

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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Agenda item 5.2

CX/FL 24/48/5-Add.1 (Part B)

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD LABELLING

Forty-eighth Session

Quebec City, Canada

27 October – 1 November 2024

GUIDELINES ON THE USE OF PRECAUTIONARY ALLERGEN LABELLING (STEP 4)

Comments in reply to CL 2024/53-FL (Part B)

Comments by Argentina, Australia, Brazil, Canada, Chile, Colombia, Costa Rica, Ecuador, Egypt, European Union, Guatemala, Honduras, India, Indonesia, Japan, New Zealand, Paraguay, Saudi Arabia, South Africa, Thailand, Uganda, United Kingdom, Uruguay, USA and Alianza Latinoamericana de Asociaciones de la Industria de Alimentos y Bebidas (ALAIAB), Association Of European Coeliac Societies Codex and Regulatory Affairs, European Federation of Allergy and Airways Diseases Patients' Associations, Food Industry Asia, FoodDrinkEurope, ICBA, ICGA, ICGMA, ICUMSA, IDF/FIL, International Association of Consumer Food Organizations, International Confectionery Association, International Special Dietary Food Industries, The European Federation of the Associations of Dietitians (EFAD)

Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2024/53-FL issued in August 2024. Under the OCS, comments are compiled in the following order: general comments are listed first, followed by comments on specific sections.

Explanatory notes on the Annex

2. The comments submitted through the OCS are hereby attached as **Annex I** and are presented in table format.

3. Comments received on the Revision to the *General Standard for the Labelling of Pre-packaged Foods* (CXS 1-1985): Provisions relevant to allergen labelling (Step 7) have been included in CX/FL 24/48/5-Add.1 (Part A).

4. Comments received on the guidelines on the use of precautionary allergen labelling (PAL) have been included in CX/FL 24/48/5-Add.1 (Part B).

Annex I

GENERAL COMMENTS	MEMBER / OBSERVER
<p>(ii) Las Directrices para el uso del etiquetado precautorio de alérgenos (EPA) que figura en el Apéndice II del documento CX/FL 24/48/5 (Parte B), en concreto sobre:</p> <p>a. La sección “Finalidad” con respecto a determinar si los umbrales del EPA pueden abordar el contacto cruzado de cereales que contienen gluten para consumidores con enfermedad celíaca.</p> <p>Respuesta:</p> <p>Chile considera que es fundamental promover un mayor debate acerca de la inclusión de umbrales del etiquetado precautorio que puedan abordar el contacto cruzado de cereales que contienen gluten, especialmente en lo que respecta a los consumidores con enfermedad celíaca. Actualmente, no se ha establecido una dosis de referencia específica para estos cereales, lo que genera incertidumbre en la efectividad de las directrices propuestas.</p> <p>Adicionalmente, expresamos nuestra discrepancia con la incorporación de la enfermedad celíaca en el ámbito de aplicación del etiquetado precautorio. Consideramos que no todos los alimentos e ingredientes relevantes han sido adecuadamente evaluados en los informes del Comité de Expertos, por lo que creemos que el enfoque del etiquetado debería limitarse a la alergia alimentaria. Esta restricción permitiría una mayor claridad y eficacia en la protección de los consumidores.</p> <p>Por lo tanto, Chile insta a realizar un análisis más exhaustivo y a considerar la necesidad de establecer criterios claros y bien fundamentados que aborden específicamente la problemática del contacto cruzado en cereales con gluten, priorizando la salud y seguridad de los consumidores.</p> <p>b. El Principio 4.2 en relación con el texto alternativo propuesto sobre los tipos de evaluación de riesgos.</p> <p>Respuesta:</p> <p>Chile continúa apoyando esta sección propuesta tal como está redactada.</p> <p>c. El Principio 4.3 y el cuadro de dosis de referencia en la Sección 4.3.1, en concreto en relación con la inclusión del gluten.</p> <p>Respuesta:</p> <p>Chile apoya el texto propuesto en el Principio 4.3 y el cuadro de dosis de referencia de la Sección 4.3.1, ya que proporciona claridad en la evaluación de riesgos. Sin embargo, como se señaló en instancia anteriores, es importante contar con una dosis de referencia específica para los cereales que contienen gluten. Por lo tanto, Chile busca una aclaración sobre cuál podría ser el enfoque apropiado para establecer esta dosis, dado que actualmente no se incluyen dosis de referencia para cereales como el centeno y la cebada en los informes del Comité de Expertos.</p> <p>Esto garantizará una aplicación efectiva del etiquetado precautorio, priorizando la seguridad de los consumidores y respondiendo a las necesidades de salud pública.</p> <p>d. Si el texto está listo para avanzar al trámite 5.</p> <p>Respuesta:</p>	<p>Chile</p>

<p>Chile considera que una vez que se resuelva la discusión en torno a la dosis de referencia para los cereales que contienen gluten y la “enfermedad celíaca”, se considera que el documento estaría listo para avanzar al Paso 5.</p> <p>(iii) Si proporcionar más asesoramiento al CCFH para garantizar la coherencia del Código de prácticas sobre la gestión de los alérgenos alimentarios por parte de los operadores de empresas de alimentos (CXC 80-2020) con la revisión de la NGEAP y las directrices para el uso del etiquetado precautorio de alérgenos.</p> <p>Respuesta:</p> <p>Considerando que este trabajo está vinculado al trabajo del Comité del Codex sobre Higiene de los Alimentos (CCFH) sobre gestión de alérgenos, Chile considera que es pertinente proporcionar al CCFH más asesoramiento sobre los avances para ayudar a mantener la coherencia entre los textos, especialmente en lo que respecta a las definiciones y las listas de prioridades de los alérgenos.</p>	
<p>(iii) Si proporcionar más asesoramiento al CCFH para garantizar la coherencia del Código de prácticas sobre la gestión de los alérgenos alimentarios por parte de los operadores de empresas de alimentos (CXC 80-2020) con la revisión de la NGEAP y las directrices para el uso del etiquetado precautorio de alérgenos.</p> <p>De acuerdo</p> <p>Se considera que ofrecer más asesoramiento al CCFH es adecuado con fines de coherencia entre la NGEAP, las directrices de etiquetado precautorio y el CXC 80-2020.</p>	Colombia
<p>Respecto a las Directrices para el uso del etiquetado precautorio de alérgenos (EPA), una vez resuelta la discusión en torno a la dosis de referencia para los cereales que contienen gluten y la “enfermedad celíaca”, consideramos que el documento está listo para avanzar al trámite 5.</p> <p>Adicionalmente, Costa Rica considera fundamental mantener al CCFH informado sobre el progreso del trabajo en curso, con el fin de garantizar la coherencia entre los textos.</p>	Costa Rica
<p>iii) The European Union and its Member States (EUMS) would like to thank Australia, the United Kingdom, and the United States of America for their efforts in preparing the document ‘CX/FL 24/48/5 (Part B) – Proposed Draft Annex to the GSLPF: Guidelines on the Use of Precautionary Allergen Labelling.’</p> <p>The EUMS would like to offer the following comments on the relevant sections to enhance the text. The EUMS also support CCFL in providing further guidance to the Codex Committee on Food Hygiene (CCFH) on an Unintended Allergen Presence risk assessment. This is aimed at ensuring that the Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020) aligns with the Guidelines on the use of PAL, in view of maintaining consistency across international food safety and labelling standards.</p> <p>Provided there is agreement on the remaining points for discussion at CCFL48, the EU believes that the text is ready to progress to Step 5.</p>	European Union
<p>Indonesia supports that the text is ready to advance in the step process.</p>	Indonesia
<p>New Zealand would like to thank Australia and the USA for their work on the revised paper. New Zealand is comfortable with the majority of the proposed revision and agrees with the EWG chair that CCFL48 should focus on the 4 issues identified in order to progress the work. We have therefore only provided comments on these sections.</p>	New Zealand

<p>Saudi Arabia supports the advancement of the text to Step 5.</p> <p>Saudi Arabia supports the provision of further advice to CCFH to ensure consistency of the Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020) with the revision to the GSLPF and the guidelines on the use of PAL.</p> <p>Maintaining consistency across these critical documents is crucial for implementing robust allergen management strategies and protecting consumer health.</p>	<p>Saudi Arabia</p>
<p>(d) whether the text is ready for advancement to Step 5.</p> <p>SA position and rationale:</p> <ul style="list-style-type: none"> South Africa is of the opinion that the discussion around quantitative and qualitative risk assessment should be reopened. We believe quantitative risk assessment should take precedence. We seek clear guidance on when PAL, based on reference doses can be applied based on a qualitative risk assessment. We are also concerned that the acceptance of both, without clear guidance will not achieve the objective of harmonising PAL. <p>(iii) whether to provide further advice to CCFH to ensure consistency of the Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020) with the revision to the GSLPF and the guidelines on the use of PAL.</p> <p>SA position and rationale:</p> <ul style="list-style-type: none"> South Africa agrees that it is necessary to provide further advice to CCFH to ensure consistency with the Code of Practice on Allergen Management for Food Business Operators with the revision to the GSLPF and the guidelines on the use of PAL (UAP risk assessment). <p>Other specific comments:</p> <p>1. South Africa suggests the following amendment to Section 4.1.</p> <ul style="list-style-type: none"> Section 4.1: Effective allergen management practices including controls to prevent or minimize the unintended presence of food allergens caused by cross-contact shall be implemented in accordance with the Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020). The use of PAL shall be restricted to those situations in which the unintended presence of a food allergen(s), in spite of the best efforts of food businesses, cannot be prevented or controlled using these allergen management practices and may result in an exposure above a reference dose. <p>Rationale:</p> <p>It is important to highlight that PAL should only be used if food businesses are making an effort to control allergens, but cannot eliminate or control the risk at levels below the reference dose and action levels.</p> <p>2. Footnotes 1,2,3: Combine these footnotes into one to reduce amount of text in the footnote.</p> <p>South Africa suggests minor changes to Footnotes 6 to simplify and improve readability.</p> <p>Action level (mg total protein from the allergen / kg food) = Reference dose (mg total protein from the allergen) / Amount of the food (kg). The amount of food should be established based a single eating occasion intake of the food preferably using the 50th percentile or mean of consumption data for the respective population(s) where available.</p>	<p>South Africa</p>

<ul style="list-style-type: none"> Action level (mg total protein from the allergen / kg food) = Reference dose (mg total protein from the allergen) / Amount of the food (kg). The amount of food should be based on a single eating occasion intake of the food using, the 50th percentile or mean of consumption data for the respective population(s) where available. 	
Uganda supports for further advice to CCFH to ensure consistency between the Code of Practice (CXC 80-2020) and the GSLPF revisions, emphasizing scientific guidance, best practices, consumer safety, and collaboration. This approach will contribute to a more effective framework for allergen management and labelling in the food industry.	Uganda
<p>The UK is supportive of the purpose and the majority of the text within the PAL standard, however, we consider that the use of thresholds requires significant further work within the Allergen Labelling eWG prior to CCFL49.</p> <p>The UK would like to thank Australia as Chair, for leading on the revision of the provisions relevant to allergen labelling in the General Standard for the Labelling of Pre-packaged Foods and on the Guidelines on the Use of Precautionary Allergen Labelling.</p> <p>UK supports that CCFL provides further advice to CCFH to ensure consistency between the texts. The UK also believes further detail on the requirements of an allergen cross-contact risk assessment – including sampling frameworks – needs to be provided within the Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020).</p>	United Kingdom
Respecto a las Directrices para el uso de etiquetado precautorio, Uruguay considera que se debe seguir discutiendo	Uruguay
Regarding part B, the United States acknowledges that there have been divergent views in the Committee regarding the application of PAL and the risk assessment that underpins it. If the Committee is able to have productive discussions and make significant progress on these guidelines, then the United States could likely support advancement to step 5.	USA
<p>Una vez resuelta la discusión en torno a la dosis de referencia para los cereales que contienen gluten y la “enfermedad celíaca”, ALAIAB considera que el documento está listo para avanzar al Paso 5. (ver observaciones en el documento).</p> <p>ALAIAB apoya que el CCFL proporcione más asesoramiento al CCFH para garantizar la coherencia del Código de Prácticas sobre la Gestión de Alérgenos para los Operadores de Empresas Alimentarias (CXC 80-2020) con la revisión del GSLPF y las directrices sobre el uso de PAL.</p>	Alianza Latinoamericana de Asociaciones de la Industria de Alimentos y Bebidas (ALAIAB)
For consistency and alignment across all Codex text, FIA views that it is important that CCFH be updated on the allergen labelling and PAL discussion at CCFL. For the sake of timeliness, we suggest a discussion paper with a new project document be proposed at CCFH55.	Food Industry Asia
<p>FoodDrinkEurope supports that CCFL provides further advice to CCFH to ensure consistency of the Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020) with the revision to the GSLPF and the guidelines on the use of PAL.</p> <p>In our view the text is not ready for advancement to Step 8 given that there are still contentious points that require further consideration, ongoing debate in-Committee and other aspects that bear on this matter such as Part B text, CCFH activities, etc.</p>	FoodDrinkEurope
<p>ICGA would like to thank Australia, the United Kingdom and the United States of America, for the time they invested in animating the intersessional electronic working group, which led to this result. ICGA contributed to this exercise in the past.</p> <p>ICGA appreciates the opportunity to provide the following comments in response to this circular letter.</p> <p>ICGA has also several adjustment proposals to the PAL Guidelines.</p>	ICGA

<p>ICGA generally supports the proposed Guidelines on the Use of Precautionary Allergen Labelling (PAL), when there is an adventitious presence of an allergen above a certain threshold and when all the effective allergen management practices have been duly put in place to prevent or minimize the unintended presence of such food allergens.</p> <p>On the last question (iii) whether to provide further advice to CCFH to ensure consistency of the Code of Practice (CoP) on Allergen Management for Food Business Operators (CXC 80, 2020 version) with the revision to the GSLPF and the guidelines on the use of PA, ICGA believes It may be more prudent to wait until CCFL has fully completed its work on the Guidelines on the use of PAL – namely adoption at step 8 – before CCFH may start new work on the revision of the CoP CXC 80.</p> <p>ICGA is looking forward discussing all its other proposals with the CCFL community during the pre-session Virtual Working Group and during the final discussions at the CCFL48 meeting, which will be likely based on some if not all the recommendations from the VWG.</p>	
The texts as provided are ready for advancement.	ICUMSA
Regarding the guidelines on the use of PAL (Appendix II), IDF believes the text is ready for advancement to Step 5. Only some editorial changes are needed around the placement of footnotes to GSLPF definitions.	IDF/FIL
<p>ICA comments on iii) as referenced above.</p> <p>Our members support any effort on behalf of CCFL to ensure consistency between these standards and CCFH's Code of Practice on Allergen Management for Food Business Operators. Any efforts to ensure consistency should be initiated after CCFL has completed its work on amendments to the GSLPF and Guidelines on the use of PAL. At which time, CCFL and CCFH could convene a working group to review the Code of Practice on Allergen Management for Food Business Operators for consistency.</p>	International Confectionery Association
<p>ISDI supports CCFL in requesting CCFH to act as follows:</p> <p>Ensure consistency of CXC 80-2020 with the revised GSLPF and guidelines on the use of PAL. This shall ensure consistency of Codex texts.</p> <ul style="list-style-type: none"> Consider providing guidance on UAP risk assessment. 	International Special Dietary Food Industries
<p>Se considera que el documento aun no está en condiciones de avanzar al trámite 5.</p> <p>Teniendo en cuenta que este trabajo está vinculado al trabajo del Comité del Codex sobre Higiene de los Alimentos (CCFH) sobre la gestión de alérgenos, es pertinente proporcionar al CCFH asesoramiento adicional sobre los avances para ayudar a mantener la coherencia entre los textos, especialmente en lo que respecta a las definiciones y las listas de alérgenos prioritarios.</p>	Argentina
<p>Comment whether the text is ready for advancement to Step 5.</p> <p>ISDI would like to thank again the Electronic Working Group for preparing this document.</p> <p>ISDI supports the advancement of this text at Step 5 and encourages CCFL to request CCFH providing guidance on the risk assessment of unintended allergen presence (UAP), to ensure consistency of CXC 80-2020 with the Annex to GSLPF, and to follow up on the work requested from CCMAS.</p>	International Special Dietary Food Industries
<p>General Comments on the Section:</p> <p>ISDI supports the draft PAL guidelines do not include any provision relating to a risk assessment indicator.</p>	International Special Dietary Food Industries

<p>•Comment on method analysis and sampling</p> <p>ISDI supports the inclusion of a reference to methods of analysis and sampling in the GSLPF similar to other Codex texts (e.g. CXS 73-1981) as follows:</p> <p>“For checking the compliance with this standard, the methods of analysis and sampling contained in the Recommended Methods of Analysis and Sampling (CXS 234-1999) relevant to the provisions in this standard, shall be used.”</p>	
Honduras considera que el documento no esta listo para tramite 5	Honduras
Una vez resuelta la discusión en torno a la dosis de referencia para los cereales que contienen gluten y la “enfermedad celíaca”, consideramos que el documento está listo para avanzar al Paso 5	Guatemala
Indonesia supports that the text is ready to advance in the step process.	Indonesia
<p>ISDI recommends that the addition of footnotes to support the definition of terms be harmonised throughout the document.</p> <p>As an example, in section 1 which clarifies the purpose of the text, a footnote referring to the definition of the term ‘food allergy’ is present, but there is no reference to the term ‘coeliac disease’. In addition, the term ‘cross-contact’ which appears for the first time in this section is not referenced, whereas this is subsequently done in section 3.</p>	International Special Dietary Food Industries
FoodDrinkEurope supports that CCFL provides further advice to CCFH to ensure consistency of the Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020) with the revision to the GSLPF and the guidelines on the use of PAL.	FoodDrinkEurope
Puede pasar al siguiente trámite	Paraguay
Guatemala indica estar de acuerdo en solicitar al CCFH un asesoramiento para garantizar la coherencia con el Código de prácticas sobre gestión de alérgenos para operadores de empresas alimentarias (CXC 80-2020) y con la revisión de la GSLPF y las directrices sobre el uso de PAL.	Guatemala
<p>EFA insists on its central demand that PAL should be made mandatory. This is, among others, in line with one of the key recommendations of the FAO/WHO expert group report 3, published in June 2023. (https://www.who.int/publications/i/item/9789240072510, pp 55).</p> <p>Although the CCFL has not included this recommendation in the revised text, we continue to consider it critical to ensure the safety of consumers with food allergy.</p> <p>In this respect, we would like to remind the Chairs that a voluntary PAL puts consumers with allergy at risk, as the lack of PAL is frequently misinterpreted as a lack of risk; while it is also often that PAL is not comprehensive.</p> <p>Alternatively, in case mandatory PAL is no option for Codex, there must surely be an indication that risk assessment has been applied.</p>	European Federation of Allergy and Airways Diseases Patients’ Associations
<p>(iii) whether to provide further advice to CCFH to ensure consistency of the Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020) with the revision to the GSLPF and the guidelines on the use of PAL.</p> <p>New Zealand supports consistency across Codex texts and as such considers CCFH should be provided with an update of progress on the PAL guidance.</p> <p>The guidelines on the use of PAL in Appendix II of CX/FL 24/48/5 (Part B), in particular:</p>	New Zealand

<p>a. purpose section in regard to determining if and how PAL thresholds can address cross contact from gluten containing cereals for consumers with coeliac disease.</p> <p>Purpose:</p> <p>New Zealand does not oppose the inclusion of 'coeliac disease' in the purpose. It is New Zealand's view that coeliac disease is already included in the purpose via reference to 'food allergy'. However, for consistency with clause 4.2.1.4 in the proposed amendments to the General standard for the labelling of prepackaged foods we support the inclusion. If 'coeliac disease' is included the definition in the General standard should be referenced as with the definition of food allergy.</p> <p>We consider the reference to 'allergens' in the purpose should be corrected to 'food allergens' to refer to the term defined in the general standard.</p> <p>Purpose:</p> <p>To facilitate a consistent and harmonized approach to the effective use of precautionary allergen labelling (PAL) for communicating to consumers with food allergy¹ or coeliac disease about the risk from the unintended presence of food allergens in food due to cross-contact.</p>	
<p>FIA believes that the criteria on the use of footnote is unclear. For example, on the first instance that "cross-contact" appears in PAL, there is no footnote referencing the definition in Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020). Instead, it is in section 3 that the footnote is attached to "cross-contact".</p> <p>FIA recommends a review of footnotes used for consistency, such as attaching footnotes to the first instance of the term appearing, all instances, or all instances within the definition. Furthermore, we view that footnote referencing the GSLPF should be removed considering that this guideline is part of the GSLPF.</p>	Food Industry Asia
<p>Once the discussion on reference dose for gluten-containing cereals and 'coeliac disease' is resolved, FIA would consider the guidelines ready to advance to Step 5.</p>	Food Industry Asia
<p>Uganda supports the text to be advanced to step 5</p>	Uganda
<p>Subject to CCFL discussions, Australia considers the text can be advanced to Step 5.</p> <p>In relation to providing advice to CCFH, Australia supports this to ensure consistency between the Code of Practice on food allergen management for food business operators (CXC 80-2020) and the proposed draft PAL guidelines. We also support requesting CCFH specifically consider providing guidance in the Code of Practice to assist food businesses undertake unintended allergen presence (UAP) risk assessments (see further response below).</p>	Australia
<p>A move to step 5 may be appropriate at this stage.</p>	FoodDrinkEurope
<p>Guidelines on the Use of Precautionary Allergen Labelling (STEP 4).</p> <p>In relation to the purpose section, Brazil supports the proposal to include coeliac disease within the scope of the document, as the definitions for both food allergy and food allergen encompass non-IgE antibody or other immune-mediated responses.</p> <p>However, we would like to note that this inclusion will require further consideration by CCFL on how to manage precautionary allergen labelling (PAL), given the different thresholds for gluten-free foods (20 mg/kg) in the Standard for Foods for Special Dietary Use for</p>	Brazil

Persons Intolerant to Gluten and the proposed reference dose for wheat (5 mg of protein per amount of food consumed in a single eating occasion).

This situation could cause discrepancies in PAL declarations. Certain foods consumed in small amounts may not require PAL, as the UAP of wheat would be below the action level, yet the gluten concentration could reach more than 20 mg/kg, leaving individuals with coeliac disease without the necessary information to protect their health. Conversely, foods with PAL for wheat could be suitable for people with coeliac disease if the gluten concentration is below 20 mg/kg.

Regarding section 4.1, Brazil suggests deleting the phrase 'and may result in exposure above a reference dose.'

We understand that this section should focus exclusively on guidance for allergen management practices, while guidance on PAL is addressed in sections 4.2 to 4.4. Furthermore, Brazil does not support limiting the declaration of PAL to cases where exposure to UAP exceeds a reference dose.

This approach would not be applicable in instances where the decision to declare PAL is based on a qualitative risk assessment or when the risk management considers the needs of individuals with food allergies who have higher sensitivity and may react to exposures below the reference dose.

4.1 Effective allergen management practices including controls to prevent or minimize the unintended presence of food allergens caused by cross-contact shall be implemented in accordance with the Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020). The use of PAL shall be restricted to those situations in which the unintended presence of a food allergen(s) cannot be prevented or controlled using these allergen management practices.

In relation to section 4.2, Brazil suggests the inclusion of the terms 'quantitative and/or qualitative' before 'risk assessment' to clarify that both approaches can be applied in the decision to use PAL.

Additionally, Brazil recommends deleting the phrase 'to determine potential exposure above a reference dose,' as we do not support restricting PAL declarations to situations where exposure to UAP exceeds a reference dose. Brazil emphasizes the need for a more flexible approach, considering the potential negative impacts of requiring PAL declarations only when exposure to UAP is above the reference dose. We understand that such an approach will not provide an adequate level of consumer health protection and could:

- Lead to adverse health effects in individuals with food allergies.
- Undermine consumer confidence in PAL, reducing its effectiveness in communicating allergen risks due to cross-contact.
- Leave sensitive consumers without the necessary information to protect their health.
- Place an excessive burden on many food business operators, particularly small producers, as well as national authorities, complicating the implementation, use, and enforcement of PAL.
- Require the widespread availability of suitable analytical methods and sampling plans for testing allergens in foods and on surfaces for each potential action level.
- Create legal uncertainty for food manufacturers and increase litigation.
- Increase trade barriers, as an allergen in a specific food might have two or more different action levels depending on the amount of food used as a reference in each country or by different food business operators.

4.2 The decision to use PAL shall be based on the findings of a qualitative and/or quantitative risk assessment ⁵ of unintended allergen presence.	
<p>Responses not related to a specific section of the draft:</p> <p>ii) d. whether the text is ready for advancement to Step 5.</p> <p>Once the discussion around reference dose for gluten-containing cereals and “coeliac disease” is resolved, we consider the document ready to advance to Step 5.</p> <p>iii) whether to provide further advice to CCFH to ensure consistency of the Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020) with the revision to the GSLPF and the guidelines on the use of PAL.</p> <p>Yes. ICBA supports providing further advice to CCFH. Furthermore, for the sake of timeliness, we suggest a discussion paper with a new project document be proposed at the next CCFH meeting rather than waiting another year to begin the process.</p>	ICBA
EFAD supports the section as it is and believe it is ready to advance to the Step 5	The European Federation of the Associations of Dietitians (EFAD)
SPECIFIC COMMENTS	
1. PURPOSE	
Honduras considera que la finalidad planteada, es la correcta, pero consideramos que no se debe hacer en documento aparte de la NGEAP	Honduras
De acuerdo dado que este cambio es consistente con la propuesta de enmienda a la norma general de etiquetado con respecto a alérgenos.	Colombia
ALAIAB cree que puede ser necesario un mayor debate ya que no se ha establecido una dosis de referencia para los cereales que contienen gluten.	Alianza Latinoamericana de Asociaciones de la Industria de Alimentos y Bebidas (ALAIAB)
Title, purpose and scope seem appropriate and consistent with the definitions provided in the GSLPF	FoodDrinkEurope
Indonesia supports the proposed text in the Purpose section.	Indonesia
<p>We propose to not include within the Guidelines any explicit statements that refer to coeliac disease or to gluten as the food constituent for causing symptoms to people with this disease. We offer the following points for consideration:</p> <ul style="list-style-type: none"> Within part A of the circular the following definition for ‘Food allergy’ is proposed: <p>“Food allergy” means a reproducible adverse health effect arising from an immunoglobulin class E (IgE) antibody or non-IgE antibody immune-mediated response following oral exposure to a food.”</p>	FoodDrinkEurope

<p>Gluten and coeliac disease (CD) are clearly captured by this definition, and thus are also part of the Purpose and Scope of the Guidelines.</p> <ul style="list-style-type: none"> The reference dose (RfD) for wheat is derived from patients with an IgE-mediated food allergy and is not directly applicable to the health effects that CD patients will experience from exposure to gluten. <p>Whilst there is a defined concentration of gluten in foods that is considered to pose a low risk to people with CD (< 20 mg/kg), it is not based on a RfD. In contrast to IgE-mediated food allergy symptoms, those experienced by people with CD develop over longer timescales and are related to daily intakes of gluten (not 'doses' during single eating occasions).</p> <p>All the current wording around PAL in the draft guidelines is linked to RfDs (or risk management values) derived from clinical challenge data from individuals with IgE-mediated food allergies. Additionally, intake assessments for PAL are based on single eating occasions, whereas total daily intakes are more relevant for CD.</p> <p>Introducing guidelines on PAL for CD would require all the current proposed text to be revisited and revised; a clear explanation of the basis on which any limit (and intake assessment) for PAL for gluten for CD should be defined & clearly documented.</p> <ul style="list-style-type: none"> We assume that most CD patients are aware that they must avoid the priority food allergens wheat, barley and rye. Where product information contains allergen information on these foods, the coeliac patient is informed about the health risks of such product. <p>We also note that Barley and Rye are listed as priority allergens, yet the FAO/WHO Expert Reports contain neither a RfD nor a Risk Management Value for these allergens. As the Guidelines on Precautionary Allergen Labelling seek to address priority allergens, we would prefer that reference to Barley and Rye is made under section 4.3.1.</p> <p>As mentioned above, we feel that including Barley and Rye in the list of food allergens to be part of the risk assessment for inclusion in a PAL statement, would address the information needs of coeliac patients.</p>	
Saudi Arabia supports the Purpose section, specifically concerning the evaluation of how PAL (Precautionary Allergen Labeling) thresholds can address cross-contact from gluten-containing cereals for consumers with coeliac disease.	Saudi Arabia
Costa Rica considera que debe someterse a más discusión antes de decidir la pertinencia de estos umbrales respecto a la enfermedad celíaca.	Costa Rica
Guatemala considera que debe ser necesario un mayor debate, ya que no se ha establecido una dosis de referencia para los cereales que contienen gluten.	Guatemala
<p>No se está de acuerdo con que el texto propuesto para que la sección de propósitos incluya la enfermedad celíaca, ya que no todos los alimentos/ingredientes relevantes fueron considerados en los informes del Comité de Expertos.</p> <p>En todo caso, evaluar la posibilidad de hacer mención en una nota al pie, como venía considerándose en versiones anteriores del documento.</p>	Argentina
Uruguay esta de acuerdo con esta propuesta.	Uruguay
The United States is of the view that unintended presence of allergenic foods including gluten containing grains resulting from cross-contact are relevant to allergenic individuals and those with celiac disease, respectively, and can be managed effectively through PAL	USA

based on risk management principles. The United States therefore supports inclusion of celiac disease in the purpose section of the guidelines on the use of PAL.	
<p>EFA would like to remind that a long-standing tolerance threshold has been established and implemented for coeliac disease at 20ppm for gluten, based on a Codex standard (CXS 118-1979). This makes it possible for food business operators to produce food that is "free from gluten".</p> <p>However, coeliac-friendly products containing less than this amount of gluten may not always be safe for gluten-allergic individuals. Therefore, using PAL should not be restricted solely to meet the requirements for coeliac gluten-free claims.</p> <p>In this light, EFA would highly recommend to either delete coeliac disease from this provision or to apply a separate section on PAL for gluten with regards to coeliac disease, because it is not properly covered in the current document.</p> <p>Should a reference to coeliac disease remain here, there needs to be different thresholds from those who apply to patients allergic to wheat.</p> <p>Finally, one aspect that must definitely be stressed is that gluten allergy and coeliac disease are two different medical conditions with not only different information thresholds but also different regulatory requirements and legislation.</p>	European Federation of Allergy and Airways Diseases Patients' Associations
<ul style="list-style-type: none"> • South Africa supports the proposed purpose and scope sections, with the following minor changes. <p>Add a reference to the General Standard for the Labelling of Prepackaged Foods (CXS 1-1985) for coeliac disease as a footnote. And Change phrasing to "consumers with food allergies" or "consumers with a food allergy" to improve the readability, as follows:</p> <ul style="list-style-type: none"> • To facilitate a consistent and harmonized approach to the effective use of precautionary allergen labelling (PAL) for communicating to consumers with food allergies or coeliac disease¹ about the risk from the unintended presence of allergens in food due to cross-contact. • To facilitate a consistent and harmonized approach to the effective use of precautionary allergen labelling (PAL) for communicating to consumers with a food allergy or coeliac disease¹ about the risk from the unintended presence of allergens in food due to cross-contact. <p>The purpose and the scope of the guideline regarding determining if and how PAL thresholds can address cross contact from gluten-containing cereals for consumers with coeliac disease:</p> <ul style="list-style-type: none"> • South Africa supports including wheat and gluten in the scope of the document, but not barley and rye. We also recommend adding a clause that specifically addresses gluten cross-contact. 	South Africa
The EUMS support the proposed revision of the text in the section on purpose.	European Union
<p>To facilitate a consistent and harmonized approach to the effective use of precautionary allergen labelling (PAL) for communicating to consumers with food allergy⁹ or coeliac disease about the risk from the unintended presence of allergens in food due to cross-contact.</p> <p>We do not support the inclusion of coeliac disease being considered in scope since it should be restricted to the allergens that cause IgE immune-mediated response, of which RfDs are established.</p>	Thailand

<p>We agree with the purpose as outlined and the reference to coeliac disease. However, we note the purpose itself as drafted does not mention thresholds, so this should not be taken as agreement to the use of thresholds elsewhere in the text.</p> <p>The UK has reservations, because there is insufficient evidence to set the specific allergen thresholds proposed at this time.</p> <p>Additionally, were thresholds to be used, we consider that there is a need for flexibility, so food businesses can operate to more stringent standards than the threshold selected (ED05) in certain scenarios, to ensure consumer safety.</p>	United Kingdom
FIA believes further discussion may be necessary as a reference dose for gluten-containing cereals has not been established.	Food Industry Asia
<p>Australia supports the inclusion of 'or coeliac disease' in the purpose section of the PAL guidelines. Although the FAO/WHO Expert Consultation on Risk Assessment of food allergen (Part 2 report) did not indicate a reference dose (RfD) for gluten containing cereals, we are aware there is international collaboration (through The International Society for the Study of Celiac Disease (ISSCD)) currently underway to establish a RfD for gluten containing cereals in respect to Coeliac disease which once established could potentially be added to Table 4.3.1 although at this time, we do not support including a RfD in the table to 4.3.1 (see further response below). In the meantime, the inclusion of coeliac disease in the purpose section will future-ready the PAL guidelines for when a RfD is established and can be considered by CCFL for inclusion in the table to 4.3.1.</p>	Australia
Canada supports the inclusion of celiac disease in the purpose but notes that the development of a threshold/reference dose for gluten could be challenging.	Canada
<p>Egypt support the purpose section in regard to determining if and how PAL thresholds can address cross contact from gluten containing cereals for consumers with coeliac disease.</p>	Egypt
<p>ISDI supports the amended section 1 (see below), since the definition of 'coeliac disease' is part of GSLPF and needs to be considered in the purpose definition.</p> <p>"1. PURPOSE</p> <p>To facilitate a consistent and harmonized approach to the effective use of precautionary allergen labelling (PAL) for communicating to consumers with food allergy¹ or coeliac disease about the risk from the unintended presence of allergens in food due to cross-contact."</p>	International Special Dietary Food Industries
AOECS welcomes the addition of coeliac disease in the purpose section of the revised guidelines on the use of precautionary allergen labelling, since millions of consumers with coeliac disease rely on PAL to make an informed and safe choice.	Association Of European Coeliac Societies Codex and Regulatory Affairs
<p>The criteria for when to use a footnote is unclear. For example, here is the first instance that "cross-contact" appears in PAL but there is no footnote referencing the definition in GSLPF. Instead, it is in section 3 that the footnote is attached to "cross-contact".</p> <p>IDF recommends a review of when footnotes referencing GSLPF definitions are used for consistency e.g. either attach footnote to the first instance of the term appearing, or all instances, or all instances within the definition</p>	IDF/FIL
We have no objections to the addition of coeliac disease into the purpose	IDF/FIL
ICBA believes further discussion may be necessary as a reference dose has not been established for gluten-containing cereals.	ICBA

Paraguay: respecto al agregado de la expresión "o enfermedad celíaca", no acordamos con la misma teniendo en cuenta que no es significativo el aporte de dicha expresión teniendo en cuenta que el gluten no esta citado como un alérgeno, además se cuenta con una directriz CODEX especifica para lo referente al Gluten y enfermedad celiaca.	Paraguay
ICGMA believes that further discussion is needed as a reference dose has not been established for gluten-containing cereals.	ICGMA
2. SCOPE	
These guidelines apply to PAL when used to indicate the risk from the unintended presence of a food allergen(s) caused by cross-contact in prepackaged¹⁰ foods. These guidelines apply to PAL when used in the labelling of prepackaged foods to indicate the risk from the unintended presence of a food allergen(s) caused by cross-contact.	USA
The United States suggests a minor edit to the scope to clarify that these guidelines apply to the labeling of prepackaged foods. Scope: These guidelines apply to PAL when used in the labelling of prepackaged foods to indicate the risk from the unintended presence of a food allergen(s) caused by cross-contact.	
The EUMS support the proposed revision of the text in the section on scope.	
ISDI supports the amendment of section 2 (see below), since the GSLPF defines ‘food allergen’. “2. SCOPE These guidelines apply to PAL when used to indicate the risk from the unintended presence of a food allergen(s) ¹ caused by cross-contact in prepackaged foods. 1As defined in the General Standard for the Labelling of Prepackaged Foods (CXS 1-1985).”	International Special Dietary Food Industries
As above, this is the first instance of “food allergen” but there is no footnote referencing the GSLPF definition	IDF/FIL
3. DEFINITION OF PRECAUTIONARY ALLERGEN LABELLING	
The definition of PAL is consistent with other Codex texts and with recommendations of the Expert Committee.	FoodDrinkEurope
The EUMS support the proposed revision of the text in the section on scope.	European Union
We note that there had previously been a footnote referencing the GSLPF definition after “prepackaged” in section 3 but that footnote has now been removed. However, other terms in this definition still have their footnote referencing the GSLPF	IDF/FIL
4. GENERAL PRINCIPLES	
Regarding section 4 more generally, the United States is of the view that, in line with general principle 3.1 of the GSLPF, an additional general principle is necessary in section 4 to ensure that PAL is not misleading or in conflict with other statements used in labeling. The United States suggests the following additional provision to section 4: 4.2bis Foods that have a PAL statement on the label should not also carry “free from” claims related to the food allergens subject to the PAL statement (e.g., “gluten free”).	USA

In general principles, the term “shall” should be revised to “should” throughout the text to improve the flexibility, thus can be better adapted to national context.	Thailand
4.1 Effective allergen management practices including controls to prevent or minimize the unintended presence of food allergens caused by cross-contact shall be implemented in accordance with the Code of Practice on Food Allergen Management for Food Business Operators (CXC 80-2020). The use of PAL shall be restricted to those situations in which the unintended presence of a food allergen(s) cannot be prevented or controlled using these allergen management practices and may result in an exposure above a reference dose.	
4.1 We support the requirement that manufactures adhere strictly to a hierarchy of controls as specified above in 4.1. The first responsibility of the manufacturer is to use good manufacturing controls to prevent or minimize the unintended presence of allergens caused by cross contact. Only if this is not possible should precautionary allergen labeling be used.	International Association of Consumer Organizations of Food
4.1 The EUMS support the proposed text in Principles 4.1 and 4.2, as presented by the Chairs in Appendix II.	European Union
4.1 Effective allergen management practices including controls to prevent or minimize the unintended presence of food allergens caused by cross-contact shall be implemented in accordance with the Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020). The use of PAL shall <u>should</u> be restricted to those situations in which the unintended presence of a food allergen(s) cannot be prevented or controlled using these allergen management practices and may result in an exposure above a reference dose.	Thailand
4.1 Effective allergen management practices including controls to prevent or minimize the unintended presence of food allergens caused by cross-contact shall be implemented in accordance with the Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020). The use of PAL shall be restricted to those situations in which the unintended presence of a food allergen(s) cannot be prevented or controlled using these allergen management practices and may result in an exposure <u>potentially</u> above a reference dose. We propose the addition of “potentially” to enhance the flexibility of this principle in case qualitative risk assessment is used.	Thailand
4.1 Proposed text is consistent with other Codex texts and with recommendations of the Expert Committee.	FoodDrinkEurope
4.1 ISDI supports the revised wording for Principle 4.1 (as below) in the draft PAL guidelines. The revised wording provides more clarity and is consistent with the objectives (section 1) of the Code of Practice on Allergen Management for Business Operators (CXC 80-2020). “4.1 Effective allergen management practices including controls to prevent or minimize the unintended presence of food allergens caused by cross-contact shall be implemented in accordance with the Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020). The use of PAL shall be restricted to those situations in which the unintended presence of a food allergen(s) cannot be prevented or controlled using these allergen management practices and may result in an exposure above a reference dose.”	International Special Dietary Food Industries
4.1 Effective allergen management practices including controls to prevent or minimize the unintended presence of food allergens caused by cross-contact shall be implemented in accordance with the Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020). The use of PAL shall be restricted to those situations in which the unintended presence of a food allergen(s) cannot be prevented or controlled using these allergen management practices and may result in an exposure above a reference dose practices .	Brazil

4.1 Effective allergen management practices including controls to prevent or minimize the unintended presence of food allergens caused by cross-contact shall be implemented in accordance with the Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020). The use of PAL shall be restricted to those situations in which the unintended presence of a food allergen(s) cannot be prevented or controlled using these allergen management practices.	
4.1 We support this text	IDF/FIL
4.1 Paraguay: acuerdo con la propuesta de redaccion es claro e implementable	Paraguay
4.2 The decision to use PAL shall be based on the findings of a risk assessment⁵ of unintended allergen presence to determine potential exposure above a reference dose.	
4.2 Honduras considera que para algunos países incluyendo Honduras será muy difícil aplicar una evaluación de riesgo de este tipo	Honduras
4.2 Costa Rica apoya el principio propuesto	Costa Rica
4.2 Guatemala está de acuerdo con la propuesta de redacción del Principio 4.2	Guatemala
4.2 El texto alternativo resulta más acorde con el informe del Comité de expertos, dado que reconoce los diferentes enfoques para la evaluación del riesgo los cuales pueden ser cualitativos o cuantitativos.	Colombia
4.2 No hay objeciones al texto alternativo propuesto. Por lo tanto, se entiende que se podría acordar con contemplar de base la evaluación de riesgos originados por la presencia no intencional de un alérgeno.	Argentina
4.2 Uruguay acompaña la redacción de este punto.	Uruguay
<p>4.2 We appreciate the amendment to the text, which gives flexibility to utilize both qualitative and/or quantitative risk assessment measures as appropriate for the purposes of PAL determinations. Further, we support the reference to the FAO/WHO Report 3, which notes that both of these measures are appropriate tools for risk assessment purposes.</p> <p>To provide additional clarity on the application of PAL, we support the suggested alternative language proposed in CX/FL24/48/5 Part B of the background document,</p> <p>Suggested language for principle 4.2: “The decision to use PAL shall be based on the findings of a risk assessment (quantitative, qualitative, or both) to determine the risk of presence of amounts of unintended food allergens relative to an appropriate action level.”</p>	ICGMA
<p>4.2 The decision to use PAL shall <u>should</u> be based on the findings of a risk assessment¹³ (quantitative, qualitative, or both) to determine the risk of unintended food allergen presence relative to determine potential an appropriate action level exposure above a reference dose.</p> <p>The United States understands and appreciates the EWG chairs’ proposal to address ambiguity; however, the United States continues to be of the view that flexibility and clarity are needed regarding the types of risk assessments available to Food Business Operators (FBOs). In addition, the United States notes that the decision to use PAL is in relation to action levels based on the reference doses. The United States therefore suggests the following edit to principle 4.2.</p>	USA

<p>4.2 Japan considers that it is too early to reach consensus on the texts of these guidelines while we are waiting for the CCMAS report on the analytical methodology.</p>	<p>Japan</p>
<p>4.2 We support that precautionary allergen labeling should be based on the findings of a risk assessment but urge the that the document specify a “quantitative” risk assessment. This is because manufacturers necessarily must quantify the potential for allergen presence in order to verify that the allergen may be present at a threshold above the reference dose. Quantitative risk assessment as the basis of precautionary allergen labeling is crucial to protect consumers with food allergies and celiac disease from potential adverse reactions. We also believe that the language should clarify the circumstances under which such risk assessment should be updated. However, we acknowledge that quantitative risk assessment may not need to be conducted continuously or even on a regular schedule, provided no significant changes are made to the production process. For example, with sound food allergen and ingredient management controls, periodic quantitative testing to benchmark a manufacturer’s food allergen controls is likely sufficient.</p> <p>We therefore recommend the following amendment:</p> <p>...The decision to use PAL shall be based on the findings of a quantitative risk assessment[13] of unintended allergen presence to determine potential exposure above a reference dose. Such risk quantitative risk assessment should be updated as necessary to reflect changes in the manufacturing process.</p>	<p>International Association of Consumer Food Organizations</p>
<p>4.2 The decision to use PAL shall be based on the findings of a risk assessment<u>assessment (quantitative, qualitative, or both)</u>¹³ <u>to determine the risk of unintended allergen the presence of amounts of unintended allergen, relative to determine potential an appropriate action level-exposure above a reference dose.</u></p> <p>ICGA appreciates the amended text, as it provides the necessary flexibility to use the results of all types risk assessments (qualitative, quantitative, or both) to help informing in the PAL determination.</p> <p>We note in particular that Part. 3 of the report of the FAO/WHO Expert Consultation does refer to both measure types, as appropriate tools for such risk assessment.</p> <p>Perhaps, to provide further clarity on the application of PAL measures, we could suggest the following alternative language for principle 4.2: “The decision to use PAL shall be based on the findings of a risk assessment (quantitative, qualitative, or both) to determine the risk of presence of amounts of unintended food allergens, relative to an appropriate action level.”</p> <p>Indeed, we can generally support the suggested alternative language proposed in CX/FL24/48/5 Part B working document.</p>	<p>ICGA</p>
<p>4.2 India supports Principle 4.2 as the footnote references the FAO/WHO Part 3 where details on risk assessments for PAL are fully elaborated.</p>	<p>India</p>
<p>4.2 EFA reiterates that both quantitative and qualitative approaches can be taken for the assessment of risks from unintended allergen presence. However, quantitative risk assessments are the most effective method in determining whether a PAL statement should be used or not. We strongly encourage the Chairs to reflect this in the text, choosing one of the following options:</p> <p>‘...shall be based on the findings of a risk assessment, which shall include, where possible, quantitative risk assessment of unintended allergen presence’,</p> <p>or at least go back to a previously proposed version of the text: ‘...shall be based on the findings of a risk assessment, which shall include, but is not limited to, quantitative risk assessment of unintended allergen presence’.</p>	<p>European Federation of Allergy and Airways Diseases Patients’ Associations</p>

<p>Moreover, we take positive note of the addition of the word 'potential', as compared with the previous version of the text.</p> <p>Overall, practice and safety should be consistent. To this end, education should also be included as a general principle to communicate risk and increase consumer understanding of PAL.</p>	
<p>4.2 SA position and rationale:</p> <ul style="list-style-type: none"> South Africa does not support the proposed 4.2 text as per pages 5 and 11 of CX/FL 24/48/5B based on the facts that for comparison to reference doses and action levels, quantitative risk assessments should be performed. <p>Proposed amendments to 4.2:</p> <ul style="list-style-type: none"> The decision to use PAL shall be based on the findings of a quantitative risk assessment of unintentional allergen presence to determine potential exposure above a reference dose. <p>Proposed amendments to footnote 5:</p> <ul style="list-style-type: none"> South Africa also recommends that footnotes⁵ be amended as follows: <p>FAO and WHO (2023). Risk assessment of food allergens – Part 3: Review and establish precautionary labelling in foods of the priority allergens (Sections 3.3.1). https://doi.org/10.4060/cc6081en</p>	<p>South Africa</p>
<p>4.2 ALAIAB apoya la propuesta.</p>	<p>Alianza Latinoamericana de Asociaciones de la Industria de Alimentos y Bebidas (ALAIAB)</p>
<p>4.2 B. Principle 4.2 in regard to proposed alternative text on the types of risk assessment.</p> <p>New Zealand supports the text proposed for principle 4.2. However the reference to 'allergen' should be amended to reference 'food allergen' as this is the term defined in the general standard.</p> <p>4.2 The decision to use PAL shall be based on the findings of a risk assessment⁵ of unintended food allergen presence to determine potential exposure above a reference dose</p> <p>5(FAO and WHO (2023). Risk assessment of food allergens – Part 3: Review and establish precautionary labelling in foods of the priority allergens (Sections 3.3.1 to 3.3.6). https://doi.org/10.4060/cc6081en)</p>	<p>New Zealand</p>
<p>4.2 The decision to use PAL shall be based on the findings of a risk assessment (quantitative, qualitative, or both) to determine the risk of presence of amounts of unintended food allergens relative to an appropriate action level.⁴³ of unintended allergen presence to determine potential exposure above a reference dose.</p> <p>We appreciate the amendment to the text, which gives flexibility to utilize both qualitative and/or quantitative risk assessment measures as appropriate for the purposes of PAL determinations. Further, we support the reference to the FAO/WHO Report 3, which notes that both of these measures are appropriate tools for risk assessment purposes.</p>	<p>International Confectionery Association</p>

<p>To provide additional clarity on the application of PAL, we support the suggested alternative language proposed in CX/FL24/48/5 Part B of the background document,</p> <p>Alternative language for principle 4.2: “The decision to use PAL shall be based on the findings of a risk assessment (quantitative, qualitative, or both) to determine the risk of presence of amounts of unintended food allergens relative to an appropriate action level.”</p>	
<p>4.2 The EUMS support the proposed text in Principles 4.1 and 4.2, as presented by the Chairs in Appendix II.</p>	<p>European Union</p>
<p>4.2 The decision to use PAL shall<u>should</u> be based on the findings of a risk assessment¹³ of unintended allergen presence to determine potential exposure above a reference dose.</p> <p>We do not support to solely rely on the use of RfD to determine PAL declaration. Implementing RfDs presents several challenges, including expensive analytical methods and the need for proper sampling techniques. Additionally, the levels established may not adequately protect all consumers in the world with varying allergen sensitivities. Furthermore, certain RfDs specified in Table 4.3.1 are based on data with high uncertainty.</p> <p>In practices, even with the best practices and thorough quantitative risk assessment, we cannot guarantee the complete elimination of allergen cross-contact. For example, FBOs may find that allergen levels are below RfD after conducting a quantitative risk assessment, leading them to decide against declaring PAL. However, allergen cross-contact can still occur, exposing consumers to allergens without notice or warranty, potentially making FBOs liable.</p> <p>For these reasons, Thailand believes that the use of quantitative risk assessment and reference to RfD is not practical and should not be set as international standard, of which referred to by WTO.</p>	<p>Thailand</p>
<p>4.2 Within the text, or as a footnote, be explicit that a risk assessment can be qualitative as well as quantitative, because quantitative risk assessments are not feasible in all scenarios.</p>	<p>United Kingdom</p>
<p>4.2 FIA supports Principle 4.2 and is supportive of the addition “potential” for “potential exposure above a reference dose” because PAL is used when there might be exposure above a reference dose. For example, levels of allergens may fluctuate over a manufacturing run due to residual cross-contact allergen from a previous product being flushed out over time.</p>	<p>Food Industry Asia</p>
<p>4.2 Uganda supports the amended text as presented in appendix II.</p> <p>Rationale: it’s because the amendment provides clarity about a scientifically sound, flexible, and consumer-protective approach to allergen labelling, which ensures that decisions are made based on thorough risk assessments.</p>	<p>Uganda</p>
<p>4.2 Australia supports the proposed text for principle 4.2 as we consider a risk assessment of unintended allergen presence (UAP) should be undertaken to ensure PAL is not used indiscriminately on food labels. This reflects the recommendations from the Expert Committee. We note guidance on undertaking an appropriate risk assessment to characterize and quantify UAP is provided in the Expert Committee’s Part 3 report as captured in the footnote.</p> <p>We also support CCFL requesting CCFH to consider revising the Code of Practice on food allergen management for food business operators (CXC 80-2020) to provide food businesses with guidance on how to assess for UAP to inform a decision to use PAL. Guidance on UAP risk assessment could be based on the Expert Committee’s Part 3 report. Such guidance through the CoP could complement and support implementation of Principle 4.2 in the proposed draft PAL guidelines</p>	<p>Australia</p>

<p>4.2 Canada questions if the inclusion of the footnote means that the risk assessment must/shall follow the general outline of what is in FAO/WHO part 3, or this is just an example of how risk assessments can be performed? Does the purpose of the footnote need to be stated explicitly or clarified?</p> <p>Canada supports the addition of the word “potential” to the “exposure above a reference dose”.</p>	Canada
<p>4.2 Egypt supports the proposed alternative text on the types of risk assessment as written.</p>	Egypt
<p>4.2 ISDI supports the amended wording for Principle 4.2 as proposed below, as it is aligned with with Principle 4.1.</p> <p>“4.2 The decision to use PAL shall be based on the findings of a risk assessment⁵ of unintended allergen presence to determine potential exposure above a reference dose.</p> <p>5FAO and WHO (2023). Risk assessment of food allergens – Part 3: Review and establish precautionary labelling in foods of the priority allergens (Sections 3.3.1 to 3.3.6). https://doi.org/10.4060/cc6081en”.</p>	International Special Dietary Food Industries
<p>4.2 Indonesia supports the proposed text in section 4.2.</p>	Indonesia
<p>4.2 FoodDrinkEurope agrees with the updated proposal.</p> <p>The current proposal from the EWG has acknowledged our previous comments and propose now to simplify the text under 4.2 but include an explicit reference to the sections in the FAO/WHO Report which covers the requirements for a risk assessment.</p>	FoodDrinkEurope
<p>4.2 The decision to use PAL shall be based on the findings of a <u>qualitative and/or quantitative</u> risk assessment¹³ of unintended allergen presence to determine potential presence-exposure above a reference dose.</p> <p>4.2 The decision to use PAL shall be based on the findings of a qualitative and/or quantitative risk assessment⁵ of unintended allergen presence.</p>	Brazil
<p>4.2 IDF is supportive of the removal of text referencing “quantitative risk assessment” as the Expert Committee recognised that either quantitative or qualitative risk assessments could be used, so a quantitative risk assessment was not mandatory.</p> <p>We equally support the alternative wording that replaces “shall” with “can” because we believe this achieves the same purpose:</p> <p>“4.2 The decision to use PAL shall be based on the findings of a risk assessment³ which can include but is not limited to quantitative risk assessment of unintentional allergen presence to determine potential exposure above a reference dose. “</p> <p>We do not prefer but do not oppose the other proposed option which we believe achieves a similar purpose:</p> <p>“4.2 The decision to use PAL shall be based on the findings of a risk assessment (quantitative, qualitative, or both) to determine the risk of presence of amounts of unintended food allergens relative to an appropriate action level. “</p> <p>We are also supportive of the addition of the word “potential” for “potential exposure above a reference dose” because PAL is used when there might be exposure above a reference dose. For example, levels of allergens may fluctuate over a manufacturing run due to residual cross-contact allergen from a previous product being flushed out over time</p>	IDF/FIL
<p>4.2 ICBA continues to support this proposed section as written.</p>	ICBA
<p>4.2 De acuerdo con la propuesta</p>	Paraguay

4.2 Saudi Arabia supports Principle 4.2 and the proposed alternative text concerning the types of risk assessment. This principle is fundamental in ensuring that risk assessments are conducted comprehensively and accurately.	Saudi Arabia
4.2 footnote 5 <i>FAO and WHO (2023). Risk assessment of food allergens – Part 3: Review and establish precautionary labelling in foods of the priority allergens (Sections 3.3.1 to 3.3.6)</i> ⁶ <i>provide guidance for the risk assessment of UAP</i> . https://doi.org/10.4060/cc6081en This is to clarify that these sections of the report provide guidance, not requirements.	Thailand
4.3 PAL shall only be used if unintended allergen presence cannot be mitigated to a level at or below the action level⁶ for a food allergen based on the reference doses in the table at 4.3.1.	
4.3 Honduras no considera que el principio 4.3 incluya un abordaje correcto para las personas que padecen de enfermedad celiaca, ya que no están listados todos estos en la tabla de dosis de referencia, (no se cuenta con referencias para avena, cebada y centeno, y otros)	Honduras
4.3 Costa Rica considera que debe someterse a más discusión sobre cuál podría ser el enfoque apropiado para establecer una dosis de referencia para los cereales que contienen gluten y abordar la coexistencia de la frase “gluten free/ libre de gluten” con el EPA sobre posible presencia de gluten en cualquier tipo de alimento. Adicionalmente, se debe esperar la retroalimentación del CCMAS al respecto a la solicitud de asesoramiento realizada durante el CCFL47 sobre el “Etiquetado de alérgenos alimentarios: métodos analíticos y planes de muestreo”.	Costa Rica
4.3 Como se señaló anteriormente en el inciso a, Guatemala considera que sin una dosis de referencia para los cereales que contienen gluten, no se puede apoyar la tabla establecida en el apartado 4.3.1 y por lo cual, solicita que se aborde a más detalle sobre cual podría ser el enfoque apropiado para establecer la dosis de referencia.	Guatemala
4.3 d) Si el texto está listo para avanzar al trámite 5. De acuerdo Se considera que el texto está listo para avanzar al trámite 5.	Colombia
4.3 Estamos de acuerdo con considerar que el principio 4.3 permita el uso de EPA a niveles de presencia no intencional de alérgenos en o por debajo de un nivel de acción, dado que permitiría que individuos con sensibilidad severa (que puedan desarrollar alergias en niveles inferiores a la dosis de referencia), estén informados de la presencia del alérgeno en el alimento. En el texto se indica que el EPA solo se usará si la “presencia no intencional del alérgeno” no puede reducirse a un nivel igual o inferior al “nivel de acción”. Esto implica que dicha “presencia no intencional” debería ser también cuantificada para poder realizar una comparación con el “nivel de acción”. En este sentido, el texto propuesto para este numeral no ofrece suficiente claridad al respecto. Se reitera al grupo de trabajo que, si bien la probabilidad de efectos severos o letales en la población susceptible a los alérgenos es muy baja según el comité de expertos, esto no garantiza un riesgo “cero”, por lo que una pequeña proporción de individuos altamente susceptibles perdería su derecho a ser informada sobre la presencia de un alérgeno alimentario a través del etiquetado	Colombia
4.3 No hay objeciones ni al texto propuesto para 4.3 ni al cuadro de dosis de referencia en 4.3.1. El texto del punto 4.3 proporciona claridad con respecto a la evaluación de riesgos y la medida práctica de alérgenos no deseados de manera consistente con las consideraciones del informe del Comité de Expertos, al tiempo que aborda las complejidades locales con	Argentina

<p>respecto a los datos de consumo. Dado que en los informes del Comité de Expertos no se consideraron las dosis de referencia para el centeno, la cebada o el gluten, no deberían considerarse en el cuadro del 4.3.1.</p> <p>Se mantiene la posición emitida oportunamente como posición Argentina. Se considera que la evaluación de riesgo cuantitativa no debe ser definitoria al momento de decidir la utilización de PAL (etiquetado precautorio de alérgenos), tal como se plantea en el ítem 4.3 de este anteproyecto de directriz. Por otro lado, debería plantearse si el RfD (dosis de referencia recomendadas) debería de ser del alérgeno en sí o de la posible presencia de los alérgenos totales en el alimento final o de su consumo en simultáneo con otros alimentos en similar situación.</p> <p>Asimismo, de acuerdo a las conclusiones obtenidas en el Informe Risk Assessment of Food Allergens. Part 2: Review and establish threshold levels in foods for the priority allergens, las dosis de referencia (RfD) recomendadas en el informe se pueden implementar y monitorear hasta cierto punto con las capacidades analíticas actuales. Todos los métodos tienen limitaciones importantes y se las deben tener en cuenta al interpretar y utilizar los resultados.</p> <p>Además, se considera que la redacción del texto se ha vuelto demasiado complicado para la GSLPF y que es demasiado específico dado que están disponibles otros métodos de cálculo basados en el uso de Dosis de Referencia. Cabe señalar, que una Evaluación Cualitativa de Riesgos no siempre es adecuada a la hora de decidir el uso de PAL. Además, se necesita urgentemente desarrollar capacidades para que los miembros realicen evaluaciones de riesgos, con relación a ello, la FAO y la OMS son muy conscientes de esta necesidad y están evaluando sobre cómo hacerlo en colaboración o asociación con los países.</p> <p>Considerando que la mayoría de las respuestas apoyaron la propuesta de no incluir una disposición para el uso de un indicador de evaluación de riesgos principalmente debido a la dificultad práctica que esto supondría tanto para los operadores de empresas alimentarias como para las autoridades alimentarias nacionales. Es por ello que se considera que el proyecto de directrices PAL no debería incluir ninguna disposición relativa a un indicador cuantitativo de evaluación de riesgos.</p>	
<p>4.3 Uruguay considera que debería agregarse a la lista de dosis de referencia todos los cereales que contengan gluten. Por ejemplo: Cebada y Centeno.</p> <p>En lo que refiere al nivel de acción Uruguay considera que el percentil 50 utilizado para definir el nivel de acción es bajo y se debería definir un percentil mas alto. Desde la perspectiva que la población infantil sería la que queda más vulnerable a quedar expuesta</p>	Uruguay
<p>4.3 PAL shall should only be used if unintended allergen presence cannot be mitigated to a level at or below the action level¹⁴ for a food allergen based on the reference doses in the table at 4.3.1.</p> <p>The United States is of the view that principle 4.3 would benefit from similar flexibility as the edit we propose to principle 4.2, accounting for diverse supply chain scenarios and capability to conduct various types of risk assessments. The United States therefore recommends the following edit to principle 4.3.</p>	USA
<p>4.3 Japan considers that it is too early to reach consensus on the texts of these guidelines while we are waiting for the CCMAS report on the analytical methodology.</p>	Japan
<p>4.3 We support this language specifying that PAL (precautionary allergen labeling) should only be used when preventative controls fail to mitigate the risk below the specified level. We suggest the following amendment to this paragraph, referring back to paragraph 4.1 to clarify the level of mitigation required in this case.</p>	International Association of Consumer Food Organizations

4.3 PAL shall only be used if unintended allergen presence cannot be mitigated using controls specified in paragraph 4.1 to a level at or below the action level[14] for a food allergen based on the reference doses in the table at 4.3.1.	
4.3 Unlike the principle set in 4.2, the principle set in 4.3 relies specifically on using quantitative risk assessment measures alone. Further flexibility may be also warranted there to recognize the importance of qualitative risk assessment. Other factors, such as the history of safe consumption for allergen cross-contact in agricultural commodities at farm level, frequency of occurrence, variability in data (where products are subjected to analysis), and the sensitivity of specific population groups.	ICGA
4.3 EFA strongly holds that the decision to use PAL must be based on a risk assessment and the implementation of effective allergen control measures. This would include using allergen thresholds as one component of an overall effective allergen control plan.	European Federation of Allergy and Airways Diseases Patients' Association
4.3 SA position: <ul style="list-style-type: none"> South Africa supports the table of reference doses per pages 11 and 12 of CX/FL 24/48/5B, however, we do not support including gluten-containing cereals in the table, per page 8. South Africa also recommends adding a clause that specifically addresses gluten cross-contact as follows: 4.3.3 PAL for gluten shall only be used if unintended gluten presence cannot be mitigated to a level at or below 20 mg gluten per kg product as offered to the consumer.	South Africa
4.3 Como se señaló anteriormente, sin una dosis de referencia para los cereales que contienen gluten, ALAIAB busca una aclaración sobre cuál podría ser el enfoque apropiado para establecer la dosis de referencia.	Alianza Latinoamericana de Asociaciones de la Industria de Alimentos y Bebidas (ALAIAB)
4.3 C. Principle 4.3 and the table of reference doses in 4.3.1 particularly in relation to inclusion of gluten. New Zealand supports the text at 4.3. We consider the inclusion in footnote 6 of the use of single eating occasion data where up to date population based consumption data is not available is pragmatic. Regarding 'only' New Zealand supports the use of PAL only when there is a real risk of unintended food allergen presence above a level that would pose a risk to an allergic consumer. This ensures PAL provides maximum choice and maximum safety to people with food allergies or coeliac disease when they are purchasing food. Overuse of PAL (when a risk assessment determines the potential UAP is below the reference dose) unnecessarily limits food choice for allergenic consumers. Table to 4.3.1 New Zealand considers that a reference dose for gluten should be added to table to 4.3.1 in line with our support for the inclusion of coeliac disease in the purpose of these guidelines. This should be based on a risk assessment following the process outlined in the Expert Committee's Part 2 Report. Consequential amendments may be needed to Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten (CXS 118-1979).	New Zealand

<p>New Zealand notes that the Expert Committee worked to the principle that risk management is best served if reference doses for known allergens are derived where possible even where data is not adequate to fulfil the recommended criteria. Based on that principle, New Zealand can support listing those reference doses that do not have adequate data to fulfill the criteria used to determine reference doses for the priority allergens (listed in 4.2.1.4) but have been provided for risk management purposes. However, we recommend these be identified as such in Table 4.3.1. e.g.by an asterisk or something and a related foot note stating they are not based on risk assessment but provided for risk management purposes.</p> <p>New Zealand considers that for consistency and completeness, if it is agreed to list the particular species names for tree nuts that require allergen declaration in 4.2.1.4. and 4.2.1.5, these should also be listed in Table 4.3.1 of the PAL Guidance.</p>	
<p>4.3 Unlike principle 4.2, this principle (4.3) relies on utilizing quantitative risk assessment measures. alone. We request that further flexibility be provided here to recognize the importance of qualitative risk assessment. Notably, it is necessary to consider other factors such as history of safe consumption, frequency of occurrence, variability in data (where products are subjected to analysis), and the sensitivity of specific population groups.</p> <p>We support the inclusion of the reference doses in Table 4.3.1. However, we request the following amendment to footnote 6 in provision 4.3. Regarding footnote 6, we ask the Committee to consider the following amendment to the footnote below to accommodate prepackaged foods that contain multiple portions or servings.</p> <p>Alternate Text for Footnote 14: Action level (mg total protein from the allergen / kg food) = Reference dose (mg total protein from the allergen) / Amount of the food (kg). The amount of food should be established based the quantity that can reasonably be expected to be consumed in a single eating occasion preferably using the 50th percentile or mean of consumption data for the respective population(s) where available.</p> <p>For prepacked foods comprising multiple portions or servings, some consumers could, theoretically, eat the entire product instead of the recommended serving. Food business operators generally understand how much consumers typically eat in one eating occasion and can, therefore, factor this information into their assessment. We recommend the Committee use the language above within the footnote to help account for this variance in consumption patterns.</p>	<p>International Confectionery Association</p>
<p>4.3 The EUMS also support the proposed text in Principle 4.3.</p> <p>However, the EUMS do not support the changes proposed in Principle 4.3 by other Codex Members, specifically the allowance of PAL at UAP levels at or below an action level. Such flexibility would compromise the objectivity of PAL usage. The aim of these guidelines is to define and establish clear principles and criteria for the application of PAL, and allowing for such a possibility would not only jeopardise the consistent use of PAL but also undermine the efforts invested in developing these guidelines.</p> <p>Furthermore, the EUMS support footnote 6 as it currently appears in the draft Guidelines on PAL (Appendix II). The EUMS do not find it necessary to provide further clarity in that footnote regarding the use of serving or portion sizes in calculating the amount of food. Introducing portion sizes risks introducing significant errors and variability in these calculations. Additionally, portion sizes are not always indicated on labels, they vary across different food products, and it cannot be assumed that consumers consistently consume the exact portion size specified.</p>	<p>European Union</p>
<p>4.3 PAL shall only be used if unintended allergen presence cannot be mitigated to a level at or below the action level¹⁴ for a food allergen based on the reference doses in the table at 4.3.1.</p>	<p>Thailand</p>

<p>4.3 Since coeliac disease is added to the purpose, and to communicate the risk of unintended allergen presence consumers with coeliac disease, the Committee should add a paragraph that links back to Codex Standard CXS 118-1979 for foods for special dietary use for persons intolerant to gluten, and require that food manufacturers include in their risk assessment the evaluation of risk of unintended presence of gluten, and that this should not exceed 20mg/kg (20ppm).</p> <p>This is because a reference dose for wheat (based on an action level per serving) does not protect people with coeliac disease sufficiently because of 2 reasons:</p> <ol style="list-style-type: none"> 1. Other cereals containing gluten are neglected 2. The reference dose for wheat is based on a concentration and portion size. The safe threshold for gluten is based on a concentration. Typically, in products consumed in portions sizes below 200g, the concentration of gluten may well exceed 20 mg/kg whereas a 5,0 mg RFD for wheat is not triggered. (please see our document with further explanatory graphs and information: https://aoecs.azurewebsites.net/media/o5nnx00t/aoecs-comments-codex-part-b-pal-guidelines.pdf). <p>By including a provision that links back to the established threshold (i.e. $\leq 20\text{mg/kg}$ gluten), the guidelines would also cover the unintended presence of gluten from other cereals containing gluten (i.e. barley, rye, spelt, Khorasan, and other specific cereals containing gluten that are species or hybridized strains under the genus names of Triticum, Secale and Hordeum) as all sources would need to be taken into consideration.</p> <p>We therefore call on the Committee to review the information (https://aoecs.azurewebsites.net/media/o5nnx00t/aoecs-comments-codex-part-b-pal-guidelines.pdf) provided to address the need to include in the revised guidelines, a provision for gluten content in foods to advise the food industry on how to communicate PAL in a way that both consumers allergic to cereals containing gluten and consumers with coeliac disease are safe and their choices not unnecessarily restricted. We advise the Committee to consult experts from the Prolamin Working Group and the International Society for the Study of Celiac Disease.</p>	<p>Association Of European Coeliac Societies Codex and Regulatory Affairs</p>
<p>4.3 FIA supports Principle 4.3, including the text in footnote 6. We are supportive of the inclusion of “preferably” in the footnote to allow for cases where the 50th percentile is not known.</p>	<p>Food Industry Asia</p>
<p>4.3 Uganda supports the agreed with text</p> <p>Rationale: it highlights the conditional nature of PAL use, the importance of reference doses, consumer protection, and the encouragement of effective allergen management practices, all aimed at ensuring food safety and minimizing allergen exposure risks.</p>	<p>Uganda</p>
<p>4.3 Australia supports the proposed text for principle 4.3. We also support the revised text for the associated footnote, as it is reflective of the recommendations from the Expert Committee’s Part 3 report, while still providing options for when population consumption data may not be available.</p>	<p>Australia</p>
<p>4.3 PAL shall only be used if unintended allergen presence cannot be mitigated to a level at or below the action level¹⁴ for a food allergen based on the reference doses in the table at 4.3.1.</p> <p>Canada believe that the use of the word “only” is too restrictive as it would not permit the use of PAL under any circumstances at levels below the reference dose.</p>	<p>Canada</p>

<p>In addition, Canada notes that the UAP should be mitigated to a level below the action level in order for PAL not to be used (not “at or below” as in the current wording). This is based on the premise that when there is potential for PAL to be present at the action level PAL should be used.</p>	
<p>4.3 Egypt supports the FAO and WHO regarding Risk assessment of food allergens(2023) and thus supports the principle 4.3 and the table of reference doses in 4.3.1 particularly in relation to inclusion of gluten.</p>	Egypt
<p>4.3 ISDI supports the revised text for Principle 4.3 (shown below) as it provides a practical approach for determining the action level.</p> <p>“4.3 PAL shall only be used if unintended allergen presence cannot be mitigated to a level at or below the action level⁵ for a food allergen based on reference doses in the table at 4.3.1.</p> <p>5Action level (mg total protein from the allergen / kg food) = Reference dose (mg total protein from the allergen) / Amount of the food (kg). The amount of food should be established based on a single eating occasion intake of the food preferably using the 50th percentile or mean of consumption data for the respective population(s) where available.”</p> <p>5 FAO and WHO (2023). Risk assessment of food allergens – Part 3: Review and establish precautionary labelling in foods of the priority allergens (Sections 3.3.1 to 3.3.6). https://doi.org/10.4060/cc6081en</p>	International Special Dietary Food Industries
<p>4.3 We do not agree with including the word ‘only’ in the principle. For guidance and rulemaking, “shall only” is restrictive, whereas “shall” is prescriptive.</p> <p>We also suggest further changes below.</p> <p>FoodDrinkEurope recognises the foundational value of ED05 RfDs for application of PAL as recommended by the Expert Committee, and we support that PAL is prescribed when the unintended allergen presence (UAP) exceeds this value. Nonetheless, FBOs may need to deviate from their use and apply PAL when the UAP is ≤ED05 values, when detailed risk assessments indicate that this is required to meet a consumer safety goal. FoodDrinkEurope therefore supports use of ED05-based RfDs as recommended by the Expert Committee provided these are described as part of a more flexibly worded Principle.</p> <p>This is a de facto option when the term “only” is removed. However, “shall only” does not allow for this second circumstance. We propose the following amendment to Principle 4.3:</p> <p>4.3 PAL shall be used if unintended allergen presence cannot be mitigated to a level at or below the action level for a food allergen based on the reference doses in the table at 4.3.1.</p> <p>In addition, we note that the table under 4.3.1 of the Guidelines contains RfD values based on an ED05, but it also contains values for allergens where no RfD could be obtained due to lack of sufficient scientific data for those allergens, and here the FAO/WHO reports have proposed Risk Management Values for these allergens. We believe this distinction must be made clear in the wording of the table. It is important for be fully transparent and accurate in describing the different values provided.</p> <p>Please also see the first response on Part B (i.e. response ‘a’), which provides further detail concerning why we would propose not adding gluten to the table. Furthermore, even if steps were taken to revisit the entire guideline text to accommodate gluten, and as noted by the members who proposed this measure, appropriate education of consumers would be needed and to make the distinction between PAL for wheat and PAL for gluten. And, as there is already a significant challenge associated with delivery of education around PAL for IgE-mediated allergies this would add further complexity to the matter.</p>	FoodDrinkEurope

<p>4.3 PAL shall only be used if unintended allergen presence cannot be mitigated to a level at or below the action level¹⁴ for a food allergen based on the reference doses in the table at 4.3.1.[6] for a food allergen based on the reference doses [5].[6] Action level (mg total protein from the allergen / kg food) = Reference dose (mg total protein from the allergen) / Amount of the food (kg). The amount of food should be established based on a single eating occasion intake of the food preferably using the 95th of consumption data for the respective population(s) where available. <u>Brazil understands that the document should not advance in the step procedure until the CCMAS's work on methods of analysis and sampling is finalized because risk management must consider the methods of analysis, sampling, and the feasibility of enforcement and compliance. Moreover, the proposal to use PAL only when UAP exceeds the action level based on the reference dose depends on the widespread availability of these methods and sampling protocols.</u></p> <p>Regarding section 4.3, Brazil suggests deleting the word 'only,' as we do not support the principle that PAL declarations should be used solely when UAP is above the action level for an allergen based on the reference dose as explained earlier.</p> <p>Brazil also proposes deleting the words 'in the table at 4.3.1' and section 4.3.1 itself, as we believe it is premature to include ED05-based RfD values in the draft PAL Guidelines. Instead, we suggest adding footnote 5 after 'reference dose,' referring to the Expert Committee's report.</p> <p>Moreover, Brazil understands that determining action levels based on the 50th percentile or population mean for a single eating occasion intake of food does not sufficiently protect subgroups of allergic consumers who consume larger quantities of specific food items. Considering the acute nature of allergic reactions, it is inappropriate to base these levels on lower percentiles. We recommend using higher percentiles of food consumption data (e.g., 90th, 95th, or 97.5th) to ensure adequate protection for allergic consumers.</p> <p>Finally, the use of action levels based on the amount of food consumed in a single eating occasion to guide PAL declarations could create additional trade barriers, as an allergen present in a specific food could have varying action levels depending on the reference food quantity used by different countries or food business operators. This potential negative impact should be considered, and alternative options should be explored to achieve harmonized action levels.</p>	Brazil
<p>4.3 We are supportive of the proposed text in section 4.3 including the text in footnote 6. We are supportive of the inclusion of "preferably" in the footnote to allow for cases where the 50th percentile is not known.</p>	IDF/FIL
<p>4.3 As noted above, without a reference dose for gluten-containing cereals, ICBA seeks clarification on what an appropriate approach might be to establish the reference dose.</p>	ICBA
<p>4.3 Saudi Arabia supports Principle 4.3 and the associated table of reference doses in 4.3.1, particularly with respect to the inclusion of gluten. This principle and the table are crucial for establishing appropriate reference doses that account for potential risks associated with gluten exposure.</p>	Saudi Arabia
<p>4.3 footnote 6 En lo que refiere al nivel de acción Uruguay consideró que el percentil 50 utilizado para definir el nivel de acción es bajo y se debería definir un percentil mas alto. Desde la perspectiva que la población infantil sería la que queda más vulnerable a quedar expuesta</p>	Uruguay
<p>4.3 footnote 6 Action level (mg total protein from the allergen / kg food) = Reference dose (mg total protein from the allergen) / Amount of the food (kg). The amount of food should be established based <u>on the quantity that can reasonably be expected to be consumed in a single eating occasion intake of the food occasion, which is generally determined by</u> preferably using the 50th percentile or mean of consumption data for the respective population(s) where available.</p>	ICGA

<p>Footnote 14 here (footnote 6 of the guidelines) attached to the Principle set in 4.3 could be amended to address the cases of prepackaged foods in with multiple individual portions.</p> <p>“Action level (mg total protein from the allergen / kg food) = Reference dose (mg total protein from the allergen) / Amount of the food (kg). The amount of food should be established based on the quantity that can reasonably be expected to be consumed in a single eating occasion which generally is determined by preferably using the 50th percentile or the mean of consumption data for the respective population(s) where available.”</p> <p>For prepacked foods comprising multiple portions, consumers could, theoretically, eat all portions, instead of one or two of them. Food business operators generally understand how much consumers would typically eat at each eating occasion and could, therefore, take into account that information into their own assessment. By accepting the proposed above revised language for this footnote, the CCFL community would integrate in the guidelines that variance of consumption patterns.</p>	
<p>4.3 footnote 6 Action level (mg total protein from the allergen / kg food) = Reference dose (mg total protein from the allergen) / Amount of the food (kg). The amount of food should be established based <u>on the quantity that can be reasonably expected to be consumed in a single eating occasion</u> intake of the food preferably using the 50th percentile or mean of consumption data for the respective population(s) where available.</p>	<p>International Confectionery Association</p>
<p>4.3.1 Reference doses</p>	
<p>4.3.1 La inclusión del gluten en la sección 4.3.1 es coherente con la propuesta de enmienda a la norma general de etiquetado con respecto a alérgenos.</p>	<p>Colombia</p>
<p>4.3.1 Regarding table 4.3.1, the United States suggests separating Pistachio and Pecan on their own rows. The United States also proposes adding to the row containing wheat, “other gluten-containing grains” and welcomes a discussion in the Committee and with the experts of the ad hoc expert group around an appropriate reference value if this were included in the table.</p>	<p>USA</p>
<p>4.3.1 ICGA supports the inclusion of the reference doses presented in Table 4.3.1. See a substance comment suggested to footnote 14 of this document (footnote 6 of the guidelines).</p>	<p>ICGA</p>
<p>4.3.1 Reference doses Thailand believes that the use of quantitative risk assessment and reference to RfD is not practical and should not be set as international standard. Hence this table under 4.3.1 should be deleted and only reference to the specific reports of the Experts may be mentioned in this draft document.</p>	<p>Thailand</p>
<p>4.3.1 D. Whether the text is ready for advancement to Step 5.</p> <p>New Zealand could support the advancement of this work to Step 5 subject to this allowing for the subsequent addition of a reference dose/action level for gluten to table 4.3.1.</p>	<p>New Zealand</p>
<p>4.3.1 With respect to Principle 4.3.1, and as raised previously, the EUMS strongly advocate for the inclusion of gluten in the table of reference doses, with a separate indication for gluten The inclusion of gluten in the scope of PAL will be a significant step forward in ensuring that consumers are adequately informed and protected, and for maintaining consistency with the revised General Standard for the Labelling of Prepackaged Foods (GSLPF).</p> <p>The specific threshold values for gluten merit more extensive discussions and could be fine-tuned at a more appropriate pace, with the input from experts, if necessary.</p>	<p>European Union</p>

<p>Upon reflection, the EUMS propose to consider an alternative to the previously suggested 20mg gluten/kg concentration: a reference dose of 4 mg gluten in Table 4.3.1. This reference dose would account for coeliac disease in PAL and consider other gluten-containing cereals beyond wheat. The proposed 4 mg reference dose is based on the wheat protein reference dose which is already in the table (gluten constituting approximately 80% of wheat protein) and is also more coherent with the 'system' of the reference doses in the table that form the base for a precautionary allergen labelling, as oppose to an "allergen-free" labelling (that is inherent to the concentration of 20 mg gluten/kg).</p> <p>While this value is not directly derived from coeliac disease-specific data, it is widely understood that the daily intake of gluten should be as low as possible for consumers with coeliac disease. The reference doses in Table 4.3.1 are designed to protect 95% of allergic consumers, a decision made by the Expert Committee and supported by the vast majority of the eWG. Thus, the EUMS believe that the reference doses should offer similar protection for consumers with coeliac disease as for those with wheat allergies.</p>	
<p>4.3.1 We do not agree with the text of this principle as currently drafted including the reference to the Table at 4.3.1. As noted previously the UK view is that there is insufficient evidence to set the specific allergen thresholds proposed at this time. Additionally, if thresholds were to be adopted:</p> <ul style="list-style-type: none"> - further consideration needs to be given on the interaction with the Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten. - UK suggests a footnote making reference to this standard and the requirement for food businesses to consider the gluten free threshold in addition to the reference doses for individual cereal species when deciding if a PAL for a cereal and/or a free-from gluten statement is needed on a food product. - With regard to footnote 6. The UK has not yet assessed the evidence base in relation to consumption amounts, although our initial view is that determining action levels based on the 50th percentile for a single eating occasion intake of food may not be sufficiently protective of people with a food hypersensitivity who consume larger quantities of certain food items. 	United Kingdom
<p>4.3.1 As there is no reference dose been established for gluten-containing cereals, FIA views that further discussion is necessary.</p>	Food Industry Asia
<p>4.3.1 Australia supports the Table to 4.3.1 as proposed. As noted above we do not support the inclusion of 'cereals containing gluten' (listed as gluten) in the table at this time. A threshold based on a wheat RfD or 20ppm has not been assessed as safe for consumers with coeliac disease. We note a 20ppm level of gluten is provided in the Standard for foods for special dietary use for persons intolerant to gluten (CXS 118-1979) for the purpose of labelling foods as 'gluten free'. In Australia foods are only permitted to be labelled as 'gluten free' if they meet a criterion of no delectable' gluten not 20ppm. This is based on the available evidence which has not established a safe level of gluten exposure for consumers with coeliac disease.</p> <p>Noting there is research underway to establish a RfD for gluten containing cereals, once this is completed CCFL could then consider including a RfD in the Table to 4.3.1. However, at this time, we do not support including a RfD in the table to 4.3.1.</p>	Australia
<p>4.3.1 Canada has concerns that the reference dose values (based on ED05s) may not be protective enough and questions the impact that using these reference doses would have on the most sensitive allergic consumers. Recognizing that the use of the reference dose values has the potential to improve things for 95% of the allergic population, those most sensitive would be unable to trust prepackaged food labels (since any prepackaged food that did not have PAL on it could contain enough allergen to trigger an allergic reaction).</p> <p>With regards to the addition of a reference dose for gluten Canada would not support the use of a 20 ppm action limit as the reference dose for gluten. Canada notes that the 20 ppm value is a generally accepted threshold for making gluten free claims and the use of</p>	Canada

<p>this same threshold to decide whether to apply PAL when gluten is present due to UAP would be inconsistent with the approach that has been taken for food allergens.</p> <p>In order to be consistent, a different threshold/reference dose would need to be developed for gluten which would determine a level of gluten which would be safe for most people with celiac disease but could still impact a small percentage of the most sensitive celiac population while triggering mainly mild symptoms in those most sensitive individuals.</p>	
<p>4.3.1 ISDI supports the proposed table however notes that risk assessing 'wheat' will not ensure the safety of gluten intolerant consumers, since they are intolerant to gluten which may arise from e.g. wheat, rye or barley.</p> <p>Since the purpose of the present guidelines on the use of PAL Appendix II is to communicate to consumers with food allergy or coeliac disease, ISDI supports adding 'Wheat/Cereals containing gluten' and the corresponding reference dose as '(5.0 (with a maximum of 20 mg gluten/kg))'.</p> <p>ISDI would appreciate the Committee advice on how to convert wheat, rye, barley or any other hybridised cereal proteins into gluten equivalents.</p>	<p>International Special Dietary Food Industries</p>
<p>4.3.1 Same as comment on 4.3: without a reference dose for gluten-containing cereals, ICBA seeks clarification on what an appropriate approach might be to establish the reference dose.</p>	<p>ICBA</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 or national authorities can establish a reference dose consistent with recognized principles⁷ for the purposes of determining an action level.</p>	
<p>4.3.2 Advancement to Step 5 is dependent on determining how to handle coeliac disease and gluten as part of PAL. Further discussion is needed to resolve it before advancement.</p> <p>Unlike principle 4.2, this principle (4.3) relies on utilizing quantitative risk assessment measure alone. We request that further flexibility be provided here to recognize the importance of qualitative risk assessment. Notably, it is necessary to consider other factors such as frequency of occurrence, variability in data (where products are subjected to analysis), and the sensitivity of specific population groups.</p> <p>We support the inclusion of the reference doses in Table 4.3.1. However, we request the following amendment to footnote 6 in provision 4.3. Regarding footnote 6, we ask the Committee to consider the following amendment to the footnote below to accommodate prepackaged foods that contain multiple portions or servings.</p> <p>Footnote 6: Action level (mg total protein from the allergen / kg food) = Reference dose (mg total protein from the allergen) / Amount of the food (kg). The amount of food should be established based on the 50th percentile or population mean for the quantity that can reasonably be expected to be consumed in a single eating occasion intake of the food preferably using the 50th percentile or mean of consumption data for the respective population(s) where available.</p> <p>For prepacked foods comprising multiple portions or servings, some consumers could, theoretically, eat the entire product instead of the recommended serving. Food business operators generally understand how much consumers typically eat in one eating occasion and can, therefore, factor this information into their assessment. We recommend the Committee use the language above within the footnote to help account for this variance in consumption patterns.</p> <p>As noted above, without a reference dose for gluten-containing cereals, ICGMA seeks clarification or discussion on what an appropriate approach might be for establishing a reference dose.</p>	<p>ICGMA</p>

4.3.2 To comply with determining action levels based on the FAO/WHO expert advice, "can" should be replaced with "shall".	European Federation of Allergy and Airways Diseases Patients' Associations
4.3.2 EUMS support the proposed text in Principle 4.3.2.	European Union
<p>4.3.2 As regards section 4.3.2, although FoodDrinkEurope supports in principle the possibility for national authorities to determine RfDs that align with recognised principles for determining an action level, we do not believe that such information is appropriate or helpful to be included within a Codex text. Moreover, the establishment of a national RfD should be based on robust scientific data.</p> <p>Irrespectively, we would like to emphasize that harmonization of reference doses (by applying the same scientific approach) should be strongly considered, provided that sufficient data is available, to ensure a consistent approach, fair practices in international trade and to enable consumer to make informed and safe food choices.</p>	FoodDrinkEurope
<p>4.3.2 ISDI supports in principle the possibility for national/regional authorities to determine RfDs that align with recognised principles for determining an action level. However, ISDI believes that the establishment of a national/regional RfD should be based on robust scientific data and that harmonisation of reference doses (by applying the same scientific approach) should be strongly considered to ensure a consistent approach, fair practices in international trade and to enable consumer to make informed and safe choices.</p> <p>ISDI therefore suggests the section Principle 4.3.2 be amended as follows:</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 or national authorities can establish a reference dose consistent with recognized principles⁷ for the purposes of determining an action level. This specific local reference dose for a food allergen, should, where appropriate, be harmonised at regional/global level.</p> <p>⁷ FAO and WHO (2022). Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens: Part 2: Review and establish threshold levels in foods of the priority allergens. https://doi.org/10.4060/cc2946en."</p> <p>ISDI finally also suggests defining a process for the update of the list of exemptions, which should consider the inclusion of foods evaluated by regional or national authorities using established criteria⁷.</p>	International Special Dietary Food Industries
4.3.2 footnote 7 Thailand proposes the specific reference in the Report Part 2 to the "recognized principles" be provided in this footnote. This would be very useful for national authorities to correctly refer to and prevent any misinterpretation of the important principles.	Thailand
4.4 PAL shall be accompanied by education/information programs to ensure understanding and appropriate use of PAL by consumers, health care providers and food business operators.	
4.4 We strongly support this statement requiring education/information programs to ensure understanding of Precautionary Allergen Labeling (PAL) among various groups of people. Currently, research shows that PAL is poorly understood. It is vital that education accompany a threshold approach, as this will be new to consumers, health care providers, and food business operators. Lack of education could lead to confusion about which items are safe to consume which could lead to adverse reactions in consumers. For example, since PAL statements are not currently risk-based, research shows that some consumers mistakenly believe certain labels are "safe" while others are to be avoided based on past experiences. This could pose a problem if, for example "may contain" is chosen as the label, a consumer perceives "may contain" as "safe", and they start to consume products that they should be avoiding. Additionally, lack of education for food business operators could lead to low adoption of the new risk-based PAL system, which would	International Association of Consumer Food Organizations

lead to the new system failing to accomplish its goal of reducing excess PAL labeling on products that do not pose a high risk. Finally, consumers who are highly sensitive would need to discuss with their healthcare providers how to manage risk posed by potentially unlabeled unintended allergen presence, thus the need for education at the health care provider level.	
<p>4.4 As per our previous recommendations, EFA reiterates that there needs to be an appropriate education strategy to cater for all food allergy patients, including those reacting to lower doses than ED05.</p> <p>This is why it is so important to be able, in the near future, to provide allergen-free labels and educate consumers on interpreting PAL. EFA has also suggested that national authorities collaborate with food allergy patient associations to develop an education strategy that supports patients, consumers, healthcare providers, and food business operators.</p>	European Federation of Allergy and Airways Diseases Patients' Associations
4.4 EUMS support the proposed text in Principle 4.4.	European Union
<p>4.4 PAL shall <u>should</u> be accompanied by education/information programs to ensure understanding and appropriate use of PAL by consumers, health care providers and food business operators.</p> <p>We reiterate our position that the education program is the responsibility of the national government to support advocacy and education campaigns on food allergy appropriately to the context of their countries</p>	Thailand
4.4 As the purpose of allergen declaration is ultimately informing consumers about potential risk, ensuring the public correctly understands the message is desirable and important. Based on the level of awareness amongst consumers, education programs can be performed based on national authorities' evaluations.	FoodDrinkEurope
<p>4.4 ISDI supports Principle 4.4, as proposed below. It is aligned with Expert Committee Report Part 3 which recommends education of consumers with food allergy and other relevant stakeholders (e.g. risk assessors, risk managers, healthcare providers, food business operators) is critical to ensure understanding of the applied principles and the implications of PAL.</p> <p>However, ISDI stresses that the ongoing work should reduce confusion among consumers and wants to ensure that educational information is not expected on product labels.</p> <p>"4.4 PAL shall be accompanied by education/information programs to ensure understanding and appropriate use of PAL by consumers, health care providers and food business operators."</p>	International Special Dietary Food Industries
5. PRESENTATION OF PAL	
5.2 PAL should appear as a separate statement directly under or in close proximity to the ingredient list (when present).	
The EUMS support the proposed revision of the text in the section on presentation.	European Union
<p>5.2 As in our response to the 8.3.2.1 section of the consultation on the allergen-related provisions of the GSLPF, EFA strongly suggests to delete 'in close proximity'. Our concern is that it would be interpreted as 'on the other side of the box', for example, which would make it difficult to find for people with food allergy.</p> <p>Therefore a precise indication where to find PAL is necessary. EFA strongly believes that PAL should appear as a separate statement directly under to the ingredient list.</p>	European Federation of Allergy and Airways Diseases Patients' Associations
5.2 PAL should appear as a separate statement directly under or in close proximity to the ingredient list (when present), <u>where applicable</u> .	Thailand

We propose the addition of “where applicable” for flexibility. There may be certain cases that the package size is limiting and the ingredient list may be long or use various language thus the position of this separate statement should be flexible but still prominent and readily legible.	
5.2 FIA can support this new text as it allows some degree of flexibility (i.e. not just “directly under”) while still keeping the PAL in close proximity for the consumer’s ease of finding it.	Food Industry Asia
5.2 ISDI proposes to change the wording of Principle 5.2 in order to bring it into line with the wording used in section 8.3.2.1 as follows: “5.2 PAL should appear as a separate statement directly under or in close proximity to the list of ingredients when present.”	International Special Dietary Food Industries
5.2 We can support this new text as it allows some degree of flexibility (i.e. not just “directly under”)while still keeping the PAL in close proximity for the consumer’s ease of finding it	IDF/FIL
5.2.1 A PAL statement shall commence with the words ‘May contain’ (or equivalent words) and include the identified allergens using the specified names as listed in sections 4.2.1.4 and where applicable 4.2.1.5 of the GSLPF.	
5.2.1 We support advising CCFH so that the COP on allergens can be updated to ensure consistency with the amended GSLPF and PAL guidelines.	ICGMA
<p>5.2.1 We recommend the following amendment to 5.2.1:</p> <p>A PAL statement shall commence with the words ‘May contain’, ‘Not suitable for people allergic to’, (or equivalent words) and include the identified allergens using the specified names as listed in sections 4.2.1.4 and where applicable 4.2.1.5 of the GSLPF.</p> <p>We recognize the value to consumers in having one, consistent Precautionary allergen labeling (PAL) statement. However, further consideration of the best language for this single statement is needed. The WHO/FAO report found that in survey research consumers generally preferred “not suitable for” PAL statements. “Not suitable for people allergic to (____)” sends a clear message to consumers that a product is to be avoided based on a risk assessment, whereas “may contain” introduces more uncertainty.</p> <p>The drawback to the “not suitable for” language is that it does not specifically convey that it describes unintentional presence of allergens through cross-contact. Accordingly, if “not suitable for” is chosen, we urge consideration of incorporating intentionally added allergen ingredients into this statement, so that both intentional and unintentional presence of allergens can be covered in a single, easy to understand statement. Otherwise, consumers may read the “not suitable for” language, presume that it is comprehensive, and fail to also check the ingredients statement, which could be harder to read if it contains multiple ingredients beyond allergens. Before final selection of PAL language, additional consumer research is needed to assess consumer understanding of “not suitable for” labels.</p>	International Association of Consumer Food Organizations
5.2.1 Linked again to our response in the 8.3.2.1 section of the consultation on the allergen-related provisions of GSLPF, EFA suggests the deletion of the ‘(or equivalent words)’. We believe that only one harmonized statement should be allowed to be used, as other options might create confusion and result in interpretation about the potential allergen content, which is not justified or helpful (e.g. "May contain traces" might lead someone to think that this means less allergen content than in "May contain" - which is not true)	European Federation of Allergy and Airways Diseases Patients’ Association
<p>5.2.1 ISDI supports Principles 5.1, 5.2, 5.2.1 and 5.2.2 as proposed below, including the wording change proposed above. All listed principles are consistent with section 8.3 of the GSLPF.</p> <p>“5.1 Section 8.1.1, 8.1.2 and 8.1.3 and 8.2 of the General Standard for the Labelling of Prepackaged Foods (GSLPF) (CXS 1-1985) apply to PAL labelling.</p>	International Special Dietary Food Industries

<p>5.2 PAL should appear as a separate statement directly under or in close proximity to the list of ingredients when present.</p> <p>5.2.1 A PAL statement shall commence with the words 'May contain' (or equivalent words) and include the identified allergens using the specified names as listed in sections 4.2.1.4 and where applicable 4.2.1.5 of the GSLPF.</p> <p>5.2.2 A PAL statement shall contrast distinctly from surrounding text such as through the same font type, style or colour used for declarations in accordance with section 8.3.1 of the GSLPF."</p>	
5.2.1 We are supportive of "may contain" and we are open to allowing "equivalent words"	IDF/FIL
5.2.2 A PAL statement shall contrast distinctly from surrounding text such as through the same font type, style or colour used for declarations in accordance with section 8.3.1 of the GSLPF.	
5.2.2 FIA is supportive of this proposed text, and to having it in a separate section 5.2.2	Food Industry Asia
5.2.2 We are supportive of this proposed text, and to having it in a separate section 5.2.2	IDF/FIL
Additional comments: New Section 6	
<p>In addition to the comments above, the United States is of the view that it may be appropriate to introduce a new section 6 to these guidelines to inform consumers of the presence of allergenic foods in supply chains and/or production facilities even when it may be below the action level. When allergenic foods are present in the same facilities or supply chain and there is either no cross contact or cross contact is managed below the action level, FBOs should have the flexibility to use a separate statement communicating this truthful food information. The United States proposes the following as a potential statement: "manufactured in a facility that also processes ...".</p>	USA