CODEX ALIMENTARIUS COMMISSION

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Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda item 5 **CX/FL 23/47/5 Add.1**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD LABELLING

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15 – 19 May 2023

FOOD ALLERGEN LABELLING

Comments in reply to CL 2023/06/OCS-FL

Comments of Argentina, Australia, Brazil, Canada, Chile, Colombia, Costa Rica, Cuba, Dominican Republic, Ecuador, European Union, Guatemala, Honduras, Indonesia, Japan, Kenya, New Zealand, Panama, Paraguay, Peru, Saudi Arabia, South Africa, Thailand, Uganda, United Kingdom, Uruguay, USA, ALAIAB, AOECS, EFA, FIVS, FIA, FoodDrinkEurope, ICBA, ICGA, ICGMA, ICUMSA,IDF/FIL, ICA/IOCCC and ISDI

Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2023/06/OCS-FL issued in March 2023. Under the OCS, comments are compiled in the following order: general comments are listed first, followed by comments on specific sections.

Explanatory notes on the appendix

2. The comments submitted through the OCS are hereby attached as **Annex** and are presented in table format.

ANNEX

GENERAL COMMENTS	MEMBER / OBSERVER
It is considered appropriate that the guidelines be annexed to the GSLPF to ensure consistency with such General Standard. That means it should be included as an Annex since it is part of the GSLPF.	**Argentina**
The view of AOECS is that coeliac disease has been overlooked in the proposals for the GSLPF, which would lead to a harmful situation for patients with coeliac disease if these proposals presented are not amended. With regards to the proposal to de-prioritise oats from 4.2.1.4 this would conflict with the Codex Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten 118-1979 where 'oats' are listed under the definition of gluten. AOECS has presented further comments on the proposal to remove oats from 4.2.1.4. based on discussions with dedicated coeliac clinicians and oats researchers and coeliac patient representative organisations from Europe, USA and Australia.	**Association Of European Coeliac Societies Codex and Regulatory Affairs**
whether to provide any advice to CCFH to ensure consistency with the *Code of Practice on Allergen Management for Food Business Operators* (CXC 80-2020). Australia considers advice should be provided to CCFH on the proposed PAL guidelines. We note that CAC has asked for there to be close collaboration between CCFL and CCFH on allergen work to ensure consistency between texts. Subject to discussions at CCFL47, it could be timely to update CCFH on the allergen labelling work, particularly in light of the outcomes from the FAO/WHO Expert Committee and the proposed draft PAL guidance including definitions. This will be important for ensuring consistency between the two documents moving forward. Australia also notes that if CCFL decides to seek advice from CCMAS on analytical methods and sampling this could also be of relevance to CCFH. CXC 80-2020 includes guidance on how to conduct risk assessments, so CCFH may therefore also consider methods of analysis and sampling in any updates to CXC 80-2020.	**Australia**
Canada appreciates the opportunity to provide comments on the Proposed Draft Revisions to the GSLPF Relevant to Allergen Labelling. Canada believes that the work on allergen labelling is important to help harmonize labelling of food allergens in prepackaged foods.	**Canada**
whether to provide any advice to CCFH to ensure consistency with the *Code of Practice on Allergen Management for Food Business Operators* (CXC 80-2020). Canada support actions to ensure alignment with CCFH mandates, such as CXC 80-2020 once PAL guidelines are agreed.	
whether to provide any advice to CCFH to ensure consistency with the *Code of Practice on Allergen Management for Food Business Operators* (CXC 80-2020). Chile supports all actions to ensure alignment with the mandates of the Codex Committee on Food Hygiene (CCFH), in order to ensure consistency with the Code of Practice on Food Allergen Management.	**Chile**
whether to provide any advice to CCFH to ensure consistency with the *Code of Practice on Allergen Management for Food Business Operators* (CXC 80-2020). Colombia considers that advice should be provided to the Codex Committee on Food Hygiene (CCFH) to ensure consistency with the Code of Practice on Food Allergen Management for Food Business Operators (CXC 80-2020).	**Colombia**

GENERAL COMMENTS	MEMBER / OBSERVER
whether to provide any advice to CCFH to ensure consistency with the *Code of Practice on Allergen Management for Food Business Operators* (CXC 80-2020). Costa Rica supports this.	**Costa Rica**
the proposed draft revision to the GSLPF in Appendix II of CX/FL 23/47/5 Costa Rica supports, in general, the proposal considering the comments indicated below.	
whether to provide any advice to CCFH to ensure consistency with the *Code of Practice on Allergen Management for Food Business Operators* (CXC 80-2020). Costa Rica supports this proposition.	
whether to provide any advice to CCFH to ensure consistency with the *Code of Practice on Allergen Management for Food Business Operators* (CXC 80-2020). Cuba's response to Circular Letter CL 2023/06/OCS-FL: Request for comments on food allergen labelling. i) *Proposed Draft Revision* of the General Standard for the Labelling of Prepackaged Foods (GSLPF): provisions relating to allergen labelling.	**Cuba**
whether to provide any advice to CCFH to ensure consistency with the *Code of Practice on Allergen Management for Food Business Operators* (CXC 80-2020). The country believes that as long as the greatest pronouncement by the competent committees exists, there would be a broader criterion, allowing the best decision to be taken.	**Ecuador**
whether to provide any advice to CCFH to ensure consistency with the *Code of Practice on Allergen Management for Food Business Operators* (CXC 80-2020). EFA strongly advises that the topics discussed here are integrated in the Code of Practice on Allergen Management for Food Business Operators of the Codex Committee on Food Hygiene.	**European Federation of Allergy and Airways Diseases Patients' Associations**
EFA definitely believes that CCFL must ensure consistency with the CCFH Code of Practice on Allergen Management for Food Business Operators, given the close connection of seceral aspects addressed in both documents, including the risk assessment process and the need for training and education of all involved actors (e.g. consumers, healthcare professionals, food business operators, food inspectors) in allergen management and labelling.	
whether to provide any advice to CCFH to ensure consistency with the *Code of Practice on Allergen Management for Food Business Operators* (CXC 80-2020). As regards the timing to provide advice to CCFH, the EU considers that it may be more appropriate that this is done at Step 5 of the text, when a more stable text is available.	**European Union**
FIA supports the inclusion of "gluten" as an additional voluntary specified name for the listed cereals containing gluten to be in line with international regulations and flexibility for multi-market packaging. In Australia, gluten is typically declared when gluten protein is still present within the food product and is in addition to the declaration of the specific cereal.	**Food Industry Asia**

GENERAL COMMENTS	MEMBER / OBSERVER
whether to provide any advice to CCFH to ensure consistency with the *Code of Practice on Allergen Management for Food Business Operators* (CXC 80-2020). FIA supports the consistency between this work and the CCFH Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020).	
whether to provide any advice to CCFH to ensure consistency with the *Code of Practice on Allergen Management for Food Business Operators* (CXC 80-2020). FoodDrinkEurope supports CCFL to provide any advice to CCFH to ensure consistency with the Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020).	**FoodDrinkEurope**
whether to provide any advice to CCFH to ensure consistency with the *Code of Practice on Allergen Management for Food Business Operators* (CXC 80-2020). Requests an update to the Codex Committee on Food Hygiene (CCFH) to ensure consistency with the Code of Practice on the Management of Food Allergens by Food Business Operators (CXC 80-2020). Verify the relevance of the advice to the CCFH. Appendix II section 4.2.1.7 **the proposed draft revision to the GSLPF in Appendix II** You propose the deletion of section 4.2.1.5 as it may lead to different interpretations that could cause confusion to consumers, could lead to inconsistencies in the labelling of global trade. Due to insufficient population studies.	**Guatemala**
whether to provide any advice to CCFH to ensure consistency with the *Code of Practice on Allergen Management for Food Business Operators* (CXC 80-2020). We support actions to ensure alignment with CCFH mandates once this work is near completion or completed.	**ICGMA**
whether to provide any advice to CCFH to ensure consistency with the *Code of Practice on Allergen Management for Food Business Operators* (CXC 80-2020). Ideally, the CCFH COP and the GSLPF guidance on allergens would be consistent, therefore IDF is in support of providing advice to CCFH e.g. around definitions of terms such as "food allergy".	**IDF/FIL**
the proposed draft revision to the GSLPF in Appendix II of See ICA comments throughout the draft	**International Confectionery Association**
the need to seek advice on standardised analytical methods and sampling from CCMAS (i.e. whether there is agreement to seek advice on appropriate methods for undertaking risk assessments, taking into account information provided within FAO/WHO scientific advice reports) ISDI supports seeking advice from CCMAS on analytical methods and sampling.	**International Special Dietary Food Industries**
whether to provide any advice to CCFH to ensure consistency with the *Code of Practice on Allergen Management for Food Business Operators* (CXC 80-2020).	

GENERAL COMMENTS	MEMBER / OBSERVER
ISDI supports taking action to ensure alignment with CCFH texts.	
the proposed draft revision to the GSLPF in Appendix II of Please find ISDI detailed comments related to the revisions to the GSLPF and the PAL text below. ISDI does not agree with including section 4.2.1.5 for the following reasons: • It may result in inconsistencies in labelling approaches in global trade; • Differences in interpretations could cause confusion among consumers; Listing national level allergens within the Codex text would defeat the purpose of such national level actions, by reducing the ability to respond rapidly to local emerging food safety issues. ISDI recommends that section 4.2.1.5 be deleted and for a footnote to be added with a reference to the FAO/WHO Allergen expert panel report for national governments to refer to, rather than the Codex GSLPF text.	
whether to provide any advice to CCFH to ensure consistency with the *Code of Practice on Allergen Management for Food Business Operators* (CXC 80-2020). We do not think it is necessary to submit comments to the CCFH, but we suggest that the definition of "allergen" in the GSLPF should be aligned.	**Japan**
New Zealand is generally supportive of the proposed changes including proposed drafting and we are therefore commenting only where NZ does not support/agree	**New Zealand**
the proposed draft revision to the GSLPF in Appendix II of We have provided comments against the respective clauses below	
whether to provide any advice to CCFH to ensure consistency with the *Code of Practice on Allergen Management for Food Business Operators* (CXC 80-2020). Panama fully agrees with the need for advice to the Codex Committee on Food Hygiene (CCFH) to ensure consistency Code of Practice on Food Allergen Management for Food Business Operators.	**Panama**
whether to provide any advice to CCFH to ensure consistency with the *Code of Practice on Allergen Management for Food Business Operators* (CXC 80-2020). Panama would agree to the proposed location as an annex to the GSLPF.	
whether to provide any advice to CCFH to ensure consistency with the *Code of Practice on Allergen Management for Food Business Operators* (CXC 80-2020). Paraguay agrees.	**Paraguay**
the proposed draft revision to the GSLPF in Appendix II of • Item 4.2.1.4 (1) The definition of gluten must be updated in CXS 118-1979 as oats was removed on the proposed draft (Appendix II).	**Saudi Arabia**

GENERAL COMMENTS	MEMBER / OBSERVER
• Item 8 o We suggest to use the following declaration forms of allergens, (bearing in mind that national/regional authorities shall determine the most suitable declaration requirements for their population): 1. The use of “contains” to declare the allergens present in food. In addition, using the word “may contain”, when there might be an allergen contamination present. 2. Using a bold, underline, or symbols to declare the allergens on the label.	
the proposed draft revision to the GSLPF in Appendix II of The Kingdom of Saudi Arabia supports the incorporation of the guidelines as an annex to the GSLPF to ensure consistency with the GSLPF. With that being said, we highly recommend that all detailed and specified information related to allergen labeling be in a separate guideline for in-depth requirements, not to mention that the guideline might require frequent updating when compared to GSLPF.	
whether to provide any advice to CCFH to ensure consistency with the *Code of Practice on Allergen Management for Food Business Operators* (CXC 80-2020). South Africa agrees that it is necessary to provide advice to CCFH to ensure consistency with the Code of Practice on Allergen Management for Food Business Operators. Since it is proposed that the GSLPF will include Appendix related to PAL, the Code of Practice on Allergen Management for Food Business Operators should be amended accordingly.	**South Africa**
the proposed draft revision to the GSLPF in Appendix II of Uganda supports considering the new proposed additions and deletions wherever made in the draft revision as presented by the EWG Rationale: More clarity will be brought out in the GSLPF.	**Uganda**
whether to provide any advice to CCFH to ensure consistency with the *Code of Practice on Allergen Management for Food Business Operators* (CXC 80-2020). Uruguay reiterates its opinion sent in response to the CL 2021/21/OCS-FL as the guideline is understood to refer to other substances, and not only to allergens, so this should be reflected in the name and other sections of the guideline.	**Uruguay**
The United States notes the significant progress made and generally supports the current text, however, there remain areas for discussion and refinement. The United States agrees the scope of the work of CCFL should remain focused on prepackaged foods, but notes the scientific advice, definition, and general approach could be used by authorities to guide allergen disclosure in the catering and restaurant trade. The United States has provided further specific comments in track changes in the document notably on Section 4.2.1.5 and 4.2.4.2.	**USA**
Part A: Proposed draft revision to the *General Standard for the Labelling of Prepackaged Foods* – Provisions relevant to allergen labelling	

SPECIFIC COMMENTS	MEMBER / OBSERVER
Panama generally supports the proposed updates and amendments.	**Panama**

SPECIFIC COMMENTS	MEMBER / OBSERVER
It is suggested to include a specific numeral in which the exception of allergen labeling is considered for those highly refined foods and ingredients as, by its process, the protein fraction that causes the allergic reaction is eliminated, as it is already applied in other regulations such as the Food Allergen Labeling and Consumer Protection Act - U.S. Food and Drug Administration FALCPA-FDA. *https://www.fda.gov/food/food-allergensgluten-free-guidance-documents-regulatory-information/food-allergen-labeling-and-consumer-protection-act-2004-falcpa*	**Peru**
2. DEFINITION OF TERMS	
AOECS strongly disagrees with having the definition of coeliac disease incorporated in a footnote. Rather a separate definition in the main body of text within the standard is the most appropriate approach. The proposed text 'food allergy' includes both IgE-mediated and non-IgE-mediated conditions, which is coeliac disease. This is incredibly confusing because coeliac disease is distinct from food allergy. It would be more appropriate to keep the definition of 'hypersensitivity - food allergy or coeliac disease' and have an additional definition for coeliac disease. In addition, the proposed definition for coeliac disease that has been included in the footnote is not a fully accurate definition. Coeliac disease is not only an intestinal disease, but a systemic condition and can affect other organs. Since coeliac disease is not a well understood condition outside of the expert field of academia or healthcare, it is important to ensure that the food industry is correctly and adequately informed about coeliac disease as it is different from a food allergy.	**Association Of European Coeliac Societies Codex and Regulatory Affairs**
The EU agrees with the definition proposed for food allergy and with the replacement of the term 'hypersensitivity' later in the text.	**European Union**
***"Food allergy"* means a reproducible adverse health effect arising from an immunoglobulin class E (IgE) antibody or non-IgE antibody immune-mediated response following oral exposure to a food."** FIVS supports this definition.	**FIVS**
***"Food allergy"* means a reproducible adverse health effect arising from an immunoglobulin class E (IgE) antibody or non-IgE antibody immune-mediated response following oral exposure to a food."** We disagree the removal from the definition of food allergy that it is an immune response that occurs through proteins. Because it differs from the definition of food allergy set out in the Code of Practice on Food Allergen Management for Food Business Operators (CXC80-2020).	**Japan**
***"Food allergy"* means a reproducible adverse health effect arising from an immunoglobulin class E (IgE) antibody or non-IgE antibody immune-mediated response following oral exposure to a food."** Chile supports the addition to the NGEAP of the proposed definition for "food allergy".	**Chile**
***"Food allergy"* means a reproducible adverse health effect arising from an immunoglobulin class E (IgE) antibody or non-IgE antibody immune-mediated response following oral exposure to a food."** We support the addition to the GSLPF of the proposed definition for "food allergy."	**ICGMA**
***"Food allergy"* means a reproducible adverse health effect arising from an immunoglobulin class E (IgE) antibody or non-IgE antibody immune-mediated response following oral exposure to a food."** Kenya proposes the definition to be amended to read, "Food allergy" means a reproducible adverse health effect arising from an immunoglobulin class E (IgE) antibody or non-IgE antibody immune-mediated response following intake food." i.e substitute "oral exposure to' with intake Rationale: The definition as provided is self-limiting to only food orally taken. We note is some cases alternative feeding may be applied such as tube feeding and thus the aim of the definition should be to cover any food ingested into the body.	**Kenya**
***"Food allergy"* means a reproducible adverse health effect arising from an immunoglobulin class E (IgE) antibody or non-IgE antibody immune-mediated response following oral exposure to a food."**	**International Special Dietary Food Industries**

SPECIFIC COMMENTS	MEMBER / OBSERVER
ISDI supports adding this new definition to the GSLPF.	
***"Food allergy"* means a reproducible adverse health effect arising from an immunoglobulin class E (IgE) antibody or non-IgE antibody immune-mediated response following oral exposure to a food."** Indonesia supports the definition of "food allergy".	**Indonesia**
***"Food allergy"* means a reproducible adverse health effect arising from an immunoglobulin class E (IgE) antibody or non-IgE antibody immune-mediated response following oral exposure to a food."** Canada supports the addition of the definition of "food allergy" to the GSLPF	**Canada**
***"Food allergy"* means a reproducible adverse health effect arising from an immunoglobulin class E (IgE) antibody or non-IgE antibody immune-mediated response following oral exposure to a food."** The United States supports the proposed definition.	**USA**
***"Food allergy"* means a reproducible adverse health effect arising from an immunoglobulin class E (IgE) antibody or non-IgE antibody immune-mediated response following oral exposure to a food."** The Dominican Republic supports the new definition of food allergy.	**Dominican Republic**
***"Food allergy"* means a reproducible adverse health effect arising from an immunoglobulin class E (IgE) antibody or non-IgE antibody immune-mediated response following oral exposure to a food."** Chile supports the addition to the GSLPF of the proposed definition of "food allergy".	**Chile**
***"Food allergy"* means a reproducible adverse health effect arising from an immunoglobulin class E (IgE) antibody or non-IgE antibody immune-mediated response following oral exposure to a food."** "Food allergy" means a reproducible adverse health effect from an Immunoglobulin class E (IgE) antibody or an immunoantibody-mediated response without IgE following oral exposure to a food. " "Hypersensitivity" means the repeated and exaggerated adverse reaction to an allergen or other substance in food associated with an IgE-mediated food allergy, a non-IgE1-mediated food allergy, or food intolerance.	**Uruguay**
***"Food allergy"* means a reproducible adverse health effect arising from an immunoglobulin class E (IgE) antibody or non-IgE antibody immune-mediated response following oral exposure to a food."** Paraguay proposes the following wording. Food allergy refers to reproducible adverse reactions, mediated by specific immunological mechanisms, which occur in sensitive individuals after the consumption of certain foods. Our proposal aims to emphasize that allergic reactions occur only in sensitive individuals, not in the general population, in whom such a reaction would not occur.	**Paraguay**
4. MANDATORY LABELLING OF PREPACKAGED FOODS	
Kenya agrees and supports the proposed amendments including the new clauses introduced Rationale: The amendments are based on the technical report of the ad Hoc FAO/WHO hence the amendments are based on sound scientific evidence. We are in support of the listing of clause 4.2.1.4 whose ingredients were listed based on prevalence, severity and potency of the allergens.	**Kenya**
4.2.1.3 EFA recommends that allergens must be declared in all cases, and even below the 5% threshold. Codex should consider foods that are not (yet) priority allergens or they are emerging allergens, about which consumers need to be informed. We therefore urge CCFL to delete this 5% rule, and keep the text in line with the current EU and some non-EU practice such as Switzerland.	**European Federation of Allergy and Airways Diseases Patients' Associations**

SPECIFIC COMMENTS	MEMBER / OBSERVER
4.2.1.3 Where an ingredient is itself the product of two or more ingredients, such a compound ingredient may be declared, as such, in the list of ingredients, provided that it is immediately accompanied by a list, in brackets, of its ingredients in descending order of proportion (m/m). Where a compound ingredient (for which a name has been established in a Codex standard or in national legislation) constitutes less than 5% of the food, the ingredients ~~, other than~~ **need not be declared, except for the foods and ingredients listed in ~~section~~ sections 4.2.1.4, 4.2.1.6 and where applicable section 4.2.1.5 and** food additives which serve a technological function in the finished product~~, need not be declared~~. The EU supports the proposed draft revision and the editorial changes that have been incorporated in Section 4.2. The EU suggests an additional editorial correction.	**European Union**
4.2.1.3 Considering ①consistency from the viewpoint of patient convenience, ②surface area from the viewpoint of convenience of business operators,③ current popularized status etc, We suggest it is necessary to allow to be listed collectively at the end of the ingredients column to the effect that specified ingredients (allergen) are included. For example, In Japan, allergen must be listed individually in principle but it also may allow to be listed collectively at the end of the ingredients column.	**Japan**
4.2.1.3 Chile supports the revisions of the NGEAP corresponding to section 4.2.1.3. However, we note that certain National Authorities apply the guidance given in 4.2.1.3 subject to local conditions: not all countries exempt the declaration of compound ingredients in <5%.	**Chile**
4.2.1.3 Comment: Revisions to the GSLPF 4.2.1.3 are also appropriate. Here, however we note that certain National Authorities apply the guidance offered in 4.2.1.3 subject to local conditions: not all countries exempt compound ingredients declaration at <5%.	**ICGMA**
4.2.1.3 Canada supports the changes to 4.2.1.3, noting that Canadian regulations have a specific list of ingredients that are exempt from component (sub-ingredient) declaration and does not use the 5% rule as outlined in 4.2.1.3	**Canada**
4.2.1.3 Thailand does not object the revised text in section 4.2.1.3 for better clarity.	**Thailand**
4.2.1.3 Dominican Republic supports paragraph 4.2.1.3	**Dominican Republic**
4.2.1.3 Chile supports the revisions of the GSLPF corresponding to section 4.2.1.3. However, we note that certain National Authorities apply the guidance offered in 4.2.1.3 subject to local conditions: not all countries exempt the declaration of compound ingredients by <5%.	**Chile**
4.2.1.3 Paraguay agrees with the proposed amendment and inclusion of the paragraph, considering the new proposal to define Food Allergy.	**Paraguay**
4.2.1.4 Regarding the specified names for foods and ingredients listed in section 4.2.1.4 that are to be used when declaring 'allergens', AOECS would expect that the full ingredient name such as wheat starch, barley malt extract, barley malt vinegar etc. are seen on the label to ensure the consumer can identify the food or ingredient accurately.	**Association Of European Coeliac Societies Codex and Regulatory Affairs**
4.2.1.4 With regards to the labelling of priority allergens, EFA raises the following comments: 1. CCFL needs to clarify what is the suggestion with specified names. Are specified names supposed to be used alone or in conjunction with the ingredient name?Consumers need to know both the ingredient and the allergen that it is made of (in brackets). Both information should be there. An example can be found for a product of milk e.g. "whey protein (milk)". As a reminder, this is the legal requirement in the EU. 2. Gluten-containing cereals are relevant to two different allergic diseases that need to be covered: coeliac disease as well as IgE mediated food allergies. Both consumer groups need specific information, which should be included in the labelling. This means, that both the specific gluten containing cereal as well as the presence of gluten must be labelled. Therefore, EFA	**European Federation of Allergy and Airways Diseases Patients' Associations**

SPECIFIC COMMENTS	MEMBER / OBSERVER
suggests to add 'gluten' as 'specified name' below 'wheat', 'rye' and 'barley'. As an example, when a product of a triticum species is used as ingredient, such as speltflour, the ingredient list should read: "... speltflour (wheat/gluten) ..." 3. With regards to fish and crustacea, EFA suggests to treat both these foods as broad categories. We ask CCFL to take the following considerations into account: - some consumers can be allergic only to one or two fish species while others must avoid all fish (and the same with crustacea) - the names of some fish species (e.g. tilapia) and crustacea species are not always easily recognisable by consumers. Given the above considerations, EFA suggests that the mandatory labelling for fish and crustacea should include both the common name of the individual fish species AND 'fish' as the specified name. Therefore, EFA suggests to change the text in the column of specified names to 'fish and the common name of individual fish species' (instead of or). The resulting labelling must appear as follows: 'fish species (fish)' e.g. tilapia (fish).	
4.2.1.4 EFA recommends to add '...in addition to the ingredient name' at the end of this sentence. EFA suggests using words that attribute the obligatory nature of priority allergen labelling, and therefore substitute 'shall' with 'must'. Similar wording must adapt throughout the document text.	**European Federation of Allergy and Airways Diseases Patients' Associations**
4.2.1.4 AOECS agrees with the text that the foods and ingredients in this section are known to cause 'food allergy or coeliac disease'. However, as stated above, coeliac disease should be included in the Definitions of Terms as previously requested	**Association Of European Coeliac Societies Codex and Regulatory Affairs**
4.2.1.4 The EU welcomes the proposed approach of the two lists (priority and national or regional allergens). As regards the footnote for the coeliac disease, the EU considers that footnotes in Codex Standards should be avoided. However, in the light of the justification provided in background document CX/FL 23/47/5, the footnote 1 can be accepted. With regards to the definition provided for coeliac disease, the EU considers that the definition proposed misses explicit reference to autoimmunity. In addition, the EU would avoid defining coeliac disease as an "intestinal" disease, as symptoms can be quite systemic (although diagnosis is made on the enteropathy). The EU has the following suggestions to improve the text: "Coeliac disease is a chronic autoimmune systemic disorder triggered in genetically predisposed individuals by exposure to dietary gluten proteins that come from wheat, rye, barley and triticale (a cross between wheat and rye)." Table on "FOODS AND INGREDIENTS" SPECIFIED NAME: The EU agrees that allergen information must be clear to understand and that substances must be indicated in the list of ingredients with a clear reference to their name as listed therein (e.g., eggs, fish, milk etc.), except for cases where the ingredient is common and a well-understood term by consumers e.g., cream, cheese. The EU also considers that the specified names indicated in sections 4.2.1.4 and 4.2.1.5 should allow the possibility to complete with additional well-understood terms, where appropriate. The EU suggests adding one line space above the word "wheat" so that the specified names in the second column align to the foods and ingredients listed in the first column. The same applies to the 'specific tree nuts' section, above the word 'almond'. Cereals containing gluten : The EU would like to see Khorasan wheat be included in the list. The footnote for cereals containing gluten should read: "Includes spelt, Khorasan wheat and other specific cereals containing gluten that are species or hybridized strains under the genus names of Triticum, Secale and Hordeum. Specified names are to be used according to the associated genus. Hybridized strains are to use specified names in conjunction from all of the parent genera (e.g. 'wheat' and 'rye' for triticale)." 'wheat': With respect to "cereals containing gluten", the EU considers that:	**European Union**

SPECIFIC COMMENTS	MEMBER / OBSERVER
- some flexibility should be allowed as regards the word 'wheat' to be accompanied by the word 'durum', 'spelt' or 'khorasan' on a voluntary basis, where 'spelt', 'khorasan' or 'durum' is used. For example: wheat or wheat (durum) or durum wheat, wheat or wheat (spelt) or spelt wheat. - some flexibility should be allowed as regards the indication of a specific type of cereal to be accompanied by the word 'gluten', on a voluntary basis, For example: wheat flour (contains gluten) or wheat flour (gluten). 'milk': The EU considers that the specified name should not be restricted to 'milk'. It should instead read: "'milk' or the common name of individual milk products"; as for fish and crustaceans. This will allow on a voluntary basis, other common names to be used for milk, such as cheese and cream. Some flexibility should be provided for cases where, e.g. a food is sold under a name such as 'cheese', 'cream' which clearly refers to one of the allergens listed in section 4.2.1.4 (e.g. milk) and for which it is not required to bear a list of ingredients, the allergen in question does not have to be indicated on the label. Specific tree nuts: The EU believes that, as provided for the cereals, it would be useful, for clarity purposes, to provide the scientific names for the tree nuts category as well, such as for example: Almonds (Amygdalus communis L.), hazelnuts (Corylus avellana), walnuts (Juglans regia), cashews (Anacardium occidentale), pecan nuts (Carya illinoinensis (Wangenh.) K. Koch), Brazil nuts (Bertholletia excelsa), pistachio nuts (Pistacia vera), macadamia or Queensland nuts (Macadamia ternifolia). The rationale behind this proposal is that Codex texts are used at global level and translations are provided only in some languages, not in all. The scientific name of tree nuts is considered a global name and therefore, mentioning the scientific names in the text will ensure consistency with the international nature of these standards.	
4.2.1.4 Australia recommends that footnote 1 is amended by replacing 'cross' with 'hybrid', for consistency with 'hybridized' in footnote 2.	**Australia**
4.2.1.4 Chile supports the revisions of the text in section 4.2.1.4, as well as with the modified text. On the other hand, Chile supports the addition of footnotes (22 and 23).	**Chile**
4.2.1.4 FoodDrinkEurope agrees with adding the specified name "gluten" for cereals containing gluten. This ensures the use of the word "gluten" can be used additional in the list of ingredients next to the type of cereal to clarify those cereals contains gluten. But more important, when the word "gluten" is not listed in this section it is also not allowed in the wording of a PAL. Section 5.2.1 of Annex III (wording of a PAL) refers to the specified names. A clearer explanation on the use of specified names is needed in general. For example is the specified name additional to the common ingredient name (in case they are not the same) or can it be used instead? In case of crustaceans the word 'or' is used. So a shrimp cracker can list just 'crustaceans'? Also other examples were the use is not clear 'whey powder (milk)' of just 'milk' and 'spelt (wheat)' or just 'wheat'? Suggested wording: … always be declared2 using the name specified next to common name in case they are not the same.	**FoodDrinkEurope**
4.2.1.4 4.2.1.4 - New Zealand does not support the inclusion under "specified name" of the common name of individual species as alternatives to the terms 'crustacea' or 'fish'. New Zealand considers that unless there is a discernible difference in the allergenicity of different fish and/or crustacea species (in the way there is for different tree nuts which requires the listing of specific tree nuts separately) all species should be declared by the common terms 'fish' and 'crustacea' respectively. We note that consumer evidence provided by the ISSLG supports the use of consistent, simple terms for the declaration of allergens.	**New Zealand**
4.2.1.4 In principle, Thailand does not object that the list in section 4.2.1.4 only includes foods and ingredients associated with IgE-mediated reactions and coeliac disease, except for sesame. We propose to include sesame in section 4.2.1.5 instead since Allergic reaction from consumers with sesame allergies is rarely reported in Asia. Thus, sesame is not considered a significant	**Thailand**

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allergen in this region. In addition, the severity assessment of sesame needs more data relating to frequencies of anaphylaxis prior to including sesame as a priority food allergens. Furthermore, Thailand would like to proposes to move the text from footnote 2 into the table for the purpose of emphasizing awareness and for better clarity as follows: FOOD AND INGREDIENTS — SPECIED NAME Cereals containing gluten - wheat and other Triticum species — 'wheat' - rye and other Secale species — 'rye' - barley and other Hordeum species — 'barley" - Includes spelt and other specific cereals containing gluten that are species or hybridized strains under the genus names of Triticum, Secale and Hordeum and products thereof — Specified names are to be used according to the associated genus, Hybridized strains are to use specified name in conjunction from all of the parent genera(e.g. wheat' and 'rye' for triticale)	
4.2.1.4 Specific comment: Add "sesame seed" and "sesame seeds" to the list of allergens if required. Canada questions whether the use of "sesame seed" or "sesame seeds" would be permitted for the declaration of "sesame", given that they contain the required "specified name" "sesame". Canada would prefer for all three of "sesame", "sesame seed" and "sesame seeds" to be permitted. Add "triticale" to the list of cereals containing gluten. Canada notes that under the specified names provided triticale, which is a hybrid of wheat and rye, would have to be declared as both "wheat" and "rye" rather than just "triticale". Canada suggests that "triticale" be added to the table along with "wheat", "rye" and "barley".	**Canada**
4.2.1.4 It would be better to align the Specified Names with the Foods and Ingredients. Currently, they are not aligned in the table.	**ICUMSA**
4.2.1.4 Indonesia considers that sesame should not be included in 4.2.1.4 considering the low prevalence of sesame allergy. Indonesia proposes to include sesame in section 4.2.1.5.	**Indonesia**
4.2.1.4 General comment: Canada supports the inclusion of the footnote definition of Coeliac disease. Specific comment: Canada notes that the specified name for fish and crustacea allow either the common name of the species or the more generic terms "fish" or "crustacea". While the generic term "fish" or "crustacea" might be acceptable for certain situations (e.g. in a Contains statement particularly if multiple sources of fish or crustacea are present in the food), Canada does not believe that those generic terms would be acceptable for including in the list of ingredients for a food, rather the more specific species name for the ingredient which is actually present should be required.	**Canada**
4.2.1.4 The following foods and ingredients are known to ~~cause~~ trigger ~~hypersensitivity~~ **food allergy or coeliac disease[1].** and shall always be declared[2] **using the name specified**:	**Canada**

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Canada notes that while these foods and ingredients can be the trigger for allergic reactions, the actual cause of food allergy or celiac disease includes genetic and other factors, some of which are still not well understood. Canada suggests replacing the word “cause” with the word “trigger”. Canada notes that the specified names are listed in the singular and questions whether the plural forms would also be permitted under the rule as written, e.g. “peanuts”, “eggs”, “walnuts” etc. Canada would prefer for both singular and plural forms to be permitted.	
4.2.1.4 The Kingdom of Saudi Arabia suggests that the definition of gluten must be updated in CXS 118-1979 as oats was removed on the proposed draft (Appendix II). n addition, since there is no sufficient evidence supporting the declaration of food ingredients listed in section 4.2.1.5, thus, the Kingdom of Saudi Arabia recommends that section 4.1.2.4 to be the main food allergens declared in all food products. Moreover, we suggest referencing the “B Listed” allergens in the FAO/WHO Allergen Expert Panel Report Part 1 in a footnote to Section 4.2.1.4 for national governments’ awareness. Should the Committee decide to keep 4.2.1.5, we would suggest adding a footnote referencing the report of the 1st meeting of the FAO/WHO Allergen Expert Panel Report, which indicates this list of foods and ingredients lacked adequate and sufficient data that elevated them as being ‘known to cause hypersensitivity globally.	**Saudi Arabia**
4.2.1.4 It would be better to align the Specified Names with the Foods and Ingredients. Currently, they are not aligned in the table.	**ICUMSA**
4.2.1.4 Dominican Republic supports paragraph 4.2.1.4	**Dominican Republic**
4.2.1.4 Chile supports the revisions to the text in section 4.2.1.4, as well as to the amended text. On the other hand, Chile supports the addition of footnotes (22 and 23).	**Chile**
4.2.1.4 It would be better to align the Specified Names with the Foods and Ingredients. Currently, they are not aligned in the table.	**ICUMSA**
4.2.1.4 Definition of terms: as the topic of celiac disease is highlighted, it is considered relevant that the concept indicated in the note to the table in point 4.2.1.4 be included in the definitions section.	**Colombia**
4.2.1.4 Paraguay agrees with the proposed amendment to the paragraph, which is our view that it gives greater clarity to the document.	**Paraguay**
Note 1 ***Coeliac disease*** **is a chronic immune-mediated intestinal disease in genetically predisposed individuals induced by exposure to dietary gluten proteins that come from wheat, rye, barley and triticale (a cross between wheat and rye).** To ensure that the definition of coeliac disease is not overlooked, rather than be provided as a footnote, it should be included within the ‘Definition of Terms’ section at the start of the document.	**United Kingdom**
Note 1 ***Coeliac disease*** **is a chronic immune-mediated intestinal disease in genetically predisposed individuals induced by exposure to dietary gluten proteins that come from wheat, rye, barley and triticale (a cross between wheat and rye).** AOECS strongly disagrees with having the definition of coeliac disease incorporated in a footnote. Rather a separate definition in the main body of text within the standard is the most appropriate approach.	**Association Of European Coeliac Societies Codex and Regulatory Affairs**
Note 1 ***Coeliac disease*** **is a chronic ~~immune-mediated intestinal disease~~ autoimmune systemic disorder triggered in genetically predisposed individuals induced by exposure to dietary gluten proteins that come from wheat, rye, barley and triticale (a cross between wheat and rye).**	**European Union**
Note 1 **Celiac disease is a chronic immune-mediated intestinal disease in genetically predisposed individuals induced by exposure to dietary gluten proteins that come from wheat, rye, barley, and triticale (a cross between wheat and rye).** In accordance with the recommendations of the Committee of Experts, Paraguay agrees with the proposal.	**Paraguay**

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~~Cereals containing gluten; i.e., wheat, rye, barley, oats, spelt or their hybridized strains and products of these;~~ The UK believe that oats should be retained on the priority allergen list. The Joint FAO/WHO Expert Committee recognised that "oats are generally contaminated, and often at significant levels, with gluten containing cereals." If oats were taken off the priority allergen list, a consequence could be countries removing requirements for it to be highlighted within ingredients or listed within a 'contains' statement on prepacked food products. This could limit the ability for people with coeliac disease to make an informed choice, resulting in the inadvertent consumption of products that are made with oats contaminated with gluten. It could be considered more appropriate for oats to be labelled with a PAL for gluten, given that any presence of gluten would be due to cross-contamination. However, the current application of PAL is inconsistent and this may prevent the effective provision of information to consumers with coeliac disease. The general nature of the cross-contamination of oats with gluten means that oats should remain on the priority allergen list, until a future point where controls for cross-contamination of oats by other grains are effective at a global level and/or PAL is applied in a more standardised manner, informed by appropriate cross-contact risk analysis. In addition, further consideration should be given to published literature on the potential immunogenicity of avenin.	**United Kingdom**
~~Cereals containing gluten; i.e., wheat, rye, barley, oats, spelt or their hybridized strains and products of these;~~ AOECS highly recommends oats should not be removed from section 4.2.1.4. Removing oats from the priority allergen list also eliminates informed choice for the coeliac consumer, which is especially concerning for those who are biologically sensitive to oats and medically need to avoid them. The proposal to remove oats from the priority allergens list conflicts with the definition of gluten in the Codex Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten 118-1979. At the recent International Celiac Disease Symposium, 2022 an Oats Working Group consisting of coeliac clinicians and oats researchers and coeliac patient representative organisations met to discuss the proposal to exclude oats. The group agreed on several recommendations for people with coeliac disease: 1. Multiple studies have confirmed that commercial oats are commonly and often extensively contaminated with gluten containing cereals such as wheat, rye and barley. Recommendation: Standard commercial brand oats are frequently contaminated with gluten and should be avoided by people with coeliac disease. 2. Clinical studies have confirmed that harm i.e. adverse symptoms and/or small intestinal damage is uncommon for most people with coeliac disease who consume uncontaminated oats Recommendation: Uncontaminated oats can be consumed by people with coeliac disease if they elect to do so and tolerate it. 3. Uncontaminated pure oats protein (avenin) does trigger adverse symptoms and pro-inflammatory immune responses, similar to those seen after gluten-containing cereals such as wheat, in a small proportion of people with coeliac disease. Recommendation: People with coeliac disease should make an informed choice whether to exclude uncontaminated oats from their diet and this needs to be supported by clear food labelling. The implications of these recommendations is that oat consumption in coeliac disease is nuanced and based on two issues: (i) frequent contamination of oats with cereals containing gluten, and (ii) a minority of coeliac patients who experience adverse effects to uncontaminated oats. Therefore, clarity with food labelling is paramount when oats are designated as a priority allergen.	**Association Of European Coeliac Societies Codex and Regulatory Affairs**
4.2.1.5 Chile accepts the new section proposed in 4.2.1.5, as long as a footnote is added referring to the report of the FAO/WHO Expert Panel on Allergens (2022) "Risk assessment of food allergens".	**Chile**

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Specifically, Part 1: Review and validation of the list of priority allergens of the Codex Alimentarius through risk assessment" in its section 8. Conclusions and Recommendations, which indicates: "The Expert Committee also evaluated mustard, soy, lupine, Brazil nut, kiwi, pine nuts, molluscs, coconut, chestnuts, celery, macadamia and buckwheat, but decided not to include them as part of the global priority list for the reasons outlined in this report." It can be seen in detail in its Annex A 3.2 "PLANT FOOD ALLERGENS", about this conclusion that appears at the beginning of the review of each of the foods and ingredients listed, in the sense that they lack adequate and sufficient data to raise them, for causing hypersensitivity worldwide. In addition, Chile's opinion is that it should be considered that each listed food or ingredient should be analyzed one by one, that is, for each allergen and not through a a transversal recommendation.	
4.2.1.5 Section 4.2.1.5, Table on "FOODS AND INGREDIENTS" Specific tree nuts: modify to "macadamia or Queensland nuts". "Queensland nuts" share the same scientific name as macadamia nuts. For completeness, the EU proposes to include Queensland nuts in the list of tree nuts, alongside macadamia. The EU suggests adding a new line: "Molluscs and products thereof". From the WHO report on risk assessment: "The Expert Committee also assessed mustard, soybean, lupin, Brazil nut, kiwi, pine nuts, molluscan shellfish, coconut, chestnuts, celery, macadamia and buckwheat, but decided not to include them as part of the global priority list for reasons provided in this report. However, the Expert Committee also reached a consensus that some of the allergens, such as mustard, lupin, soybean, tree nuts (Brazil nut, macadamia, pine nuts), oats, celery and buckwheat may need be considered at regional levels. The risk managers could base their decision to include other food allergens on their regional priority lists on the scientific evidence, depending on their specific situation." On this basis, The EU would like to see "Molluscs and products thereof" be included in the national or regional allergen list. According to the 'EFSA opinion on the evaluation of allergenic foods and food ingredients for labelling purposes', molluscs can cause severe and occasionally life-threatening food-allergic reactions.	**European Union**
4.2.1.5 Australia supports the inclusion of a regional list of allergens at section 4.2.1.5 which allows national and regional authorities to require declaration of the listed foods and ingredients subject to an assessment of risk for their respective population using the criteria established by the Expert Committee	**Australia**
4.2.1.5 Comment: As expressed in our previous comments, we do not support the inclusion of new section 4.2.1.5, as adding it is likely to result in inconsistencies in labelling approaches in global trade resulting from different interpretations at the national/regional level. There is a distinct difference from 4.2.1.4 as allergens listed in 4.2.1.5 are not equal in evidence and prevalence to the updated list of Global Allergens provided in section 4.1.2.4. We would recommend deleting section 4.2.1.5. from the GSLPF text. Instead, we suggest referencing the "B Listed" allergens in the FAO/WHO Allergen Expert Panel Report Part 1 in a footnote to Section 4.2.1.4 for national governments' awareness. The removal of this section 4.2.1.5 would have consequential impact and require its removal within sections 4.2.1.3, 4.2.1.7, 4.2.2, 4.2.3, 6, 8.3.1, 8.3.2, 8.8.3 and 8.3.4. Should the Committee decide to keep 4.2.1.5, we would suggest adding a footnote referencing the report of the 1st meeting of the FAO/WHO Allergen Expert Panel Report, which indicates this list of foods and ingredients lacked adequate and sufficient data that elevate them as being 'known to cause hypersensitivity' globally.	**ICGMA**
4.2.1.5 FoodDrinkEurope does not agree with including section 4.2.1.5 for the following reasons: - It may result in inconsistencies in labelling approaches in global trade;- There may be several interpretations of section 4.2.1.5 at a national level, which could cause confusion among consumers;- We do not believe that national level regulations are within the scope of this global activity of Codex Alimentarius;- Furthermore, listing national level allergens within the	**FoodDrinkEurope**

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Codex text would defeat the purpose of such national level actions, by reducing the ability to respond rapidly to local emerging food safety issues. FoodDrinkEurope recommends that section 4.2.1.5 be either deleted or added as a footnote with a reference to the FAO/WHO Allergen expert panel report for national governments to refer to, rather than the Codex GSLPF text. If the section is retained, FoodDrinkEurope would seek greater clarity on the species of Lupin and Mustard. Therefore, we suggest deleting the reference to section 4.2.1.5 from sections 4.2.2, 4.2.3/4.2.3.1, 4.2.4.2, 8.3.1, 8.3.2/8.3.2.1, 8.3.3, 8.3.4.	
4.2.1.5 New Zealand does not consider there is a need to list the foods and ingredients that could be considered for declaration at a regional or national level. New Zealand supports national or regional authorities having the ability to require the declaration of other foods and ingredients not listed in 4.2.1.4. but we do not see the need to list these. Indeed, we consider creating a list could cause issues around whether the list is exhaustive or not. We agree that it is imperative that the requirement to declare any food or ingredient is always based on a risk assessment of that food or ingredient based on the criteria used by the expert group to determine the list at 4,2,1,4. New Zealand agrees that such a risk assessment must show that despite there being insufficient data to satisfy the criteria to be on the global list at 4.2.1.4, the food or ingredient meets these criteria in the national or regional setting. New Zealand therefore suggests removing the words 'any of the following' and replacing with the word 'other' and removing 'using the name specified'. We also recommend removing the table to this clause (the list itself). 4.2.1.5 would then read: In addition to the foods and ingredients listed in section 4.2.1.4, national or regional authorities may also require the declaration other foods and ingredients, based on an assessment of risk of food allergy or coeliac disease in their respective population(s). New Zealand considers that the resulting text at clause 4.2.1.5 in combination with the footnote still makes it clear what the risk assessment must be based on to require the declaration of any food or ingredient on the list. This may result in the need for consequential changes in other areas of the proposed text.	**New Zealand**
4.2.1.5 As with the comment above on “sesame” in 4.2.1.4, Canada questions whether the inclusion of “soy” and “mustard” in Section 4.2.1.5 as ingredients that national or regional authorities may also require the declaration of “using the name specified” would permit the use of other terms like “soybean” or “soybeans” or “mustard seed” or “mustard seeds”.	**Canada**
4.2.1.5 Canada supports the inclusion of section 4.2.1.5 with allergens that may be further recognized by national or regional authorities. Canada suggests including some text to clarify that this list is not exhaustive or definitive and to allow for the possibility that other ‘emerging’ allergens may be identified.	**Canada**
4.2.1.5 It would be better to align the Specified Names with the Foods and Ingredients. Currently, they are not aligned in the table.	**ICUMSA**
4.2.1.5 We support including the list of allergenic foods of regional or national importance in section 4.2.1.5 but recommend the list also indicate the region or nations where these allergenic foods are important based on the scientific advice. This list provides a common framework internationally and will help ensure trade regulations are not overly burdensome. The United States does not support listing oats as a part of allergenic foods of regional or national importance as oats are not a gluten-containing grain and therefore are not directly an allergenic food. Cross contact of oats with gluten containing grains should be addressed as a part of the Guideline on Precautionary Allergen Labelling (PAL). The United States supports exemptions being addressed on a case-by-case basis using the framework outlined in the 4th report of the WHO/FAO expert advice. We suggest Codex (CCFL) discuss if a global list of exempted foods with specifications might be helpful for reducing trade barriers and fostering international consistency.	**USA**

SPECIFIC COMMENTS	MEMBER / OBSERVER
4.2.1.5 It would be better to align the Specified Names with the Foods and Ingredients. Currently, they are not aligned in the table.	**ICUMSA**
~~In addition to the foods and ingredients listed in section 4.2.1.4, national or regional authorities may also require the declaration of any of the following foods and ingredients using the name specified, based on an assessment of risk of food allergy or coeliac disease in~~ In addition to the foods and ingredients listed in section 4.2.1.4, national or regional authorities may also require the declaration of any of the following foods and ingredients using the specified name, based on a risk assessment of food allergy or celiac disease in ~~their respective population(s)~~ their respective population(s) [3][3]: We are concerned about the inclusion of the new section 4.2.1.5 as it may lead to inconsistencies in labelling approaches in world trade due to a poor understanding of what this national/regional list represents. There is a clear difference with 4.2.1.4, as the allergens listed in 4.2.1.5 are not equal in evidence and prevalence to the new global allergens provided in section 4.1.2.4. It is recommended to delete section 4.2.1.5. from the GSLPF text and refer instead to "List B" allergens in Part 1 of the FAO/WHO Allergen Expert Panel Report as a footnote to Section 4.2.1.4. for information of national governments.	**Alianza Latinoamericana de Asociaciones de la Industria de Alimentos y Bebidas (ALAIAB)**
In addition to the foods and ingredients listed in section 4.2.1.4, national or regional authorities may also require the declaration of ~~any of the following foods and ingredients using the name specified, based on~~ additional allergens subject to an assessment of ~~risk~~ the risks of ~~food allergy or coeliac disease~~ allergenicity in their respective population(s)[3]: ICGA is seeking clarification why such a variability compared to international standard list is warranted here. The dual mandate of Codex is to ensure harmonization of rules and convergence of national legislations, regulations and standards towards one reference point. As currently drafted, this new section 4.2.1.5 may result in wide inconsistencies in labelling approaches which inevitably will result with SPS-related technical barrier to trade and render CXS 1 fairly incompatible with WTO SPS and TBT Agreement whereas Codex standards to the contrary are deemed to be consistent with the objectives set in those agreements. ICGA shares the same concerns than other global trade operators why this section would list specific allergens that are determined based on regional specificity. Rather, ICGA proposes the section to read rather as follows: “In addition to the foods and ingredients listed in section 4.2.1.4 of this standard, national or regional authorities may also require the declaration of additional allergens subject to an assessment of risk of allergenicity in their respective populations.” Throughout the document ICGA has maintained the references to this new section 4.2.1.5 with the understanding that it refers to the amended provision above. Should CCFL47 meeting does not accept to amend the section along these lines, ICGA would recommend removing any reference to 4.2.1.5 throughout the draft and delete section 4.2.1.5 in its entirety. Should the CCFL47 meeting decide to keep section 4.2.1.5 as currently proposed, we would respectfully suggest that the currently proposed footnote 3 referencing to the report of the 1st meeting of the FAO/WHO Allergen Expert Panel Report, be added to that section, rather than to the proposed new section 4.2.1.7. As such the list of additional allergens proposed in the text should be deleted (which technically was not possible to do on OCS system)...	**ICGA**
In addition to the foods and ingredients listed in section 4.2.1.4, national or regional authorities may also require the declaration of any of the following foods and ingredients using the name specified, based on an assessment of risk of food allergy or coeliac disease in their respective population(s)[3]: FIVS is concerned that the inclusion of a seperate list of regional allergens might lead to inconsistent labelling practices in international trade.	**FIVS**
~~In addition to the foods and ingredients listed in section 4.2.1.4, national or regional authorities may also require the declaration of any of the following foods and ingredients using the name specified, based on an assessment of risk of food allergy or coeliac disease in their respective population(s)[3]:~~ Suggested new language for the section: 4.2.1.5 In addition to the foods and ingredients listed in section 4.2.1.4, national or regional authorities may also require the declaration of	**International Confectionery Association**

SPECIFIC COMMENTS	MEMBER / OBSERVER
additional allergens subject to an assessment of risk of allergenicity in their respective populations.STRIKE THROUGH INCLUDES LIST OF FOOD/INGREDIENTS BELOW. OCS would not permit edits. ICA proposes the removal of the current section 4.2.1.5 above to facilitate the harmonization of allergen labelling. As currently proposed section 4.2.1.5 may result in inconsistencies in labelling approaches in global trade. ICA questions why this section would list specific allergens that are determined based on regional specificity. Rather, ICA proposes that the section is replaced with the following "In addition to the foods and ingredients listed in section 4.2.1.4, national or regional authorities may also require the declaration of additional allergens subject to an assessment of risk of allergenicity in their respective populations." Throughout the document ICA has maintained the references to 4.2.1.5 with the understanding that it refers to the amended provision above. If the committee does not accept the amended provision, ICA recommends removing references to 4.2.1.5 throughout the draft. Should the Committee decide to keep 4.2.1.5 as currently drafted, we would suggest adding a footnote referencing the report of the 1st meeting of the FAO/WHO Allergen Expert Panel Report, which indicates this list of foods and ingredients lacked adequate and sufficient data that elevated them as being 'known to cause hypersensitivity' globally.	
~~**In addition to the foods and ingredients listed in section 4.2.1.4, national or regional authorities may also require the declaration of any of the following foods and ingredients using the name specified, based on an assessment of risk of food allergy or coeliac disease in their respective population(s)[3]:**~~ IDF does not support the inclusion of section 4.2.1.5. because it can create inconsistencies in labelling approaches in global trade. We question the need to have a second tier list of allergens given that national or regional authorities are always able to regulate for local conditions even without such a section. This second list of allergens in Codex could lead to confusion and differences of interpretation as to the status of these allergens.	**IDF/FIL**
In addition to the foods and ingredients listed in section 4.2.1.4, national or regional authorities may also require the declaration of any of the following foods and ingredients using the name specified, based on an assessment of risk of food allergy or coeliac disease in their respective population(s)[3]: We do not agree with provisions of Oats based on the potential for contamination. Because it is stipulated that the business operators must take measures to prevent contamination in the Code of Practice on Food Allergen Management for Food Business Operators (CXC80-2020). We are concerned that it will be misunderstood as a subject of mandatory labelling by stipulating in the same format as 4.2.1.4, and that consideration will begin that does not take into account the dietary habits of each country.Therefore, we suggest it is sufficient to delete 4.2.1.5 and record in the report of the FAO/WHO Expert Committee that although it is a causative food of food allergies, it is not mandatory labelling due to regional characteristics.	**Japan**
In addition to the foods and ingredients listed in section 4.2.1.4, national or regional authorities may also require the declaration of any of the following foods and ingredients using the name specified, based on an assessment of risk of food allergy or coeliac disease in their respective population(s)[3]: Australia supports the inclusion of oats in the regional list at section 4.2.1.5. Consensus was reached by the FAO/WHO Expert Committee to not include oats as a global priority allergen, but that oats may be kept on a list of allergens for regional consideration. Australian recommendations for individuals with coeliac disease are that oats not be included as part of a gluten free diet. This is due to contamination with other gluten containing cereals as well as there being some evidence that oats can produce adverse immune reactions in some individuals with coeliac disease.	**Australia**

SPECIFIC COMMENTS	MEMBER / OBSERVER
In addition to the foods and ingredients listed in section 4.2.1.4, national or regional authorities may also require the declaration of any of the following foods and ingredients using the name specified, based on an assessment of risk of food allergy or coeliac disease in their respective population(s)[3]: We do not agree with this new section. The updated global list of allergens is considered sufficient. This new section may also lead to labelling inconsistencies. It could however be added as a footnote for awareness.	**IFU**
In addition to the foods and ingredients listed in section 4.2.1.4, national or regional authorities may also require the declaration of any of the following foods and ingredients using the name specified, based on an assessment of risk of food allergy or coeliac disease in their respective population(s)[3]: In principle, Thailand does not object to the national or regional list in section 4.2.1.5. However, relevant information concerning the risk from the contamination of oats with other cereals containing gluten should be included in CXS 1-1985 for clarity. The additional text may be mentioned as a footnote in " Oats and other Avena species (and their hybridized strains) and products thereof".	**Thailand**
In addition to the foods and ingredients listed in section 4.2.1.4, national or regional authorities may also require the declaration of any of the following foods and ingredients using the name specified, based on an assessment of risk of food allergy or coeliac disease in their respective population(s)[3]: FIA does not support the inclusion of the new section 4.2.1.5 as the addition is likely to result in inconsistencies in labelling approaches in global trade due to different interpretations at national and/or regional level. There is a distinct difference from 4.2.1.4, because allergens listed in 4.2.1.5 are not equal in evidence and prevalence to the updated priority list of allergen provided in section 4.1.2.4. We would recommend deleting section 4.2.1.5. from the GSLPF text. Instead, we suggest referencing the "B Listed" allergens in the FAO/WHO Allergen Expert Panel Report Part 1 in a footnote to Section 4.2.1.4 for national governments' awareness. The removal of this section 4.2.1.5 would have consequential impact and require its removal within sections 4.2.1.3, 4.2.1.7, 4.2.2, 4.2.3, 6, 8.3.1, 8.3.2, 8.8.3 and 8.3.4. However, should the Committee decide to keep 4.2.1.5, we would suggest adding a footnote referencing the report of the 1st meeting of the FAO/WHO Allergen Expert Panel Report, which indicates this list of foods and ingredients lacked adequate and sufficient data that elevated them as being 'known to cause hypersensitivity globally'.	**Food Industry Asia**
In addition to the foods and ingredients listed in section 4.2.1.4, national or regional authorities may also require the declaration of any of the following foods and ingredients using the name specified, based on an assessment of risk of food allergy or coeliac disease in their respective population(s)[3]: ISDI does not support the inclusion of new section 4.2.1.5, as adding it is likely to result in inconsistencies in labelling approaches in global trade resulting from different interpretations at the national/regional level. We do not believe that national level regulation is within the scope of this global activity of Codex Alimentarius. Furthermore, listing national level allergens within Codex text would defeat the purpose of such national level actions, by reducing the ability to respond rapidly to local emerging food safety issues. There is also a distinct difference in the allergens listed in the new 4.2.1.5 compared to those in 4.2.1.4, because allergens listed in 4.2.1.5 are not equal in evidence and prevalence to the updated list of Global Allergens provided in section 4.2.1.4. ISDI would recommend deleting section 4.2.1.5 from the GSLPF text. ISDI suggests referencing the "B Listed" allergens in the FAO/WHO Allergen Expert Panel Report Part 1 in a footnote to Section 4.2.1.4 for national governments' awareness. The removal of this section 4.2.1.5 would have consequential impact and require its removal within sections 4.2.1.3, 4.2.1.7, 4.2.2, 4.2.3, 6, 8.3.1, 8.3.2, 8.8.3 and 8.3.4.	**International Special Dietary Food Industries**

SPECIFIC COMMENTS	MEMBER / OBSERVER
In addition to the foods and ingredients listed in section 4.2.1.4, national or regional authorities may also require the declaration of any of the following foods and ingredients using the name specified, based on an assessment of risk of food allergy or coeliac disease in their respective population(s)[3]: Indonesia proposes to include sesame in section 4.2.1.5 considering the low prevalence of sesame allergy.	**Indonesia**
In addition to the foods and ingredients listed in section 4.2.1.4, national or regional authorities may also require the declaration of any of the following foods and ingredients using the name specified, based on an assessment of risk of food allergy or coeliac disease in their respective population(s)[3]: The Kingdom of Saudi Arabia recommends developing an information source on conducting a Quantitative Risk Assessment (QRA) to assist national governments and food business operators in the best practices for conducting a QRA. This would ensure a consistent, robust approach is applied globally.	**Saudi Arabia**
In addition to the foods and ingredients listed in section 4.2.1.4, national or regional authorities may also require the declaration of any of the following foods and ingredients using the name specified, based on an assessment of risk of food allergy or coeliac disease in their respective population(s)[3]: This footnote appears to be a combination of the current and former format. It should be [3] as a superscript.	**ICUMSA**
4.2.1.5 It would be better to align the Specified Names with the Foods and Ingredients. Currently, they are not aligned in the table.	**ICUMSA**
Note 3 South Africa is of the opinion that, in relation to clause 4.2.1.5. of Part 1 report "Review and validation of Codex Alimentarius priority allergen list through risk assessment" (Pages 15 – 20) address criteria for derivatives and do not refer to criteria for selecting priority allergens. Thus, it will be more appropriate to reference the page numbers that describe the criteria for selecting priority allergens in the footnote (P 9-13).	**South Africa**
Note 3 The assessment of risk to be based on the evidence criteria of prevalence, potency and severity of immune mediated adverse reactions to the food or ingredient in the respective population(s). FAO and WHO (2022). (4) Risk assessment of food allergens: Part 1: Review and validation of Codex Alimentarius priority allergen list through risk assessment. p15-20. .	**Thailand**
Note 3 Paraguay agrees	**Paraguay**
In addition to the foods and ingredients listed in section 4.2.1.4, national or regional authorities may also require the declaration of any of the following foods and ingredients using the name specified, based on an assessment of risk of food allergy or coeliac disease in their respective population(s)[3]: The Dominican Republic suggests adding a note indicating that member countries may contact the Allergen Expert Panel to support authorities in developing national or regional regulations based on scientific data.	**Dominican Republic**
In addition to the foods and ingredients listed in section 4.2.1.4, national or regional authorities may ~~also~~ request ~~require~~ the declaration of any of the following foods and ingredients using the name specified, based on an assessment of risk of food allergy or coeliac disease in their respective population(s)[3]: Costa Rica believes that the inclusion of this section may lead to inconsistencies in world trade, particularly as the lack of data on the prevalence, potency and severity of some allergens makes it difficult for countries to develop their own risk assessments. Therefore, Costa Rica suggests that Codex defines a periodic review of the list of allergens for future updates instead of including this section. If this list is maintained, it should be specified by a footnote or other means that oats may contain gluten due to cross-contact. Additionally, it suggests a modification of the form.	**Costa Rica**
In addition to the foods and ingredients listed in section 4.2.1.4, national or regional authorities may also require the declaration of any of the following foods and ingredients using the name specified, based on an assessment of risk of food allergy or coeliac disease in their respective population(s)[3]:	**Argentina**

SPECIFIC COMMENTS	MEMBER / OBSERVER
The following modifications are proposed in the text to item 4.2.1.5: -Replace the expression "In addition to" with "Additionally". -Replace the phrase " **the declaration of any of the following foods and ingredients using the specified name, based on a risk assessment of food allergy or celiac disease in their respective population(s)[3]**:." with "the following foods and ingredients may be optionally declared using their specific name(s)". Proposed text: "4.2.1.5 Additionally to the listed foods and ingredients listed in Section 4.2.1.4, the following foods and ingredients may be optionally declared using their specific name(s):" Rationale: Given that Codex is an international normative reference, it is not considered appropriate to make immediate reference to national and/or regional standards. However, it may be necessary to have a reference list for cases where it is considered appropriate to declare other foods and/or ingredients. It is also considered that there should be no reference to these declarations being directly subject to the definition at the local level, considering that this could accentuate the differences in criteria between countries and lead to a potential disharmonisation with reference to these declarations. However, considering that the presence of allergens implies health issues -associated with local realities- having the "B List" of allergens referenced in the Report of the FAO/WHO Expert Panel on Allergens would allow some of the listed allergens to be incorporated. In addition, while this list is not exhaustive, it could be updated in the light of FAO/WHO studies.	
In addition to the foods and ingredients listed in section 4.2.1.4, national or regional authorities may also require the declaration of any of the following foods and ingredients using the name specified, based on an assessment of risk of food allergy or coeliac disease in their respective population(s)[3]: The committee suggests revising the wording of subchapter 4.2.1.5 in such a way as to specify the information to be included in this section, considering that many countries do not have the resources to carry out specific risk assessments in the population.	**Peru**
In addition to the foods and ingredients listed in section 4.2.1.4, national or regional authorities may also require the declaration of any of the following foods and ingredients using the name specified, based on an assessment of risk of food allergy or coeliac disease in their respective population(s)[3]: Chile accepts the proposed new section in 4.2.1.5, provided that a footnote is added referring to the report of the FAO/WHO Expert Panel on Allergens (2022) "Risk assessment of food allergens". Specifically, Part 1: Review and validation of the Codex Alimentarius list of priority allergens through risk assessment" in its section 8, Conclusions and Recommendations, which states: "The Expert Committee also evaluated mustard, soybeans, lupine, Brazil nut, kiwi, pine nuts, molluscs, coconut, chestnuts, celery, macadamia and buckwheat, but decided not to include them as part of the list of global priorities for the reasons set out in this report." This conclusion, which appears at the beginning of the review of each of the foods and ingredients listed, in the sense that they lack adequate and sufficient data to include them as causing hypersensitivity worldwide, can be examined in detail in its Annex A3.2 "PLANT FOOD ALLERGENS". In addition, Chile is of the opinion that consideration should be given to analyze, one by one, each food or ingredient listed, for each allergen and not through a cross-cutting recommendation.	**Chile**
In addition to the foods and ingredients listed in section 4.2.1.4, national or regional authorities may also require the declaration of any of the following foods and ingredients using the name specified, based on an assessment of risk of food allergy or coeliac disease in their respective population(s)[3]: Paraguay understands that the proposal to divide the list of Allergens could generate some inconveniences in its application if there are no regional studies that support such a change. However, considering the recommendation of the Panel of experts, on allergen risk assessment, we could agree with the proposal.	**Paraguay**
Delete the above table, if section 4.2.1.5 is not amended as previously suggested (option to delete that table was technically impossible under the OCS system)	**ICGA**

SPECIFIC COMMENTS	MEMBER / OBSERVER
We do not support the inclusion of new section 4.2.1.5, as adding it is likely to result in inconsistencies in labelling approaches in global trade resulting due to different interpretations at the national/regional level. There is a distinct difference from 4.2.1.4 as allergens listed in 4.2.1.5 are not equal in evidence and prevalence to the updated list of Global Allergens provided in section 4.1.2.4. ICBA would recommend deleting section 4.2.1.5. from the GSLPF text. Instead, we suggest referencing the "B Listed" allergens in the FAO/WHO Allergen Expert Panel Report Part 1 in a footnote to Section 4.2.1.4 for national governments' awareness. The removal of this section 4.2.1.5 would have consequential impact and require its removal within sections 4.2.1.3, 4.2.1.7, 4.2.2, 4.2.3, 6, 8.3.1, 8.3.2, 8.8.3 and 8.3.4. Should the Committee decide to keep 4.2.1.5, we would suggest adding a footnote referencing the report of the 1st meeting of the FAO/WHO Allergen Expert Panel Report, which indicates this list of foods and ingredients lacked adequate and sufficient data that elevated them as being 'known to cause hypersensitivity globally.	**ICBA**
4.2.1.6 FIVS welcomes the retention of sulphites in the text. FIVS believes a new risk assessment should be conducted on sulphites by the Expert Committee (or other relevant scientific body) before supporting its removal from this section.	**FIVS**
4.2.1.6 When ~~added sulphite~~ the Total sulfite (from all sources) is present in a ~~food, and the total concentration exceeds~~ prepared food at concentrations of 10 ~~mg/kg~~mg/kg or more, it ~~shall~~ should always be declared using the ~~specified~~ specific name ~~'sulphite'~~"sulfite". Chile considers that Section 4.2.1.6 can be improved by adding the text "as prepared" or "from all sources", and deleting "added" since the body will not differentiate the source. On the other hand, it is suggested to cite the GENERAL STANDARD FOR FOOD ADDITIVES CODEX STAN 192-1995, where it specifies in point I. FOOD ADDITIVES, BASIC PRINCIPLES TO CALCULATE DOSES FOR USE Guideline 1, that the calculation of additives must be carried out in the ready-to-eat product.	**Chile**
4.2.1.6 When added sulphite or sulphur dioxide is present in a food, and the total concentration exceeds 10 mg/kg, ~~it~~ they shall always be declared using the specified name ~~'sulphite'~~'sulphite' or 'sulphur dioxide'. The EU would like to seek clarification as to why sulphur dioxide has not been included in provision 4.2.1.6. The EU suggests that sulphur dioxide is included in this provision and proposes the following wording.	**European Union**
4.2.1.6 There are described that'This Code does not cover hypersensitivities with a non-immunological aetiology such as lactose intolerance and sulphite sensitivity.' in the Code of Practice on Food Allergen Management for Food Business Operators (CXC80-2020). That is why we suggest health effects of sulphite should be discussed elsewhere rather than in the agenda of allergen labelling in the CCFL. In addition, sulphite used as food additives would be described as food additives, which is why we do not think that there is a need of separate labelling. If the description of sulphite and the exemption of 4.2.1.7 are retained, the numbers of 4.2.1.6 and 4.2.1.7 should be exchanged. Because, 4.2.1.4 and 4.2.1.5 are related to food allergy or celiac disease, and 4.2.1.7 indicates exemptions for these two items. We think it is not appropriate to list sulphites that are not related with food allergies or celiac disease in 4.2.1.6 and the order of paragraphs is not appropriate.	**Japan**
4.2.1.6 Australia understands the inclusion of sulphite in section 4.2.1.4 was originally based on advice from the Joint FAO/WHO Expert Committee on Food Additives (JECFA). Therefore, in the absence of an updated risk assessment on adverse reactions to sulphites, Australia supports retaining the declaration requirement for added sulphite in the GSLPF at this time.	**Australia**
4.2.1.6 When added sulphite is present in a food, and the total concentration from all sources exceeds 10 mg/kg, considering the product ready for consumption, it shall always be declared using the specified name 'sulphite'.	**Brazil**

SPECIFIC COMMENTS	MEMBER / OBSERVER
Brazilian comments: Brazil suggests the inclusion of additional text to clarify that the total concentration of sulphites should consider all sources of this substance, including added and natural sulphites, and should be calculated in the product ready for consumption.	
4.2.1.6 When ~~added~~ total sulphite (from all sources) is present in a ~~food, and the total concentration exceeds~~ food as prepared in concentrations of 10 ~~mg/kg~~mg/kg or more, it shall always be declared using the specified name 'sulphite'. Comment: Section 4.2.1.6 may be improved by adding text "as prepared" and "from all sources" and removing 'added' as the body will not differentiate the source. Suggested text as follows: When total sulphite (from all sources) is present in a food as prepared in concentrations of 10 mg/kg or more, it shall always be declared using the specified name 'sulphite.'	**ICGMA**
4.2.1.6 With regard to section 4.2.1.6 When added sulphite is present in a food, and the total concentration exceeds 10 mg/kg, it shall always be declared using the specified name 'sulphite', clarification is needed as to whether the 10 mg/kg is as consumed or not, as this may cause confusion for products that require dilution before consumption (e.g. dry soups and bouillon powder).	**FoodDrinkEurope**
4.2.1.6 South Africa request clarification for section 4.2.1.6 as to whether the 10 mg/kg is as sold or as consumed as this may cause confusion with products that require preparation (e.g., dry soups and bouillon powder) before consumption.	**South Africa**
4.2.1.6 When added sulphite is present in a ~~food, and the~~ food at a total concentration ~~exceeds~~ of 10 ~~mg/kg~~mg/kg or above, it shall always be declared using the specified name 'sulphite'. Specific comment: Canada supports 4.2.1.6, but notes that as worded the rule would only apply at levels above 10 ppm and not at 10 ppm. Previously "Sulphite in concentrations of 10 mg/kg or more" was in the list of "foods and ingredients known to cause hypersensitivity". Canada suggests a small change in order to include the level of 10 mg/kg in the requirement for labelling.	**Canada**
4.2.1.6 When added sulphite (directly or as carry over) is present in a food, and ~~the~~ in total concentration ~~exceeds~~ of 10 ~~mg/kg~~mg/kg or more, it shall always be declared using the specified name 'sulphite'. Indonesia proposes to modify the sentence in section 4.2.1.6 by adding the statement 'added sulphite (directly or as carry over)' since the presence of sulphite in food is not only directly added but also indirectly or as carry over, as follows: 4.2.1.6 When added sulphite (directly or as carry over) is present in a food, and the in total concentration of exceeds 10 mg/kg or more, it shall always be declared using the specified name 'sulphite'.	**Indonesia**
4.2.1.6 Thailand does not object to moving sulphite from the list in section 4.2.1.4 to a new, separated provision in section 4.2.1.6. However, further clarifications on some issues in the revised text are needed.- Thailand notes that the term "added" has been introduced and it causes confusion. Sulphites can be presented naturally in food, or used as additives, or carried over from raw materials or ingredients. The scope of "added sulphite", therefore should be clarified.- It should also be clarified whether the presence of sulphite at 10 mg/kg is now exempted from the declaration according to this revised text. In the current version of CXS 1-1985, this level of sulphite needs to be declared on the label. It may also be worthwhile to specify the presence of sulphite is set on the final product as consumed, or otherwise.	**Thailand**
4.2.1.7 Subject to evaluation using established criteria[3], ~~national authorities~~ FAO/WHO ad hoc consultations may make recommendations to the Codex Alimentarius Commission and its subsidiary body in charge of labelling (i.e., CCFL) to exempt ingredients derived from foods listed in section 4.2.1.~~4, and where applicable section 4.2.1.5,~~ 4 from being ~~declared~~declared as allergens.	**ICGA**
4.2.1.7 ICGA previously commented in 2021 that it is up to the Codex alimentarius CCFL with the help of FAO/WHO expert consultations as well as countries or groups of countries which have already made such determination to come up with a list of	**ICGA**

SPECIFIC COMMENTS	MEMBER / OBSERVER
exemptions of highly refined food ingredients, food additives or processing aids derived from ingredients listed as allergens, to be subject to exemption from allergen labelling. To leave it to national and/or regional authorities is not fullfilling the dual mandate of Codex alimentarius properly, nor makes CXS 1 "deemed to be consistent" with WTO SPS and TBT Agreement objectives to reduce the burden of non-tariff barriers to international trade. ICGA reiterates its call for CCFL47 to be more ambitious in harmonizing that very important aspect of the revision of CXS1. In particular, ICGA recommends considering as Codex approved exemptions the following substances, subject to a case-by-case review by ad hoc FAO/WHO expert consultations:- (a) wheat-based glucose syrups including dextrose and wheat-based maltodextrins ; and their products thereof, in so far as the process that they have undergone is not likely to increase the level of allergenicity assessed by [based on relevant FAO/WHO scientific advice] for the relevant product from which they originated; (b) glucose syrups based on barley; (c) cereals used for making alcoholic distillates including ethyl alcohol of agricultural origin. - fish gelatine used as carrier for vitamin or carotenoid preparations; (b) fish gelatine or Isinglass used as fining agent in beer and wine; - (a) fully refined soybean oil and fat and their products thereof, in so far as the process that they have undergone is not likely to increase the level of allergenicity assessed by [based on relevant FAO/WHO scientific advice] for the relevant product from which they originated; (b) natural mixed tocopherols (E306), natural D-alpha tocopherol, natural D- alpha tocopherol acetate, and natural D-alpha tocopherol succinate from soybean sources; (c) vegetable oils derived phytosterols and phytosterol esters from soybean sources; and (d) plant stanol ester produced from vegetable oil sterols from soybean sources; - whey used for making alcoholic distillates including ethyl alcohol of agricultural origin; (b) lactitol; - nuts used for making alcoholic distillates including ethyl alcohol of agricultural origin. In that regard, CCFL47 may also wish to add a new footnote (Footnote 4) to cross-referencing the decision-tree proposed by the FAO/WHO Expert Consultation held in January 2023 "Part 4 - Review and establish exemptions for the food allergens" (see https://cdn.who.int/media/docs/default-source/food-safety/jemra/4th-allergen-summary-report-nov2022.pdf?sfvrsn=6603dbb9_3). For the purpose of global harmonization, this section cannot be adopted without at the very much same time include guidelines for countries to determine appropriate exemptions based upon the degree of risk using all available science, technology, and clinical data.	
4.2.1.7 ICA strongly supports the inclusion of a generic provision that allows labelling exemptions for these ingredients on a case-by-case basis based upon the degree of risk using all available science, technology, and clinical data. If the food additive or processing aid has itself been demonstrated not to cause an allergic response based on the removal of the allergenic protein, it should not need to be declared. For the purpose of harmonization, Codex should include guidelines for countries to determine appropriate exemptions based upon the degree of risk using all available science, technology, and clinical data.	**International Confectionery Association**
4.2.1.7 EFA recommends GSLPF to include a list of ingredients exempted from allergen labelling that have already been assessed by national authorities. This applies for example to maltodextrin from wheat or highly refined soybean oil and its derivates. Furthermore, in paragraph 4.2.1.7 reference should be made to Summary Report 4 of the FAO/WHO scientific expert group on the Review and establishment of exemptions for the food allergens (conclusions published in January).	**European Federation of Allergy and Airways Diseases Patients' Associations**
4.2.1.7 Subject to evaluation using established criteria[3], national <u>or regional</u> authorities may exempt ingredients derived from foods listed in section 4.2.1.4, and where applicable section 4.2.1.5, from being declared. The EU agrees with the generic provision for allowing exemptions on a case-by-case basis, however, would like to add "…national or regional authorities may exempt…."	**European Union**

SPECIFIC COMMENTS	MEMBER / OBSERVER
4.2.1.7 We agree with the provision of exemptions. However, regarding the analysis for quantitative evaluation of PAL, the report of the 2nd Expert Meeting states, "The limit of quantification of the analytical method shall be one-third or less of the payload of each food product.". If this PAL threshold is cited as the amount of protein to consider the exemption from labelling, we think that it is not a method that can actually be used by business operators in each country and that it is not a method that will spread to the general public. In addition, although the use of PAL without quantitative assessment is possible, we think that the correlation between the results of risk management measures by business operators and thresholds is ambiguous. Therefore, we think that using the PAL threshold is not practical. Based on this idea, we do not agree with the establishment of the PAL.	**Japan**
4.2.1.7 Australia supports provisions for exempting foods from the declaration requirements in section 4.2.1.4 and 4.2.1.5. The Australia New Zealand Food Standards Code currently provides exemptions (with conditions) for a number of foods that have been assessed as being safe for individuals with allergies. Australia also notes that further advice on exemptions is expected later in 2023, so proposed section 4.2.1.7 may need to be updated once the outcomes of the FAO/WHO Expert consultation Part 4 are fully available.	**Australia**
4.2.1.7 General comment: Canada is generally supportive of the inclusion of Section 4.2.1.7 but would like to be able to study the “established criteria” for exemptions more carefully before providing further input.	**Canada**
4.2.1.7 This footnote doesn't follow the format used for the previous footnotes. It should be [3] as a superscript.	**ICUMSA**
4.2.1.7 We do not object to the provision in section 4.2.1.7 relating to exemptions for certain foods and ingredients from declaration subject to a case-by-case evaluation by national authorities using established criteria. We, nevertheless, propose that “the established criteria” should be included either in the CXS 1-1985 or in the information document of CCFL so member countries can refer to them for their ease of use. We propose to consider the crite-ria further once the full report of the FAO/WHO Expert meeting Part 4: Review and establish exemptions for the food allergens is published.	**Thailand**
4.2.1.7 Footnote numbering may be incorrect.	**Thailand**
4.2.1.7 This footnote doesn't follow the format used for the previous footnotes. It should be [3] as a superscript.	**ICUMSA**
Table - Honduras requests to standardize the terms soja y soya *(preferably the term soya*), since for Spanish-speaking countries, both words are used (*NT this only applies to the spelling of soy in the Spanish version)*	**Honduras**
4.2.1.6 Dominican Republic supports the wording of paragraph 4.2.1.6	**Dominican Republic**
4.2.1.6 4.2.1.6. It is considered necessary to clarify that 10 mg/kg refers to the "ready-to-eat" food/beverage, as this may cause confusion for products that require dilution before consumption (e.g., powders for preparing beverages, dry soups, etc.). For this purpose, we suggest to use the following wording aligned with EU Regulations 1169/2011: "*Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/litre in terms of the total SO 2 which are to be calculated for products as proposed ready for consumption or as reconstituted according to the instructions of the manufacturers* (Item 12. Annex II: Substances or products that cause allergies or intolerances). It is proposed to incorporate the following clarification "10 mg/litre in terms of the total SO 2 which are to be calculated for products as proposed ready for consumption or as reconstituted according to the instructions of the manufacturers". Proposed text: 4.2.1.6. When the added sulphite is present in a food and the total concentration is more than 10 mg/kg or 10 mg/litre in terms of the total SO 2 which are to be calculated for products as proposed ready for consumption or as reconstituted according to the instructions of the manufacturers it shall always be declared using the specified designation of "sulphite".	**Argentina**

SPECIFIC COMMENTS	MEMBER / OBSERVER
4.2.1.6 When the total ~~added~~ sulphite from all sources) is present in a food ~~and the total concentration exceeds 10 mg/kg~~ prepared at concentrations of 10 mg/kg or more~~, the specific name "sulphite"~~ shall always be declared using the specified name of "sulphite". Chile considers that Section 4.2.1.6 can be improved by adding the text "prepared" or "from all sources" and deleting "added" since the body will not differentiate the source. On the other hand, it is suggested to cite the GENERAL STANDARD FOR FOOD ADDITIVES CODEX STAN 192-1995, where it specifies in point I. FOOD ADDITIVES, BASIC PRINCIPLES FOR CALCULATING THE DOSES OF USE Guideline 1, that the calculation of additives should be carried out in the product ready for consumption.	**Chile**
4.2.1.6 It should read: Where the added sulphite is present in a food ready for use and the total concentration exceeds 10 mg/kg, it shall always be declared using the specified designation of "sulphite". Another comment: Point 4.2.1.6 is supported for sulphites, but an additional note should be included "to calculate as total SO2 (ready-to-eat products and those that are reconstituted according to the preparation instructions on the label)" as in EU Regulation 1169/2011. https://www.boe.es/doue/2011/304/L00018-00063.pdf	**Peru**
4.2.1.6 Where the added sulphite is present in a food and the total concentration in the finished product exceeds 10 mg/kg, it shall always be declared using the specified designation of "sulphite".[For the calculation of the total concentration in the finished product, account shall be taken of the sulphite present in the food plus that added in the process]	**Colombia**
4.2.1.6 Paraguay agrees with the proposal. We also believe it is necessary to add the definition of intolerance that is also found in the recommendations of the Committee of Experts, as this would give greater clarity to the entire document.	**Paraguay**
4.2.2 EFA considers that this is a provision requiring further clarifications and guidance on how to deal with ingredients obtained through biotechnology. If there is e.g. a novel food created through biotechnology, we need to make sure that a safety assessment is performed, leading to separate statement on potential allergic risks e.g. rapeseed protein. Other cases include insects or non-animal milk proteins, known for their cross-reactivity. Indeed, it appears that insects have not been evaluated in this context, which treat only priority allergens. EFA encourages adding a separate paragraph on new allergens derived from novel food like insects. Such a paragraph should establish the use of an additional 'allergy warning statement' related to the products derived from biotechnology; or even define criteria for inclusion in the list of priority allergens, when allergen cross-reactivity has been demonstrated. From a procedural perspective, it is also important that these ingredients go through a safety assessment, including an allergenicity assessment.	**European Federation of Allergy and Airways Diseases Patients' Associations**
4.2.2 The presence in any food or food ingredients obtained through biotechnology of an allergen transferred from any of the ~~products~~ **foods and ingredients** listed in section**s** 4.2.1.~~4~~ 4, 4.2.1.6 **and where applicable 4.2.1.5** shall be declared. When it is not possible to provide adequate information on the presence of an allergen through labelling, the food containing the allergen should not be marketed. The EU notes that a reference to section 4.2.1.6 is missing from this paragraph. The EU wonders if this has been intentional (and why) or due to an omission.	**European Union**
4.2.2 Although there is a description of "allergen", it is indicated as "food allergy or coeliac disease" in 4.2.1.4 and 4.2.1.5. "Allergen " is also used in the GSLPF, but it is necessary to use this term appropriately.	**Japan**
4.2.2 Section 4.2.2 refers to Novel Foods (ingredients obtained through biotechnology). FoodDrinkEurope asks to make reference to the safety approval of Novel Foods, including an allergenicity assessment. From this assessment, additional allergen labelling requirements may be needed. This was also the case for insects or rape seed proteins in Europe and canary	**FoodDrinkEurope**

SPECIFIC COMMENTS	MEMBER / OBSERVER
seed in Canada. This type of allergen labelling is not covered by the Standard (it is not a PAL and also no ingredient). This additional allergen warning statement needs it is own definition and labelling requirements. Development of non-animal milk proteins by bacteria is an example. Non-animal milk proteins are already used in the US. The listing of milk on the products is not always clear because specific requirements are not defined in the FDA Gras-approval (only refers to “proper labeling”) https://www.fda.gov/media/136754/download)	
4.2.2 New Zealand requests clarification on the intended meaning of ‘allergen’ in 4.2.2. We note the term ‘allergen’ is not defined in the GSLPF but is proposed to be defined in the Guidelines on the Use of Precautionary Allergen labelling. We suggest it may be useful either to remove reference to allergens in this clause (in line with the rest of the GSLPF text) or for ‘allergen’ to be added to the definitions in the GSLPF.	**New Zealand**
4.2.1.7 The Dominican Republic supports amending paragraph 4.2.1.7 to read: "Based on an assessment using established criteria, national authorities may exempt ingredients derived from foods listed in section 4.2.1.4 and, if relevant, in section 4.2.1.5."	**Dominican Republic**
4.2.1.7 Costa Rica considers that the exemptions from the declaration of foods and ingredients listed in section 4.2.1.4 should be listed in this section taking into account the criteria and recommendations of the Committee of Experts or available in a public database managed by the Committee of Experts. The above, in order to favor harmonization, since leaving the evaluation to national authorities in this case could result in technical barriers to trade.	**Costa Rica**
4.2.1.7 This footnote doesn't follow the format used for the previous footnotes. It should be [3] as a superscript.	**ICUMSA**
4.2.1.7 Subject to evaluation <u>of risk</u> using established criteria[3], national authorities may exempt ingredients derived from foods listed in section 4.2.1.4, and where applicable section 4.2.1.5, from being declared.	**Colombia**
4.2.1.7 Paraguay agrees with this addition as the derivatives of the food listed in sections 4.2.1.4 and 4.2.1.5 respectively will be studied on a case-by-case basis.	**Paraguay**
4.2.3 EFA suggests to change this sentence as follows: 'Except for those foods and ingredients listed in sections 4.2.1.4, 4.2.1.6 and where applicable 4.2.1.5 and section 4.2.2'. Additional allergen labelling could be needed for ingredients obtained through biotechnology. This addition must adapt throughout the text of the document.	**European Federation of Allergy and Airways Diseases Patients’ Associations**
4.2.3.1 AOECS would like further clarification on how the “specified name” for cereals containing gluten will be used. For example, if an ingredient such as Spelt, Einkorn, Emmer, Khorasan Wheat are used as an ingredient, it would not be suitable to only label it simply as ‘wheat’.	**Association Of European Coeliac Societies Codex and Regulatory Affairs**
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 sections 4.2.1.4, 4.2.1.6 and where applicable 4.2.1.5 shall be declared <u>by</u> using the specified names listed in those sections.**	**European Union**
4.2.3.1 New Zealand agrees with the intent of this clause however suggests clarifying the wording. We propose the following clarified wording: 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 the following class names may be used unless a general class name would be more informative, (table then included) 4.2.3.2. In all cases, the food and ingredients listed in sections 4.2.1.4, 4.2.1.6 and where applicable 4.2.1.5 shall be declared using the specified names listed in those sections. (Note 4.2.3.2, 4.2.3.3and 4.2.3.4 would consequently need to be renumbered)	**New Zealand**
4.2.2 Paraguay agrees to this incorporation.	**Paraguay**

SPECIFIC COMMENTS	MEMBER / OBSERVER
4.2.3Except for foods and ingredients listed in Sections 4.2.1.4, 4.2.1.6 and, where applicable, 4.2.1.5 , a specific name shall be used for ingredients in the list of ingredients in accordance with the provisions set out in Section 4.1 (Name of food), ~~except:~~. Editorial modification, to avoid repetition.	**Costa Rica**
4.2.3 The exception referred to at the end of section 4.2.3 "except:" is not clear as section 4.2.3.1 refers to the use of general class names that are more informative, however, it excludes foods and ingredients listed in points 4.2.1.4, 4.2.1.6 and, when relevant, 4.2.1.5	**Colombia**
4.2.3 Paraguay agrees to the proposed changes.	**Paraguay**
4.2.4.2 A food additive carried over into foods at a level less than that required to achieve a technological function, and processing aids, are exempted from declaration in the list of ingredients. The exemption does not apply to food additives and processing aids **that contain the foods and ingredients** listed in section**s** 4.2.1.4, **4.2.1.6 and where applicable 4.2.1.5~~5~~ unless exempted through provisions specified in section 4.2.1.7**. The provision should reflect situations where national authorities have exempted ingredients based on absence of allergenic protein. Therefore, we have included the recommended language in red above.	**ICGA**
4.2.4.2 FIVS supports the exemption from declaring foods and ingredients listed in section 4.2.1.4 and 4.2.1.6 when they are not present in the final product (or are below potential threshold levels) and where these ingredients/foods may have been processed to remove the allergenic component. FIVS would like to point that in the case of wine, there is both scientific and empirical data that demonstrates that when best fining practices for winemaking, together with the validation procedures, are respected, residual levels of egg, fish, milk proteins used as fining agents in winemaking are removed from the final wine product (FIVS Good Fining Practices - Guidelines for the fining of wine using proteinaceous agents with allergenic potential).	**FIVS**
4.2.4.2 A food additive carried over into foods at a level less than that required to achieve a technological function, and processing aids, are exempted from declaration in the list of ingredients. The exemption does not apply to food additives and processing aids **that contain the foods and ingredients** listed in section**s** 4.2.1.4, **4.2.1.6 and where applicable 4.2.1.5~~5~~ unless exempt through national authorities as specified in section 4.2.1.7**. The provision should reflect situations where national authorities have exempted ingredients based on absence of allergenic protein. Therefore, we have included the recommended language in red above.	**International Confectionery Association**
4.2.4.2 The United States suggests that consideration be given to applying the exemptions framework to determine the need for labelling rather than making labelling required for any amount of process aid or carry over additive contained in the lists of allergens (Sections 4.2.1.4, 4.2.1.6, and where applicable 4.2.1.5) regardless of how low the level of allergenic food or food protein may be.	**USA**
4.2.3.1 The exception referred to at the end of section 4.2.3 "except:" is not clear as section 4.2.3.1 refers to the use of general class names that are more informative, however, it excludes foods and ingredients listed in points 4.2.1.4, 4.2.1.6 and, when relevant, 4.2.1.5 **4.2.3.1** Compared to numeral 4.2.3.1, when it is indicated that certain class names are suggested, there is not enough clarity about class names.	**Colombia**
4.2.3.1 Paraguay agrees, in accordance with all the changes already proposed throughout the document.	**Paraguay**
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 sections 4.2.1.4, 4.2.1.6 and where applicable 4.2.1.5~~5~~ and in 4.2.1.7.**	**ICGA**

SPECIFIC COMMENTS	MEMBER / OBSERVER
Change consistent with previous comments on 4.2.1.5 and 4.2.1.7	
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 sections 4.2.1.4, 4.2.1.6 and where applicable 4.2.1.~~5~~5 and 4.2.17.**	**International Confectionery Association**
4.2.4.2 Paraguay agrees	**Paraguay**
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 sections 4.2.1.4, 4.2.1.6 and where applicable 4.2.1.5.** Paraguay agrees.	**Paraguay**
8. PRESENTATION OF MANDATORY INFORMATION	
In section 8, we are of the view that the declaration of foods and ingredients listed in sections 4.2.1.4, 4.2.1.5 and 4.2.1.6 can be either in the list of ingredients or in a separate statement, or both. In other words, section 8.3.2 should also be applied as an alternative to section 8.3.1, or both options can be used together for flexibility in their application considering the various customs of different countries. Change in the presentation can be a burden to the food industry, especially small food producers in developing countries, like Thailand.	**Thailand**
The Kingdom of Saudi Arabia suggest using the following declaration forms of allergens, (bearing in mind that national/regional authorities shall determine the most suitable declaration requirements for their population): 1. The use of “contains” to declare the allergens present in food. In addition, using the word “may contain”, when there might be an allergen contamination present.2. Using a bold, underline, or symbols to declare the allergens on the label.	**Saudi Arabia**
Australia supports the text for inclusion in the GSLPF at section 8.3. We note the evidence in the ISSLG report supports including provisions on the presentation of allergen information to assist consumers in more easily identifying allergens in food.	**Australia**
8.3 Declaration of certain foods and ingredients Chile has concerns in section 8.3 “Declaration of certain foods and ingredients”. Mainly, because of the way in which all its points are written. We think that the wording suggests that point 4.2.1.5 should be labeled in a mandatory manner (“…and, when relevant…”). Therefore, we believe that it would be different if the labeling was clearly mentioned in points 4.2.1.4, 4.2.1.6, and at the end, there was an explanatory note for point 4.2.1.5, referring to the risk assessment on allergens developed by each country and taking into account the evaluation of the FAO/WHO expert report (2022) " Risk assessment of food allergens”. Without this information or reference, we believe that situations could be caused or produced in which, in a recommendation, the countries understand or understand that it is something mandatory at all events. In addition to the above, we think that points 8.3.1, 8.3.2, 8.3.3 and 8.3.4 could be written in another way. Wording is proposed: “and, when pertinent, in any of the allergens in list 4.2.1.5 they will be declared so that they contrast…”. That is, if the country has carried out a risk assessment.	**Chile**
8.3.1 FIVS supports the revised text for section 8.3.1 as it offers sufficient flexibility for the presentation of declarations of foods and ingredients to cause hypersensitivity, including bolding, italicisation, fonts and other strategies to effectively demonstrate contrast.	**FIVS**
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 <u>in the list of ingredients</u> so as to contrast distinctly from the surrounding text, such as through the use of font type, style or colour.	**European Union**
8.3.1 We do not agree with requiring the use of font type, style or colour that contrasts distinctly in allergen labelling.In Japan, it is allowed to just use parentheses to show allergens in mandatory labelling, and there is no problem with that. Thus, we do not	**Japan**

SPECIFIC COMMENTS	MEMBER / OBSERVER
think that there is a need to require the use of special font type, style or colour.Even in Japan, it is allowed to change fonts, etc. so that the labelling is easy for food allergic consumers to understand, but it is within the scope of voluntary labelling.	
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~~ clearly distinguishable on the ~~surrounding text~~label, such as through the use of contrast, font type, style or colour. Canada notes that the proposed text for 8.3.1 would require allergens to be contrasted from surrounding text (such as bolding or use of a different color). Canada is supportive of allergens being clearly identifiable on food labels but prefers to not be overly prescriptive about how this is achieved by different jurisdictions. Canada has suggested wording requiring the allergens to be "clearly distinguishable on the label".	**Canada**
8.3.2 FIVS agrees that the inclusion of a separate statement should remain optional, given that opportunity is provided for effective labelling communication via contrasting features in 8.3.1.	**FIVS**
8.3.2 AOECS does not agree that a separate statement should be allowed when declaring ingredients in 4.2.1.4. Since EU Regulation 1169/2011 'Food Information to Consumers' was introduced, a separate box listing all the 'allergens' that a food contains is no longer allowed. Research shows that the consumer doesn't want to have to look in multiple places to find 'allergen' information. It is safer and easier to keep the 'allergens' the food contains in the full ingredients list. Moreover, some products labelled gluten-free contain ingredients such as barley malt extract and gluten-free wheat starch. Labelling these products gluten-free informs people with coeliac disease that they are suitable for their gluten-free diet. However, if a separate statement indicates "contains wheat" when the ingredient is gluten-free wheat starch, this causes confusion for the consumer.	**Association Of European Coeliac Societies Codex and Regulatory Affairs**
8.3.2 EFA considers that separate statements must be placed 'directly next to the list of ingredients' and not just '...near and in the same field of vision as the list of ingredients'. Furthermore, they should apply to all types of allergen information, including PAL and other aspects e.g. 4.2.2 related to this safety assessment	**European Federation of Allergy and Airways Diseases Patients' Associations**
8.3.2 ~~When the foods and ingredients in sections 4.2.1.4, 4.2.1.6 and where applicable 4.2.1.5 are declared in the list of ingredients, they may also be declared in a separate statement, which shall be placed near and in the same field of vision as the list of ingredients.~~ The EU has stressed in all previous consultations that the revised text, for paragraphs 8.3.2 and 8.3.2.1, is problematic and that the EU cannot support it for the reasons described below. In the EU the use of a separate statement about allergens is not permitted when a list of ingredients exists. By always and exclusively declaring the allergens in the list of ingredients, it ensures consistency in the way of providing information to Consumers with food allergies. The EU believes that the safest approach is to educate consumers with allergies to systematically read and verify the list of ingredients for the presence of any allergenic foods or substances in a product, since allergenic ingredients must always be declared and contrasted in the list of ingredients. The EU insists that the use of separate statements will seriously increase the risk that consumers confuse the actual presence of allergens still present in the final product and the potential presence of allergens in the context of precautionary allergen labelling (PAL). There is a high risk that consumers misinterpret that anything in a separate box is PAL, and risk ignoring information on allergens in the list of ingredients. Another point is that if such separate statements on allergen labelling are provided on a voluntary basis consumers will be even further misled, should they think that foods without 'allergen boxes' or without 'separate statements' do not contain any allergens.	**European Union**

SPECIFIC COMMENTS	MEMBER / OBSERVER
Against this background, in the EU, it is not permitted to repeat information on allergens outside the list of ingredients (see Recital 47, Article 21(1), read in conjunction with Article 36(1), of Regulation (EU) No 1169/2011 on the provision of food information to consumers). The EU strongly believes that different schemes of providing information to consumers may result in confusing consumers. For the reasons above, the EU proposes the deletion of these two paragraphs.	
8.3.2 We do not support the addition of allergens in a separate statement as per point 8.3.2 / 8.3.2.1 as this may trigger an increase of food labelling mistakes and consequently the food safety aspect might not be ensured for the consumer anymore. Furthermore, the addition of a summary statement may also compromise the legibility of the labels, especially for small packs.	**FoodDrinkEurope**
8.3.2 ~~When the foods~~ Foods and ingredients in sections 4.2.1.4, 4.2.1.6 and where applicable 4.2.1.5 ~~are~~ shall be declared in the list of ~~ingredients, they may also be~~ ingredients and/or declared in a separate statement, which shall be placed near and in the same field of vision as the list of ingredients. Canada notes that there are many situations where directly added ingredients that are or are derived from food allergens must be declared in the list of ingredients on a food label. However, Canada questions how multicomponent ingredients containing an allergen or how an ingredient whose common name doesn't include the name of the allergen that it is derived from, such as a dairy product e.g. "cheddar cheese", should be labelled and would like additional clarification on this point. In these cases, it would be Canada's position that the allergen name (e.g. "milk) should be able to be declared either in the list of ingredients or in a separate statement. However, 4.2.3.1 and 8.3.2 and 8.3.2.1 seem to indicate that the allergen name must always appear in the list of ingredients and "may also be declared" in a separate statement. This would have the impact of requiring declaration twice when the "Contains" statement is present. Canada has suggested some edits to 8.3.2 to reflect this. Canada notes that the suggested edits would permit declaration of allergens in three ways, the list of ingredients, the Contains statement, or in both. For example if a flavour contained the allergen milk could be labelled via 3 scenarios:1) INGREDIENTS: FLAVOUR (MILK) Or 2) INGREDIENTS: FLAVOUR CONTAINS: MILK Or 3) INGREDIENTS: FLAVOUR (MILK) CONTAINS: MILK	**Canada**
8.3 Declaration of certain foods and ingredients On the other hand, Chile has concerns in section 8.3 "Declaration of certain foods and ingredients". Mainly, because of the way in which all its points are written. We think that the wording suggests that point 4.2.1.5 should be labeled in a mandatory manner ("... and, where relevant..."). Therefore, we believe that it would be different if the labeling were clearly mentioned in points 4.2.1.4, 4.2.1.6, and at the end, there was an explanatory note for point 4.2.1.5, referring to the allergen risk assessment developed by each country and taking into account the evaluation of the FAO/WHO expert report (2022) "Risk assessment of food allergens". Without this information or reference, we believe that situations could arise or occur in which, in a recommendation, countries understand or understand that it is mandatory for all events. In addition to the above, we think that points 8.3.1, 8.3.2, 8.3.3 and 8.3.4 could be worded differently. Wording is proposed: "and, where relevant, any of the allergens in listing 4.2.1.5 shall be declared in a contrasting manner...". That is, if the country has carried out a risk assessment.	**Chile**
8.3.2.1 ~~The statement shall commence with the word 'Contains' (or equivalent word) and must declare all the foods and ingredients which are declared in the list of ingredients as applicable in accordance with section 8.3.1.~~	**European Union**

SPECIFIC COMMENTS	MEMBER / OBSERVER
8.3.2.1 South Africa suggests the addition of the word “allergens” after “contains”, to assist consumers to make safe informed choice about the presence of allergens in a food. 8.3.2.1 The statement shall commence with the word “Contains Allergens” (or equivalent word) and must declare all the foods and ingredients which are declared in the list of ingredients as applicable in accordance with section 8.3.1.	**South Africa**
8.3.1 The foods and ingredients listed in points 4.2.1.4, 4.2.1.6 and, when relevant, 4.2.1.5 shall be declared in such a way that they contrast clearly with the surrounding text, ~~for example by using font, style, or colour.~~ Honduras considers that the example is not necessary since this is clearly specified in paragraph 8.1.2 of the GSLPF.	**Honduras**
8.3.1 Paraguay agrees with this proposal, we understand that defining these parameters for the declaration on the label would help to provide adequate information to the final consumer.	**Paraguay**
8.3.3 ICA supports section 8 on presentation of mandatory information. ICA particularly supports 8.3.3 and the ability to use a contains statement in these circumstances. ICA is keeping the references to provision 4.2.1.5 in this section with the understanding that this provision refers to the more general language. ICA has proposed in comments above. If the language from ICA in 4.2.1.5 is not adopted, we recommend striking provision 4.2.1.5 from this section.	**International Confectionery Association**
8.3.3 In the light of the comments in the section above, the EU proposes the following changes to the text of paragraphs 8.3.3 and 8.3.4. Further the EU proposes the addition of a new paragraph 8.3.5 to clarify the labelling needs in situations where several ingredients originate from a single allergen.	**European Union**
8.3.3 Where a food is exempt from declaring a list of ingredients, the foods and ingredients listed in sections 4.2.1.4, 4.2.1.6 and where applicable 4.2.1.5 shall be ~~declared, such as~~ declared by comprising the word ‘contains’ followed by the name of the food or ingredient listed in ~~a statement made in accordance with section 8~~sections 4.~~3~~2.1.4, 4.2.1.6 and where applicable 4.2.1.5.	**European Union**
8.3.2 Dominican Republic suggests deleting: "near and in the same field of vision" and replacing with "immediately after the list of ingredients."	**Dominican Republic**
8.3.2 Honduras considers that the "may" in this section 8.3.2, contradicts what is indicated in 8.3.2.1 since this numeral indicates to make a statement of "contains:" We also suggest placing precautionary statements such as "must have traces" (allergen) as mandatory, in the declaration of the list of ingredients; as well as the separate declaration. We suggest that (NT *in the Spanish version) debe (*"must") be used instead of *podrá* (“may”) as in English "must" is indicated in this context.	**Honduras**
8.3.2 Paraguay understands that the paragraph is not clear enough for its application, we understand that the list referred to in points 4.2.1.4 and 4.2.1.6 are mandatory, and in the paragraph, reference is made to the fact that it may be optionally declared in a separate declaration, for us this declaration should also be mandatory.	**Paraguay**
8.3.4 For single ingredient foods, section 8.3.3 does not apply where foods and ingredients listed in sections 4.2.1.4, 4.2.1.6 and where applicable 4.2.1.5 are declared as part of, or in conjunction with, the name of the food.8.3.5 Where several ingredients or processing aids of a food originate from a single food and ingredient listed in sections 4.2.1.4, 4.2.1.6 and where applicable 4.2.1.5, the labelling shall make it clear for each ingredient or processing aid concerned.	**European Union**
8.3.2.1 Paraguay agrees	**Paraguay**
8.3.3 ICGA supports the overall section 8 regarding the presentation of mandatory information. ICGA particularly supports the wording in section 8.3.3 and the ability to use a "contains" statement in these circumstances. Consistent with comments made on section 4.2.1.5, ICGA reserves its right to request a deletion to the reference made to 4.2.1.5 in this section, should section 4.2.1.5 is not revised along the lines of our comments, we recommend striking out the reference to section 4.2.1.5 as presented in this section.	**ICGA**

SPECIFIC COMMENTS	MEMBER / OBSERVER
8.3.3 Honduras suggests that an additional paragraph may be incorporated: If any of the ingredients or additives in the previous point or the substances they contain, such as gluten or lactose, could be present in the final product, even if unintentionally, the possibility of their presence must be clearly indicated.	**Honduras**
8.3.3 Where a food is exempt from ~~being declared~~ declaring a list of ingredients, the foods and ingredients listed in Sections 4.2.1.4, 4.2.1.6 and, when relevant, 4.2.1.5 shall be declared as in a claim made in accordance with Section 8.3.2.1.	**Colombia**
8.3.3 Paraguay agrees.	**Paraguay**
8.3.4 8.3.4. A modification in the wording is proposed to align with the provisions of the current national regulations referring to the declaration of allergens (Art. 235 fifth. Chapter V of the Argentine Food Code). Proposed text: 8.3.4 For single-ingredient foods, section 8.3.3 may not apply where foods and ingredients listed in sections 4.2.1.4, 4.2.1.6 and, when relevant, 4.2.1.5 are declared as part of or together with the name of the food.	**Argentina**
8.3.4 Paraguay agrees.	**Paraguay**
PART B: GUIDANCE OF PRECAUTIONARY ALLERGEN LABELLING	
GENERAL COMMENTS	
The view of AOECS is that coeliac disease has been overlooked in the proposals for the GSLPF and guidelines on PAL, which would lead to a harmful situation for patients with coeliac disease if these proposals presented are not amended. With regards to the proposal for PAL guidelines, coeliac disease has not been taken into consideration yet conusmers with coeliac disease also rely on PAL when making an informed food choice. The guidance for how PAL should be used must take this into consideration.	**Association Of European Coeliac Societies Codex and Regulatory Affairs**
the need to seek advice on standardised analytical methods and sampling from CCMAS (i.e. whether there is agreement to seek advice on appropriate methods for undertaking risk assessments, taking into account information provided within FAO/WHO scientific advice reports) Australia considers it would be appropriate to seek advice from CCMAS on standard analytical methods and sampling to assist validation of risk assessments. Although we note the PAL guidelines do not necessarily have to include specific methods of analysis but rather could provide general guidance on the types of methods to be used. However, this may depend on whether CCFH decides, based on the outcomes from the FAO/WHO Expert Committee, to update the Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020) to incorporate guidance on undertaking risk assessments. In which case, methods of analysis and sampling may be included in CXC 80-2020. CCFL may therefore need to also seek advice from CCFH in relation to any update to CXC-2020 (see response to (ii) below). However, we recommend the work on the PAL guidance not be delayed while waiting for any advice from CCMAS and/or CCFH.	**Australia**
the proposed location as an annex to the GSLPF (i.e. whether the guidelines should be incorporated as an annex to the GSLPF to ensure consistency with the GSLPF) Australia supports the proposal to locate the draft guidelines on the use of precautionary allergen labelling (PAL) as an annex to the GSLPF. This location will enable consistency between the PAL guidelines and the GSLPF, and will keep all provisions relevant to allergen labelling (including PAL) within the same Codex text.	

SPECIFIC COMMENTS	MEMBER / OBSERVER
Brazil would also like to present specific comments to Appendix III - Proposed draft annex to the GSLPF: Guideline on the use of precautionary allergen labelling 3. DEFINITIONS Brazil understands that the proposed definition for "allergen" is not adequate, as it simply cross-references the foods and ingredients listed in sections 4.2.1.4 and 4.2.1.5. It does not adequately explain the concept of allergens that are different from the foods and ingredients that contain them. Additionally, this proposal creates inconsistency with the definition of allergen in the Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020). Therefore, Brazil suggests adopting the allergen definition from CXC 80-2020, with the inclusion of the word "typically" to clarify that not all allergens are proteins. To read 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 typically a protein which is found in food capable of triggering a response in individuals sensitised to it. 4. GENERAL PRINCIPLES On paragraph 4.2 Brazil suggests replacing the word “shall” with “may” to provide greater flexibility in relation to the application of qualitative risk assessments to guide the decision to use PAL. New paragraph 4.2 would read as follows: The decision to use PAL should be based on the findings of a risk assessment which may include, but is not limited to, quantitative risk assessment.	**Brazil**
Brazil would like to express its gratitude to Australia, the United Kingdom, and the United States of America for their coordination of the electronic working group (e-WG) and for preparing the proposed drafts for circulation at Step 3 (CX/FL 23/47/5) and for consideration by CCFL47. We welcome the opportunity to provide comments on these proposals. We would also like to thank the Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens for providing scientific advice to CCFL on the list of foods and ingredients known to cause food allergy and coeliac disease and on precautionary allergen labelling (PAL). Brazil acknowledges the importance of the proposed amendments in the GSLPF. In general, we support the following proposals: • The proposed new definition of "food allergy". • The inclusion of a footnote to define coeliac disease. • The substitution of the term “hypersensitivity” with “food allergy or coeliac disease” • The proposed revisions to the labelling provisions for allergens found in compound ingredients (section 4.2.1.3) and in food additives and processing aids (section 4.2.4.2). • The amendments to clarify the mandatory declaration of allergens in small packages (section 6). • The adoption of new provisions on the presentation of allergen declaration (sections 8.3, 8.3.1, 8.3.2, 8.3.3 and 8.3.4). We are also in favour of adopting a consistent and harmonized approach to PAL declaration. Overall, Brazil agrees with the following proposals:	

SPECIFIC COMMENTS	MEMBER / OBSERVER
• The adoption of the proposed purpose and scope sections (sections 1 and 2 of the draft PAL Guidelines). • The proposed definition of precautionary allergen labelling and a cross reference to the definition of "allergen cross-contact" in the Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020). • The proposed new principle on the adoption of effective management practices and controls to prevent or minimize the unintended presence of allergens caused by cross-contact (section 4.1 of the draft PAL Guidelines). • The proposed new principle on the adoption of education programs to ensure understanding and appropriate use of PAL (section 4.4 of the draft PAL Guidelines). • The proposed provisions on presentation of PAL (section 5 of the draft PAL Guidelines). However, we believe that the ongoing work involves complex points that will require further discussions, particularly regarding the lists of foods and ingredients in sections 4.2.1.4 and 4.2.1.5 of the GSLPF, the exemptions of ingredients derived from these foods (section 4.2.1.7) and the use of quantitative risk assessment, reference doses (RfD), and action levels to guide the use of PAL on prepackaged foods. Lists of foods and ingredients known to cause food allergy and coeliac disease (sections 4.2.1.4 and 4.2.1.5 of the GSLPF): In relation to the use of specified names for foods and ingredients known to cause food allergy or coeliac disease, Brazil would like to seek clarification on the proposed wording of sections 4.2.1.4 and 4.2.1.5 of the GSLPF. We are of the opinion that these foods and ingredients should be declared using their specific names, in accordance with the provisions outlined in Section 4.1 of the GSLPF, along with the declaration of the respective specified name listed in sections 4.2.1.4 and 4.2.1.5. For instance, if "albumin" is used as an ingredient of a particular food, its declaration in the list of ingredients should be "albumin (egg)" or "egg albumin", rather them simply "egg". However, the wording used in these sections has raised doubt if the intention is to replace the specific name of the ingredient (e.g., albumin) by the specified name (e.g., egg). Regarding the proposed regional list of foods and ingredients known to cause food allergies or coeliac disease (section 4.2.1.5), we are aware that this proposal takes into consideration the scientific advice of the Expert Committee, as these foods and ingredients were not classified as priority allergens due to the lack of data on prevalence, potency, or severity. It would also allow national or regional authorities to carry out their own risk assessments. Nonetheless, Brazil believes that other factors must be considered by CCFL when defining the list of priority allergens to ensure that the risk management measures related to the labelling of these foods and ingredients are effective in protecting consumer health and facilitating international trade. Soybean is already recognized as a priority allergen by Codex Alimentarius and most national authorities. Therefore, food business operators are familiar with implementing risk management controls for this allergen, and consumers with soy allergy are used to checking for the declaration of soy presence in food products. Soybeans and soy-derived ingredients are widely used in food products, leading to significant exposure to soy protein in many populations and increasing the risk of accidental consumption by individuals with soy allergy. Additionally, soy allergy is more prevalent in infants, especially among those who are allergic to milk. Soybean is also known to trigger non-IgE mediated food allergies, such as food protein-induced enterocolitis syndrome (FPIES), food protein-induced enteropathy, food protein-induced allergic proctocolitis, and eosinophilic esophagitis. These conditions can cause significant	

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adverse health effects, particularly in infants and young children, and were not within the scope of the Expert Committee risk assessment. Therefore, maintaining the regulatory status of soy as a priority allergen would not result in additional impacts for food business operators, and it would keep the level of health protection for consumers with soy allergy, particularly vulnerable groups such as infant and young children. For other foods and ingredients on the regional list of allergens, the severity of allergic reactions may warrant their classification as priority allergens. This is exemplified by Brazil nuts, which have been identified by the Expert Committee as a food implicated in a higher proportion of anaphylaxis in three or more regions, as well as several fatalities, and by Macadamia and Pine nuts, which are implicated in a higher proportion of anaphylaxis in one or two regions. In the case of these tree nuts, it should be noted that there are concerns with potential cross-reactive with peanut, sesame and other tree nuts included in the list of priority allergens, which can further justify their classification as such. Due to the high frequency of severe allergic reactions and concerns about potential cross-reactivity, individuals with allergy to tree nuts are often advised to avoid all tree nuts. Thus, Brazil proposes the adoption of a unified list of priority allergens by merging the lists from sections 4.2.1.4 and 4.2.1.5. This approach would also promote more consistent practices in international trade. It there is no support for this alternative, Brazil would request the inclusion of soy, Brazil nut, macadamia and pine nut in the list of priority allergens based on the rationally presented. Exemptions of ingredients derived from foods and ingredients known to cause food allergy and coeliac disease (section 4.2.1.7 of the GSLPF): Brazil notes that the Expert Committee's Part 4 report have not yet been fully published and will not be accessible in time for consideration by CCFL47. As a result, we request that section 4.2.1.7 that deals with the exemption of ingredients derived from foods and ingredients known to cause food allergy and coeliac disease be kept in square brackets until the complete versions of these publications become available. The use of quantitative risk assessment, reference doses (RfD), and action levels to guide the use of PAL on prepackaged foods (sections 4.2 and 4.3 of the draft PAL Guidelines): Brazil believes that the regulatory approach to guide the declaration of PAL in prepackaged foods must be effective and proportional, taking into account the severity and high variability of food allergic reactions, the quality of the scientific evidence available to set RfD, the need to provide clear and trustworthy information to consumers with food allergies and the capacity of food business operators and national authorities to implement and enforce PAL. In this regard, the proposal to use of quantitative risk assessments as the primary approach for declaring PAL on prepackaged foods has raised concerns about its effectiveness in protecting consumer health and facilitating international trade. The use of proposed RfD and their corresponding action levels to guide the declaration of PAL will not prevent adverse health effects in individuals with food allergy. According to the Expert Committee, it is estimated that around 14 to 75% of individuals with food allergies may experience adverse symptom at the level of exposure of the proposed RfD for the priority allergens. In cases where objective symptoms are present, the expected rate would be between 8 to 25%. Additionally, many adverse effects	

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that were not considered by the Expert Committee for the purpose of defining RfD may be perceived as severe by consumers with food allergies, food business operators, and national authorities. Furthermore, the proposed prohibition on using PAL when the presence of an allergen is confirmed but falls below the action level for that allergen would leave consumers with food allergies, especially those who are most sensitive, without information to guide them in avoiding potentially triggering foods. As a result, consumers with food allergies may lose confidence in the accuracy and usefulness of PAL declarations on prepackaged foods, diminishing the effectiveness of such declarations in communicating the risk of unintended presence of an allergen due to cross-contact. Another concern about linking PAL declaration in prepackaged foods to quantitative risk assessments is its impact on food manufacturers, especially small producers who may lack the capacity to perform such assessments. This could represent an excessive burden for many food business operators and discourage the use of PAL declarations on labels. Moreover, the proposed prohibition on using PAL when the presence of an allergen is confirmed but falls below the action level for that allergen may result in legal uncertainty for food manufacturers and potentially increase litigation. Another uncertainty identified in the application of quantitative risk assessment is the availability of appropriate analytical methods and sampling plans for testing allergens in foods and surfaces. The Expert Committee has indicated that current methods have significant limitations, and the limits of quantification (LoQ) of any method used for a specific food should be 3-fold lower than the action level for that food. This is to account for real-world performance variability and to ensure that the analytical result is truly at or below the action level. The following deficiencies and inconsistencies in analytical methodologies and methods were highlighted: • Lack of methods that are fit for purpose in identifying and quantifying many priority allergens. • Limited information on specificity of many test methods, and lack of sufficient data on validation, especially for quantifying the analyte in food matrices. • Specificity issues with fish, crustacea and wheat, as fit for purpose test methods are largely lacking for these priority allergens. • Limited availability of reference materials and absence of reference methods. • Poor recovery or ability to extract proteins from complex food matrices, and lack of validation in a sufficient diversity of food matrices. • Poor recovery of proteins from food matrices due to processing unit operations, including thermal processing and fermentation. • The need for harmonized test method reporting units to express them in mg of total protein from the allergenic source per kilogram of food containing the putative allergen unintentionally. • The need to develop or adapt sampling plans to facilitate the monitoring of adherence to an established RfD. Therefore, without the assurance that there are appropriate analytical and sampling methods to quantify all priority allergens in various food matrices, it is not feasible to recommend the application of this approach by food business operators. Brazil also believes that the proposed principles do not provide clear guidance on how action levels should be calculated, particularly in terms of determining the amount of food that should be used, considering the diversity of dietary habits among	

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populations. Thus, it is likely that the use of action levels to guide the declaration of PAL will create additional trade barriers, as an allergen present in a particular food could have two or more different action levels depending on the amount of food used as a reference in each country or by different food business operators. Proposed location as an annex to the GSLPF. With regards to the placement of the proposed draft PAL guidelines, Brazil supports the e-WG's proposal to incorporate them as an annex to the GSLPF. This approach ensures consistency with the GSLPF and allows provisions related to allergen labeling, including PAL, to be located within the same text. Need to seek advice on standardised analytical methods and sampling from CCMAS. One of Brazil's main concerns regarding the adoption of RfD and action levels to guide the declaration of PAL in prepackaged foods is the availability of appropriate analytical methods and sampling plans for testing allergens in foods and surfaces. The Expert Committee has indicated that current methods have several significant limitations. Therefore, Brazil fully endorses the proposal to seek advice on standardized analytical methods and sampling from CCMAS for undertaking risk assessments for PAL declaration in prepackaged food. Additionally, this consultation should also encompass advice on appropriate methods for undertaking risk assessments for exempting ingredients derived from foods listed in sections 4.2.1.4 and 4.2.1.5 of the GSLPF, taking into consideration the recommendations from the Expert Committee's Part 4 report. Need to provide any advice to CCFH to ensure consistency with the Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020). Brazil is also in favour to provide advice to CCFL on work progress to ensure consistency with the Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020).	
Canada appreciates the opportunity to provide comments on the Proposed Guidelines on the Use of Precautionary Allergen Labelling. Canada believes that the work on precautionary allergen labelling will help to provide guidance to food manufacturers, allergic consumers, regulatory bodies and other stakeholders on best practices for the use of PAL on labels of prepackaged foods. **the proposed location as an annex to the GSLPF (i.e. whether the guidelines should be incorporated as an annex to the GSLPF to ensure consistency with the GSLPF)** Canada supports adding PAL guidelines as an annex to the GSLPF due to the close linkage with the allergen provisions in the GSLPF **the need to seek advice on standardised analytical methods and sampling from CCMAS (i.e. whether there is agreement to seek advice on appropriate methods for undertaking risk assessments, taking into account information provided within FAO/WHO scientific advice reports)** Canada supports seeking advice on standardized analytical methods and sampling from CCMAS given that the Expert Committee provided a discussion on appropriate methods of analysis in its Part 2 report and concluded that significant limitations on method performance exist. Both advice on standardized methods and sampling are critical for obtaining accurate analytical	**Canada**

SPECIFIC COMMENTS	MEMBER / OBSERVER
results. Canada notes that sampling for cross contact of allergens, which are often heterogeneously distributed in foods or present only sporadically, will be particularly challenging.	
the proposed location as an annex to the GSLPF (i.e. whether the guidelines should be annexed to the GSLPF to ensure consistency with such Standard), and Chile agrees that the guidelines should be annexed to the GSLPF to ensure consistency with the Standard. Mainly because, if this were not the case, it could lead to divergences and result in different companies and/or authorities being able to interpret the document differently. **the need to seek advice on standardised analytical methods and sampling from CCMAS (i.e. whether there is agreement to seek advice on appropriate methods for undertaking risk assessments, taking into account information provided within FAO/WHO scientific advice reports)** Chile thinks it is important to seek advice on standardized analytical methods and sampling from this committee because this ensures that reliable and standardized methods are used for allergen risk assessment in food. The use of standard methods of analysis and sampling is essential to ensure comparability of results between different laboratories and countries, which in turn helps protect the health of consumers and facilitates international trade. Additionally, by using standardized methods, the efficiency of quality control processes can be improved and costs associated with food safety assessment can be reduced. In summary, seeking advice on standard analytical methods and sampling from the Codex Committee on Methods of Analysis and Sampling is important because it ensures that reliable and standardized methods for the assessment of allergens in foods appropriate to carry out the risk assessments, which in turn protects the health of consumers, facilitates international trade and improves the efficiency of quality control processes	**Chile**
the proposed location as an annex to the GSLPF (i.e. whether the guidelines should be annexed to the GSLPF to ensure consistency with such Standard), and Colombia agrees that it should be an annex to the GSLPF to ensure consistency with that Standard and to facilitate its adoption by countries that consider it to be so. **the need to seek advice on standardized analytical methods and sampling from the Codex Committee on Methods of Analysis and Sampling (CCMAS) (i.e., whether there is agreement to seek advice on appropriate methods for conducting risk assessments, considering the information provided in FAO/WHO scientific advice reports).** Colombia agrees to seek advice from the Codex Committee on Methods of Analysis and Sampling (CCMAS) on appropriate methods for conducting risk assessments, with a view to unifying methods and achieving standardization of results.	**Colombia**
the need to seek advice on standardized analytical methods and sampling from the Codex Committee on Methods of Analysis and Sampling (CCMAS) (i.e., whether there is agreement to seek advice on appropriate methods for conducting risk assessments, considering the information provided in FAO/WHO scientific advice reports). Costa Rica agrees to seek advice from the CCMAS on appropriate methods for conducting risk assessments.	**Costa Rica**

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the proposed location as an annex to the GSLPF (i.e. whether the guidelines should be annexed to the GSLPF to ensure consistency with such Standard), and Costa Rica supports the inclusion of the PAL proposal as an annex to the GSLPF because of its close relationship with the allergen provisions in that standard.	
Proposed Draft Guidelines on Precautionary Allergen Labelling. Cuba is of the opinion that the document prepared is necessary and contributes to the buyer being able to make his purchase choice in a safer manner, particularly if he or she suffers from a food allergy or hypersensitivity. It also allows food business operators to improve allergen management, when processing foods that cause food allergies, as far as labeling is concerned. Judging by the elements set out in the circular letter itself, we consider it premature to advance the preparation of the document until the Codex Committee for Analysis and Sampling proposes the test methods to be applied to determine the presence of an allergen protein.	**Cuba**
the proposed location as an annex to the GSLPF (i.e. whether the guidelines should be annexed to the GSLPF to ensure consistency with such Standard), and Dominican Republic supports placing Appendix III Proposed Draft Guidelines for the Use of PAL, as an annex to CXS 1 1985.	**Dominican Republic**
whether advice should be provided to the Codex Committee on Food Hygiene (CCFH) to ensure consistency with the *Code of Practice on Food Allergen Management for Food Business Operators* (CXC 80-2020). The Dominican Republic supports the provision of advice to the Codex Committee on Food Hygiene (CCFH) to ensure that actions developed by that committee are aligned with the PAL Guidelines.	
The Proposed Draft Guidelines for the Use of Precautionary Allergen Labelling contained in Appendix III to document CX/FL 23/47/5, including: The country considers that the document in general is very well structured considering technical considerations based on what was addressed by the group of experts and the GTE; Therefore, we do not have specific comments regarding this. **the need to seek advice on standardized analytical methods and sampling from the Codex Committee on Methods of Analysis and Sampling (CCMAS) (i.e. whether there is agreement to seek advice on appropriate methods for conducting risk assessments,** considering **the information provided in FAO/WHO scientific advice reports).** The country considers that, in view of the determinations of the expert group and the GTE, there is still a discrepancy in the determination of analytical methods, so that the criteria and considerations of the CCMAS would be valuable; however, a best decision at the CCFL47 is encouraged. **the proposed location as an annex to the GSLPF (i.e. whether the guidelines should be annexed to the GSLPF to ensure consistency with such Standard), and** The country considers that the guidelines for the use of precautionary allergen labeling, should indeed be incorporated as an annex to the GSLPF, as the criteria are aligned with that Standard. In addition, it is suggested that in the table located in 4.3.1 Reference Dose, the name "Food" be placed in the heading of the first column.	**Ecuador**

SPECIFIC COMMENTS	MEMBER / OBSERVER
the proposed location as an annex to the GSLPF (i.e. whether the guidelines should be incorporated as an annex to the GSLPF to ensure consistency with the GSLPF) ; and EFA strongly suggests that the PAL guidelines must be incorporated as an annex to the General Standard for the Labelling of Prepackaged Food to ensure consistency with it. **the need to seek advice on standardised analytical methods and sampling from CCMAS (i.e. whether there is agreement to seek advice on appropriate methods for undertaking risk assessments, taking into account information provided within FAO/WHO scientific advice reports)** EFA agrees that such an advice would be recommended to ensure good standards in risk assessments.	**European Federation of Allergy and Airways Diseases Patients' Associations**
the need to seek advice on standardised analytical methods and sampling from CCMAS (i.e. whether there is agreement to seek advice on appropriate methods for undertaking risk assessments, taking into account information provided within FAO/WHO scientific advice reports) The EUMS support the need to seek advice on standardised analytical methods and sampling from CCMAS. **the proposed location as an annex to the GSLPF (i.e. whether the guidelines should be incorporated as an annex to the GSLPF to ensure consistency with the GSLPF)** The EUMS support the proposed location as annex to the GSLPF, as long as the revision of the GSLPF and the draft PAL guidelines do not delay each other.	**European Union**
the proposed draft revision to the GSLPF in Appendix II of FIA supports the PAL guidelines as an annex to the GSLPF due to close linkage with the allergen provisions. We also support seeking advice from CCMAS on the analytical methods and sampling.	**Food Industry Asia**
the need to seek advice on standardised analytical methods and sampling from CCMAS (i.e. whether there is agreement to seek advice on appropriate methods for undertaking risk assessments, taking into account information provided within FAO/WHO scientific advice reports) FoodDrinkEurope suggests that CCFL consults CCMAS to seek advice on standardised analytical methods and sampling. **the proposed location as an annex to the GSLPF (i.e. whether the guidelines should be incorporated as an annex to the GSLPF to ensure consistency with the GSLPF)** FoodDrinkEurope suggests waiting until the work on the draft guideline has progressed before considering its possible location in the GSLPF.	**FoodDrinkEurope**

SPECIFIC COMMENTS	MEMBER / OBSERVER
the proposed draft guidelines for the use of PAL in Appendix III: We would support the addition of a footnote with reference to the FAO/WHO Allergen Expert Group report that supports authorities in the science-based development of national/regional regulation and to ensure food safety for consumers. Delete the reference to section 4.2.1.5 in sections 4.2.2, 4.2.3/4.2.3.1, 4.2.4.2, 8.3.1, 8.3.2/8.3.2.1, 8.3.3, 8.3.4, 4.2.1.7, 4.2.1.3. **the proposed location as an annex to the GSLPF (i.e. whether the guidelines should be incorporated as an annex to the GSLPF to ensure consistency with the GSLPF)** We agree that it should be left as an Annex to the GSLPF, considering the relationship that these guidelines have with the Labeling Standard. **the need to seek advice on standardised analytical methods and sampling from CCMAS (i.e. whether there is agreement to seek advice on appropriate methods for undertaking risk assessments, taking into account information provided within FAO/WHO scientific advice reports)** We agree to seek advice from the CCMAS Committee.	**Guatemala**
ICBA Overall Comment: We support PAL guidelines as annex to the GSLPF due to the close linkage with the allergen provisions.◦ We also support seeking advice from CCMAS on analytical methods and sampling.	**ICBA**
On behalf of its members, the International Chewing Gum Association (ICGA) thanks the Codex Alimentarius Commission secretariat for the opportunity to provide comments in response to CL 2023/06/OCS-FL on the revision of the Codex standard CXS 1 on allergen labeling and about the proposed draft guidelines on precautionary allergen labeling. Our detailed comments are embedded in the document's Annex II and III.	**ICGA**
the need to seek advice on standardised analytical methods and sampling from CCMAS (i.e. whether there is agreement to seek advice on appropriate methods for undertaking risk assessments, taking into account information provided within FAO/WHO scientific advice reports) Comment: We note that accurate quantification of allergens is challenging. As such, we support seeking advice from CCMAS on analytical methods and sampling. In regard to whether information in the FAO/WHO scientific reports needs to be taken into account (without full visibility of the report for Para 3 of the consultation), at this time, we cannot comment on this. **whether to provide any advice to CCFH to ensure consistency with the *Code of Practice on Allergen Management for Food Business Operators* (CXC 80-2020).** We support actions to ensure alignment with CCFH mandates once the PAL guidelines are agreed. **the proposed location as an annex to the GSLPF (i.e. whether the guidelines should be incorporated as an annex to the GSLPF to ensure consistency with the GSLPF) ; and**	**ICGMA**

SPECIFIC COMMENTS	MEMBER / OBSERVER
We support adding PAL guidelines as an annex to the GSLPF due to the close linkage with the allergen provisions in the GSLPF.	
the proposed location as an annex to the GSLPF (i.e. whether the guidelines should be incorporated as an annex to the GSLPF to ensure consistency with the GSLPF); and IDF agrees with the proposed location as an annex to the GSLPF, provided that the reference to this annex does not make it mandatory to use PAL. **the need to seek advice on standardised analytical methods and sampling from CCMAS (i.e. whether there is agreement to seek advice on appropriate methods for undertaking risk assessments, taking into account information provided within FAO/WHO scientific advice reports)** IDF supports seeking advice from CCMAS. CCMAS may be able to advise also on the challenges with quantitative risk assessments in relation to the reference doses	**IDF/FIL**
the proposed location as an annex to the GSLPF (i.e. whether the guidelines should be incorporated as an annex to the GSLPF to ensure consistency with the GSLPF); and At this stage, ISDI supports including the PAL guidelines as an annex to the GSLPF due to the close linkage with the allergen provisions in that text. However, ISDI also considers that the eventual decision should take into account the final document and how the work has been progressed. If the PAL guidelines form an annex of the GSLPF, ISDI believes the way the PAL annex is incorporated by reference in the GSLPF should not suggest that PAL is mandatory.	**International Special Dietary Food Industries**
the proposed draft guidelines for the use of PAL in Appendix III: In relation to section 4.3, ISDI would like to express its concerns regarding the section as: • It suggests that only with a quantitative risk assessment PAL is justified; • It suggests that the RfD in the table is always the decisive threshold; • A risk assessment should be broader than just quantitative and the RfD is only helpful on the dose of an allergen but not on frequency. Where frequency is expected to be high or expected to be low, a separate conclusion on PAL may be more appropriate. • A quantitative risk assessment may not be possible in cases where the limit of quantification is above the RfD or where a supplier has not provided sufficient information on their ingredients' allergen levels to allow for calculations. Consequently, ISDI suggests rewording this section as follows: "4.3 Best practice is that PAL shall only be used if the presence of a protein from an allergen is equal to or above the action level3 for this allergen, using the listed reference dose values in 4.3.1." "4.2 The decision to use PAL should be based on the findings of a risk assessment which shall include where possible, but is not limited to, quantitative risk assessment."	

SPECIFIC COMMENTS	MEMBER / OBSERVER
With regard to Section '4.3.1 References doses', ISDI suggests adding a footnote to state that, where reference doses (RfDs) for other allergens are established in the future, section 4.3.1 will be updated to include those RfDs. As regards section 4.3.2, although ISDI supports in principle the possibility for national authorities to determine reference doses that align with recognised principles for determining an action level, ISDI does not believe that such information is appropriate or helpful to be included within a Codex text. The establishment of a national reference dose should be based on robust scientific data. In addition, ISDI would like to emphasize that harmonization of reference doses (by applying the same scientific approach) should be strongly considered to ensure a consistent approach, fair practices in international trade and to enable consumer to make informed and safe food choices.	
the proposed draft guidelines for the use of PAL in Appendix III: Regarding the analysis for quantitative evaluation of PAL, the report of the 2nd Expert Meeting states, "The limit of quantification of the analytical method shall be one-third or less of the payload of each food product.", but we think that it is not a method that can actually be used by business operators in each country and that it is not a method that will spread to the general public. In addition, although the use of PAL without quantitative assessment is possible, we think that the correlation between the results of risk management measures by business operators and thresholds is ambiguous. We do not agree with the establishment of a PAL because if the business operators is unable to provide an appropriate PAL for allergy sufferers, the patient's range of food choices will be narrowed.	**Japan**
General Comment: Kenya is generally in support of the draft PAL as presented and proposes that once discussion and agreement is arrived at, it is included as annex to CXS 1-1985 Rationale: The content of PAL is closely related to the provisions of the requirements in clause 4 of CXS 1-1985 and aims to provide further guidance on how the labelling should be done for the allergens Issue 1: Principle number 4.3 Comment: Kenya proposes the reference to the RfD table be deleted and only apply to where a suspected unintended presence of allergen may be present such that it reads, PAL shall only be used if the presence of a protein from an allergen may be present Rationale: The principle as currently drafted appears to only require precautions be provided when only the RfD for the various allergens are exceeded. Further, guidance (5.2.1 of the draft) indicates that, whenever the thresholds are exceeded, the words, 'may contain' is used. This is quite misleading because at that point the consumers are certainly exposed to the risk of allergy given that the RfD is already achieve and hence consumer may consume the product on the assumption that it's a chance. Taking note of plain meaning of the word 'precaution', it is untended to 'warn' people against a potential risk. As a result, we propose consistency of such warning as indicated on our proposal, with the alternative of the words, 'is equal to or above' being replaced with 'below'.	**Kenya**

SPECIFIC COMMENTS	MEMBER / OBSERVER
whether to provide any advice to CCFH to ensure consistency with the *Code of Practice on Allergen Management for Food Business Operators* (CXC 80-2020). Ideally the Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020) and the proposed draft guidelines for the use of PAL would be consistent. As such, in addition to providing any advice on methods of analysis received from CCMAS (see response re b above) New Zealand also considers it appropriate for CCFL to forward the definition of allergen to be used by CCFL to CCFH for their consideration in relation to the Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020). New Zealand supports consistency in definitions across Codex texts. The definition used in the proposed draft guidelines for the use of PAL is based on the latest advice and therefore would be the appropriate definition to be adopted across Codex texts. **the proposed location as an annex to the GSLPF (i.e. whether the guidelines should be incorporated as an annex to the GSLPF to ensure consistency with the GSLPF)** New Zealand considers this draft text should be a supplementary text to the GSLPF as it does not extend beyond the scope of the GSLPF. We agree that incorporating as an annex to the GSLPF would ensure consistency with the GSLPF. New Zealand would welcome discussion in the Committee on the criteria to be considered when deciding whether a text should be supplementary to an existing standard or guideline or a stand-alone document. We are of the view that the Committee should be consistent in its decision making on this regard and note that there are other current work items for which a decision on placement will need to be taken. **the need to seek advice on standardised analytical methods and sampling from CCMAS (i.e. whether there is agreement to seek advice on appropriate methods for undertaking risk assessments, taking into account information provided within FAO/WHO scientific advice reports)** New Zealand supports seeking guidance from CCMAS on appropriate methods for undertaking risk assessments and any associated challenges associated with those methods. We suggest any advice on methods of analysis received from CCMAS also be provided to CCFH to ensure consistency with the Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020)	**New Zealand**
the proposed draft guidelines for the use of PAL in Appendix III of CX/FL 23/47/5, including: Panama supports the advancement of the Proposed Draft. It believes that the proposed text is necessary and in line with the scope of the GSLPF. ***Proposed draft annex to the GSLPF:*** Panama agrees with the wording of the document.	**Panama**
the need to seek advice on standardized analytical methods and sampling from CCMAS (i.e. whether there is agreement to seek advice on appropriate methods for undertaking risk assessments, taking into account information provided within FAO/WHO scientific advice reports) Panama would also agree to seek advice on appropriate methods for conducting risk assessments, as suggested.	

SPECIFIC COMMENTS	MEMBER / OBSERVER
the need to seek advice on standardized analytical methods and sampling from CCMAS (i.e. whether there is agreement to seek advice on appropriate methods for undertaking risk assessments, taking into account information provided within FAO/WHO scientific advice reports) Paraguay believes it is advisable to request the appropriate advice from the CCMAS Committee to bring clarity and precision to these guidelines. **the proposed location as an annex to the GSLPF (i.e. whether the guidelines should be incorporated as an annex to the GSLPF to ensure consistency with the GSLPF)** Paraguay agrees that these guidelines be annexed to the GSLPF.	**Paraguay**
Regarding the Proposed Draft Guidelines for the Use of Precautionary Allergen Labelling, the Committee considers that the Guidelines should be annexed to the GSLPF to ensure consistency with such standard. Regarding the need for some type of advice from other Codex Committees, the Committee considers that it should request advice or opinion from the Codex CCMAS and CCFH Committees	**Peru**
the need to seek advice on standardised analytical methods and sampling from CCMAS (i.e. whether there is agreement to seek advice on appropriate methods for undertaking risk assessments, taking into account information provided within FAO/WHO scientific advice reports) South Africa agrees that it is always beneficial to seek advice on standardised analytical methods and sampling from the CCMAS **the proposed location as an annex to the GSLPF (i.e. whether the guidelines should be incorporated as an annex to the GSLPF to ensure consistency with the GSLPF)** South Africa supports the inclusion of the proposed draft guidelines as an annex to the GSLPF so as to ensure consistency with the GSLPF, and so that provisions relevant to allergen labelling including PAL are located within the same text.	**South Africa**
Thailand does not object the inclusion of the draft PAL guideline as an annex to the CXS 1-1985.	**Thailand**
the proposed location as an annex to the GSLPF (i.e. whether the guidelines should be incorporated as an annex to the GSLPF to ensure consistency with the GSLPF) Uganda proposes that this guideline is annexed to the GSLPF Rationale: It will ease reference of use by the industry and consumers as well as ensuring consistence with the GSLPF	**Uganda**
the need to seek advice on standardised analytical methods and sampling from CCMAS (i.e. whether there is agreement to seek advice on appropriate methods for undertaking risk assessments, taking into account information provided within FAO/WHO scientific advice reports) Typically commodity committees supply methods of analysis and performance criteria for CCMAS to assess, so CCMAS may not be in a position to provide specific advice on standardised analytical methods and sampling for allergens, other than on how they should be validated. We suggest that CCFL request FAO/WHO convene an expert committee to provide advice on methods of analysis.	**United Kingdom**

SPECIFIC COMMENTS	MEMBER / OBSERVER
the proposed location as an annex to the GSLPF (i.e. whether the guidelines should be incorporated as an annex to the GSLPF to ensure consistency with the GSLPF) Uruguay considers that these guidelines should be placed as an annex to the GSLPF.	**Uruguay**
With regard to the Proposed draft Guidance on Precautionary Allergen Labelling, the United States supports the recommendation to have the Guidance on Precautionary Allergen Labelling as an annex to the GSLPF. The United States continues to have the view that the text should have flexibility as to how PAL is referenced and would like to see the option of Advisory Allergen Labelling be maintained. The United States supports the scope as recommended in Section 2 and generally supports the draft definitions and the general principles in section 4. The United States also has some specific comments in track changes in the definitions and in sections 4.3.2 and 5.2.1.	**USA**
1. PURPOSE	
The EUMS agree with the proposed text for the purpose of the guidelines.	**European Union**
Canada supports the Purpose in the draft annex.	**Canada**
AOECS does not agree with the purpose of the guidelines as it includes no mention of those with coeliac disease and only refers to food allergy.	**Association Of European Coeliac Societies Codex and Regulatory Affairs**
~~To facilitate a consistent and harmonized approach to the effective use of precautionary allergen labelling (PAL) for communicating to consumers with food allergy about the risk from the unintended presence of allergens in food due to cross-contact.~~Facilitate a consistent and harmonized approach to the effective use of Precautionary Allergen Labeling (PAL) so that the developer of the food can communicate to consumers with food allergies about the risk of unintended presence of allergens in food due to cross-contact. It is not clear for whom this risk assessment is defined, ie if it is exclusively for processors/operators, for governments, or both. For this reason, we suggest adding in section No. 1-Purpose, who is in charge of communicating to consumers. It is proposed above.	**Chile**
For Paraguay, the introduction of this section would help to clarify the purpose of the text.	**Paraguay**
2. SCOPE	
Canada supports the Scope in the draft annex.	**Canada**
~~Facilitate a consistent and harmonised approach for the effective use of precautionary allergen labelling (PAL) to communicate consumers with food allergy about the risk of unintended presence of allergens in food due to cross-contact.~~ "Facilitate a consistent and harmonised approach for the effective use of Precautionary Allergen Labelling (PAL) so that the food processor can communicate to consumers with food allergies, about the risk of unintended presence of allergens in food due to cross-contact." It is not clear for whom this risk assessment is defined, i.e., whether it is exclusive to processors/operators, governments, or both. For this reason, we suggest adding in section 1. Purpose, who is responsible for communicating to consumers. The following is proposed:	**Chile**

SPECIFIC COMMENTS	MEMBER / OBSERVER
EFA reiterates the need to extend the guidelines to provide with PAL information in non-prepacked food upon consumers request.	**European Federation of Allergy and Airways Diseases Patients' Associations**
These guidelines apply to PAL when used to indicate the risk from the unintended presence of allergens caused by ~~cross-contact in prepackaged~~cross-contact[1] ~~foods~~. The EUMS consider that it is not needed to specifically refer to "pre-packaged foods" in the text of the scope, since the PAL guidelines are annexed to the GSLPF text. The EUMS also consider the footnote redundant, as these guidelines will be part of the General Standard for the Labelling of Prepackaged Foods (CXS 1-1985).	**European Union**
Paraguay agrees with this section	**Paraguay**
COMMENTS ON SECTION 3. DEFINITIONS	
3. DEFINITIONS AOECS disagrees with the definitions included in these draft guidelines as they do not include the definition for coeliac disease. The guidelines should include the definition for hypersensitivity which means food allergy or coeliac disease as per our comments to the revisions of the GSLPF. It is important to note that people with coeliac disease also rely on information about precautionary allergen labelling (PAL) because not all foods are labelled gluten-free.	**Association Of European Coeliac Societies Codex and Regulatory Affairs**
3. DEFINITIONS The EUMS support the terms included and the definitions provided for this section.	**European Union**
3. DEFINITIONS Canada supports the Definitions in the draft annex.	**Canada**
Precautionary allergen labelling is a statement made in the labelling of prepackaged foods to indicate a risk from the unintended presence of an allergen(s) due to cross-contact[2]*,based on risk assessment*. The United States would suggest including the concept of risk assessment as a part of the PAL definition as risk assessment is a critical part of the framework.	**USA**
Allergen means the foods and ingredients listed in sections 4.2.1.4 and, where applicable, 4.2.1.5 of the *General Standard for the Labelling of Prepackaged Foods (CXS 1-1985).* For Paraguay, this definition is not clear, and therefore we believe that improving the wording could contribute to the understanding of the paragraph. Allergen: are substances contained in foods and ingredients listed in sections 4.2.1.4 and, where applicable, 4.2.1.5 of the *General Standard for the Labelling of Prepackaged Foods* (CXS 1-1985) that cause an allergic reaction in persons sensitive to them. Or you could opt for the definition of allergen already described in the document (CXC 80-2020) Code of Practice on Food Allergen Management for Food Business Operators	**Paraguay**
Precautionary allergen labelling is a statement made on the labelling of prepackaged foods to indicate a risk of the unintended presence of an allergen or allergens due to cross-contact[2].	**Paraguay**

SPECIFIC COMMENTS	MEMBER / OBSERVER
Paraguay agrees with the proposed definition.	
4. GENERAL PRINCIPLES	
EFA suggests adding a new paragraph (4.5) under 'General Principles' specifying that PAL must not be used in conjunction with a 'free-from allergen' statement referring to an IgE mediated food allergy. Drawing from a real-life example, it is extremely confusing for consumers to see a 'free-from egg' or a 'free-from milk' statement next to a PAL like 'made in a facility that processes egg' or 'may contain traces of milk', respectively.	**European Federation of Allergy and Airways Diseases Patients' Associations**
In general principles, the term "shall" should be revised to "should" throughout the text to improve the flexibility, thus can be better adapted to national context.	**Thailand**
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~~ reduced below appropriate action levels6 (calculated using ~~these~~ reference dose values in 4.3.1) using relevant allergen management practices. ICGA supports the addition of principle 4.1. Precautionary allergen labelling (PAL) should be limited to situations where allergen presence cannot be controlled despite manufacturers implementing allergen management practices (as per e.g., Codex Code of Practice CXG 80). However, we suggest to remove the word "sufficiently controlled" and replace it with a more specific language as there are various interpretations of what "sufficiently controlled" could mean.	**ICGA**
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~~ reduced below appropriate action levels [3] (calculated using ~~these~~ reference dose values in 4.3.1) using allergen management practices~~.~~. Footnote 3-current footnote that states "action level (mg total protein from the allergen / kg food) = Reference dose (mg total protein from the allergen) / Amount of the food (kg)) ICA supports the addition of principle 4.1. PAL should be limited to situations where allergen presence cannot be controlled despite manufacturers implementing allergen management practices. However, we suggest removed the word "controlled" and replacing it with the language above as there are various interpretations of what "controlled" could mean.	**International Confectionery Association**
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~~ demonstrated to result in an exposure which is below the reference dose using these allergen management practices. Comment: We suggest the word "controlled" be replaced with "demonstrated to result in an exposure which is below the reference dose" as shown above. There may be various interpretations of what "control" means, including whether if PAL is used, then presence of allergens does not need to be controlled.	**ICGMA**
4.1 In EFA's view, PAL needs to become mandatory labelling. If PAL is kept voluntary (as it currently is in most jurisdictions), uncertainty will remain for consumers with food allergies as to whether a food is safe for them. This uncertainty would be even greater in cases where a food does not carry a PAL statement, as the patient would have no way to know if a proper risk assessment has been performed. Therefore, EFA recommends subsituting 'shall' with 'must' throughout the document.	**European Federation of Allergy and Airways Diseases Patients' Associations**

SPECIFIC COMMENTS	MEMBER / OBSERVER
4.1 The EUMS support principle 4.1	**European Union**
4.1 Australia notes the Expert Committee Part 3 summary and conclusions that the use of PAL is not appropriate where deviations from allergen management practices may occur. Codex guidelines on allergen management practices have been established under CXC 80-2020, and we therefore support the inclusion of this principle. However, for consistency, Australia proposes minor edits for ensure consistency with CXC 80-2020 as follows: 4.1 Effective allergen management policies, practices and controls …. etc.	**Australia**
4.1 Regarding the general principles, Chile proposes a modification in the wording of section 4.1. In the end, when "cannot be controlled" is mentioned, the wording should be maintained as mentioned at the beginning, that is; “when it cannot be prevented or, up to the reference dose (RfD)”. It is not well understood what the word "control" refers to.	**Chile**
4.1 We recommend that "controlled" is replaced with "reduced to or maintained at a level below the reference dose".	**IFU**
4.1 New Zealand supports the intent of 4.1 that PAL should only be used when despite all efforts to minimize the unintended presence of allergens it is likely that unintended presence of an allergen/s above the threshold levels in 4.3 remains. However, we consider the term ‘sufficiently controlled’ to be subjective and propose that this either be replaced by: ‘eliminated or reduced to below the action levels calculated from the reference dose/s listed in 4.3’ or that the words ‘sufficiently controlled’ be defined in a foot note such as: ‘sufficiently controlled’ means eliminated or reduced to below the action levels calculated from the reference dose/s listed in 4.3 using the allergen management practices as outlined in the Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020). We consider this takes away any subjectivity as to when PAL should and shouldn’t be used. Drafting would then read either: 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 eliminated or reduced to below the action levels calculated from the reference dose/s listed in 4.3 using these allergen management practices. Or 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. (footnote) *sufficiently controlled means eliminated or reduced to below the action levels calculated from the reference dose/s listed in 4.3 using the allergen management practices as outlined in the Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020).	**New Zealand**
4.1 New Zealand supports the intent of 4.1 that PAL should only be used when despite all efforts to minimize the unintended presence of allergens it is likely that unintended presence of an allergen/s above the threshold levels in 4.3 remains. However, we consider the term ‘sufficiently controlled’ to be subjective and propose that this either be replaced by: ‘eliminated or reduced to below the action levels calculated from the reference dose/s listed in 4.3’ or that the words ‘sufficiently controlled’ be defined in a foot note such as: ‘sufficiently controlled’ means eliminated or reduced to below the action levels calculated from the reference dose/s listed in 4.3 using the allergen management practices as outlined in the Code of Practice on Allergen Management for	**New Zealand**

SPECIFIC COMMENTS	MEMBER / OBSERVER
Food Business Operators (CXC 80-2020). We consider this takes away any subjectivity as to when PAL should and shouldn't be used. Drafting would then read either: 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 eliminated or reduced to below the action levels calculated from the reference dose/s listed in 4.3 using these allergen management practices. Or 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. Footnote:*sufficiently controlled means eliminated or reduced to below the action levels calculated from the reference dose/s listed in 4.3 using the allergen management practices as outlined in the Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020).	
4.1 There may be various interpretations of what "control" means, including that if PAL is used, then the presence of allergens does not need to be controlled. As shown below, ISDI suggests the following changes: "…proven or predicted to result in an exposure which is below the reference dose…" "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 proven or predicted to result in an exposure which is below the reference dose using these allergen management practices".	**International Special Dietary Food Industries**
4.1 FIA suggest to replace the word "sufficiently controlled" with "sufficiently reduced to below the reference dose" as there may be different and unintended interpretations of what "control" means. One such interpretation could be that if PAL is used, then the presence of allergens does not need to be controlled.	**Food Industry Asia**
4.1 General comment: Canada supports general principal 4.1, that the use of PAL shall be restricted to those situations in which the unintended presence of an allergen(s) cannot be sufficiently controlled.	**Canada**
4.1 Effective management practices and controls to prevent or minimize the unintended presence of allergens caused by cross-contact ~~shall~~ should 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.	**Thailand**
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	**ICBA**

SPECIFIC COMMENTS	MEMBER / OBSERVER
be sufficiently ~~controlled~~ reduced to or maintained at a level below the reference dose using these allergen management practices. ICBA suggests the word “controlled” could be replaced with “reduced to or maintained at a level below the reference dose” as shown above. The reason for this is there may be various interpretations of what “control” means, including that if PAL is indeed used, then presence of allergens does not need to be controlled.	
4.2 ICGA could agree that a decision to use PAL should be based on the findings of a risk assessment which may include, but is not limited to, a quantitative risk assessment (QRA). It is important to continue emphasizing in this draft that while quantitative risk assessment is an important element, it should not be used alone. Decisions on PAL should have a multipronged approach and could include a range of risk management tools including both quantitative risk and qualitative assessments. PAL should never be used in place of Good Manufacturing Practices (GMPs) e.g., run scheduling, sanitation, validation, etc. ICGA would like to highlight the importance of the work of the CCFH to guide practices for these risks assessments (see adopted CXG 80). We believe there should be an information source provided about conducting QRA by food businesses operators. A source such as an expert guidance or interpretation for QRA should be referenced to assist national governments and food business operators in the best practices for conducting a QRA. This would ensure a consistent, robust approach is applied globally. These concerns could be also referred to CCFH for further inputs.	**ICGA**
4.2 ICA agrees that the decision to use PAL should be based on the findings of a risk assessment which can include, but not limited to, quantitative risk assessment (QRA). It is important to continue emphasizing in this draft that while quantitative risk assessment is an important element, it should not be used alone. Decisions on PAL should have a multipronged approach can include a range of risk management tools including both quantitative risk and qualitative assessment. PAL should never be used in place of Good Manufacturing Practices (GMPs) e.g., run scheduling, sanitation, validation, etc. ICA highlights the importance of the work of CCFH to guide practices for these risks assessments. We believe there should be an information source provided about conducting QRA by food businesses operators. A source such as an expert guidance or interpretation for QRA should be referenced to assist national governments and food business operators in the best practices for conducting a QRA. This would ensure a consistent, robust approach is applied globally.	**International Confectionery Association**
4.2 The decision to use PAL should be based on the findings of a risk assessment which shall include, ~~but is~~ where possible and not limited to, quantitative risk assessment. While quantitative risk assessments should be encouraged, they are not always possible. For example, the limit of quantification for some test methods may be above the reference dose so it is not possible to know whether the level of above or below the reference dose. Calculations are also not always possible given that ingredient suppliers may not always provide information on the level of allergens in their ingredients. Therefore, IDF suggests the proposed rewording.	**IDF/FIL**
4.2 Comment: We believe there should be an information source provided about conducting a Quantitative Risk Assessment (QRA) by food businesses operators. A source such as an expert guidance or interpretation for QRA should be referenced to assist national governments and food business operators in the best practices for conducting a QRA. This would ensure a consistent, robust approach is applied globally.	**ICGMA**
4.2 The intended use of PAL is that it should only be used when, following a thorough risk assessment, a genuine risk of allergen cross contact is identified that cannot be removed through risk management actions. Therefore, only in cases where there is a true risk of cross contact it should be allowed.	**Association Of European Coeliac Societies Codex and Regulatory Affairs**

SPECIFIC COMMENTS	MEMBER / OBSERVER
4.2 EFA proposes to change this paragraph as follows: 'The decision to use PAL should be based on the findings of a risk assessment which shall include, but is not limited to, quantitative risk assessment. The quantitative risk assessment must be factual and analytical of the cross-contact that actually takes place, with an eye to avoid PAL labelling in cases where contamination is highly unlikely to happen'	**European Federation of Allergy and Airways Diseases Patients' Associations**
4.2 The decision to use PAL ~~should~~ shall be based on the findings of a risk assessment which shall include, but is not limited to, quantitative risk assessment. The EUMS support principle 4.2 with an editorial modification.	**European Union**
4.2 In principle, Australia supports the proposed general principle 4.2. However, we consider that the principle needs to more clearly reflect the advice from the Expert Committee. The Expert Committee's Part 3 summary and conclusions state that PAL is to be used when the unintended allergen presence (UAP) exceeds the relevant reference dose (RfD), and to not use PAL when UAP does not exceed the relevant RfD. Australia therefore considers that a quantitative risk assessment should be part of any decision to use PAL. Qualitative risk assessment can be used, but only in addition to, and not as a replacement for, quantitative risk assessment. Therefore, we propose amending principle 4.2 be amended to better reflect the Expert Committee's flowchart (as attached to the Part 3 summary and conclusions report) as follows: The decision to use PAL shall be based on the findings of a risk assessment that quantifies the possible unintended allergen presence.	**Australia**
4.2 in section 4.2, Chile believes that there should be a quantitative risk assessment or risk interpretation guide, both for food companies and for governments that regulate the matter in general, in order to can standardize what this point refers to, thus opting to execute the best practices available, as a reference, thus giving coherence and consistency between countries. At the same time, it is not clear for whom this risk assessment is defined, ie if it is exclusively for processors/operators, for governments, or both. For this reason, we suggest adding in section No. 1-Purpose, who is in charge of communicating to consumers. It is proposed: "Facilitate a consistent and harmonized approach to the effective use of Precautionary Allergen Labeling (PAL) so that the developer of the food can communicate to consumers with food allergies about the risk of unintended presence of allergens in food due to cross-contact.	**Chile**
4.2 It is suggested that a reference source be included to assist governments and business operators apply best practice for conducting a quantitative risk assessment.	**IFU**
4.2 New Zealand supports PAL being restricted to situations where, despite all practicable measures being taken, there is a real risk of the unintended presence of an allergen due to cross-contact. As currently drafted, the proposed text requires a quantitative risk assessment to determine whether PAL is used or not. New Zealand requests clarification whether this is the intent or whether the intent was to also allow for situations in which a quantitative risk assessment is not possible.	**New Zealand**
4.2 New Zealand supports PAL being restricted to situations where, despite all practicable measures being taken, there is a real risk of the unintended presence of an allergen due to cross-contact. As currently drafted, the proposed text requires a quantitative risk assessment to determine whether PAL is used or not. New Zealand requests clarification whether this is the intent or whether the intent was to also allow for situations in which a quantitative risk assessment is not possible.	**New Zealand**

SPECIFIC COMMENTS	MEMBER / OBSERVER
4.2 In principle 4.2, It should be noted that there are still limitations in the current analytical methods of allergen for quantitative risk assessment. The options for other risk assessment approaches should be included. Hence, we propose to revise the text to provide greater flexibility, for example, "The decision to use PAL should be based on the findings of a risk assessment which could be either qualitative risk assessment or quantitative risk assessment. The use of quantitative risk assessment is preferred when sufficient data and suitable method of analysis are available." To ensure that it is practical for food manufacturers to follow this principle without excessive burdens in implementation, we propose that CCFL should seek advice from CCMAS on standardized analytical methods and sampling of allergens for undertaking quantitative risk assessments. The general principles may be reconsidered afterwards. It is necessary to note that consumers with a food allergy may face the risk of unintentional allergen cross-contamination if PAL is not declared due to a lack of capacity to conduct a quantitative risk assessment, especially when the actual risk of allergen cross-contact is present.	**Thailand**
4.2 ISDI believes that while quantitative risk assessments should be encouraged, they are not always possible. For example, the limit of quantification for some test methods may be above the reference dose so it is not possible to know whether the level of above or below the reference dose. Calculations are also not always possible given that ingredient suppliers may not always provide information on the level of allergens in their ingredients. Therefore we believe this should be reworded to allow for qualitative risk assessments where quantitative risk assessments are not possible: "4.2 The decision to use PAL should be based on the findings of a risk assessment which shall include where possible, but is not limited to, quantitative risk assessment." ISDI believe there should also be an information source provided about conducting a Quantitative Risk Assessment (QRA) by food businesses operators. A source such as an expert guidance or interpretation for QRA should be referenced to assist national governments and food business operators in the best practices for conducting a QRA. This would ensure a consistent, robust approach is applied globally.	**International Special Dietary Food Industries**
4.2 While quantitative risk assessments should be encouraged, they are not always be possible. For example, the limit of quantification for some test methods may be above the reference dose so it is not possible to know whether the level of above or below the reference dose. Calculations are also not always possible given that ingredient suppliers may not always provide information on the level of allergens in their ingredients. Therefore, FIA would like to suggest the following amendment : "The decision to use PAL should be based on the findings of a risk assessment which shall include, where possible and not limited to, quantitative risk assessment."	**Food Industry Asia**
4.2 The decision to use PAL should be based on the findings of a risk assessment which ~~shall include, but is not limited to,~~ could be either qualitative risk assessment or quantitative risk assessment. The use of quantitative risk assessment is preferred when sufficient data and suitable method of analysis are available.	**Thailand**
4.2 Specific comment: Canada notes an apparent conflict between proposed text in 4.2 and 4.3. Section 4.2 recognises while quantitative risk assessment can be used in decisions on whether PAL should be added to the label of a food, it is not the only relevant approach for assessing whether or not PAL is required. Section 4.3 does not seem to	**Canada**

SPECIFIC COMMENTS	MEMBER / OBSERVER
recognise this because it suggests that the RfDs in the table to 4.3.1 are the only relevant, decisive factor for whether PAL should be used. Canada believes that a risk assessment should be broader than just quantitative and that frequency of the presence of the allergen in the food is an important consideration in the risk assessment.	
4.2 Specific comment: Canada supports the general principle in 4.2 that the decision to use PAL should be based on the findings of a risk assessment. Canada is also supportive of the fact that the risk assessment should include but not be limited to a quantitative risk assessment. Canada suggests that more guidance/specificity may be required regarding what a risk assessment is in the context of food allergies/PAL and how food manufacturers can conduct a risk assessment.	**Canada**
4.2 The decision to use PAL should be based on the findings of a risk assessment which ~~shall~~ should include, but is not limited to, quantitative risk assessment.	**Thailand**
4.2 There should be an information source provided about conducting a Quantitative Risk Assessment (QRA) by food businesses operators. A source such as an expert guidance or interpretation for QRA should be referenced to assist national governments and food business operators in the best practices for conducting a QRA. This would ensure a consistent, robust approach is applied globally.	**ICBA**
4.1 Chile proposes a drafting amendment to section 4.1. At the end when "cannot be controlled" is mentioned, the wording should be maintained as mentioned at the beginning, which is; "when it cannot be prevented or, up to the Reference Dose (RfD)". It is not clear what the word "control" refers to.	**Chile**
4.1 The use of PAL shall be limited to situations where the unintended presence of one or more allergens cannot be sufficiently controlled "despite these allergen management practices". It is our believe that the proposed amendment of the text would make such text clearer.	**Paraguay**
4.3 ICGA would like to seek clarification on this principle as it could be interpreted that PAL may only be justified when a formal quantitative risk assessment and numerical action levels have been calculated by using the RfD mentioned in table 4.3.1. As noted in the proposed text for section 4.2, the principle above does not appear to address other allergen management practices such as qualitative tools that may be used as part of the decision-making process on when a PAL statement is appropriate. It is important not to restrict flexibility in applying such tools. We respectfully ask CCFL47 to address this matter before adopting the principle set in this section 4.3.	**ICGA**
4.3 ICA requests clarification on this principle as it could be interpreted that PAL can only be justified with a quantitative risk assessment and action levels calculated using the RfD in table 4.3.1. As noted in 4.2, the principle above does not appear to address other allergen management practices such as qualitative tools that may be used as part of the decision-making process on when a PAL statement is appropriate. It is important not to restrict flexibility in applying these tools. We ask the Committee to address this matter before adopting principle 4.3.	**International Confectionery Association**
4.3 Best practice is that PAL shall only be used if the presence of a protein from an allergen is equal to or above the action level[3] for this allergen, using the listed reference dose values in 4.3.1. Given that it is not always possible to quantitatively determine whether the protein from an allergen is equal to or above the action level, this should be reworded to set the use of reference doses as best practice but not mandatory so that qualitative risk assessments are still permitted as a basis for using PAL.	**IDF/FIL**

SPECIFIC COMMENTS	MEMBER / OBSERVER
4.3 ~~PAL shall only be used if the presence of~~ Where a ~~protein from~~ quantitative risk assessment indicates exposure to an allergen that is ~~equal to or~~ above the ~~action level~~established reference dose for that allergen as listed in section 4.3.1, PAL should be applied. Under specific circumstances, other risk factors may support deviation from these values. [3] ~~for this allergen, using the listed reference dose values in 4.3.1.~~ Comment: We would also like to call attention to the following: • The wording of this principle is at odds with the wording in 4.2. • 4.3 suggests that PAL can only be justified with a quantitative risk assessment and that the RfD in the table is always the decisive threshold. However, there may be other factors to consider in addition to the results of a quantitative risk assessment. As per allergen management practices there are a range of both qualitative and quantitative tools that may be applied as part of decision-making on when PAL is appropriate. It is important not to restrict flexibility in applying these tools. • Further, the RfD is only helpful for the dose of an allergen, not the frequency. Where frequency is expected to be high or expected to be low, a separate conclusion on PAL may be more appropriate. We suggest rewording 4.3 as follows: Where a quantitative risk assessment indicates exposure to an allergen that is above the established reference dose for that allergen as listed in section 4.3.1, PAL should be applied. Under specific circumstances, other risk factors may support deviation from these values.	**ICGMA**
4.3 While individuals with a wheat allergy can react to any single protein found in wheat, individuals with coeliac disease are affected by the gluten fraction, which accounts for approximately 80% of the total protein content of wheat. Furthermore, gluten is not only present in wheat, but other cereals containing gluten, yet only wheat has been included in these guidelines. Therefore the current proposed method for using PAL does not take into account the unintentional presence of other 'cereals containing gluten' that are listed in 4.2.1.4 of the GSLPF when using PAL.	**Association Of European Coeliac Societies Codex and Regulatory Affairs**
4.3 PAL shall only be used if the presence of a protein from an allergen is equal to or above the action level[3] for this ~~allergen~~allergen in a specific food, using the listed reference dose values in 4.3.1. The EUMS support principle 4.3 with a modification.	**European Union**
4.3 In relation to section 4.3., we would like to highlight that: • It suggests that only with a quantitative risk assessment PAL is justified; • It suggests that the RfD in the table is always the decisive threshold; • A risk assessment should be broader than just quantitative and the RfD is only helpful on the dose of an allergen but not on frequency. Where frequency is expected to be high or expected to be low, a separate conclusion on PAL may be more appropriate. We would like to emphasise that the risk assessment for unintended allergen presence includes qualitative and quantitative elements. Therefore, other risk factors may be decisive in deviating from the recommended RfDs for a final decision on PAL. Such factors may include: a. the variability in quality and quantity of data across the allergens; b. indicated increased sensitivity of certain population subgroups (e.g., children less than 3,5 years old to milk) and the likelihood that such population subgroups will consume the product; c. the frequency of the incidental contamination level being above the RfD.	**FoodDrinkEurope**

SPECIFIC COMMENTS	MEMBER / OBSERVER
We would also like to raise that analytical capability and performance criteria should not only be considered in the context of final product analysis, because analytical testing is also applied earlier in the supply chain (e.g., for testing ingredients and cleaning validation / verification) and 'surrogate' allergens for which there are assays available with a lower LOQ may be used to assess unintended allergen levels. Such approaches are highly relevant for the quantitative risk assessment of allergen cross contamination and various food businesses across the globe are already applying risk assessment and making PAL decisions based on ED01 based RfDs as a well-recognised approach. The application of quantitative risk assessment needs to be set within the wider context of allergen management within supply chains, and includes understanding data availability and quality for multiple variables including the change of occurrence of cross contact, the form, distribution, frequency and concentration of cross contact resulting from the specific cross contact scenario in question. The evaluation of these and other parameters and how they are used in the context of QRA is the subject of recent stakeholder guidance. It is for this reason that we propose the rewording this section as follows: 4.3 Where a quantitative risk assessment indicates exposure to an allergen that is above the established reference dose for that allergen as listed in section 4.3.1, PAL should be applied. Yet, under specific circumstances, other risk factors may be decisive to deviate below these values.	
4.3 South Africa is of the opinion that Section 4.3 suggests that a quantitative risk assessment justifies the use of precautionary allergen labelling (PAL). However, the presence of allergen residues in particulate form - which in essence cannot be quantified – may also justify PAL. We would therefore recommend the section to be reworded as follows: "Where all allergens or allergen residues can be quantified", PAL should be used if the presence of a the total protein from an allergen is equal to or above the action level for this allergen, using the listed reference dose values in 4.3.1".	**South Africa**
4.3 South Africa suggests the inclusion of the following amendment: "PAL shall only be used if the presence of "the total protein" from an allergen is equal to or above the action level 3 for this allergen, using the listed reference dose values in 4.3.1". The removal of "a" as it implies a single protein. It is recommended to rephrase the clause to echo the units of the reference doses – mg total protein from the allergen.	**South Africa**
4.3 New Zealand considers the term used in the equation for 'action level' (footnote 28) should refer to 'Amount of the food consumed' rather than 'Amount of the food' as per the FAO and WHO (2022). Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens: Part 2: Review and establish threshold levels in foods of the priority allergens (p61). This would then read: Action level (mg total protein from the allergen / kg food) = Reference dose (mg total protein from the allergen) / Amount of the food (kg) New Zealand supports requesting CCMAS provide advice of appropriate methods for undertaking risk assessments to support decisions on the use (or not) of PAL.	**New Zealand**
4.3 New Zealand considers the term used in the equation for 'action level' (footnote 28) should refer to 'Amount of the food consumed' rather than 'Amount of the food' as per the FAO and WHO (2022). Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens: Part 2: Review and establish threshold levels in foods of the priority allergens (p61). This would then read:	**New Zealand**

SPECIFIC COMMENTS	MEMBER / OBSERVER
Action level (mg total protein from the allergen / kg food) = Reference dose (mg total protein from the allergen) / Amount of the food consumed (kg) New Zealand supports requesting CCMAS provide advice of appropriate methods for undertaking risk assessments to support decisions on the use (or not) of PAL.	
4.3 ISDI would like to express its concerns regarding the section as: • It suggests that only with a quantitative risk assessment PAL is justified; • It suggests that the RfD in the table is always the decisive threshold; • A risk assessment should be broader than just quantitative and the RfD is only helpful on the dose of an allergen but not on frequency. Where frequency is expected to be high or expected to be low, a separate conclusion on PAL may be more appropriate. • A quantitative risk assessment may not be possible in cases where the limit of quantification is above the RfD or where a supplier has not provided sufficient information on their ingredients' allergen levels to allow for calculations. Consequently, ISDI suggests rewording this section as follows: "4.3 Best practice is that 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, using the listed reference dose values in 4.3.1."	**International Special Dietary Food Industries**
4.3 Principle 4.3 suggested that PAL can only be justified with a quantitative risk assessment and that the reference dose (RfD) in the table is always the decisive threshold. However, a risk assessment should be broader than just quantitative. Furthermore, the RfD is only helpful for the dose of an allergen and not the frequency. Where the frequency is expected to be high or low, a separate conclusion on the PAL may be more appropriate. FIA suggests the following rewording: "Where a quantitative risk assessment indicates exposure to an allergen that is above the established reference dose for that allergen as listed in Section 4.3.1. PAL should be applied. Under specific circumstances, other risk factors may support deviation from these values."	**Food Industry Asia**
4.3 "When quantitative risk assessment is performed, PAL ~~shall~~ should only be used if the presence of a protein from an allergen is equal to or above the action level[3] for this allergen, using the listed reference dose values in 4.3.1. For the text in principle 4.3, it should also be revised to provide greater flexibility, for example, "When quantitative risk assessment is performed, PAL should only be used if the presence of a protein from an allergen is equal to or above the action level3 for this allergen, using the listed reference dose values in 4.3.1."	**Thailand**
4.3 PAL shall ~~only~~ be used if ~~the presence of a protein from~~ an allergen ~~is~~ may be present in an amount equal to or above the action level[3] for this allergen, using the listed reference dose values in 4.3.1. General comment: Canada believes that the guidelines on the use of PAL should be expanded to address the question of frequency of the presence of the allergen, particularly in the case of sporadic presence of allergens in a food (where a small percentage of units of the food in a particular lot contain the allergen but most of the units do not) as well as to address circumstances where the amount of allergen in a lot of the food from cross contact fluctuates and is sometimes above but sometimes below the action level. Canada suggests that this may either require further consideration in the PAL guidelines and/or advice from the FAO/WHO Ad hoc Expert Committee. Specific comment:	**Canada**

SPECIFIC COMMENTS	MEMBER / OBSERVER
Canada notes that it is not the presence but the amount present that should be referenced. In addition, Canada suggests that the wording “the presence of a protein from an allergen is equal to or above” does not reflect the fact that cross contact is often sporadic or that the amount of allergen present can vary significantly within a lot of product. This is why PAL statements often use wording like “may contain” or “may be present”. Canada is suggesting some changes in the wording to 4.3 that reflect the fact that the allergen may not always be present in all of the product when PAL is used. Canada agrees with the general principle that the unintended presence of allergens at levels above the RfDs (which are based on the ED05 values) should result in the use of PAL. However, Canada suggests that there may also be situations where the unintended presence of allergens below the ED05 level could justify the use of PAL and that a prohibition against use of PAL below the RfD should be reconsidered. As one example, a product produced and distributed in large quantities that contained unintended allergen presences (UAP) at levels between the ED01 and ED05 would be predicted to provoke numerous allergic reactions. While most of these reactions would be likely to be mild reactions, a manufacturer of such a product might still wish to apply PAL. For this reason, Canada does not support the prohibition in 4.3 against the use of PAL at levels below the RfDs and suggests removing the word “only” from 4.3.	
4.3 ICBA calls attention to the following: • 4.3 suggests that PAL can only be justified with a quantitative risk assessment and that the RfD in the table is always the decisive threshold. However, a risk assessment should be broader than just quantitative. • Further, the RfD is only helpful for the dose of an allergen, not the frequency. Where frequency is expected to be high or expected to be low, a separate conclusion on PAL may be more appropriate. We suggest rewording 4.3 as follows: Where a quantitative risk assessment indicates exposure to an allergen that is above the established reference dose for that allergen as listed in section 4.3.1, PAL should be applied. Under specific circumstances, other risk factors may support deviation from these values.	**ICBA**
4.2 On the other hand, in section 4.2, Chile believes that there should be a guide for quantitative risk assessment or risk interpretation, both for food companies and for governments that regulate the matter in general, so what this point refers to can be standardized, thus opting to implement the best available practices, as a reference, thus giving coherence and consistency between countries. At the same time, it is not clear for whom this risk assessment is defined, i.e., whether it is exclusive for processors/operators, governments, or both. For this reason, we suggest adding in section N° 1-Purpose, who oversees communicating to consumers. It is proposed: "Facilitate a consistent and harmonised approach for the effective use of Precautionary Allergen Labelling (PAL) so that the food processor can communicate to consumers with food allergies about the risk of unintended presence of allergens in food due to cross-contact."	**Chile**
4.2 we agree.	**Paraguay**
Note 3 South Africa suggests inclusion of the following amendments: As it is not clear what is meant by “Amount of the food”.	**South Africa**

SPECIFIC COMMENTS	MEMBER / OBSERVER
Action level (mg total protein from the allergen / kg food) = Reference dose (mg total protein from the allergen) / "Food exposure amount (kg)".	
Note 3 Action level (mg total protein from the allergen / kg food) = Reference dose (mg total protein from the allergen) / Amount of the food consumed (kg)	**Thailand**
Note 3 For converting the reference doses into action levels, the formula included as a footnote in section 4.3 should be revised to “amount of food consumed”. It could be referenced to Ta-ble 11 in the full report of the FAO/WHO Expert meeting Part 2: review and establish threshold levels in foods of the priority allergens for additional relevant data.	**Thailand**
4.3 The Dominican Republic wishes to make the following proposals: Modify 4.3: - PAL shall only be used if the presence of an allergen protein is equal to or greater than the action level for that allergen[3], using the reference dose value indicated in 4.3.1, Proposal 4.3: When allergens can be quantified, PAL shall be used if the presence of an allergen protein is equal to or greater than the action level for that allergen, using the reference dose value indicated in 4.3.1, "which are neither exhaustive nor definitive". In addition, the Dominican Republic suggests adding the following foot note: Section 4.3.1 should be updated “when establishing reference doses for other allergens.¨	**Dominican Republic**
4.3 We consider that the quantitative risk assessment should not be decisive when determining the use of PAL (Precautionary Allergen Labeling), as proposed in item 4.2. On the other hand, consideration should be given regarding whether the RfD (recommended Reference Dose) would correspond to the allergen itself or the possible presence of the total allergens in the final food or in their simultaneous consumption with other foods in a similar situation. Also, considering that it may be necessary to inform the consumer about the potential presence of an allergen even though it does not have an established Codex threshold. Therefore, the following drafting proposal is proposed for items 4.2 and 4.3: Proposed text: 4.2. Additionally, PAL may be indicated for other allergens that do not have established a particular reference threshold (in section 4.3.1), and that after management by the OEA, the probability of the existence of the presence of a certain allergen is determined.	**Argentina**
4.3 It should read: When you do not have the respective analysis that shows that the levels of an allergen are below what is indicated in section 4.3.1 then PAL should be used. Another comment: For clarity, we suggest the text in the "should read".	**Peru**
4.3 Numeral 4.3. Taking into account the nature and purpose of a precautionary label, which is to serve as a warning to susceptible individuals, it is worth reflecting on whether it is appropriate to base its incorporation on the basis of a Reference Dose (RfD), while taking into account that this dose does not guarantee, by itself, that the entire susceptible population will not be potentially affected by the danger.	**Colombia**

SPECIFIC COMMENTS	MEMBER / OBSERVER
The reference doses indicated in the table of this numeral were derived from the ED (Eliciting Dose) defined by the expert committee. However, it is evident that, even under a conservative value of the ED (e.g., ED01), part of the population could develop an allergic reaction. Therefore, defining the incorporation or not of PAL, under the perspective of an RfD, could result in this exposed population not receiving warning about the presence of the danger in the food. It is suggested to include a note of clarification indicating that the Codex Committee will consider future additions. Deletions or modifications of RFd from the list, considering the advice provided by committees such as FAO/WHO.	
4.3 We agree.	**Paraguay**
4.3.1 References doses ICGA could agree in implementing the ad hoc FAO/WHO Expert Consultations recommendation of basing references doses on ED05.	**ICGA**
4.3.1 References doses ICA does not object to implementing the Expert Committee's recommendation of basing references doses on ED05.	**International Confectionery Association**
4.3.1 References doses The UK supports the establishment of reference doses to inform precautionary allergen labelling, but reserves its judgement on whether these should be established based on ED05 values, pending domestic risk assessment advice.	**United Kingdom**
4.3.1 References doses Comment: We recommend adding a footnote which indicates the FAO/WHO Allergen Expert Panel Report Meeting #2 used an ED05 to derive these RfD. The expert panel agreed that for all priority allergens, the safety objective would be met using ED05. This language is on page XVI of the full report and is an important qualifier that should be indicated here. We also note that in order to future-proof the guidance, it should be noted that the list and the RfDs themselves are not exhaustive nor definitive. This will allow for future updates if necessary.	**ICGMA**
4.3.1 References doses AOECS is concerned about products containing traces of gluten above 20 mg/kg not having a PAL because of the proposed system. AOECS is also concerned about the risk of increasing use of PAL alongside a gluten-free claim and the confusion this will cause for the coeliac community. The approach taken in the PAL guidelines regarding 'Wheat' leads to a 'clash' of different systems: The proposed assessment for use of PAL is based on assigning an action level calculated using a reference dose of wheat (measure as total protein in mg of the allergen) and reference amount using serving size. This differs to how gluten free foods are labelled, gluten free status is measured as < 20 mg/kg as sold to the consumer irrespective of portion size or amount of food consumed. It is important to note that the different systems reflect a fundamental difference in the underlying physiological mechanisms of the autoimmune coeliac disease and IgE-mediated allergies. The immune system of people with coeliac disease can be triggered by an accumulation of small amounts of gluten throughout the day. They are not protected by a threshold based on portion size, because this neglects the accumulation. Many small portions with small amounts of gluten are harmful and therefore the current proposal does not protect people with coeliac disease. This could lead to someone with coeliac disease consuming products that are contaminated with gluten as they may not have a PAL statement. This could also lead to products being labelled gluten-free and in addition having a PAL statement, which would cause confusion for the coeliac consumer.	**Association Of European Coeliac Societies Codex and Regulatory Affairs**

SPECIFIC COMMENTS	MEMBER / OBSERVER
4.3.1 References doses EFA wishes to draw attention to the fact that the use of the proposed reference dose for wheat (5mg total protein/portion size) and the application of a gluten-free claim (which requires the product to contain less or equal to 20ppm of gluten) on the same product might lead to confusing information depending on the portion size of the product. This is due to the scenarios arising from different frameworks: reference dose of total protein per portion for wheat vs. concentration for gluten.	**European Federation of Allergy and Airways Diseases Patients' Associations**
4.3.1 References doses EFA suggests that 'barley' and 'rye' should appear in brackets next to 'wheat' in this list of allergen reference doses, so that both are attached to the wheat reference dose for (ED05 = 5mg). Such an addition is in line with the example of cashew and walnut (and their cross-reactive allergens, pecan and pistachio respectively). This is because, with regards to IgE mediated allergy, wheat is the lead allergen (the equivalent of cashew and walnut) and barley and rye are the cross-reactive allergens.	**European Federation of Allergy and Airways Diseases Patients' Associations**
4.3.1 References doses The EUMS have the following question in relation to the Reference doses: The reference doses in the table are written as total mg protein from the allergen. - Gluten constitutes approximately 80 % of the wheat proteins. For this reason, the EUMS propose that a footnote is added to the table for the entry "wheat" stating: "Gluten constitutes approximately 80% of the wheat proteins". - How shall walnut (and pecan) and cashew (and pistachio) be expressed? The analytical methods to walnut and cashew might cross-react to pecan and pistachio respectively. In addition, this cross-reactivity might also be found among allergic consumers. Thus, the total amount from walnut/pecan and cashew/pistachio respectively might be best to use in the calculations? Should the wording be walnut (including pecan) and cashew (including pistachio)? - How were the confidence intervals for the ED05 considered when the reference doses were set? The EUMS find the explanations for fish and crustaceae (page 89-90 Risk assessment of food allergens: part 2: review and establish threshold levels in foods for the priority allergens: meeting report (who.int)) justifiable but wonder regarding e.g. the tree nuts.	**European Union**
4.3.1 References doses Chile proposes to include a reference to the Reference Dose (RfD) table in section 4.3.1, in relation to the allergen expert panel meeting. [4] FAO/WHO Allergen Expert Panel Meeting #2 pp. XVI (Reference) Regarding Section 4.3.1 and the RfD table: In preparing the guidance for the future, it should be noted that the list and the RfDs themselves are not exhaustive or definitive. This will allow for later review.	**Chile**
4.3.1 References doses With regard to Section '4.3.1 References doses', we suggest adding a footnote to state that, where reference doses (RfDs) for other allergens are established in the future, section 4.3.1 will be updated to include those RfDs. In the table only a RfD for wheat is listed, while in paragraph 4.2.1.4 wheat, rye and barley are defined as priority allergen. Adjust „Wheat" to "Wheat, rye and barley". Currently no quantitative analysis methods are available for each type of cereal. Only the gluten content can be analysed. If gluten is detected, the origin of the contamination and also the type of cereal is often unknown, for example in the case of contamination of the land (agricultural comingling). When testing gluten in most cases no distinction can be made between gluten and its specific cereal origin. When gluten is detected above the action limit but it is unknown whether a specific cereal exceeds the RfD, it is not possible to list those species in a PAL. But the PAL could list 'gluten'. Also the word gluten is a trigger for coeliacs and therefore helpful to mention in a PAL. So the word "gluten" should be added as specified name in appendix II (see before). But this also creates a discrepancy between an action limit based on ED05 and the 20 ppm limit for gluten-free products. For consumption sizes up to 250 grams the action limit is above 20 ppm (10 grams: 500ppm, 50 grams: 100 ppm, 100 grams: 50 ppm). When cross-contact occurs in concentrations of 60 ppm no PAL for gluten containing cereals is needed, although the limit of 20 ppm is exceeded. From a	**FoodDrinkEurope**

SPECIFIC COMMENTS	MEMBER / OBSERVER
strictly technical point of view a PAL for gluten is different from wheat. In case this difference could be made what should be labelled in a PAL: 'gluten' from 20 ppm to the action level and 'wheat (gluten)' above the action level? This is very hard to understand for consumers, industry and enforcement bodies. The difference of the 20 ppm limit and action limit needs further discussion and clarification.	
4.3.1 References doses ISDI also recommends adding a footnote which indicates the FAO/WHO Allergen Expert Panel Report Meeting #2 used an ED05 to derive these RfD. The expert panel agreed that for all priority allergens, the safety objective would be met using ED05. This language is on page XVI of the full report and is an important qualifier that should be indicated here.	**International Special Dietary Food Industries**
4.3.1 References doses FIA recommend the additional of footnote 4 to the heading row of the table "Reference does (RfD) (mg total protein from the allergen)" to indicate that the FAO/WHO Allergen Expert Panel Report Meeting #2 used an ED05 to derive these reference dose values. The expert panel agreed that, for all priority allergens, the safety objective would be met by using ED05 as the foundation for defining RfDs. This language is found on page XVI of the full report and we feel that it is a very important qualifier.	**Food Industry Asia**
4.3.1 References dosesICBA recommends adding a footnote which indicates the FAO/WHO Allergen Expert Panel Report Meeting #2 used an ED05 to derive these RfD. The expert panel agreed that for all priority allergens, the safety objective would be met using ED05. This language is on page XVI of the full report and is an important qualifier that should be indicated here. Footnote 5: FAO/WHO Allergen Expert Panel Meeting #2 pp. XVI	**ICBA**
4.3.1 Reference dose Costa Rica recommends adding a footnote indicating that the meeting No. 2 of the FAO/WHO Allergen Expert Panel report used an ED05 to derive these RFDs. The expert panel agreed that, for all priority allergens, the safety objective would be achieved using ED05.	**Costa Rica**
4.3.1 Reference dose Chile proposes to include a reference to the Reference Dose Table (RfD) in section 4.3.1, in relation to the Allergen Expert Panel Meeting. [4] FAO/WHO Allergen Expert Panel Meeting #2 p. XVI (Reference) With respect to Section 4.3.1 and the RfD table: To prepare guidance for the future, it should be noted that the list and the RfD themselves are not exhaustive or definitive. This will allow for a later review.	**Chile**
4.3.2 EFA strongly advices CCFL to establish reference doses also for the non-priority allergens listed under 4.2.1.5 of GSLPF (allergens identified by national competent authorities to be priority allergens in that specific region/country).	**European Federation of Allergy and Airways Diseases Patients' Associations**
4.3.2 Where a reference dose is not established for a particular allergen by section 4.3.1 above, national or regional authorities can establish a reference dose consistent with recognized principles[4] for the purposes of determining an action level.	**European Union**
4.3.2 Australia supports the establishment of regional reference doses provided they are based on the principles established by the Expert Committee. We note that the Expert Committee is considering the development of reference doses for regional priority allergens, which may also be included in the PAL guidelines.	**Australia**
4.3.2 As regards section 4.3.2, although FoodDrinkEurope supports in principle the possibility for national authorities to determine RfDs that align with recognised principles for determining an action level, we do not believe that such information is	**FoodDrinkEurope**

SPECIFIC COMMENTS	MEMBER / OBSERVER
appropriate or helpful to be included within a Codex text. Moreover, the establishment of a national RfD should be based on robust scientific data. Irrespectively, we would like to emphasize that harmonization of reference doses (by applying the same scientific approach) should be strongly considered to ensure a consistent approach, fair practices in international trade and to enable consumer to make informed and safe food choices.	
4.3.2 ISDI supports in principle the possibility for national authorities to determine reference doses that align with recognized principles for determining an action level, ISDI does not believe that such information is appropriate or helpful to be included within a Codex text. The establishment of a national reference dose should be based on robust scientific data. ISDI therefore suggests deleting section 4.3.2. In addition, ISDI would like to emphasize that harmonization of reference doses (by applying the same scientific approach) should be strongly considered to ensure a consistent approach, fair practices in international trade and to enable consumer to make informed and safe food choices.	**International Special Dietary Food Industries**
4.3.2 The text in section 4.3.2 should be revised to provide a clearer understanding of “recognized principles”. We propose to provide a specific citation or additional information relating to the principles as a footnote in this section.	**Thailand**
4.3.2 General Comment: Canada is supportive of the general principle that national authorities can establish reference doses for allergens not included in 4.3.1. However, Canada notes that this could lead to inconsistencies between reference doses established by different countries. Canada suggests that it would be preferable if reference doses for other allergens could be established by the Ad Hoc expert committee, for example for the list of regional allergens proposed in Section 4.2.1.5 of the GSLPF.	**Canada**
4.3.2 The United States notes that section 4.3.2 will need to be amended as the FAO/WHO experts will provide reference or action levels for allergenic foods on the regional and national list.	**USA**
4.3.2 Costa Rica considers that, if there is consensus on the part of the members to incorporate section 4.2.1.5 in the GSLPF, it is necessary to establish the reference doses for each allergen that the countries consider relevant to include according to their needs. However, it should be taken into consideration that determining such RFDs can be complex and cause variability in the values used in different countries or regions. Therefore, Codex in collaboration with other recognized organizations that generate evidence-based data, could seek alternatives that allow countries to provide the necessary updates of these RfDs and that can be accessed in a public database to ensure consistency and reliability in the values used worldwide.	**Costa Rica**
4.3.2 Numeral 4.3.2. Given with this issue, it is worth considering whether all member countries have the specialized technical capacity to establish reference doses for allergens.	**Colombia**
4.3.2 We agree	**Paraguay**
4.4 EFA maintains that education of all involved actors on allergen labelling (e.g. consumers, healthcare professionals, food business operators, food inspectors), is paramount and must be mandatory. Educational programmes are particularly important here, as they would be key to ensure the appropriate use of PAL among all stakeholders. Moreover, we stress the need to develop a communication guideline addressed to consumers who react to very low doses of the priority allergens (below ED0,5), and how to communicate these principles to them.	**European Federation of Allergy and Airways Diseases Patients’ Associations**

SPECIFIC COMMENTS	MEMBER / OBSERVER
Transparent information, communication and feedback is the most critical part of an overall educational initiative addressed to consumers, as it must address the needs of those that could be at risk of a reaction when allergens are not declared in a PAL statement on the label.	
4.4 The EUMS support principle 4.4	**European Union**
4.4 Australia supports including this provision relating to education programs on PAL as both the ISSLG and Expert Committee (part 3) reports identified this as being important.	**Australia**
4.4 We are of the view that the education program is the responsibility of the national govern-ment to support advocacy and education campaigns on food allergy appropriately to the context of their countries. Therefore, it may not be necessary to include this as part of the general principles of PAL.	**Thailand**
4.4 General comment: Canada supports the general principle that education/information programs are required to ensure understanding and appropriate use of PAL by various stakeholders including consumers with food allergies, food business operators, health care providers and regulatory agencies. Canada believes that a communications strategy must address the needs of those sensitive allergic consumers who can react at levels below whatever reference dose or action level is established for use of PAL. These consumers could still have allergic reactions to foods that do not have any PAL on their label.	**Canada**
4.4 We agree	**Paraguay**
5. PRESENTATION OF PAL	
5. PRESENTATION OF PAL EFA reiterates our call to Codex to propose a comprehensive 'Allergen Statement', which could bring all allergen information in one place, whether related to ingredients (ingredient list), potential cross-contamination (PAL) and other aspects like free-from claims or information on risk assessment or certain agreed symbols.	**European Federation of Allergy and Airways Diseases Patients' Associations**
5. PRESENTATION OF PAL Australia supports inclusion of provisions relating to the presentation of PAL. Both the ISSLG and the Expert Committee highlighted the importance of clarity and consistency.	**Australia**
5. Panama supports the advance of the Proposed Draft. It believes that the proposed text is necessary and in line with the scope of the GSLPF.	**Panama**
5.2 ICGA could support presenting PAL statements in such a way that is as clear as technically possibly and reasonably feasible to the average consumer.	**ICGA**
5.2 ICA supports presenting PAL statements in a way that is the clearest to consumers. Therefore, ICA supports this language	**International Confectionery Association**
5.2 The EUMS have serious concerns if sections 8.3.2 and 8.3.2.1 are maintained in the GSLPF. The EU insists that the use of many separate statements on the label to indicate the presence of allergens in the final product (allergen labelling) and the potential presence of allergens (PAL) will be overloading consumers with information and will not actually train/educate them to always look at the list of ingredient to ensure the absence of any allergens in food.	**European Union**
5.2 For section 5.2, we suggest the following amendments:	**FoodDrinkEurope**

SPECIFIC COMMENTS	MEMBER / OBSERVER
"PAL should appear at the end of the ingredient list (when present) and contrast distinctly from surrounding text, such as through the use of font type, style and/or colour (where applicable, using the same format for PAL as for the allergens in the ingredients list)".	
5.2 South Africa suggests the following amendments to section 5.2: PAL should appear as a separate statement in "immediate proximity at the end of" the ingredient list (when present), and contrast distinctly from surrounding text such as through the use of font type, style and/or colour. "The same font format used for the allergens in the ingredient list shall be used for PAL".	**South Africa**
5.2 In section 5.2, Thailand proposes deleting the text "in the same manner as Section 8.3.1 in the GSLPF". The remaining text is clear as it stands without this clause. In addition, the clause may cause confusion as Section 8.3.1 refers to the declaration in an ingredient list, not as a separate statement.	**Thailand**
5.2 Canada supports the guidance that PAL should appear as a separate statement. Canadian requirements for presentation of PAL require that the PAL statement either start on a new line, immediately after the list of ingredients or the Contains statement if one is present, or that the title wording, e.g. "May contain" must be bolded in order to be seen more readily.	**Canada**
5.2 PAL should appear as a separate statement in the same field of vision as the ingredient list (when present), and contrast distinctly from surrounding text, such as through the use of font type, style or colour ~~in the same manner as Section 8.3.1 in the GSLPF.~~	**Thailand**
5.2.1 ICGA supports a harmonized approach to the language for precautionary allergen labelling. We do not object to the use of "may contain x", as this is commonly used across worldwide jurisdictions. ICGA reiterates its previous reservations about references to 4.2.1.5, should the current proposed draft text of that section would be approved in the revised CXS 1 by CCFL47.	**ICGA**
5.2.1 ICA supports a harmonized approach to the language for precautionary allergen labelling. We do not object to use of "may contain x" as this is commonly used across the food industry.	**International Confectionery Association**
5.2.1 The ISSLG 2019 Consumers and Allergen Labelling Literature Review that contributed to the CCFL evidence base on allergen labelling and precautionary allergen labelling found that certain forms of precautionary statement were less likely to be ignored by food allergic consumers than others, despite there being no directive for PAL phrasing to correspond to different levels of allergen cross-contact risk present. Given the confusion that the use of a range of PAL phrases can cause, we think that to provide consistency and clarity internationally for producers and consumers alike, there should be a single form of wording that is applied to prepacked food products when reference doses are exceeded. We think this wording should be 'not suitable for': Extensive consultation with UK stakeholders found that this clear and unambiguous statement is preferred over other PAL statements. However, if consensus around a single form of wording cannot be found, we suggest that the Codex provision is that only a single form of wording for PAL statements be employed within each national or regional authority, with each authority deciding which wording best communicates the risk of allergen cross-contact to their consumers.	**United Kingdom**
5.2.1 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. Comment: If 4.2.1.5 is deleted above, reference to section 4.2.1.5 should be deleted in this principle as well	**ICGMA**

SPECIFIC COMMENTS	MEMBER / OBSERVER
5.2.1 In line with our views expressed in the previous consultation, the EFA food allergy community holds that 'may contain' is not ideal wording for PAL, as it does not help food allergy consumers distinguish the food product that has undergone risk assessment from the one that has not. Moreover, the 'may contain' option is currently overused and linked to lack of transparency and reduced consumer credibility. Besides, it would be difficult to distinguish between the previous 'may contain' statements with the new ones based on ED05. From different studies among consumers on the issue of PAL wording, different wordings have been flagged as preferred ones. It seems that the need for trustworthiness and consistency of a PAL is be more important than the actual wording. As EFA has stressed in previous feedback processes, the ideal course of action would be to conduct a survey that directly addresses the issue, asking consumers with food allergy on their views. But, given that, at this point, such an initiative would delay the overall process of the guideline, EFA stresses that this challenge would be overcome by making PAL mandatory, based on a unified (harmonised) wording and a defined, evidence-based risk assessment process. In this case, there would be only one option of a statement that a food business operator can use and it would be mandatory to only use this statement after having applied a defined risk assessment.	**European Federation of Allergy and Airways Diseases Patients' Associations**
5.2.1 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. Both the ISSLG literature review and Expert Committee Part 3 Summary and conclusions indicate a consistent and harmonised approach to PAL including a single PAL statement is important for communicating to consumers with food allergy about the risk from unintended allergen presence. For this reason, the EUMS question the need for the addition of 'or equivalent words', as this could allow for deviations from the commonly agreed statement 'may contain'. For this reason, the EUMS propose to delete this reference.	**European Union**
5.2.1 Reference to section 4.2.1.5 should be removed.	**FoodDrinkEurope**
5.2.1 New Zealand supports consistency in the way PAL is labelled and therefore supports the use of a single statement for PAL. We can support PAL statements being required to start with "May contain". We question the addition of '(or equivalent words)' as this appears to go against the ISSLG literature review and Expert Committee Part 3 Summary and conclusions which indicate a consistent and harmonised approach to PAL including a single PAL statement is important for communicating to consumers with food allergy about the risk from unintended allergen presence.	**New Zealand**
5.2.1 New Zealand supports consistency in the way PAL is labelled and therefore supports the use of a single statement for PAL. We can support PAL statements being required to start with "May contain". We question the addition of '(or equivalent words)' as this appears to go against the ISSLG literature review and Expert Committee Part 3 Summary and conclusions which indicate a consistent and harmonised approach to PAL including a single PAL statement is important for communicating to consumers with food allergy about the risk from unintended allergen presence.	**New Zealand**
5.2.1 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.<u>5.2.2 The term "tree nuts" may be used in a PAL statement if the intent is to warn about the possible presence of two or more tree nuts concurrently.</u> Specific Comment: Canada notes that it is common practice to use the term "tree nuts" in PAL when manufacturers have concerns about possible cross contact with multiple tree nuts (two or more of the following : almond, cashew, hazelnut, pecan, pistachio, walnut, Brazil	**Canada**

SPECIFIC COMMENTS	MEMBER / OBSERVER
nut, macadamia nut, pine nut). Similarly PAL statements indicating that a food “may contain fish” or “may contain crustaceans” can also be found on foods. Canada notes that Section 5.2.1, as currently written, would not permit the use of the class/group name like “tree nuts” and would require each tree nut to be listed separately, which may not have been the intent. Canada has suggested wording for a new clause 5.2.2, which could specify that the intent of 5.2.1 was not to prohibit the use of the term “tree nuts”.	
5.2.1 General comment: Canada supports the guidance that PAL statements commence with the wording “may contain” and in general supports the use of the specified names as listed in Section 4.2.1.4 and 4.2.1.5.	**Canada**
5.2.1 Regarding the wording of a Codex PAL statement in section 5.2.1, the United States has the position that it is premature to choose the ideal statement(s) and that additional input from consumer studies of allergenic persons is needed to inform the development of appropriate PAL statements. Is a single statement sufficient or are multiple statements needed? We note the FAO/WHO experts were not of the view that a “may contains” statement was sufficient or suitable for foods with regular unintended allergen presence (UAP) above the reference dose. The United States does not support the use of an indicator symbol as it adds further complexity and takes up label space.	**USA**
5.2.1 Dominican Republic suggests that PAL should appear immediately after the list of ingredients.	**Dominican Republic**
5.2.1 Costa Rica notes that, in paragraph 5.2, there is no clarity regarding the ubication of in cases of single-ingredient foods that do not have an ingredient list but may have had unintentional cross-contact with an allergen.	**Costa Rica**
5.2.1 We agree.	**Paraguay**