

# CODEx ALIMENTARIUS COMMISSION



Food and Agriculture  
Organization of the  
United Nations



World Health  
Organization

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Agenda Item 5

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## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEx COMMITTEE ON FOOD LABELLING

Forty-seventh Session

Gatineau, Canada

15 – 19 May 2023

### REPORT OF 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*

*Prepared by the Virtual-Physical Working Group chaired by Australia and co-chaired by the USA and the UK*

#### Introduction

The Virtual-Physical Working Group (VPWG) met on May 9 – 10, 2023, prior to the 47<sup>th</sup> session of the CCFL. The focus of the working group was to discuss the proposed revisions from the Electronic Working Group (EWG) and progress work on Part A – proposed draft revisions to the *General Standard for the Labelling of Prepackaged Foods (GSLPF)* (CXS 1-1985) relevant to allergen labelling (Appendix II to CX/FL 23/4/5). Specifically:

1. Section 2 Definition of Terms
2. Section 4 Mandatory Labelling of Prepackaged Foods
3. Section 6 Exemptions from Mandatory Labelling Requirements
4. Section 8 Presentation of Mandatory Information

Discussion on Part B Precautionary Allergen Labelling will occur in the plenary at CCFL47.

The VPWG Chair introduced the programme for the working group and background documents (Agenda paper 5 CX/FL 23/4/5, Comments in Response to Circular Letter (CL) CL 2023/06/OCS-FL in CX/FL 23/47/5 Add.1, Summary of responses to CL 2023/06/OCS-FL). A representative from the Joint FAO/WHO expert consultation (henceforth “expert committee”) was in attendance to provide scientific advice. The VPWG agreed to proceed with the programme as proposed by the VPWG Chair.

#### Discussion and recommendations on Part A – proposed draft revisions to the GSLPF

##### 1. Section 2 Definition of Terms

Proposal from the EWG:

#### 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.”

A summary of the VPWG discussion and recommendations is presented below:

The VPWG Chair encouraged the VPWG to focus the discussion on the proposed definition for “Food allergy” in Appendix II and recalled that the proposed definition had been adapted from the definition in the expert committee’s report. The VPWG heard suggestions to add definitions (*i.e.*, allergen, hypersensitivity, coeliac disease), and concerns that the definition for “Food allergy” did not refer to protein and with the meaning of ‘oral exposure’. The expert committee advised that the definition for “Food allergy” from the expert report captured the

participants' concerns. The VPWG agreed to accept the "Food allergy" definition as proposed.

Based on later discussion (see below), the VPWG also agreed to move the definition of coeliac disease from footnote 1 in section 4.2.1.4 to the Definition of Terms.

**Recommendation:** The VPWG recommends that the Committee agree to the proposed definitions for Food Allergy and Coeliac disease, and to add the definition for Coeliac disease to the Definition of Terms section.

## 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."

"*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).

### 2. Section 4 Mandatory Labelling of Prepackaged Foods

Proposal from the EWG:

#### 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.~~

A summary of the VPWG discussion and recommendations is presented below:

Due to the limited CL comments received, the VPWG agreed to the Chair's proposal not to discuss this section and proceed to section 4.2.1.4.

**Recommendation:** The VPWG recommends that the Committee discuss section 4.2.1.3 during the plenary session.

Proposal from the EWG:

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

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

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

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

<b>FOODS AND INGREDIENTS</b>	<b>SPECIFIED NAME</b>
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	

A summary of the VPWG discussion and recommendations is presented below:

The VPWG Chair proposed to structure the discussion as follows: the list of foods and ingredients, the introductory sentence, the specified names, and the footnotes. The VPWG Chair clarified that the intention of the specified name was to make it easier for consumers to identify allergens through consistent and clear terms and reminded the VPWG that the list of foods and ingredients in Column 1 had been drawn from the list of global priority allergens from the expert committee.

#### Foods and Ingredients

The VPWG discussed including the scientific names for the specific tree nuts in Column 1 to be clear about what is to be declared. There was general agreement on this proposal. Although there are several scientific names for certain tree nuts, and as the VPWG did not discuss which names to include, a reference with the agreed scientific names will need to be considered by the committee.

The Chair noted requests to move soybean, oats, and the specific tree nuts from the list in 4.2.1.5 and sought the expert committee's advice. The expert committee advised that soybean, tree nuts, and uncontaminated oats in 4.2.1.5 were excluded from the priority list due to lack of global data and ranking of severity, potency, and prevalence. A similar request to move sesame from the list in 4.2.1.4 to the list in 4.2.1.5 was heard, and the expert committee clarified that sesame had been included in the priority list based on the meeting the criteria for global priority allergens. The VPWG agreed to accept the scientific advice from the expert committee and include the foods and ingredients in Column 1 as proposed by the EWG.

#### Introductory Sentence

The VPWG proposed edits to clarify the intention of the first sentence in regard to the use of specified names and meeting the requirements for ingredient labelling. The VPWG agreed to recommend the edits.

#### Specified Names

The VPWG discussed the need for consumers to have information on common and/or species names for fish and crustacea. Other suggestions to include species names for the origin of milk and common names for milk products were heard. The VPWG proposed adding a new footnote 2 that references section 4.1.1 of the *GSLPF* to the introductory sentence to address the concerns around using specific names in the ingredient declaration and remove reference to common or species name in the table. Regarding common and/or species names for fish, it was noted that section 4.2.3.1 on class names may need to be reviewed, e.g., use of 'fish'.

#### Footnotes

With regard to footnote 1, the VPWG heard comments that coeliac disease was a systemic disease and not an intestinal disease. Edits were suggested to this effect, though the expert committee advised that the definition from the expert committee report captured the proposed additions. The VPWG ultimately agreed to recommend that the text on coeliac disease be taken up as proposed in footnote 1.

There was consensus in the VPWG that footnote 1 serves as a definition, and agreement to move the text in footnote 1 to the Definition of Terms section as a definition for coeliac disease.

Regarding footnote 2 there was some discussion around moving the text into Column 1 of the table. The VPWG ultimately agreed to maintain this text as a footnote for clarity and legibility. A suggestion was made to add “Khorasan” to the footnote; this was agreed to by the VWGP.

**Recommendation:** The VPWG recommends that the Committee accept section 4.2.1.4 as proposed below and, upon review of an appropriate reference, include the scientific names for the specific tree nuts listed in Column 1.

**4.2.1.4** The following foods and ingredients are known to trigger food allergy or coeliac disease and shall always be declared using the specified name in addition to or as part of the ingredient name<sup>1</sup>:

FOODS AND INGREDIENTS	SPECIFIED NAME
Cereals containing gluten <sup>2</sup> :	‘wheat’
– wheat and other <i>Triticum</i> species	‘rye’
– rye and other <i>Secale</i> species	‘barley’
barley and other <i>Hordeum</i> species and products thereof	
Crustacea and products thereof	‘crustacea’
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’
– Almond	‘cashew’
– Cashew	‘hazelnut’
– Hazelnut	‘pecan’
– Pecan	‘pistachio’
– pistachio	‘walnut’
– walnut	
and products thereof	

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

<sup>2</sup> 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.

Proposal from the EWG:

#### 4.2.1.5

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

<sup>3</sup> The assessment of risk to be based on the evidence criteria of prevalence, potency and severity of immune mediated adverse reactions to the food or ingredient in the respective population(s).

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	

A summary of the VPWG discussion and recommendations is presented below:

The VPWG Chair noted the expert committee's recommendation that the foods and ingredients in 4.1.2.5 may be considered by individual countries or regions. The VPWG Chair noted previous interventions on oats, soybean, and tree nuts included in this section, and asked the VPWG to first consider the inclusion of this section and then the list of foods and ingredients.

There was general support for the inclusion of section 4.2.1.5. Some concerns were raised regarding the exhaustive nature of the list, how the list of foods and ingredients was determined, and the potential for misinterpretation. Multiple proposals were made to remedy these concerns, which the VPWG discussed at length. Support for the inclusion of 4.2.1.5 centred around the need to provide clarity and guidance to regions and countries where risk management considerations would indicate the need for the declaration of the foods listed in 4.2.1.5, and to provide consistency in the labelling of these allergens through the use of specified names.

The VPWG discussed whether oats, being a cross-contamination issue, would be more appropriately addressed through risk-management frameworks such as Precautionary Allergen Labelling; additional suggestions were heard to include molluscs and chestnuts in the list in 4.2.1.5. The expert committee advised the VPWG that molluscs and chestnuts were not included due to limited data on prevalence and potency. The VPWG agreed to keep oats on the list in 4.2.1.5 and include the footnote from the *Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten* (CXS 118-1979) to note the declaration of oats may be determined at a national level. Noting support to retain the recommendations of the expert committee for 4.2.1.4, the VPWG agreed to do the same for 4.2.1.5 and not make additions to the list as presented.

To address concerns with regard to the intention of section 4.2.1.5, the VPWG Chair proposed a revised chapeau of section 4.1.2.5. Upon reviewing this proposal, the VPWG discussed whether there was a need to reiterate that national and/or regional authorities could require the declaration of other foods, and whether the VPWG Chair's proposal introduced section 4.2.1.5 as an exhaustive list. The VPWG Chair proposed edits to make clear that the list is not exhaustive and clarified that national and/or regional authorities can undertake their own risk assessments and could require the declaration of other foods. The VPWG Chair additionally clarified that proposed edits intended to capture that countries could draw from the expert committee report when establishing their own risk management priorities as the report produced risk assessment information at the population level.

Another revised chapeau was proposed expressly stating that national or regional authorities may require the declaration of any other foods in addition to the list in 4.2.1.5, as well as another proposal to include a simple statement of national and regional authorities' ability to require the declaration of any foods instead of 4.2.1.5. The VPWG agreed that the VPWG Chair's proposal captured the elements of other proposals and there was broad support for the VPWG Chair's proposed chapeau. A request was made for the VPWG to put forward the VPWG Chair's proposal in square brackets for consideration during the plenary session.

The VPWG agreed to the suggestions to provide for the use of specified names for both the foods listed in 4.2.1.5 and any other foods as determined by national and/or regional authorities. There was additional discussion about whether to include a footnote to clarify why the foods and ingredients were not included in 4.2.1.4. The expert committee advised that the foods and ingredients in section 4.2.1.5 were not included in 4.2.1.4 due to a lack of global data and advised the VPWG on its risk assessment approach for recommending the foods in section 4.2.1.5. The VPWG generally agreed to include a footnote clarifying how the list of foods and ingredients was determined.

**Recommendation:** The VPWG recommends that the Committee consider the below revised section 4.1.2.5 during the plenary session.

**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<sup>x</sup> using a specified name in addition to or as part of the ingredient name<sup>y</sup>. This shall be based on risk management considerations, taking into account available risk assessment data for respective population(s)<sup>z</sup>.

<sup>x</sup> These foods and ingredients are not included in section 4.2.1.4 due to lack of global data and/or not meeting the evidence criteria on a global level but have been recommended to be considered for declaration of allergens in individual countries or regions (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>).

Proposed Revision to Footnote x: These foods and ingredients are not included in 4.2.1.4 but have been recommended to be considered for declaration of allergens in individual countries or regions (see FAO and WHO Risk assessment of food allergens: Part 1: Review and validation of Codex Alimentarius priority allergen list through risk assessment. P9 -13. <https://doi.org/10.4060/cb9070en>.)

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

<sup>z</sup> The assessment of risk in a 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>.

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 <sup>#</sup>	'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	

<sup>#</sup> 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."

Proposal from the EWG:

**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'.

A summary of the VPWG discussion and recommendations is presented below:

A suggestion was made to set the threshold for declaration of sulphites at or above a total concentration of 10mg/kg to reflect the fact that this threshold is how it is currently expressed in the *GSLPF*. The VPWG supported this suggestion. There was discussion regarding the need to specify that the total concentration applied to both added and naturally occurring sulphites. The Chair confirmed that total concentration refers to both added and naturally occurring sulphites, and the VPWG agreed to remove the term "added" from the proposed text.

The VPWG heard additional suggestions to specify that this threshold should apply to the "final product as consumed"; however, a concern was raised regarding "as consumed" given that it would introduce uncertainty for manufacturers. The VPWG also agreed to move 4.2.1.6 given that reactions to sulphites are not allergies but rather hypersensitivities and the provision would be more appropriately positioned below 4.2.1.7. There was also a suggestion to include sulphur dioxide in 4.2.1.6, and discussion about whether this was captured by the term "sulphite".

**Recommendation:** The VPWG recommends the Committee consider and accept the following revision to 4.2.1.6 and move the text to be positioned below 4.2.1.7:

Renumber 4.2.1.7 to 4.2.1.6 Subject to evaluation using established criteria<sup>4</sup>, national authorities may exempt ingredients derived from foods listed in section 4.2.1.4, and where applicable section 4.2.1.5, from being declared.

Renumber 4.2.1.6 to 4.2.1.7 When sulphite is present in a food, at a total concentration of 10 mg/kg or above in the final product, it shall always be declared using the specified name 'sulphite'.

Proposal from the EWG:

4.2.1.7 Subject to evaluation using established criteria<sup>4</sup>, national authorities may exempt ingredients derived from foods listed in section 4.2.1.4, and where applicable section 4.2.1.5, from being declared.

#### **RENUMBER existing sections 4.2.1.5 and 4.2.1.6 to 4.2.1.8 and 4.2.1.9 respectively**

**4.2.2** The presence in any food or food ingredients obtained through biotechnology of an allergen transferred 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 an allergen through labelling, the food containing the allergen should not be marketed.

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

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

#### **4.2.4 Processing Aids and Carry-Over of Food Additives**

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

<sup>4</sup> 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>.

**Recommendation:** Due to time constraints and noting the forthcoming expert committee report on establishing exemptions for food allergens, the VPWG agreed to the VPWG Chair's proposal to proceed to discuss section 8. Presentation of Mandatory Information, and recommends to the Committee that sections 4.2.1.7, and 4.2.2 – 4.2.4.2 be discussed in plenary.

Proposal from the EWG:

## 6. EXEMPTIONS FROM MANDATORY LABELLING REQUIREMENTS

With the exception of spices and herbs, small units, where the largest surface area is less than 10 cm<sup>2</sup>, may be exempted from the requirements of paragraphs 4.2 and 4.6 to 4.8. **This exemption does not apply to the declaration of foods and ingredients listed in sections 4.2.1.4, 4.2.1.6 and where applicable 4.2.1.5.**

A summary of the VPWG discussion and recommendations is presented below:

Due to the limited CL comments received and the forthcoming expert committee report, the VPWG agreed to the VPWG Chair's proposal not to discuss this section.

**Recommendation:** The VPWG recommends that the Committee discuss section 6. Exemptions from Mandatory Labelling Requirements in the plenary.

### Section 8 Presentation of Mandatory Information

Proposal from the EWG:

## 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, 4.2.1.6 and where applicable 4.2.1.5 shall be declared so as to contrast distinctly from the surrounding text, such as through the use of font type, style or colour.

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

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

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

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

A summary of the VPWG discussion and recommendations is presented below:

The VPWG Chair suggested taking comments of a general nature on the whole section and reminded the VPWG that the intention of this section was to provide information as to how allergens are to be declared to assist consumers in identifying allergens, and to ensure flexibility for national and/or regional authorities to have the declaration that is suitable for their population. There was significant discussion regarding this section.

The VPWG heard concerns about the provision to require that the declaration of allergens in ingredient lists contrast distinctly from the surrounding texts. The VPWG agreed to include "whenever possible" to add flexibility to 8.3.1. The VPWG also agreed to edit 8.3.2 to reflect that the position of a separate declaration statement should be "directly under" the list of ingredients as this was preferable to the statement being in the same field of vision as the ingredient list.

Although there were concerns raised that 8.3.2 and 8.3.2.1 introduced the risk of confusing consumers with separate schemes—along with a suggestion to delete the sections and propose corresponding edits to section 8.3.3—the VPWG voiced broad support for maintaining these sections citing the following: a need for clarity in using "contains" statements, that the approaches in 8.3.2 and 8.3.2.1 are effective for informing consumers with allergies, and that these sections provide necessary flexibility for countries.



**Recommendation:** The VPWG recommends the Committee consider the following proposed changes to Section 8, which capture the above comments and concerns of the VPWG:

## **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, 4.2.1.6 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, 4.2.1.6 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~~ 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, 4.2.1.6 and where applicable 4.2.1.5 shall be declared, such as in a statement made in accordance with section 8.3.2.1.

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

**APPENDIX II****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.”

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

**4. MANDATORY LABELLING OF PREPACKAGED FOODS****4.2 List of ingredients**

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

**4.2.1.4** The following foods and ingredients are known to trigger food allergy or coeliac disease and shall always be declared using the specified name in addition to or as part of the ingredient name<sup>5</sup>:

<b>FOODS AND INGREDIENTS</b>	<b>SPECIFIED NAME</b>
Cereals containing gluten <sup>6</sup> :	‘wheat’
– wheat and other <i>Triticum</i> species	‘rye’
– rye and other <i>Secale</i> species	‘barley’
– barley and other <i>Hordeum</i> species and products thereof	
Crustacea and products thereof	‘crustacea’
Eggs and products thereof	‘egg’
Fish and products thereof	‘fish’
Peanuts and products thereof	‘peanut’
Milk and products thereof	‘milk’ or the common name of individual milk products
Sesame and products thereof	‘sesame’
Specific tree nuts	‘almond’
– Almond	‘cashew’
– Cashew	‘hazelnut’
– Hazelnut	‘pecan’
– Pecan	‘pistachio’
– pistachio	

<sup>5</sup> In accordance with Section 4.1.1 of the *General Standard for the Labelling of Prepackaged Foods* (CXS 1-1985), the ingredient declaration should specify the true nature of the food and be specific and not generic.

<sup>6</sup> 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).

FOODS AND INGREDIENTS	SPECIFIED NAME
– walnut and products thereof	‘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<sup>x</sup> using a specified name in addition to or as part of the ingredient name<sup>y</sup>. This shall be based on risk management considerations, taking into account available risk assessment data for respective population(s)<sup>z</sup>.

<sup>x</sup> These foods and ingredients are not included in section 4.2.1.4 due to lack of global data and/or not meeting the evidence criteria on a global level but have been recommended to be considered for declaration of allergens in individual countries or regions (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>).

Proposed Revision to Footnote x: These foods and ingredients are not included in 4.2.1.4 but have been recommended to be considered for declaration of allergens in individual countries or regions (see FAO and WHO Risk assessment of food allergens: Part 1: Review and validation of Codex Alimentarius priority allergen list through risk assessment. P9 -13. <https://doi.org/10.4060/cb9070en>.)

<sup>y</sup> In accordance with Section 4.1.1 of the *General Standard for the Labelling of Prepackaged Foods* (CXS 1-1985), the ingredient declaration should specify the true nature of the food and be specific and not generic

<sup>z</sup> The assessment of risk in a 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>.

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 <sup>7</sup>	‘oats’
Lupin and products thereof	‘lupin’
Mustard and products thereof	‘mustard’
Soybean and products thereof	‘soy’
Specific tree nuts	‘Brazil nut’
– Brazil nut	‘macadamia’
– macadamia	‘pine nut’
– pine nut	
and products thereof	

4.2.1.6 Subject to evaluation using established criteria<sup>8</sup>, national authorities may exempt ingredients derived from foods listed in section 4.2.1.4, and where applicable section 4.2.1.5, from being declared.

4.2.1.7 When sulphite is present in a food, at a total concentration of 10 mg/kg or above in the final product, it shall always be declared using the specified name ‘sulphite’.

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

**4.2.2** The presence in any food or food ingredients obtained through biotechnology of an allergen transferred

<sup>7</sup> 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."

<sup>8</sup> FAO and WHO (2022). Risk assessment of food allergens: Part 1: Review and validation of Codex Alimentarius priority allergen list through risk assessment. p15-20. <https://doi.org/10.4060/cb9070en>.

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

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

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

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

#### **4.2.4 Processing Aids and Carry-Over of Food Additives**

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

## **6. EXEMPTIONS FROM MANDATORY LABELLING REQUIREMENTS**

With the exception of spices and herbs, small units, where the largest surface area is less than 10 cm<sup>2</sup>, may be exempted from the requirements of paragraphs 4.2 and 4.6 to 4.8. **This exemption does not apply to the declaration of foods and ingredients listed in sections 4.2.1.4, 4.2.1.6 and where applicable 4.2.1.5.**

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

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

8.3.1 The foods and ingredients listed in sections 4.2.1.4, 4.2.1.6 and where applicable 4.2.1.5 shall be declared so as to contrast distinctly from the surrounding text, [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, 4.2.1.6 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 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, 4.2.1.6 and where applicable 4.2.1.5 shall be declared, such as in a statement made in accordance with section 8.3.2.1.

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

### List of Participants

Australia	Portugal
Austria	Romania
Bangladesh	Saint Lucia
Belgium	Singapore
Brazil	South Africa
Canada	Spain
China	Sweden
Colombia	Switzerland
Denmark	Thailand
Dominican Republic	Trinidad and Tobago
Ecuador	United Kingdom
Egypt	United Republic of Tanzania
Estonia	United States of America
European Union	Venezuela
Finland	Alianza Latinoamericana de Asociaciones de la Industria de Alimentos y Bebidas (ALAIAB)
France	Association of European Coeliac Societies (OAECS)
Germany	Council for Responsible Nutrition
Guinea	European Federation of Allergy and Airways
Guyana	Fédération internationale des vins et spiritueux (FIVS)
Haiti	Food Industry Asia
Honduras	FoodDrinkEurope
Hungary	Institute of Food Technologists (IFT)
India	Inter-American Institute for Cooperation on Agriculture (IICA)
Indonesia	International Confectionery Association (ICA/IOCCC)
Iran	International Council of Beverages Associations (ICBA)
Italy	International Chewing Gum Association (ICGA)
Jamaica	International Council of Grocery Manufacturers Associations (ICGMA)
Japan	International Co-operative Alliance (ICA)
Kenya	International Dairy Federation (IDF/FIL)
Malaysia	International Special Dietary Foods Industries (ISDI)
Morocco	Safe Supply of Affordable Foods Everywhere (SSAFE)
Netherlands	FAO
New Zealand	WHO
Nigeria	Codex Secretariat
Norway	CCFL Chairperson
Panama	
Paraguay	