría que, cuando se apliquen adecuadamente dichas prácticas, el uso del EPA sea técnicamente justificado, facilitando además una implementación progresiva por parte de las empresas, sin comprometer la adecuada gestión del riesgo de alérgenos ni la protección del consumidor.

En atención a ello El Salvador propone modificar el párrafo 4.3 como se indica a continuación “No obstante el EPA podrá utilizarse en función de los resultados de una evaluación cualitativa en la cual se determine la posibilidad de la presencia del alérgeno”.

- **Principios generales en numeral 4.3.3** se selecciona la palabra entre corchete [se utiliza] [utilizarse] [en el etiquetado], a continuación, se presenta tachado el texto que no se apoya:

Si en la etiqueta ~~[figura/~~**se utiliza** una declaración de EPA para cereales que contienen gluten, no debe ~~[figurar/~~**utilizarse** en la etiqueta **[o en el etiquetado]** la declaración “exento de gluten”.

#### **Justificación:**

• En concordancia, la Norma General para el Etiquetado de los Alimentos Preenvasados (CXS 1-1985) establece en su apartado 3.1 que los alimentos no deben describirse ni presentarse de manera falsa, equívoca o engañosa, ni susceptible de inducir a error respecto de su verdadera naturaleza.

• Por lo tanto, El Salvador apoya que ambas declaraciones no sean utilizadas de manera conjunta cuando resulten incompatibles, a fin de asegurar coherencia en la información y proteger al consumidor.

- **Principios generales 4.4:** Se apoya los cambios propuestos en dicho numeral.

El EPA ~~debe~~ **debería acompañado complementarse** con programas educativos/informativos **dirigidos por las autoridades competentes** para garantizar una comprensión y un uso **adecuados** del EPA por parte de los consumidores, los proveedores de servicios de salud, los operadores del sector alimentario **y otras partes interesadas**.

- **Presentación del EPA 5.2 bis:** Se apoya la disposición en dicho numeral como se presenta en el documento.

**5.2 bis Cuando el alimento esté exento de incluir la lista de ingredientes, y no haya una lista de ingredientes, la declaración de EPA debe aparecer en un lugar destacado de la etiqueta. Cuando en la etiqueta aparezca una declaración separada de conformidad con la Sección 8.3.2.1 de la NGEAP, la declaración de EPA debe estar en el mismo campo de visión que dicha declaración separada.**

#### **Justificación:**

En el sentido de que la declaración de etiquetado precautorio de alérgenos (EPA) debe presentarse en un lugar destacado cuando el alimento esté exento de lista de ingredientes, y mantenerse en el mismo campo de visión cuando exista una declaración separada conforme a la Sección 8.3.2.1 de la Norma General para el Etiquetado de los Alimentos Preenvasados (CXS 1-1985).

Lo anterior es consistente con dicha Sección 8.3.2.1, la cual establece la posibilidad de presentar una declaración separada de alérgenos junto con la lista de ingredientes, con el objetivo de garantizar la visibilidad y claridad de la información para el consumidor.

- **Presentación del EPA 5.2.1:** Se apoya la disposición en dicho numeral como se presenta en el documento.

**5.2.1 La declaración de EPA debe comenzar con las palabras ‘Puede contener’ (o palabras equivalentes **como ‘puede estar presente’**) y debe incluir **declarar los** alérgenos alimentarios ~~identificados~~ usando los nombres especificados para los alimentos e ingredientes que figuran en la Sección 4.2.1.4 y, si corresponde, en la Sección 4.2.1.5 de la *Norma general para el etiquetado de los alimentos preenvasados* (CXS 1-1985).<sup>4bis, 4ter</sup>**

#### **Justificación:**

Permitir el uso de las expresiones “puede contener” o equivalentes como “puede estar presente”, ya que esta flexibilidad facilita la adaptación del etiquetado a distintas formulaciones lingüísticas sin alterar el sentido precautorio de la declaración EPA.

Asimismo, se considera adecuado que las empresas dispongan de margen para emplear frases alternativas que mantengan la referencia clara a la posible presencia de alérgenos, siempre en coherencia con los requisitos de la norma de etiquetado de alimentos preenvasados (CXS 1-1985).

### India

India appreciates the work done by the EWG Chair United States of America and co-chair Australia and United Kingdom in drafting food allergen labelling.

#### i. Table 4.3.1.

- India would like to seek clarification regarding the presentation and interpretation of cereals containing gluten in Table 4.3.1.

Guidance is needed on how these elements should be applied in practice such as how the gluten-based reference dose should be applied in relation to cereal-specific entries; for e.g. when a product contains wheat as well as barley and rye then RfD of gluten i.e. 4 will apply or RfD of total protein of wheat i.e. 5 will apply.

Rationale: Having 2 different reference doses for wheat could be confusing to implement and shall be further discussed on how to determine action levels for PAL. Also, it raises the question on whether this distinction is clearly shown in the GSLPF in Section 4.2.1.4 as mentioned is ONLY cereals containing gluten and not IgE mediated wheat allergy. We believe this likely needs to be further discussed and determine whether edits are needed to ensure clarity and understanding

- Further, for Barley and Rye, India proposes to indicate as **"not determined"** in replacement of the dash in RfD (mg total protein from Allergic food).

#### ii. Footnote 4bis

'When gluten is unintentionally present above the action level and the source of the gluten cannot be verified by risk assessment, the specified names of all cereals containing gluten (i.e. wheat, barley, and rye) **or a simple mention of 'gluten'** shall be included in the PAL statement. ~~In addition to the specified name of wheat, rye, and barley, the word 'gluten' may be used~~

Rationale : The term "gluten" is widely understood and allows for flexibility in cases where the packaging size may limit the character length of the PAL statement.

### Japan

Japan appreciates the progress of this work and is generally supportive of the current draft of guidelines. At the same time, Japan would like to note the following points.

#### ● Section 4.3

Japan appreciates the FAO/WHO experts for providing scientific basis for establishment of the reference doses (RfDs), as well as CCMAS for its works to reply to the request from CCFL.

Japan recognizes the importance of setting thresholds to prevent the overuse of PAL. At the same time, given that the sensitivity to specific allergens may vary across populations, Japan considers it important to maintain an appropriate flexibility in the application of the guideline, including to allow competent authorities to set the PAL thresholds based on an appropriate risk assessment and national/regional circumstances. In light of this, Japan supports the current wording of 'should' in the provision 4.3, and use of 'shall' should be avoided.

#### ● Section 5.2.1

Japan understands that harmonization of PAL statements play an important role in clearly conveying the potential unintended allergen presence (UAP) risks to allergic consumers. At the same time, Japan would like to stress that it is essential to give competent authorities discretions to set their rules on PAL statements at national or regional levels, considering that language, custom, and consumers' perception for wording may differ significantly across regions.

In Part 3 of the FAO/WHO report 'Risk assessment of food allergens', it is pointed out by the Expert Committee that 'a single, clear and concise phrase should mitigate against the current situation in which many PAL statements are ignored by consumers' (p.48). We assume that the current draft of 5.2.1 is based on this recommendation. However, the Expert Committee also notes that phrases like 'may contain' or 'may be present' are 'not specifically endorsed by the committee' (p.47-48), and that 'more research is needed to understand consumer PAL phrase preferences in different regions. Other single PAL phrases could work in different regions as long as there are communication and education efforts in these regions....' (p.48). Furthermore, literature cited by the FAO/WHO report only refers to the researches conducted in limited regions such as Australia, Europe and North America. Notably, Table1 (p.5), which summarizes the results of consumer surveys

conducted by several researchers, only reflects the data from these regions and does not include that from other regions such as Asia, Africa and Latin America. Therefore, Japan considers that further consideration on national/regional differences in consumer perception and preferred PAL wordings is needed.

In Japan, the national rule requires FBOs to describe the objective information on harvesting or manufacturing process to alert the potential risks of UAP to consumers (for example, 'shellfish being harvested using methods where small shrimp may be present', or 'products being manufactured in facilities that also produce foods containing XX (specific allergens)'). This approach has long been used in Japan, as such information is considered useful for allergic consumers to assess risk for themselves. By contrast, statements like 'may contain' are perceived too ambiguous to adequately convey the risks to consumers, and therefore use of such words is not permitted. This illustrates that language preference may vary across countries and regions, and that even where the intent is the same, PAL statements may be expressed in different ways. In light of this, Japan considers it important not to strictly uniform the wording of PAL statements across all regions over the world.

For these reasons, Japan considers that :

- 'or equivalent words' is essential in 5.2.1;
- PAL statements should not be limited only to 'may contain' or 'may be present', and therefore;
- additional texts which explicitly preclude use of other words such as 'made in a factory that produces', including cases where such texts are provided as supplementary factual information explaining the basis for a 'may contain' statement, should not be included.

Japan appreciates the balanced approach reflected in the current draft and can support the text provided that sufficient flexibilities are ensured for competent authorities to set their rules for PAL statements at national or regional levels. However, if the text is revised to narrowly limit the PAL statements only to 'may contain' and 'may be present', Japan has some concerns on such approach.

#### Kenya

Kenya welcomes the progress made by CCFL48 on both the revision of the General Standard for the Labelling of Prepackaged Foods (CXS 1-1985) and the Draft Guidelines on the Use of Precautionary Allergen Labelling (PAL). Kenya supports the advancement of the PAL guidelines to Step 8, recognizing their critical role in protecting consumers from allergen-related health risks through clear, prominent, and consistent labelling.

Kenya notes that PAL should be grounded in a science-based and risk-proportionate approach, supported by internationally validated analytical methods, harmonized reporting units, and clear guidance on equivalent wording, gluten declarations, and allergen thresholds. Kenya also underscores the importance of accessible, non-proprietary methods and practical implementation considerations to support effective enforcement, particularly in developing countries.

#### Nigeria

Nigeria wishes to thank the Electronic Working Group chaired by the United States of America, Australia, and the United Kingdom on annex to the general standard for the labelling of pre-packaged foods (CXS1-1985): guidelines on the use of precautionary allergen labelling.

#### Paragraph 31, Table 4.3.1

Nigeria supports cross reference to the general standard for the labelling of Pre-packaged food for PAL Requirements and the foot notes

- I. Nigeria supports the adoption of 4mg threshold for gluten in cereal -based commodities The square bracket should be removed from 4.3.1 to 4.3.3 to read ***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***
- II. Nigeria supports the advancement of the standard to step 8 for adoption

#### Rationale:

The establishment of the reference dose (RFDs) we're established based on risk-based principles and derived from global clinical data

There is provision for regional/ national competent authorities to establish reference dose for particular food allergens not included in the table 4.3.1 for the purpose of determining action level.

#### The Philippines

Section	Category	Proposed Text	Comment/Rationale
<p>For the purpose of these guidelines, the following definition shall be used in conjunction with the definitions in Section 2 of the General Standard for the labelling of pre-packaged Foods (CXS 1-1985):</p> <p><b>“Precautionary allergen labelling”</b> is a statement made in the labelling of pre-packaged foods to indicate a risk from the unintended presence of a food allergen(s) due to cross-contact with an allergenic food that has been identified by a risk assessment.</p>			<p>The Philippines supports the proposed definition of Precautionary Allergen Labelling (PAL) as it provides a clear and practical basis for the consistent application of precautionary statements in food labelling.</p>
<b>4. General Principles</b>			
<p>4.2 The decision to use PAL should be based on the findings of a risk assessment<sup>2</sup>, which can include but is not limited to a quantitative risk assessment, of unintended food allergen presence.</p> <p><del>4.3 PAL [shall / should] [only] be used when it is demonstrated that unintended food allergen presence cannot be mitigated to a level at or below the action level<sup>3</sup> for a food allergen based on the reference doses in the table at 4.3.1.</del></p> <p><b>[4.3 PAL should only</b> be used when it is demonstrated that unintended food allergen presence cannot be mitigated to a level at or below the action level<sup>3</sup> for a food allergen based on the reference doses in the table at 4.3.1.</p>	Editorial	<p>Proposed text for 4.3.</p> <p>4.3 PAL <b>should</b> be used when it is demonstrated that unintended food allergen presence cannot be mitigated to a level at or below the action level<sup>3</sup> for a food allergen based on the reference doses in the table at 4.3.1.</p>	<p>The Philippines supports the provision that the decision to apply PAL should be based on the findings of a risk assessment of unintended allergen presence.</p> <p>We note positively that the text allows flexibility by recognizing that risk assessment may be quantitative or other appropriate approaches.</p> <p>Anchoring PAL on risk assessment helps ensure that its use is justified, evidence-based, and not arbitrary.</p> <p>The Philippines supports the principle that PAL <b>should</b> be used when unintended allergen presence cannot be reduced to acceptable levels despite the application of appropriate control measures.</p> <p>Moreover, the use of the word “only” could be restrictive.</p>
<p>4.3.2 Where a reference dose is not established for a particular food allergen in the table to 4.3.1 above, regional/national <b>competent</b> authorities can establish a reference dose consistent with recognized principles<sup>4</sup> for the purposes of determining an action level.]</p>			<p>The Philippines supports Section 4.3.2.</p> <p>We recognize the importance of providing flexibility for regional and national competent authorities to establish reference doses where these are not yet available in the Codex table. This provision enables countries to take appropriate risk management decisions based on available scientific evidence and recognized principles.</p>

Section	Category	Proposed Text	Comment/Rationale
<b>4.3.3. If a PAL statement for cereal(s) containing gluten [appears / is used] on the label, then the term “gluten free” shall not [appear/ be used] on the label [or in labelling].</b>	Editorial	Proposed text: 4.3.3. If a PAL statement for cereal(s) containing gluten <b>is used</b> on the label, then the term “gluten free” shall not <b>appear</b> on the label <b>or in labelling</b> .	The Philippines supports Section 4.3.3 with wording preference.  We agree that where a precautionary allergen labelling statement for cereals containing gluten is used, the term “gluten free” shall not be used on the label or in labelling. This provision is important to prevent conflicting information and ensure that consumers are not misled.  The Philippines prefers the use of the term “ <b>is used</b> ” on the first part of the provision and the word “ <b>appear</b> ” on the second part. We also support retaining “ <b>or in labelling</b> ” to ensure that the restriction applies to all forms of communication, not only the physical label.
4.4 — PAL shall <b>should</b> be accompanied <b>complemented</b> by education/information programs <b>led by competent authorities</b> to ensure <b>proper</b> understanding and appropriate use of PAL by consumers, healthcare providers, food business operators, <b>and other stakeholders</b> .			The Philippines supports Section 4.4.  The Philippines prefers the use of “should” rather than “shall,” to allow flexibility in implementation across different national contexts.
5.2 PAL <del>should</del> <b>shall</b> appear as a separate statement directly under or in close proximity to the ingredient list (when present).	Editorial	5.2 PAL <b>shall</b> appear as a separate statement directly under or in close proximity to the ingredient list (when present) or <b>allergenic foods declaration</b> .  Sample text:  Ingredients:  Lorem ipsum, Lorem ipsum, Lorem ipsum, Lorem ipsum, Lorem ipsum  Food Allergen Information: Mustard  May contain: Fish	The Philippines supports Section 5.2 with minor wording addition.  In most cases, the allergenic food declaration is declared directly under the Ingredients List. To address this, we proposed to add the phrase “or allergenic foods declaration.”
<b>5.2 bis Where a food is exempt from declaring a list of ingredients, and no list of ingredients is present, PAL shall be declared in a prominent</b>			The Philippines supports Section 5.2 bis.



Section	Category	Proposed Text	Comment/Rationale
<b><u>position on the label. Where a separate statement made in accordance with Section 8.3.2.1 of the GSLPF exists on the label, the PAL declaration shall be in the same field of vision as the separate statement.</u></b>			We agree that where a food is exempt from declaring a list of ingredients, precautionary allergen labelling shall be presented in a prominent position on the label to ensure visibility. We also support the requirement that, where a separate allergen statement is present, the PAL declaration shall appear in the same field of vision to promote clarity and consistency for consumers.
<p>5.2.1 A PAL statement shall commence with the words 'May contain' (or equivalent words <b>such as 'may be present'</b>) and <del>include the identified</del> <b>declare the</b> allergenic food(s) using the specified names for the foods and ingredients as listed in sections 4.2.1.4 and where applicable 4.2.1.5 of the General Standard for the labelling of pre-packaged foods (CXS 1-1985).<sup>4bis, 4ter</sup></p> <p><b><u>4bis When gluten is present above the action level and the source of the gluten cannot be verified by risk assessment, the specified names of all cereals containing gluten (i.e. wheat, barley, and rye) shall be included in the PAL statement.</u></b></p> <p><b><u>4ter In addition to the specified name of wheat, rye, and barley, the word 'gluten' may be used.</u></b></p>			The Philippines supports Section 5.2.1. and 4bis.
<p>5.2.2 A PAL statement shall <b><u>be declared in a clear and distinct manner such as through the use of contrast distinctly from surrounding text such as through the same font type, style or colour that contrasts from the surrounding text</u></b> <del>used for declarations</del> in accordance with section 8.3.1 of the General Standard for the labelling of prepackaged foods (CXS 1-1985).</p>			<p>The Philippines supports Section 5.2.2.</p> <p>We agree that precautionary allergen labelling should be presented in a clear and distinct manner, including the use of contrasting font type, style, or color, and should be easily distinguishable from surrounding text.</p>

### Republic of Korea

In line with FAO and WHO (2023), Risk Assessment of Food Allergens – Part 3, page 17, the Republic of Korea proposes that paragraph 4.2 be amended to read: "4.2 The decision to use PAL should be based on the findings of a quantitative or qualitative risk assessment, which can include but is not limited to a quantitative risk assessment, of unintended food allergen presence," on the grounds that the decision to use PAL should be based on the findings of a risk assessment that encompasses both qualitative and quantitative approaches and is not limited to quantitative risk assessment alone.

[4.3]

The Republic of Korea recognizes the intent of establishing a quantitative Reference Dose (RfD) to prevent the misuse of PAL statements.

However, taking into account the analytical challenges and cost burdens that vary according to company size and national infrastructure capacity, as well as the fact that validated analytical methods for quantitative allergen measurement applicable to RfD-based thresholds have not yet been clearly established at the CCMAS level, the Republic of Korea is also concerned that the premature mandatory application of RfD-based quantitative requirements could create disproportionate compliance burdens, particularly for small and medium-sized enterprises and developing countries, and may risk functioning as de facto non-tariff barriers to trade if not carefully designed with sufficient flexibility and transitional arrangements.

[5.2, 5.2bis, 5.2.2]

With regard to PAL labelling methods, the Republic of Korea is of the view that, unlike mandatory allergen labelling, it would be appropriate to grant food business operators flexibility, under their own responsibility, in determining the location and format of PAL statements.

[5.2.1]

Concerning "equivalent words," the Republic of Korea is of the view that the expression "made in a factory that" would also be appropriate for conveying the risk of unintended allergen cross-contact.

## Senegal

### Contexte :

. Le CCFL48 en 2024 a finalisé les révisions de la Norme générale sur l'étiquetage des denrées alimentaires préemballées. Il a fait progresser le projet de Directives sur l'utilisation de l'étiquetage de précaution des allergènes (ÉPA), en le faisant passer à l'étape 5 en vue de son adoption provisoire par la Commission du Codex Alimentarius. Le Comité a approuvé l'objectif, la portée, les définitions ainsi que les sections 4.1 et 4.2 du projet de directives.

. Consultation mixte d'experts FAO/OMS ad hoc sur l'évaluation des risques liés aux allergènes alimentaires – orientations pour l'évaluation qualitative des risques (Siège de la FAO, Rome, Italie : 16– 20 juin 2025): Les allergènes alimentaires doivent être contrôlés au moyen de systèmes de gestion de l'innocuité des aliments appropriés.

. Consultation mixte d'experts FAO/OMS ad hoc sur l'évaluation des risques liés aux allergènes alimentaires – dose(s) de référence pour les céréales contenant du gluten (Siège de la FAO, Rome, Italie : 3 – 7 novembre 2025): Une dose de référence (DDR) de 4 mg de gluten est recommandée pour l'évaluation des risques de présence involontaire de gluten dans les produits alimentaires, ainsi que dans les céréales contenant du gluten, et sert de base pour décider si un ÉPA doit être appliqué.

. Atelier pour le renforcement des capacités FAO/OMS sur l'ÉPA et l'évaluation des risques des allergènes alimentaires à Nanning, en Chine (19 – 20 septembre 2025) : La FAO et l'OMS ont dispensé une formation pour le renforcement des capacités à 60 participants issus de 11 pays (Brunei, Brésil, Chine, Japon, République démocratique populaire lao, Malaisie, Maldives, Nigeria, Singapour, Tanzanie et Thaïlande), ainsi que d'organisations internationales et d'exploitants du secteur alimentaire.

. Le GTÉ a été établi en mars 2025 pour travailler sur l'utilisation de l'EPA sections 4.3, 4.3.2, 4.4 et 5 ; et des commentaires sur les doses de référence figurant dans le tableau 4.3.1.

. Le GTÉ, mis en place, a rempli son mandat tel que défini par le CCFL48 et soumet le projet de directives mises à jour, présenté à l'Annexe I, pour examen par le CCFL49.

### Position :

Le Sénégal soutient la proposition d'inclusion de la DR recommandée (4 mg de gluten) dans le tableau, son renvoi à la NGEDAP pour les exigences d'EPA et la suppression de la note de bas de page tel qu'indiquée par les membres du GTE.

En conclusion, Le Sénégal soutient l'adoption à l'étape 8.

### Justification :

Les DR recommandées ont été établies sur la base de principes fondés sur les risques, dérivés de données cliniques mondiales caractérisant les réactions à des quantités connues de protéines provenant d'aliments allergéniques, et fixées à des niveaux d'exposition visant à limiter les risques appréciables pour la santé ou les réactions indésirables chez les personnes sensibles.

Il existe différents facteurs de conversion, à la fois entre et au sein des différentes céréales contenant du gluten, et que ces facteurs de conversion n'étaient pas nécessaires aux fins du CCFL.



Enfin, les sections 8.1.1, 8.1.2, 8.1.3 et 8.2 de la Norme générale sur l'étiquetage des denrées alimentaires préemballées modifiées comblent les exigences spécifiques des EPA, tout en prenant en compte la mention des éventuelles contaminations croisées.

Il s'y ajoute que dans la pratique les consommateurs n'ont pas assez de temps pour chercher toutes les informations utiles notamment la présence d'allergènes, à la prise de décisions d'acheter ou de ne pas acheter. Dès lors, exiger un regroupement de toutes ces informations en un seul lieu sur l'emballage et éliminer le bas de page sur la NGEDAP est pertinent.

#### United Republic of Tanzania

The United Republic of Tanzania (URT) welcomes the progress made by CCFL48 on both the revision of the General Standard for the Labelling of Prepackaged Foods (CXS 1-1985) and the Draft Guidelines on the Use of Precautionary Allergen Labelling (PAL). The United Republic of Tanzania (URT) supports the advancement of the PAL guidelines to Step 8, recognizing their critical role in protecting consumers from allergen-related health risks through clear, prominent, and consistent labelling.

The United Republic of Tanzania (URT) notes that PAL should be grounded in a science-based and risk-proportionate approach, supported by internationally validated analytical methods, harmonized reporting units, and clear guidance on equivalent wording, gluten declarations, and allergen thresholds. The United Republic of Tanzania (URT) also underscores the importance of accessible, non-proprietary methods and practical implementation considerations to support effective enforcement, particularly in developing countries.

#### Zambia

Zambia supports cross-reference to the General Standard for the Labelling of Prepackaged Foods for PAL requirements and footnotes. We also supports the 4 mg threshold for gluten in cereal-based commodities and calls for the need to have more consumer information on labelling requirements at food purchase points. In this view, Zambia supports advancement of the annex on precautionary allergen labelling guidelines from Step 7 to Step 8 and supports removal of footnote and review of text on language acceptability and general criteria

The RfDs were established on the basis of risk-based principles, derived from global clinical data characterising reactions to known quantities of proteins from allergenic foods, and set at exposure levels intended to limit appreciable health risks or adverse reactions in sensitive individuals. Sections 8.1.1, 8.1.2, 8.1.3 and 8.2 of the General Standard for the Labelling of Prepackaged Foods meet the specific requirements for PAL.

#### Institute of Food Technologists (IFT)

Dear CCFL Colleagues,

The Institute of Food Technologists (IFT), a global scientific organization of individual members committed to advancing the science of food, thanks the members of the electronic working group, chaired by the USA, and co-chaired by Australia and the UK, for preparing the revision to the Guidelines on the Use of Precautionary Allergen Labeling for consideration by the committee at Step 7. We would like to reiterate comments on the proposed revision to the guidelines, which have previously been made in the response to the Circular Letter on this topic (CL 2026/07-FL).

IFT considers that the revised text of the guidelines is not ready for advancement to Step 8 in its current form. It should be reviewed further and revised by the physical working group such that it may be ready for endorsement by CCFL at the plenary meeting. In particular, whilst we welcome the revision of the table to reflect the outcome of the "Ad hoc joint FAO/WHO expert consultation on risk assessment of food allergens – reference dose(s) for cereals containing gluten and gluten" <https://openknowledge.fao.org/items/2ed0849b-cd11-4c94-881f-d1b41dbc215f> ~~we~~ <sup>we</sup> consider that the table is still unclear. It is particularly unclear in terms of which Reference Dose (RfD) should be adopted for wheat to ensure consumers are protected. We recommend that the table is reconsidered at the forthcoming physical working group scheduled for 10 May.

A possible solution to address the current confusion may be to delete the right hand column ("Total mg Gluten from Cereal containing gluten") of the table included in the Circular Letter (CL 2026/07-FL) and to also replace the current RfD of 5 for wheat in the column "mg protein from the allergenic food" in the table with the value of 4 (and specifically referencing gluten) given this would be protective of those sensitive to gluten and those who are allergic to protein from wheat. The reference to barley and rye could then be included alongside the mention of wheat in a single line in the table.

Furthermore, we suggest that Footnote 3 of the guidelines should be ~~revisited~~ <sup>revised</sup>. It is unclear why the 50th percentile for food consumption on a single eating occasion has been proposed for the determination of an action level for an allergenic food. It would seem more appropriate to suggest a higher percentile consumption figure to ensure a greater proportion of the potentially allergenic populations are protected in realistic exposure scenarios, including those who are high consumers of foods. For example, the FDA

Guidance for Industry: Recommendations for Submission of Chemical and Technological Data for Direct Food Additive Petitions<sup>[1]</sup> states: “*The petitioner should provide, at minimum, a mean EDI (to represent the “average” consumer) and the EDI at the 90th percentile (to represent the “high” consumer)*”. In addition, clarification/guidance should be included on how to obtain appropriate food consumption data for determining action levels in a particular country and on how to proceed if those data are not available.

We also consider that it would be appropriate under Section 4.2 of the draft guideline to include reference to the general principles of risk analysis set out in Section 4 “Risk Analysis” of the Codex Procedural Manual. The physical Working ~~Group~~Group, due to be held before CCFL, could further consider whether a particular sub-section of Section 4 of the Procedural Manual would provide effective further detail of the procedures to be followed.

<sup>[1]</sup> <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-recommendations-submission-chemical-and-technological-data-direct-food-additive#intake>