



JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEx COMMITTEE ON FOOD LABELLING

Forty-eighth Session

Québec City, Québec, Canada

27 October - 01 November, 2024

REPORT OF THE VIRTUAL WORKING GROUP ON THE DRAFT REVISIONS TO THE *GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS* (GSLPF): RELEVANT TO ALLERGEN LABELLING (PART A) AND DRAFT GUIDELINES ON THE USE OF PRECAUTIONARY ALLERGEN LABELLING (PART B)

Prepared by the Virtual Working Group chaired by Australia, and Co-Chaired by the United States of America and the United Kingdom

Introduction

1. The Virtual Working Group (VWG) met on 21 and 22 October 2024 prior to the 48th session of the Codex Committee on Food Labelling (CCFL48). A list of work group participants is provided at Appendix 3.
2. On 21 October the VWG focused the discussion on the draft revisions to the *General Standard for the Labelling of Prepackaged Foods* (CXS 1-1985; GSLPF), or Part A, and agreed to the following program for the discussion:
 - Definition of food allergen
 - Section 4.2.1.6 – Exemptions
 - Section 4.2.1.7 – Sulphite
 - Sections 8.3.1, 8.3.2 and 8.3.2.1
 - Other key issues - Sections 4.2.1.4 and 4.2.1.5
3. On 22 October the VWG focused the discussion on the draft guidelines on the use of precautionary allergen labelling (PAL), or Part B, and agreed to the following program for the discussion:
 - Purpose, scope and definition
 - General Principles
 - Principle 4.2
 - Principle 4.3 including 4.3.1 and 4.3.2
 - Section 5 – Presentation
 - Question (iii) advice to CCFH

Recommendations

Part A

The VWG recommends CCFL48 consider the proposed draft revisions (Appendix 1) and:

- Agree to the amended definition for “food allergen” and new definition for “allergenic food”, the amended text in 4.2.1.6 and its associated footnote 7, the amended text in 4.2.1.7, and the amended text in 8.3.1.
- Agree to the Chair’s proposed edits to include the terms “allergenic food” and “food allergen” where appropriate in Part A.

- Discuss sections 8.3.2, 8.3.2.1, and any outstanding key issues for sections 4.2.1.4 and 4.2.1.5.
- Consider whether the proposed draft revisions to the GSLPF provisions relevant to allergen labelling are ready for advancement to step 8.
- Consider whether to provide further advice to the Codex Committee on Food Hygiene (CCFH) to ensure consistency of the Code of Practice on Allergen Management for Food Business Operators (CXC 80 - 2020) with the proposed draft revisions.

Part B

The VWG recommends CCFL48 consider the proposed draft guidelines (Appendix 2) and:

- Agree to the purpose, scope, definitions, and general principles 4.1, 4.2, and 4.3, including the amended footnote 3, as proposed by the VWG.
- Agree to the Chair's proposed edits to include the terms "allergenic food" and "food allergen" where appropriate in Part B.
- Consider including a placeholder in the text for cereals containing gluten and requesting the FAO/WHO expert consultation provide advice on a potential reference dose or equivalent for cereals containing gluten.
- Discuss Principle 4.3.2, Section 5 – Presentation and any other outstanding issues.
- Consider whether the proposed draft guidelines on the use of precautionary allergen labelling are ready for advancement to step 5.
- Consider 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) and the Annex to the GSLPF, and request CCFH consider providing guidance on unintended allergen presence (UAP) risk assessment.

SUMMARY OF THE DISCUSSION REGARDING PART A

Definition of food allergen

4. The Chair of the VWG provided background from the electronic working group (EWG) and Circular Letter (CL) response in explaining the two options for defining "Food Allergen". The Chair shared that more CL responses supported the second option.
5. Delegations suggested various edits to both definition options around 'protein and protein derivatives' and their locations in the definition under consideration. A few delegations noted that there may be a need to define 'allergenic food' and 'food allergen' as two separate terms. In light of this, the VWG discussed the following options:
 - *"Allergenic Food"* means a food (including ingredients, food additives and processing aids) that can elicit IgE-mediated or other specific immune-mediated reactions in susceptible individuals.
 - *"Food Allergen"* means the substance in an allergenic food, usually a protein or protein derivative that can elicit IgE-mediated or other specific immune-mediated reactions in susceptible individuals.
6. There was general support for both definitions, but one delegation raised that the definition for "allergenic food" is not needed as the term is not used in the GSLP and questioned if step 7 was too late in the process to add definitions. The Codex Secretariat explained definitions may be added at any stage of the work.
7. One delegation shared there are opportunities to use the term 'allergenic food' in the text, such as when exclusion criteria is discussed. The Chair clarified that, if the VWG agreed to include a definition for "allergenic food", the Chair and Co-Chairs would review both Part A and Part B before plenary and propose edits to include "allergenic food" and "food allergen" where appropriate in the respective texts for CCFL48's consideration.

Conclusion for Definition of food allergen

8. Several delegations supported having both a definition for "allergenic food" and "food allergen", and no objections were heard. The VWG agreed to include the following definitions for "allergenic food" and "food allergen" in the draft revision:
 - *"Allergenic Food"* means a food (including ingredients, food additives and processing aids) that can elicit IgE-mediated or other specific immune-mediated reactions in susceptible individuals.

- “Food Allergen” means the substance in an allergenic food, usually a protein or protein derivative that can elicit IgE-mediated or other specific immune-mediated reactions in susceptible individuals

9. The Chair and Co-Chairs reviewed Part A and Part B and have proposed edits to include “allergenic foods” and “food allergen” where appropriate in the respective texts for Part A and Part B. These edits were not agreed to by the VWG but are provided in this report and in Appendices 1 and 2 for CCFL48’s consideration and agreement.

Section 4.2.1.6 – Exemptions

The Chair provided background that this section was not discussed at CCFL47, as the FAO/WHO expert consultation on allergens report on this topic was not released. However, after its release in February 2024 the EWG considered the report, and the Chair noted the VWG’s discussion would first focus on 4.2.1.6, and then a potential list or examples of exemptions.

10. One delegation did not support including the proposed reference to the criteria and did not agree that they are justified for all uses, such as for fish and similar species, and believed that exemptions should be controlled by each country/region.
11. Another delegation supported the text in 4.2.1.6 but specified that the reference to declaration should include “... in accordance with section 8.3.” to clarify the exemption is only from allergen labelling, not from all labelling requirements.
12. Another delegation suggested adding the sentence “Such exemptions shall be subject to evaluation that should include an exposure assessment and other established criteria.” There was support for the intent of this addition, but it was noted that the FAO/WHO expert consultation report did not deem exposure assessment as always necessary. The phrase “risk analysis” was offered instead of “exposure assessment” by a delegation noting this gives flexibility and there was some support from other delegations. As a compromise the text was reordered and the term “risk assessment” was suggested as it was encompassing of exposure assessments.
13. One delegation proposed an addition to footnote 7 to specify which figure and annex in the report detailed the process for consideration and examples of exemptions; however another delegation noted that the VWG had not agreed to inclusion of examples at this stage and given that the examples were not under discussion the VWG agreed not to include the addition.
14. Delegations proposed edits to the text in footnote 7 to ensure the FAO/WHO 2024 Risk assessment of food allergens: Part 4, was identified as an example. There were no objections to this suggestion.
15. The Chair then sought views on the inclusion of a list of or examples of exemptions. Most delegations did not support having a list of exempted food products or examples included in the text.

Conclusion for Section 4.2.1.6 – Exemptions

16. The VWG agreed to the following amended text for section 4.2.1.6 and its associated footnote 7:
 - 4.2.1.6 ~~Subject to evaluation using established criteria⁷, R~~egional or national authorities may exempt ingredients derived from foods listed in section 4.2.1.4, and where applicable section 4.2.1.5, from being declared in accordance with section 8.3. Such exemptions shall be subject to a risk assessment⁷. ~~evaluation using established criteria,~~
 - Footnote 7 – For example, FAO and WHO (2024). Risk assessment of food allergens: Part 4: Establishing exemptions from mandatory declaration for priority food allergens <https://doi.org/10.4060/cc9554en>
17. The VWG agreed not to include a list of or examples of exemptions.

Section 4.2.1.7 – Sulphite

18. The Chair introduced the options in square brackets for the VWG’s consideration. Several delegations offered their preference or suggested edits to the bracketed text including “as offered to the consumer”, “as consumed”, removing brackets and keeping both options, introducing “as sold”, and removing the bracketed text completely.
19. There was wide-ranging discussion on this section. Support for “as offered to the consumer” or “as sold” included the views that the text should be as clear as possible for international trade and conformity compliance and “as sold” would be the most conservative approach as it takes into account that the manufacturers’ instructions are not always followed when the product is consumed. Support for “as consumed” noted that it was consistent with the *General Standard for Food Additives* (CXS 192-1995) and certain Members’ national legislations, and the view that food choices should not be unnecessarily restricted for allergenic consumers was also expressed.

20. An observer organization raised that it was suggested through the EWG to remove the bracketed text as a compromise. Several delegations supported this suggestion noting the GSLPF is already scoped to “foods to be offered as such to the consumer” and other delegations supported this suggestion noting this would give flexibility to regional or national authorities. Although a few delegations continued to prefer “as consumed in accordance with the manufacturer’s instructions,” they supported removing the text in square brackets as a compromise.
21. An observer organization raised a proposed edit to footnote 8 to avoid repetition: “Sulphite measured on a sulphur dioxide (SO₂) equivalents basis.” The Chair suggested this be raised in plenary as there was not time to have any discussion on the proposed edit.

Conclusion for Section 4.2.1.7 – Sulphite

22. The VWG agreed to the following text for section 4.2.1.7:
 - 4.2.1.7 Sulphite when present in concentrations of 10 mg/kg or more⁸ in a food ~~[as offered to the consumer/as consumed]~~ shall always be declared using the specified name ‘sulphite’ or ‘sulfite’ in addition to or as part of the ingredient name.

Section 8.3.1

23. The Chair explained that the EWG incorporated flexibility into the provision to accommodate national contexts. Some delegations supported replacing ‘so as to contrast distinctly from the surrounding text’ with ‘in a clear and apparent manner’. One delegation suggested deleting the examples of ‘font type, style or colour’ noting it was overly prescriptive and that national authorities have other tools to ensure the text is clear, apparent, and distinctly contrasted.
24. Several delegations supported keeping the original text. One delegation noted that everything on the label should be ‘clear and apparent’ and that deleting “contrast” would change the intent of the proposal.
25. To accommodate both views, one delegation suggested deleting the word ‘contrast’ and maintaining ‘distinct from’ as well as the examples of ‘font type, style or colour’. Several delegations supported this proposed wording, and one delegation suggested capturing the concept around contrast at the end of the sentence. There were no further objections.

Conclusion for Section 8.3.1

26. The VWG agreed to the following text for section 8.3.1:
 - The specified name for the foods and ingredients listed in sections 4.2.1.4, 4.2.1.7 and where applicable 4.2.1.5 shall be declared in a clear and distinct manner ~~so as to contrast distinctly from the surrounding text~~ such as through the use of font type, style or colour that contrasts from the surrounding text.

Sections 8.3.2, 8.3.2.1 and other key issues in sections 4.2.1.4 and 4.2.1.5

The VWG did not have sufficient time to discuss 8.3.2, 8.3.2.1, and other key issues in sections 4.2.1.4 and 4.2.1.5.

The proposed draft revision incorporating the revisions from the VWG is provided at Appendix 1.

SUMMARY OF THE DISCUSSION REGARDING PART B

Note: As reported in paragraph 9 of this VWG report the Chair and Co-Chairs have reviewed and incorporated “allergenic food” and “food allergen” where appropriate into Part B. The proposed revised guidelines therefore incorporate changes not agreed to by the VWG but are included in this report for CFL48’s consideration and agreement.

Section 1. Purpose

27. The Chair provided a summary of the EWG responses regarding the purpose section of the draft guidelines and noted the majority support in the EWG for the proposed purpose as well as some support for including coeliac disease.
28. Several delegations voiced their support for coeliac disease being removed from the purpose noting concerns with the scope and potential conflict with the “gluten-free” definition.
29. Several other delegations supported retaining coeliac disease in the purpose noting that it is included in the definitions of the revisions to the GSLPF and is helpful for consumers to have accurate information. They acknowledged the potential challenges with action levels.

30. One delegation noted that including coeliac disease may require more scientific advice which could delay the work. The Chair offered that the text could still be progressed in the step process while indicating that the Committee is still working on a related threshold or reference dose.

Conclusion for Section 1. Purpose

31. The VWG agreed to the following text for the purpose section as well as the inclusion of “coeliac disease” in the purpose of the draft guidelines:
- 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 ~~allergens~~ **an allergenic food** ~~in food~~ due to cross-contact.

Section 2. Scope

32. The Chair noted support in the EWG for the scope section and provided background regarding a comment in the CL responses suggesting an edit to clarify that the guidelines apply to the labelling of prepackaged foods. The Chair asked if the VWG could accept the amendment.
33. There was general agreement regarding the proposed amendment. One delegation asked if the scope would preclude the use of PAL in areas beyond prepackaged foods such as e-commerce. The delegation agreed that they could consider the proposed amendment further and raise the question again at CCFL48 if needed.

Conclusion for Section 2. Scope

34. The VWG agreed to the following text for the scope section:
- 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)~~ **an allergenic food** caused by cross-contact¹ ~~in prepackaged foods~~.

Section 3 Definition of Precautionary allergen labelling

35. The Chair provided background that the CL responses indicated inconsistent and repetitive use of footnotes and proposed a brief preamble could help address this issue and make clear the relevant definitions in the GSLPF are captured. This would also remove footnotes 1, 2, and 3. The Chair also proposed an edit to the title of section 3 to clarify that the section refers to more than one definition.
36. The VWG supported the proposed revised text.

Conclusion for Section 3 Definition of Precautionary allergen labelling

37. The VWG agreed to the following amended text for section 3 regarding definitions:

• 3. DEFINITIONS OF PRECAUTIONARY ALLERGEN LABELLING

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 Prepackaged Foods (CXS 1-1985):

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

Section 4 General Principles 4.1, 4.2, and 4.3

38. The Chair, noting the significant discussion in the EWG around principle 4.2, suggested focusing the discussion first on general principle 4.2 and returning to general principle 4.1 if time permitted. There were no objections to this proposal.
39. The Chair provided background that there were differing views in the EWG regarding how risk assessment should be undertaken to assess the risk of unintended allergen presence as well as suggestions regarding CCFH revising the *Code of Practice for Allergen Management*.

¹ Allergen cross-contact as defined in *Code of Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020)*.

40. Several changes to principle 4.2 were suggested by delegations, including:
- Removing the phrase “above a reference dose” and replacing with “that is likely to cause an allergic reaction”, noting that some sensitive populations may respond at a lower level
 - The addition of “quantitative or qualitative” to specify that either type of risk assessment was appropriate. This was later refined to “a risk assessment, which can include but is not limited to a quantitative risk assessment.”
 - Changing the word “shall” to “should” was also suggested to provide for a more flexible approach.
41. Many delegations supported keeping the mention of “reference dose”. It was noted that “likely to cause an allergic reaction” is difficult to define and that the advice of the FAO/WHO expert consultation included reference doses which could be applied to risk management decisions about when it is recommended to use PAL. Delegations supporting the inclusion of “reference dose” also expressed concern about the overuse of PAL if reference dose was not included noting that this would not help consumers with food allergies.
42. One delegation, on the basis of the comments regarding concern for more sensitive individuals at lower exposures, suggested the possibility of another statement separate from PAL that could be used below the reference dose.
43. Some delegations supported putting 4.2 in square brackets, noting that CCMAS has not validated analytical methods, that reference doses extend beyond labelling and into manufacturing practices, and it was too early to establish the PAL principle. An expert from the FAO/WHO expert consultation explained that the work is based on the reference doses from the second report which were developed based on analytical methods that are current and available.
44. In light of this clarification and noting CCMAS’ ongoing work regarding methods of analysis, the Chair suggested there was no need to put the full principle 4.2 in square brackets and based on the broad support to retain “reference dose”, suggested removing the alternative language “that is likely to cause an allergic reaction”.
45. A delegation, acknowledging the comments in relation to retaining “reference dose”, expressed concern for consumer safety when requiring that PAL be used only when exposure is above the reference dose, and suggested replacing “above” with “in relation to the reference dose”. Another delegation’s addition of “and appropriate action level,” on the basis that reference doses need to be converted into an action level. This was refined by another delegation to “and a corresponding action level”.
46. Several delegations continued to oppose “in relation to” with regard to the reference dose noting that the definitive nature of “above” was important to guide the use of PAL.
47. Understanding the divergent views regarding principle 4.2, the Chair proposed to place principle 4.2 in square brackets and proposed an additional principle to allow for the potential application of an alternative statement when the exposure is below the action level in an effort to address concerns. Several delegations did not support including the new text, noting it introduced confusion, did not add value to consumers, and was not precluded from use given that it was a factual statement.
48. One delegation suggested an alternative approach and recommended adjusting the text of 4.1, 4.2, and 4.3 so that each would address an individual aspect. Principle 4.1 would delete “and may result in an exposure above a reference dose” to ensure 4.1 was only about allergen management practices, 4.2 would remove the text regarding reference dose to ensure it was only about risk assessment, and 4.3 was about how to apply PAL in relation to the action levels and the delegation suggested deleting the word “only” to allow flexibility in the application of PAL in 4.3.
49. There was broad support for the approach by the VWG. Several delegations supported removing the word “only” noting that it was too prescriptive while other delegations emphasized the need to retain the word “only” reiterating concerns around the potential overuse of PAL.
50. Several delegations sought similar flexibility by introducing the word “should” instead of “shall” to principle 4.3. Another compromise was proposed to use the word “shall” but delete the word “only”. While this was met with some support, other delegations continued to have concerns regarding the overuse of PAL. The VWG agreed to retain this text in square brackets.
51. A delegation asked for consideration that it may not be possible to mitigate the risk of allergen presence and proposed to add “when it is demonstrated the unintended food allergen presence cannot be mitigated....”

52. Regarding footnote 6 (now footnote 3 in Appendix 3), the Chair summarized the comments from the EWG, noting the general support for footnote 3.
53. A delegation suggested using a higher food consumption percentile, replacing 50th with 95th and removing the mention of the mean. The Chair noted the understanding that the 50th percentile was part of the report from the FAO/WHO expert consultation.
54. Another delegation proposed rewording to add “on the quantity that can reasonably be expected to be consumed on a single eating occasion”, noting that since the expert report is referenced in the previous footnote, it was not necessary to include the 50th percentile in footnote 3. There was some support for this suggestion. Another delegation shared that their understanding the FAO/WHO expert consultation had taken expected intake into account to ensure ED05 is protective of 95% of consumers and shared their preference to include the 50th percentile in the footnote.

Conclusion for Section 4 General Principles 4.1, 4.2, and 4.3

55. The VWG agreed to the following text for section 4, including footnote 3 (previously footnote 6):

- **4. GENERAL PRINCIPLES**

4.1 Effective food allergen management practices including controls to prevent or minimize the unintended presence of an allergenic food ~~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 an allergenic food ~~food allergen(s)~~ cannot be prevented or controlled using these allergen management practices ~~and may result in an exposure above a reference dose.~~

4.2 The decision to use PAL ~~shall~~ **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, ~~to determine potential exposure above a reference dose.~~

4.3 PAL [shall / **should**] [only] be used **when it is demonstrated that** if 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 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 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.~~

Table to 4.3.1

56. The Chair asked the VWG if there were any comments regarding the table as it stands now. There were no comments regarding the table as presented to the VWG.
57. An observer organization raised that barley and rye are listed as allergens in Part A, but the FAO/WHO expert consultation report does not include reference doses for these two. Another observer commented that while it might be helpful to have reference doses for these allergenic foods, it would not solve the problem with gluten declaration and a separate reference dose was needed for gluten, not the cereals.
58. The Chair noted that the CL and EWG did not include cereals containing gluten in its discussion and acknowledged some delegations supported including it and others noted challenges for determining a suitable reference dose or equivalent. The Chair proposed there may be an opportunity to establish a reference dose in the future with more scientific advice and one approach would be to foreshadow this in the text e.g. including a place hold in square brackets.
59. There was support to discuss this proposal further at plenary.

Conclusion for Table 4.3.1

60. The VWG agreed to the table 4.3.1 as presented and also to consider further at CCFL48 what to do about a reference dose or equivalent for cereals containing gluten.

Principle 4.3.2, Section 5 – Presentation, Question (iii) advice to CCFH

The VWG did not have sufficient time to discuss these sections.

The proposed draft revision incorporating the revisions from the VWG is provided in Appendix 2.

Appendix 1 (Part A)

PROPOSED DRAFT REVISION OF THE GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS (CXS 1-1985) RELEVANT TO ALLERGEN LABELLING

(revisions to GSLPF are presented as **bolded** additions and ~~strike through~~ deletions)

2. DEFINITION OF TERMS

“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.

~~“Food allergen” means a food or ingredient [or substance or processing aid] including a food additive or processing aid usually containing a protein or protein derivative, that can elicit IgE-mediated or other specific immune-mediated reactions in susceptible individuals.~~

OR

“Food Allergen Allergenic Food” means a food (including ingredients, food additives and processing aids) that can elicit IgE-mediated or other specific immune-mediated reactions in susceptible individuals, ~~usually caused by a protein or protein derivative in the food.~~

“Food allergen” means the substance in an allergenic food, usually a protein or protein derivative that can elicit IgE-mediated or other specific immune-mediated reactions in susceptible individuals.

“Coeliac disease” means a chronic immune-mediated intestinal disease in genetically predisposed individuals induced by exposure to dietary gluten proteins that come from wheat, rye, barley and triticale (a cross between wheat and rye).

4. MANDATORY LABELLING OF PREPACKAGED FOODS

4.2 List of ingredients

4.2.1.3 Where an ingredient is itself the product of two or more ingredients, such a compound ingredient may be declared, as such, in the list of ingredients, provided that it is immediately accompanied by a list, in brackets, of its ingredients in descending order of proportion (m/m). Where a compound ingredient (for which a name has been established in a Codex standard or in national legislation) constitutes less than 5% of the food, the ingredients need not be declared, except for the foods and ingredients listed in section 4.2.1.4, 4.2.1.7 and where applicable section 4.2.1.5 and food additives which serve a technological function in the finished product.

4.2.1.4 The following foods and ingredients are known to trigger food allergy or coeliac disease and shall always be declared **as allergenic foods** using the specified name in addition to or as part of the ingredient name²:

FOODS AND INGREDIENTS	SPECIFIED NAME
Cereals containing gluten ³	
– wheat and other <i>Triticum</i> species	‘wheat’
– rye and other <i>Secale</i> species	‘rye’
– barley and other <i>Hordeum</i> species	‘barley’
and products thereof	
Crustacea and products thereof	‘crustacea’
Eggs and products thereof	‘egg’
Fish and products thereof	‘fish’
Peanuts and products thereof	‘peanut’

² In accordance with Section 4.1.1 of the *General Standard for the Labelling of Pre-packaged Foods* (CXS 1-1985), the ingredient declaration should specify the true nature of the food and be specific and not generic.

³ Includes spelt, Khorasan, and other specific cereals containing gluten that are species or hybridized strains under the genus names of *Triticum*, *Secale* and *Hordeum*. Specified names are to be used according to the associated genus. Hybridized strains are to use specified names in conjunction from all of the parent genera (e.g. ‘wheat’ and ‘rye’ for triticale).

Milk and products thereof	'milk'
Sesame and products thereof	'sesame'
Specific tree nuts	
– Almond (<i>Prunus amygdalus</i>)	'almond'
– Cashew (<i>Anacardium occidentale</i>)	'cashew'
– Hazelnut (<i>Corylus spp.</i>)	'hazelnut'
– Pecan (<i>Carya illinoensis</i>)	'pecan'
– pistachio (<i>Pistacia vera</i>)	'pistachio'
– walnut (<i>Juglans spp.</i>)	'walnut'
and products thereof	

4.2.1.5 In addition to the foods and ingredients listed in section 4.2.1.4, the declaration of any other foods and ingredients as allergenic foods, including those listed below may also be required⁴ using a specified name in addition to or as part of the ingredient name⁵. This shall be based on available risk assessment data for the respective population(s)⁶ taking into account risk management considerations.

FOODS AND INGREDIENTS	SPECIFIED NAME
Buckwheat and products thereof	'buckwheat'
Celery and products thereof	'celery'
Oats and other <i>Avena</i> species (and their hybridized strains) and products thereof ⁷	'oats'
Lupin and products thereof	'lupin'
Mustard and products thereof	'mustard'
Soybean and products thereof	'soy'
Specific tree nuts	
– Brazil nut (<i>Bertholletia excelsa</i>)	'Brazil nut'
– macadamia (<i>Macadamia integrifolia</i> , <i>Macadamia tetraphylla</i>)	'macadamia'
– pine nut (<i>Pinus spp.</i>)	'pine nut'
and products thereof	

4.2.1.6 ~~Subject to evaluation using established criteria⁷, Regional or national authorities may exempt ingredients derived from foods listed in section 4.2.1.4, and where applicable section 4.2.1.5, from being declared in accordance with section 8.3. Such exemptions shall be subject to a risk assessment⁸.~~ evaluation using established criteria,

4.2.1.7 Sulphite when present in concentrations of 10 mg/kg or more⁹ in a food ~~[as offered to the~~

⁴ These foods and ingredients are not included in 4.2.1.4 but have been recommended to be considered for risk management at the regional or national level (see FAO and WHO Risk assessment of food allergens: Part 1: Review and validation of Codex Alimentarius priority allergen list through risk assessment <https://doi.org/10.4060/cb9070en>).

⁵ In accordance with Section 4.1.1 of the *General Standard for the Labelling of Pre-packaged Foods* (CXS 1- 1985), the ingredient declaration should specify the true nature of the food and be specific and not generic.

⁶ The assessment of risk in the respective population(s) to be based on the evidence criteria of prevalence, potency and severity of immune mediated adverse reactions to the food or ingredient as established by FAO and WHO Risk assessment of food allergens: Part 1: Review and validation of Codex Alimentarius priority allergen list through risk assessment. <https://doi.org/10.4060/cb9070en>

⁷ Oats can be tolerated by most but not all people who are intolerant to gluten. Therefore, the allowance of oats that are not contaminated with wheat, rye or barley in foods covered by this standard may be determined at the national level.

⁸ **For example, FAO and WHO (2024). Risk assessment of food allergens: Part 4: Establishing exemptions from mandatory declaration for priority food allergens <https://doi.org/10.4060/cc9554en>**

⁹ Sulphite measured as the total concentration of sulphur dioxide (SO₂) and sulphur dioxide equivalents.

~~consumer/as consumed]~~ shall always be declared using the specified name 'sulphite' or 'sulfite' in addition to or as part of the ingredient name.

RENUMBER existing sections 4.2.1.5 and 4.2.1.6 to 4.2.1.8 and 4.2.1.9 respectively.

4.2.2 The presence in any food or food ingredients obtained through biotechnology of an **food** allergen transferred from any of the foods and ingredients listed in sections 4.2.1.4 and where applicable 4.2.1.5 shall be declared.

When it is not possible to provide adequate information on the presence of these **food** allergens through labelling, the food containing the **food** allergen should not be marketed.

4.2.3 Except for those foods and ingredients ~~as~~ listed in sections 4.2.1.4, 4.2.1.7 and where applicable 4.2.1.5 **that must be declared using the specified name in addition to or as part of the ingredient name**, ~~a specific name shall be used for ingredients in the list of ingredients~~ **shall be declared** in accordance with the provisions set out in Section 4.1 (Name of the Food) except that:

4.2.3.1 Unless a general class name would be more informative, the following class names may be used. ~~In all cases, the food and ingredients listed in sections 4.2.1.4, 4.2.1.7 and where applicable 4.2.1.5 shall be declared using the specified names listed in those sections.~~ **When a class name is used, the foods and ingredients listed in sections 4.2.1.4, 4.2.1.7 and where applicable 4.2.1.5 shall be declared using the specified name in addition to or as part of the class name.**

4.2.4 Processing aids and carry-over of food additives.

4.2.4.2 A food additive carried over into foods at a level less than that required to achieve a technological function, and processing aids, are exempted from declaration in the list of ingredients. The exemption does not apply to food additives and processing aids that contain the foods and ingredients listed in sections 4.2.1.4, 4.2.1.7 and where applicable 4.2.1.5.

6. EXEMPTIONS FROM MANDATORY LABELLING REQUIREMENTS

With the exception of spices and herbs, small units, where the largest surface area is less than 10 cm², may be exempted from the requirements of paragraphs 4.2 and 4.6 to 4.8. This exemption does not apply to the declaration of foods and ingredients listed in sections 4.2.1.4, 4.2.1.7 and where applicable 4.2.1.5.

8. PRESENTATION OF MANDATORY INFORMATION

8.3 Declaration of certain foods and ingredients

8.3.1 The specified name for the foods and ingredients listed in sections 4.2.1.4, 4.2.1.7 and where applicable 4.2.1.5 shall be declared **in a clear and distinct manner** ~~so as to contrast distinctly from the surrounding text~~ such as through the use of font type, style or colour that contrasts from the surrounding text.

8.3.2 The specified name for the foods and ingredients in sections 4.2.1.4, 4.2.1.7 and where applicable 4.2.1.5 shall be declared in the list of ingredients or in a separate statement or in both.

8.3.2.1 If used the separate statement shall commence with the word 'Contains' (or equivalent word) and be placed directly under or in close proximity to the list of ingredients when present.

8.3.3 Where a food is exempt from declaring a list of ingredients, the foods and ingredients listed in sections 4.2.1.4, 4.2.1.7 and where applicable 4.2.1.5 shall be declared, such as in a separate statement made in accordance with section 8.3.2.1.

8.3.4 For single ingredient foods, section 8.3.3 does not apply where foods and ingredients listed in sections 4.2.1.4, 4.2.1.7 and where applicable 4.2.1.5 are declared as part of, or in conjunction with, the name of the food.

Appendix 2 (Part B)

**PROPOSED DRAFT ANNEX TO THE GSLPF:
GUIDELINES ON THE USE OF PRECAUTIONARY ALLERGEN LABELLING**

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 allergens **an allergenic food** ~~in food~~ due to cross-contact.

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 prepackaged 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) **an allergenic food** caused by cross-contact¹⁰ ~~in prepackaged foods.~~

3. DEFINITION OF PRECAUTIONARY ALLERGEN LABELLING

~~For the purpose of these guidelines:~~

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

3. DEFINITIONS OF PRECAUTIONARY ALLERGEN LABELLING

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 Prepackaged Foods (CXS 1-1985):

“Precautionary allergen labelling” is a statement made in the labelling of prepackaged foods to indicate a risk from the unintended presence of an allergenic food ~~food allergen(s)~~ due to cross-contact 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 **an allergenic food** ~~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 **an allergenic food** ~~food allergen(s)~~ cannot be prevented or controlled using these allergen management practices ~~and may result in an exposure above a reference dose.~~

4.2 The decision to use PAL shall ~~should~~ be based on the findings of a risk assessment¹¹, **which can include but is not limited to a quantitative risk assessment,** of unintended **food** allergen presence, ~~to determine potential exposure above a reference dose.~~

4.3 PAL [shall / **should**] [only] be used **when it is demonstrated that** if unintended **food** allergen presence cannot be mitigated to a level at or below the action level¹² for a food allergen based on the reference doses in the table at 4.3.1.

4.3.1 Reference doses

	Reference dose (RfD)
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¹⁰ Allergen cross-contact as defined in Code of Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020).

¹¹ 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>

¹² 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 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.~~

	(mg total protein from the allergen)
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	5.0
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 or national authorities can establish a reference dose consistent with recognized principles¹³ for the purposes of determining an action level.

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.

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 Prepackaged Foods (GSLPF) (CXS 1-1985) apply to PAL labelling.

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

5.2.1 A PAL statement shall commence with the words 'May contain' (or equivalent words) and include the identified ~~allergens~~ **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 GSLPF.

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.

¹³ 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>.

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