



## JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON FOOD LABELLING

**Forty-seventh Session  
Gatineau, Quebec, Canada  
15 – 19 May 2023**

### FOOD ALLERGEN LABELLING

(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 2023/06/OCS-FL available on the Codex webpage/Circular Letters: <http://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/>

#### INTRODUCTION

1. 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 Prepackaged Foods* (CXS 1-1985) (GSLPF) and develop guidance on precautionary allergen labelling (PAL)<sup>1</sup>.
2. 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 texts<sup>2</sup>.
3. CCFL45 also agreed to request scientific advice from FAO/WHO<sup>3</sup> relating to the list of foods and ingredients in section 4.2.1.4 of the GSLPF. The CCFH has also requested FAO/WHO provide scientific advice on threshold levels for the priority allergens in relation to the *Code of Practice on Allergen Management for Food Business Operators* ([CXC 80-2020](#)).
4. 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 convened four times, and issued full reports for Parts 1 and 2, and summary and conclusions reports for Parts 3 and 4 (see table below):

Meeting date	Reports
30 November – 11 December 2020	<a href="#">Part 1: Review and validation of Codex priority allergen list through risk assessment</a>
15 March – 2 April 2021	<a href="#">Part 2: Review and establish threshold levels in foods for the priority allergens</a>
18 October – 3 November 2021	<a href="#">Part 3: Review and establish precautionary labelling in foods of the priority allergens</a> – Summary and conclusions
14 November – 18 November 2022	<a href="#">Part 4: Review and establish exemptions for the food allergens</a> – Summary and conclusions

5. 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) as members of the International Social Science Liaison Group (ISSLG)<sup>4</sup>, have collaborated on a [literature](#)

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

<sup>2</sup> [REP19/CAC](#) para 99

<sup>3</sup> [REP19/FL](#), para. 98(c)

<sup>4</sup> 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.

[review](#) to provide evidence for the revision of the GSLPF and development of guidance on PAL.

6. At CCFL46, the Committee considered draft revisions to the GSLPF and draft PAL guidelines<sup>5</sup> and agreed to re-establish an electronic working group (EWG) chaired by Australia and co-chaired by the United Kingdom and the United States of America.

#### TERMS OF REFERENCE

7. Working in English, the EWG was to:

- a. prepare the proposed draft revision to the GSLPF and the proposed draft PAL guidelines taking into account the discussion in the Committee<sup>6</sup> and all the written comments submitted<sup>7</sup>, for consideration by CCFL47; and
- b. take into account the scientific advice from FAO/WHO and evidence based consumer understanding of allergen labelling and advisory statements.

#### PARTICIPATION AND METHODOLOGY

8. An EWG was established in February 2022 with 34 Codex members (CM), one Codex member organization (CMO), and 19 Codex observers (CO). A list of participants is provided at Appendix IV.

9. In May 2022 a consultation paper (CP1) on the proposed draft revision to GSLPF relevant to allergen labelling was circulated to the EWG with 24 responses (14 CM, one CMO, nine CO) received.

10. A second consultation paper (CP2) was circulated to the EWG in October 2022 seeking further comment on the draft revision to the GSLPF (Part A) and proposed draft guidelines for PAL (Part B). Twenty-four responses (13 CM, one CMO, 10 CO) were received.

11. This paper provides an overview of EWG discussions (Appendix I) and presents proposed draft revisions to the GSLPF (Appendix II) and proposed draft PAL guidelines (Appendix III).

#### CONCLUSIONS

12. Consistent with the Terms of Reference, the EWG has taken into account discussion and written comments from CCFL46 and reviewed provisions relevant to allergen labelling in the GSLPF, and has also developed draft guidance on the use of PAL.

13. The EWG has also taken into account the available scientific advice from FAO/WHO to date and evidence base on consumer understanding of allergen labelling and advisory statements. Because the Expert Committee has yet to release the final reports for Parts 3 and 4 of its consultations, and released the final report for Part 2 and the Summary and conclusions for Part 4 after CP2, the EWG was not able to fully consider all aspects of the proposed draft revision to the GSLPF or the draft PAL guidance.

14. In some cases EWG members have only indicated conditional support for the proposed draft text noting a preference to wait for the final reports of the scientific advice from the Expert Committee. This was particularly relevant for the proposed provisions relating to exemptions for certain foods from declaration requirements (Expert Committee's Part 4 report) and the PAL guidance (Expert Committee's Part 2 & 3 report).

15. The EWG has also considered the location of the proposed draft PAL guidelines and proposes to incorporate the guidelines as an annex to the GSLPF to ensure consistency with the GSLPF, and so that provisions relevant to allergen labelling (including PAL) are located within the same text.

16. The EWG has also had regard to consistency with other relevant texts including the *Code of Practice on Allergen Management for Food Business Operators* (CXC 80-2020). Subject to agreement at CCFL47 it may be timely to advise CCFH on progress to help maintain consistency between texts.

17. In relation to the PAL guidance, the EWG has identified a need for standardised methods of analysis and sampling of allergens for use in risk assessments underpinning the decision to use PAL, noting the Expert Committee has concluded that significant limitations on method performance exist. It is therefore recommended that CCFL seeks advice from the Codex Committee on Methods of Analysis and Sampling (CCMAS) on appropriate methods for undertaking PAL risk assessments, taking into account information provided within WHO/FAO scientific advice reports.

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<sup>5</sup> [CX/FL 21/46/8](#)

<sup>6</sup> [REP21/FL](#) paragraphs 134-135.

<sup>7</sup> Includes responses to CL 2021/21/OCS-FL ([CX/FL 21/46/8 Add.1](#)) and CCFL46 CRD07, CRD08, CRD11, CRD12, CRD20, CRD21, CRD26.

**RECOMMENDATIONS**

18. Noting the available scientific advice from FAO/WHO to date and the consumer evidence provided by ISSLG, the Committee is invited to consider:

- a) the overview of EWG discussions in Appendix I
- b) the proposed draft revision to the GSLPF in Appendix II
- c) the proposed draft guidelines for the use of PAL in Appendix III, including:
  - a. the proposed location as an annex to the GSLPF; and
  - b. the need to seek advice on standardised analytical methods and sampling from CCMAS
- d) whether to provide any advice to CCFH to ensure consistency with the *Code of Practice on Allergen Management for Food Business Operators* (CXC 80-2020)

## OVERVIEW OF DISCUSSION

## PART A – REVIEW OF ALLERGEN LABELLING PROVISIONS IN THE GSLPF

1. This part discusses the proposed draft revision of the sections in the GSLPF relevant to allergen labelling, taking into account comments from CCFL46 and the EWG feedback received through CP1 and CP2. The Expert Committee's Part 1 report and the ISSLG literature review have also informed the proposed draft revision of the GSLPF as provided at Appendix II.

**Scope**

2. There was discussion and written comments at CCFL46 that supported extending the scope of allergen labelling to non-prepackaged foods. However the EWG Chairs note the scope of work was to review and clarify provisions in the GSLPF relevant to allergen labelling. The scope of the GSLPF 'applies to the labelling of all prepackaged food'. An extension of allergen labelling to non-prepackaged food goes beyond the scope of the GSLPF and the scope of work on allergen labelling. The EWG therefore did not consider this issue further.

**Definition of terms**

3. The proposed draft revision to the GSLPF presented at CCFL46 included definitions for 'hypersensitivity' 'allergen', 'food allergy' (incorporating a footnote to recognise coeliac disease), and 'food intolerance'. However, subsequent revisions to the GSLPF considered by the EWG did not refer to 'allergen' and 'food intolerance' so definitions for these terms were not considered further.

4. In the Expert Committee's Part 1 report food allergy<sup>1</sup> is defined as:

*Food allergy is defined as an adverse health effect arising from a specific immune-mediated response that occurs reproducibly on oral exposure to a given food, which may or may not be mediated by food-specific immunoglobulin class E (IgE) antibodies.*

5. Drawing on this definition, and considering the Expert Committee determined the scope was limited to immune-mediated food allergies and coeliac disease (i.e. excluded food intolerances), the EWG considered the following definitions for 'food allergy' and 'hypersensitivity':

*"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.

*"hypersensitivity"* means food allergy and coeliac disease.

6. As coeliac disease is an established well-known medical condition, a definition was not considered necessary.

7. The majority of EWG members supported the proposed definition for food allergy. In relation to the definition of hypersensitivity, one CM proposed for clarity it should be 'food hypersensitivity'. Another questioned the need for defining hypersensitivity noting the current definition of 'food allergy' is broad enough to include coeliac disease, because the Expert Committee had identified it as a non-IgE antibody immune-mediated response to gluten<sup>2</sup>. One CMO noted hypersensitivity traditionally refers to non-immune mediated reactions, and suggesting replacing 'hypersensitivity' with 'food allergy or coeliac disease'. There were also three EWG members who disagreed with not defining coeliac disease.

8. Based on EWG feedback, and to provide clarity, the term 'hypersensitivity' has been replaced with 'food allergy or coeliac disease' and a definition for food allergy proposed as above. A definition for coeliac disease has not be proposed. Although noting the Expert Committee defined coeliac disease<sup>3</sup> as:

*Coeliac disease* is 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).

this is included as a footnote in the proposed draft revision at Appendix II. Including a footnote is consistent with the approach used in the CCFH *Code of Practice on Allergen Management for Food Business Operators*

<sup>1</sup> [Part 1: Review and validation of Codex priority allergen list through risk assessment](#) Section 2.2.1

<sup>2</sup> [Part 1: Review and validation of Codex priority allergen list through risk assessment](#) Figure 1 page 8

<sup>3</sup> [Part 1: Review and validation of Codex priority allergen list through risk assessment](#) Section 2.2.2

(CXC 80-2020).

## **Mandatory labelling of prepackaged foods**

### Compound ingredients (section 4.2.1.3)

9. Comments received at CCFL46 generally supported the proposed draft revision to section 4.2.1.3 of the GSLPF with minor editorial changes. Following EWG consideration, only further editorial changes are incorporated to reflect the introduction of new sections 4.2.1.5 and 4.2.1.6.

### Foods and ingredients to be declared (section 4.2.1.4 and new section 4.2.1.5)

#### *Priority and regional allergens*

10. The Expert Committee identified that only immune-mediated hypersensitivities such as IgE-mediated food allergies and coeliac disease should be included on the list of foods and ingredients included in section 4.2.1.4 of the GSLPF. This was because consideration of the established criteria (prevalence, severity and potency) was primarily given to IgE-mediated food allergies and coeliac disease since these diseases are well documented to cause serious adverse public health outcomes.

11. Based on the criteria, the Expert Committee recommended the following should be listed as priority allergens:

- cereals containing gluten (e.g. wheat and other *Triticum* species, rye and other *Secale* species, barley and other *Hordeum* species and their hybridized strains)
- crustacea
- eggs
- fish
- milk
- peanuts
- sesame
- specific tree nuts (almond, cashew, hazelnut, pecan, pistachio and walnut).

In general the EWG supported including the above list of priority allergens in section 4.2.1.4 of the GSLPF.

12. Noting spelt was no longer explicitly listed as a cereal containing gluten and that the Expert Committee recommended a footnote may be needed to clarify what cereals are captured, the EWG supported including the following footnote:

*Includes spelt and other specific cereals containing gluten that are species or hybridized strains under the genus names of *Triticum*, *Secale* and *Hordeum*.*

13. Due to the lack of data on prevalence, severity and/or potency, or regional consumption of some foods, the Expert Committee recommended buckwheat, celery, lupin, mustard, oats, soybean and specific tree nuts (Brazil nut, macadamia and pine nuts) not be listed as priority allergens but may need be considered at regional levels. They noted risk managers could base their decision to include other food allergens on their regional priority lists on the scientific evidence, depending on their specific situation<sup>4</sup>.

14. Some EWG members noted a lack of sufficient evidence to meet the criteria is not the same as having sufficient evidence that these foods/ingredients are safe, and that other factors should be taken in account including, in addition to the extent of use in food, the severity of allergic reactions and/or the high regional prevalence of food allergy. Based on these comments, the EWG considered an option of including a separate list of regional allergens which will allow national/regional authorities to determine if they should be declared based on their own risk assessment using the evidence criteria established by the Expert Committee.

15. There was some EWG support for this option (7 CM, 1 CMO, 5 CO) but others (3 CM, 6 CO) argued against the inclusion of the regional list because it could suggest these allergens have the same status as the priority list, would result in inconsistent labelling practices in international trade, and questioned whether countries would have sufficient data or resources to generate data to undertake their own risk assessments.

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<sup>4</sup> [Part 1: Review and validation of Codex priority allergen list through risk assessment](#) Chapter 8, Conclusions and Recommendation (page 71)

16. In relation to the regional list, a number of EWG members were also against including oats (1 CM, 3 CO) citing the issue is about cross contact with gluten containing cereals and therefore could be managed through PAL. However others (1 CM, 2 CO) considered oats should be declared, with several members noting evidence that some people with coeliac disease do have an immune response to uncontaminated oats.

17. Based on there being general EWG agreement, the list of priority allergens as recommended by the Expert Committee is proposed to be included in section 4.2.1.4. In addition a new section 4.2.1.5 has also been proposed that provides a separate list of allergens including oats, that allow national/regional authorities to determine if these are to be declared based on their own risk assessment.

#### *Specified names*

18. At CCFL46 the proposed draft revision to the GSLPF included a new section that would require the use of commonly known terms for declaring allergens (e.g. milk), in recognition of evidence that consumers benefit from the use of consistent, simple and specific terminology when declaring allergens and they have a strong preference for the source allergen to be identified<sup>5</sup>. There was support for this approach however comments received noted the requirement for 'commonly known terms' was non-specific and lacked clarity.

19. To address this issue the EWG considered the option of incorporating specific names for allergens to be used when making declaring declarations. To ensure consistency, the use of these names would apply to declarations made in the ingredient list and elsewhere such as in a separate statement.

20. EWG members supported this approach and specified names for the priority allergens (revised section 4.2.1.4) and the proposed new section 4.2.1.5 for regional allergens are included in the proposed draft revision to the GSLPF.

21. However some proposed changes to the specified names were raised by some EWG members. Two CMs, one CO and one CMO requested the use of 'gluten' either as a mandatory or voluntary addition to the specified names for each gluten-containing cereal (e.g. 'wheat, gluten'). One CMO and one CO asked that common names be permitted for individual milk products instead of the specified name 'milk', such as 'cheese', 'butter' etc. One CM and one CMO requested clarity on how specified names apply to the cereals mentioned in the footnote to cereals containing gluten (e.g. spelt), while another CM requested clarity on the use of specified names for hybrid cereals.

22. Noting the importance of consistent and specific terminology for consumers, no changes are proposed to allow the use of other common names. For cereals containing gluten additional text is included in the footnote to help provide clarity that 'wheat', 'rye' and 'barley' are to be declared according to the cereal genus, noting this is the risk profile identified by the Expert Committee. However, CCFL may wish to consider whether 'gluten' can be included as an additional specified name for the listed cereals containing gluten.

#### Lactose and sulphites (new section 4.2.1.6)

23. The Expert Committee did not consider non-immune mediated diseases such as lactose intolerance or reactions to sulphite as part of its assessments.

24. Noting lactose was originally included in section 4.2.1.4 based on prevalence of lactose intolerance only, and sulphite was included following a JECFA risk assessment<sup>6</sup> and consideration by CCFA17 (1985)<sup>7</sup>, which identified that sulphite in a dose above 10 mg/kg has the potential to cause severe reactions, the EWG were asked if they supported lactose and sulphite remaining in the list to section 4.2.1.4 when no new risk assessment was available.

25. The majority of the EWG (9 CM, 8 CO) did not support retaining lactose due to there being a lack of sufficient data and evidence that lactose intolerance causes serious adverse health outcomes, and that the declaration of milk can act as a proxy alert for individuals with lactose intolerance.

26. There were divided views on sulphite remaining in the section 4.2.1.4 list with those against (6 CM, 8 CO) noting the list at section 4.2.1.4 should only include foods associated with IgE mediated reactions and coeliac disease, and that the disclosure of sulphite will occur as part of normal additive ingredient labelling when present above 10 mg/kg. However others (9 CM, 1 CMO, 1CO) considered a declaration requirement for sulphite should remain given there was no new risk assessment, and earlier and more recent<sup>8</sup> risk

<sup>5</sup> [Consumers and Allergen Labelling: a literature review on consumer response to allergen declarations and precautionary allergen labelling](#) FSANZ and Food Standards Agency (UK) (October 2020)

<sup>6</sup> World Health Organization (1987). Evaluation of certain food additives and contaminants. WHO Technical report series 751:32-33. [WHO\\_TRS\\_751.pdf](#) Accessed 11/4/2022.

<sup>7</sup> Codex Committee on Food Additives CX/FA 85/5-Add 1. Intolerance to food additives especially food colours.

<sup>8</sup> EFSA (2014). Scientific Opinion on the evaluation of allergenic foods and food ingredients for labelling purposes. EFSA Journal 2014 12(11):3894. <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2014.3894> Accessed on 12/9/2022.

assessment findings demonstrate that a serious risk remains.

27. Based on EWG feedback, lactose was removed from the revised list in section 4.2.1.4. For sulphites, a new section 4.2.1.6 for the declaration of sulphite using the specified name 'sulphite' is included in the proposed draft revision. This allows separation from section 4.2.1.4 (priority allergens) and the proposed new section 4.2.1.5 (regional allergens), which both list only foods and ingredients associated with IgE mediated reactions and coeliac disease.

#### Exemption from declaration (new section 4.2.1.7)

28. In its Part 1 report, the Expert Committee identified that for ingredients derived from foods on the priority list, some can contain very high levels of protein from the source food, and others can contain almost non-detectable levels. Therefore, the Expert Committee recommended a case-by-case evaluation based upon the degree of risk using available scientific and clinical data and that decisions regarding labelling exemptions from source labelling can be based upon several criteria<sup>9</sup>.

29. In the light of the Expert Committee's advice, the EWG was asked to consider if an approach to exemptions could be incorporated into the GSLPF. The majority of members supported including a generic provision allowing exemptions, subject to case-by-case evaluation against the criteria (from the Expert Committee) by national authorities. On this basis, a new section 4.2.1.7 for exemptions is proposed in the draft revision.

30. In November 2022 the Expert Committee held a fourth consultation specifically to *further elaborate on the recommendations of the 1<sup>st</sup> meeting on derivatives of food allergens and to establish a framework for evaluating labelling exemptions for derivatives of priority allergenic foods*. Due to the timing of this meeting, the EWG did not have the opportunity to consider the proposed new section in light of the [Part 4 Summary and Conclusions report](#).

#### **Ingredients obtained through biotechnology (section 4.2.2)**

31. At CCFL46, no changes were proposed to section 4.2.2. However changes are proposed in the draft revision to ensure reference to the lists of food and ingredients in section 4.2.1.4 and new section 4.2.1.5.

#### **Ingredient and class names (section 4.2.3 and 4.2.3.1)**

32. Comments made at CCFL46 indicated general support for the proposed draft revision of sections 4.2.3 and 4.2.3.1. Further minor changes are incorporated in the proposed draft revision to reflect the introduction of new sections 4.2.1.5 and 4.2.1.6.

#### **Processing aids and carry-over of food additives (section 4.2.4.2)**

33. There was support for the proposed changes to section 4.2.4.2 as presented at CCFL46. Further minor changes are incorporated in the proposed draft revision to reflect the introduction of new sections 4.2.1.5 and 4.2.1.6.

#### **Exemptions from mandatory labelling requirements (Section 6)**

34. There was support for the proposed draft revision of Section 6 following CCFL46, so only minor changes are proposed to cross reference the new sections 4.2.1.5 and 4.2.1.6.

#### **Declaration of certain foods and ingredients (new Section 8.3)**

35. At CCFL46, there was support for including a new section 8.3 on how declarations are to be presented within Section 8 – Presentation of Mandatory Information of the GSLPF. Specific mention was made to the consumer evidence which indicates the importance of clear and consistent allergen information for consumers with food allergy. However, there were differing views on what aspects of presentation in the proposed new section should be included as follows:

- Support for provisions relating to the format of allergen declarations, such as highlighting declarations through the use of contrasting text. However, there was less support for including more specific requirements for font type and size to allow flexibility for national authorities to determine these requirements.
- General support for allowing a separate statement to be made in addition to declaration in the ingredient list, which would summarise the allergens present in a food. Although there were differing views whether it should be mandatory or optional labelling.

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<sup>9</sup> [Part 1: Review and validation of Codex priority allergen list through risk assessment](#) Section 2.4 Criteria for derivatives recommended to be exempted from labelling (pages 15-20, 67).

- The need to clarify that the presentation requirements apply to both declarations made in the ingredient list and the separate summary statement.
- General support for introducing an alternative for declaring allergens when there is no ingredient list (such as in a summary statement or in the name of the food).

36. Given the broad support for including this section, the EWG considered revised text which removed aspects related to font size and legibility, and made changes to add clarity to the text. Most members (12 CM, 3 CO) supported the revised text. Those not supporting the text (1 CMO, 1 CO) were concerned about consumers being misled by the use of voluntary summary statements (as proposed in sections 8.3.2 and 8.3.2.1), as consumers may assume foods without a summary statement do not contain allergens. There was also concern about consumer confusion between these statements and PAL.

37. However, sections 8.3.2 and 8.3.2.1 are intended to accommodate the differing approaches used by national and regional authorities for declaring allergens, by allowing the optional use of a 'Contains' summary statement in addition to declarations made in the ingredient list, or in the case of when a food is exempt from having an ingredient list (e.g. small packages). The proposed draft revised section 8.3.2 is intended to provide flexibility for national/regional authorities to determine the most suitable declaration requirements for their population. The proposed sections have drawn on the evidence provided by the ISSLG literature review.

38. Some EWG comments supporting section 8.3 (3 CM, 2 CO) also requested further changes to section 8.3.2 to provide greater flexibility, by allowing declarations either in the ingredients list, a summary 'Contains' statement, or in both locations. However, section 4.2.1.4 as a section of paragraph 4.2 (List of ingredients) requires the declaration of food and ingredients known to cause hypersensitivity in the list of ingredients. Also, the ISSLG literature review identified that consumers prefer the use of an allergen summary statement in addition to the inclusion of allergen information in list of ingredients. On this basis, the proposed draft revision at Appendix II does not provide for declarations to be made in a separate statement as an alternative to the ingredient list (unless an ingredient list is not present).

## PART B – GUIDELINES ON THE USE OF PRECAUTIONARY ALLERGEN LABELLING

(This part discusses the proposed draft PAL guidelines based on feedback received at CCFL46 and from the EWG in response to CP2. The Expert Committee's Part 2 and 3 reports and the ISSLG literature review have also informed the proposed draft guidelines (noting the Expert Committee's Part 3 full report is yet to be published) as provided at Appendix III.)

### Location of the PAL guidelines

39. In the CCFL46 agenda paper views were sought on the location and appropriate Codex text(s) for the draft guidelines (e.g. an annex to the GSLPF or as standalone guidance). The majority of responses including the PAL guidance as an annex to the GSLPF to maintain a link to, and provide consistency with, the allergen provisions in the GSLPF. Other responses expressed the view it was too early to consider placement of the text preferring to wait until the work had progressed further.

40. The EWG did consider the location of the proposed PAL guideline with 21 from 24 EWG responses supporting inclusion as an annex to ensure consistency with the GSLPF, and so that provisions relevant to allergen labelling (including PAL) are located within the same text. The draft guidelines at Appendix III are therefore being proposed as an annex to the GSLPF.

### Title and purpose

41. At CCFL46 the following title was proposed: *Guidelines for the Use of Precautionary Allergen and Advisory Labelling*. From the comments received, there was general support for removing 'advisory' from the title. The reasons provided were that 'precautionary allergen labelling' reflects the terminology used in scientific literature, is more specific and descriptive, and is well understood by industry, relevant authorities and consumers. There was a preference not to include 'advisory' due to this conveying a different meaning and potentially creating confusion.

42. There was also general support from CCFL46 for the proposed purpose. However some comments noted the purpose needs to be explicit and reflect the main objectives of PAL; the reference to 'risk' should be removed because the communication is about the unintended presence of allergens; and the purpose should include 'potential' or 'possible' in relation to the unintentional presence of allergens.

43. The EWG noted that the Expert Committee's Part 3 summary and conclusions report refers to 'unintended allergen presence (UAP)', and not potential or possible unintended presence, and also recommends (emphasis added) that '*a consistent and harmonized approach is the most effective use of PAL for communicating to consumers with food allergy about the risk from UAP*'.



44. Based on the above, the proposed text as proposed at CCFL46 has been maintained in the draft guidelines as follows:

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

### Scope

45. At CCFL46 the following scope was proposed:

- 2.1 *These guidelines apply to PAL when used to indicate the possible unintentional presence of allergens caused by cross-contact in prepackaged foods that are within the scope of the General Standard for the Labelling of Prepackaged Foods (CXS 1-1985).*
- 2.2 *The Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020) provides guidance on effective management practices and controls to prevent or minimise the potential for allergen cross-contact.*

46. Noting the Expert Committee's recommendation that the decision to use PAL should be based on hazard identification and risk characterization, combined with adherence to the Code of Practice on allergen management for food business operators ([CXC 80-2020](#)), GMP, and HACCP, section 2.2 was removed and considered by the EWG in the general principles instead (see below). For section 2.1, EWG members proposed to add the words 'the risk from' to make the scope text consistent with the purpose text.

47. Some EWG member (1 CM, 1 CMO, 1 CO) proposed the scope be broadened to cover PAL on unpackaged foods, as well as any PAL information provided to businesses as part of the supply chain. However, noting CXC 80-2020 includes requirements for providing information to food businesses (see Section IX) and the proposal to locate the PAL guidance as an annex to the GSLPF the scope of which relates to the labelling of prepackaged foods, a footnote is included to make clear the scope applies to prepackaged foods as defined in the GSLPF.

### Definitions

48. At CCFL46, definitions for 'allergen', 'allergen cross-contact' and 'precautionary allergen labelling' were proposed. However, having considered the feedback received, and based on the terms used in the proposed draft guideline, the EWG considered definitions for 'allergen' and 'precautionary allergen labelling'. A definition for 'allergen cross-contact' was considered unnecessary as the term was not used in the draft guidelines except in the definition of precautionary allergen labelling. Instead, a cross reference to the definition of 'allergen cross-contact' in CXC 80-2020 was proposed as a footnote. In addition, the proposed definition for 'allergen' was revised and simplified by referring to only those foods and ingredients listed in the proposed draft revisions of the GSLPF for sections 4.1.2.4 and 4.1.2.5.

The majority of the EWG supported the proposed definitions. Some EWG members did not support the definition of allergen because it included reference to section 4.2.1.5, which they opposed for inclusion in the GSLPF. The proposed revised definitions are:

*For the purpose of these guidelines:*

*Allergen means the foods and ingredients listed in sections 4.2.1.4 and where applicable 4.2.1.5 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 allergen(s) due to cross-contact<sup>2</sup>.*

<sup>2</sup> *Allergen cross-contact as defined in Code of Code of Practice on Allergen Management for Food Business Operators ([CXC 80-2020](#))*

### General principles (section 4)

49. The following principles were included in the draft PAL guidelines presented to CCFL46:

- 1.1 *The decision to use PAL should be based on the findings of a risk assessment which can include, but not limited to, quantitative risk assessment. The use of PAL should be restricted to those situations in which allergen cross-contact cannot be controlled to the extent that the product may present a risk to allergic consumers.*
- 1.2 *PAL should only be used if exposure to the allergen from the food is above an established reference dose. If a reference dose is not established for a particular allergen, an estimated reference dose can be used. If a quantitative risk assessment cannot be performed, then PAL*

*should only be applied if any risk of allergen-cross contact identified through a risk assessment cannot be removed through risk management actions, such as segregation and cleaning.*

50. Comments received were divided with those supporting the principles, noting that without a scientifically-based risk assessment it is difficult to interpret whether cross-contact is significant or not. Whereas others noted it was important not to impose excessive burdens on food businesses, especially small food producers, which do not have the capacity to perform quantitative risk assessments. There was broad support for the use of established reference doses, although comments noted the need for clarity on what reference doses should apply.

51. Taking into account these comments, and the recommendations from the Expert Committee's Part 2 report and Part 3 Summary and conclusions, the general principles were revised for EWG comment as follows:

- The Expert Committee recommended that the decision whether or not to use PAL should be based on hazard identification and risk characterization combined with food business operators implementing allergen management practices and controls. Proposed principle 4.1 reflects this intent and includes a reference to CXC 80-2020 that was moved from the scope.
- The Expert Committee recommended the use of quantitative risk assessment is preferred for making PAL decisions. Proposed principle 4.2 therefore includes a requirement to use a quantitative risk assessment. However, noting comments about the need to consider the burden on food businesses, the option for other risk assessment approaches to be used is also included.
- The Expert Committee also recommended that the decision whether or not to use PAL requires food business operators to use PAL when an unintended allergen presence exceeds the relevant reference dose (RfD), and to *not* use PAL when an unintended allergen presence does not exceed the relevant RfD. A new third principle 4.3 is included to reflect this including section 4.3.1 that provides a list of reference doses (RfD) based on ED05 as recommended by the Expert Committee.
- In the Part 3 Summary and conclusions, the Expert Committee recommended that if an RfD is not established for a particular priority allergen, an estimated RfD can be used provided it is determined following the principles elaborated in the second meeting of the Expert Committee (Part 2). Therefore section 4.3.2 was proposed to recognize the establishment of reference doses by national authorities, subject to a determination consistent with the Expert Committee's principles.

52. The majority of the EWG members supported the proposed principles with some editorial changes to provide clarity. For section 4.2, a group of EWG members (4 CM, 2 CO) argued that quantitative risk assessments are difficult and costly, and so cannot always be undertaken by food manufacturers; and information may not be available to generate a quantitative risk assessment. However, section 4.2 has been worded so that risk assessments are not limited to quantitative assessments, which provides an option to use alternative assessment methods.

53. One CMO and one CM noted the general principles should explain how levels of allergenic substances in food can be derived (i.e. action levels). The EWG Chairs note the Expert Committee's Part 2 report<sup>10</sup> provides a translation of the recommended reference doses (RfD) into action levels (AL) that can be used as a practical measure of the unintended allergen presence in a food. This translation (an equation) into action levels has therefore been included as a footnote in section 4.3, with reference to the table of RfD values as follows:

$$\text{Action level (mg total protein from the allergen / kg food)} = \text{Reference dose (mg total protein from the allergen)} / \text{Amount of the food (kg)}$$

54. In comments on section 4.3.1, a group of EWG members (1 CMO, 4 CO) noted that Codex should work on standardised methods of analysis and sampling of allergens for use in risk assessments underpinning the decision to use PAL. The Expert Committee has provided a discussion on appropriate methods of analysis in its Part 2 report and concluded that significant limitations on method performance exist<sup>11</sup>. It is therefore recommended that CCFL seeks advice from the Codex Committee on Methods of Analysis and Sampling (CCMAS) on appropriate methods for undertaking PAL risk assessments.

55. Some EWG members also made comments on the recommended RfDs. Noting the Expert Committee has used 'shrimp' and 'crustacea' interchangeably<sup>12</sup>, 'shrimp' is replaced with 'crustacea' to reflect the term used in the GSLPF. Comments were also received that 'wheat' should be replaced with 'cereals containing gluten', and each tree nut should be on a separate line. However, as the Expert Committee did not assess

<sup>10</sup> [Part 2: Review and establish threshold levels in foods for the priority allergens](#). Page 61

<sup>11</sup> [Part 2: Review and establish threshold levels in foods for the priority allergens](#). Pages 73-82

<sup>12</sup> [Part 2: Review and establish threshold levels in foods for the priority allergens](#). Page 90

other cereals containing gluten besides wheat, and also identified cross-reactivity in the reactions between certain tree nuts, resulting in grouped reference doses, these changes have not been included.

56. The majority of EWG members (9 CM, 6 CO) supported the inclusion of principle 4.3.2 because a framework has been provided by the Expert Committee for making additional determinations on reference doses, and that there are regional differences in allergen risk globally. Some EWG members (3 CM, 3 CO) opposed the establishment of regional reference doses because of the potential for international inconsistency in allergen threshold levels. The EWG Chairs note that a list of reference doses for the regional allergens proposed in section 4.2.1.5 of the GSLPF would assist to provide consistency and understands the Expert Committee is undertaking further work to provide advice on reference doses for regional allergens in the future.

#### Education programs

57. The ISSLG literature review identified that consumers often do not understand what PAL means, and that there is a lack of trust in how PAL is currently used, with the motivations behind its presence considered to be questionable<sup>13</sup>. The Expert Committee also recommended that 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 the chosen phraseology for PAL<sup>14</sup>.

58. Comments from CCFL46 indicated mixed views on the inclusion of a principle for the use of education programs. Some comments stated that education initiatives are not within the scope or remit of Codex and CCFL whereas other comments were supportive as communication is an important aspect of making PAL effective. It was also noted that education is included in the *Guidelines on Front-of-pack Nutrition Labelling* (Annex to CXG 2 -1985) and in the *Code of Practice on Allergen Management for Food Business Operators* (CXC 80-2020).

59. The majority of the EWG supported including a principle about education programs with a CMO suggesting it is best placed as a general principle. Consequently a new principle 4.5 is included in the proposed draft guidelines at Appendix III.

#### **Presentation of PAL (section 5)**

60. At CCFL46 principles relating to the presentation of PAL were proposed to be included once the work on the revision of the GSLPF had progressed further and the Expert Committee's advice was available. The EWG, taking into account the ISSLG literature review and the Expert Committee's Part 3 Summary and Conclusions, discussed the following aspects.

#### Format and location of PAL statements

61. Previous comments received indicated a preference for the PAL guidelines to include the following:

- PAL statements should be clearly distinguishable from the surrounding text, such as through the use of bold font.
- Locating PAL statements near the ingredient list, so all relevant information about allergens is available to consumers.

62. Neither the ISSLG literature review or Expert Committee specifically made conclusions or recommendations relating to the format or location of PAL. However, locating PAL information within the same field of vision as the ingredient list (when present) would be appropriate given consumers look for allergen information declared in the ingredient list. Further, indicating PAL statements should be clearly distinguishable from surrounding text would also seem appropriate to assist consumers to identify PAL information. Nearly all EWG members supported including location and format in the principles and considered the following proposed principle:

*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.*

63. However several EWG members considered the principle by itself did not provide enough clarity on where a PAL statement should be located when an ingredient list is not present, and should require the PAL statement to have the same format as the allergen summary statement. Consequently, additional principles have been included in the proposed draft guidelines for consideration by CCFL.

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<sup>13</sup> [Consumers and Allergen Labelling: a literature review on consumer response to allergen declarations and precautionary allergen labelling](#) FSANZ and Food Standards Agency (UK) (October 2020)

<sup>14</sup> [Part 3: Review and establish precautionary labelling in foods of the priority allergens](#) – Summary and conclusions

### Wording of PAL statements

64. Both the ISSLG literature review and Expert Committee Part 3 Summary and conclusions indicate a consistent and harmonised approach to PAL including a single PAL statement is important for communicating to consumers with food allergy about the risk from unintended allergen presence. The Expert Committee further recommended the wording of the statement should convey to individuals with an allergy that a particular food 'is not suitable' for them e.g. 'Not suitable for x allergy' or 'Not suitable for consumers/individuals with a x allergy, y allergy..'

65. The ISSLG literature review included how reported consumer behaviour differs according to the wording of the PAL statement used. For example, within the included studies, products labelled with 'not suitable for' and 'may contain' tended to be more likely to be avoided. Although it was also noted that findings relating to preferences for PAL suggested 'may contain' was often the least preferred statement by consumers in the included studies.

66. The EWG also noted that existing PAL in some parts of the world use other wording such as the VITAL program in Australia and New Zealand which uses 'May be present: x' and that a proposal to include a single harmonised PAL statement in the guidelines means the preferred PAL statement must be able to be translated into different languages and still be able to convey the risk posed by a food to consumers with food allergy.

67. The EWG therefore considered the following options:

*Option 1 – 'Not suitable for people with a x allergy' or 'Not suitable for x allergy'*

*Option 2 – 'May contain x'*

*Option 3 – 'May be present: x'*

68. There was little support the Expert Committee's recommended PAL wording '*Not suitable for people with a x allergy' or 'Not suitable for x allergy'* on the basis there is a potential risk a consumer could miss information pertaining to other allergens present in a food. Two CM supported Option 3 because it is a simple statement that is less likely to be confused with a summary statement that use the words 'Contains'.

69. The majority of EWG members (6 CM, 1 CMO, 5 CO) supported Option 2 stating it is familiar, short and clear, and well understood by consumers, and this the most commonly PAL statement in many countries globally. However other EWG members (3 CM, 5 CO) did not indicate support for any option because they considered it was too early to determine the wording of the statement and that further discussion by CCFL was needed. The proposed draft guidelines include 'May contain (or equivalent wording)' for consideration by CCFL.

### Use of an indicator that an allergen risk assessment has been undertaken

70. In the Part 3 Summary and conclusions, the Expert Committee recommended for food labels to provide an indication on the label (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. The EWG was therefore asked to comment on including a principle on the use of an indication on the label (e.g. use of a symbol) to show a risk assessment has been undertaken.

71. The majority of the EWG did not support including a principle because the time and complexity to practically implement a symbol would be too high for most governments, and a cost burden to the food industry. Also if the indicator is absent from a food, then consumers are likely to be confused on whether there is a risk or not of the unintended presence of allergens. On the basis of this feedback, the proposed draft guidelines do not included a principle relating to the need to indicate on the label that a risk assessment has been undertaken.

## APPENDIX II

**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)

**(FOR COMMENTS AT STEP 3 THROUGH CL 2023/06/OCS-FL)**

## 2. DEFINITION OF TERMS

(New)

**“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.”

## 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, ~~other than~~ **need not be declared, except for the foods and ingredients listed in section 4.2.1.4, 4.2.1.6 and where applicable section 4.2.1.5** and food additives which serve a technological function in the finished product, ~~need not be declared.~~

**4.2.1.4** The following foods and ingredients are known to cause ~~hypersensitivity~~ **food allergy or coeliac disease**<sup>1</sup>. and shall always be declared<sup>2</sup> **using the name specified:**

- ~~Cereals containing gluten; i.e., wheat, rye, barley, oats, spelt or their hybridized strains and products of these;~~
- ~~Crustacea and products of these;~~
- ~~Eggs and egg products;~~
- ~~Fish and fish products;~~
- ~~Peanuts [, soybeans and] products of these;~~
- ~~Milk and milk products [(lactose included)];~~
- ~~tree nuts and nut products; and~~
- ~~Sulphite in concentrations of 10 mg/kg or more~~

FOODS AND INGREDIENTS	SPECIFIED NAME
Cereals containing gluten <sup>2</sup> :	‘wheat’
– wheat and other <i>Triticum</i> species	‘rye’
– rye and other <i>Secale</i> species	‘barley’
– barley and other <i>Hordeum</i> species	
and products thereof	
Crustacea and products thereof	‘crustacea’ or the common name of

<sup>1</sup> **Coeliac disease** is 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).

<sup>2</sup> Includes spelt 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).

<sup>2</sup> Future additions to and/or deletions from this list will be considered by the Codex Committee on Food Labelling taking into account the advice provided by the joint FAO/WHO Expert Committee on Food Additives (JECFA)

FOODS AND INGREDIENTS	SPECIFIED NAME
	individual crustacean species
Eggs and products thereof	'egg'
Fish and products thereof	'fish' or the common name of individual fish species
Peanuts and products thereof	'peanut'
Milk and products thereof	'milk'
Sesame and products thereof	'sesame'
Specific tree nuts	'almond'
– Almond	'cashew'
– Cashew	'hazelnut'
– hazelnut	'pecan'
– pecan	'pistachio'
– pistachio	'walnut'
– walnut	
and products thereof	

### (New Sections)

#### 4.2.1.5

In addition to the foods and ingredients listed in section 4.2.1.4, national or regional authorities may also require the declaration of any of the following foods and ingredients using the name specified, based on an assessment of risk of food allergy or coeliac disease in their respective population(s)<sup>3</sup>:

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	'oats'
Lupin and products thereof	'lupin'
Mustard and products thereof	'mustard'
Soybean and products thereof	'soy'
Specific tree nuts	'Brazil nut'
– Brazil nut	'macadamia'
– macadamia	'pine nut'
– pine nut	
and products thereof	

**4.2.1.6** When added sulphite is present in a food, and the total concentration exceeds 10 mg/kg, it shall always be declared using the specified name 'sulphite'.

**4.2.1.7** Subject to evaluation using established criteria<sup>3</sup>, 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.

**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 allergen transferred

<sup>3</sup> The assessment of risk to be based on the evidence criteria of prevalence, potency and severity of immune mediated adverse reactions to the food or ingredient in the respective population(s). FAO and WHO (2022). Risk assessment of food allergens: Part 1: Review and validation of Codex Alimentarius priority allergen list through risk assessment. p15-20. <https://doi.org/10.4060/cb9070en>.

from any of the products **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 an allergen through labelling, the food containing the allergen should not be marketed.

**4.2.3 Except for those foods and ingredients listed in sections 4.2.1.4, 4.2.1.6 and where applicable 4.2.1.5, A** specific name shall be used for ingredients in the list of ingredients in accordance with the provisions set out in Section 4.1 (Name of the Food) except that:

**4.2.3.1 Except for those ingredients listed in section 4.2.1.4, and u**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, 4.2.1.6 and where applicable 4.2.1.5 shall be declared using the specified names listed in those sections.**

#### **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, 4.2.1.6 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 cm<sup>2</sup>, 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, 4.2.1.6 and where applicable 4.2.1.5.**

## **8. PRESENTATION OF MANDATORY INFORMATION**

(New)

### **8.3 Declaration of certain foods and ingredients**

**8.3.1** The foods and ingredients listed in sections 4.2.1.4, 4.2.1.6 and where applicable 4.2.1.5 shall be declared so as to contrast distinctly from the surrounding text, such as through the use of font type, style or colour.

**8.3.2** When the foods and ingredients in sections 4.2.1.4, 4.2.1.6 and where applicable 4.2.1.5 are declared in the list of ingredients, they may also be declared in a separate statement, which shall be placed near and in the same field of vision as the list of ingredients.

**8.3.2.1** The statement shall commence with the word 'Contains' (or equivalent word) and must declare all the foods and ingredients which are declared in the list of ingredients as applicable in accordance with section 8.3.1.

**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, 4.2.1.6 and where applicable 4.2.1.5 shall be declared, such as in a 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, 4.2.1.6 and where applicable 4.2.1.5 are declared as part of, or in conjunction with, the name of the food.

**PROPOSED DRAFT ANNEX TO THE GSLPF:  
GUIDELINES ON THE USE OF PRECAUTIONARY ALLERGEN LABELLING  
(FOR COMMENT AT STEP 3 THROUGH CL 2023/06/OCS-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 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 allergens caused by cross-contact in prepackaged<sup>1</sup> foods.

## 3. DEFINITIONS

For the purpose of these guidelines:

*Allergen* means the foods and ingredients listed in sections 4.2.1.4 and where applicable 4.2.1.5 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 allergen(s) due to cross-contact<sup>2</sup>.

## 4. GENERAL PRINCIPLES

4.1 Effective management practices and controls to prevent or minimize the unintended presence of allergens caused by cross-contact shall be implemented as outlined in 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 allergen(s) cannot be sufficiently controlled using these allergen management practices.

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.

4.3 PAL shall only be used if the presence of a protein from an allergen is equal to or above the action level<sup>3</sup> for this allergen, using the listed reference dose values in 4.3.1.

### 4.3.1 Reference doses

	<b>Reference dose (RfD) (mg total protein from the allergen)</b>
Walnut (and Pecan)	1.0
Cashew (and Pistachio)	1.0
Almond	1.0
Peanut	2.0
Egg	2.0
Milk	2.0
Sesame	2.0
Hazelnut	3.0
Wheat	5.0
Fish	5.0
Crustacea	200

<sup>1</sup> As defined in the *General Standard for the Labelling of Prepackaged Foods (CXS 1-1985)*

<sup>2</sup> *Allergen cross-contact* as defined in *Code of Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020)*

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



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 principles<sup>4</sup> for the purposes of determining an action level.

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.

## **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 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.

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<sup>4</sup> 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>.

**APPENDIX IV****LIST OF PARTICIPANTS****Members**

Australia  
Brazil  
Canada  
Chile  
China  
Columbia  
Costa Rica  
Cyprus  
El Salvador  
European Union  
France  
Greece  
Hungary  
India  
Indonesia  
Iran  
Ireland  
Japan  
Republic of Korea  
México  
Morocco  
Netherlands  
New Zealand  
Norway  
Poland  
Saudi Arabia  
Singapore  
South Africa  
Spain  
Sweden  
Switzerland  
Thailand  
Uruguay  
United Kingdom  
United States of America

**Observers**

Association of European Coeliac Societies  
European Chemical Industry Council  
European Federation of Allergy and Airways Disease  
European Vegetable Oil and Proteinmeal Industry  
Federation Internationale des Vins et Spiritueux  
Food Industry Asia  
FoodDrinkEurope  
Global Organization for EPA and DHA Omega-3  
Institute of Food Technologists  
International Chewing Gum Association  
International Confectionery Association  
International Council of Beverage Associations  
International Council of Grocery Manufacturers Associations  
International Dairy Federation  
International Fruit and Vegetable Juice Association  
International Food Additives Council  
International Probiotics Association  
International Special Dietary Foods Industries  
Organisation Internationale de la vigne et du vin