



Food and Agriculture
Organization of the
United Nations



World Health
Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda Item 5.1

CX/FL 24/48/5 (Part A)
August 2024

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD LABELLING

Forty-eighth Session

Quebec City, Canada

27 October – 1 November 2024

REVISION TO THE GENERAL STANDARD FOR THE LABELLING OF PRE-PACKAGED FOODS (CXS 1-1985): PROVISIONS RELEVANT TO ALLERGEN LABELLING (STEP 7)

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

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

INTRODUCTION

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

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

- The work also includes consideration of evidence based consumer understanding of allergen labelling and

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

² [REP19/CAC](#) para 99

³ [REP19/FL](#), para. 98(c)

advisory statements. Food Standards Australia New Zealand (FSANZ) and the Food Standards Agency (UK) as members of the International Social Science Liaison Group (ISSLG)⁴, collaborated on a [literature review](#) to provide evidence for the revision of the GSLPF and development of guidance on PAL.

6. At CCFL47, the Committee considered draft revisions to the GSLPF⁵ and agreed to:
 - a) forward the revision to the GSLPF provisions relevant to allergen labelling (Appendix II of REP23/FL) to CAC46 for adoption at Step 5.
 - b) re-establish the EWG, chaired by Australia, the United Kingdom and United States of America.
 - c) inform CCFH of the progress of the work and in particular draw their attention to the definition for food allergen and the lists of allergens in 4.2.1.4 and 4.2.1.5.
7. At CAC46 the proposed draft revision to the GSLPF provisions relevant to allergen labelling was adopted at Step 5⁶.
8. The proposed timeline for the allergen labelling work included in the project document⁷ set an expectation that work could be completed in three sessions i.e. at CCFL48.

TERMS OF REFERENCE

9. Working in English, the EWG was to further develop the draft revision of the GSLPF relevant to allergen labelling taking into account discussions at CCFL47, for circulation at Step 6 and consideration by CCFL48.

PARTICIPATION AND METHODOLOGY

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

CONCLUSIONS

15. Consistent with the Terms of Reference, the EWG has taken into account the discussion and written comments from CCFL47 and further developed the draft revision of the GSLPF relevant to allergen labelling.
16. As the Expert Committee released all final reports by February 2024 the EWG was able to take into account all available scientific advice from the Expert Committee when considering the proposed draft revision to the GSLPF. The EWG also considered the ISSLG evidence on consumer understanding of allergen labelling.
17. Noting the GSLPF provisions relevant to allergen labelling was adopted at Step 5 and advanced to Step 6 and as the EWG did not reach agreement on all aspects of the draft text, to move the proposed draft text forward the EWG Chairs suggest CCFL focus its discussion on the following areas:
 - a) Definition of 'food allergen' – two draft definitions are provided in Appendix II for CCFL consideration.
 - b) Section 4.2.1.6 - Exemptions in relation to the scientific advice and proposed alternate text, and whether to provide a list of exemptions in the GSLPF (or elsewhere), or alternatively to reference the 'current accepted exemptions' as examples.
 - c) Section 4.2.1.7 - Sulphite and proposed revised text which includes the option of 'food as offered to the consumer' and 'food as consumed'.
 - d) Section 8.3 – Declaration of certain foods and ingredients and specifically the proposed revised text for sections 8.3.1, 8.3.2 and 8.3.2.1.

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

⁵ [REP23/FL](#) paragraphs 19-54

⁶ [REP23/CAC](#) paragraphs 88-90

⁷ [REP19/FL](#) Appendix IV

18. Subject to agreement at CCFL48 it would be timely to again provide CCFH with advice on progress to help maintain consistency between texts particularly in regard to relevant definitions and the lists of priority allergens.

RECOMMENDATIONS

19. CCFL48 is invited to consider:
- i) key issues described in paragraph 17.
 - ii) whether the revision to the GSLPF (Appendix II) is ready to advance to Step 8.
 - iii) whether to provide further advice to CCFH to ensure consistency of the *Code of Practice on Allergen Management for Food Business Operators* (CXC 80-2020) with the proposed draft revision.

APPENDIX I**OVERVIEW OF EWG DISCUSSIONS****REVISION OF ALLERGEN LABELLING PROVISIONS IN THE GSLPF**

1. This part discusses the proposed draft revision to the GSLPF provisions relevant to allergen labelling as provided at Appendix II, taking into account comments from CCFL47 and the EWG feedback received through CP1 and CP2.

2. Based on the level of agreement and CCFL47 agreeing to advance the proposed draft text to CAC for adoption at Step 5, the EWG discussion focused on the following sections to progress revision of the GSLPF.

Section 2 – Definition of ‘food allergen’

3. At CCFL47 the Committee agreed to a definition of ‘food allergen’ but to keep ‘substance or processing aid’ in square brackets for further consideration.

4. The EWG considered the bracketed text and the existing definitions of ‘food’ and ‘ingredient’ in the GSLPF which capture ‘substance’, ‘food additive’ and ‘processing aid’. EWG feedback supported removal of ‘substance’ but for clarity and consistency including reference to both ‘food additive’ and ‘processing aid’, and also to remove ‘used in food’ as this was considered redundant. A further change was made by adding ‘containing’ to ensure consistency with the draft PAL guidelines that are proposed to also rely on this definition, but refer to ‘food allergen’ as being the foods listed in the reference dose table (and not to proteins as in the proposed definition). The draft definition was revised as follows:

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

Clean version

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

5. The majority of EWG members (31/33 responses) supported the amended definition. However, a CM proposed that as the definition for ‘food’ already includes the term ‘substance’ which covers ingredients, food additives and processing aids (as per the existing definitions in the GSLPF), and labelling is applied to a food allergen not the protein in the allergenic food, it would help clarity to amend the draft definition as follows:

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

Clean version

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

6. As CCFL47 had agreed to the draft definition with bracketed text, the Chairs have included both draft definitions in Appendix II to allow CCFL the opportunity to further consider the draft food allergen definition.

7. Noting the need for coordination with CCFH, it is also suggested that once a final definition of food allergen is agreed by CCFL, this should be referred to CCFH for their consideration in relation to the *Code of Practice on Allergen Management for Food Business Operators* (CXC 80-2020).

Section 4.2.1.4 and 4.2.1.5 – Scientific names for tree nuts

8. At CCFL47 it was noted that as agreed by the Virtual Working Group the scientific names for specific tree nuts in sections 4.2.1.4 and 4.2.1.5 would be included in the draft text at a later stage¹.

9. Based on allergy risk assessments by the European Food Safety Authority (EFSA)², the EWG considered the following scientific names, noting these names are also used in other Codex texts^{3,4}:

¹ [REP23/FL](#) paragraph 37

² EFSA (2014) Scientific Opinion on the evaluation of allergenic foods and food ingredients for labelling purposes. EFSA Journal 2014;12(11):3894. Doi: [10.2903/j.efsa.2014.3894](#).

³ *Code of practice for the prevention and reduction of aflatoxin contamination in tree nuts* (CXC 59-2005)

⁴ *Standard for unshelled pistachio nuts* (CXS 131-1981)

Tree nuts listed in section 4.2.1.4

- Almond (*Prunus amygdalus*)
- Cashew (*Anacardium occidentale*)
- Hazelnut (*Corylus avellana*)
- Pecan (*Carya illinoensis*)
- pistachio (*Pistacia vera*)
- walnut (*Juglans regia*, *Juglans nigra*)

Tree nuts listed in section 4.2.1.5

- Brazil nut (*Bertholletia excelsa*)
- macadamia (*Macadamia integrifolia*, *Macadamia tetraphylla*)
- pine nut (*Pinus spp.*)

10. Some EWG members commented that the proposed species for hazelnut, macadamia, pecan, pistachio and walnut do not encompass all species of these tree nuts known to cause allergies that could be marketed and consumed globally. It was noted for hazelnut and walnut there can be some species not listed that are locally harvested but this was not the case for pecan, pistachio and macadamia. Therefore for hazelnut and walnut the collective species *Corylus spp.* and *Juglans spp.* respectively are included in the proposed draft text in Appendix II.

Section 4.2.1.6 – Exemptions

11. At CCFL47 section 4.2.1.6 was retained in square brackets pending the availability of the Expert Committee's Part 4 report as follows:

[4.2.1.6 Subject to evaluation using established criteria⁷, 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.]

⁷FAO 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>.

12. The Expert Committee's Part 4 report was released in February 2024 allowing the EWG to consider section 4.2.1.6 in CP2. Noting the report recommends and outlines a flowchart process⁵ that can be used to guide future development and evaluation of derivative exemptions, the Chairs proposed to remove the square brackets and update footnote 7 to reference the Part 4 report. EWG feedback generally supported (29/33 responses) this, although two CM and one CO did not support removing the square brackets until CCMAS has finished work on analytical methods for detecting allergenic protein in foods.

13. A CMO while supporting removal of the square brackets, considered the Part 4 report and in particular the flow chart should not be binding as criteria. They agreed with a weight of evidence approach and that an exposure assessment is an essential component of the safety assessment process as stated by the Expert Committee's report, but noted the flowchart does not always require an exposure assessment and therefore considered it is unclear how an established history of safe use can be determined without an exposure assessment. They also sought clarification on why the evaluation of the production process comes at the end of the risk assessment process rather than before the exposure assessment. To address this they proposed the following alternate text with an additional change to include 'regional authorities':

~~*[4.2.1.6 Subject to evaluation using established criteria⁷, 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. Such exemptions shall be subject to an evaluation that should follow a weight of evidence approach that includes an exposure assessment and other established criteria⁷.]*~~ ***Regional or national authorities may exempt ingredients derived from foods listed in section 4.2.1.4, and where applicable section 4.2.1.5, from being declared. Such exemptions shall be subject to an evaluation that should follow a weight of evidence approach that includes an exposure assessment and other established criteria⁷.]***

⁷FAO and WHO (2024). Risk assessment of food allergens: Part 4: Establishing exemptions from mandatory declaration for priority food allergens <https://doi.org/10.4060/cc9554en>

14. On the basis of the EWG feedback, the Chairs have retained section 4.2.1.6 in Appendix II and amending the text to include 'regional' with footnote 7 updated to reference the Expert Committee's Part 4 report. CCFL may wish to consider the issues raised about the flowchart process recommended by the Expert

⁵ FAO and WHO (2024). Risk assessment of food allergens: Part 4: Establishing exemptions from mandatory declaration for priority food allergens <https://doi.org/10.4060/cc9554en>. Figure 1, p18.

Committee and the above proposed alternate text.

List of exemptions

15. The Part 4 report also includes a table of 'current accepted exemptions'⁶ which lists foods and ingredients from previously established national/regional lists of exemptions from allergen labelling. The Expert Committee did not endorse this list, but rather stated *there is an established history of safe consumption*⁷ for these exemptions.

16. EWG members were asked whether they support providing a list of exemptions in the GSLPF based on the 'current accepted exemptions'. It was noted this could promote harmonisation and facilitate trade, assist countries that may not have the resources to undertake evaluations for exemptions, and potentially increase the range of safe foods available to food allergic consumers.

17. EWG responses were divided with most supporting providing a list of exemptions (14 CM, 8 CO) for the reasons mentioned above, while others (7 CM, 1 CMO, 2CO) did not support this because the Expert Committee had not undertaken a risk assessment of these exemptions or formally recommended any exemptions, and that reaching agreement on a list would be complex and likely difficult.

18. There were comments (3 CM, 1 CMO, 1 CO) that if a list of exemptions was provided, then a process for updating the list would be needed. Another CM also stated it was not appropriate to include such a list in the GSLPF and suggested a separate standalone list could be regularly updated and revised, possibly with the support of a group like the Expert Committee.

19. As an alternative to creating a positive list of exemptions, two CM suggested referencing the 'current accepted exemptions' as examples for national/regional authorities.

20. Given the diverse EWG views, the Chairs have not proposed providing a list of exemptions in the GSLPF. However CCFL may wish to consider whether a list of exemptions can be provided in the GSLPF (or elsewhere), or alternatively to reference the 'current accepted exemptions' as examples for national/regional authorities.

Section 4.2.1.7 – Sulphite

21. At CCFL47 the report of the VPWG⁸ noted suggestions to specify the threshold amount should apply to the 'final product as consumed'; however others were concerned this would introduce uncertainty for manufacturers. Due to a lack of consensus in the plenary on what the concentration of sulphite applied to, it was agreed the following text be retained with text kept in square brackets:

4.2.1.7 *When sulphite is present in a [ready-to-eat] food [or products as reconstituted according to the instructions of the manufacturer], at a total concentration of 10 mg/kg or above, it shall always be declared using the specified name 'sulphite'.*

22. The addition of a footnote was also proposed to clarify that sulphite should be measured as residue of sulphur dioxide (SO₂).

23. In CP1 the Chairs noted that applying the provision to food 'as consumed' changes the intent of the existing declaration in the GSLPF which does not specify whether the concentration of sulphite applies to a food as consumed or not. It was also noted the original 1985 JECFA risk assessment considered food consumption when identifying the risk from sulphite to asthmatics and proposed an acceptable daily intake (ADI) for sulphite exposure⁹. As the original risk assessment was based on an ADI, and not an acute exposure, the Chairs proposed to remove the text in square brackets and noting the ADI is measured as sulphur dioxide and sulphur dioxide equivalents to include a footnote to reflect this.

24. EWG responses were divided with those in support (16 CM, 3 CO) highlighting the original text (without the bracketed text) is consistent with the JECFA assessment and that manufacturers should not be responsible to label a food according to future preparation, as they have no control over whether a consumer will follow preparation instructions or what the sulphite content may be if other foods are used during preparation. Those not in support (5 CM, 1 CMO, 5 CO) stated the risk from sulphite should be managed for a food as consumed,

⁶ FAO and WHO (2024). Risk assessment of food allergens: Part 4: Establishing exemptions from mandatory declaration for priority food allergens <https://doi.org/10.4060/cc9554en>. Table A1.1, p49–52)

⁷ FAO and WHO (2024). Risk assessment of food allergens: Part 4: Establishing exemptions from mandatory declaration for priority food allergens <https://doi.org/10.4060/cc9554en>. p38.

⁸ FL/47 CRD 02 Report of the Virtual Physical Working Group on the draft revision of the General Standard for the Labeling of Pre-packaged Foods (CXS 1-1985) relevant to allergen labelling. <https://www.fao.org/fao-who-codexalimentarius/meetings/detail/en/?meeting=CCFL&session=47>, Accessed 5 August 2024.

⁹ World Health Organization (1987). Evaluation of certain food additives and contaminants. WHO Technical report series 751:32-33. [WHO TRS 751.pdf](https://www.who.int/publications-detail/9789240675100) Accessed 4/10/2023.

because the risk is related to the exposure at the point of consumption.

25. A CMO suggested applying to sulphite the same approach for other foods and ingredients in sections 4.2.1.4 and 4.2.1.5 in regard to the declaration being 'in addition to or as part of the ingredient name'. A CO also sought clarification on whether the specified name for sulphite should allow for different spelling i.e. 'sulfite' noting this spelling is used in other Codex texts (e.g. *General Standard for Food Additives* (Codex STAN 192-1995)).

26. In CP2, the Chairs noted as there is no updated risk assessment, section 4.2.1.7 should reflect the existing declaration in the GSLPF as for other 'foods and ingredients' i.e. the declaration of sulphite applies when it is present as a food or ingredient (e.g. as a food additive) in concentrations of 10 mg/kg or more in a food and proposed the following revised text:

4.2.1.7 In addition to the foods and ingredients listed in section 4.2.1.4, When sulphite is present in a ~~ready-to-eat~~ food ~~for products as reconstituted according to the instructions of the manufacturer~~, at a total in concentrations of 10 mg/kg or more above⁸, it shall always be declared using the specified name 'sulphite' or 'sulfite' in addition to or as part of the ingredient name.

⁸Sulphite measured as the total concentration of sulphur dioxide (SO₂) and sulphur dioxide equivalents.

27. EWG members were again divided on the proposed draft text. Those in support (14 CM, 4 CO) considered the text was consistent with the original JECFA risk assessment and reflects the existing declaration in the GSLPF noting the standard applies to pre-packaged foods not ready-to-eat foods. However, the differing understandings amongst EWG members on how the threshold applies (i.e. to the food as sold or as consumed) was acknowledged, and that the proposed revised text would unlikely resolve this. Two EWG members (1 CM, 1 CO) also noted the text did not make clear whether the threshold applies to both added sulphite and naturally occurring sulphite and sought clarification.

28. Those not supporting the proposed revised text (6 CM, 1 CMO, 5 CO) highlighted the presence of sulphites in a food product should not follow the same labelling rules as other foods and ingredients listed in sections 4.2.1.4 and 4.2.1.5 because sulphite is not food protein, and its presence should only be declared where a threshold is exceeded.

29. Different wording was suggested by EWG members including that the declaration should apply to 'food as offered to the consumer' or 'food as consumed' or 'food as ready for consumption or as reconstituted according to the instructions of the manufacturer'.

30. Two EWG members (1 CM, 1 CMO) considered the text needed to explicitly clarify that the declaration should be made when sulphite is 'present' in a 'food as consumed' with one noting this is consistent with the *General Standard for Food Additives* (GSFA) (CXS192-1995) which by default sets maximum levels on the final product as consumed. Another CM noted the GSFA also considers reconstitution in Note 127 (*On the served to the consumer basis*) for some food product categories e.g. concentrated fruit and vegetable juices.

31. Some EWG members noted 'in addition to the foods and ingredients listed in section 4.2.1.4' is not needed and that retaining 'present' better explains the declaration relates to sulphite present in a food regardless of how it came to be present (natural or added or both).

32. Based on EWG feedback, and in the spirit of finding a compromise, the Chairs propose revised text which includes 'food as offered to the consumer' and 'food as consumed' in square brackets for CCFL to consider as follows:

4.2.1.7 When sulphite is when present in a ~~ready-to-eat~~ food ~~for products as reconstituted according to the instructions of the manufacturer~~, at a total concentrations of 10 mg/kg or above⁸ in a food [as offered to the consumer/as consumed] it shall always be declared using the specified name 'sulphite' or 'sulfite' in addition to or as part of the ingredient name..

⁸Sulphite measured as the total concentration of sulphur dioxide (SO₂) and sulphur dioxide equivalents.

Clean version

4.2.1.7 Sulphite when present in concentrations of 10 mg/kg or more⁸ in a food [as offered to the consumer/as consumed] shall always be declared using the specified name 'sulphite' or 'sulfite' in addition to or as part of the ingredient name.

⁸Sulphite measured as the total concentration of sulphur dioxide (SO₂) and sulphur dioxide equivalents.

Section 4.2.2 – food and ingredients obtained through biotechnology

33. For consistency Section 4.2.2 was revised to include reference to ‘food allergen’.

Sections 4.2.3 and 4.2.3.1 – class names

34. At CCFL47 clarification was sought on the distinction between ‘specified name’ and ‘specific name’ in section 4.2.3 and its potential impact on other provisions. The EWG considered this noting the current wording may allow a class name (section 4.2.3.1) to be used instead of a ‘specified name’. Most EWG members supported changes to section 4.2.3 to provide distinction, but also identified the potential for confusion with section 4.3.2.1 on whether specified names are required because of the use of ‘except’ at the beginning and end of the section 4.2.3.

35. Based on EWG feedback, the Chairs proposed text changes to remove ‘specific name’ to provide distinction from ‘specified name’, and revise the second sentence in section 4.3.2.1 to make explicit specified names are required when a class name is used. The proposed revised text is:

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

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

Section 4.2.4 - Processing aids and carry-over of food additives

36. At CCFL47, it was noted the Expert Committee’s Part 4 report on exemptions might apply to section 4.2.4 and that CCFL could take this into account. However the EWG noted this report does not address exemptions from declaring food additives. Therefore the text for section 4.2.4.2 is retained without further change.

Sections 8.3 – Declaration of certain foods and ingredients

37. At CCFL47, the Committee noted proposals for flexibility in how declarations should be presented as there are already certain practices in countries preferred by their consumers and used by industry. Members agreed to keep three proposals for section 8.3.2¹⁰ and section 8.3.2.1 in square brackets for consideration and for section 8.3.1 to include ‘whenever possible’ in square brackets.

Section 8.3.1

38. In response to CP1 the majority of EWG members (27/32 responses) did not support including ‘whenever possible’ because of the importance for consumers to be able to easily identify allergen information, and that the flexibility afforded by ‘whenever possible’ would make section 8.3.1 optional thereby leading to a lack of harmonisation. EWG comments also noted section 8.3.1 should apply to the ‘specified name’ rather than the food and ingredients listed in sections 4.2.1.4, 4.2.1.7 and where applicable 4.2.1.5.

39. As similar support was received in response to CP2, the Chairs proposed the following revised text:

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

Sections 8.3.2 and 8.3.2.1

40. Of the three proposed options for section 8.3.2, there was no consensus in EWG responses to CP1 with five members supporting the first option, 11 the second (Bis) option, six the third (Ter) option and seven either proposing text changes or not supporting any option. Comments received also noted challenges in requiring the separate statement be ‘placed directly under’ the ingredient list, and proposed flexibility by including ‘or in close proximity to’.

41. In CP2 the EWG Chairs presented an amended Bis option as a potential compromise to provide flexibility for national authorities to determine the most appropriate approach for declaring allergens for their respective population(s), amending the text relating to the placement of the separate statement from ‘directly under the list of ingredients’ to ‘directly under or in close proximity to the list of ingredients’ and moving this to

¹⁰ [REP23/FL](#) paragraphs 50 -51 and Appendix II

section 8.3.2.1, and including 'specified name' similar to changes proposed for section 8.3.1.

42. The majority of EWG members (26/32 responses) supported the proposed compromise approach. Five members (3 CM, 2 CO) did not support including 'as determined by national competent authorities' either considering it unnecessary or because it will reduce harmonisation for consumers. A CMO requested 'regional' be included in addition to national authorities.

43. Three members (2 CM, 1 CO) did not support the addition of 'in close proximity to' as they considered the separate statement should always appear below the list of ingredients. One CM also proposed that because a separate statement is optional, section 8.3.2.1 should be prefaced with 'If used' and that legibility for consumers would be improved if the statement was also required to be in the same orientation as the list of ingredients.

44. Two CM proposed removing 'in the list of ingredients as applicable' from section 8.3.2.1 as being redundant given it implies specified names need to be declared in the list of ingredients, which is not the case as proposed by section 8.3.2. One also questioned whether 'as applicable in accordance with section 8.3.1' should actually be 'as applicable in accordance with Sections 4.2.1.4, 4.2.1.7 and where applicable 4.2.1.5'. However, the Chairs note because of the proposed changes to sections 8.3.1 and 8.3.2, section 8.3.2.1 does not need to duplicate requirements and that the text can be simplified.

45. Sections 8.3.3 and 8.3.4 are retained unchanged, however the Chairs proposed to include 'when present' in section 8.3.2.1 to accommodate for these sections that relate to when a food is exempt from declaring a list of ingredients.

46. The proposed text for sections 8.3.2 and 8.3.2.1 is as follows:

~~{8.3.2 The specified name for the~~ ~~Foods and ingredients in sections 4.2.1.4, 4.2.1.7 and where applicable 4.2.1.5 shall be declared in the list of ingredients or in a separate statement which shall be [placed directly under or in close proximity to] the list of ingredients or in both as determined~~ ~~The most appropriate manner to declare these foods and ingredients shall be decided by national competent authorities.~~

8.3.2.1 If used ~~the separate statement shall commence with the word 'Contains' (or equivalent word) and be [placed directly under or in close proximity to] the list of ingredients when present. The statement must declare the specified names of all the foods and ingredients which are declared in the list of ingredients as applicable in accordance with section 8.3.1.]~~

Clean version

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

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

APPENDIX II

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

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

(For comments through CL 2024/53-FL)

2. DEFINITION OF TERMS

“Food allergy” means a reproducible adverse health effect arising from an immunoglobulin class E (IgE) antibody or non-IgE antibody immune-mediated response following oral exposure to a food.

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

OR

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

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

4. MANDATORY LABELLING OF PRE-PACKAGED FOODS

4.2 List of ingredients

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

4.2.1.4 The following foods and ingredients are known to trigger food allergy or coeliac disease and shall always be declared using the specified name in addition to or as part of the ingredient name¹:

FOODS AND INGREDIENTS	SPECIFIED NAME
Cereals containing gluten ² – wheat and other <i>Triticum</i> species – rye and other <i>Secale</i> species – barley and other <i>Hordeum</i> species and products thereof	‘wheat’ ‘rye’ ‘barley’
Crustacea and products thereof	‘crustacea’
Eggs and products thereof	‘egg’
Fish and products thereof	‘fish’
Peanuts and products thereof	‘peanut’
Milk and products thereof	‘milk’
Sesame and products thereof	‘sesame’

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

² Includes spelt, Khorasan, and other specific cereals containing gluten that are species or hybridized strains under the genus names of *Triticum*, *Secale* and *Hordeum*. Specified names are to be used according to the associated genus. Hybridized strains are to use specified names in conjunction from all of the parent genera (e.g. ‘wheat’ and ‘rye’ for triticale).

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

4.2.1.5 In addition to the foods and ingredients listed in section 4.2.1.4, the declaration of any other foods and ingredients, including those listed below may also be required³ using a specified name in addition to or as part of the ingredient name⁴. This shall be based on available risk assessment data for the respective population(s)⁵ taking into account risk management considerations.

FOODS AND INGREDIENTS	SPECIFIED NAME
Buckwheat and products thereof	‘buckwheat’
Celery and products thereof	‘celery’
Oats and other <i>Avena</i> species (and their hybridized strains) and products thereof ⁶	‘oats’
Lupin and products thereof	‘lupin’
Mustard and products thereof	‘mustard’
Soybean and products thereof	‘soy’
Specific tree nuts	‘Brazil nut’
– Brazil nut (<i>Bertholletia excelsa</i>)	‘macadamia’
– macadamia (<i>Macadamia integrifolia</i> , <i>Macadamia tetraphylla</i>)	‘pine nut’
– pine nut (<i>Pinus spp.</i>)	
and products thereof	

4.2.1.6 Subject to evaluation using established criteria⁷, regional or national authorities may exempt ingredients derived from foods listed in section 4.2.1.4, and where applicable section 4.2.1.5, from being declared.

4.2.1.7 Sulphite when present in concentrations of 10 mg/kg or more⁸ in a food [as offered to the consumer/as consumed] shall always be declared using the specified name ‘sulphite’ or ‘sulfite’ in addition to or as part of the ingredient name.

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

³ These foods and ingredients are not included in 4.2.1.4 but have been recommended to be considered for risk management at the regional or national level (see FAO and WHO Risk assessment of food allergens: Part 1: Review and validation of Codex Alimentarius priority allergen list through risk assessment <https://doi.org/10.4060/cb9070en>).

⁴ In accordance with Section 4.1.1 of the *General Standard for the Labelling of Pre-packaged Foods* (CXS 1-1985), the ingredient declaration should specify the true nature of the food and be specific and not generic.

⁵ The assessment of risk in the respective population(s) to be based on the evidence criteria of prevalence, potency and severity of immune mediated adverse reactions to the food or ingredient as established by FAO and WHO Risk assessment of food allergens: Part 1: Review and validation of Codex Alimentarius priority allergen list through risk assessment. <https://doi.org/10.4060/cb9070en>

⁶ Oats can be tolerated by most but not all people who are intolerant to gluten. Therefore, the allowance of oats that are not contaminated with wheat, rye or barley in foods covered by this standard may be determined at the national level.

⁷ **FAO and WHO (2024). Risk assessment of food allergens: Part 4: Establishing exemptions from mandatory declaration for priority food allergens** <https://doi.org/10.4060/cc9554en>

⁸ Sulphite measured as the total concentration of sulphur dioxide (SO₂) and sulphur dioxide equivalents.

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

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

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

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

4.2.4 Processing aids and carry-over of food additives.

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

6. EXEMPTIONS FROM MANDATORY LABELLING REQUIREMENTS

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

8. PRESENTATION OF MANDATORY INFORMATION

8.3 Declaration of certain foods and ingredients

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

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

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

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

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

APPENDIX III**LIST OF PARTICIPANTS****Members**

Argentina	Singapore
Australia	South Africa
Brazil	Sweden
Canada	Switzerland
Chile	Thailand
China	Uruguay
Columbia	United Kingdom
Costa Rica	United States of America
Ecuador	
European Union	Observers
Federation of St. Kitts and Nevis	Association of European Coeliac Societies
Finland	European Federation of Allergy and Airways Disease
Guatemala	Food Industry Asia
Hungary	FoodDrinkEurope
India	International Chewing Gum Association
Indonesia	International Confectionery Association
Islamic Republic of Iran	International Council of Beverage Associations
Japan	International Council of Grocery Manufacturers Associations
Republic of Korea	International Dairy Federation
Mauritius	International Fruit and Vegetable Juice Association
Netherlands	International Special Dietary Foods Industries
New Zealand	Latin American Alliance of Food and Beverage Industry Associations
Norway	
Panama	
Philippines	
Kingdom of Saudi Arabia	