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Agenda Item 5.2

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD LABELLING

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27 October – 1 November 2024

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

(Prepared by the Electronic Working Group chaired by Australia and co-chaired by the United Kingdom and the United States of America)

Codex Members and Observers wishing to submit comments on the recommendations in this document should do so as instructed in CL 2024/53-FL available on the Codex webpage/Circular Letters: <http://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/>

INTRODUCTION

- At the 45th Session of the Codex Committee on Food Labelling (CCFL45), the Committee agreed to review and clarify the provisions relevant to allergen labelling in the *General Standard for the Labelling of Pre-packaged Foods* (CXS 1-1985) (GSLPF) and develop guidance on precautionary allergen labelling (PAL)¹.
- In approving the new work, the Codex Alimentarius Commission (CAC) noted this work is linked to the work of the Codex Committee on Food Hygiene (CCFH) on allergen management and therefore close collaboration between CCFL and CCFH on this issue is important to ensure consistency between the two texts².
- CCFL45 also agreed to request scientific advice from FAO/WHO³ relating to the list of foods and ingredients in section 4.2.1.4 of the GSLPF. The CCFH also requested FAO/WHO provide scientific advice on threshold levels for the priority allergens in relation to the *Code of Practice on Food Allergen Management for Food Business Operators* (CXC 80-2020).
- In response to these requests for scientific advice, an [Ad-hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens](#) (Expert Committee) has issued five reports as listed in the table below:

Meeting date	Reports	Publication Date
30 November – 11 December 2020	Part 1: Review and validation of Codex priority allergen list through risk assessment	29 March 2022
15 March – 2 April 2021	Part 2: Review and establish threshold levels in foods of the priority allergens	24 January 2023
18 October – 3 November 2021	Part 3: Review and establish precautionary labelling in foods of the priority allergens	16 June 2023
14 – 18 November 2022	Part 4: Review and establish exemptions for the food allergens	26 February 2024
Out-of-session	Part 5: Review and establish threshold levels for specific tree nuts (Brazil nut, macadamia nut or Queensland nut, pine nut), soy, celery, lupin, mustard, buckwheat and oats	15 November 2023

- The work also includes consideration of evidence based consumer understanding of allergen labelling and advisory statements. Food Standards Australia New Zealand (FSANZ) and the Food Standards Agency (UK)

¹ [REP19/FL](#) para 98(a) and Appendix IV

as members of the International Social Science Liaison Group (ISSLG)⁴, collaborated on a [literature review](#) to provide evidence for the revision of the GSLPF and development of guidance on PAL.

6. At CCFL47, the Committee considered the PAL guidelines, CCFL47 agreed to⁵:
 - a) return the Annex to the GSLPF – Guidelines on the use of precautionary allergen labelling to Step 2, for further drafting.
 - b) re-establish an EWG chaired by the Australia and co-chaired by the United Kingdom and the United States of America.
 - c) request the Codex Committee on Methods of Analysis and Sampling (CCMAS) to recommend suitable analytical methods and guidance on their validation and applications including sampling plans for determining allergenic protein in foods.
7. The proposed timeline for the allergen labelling work included in the project document⁶ set an expectation that work could be completed in three sessions i.e. at CCFL48.

TERMS OF REFERENCE

8. Working in English, the EWG was to continue drafting the PAL guidelines, taking into account the discussions and comments submitted at CCFL47, for circulation for comments at Step 3 and consideration by CCFL48.

PARTICIPATION AND METHODOLOGY

9. An EWG was established in August 2023 with 32 Codex Members (CM), one Codex Member Organization (CMO), and 12 Codex observers (CO). A list of participants is provided at Appendix III.
10. In February 2024 a consultation paper (CP1) on the proposed draft revision to GSLPF relevant to allergen labelling (Part A) and proposed draft guidelines for PAL (Part B) was circulated to the EWG with 32 responses (21 CM, one CMO, 10 CO) received.
11. A second EWG consultation paper (CP2) was circulated in June 2024 seeking further comment on both Parts A and B. Thirty-three responses (21 CM, one CMO, 11 CO) were received.
12. This paper provides an overview of EWG discussions (Appendix I) and presents for CCFL consideration the draft Annex to the GSLPF – Guidelines on the use of PAL at Step 3 (Appendix II).
13. The EWG report for the revision to the provisions relevant to allergen labelling in GSLPF is presented in CX/FL 24/48/5 Part A.

CONCLUSIONS

14. Consistent with the Terms of Reference, the EWG has taken into account the discussion and written comments from CCFL47 and continued drafting proposed guidance on the use of PAL.
15. As the Expert Committee released all final reports by February 2024 the EWG was able to take into account all available scientific advice from the Expert Committee when considering the PAL guidance. The EWG also considered the ISSLG evidence on consumer understanding of allergen labelling and advisory statements.
16. In relation to the PAL guidelines, EWG discussion has identified the following key issues for CCFL to consider:
 - 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.
 - b) Principle 4.2 in regard to proposed alternative text on the types of risk assessment.
 - c) Principle 4.3 and the table of reference doses in 4.3.1 particularly in relation to inclusion of gluten.
17. Based on comments in the EWG, CCFL may like to request CCFH consider providing guidance on the risk assessment of unintended allergen presence (UAP) to complement and support implementation of the PAL guidelines.
18. With the EWG feedback received and the areas of focus identified above, CCFL48 has a path to progress the PAL guidelines while CCMAS concurrently works on developing recommendations for CCFL on food allergen detection methods for UAP. Especially as CCMAS43 has re-established an EWG on this topic and CCMAS44 will meet before CCFL49.

⁴ The ISSLG is a group of government organisations involved in the social sciences of food regulation, food safety and public health nutrition from Canada, the United States of America, New Zealand, the United Kingdom, Australia and the European Food Safety Authority.

⁵ [REP23/FL](#) paragraphs 55-61

⁶ [REP19/FL](#) Appendix IV

RECOMMENDATIONS

CCFL48 is invited to consider:

- i) the key issues described in paragraph 16.
- ii) whether the Annex to the GSLPF – Guidelines on the use of precautionary allergen labelling (Appendix II) is ready to advance to Step 5.
- iii) whether to provide further advice to CCFH to ensure consistency of the *Code of Practice on Food Allergen Management for Food Business Operators* (CXC 80-2020) and the Annex to the GSLPF, and request CCFH consider providing guidance on UAP risk assessment.

APPENDIX I**OVERVIEW OF EWG DISCUSSIONS****ANNEX TO THE GSLPF - GUIDELINES ON THE USE OF PRECAUTIONARY ALLERGEN LABELLING**

(changes are in **bold/underline** or ~~striketrough~~ mode)

1. This part discusses proposed draft Annex to the GSLPF – Guidelines on the use of precautionary allergen labelling (PAL) as provided at Appendix II taking into account comments from CCFL47 and the EWG feedback received through CP1 and CP2. The Expert Committee's Part 2, 3 and 5 reports and the ISSLG literature review have also informed the EWG discussions.

Title, Purpose and Scope

2. The EWG considered the Title, Purpose and Scope with little change from that presented at CCFL47. For the purpose and scope a footnote to 'food allergy' and reference to 'food allergen(s)' was included because definitions for these terms are proposed to be included in the GSLPF.

3. Noting questions at CCFL47 about whether the PAL Guidelines would take into consideration consumers with coeliac disease and how the Guidelines would interact with the labelling of gluten-free foods as defined in the *Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten* (CXS118-1979), the Chairs noted the Expert Committee's Part 5 report provides reference doses for allergens proposed for section 4.2.1.5 of the GSLPF¹ but not for barley and rye (or gluten) and that these foods/ingredients were also not considered in the Expert Committee's Part 2 report. Therefore, the scope was proposed to capture food allergy only.

4. Most EWG responses to CP1 (29/33 responses) supported the proposed Title, Purpose and Scope. However comments from a CMO and 2 CO supported coeliac disease being considered in scope. They noted the definitions for both food allergy and food allergen include non-IgE antibody or other immune-mediated response/reaction and proposed amending the Purpose section to include coeliac disease.

5. Based on the EWG feedback the Title, Purpose and Scope is proposed as below. The Purpose section has been amended to include 'coeliac disease' to allow CCFL the opportunity to consider the scope of the guidelines:

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**¹ or **coeliac disease** about the risk from the unintended presence of allergens 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)**¹ caused by cross-contact in pre-packaged foods.*

¹As defined in the *General Standard for the Labelling of Pre-packaged Foods* (CXS 1-1985).

Definitions

6. As noted above, reference to the proposed definitions for 'food allergy' and 'food allergen' have been included in the Purpose and Scope sections respectively. Therefore the EWG considered the proposed definition for 'precautionary allergen labelling'. It was noted the proposed definition contains similar elements to the definition of PAL used by the Expert Committee² and includes a reference to 'risk assessment' as an important foundation element. To ensure consistency, footnote references were included to the definition for 'food allergen' and to the definition of 'cross-contact' (from *Code of Practice on Food Allergen Management for Food Business Operators* (CXC 80-2020)). As the section is proposed to only include a definition for PAL, the title to the section was also amended.

7. Feedback from the EWG supported these changes and the proposed definition section is as follows:

3. DEFINITION OF PRECAUTIONARY ALLERGEN LABELLING

For the purpose of these guidelines:

¹ Buckwheat, celery, oats, lupin, mustard, soybean, Brazil nut, macadamia nut and pine nut.

² "Precautionary allergen labelling" is a statement indicating (a more than appreciable risk of) possible unintended allergen presence (based on the recommended single PAL system)". Annex 1 of Part 3: Review and Establish Precautionary Labelling in Foods of the Priority Allergens.

“Precautionary allergen labelling” (PAL) is a statement made in the labelling of pre-packaged foods to indicate a risk from the unintended presence of a food allergen(s)³ due to cross-contact⁴ that has been identified by a risk assessment.

³As defined in the General Standard for the Labelling of Pre-packaged Foods (CXS 1-1985).

⁴Allergen cross-contact as defined in Code of Practice on Food Allergen Management for Food Business Operators (CXC 80-2020).

Section 4 - General principles

Principle 4.1

8. Comments at CCFL47 supported the intent of Principle 4.1 but proposed changes to provide clarity. Considering this, the EWG Chairs revised the text to be consistent with the objectives of *Code of Practice on Food Allergen Management for Food Business Operators* (CXC 80-2020) and recommendations in the Expert Committee’s Part 3 report that PAL ‘should be restricted and applied to those situations where unintended allergen presence (UAP) cannot be prevented and may result in an exposure above the reference dose’.

9. In response to CP1 most EWG members (28/31 responses) supported the revised text with some responses suggesting further minor edits. Based on this feedback, the following revised text is proposed:

4.1 Effective allergen management practices and including controls to prevent or minimize the unintended presence of food allergens caused by cross-contact shall be implemented in accordance with as outlined in 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 an food allergen(s) cannot be prevented or sufficiently controlled using these allergen management practices and may result in an exposure above a reference dose.

Principle 4.2

10. At CCFL47 Principle 4.2 was included as follows:

4.2 The decision to use PAL should be based on the findings of a risk assessment which shall include, but is not limited to, quantitative risk assessment.

11. Comments received noted a quantitative risk assessment should not be the only decisive factor when determining the use of PAL, and it should also be considered to apply a qualitative risk assessment.

12. In CP1 the Chairs noted the Expert Committee’s Part 3 report³ acknowledges both qualitative and quantitative approaches can be used to provide risk assessment information as a means to characterize and quantify UAP for the purpose of making an appropriate risk assessment. It was also noted that as CCFH are yet to consider the Expert Committee’s advice, it is unclear whether the *Code of Practice on Food Allergen Management for Food Business Operators* (CXC 80-2020) may be revised to reflect aspects of the risk assessment approach as outlined by the Expert Committee. In which case it may be more appropriate for the draft PAL guidance to refer to CXC 80-2020 in the future.

13. The following revised Principle 4.2 was considered by the EWG with a footnote reference to the Expert Committee’s Part 2 report:

4.2 The decision to use PAL should be based on the findings of an appropriate risk assessment which shall include, but is not limited to, quantitative risk assessment of unintended allergen presence to indicate exposure above a reference dose.

14. Although most EWG members supported the revised text (20/32 response), others did not support the text because either it required a quantitative risk assessment for all PAL decisions, or it did not explicitly mention a qualitative risk assessment could be used. Some responses also proposed changing the word ‘shall’ to ‘may’, because they considered a quantitative risk assessment should not be mandatory. Others proposed changes to better reflect the Expert Committee Part 3 report including a reference to this report (instead of Part 2) in the footnote.

15. Although there were divided views over whether a quantitative risk assessment is required or not, there was a near unanimous view that a risk assessment shall always be conducted as part of the decision to use PAL. Based on the comments received, the Chairs proposed to remove reference to ‘quantitative risk assessment’ to address any ambiguity, to footnote reference the Expert Committee’s Part 3 report, and change ‘indicate’ to ‘determine’ to better reflect the language used in the Expert Committee’s report.

³FAO and WHO (2023). Risk assessment of food allergens – Part 3: Review and establish precautionary labelling in foods of the priority allergens. p17. <https://doi.org/10.4060/cc6081en>.

16. In CP2 the EWG considered the following revised text:

4.2 The decision to use PAL ~~should~~ **shall** be based on the findings of ~~an appropriate~~ **a risk assessment**³ ~~which shall include, but is not limited to, quantitative risk assessment of unintentional allergen presence to indicate~~ **determine** exposure above a reference dose.

³**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>

17. EWG responses were again divided with 18 (12 CM, 1 CMO, 5 CO) supporting, 12 (8 CM, 4 CO) not supporting and 2 CO members not indicating either way. Most responses whether in support or not, proposed text changes. For consistency with Principle 4.1 which refers to 'may result in an exposure above a reference dose', many responses proposed including 'potential' before 'exposure above the reference dose'. One CM while supporting the proposed text questioned whether there was enough specific information about what should be part of a risk assessment.

18. Two CO noted confusion between a quantification of risk and quantification of actual allergen levels by analytical methods. They commented that analytical quantification is not a prerequisite for quantitative risk assessment as assessment may also be conducted by quantification of other elements, such as the amount of product retained on the factory line in a switch from one product to the next, and that ultimately, quantification of some kind must be undertaken to calculate whether the resulting product will exceed the reference dose.

19. Three EWG members (1 CMO, 1 CM, 1 CO) considered the ambiguity relating to the previous text was due to use of 'shall' and proposed a change to 'can include' and including 'potential' as follows:

4.2 The decision to use PAL shall be based on the findings of a risk assessment³ which ~~shall~~ **can** include but is not limited to quantitative risk assessment of unintentional allergen presence to determine **potential** exposure above a reference dose.

20. One CM suggested CCFL could request CCFH consider providing guidance on UAP risk assessment based on the Expert Committee's Part 3 report noting such guidance could complement and support implementation of the PAL guidelines.

21. Similarly another CM considered specific guidance around assessing the risk of UAP is within the purview of CCFH and suggested the following amendments to Principle 4.2 to allow flexibility and clarity on the types of risk assessments available to the appropriate authorities:

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.

22. Based on majority EWG support, the Chairs proposed the following text but note CCFL could also consider the merits of the alternative approaches as presented above:

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.

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>

Principle 4.3

23. At CCFL47 Principle 4.3 was proposed as follows:

4.3 PAL shall only be used if the presence of a protein from an allergen is equal to or above the action level³ for this allergen, using the listed reference dose values in 4.3.1.

³**Action level (mg total protein from the allergen / kg food) = Reference dose (mg total protein from the allergen) / Amount of the food (kg)**

24. In CP1 the Chairs noted the Expert Committee Part 3 report recommends a measurement of the UAP against a reference dose is required, and only if UAP concentrations are above the action levels, then the use of PAL may be warranted. The Expert Committee also considered methods that may be used to estimate the risk of UAP rather than analytical measurement such as knowledge of the type of processing leading to UAP, the nature of the manufacturing facility, recipe information, along with visual inspection and observation to provide quantitative information to estimate UAP. The Part 3 report also specified the use of population consumption data (50th percentile or population mean for a single eating occasion intake) to determine the amount of food component in the calculation of an action level.

25. Based on this, Principle 4.3 was revised to provide more clarity including in the footnote on how action

levels should be calculated, specifically in determining the amount of food that should be used.

4.3 PAL shall only be used if the **unintended allergen** presence cannot be **mitigated** to a level at or below ~~of a protein from an allergen is equal to or above~~ the action level³ for **a food allergen based on** ~~, using the listed reference dose values in the table at 4.3.1.~~

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 50th percentile or population mean for a single eating occasion intake of the food.**

26. The EWG response was mixed with some supporting (14/31 responses) or not supporting (9/31), and others (8/31) not indicating either way. Comments included that the requirement for UAP to be above an action level would necessitate the use of a quantitative risk assessment, frequency of occurrence was not considered, the restriction on PAL to situations where UAP was above ED05 values would not allow manufacturers to use PAL below these levels to communicate to highly allergen-sensitive consumers, there is no guidance on risk assessments when data is unavailable to calculate an action level, and that some countries would find it difficult to implement the 50th percentile/mean requirement, as not all have the required consumption data or capability to collect it.

27. To maintain consistency with the Expert Committee's Part 3 report, the EWG Chairs did not change the restriction for PAL to be used when UAP cannot be mitigated at or below an action level. The footnote was revised to only required single eating occasion data, but that it was preferred to use 50th percentile or population mean data when available. This was intended to allow a single eating occasion to be determined using alternatives to consumption data (e.g. using a serving (or portion) as quantified on the label).

28. In response to CP2, most EWG members supported (20/28) the revised principle. While supporting the revised text, two CM and three CO requested further clarity in the footnote on the alternatives that can be used instead of the 50th percentile or mean single eating occasion data. They suggested an additional sentence to footnote 3 which explicitly states that the amount of food could be estimated using the serving or portion size referenced on the food label.

29. Two CM and one CO did not support the revised text because it did not permit the use of PAL when the UAP is below an action level based on ED05 and where there is also an appropriate justification for PAL from a risk assessment (e.g. data variability, frequency of UAP). These respondents proposed that 'only' is removed from the text, or additional wording added stating that PAL can also be used when UAP is at or below an action level.

30. Given EWG support for the revised text and associated footnote text proposed in CP2, the Chairs have included the following in the draft guidelines: However, CCFL may wish to consider the changes proposed that Principle 4.3 should allow PAL at UAP levels at or below an action level, and the need for clarity in the footnote on the use of serving/portion sizes for calculating the amount of the food.

4.3 PAL shall only be used if **unintended allergen** presence cannot be **mitigated** to a level at or below ~~of a protein from an allergen is equal to or above~~ the action level⁵ for **a food allergen based on** ~~, using the listed reference doses values in the table at 4.3.1.~~

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.**

Table to 4.3.1

31. At CCFL47, a table of reference doses based on a 5% eliciting dose (ED05) for use in the calculation of action levels from the Expert Committee's Part 2 report was included in a table to 4.3.1. At the time only reference doses for the priority allergens listed in section 4.2.1.4 were available. Following the release of the Expert Committee's Part 5 report, reference doses for regional allergens listed in section 4.2.1.5 were incorporated into the table for EWG consideration.

32. The majority of responses (24/31) supported the ED05 reference doses provided in the table at 4.3.1. Those not supporting considered reference doses should not be the only criterion for deciding whether or not to use PAL, or that gluten should also be included. Three CM noted the reference doses for regional allergens according the Expert Committee report were not based on a risk assessment, have only been provided for risk management purposes, and may change if new data becomes available. In which case one member considered these values should be clearly identified/differentiated as 'suggested' levels in comparison with the other references doses. Another response also questioned whether reference doses should be given to regional allergens besides celery and soy, as these two allergens were the only ones that had enough data to establish a final reference dose.

33. Two EWG members (1 CMO, 1 CO) reiterated support for taking all cereals containing gluten into account noting rye and barley play a significant role in the contaminant risk of gluten-free cereals in agricultural production. They suggested to either adding 'Wheat/Cereals containing gluten' and the corresponding reference dose as '5.0 (with a maximum of 20 mg/kg)' or providing a separate indication of the maximum gluten concentration of 20 mg/kg in the table as indicated below:

	Reference dose (RfD) (mg total protein from the allergen)
Wheat	5.0
Cereals containing gluten (listed as 'Gluten')	Maximum action limit 20 mg gluten/kg

34. They also note this would require CCFL to consider whether 'Gluten' would need to be added to the specified names in section 4.2.1.4 for "Cereals containing gluten" and that with appropriate education campaigns, consumers would be informed and able to make the distinction between a PAL for wheat and a PAL for gluten

35. Based on EWG responses, the following proposed table to 4.3.1 is included in draft guidelines:

	Reference dose (RfD) (mg total protein from the allergen)
Almond (provisional)	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

Principle 4.3.2

36. At CCFL47 Principle 4.3.2 was proposed based on the Expert Committee's advice that if a reference dose is not established for a particular food allergen, then an estimated reference dose can be used, provided it is determined following the guiding principles in the Part 2 report:

4.3.2 *Where a reference dose is not established for a particular allergen by 4.3.1 above, national authorities can establish a reference dose consistent with recognized principles⁴ for the purposes of determining an action level.*

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.*

37. In CP1 the EWG considered this text with a change for consistency from 'allergen' to 'food allergen'. Most responses supported (19/31) the principle noting reference doses for regional allergens proposed for inclusion in the table to 4.3.1 may help address global PAL inconsistencies and that some regions may have population exposures to some allergens that are not included in the lists of the GSLPF (sections 4.2.1.4 and 4.2.1.5) due to a lack of data.

38. Those not in support (9/31) considered reference doses should be harmonised at a global level, and that some nations may not have the scientific capability to develop their own reference doses.

39. Based on EWG feedback, the Chairs are proposing the following text:

4.3.2 *Where a reference dose is not established for a particular **food allergen** ~~by~~ 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.*

⁷FAO 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>.

Principle 4.4

40. At CCFL47 the draft guidelines included:

4.4 PAL should be accompanied by education/information programs to ensure understanding and appropriate use of PAL by consumers, health care providers and food business operators.

41. The EWG considered this principle in CP1, noting the Expert Committee's Part 3 report recommends the 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. Thirty-one of the 32 responses received supported the proposed text with one CM proposing an edit to replace 'should' with 'shall'. One CM suggested including a specific principle dedicated to education programs may not be necessary.

42. Given the EWG feedback, the Chairs have retained the text with one change to replace 'should' with 'shall'.

Section 5: Presentation of PAL

43. Both the ISSLG literature review and Expert Committee Part 3 report identify the need for a consistent and harmonised approach to PAL, including the use of a single PAL statement. At CCFL47 the following sections were included in the proposed draft guidelines:

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

5.2 PAL should appear as a separate statement in the same field of vision as the ingredient list (when present), and contrast distinctly from surrounding text, such as through the use of font type, style or colour in the same manner as Section 8.3.1 in the GSLPF.

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.

44. There was general support at CCFL47 to include a section on the presentation of PAL. One comment requested section 5.2 refer to all of section 8.3 of the GSLPF rather than specifically section 8.3.1. There was support for 'may contain' as being well-established wording most commonly used internationally. However, others noted the evidence from the Expert Committee (Part 3 report) supports 'not suitable for' and that 'may contain' is confusing for consumers.

45. In CP1 the EWG considered revised text on formatting by separating aspects into a new section 5.2.2, to clarify that it is the requirements of section 8.3.1 of the GSLPF that are being applied to the PAL statement. The requirement for 'may contain' was retained unchanged.

46. EWG feedback generally supported (23/31) the revised text. Those not supporting the text (4 CM, 4 CO) was because they either did not agree with '(or equivalent words)' being included, or because the revised text did not require a PAL statement to be placed immediately after the ingredient list or an allergen summary statement. Another CM considered there was insufficient data on consumer understanding to determine whether an advisory statement (e.g., "may contains") or a precautionary statement (e.g., "not suitable for") is preferred.

47. Noting the presentation for allergen declarations in draft section 8.3 of the GSLPF are still under discussion and that section 5 has been drafted for consistency with this section, in CP2 the Chairs proposed the following text:

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

5.2 PAL should appear as a separate statement in the same field of vision as 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 using the specified names 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 made in accordance with section 8.3.1 of the GSLPF.

48. In response 3 members (1 CM, 1 CMO, 1CO) proposed a change to make explicit that PAL should be placed directly under or in close proximity to the list of ingredients (when present), and not just in the same field of vision. Given there was EWG support for this approach in regard to the separate statement in section 8.2.3.1 of the GSLPF (Part A) this has been incorporated into section 5.2 as follows:

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

Use of a risk assessment indicator

49. The Expert Committee's Part 3 report recommends food labels provide an indication (e.g. a symbol) that a qualified risk assessment has been undertaken, irrespective of whether the risk assessment identifies the use of PAL or not. The ISSLG literature review also identified that consumers' trust in a product increases if they are aware a quantitative risk assessment has been undertaken. However, previous CCFL feedback has indicated minimal support for a risk assessment indicator.

50. In CP1 EWG members were asked if they supported not including a provision for the use of a risk assessment indicator. All but one EWG response supported this primarily due to the practical difficulty an indicator would place on both food business operators and national food authorities to implement. The draft PAL guidelines therefore do not include any provision relating to a risk assessment indicator.

Methods of analysis and sampling

51. Five EWG members (4 CM, 1 CO) highlighted the importance of CCMAS providing guidance regarding validated quantitative methods for allergen detection and that the use of PAL only if the UAP is above the action level based on the reference dose relies on the widespread availability of these methods and sampling protocols. It was suggested the PAL guidelines should not advance in the step procedure until CCMAS's work on methods of analysis and sampling is finalised.

52. Two members (1 CM, 1 CO) proposed including a reference to methods of analysis and sampling in the GSLPF similar to other Codex texts (e.g. CXS 73-1981) as follows:

"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.

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

(For comment through CL 2024/53-FL)

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 ¹ **or coeliac disease** about the risk from the unintended presence of allergens 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 pre-packaged² foods.

3. DEFINITION OF PRECAUTIONARY ALLERGEN LABELLING

For the purpose of these guidelines:

“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)³ due to cross-contact⁴ that has been identified by a risk assessment..

4. GENERAL PRINCIPLES

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.

4.2 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.

4.3 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.

4.3.1 References doses

	Reference dose (RfD) (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

¹ As defined in the *General Standard for the Labelling of Pre-packaged Foods* (CXS 1-1985)

² As defined in the *General Standard for the Labelling of Pre-packaged Foods* (CXS 1-1985)

³ As defined in the *General Standard for the Labelling of Pre-packaged Foods* (CXS 1-1985).

⁴ Allergen cross-contact as defined in *Code of Practice on Food Allergen Management for Food Business Operators* (CXC 80-2020).

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>

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 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.

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 principles⁷ 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 Pre-packaged 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 using the specified names 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.

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>.

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