

PLEASE CLICK HERE TO INSERT GENERAL COMMENTS ON APPENDIX II

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 in **bold font**)

2. DEFINITION OF TERMS

For the purpose of this standard:

NEW

“Allergen” means an otherwise harmless substance capable of triggering a response that starts in the immune system and results in an allergic reaction in certain individuals. In the case of foods, it is **typically** a protein which is found in food capable of triggering a response in individuals sensitised to it.

“Food allergy” means adverse immune reactions to certain food proteins, which may be immunoglobulin E (IgE) mediated and associated with anaphylaxis, non-IgE mediated¹, or a combination of both.

“Food intolerance” means adverse reactions to food components that occur through non-immunological mechanisms.

“Hypersensitivity” means the repeatable adverse reaction to an allergen or other substance in food associated with IgE mediated food allergy, non-IgE mediated food allergy¹, or food intolerance (i.e. sulphites, lactose).

Comment from the European Federation of Allergy and Airways Diseases Patients’ Associations (EFA):

- We propose to add the word “typically” to the definition of an allergen, since not only proteins but also other sources may cause an allergic reaction (i.e. Alpha-Gal found in mammalian meat). While it is not a priority allergen, it demonstrates that other triggers for IgE-mediated food allergies exist beyond proteins. This fact that allergen sources are not limited to proteins should be recognized in this definition, but also be introduced in the Code of Practice on Food Allergen Management for Food Business Operators (CXC 80-2020).

- EFA encourages Codex to establish definitions that highlight the clear differences between food allergies (IgE-mediated and non-IgE-mediated) and food intolerances as non-IgE-mediated food hypersensitivities. From our patient perspective, we believe the definitions should serve to help distinguish between the different diseases. The purpose of this framework for allergen labelling within GSLPF should be addressed to apply only to food allergies (IgE-mediated and non-IgE-mediated including Coeliac Disease). This should be clearly emphasized in the text. Our proposal is in line with both the recommendation of the ad hoc joint FAO/WHO expert consultation on Risk Assessment of Food Allergens (1st report – issued in May 2021) as well as with the Code of Practice CXC 80-2020 (Section II, 2.1 Scope, page 5:

“This Code does not cover hypersensitivities with a non-immunological aetiology such as lactose intolerance and sulphite sensitivity. Food intolerance adverse reactions usually result from a non-immune mediated reaction to food, such as a lack of an enzyme to process foods effectively (e.g. the absence or deficit of lactase in those with lactose intolerance). While intolerances are not explicitly mentioned in the following text, some of the controls described here could be applied to protect those with food intolerances.”

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 of its ingredients, in brackets, in a 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 [those listed in section 4.2.1.4 and] food additives which serve a technological function in the finished product, need not be declared.~~

Comment from the European Federation of Allergy and Airways Diseases Patients' Associations (EFA):

We propose to establish a labelling requirement for compound ingredients, in alignment with the information for each of the other components of pre-packaged foods. Given the rise in other non-priority food allergens (i.e. allergy to legumes, to insects) and the significant number of individuals who are allergic to unusual ingredients like fruit and spices, such an indication would enable consumers with food allergies to better protect themselves.

Following the suggestion of the ad hoc FAO/WHO expert consultation to develop a watch-list for these allergens, EFA holds that it should be possible to identify them in food products, independently of their percentage in the food. In fact, food allergens can elicit allergic reactions in even small amounts, and that is the reason why they must be declared. EFA therefore recommends to remove the 5% rule to enable patients to identify all ingredients used in a food product.

[4.2.1.4 The following foods and ingredients are known to cause hypersensitivity (IgE and non-IgE mediated) food allergies and shall always be declared:²

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

Comment from the European Federation of Allergy and Airways Diseases Patients' Associations (EFA):

Although at this stage there is no proposal for the list of priority allergens, EFA would like to emphasize why our proposed amendments are necessary and helpful from the patients' perspective:

- Cereals containing gluten: in agreement with the ad hoc joint FAO/WHO expert consultation on Risk Assessment of Food Allergens (1st report) the three main species (wheat, rye, and barley) should be listed and their hybridized strains included.
- Peanuts and soybeans should be listed separately.
- As a patients organisation, EFA strongly recommends that soy remains in the list of priority allergens, because soy is capable to elicit anaphylactic reactions (not only as exercised induced anaphylaxis) and is prevalent in many European countries as well as in other countries of the world. With regards to potency, the reference dose for soy established by the VITAL 3.0 (ED01) is below the reference dose for foods still considered to be priority allergens, such as fish, wheat, and shrimps, which suggests a greater potency of soy. Our main concern is that soy, widely used as a substitute for children with cow's milk allergy, will not be recognized as potentially harmful if it is taken off the list

of priority allergens. Finally, our concern is not only related to-IgE mediated soy allergy, but also to Food Protein Induced Enterocolitis Syndrome (FPIES), where soy is one of the most common eliciting allergens.

- We support the recommendation of adding sesame to the list of priority allergens.
- In line with our recommendation on the definition of an allergen, and therefore to include only foods and ingredients that are known to cause IgE and non-IgE-mediated food allergies, EFA suggests deleting sulphite in concentrations of 10mg/ kg or more from the list. (The rule as such to label sulphite in concentrations of 10mg/ kg or more does not need to be affected. However, it should not be part of the allergen labelling).

NEW

[4.2.1.5 Declaration of the foods and ingredients listed in section 4.2.1.4 shall be made using commonly known terms for the source of the food and ingredient as part of, or in conjunction with, the relevant ingredient name.]

[Comment from the European Federation of Allergy and Airways Diseases Patients' Associations \(EFA\):](#)

We agree. Some examples:

- Casein (milk), whey protein (milk).
- Gluten containing cereals need to be listed with their species: wheat, barley or rye.
- Tree nuts need to be listed with their species: i. e. hazelnut, pistachio, cashew, walnut, pekan nut, almond.

RENUMBER existing 4.2.1.5 and 4.2.1.6

¹ Includes coeliac disease which is a serious lifelong illness where the body's immune system attacks its own tissues when gluten is consumed. This causes damage to the lining of the gut and results in the inability of the body to properly absorb nutrients from food.

² 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).

4.2.3 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 section 4.2.1.4 must be declared in accordance with section 4.2.1.5.]**

[Comment from the European Federation of Allergy and Airways Diseases Patients' Associations \(EFA\):](#)

We agree.

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 additive and processing aids **[that contain or are derived from the foods and ingredients]** listed in section 4.2.1.4.-

[Comment from the European Federation of Allergy and Airways Diseases Patients' Associations \(EFA\):](#)

We agree.

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 section 4.2.1.4.]**

Comment from the European Federation of Allergy and Airways Diseases Patients' Associations (EFA):

We agree.

8. PRESENTATION OF MANDATORY INFORMATION

(NEW)

8.3 Declared foods and ingredients known to cause food allergies. hypersensitivity

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

8.3.1.1 The font type, style and a minimum font size as well as the use of upper and lower case letters should be considered by competent authorities to ensure legibility of declarations about foods and ingredients known to cause food allergies. hypersensitivity.

8.3.2 In addition to the list of ingredients, the foods and ingredients listed in section 4.2.1.4 may be declared in a separate statement, which shall be placed directly following ~~near~~ and within the same field of view as the list of ingredients.

8.3.2.1 This statement shall commence with the word 'Contains' (or equivalent word) and declare all foods and ingredients known to cause food allergies, hypersensitivity using commonly known terms for the source of the food and ingredient.

8.3.3 Where a food is exempt from declaring a list of ingredients, the foods and ingredients listed in section 4.2.1.4 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 known to cause food allergies hypersensitivity are declared as part of, or in conjunction with, the name of the food in accordance with section 4.2.1.5.

Comment from the European Federation of Allergy and Airways Diseases Patients' Associations (EFA):

- EFA agrees with all the above-mentioned aspects to clarify and emphasize allergen labelling and make it clearer, easier, and more understandable for consumers with food allergies and those providing food to them.

We urge using only the term "food allergy" (comprising IgE and non-IgE-mediated food allergies), thus discriminating other food hypersensitivities in the approach to define allergen labelling. This recommendation is consistent with the CCFH Code of Practice CXC 80-2020, as well as with the recommendation in the 1st report of the ad hoc joint FAO/WHO expert consultation on Risk Assessment of Food Allergens.

PROPOSED DRAFT GUIDELINES FOR THE USE OF [PRECAUTIONARY ALLERGEN OR ADVISORY LABELLING]

1. PURPOSE

To facilitate consistent and harmonised approaches to the effective use of [precautionary allergen or advisory labelling] (PAL) for communicating to consumers with food allergy about the health risks from the unintentional presence of allergens in food due to cross-contact **although all possible mitigation measures have been taken.**

2. SCOPE

2.1 These guidelines apply to PAL when used to indicate the possible unintentional presence of allergens caused by cross-contact in prepackaged foods that are within the scope of the *General Standard for the Labelling of Prepackaged Foods* (CXS 1-1985).

2.2 The *Code of Practice on Allergen Management for Food Business Operators* (CXC 80-2020) provides guidance on effective management practices and controls to prevent or minimise the potential for allergen cross-contact.

3. DEFINITIONS

For the purpose of these guidelines:

Allergen means an otherwise harmless substance capable of triggering a response that starts in the immune system and results in an allergic reaction in certain individuals. In the case of foods, it is **typically** a protein which is found in food capable of triggering a response in individuals sensitised to it.

Allergen cross-contact occurs when an allergenic food, or ingredient, is unintentionally incorporated into another food that is not intended to contain that allergenic food.

[*Precautionary allergen or advisory labelling*] is a statement indicating the allergen(s) that may be present in a food due to allergen cross-contact during the production, manufacture and transport of food. **This may occur above a threshold (action) level** despite **implementing** allergen management practices and controls such as in the *Code of Practice on Food Allergen Management for Food Business Operators* (CXC 80-2020).

4. GENERAL PRINCIPLES

4.1 The decision to use PAL should be based on the findings of a risk assessment which ~~can~~ **should** be quantitative risk assessment. The use of PAL should be restricted to those situations in which allergen cross-contact cannot be controlled to the extent that the product may present a **health** risk to allergic consumers.

4.2 PAL should only be used if exposure to the allergen from the food is above an established reference dose. If a reference dose is not established for a particular allergen, an estimated reference dose can be used. If a quantitative risk assessment cannot be performed, then PAL should only be applied if ~~any~~ **the** risk of allergen-cross contact identified through a risk assessment cannot be removed through risk management actions, such as segregation and cleaning.

5. PRESENTATION OF PAL

Yet to be drafted but to include guidance on location on label, format and language.

Comment from the European Federation of Allergy and Airways Diseases Patients' Associations (EFA):

Title:

- PAL should be referred to as Precautionary Allergen Labelling, and not as "advisory labelling". "Precautionary Allergen Labelling" is more specific and descriptive, while also being an already established term within the patients and consumers communities.

Purpose:

- From our patients' perspective we disagree to delete the half sentence "*although all possible mitigation measures have been taken*". While we understand the rationale behind the proposal with reference to the Code of practice (CXC 80-2020), we believe that the message this statement carries

is so crucial, that it cannot be stressed prominently enough. EFA recommends to re-insert it from the beginning under the headline “Purpose” of the PAL Guidance.

Definitions:

- “Allergen” – add “typically” to the text (see “allergen” definition page 1)
- “Precautionary allergen labelling” – it should be stressed that PAL is a statement that can only be used when the food product poses a risk to health of allergic consumers. This risk is assessed, when the unintended allergen presence due to cross-contact is above a (get to agree upon) threshold (action) level. We believe this important aspect should be reflected in the definition of PAL.

General Principles:

- **4.1.** The draft text of the previous version said: “The decision to use PAL should be based on findings of a quantitative risk assessment” (QRA)

We note that the current version limits substantially the importance of QRA. In EFA’s opinion, QRA is just one (important) part of a greater allergen management strategy. Qualitative measures as such as allergen management frameworks have to be considered too. The significance of a quantification of unintended allergen presence in a product should be the basis. If it is offered as an option, the more risk averse FBOs will still have the option to use PAL, even if the product does not pose a risk to allergic consumers. On the other hand – less risk adverse FBO may choose not to label despite a health risk.

- **4.2** There needs to be more clarification on the sentence

“If a reference dose is not established for a particular allergen, an estimated reference dose be used.”

How will estimates be evaluated to determine the safety of consumers with that food allergy?

The use of the word “any” in the context of “any risk of cross-contact” is not acceptable because 1) it does not reflect the relevance for health for allergic consumers and 2) it might lead to a wider and unnecessary use of PAL. We encourage Codex to be clearer and stressed that not “any risk of cross contact” should lead to the application of PAL, but rather only a risk that is likely to have an adverse health impact to consumers with food allergies. Our proposal should be included in Purpose, Scope, Definitions and General Principles

As an overall note regarding the important issues of GSLPF revision and PAL guidance, EFA’s recommendation would be to work on these documents separately. The reason is that PAL guidance will probably take more time to be finalized, and is therefore likely to cause unnecessary delays to the revision of the GSLPF.

Finally, EFA and its community of consumers with food allergies stands ready to assist CCFL in its ongoing and future work on allergen labelling or more specifically on PAL by addressing them directly to our community.

Submitted by:

European Federation of
Allergy and Airways Diseases
Patients’ Associations



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