

# CODEX ALIMENTARIUS COMMISSION



Food and Agriculture  
Organization of the  
United Nations



World Health  
Organization

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**CL 2021/9/OCS-FL**

**February 2021**

**TO:** Codex Contact Points  
Contact Points of international organizations having observer status with Codex

**FROM:** Secretariat, Codex Alimentarius Commission,  
Joint FAO/WHO Food Standards Programme

**SUBJECT: Request for comments / information on allergen labelling: revision of the General Standard for the Labelling of Prepackaged Foods (CXS 1 1985)**

**DEADLINE:** 31 March 2021

## **BACKGROUND**

1. The 45<sup>th</sup> Session of the Committee on Food Labelling (CCFL45) agreed to start new work to review and clarify the provisions relevant to allergen labelling in the *General Standard for the Labelling of Prepackaged Foods* (CXS 1 – 1985) (GSLPF) and to develop guidance on precautionary allergen or advisory labelling.<sup>1</sup>
2. This work was approved by CAC42 (July 2019).<sup>2</sup>
3. CCFL45 further agreed that an electronic working group (EWG) chaired by Australia, and co-chaired by the United Kingdom and the United States of America would prepare proposed draft revisions and guidelines for consideration by CCFL46.<sup>3</sup>
4. In view of the postponement of CCFL46 to 2021 due to the COVID19 pandemic, and taking advantage of the additional time at our disposal, the EWG has prepared a report of their work to update members and observers. A set of questions on key issues to be addressed in the revision of the GSLPF have been prepared for inputs by all interested members and observers.
5. Comments in reply to this Circular Letter will assist the EWG to further the work to date.

## **REQUEST FOR COMMENTS**

6. Codex members and observers are kindly invited to respond to the questions in Appendix III, taking into account the report of the EWG (Appendix I) and the proposed draft revisions to the GSLPF (Appendix II).
7. The aforementioned questions are uploaded to the Codex Online Commenting System (OCS): <https://ocs.codexalimentarius.org/>, as per the guidance below.

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<sup>1</sup> [REP19/FL](#) para 98(a)

<sup>2</sup> [REP19/CAC](#) para 99

<sup>3</sup> REP19/FL para. 98(b)

**GUIDANCE ON THE PROVISION OF COMMENTS**

8. Comments should be submitted through the Codex Contact Points of Codex members and observers using the OCS.
9. Contact Points of Codex members and observers may login to the OCS and access the document open for comments by selecting “Enter” in the “My reviews” page, available after login to the system.
10. Other OCS resources, including the user manual and short guide, can be found at the following link: <http://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/>.
11. For questions on the OCS, please contact [Codex-OCS@fao.org](mailto:Codex-OCS@fao.org).

## APPENDIX I

## REPORT OF THE EWG ON ALLERGEN LABELLING

(Chaired by Australia, and co-chaired by the United Kingdom and the United States of America)

## 1. INTRODUCTION AND BACKGROUND

At the 45<sup>th</sup> Session of the Codex Committee on Food Labelling (CCFL), the Committee agreed to start new work to review and clarify the provisions relevant to allergen labelling in the *General Standard for the Labelling of Prepackaged Foods* (CXS 1-1985) (GSLPF) and develop guidance on precautionary allergen or advisory labelling<sup>4</sup>. CCFL45 further agreed to establish an electronic working group (eWG) chaired by Australia, and co-chaired by the United Kingdom and the United States of America.

In approving the new work, the Codex Alimentarius Commission (CAC) in July 2019 noted *this work is linked to the work of the Codex Committee on Food Hygiene (CCFH) on allergen management and therefore close collaboration between CCFL and CCFH on this issue is important to ensure consistency between the two texts*<sup>5</sup>.

CCFL45 also agreed to request scientific advice from FAO/WHO<sup>6</sup> as outlined also in the allergen labelling project document relating to the list of foods and ingredients in section 4.2.1.4 of the GSLPF on:

- a) Whether the published criteria<sup>7</sup> for assessing additions and exclusions to the list is still current and appropriate.
- b) Subject to the advice on the criteria above:
  - i) whether there are foods and ingredients that should be added to or deleted from the list.
  - ii) clarification of the groupings of foods and ingredients in the list.
  - iii) whether certain foods and ingredients, such as highly refined foods and ingredients, that are derived from the list of foods known to cause hypersensitivity can be exempted from mandatory declaration.

The project document also foreshadows consideration of evidence based consumer understanding of allergen labelling and advisory statements to inform the work.

The CCFH has also requested FAO/WHO convene an expert consultation to provide scientific advice on threshold levels for the priority allergens in relation to the *Code of Practice on Allergen Management for Food Business Operators* (CXC 80-2020), which was adopted at CAC43<sup>8</sup>. CAC noted the CoP could be revised following scientific advice from FAO/WHO and completion of the work on guidance on precautionary allergen labelling in CCFL.

In response to the request for scientific advice, an [Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens](#) was convened between 30 November – 11 December 2020 for Part 1: Review and validation of Codex priority allergen list through risk assessment.

In view of the postponement of CCFL46, and taking advantage of the additional time available, this paper seeks broader comment on the direction for the review of the provisions in the GSLPF relevant to allergen labelling. By way of example and to help facilitate comment, proposed draft changes to the GSLPF are provided at Appendix II. Responses to the specific questions in Appendix III will help the eWG to further the work to date.

Please note comments on developing the guidance on precautionary allergen or advisory labelling (PAL) are not being sought at this time. A full report from the eWG on both the review of the GSLPF and the draft guidance on PAL, and including available scientific advice and consumer evidence to date, will be provided to CCFL46.

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<sup>4</sup> [REP19/FL](#) para 98(a) and Appendix IV

<sup>5</sup> [REP19/CAC](#) para 99

<sup>6</sup> REP19/FL, para. 98 (c)

<sup>7</sup> WHO Technical Report Series 896 (2000). Report of an ad hoc Panel on Food Allergens. Annex 4 of Evaluation of certain food additives and contaminants. Fifty-third report of the Joint FAO/WHO Expert Committee on Food Additives. <https://www.who.int/foodsafety/publications/jecfa-reports/en/>.

<sup>8</sup> [REP20/CAC](#), para 69 - 70

## TERMS OF REFERENCE

Working in English the eWG was to:

- Prepare proposed draft revisions and guidelines for circulation for comments at Step 3 and consideration by CCFL46;
- Take into account the scientific advice from the FAO/WHO and evidence based consumer understanding of allergen labelling and advisory statements.

## PARTICIPATION AND METHODOLOGY

An eWG was established in September 2019 with 33 Codex members, one Codex member organization, and 16 Codex observers participating since that time. A list of members is provided at Annex 1.

In October 2019 the eWG provided comment on a paper consisting of two parts. Part 1 discussed the revision of the GSLPF relevant to allergen labelling. The second part considered the development of guidance on PAL. A total of 28 eWG responses (21 Codex Members, one Codex Member Organization, six Codex Observers) were received.

A second consultation paper was circulated to the eWG in May 2020 seeking further comment on the scope and definitions for allergen labelling provisions in the GSLPF (Part 1) and the title, purpose, scope, definitions, and general principles for developing PAL guidance (Part 2). There were 32 eWG responses received (23 Codex Members, one Codex Member Organization, eight Codex Observers).

## SUMMARY OF DISCUSSION

### 1) Scope and structure of the GSLPF relevant to allergen labelling

#### 1.1 Scope

The eWG had differing views on whether the current scope of the GSLPF is suitable and sufficiently clear for the purpose of declaring foods and ingredients known to cause hypersensitivity. This was particularly in regard to two elements of the scope: 'offered as such to the consumer' and 'for catering purposes' which were both seen by some as needing to be clarified. The words 'where food is offered for immediate consumption' within the definition for 'foods for catering purposes'<sup>9</sup> was also seen as a source of confusion. However, the GSLPF appears to apply to 'prepackaged foods'<sup>10</sup> when sold to consumers or to caterers for further preparation before a final product is sold to consumers, but does not apply to prepared foods sold by caterers, unless the caterer sells 'prepackaged foods' to consumers.

Some eWG members supported extending the provision of allergen information to non-prepackaged foods noting allergen declarations could be provided in some manner other than the label. However, others viewed the GSLPF as applying only to prepackaged food and so the scope was clear including for food for catering purposes.

Some eWG members noted the scope issue relating to 'foods for catering purposes' was also relevant to other current CCFL work on the labelling of non-retail containers and internet sales/e-commerce and supported discussion and alignment across the differing work groups on the issue.

As there were differing views amongst the eWG members about the need to clarify the scope of the GSLPF as it applies to 'foods for catering purposes', the Co-Chairs are seeking broader feedback on this issue and in particular how clarity could be achieved if needed.

#### 1.2 Structure

The current scope of the GSLPF applies to 'labelling'<sup>11</sup> of prepackaged foods. However, section 4.2.1.4 as a section of paragraph 4.2 (List of ingredients) locates the declaration of food and ingredients known to cause hypersensitivity in the list of ingredients on the 'label'. The majority of the

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<sup>9</sup> "Foods for Catering Purposes" means those foods for use in restaurants, canteens, schools, hospitals and similar institutions where food is offered for immediate consumption.

<sup>10</sup> "Prepackaged" means packaged or made up in advance in a container, ready for offer to the consumer, or for catering purposes.

<sup>11</sup> "Labelling" includes any written, printed or graphic matter that is present on the label, accompanies the food, or is displayed near the food, including that for the purpose of promoting its sale or disposal.

eWG were of the view the declaration of the foods and ingredients listed in section 4.2.1.4 should apply to both the list of ingredients and labelling more broadly.

This could be achieved by including specific labelling provisions in the GSLPF for the declaration of foods and ingredients known to cause hypersensitivity. EWG members supporting this approach noted it would allow for greater consistency in the application, and tailoring, of requirements for declarations, including for foods which do not have ingredient lists or where allergen information is also provided outside the ingredient list. Those members that did not support this approach expressed concern that a new separate paragraph could extend declaration provisions to unpackaged foods, which would be outside the scope of the GSLPF.

Based on eWG feedback, the Co-Chairs are proposing to incorporate a new paragraph in Section 8 (Presentation of Mandatory Information) with specific labelling provisions for the presentation of declarations of foods and ingredients known to cause hypersensitivity in the GSLPF (see new paragraph 8.3 in Appendix II) and are seeking broader comment on this proposed approach.

## 2) Definitions

### 2.1 Definitions of 'food' and 'ingredient'

Most eWG members were of the view the existing definitions for 'food' and 'ingredient' in GSLPF are appropriate for the purposes of section 4.2.1.4. Others thought the definition of 'ingredient' could be clearer about the intent of 'in a modified form' and that it specifically refers to food additives, but not processing aids. It is noted that for the purposes of declaration of foods and ingredients known to cause hypersensitivity, processing aids are captured in section 4.2.4.2 of the GSLPF.

Based on the eWG feedback, the Co-Chairs are not proposing changes to these definitions at this stage. CCFL may wish to give further consideration to the definition of 'ingredient' once scientific advice is received from FAO and WHO on the list of foods and ingredients in section 4.2.1.4.

### 2.2 Proposed new definitions

There are no definitions specific to the declaration of foods and ingredients known to cause hypersensitivity in the GSLPF.

Most eWG members supported continuing to refer to 'hypersensitivity' in the GSLPF, with many in support of defining 'hypersensitivity' in the GSLPF to clarify:

- that the term encompasses both allergy and adverse reactions that do not have an immune basis, noting section 4.2.1.4 includes declaration of added sulphites, lactose and cereals containing gluten.
- how 'hypersensitivity' applies to certain foods, or the part of the food causing a hypersensitive response (e.g. the protein in the case of allergies).

There were also comments that definitions for 'food allergy' (or 'food allergen') and 'food intolerance' may be needed to provide sufficient clarity on the scope of adverse reactions to the foods and ingredients listed in section 4.2.1.4. Several eWG members noted that food allergy and food intolerance were separate conditions with different levels of health risk which required them to be defined separately. It was also noted that if only one term is defined (e.g. food allergen) and not another (e.g. food intolerance) then a definition of hypersensitivity will not be sufficiently clear.

In commenting on a proposed definition for 'hypersensitivity', eWG members supported including references to 'allergen', 'food allergy' and 'food intolerance'. Some members also supported a separate reference to 'Coeliac disease'.

Based on eWG comments, the Co-Chairs are proposing the following definition for hypersensitivity in the GSLPF:

"Hypersensitivity" means the repeatable adverse reaction to an allergen or other substance in food associated with food allergy, food intolerance or Coeliac disease.

To provide consistency with the *Code of Practice on Food Allergen Management for Food Business Operators* (CXC 80-2020) there was eWG support for the definition of 'allergen' as used in CXC 80-2020 as follows:

*“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 a protein which is found in food capable of triggering a response in individuals sensitised to it.*

Noting the CXC 80-2020 also includes a footnote for coeliac disease, many of the eWG agreed that including a similar footnote could aid clarity for the proposed definition of hypersensitivity:

*<sup>3</sup>Coeliac disease 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.*

However others suggested a more general reference to ‘auto-immune disease’ or ‘gluten-related disorders’ instead of Coeliac disease should be included in the definition of hypersensitivity.

Sources<sup>12,13</sup> have been identified that provide similar and consistent definitions of ‘food allergy’ and are consistent with references to food allergy in the CXC 80-2020. Based on these sources, the Co-Chairs are proposing the following definition:

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

A few eWG members noted ‘food intolerance’ was characterized by the 1999 FAO/WHO Ad Hoc Panel on Food Allergens<sup>14</sup>. The Co-Chairs consider a definition sourced from this report could be:

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

The Co-Chairs are seeking feedback on the proposed definitions, noting that CCFL can give further consideration to these definitions once scientific advice is received from FAO/WHO.

### **3) Mandatory labelling of prepackaged foods**

As scientific advice has been requested from FAO and WHO relating to the list of foods and ingredients in section 4.2.1.4, the eWG did not discuss revision of this section. However, the eWG did consider other aspects of Section 4 Mandatory Labelling of Prepackaged Foods in the GSLPF.

#### **3.1 Compound ingredients**

Section 4.2.1.3 of the GSLPF provides for the labelling of compound ingredients in the list of ingredients. This section includes the following text:

*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 food additives which serve a technological function in the finished product, need not be declared.*

There was majority eWG support for foods and ingredients known to cause hypersensitivity to always be declared, even when present as part of a compound ingredient that constitutes less than 5% of the food on the basis these foods and ingredients can still pose a risk to consumers.

Therefore the Co-Chairs are proposing to amend section 4.2.1.3 to apply the declaration requirements of section 4.2.1.4 to all compound ingredients including those that constitute less than 5 % of a food (see revised section 4.2.1.3 in Appendix II).

#### **3.2 Use of terminology for declarations**

Section 4.2.1.4 includes a list of foods and ingredients known to cause hypersensitivity that must be declared, but does not specify terms (words) to be used when making this declaration.

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<sup>12</sup> European Food Safety Authority (2014). Scientific Opinion on the evaluation of allergenic foods and food ingredients for labelling purposes. EFSA Journal 12(11): 3896-4180. <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2014.3894>, accessed 22/1/2021.

<sup>13</sup> World Allergy Organization (2017). Food Allergy. <https://www.worldallergy.org/education-and-programs/education/allergic-disease-resource-center/professionals/food-allergy>, accessed 22/1/2021.

<sup>14</sup> World Health Organization (2000). Evaluation of Certain Food Additives and Contaminants. WHO\_TRS\_896. [https://apps.who.int/iris/bitstream/10665/42378/1/WHO\\_TRS\\_896.pdf](https://apps.who.int/iris/bitstream/10665/42378/1/WHO_TRS_896.pdf). Accessed 23 December 2020.

The eWG expressed support for including provisions for standardising or aligning declaration terminology (or wording) to increase consistency and harmonization for consumers and industry alike. EWG members considered at a minimum, the GSLPF should require allergen information to be clear and easy to understand in simple, plain language, preferably with reference to the common name or source of the allergen (e.g. milk).

Based on this, the Co-Chairs are proposing to include provisions in the GSLPF for using common and well understood terms for the source of the food and ingredient known to cause hypersensitivity as part of, or in conjunction with, the relevant ingredient name (see new section 4.2.1.5 in Appendix II).

CCFL may wish to further consider whether individual source names are to be specified in the GSLPF once the scientific advice is received from FAO and WHO on the list of foods and ingredients in section 4.2.1.4.

### 3.3 Ingredients obtained through biotechnology

Section 4.2.2 of the GSLPF states the following:

*The presence in any food or food ingredients obtained through biotechnology of an allergen transferred from any of the products listed in Section 4.2.1.4 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.*

This section was added to the GSLPF in 2001<sup>15</sup> and resulted from work to identify labelling requirements for foods produced through biotechnology (upon request by CAC). The CCFL identified from a WHO risk assessment<sup>16</sup> that allergenicity was a concern with biotechnology, and decided consumers needed to be alerted to this. Although at the time 'allergen' was not defined, reference was made to substances that produce a positive 'test' result, so it could be assumed to refer to immune reactions to food protein rather than food intolerances.

The eWG was divided on the revision of this section with some eWG members being satisfied with the existing text whereas others commented that changes were needed because the text only refers to 'allergen', and not to the broader scope captured by foods and ingredients known to cause hypersensitivity (e.g. gluten). It should be noted that a new definition of 'allergen' is proposed by the eWG (see part 2.3 above), will likely assist to clarify reference to this term in section 4.2.2 of the GSLPF.

Some eWG members supported removal of section 4.2.2, because of the view that biotechnological processes used in the production of ingredients are well controlled including the presence of notifiable allergens. One eWG member suggested this section could be expanded beyond biotechnology, to production of foods from other novel technologies and to allergenic proteins coming from novel sources (e.g. yeast producing milk proteins). However this extends beyond the scope of the work on allergen labelling.

At this stage the Co-Chairs are not proposing any change to this section in relation to allergen labelling but would welcome comment from members and observers on the need to change this section. CCFL may wish to consider if other work is needed to review section 4.2.2 more generally.

### 3.4 Ingredient and class names

The majority of eWG members were of the view there is a need to clarify the use of permitted class names associated with the declaration of the foods and ingredients known to cause hypersensitivity. This was particularly in regards to revising the use of class names to ensure the source of an ingredient known to cause hypersensitivity is clearly identified (e.g. starch derived from wheat, caseinates from milk), and that there is use of consistent terminology (or wording) when referring to an allergen in a class name. Some eWG members noted that if a class name in section 4.2.3 is more informative than the name mentioned in section 4.2.1.4 with regard to allergenicity, then the class name should be allowed for making a declaration. However others considered that the name of the allergen should be declared in all instances where a class name is used.

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<sup>15</sup> Codex Alimentarius (2001). Codex Alimentarius Commission: Twenty-fourth Session, Geneva, 2-7 July 2001. AI01\_41e: <http://www.fao.org/fao-who-codexalimentarius/committees/cac/meetings/en/>. Accessed 10 September 2019.

<sup>16</sup> World Health Organization (1991). Strategies for assessing the safety of foods produced by biotechnology. <https://apps.who.int/iris/handle/10665/41465>. Accessed 10 September 2019.

Discussion within the eWG indicates there is a need to clarify the intent of section 4.2.3, with reference to the use of names of the foods and ingredients listed in section 4.2.1.4. To a large extent, including provision in the GSLPF for using common and well understood terms for the source of the food and ingredient known to cause hypersensitivity will provide clarity that specific terms must be used when declaring these foods and ingredients (see Section 3.2 above). However, the Co-Chairs are proposing to amend section 4.2.3.1 to provide clarify that the proposed new provision for using terms for the source of the food and ingredient listed in section 4.2.1.4 (new section 4.2.1.5 in Appendix II) would apply to class names.

### **3.5 Processing aids and carry-over of food additives**

Section 4.2.4.2 specifies that *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 listed in section 4.2.1.4.*

However, section 4.2.1.4 does not overtly recognise food additives and processing aids as foods and ingredients known to cause hypersensitivity, but rather they are captured by virtue of being derived as products of these foods and ingredients. The majority of the eWG supported the need for further clarity on food additives and processing aids not being exempt from declaration in the list of ingredients.

The Co-Chairs are therefore proposing to amend section 4.2.4.2 to clarify that the exemption does not apply to food additives and processing aids that contain or are derived from the foods and ingredients in section 4.2.1.4.

### **3.6 Exemptions from mandatory labelling requirements**

Section 6 of the GSLPF states '*With the exception of spices and herbs, small units, where the largest surface area is less than 10cm<sup>2</sup>, may be exempted from the requirements of paragraphs 4.2 and 4.6 to 4.8*'. Note in this context the 'largest surface area' is a reference to the 'largest individual surface', and not to the total surface area of a food package<sup>17</sup>.

This exemption is primarily about accommodating small packages (with limited labelling space) from having to provide a list of ingredients. The majority of the eWG were of the view the exemption should not apply to section 4.2.1.4 given the health risk associated with foods and ingredients known to cause hypersensitivity is the same regardless of the surface area of the package containing a food.

The eWG were asked to comment on approaches for declaring foods and ingredients known to cause hypersensitivity on small packages with some eWG members suggesting use of a statement (e.g. 'Contains....') should be permitted as an alternative.

Given eWG support for there being no exemptions from declaring foods and ingredients listed in section 4.2.1.4, the Co-Chairs are proposing changes to Section 6 of the GSLPF to remove the exemption to section 4.2.1.4 as it currently applies to small packages. In addition the proposed introduction of provisions for the presentation of declarations (see Section 4 below) allow for declarations where a food is not required to be labelled with an ingredient list.

## **4) Presentation of mandatory information**

Section 8 of the GSLPF provides guidance for the presentation of mandatory information on the labels of prepackaged foods. However, this section does not explicitly state how the declaration of foods and ingredients known to cause hypersensitivity should be presented. The lack of provisions on the presentation of declarations potentially means important information could be missed or have less utility for consumers.

Many eWG members supported including specific provisions for how the declaration of foods and ingredients known to cause hypersensitivity should be made as a means of facilitating international harmonization. There was support for specifying that declarations must be clearly distinguishable from the surrounding text such as through the use of bold font, colour or a minimum font size.

There was also support for allowing allergens to be declared in other locations on the food label in addition to the list of ingredients, such as a summary statement/contains statement/secondary information. It was suggested this this statement should list all allergens present in the food, and

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<sup>17</sup> Codex Alimentarius (1985). Report of the Eighteenth session of the Codex Committee on Food Labelling: Ottawa, Canada, 11-18 March 1985. <http://www.fao.org/fao-who-codexalimentarius/committees/committee/related-meetings/en/?committee=CCFL>. Accessed 10 September 2019.



appear in close proximity to the list of ingredients. However several members also commented that there needs to be flexibility provided to countries and/or regions to tailor the format and presentation of allergen labelling to suit their consumers' needs.

As discussed above in Section 1.2, the Co-Chairs are proposing to include labelling provisions in Section 8 (presentation of mandatory information) of the GSLPF relating to how declarations are to be presented (see new paragraph 8.3 in Appendix II). The Co-Chairs welcome feedback on the inclusion of these provisions and note CCFL may wish to consider this further in light of any consumer evidence received.

### **NEXT STEPS**

Following two rounds of eWG comment, the Co-Chairs are now seeking broader comment on the proposed approach to review and clarify the provisions relevant to allergen labelling in the GSLPF. Feedback received will assist the eWG to prepare revisions to the GSLPF for consideration by CCFL46.

### **CONCLUSIONS AND RECOMMENDATIONS**

Members and Observers are invited to:

1. Consider the approach and discussion of issues as provided in Appendix I
2. Review Appendix II (Proposed draft amendments to the GSLPF relevant to allergen labelling)
3. Provide responses to the questions in Appendix III. In doing so please provide reasons for your response and in the case where proposed changes are not supported whether there is an alternative approach(es) that should be considered.

## Annex 1

## LIST OF EWG PARTICIPANTS

**Members**

Argentina  
Australia  
Brazil  
Canada  
Chile  
China  
Costa Rica  
Egypt  
European Union  
Germany  
Greece  
Guatemala  
Honduras  
Hungary  
India  
Indonesia  
Iran  
Ireland  
Japan  
Malaysia  
México  
New Zealand  
Nicaragua  
Peru  
Philippines  
Poland  
Russia  
Singapore  
South Korea  
Sweden  
Switzerland  
United Kingdom  
United States of America

**Observers**

European Federation of Allergy and Airways Disease  
Federation Internationale des Vins et Spiritueux  
Food Industry Asia  
FoodDrinkEurope  
Global organization for EPA and DHA Omega-3  
Institute of Food Technologists  
International Chewing Gum Association  
International Confectioners Association  
International Council of Beverage Associations  
International Council of Grocery Manufacturers Associations  
International Dairy Federation  
International Food Additives Council  
International Organization of the Flavor Industry  
International Special Dietary Foods Industries  
Organisation Internationale de la vigne et du vin  
Safe Supply of Affordable Food Everywhere

## APPENDIX II

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

**2. DEFINITION OF TERMS**

For the purpose of this standard:

**NEW**

**“Hypersensitivity”** means the repeatable adverse reaction to an allergen or other substance in food associated with IgE mediated food allergy, non-IgE mediated immunological reactions, or food intolerance.

**“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 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, non-IgE mediated, or a combination of both.

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

**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 **[those listed in section 4.2.1.4 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 and shall always be declared:<sup>18</sup>

- 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.]

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<sup>18</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).

**NEW**

**4.2.1.5 Declaration of the foods and ingredients listed in section 4.2.1.4 shall be made using common and well understood terms for the source of the food and ingredient as part of, or in conjunction with, the relevant ingredient name.**

**RENUMBER existing 4.2.1.5 and 4.2.1.6**

**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.]**

**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.

**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 section 4.2.1.4.]**

**8. PRESENTATION OF MANDATORY INFORMATION****NEW****[8.3 Declared foods and ingredients**

**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.

**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 and placed in close proximity to the list of ingredients.

**8.3.2.1** This statement shall commence with the word 'Contains' (or equivalent word) and make declarations using common and well understood 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 in a statement made in accordance with section 8.3.2.1.]

**APPENDIX III****CONSULTATION QUESTIONS**

(replies should be submitted through the online commenting system (OCS))

**Question 1**

Does the scope of the GSLPF need clarifying as it applies to 'food for catering purposes' for the purpose of declaring foods and ingredients known to cause hypersensitivity (see Section 1.1 of Appendix I)? Please provide reasons for your response.

If yes, then how should the scope of the GSLPF as it applies to 'food for catering purposes' be clarified for the purpose of declaring foods and ingredients known to cause hypersensitivity?

**Question 2**

Do you agree with including specific provisions for the presentation of declarations of foods and ingredients known to cause hypersensitivity in Section 8 (Presentation of mandatory information) in the GSLPF (see Sections 1.2 and 4 in Appendix I)? Please provide reasons for your response.

**Question 3**

Do you agree with including definitions for 'hypersensitivity', 'allergen', 'food allergy' and 'food intolerance' in the GSLPF (see Section 2.2 of Appendix I)? Please provide reasons for your response.

If yes, then please provide comments on these proposed definitions.

**Question 4**

Do you agree with amending section 4.2.1.3 of the GSLPF so that the declaration of foods and ingredients in section 4.2.1.4 apply to all compound ingredients including those that constitute less than 5% of the food (see Section 3.1 of Appendix I)? Please provide reasons for your response.

**Question 5**

Do you agree with specifying the use of common and well understood terms (words) for the source of the food and ingredient known to cause hypersensitivity as part of, or in conjunction with, the relevant ingredient name when declarations are made on prepackaged foods (see Section 3.2 of Appendix I)? Please provide reasons for your response.

**Question 6**

Do you agree that section 4.2.2 of the GSLPF requires no change in relation to allergen labelling (see Section 3.3 of Appendix I)?

**Question 7**

Do you agree with the proposal to amend to section 4.2.3.1 in relation to the ingredients listed in section 4.2.1.4 and class names (See Section 3.4 of Appendix I)? Please provide reasons for your response.

**Question 8**

Do you agree with the proposal to amend section 4.2.4.2 to clarify the exemption applying to processing aids and the carry-over of food additives (see Section 3.5 of Appendix I)?

**Question 9**

Do you agree with the proposal to remove the exemption from declaring foods and ingredients listed in section 4.2.1.4 as it currently applies to small units (see Section 3.6 of Appendix I)?

**Question 10**

Do you have any other comments about the proposed approach or proposed revisions in Appendix II?