

**APPENDIX II****PROPOSED DRAFT REVISION OF THE GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS (CXS 1-1985) RELEVANT TO ALLERGEN LABELLING****(FOR ADOPTION AT STEP 5)****2. DEFINITION OF TERMS**

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

“*Food allergen*” means a food or ingredient [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.

“*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 need not be declared, except for the foods and ingredients listed in section 4.2.1.4, 4.2.1.7 and where applicable section 4.2.1.5 and food additives which serve a technological function in the finished product.

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

<b>FOODS AND INGREDIENTS</b>	<b>SPECIFIED NAME</b>
Cereals containing gluten <sup>2</sup> :	
– wheat and other <i>Triticum</i> species	‘wheat’
– rye and other <i>Secale</i> species	‘rye’
– barley and other <i>Hordeum</i> species	‘barley’
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	

**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

<sup>1</sup> 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.

<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. Hybridized strains are to use specified names in conjunction from all of the parent genera (e.g. ‘wheat’ and ‘rye’ for triticale).

ingredients, including those listed below may also be required<sup>3i</sup> using a specified name in addition to or as part of the ingredient name<sup>4</sup>. This shall be based on available risk assessment data for the respective population(s)<sup>5</sup> taking into account risk management considerations.

FOODS AND INGREDIENTS	SPECIFIED NAME
Buckwheat and products thereof	'buckwheat'
Celery and products thereof	'celery'
Oats and other <i>Avena</i> species (and their hybridized strains) and products thereof <sup>6</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>7</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 [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'.

#### **RENUMBER existing sections 4.2.1.5 and 4.2.1.7 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 these allergens 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, 4.2.1.7 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** 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

<sup>3</sup> 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>).

<sup>4</sup> 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.

<sup>5</sup> 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>.

<sup>6</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>7</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>.

not apply to food additives and processing aids that contain the foods and ingredients listed in sections 4.2.1.4, 4.2.1.7 and where applicable 4.2.1.5.

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

With the exception of spices and herbs, small units, where the largest surface area is less than 10 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, 4.2.1.7 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, 4.2.1.6 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 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.]

**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.

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