

CODEx ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda Item 7, 8

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEx COMMITTEE ON FOOD LABELLING

Forty-sixth Session

Virtual

27 September - October 1 and 7, 2021

(Comments from EFA)

Agenda Item 7

Prepacked food offered by e-commerce has increased in the last few years. The pandemic has boosted internet sales, leading the market to a radical change; in this scenario, people with food allergies still need accurate and timely information for allergens in their food labeling. The awareness regarding the products is essential to guarantee protection of health, and it's fundamental to adapt this technological change in the direction of care and sustainability.

Aligned with our suggestion to include non-prepacked food in the scope of the General Standard for the Labelling of Prepacked Food (GSLPF), we would like to include non-prepacked food also within the scope of the guidelines on the internet sales/e-commerce of food.

EFA has reviewed the proposed draft guidelines on internet sales/e-commerce of the Codex Committee on Food Labelling and would like to draw your attention to the following considerations.

In **Section 3: General principles**, it is indicated that:

*'All food information requirements within the GSLPF and any other Codex texts shall be met **at the point of delivery** through the information provided on the product label, unless specified otherwise within this text.'*

At EFA we believe that foods supplied through internet sales/e-commerce must be subject to the same information requirements for foods sold in stores. Given the context, it is necessary to clarify that mandatory information on foods must be available before purchasing. This is because consumers with food allergies need to be able to make informed choices on whether to purchase food, based on knowing if it is safe for them to consume. Therefore, all ingredient information must be provided *both at the point of e-commerce sale and the point of delivery*.

EFA's recommendation would be to add 'point of e-commerce sale'.

In the first paragraph of **Section 4: Information requirements for pre-packaged foods sold through e-commerce**, it is mentioned that:

*'Information specified in sections 4 and 5 of the GSLPF (CXS 1-1985) shall, **whenever possible**, appear on the product information e-page or other primary consumer-facing virtual depiction of pre-packaged foods presented for sale through e-commerce prior to the point of e-commerce sale, except to the extent otherwise expressly provided in an individual Codex standard and as noted in Section 5 ("Exemptions from Food Information requirements") of this guidance.'*

We think that, for safety reasons, consumers with food allergies always need information about the presence of allergens in their food. There should not be an option for Food Business Operators (FBOs) selling food through e-commerce to not provide relevant allergen information. **Thus our recommendation is to replace 'whenever possible' by 'always'.**

In addition, small units of food packages sold in physical retailers are exempt from giving ingredient information because of limited labelling space. E-commerce does not have this limitation. Therefore, full ingredient disclosure should be given, independently of the size of the product. **EFA's recommendation is that the exemption for ingredient labelling shall not apply to e-commerce/internet sales.**

Later in the same section it is stipulated that:

'In some circumstances it may not be possible to provide accurate information on the product information page at the point of sale regarding the above requirements. This includes cases where ingredients may alter slightly from those provided on the product information page owing to ongoing recipe adjustments.'

For safety reasons, consumers with food allergies need to have accurate and up-to-date ingredient information (including Precautionary Allergen Labelling, when necessary) at the time of purchase to make informed food choices. This is especially so in our days, as the world goes through a global pandemic, which has seen online trade of goods, including food, rise. **Therefore, EFA's recommendation is to delete the sentence.**

Regarding the following provision:

'[If the composition of the pre-packaged food offered for sale through e-commerce is subject to minor variations by the substitution of an ingredient which performs a similar function, the statement of ingredients on the digital product information sheet may list both ingredients in a way which makes it clear that alternative or substitute ingredients are being declared.]'

'[A statement shall appear on the digital product information page to the effect that the customer should check the information on the physical label before consumption.]'

...as well as on the proposed alternative wording of Section 4.2:

'If the composition of the pre-packaged food offered for sale through e-commerce is subject to minor variations by the substitution of an ingredient which performs a similar function, the statement of ingredients on the digital product information sheet may list both ingredients in a way which makes it clear that alternative or substitute ingredients are being declared.'

EFA would like to ask for some clarifications:

- › **What is considered to be a 'minor variation'? How is this defined?**
- › **What will happen if the substituted ingredient is a priority allergen?**

Prepacked foods always need an ingredient list. In the ingredient list it is not foreseen to include information about minor variations by the substitution of an ingredient which performs a similar function unless a class name is used. This is one of the reasons why mandatory allergen labelling is considered necessary: for safety reasons, consumers with food allergies ALWAYS must be informed on the presence of an ingredient that is a priority allergen. The information about the actual ingredient must be available for consumers with food allergies at the point of e-commerce sale for informed and safe food choices.

EFA would like to suggest to extend the guideline for internet sales/e-commerce to also include non-prepacked food.

EFA reiterates its willingness to contribute in a constructive way to the discussions of the CCFL on allergen labeling and the relevant work of the Codex Alimentarius Commission. Our efforts will always go in the direction of advocating patient/consumers' needs, providing continuous feedback.

Agenda Item 8

EFA statement on the review of the allergen labelling provisions in the General Standard for the Labelling of Prepacked Food (GSLPF)

Codex Committee for Food Labelling meeting Agenda item 8

The European Federation of Allergy and Airways Diseases Patients' Associations (EFA) is the umbrella organisation representing the voice of people living with allergy, asthma and Chronic Obstructive Pulmonary Disease (COPD) in Europe. Our membership consists of 42 national associations in 25 countries across the European region.

EFA and our vibrant patient community of people living with food allergy consider food safety of vital importance. In this context, food allergen information is key to enable them make safe and informed food choices.

In addition to EFA's response to the [request for comments](#) of the Codex Committee for Food Labelling regarding the Annex II of the General Standard for the Labelling of Prepacked Food (GSLPF), which was submitted on 6 September, we would like to also comment on the scope of the standard.

For safety reasons, consumers with food allergies must always be able to make informed food choices. This includes safe choices on non-prepacked food. Therefore, as regards the provision of information on allergens in food, **EFA strongly suggests to extend the scope of the GSLPF to all non-prepacked foods** as far as the provision of the information on allergen is concerned.

According to feedback from our community, allergic reactions occur to both prepacked and non-prepacked food. Therefore clear, timely and accurate allergen information must be provided at all times.

We thank the Chair of the Codex Committee on Food Labelling for considering this request.

Agenda Item 8

Comments from EFA – European Federation of Allergy and Airway Diseases Patients' Association
06. September 2021

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 regard 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

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.

PLEASE CLICK HERE TO INSERT GENERAL COMMENTS ON APPENDIX III

Appendix III

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 crosscontact 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.