



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

46<sup>th</sup> Session

Virtual

27 September - 1 and 7 October 2021

### 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 at Step 3 on this draft should do so as instructed in CL 2021/21/OCS-FL available on the Codex webpage/Circular Letters 2021: <http://www.fao.org/fao-who-codexalimentarius/circular-letters/en/>

### INTRODUCTION

1. At the 45<sup>th</sup> Session of the Codex Committee on Food Labelling (CCFL45), the Committee agreed to start work 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 or advisory labelling (PAL)<sup>1</sup>. CCFL45 agreed to establish an electronic working group (eWG) chaired by Australia, and co-chaired by the United Kingdom and the United States of America.
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 on:
  - a) Whether the published criteria<sup>4</sup> for assessing additions and exclusions to the list is still current and appropriate.
  - b) Subject to the advice on the criteria above:
    - i) whether there are foods and ingredients that should be added to or deleted from the list.
    - ii) clarification of the groupings of foods and ingredients in the list.
    - iii) whether certain foods and ingredients, such as highly refined foods and ingredients, that are derived from the list of foods known to cause hypersensitivity can be exempted from mandatory declaration.
4. The CCFH has also requested FAO/WHO to 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) adopted at CAC43<sup>5</sup>. CAC noted CXC 80-2020<sup>6</sup> could be revised following scientific advice from FAO/WHO and completion of the work on guidance for PAL by CCFL.

<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> WHO Technical Report Series 896 (2000). Report of an ad hoc Panel on Food Allergens. Annex 4 of Evaluation of certain food additives and contaminants. Fifty-third report of the Joint FAO/WHO Expert Committee on Food Additives. <https://www.who.int/foodsafety/publications/jecfa-reports/en/>.

<sup>5</sup> [REP20/CAC](#), para 69 - 70

<sup>6</sup> [http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXC%2B80-2020%252FCXC\\_080e.pdf](http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXC%2B80-2020%252FCXC_080e.pdf)

5. In response to requests for scientific advice, an [Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens](#) (hereafter referred to as the FAO/WHO Expert Consultation) was convened between 30 November – 11 December 2020 for Part 1: Review and validation of Codex priority allergen list through risk assessment and 15 March – 2 April 2021 for Part 2: Review and establish threshold levels in foods of the priority allergens. A summary and conclusions report<sup>7</sup> for Part 1 was issued on 10 May 2021. Part 3 relating to PAL is expected later in 2021.

6. The project document also includes consideration of evidence based consumer understanding of allergen labelling and advisory statements. To this point, as members of the International Social Science Liaison Group (ISSLG)<sup>8</sup>, Food Standards Australia New Zealand (FSANZ) and the Food Standards Agency of the United Kingdom (FSA) collaborated on a literature review<sup>9</sup> of consumer response to allergen declarations and PAL to provide evidence for the revision of the GSLPF and development of guidance on PAL.

## TERMS OF REFERENCE

7. Working in English the eWG was to:

- Prepare proposed draft revisions and guidelines for circulation for comments at Step 3 and consideration by CCFL46;
- Take into account the scientific advice from the FAO/WHO and evidence based consumer understanding of allergen labelling and advisory statements.

## PARTICIPATION AND METHODOLOGY

8. An eWG was established in September 2019 with 33 Codex members, one Codex member organization, and 16 Codex observers participating since that time. A list of participants is provided at Appendix IV.

9. In October 2019 a consultation paper on the provisions in the GSLPF relevant to allergen labelling (Part 1) and development of guidance on PAL (Part 2) was circulated to the eWG with 28 responses (21 Codex Members, one Codex Member Organization, six Codex Observers) received.

10. A second consultation paper was circulated to the eWG in May 2020 seeking further comment on the scope and definitions for allergen labelling provisions in the GSLPF (Part 1) and the title, purpose, scope, definitions, and general principles for developing PAL guidance (Part 2). Thirty-two responses (23 Codex Members, one Codex Member Organization, eight Codex Observers) were received.

11. In view of the postponement of CCFL46, and taking advantage of the additional time available, a Circular Letter CL2021/9/OCS-FL relating only to the revision of provisions in the GSLPF relevant to allergen labelling (Part 1) was circulated in February 2021 to facilitate broader comment. Forty-one responses (28 Codex Members, 13 Codex Observers) were received. The list of respondents is provided at Appendix V.

12. In all eWG discussions, members consistently raised the need to take into account, when available, the scientific advice from the FAO/WHO and evidence based consumer understanding of allergen labelling.

13. This paper sets out the summary of discussions and presents proposals for the revision of GSLPF (Part 1) (Appendix II) and proposals for Guidance on precautionary allergen labelling (Part 2) (Appendix III). The full summary of discussions in the EWG and comments to CL2021/9/OCS-FL is presented in Appendix I.

## CONCLUSIONS

14. Consistent with the Terms of Reference, the eWG has worked through the GSLPF and reviewed provisions relevant to allergen labelling (with the exception of section 4.2.1.4 which is subject to FAO/WHO scientific advice) and also considered the development of guidance on the use of PAL. This has involved two rounds of eWG consultation, a Circular Letter, CL2021/09/OCS-FL to provide broader comment and having regard to consistency with other relevant texts including the *Code of Practice on Allergen Management for Food Business Operators* (CXC 80-2020).

---

<sup>7</sup> <http://www.fao.org/3/cb4653en/cb4653en.pdf>

<sup>8</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.

<sup>9</sup> Consumers and Allergen Labelling: a literature review on consumer response to allergen declarations and precautionary allergen labelling (October 2020) <https://www.foodstandards.gov.au/publications/Pages/Consumers-and-Allergen-Labelling.aspx> and <https://www.food.gov.uk/research/food-allergy-and-intolerance-research/consumers-and-allergen-labelling-literature-review>

15. Noting the Ad-hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens issued a summary and conclusions report<sup>10</sup> for *Part 1: Review and validation of Codex priority allergen list through risk assessment* on 10 May 2021, the eWG has not been able to consider this to provide recommendations.

16. In reviewing the GSLPF, new provisions specific to the declaration of foods and ingredients known to cause hypersensitivity have been considered to ensure allergen labelling assists consumers to make safe food choices and to increase harmonization and facilitate trade.

17. In developing guidance on use of PAL, the eWG has considered the title, purpose, scope, definitions, and general principles. Discussion on where the guidance should be located, any additional principles needed, and further consideration of provisions for the presentation of PAL have been held over to allow further progress on the review of provisions in the GSLPF, and to enable CCFL to consider the FAO/WHO scientific advice and the available consumer evidence including the ISSLG literature review.

## RECOMMENDATIONS

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

- i) proposed draft revisions to the GSLPF in Appendix II
- ii) proposed draft guidance for the use of PAL in Appendix III ; and the location and appropriate Codex text(s) for the guidance (e.g. an annex to the GSLPF or as standalone guidance).

19. Given the interrelationship between, and the complexity of the issues involved in, both parts of this work program (i.e. revision of provisions relevant to allergen labelling in the GSLPF (Part 1) and the development of guidance on the use of PAL (Part 2)), the Committee is invited to:

- a. consider whether the work should continue to be progressed together or separately.

---

<sup>10</sup> <http://www.fao.org/3/cb4653en/cb4653en.pdf>

## SUMMARY OF DISCUSSION

### PART 1 – REVIEW OF ALLERGEN LABELLING PROVISIONS IN THE GSLPF

20. The project document outlines the following elements for reviewing the allergen labelling provisions in the GSLPF (and related texts as required):

- a) Scope, definitions and clarity of the existing provisions.
- b) Presentation, legibility and the terms to be used, including the suitability of ingredient labelling provisions when making declarations.
- c) Subject to expert advice, the list of foods and ingredients in section 4.2.1.4 (i.e. additions, deletions or exemptions) and the clarity of the groupings in that list.

As item (c) is subject to the scientific advice from the FAO/WHO, the eWG only considered matters relating to a) and b) above.

#### i) Scope

21. The eWG had differing views on whether the current scope of the GSLPF is suitable and sufficiently clear for the purpose of declaring foods and ingredients known to cause hypersensitivity. This was particularly in regard to two elements: 'offered as such to the consumer' and 'for catering purposes' which were viewed by some as requiring clarification. Some eWG members noted the issue relating to 'foods for catering purposes' was broader than allergen labelling as it was also relevant to other CCFL work on the labelling of non-retail containers and internet sales/e-commerce, and they supported discussion and alignment across the differing work groups.

22. Given the differing views in the eWG, the Chairs sought broader feedback in the CL. In response most considered the scope of the GSLPF was clear and that it applied to prepackaged food only. Some responses also were of the view that a change to the scope of the GSLPF was outside the eWG terms of reference.

23. The CL also sought broader feedback on incorporating a new paragraph in Section 8 (Presentation of Mandatory Information) of the GSLPF with specific labelling provisions for the presentation of declarations of foods and ingredients known to cause hypersensitivity. This was proposed because the current scope of the GSLPF applies to 'labelling'<sup>11</sup> of prepackaged foods. However, section 4.2.1.4 as a section of paragraph 4.2 (List of ingredients) locates the declaration of food and ingredients known to cause hypersensitivity in the list of ingredients on the 'label'. The majority of the eWG agreed the declaration of the foods and ingredients listed in section 4.2.1.4 should apply to both the list of ingredients and labelling more broadly. This approach was supported to allow for greater consistency in the application, and tailoring, of requirements for declarations, including for foods which do not have ingredient lists or where allergen information is also provided outside the ingredient list.

24. Responses to the CL also supported this approach to improve harmonization, increase clarity for consumers, and make allergen declarations easier to understand. There were suggestions for edits to the drafted text as outlined below (see section iv below).

25. The Chairs are proposing no changes to the scope of the GSLPF but to include a new paragraph in Section 8 (Presentation of Mandatory Information) to ensure the declaration of the foods and ingredients listed in section 4.2.1.4 applies more broadly.

#### ii) Definitions

26. Most eWG members viewed the definitions for 'food' and 'ingredient' in GSLPF as appropriate for the purposes of section 4.2.1.4. The Chairs are not proposing changes to these definitions but CCFL may wish to give further consideration to the definition of 'ingredient' when the scientific advice from the FAO/WHO is received on the list of foods and ingredients in section 4.2.1.4.

27. As there are no definitions specific to the declaration of foods and ingredients known to cause hypersensitivity in the GSLPF, the eWG supported consistency where possible with other Codex texts including the *Code of Practice on Allergen Management for Food Business Operators* (CXC 80-2020). The eWG discussed proposed definitions for 'hypersensitivity', 'allergen', 'food allergy' and 'food intolerance'.

28. Responses to the CL were generally supportive of these proposed definitions but some preferred to consider them further once the FAO/WHO scientific advice is received. Others supported the definitions in principle but proposed some text changes. In particular a number of responses supported including reference

---

<sup>11</sup> "Labelling" includes any written, printed or graphic matter that is present on the label, accompanies the food, or is displayed near the food, including that for the purpose of promoting its sale or disposal.

to sulphites and lactose in the definition of hypersensitivity to ensure consistency with CXC 80-2020. Although the Chairs note the FAO/WHO Expert Consultation summary report subsequently issued recommends that foods and ingredients like lactose and sulphites, which cause food intolerances rather than immune-mediated responses, should be excluded from the list in section 4.2.1.4.

29. Some responses also supported inserting 'typically' before 'a protein' in the definition of allergen because it is not always the case that protein is the cause. The example of alpha-galactose as the causal agent for mammalian meat allergy was cited. However this change would require a change to CXC 80-2020 to maintain consistency.

30. Two responses also supported including reference to anaphylaxis in the 'food allergy' definition because it is a life-threatening reaction, medically documented and distinguishes it from non-immune mediated food hypersensitivities and food intolerances. Another supported including a footnote to 'non-IgE mediated' that describes Coeliac disease, to align with the approach used in CXC 80-2020.

31. Therefore, the Chairs are proposing for consistency with CXC 80-2020 to adopt the definition for 'allergen' and the footnote relating to coeliac disease along with the following proposed definitions for 'food allergy', 'food intolerance' and 'hypersensitivity' in the GSLPF. Although CCFL will need to consider inclusion of food intolerance in the definition for hypersensitivity based on the recommendations from the FAO/WHO Expert Consultation.

*"Allergen" means an otherwise harmless substance capable of triggering a response that starts in the immune system and results in an allergic reaction in certain individuals. In the case of foods, it is a protein which is found in food capable of triggering a response in individuals sensitised to it.*

*"Food allergy" means adverse immune reactions to certain food proteins, which may be immunoglobulin E (IgE) mediated and associated with anaphylaxis, non-IgE mediated<sup>1</sup>, or a combination of both.*

*"Food intolerance" means adverse reactions to food components that occur through non-immunological mechanisms.*

*"Hypersensitivity" means the repeatable adverse reaction to an allergen or other substance in food associated with IgE mediated food allergy, non-IgE mediated food allergy<sup>1</sup>, or food intolerance (i.e. sulphites, lactose).*

<sup>1</sup>*Includes coeliac disease which is a serious lifelong illness where the body's immune system attacks its own tissues when gluten is consumed. This causes damage to the lining of the gut and results in the inability of the body to properly absorb nutrients from food.*

### iii) **Mandatory Labelling of Prepackaged Foods**

32. The eWG considered text relating to mandatory declaration requirements in Section 4 Mandatory Labelling of Prepackaged Foods and Section 6 Exemptions from Mandatory Labelling Requirements. The eWG did not consider the list of foods and ingredients in section 4.2.1.4 as this is subject to the FAO/WHO scientific advice.

#### Compound ingredients

33. Section 4.2.1.3 of the GSLPF provides for the labelling of compound ingredients in the list of ingredients. The majority of eWG members supported foods and ingredients known to cause hypersensitivity to always be declared, even when present as part of a compound ingredient that constitutes less than 5% of the food, on the basis these foods and ingredients can still pose a risk to consumers. This view was also supported in CL responses. The eWG considered exceptions to this principle should only be made for individual foods and ingredients that have a demonstrated evidence of safety with food allergies, which is a subject currently being considered by the FAO/WHO expert consultation. The Chairs are therefore proposing changes to ensure foods and ingredients known to cause hypersensitivity when present in compound ingredients are always declared.

#### Terminology for declarations

34. Section 4.2.1.4 includes the list of foods and ingredients known to cause hypersensitivity that must be declared, but does not specify terms (words) to be used when making this declaration. The eWG and CL responses were generally supportive of standardising or aligning declaration terminology (or wording) to increase consistency and harmonization for consumers and industry alike.

35. There was support for including a new section in the GSLPF that would require allergen information to be provided in simple, plain language, preferably with reference to the common name or source of the allergen (e.g. milk). Some CL responses commented the proposed text for the new section 4.2.1.5 was ambiguous (particularly 'well understood') and needed to be made more specific. It was suggested this could be achieved by requiring the use of terms listed in section 4.2.1.4 or providing examples. However, the Chairs recognise

that 'well understood' may not be clear, and have proposed replacing these words with the alternative of 'commonly known'.

#### Ingredients obtained through biotechnology

36. Section 4.2.2 relates to ingredients obtained through biotechnology and the need to provide adequate information on the presence of an allergen. The eWG considered whether changes were required to this section but most supported retaining the section unchanged. Some eWG members supported removal of section 4.2.2, because biotechnological processes used in the production of ingredients are well controlled, including the presence of notifiable allergens. One eWG member suggested the section could be expanded beyond biotechnology, to production of foods from other novel technologies and to allergenic proteins coming from novel sources (e.g. yeast producing milk proteins). However this extends beyond the scope of the work on allergen labelling.

37. The CL responses generally supported the proposal to retain the text unchanged. However several responses considered section 4.2.2 was unnecessary either because there has been significant progress in developing greater and more rigorous safety assessments for biotechnology, or because there are Codex guidelines for the safety of biotechnology (i.e. CXG 44-2003, CXG 45-2003, CXG 46-2003). The Chairs consider there was strong support for retaining section 4.2.2 in its current form, and so are not proposing any changes. However, CCFL may wish to consider if other work is needed to review section 4.2.2 more generally.

#### Ingredient and class names

38. Most eWG members considered there was a need to clarify the use of class names to ensure the source of an ingredient known to cause hypersensitivity is clearly identified (e.g. starch derived from wheat, caseinates from milk), and that there is consistent terminology (or wording) when referring to an allergen in a class name. Specifically, class names should include reference to the names of the foods and ingredients listed in section 4.2.1.4, by listing the food and ingredient alongside the class name unless the class name itself already refers to the food and ingredient (e.g. 'fish').

39. On the basis of eWG feedback, the Chairs proposed an amendment to section 4.2.3.1 so that the proposed new provision for using terms for the source of the food and ingredient listed in section 4.2.1.4 (new section 4.2.1.5) would apply to class names. The majority of CL responses supported this approach citing the amendments would result in clarity for food-allergic consumers and would assist national governments in setting more specific class naming requirements. A smaller number preferred to wait for the outcomes of the FAO/WHO expert consultation before supporting any changes to section 4.2.3.1. However, the Chairs are proposing amendment to section 4.2.3.1.

#### Processing aids and carry-over of food additives

40. Section 4.2.4.2 exempts certain food additives and processing aids from declaration in the list of ingredients. The section also states the exemption does not apply to food additives and processing aids listed in section 4.2.1.4. However, section 4.2.1.4 does not overtly recognise food additives and processing aids as foods and ingredients known to cause hypersensitivity, but rather they are captured by virtue of being derived as products of these foods and ingredients.

41. The majority of the eWG and responses to the CL supported the need for further clarity on food additives and processing aids not being exempt from declaration in the list of ingredients. However, some commented that further clarification is required for food additives or processing aids which have been refined/processed so the allergenic protein has been removed or is below a defined limit. The Chairs note the request for scientific advice includes whether certain foods and ingredients, such as highly refined foods and ingredients, that are derived from the list of foods known to cause hypersensitivity can be exempted from mandatory declaration. At this time the Chairs are proposing to amend section 4.2.4.2 to clarify that the exemption does not apply to food additives and processing aids that contain or are derived from the foods and ingredients listed in 4.2.1.4. However, CCFL may wish to consider exemptions in the light of the FAO/WHO Expert Consultation recommendations.

#### Exemptions for mandatory labelling requirements

42. Section 6 of the GSLPF provides small units (largest surface area is less than 10cm) with an exemption from section 4.2 (List of Ingredients), which results in small packages being exempt from declaring foods and ingredients known to cause hypersensitivity as listed in section 4.2.1.4.

43. Most eWG members were of the view the exemption should not apply to section 4.2.1.4, given the health risk associated with foods and ingredients known to cause hypersensitivity is the same regardless of the surface area of the package containing a food. The majority of CL responses supported removing this exemption for similar reasons. In addition, responses also noted the draft provision in section 8 of the GSLPF for a statement summarising allergens (see below) would provide small units with a limited space option for declaring foods and ingredients known to cause hypersensitivity.

## Proposed amendments to Section 4 and Section 6

44. Based on the comments received as discussed above, the Chairs are proposing the changes (bolded and strikethrough) to the following sections in Section 4 Mandatory Labelling of Prepackaged Foods and to Section 6 Exemptions from Mandatory Labelling Requirements in the GSLPF:

*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 **[those listed in section 4.2.1.4 and]** food additives which serve a technological function in the finished product, need not be declared.*

**[4.2.1.5 Declaration of the foods and ingredients listed in section 4.2.1.4 shall be made using commonly known terms for the source of the food and ingredient as part of, or in conjunction with, the relevant ingredient name.]**

~~4.2.3.1 [Except for those ingredients listed in section 4.2.1.4, and~~ Unless a general class name would be more informative, the following class names may be used. **In all cases, the foods and ingredients listed in section 4.2.1.4 must be declared in accordance with section 4.2.1.5.]**

*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 additive and processing aids **[that contain or are derived from the foods and ingredients]** listed in section 4.2.1.4.*

## 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 section 4.2.1.4.]***

### iv) Presentation of mandatory information

45. Evidence indicates the presentation (location, format and terminology) of allergen information plays an important role in the communication of allergen information on food labels<sup>12</sup>. In particular consumers prefer allergen information to be placed in a consistent location and format, using plain language, to enable the faster and easier identification of allergen information.

46. Section 8 of the GSLPF includes provisions for the presentation of mandatory information on the labels of prepackaged foods but does not include specific provisions for the declaration of foods and ingredients known to cause hypersensitivity. The majority of eWG members supported including provisions for the format and presentation of declarations.

47. As noted previously (see section i Scope and structure), a new section 8.3 was proposed in the GSLPF with provisions for the presentation of declarations of the foods and ingredients known to cause hypersensitivity. The majority of responses to the CL supported the inclusion of this new section. Some responses commented that section 8.3 should have flexibility so that countries can choose to present the information in a way that best suits their consumers and that the heading should be changed to 'Declarations of foods and ingredients known to cause hypersensitivity' for consistency with the terminology used elsewhere in the GSLPF. Others also commented that further guidance should be provided on "contrast distinctly from surrounding text" in proposed section 8.3.1 and on needing another section to ensure legibility of information, using similar text to that already used in the *Guidelines on Nutrition Labelling* (CXG 2-1985).

48. There were also comments on the provision for making declarations in a separate statement (proposed section 8.3.2) including that it be 'placed in close proximity to the statement of ingredients' is not specific enough and consideration is given to requiring all foods and ingredients listed in section 4.2.1.4 to be included in the 'contains' statement. For foods exempt from providing an ingredient list, two responses supported providing flexibility by allowing declarations to be made in other formats e.g. voluntarily providing an ingredient list.

49. Some responses also noted clarity was needed on how to declare foods and ingredients known to cause hypersensitivity for single ingredient foods and proposed the addition of another section.

<sup>12</sup> Consumers and Allergen Labelling: a literature review on consumer response to allergen declarations and precautionary allergen labelling (October 2020) <https://www.foodstandards.gov.au/publications/Pages/Consumers-and-Allergen-Labelling.aspx> and <https://www.food.gov.uk/research/food-allergy-and-intolerance-research/consumers-and-allergen-labelling-literature-review>

50. One response questioned how declaration of cereals containing gluten would be managed in a summary statement in relation to the gluten-free conditions in *Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten* (CXS 118-1979), 2.1 Definition, 2.1.1 (contains wheat, barley, rye or oats and has less than 20 mg/kg gluten). However the Chairs note this is the situation for the existing requirement to declare cereals containing gluten in the ingredient list, and while CCFL may wish to consider how cereal declarations operate in conjunction with CXS 118-1979, this should not preclude the inclusion of provisions for a 'contains' statement.

51. Based on the comments received, the Chairs are proposing the following draft section 8.3 for inclusion in the GSLPF.

*8.3 Declared foods and ingredients known to cause hypersensitivity*

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

*8.3.1.1 The font type, style and a minimum font size as well as the use of upper and lower case letters should be considered by competent authorities to ensure legibility of declarations about foods and ingredients known to cause hypersensitivity.*

*8.3.2 In addition to the list of ingredients, the foods and ingredients listed in section 4.2.1.4 may be declared in a separate statement, which shall be placed near and within the same field of view as the list of ingredients.*

*8.3.2.1 This statement shall commence with the word 'Contains' (or equivalent word) and declare all foods and ingredients known to cause hypersensitivity in the food using commonly known terms for the source of the food and ingredient.*

*8.3.3 Where a food is exempt from declaring a list of ingredients, the foods and ingredients listed in section 4.2.1.4 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 known to cause hypersensitivity are declared as part of, or in conjunction with, the name of the food in accordance with section 4.2.1.5.*

## **PART 2 – GUIDANCE ON THE USE OF PRECAUTIONARY ALLERGEN OR ADVISORY LABELLING**

52. Internationally PAL is used as a means of providing consumers with information about the unintentional presence of allergens due to cross-contact during handling, storage, transport and manufacturing of food. Examples of PAL statements include *May contain...*, *May be present...*, *Made in a factory which also handles...*

53. There is no internationally agreed approach for PAL. Some nations/regions regulate the use of PAL statements, while others allow the voluntary use of PAL, but may require specific wording (for example, 'may contain...'). There are also no defined international reference doses to derive threshold (action) levels to inform risk management decisions on the use of PAL. Some countries specify threshold (action) levels for the use of PAL whereas other countries require a specific PAL statement when there is the risk of allergen cross-contact, but do not set any regulatory thresholds.

54. Inconsistent application of PAL reduces its effectiveness, and that inconsistency may be attributed to a lack of agreed threshold (action) levels and assessment tools for making decisions to use PAL. The absence of thresholds and tools can lead to an overuse of PAL. As a consequence, the presence of PAL does not always reflect potential allergen cross-contact and risk to the consumer. Further, consumers cannot be confident that the absence of PAL means a risk assessment has been performed and the food is safe to eat. It is therefore not surprising that evidence indicates consumers view PAL as unhelpful and confusing, and that it ultimately restricts rather than enables safe food choices<sup>13</sup>. Consistent and harmonised approaches to the use of PAL can help consumers make safer food choices.

55. The project document outlines the main aspects for developing guidance on the use of PAL as including:

- a) Principles for the use of PAL
- b) Labelling provisions, including definition(s) for PAL
- c) The location and appropriate Codex text(s) for the guidance.

---

<sup>13</sup> Consumers and Allergen Labelling: a literature review on consumer response to allergen declarations and precautionary allergen labelling (October 2020) <https://www.foodstandards.gov.au/publications/Pages/Consumers-and-Allergen-Labelling.aspx> and <https://www.food.gov.uk/research/food-allergy-and-intolerance-research/consumers-and-allergen-labelling-literature-review>

The eWG only considered a) and b) above. Discussion on where the guidance should be located (e.g. as an annex to the GSLPF, or a standalone text) was proposed to occur at a later point.

#### v) Title of the guidance

56. There were mixed eWG views on the name for the labelling of the unintentional presence of allergens and therefore the title of the proposed draft guidance. Most supported 'Guidelines for the use of Precautionary Allergen Labelling' noting 'precautionary allergen labelling' is a well-known term used internationally and in scientific literature, which correctly reflects the nature and purpose of the labelling in question. The term 'advisory' was considered not specific to food allergy and therefore confusing. Those supporting 'precautionary allergen or advisory labelling' indicated that it provided a single harmonised term but did not preclude countries from using other terms. As an alternative, one member proposed 'precautionary or advisory allergen labelling'.

57. Some members noted the title should reflect the agreed purpose, scope and definitions of the guidance and supported keeping the title in square brackets until CCFL has discussed the draft guidance and considered the scientific advice and consumer evidence. Therefore, the Chairs have placed the title in square brackets and used the 'PAL' acronym in the draft guidance.

#### vi) Purpose

58. There was general support for the proposed draft purpose, although a number of eWG members made suggested changes to simplify and clarify the text. Some eWG members noted the importance of having consistency with CXC 80-2020 for example by including the element of 'risk from the unintentional presence of allergens due to cross-contact'. There was also support for the purpose being to 'facilitate consistent and harmonised approaches' to the use of PAL plus a suggestion from one eWG member to include reference to ensuring PAL is 'effective'.

59. Most considered a reference to 'informing appropriate risk management decisions' was not needed because PAL should be based on a risk assessment process, and that this can be incorporated into the guidelines. Equally the concept of 'all possible mitigation measures being taken' to minimise the cross-contact risk was considered unnecessary. The Chairs note that including a reference to CXC 80-2020 in the guidance (e.g. in the scope section) should capture this concept anyway.

60. The Chairs are proposing the following draft purpose:

*To facilitate consistent and harmonised approaches to the effective use of [precautionary allergen or advisory labelling] (PAL) for communicating to consumers with food allergy about the risk from the unintentional presence of allergens in food due to cross-contact.*

#### vii) Scope

61. The eWG was divided in their support for the proposed scope. The key issues included the need to clarify the application to foods 'for catering purposes' (given the broader discussion on the scope of the GSLPF); to include specific reference to the foods and ingredients listed in section 4.2.1.4 of the GSLPF; and whether to include 'risk' from the 'possible' unintentional presence of allergens, due to the view that PAL is intended to indicate a possible rather than definite unintended presence.

62. Noting CXC 80-2020 definitions for 'allergens' and 'allergen cross-contact' are proposed to be included in the guidance (see below), and that CCFH has asked for scientific advice on threshold levels for the priority allergens relevant to CXC 80-2020, reference to the listed foods and ingredients in section 4.2.1.4 has not been included. In regard to 'for catering purposes', the Chairs are proposing the approach for prepackaged foods, as it applies to the GSLPF (i.e. all prepackaged food offered as such to the consumer or for catering purposes'), is also applied to the guidance. Inclusion of a reference to CXC 80-2020 recognises its role in managing cross-contact and supporting the appropriate use of PAL.

63. The Chairs are proposing the following draft scope:

*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).*

*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.*

#### viii) Definitions

64. The eWG identified various definitions that may be required for the guidance. For consistency and harmonisation across Codex texts the eWG supported adopting CXC 80-2020 definitions for 'allergen' and 'allergen cross-contact'.

*Allergen means an otherwise harmless substance capable of triggering a response that starts in the immune system and results in an allergic reaction in certain individuals. In the case of foods, it is a protein which is found in food capable of triggering a response in individuals sensitised to it.*

*Allergen cross-contact occurs when an allergenic food, or ingredient, is unintentionally incorporated into another food that is not intended to contain that allergenic food.*

65. However, the eWG was divided in support for the draft PAL definition<sup>14</sup> as proposed by CCFH when developing CXC 80-2020. The definition was revised to make it more consistent with, and provide a reference to CXC 80-2020, and to clarify that PAL is a statement and not a label (as defined in the GSLPF). Some members proposed to also include reference to Good Manufacturing Practice (GMP), however CXC 80-2020 refers to Good Hygiene Practices (GHP) consistent with the General Principles of Food Hygiene (CXC 1-1969).

66. Noting the proposed adoption of 'allergen' and 'allergen cross-contact' from CXC 80-2020, the Chairs are proposing the following definition for PAL:

*[Precautionary allergen or advisory labelling] is a statement indicating the allergen(s) that may be present in a food due to allergen cross-contact during the production, manufacture and transport of food, which may occur despite implementing allergen management practices and controls such as in the Code of Practice on Food Allergen Management for Food Business Operators (CXC 80-2020).*

67. In addition, the Chairs are proposing to include relevant definitions in the GSLPF e.g. 'consumer', 'prepackaged', 'labelling' and 'label' as may be appropriate.

#### **ix) General Principles**

68. The eWG considered a number of general principles that could apply to the use of PAL relating to evidence based assessment of risk, the use of established reference doses, and the clarity and comprehension of PAL statements.

69. For the first principle relating to the use of quantitative risk assessment, some eWG members preferred to wait for FAO/WHO scientific advice on whether this approach is feasible to inform risk management decisions for the use of PAL. Other members were of the view that not all businesses have the capacity to perform quantitative risk assessments and suggested changes to recognise that quantitative risk assessments are important but not the only tool for informing the decision to use PAL (i.e. qualitative assessments may be useful also).

70. The eWG also had mixed views on the second principle relating to the use of PAL statements based on established reference doses. Some eWG members considered the current absence of any internationally agreed threshold values meant that the proposed principle could not be supported. However, others agreed with including the principle, noting established reference doses are essential to any regulatory framework for PAL, and that setting thresholds would prevent the indiscriminate use of PAL. Some eWG members requested guidance on alternative methods for situations where threshold levels prove to be scientifically impossible or difficult to establish for an allergen. However, others disagreed with including alternative methods, either because it is unclear how alternatives to established reference doses, such as general delimitations, could be established, or that these alternatives need further definition.

71. Noting the FAO/WHO expert group is considering thresholds, at this stage the Chairs are proposing the following general principles:

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

*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.*

#### **x) Clarity and comprehension of PAL**

<sup>14</sup> Precautionary allergen labelling means a label indicating the allergens (other than those that are listed as ingredients) that may be present in the product because of unavoidable cross-contact (e.g. "may contain") REP19/FH Appendix III

72. The need for PAL to be clear and understandable is supported by consumer evidence<sup>15</sup>. Findings also indicate consumers find it difficult to understand the risks from consuming a product with PAL due to the often unclear and vague nature of these statements.

73. The eWG considered consumer understanding of PAL is important for effectively managing the risk from allergen cross-contact. Based on this, the eWG was supportive of the need for harmonisation in respect to the location, format and presentation, including standardised wording of PAL. Some eWG members noted inclusion of these aspects would result in clearer, more consistent information for consumers and facilitate trade.

74. The eWG had mixed views on whether to include a principle about consumer messaging and education programs for communicating risk and increasing consumer understanding of PAL. Some eWG members were generally supportive of these types of initiatives but noted they were outside the remit of Codex and were a matter for national governments. Whereas other eWG members noted the proposed draft guidance on front-of-pack nutrition labelling has high level principles about consumer awareness and education programs.

75. The FAO/WHO expert consultation is to consider PAL in the latter half of 2021, which may assist with the development of specific guidance to ensure PAL is clear and understandable to consumers. Further, a number of comments noted the interrelationship between the review of allergen labelling provisions in the GSLPF and the development of guidance for PAL, specific to how PAL information could be presented.

76. On this basis, the Chairs are proposing that once the review of provisions relevant to allergen labelling have been considered, and the scientific advice is received, then guidance relating to the following can be drafted:

- The presentation of PAL such as the location on the label (e.g. near the ingredient list) and format (e.g. distinguishable from surrounding text).
- Language and the use of standardised wording for PAL, including designated prefix(es) (e.g. 'may contain' or similar words).
- The need for governments to provide consumer messaging and education programs for communicating risk and increasing consumer understanding of PAL.

---

<sup>15</sup> Consumers and Allergen Labelling: a literature review on consumer response to allergen declarations and precautionary allergen labelling (October 2020) <https://www.foodstandards.gov.au/publications/Pages/Consumers-and-Allergen-Labelling.aspx> and <https://www.food.gov.uk/research/food-allergy-and-intolerance-research/consumers-and-allergen-labelling-literature-review>

**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 in **bold font**)

**(FOR COMMENTS THROUGH CL 2021/21/OCS-FL)**

## **2. DEFINITION OF TERMS**

For the purpose of this standard:

### **NEW**

**“Allergen”** means an otherwise harmless substance capable of triggering a response that starts in the immune system and results in an allergic reaction in certain individuals. In the case of foods, it is a protein which is found in food capable of triggering a response in individuals sensitised to it.

**“Food allergy”** means adverse immune reactions to certain food proteins, which may be immunoglobulin E (IgE) mediated and associated with anaphylaxis, non-IgE mediated<sup>1</sup>, or a combination of both.

**“Food intolerance”** means adverse reactions to food components that occur through non-immunological mechanisms.

**“Hypersensitivity”** means the repeatable adverse reaction to an allergen or other substance in food associated with IgE mediated food allergy, non-IgE mediated food allergy<sup>1</sup>, or food intolerance (i.e. sulphites, lactose).

## **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 **[those listed in section 4.2.1.4 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 and shall always be declared:<sup>2</sup>

- 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.]

### **NEW**

**[4.2.1.5 Declaration of the foods and ingredients listed in section 4.2.1.4 shall be made using commonly known terms for the source of the food and ingredient as part of, or in conjunction with, the relevant ingredient name.]**

### **RENUMBER existing 4.2.1.5 and 4.2.1.6**

<sup>1</sup> Includes coeliac disease which is a serious lifelong illness where the body's immune system attacks its own tissues when gluten is consumed. This causes damage to the lining of the gut and results in the inability of the body to properly absorb nutrients from food.

<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).

**4.2.3** 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 section 4.2.1.4 must be declared in accordance with section 4.2.1.5.]**

#### **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 additive and processing aids **[that contain or are derived from the foods and ingredients]** listed in section 4.2.1.4.

### **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 section 4.2.1.4.]**

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

**(NEW)**

#### **8.3 Declared foods and ingredients known to cause hypersensitivity**

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

**8.3.1.1** The font type, style and a minimum font size as well as the use of upper and lower case letters should be considered by competent authorities to ensure legibility of declarations about foods and ingredients known to cause hypersensitivity.

**8.3.2** In addition to the list of ingredients, the foods and ingredients listed in section 4.2.1.4 may be declared in a separate statement, which shall be placed near and within the same field of view as the list of ingredients.

**8.3.2.1** This statement shall commence with the word 'Contains' (or equivalent word) and declare all foods and ingredients known to cause hypersensitivity in the food using commonly known terms for the source of the food and ingredient.

**8.3.3** Where a food is exempt from declaring a list of ingredients, the foods and ingredients listed in section 4.2.1.4 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 known to cause hypersensitivity are declared as part of, or in conjunction with, the name of the food in accordance with section 4.2.1.5.

**PROPOSED DRAFT GUIDELINES FOR THE USE OF  
[PRECAUTIONARY ALLERGEN OR ADVISORY LABELLING]  
(FOR COMMENT THROUGH CL2021/21/OCS-FL)**

## **1. PURPOSE**

To facilitate consistent and harmonised approaches to the effective use of [precautionary allergen or advisory labelling] (PAL) for communicating to consumers with food allergy about the risk from the unintentional presence of allergens in food due to cross-contact.

## **2. SCOPE**

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.

## **3. DEFINITIONS**

For the purpose of these guidelines:

*Allergen* means an otherwise harmless substance capable of triggering a response that starts in the immune system and results in an allergic reaction in certain individuals. In the case of foods, it is a protein which is found in food capable of triggering a response in individuals sensitised to it.

*Allergen cross-contact* occurs when an allergenic food, or ingredient, is unintentionally incorporated into another food that is not intended to contain that allergenic food.

*[Precautionary allergen or advisory labelling]* is a statement indicating the allergen(s) that may be present in a food due to allergen cross-contact during the production, manufacture and transport of food, which may occur despite implementing allergen management practices and controls such as in the *Code of Practice on Food Allergen Management for Food Business Operators* (CXC 80-2020).

## **4. GENERAL PRINCIPLES**

4.1 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.

4.2 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.

## **5. PRESENTATION OF PAL**

*Yet to be drafted but to include guidance on location on label, format and language.*

## LIST OF eWG PARTICIPANTS

**Members**

Argentina  
Australia  
Brazil  
Canada  
Chile  
China  
Costa Rica  
Egypt  
European Union  
Germany  
Greece  
Guatemala  
Honduras  
Hungary  
India  
Indonesia  
Iran  
Ireland  
Japan  
Malaysia  
México  
New Zealand  
Nicaragua  
Peru  
Philippines  
Poland  
Russia  
Singapore  
South Korea  
Sweden  
Switzerland  
United Kingdom  
United States of America

**Observers**

European Federation of Allergy and Airways Disease  
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 Food Additives Council  
International Organization of the Flavor Industry  
International Special Dietary Foods Industries  
Organisation Internationale de la vigne et du vin  
Safe Supply of Affordable Food Everywhere

**LIST OF RESPONDENTS TO CL2021/9/OCS-FL****Members**

Argentina  
 Australia  
 Brazil  
 Canada  
 Chile  
 Colombia  
 Costa Rica  
 Cuba  
 Dominican Republic  
 Ecuador  
 Egypt  
 Guatemala  
 Honduras  
 India  
 Iran  
 Japan  
 Kenya  
 Mexico  
 New Zealand  
 Panama  
 Peru  
 Philippines  
 Paraguay  
 Thailand  
 United Arab Emirates  
 United States of America  
 Uruguay  
 Venezuela (Bolivarian Republic of)

**Observers**

Association of European Coeliac Societies  
 European Federation of Allergy and Airways  
 Diseases Patients' Associations  
 The European Federation of the Associations of  
 Dietitians  
 FoodDrinkEurope  
 Food Industry Asia  
 Federation Internationale des Vins et Spiritueux  
 International Confectionery Association  
 International Council of Beverage Associations  
 International Council of Grocery Manufacturers  
 Associations  
 International Dairy Federation  
 International Food Additives Council  
 International Fruit and Vegetable Juice  
 Association  
 International Special Dietary Food Industries