

# 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](mailto:codex@fao.org) - [www.codexalimentarius.org](http://www.codexalimentarius.org)

Agenda Item 5

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## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON FOOD LABELLING

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Gatineau, Canada

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### FOOD ALLERGEN LABELLING

(Comments from China, AOECs, IUFOST)

#### China

#### Background

China appreciates the work done by the EWG and would like to take the opportunity to provide comment on agenda item 5.1 Proposed draft revision to the General Standard for the Labelling of Prepackaged Foods – Provisions relevant to allergen labelling to be discussed by the 47<sup>th</sup> Codex Committee on Food Labelling.

#### Agenda item 5.1

CX/FL 23/47/5 (Part A), CRD02

#### Proposed draft revision to the General Standard for the Labelling of Prepackaged Foods – Provisions relevant to allergen labelling

#### SPECIFIC COMMENT

China would like to make the following suggestions on paragraph 8.3 to ensure that the relevant provisions meet the needs of more countries and consumers.

#### **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) 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 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 in a separate statement made in accordance with section 8.3.1.

8.3.3 For single ingredient foods, section 8.3.2 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.

## Rational

China's national food safety standard allows the food allergens to be declared either in a separate statement or so as to contrast distinctly from the surrounding text in ingredients list.

And most of the prepackaged food in China including imported foods declare the allergens in a separate statement, which is the way that consumers prefer in China based on our survey of consumers.

On the premise of achieving the purpose of risk management on food allergen, in order to better take care of consumer preferences, at the same time to accommodate the trade needs of more countries, China believes that more flexibilities needs to be provided that to allow the allergen declaration in different approaches like most countries provided.

## AOECS

### Comment to item 5 - FL/47 CRD02, Appendix II

#### 2. DEFINITION OF TERMS

AOECS thanks the Chair and the Working Group members that the definition of coeliac disease was taken into the main body of the Standard, however we would like to propose few amendments. The reason is to provide correct information that neither any food allergy or coeliac disease can be diagnosed with food intolerance test kits based on IgG-antibody. To include "non-IgE-mediated" would give room for such an interpretation. Food intolerance test kits are frequently used and the results of these test kits often provide incorrect positive results, specifically regarding wheat and milk. Due to these test kits based on IgG-antibodies, individuals can be told they have an intolerance/sensitivity to multiple foods (the IgG test kits usually look at 90-110 foods on a single panel) which can lead to malnutrition. We believe that the "Definition of Terms" can play an important rule for consumer health and provide an opportunity to ensure that IgG-antibody are not an appropriate method to diagnose either food allergy or coeliac disease.

Therefore we propose **to delete "or non-IgE antibody" in the text of "Food allergy"**, and amend the text of **"Coeliac disease"**. Regarding the foods listed in the definition of coeliac disease, it should correspond with CXS 118-1979. Further, we would like to request new text is inserted for the definition of "allergen" because the word "allergen" is often written in the revision of CXS 1-1985 and also in CXC 80-2020.

Our proposal is:

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

"Coeliac disease" **means a reproducible adverse health effect arising from an immunoglobulin class A (IgA) antibody and** is a chronic **autoimmune-mediated systemic** disease in genetically predisposed individuals induced by exposure to dietary gluten proteins **as defined in CXS 118-1979: wheat (i.e. all Triticum species, such as durum wheat, spelt, and khorsan wheat, which is also marketed under different trademarks such as KAMUT), rye, barley, oats<sup>1</sup> or their crossbred varieties.**

**"Allergen" means any food or ingredient which causes either food allergy or coeliac disease.**

#### 4.2.1.4 Foods and Ingredients

##### Specified Name

AOECS support the comments that were made by other delegates that **"gluten"** should be included under the specified name column for cereals containing gluten and its use should be mandatory, e.g. 'wheat/gluten' etc. People with coeliac disease are affected by exposure to gluten which is the protein found in cereals containing gluten, therefore it would be appropriate to alert coeliac consumers to the fact that gluten is present in these foods.

#### Footnote 6

AOECS agree that footnote 6 provides additional information regarding cereals containing gluten however the text should be in line with CXS 118-1979. AOECS proposes the text for footnote 6 is changed to the following :

**<sup>6</sup>Includes all Triticum species (i.e. durum wheat, spelt and Khorasan wheat, which is also marketed under different trademarks such as KAMUT) or their cross bred varieties. 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).**

#### **4.2.1.5 Foods and Ingredients**

AOECS does not agree with the scientific advice that was given from the expert committee that “oats” should be removed from 4.2.1.4 and included in 4.2.1.5 based on the fact that there is ongoing research into the immunogenicity of avenin in people with coeliac disease which has not yet been published but is of significant importance.

The expert committee have based the exclusion of oats from the priority list due to lack of global data and ranking of severity, potency and prevalence. However, there is ongoing research looking at whether oats are safe to consumer in coeliac disease as it has been shown that a proportion of people with coeliac disease have T cells that are activated by avenin in oats resulting in an inflammatory immune response. The research has not concluded but the results to date have shown there are a subset of biologically sensitive individuals who need to avoid uncontaminated oats. We believe it is premature to remove oats from the priority list because there is a lack of evidence available. In addition, coeliac patient organisations across Europe frequently hear from the coeliac community that uncontaminated gluten free oats cause symptoms.

AOECS does not agree that oats would be more appropriately addressed through risk management frameworks such as precautionary allergen labelling based on the reasons given above and that the current proposal for the precautionary allergen labelling standard does not take coeliac disease or the gluten-free threshold into account.

Additionally, there are further Codex texts which state the risks of oats for people with coeliac disease:

**CXS 118-1979** (Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten) defines gluten-free foods as:

##### “2.1.1 Gluten-free foods

Gluten-free foods are dietary foods

a) consisting of or made only from one or more ingredients which do not contain wheat (i.e. all Triticum species, such as durum wheat, spelt, and khorasan wheat, which is also marketed under different trademarks such as KAMUT), rye, barley, **oats**<sup>1</sup> or their crossbred varieties, and the gluten level does not exceed 20 mg/kg in total, based on the food as sold or distributed to the consumer,

and/or

b) consisting of one or more ingredients from wheat (i.e. all Triticum species, such as durum wheat, spelt, and khorasan wheat, which is also marketed under different trademarks such as KAMUT), rye, barley, **oats**<sup>1</sup> or their crossbred varieties, which have been specially processed to remove gluten, and the gluten level does not exceed 20 mg/kg in total, based on the food as sold or distributed to the consumer.”

<sup>1</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.

## IUFoST<sup>1</sup>

IUFoST thanks all codex delegations who contributed to the proposed changes to the General Standard on Labelling of Prepackaged Foods (GSLPF) related to allergens and to the proposed guidelines on Precautionary Allergen Labelling (PAL), for the efforts made to update the current Codex guidance, considering the impacts they are likely to have on the enhanced protection of food allergic consumers.

IUFoST's comments on the proposed Codex texts being considered at CCFL47 were developed in accordance with the following principles:

- Our attempt to ensure that the latest updates in the scientific assessment related to food allergens are reflected in the proposed codex text,
- That allergic consumers benefit from enhanced protection with the provision of accurate and clear information on food labels,
- That allergic consumers benefit from added choice in food alternatives, with requirements set to limit the overuse of precautionary statements which is currently resulting in depriving food allergic consumers from safe food alternatives,
- Our attempt to contribute to maintaining the consistency between Codex texts.

I- **Comments on APPENDIX II (PROPOSED DRAFT REVISION OF THE GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS (CXS 1-1985) RELEVANT TO ALLERGEN LABELLING)**

- ❖ The proposed list of priority allergens (identified in section 4.2.1.4 of the allergen labelling provisions) reflects the most up-to-date scientific advice globally and offers change to the list of what was known as “the Big eight”.

While this list is indeed of global relevance, as established by the scientific opinion provided to CCFL, it may be useful that a mention be made in the Codex text of **the criteria** that led to update this list. Such mention may support food regulators in their effort(s) to review the adaptability of the ingredients included in this list for their national jurisdictions. A sentence to this effect could be added at the end of the list such as:

**“The list of food identified to cause food allergy was set based on a scientific evaluation that considered the criteria of prevalence, severity and/or potency.”**

- ❖ IUFoST proposes a change in the wording of Section 4.2.1.4 as follows:  
 “The following foods and ingredients are known to cause hypersensitivity: **food allergy or coeliac disease<sup>1</sup> when any protein fraction of these foods and ingredients is present as a result of deliberate addition to the food (composition),** and shall, **as result of such presence,** always be declared<sup>2</sup> **using the name specified”**.”

This proposal is meant to reflect the fact that that allergic reactions are related to exposure to **the protein fraction of the (priority) ingredients identified in the list**. Therefore, the trigger of declaration on food labels should be the **deliberate presence of any protein fraction** of these ingredients in the food, as part of the intended recipe.

Any other extract of these ingredients that excludes the protein fraction (e.g., Maltodextrin derived from wheat), should not cause an allergic reaction, and should not trigger the mandatory labelling provision. Proceeding otherwise would lead to “**over labelling**” and would therefore restrict food choices unduly to food allergic consumers. The identification of the protein fraction, as the basis for mandatory labelling, would support a lesser reliance on the process of exemption from mandatory declaration (discussed later in the Codex text) when the ingredient derived from these foods is well known to exclude the protein fraction.

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<sup>1</sup> This review was developed by the Disciplinary Group of the International Union of Food Science and Technology (IUFoST) for Food Regulatory Science, the Global Food Regulatory Science Society (GFoRSS). This review was supported by the Codex outreach initiative funded by the US Codex Office, implemented by Laval University's Platform of Food Risk Analysis (PARERA), IUFoST Country adhering body for Canada and the Global Food Regulatory Science Society (GFoRSS).

Moreover, the current wording of section 4.2.1.4 implies that any source of the foods or ingredients identified in the priority list is to be declared on food labels, regardless of whether this is an intended presence or unintended one (cross-contact). It is therefore important to explicitly specify that this mandatory declaration provision is to be applied in the context of the **deliberate addition of the ingredient**.

- ❖ IUFoST also proposes a change to the wording of Section 4.2.1.5 as follows:

“In addition to the foods and ingredients listed in section 4.2.1.4, national or regional authorities may also require the declaration of **other food and ingredients, such as those identified in the following list, 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)”.

Section 4.2.1.5 is an addition to the existing Codex text and offers more guidance on foods known to cause food allergies but not of global relevance, rather of regional importance. However, the way the statement frames the ingredients of this list seems to indicate that such foods and ingredients of regional relevance are restricted to the items proposed in the list, at the exclusion of others. The text may need to convey that these are examples and that other foods may be identified based on a risk assessment, that uses the same criteria of prevalence, severity and/or potency.

**It may be beneficial to add**, that other foods beyond those included in the list recommended of regional relevance, could be considered for addition to the list requiring mandatory labelling, based **on a risk assessment** by national/regional jurisdictions that **uses the criteria of national /regional prevalence, severity of the reaction induced and/or its potency**, as established by the FAO/WHO ad hoc expert consultation.

- ❖ IUFoST recommends the removal of “Oats and other *Avena* species (and their hybridized strains) and products thereof” from the list of regional relevance.

Based on the available scientific evidence, pure oats are not harmful to food allergic consumers nor to most celiac individuals. Reactions to oats, observed both with wheat allergic consumers and with celiac patients is mainly due to issues of cross-contamination of oats with other cereals, such as wheat.

## II- Comments on **APPENDIX III (GUIDELINES ON THE USE OF PRECAUTIONARY ALLERGEN LABELLING )**

IUFoST congratulates the EWG for the proposed set of principles developed to guide the reliance on Precautionary Allergen Labelling (PAL) to become a more effective tool, providing consumers with more relevant and reliable information on the possible unintended presence of food allergens in pre-packaged foods resulting from cross-contamination or cross-contact.

IUFoST notes the efforts made to maintain consistency between the suggested principles in the proposed guidelines and CXC 80-2020, in particular consistency in the definition of cross-contact.

IUFoST would like to make the following comments and suggestions, based on the same principles outlined above:

- ❖ IUFoST suggests the following amendment to Principle 4.1:

“Effective management practices and controls to prevent or minimize the unintended presence of allergens caused by cross-contact shall be implemented as outlined in the Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020). The use of PAL shall be restricted to those situations in which

the unintended presence of an allergen(s) cannot be sufficiently controlled using these allergen management practices. **When such situations are met, the mandatory declaration of the foods and ingredients warranted by section 4.2.1.4 of the GSLPF shall apply using a Precautionary Allergen Labelling instead of an ingredient declaration. The same would apply for food and ingredients identified in Section 4.2.1.5 where relevant.**"

Principle 4.1 as written helps to address and curb the possible over-use of Precautionary Labelling by indicating that the "use of PAL shall be restricted to those situations in which the unintended presence of an allergen(s) cannot be sufficiently controlled using these allergen management practices". However, it does not appear to be consistent with the food allergen labelling provision in 4.2.1.4, which **requires mandatory declaration** of allergens to avoid situations of "hidden allergens".

An amendment to the text is proposed to require such **mandatory reliance on PAL statements** when the conditions of their use are met.

The current absence of mandatory requirement to use precautionary labelling, with a clear guidance, and when deemed necessary is leading to **a patchwork of regulatory actions internationally**, where some jurisdictions would take recall actions when these statements are missing and the allergen is proven to be present, and others would be silent on the matter. This, in turn is leading to an unpredictable food regulatory environment.

**It is our opinion that the guidance on the use of precautionary statements needs to be consistent with and mirror the provisions of allergen labelling in the in the General Standard for the Labelling of Prepackaged Foods (GSLPF), which trigger a mandatory labelling provision, when there is a risk for hidden sources of allergens in the food (resulting from deliberate addition).** We therefore recommend that the proposed Codex text be directive enough and **mandates the use PAL**, when allergen control measures for cross-contact situations conclude to a possible risk for allergic consumers.

The formulation proposed referring to 4.2.1.4 of the GSLPF allows to rely on the same requirements of declaration based on the possible "unintended" presence of the protein fraction of the priority ingredients (leading to an identified risk to food allergic consumers).

❖ IUFoST suggests a minor change to the formulation of principle 4.2 as follows:

« The decision to use PAL should be based on the findings of a risk assessment which shall **be a qualitative and/or a quantitative** ~~include, but is not limited to,~~ quantitative risk assessment

It is our opinion that this formulation offers a more flexible approach where qualitative risk assessments, more achievable for smaller enterprises, are identified as a possible approach to determine the risk to allergic consumers resulting from situations of unintended presence of food allergens or cross-contact.

❖ IUFoST recommends a change to the formulation of Principle 4.3 as follows:

"PAL shall only be used if the presence of a protein from an allergen is equal to or above the action level for this allergen, **which is defined as:**

**Action level (mg total protein from the allergen / kg food) = Reference dose (mg total protein from the allergen) / Amount of the food (kg)**

**The reference dose may be chosen from the listed reference dose values in 4.3.1 or be developed by national jurisdictions based on their own risk assessments.**

**Should the Reference Dose chosen by a given competent authority be different from the listed values in 4.3.1, it would need to be disclosed and made available to industry and consumers, with the relevant justification."**

The current formulation of this principle imposes to rely upon the **thresholds or reference doses** as recommended by the FAO/WHO expert consultation which used the ED05 to derive the allergen

threshold. While this approach is scientifically robust, the inclusion of the ED05 as the basis of risk management in a Codex text implies that the same level of protection ought to be applied for the protection of consumers with food allergy, while it is understood that there are significant regional differences in consumers' sensitivity and response when exposed to the culprit allergen(s) and therefore it is legitimate to consider varying degrees of levels of protection that competent authorities may need to apply.

It would be important however that any threshold developed by a food competent authority in this context be justified by a risk assessment following the same rigor of the FAO/WHO Expert advice.

The proposed amended wording offers a more flexible **approach** for the formulation of this principle, while ensuring the harmonized practice desired through a Codex guidance.

Reference Doses could therefore be suggested to be those adopted by the Adhoc Expert Consultation, or other reference doses established by national jurisdictions based on their own risk assessments.

It would be however warranted that these RfDs be publicly disclosed when they are different from the recommended ones.

- ❖ IUFoST recommends that Provision 5.2.1 of the proposed guideline, relating to the way PAL statements are to be expressed on the label offer more flexibility to account of the way consumers globally would react to this statement. "may contain" may be understood in some countries and may have a different significance in others. It will be important that any statement adopted be supported by consumer research, to corroborate its effectiveness as a risk management tool.

A proposed addition to the 5.2.1. can be envisaged as follows:

A PAL statement shall commence with the words 'May contain' (or equivalent words) and include the identified allergens using the specified names as listed in sections 4.2.1.4 and where applicable 4.2.1.5 of the GSLPF. **Other equivalent statements may be used and shall be supported by consumer research.**

- ❖ IUFoST supports the opportunity to have robust advice on the performance of food allergen analytical methods, given the importance of allergen testing results in guiding risk assessments and therefore decisions to adopt a PAL on food labels. It is therefore recommended that CCMAS consider this area as part of its future activities.

### *Conclusion*

Considerable progress has been made in the development of the proposed texts. IUFoST supports the progress of the allergen labelling texts for possible adoption through the accelerated procedure at step 5/8.