

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
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Agenda Item 5

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD LABELLING

Forty-ninth Session

11-15 May 2026

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

(Prepared by the EWG chaired by the United States of America, Australia, and the United Kingdom)

Codex Members and Observers wishing to submit comments on the draft guidelines in the Appendix I should do so as instructed in CL 2026/07-FL available on the Codex webpage/Circular Letters:
<http://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/>

INTRODUCTION

1. CCFL48(2024) finalized the revisions to the *General standard for the labelling of prepackaged foods* (CXG 1-1985, GSLPF). CCFL48 also made progress on the draft guidelines on the use of precautionary allergen labelling (PAL), advancing the draft to step 5 for interim adoption by CAC47. CAC47 adopted the draft guidelines on the use of PAL at step 5 and granted the committee an extension to complete the work by CCFL49.
2. During CCFL48 the committee agreed the purpose, scope, definitions and sections 4.1 and 4.2 of the draft guidelines. CCFL48 also agreed to include section 4.3, regarding when to use PAL, but consensus still needed to be reached on the text in square brackets “[shall/should] [only]”. The remainder of Section 4.3 was also placed in square brackets for further consideration. The Committee agreed to have a placeholder for a reference dose (RfD) for cereals containing gluten or gluten in section 4.3.1 pending scientific advice from FAO/WHO; the RfDs in 4.3.1 and the provision 4.3.2 were kept in square brackets for further consideration by an EWG. Agreement in principle was obtained for section 4.4, as well as support for the intent of section 5.
3. After agreeing to advance the draft guidelines to step 5, CCFL48 re-established the electronic working group (EWG) to continue drafting the guidelines taking into account the discussions at CCFL, the scientific advice received to date, and the advice from CCMAS.
4. CCFL48 additionally agreed to request additional scientific advice in support of the draft guidelines. FAO/WHO was requested to provide guidance for:
 - a. qualitative risk assessment
 - b. scientific advice on the level of RfDs or concentrations for cereals containing gluten or gluten, and
 - c. capacity building activities to countries on PAL and related risk assessment.
5. Two *ad hoc* joint FAO/WHO expert consultations took place in 2025 in response to the first two requests and a workshop was held in Nanning, China in response to the third request.
6. As CCFL awaits the publication in 2026 of the results from these three meetings that took place in response to CCFL48’s requests, the Chairs decided to provide in this agenda paper a high-level summary of those meetings based on the summary and conclusions.

Ad hoc joint FAO/WHO expert consultation on risk assessment of food allergens – guidance for qualitative risk assessment (FAO HQ, Rome, Italy: 16 – 20 June 2025)

7. Food allergens should be controlled through appropriate food safety management systems.
- (i) This includes compliance with existing Codex documents (e.g., codes of practice), good allergen management, and other quality systems.
 - (ii) By adhering to existing food allergen labelling and information requirements, food business operators (FBOs) already hold much of the information needed to conduct food allergen risk assessment.
 - (iii) Unintended allergen presence (UAP) of priority allergenic foods¹ (including ingredients, food additives and processing aids) due to cross-contact should be eliminated or mitigated/controlled to a level as low as reasonably possible through good hygiene practices (GHPs), good agricultural practices (GAP), good manufacturing practices (GMP), and procedures based on HACCP principles (e.g., General Principles of Food Hygiene CXC 1-1969; Code of Practice on Food Allergen Management CXC 80-2020).

Footnote 1: Priority allergenic foods refer to the global priority allergenic foods and those relevant to the applicable national or regional jurisdictions.

8. The goal of food allergen risk assessment is to support informed decisions, e.g., on labelling or process control, and communication through the supply chain.
9. The risk assessment process for food allergens is applicable and achievable for all FBOs including primary producers.
10. Risk assessment of food allergens is part of a stepwise and iterative process with information requirements that may differ depending on the application.
11. Irrespective of the size of the business, risk assessment for food allergens should be evidence-based, and information should be collected and be able to support a decision.
- (i) Information required for such risk assessment is qualitative and, depending on the situation, may need to be supplemented with quantitative information.
 - (ii) Very often risk assessment can be completed without analytical data.
 - (iii) Analytical data in isolation is insufficient to complete a risk assessment.
12. Conducting a risk assessment is required to justify PAL decisions.

Ad hoc joint FAO/WHO expert consultation on risk assessment of food allergens – reference dose(s) for cereals containing gluten and gluten (FAO HQ, Rome, Italy: 3 – 7 November 2025)

13. A RfD of 4 mg gluten is recommended for risk assessment of unintended presence of gluten and cereals containing gluten in food products as the basis for deciding whether or not PAL for cereals containing gluten should be applied.
14. For guidance on PAL, the previously established RfD of 5 mg total protein for wheat should be replaced with a RfD of 4 mg gluten.
15. Where gluten-containing cereals are present in the ingredient list (e.g. barley), and the food contains cross-contact above the RfD from other gluten containing cereals (e.g. wheat), competent authorities should consider how the specified cereal name and the optional term “gluten” appear in the ingredient list (e.g. barley (gluten)), separate statement (e.g. “contains: barley (gluten)”) and the PAL statement “may contain” (e.g. “may contain: wheat (gluten)”).
16. For comparison of an expected exposure expressed in units of total protein from the source to the gluten RfD, a conversion to mg gluten would be required.
17. Where the portion sizes consumed are large (> 200 grams), some foods could meet criteria for both a gluten-free claim for containing levels of gluten no higher than 20 mg/kg and a PAL for exceeding the 4 mg gluten RfD. This situation causes confusion to consumers who avoid wheat and/or gluten and might pose a health risk to those with IgE-mediated wheat allergy who assume that consumption is safe because the product is labelled gluten-free. Steps be taken to prevent these scenarios from occurring.

FAO/WHO capacity building workshop on PAL and risk assessment of food allergens in Nanning, China (19 – 20 September 2025)

18. FAO/WHO provided capacity building training to 60 participants from 11 countries (Brunei, Brazil, China, Japan, Lao People's Democratic Republic, Malaysia, Maldives, Nigeria, Singapore, Tanzania, and Thailand), international organizations and food business operators.

19. Key topics included the FAO/WHO reports on food allergens, which were introduced and discussed. Participants engaged with the knowledge and techniques from FAO/WHO's work, expressing appreciation for its practical applications. Homework on risk assessment of different food allergens was carried out after the first day. During a field exercise, participants used a risk-based approach to evaluate the processing line of dairy products. FAO and WHO intend to publish a report of the workshop in 2026.

PARTICIPATION AND METHODOLOGY

20. The EWG was established in March 2025 with 41 Codex members, one Codex member organization, and 16 Codex observers. A list of participants is provided in Appendix II.

21. The EWG Chairs undertook the work of the EWG through two consultation papers. The first consultation paper (CP1) focused on obtaining comments on sections 4.3, 4.3.2, 4.4, and 5 with the objective of reaching consensus on these sections. 19 members, one member organization, and 12 observers responded to CP1.

22. The second consultation paper (CP2) focused on obtaining comments on the reference doses in table 4.3.1, addressing areas which may need further consideration based on feedback from CP1 such as presentation in the absence of an ingredient list, and incorporating advice from the FAO/WHO Expert Consultation on risk assessment of food allergens – reference dose(s) for cereals containing gluten or gluten, including how to manage the rare case where PAL for cereals containing gluten may conflict with “gluten-free” labelling. 18 members, one member organization, and 11 observers responded to CP2. CP2 also provided updated draft guidelines which reflected the consensus reached in CP1.

23. The questions and feedback received in CP1 and CP2 are summarized below. Appendix I contains the updated draft guidelines that takes into account the recommendations of the EWG and the discussions as CCFL48 outlined in the EWG's terms of reference.

SUMMARY OF DISCUSSION

Section 4.3: When to use PAL

24. CP1 queried the EWG on section 4.3, presenting the EWG with all possible iterations of the provision regarding when to use PAL. There was general agreement from the feedback received at CP1 that PAL statements can only be used when unintended allergen presence cannot be mitigated through preventive controls to a level at or below the action level for a food allergen based on the reference dose, and that unnecessary overuse of PAL should be limited. While there was agreement on these principles, there were differing views as to which of the statements provided the best guidance for assuring the principles were followed. There were concerns by some members that the term “shall” was too prescriptive to accommodate the qualitative risk assessment and supported the use of “should” in section 4.3. Nevertheless, a majority of EWG members indicated that they could support “should only” as a compromise (25 EWG members ranked it in their top three choices and others indicated support as a compromise).

25. Based on the EWG feedback, the text of section 4.3 was updated as follows:

[4.3 PAL should only be used when it is demonstrated that unintended food allergen presence cannot be mitigated to a level at or below the action level³ for a food allergen based on the reference doses in the table at 4.3.1.

Footnote 3: Action level (mg total protein from the allergenic **food** / kg food) = Reference dose (mg total protein from the ~~allergen~~ **allergenic food**) / Amount of the food (kg). The amount of food should be established based on the quantity that can reasonably be expected to be consumed on a single eating occasion preferably using the 50th percentile.

26. The update from “allergen” to “allergenic food” was made to align the terminology with that of the FAO/WHO expert consultation. The Chairs have made this update wherever relevant throughout the guidelines.

Section 4.3.1: Table of reference doses

27. Following the release of the summary and recommendations of the *ad hoc* joint FAO/WHO expert

consultation on reference dose(s) for cereals containing gluten and gluten in November 2025, the Chairs proposed including the recommended RfD (4 mg gluten) in the table and sought the EWG's feedback on section 4.3.1 in CP2. The Chairs noted for the EWG that the RfDs were established based on risk-based principles, derived from global clinical data characterizing reactions to known amounts of proteins from allergenic foods and set at levels of exposure that limit appreciable health risks or adverse reactions in sensitive persons. The ED05-based exposure levels were selected by the expert consultation as there were minimal reductions in health risk or adverse reactions relative to setting RfDs at an ED01 exposure level and enabled effective risk assessment (quantitative and qualitative) by FBOs which would see increased difficulty at RfDs of ED01 due to lack of analytical methods and other control measures.

28. There was broad support in CP2 from the EWG for the RfDs in the table of section 4.3.1, including for the 4 mg RfD for cereals containing gluten or gluten (22 EWG members supporting, 7 EWG members expressing concerns, and one did not answer the question). One member did not support the use of thresholds as a basis for PAL. Another member expressed that the RfD for gluten established by the FAO/WHO experts was too low. There were concerns raised by two observers that the RfDs may not be sufficiently protective for older infants and young children and it should therefore be indicated that they do not apply to those foods.

29. There were numerous comments, including among those who supported the table, that the RfD for wheat needed to be included to ensure that IgE-mediated wheat allergy was reflected appropriately and distinctly from gluten. Feedback also indicated that the RfD of 4 mg gluten was for total gluten in foods from cross contact (*i.e.* total gluten from wheat, rye, and barley) and the table needed to accurately reflect this (one member suggested merging the cells containing 4 mg gluten across all three cereals containing gluten).

30. At CP2, Chairs proposed including a footnote listing the conversion factors both across and within cereals containing gluten, noting that the FAO/WHO experts referred to a need to convert exposure in units of total protein to mg gluten to use the gluten RfD. Feedback from EWG members indicated that the footnote should be removed as there are different conversion factors both across and within the different gluten containing cereals, and that the conversion factors were not necessary for CCFL's purposes. There were several comments that indicated that analytical methods for gluten cannot determine the source of gluten. This may be a point for further discussion in the PWG and CCFL49 with regard to declaration.

31. Based on the EWG feedback, section 4.3.1 has been updated as follows:

Table 4.3.1

	Reference dose (RfD) (mg total protein from the Allergen Allergenic Food)	Reference dose (RfD) Total mg Gluten^{3bis} from Cereal containing gluten
Almond	1.0	
Brazil nut	1.0	
Cashew (and Pistachio)	1.0	
Macadamia	1.0	
Pine nut	1.0	
Walnut (and Pecan)	1.0	
Celery	1.0	
Mustard	1.0	
Peanut	2.0	
Egg	2.0	
Milk	2.0	
Sesame	2.0	
Hazelnut	3.0	
Wheat ^{3bis}	<u>5.0</u>	<u>4.0</u>
<u>Barley^{3bis}</u> <u>Rye^{3bis}</u>	-	
Fish	5.0	
Buckwheat	10	
Lupin	10	
Soy	10	
Crustacea	200	

Footnote 3bis: Rye and barley are cereals containing gluten and so have a gluten RfD assigned. Wheat is a cereal identified as a priority food of concern for both IgE-mediated allergies and coeliac disease, and so has an RfD for total protein as well as an RfD for gluten.

Section 4.3.2: Flexibilities for competent authorities

32. CCFL48 placed square brackets around section 4.3.2 as there was insufficient time to discuss and agree to this section. Taking into account the discussion at CCFL48 around ED05 and ED01 in relation to the RfDs, at CP1 the Chairs proposed an amendment to section 4.3.2 with the aim of facilitating consensus around section 4 in general. The initial intent of section 4.3.2 was to allow for RfDs to be established for allergens that were not listed in section 4.3.1. The Chairs' proposal expanded the purpose of this section to account for the ongoing discussion among members regarding the expert advice to use the ED05 as the RfD and took into consideration a member's views at CCFL48 that local factors could influence a competent authority's decision to use ED05 or other safety values as a RfD.

33. The majority of EWG members' feedback at CP1 indicated that they did not support the expanded intent of the section proposed by the Chairs. In its objection to this expansion, the EWG had consensus that an international harmonized set of RfDs should be used based on the recommendations provided from the FAO/WHO expert consultation. In both CP1 and CP2, support was received for the original text in section 4.3.2 which provides for competent authorities to establish an RfD when an RfD is not established in table 4.3.1.

34. Based on the feedback of the EWG, the text proposed to be maintained as originally drafted, with a minor

edit for consistency with other Codex texts.

4.3.2 Where a reference dose is not established for a particular food allergen in the table to 4.3.1 above, regional/national **competent** authorities can establish a reference dose consistent with recognized principles⁴ for the purposes of determining an action level.]

Footnote 4: 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>

New Section 4.3.3: PAL and gluten free claims

35. For a minority of products (those with portion sizes of 200 grams or more), foods containing 4 mg gluten or more could, in some cases, contain less than 20 mg gluten per kg of the food (*i.e.* 20 ppm). These foods would meet the definition for gluten free in accordance with the *Standard for foods for special dietary use for persons intolerant to gluten* (CXS 118-1979). The FAO/WHO expert consultation on cereals containing gluten and gluten suggested CCFL consider risk management to prevent consumer confusion when a product might both a) meet the 20 ppm gluten threshold and carry a “gluten free” claim and b) might also need a PAL statement for cereals containing gluten (wheat, rye, or barley) due to a product containing more than 4 mg gluten per portion. The experts concluded that the RfDs for gluten for the PAL framework should not be used as the basis for defining gluten-free labelling, and there was no need to update the 20 ppm threshold for the gluten-free claim at this time.

36. The Chairs proposed three potential paths to the EWG in CP2. The first two options proposed provisions that limit labeling in these circumstances to the use of only one of the two labels (*i.e.* PAL or “gluten free”). The third option proposed not to act on the advice and allow products to carry both a gluten-free claim and/or a PAL statement. The options were as follows:

Option A:

4.3.3bis If a food carries the term “gluten free” as per the *Standard for foods for special dietary use for persons intolerant to gluten* (CXS 118-1979), then a PAL statement for cereal(s) containing gluten shall not appear on the label.

Option B:

4.3.3ter If a food requires a PAL statement for cereal(s) containing gluten, then the term “gluten free” shall not appear on the label.

Option C:

Allow both “gluten free” and a PAL statement for cereal(s) containing gluten to appear on the labels of the relevant products. This option would not require the inclusion of new text in the guidelines.

37. There was a strong preference by the EWG for option B (24 EWG members supported option B, one supported option A, two supported option C, one supported both options A and B, and two did not answer). Most members indicated that option B was risk-based, avoided contradictory labelling, and best prioritized consumer safety. One EWG member indicated a need for flexibility and that education could help overcome potential confusion. One member who supported option B provided suggested edits to the text for clarity, which the Chairs have incorporated.

38. Based on the feedback from the EWG, the guidelines have been updated to include a new section 4.3.3 as follows:

4.3.3. If a PAL statement for cereal(s) containing gluten [appears / is used] on the label, then the term “gluten free” shall not [appear/ be used] on the label [or in labelling].

Section 4.4 Education/information programs

39. CCFL48 agreed with the principle of section 4.4, although there was insufficient time to discuss and reach consensus on the provision in detail. CCFL48 noted two comments, that education information and programs should not be provided through the label and should be done in collaboration with competent authorities. Given the agreement in principle at CCFL48, the Chairs did not propose any amendments to section 4.4 at CP1 and sought EWG Members’ views on the provision.

40. There was broad support at CP1 for section 4.4. Some EWG members expressed a need for more clarity, especially regarding who should lead the programs. Several other EWG members expressed the view that education should not be provided through product labelling. There was also a comment that education/information

should be as broad as possible and include all relevant stakeholders.

41. Based on the EWG feedback, section 4.4 was updated as follows:

4.4 PAL ~~shall~~ should be accompanied ~~complemented~~ by education/information programs led by competent authorities to ensure proper understanding and appropriate use of PAL by consumers, healthcare providers, food business operators, and other stakeholders.

42. Several EWG members confirmed their support for the updated text above in their additional comments to CP2.

Section 5: Presentation of PAL

43. There was broad support for the intent of section 5 at CCFL48. CCFL48 agreed to align section 5.2.2 with the corresponding section of the GSLPF. There was also a suggestion to introduce the idea of comprehensive allergen statements that would include all relevant information in one place on the label. At CP1, the Chairs welcomed proposals for section 5 that would capture this suggestion; however, no such proposal was made. The Chairs proposed edits at CP1 to align section 5 with the corresponding section in the GSLPF.

44. At CP1, there was broad support for section 5.1 (application of sections 8.1.1, 8.1.2, 8.1.3 and 8.2 of the GSLPF to PAL labelling) as proposed by the Chairs. With respect to section 5.2 (where a PAL statement appears), there was general support for “shall”, but differing views regarding whether the PAL statement should be placed in close proximity to the ingredient list or directly under the ingredient list. As most EWG members agreed to have section 5 in general align with the corresponding provisions of the GSLPF, the Chairs decided to maintain the existing text, “directly under or in close proximity to [...]”.

45. The EWG received feedback that an additional provision was needed for foods that do not have an ingredient list to guide placement of PAL when an ingredient list is not present. The Chairs proposed a new provision along these lines at CP2, which received broad support (24 EWG members supported it, 5 EWG members did not agree with the proposal, and one did not answer). Of the five that did not support the proposal, four EWG members proposed edits to improve the text to ensure that it was not more strict or prescriptive than the allergen declaration provisions in the GSLPF and to address what to do when a separate allergen statement is present. The Chairs have incorporated these suggestions in the updated draft guidelines.

46. Regarding section 5.2.1, there was general support that PAL should use the words “may contain”. Questions were raised at CCFL48 and in the EWG with regard to what “equivalent words” was intended to communicate. The Chairs note that “or equivalent words” was added in response to member feedback during CCFL47 and CCFL48 to provide additional flexibility and facilitate trade between countries. The flexibility was intended to allow slight adjustments to the wording of the PAL statement, without compromising its intent or meaning. The word “equivalent” was deliberately included to prevent the use of statements with different meanings to “may contain”, such as “contains traces of” or “made in a factory that produces”. Based on feedback received in CP1 and CP2 of this EWG, the Chairs recommend maintaining the current wording of 5.2.1; however, the Chairs have added an example “such as ‘may be present’” to address the need raised by EWG members.

47. Comments received in CP2 also indicated a need for additional clarity in section 5.2.1 with regard to PAL for cereals containing gluten (wheat, barley, and rye). Several comments expressed that “gluten” should be used rather than the specified name, while others noted that “wheat” would still need to be included to inform both those with IgA-mediated wheat allergy and persons with celiac disease. The Chairs have added two proposed footnotes (4bis and 4ter) to section 5.2.1 in an attempt to address these comments and align the declaration with the GSLPF.

48. Regarding section 5.2.2, there was broad support in CP1 for the proposed text as it aligned with the agreed text in the GSLPF.

49. Based on the feedback in the EWG, the Chairs have updated section 5 as follows:

5.1 Section 8.1.1, 8.1.2 and 8.1.3 and 8.2 of the *General Standard for the labelling of pre-packaged foods* (CXS 1-1985) apply to PAL labelling.

5.2 PAL ~~should~~ shall appear as a separate statement directly under or in close proximity to the ingredient list (when present).

5.2bis Where a food is exempt from declaring a list of ingredients, and no list of ingredients is present, PAL shall be declared in a prominent position on the label. Where a separate statement made in accordance with Section 8.3.2.1 of the GSLPF exists on the label, the PAL declaration shall be in the same field of vision as the separate statement.

5.2.1 A PAL statement shall commence with the words 'May contain' (or equivalent words **such as 'may be present'**) and ~~include the identified~~ **declare the** allergenic food(s) using the specified names for the foods and ingredients as listed in sections 4.2.1.4 and where applicable 4.2.1.5 of the General Standard for the labelling of pre-packaged foods (CXS 1-1985).^{**4bis, 4ter**}

Footnote 4bis: When gluten is present above the action level and the source of the gluten cannot be verified by risk assessment, the specified names of all cereals containing gluten (i.e. wheat, barley, and rye) shall be included in the PAL statement.

Footnote 4ter: In addition to the specified name of wheat, rye, and barley, the word 'gluten' may be used.

5.2.2 A PAL statement shall **be declared in a clear and distinct manner such as through the use of contrast distinctly from surrounding text such as through the same font type, style or colour that contrasts from the surrounding text** used for declarations in accordance with section 8.3.1 of the General Standard for the labelling of prepackaged foods (CXS 1-1985).

CONCLUSION

50. The EWG fulfilled its Terms of Reference as provided by CCFL48 and provides the updated draft guidelines in Appendix I for CCFL49's consideration.

RECOMMENDATIONS

51. CCFL49 is invited to:

- (i) consider the draft guidelines in Appendix I, and particularly the following areas:
 - (a) The updated configuration of the table in 4.3.1 and its footnote;
 - (b) The updated text in section 5, in particular the proposed section 5.2bis, the proposed example to demonstrate "equivalent words" in section 5.2.1, and the proposed footnotes to address gluten declaration.
- (ii) consider if the text is ready for advancement to Step 8.

APPENDIX I

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

At Step 7

(Proposed additions and/or revisions to the draft text are indicated in **99bold and underline** text while deletions are indicated in ~~strike through~~)

1. PURPOSE

To facilitate a consistent and harmonized approach to the effective use of precautionary allergen labelling (PAL) for communicating to consumers with food allergy or coeliac disease about the risk from the unintended presence of food allergens due to cross-contact with allergenic food.

2. SCOPE

These guidelines apply to PAL when used in the labelling of pre-packaged foods to indicate the risk from the unintended presence of a food allergen(s) caused by cross-contact¹ with allergenic food.

3. DEFINITIONS

For the purpose of these guidelines, the following definition shall be used in conjunction with the definitions in Section 2 of the *General Standard for the labelling of pre-packaged Foods* (CXS 1-1985):

“Precautionary allergen labelling” is a statement made in the labelling of pre-packaged foods to indicate a risk from the unintended presence of a food allergen(s) due to cross-contact with an allergenic food that has been identified by a risk assessment.

4. GENERAL PRINCIPLES

4.1 Effective food allergen management practices including controls to prevent or minimize the unintended presence of food allergens caused by cross-contact with allergenic foods 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.

4.2 The decision to use PAL should be based on the findings of a risk assessment², which can include but is not limited to a quantitative risk assessment, of unintended food allergen presence.

~~**4.3** PAL [shall / should] [only] be used when it is demonstrated that unintended food allergen presence cannot be mitigated to a level at or below the action level³ for a food allergen based on the reference doses in the table at 4.3.1.~~

[4.3 PAL **should only** be used when it is demonstrated that unintended food allergen presence cannot be mitigated to a level at or below the action level³ for a food allergen based on the reference doses in the table at 4.3.1.

¹ Allergen cross-contact as defined in *Code of practice on allergen management for food business operators* (CXC 80-2020).

² 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 provide guidance for the risk assessment of unintended food allergen presence). <https://doi.org/10.4060/cc6081en>

³ Action level (mg total protein from the allergenic food / kg food) = Reference dose (mg total protein from the allergenic food) / Amount of the food (kg). The amount of food should be established based on the quantity that can reasonably be expected to be consumed on a single eating occasion preferably using the 50th percentile.

Table 4.3.1

	Reference dose (RfD) (mg total protein from the Allergen Allergenic Food)	Reference dose (RfD) Total mg Gluten^{3bis} from Cereals containing gluten
Almond	1.0	
Brazil nut	1.0	
Cashew (and Pistachio)	1.0	
Macadamia	1.0	
Pine nut	1.0	
Walnut (and Pecan)	1.0	
Celery	1.0	
Mustard	1.0	
Peanut	2.0	
Egg	2.0	
Milk	2.0	
Sesame	2.0	
Hazelnut	3.0	
Wheat	<u>5.0</u>	<u>4.0</u>
<u>Barley^{3bis}</u> <u>Rye^{3bis}</u>	-	
Fish	5.0	
Buckwheat	10	
Lupin	10	
Soy	10	
Crustacea	200	

4.3.2 Where a reference dose is not established for a particular food allergen in the table to 4.3.1 above, regional/national **competent** authorities can establish a reference dose consistent with recognized principles⁴ for the purposes of determining an action level.]

4.3.3. If a PAL statement for cereal(s) containing gluten [appears / is used] on the label, then the term “gluten free” shall not [appear/ be used] on the label [or in labelling].

4.4 PAL ~~shall~~ **should** be accompanied ~~complemented~~ by education/information programs **led by competent authorities** to ensure **proper** understanding and appropriate use of PAL by consumers, healthcare providers, food business operators, **and other stakeholders**.

5. PRESENTATION OF PAL

5.1 Section 8.1.1, 8.1.2 and 8.1.3 and 8.2 of the *General Standard for the labelling of pre-packaged foods* (CXS 1-

^{3bis} **Rye and barley are cereals containing gluten and so have a gluten RfD assigned. Wheat is a cereal identified as a priority food of concern for both IgE-mediated allergies and coeliac disease, and so has an RfD for total protein as well as an RfD for gluten.**

⁴ 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>.

1985) apply to PAL labelling.

- 5.2 PAL ~~should~~ **shall** appear as a separate statement directly under or in close proximity to the ingredient list (when present).

5.2bis Where a food is exempt from declaring a list of ingredients, and no list of ingredients is present, PAL shall be declared in a prominent position on the label. Where a separate statement made in accordance with Section 8.3.2.1 of the GSLPF exists on the label, the PAL declaration shall be in the same field of vision as the separate statement.

- 5.2.1 A PAL statement shall commence with the words 'May contain' (or equivalent words **such as 'may be present'**) and ~~include the identified~~ **declare the** allergenic food(s) using the specified names for the foods and ingredients as listed in sections 4.2.1.4 and where applicable 4.2.1.5 of the General Standard for the labelling of pre-packaged foods (CXS 1-1985).^{4bis, 4ter}

- 5.2.2 A PAL statement shall **be declared in a clear and distinct manner such as through the use of** ~~contrast distinctly from surrounding text such as through the same font type, style or colour~~ **that contrasts from the surrounding text** ~~used for declarations~~ in accordance with section 8.3.1 of the General Standard for the labelling of prepackaged foods (CXS 1-1985).

^{4bis} **When gluten is present above the action level and the source of the gluten cannot be verified by risk assessment, the specified names of all cereals containing gluten (i.e. wheat, barley, and rye) shall be included in the PAL statement.**
^{4ter} **In addition to the specified name of wheat, rye, and barley, the word 'gluten' may be used.**

APPENDIX II**LIST OF PARTICIPANTS****CHAIR** United States of America**CO-CHAIRS**

Australia

United Kingdom

MEMBERS

Argentina

Australia

Brazil

Brunei Darussalam

Canada

Chile

China

Colombia

Costa Rica

Côte d'Ivoire

Ecuador

Egypt

European Union

Finland

France

Germany

Ghana

Guatemala

Hungary

Indonesia

India

Iran

Japan

Malaysia

Mexico

New Zealand

Norway

The Netherlands

Peru

Qatar

Republic of Korea

Russia

Saudi Arabia

Senegal

Singapore

South Africa

Sweden

Switzerland

Thailand

Türkiye

United Kingdom

United States of America

OBSERVERS

ALAIAB

Association of European Coeliac Societies

European Federation of Allergy and Airways
Diseases

European Federation of Associations of Dietitians

FAO

Food Drink Europe

FIVS

International Association of Fish Inspectors

International Chewing Gum Association

International Confectionary Association

International Council of Beverages Associations

International Dairy Federation

IMACE

International Special Dietary Foods Industries

PAHO

WHO