CODEX COMMITTEE ON FOOD LABELLING

FOOD ALLERGEN LABELLING

ELECTRONIC WORKING GROUP

(Chaired by Australia, the United Kingdom and the United States of America)

CONSULTATION PAPER, FEBRUARY 2024

Please respond to the questions in this consultation paper using the response sheet provided (Appendix III) and post on the **online platform** by **28 MARCH 2024**

Note: Only one response per Codex Member or Codex Observer is permitted.

1. Background

At the 45th Session of the Codex Committee on Food Labelling (CCFL45), the Committee agreed to review and clarify the provisions relevant to allergen labelling in the *General Standard for the Labelling of Prepackaged Foods* (CXS 1-1985) (GSLPF) and develop guidance on precautionary allergen or advisory 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 texts*[2].

CCFL45 also agreed to request scientific advice from FAO/WHO[3] relating to the list of foods and ingredients in section 4.2.1.4 of the GSLPF. The CCFH has also requested FAO/WHO provide scientific advice on threshold levels for the priority allergens in relation to the *Code of Practice on Allergen Management for Food Business Operators* (CXC 80-2020).

In response to the CCFL and CCFH requests for scientific advice, an *Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens* (Expert Committee) has convened four times and to date has issued full reports for four parts (see table below). Only a summary and conclusion report is available for Part 4.

Meeting date	Reports
30 November – 11 December 2020	Part 1: Review and validation of Codex priority allergen list through risk assessment
15 March – 2 April 2021	Part 2: Review and establish threshold levels in foods of the priority allergens
18 October – 3 November 2021	Part 3: Review and establish precautionary labelling in foods of the priority allergens
14 November – 18 November 2022	Part 4: Review and establish exemptions for the food allergens (summary and conclusions only)
	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

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

[2] REP19/CAC para 99

[3] REP19/FL para. 98(c)

The scope of work on allergen labelling includes consideration of evidence-based consumer understanding of allergen labelling and advisory statements. Food Standards Australia New Zealand (FSANZ) and the Food Standards Agency (UK) as members of the International Social Science Liaison Group (ISSLG)[4], have collaborated on a literature review to provide evidence for the revision of the GSLPF and development of guidance on PAL.

1.1 CCFL47 outcomes

At CCFL47, the Committee considered draft revisions to the GSLPF[5] and agreed to:

i. Forward the proposed draft revision to the GSLPF provisions relevant to allergen labelling (Appendix II of REP23/FL) to CAC46 for adoption at Step 5.

ii. Re-establish the EWG, chaired by Australia, the United Kingdom and United States of America, working in English, to further develop the revision of the GSLPF taking into account discussions at CCFL47, for circulation at Step 6 and consideration by CCFL48.

iv Inform CCFH of the progress of the work and in particular to draw their attention to the definition for food allergen and the lists of allergens in 4.2.1.4 and 4.2.1.5.

In relation to the PAL guidelines, CCFL47 agreed to[6]:

i. Return the proposed draft Annex to the GSLPF – Guidelines on the use of precautionary allergen labelling to Step 2, for further drafting.

ii. Re-establish an EWG chaired by the Australia and co-chaired by the United Kingdom and the United States of America, working in English, to continue drafting the guidelines, taking into account the discussions and comments submitted at the session, for circulation for comments at Step 3 and consideration by CCFL48.

iii. Request CCMAS to recommend suitable analytical methods and guidance on their validation and applications including sampling plans for determining allergenic protein in foods.

1.2 EWG Process

Prior to CCFL48, the Chairs expect to undertake the work of the EWG through two consultation papers.

This paper seeks comment on the draft revisions to the GSLPF relevant to allergen labelling in Part A and the proposed draft PAL guidelines in Part B. Another consultation paper will consider both Part A and Part B including the Expert Committee's Part 4 report on exemptions subject to the availability of this report.

Consistent with the EWG terms of reference, this consultation paper takes into account the discussion at CCFL47 as well as comments submitted at the session[7].

The proposed draft revisions to the GSLPF and the revised draft guidelines are provided in **Appendix I** and **Appendix II** with discussion on the changes outlined in this consultation paper. EWG members are asked to respond to the questions in this consultation paper using the response sheet provided at **Appendix III**.

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[4] 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/FL paragraphs 55- 61

[7] CRD06, CRD20, CRD21, CRD22, CRD23, CRD24, CRD25, CRD26, CRD27, CRD28, CRD29

Part A

REVISION TO THE *GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS* - PROVISIONS RELEVANT TO ALLERGEN LABELING

At CCFL47 the proposed draft revision to the GSLPF was advanced to adoption at Step 5 (REP23/FL Appendix II). Taking into account discussion at CCFL47, the Chairs are seeking comment on the following areas to progress revision of the GSLPF.

Section 2 – Definition of 'food allergen'

CCFL47 agreed to include the following definition for 'food allergen' in the GSLPF and to keep 'or substance or processing aid' in square brackets for further consideration:

> ***"Food allergen"*** *means a food or ingredient [or substance or processing aid] used in food, usually a protein or protein derivative that can elicit IgE-mediated or other specific immune-mediated reactions in susceptible individuals.*

At the meeting, CCFL discussed whether it was more appropriate to just refer to 'food and ingredients' or to also include 'or substance or processing aid'. It was noted 'substance' includes both 'ingredient' and 'food additive'. The GSLPF includes the following definition for 'ingredient'.

> ***"Ingredient"*** *means any substance, including a food additive, used in the manufacture or preparation of a food and present in the final product although possibly in a modified form.*

This definition clarifies that 'ingredient' includes food additives.

The GSLPF also contains definitions of 'food' and 'processing aid':

> ***"Food"*** *means any substance, whether processed, semi-processed or raw, which is intended for human consumption, and includes drinks, chewing gum and any substance which has been used in the manufacture, preparation or treatment of "food" but does not include cosmetics or tobacco or substances used only as drugs.*
>
> ***"Processing Aid"*** *means a substance or material, not including apparatus or utensils, and not consumed as a food ingredient by itself, intentionally used in the processing of raw materials, foods or its ingredients, to fulfil a certain technological purpose during treatment or processing and which may result in the non-intentional but unavoidable presence of residues or derivatives in the final product.*

The definition of 'food' refers to any substance *which has been used in the manufacture, preparation or treatment of food* which therefore includes processing aids.

Based on the existing definitions of 'food' and 'ingredient' in the GSLPF which capture 'substance', 'food additive' and 'processing aid' the bracketed text [or substance or processing aid] is proposed to be removed from the 'food allergen' definition.

Question 1: Do you agree to removing the bracketed text [or substance or processing aid] from the proposed definition for 'food allergen as shown below? ***"Food allergen"*** *means a food or ingredient ~~[or substance or processing aid]~~ used in food, usually a protein or protein derivative that can elicit IgE-mediated or other specific immune-mediated reactions in susceptible individuals.*	
Yes ☐	No ☐
Please provide reasons for your answer:	

Section 4.2.1.4 and 4.2.1.5 – Scientific names for tree nuts

At CCFL47 it was noted that as agreed by the Virtual Physical Working Group (VPWG) (held prior to CCFL47), the scientific names for specific tree nuts would be included in the draft revised text.

The following scientific names are proposed to be included in sections 4.2.1.4 and 4.2.1.5 of the GSLPF:

- almond (*Prunus amygdalus)*
- Brazil nut (*Bertholletia excelsa*)
- cashew (*Anacardium occidentale)*
- hazelnut (*Corylus avellana*)
- macadamia (*Macadamia integrifolia, Macadamia tetraphylla*)
- pecan (*Carya illinoinensis*)
- pine nut (*Pinus* spp.)
- pistachio (*Pistacia vera*)
- walnut (*Juglans regia, Juglans nigra*)

These scientific names were selected using allergy risk assessments conducted by the European Food Safety Authority (EFSA)[8], which specified the individual tree nut species under consideration and noting these names are used in other Codex texts[9,10]. In most cases, a single species name has been proposed except for macadamia and walnut which have two species listed, and pine nut is provided as a collective species, because these species are commercially cultivated for their nuts as well as being implicated as causing allergies.

Section 4.2.1.6 - Exemptions

From previous EWG discussions there was agreement to include a generic provision allowing exemptions, subject to case-by-case evaluation against the criteria (from the Expert Committee) by national authorities.

At CCFL47 this section was retained in square brackets pending the availability of the full Part 4 FAO/WHO Expert Consultation Report. As this report has yet to be released no changes have been made to the text at this stage.

Section 4.2.1.7 – Sulphites

At CCFL47 the following text was agreed to be retained with text kept in square brackets due to a lack of consensus on what the concentration of sulphite applied to:

> 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'.

The report of the VPWG[11] 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.

Applying this 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 is noted the original 1985 JECFA risk assessment considered food consumption when identifying the risk from sulphite to asthmatics. JECFA proposed an

[8] 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.
[9] CXC 59-2005: Code of practice for the prevention and reduction of aflatoxin contamination in tree nuts.
[10] CXS 131-1981: Standard for unshelled pistachio nuts.
[11] FL/47 CRD 02 Report f the Virtual Physical Working Group on the draft revision of the General Standard for the Labelling of Prepackaged Foods (CXS 1-1985) relevant to allergen labelling

acceptable daily intake (ADI) of 0.7 mg/kg body weight for sulphite exposure[12]. The Codex Committee on Food Additives (CCFA) identified sulphite food additives as a high risk based on the JECFA assessment, and proposed to the Codex Alimentarius Commission that it consider the mandatory labelling of sulphite additives. The final 10 mg/kg declaration threshold was developed from the minimum detectable threshold of analytical techniques available at the time[13].

As the original sulphite risk assessment was based on an ADI, and not an acute exposure, the Chairs propose to remove the text in square brackets.

At CCFL47 a footnote was proposed to clarify that sulphites should be measured as the residue of sulphur dioxide (SO_2). The Chairs note the JECFA ADI is measured as sulphur dioxide and sulphur dioxide equivalents[14]. This is because sulphite salts release sulphur dioxide, and so the presence of sulphites is therefore typically determined by measuring this end product. Based on this, the Chairs are proposing to include the following footnote to section 4.2.1.7:

> **4.2.1.7** When sulphite is present in a food at a total concentration of 10 mg/kg or above[8], it shall always be declared using the specified name 'sulphite'
>
> [8]Sulphite measured as the total concentration of sulphur dioxide (SO_2) and sulphur dioxide equivalents.

Question 2: Do you agree with the proposed text for section 4.2.1.7, including deleting the text in square brackets, and the proposed footnote?	
Yes ☐	No ☐
Please provide reasons for your answer:	

Section 4.2.2 – food and ingredients obtained through biotechnology

As a definition for 'food allergen' is proposed for the draft revision of the GSLPF, for consistency Section 4.2.2 has been revised to include reference to 'food allergen' as follows (bolded addition and strikethrough deletion).

> **4.2.2** The presence in any food or food ingredients obtained through biotechnology of a~~n~~ **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.

Section 4.2.3 – class names

At CCFL47 a request for clarification was made with respect to the distinction between 'specified name' and specific name in section 4.2.3, as the current wording may allow class names (section 4.2.3.1) to be used instead of 'specified names'.

To provide clarity, the following changes to the text at sections 4.2.3 and 4.2.3.1 are proposed:

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[12] World Health Organization (1987). Evaluation of certain food additives and contaminants. WHO Technical report series 751:32-33. WHO_TRS_751.pdf Accessed 4/10/2023.
[13] CAC16, ALINORM 87/12 (1987). Report of the eighteenth session of the Codex Committee on Food Additives. https://www.fao.org/fao-who-codexalimentarius/meetings/archives/en/?y=1987&s=1985&mf=08.
[14] World Health Organization (1987). Evaluation of certain food additives and contaminants. WHO Technical report series 751:32-33. WHO_TRS_751.pdf Accessed 12/2/2024.

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~~.*

Question 3: Do you agree with the proposed changes to section 4.2.3 and 4.2.3.1 to provide distinction between 'specified name' and specific name?	
Yes ☐	No ☐
Please provide reasons for your answer:	

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

At CCFL47, it was noted that the exemptions framework from Report 4 of the FAO/WHO Expert Consultation might apply to section 4.2.4 (processing aids and carry-over of food additives). As this report is not yet available no changes have been proposed at this stage.

Section 8.3.1 and 8.3.2 – Declaration of certain foods and ingredients

At CCFL47, some members requested flexibility in how declarations should be presented either in the ingredient list, or through a separate statement, or in both. This also included the placement of the separate statement.

As there were differing views, CCFL did not reach agreement on section 8.3.2, and several options for the text were placed in square brackets for further consideration. These proposals related to section 8.3.1 and 8.3.2 as follows:

8.3 Declaration of certain foods and ingredients

8.3.1 The foods and ingredients listed in sections 4.2.1.4, 4.2.1.7 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.

[8.3.2 When the foods and ingredients in sections 4.2.1.4, 4.2.1.7 and where applicable 4.2.1.5 are declared in the list of ingredients, they may also be declared in a separate statement, which shall be placed directly under the list of ingredients.

Bis. 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**]** the list of ingredients or in both. The most appropriate manner to declare these foods and ingredients shall be decided by national competent authorities.

Ter. 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) and/or be declared in a separate statement commence with the word 'contains' (or equivalent word) directly under the list of ingredients.**]**

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

Section 8.3.1

For section 8.3.1 (see above), the text ‘whenever possible’ was proposed, as some member countries do not require declarations to contrast distinctly from surrounding text. Others did not support this change, as they considered allergen declarations need to stand out on food labels. It is also noted that the ISSLG report identifies that consumers benefit from declarations that have emboldening, colour contrast and increased font size compared to other surrounding text.

Question 4: Do you support providing flexibility by including ‘whenever possible’ in section 8.3.1 by removing the square brackets?	
Yes ☐	No ☐
Please provide reasons for your answer:	

Section 8.3.2

At CCFL47 there was no agreement on section 8.3.2 (see above), so a compromise Bis text was proposed to provide flexibility by allowing national authorities to determine whether allergens should be declared only in an ingredient list, or in a summary statement or both. A Ter text was proposed as another alternative that just focuses on permissions for allergen declarations to be declared in either the ingredient list or in a summary statement.

For the purposes of this consultation paper, the original text at section 8.3.2 will be referred to as ‘option 1’, the Bis text as ‘option 2’, and the Ter text as ‘option 3’.

Currently, the GSLPF places allergen declaration requirements under section 4.2 of the GSLPF (specifically in section 4.2.1.4), which means that declarations must be made in the ingredient list. Despite this, the Chairs note options 2 and 3 propose for ingredient list declarations to be optional, with the intent of accommodating the existing different global approaches to allergen labelling.

Options 2 and 3 also increase the differences in allergen labelling between countries, do not provide consistency for consumers, reduce harmonisation and may create barriers to trade.

Question 5: Of the three options for section 8.3.2, which do you prefer?			
Option 1☐	Option 2 ☐	Option 3 ☐	Other ☐
Please provide reasons for your answer. If answering ‘Other’, please describe your proposed option and explain why you support this.			

PART B

DRAFT ANNEX TO THE GSLPF – GUIDELINES ON THE USE OF PRECAUTIONARY ALLERGEN LABELLING

The proposed draft PAL guidelines have been revised based on discussions and comments submitted at CCFL47. In addition, as the Expert Committee's Part 3 and Part 5 reports were released following CCFL47, the draft guidelines have also been revised in light of these reports. The proposed revised draft guidelines are provided in **Appendix II** with discussion on the changes made provided below.

Title, Purpose and Scope

The Title, Purpose and Scope is largely unchanged to that presented at CCFL47. For the Purpose and Scope, a footnote to 'food allergy' and reference to 'food allergen(s)' have been included as these are proposed defined terms in the draft revisions to the GSLPF (as discussed in Part A).

The Expert Committee's Part 5 report provides reference doses for allergens proposed for inclusion at section 4.2.1.5 of the GSLPF[15]. Reference doses have not been provided for barley and rye (or gluten); nor sulphites; and these foods/ingredients were also not considered in the Expert Committee's Part 2 report. Therefore, the scope of the PAL guidelines capture food allergens only.

The proposed text for the title, purpose and scope is:

> **GUIDELINES ON THE USE OF PRECAUTIONARY ALLERGEN LABELLING**
>
> ***1. PURPOSE***
>
> *To facilitate a consistent and harmonized approach to the effective use of precautionary allergen labelling (PAL) for communicating to consumers with **food** allergy[1] about the risk from the unintended presence of allergens in food due to cross-contact.*
>
> ***2. SCOPE***
>
> *These guidelines apply to PAL when used to indicate the risk from the unintended presence of a **food** allergen(s)[1] caused by cross-contact in prepackaged foods.*
>
> *[1]As defined in the General Standard for the Labelling of Prepackaged Foods (CXS 1-1985).*

Question 6: Do you support the Title, Purpose and Scope sections in the proposed draft PAL guidelines?	
Yes ☐	No ☐
Please provide reasons for your answer:	

[15] Buckwheat, celery, oats, lupin, mustard, soybean, Brazil nut, macadamia nut and pine nut.

Section 3: Definitions

At CCFL47 definitions for 'allergen' and 'precautionary allergen labelling' were included in the proposed draft guideline.

As CCFL agreed to include a definition for 'food allergy' and 'food allergen' in the proposed draft revisions to the GSLPF[16], and as the draft PAL guidelines are to be an Annex to the GSLPF[17], the Chairs propose to reference these definitions for consistency. As noted in the discussion above, reference to the proposed definitions in the GSLPF for 'food allergy' and 'food allergen' in the Purpose and Scope sections respectively have been included.

There was general support for the proposed 'precautionary allergen labelling' definition. The Chairs note this definition contains similar elements to the definition of PAL used by the Expert Committee[18]. To ensure consistency, footnote references to the definition for 'food allergen' from the draft revision of the GSLPF, and 'cross-contact' in the *Code of Practice on Allergen Management for Food Business Operators* (CXC 80-2020) have been included.

In addition, based on the Expert Committee recommendations that the decision to use PAL should be based on hazard identification and risk characterisation by appropriate risk assessment, reference to 'risk assessment' has also been included in the proposed definition as an important foundation element.

As the definition section now only includes a definition for PAL, the section title has been amended.

The revised proposed definition section is:

> ***3. DEFINITION OF PRECAUTIONARY ALLERGEN LABELLING***
>
> *For the purpose of these guidelines:*
>
> *Precautionary allergen labelling (PAL) is a statement made in the labelling of prepackaged foods to indicate a risk from the unintended presence of a food allergen(s)[1] due to cross-contact[2] that has been identified by a risk assessment.*
>
> *[1]As defined in the General Standard for the Labelling of Prepackaged Foods (CXS 1-1985).*
>
> *[2]Allergen cross-contact as defined in Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020).*

Question 7: Do you support the revised definition for PAL and the changes to the definition section in the proposed draft PAL guidelines?	
Yes ☐	No ☐
Please provide reasons for your answer:	

Section 4: General Principles

[16] REP23/FL paragraphs 22 and 27.

[17] REP23/FL paragraph 58.

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

Principle 4.1

The Expert Committee (Part 3 report) recommends that the decision whether or not to use PAL should be based on hazard identification and risk characterization, combined with food business operators implementing allergen management practices and controls. At CCFL47 the following Principle 4.1 was included in the draft PAL guidance:

> *4.1 Effective management practices and controls to prevent or minimize the unintended presence of allergens caused by cross-contact shall be implemented as outlined in the Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020). The use of PAL shall be restricted to those situations in which the unintended presence of an allergen(s) cannot be sufficiently controlled using these allergen management practices.*

Comments received supported the intent of this principle but proposed wording changes to provide clarity. Considering this, Principle 4.1 has been revised as follows (bolded new text and strikethrough deleted text):

> *4.1 Effective **allergen** management practices ~~and~~ **including** controls to prevent or minimize the unintended presence of food allergens caused by cross-contact shall be implemented as ~~outlined~~ in the Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020). The use of PAL shall be restricted to those situations in which the unintended presence of a~~n~~ **food** allergen(s) cannot be **prevented or** ~~sufficiently~~ controlled using these allergen management practices **and may result in an exposure above a reference dose**.*

This revised wording is consistent with the objectives (section I) of the *Code of Practice on Allergen Management for Food Business Operators* (CXC 80-2020) and recommendations in the Expert Committee's Part 3 report (pages xiv and 22) that PAL "should be restricted and applied to those situations where UAP cannot be prevented and may result in an exposure above the reference dose".

Question 8: Do you support the revised wording for Principle 4.1 in the draft PAL guidelines?	
Yes ☐	No ☐
Please provide reasons for your answer:	

Principle 4.2

At CCFL47 Principle 4.2 was included as follows:

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

Comments received were divided with some support for a minimum requirement for quantitative risk assessments whereas others supported quantitative risk assessments to be optional. There were also requests for additional clarification or explanation that quantitative risk assessments are not the only types that can be conducted, and details on when qualitative risk assessments can occur.

The Expert Committee Part 3 report (page 22) states *The decision to use PAL should be based on the findings of a risk assessment which can include but is not limited to quantitative risk assessment*. In sections 3.3.1 to 3.3.6 of the report the Expert Committee outline the appropriate risk assessment including characterization and quantification of unintended allergen presence (UAP). This notes:

- *The most effective manner for quantifying UAP for risk assessment is usually by analytical testing of protein from allergenic food in samples from the specific production line where a potential UAP issue is noted and/or by testing in finished product(s), although this is not always needed.*
- *Analytical results in combination with likely food consumption estimates based on the p50 or mean of the general population single-eating occasion intake of food (reference amounts (RfA)) can be used to calculate a UAP protein exposure estimate per eating occasion of product and be compared to reference doses (RfDs). However, analytical testing in all potential UAP situations is not often practical or feasible. In these circumstances, there may be other ways to obtain quantitative information about UAP and do an exposure assessment*[19]. This section provides some examples of ways UAP can be estimated to provide quantitative information.

The report also notes in Section 3.3.4 *that the concentration of UAP in a final product may be validated using analytical testing although this is not essential. Analytical results should not be considered in isolation from a comprehensive HACCP-based UAP risk assessment.*

Therefore the Expert Committee report acknowledges that both qualitative and quantitative approaches can be utilised to provide risk assessment information to be used as a means to characterize and quantify UAP for the purpose of making an appropriate risk assessment.

As CCFH are yet to consider the Expert Committee's reports it is unclear whether the *Code of Practice on Allergen Management for Food Business Operators* (CXC 80-2020) may be revised to reflect aspects of the risk assessment approach as outlined by the Expert Committee. In which case it may be more appropriate for the draft CCFL guidance to refer to CXC 80-2020 in the future.

However, at this stage based on the recommendations of the Expert Committee, and to provide clarity on the risk assessment approach which is to be applied, Principle 4.2 has be revised as follows (bolded new text):

> *4.2 The decision to use PAL should be based on the findings of* ***an appropriate*** *risk assessment*[***3***] *which shall include, but is not limited to, quantitative risk assessment* ***of unintended allergen presence to indicate exposure above a reference dose****.*
>
> ***[3] FAO and WHO (2022). Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens: Part 2: Review and establish threshold levels in foods of the priority allergens. https://doi.org/10.4060/cc2946en*****.**

Question 9: Do you support the revised wording for Principle 4.2 in the draft PAL guidelines?	
Yes ☐	No ☐
Please provide reasons for your answer:	

Principle 4.3

At CCFL47 Principle 4.3 was proposed as follows:

> *4.3 PAL shall only be used if the presence of a protein from an allergen is equal to or above the action level*[*3*] *for this allergen, using the listed reference dose values in 4.3.1.*
>
> [*3*] *Action level (mg total protein from the allergen / kg food) = Reference dose (mg total protein from the allergen) / Amount of the food (kg)*

[19] Part 3: Review and establish precautionary labelling in foods of the priority allergens Pages 33 - 46

The footnote to principle 4.3 and the reference dose (RfDs) values in the table at section 4.3.1 (see below) are taken from the recommendations of the Expert Committee's Parts 2 and 5 reports.

Comments were divided over principle 4.3. The reason cited by those not supporting the text was that it requires the use of quantitative risk assessments for PAL decisions, which they oppose. Other respondents supported the text and the use of quantitative risk assessments, although they requested additional clarifications on the frequency of an unintended allergen presence used, or on the use of analytical methods.

The Expert Committee recommendations in the Part 3 report state that a measurement of the UAP against a reference dose is required in all circumstances. It is only if UAP concentrations are not at or below the action levels, then the use of PAL may be warranted.

However, the Expert Committee has also considered methods that may be used to estimate the risk of an unintended allergen presence (UAP) rather than analytical measurement of the amount of allergenic protein present in foods and ingredients. Knowledge of the type of processing leading to UAP, the nature of the manufacturing facility, and recipe information, along with visual inspection and observation can provide some form of quantitative information to estimate UAP. For example, information about a particle size or characteristics can assist in estimating amount of protein for risk assessment in downstream products.

Based on the Expert Committee's recommendations, Principle 4.3 requiring UAP to be at or below an action level for a food allergen has been retained but revised to provide more clarity. Further text has also been provided in a footnote to clarify how action levels should be calculated, specifically in determining the amount of food that should be used, based on the Expert Committee's Part 3 report (page 28).

The revised Principle 4.3 is proposed to read:

> 4.3 PAL shall only be used if the **unintended allergen** presence cannot be **mitigated** to a level at or below ~~of a protein from an allergen is equal to or above~~ the action level[3] for **a food** allergen **based** on ~~, using~~ the ~~listed~~ reference dose ~~values~~ in the table at 4.3.1.
>
> *[3] Action level (mg total protein from the allergen / kg food) = Reference dose (mg total protein from the allergen) / Amount of the food (kg).* ***The amount of food should be established based on the 50th percentile or population mean for a single eating occasion intake of the food.***

Question 10: Do you support the revised wording for Principle 4.3 and footnote 3 in the draft PAL guidelines?	
Yes ☐	No ☐
Please provide reasons for your answer:	

Principle 4.3.1

At CCFL47, Principle 4.3.1 included a table of RfDs based on a 5% eliciting dose (ED05), which were recommended by the Expert Committee for use in the calculation of an action level (section 4.3).

Some comments received did not support the RfDs as provided, and queried if this would give enough protection especially to vulnerable consumers who might still react at levels below the proposed RfD. The Expert Committee recommended ED05-based values because *the difference in the public health impact of choosing a more stringent RfD is expected to be*

negligible in terms of reducing public health risk, and would introduce considerable burdens and limitations for monitoring and potential unintended consequences on the application of PAL or other risk management strategies. This is particularly pertinent with respect to potential limitations to food choice for individuals with IgE-mediated food allergies (Part 2 report, page 93).

The RfD values have therefore been retained in the table to section 4.3.1.

Some comments were also received at the grouping of cashew/pistachio and walnut/pecan allergens together. However, it is noted the Expert Committee grouped some tree nut allergens because of insufficient data to assign RfDs for pecan and pistachio. These two tree nuts were grouped with walnut and cashew respectively due to the known cross-reactivities and co-existent allergies between pistachio and cashew, and pecan and walnut (Part 2 report, page 96).

The Expert Committee has recently released its Part 5 report, which assesses threshold levels for regional priority allergens. This report only recommends RfDs for soybean and celery (10 mg and 1 mg of total protein respectively). The report lists RfDs for Brazil nut Macadamia, pine nut, mustard, lupin, and buckwheat, but emphasises that these RfDs are not based on a risk assessment, have only been provided for risk management purposes, and may change if new data becomes available.

Comments received also raised that the table in section 4.3.1 did not contain RfDs for barley, rye, oats or gluten. However, it is noted the Expert Committee did not provide RfDs for gluten or gluten containing cereals, with the exception of wheat (although the RfD for wheat is based on its potential for food allergy). An RfD was also not provided for sulphites.

To reflect the Part 5 recommendations of the Expert Committee, additional RfD values have been added to the table at section 4.3.1, as shown below and in Appendix II in bold text.

	Reference dose (RfD) (mg total protein from the allergen)
Almond (provisional)	1.0
Brazil nut	**1.0**
Cashew (and Pistachio)	1.0
Macadamia	**1.0**
Pine nut	**1.0**
Walnut (and Pecan)	1.0
Celery	**1.0**
Mustard	**1.0**
Peanut	2.0
Egg	2.0
Milk	2.0
Sesame	2.0
Hazelnut	3.0
Wheat	5.0
Fish	5.0
Buckwheat	**10**

	Reference dose (RfD) (mg total protein from the allergen)
Lupin	**10**
Soy	**10**
Crustacea	200

Question 11: Do you support the use of ED05-based RfDs as recommended by the Expert Committee and provided in the table at Principle 4.3.1?	
Yes ☐	No ☐
Please provide reasons for your answer:	

Principle 4.3.2

At CCFL47 the draft guidelines included the following Principle 4.3.2

> *4.3.2 Where a reference dose is not established for a particular allergen by 4.3.1 above, national authorities can establish a reference dose consistent with recognized principles[4] for the purposes of determining an action level.*
>
> *[4]FAO and WHO (2022). Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens: Part 2: Review and establish threshold levels in foods of the priority allergens.*

This was based on the Expert Committee's recommendation that if an RfD is not established for a particular food allergen, an estimated RfD can be used, provided it is determined following the guiding principles elaborated by the second meeting of the Expert Committee (Part 2 report, page 22).

Most comments supported this principle noting RfD values for regional priority allergens may help address global PAL inconsistencies that may result from Principle 4.3.2. A small number of comments however did not support section 4.3.2 because they considered:

- reference doses should be harmonised at a global level
- national authorities should not set RfDs independently
- some nations may also not have the scientific capability to develop reference values.

Based on majority support Principle 4.3.2 is retained with a minor change to include 'food allergen' to maintain consistent terminology:

> *4.3.2 Where a reference dose is not established for a particular **food** allergen by 4.3.1 above, national authorities can establish a reference dose consistent with recognized principles[4] for the purposes of determining an action level.*
>
> *[4]FAO and WHO (2022). Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens: Part 2: Review and establish threshold levels in foods of the priority allergens.*

Question 12: Do you support Principle 4.3.2 in the draft PAL guidelines?	
Yes ☐	No ☐
Please provide reasons for your answer:	

Principle 4.4

AT CCFL47 the draft guidelines included:

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

Principle 4.4 was included because of evidence that consumers often do not understand what PAL means, and there is a lack of trust in how PAL is currently used[20]. In its Part 3 report, the Expert Committee recommend education of consumers with food allergy and other relevant stakeholders (e.g. risk assessors, risk managers, healthcare providers, food business operators) is critical to ensure understanding of the applied principles and the implications of PAL.

Comments received supported retaining this principle.

Question 13: Do you support principle 4.4 in the draft guidelines?	
Yes ☐	No ☐
Please provide reasons for your answer:	

Section 5: Presentation of PAL

Both the ISSLG literature review and Expert Committee Part 3 report identify the need for a consistent and harmonised approach to PAL, including the use of a single PAL statement. A consistent PAL statement is considered as being important for the communication about the risk from UAP to consumers with food allergy. At CCFL47 the following principles about the presentation and wording of a PAL statement were included in the proposed draft guidelines:

> *5. PRESENTATION OF PAL*
>
> *5.1 Section 8.1.1, 8.1.2 and 8.1.3 and 8.2 of the General Standard for the Labelling of Prepackaged Foods (GSLPF) (CXS 1-1985) apply to PAL labelling.*
>
> *5.2 PAL should appear as a separate statement in the same field of vision as the ingredient list (when present), and contrast distinctly from surrounding text, such as through the use of font type, style or colour in the same manner as Section 8.3.1 in the GSLPF.*
>
> *5.2.1 A PAL statement shall commence with the words 'May contain' (or equivalent words) and include the identified allergens using the specified names as listed in sections 4.2.1.4 and where applicable 4.2.1.5 of the GSLPF.*

The following comments were received on principles 5.1, 5.2 and 5.2.1.

- There was general support for including Principle 5.2 into the PAL guidelines. One comment requested the principle refer to all of section 8.3 of the GSLPF rather than section 8.3.1 specifically.
- The majority of comments on Principle 5.2.1 supported the wording 'may contain' for a PAL statement, based on the rationale that these words are most commonly used internationally and are well-established. However some of these comments did not support the bracketed '(or equivalent words)' as this would permit deviations from 'may contain', or did not support including specified names from sections 4.2.1.4 and 4.2.1.5 as this would prevent the use of 'tree nuts' in PAL statements.

[20] ISSLG consumer literature review page 29.

- Other comments did not support the wording ‘may contain’ in Principle 5.2.1, stating that the evidence from the Expert Committee supports ‘not suitable for’ and that ‘may contain’ is confusing for consumers.

Principle 5.1 was included to ensure PAL statements are subject to the same general labelling requirements as applies to all other labelling information specified by the GSLPF. As there were no comments received on this Principle, it has been retained in the proposed draft text unchanged.

In considering the comments on Principle 5.2, the Chairs note there are provisions in section 8.3 of the GSLPF that are not necessarily relevant for PAL statements (e.g. use of the word ‘contains’, exemptions from an ingredient list, reference to the allergen in the name of the food). However, to accommodate the comments received, the text on formatting in Principle 5.2 has been separated out into a new principle 5.2.2 (see below and in Appendix II), to clarify that it is the requirements of section 8.3.1 of the GSLPF that are being applied to the PAL statement.

Although the Expert Committee’s Part 3 report recommended ‘not suitable for’ phrasing of the PAL statement), the Chairs are proposing to retain ‘may contain’ as the preferred phrasing given consumer evidence indicates that statements such as “not suitable for…” and “may contain” are both more likely to deter food allergic consumers from purchasing products compared to other statements[21]. Also, the majority of comments support the wording of ‘may contain’ as it is the most commonly used wording internationally.

Based on the above considerations, the Chairs are proposing the following text for Section 5 of the PAL Guidelines.

> *5.1 Section 8.1.1, 8.1.2 and 8.1.3 and 8.2 of the General Standard for the Labelling of Prepackaged Foods (GSLPF) (CXS 1-1985) apply to PAL labelling.*
>
> *5.2 PAL should appear as a separate statement in the same field of vision as the ingredient list (when present).*
>
> *5.2.1 A PAL statement shall commence with the words ‘May contain’ (or equivalent words) and include the identified allergens using the specified names as listed in sections 4.2.1.4 and where applicable 4.2.1.5 of the GSLPF.*
>
> ***5.2.2 A PAL statement shall contrast distinctly from surrounding text such as through the same font type, style or colour used for declarations made in accordance with section 8.3.1 of the GSLPF.***

Question 14: Do you agree with the proposed revisions to Section 5 of the PAL Guidelines relating to the presentation of a PAL statement?	
Yes ☐	No ☐
Please provide reasons for your answer:	

Use of a risk assessment indicator

The Expert Committee’s Part 3 report recommends food labels provide an indication (e.g. a symbol) that a qualified risk assessment has been undertaken, irrespective of whether the risk assessment identifies the use of PAL or not. The ISSLG literature review[22] also identified

[21] ISSLG consumer literature review page 6.

[22] ISSLG consumer literature review page 29.

that consumers' trust in a product increases if they are aware a quantitative risk assessment has been undertaken.

Previous feedback has indicated minimal support for a risk assessment indicator, because the time and complexity to practically implement a symbol would be too high for most governments, and a cost burden for industry. Also if the indicator is absent from a food, then consumers are likely to be confused on whether there is a risk or not from unintended allergen presence. On the basis of this feedback, the proposed draft PAL guidelines do not include a principle relating to use of an indicator that a risk assessment has been undertaken.

Question 15: Do you support the proposed draft PAL guidelines <u>not</u> including a provision for the use of a risk assessment indicator?	
Yes ☐	No ☐
Please provide reasons for your answer:	

APPENDIX I

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

(proposed revisions with **bolded** text additions and ~~strikethrough~~ deletions and text under discussion in square brackets)

2. DEFINITION OF TERMS

(New)

"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).**

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

"Food allergen" **means a food or ingredient [~~or substance or processing aid~~] used in food, usually a protein or protein derivative that can elicit IgE-mediated or other specific immune-mediated reactions in susceptible individuals.**

4. MANDATORY LABELLING OF PREPACKAGED FOODS

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** ~~, other than~~ 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 **trigger food allergy or coeliac disease** ~~cause hypersensitivity~~ and shall always be declared **using the specified name in addition to or as part of the ingredient name:**[1]

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

FOODS AND INGREDIENTS	SPECIFIED NAME
Cereals containing gluten[2]: **− wheat and other *Triticum* species** **− rye and other *Secale* species** **− barley and other *Hordeum* species and products thereof**	**'wheat'** **'rye'** **'barley'**

[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).

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'**
Specific tree nuts **− Almond (*Prunus amygdalus)*** **− Cashew (*Anacardium occidentale)*** **− Hazelnut (*Corylus avellana*)** **− Pecan (*Carya illinoinensis*)** **− pistachio (*Pistacia vera*)** **– walnut (*Juglans regia, Juglans nigra*)** **and products thereof**	**'almond'** **'cashew'** **'hazelnut'** **'pecan'** **'pistachio'** **'walnut'**

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 required[3] using a specified name in addition to or as part of the ingredient name[4]. 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 *Avena* 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 (*Bertholletia excelsa*)** **– macadamia (*Macadamia integrifolia, Macadamia tetraphylla*)** **− pine nut (*Pinus* spp.)** **and products thereof**	**'Brazil nut'** **'macadamia'** **'pine nut'**

[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.

[4.2.1.6 Subject to evaluation using established criteria[7], 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 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**[[8]]**, it shall always be declared using the specified name 'sulphite'.

~~**4.2.1.5**~~ **4.2.1.8** Added water shall be declared in the list of ingredients except when the water forms part of an ingredient such as brine, syrup or broth used in a compound food and declared as such in the list of ingredients. Water or other volatile ingredients evaporated in the course of manufacture need not be declared.

~~**4.2.1.6**~~ **4.2.1.9** As an alternative to the general provisions of this section, dehydrated or condensed foods which are intended to be reconstituted by the addition of water only, the ingredients may be listed in order of proportion (m/m) in the reconstituted product provided that a statement such as "ingredients of the product when prepared in accordance with the directions on the label" is included.

4.2.2 The presence in any food or food ingredients obtained through biotechnology of a~~n~~ **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~~ **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 section**s** 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 cm^2, 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 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.

[8.3.2 When the foods and ingredients in sections 4.2.1.4, 4.2.1.7 and where applicable 4.2.1.5 are declared in the list of ingredients, they may also be declared in a separate statement, which shall be placed directly under the list of ingredients.

Bis. 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

[7] FAO and WHO (2022). Risk assessment of food allergens: Part 1: Review and validation of Codex Alimentarius priority allergen list through risk assessment. p15-20. https://doi.org/10.4060/cb9070en.

[8] Sulphite measured equivalent to the total concentration of sulphur dioxide (SO_2).

under] the list of ingredients or in both. The most appropriate manner to declare these foods and ingredients shall be decided by national competent authorities.

Ter. 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) and/or be declared in a separate statement commence with the word 'contains' (or equivalent word) directly under the list of ingredients.]

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

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

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

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APPENDIX II

PROPOSED DRAFT ANNEX TO THE GSLPF:

GUIDELINES ON THE USE OF PRECAUTIONARY ALLERGEN LABELLING

FOR eWG COMMENT

(proposed revisions with **bolded** text additions and ~~strikethrough~~ deletions and text under discussion in square brackets)

1. PURPOSE

To facilitate a consistent and harmonized approach to the effective use of precautionary allergen labelling (PAL) for communicating to consumers with **food** allergy[1] about the risk from the unintended presence of allergens in food due to cross-contact.

2. SCOPE

These guidelines apply to PAL when used to indicate the risk from the unintended presence of a~~n~~ **food** allergen(s) caused by cross-contact in prepackaged[1] foods.

3. DEFINITIONS

For the purpose of these guidelines:

> ***"Precautionary allergen labelling"*** *is a statement made in the labelling of prepackaged[1] foods to indicate a risk from the unintended presence of a~~n~~* ***food*** *allergen(s) due to cross-contact[2] that has been identified by a risk assessment..*

4. GENERAL PRINCIPLES

4.1 Effective **allergen** management practices ~~and~~ **including** controls to prevent or minimize the unintended presence of food allergens caused by cross-contact shall be implemented as ~~outlined~~ in the Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020). The use of PAL shall be restricted to those situations in which the unintended presence of a~~n~~ **food** allergen(s) cannot be **prevented or** ~~sufficiently~~ controlled using these allergen management practices **and may result in an exposure above a reference dose.**

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

4.3 PAL shall only be used if the **unintended allergen** presence cannot be **mitigated** to a level at or below ~~of a protein from an allergen is equal to or above~~ the action level[4] for **a food** allergen **based** on ~~, using~~ the ~~listed~~ reference dose ~~values~~ in the table at 4.3.1

4.3.1 References doses

	Reference dose (RfD) **(mg total protein from the allergen)**
Almond	1.0
Brazil nut	**1.0**
Cashew (and Pistachio)	1.0

[1] As defined in the *General Standard for the Labelling of Prepackaged Foods (CXS 1-1985)*.

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

[3] *FAO and WHO (2022). Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens: Part 2: Review and establish threshold levels in foods of the priority allergens. https://doi.org/10.4060/cc2946en*.

[4] Action level (mg total protein from the allergen / kg food) = Reference dose (mg total protein from the allergen) / Amount of the food (kg). ***The amount of food should be established based on the 50th percentile or population mean for a single eating occasion intake of the food.***

Macadamia	**1.0**
Pine nut	**1.0**
Walnut (and Pecan)	1.0
Celery	**1.0**
Mustard	**1.0**
Peanut	2.0
Egg	2.0
Milk	2.0
Sesame	2.0
Hazelnut	3.0
Wheat	5.0
Fish	5.0
Buckwheat	**10**
Lupin	**10**
Soy	**10**
Crustacea	200

4.3.2 Where a reference dose is not established for a particular **food** allergen by 4.3.1 above, national authorities can establish a reference dose consistent with recognized principles[5] for the purposes of determining an action level.

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

5. PRESENTATION OF PAL

5.1 Section 8.1.1, 8.1.2 and 8.1.3 and 8.2 of the General Standard for the Labelling of Prepackaged Foods (GSLPF) (CXS 1-1985) apply to PAL labelling.

5.2 PAL should appear as a separate statement in the same field of vision as the ingredient list (when present).

5.2.1 A PAL statement shall commence with the words 'May contain' (or equivalent words) and include the identified allergens using the specified names as listed in sections 4.2.1.4 and where applicable 4.2.1.5 of the GSLPF.

5.2.2 A PAL statement shall contrast distinctly from surrounding text such as through the same font type, style or colour used for declarations made in accordance with section 8.3.1 of the GSLPF.

[5] FAO and WHO (2022). Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens: Part 2: Review and establish threshold levels in foods of the priority allergens. https://doi.org/10.4060/cc2946en.

APPENDIX III

RESPONSE FORM

Codex Committee on Food Labelling
Electronic Working Group on Allergen Labelling

1st Consultation Paper

Please provide a response using this form and post on the Codex eWG Allergen Labelling online-forum by **28 March 2024**.

Name of Member Country/Organisation: European Federation of Allergy and Airways Diseases Patients' Associations (EFA)

Question 1: Do you agree to removing the bracketed text [or substance or processing aid] from the proposed definition for 'food allergen as shown below? ***"Food allergen"*** *means a food or ingredient ~~[or substance or processing aid]~~ used in food, usually a protein or protein derivative that can elicit IgE-mediated or other specific immune-mediated reactions in susceptible individuals.*	
Yes **X** **with clarification**	No ☐
Please provide reasons for your answer: EFA agrees with the removal of the bracketed text [or substance or processing aid] from the proposed definition of 'food allergen'. We consider that the range of food allergens is captured sufficiently by the existing reference to 'food or ingredient'.	

Question 2: Do you agree with the proposed text for section 4.2.1.7, including deleting the text in square brackets and the proposed footnote?	
Yes **X** **with clarification**	No ☐
Please provide reasons for your answer: The proposed text is clear on the threshold amount but is lacking clarification on added versus naturally present sulphites (such as in dried garlic or fermented foods). As this standard applies to the labelling of ingredients, it should be clear that it relates to 'all added sulphites', which can relate to an added ingredient or sulphites used as a plant protection product. We recommend changing the text in 4.2.1.7. to 'When **added** sulphite is present…'.	

Question 3: Do you agree with the proposed changes to section 4.2.3 and 4.2.3.1 to provide distinction between 'specified name' and specific name?	
Yes **X**	No ☐
Please provide reasons for your answer:	

EFA agrees with the proposed distinction, which helps distinguish between 'specified names' (which refer to the priority allergens as listed in sections 4.2.1.4, 4.2.1.7 and where applicable 4.2.1.5) and 'specific names' (which refer to general ingredients under section 4.1). We also take positive note of the word 'must' in the newly introduced text in section 4.2.3, demonstrating the obligatory nature of priority allergen labelling, as opposed to other wordings e.g. 'shall'.

Question 4:
Do you support providing flexibility by including 'whenever possible' in section 8.3.1 by removing the square brackets?

Yes ☐	No **X**

Please provide reasons for your answer:
EFA is strongly against providing any type of flexibility in the obligation to provide clear information about the presence of allergens in a food product. From a consumer patient perspective, **information clarity** regarding allergens requires a presentation that contrasts with the surrounding text of non-allergen ingredients. Therefore, we strongly support deleting the text within square brackets in 8.3.1 [whenever possible]. Allergen declaration through the use of a distinct font type, style or colour should not be perceived as an option, but an obligation.

Question 5:
Of the three options for section 8.3.2, which do you prefer?

Option 1 ☐	Option 2 ☐	Option 3 ☐	Other ☒

Please provide reasons for your answer.
If answering 'Other', please describe your proposed option and explain why you support this.
In previous rounds of consultations on the revision of the allergen-related provisions of the GSLPF, EFA has acknowledged the difficulties involved in the discussion about separate (summary) statements. However, based on testimonies from the European food allergy patient community we have consistently maintained that these statements can be very helpful for consumers, based on the following considerations:

- Convenience, as they enable quick screening of allergenic ingredients to consumers, reducing the pressure to go through the whole ingredients list for every product;
- Exhaustiveness, as they grant the possibility to include additional allergen information;
- Standardisation, as they offer a one-stop shop for allergen information on the label, rendering other symbols redundant e.g. those that indicate that a Qualitative Risk Assessment (QRA) has been performed.

In light of these considerations, EFA has supported **the mandatory use of separate statements, directly next to the ingredient list**. More specifically, **EFA calls for the establishment of a unified 'allergy statement'**, that would gather in one place not only information from the list of ingredients but also Precautionary Allergen Labelling (where applicable) and other allergen-related information of the food product. In this regard, EFA has also proposed relevant templates that could be used, with and without PAL statements (EFA response to the 2nd consultation on the revision of allergen-related provisions of the GSLPF, October-December 2022).

Therefore, EFA considers that none of the three options as they stand in the current proposal clearly specifies the need that **both, highlighted allergens in the ingredient list and a summary statement, should be mandatory**:

- Option 1 (8.3.2) mentions that allergens *may* also be declared in a separate statement, which excludes the highlighting of allergens in the ingredient list. However, this should also be mandatory to make allergen identification easier for food allergy patients and their carers, a finding arising also from the ISSLG consumer literature review.
- Option 2 (Bis.) mentions that allergens shall be declared in the list of ingredients *or* in a separate statement *or* in both. This is a potentially dangerous option as it entails the possibility that in some cases allergens might not be included in the primary source of information for consumers (i.e. the ingredient list).
- Option 3 (Ter.) mentions that allergens shall be declared so as to contrast distinctly from the surrounding text *and/or* be declared in a separate statement, again implying that a separate statement is not established on a mandatory basis.

EFA can agree with a proposal whereby the separate statement becomes mandatory and is placed *directly next to* the list of ingredients. Such wording could derive from Option 3 (Ter.), as long as the following conditions are fulfilled:

- the word shall is replaced with *must*
- the word or is deleted from *and/or*

Consequently, the ideal text from a food allergy patient consumer would read:
'The foods and ingredients listed in sections 4.2.1.4, 4.2.1.7 and where applicable 4.2.1.5 must be declared so as to contrast distinctly from the surrounding text (such as through the use of font type, style or colour) and be declared in a separate statement commence with the word 'contains' (or equivalent word) directly under the list of ingredients.'

Making both options part of the mandatory allergen labelling would not only equip patients/ consumers with food allergy to better identify their allergens, but also solve the issue highlighted by the eWG Chairs of having differences in allergen labelling between countries. EFA believes that our proposal provides with a harmonized approach that will not only ensure consistency towards consumers, but also help overcoming existing barriers to trade.

Question 6:

Do you support the Title, Purpose and Scope sections in the proposed draft PAL guidelines?

Yes **X with clarification**	No ☐

Please provide reasons for your answer:
EFA agrees with the proposed title, purpose and scope of the guidelines. However, we see the need to further clarify the differences between food allergy and coeliac disease, by acknowledging that that needs of both consumer groups should be viewed in this context and need to be addressed through PAL.

Question 7:

Do you support the revised definition for PAL and the changes to the definition section in the proposed draft PAL guidelines?

Yes **X but with additional aspects**	No ☐

Please provide reasons for your answer:
EFA agrees with the proposed changes and definition for PAL. However, as we take note that the new definition provides references to 'food allergen' and 'cross-contact', we think that the same would be helpful also for 'risk assessment', which is a crucial new element added in the definition.

Question 8: Do you support the revised wording for Principle 4.1 in the draft PAL guidelines?	
Yes **X**	No ☐
Please provide reasons for your answer: EFA agrees with the new text as it gives greater clarity to both the measures that need to be taken to prevent unintended allergen presence and to the overuse of unnecessary PAL. However, we stand by our principle that PAL must become mandatory labelling based on a risk assessment. Only by making PAL mandatory will the current uncertainty for consumers with food allergies be reduced, as to whether a food is safe for them. Currently, this uncertainty is even greater in cases where a food does not carry a PAL statement, as the patient has no mechanism to know whether a proper risk assessment has been performed or not. In addition, there are also increasing examples, where a PAL exists but is not comprehensive, meaning: there is a PAL for some food allergens on the label, but patients experience allergic reactions to other food allergens, that are not mentioned on the label (neither as ingredients nor as PAL), but could have been detected as unintended allergen presence. (e.g. see Blom, M. et al: Accidental food allergy reactions: Products and undeclared ingredients (2018) JACI). Therefore, EFA insists on substituting 'shall' with 'must' throughout the document, especially if it is decided to not include PAL in the GSLPF directly and PAL remains in the form of a guideline.	

Question 9: Do you support the revised wording for Principle 4.2 in the draft PAL guidelines?	
Yes ☐	No **X**
Please provide reasons for your answer: EFA acknowledges that both quantitative and qualitative approaches can be used for the assessment of risks from unintended allergen presence, in line also with the recommendations of the FAO/WHO expert consultation 'Report 3: Review and Establish Precautionary Labelling in Foods of the Priority Allergens'. However, we believe that quantitative risk assessments should be prioritised in terms of determining whether a PAL statement should be used or not. To reflect this priority, we suggest changing 'but is not limited to' to '*where possible'*.	

Question 10: Do you support the revised wording for Principle 4.3 and footnote 3 in the draft PAL guidelines?	
Yes **X with clarification**	No ☐
Please provide reasons for your answer: EFA supports the clarification in the footnote on the calculation from the RfD to the action level. A correct choice of amount of the food for this calculation is very important, especially when using ED05 instead of ED01. The reference to P50 implies the use of data and patterns arising from existing food consumption surveys. However, this data is not available for all countries, while new type of products may not have been included or consumption patterns might change over time. These limitations may lead to	

the use of incorrect data or misinterpretations and therefore to the obtention of a wide range of outcomes on the calculations of action levels that might not be accurate.

We therefore suggest that instead of using data from food consumption surveys as a starting point, the food business operator's knowledge of the product and its use should be considered.

EFA suggests using the following wording:
'The amount of food should be established, based on knowledge and characteristics of the product and its maximum use, for a normal single eating occasion intake of the food'.

Question 11:

Do you support the use of ED05-based RfDs as recommended by the Expert Committee and provided in the table at Principle 4.3.1?

Yes **X**	No ☐

Please provide reasons for your answer:
EFA has taken stock of ongoing scientific discussions as regards the most effective approach to establish reference doses (RfDs) for the priority allergens. The debate between the 5% eliciting dose (ED05) and the 1% eliciting dose (ED01) lies at the heart of this discussion, as it is linked not only with the basis for establishing these RfDs and the related risk assessment, but also with specific public health outcomes.

Ever since the publication of the FAO/WHO expert consultation 'Report 2: Review and Establish Threshold Levels in Foods for the Priority Allergens', EFA has supported the use of ED05 as the most appropriate tool for deriving RfDs for the priority allergens and the one that balances the need for safety and food choices for people with food allergy. The current consultation offers an excellent opportunity for EFA to reiterate our support to the use of ED05-based reference doses, and describe the patient perspective that leads to our position:

- At EFA, we are concerned that the use of ED01-derived RfDs, which will by definition be set at a very low cut-off level, will lead to a **proliferation of PAL statements**, as food manufacturers will be incentivised to use PAL for all unintended allergen presence above this level. This way, an ED01-based RfD will further exacerbate the existing problem of PAL overuse in the market, unnecessarily reducing food allergy patients' food choices. Meanwhile, an ED01-based RfD is likely not to be fit-for-purpose in achieving its theoretical goal of protecting 99% of the allergic population: an omnipresent PAL will eventually lose its meaning for patients who might stop taking PAL into account when choosing their food.
- According to recent scientific data, the **differences between ED05 and ED01 in health outcomes** at the population level are minor: only a small fraction of consumers experience an anaphylaxis due to exposure to ED05, and less than 1 in 1,000,000 exposures lead to a fatal episode (P.J. Turner et al., 'Peanut Can Be Used as a Reference Allergen for Hazard Characterization in Food Allergen Risk Management: A Rapid Evidence Assessment and Meta-Analysis', Journal of Allergy and Clinical Immunology, August 2021 https://www.jaci-inpractice.org/action/showPdf?pii=S2213-2198%2821%2900907-7). These findings are in line with the recommendation of the FAO/WHO expert consultation report 2, which specifies that *'the difference in the public health impact of choosing a more stringent RfD is expected to be negligible in terms of reducing significant public health risk'.*
- As regards the protection of consumers who might still react at levels below the proposed RfD, there should be parallel efforts to, on the one hand, identify these patients (e.g. through medical evaluation) and, on the other hand, to establish an additional approach

that ensures this small but vulnerable group of consumers will also be provided with food that is suitable for them.

- EFA takes note of the suggestion for a two-tiered approach, whereby PAL could still be used for allergen levels below ED05, worded as 'may contain traces of…'. However, we consider this approach to be premature at this point, especially in view of the lack of a legal definition for 'traces'. Another potential solution could be to establish additional thresholds for 'free from' (allergen) food to offer options for this group of patients.

In this light, EFA stresses that ED05 strikes the right balance between safety information for food allergy consumers while safeguarding their food choices.

Additionally, EFA emphasises the need of all stakeholders (i.e. authorities, patient/consumer organisations, healthcare professionals, food business operators) to invest in communicating the right message, to ensure that the perception of risk among by the broader public is based on sound scientific data, including countering the intuitive perception that ED01 is safer that ED05. EFA also highlights the need for patient/consumer education on the benefits of using (quantitative) risk assessment as the basis for mandatory PAL, in comparison to the current (voluntary) use of PAL, but also to ensure that those at risk of reaction clearly understand what to do when PAL is not stated.

Finally, we note that no restrictions were set by the FAO/WHO Expert Group on the use of ED05 for specific consumer groups. At the same time, the Expert Group did not make a clear recommendation on the suitability of ED05 or additional considerations for vulnerable groups such as infants and the elderly. We therefore recommend the Expert Group to issue specific advice or statement on vulnerable groups and specific foods. For some groups where, for example, the daily dietary intake consists exclusively of these products, such as milk formula for infants, precautionary considerations in addition to the choice of ED05 may influence the decision of whether or not to add a PAL statement to the product.

Question 12:

Do you support Principle 4.3.2 in the draft PAL guidelines?

Yes **X**	No ☐

Please provide reasons for your answer:
EFA supports the principle 4.3.2 as it is proposed. However, we also believe that reference doses should be harmonised globally, to allow for greater consistency in food labelling practices, as well as to ensure greater transparency for consumers. Oats is an example, in this respect, where it still needs to be generally agreed whether it is considered an allergen or not.

Question 13:

Do you support principle 4.4 in the draft guidelines?

Yes **X** **with recommendation**	No ☐

Please provide reasons for your answer:
EFA maintains that education of all involved stakeholders on allergen labelling (e.g. patients/consumers, healthcare professionals, food business operators, food inspectors), is paramount and must be mandatory. Educational programmes are crucial to ensure the appropriate use and interpretation of PAL by all stakeholders. Moreover, we stress the need to develop a communication guideline addressed to consumers who react to very low doses of the priority allergens (below ED05), and how to communicate these principles to them in an accessible way. As

noted in our response to Question 11, communication should also address common misconceptions around PAL, including explaining the different health implications at the population level of using one or another quantification method as the basis to use PAL.

Transparent information, communication and feedback is the most critical part of an overall educational initiative addressed to consumers, as it must address the needs of those that could be at risk of a reaction when allergens are not declared in a PAL statement on the label. National/international patient organisations (such as EFA) should be involved in the education programmes development by advising the regulatory authorities.

Question 14:

Do you agree with the proposed revisions to Section 5 of the PAL Guidelines relating to the presentation of a PAL statement?

Yes **X with recommendations**	No ☐

Please provide reasons for your answer:

EFA supports a consistent and clear phrasing for PAL statements. We have emphasised on multiple occasions in the past that, ideally, this phrasing should be derived from relevant consumer research, demonstrating which wording is best understood by the food allergy patient community. While we will continue insisting on the necessity of such research, we see that it is not feasible or available today.

Therefore, **EFA supports the use of 'may contain' as the least bad option from a patient perspective**. The fact that 'may contain' is currently the most common wording is beneficial, but also comes with backdrops.

However, we have several recommendations on the proposed revisions of Section 5:

- 5.2: We propose that this must be changed from 'in the same field of vision as the ingredient list' to '**directly next to the ingredient list**';
- 5.2.1: EFA stresses that **there should be one harmonized wording for PAL**. In this respect, the text 'or equivalent words' can be easily misunderstood and even possibly lead to a variety of statements.

Finally, as we have already indicated both in the context of this guideline development process and the revision of the General Standard for the Labelling of Prepackaged Food (GSLPF), EFA urges for the **establishment of an 'Allergen Statement'**, including PAL among other allergen-related information.

Question 15:

Do you support the proposed draft PAL guidelines <u>not</u> including provision for the use of a risk assessment indicator?

Yes ☐	No **X**

Please provide reasons for your answer:

Establishing a mandatory PAL statement in all foods remains the highest priority of EFA food allergy patient community. Nonetheless, if PAL is not mandatory, a symbol would be able to provide very useful information to consumers with food allergy, because otherwise patients would not be able to distinguish if a product without PAL has been risk assessed according to the recommendations or not. In other words, we do see a great value to the indication of a performed risk assessment, but only as a second-best choice in case it is decided that PAL is not become mandatory.

Therefore, we do not agree with the non-inclusion of a principle relating to the use of a risk assessment indicator.