

Summary of responses to [CL 2023/06/OCS-FL](#)

The Chairs of the Allergen Labelling Electronic Working Group have prepared this summary document of responses received to CL 2023/06/OCS-FL relating to the proposed draft revision to the *General Standard for the Labelling of Prepackaged Foods* (GSLPF). The Chairs hope this will assist participants in the upcoming virtual working group sessions. The comments are presented under the relevant section(s) of the proposed draft revision in Appendix II of [CX/FL 23/47/5](#). Comments about minor editorial changes have not been included in this document but have been noted by the Chairs. A summary of responses to the question (iii) in CL 2023/06/OCS-FL about whether to provide any advice to CCFH is also provided at the end of this document.

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

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.”

Summary of comments:

Most respondents supported the proposed definition for food allergy. One respondent did not support the definition because it removes reference to being an immune response that occurs through a protein and therefore differs to the definition for ‘allergen’ in the Code of Practice on Food Allergen Management for Food Business Operators (CXC80-2020).

One respondent disagreed with having a footnote reference to coeliac disease rather than a separate definition in the main body of text (see comments below relating to Footnotes 1 and 2).

4. MANDATORY LABELLING OF PREPACKAGED FOODS

4.2 List of ingredients

4.2.1.3 Where an ingredient is itself the product of two or more ingredients, such a compound ingredient may be declared, as such, in the list of ingredients, provided that it is immediately accompanied by a list, in brackets, of its ingredients in descending order of proportion (m/m). Where a compound ingredient (for which a name has been established in a Codex standard or in national legislation) constitutes less than 5% of the food, the ingredients, ~~other than~~ **need not be declared, except for the foods and ingredients listed in section 4.2.1.4, 4.2.1.6 and where applicable section 4.2.1.5** and food additives which serve a technological function in the finished product, ~~need not be declared~~.

Summary of comments:

A number of respondents while supporting the revised text noted that certain national authorities apply the guidance given in 4.2.1.3 subject to local conditions i.e. not all countries exempt the declaration of compound ingredients in <5%. One respondent supported removal of the 5% rule so that consumers can be informed about foods that are not (yet) priority allergens or are emerging allergens.

4.2.1.4 The following foods and ingredients are known to cause ~~hypersensitivity~~ **food allergy or coeliac disease**¹. and shall always be declared² **using the name specified:**

- ~~Cereals containing gluten; i.e., wheat, rye, barley, oats, spelt or their hybridized strains and products of these;~~
- ~~Crustacea and products of these;~~
- ~~Eggs and egg products;~~
- ~~Fish and fish products;~~

- ~~Peanuts [, soybeans and] products of these;~~
- ~~Milk and milk products [(lactose included)];~~
- ~~tree nuts and nut products; and~~
- ~~Sulphite in concentrations of 10 mg/kg or more~~

FOODS AND INGREDIENTS

SPECIFIED NAME

Cereals containing gluten ² :	'wheat'
– wheat and other <i>Triticum</i> species	'rye'
– rye and other <i>Secale</i> species	'barley'
– barley and other <i>Hordeum</i> species	
and products thereof	
Crustacea and products thereof	'crustacea' or the common name of individual crustacean species
Eggs and products thereof	'egg'
Fish and products thereof	'fish' or the common name of individual fish species
Peanuts and products thereof	'peanut'
Milk and products thereof	'milk'
Sesame and products thereof	'sesame'
Specific tree nuts	'almond'
– Almond	'cashew'
– Cashew	'hazelnut'
– hazelnut	'pecan'
– pecan	'pistachio'
– pistachio	'walnut'
– walnut	
and products thereof	

Summary of comments:

There was general support for proposed changes to section 4.2.1.4. However a number of respondents asked for clarification on the first sentence in both sections 4.2.1.4 and 4.2.1.5 relating to the use of specified names. It was noted the wording appeared in conflict with the provisions in Section 4.1 (The name of the food) of the GSLPF and is unclear about whether the intention is to replace the specific name of the ingredient (e.g., albumin) by the specified name (e.g., egg). Some respondents considered they should be additional to ingredient names, and requested this is made clear in sections 4.2.1.4 and 4.2.1.5.

List of foods and ingredients

Two respondents did not support inclusion of sesame in the list on the basis that sesame allergy has a low prevalence in Asia and proposed moving sesame to the list at section 4.2.1.5.

One respondent considered other factors must be considered by CCFL for the list of priority allergens to ensure that the risk management measures related to the labelling of these foods and ingredients are effective in protecting consumer health and facilitating international trade. They cited soy and tree nuts as examples of where other factors (e.g. prevalence across multiple regions, severity, widely used in food, exposure by vulnerable populations such as infants) should be considered and proposed merging the lists from sections 4.2.1.4 and 4.2.1.5 together to promote more consistent practices in international trade.

Specified names

One respondent considered the use of specified names should also allow for the use of other well-understood terms, where appropriate. Another noted that the specified names are listed in the singular and questioned whether plural forms would also be permitted, e.g. 'peanuts', 'eggs', 'walnuts' etc. and would prefer both singular and plural forms be permitted.

Specific comments were also received about the following:

- Cereals containing gluten: One respondent proposed that some flexibility should be allowed in regards to 'wheat' being accompanied by the word 'durum', 'spelt' or 'khorasan' on a voluntary basis, where 'spelt', 'khorasan' or 'durum' is used. Another respondent requested 'triticale' be included as a specified name rather than using 'wheat' and 'rye' for this cereal hybrid. Some respondents proposed 'gluten' be added as a specified name for wheat, barley and rye to be used in addition to the cereal name.
- Fish and crustacea: Two respondents did not support the use of common names for individual species as specified names for fish and crustacea stating that for consistency the specified names should be 'fish' and 'crustacea' only. However another respondent did not consider those generic terms would be acceptable for including in the list of ingredients and that the more specific species name for the ingredient which is actually present should be required.
- Milk: One respondent considered the specified name should not be restricted to 'milk', and should instead, as is the case for fish and crustacea, allow the common name of individual milk products such as 'cheese' and 'cream' to be used. Further that some flexibility should be provided for cases where, for example a food is sold under a name such as 'cheese', 'cream' which it is not required to bear a list of ingredients, for the allergen in question (e.g. milk) not have to be indicated on the label.
- Sesame: One respondent questioned whether the use of 'sesame seed' or 'sesame seeds' would be permitted for the declaration of 'sesame', given that they contain the required specified name of 'sesame' and supported permitting the use of all three as specified names.
- Tree nuts: One respondent considered that, as provided for cereals, it would be useful for clarity to provide the scientific names for the listed tree nuts noting Codex texts are used at global level and translations are provided only in some languages and scientific names are considered a global name and therefore, mentioning the scientific names in the text will ensure consistency with the international nature of these standards.

Footnotes 1 and 2

¹ *Coeliac disease* is a chronic immune-mediated intestinal disease in genetically predisposed individuals induced by exposure to dietary gluten proteins that come from wheat, rye, barley and triticale (a cross between wheat and rye).

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

Summary of comments:

Several respondents did not support reference to coeliac disease being included as a footnote to section 4.2.1.4, but supported a definition being included in section 2 (definition of terms). These respondents argued that 'coeliac disease' is being used as a term in the GSLPF in the same manner as 'food allergy', and to ensure that the definition of coeliac disease is not overlooked.

Although supporting inclusion of footnote 1, another respondent considered defining coeliac disease as an "intestinal" disease should be avoided as symptoms can be quite systemic. They suggested revising the footnote to: "Coeliac disease is a chronic autoimmune systemic disorder triggered in genetically predisposed individuals by exposure to dietary gluten proteins that come from wheat, rye, barley and triticale (a cross between wheat and rye)."

Another respondent recommended footnote 1 is amended by replacing 'cross' with 'hybrid', for consistency with 'hybridized' in footnote 2.

4.2.1.5

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

FOODS AND INGREDIENTS	SPECIFIED NAME
Buckwheat and products thereof	'buckwheat'
Celery and products thereof	'celery'
Oats and other <i>Avena</i> species (and their hybridized strains) and products thereof	'oats'
Lupin and products thereof	'lupin'
Mustard and products thereof	'mustard'
Soybean and products thereof	'soy'
Specific tree nuts	'Brazil nut'
– Brazil nut	'macadamia'
– macadamia	'pine nut'
– pine nut	
and products thereof	

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

<https://doi.org/10.4060/cb9070en>.

Summary of comments:

Respondent's views were divided on the inclusion of new section 4.2.1.5. Those supporting was based on the recommendations of the Expert Committee that declaration of these allergens could be considered by national or regional authorities. Others opposed inclusion of a separate list of allergens for national or regional consideration stating it would likely result in inconsistencies in interpretation of, and labelling, for global trade and create confusion. Additionally, these respondents argued that the allergens listed in 4.2.1.5 are not equal in prevalence to the priority allergens listed in section 4.1.2.4.

Some respondents proposed that if section 4.2.1.5 was retained, then a note should be added referencing the report of the 1st meeting of the FAO/WHO Expert Committee and stating that the list of foods and ingredients in section 4.2.1.5 lacked adequate and sufficient data to elevated them as global priority allergens. One respondent in support of section 4.2.1.5 recommended the list also indicate the region or nations where these allergenic foods are important based on the Expert Committee advice because the list provides a common framework internationally and will help ensure trade regulations are not overly burdensome.

Some respondents proposed section 4.2.1.5 could remain as a general provision allowing national authorities to require declarations for allergens, provided the requirements were based on there being a risk assessment undertaken in their respective population.

Specific comments were also received about the following:

- Oats: Two respondents requested oats be removed from the list at section 4.2.1.5 because it is not a gluten-containing cereal and therefore not directly an allergenic food and that cross contamination of oats with gluten containing grains can be addressed by precautionary allergen Labelling (PAL) instead. However other respondents supported to retain oats, as the Expert Committee identified a risk of cross-contamination with gluten containing cereals and that oats be considered at a national or regional level. One respondent supported retaining oats in section 4.2.1.4 until a future point where controls for cross-contamination of oats are effective at a global level and/or PAL is applied in a more standardised manner and that further consideration should be given to published literature on the potential immunogenicity of avenin.

- **Molluscs:** One respondent requested that “molluscs and products thereof” be included in section 4.2.1.5. According to the 'EFSA opinion on the evaluation of allergenic foods and food ingredients for labelling purposes', molluscs can cause severe and occasionally life-threatening food-allergic reactions.

In regards to footnote 3, some respondents while supporting its inclusion questioned whether the reference to the FAO/WHO report was correct (see also comments below relating to Footnote 3).

Chair's note: The reference to Footnote 3 in Appendix II of CX/FL 23/47/5 is incorrect for Section 4.2.1.5. It should read as follows:

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

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

Summary of comments:

One respondent did not support including sulphites noting intolerances are excluded from the Code of Practice on Food Allergen Management for Food Business Operators (CXC80-2020) and that sulphite used as a food additive will be labelling and additional labelling is not needed.

Other respondents made suggested text changes to ensure sulphite from all sources is included not just added, that the 10 mg/kg amount relates to products ready for consumption, that the amount of 10mg/kg is included not just when this amount is exceeded, and to also allow declaration using the specified name 'sulphur dioxide'.

4.2.1.7 Subject to evaluation using established criteria³, 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.

Summary of comments:

There was general support for including this provision. However some respondents did not support leaving the assessment to national authorities because of a lack of harmonization and potential to impact trade. Some respondents supported inclusion of a specific list of highly refined foods and ingredients which have already assessed by regulatory bodies as being permitted exemptions (e.g. maltodextrin from wheat or highly refined soybean oil). Other respondents noted that the FAO/WHO Expert Committee's Part 4: Review and establish exemptions for the food allergens report has not yet been fully published and requested that section 4.2.1.7 be kept in square brackets until this report becomes available. Others also supported including the 'established criteria' in the GSLPF or in another Codex guideline.

Footnote 3

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

Summary of comments:

A number of respondents while supporting its inclusion also questioned whether the footnote was correct for this section.

Chair's note: The reference to Footnote 3 in Appendix II of CX/FL 23/47/5 is incorrect for Section 4.2.1.7. It should be footnote 4 as follows:

⁴ 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>

4.2.2 The presence in any food or food ingredients obtained through biotechnology of an allergen transferred from any of the products **foods and ingredients** listed in sections 4.2.1.4 **and where applicable 4.2.1.5** shall be declared. When it is not possible to provide adequate information on the presence of an allergen through labelling, the food containing the allergen should not be marketed.

Summary of comments:

A number of respondents comments on this section. Two respondent comment on use of 'allergen' in this section as the term is not defined in the GSLPF and suggested either removing reference to 'allergen' or for a definition of 'allergen' to be included. Other respondents noted the need to also cover the safety of novel foods including an allergenicity assessment, which might then lead to additional labelling requirements citing examples of insects, non-animal milk proteins, rapeseed proteins.

4.2.3 Except for those foods and ingredients listed in sections 4.2.1.4, 4.2.1.6 and where applicable

4.2.1.5, A specific name shall be used for ingredients in the list of ingredients in accordance with the provisions set out in Section 4.1 (Name of the Food) except that:

4.2.3.1 Except for those ingredients listed in section 4.2.1.4, and uUnless a general class name would be more informative, the following class names may be used. **In all cases, the food and ingredients listed in sections 4.2.1.4, 4.2.1.6 and where applicable 4.2.1.5 shall be declared using the specified names listed in those sections.**

Summary of comments:

A few comments were received with suggestions to clarify the proposed wording of 4.2.3 and 4.3.2.1.

4.2.4 Processing Aids and Carry-Over of Food Additives

4.2.4.2 A food additive carried over into foods at a level less than that required to achieve a technological function, and processing aids, are exempted from declaration in the list of ingredients. The exemption does not apply to food additives and processing aids **that contain the foods and ingredients** listed in sections 4.2.1.4, 4.2.1.6 and where applicable 4.2.1.5.

Summary of comments:

A number of respondents commented that consideration should be given to applying the exemptions (as proposed in section 4.2.1.7) to determine the need for labelling rather than making labelling required for any amount of processing aid or carry over additive regardless of how low the level of allergenic food or food protein may be.

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, 4.2.1.6 and where applicable 4.2.1.5.**

Summary of comments:

Little comment was received on this section.

8. PRESENTATION OF MANDATORY INFORMATION

(New)

8.3 Declaration of certain foods and ingredients

Summary of comments:

Two respondents indicated concern about the wording 'where applicable 4.2.1.5' in section 8.3 suggests that the allergens listed in 4.2.1.5 should be labelled in a mandatory manner and suggested the need for an explanatory note referring to the risk assessment on allergens developed by each country and taking into account the evaluation of the FAO/WHO expert report.

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

Summary of comments:

One respondent considered declaration can be either in the list of ingredients or in a separate statement (or both) and that section 8.3.2 should also be applied as an alternative to section 8.3.1, or both used together for flexibility. Whereas another respondent proposed a change to apply section 8.3.1 only to the list of ingredients.

One respondent did not agree with requiring the use of font type, style or colour that contrasts distinctly as it did not allow use of other means such as the use of parentheses and another proposed alternate wording of 'clearly distinguishable on the label such as through the use of contrast, font type, style or colour' to provide flexibility and not be overly prescriptive.

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

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

Summary of comments:

Three respondents did not support the text in 8.3.2 and 8.3.2.1 relating to the voluntary use of a separate 'Contains' statement because in their view always and only declaring the allergens in the list of ingredients ensures consistency for consumers. One of these respondents considers the use of separate statements increases the risk that consumers will confuse the actual presence of allergens with the potential presence of allergens in the context of precautionary allergen labelling (PAL) and that there is a high risk that consumers will misinterpret anything in a separate statement as PAL, and risk ignoring information on allergens in the list of ingredients. They consider that different schemes of providing information to consumers may result in confusing consumers and propose deletion of these two sections.

Another respondent noted sections 4.2.3.1, 8.3.2 and 8.3.2.1 indicate that the allergen name must always appear in the list of ingredients and 'may also be declared' in a separate statement requiring declaration twice when the 'Contains' statement is present. They proposed wording changes to section 8.3.2 to permit declaration in three ways, the list of ingredients, the Contains statement, or in both.

Two respondents considered the use of 'may' in section 8.3.1 was unclear as it appears to contradict 8.3.2.1 or that they considered the optional declaration in a separate statement should be mandatory.

8.3.3 Where a food is exempt from declaring a list of ingredients, the foods and ingredients listed in sections 4.2.1.4, 4.2.1.6 and where applicable 4.2.1.5 shall be declared, such as in a statement made in accordance with section 8.3.2.1.

Summary of comments:

A few comments were received with proposed wording changes for this section.

8.3.4 For single ingredient foods, section 8.3.3 does not apply where foods and ingredients listed in sections 4.2.1.4, 4.2.1.6 and where applicable 4.2.1.5 are declared as part of, or in conjunction with, the name of the food.

Summary of comments:

A few comments were received with proposed wording changes for this section.

Question:

Codex members and observers are invited to submit comments on:

(ii) whether to provide any advice to CCFH to ensure consistency with the *Code of Practice on Allergen Management for Food Business Operators* (CXC 80-2020).

Summary of comments:

The majority of respondents supported providing advice to CCFH to ensure there is consistency between the Codex texts moving forward including aligning definition of terms such as 'food allergy' and 'allergen'. One respondent suggested the timing on providing advice may be more appropriately done when the proposed revised text is at Step 5.