

For background information, please see [CL 2023/06/OCS-FL](#)

Codex members and observers are invited to submit comments on:

- (i) the proposed draft revision to the GSLPF in Appendix II of [CX/FL 23/47/5](#)
- (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).

## APPENDIX II

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

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

(FOR COMMENTS AT STEP 3 THROUGH CL 2023/06/OCS-FL)

## 2. DEFINITION OF TERMS

(New)

**"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."

## 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 cause hypersensitivity **food allergy or coeliac disease**<sup>1</sup>. and shall always be declared<sup>2</sup> **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

<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).

**Commented [EFOAADPA1]: Comment (350) by European Federation of Allergy and Airways Diseases Patients' Associations (19 Apr 2023 15:49)**

EFA strongly advises that the topics discussed here are integrated in the Code of Practice on Allergen Management for Food Business Operators of the Codex Committee on Food Hygiene.

**Commented [EFOAADPA2]: Comment (352) by European Federation of Allergy and Airways Diseases Patients' Associations (19 Apr 2023 15:50)**

EFA recommends that allergens must be declared in all cases, and even below the 5% threshold. Codex should consider foods that are not (yet) priority allergens or they are emerging allergens, about which consumers need to be informed. We therefore urge CCFL to delete this 5% rule, and keep the text in line with the current EU and some non-EU practice such as Switzerland.

**Commented [EFOAADPA3]: Comment (355) by European Federation of Allergy and Airways Diseases Patients' Associations (19 Apr 2023 15:52)**

With regards to the labelling of priority allergens, EFA raises the following comments:

1. CCFL needs to clarify what is the suggestion with specified names. Are specified names supposed to be used alone or in conjunction with the ingredient name? Consumers need to know both the ingredient and the allergen that it is made of (in brackets). Both information should be there. An example can be found for a product of milk e.g. "whey protein (milk)". As a reminder, this is the legal requirement in the EU.

2. Gluten-containing cereals are relevant to two different allergic diseases that need to be covered: coeliac disease as well as IgE mediated food allergies. Both consumer groups need specific information, which should be included in the labelling. This means, that both the specific gluten containing cereal as well as the presence of gluten must be labelled. Therefore, EFA suggests to add 'gluten' as 'specified name' below 'wheat', 'rye' and 'barley'. As an example, when a product of a triticum species is used as ingredient, such as spelt flour, the ingredient list should read: "... spelt flour (wheat/gluten) ..."

3. With regards to fish and crustacea, EFA suggests to treat both these foods as broad categories. We ask CCFL to take the following considerations into account:  
- some consumers can be allergic only to one or two fish species while others must avoid all fish (and the same with crustacea)  
- the names of some fish species (e.g. tilapia) and crustacea species are not always easily recognisable by consumers. Given the above considerations, EFA suggests that the mandatory labelling for fish and crustacea should include both the common name of the individual fish species AND 'fish' as the specified name. Therefore, EFA suggests to change the text in the column of specified names to 'fish and the common name of individual fish species' (instead of or). The resulting labelling must appear as follows: 'fish species (fish)' e.g. tilapia (fish).

**Commented [EFOAADPA4]: Comment (354) by European Federation of Allergy and Airways Diseases Patients' Associations (19 Apr 2023 15:51)**

EFA recommends to add '...' in addition to the ingredient name' at the end of this sentence.

**Commented [EFOAADPA5]: Comment (353) by European Federation of Allergy and Airways Diseases Patients' Associations (19 Apr 2023 15:51)**

EFA suggests using words that attribute the obligatory nature of priority allergen labelling, and therefore substitute 'shall' with 'must'. Similar wording must adapt throughout the document text.

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

#### (New Sections)

##### 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>:

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'

<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).

<sup>2</sup> Future additions to and/or deletions from this list will be considered by the Codex Committee on Food Labelling taking into account the advice provided by the joint FAO/WHO Expert Committee on Food Additives (JECFA)

<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). 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>.

FOODS AND INGREDIENTS	SPECIFIED NAME
<ul style="list-style-type: none"> <li>- macadamia</li> <li>- pine nut</li> </ul> and products thereof	'pine nut'

**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'.

**4.2.1.7** Subject to evaluation using established criteria<sup>3</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 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.

**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 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

(New)

### 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.

**Commented [EFOAADPA6]: Comment (356) by European Federation of Allergy and Airways Diseases Patients' Associations (19 Apr 2023 15:54)**

EFA recommends GSLPF to include a list of ingredients exempted from allergen labelling that have already been assessed by national authorities. This applies for example to maltodextrin from wheat or highly refined soybean oil and its derivatives.

Furthermore, in paragraph 4.2.1.7 reference should be made to Summary Report 4 of the FAO/WHO scientific expert group on the Review and establishment of exemptions for the food allergens (conclusions published in January).

**Commented [EFOAADPA7]: Comment (357) by European Federation of Allergy and Airways Diseases Patients' Associations (19 Apr 2023 15:54)**

EFA considers that this is a provision requiring further clarifications and guidance on how to deal with ingredients obtained through biotechnology.

If there is e.g. a novel food created through biotechnology, we need to make sure that a safety assessment is performed, leading to separate statement on potential allergic risks e.g. rapeseed protein.

Other cases include insects or non-animal milk proteins, known for their cross-reactivity. Indeed, it appears that insects have not been evaluated in this context, which treat only priority allergens.

EFA encourages adding a separate paragraph on new allergens derived from novel food like insects. Such a paragraph should establish the use of an additional 'allergy warning statement' related to the products derived from biotechnology; or even define criteria for inclusion in the list of priority allergens, when allergen cross-reactivity has been demonstrated. From a procedural perspective, it is also important that these ingredients go through a safety assessment, including an allergenicity assessment.

**Commented [EFOAADPA8]: Comment (359) by European Federation of Allergy and Airways Diseases Patients' Associations (19 Apr 2023 15:56)**

EFA suggests to change this sentence as follows: 'Except for those foods and ingredients listed in sections 4.2.1.4, 4.2.1.6 and where applicable 4.2.1.5 and section 4.2.2'. Additional allergen labelling could be needed for ingredients obtained through biotechnology. This addition must adapt throughout the text of the document.

**Commented [EFOAADPA9]: Comment (361) by European Federation of Allergy and Airways Diseases Patients' Associations (19 Apr 2023 15:56)**

EFA considers that separate statements must be placed 'directly next to the list of ingredients' and not just '...near and in the same field of vision as the list of ingredients'. Furthermore, they should apply to all types of allergen information, including PAL and other aspects e.g. 4.2.2 related to this safety assessment