CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

E

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

Agenda Item 8.2 **CX/FL 21/46/8 Add.2**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD LABELLING

46th Session

Virtual
27 September – 1 October and 7 October 2021

PROPOSED DRAFT GUIDANCE ON PRECAUTIONARY ALLERGEN LABELLING

Comments in reply to CL 2021/21/OCS-FL

Comments of Algeria, Argentina, Australia, Brazil, Canada, Chile, Colombia, Costa Rica, Ecuador, Egypt, European Union, Guatemala, Indonesia, Japan, Kenya, Malaysia, New Zealand, Peru, Philippines, Saudi Arabia, Singapore, Switzerland, Thailand, Uganda, Uruguay, United States of America, EFA**,** FIA, FoodDrinkEurope, *ICA, ICBA, ICGA, ICGMA, IFT, IFU, IDF, ISDI*

Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2021/21/OCS-FL issued in June 2021. 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 I** and are presented in table format.

ANNEX I

GENERAL COMMENTS	MEMBER/OBSERVER
Algeria proposes in Annex III: • To organize separately the work of the revision of the provisions relating to the labelling of allergens in the GSLPF and the work of the development of Guidelines for the use of precautionary or advisory labelling of allergens; • To incorporate the draft Guidelines for the Use of Precautionary or Advisory Labelling of Allergens as an annex to the draft revision of the GSLPF standard; • To add allergen-related guidance as follows: • Information on the presence of a food and food ingredients causing allergies or intolerances is indicated on or near the food itself, in written form, in a legible and visible manner in cases where the food is: • Presented non-prepackaged at the point of sale to the final consumer and to the community, for example: in places where meals are offered for consumption on the premises (catering establishments); • Packaged at the point of sale at the request of the consumer.	**Algeria**
Algeria proposes to add the following points: • 8.3.5: The foodstuffs and food ingredients proposed for sale on website and which are known to cause allergies or intolerances must be clearly highlighted in the support of the sale; • 8.3.6: When several ingredients or processing aids of a foodstuff come from a single substance or a single product listed in the list of foodstuffs and food ingredients causing allergies or intolerances, the labelling must specify this for each ingredient or processing aid concerned.	**Algeria**
Brazil appreciates the opportunity to comment on the proposed revisions to GSLPF and guidance on precautionary allergen labelling. We would like to thank Australia, United Kingdom and United States of America for coordinating the electronic working group (EWG). In general, we support the proposed allergen labelling revisions to GSLPF and the proposed guidance on precautionary allergen labelling in Appendixes II and III of CX/FL 21/46/8, with a few specific comments. We understand that the two parts of work program on allergen labelling should progress separately as the scientific advice of the Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens for each part of the work will be available in different times. In addition, from the discussions in the EWG and the comments present to CL 2021/09/OCS-FL, it seems that the work on the revision of the GSLPF would be less complex than the guidance on precautionary labelling. Brazil supports the Chairs proposals to draft guidance on the presentation and format of PAL, language and the use of standardised wording for PAL and the need for governments to provide consumer messaging and education programs for communicating risk and increasing consumer understanding of PAL, once the review of provisions relevant to allergen labelling have been considered, and the scientific advice is received.	**Brazil**
We would like to thank Australia, the United Kingdom and the United States of America for preparing the Project Proposal and guideline for consideration at the 46th session of the CCFL, to be held from 26 September to 1 October 2021. We support the progress of this document during the 46th session of the CCFL.	**Colombia**
The European Union and its Member States (EUMS) would like to thank Australia, United Kingdom and the United States of America for the preparation of the document 'CX/FL 21/46/8 – Proposed revisions to the General Standard for the Labelling of Pre-packaged Foods (GSLPF) and guidance on precautionary allergen labelling'.	**European Union**

GENERAL COMMENTS	MEMBER/OBSERVER
The EUMS would like to propose the following modifications to improve further the text.	
Malaysia thanks Australia for preparing this paper.	**Malaysia**
New Zealand strongly suggests that where foods and ingredients listed in 4.2.1.4 are referred to throughout this document that the words "foods and ingredients listed in 4.2.1.4" are used rather than the terms "allergens" or "foods and ingredients known to cause hypersensitivity". The use of different terms in different parts of the guidance causes confusion. The term "allergen" is proposed to be defined in the General standard for the Labelling of Prepackaged Foods (CXS 1-1985) (GSLPF) and the guideline being developed on precautionary labelling and therefore will have a specific meaning. The list at 4.2.1.4 may be broader than allergens as defined in these two documents and will be the result of advice from the FAO/WHO expert group	**New Zealand**
In principle, we are in agreement with the proposed draft. We agree with the approach that has been proposed to process first the revision of CXS 1-1985 and then the guidance on precautionary allergen or advisory labelling.	**Thailand**
We appreciate the preparation of this document, and the opportunity to provide our comments.	**Uruguay**
ICA generally supports the development of such guidelines as they are much needed to avoid undue destructions of foods which could otherwise be suitable for human consumption, especially when trying to reduce food destructions and undue food wasting practices especially at border inspection posts. ICA members look forward to the discussions to be held at CCFL46 and would like to provide preliminary thoughts and minor edits to the text. ICA recognizes that the Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens recently released their summary conclusions on establishing threshold levels in foods of the priority allergens. These recommendations should be included throughout this work	**ICA**
A few improvements are purpose for consistency and clarity between Codex texts. For section 1 on purpose, we recommend to add the word 'potential' to make clear that there is only potential/possible unintentional presence of allergens from cross-contact: To facilitate consistent and harmonised approaches to the effective use of [precautionary allergen or advisory labelling] (PAL) for communicating to consumers with food allergy about the risk from the potential unintentional presence of allergens in food due to cross-contact. For section 2.1 we propose the following revisions to be consistent with the definition of precautionary allergen labelling: 2.1 These guidelines apply to PAL when used to indicate the possible unintentional presence of allergens during processes such as the production, manufacture and transport of food caused by cross-contact in prepackaged foods that are within the scope of the General Standard for the Labelling of Prepackaged Foods (CXS 1-1985). For section 2.2, we propose the following revisions to be consistent with the draft purpose section: 2.2 The Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020) provides guidance on effective management practices and controls to prevent or minimise the unintentional presence of allergens in food due to cross-contact	**IDF**
The Institute of Food Technologists (IFT) thanks the CCFL Committee chairs and the EWG for the opportunity to comment on the Food Allergen proposals. IFT strongly recommends that allergen labelling guidance be based on food, nutrition and consumer sciences, while also accounting for commercial practice. IFT supports the efforts of Codex on updating the General Standard for the Labelling of Prepackaged Foods (CXS 1-1985, GSLPF) regarding the labelling of food allergens. Additionally, IFT believes that the Joint FAO/WHO Expert Consultation report of May 10, 2021 provides insightful information that should be taken into account in the Codex allergen guidelines.	**IFT**
The International Council of Beverages Associations (ICBA) appreciates the work of Australia, the United Kingdom, and United States of America in leading this important work. As requested, ICBA has provided responses to the questions posed in the Circular Letter as well	**ICBA**

GENERAL COMMENTS	MEMBER/OBSERVER
as added a table with specific comments on the proposed draft revisions to the General Standard for the Labelling of Prepackaged Foods (CXS 1-1985) (Part 1) and the proposed draft guidance on precautionary allergen labelling (Part 2).	
ICGA would like to thank the drafters for the opportunity to provide technical inputs to the proposed revised text of the relevant provisions in CXS 1 as well as the new proposed guideline text on precautionary allergen labelling. ICGA generally supports the development of such guidelines as they are needed to avoid undue destruction of foods that could otherwise be suitable for human consumption, especially when trying to reduce food waste.	**ICGA**
The response of the European Federation of Allergy and Airways Diseases Patients´ Associations (EFA) in this request for comments is strongly supported by the following organisations representing consumers with food allergy: – SOS Alergia - Argentina – Allergy and Anaphylaxis Australia – Alergia Alimentar - Brazil – Food Allergy Canada – Creciendo con Alergias - Chile – The Hong Kong Allergy Association - Hong Kong – Yahel - Israel – Atopicco - Japan – Allergy New Zealand – Allergy and Immunology Awareness Programme - Qatar – Nederlands Anafylaxis Netwerk (NAN) - The Netherlands – Association Allergissima - Switzerland – Food Allergy Research & Education (FARE) - United States EFA and its community of consumers with food allergies stands ready to assist CCFL in its ongoing and future work on allergen labelling or more specifically on PAL by addressing them directly to our community	**European Federation of Allergy and Airways Diseases Patients' Associations(EFA)**
We are in full support with 4.1: PAL should be risk – based. Propose to add: 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, including the use of appropriate reference doses. Any further detail should wait for the consultation on reference doses to be concluded. Until then, we believe 4.2 is too premature in the process and may even cause confusion. Especially the sentence "If a quantitative risk assessment cannot be performed, then PAL should only be applied if any risk of allergen-cross contact identified through a risk assessment cannot be removed through risk management actions, such as segregation and cleaning » is a source of ambiguity and would need more context for us to support. During this consultation, it has already been interpreted differently by different reviewers.	**FoodDrinkEurope**
IFT supports the conclusion of the chairs of the Allergen Labelling Electronic Working Group (EWG) that additional guidance on Precautionary Allergen Labelling (PAL) should take into account the output of the Joint FAO/WHO Expert Consultation, as well as the review of evidence from consumer understanding of PAL being undertaken.	**IFT**
ISDI welcomes the Proposed draft revision of the General Standard for the Labelling of Prepackaged Foods (CXS 1-1985) relevant to Allergen Labelling and would like to congratulate the Chairs of the eWG for the progress made. As a principle, ISDI would like to emphasize that it is important to ensure that terms and definitions in Codex texts on allergen labelling are only defined once and that they are then cross referenced to avoid repetition and discrepancies between these texts.	**International Special Dietary Food Industries(ISDI)**

GENERAL COMMENTS	MEMBER/OBSERVER
Views on the location and appropriate Codex text(s) for the guidance (e.g. an annex to the GSLPF or as standalone guidance)	
Algeria proposes: • To integrate the document regarding allergen labeling as an annex in the General Standard for the Labelling of Prepackaged Foods (GSLPF).	**Algeria**
As the drafting of the guidance is at an early stage, Australia has yet to form a view about the location and appropriate text(s) for the proposed draft guidance. We suggest this is considered once the work on both the review of allergen provisions in the GSLPF and the draft guidance has been further progressed.	**Australia**
Chile agrees with a separate guidance document.	**Chile**
Since allergen labelling and guidelines on the use of precautionary allergen labelling are closely linked, we propose that the work should move forward together. This allows creating consistency and avoiding any misalignment in the texts. We propose that the guidance on precautionary allergen labeling be an annex to the GSLPF to ensure that the user has all the information in one place. As the GSLPF will have provisions related to allergen labeling, it will be appropriate for the PAL guidance to be entered as an annex to the GSLPF rather than a stand-alone document.	**Colombia**
We consider that Appendix III is well structured in terms of precautionary allergen or warning labeling and suggest that it be placed as an annex to the GSLPF.	**Ecuador**
Egypt agrees on the drafts guidance, having regard to setting provisions for allergen declaration of prepackaged food. Egypt suggests establish standard/guideline for allergen declaration of loose food or extended the scope of allergen labelling to involve allergen declaration of loose food as standalone guidance.	**Egypt**
The specific location as to where to put the separate document could be considered, once work has progressed further on it.	**European Union**
Malaysia is of the view that the Proposed draft guidance for the use of PAL in Appendix III shall be located as an annexed to the GSLPF for appropriate and easy reference	**Malaysia**
New Zealand considers the placement of this text should retain links with the text on allergen labelling in the GSLPF. An annex to the GSLPF would meet this aim. We do note however that the proposed new text on information requirements for prepackaged foods when sold via e-commerce may also be an annex to the GSLPF. It is important to ensure the GSLPF does not become so large that text is not easy to find. Therefore, New Zealand could also support this text being a standalone document referenced in the GSLPF. We note that the Code of Practice on Food Allergen Management for Food Business Operators (CXC 80-2020) is a standalone document for the CCFH.	**New Zealand**
Until there is more complete guidance developed for PAL, we believe it is premature to discuss placement at this time.	**Philippines**
Uganda proposes that the appropriate Codex text(s) for the guidance be included in the GSLPF (part1) , since separating them may cause laxity in application	**Uganda**
IDF is of the view that the guidance on precautionary allergen labelling (PAL) should be an annex to the GSLPF so that all information is together / For consistency, ISDI believes that the guidance on precautionary allergen labelling should be an annex to the GSLPF to ensure that the user has all the information in one place.	**IDF/FIL**

GENERAL COMMENTS	MEMBER/OBSERVER
ICA members believe that the guidance on PAL should be located as an annex in the GSLPF	**International Confectionery Association (ICA)**
Until there is more complete guidance developed for PAL, it may be premature to discuss placement at this time.	**Food Industry Asia (FIA)**
Until there is more complete guidance developed for PAL, we believe it is premature to discuss placement.	**IFU**
Until there is more complete guidance developed for PAL, ICBA believes it is premature to discuss placement.	**ICBA**
Given the interrelationship between, and the complexity of the issues involved in, both parts of this work program (i.e. revision of provisions relevant to allergen labelling in the GSLPF (Part 1) and the development of guidance on the use of PAL (Part 2)), the Committee is invited to consider whether the work should continue to be progressed together or separately	
Answer: It is considered that the two texts should continue to advance together in the same GSLPF standard, understanding that it is very important to ensure alignment between both documents. It is also expected that Part 2 will not delay the progress of Part 1.	**Argentina**
Chile agrees that the works should proceed separately.	**Chile**
In the first instance, Costa Rica believes that the revisions of the GSLPF and the elaboration of the guidelines of the PAL should be maintained in the same work to ensure alignment between the two documents. However, if the Committee considered that separating the two works was conducive to progress, Costa Rica would have no objection to separating them.	**Costa Rica**
The EUMS consider that both the revision of provisions relevant to allergen labelling in the GSLPF (Part 1) and the development of the guidance on the use of PAL (Part 2)) are very important. The EUMS believe that these two pieces of work should progress separately, so that they can independently progress and avoid any possible delays related to the publication of related scientific advice at different points in time (e.g. revision of criteria for section 4.2.1.4 of GSLPF, thresholds, and PAL). Furthermore, the EUMS are in favour of dealing with the revision of the GSLPF and PAL separately. This is also considering that the work with PAL needs to take into account hygiene and food safety aspects as well as the CXC 80-2020. This was also mentioned in Report of the Codex Alimentarius Commission of the Forty-third Session, where the Code of Practice on Food Allergen Management for Food Business Operators was adopted, noting that the Code of Practice could be revised in future following scientific advice from FAO/WHO and completion of the work on guidance on precautionary allergen labelling in CCFL and in the Report of the Codex Alimentarius Commission of the Forty-second Session, where it was noted that CCFH should continue to liaise with CCFL on the issue of precautionary labelling to ensure consistency with the work of CCFL.	**European Union**
Saudi Arabia recommend that the text should be revised once the Committee has received the advice of the expert panel. Saudi Arabia in position of continue the development progress for the two parts (GSLPF and PAL) tpgether.	**Saudi Arabia**
Indonesia considers this work program (i.e. revision of provisions relevant to allergen labelling in the GSLPF (Part 1) and the development of guidance on the use of PAL (Part 2) should be progressed together	**Indonesia**
Kenya agrees with recommendation of the eWG that it is a complex issue to simultaneously work on GSLPF and PAL. We propose that the text as proposed for GSLPF be concluded and included in current GSLPF and progressed at Step 5/8. The eWG should then be convened to develop specific principles preferably as guideline for the application of PAL which once completed may be annexed to CXS 1. It is complex to develop both the amendments to GSLPF and PAL simultaneously. It will be important to first agree on the amendments related to allergen then progress to develop the applicable PAL	**Kenya**

GENERAL COMMENTS	MEMBER/OBSERVER
Peru believes that the work must continue to move forward together.	**Peru**
As an overall note regarding the important issues of GSLPF revision and PAL guidance, EFA's recommendation would be to work on these documents separately. The reason is that PAL guidance will probably take more time to be finalized, and is therefore likely to cause unnecessary delays to the revision of the GSLPF.	**EFA**
IDF support the work progressing together as there are interrelationships between the two pieces of work.	**IDF/FIL**
To not delay the work on amending the GSLPF, ICA sees value in progressing the work separately for the time being.	**ICA**
We believe that the revisions to the GSLPF should be allowed to progress ahead of the PAL guidance. However, we note that it is important to ensure alignment between the two documents when possible.	**FIA**
The revisions to the GSLPF should be allowed to progress separately from the PAL guidance. However, we note that it is important to ensure alignment between the two documents where appropriate.	**IFU**
Malaysia is of the view for both proposed drafts on revision of provisions relevant to allergen labelling in the GSLPF (Part 1) and guidance on the use of PAL (Part 2) should continue to be progressed together for better coordination.	**Malaysia**
Although the proposed changes to the GSLPF are more advanced than the draft PAL guidelines, Australia considers the review of allergen labelling provisions in the GSLPF and the development of PAL guidance can continue to be progress together noting that both parts of the work can be progressed separately in the step process if required.	**Australia**
We do not deny carrying out the GSLPF revision and PAL guidelines drafting in parallel, but both of them are influenced by the results of FAO/WHO Expert Committee, and therefore, it may be more efficient to work on both together.	**Japan**
New Zealand can see merit in separating the two pieces of work as proposed. We consider this would allow for the different parts to progress without the risk of delays with one part slowing down the progress of the other. We note the proposed timing of the advice to be received from the FAO/WHO expert group and consider the advice needed to progress part one will likely be received well before the advice required to progress part two. However, we consider the two pieces of work would be strongly inter-related and it will be important that close links are retained between the two parts to ensure consistency of decisions, application and terminology.	**New Zealand**
We believe that the revisions to the GSLPF should be allowed to progress separately from the PAL guidance. However, we note that it is important to ensure alignment between the two documents where possible.	**Philippines**
Switzerland considers that the work should continue to be progressed together	**Switzerland**
Uganda proposes that the work is progressed together for clarity purposes since all the relevant information will be in one standard	**Uganda**
The United States supports separating the work on allergen disclosure from the work on PAL. Completing the work on allergen disclosure and updating the priority list should be a priority as the needed scientific advice is available. The United States notes that the summary report of the FAO/WHO consultation on allergen thresholds has recently been released; however, the final FAO/WHO scientific consultation on PAL statements is not scheduled until October 2021 and a report would not be expected until 2022. As threshold guidelines and concepts have not previously been discussed and debated within either CCFL or CCFH, the United States' position is that translating this scientific advice into clear labeling guidelines will take substantial discussion before reaching agreement. Therefore, the United States has the position that the work on PAL should proceed as a second phase, behind the work of allergen disclosure.	**USA**
ICBA believes that the revisions to the GSLPF should be allowed to progress separately from the PAL guidance. However, we note that it is important to ensure alignment between the two documents where appropriate.	**ICBA**

GENERAL COMMENTS	MEMBER/OBSERVER
We believe that the documents (Part 1) and (Part 2) should continue to be worked on together, as they are topics that go hand in hand.	**Ecuador**
From a technical point of view, Uruguay believes that the two guidelines should be developed together, however, since there is a more advanced process of revising the allergen labelling standard, it is considered that they can move forward separately and once the precautionary labelling guideline is completed, it could be incorporated into the General Standard.	**Uruguay**
SPECIFIC COMMENTS	
TITLE	
Argentina's position: It would be more appropriate to refer to "warning labeling". Since the term "precautionary" may lead to interpretations linked to " principles of precaution or precautionary principles or precautionary approach". In turn, in line with the purpose of the guideline, it is proposed to include in the title and definition the reference to "allergens", being as follows: "allergen warning labeling". Also, having analyzed the definition, it is considered that the primary production stage should be included	**Argentina**
Australia supports 'precautionary allergen labelling' because this reflects the terminology widely used in scientific literature, and is well understood by both industry and consumers. However, we recognise that some countries describe PAL in other ways, such as 'allergen advisory statements'. Therefore, we have proposed a change to the following: PROPOSED DRAFT GUIDELINES FOR THE USE OF [PRECAUTIONARY ALLERGEN LABELLING]	**Australia**
We understand that the terminology 'Precautionary Allergen Labelling' is widely used and understood by scientists, consumers groups, food industry and regulators. **PROPOSED DRAFT GUIDELINES FOR THE USE OF [PRECAUTIONARY ~~ALLERGEN OR ADVISORY~~ ALLERGEN LABELLING]**	**Brazil**
PROPOSED DRAFT GUIDELINES FOR THE USE OF [PRECAUTIONARY LABELLING ~~OR ALLERGEN WARNING LABELLING]~~ OF ALLERGENS] The justification is that "PRECAUTIONARY ALLERGEN LABELING" is a well-understood term.	**Colombia**
The EUMS are in favour of the term "precautionary allergen labelling" which correctly reflects the nature and purpose of the labelling in question. The information on unintentional presence of allergens in food is not intended to advise the consumer but to indicate the allergens that may be present because of a cross-contact.	**European Union**
Indonesia prefers 'Guidelines for the use of Precautionary Allergen Labelling'	**Indonesia**
This is not a comment to the draft at this point, but taking into consideration that has not shown yet the part 3 of the FAO/WHO Expert Committee is supposed to be held latter half this year, PAL details should be discussed after obtaining the results of this.	**Japan**
Uganda proposes the title of proposed guideline to be "Proposed draft guidelines for the use of Precautionary Allergen labelling" and its application in the draft guideline wherever everywhere a contrast between precautionary allergen or advisory labelling appears i.e. in clause 1 and clause 3 Uganda is taking a keen interest on this matter aware of the on-going discussions by FAO/WHO	**Uganda**

GENERAL COMMENTS	MEMBER/OBSERVER
~~**PROPOSED DRAFT GUIDELINES FOR THE USE OF [PRECAURIONARY OR WARNING LABELLING OF ALLERGENS**~~ PROPOSED DRAFT GUIDELINES FOR THE USE OF [PRECAURIONARY OR WARNING LABELLING OF ALLERGENS AND OTHER SUBSTANCES THAT CAUSE HYPERSENSITIVITY Consistency with the content of the standard	**Uruguay**
PAL should be referred to as Precautionary Allergen Labelling, and not as “advisory labelling“. “Precautionary Allergen Labelling” is more specific and descriptive, while also being an already established term within the patients and consumers communities. **PROPOSED DRAFT GUIDELINES FOR THE USE OF [PRECAUTIONARY ALLERGEN ~~OR ADVISORY~~ LABELLING]**	**EFA**
ISDI would propose to modify the title of the document. The term ‘Precautionary Allergen Labelling’ is generally well understood. The ‘Advisory Labelling‘ alternative included conveys a different meaning. ‘Advisory’ in this context means ‘recommended but not compulsory’. To avoid confusion, it is recommended that the title be shortened to Proposed draft Guidelines for the use of Precautionary Allergen Labelling. **PROPOSED DRAFT GUIDELINES FOR THE USE OF** **~~[PRECAUTIONARY ALLERGEN OR ADVISORY LABELLING]~~PRECAUTIONARY ALLERGEN LABELLING**	**ISDI**
ICGMA proposes to modify the title of the document. The terms “Precautionary Allergen Labelling” is generally well understood. The “Advisory Labelling “alternative included conveys a different meaning. “Advisory” in the context means ‘recommended but not compulsory’. To avoid confusion, we recommend that the title be shortened to “Proposed Draft Guidelines for the Use of Precautionary Allergen Labelling” **PROPOSED DRAFT GUIDELINES FOR THE USE OF [PRECAUTIONARY ALLERGEN ~~OR ADVISORY~~ LABELLING]**	**ICGMA**
1. PURPOSE	
To facilitate coherent and harmonised approaches for the effective use of [precautionary allergen labelling or warning labelling] (PAL) to communicate to consumers with food allergies the risk arising from the unintentional presence of allergens in food due to cross-contact. Chile prefers the sentence "precautionary food labelling", although we are not opposed to retaining the two sentences.	**Chile**
To facilitate coherent and harmonised approaches for the effective use of [precautionary allergen labelling ~~or warning labelling~~] (PAL) to communicate to consumers with food allergies the risk arising from the unintentional presence of allergens in food due to cross-contact. In line with the proposal for the title of the document, it is suggested that the term "warning" should be deleted.	**Colombia**
The EUMS are of the opinion that the purpose of the guidelines must be explicit and reflect the main objectives of the PAL in general. In addition, the reference to “advisory labelling” should be deleted. Therefore, the EUMS suggest the following wording: To facilitate consistent and harmonised approaches to the effective use of [precautionary allergen ~~or advisory~~ labelling] (PAL) for communicating to consumers with food allergy about the risk from the unintentional presence of allergens in food due to cross-contact.To ensure that precautionary allergen labelling is effective, risk-based and restrictive: - in providing the consumer with information about a food so that an informed choice of food can be made; - in providing a means for conveying information about the risk from the unintended presence of allergens in the food that may occur; To ensure that no precautionary allergen labelling is made without a risk assessment regarding cross-contact and neither without carrying out other appropriate risk management measures	**European Union**

GENERAL COMMENTS	MEMBER/OBSERVER
The Philippines proposed the following revision: To facilitate consistent and harmonised approaches to the effective use of [precautionary allergen or advisory labelling] (PAL) for communicating to consumers the presence of potential unintentional allergens in food due to cross-contact. The risk of allergen is already known. What consumers should know is that there could be other sources of allergens other than what is in the formulation, thus propose to delete "with food allergy about the risk from the." We also want to make clear that there is only potential/possible unintentional presence of allergens from cross-contact:	**Philippines**
New Zealand strongly supports the term [precautionary allergen or advisory labelling] being kept in square brackets and the term "allergens" be replaced with "foods and ingredients listed in 4.2.1.4" to allow for advice from the FAO/WHO expert group on which substances are appropriate to be included in the guidelines. As unintended presence is often not confirmed but rather a possibility due to cross- contact New Zealand suggests the word "potential" is inserted before unintended for clarity. The text would then read: To facilitate consistent and harmonised approaches to the effective use of [precautionary allergen or advisory labelling] (PAL) for communicating to consumers with food allergy about the risk from the potential unintentional presence of foods and ingredients listed in 4.2.1.4 in food due to cross-contact.	**New Zealand**
To facilitate consistent and harmonised approaches to the effective use of [precautionary allergen or advisory labelling] (PAL) for communicating to consumers with food allergy about the ~~risk from the~~ unintentional presence of allergens in food due to cross-contact. Singapore would propose the amendments to Section 1. Purpose, as below. This is because the current text may read that PAL is intended to communicate to consumer about the risk associated with the unintended presence of allergens in food (i.e. the effects of consuming the food for people with allergies), instead of simply declaring unintended presence of allergens. • To facilitate consistent and harmonised approaches to the effective use of [precautionary allergen or advisory labelling] (PAL) for communicating to consumers with food allergy about the unintentional presence of allergens in food due to cross-contact.	**Singapore**
To facilitate coherent and harmonised approaches for the effective use of [precautionary ~~allergen~~ labelling or warning labelling of allergens and other substances causing hypersensitivity] (PAL) to communicate to consumers with food allergies about the risk arising from the unintentional presence of allergens in food due to cross-contact. consistency with the content, since they are not only allergens according to the definition of these.	**Uruguay**
From our patients´ perspective we disagree to delete the half sentence "although all possible mitigation measures have been taken". While we understand the rationale behind the proposal with reference to the Code of practice (CXC 80-2020), we believe that the message this statement carries is so crucial, that it cannot be stressed prominently enough. EFA recommends to re-insert it from the beginning under the headline "Purpose" of the PAL Guidance. To facilitate consistent and harmonised approaches to the effective use of [precautionary allergen ~~or advisory~~ labelling] (PAL) for communicating to consumers with food allergy about the risk from the unintentional presence of allergens in food due to ~~cross-contact~~cross-contact although all possible mitigation measures have been taken.	**EFA**
ICA supports a purpose of the guidelines as this effectively communicates the potential risk from unintended presence of allergens in foods from cross-contact when all mitigation measures have been taken and exhausted (by commercially feasible and practical mitigation measures have been taken). However, it may be premature to comment on this given the work of the expert Committee on allergens, especially on Part 3 meetings scheduled for October 2021 that specifically deal with PAL.	**ICA**

GENERAL COMMENTS	MEMBER/OBSERVER
2. SCOPE	
2.1	
2.1 These guidelines apply to PAL when used to indicate the possible unintentional presence of allergens caused by cross-contact in prepackaged foodsthat are within the scope of the*General Standard for the Labelling of Prepackaged Foods*(CXS 1-1985). Canada suggests that this guidance should also apply to the use of PAL on any prepackaged foods/ingredients that will be used to make prepackaged foods. If a supplier provides an ingredient in bulk to a food manufacturer there should also be guidance on whether that ingredient needs to have PAL on it when it is shipped by the supplier, so that the food manufacturer who puts it in their products as an ingredient can use this to inform the labelling of the finished food.	**Canada**
2.1 These guidelines apply to PAL when used to indicate the possible unintentional presence of allergens during the production, manufacture and transportation of food caused by cross-contact on prepackaged foods that fall within the scope of the General Standard for the Labeling of Prepackaged Foods (CXS 1-1985). To be consistent with the definition of precautionary allergen labelling.	**Colombia**
The EUMS believe that, for the reasons of clarity and legal certainty, the scope of PAL should be limited to the substances listed in section 4.2.1.4 of the GSLPF. This list is based on scientific knowledge and contain substances for which there is evidence that they can cause hypersensitivity in individuals. The EUMS also consider that the scope of PAL guidelines should also encompass non-prepacked foods. Further, The EUMS maintain that it has to be clear that PAL is restricted to situations where effective management practices and controls to prevent or minimize the potential allergen cross-contact, as outlined in the Code of practice for allergen management, are not further possible. Therefore, the EUMS suggest to replace paragraph 2.2 with the New paragraph 2.2. The previous paragraph 2.2, which refers to CXC 80-2020 is deleted, as the reference to CXC 80-2020 is included in the New text. For that reason, the EUMS propose the following changes to the draft: 2.1 These guidelines apply to PAL when used to indicate the possible unintentional presence of allergens listed in section 4.2.1.4 of the GSLPF, caused by cross-contact in prepackaged foods that are within the scope of the *General Standard for the Labelling of Prepackaged Foods* (CXS ~~1–1985)~~1-1985) and non-prepackaged foods offered to the consumer or for catering purposes.	**European Union**
As per our general comment New Zealand strongly suggests that the term “allergens” be replaced with “foods and ingredients listed in 4.2.1.4” to allow for advice from the FAO/WHO expert group on which substances are appropriate to be included in the guidelines. The text would then read: 2.1 These guidelines apply to PAL when used to indicate the possible unintentional presence of foods and ingredients listed in 4.2.1.4 caused by cross-contact in prepackaged foods that are within the scope of the General Standard for the Labelling of Prepackaged Foods (CXS 1-1985).	**New Zealand**
2.1 These guidelines apply to PAL when used to indicate the possible unintentional presence of allergens caused by cross-contact in prepackaged foods that are within the scope of the *General Standard for the Labelling of Prepackaged Foods* (CXS 1-1985). these guidelines should also apply to ingredient that cause hypersensitivity (non-immune reaction), and not just to allergens (see definition in point 3). Ex: replace "allergens" with " ingredients know to cause hypersensitivity".	**Switzerland**
The Philippines recommends the addition of during processes such as the production, manufacture, transport of food and storage in 2.1 to be consistent with precautionary labelling, to read as: 2.1 These guidelines apply to PAL when used to indicate the possible unintentional presence of allergens during processes such as the	**Philippines**

GENERAL COMMENTS	MEMBER/OBSERVER
production, manufacture, transport of food and storage caused by cross-contact in prepackaged foods that are within the scope of the General Standard for the Labelling of Prepackaged Foods (CXS 1- 1985).	
2.1 These guidelines apply to PAL when used to indicate the possible unintentional presence of allergens caused by cross-contact in prepackaged foodsthat are within the scope of the*General Standard for the Labelling of Prepackaged Foods*(CXS 1-1985). The scope of this draft should be expanded to foods and ingredients known to cause hypersensitivity as it will provide better protection to consumers	**Thailand**
2.1 These guidelines apply to PAL when used to indicate the possible unintentional presence of allergens caused by cross-contact ~~in~~ **[during processes such as the production, manufacture and transport of]** prepackaged foods that are within the scope of the *General Standard for the Labelling of Prepackaged Foods* (CXS 1-1985). The listed processes are not exhaustive e.g. storage is not included. Therefore we suggest to add “processes such as” to make it non-exhaustive list.	**FIA**
2.1 These guidelines apply to PAL when used to indicate the possible unintentional presence of allergens ~~caused~~ during processes such as the production, manufacture and transport of food caused by cross-contact in prepackaged foods that are within the scope of the *General Standard for the Labelling of Prepackaged Foods* (CXS 1-1985). ISDI proposes to revise the text for consistency with the definition of precautionary allergen labelling.	**ISDI**
2.1 These guidelines apply to PAL when used to indicate the possible unintentional presence of allergens caused by cross-contact ~~in prepackaged~~ during production of foods ~~that are~~ within the scope of the *General Standard for the Labelling of Prepackaged Foods* (CXS 1-1985). For consistency with the definition of precautionary allergen labelling we recommend revising the text in 2.1 as indicated.	**ICGMA**
2.2	
~~2.2 The *Code of Practice on Allergen Management for Food Business Operators* (CXC 80-2020) provides guidance on effective management practices and controls to prevent or minimise the potential for allergen cross-contact.~~ Chile proposes to delete this paragraph from the scope and move it to another section of the document, since it does not correspond to the scope of this guideline, being rather a clarification to distinguish between the objective of the *Code of Practice on Allergen Management for Food Business Operators* and these guidelines. Chile believes that this paragraph should be located as a clarification in the purpose, or in a text called a preamble.	**Chile**
The mention of the Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020) is not clear in the scope of the guidelines peresently being studied.	**Colombia**
2.2 The Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020) provides guidance on effective management practices and controls to prevent or minimise the potential for allergen cross-contact. To be consistent with the purpose of this document.	
~~2.2 The *Code of Practice on Allergen Management for Food Business Operators* (CXC 80-2020) provides guidance on~~ . 22 PAL is restricted to situations where unintentional allergen(s) may be present despite implementing effective management practices and	**European Union**

GENERAL COMMENTS	MEMBER/OBSERVER
controls to prevent or minimise the potential ~~for~~ allergen ~~cross-contact~~cross-contact as outlined in The Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020).	
2.2 The *Code of Practice on Allergen Management for Food Business Operators* (CXC 80-2020) provides guidance on effective management practices and controls to prevent or minimise the potential for allergen cross-contact. New Zealand supports the intent of 2.2 and we note that the proposed wording aligns with the wording of CXC 80-2000 however, for consistency of language with the purpose we suggest the words 'potential for allergen cross-contact ' be deleted and replaced with the words 'unintentional presence of foods and ingredients listed in 4.2.1.4' The text would then read: 2.2 The Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020) provides guidance on effective management practices and controls to prevent or minimise the unintentional presence of foods and ingredients listed in 4.2.1.4.	**New Zealand**
2.2 The *Code of Practice on Allergen Management for Food Business Operators* (CXC 80-2020) provides guidance on effective management practices and controls to prevent or minimise the potential for allergen cross-contact.2.3 *The Code of Practice* shall be science- and evidence-based considering the latest research on allergen thresholds, derived from published dose distributions curves or thresholds derived from acceptable doses established by recognized authoritative bodies, including FAO/WHO. ICGA suggests the addition of another paragraph 2.3: "2.3 The Code of Practice shall be science- and evidence-based considering the latest research on allergen thresholds, derived from published dose distributions curves or thresholds derived from acceptable doses established by recognized authoritative bodies, including FAO/WHO." See in particular http://www.fao.org/3/cb6388en/cb6388en.pdf (Part II) and https://cdn.who.int/media/docs/default-source/food-safety/jemra/1st-allergen-summary-report-10may2021.pdf?sfvrsn=c505375a_7 (Part I)	**ICGA**
2.2 The *Code of Practice on Allergen Management for Food Business Operators* (CXC 80-2020) provides guidance on effective management practices and controls to prevent or minimise ~~the potential for allergen~~ unintentional presence of allergens in food due to cross-contact. ISDI proposes to revise the text for consistency with the definition of precautionary allergen labelling.	**ISDI**
2.2 The *Code of Practice on Allergen Management for Food Business Operators* (CXC 80-2020) provides guidance on effective management practices and controls to prevent or minimise ~~the potential for allergen~~ unintentional presence of allergens in food due to cross-contact. For consistency with the definition of precautionary allergen labelling we recommend revising the text in 2.2 as indicated.	**ICGMA**
3. DEFINITIONS	
Australia supports having consistency where possible with other Codex texts including the Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020). We also support considering the proposed definitions once the FAO/WHO scientific advice has been received.	**Australia**
The EUMS consider that it is preferable to only refer to allergens listed in section 4.2.1.4 of the GSLPF. In addition, as the purpose and scope of the guidance on PAL already refer to the concept of “unintentional presence” of substances in question, the EUMS believe that for the sake of coherence, this element should also be maintained in the definition of PAL.	**European Union**

GENERAL COMMENTS	MEMBER/OBSERVER
Therefore, the EUMS propose the following changes:	
Allergen Food allergy Food intolerance Hypersensitivity Peru will review these definitions, contrasting them with other regulations to grant approval to these terms	**Peru**
Philippines agree with the proposed definition of terms for allergens and allergen cross contact. Moreover, we support the use of Precuationary Allergen Labelling (PAL) instead of Advisory Labelling. We also propose to amend the definition of PAL to allow scenarios where cross-contact may occur, to read as: [Precautionary allergen or advisory labelling] is a statement indicating the allergen(s) that may be present in a food due to allergen cross-contact during processes such as the production, manufacture and transport of food, which may occur despite implementing allergen management practices.	**Philippines**
It should include the definition of "hypersensitivity"	**Thailand**
- "Allergen" – add "typically" to the text (see "allergen" definition page 1) - "Precautionary allergen labelling" – it should be stressed that PAL is a statement that can only be used when the food product poses a risk to health of allergic consumers. This risk is assessed, when the unintended allergen presence due to cross-contact is above a (get to agree upon) threshold (action) level. We believe this important aspect should be reflected in the definition of PAL.	**EFA**
In agreement with CCFL use of the definitions for 'allergen' and 'allergen cross-contact' from the CCFH's proposed draft Code of Practice on Food Allergen Management for Food Business Operators for the draft guidelines on PAL. This provides consistency across Codex Committee regulations and recommendations.	**ICA**
In agreement with CCFL use of the definitions for 'allergen' and 'allergen cross-contact' from the CCFH's proposed draft Code of Practice on Food allergen Management for Food Business Operators for the draft guidelines on PAL. This provides consistency across Codex Committee regulations and recommendations.	**ICGMA**
Allergen	
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. We suggest adding the word 'typically' to clarify that not all allergens are proteins. This amendment would help ensuring that the definition is in line with the available scientific knowledge. In addition, CCFL should indicate to CCFH the need to revise this definition in the Code of Practice on Food Allergen Management for Food Business Operators to guarantee consistency between the Codex documents. We can cite the alpha-galactose as an example of a non-protein causal agent for the mammalian meat allergy, according to the following scientific evidence: Rutkowski K, Wagner A, Rutkowski R, Sowa P, Pancewicz S, Moniuszko-Malinowska A. Alpha-gal syndrome: An emerging cause of food and drug allergy. Clin Exp Allergy. 2020 Aug;50(8):894-903. doi: 10.1111/cea.13683. Epub 2020 Jul 6. PMID: 32542789;	**Brazil**

GENERAL COMMENTS	MEMBER/OBSERVER
Platts-Mills TAE, Commins SP, Biedermann T, van Hage M, Levin M, Beck LA, Diuk-Wasser M, Jappe U, Apostolovic D, Minnicozzi M, Plaut M, Wilson JM. On the cause and consequences of IgE to galactose-α-1,3-galactose: A report from the National Institute of Allergy and Infectious Diseases Workshop on Understanding IgE-Mediated Mammalian Meat Allergy. J Allergy Clin Immunol. 2020 Apr;145(4):1061-1071. doi: 10.1016/j.jaci.2020.01.047. Epub 2020 Feb 10. PMID: 32057766; PMCID: PMC7301618. NIAID-Sponsored Expert Panel, Boyce JA, Assa'ad A, Burks AW, Jones SM, Sampson HA, Wood RA, Plaut M, Cooper SF, Fenton MJ, Arshad SH, Bahna SL, Beck LA, Byrd-Bredbenner C, Camargo CA Jr, Eichenfield L, Furuta GT, Hanifin JM, Jones C, Kraft M, Levy BD, Lieberman P, Luccioli S, McCall KM, Schneider LC, Simon RA, Simons FE, Teach SJ, Yawn BP, Schwaninger JM. Guidelines for the diagnosis and management of food allergy in the United States: report of the NIAID-sponsored expert panel. J Allergy Clin Immunol. 2010 Dec;126(6 Suppl): S1-58. doi: 10.1016/j.jaci.2010.10.007. PMID: 21134576; PMCID: PMC4241964.	
Allergen means an otherwise harmless substance capable of triggering a response that starts in the immune system and results in an allergic reaction in certain individuals. In the case of foods, it is a protein which is found in food capable of triggering a response in individuals ~~sensitised~~ allergic to it. Same comment as in the definition for “allergen” above.	**Canada**
It is proposed to include the definition in Spanish exactly as shown in the Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020) It is also proposed that the definition of allergens in Part 1 and Part 2 be the same to facilitate their implementation.. Allergen means an otherwise harmless substance capable of triggering a response that starts in the immune system and results in an allergic reaction in certain individuals. In the case of foods, it is a protein which is found in food capable of triggering a response in individuals sensitised to it. The spanish translation on the Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020) has terms tht provide a better understanding of the efinition, such as the term safe.	**Colombia**
As with comments on the proposed drafting for the GSLPF New Zealand suggests adding the word “typically” prior to “a protein” in the definition of “allergen”. We note that the proposed drafting aligns with the definition of “allergen” in the CCFH Code of Practice on Food Allergen Management for Food Business Operators (CXC 80-2020) and therefore suggest if this edit was included that CX 80-2020 be updated accordingly.	**New Zealand**
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 usually a protein which is found in food capable of triggering a response in individuals sensitised to it. As per Singapore's comments under Appendix II above.	**Singapore**
Does not include ingredients that cause hypersensitivity (immune AND non-immune reaction)	**Switzerland**
It is suggested to refer to the definition of the general rule for the labelling of prepackaged foods, which are found in Appendix II.	**Uruguay**
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.	**EFA**

GENERAL COMMENTS	MEMBER/OBSERVER
~~*Allergen* means an otherwise harmless substance capable of triggering a response that starts in the immune system and results in an allergic reaction in certain individuals. In the case of foods, it is a protein which is found in food capable of triggering a response in individuals sensitised to it.~~ ISDI notes that the definition of allergens included under section 3 of the Proposed draft Guidelines for the use of [Precautionary Allergen or Advisory Labelling] on page 14 of CX/FL 21/46/8 should be deleted. This will be properly covered by the definition section of the future revised GSLPF (as per new definitions proposed for insertion in the GSLPF listed on page 12 of CX/FL 21/46/8).	**ISDI**
Allergen cross-contact	
Allergen cross-contact occurs when an allergenic food, or ingredient, is unintentionally incorporated into another food that is not intended to contain that allergenic food or alergenic ingredient. Chile proposes to add the word ingredient to give coherence to the text	**Chile**
Allergen cross-contact occurs when an allergenic food, or ingredient, is unintentionally incorporated into another food that is not intended to contain that food or alergenic ingredient. Parragraph 3, definitions section. Change the final sentence from “alergenic foood” to “food or alergenic ingredient”. It is suggested to add "or ingredient" in order to be consistent with the other texts of the document that refer to foods and ingredients.	**Colombia**
New Zealand considers that ‘allergen cross-contact’ cannot be defined without first agreeing whether the term ‘allergen’ is the correct term to be using here (as opposed to ‘foods and ingredients listed in 4.2.1.4’). The appropriate term should be based on the advice received from the FAO/WHO expert group. In addition, the scope of what PAL should apply to is also dependent on the advice received from the FAO/WHO expert group. We therefore suggest that CCFL could instead agree a definition for ‘cross-contact’ and apply this to which ever term is deemed appropriate for PAL based on the advice received.	**New Zealand**
Singapore agrees with the definition.	**Singapore**
*Allergen cross-contact*occurs when an allergenic food, or ingredient, is unintentionally incorporated into another food that is not intended to contain that allergenic food. Replace "is" with "may be" or "could be" as it is a potential cross-contact	**Switzerland**
Allergen and other substances that produce hypersensibility due to cross-contact occur when ~~an allergenic~~ a food, or ingredient, unintentionally incoporates such substance ~~incorporated~~ into another food that is not intended to contain it ~~that allergenic~~ The document refers not only to allergens.	**Uruguay**
[Precautionary allergen or advisory labelling]	
Proposed editing to the following to also include 'storage' as it is identified as one factor contributing to exposure in CXC 80-2020: [Precautionary allergen or advisory labelling] is a statement indicating the allergen(s) that may be present in a food due to allergen cross-contact during the production, manufacture, storage and transport of food, which may occur despite implementing allergen management practices and controls such as in the Code of Practice on Food Allergen Management for Food Business Operators (CXC 80-2020).	**Australia**
~~[~~*Precautionary ~~allergen or advisory~~ allergen labelling*~~]~~ is a statement indicating the commonly known term for the source of allergen(s) that may be present in a food due to allergen cross-contact during the production, manufacture and transport of food, which may occur	**Brazil**

GENERAL COMMENTS	MEMBER/OBSERVER
despite implementing allergen management practices and controls such as in the *Code of Practice on Food Allergen Management for Food Business Operators* (CXC 80-2020). Considering that the precautionary allergen labelling indicates the sources of allergens (e.g. soy, milk) and not the allergen itself (e.g. name of the protein present in the product), we suggest including the words "commonly known term for the source of". This amendment would ensure consistency between this provision and the proposed new section 4.2.1.5 which is supported by the results from the literature review of consumer response to allergen declarations and precautionary allergen labelling conducted by the International Social Science Liaison Group. In addition, we understand that the terminology 'Precautionary Allergen Labelling' is widely used and understood by scientists, consumers groups, food industry and regulators and should be adopted in this document.	
[*Precautionary allergen or advisory labelling*] is a statement indicating the allergen(s) that may be present in a food due to ~~allergen~~ cross-contact during the production, manufacture and transport of ~~food, which may occur despite implementing allergen management practices and controls such as in the~~ that food ~~*Code of Practice on Food Allergen Management for Food Business Operators* (CXC 80-2020).~~ Canada notes that as written, the definition of "precautionary allergen labelling" excludes other foods or ingredients causing hypersensitivity such as gluten sources and related effects on individuals with celiac disease. CCFL may wish to consider the scope of this definition and whether further alignment with the foods and ingredients requiring allergen labelling is necessary. Canada also suggests that the last portion of the definition regarding allergen management practices can be removed and addressed in the general principles on the use of precautionary allergen labelling.	**Canada**
[*Precautionary labelling of allergens ~~allergen or advisory labelling~~*] is a statement indicating the allergen(s) that may be not intentionally present in a food due to allergen cross-contact during processes such as the production, manufacture and transport of food, which may occur despite implementing allergen management practices and controls such as those described in the *Code of Practice on Food Allergen Management for Food Business Operators* (CXC 80-2020). In line with the proposal for the title of the document, it is suggested that the term "warning labelling" should be deleted. It is suggested that the phrase "unintentionally" be added to match the purpose of the document. It is recommended to add the phrase "processes such as" since cross-contact can occur in processes other than production, manufacturing and transport and this expression allows them to be included in the definition. It is suggested to include the expression "those described" to give more clarity as the code of practice contains recommendations on the management of food allergens as, when reviewing the current wording, it can be understood that in the code of practice there is a cross-contact of allergens, which differs from the idea desired to transmit..	**Colombia**
[*Precautionary allergen ~~or advisory~~ labelling*] is a statement indicating the unintentional presence of one of the allergen(s) listed in section 4.2.1.4 of the GSLPF that may be present in a food due to allergen cross-contact during the production, manufacture and transport of food, which may occur despite implementing allergen management practices and controls such as in the *Code of Practice on Food Allergen Management for Food Business Operators* (CXC ~~80-2020)~~80-2020) and taking all possible mitigation measures.	**European Union**
[*Precautionary allergen or advisory labelling*] is a statement indicating the allergen(s) that may be present in a food due to ~~allergen~~ cross-contact with allergens during the production, manufacture and transport of food, which may occur despite implementing allergen management practices and controls such as in the *Code of Practice on Food Allergen Management for Food Business Operators* (CXC 80-2020). Singapore agrees with the proposed definition with editorial amendments reflected below:	**Singapore**

GENERAL COMMENTS	MEMBER/OBSERVER
• [Precautionary allergen or advisory labelling] is a statement indicating the allergen(s) that may be present in a food due to cross-contact with allergens during the production, manufacture and transport of food, which may occur despite implementing allergen management practices and controls such as in the Code of Practice on Food Allergen Management for Food Business Operators (CXC 80-2020).	
[*Precautionary allergen or advisory labelling*] is a statement indicating the allergen(s) that may be present in a food due to allergen cross-contact during the production, manufacture and transport of food, which may occur despite implementing allergen management practices and controls such as in the *Code of Practice on Food Allergen Management for Food Business Operators* (CXC 80-2020). Uganda proposes the definition to read as ". [Precautionary allergen labelling] is a statement indicating the allergen(s) that may be present in a food unintentionally ,due to allergen. cross-contamination during the production, manufacture and transport of food, which may occur despite implementing allergen management practices and controls such as in the Code of Practice on Food Allergen Management for Food Business Operators (CXC 80-2020)".	**Uganda**
[*Precautionary allergen or advisory labelling*] is a statement indicating the allergen(s) that may be present in a food due to allergen cross-contact during the production, manufacture and transport of ~~food~~food or ingredient, which may occur despite implementing allergen management practices and controls such as in the *Code of Practice on Food Allergen Management for Food Business Operators* (CXC 80-2020). The United States notes that substances causing hypersensitivity may become present in a food due to cross-contact during production, manufacture, or transport of food or food ingredients. To capture this, the United States offers a small edit to the definition	**USA**
[*Precautionary labelling of ~~allergens~~ or ~~advisory~~ advisory labelling*] ~~]~~ of allergens and other substances that produce hypersensitivity is a statement indicating the allergen(s) and other substances that produce hypersensitivity that may be present in a food due to ~~allergen~~ cross-contact during the production, manufacture and transport of food, which may occur despite implementing ~~allergen management~~ management practices and controls such as in the *Code of Practice on Food Allergen Management for Food Business Operators* (CXC 80-2020). Consistency with the rest of the text referring to allergens and other substances that produce hypersensitivity	**Uruguay**
[*Precautionary ~~allergen or advisory~~ allergen labelling*] is a statement indicating the allergen(s) that may be present in a food due to allergen cross-contact during the production, manufacture and transport of food, ~~, which~~ . This may occur above a threshold (action) level despite implementing allergen management practices and controls such as in the *Code of Practice on Food Allergen Management for Food Business Operators* (CXC 80-2020).	**EFA**
[*Precautionary allergen or advisory labelling*] is a statement indicating the allergen(s) that may be present in a food due to allergen cross-contact during the production, manufacture and transport of food, which may occur despite implementing allergen management practices and controls such as in the *Code of Practice on Food Allergen Management for Food Business Operators* (CXC 80-2020). ICGA supports the consistency with the definitions set in the approved Code of Practice on Food Allergen Management for Food Business Operators (CXC 80-2020) as well as those included in the general standard (CXS 1, 2018 version). Possibly a cross-reference would be enough rather than repeating these definitions.	**ICGA**
[*Precautionary allergen or advisory labelling*] is a statement indicating the allergen(s) that may be **unintentionally** present in a food due to allergen cross-contact during **processes such as** the production, manufacture and transport of food, which may occur despite	**FIA**

GENERAL COMMENTS	MEMBER/OBSERVER
implementing allergen management practices and controls such as in the *Code of Practice on Food Allergen Management for Food Business Operators* (CXC 80-2020). We support the term “precautionary allergen labelling” as it is a well understood term, and “advisory” may be misunderstood. We also propose the inclusion of the word "unintentionally" to be consistent with the draft purpose section. The listed processes are not exhaustive e.g. storage is not included. Therefore we propose to add “processes such as” to make it non-exhaustive list.	
[*Precautionary allergen or advisory labelling*] is a statement indicating the allergen(s) that may be present in a food due to allergen cross-contact during ~~the~~ processes such as the production, manufacture and transport of food, which may occur despite implementing allergen management practices and controls such as in the *Code of Practice on Food Allergen Management for Food Business Operators* (CXC 80-2020).	**ISDI**
[*Precautionary allergen ~~or advisory~~ labelling*] is a statement indicating the allergen(s) that may be present in a food due to allergen cross-contact during ~~the production, manufacture and transport of food,~~ food production which may occur despite implementing allergen management practices and controls such as in the *Code of Practice on Food Allergen Management for Food Business Operators* (CXC 80-2020). ICGMA proposes to revise the definition of precautionary allergen labelling to further streamline text and capture other scenarios that may involve cross-contact (e.g. storage).	**ICGMA**
4. GENERAL PRINCIPLES	
Argentina’s position: A risk-based approach is supported, however, comments on points 4.1 and 4.2 would be desirable to await the results of the evaluation by the FAO/WHO expert group. For this reason, it is suggested that the text be placed in square brackets and considered once the Committee has received the advice of the panel of experts.	**Argentina**
Australia supports consideration of these principles once the FAO/WHO expert advice is received.	**Australia**
4[4. GENERAL ~~PRINCIPLES~~PRINCIPLES] Brazil request that section 4 be kept in square brackets until the full report of the Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens is available. We have several concerns about the proposed principles. First, we understand that the decision to use PAL cannot be based solely in the application of quantitative risk assessment. This approach would represent an excessive burden to many food businesses, especially small food producers, which do not have the capacity to perform quantitative risk assessments. In addition, the discussion on the use of quantitative risk assessment to guide the decision on the use of PAL should consider the limitations and gaps in the scientific evidence used to set the threshold or references doses that would trigger food allergic reactions. Most of studies that have been used to set allergen thresholds had been conducted for the purpose of diagnosing allergies. Thus, these studies show significative variability in several factors that influence the individual response to food allergy, such as: (a) the characteristics of the individuals tested (e.g. geographic distribution, genetic load, sociocultural characteristics); (b) the severity of the food allergy; (c) the signs and symptoms used as a clinical outcome (e.g. objective or subjective reactions); (d) the administration protocols, challenge conditions and form of food preparation (e.g. range and total amount of allergens administered, type of food used and level of processing). Another important point is that these clinical studies exclude individuals who are more likely to have severe allergic reactions. This aspect limits the validity of the threshold sets for the protection of the most sensitive individuals.	**Brazil**

GENERAL COMMENTS	MEMBER/OBSERVER
Finally, we understand that for the evaluation of the second principle, it would be necessary to define the terms “reference dose” and “estimated reference dose can be used”.	
The EUMS believe that the draft general principles merit further clarification. Certain principles previously discussed have been lost and it would be useful that they are re-introduced in these guidelines. The EUMS consider that the use of PAL should only be explored where all possible mitigation measures available to eliminate the likelihood have been exhausted. The EUMS agree that the decision to use PAL should be based on the findings of a risk assessment. Without a proper scientifically-based risk assessment, it is difficult to interpret whether a cross-contact is significant or not. The EUMS suggest the introduction of a new paragraph 4.1 introducing the general principles and then two subparagraphs 4.1.1 and 4.1.2 setting out the principles, as below:	**European Union**
Philippines supports the provision stated in 4.1. As for 4.2, the use of a reference dose may not be adequate as it will just be too risky as some individuals can have severe reactions even for trace amounts. It is not clear as well how a reference dose or estimates should be established for a specific allergen and how reliable each of the test methods to quantify the amount. We recommend that the text be placed in square brackets and considered once the Committee has received the advice of the expert panel.	**Philippines**
We propose to put square brackets over this section as we have to wait for the outcome of the consultation of the experts. In addition, the practicability of these principles should be considered very carefully, especially in the case of SMEs. These principles should not cause a heavy burden to the FBOs.	**Thailand**
We are in full support with 4.1: PAL should be risk – based. Propose to add or amend the text: 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, including the use of appropriate reference doses. In addition, Ii a preventive strategy cannot be efficiently implemented, PAL should be applied for risk communication to food allergic consumers. This means that in case in which in a product bearing a PAL the allergen in concern is detected, then the product is not considered harmful and the product does not have to be taken off the market.	**ICA**
4.1	
For consistency of language and being the preferred reference to the target consumer, we have proposed the following change: 4.1 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. The use of PAL should be restricted to those situations in which allergen cross-contact cannot be controlled to the extent that the product may present a risk to consumers with food allergy.	**Australia**
4[4.1 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. The use of PAL should be restricted to those situations in which allergen cross-contact cannot be controlled to the extent that the product may present a risk to allergic consumers.] As already mentioned, Brazil requests that section 4 be kept in square brackets until the full report of the Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens is available. As stated before, we have several concerns about the proposed principles.	**Brazil**

GENERAL COMMENTS	MEMBER/OBSERVER
4.1 The decision to use PAL should be based on the findings of a risk assessment which can include, but is not limited to, quantitative risk assessment. The use of PAL should be restricted to those situations in which allergen cross-contact cannot be controlled to the extent that the product may present a risk to allergic consumers. Canada suggests that the definition and limits on “cannot be controlled” may have to be more precisely defined. Presumably this could be tied to “implementing allergen management practices and controls such as in the Code of Practice on Food Allergen Management for Food Business Operators (CXC 80-2020)”.	**Canada**
4.1 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. The use of PAL should be restricted to those situations in which allergen cross-contact cannot be controlled ~~to the extent that the product may present a risk to allergic consumers~~ The adjustment is suggested to give more clarity to the idea raised.	**Colombia**
Costa Rica supports the risk-based approach. However, we believe that it is premature to evaluate points 4.1 and 4.2 as the Committee is still awaiting the evaluation of the FAO/WHO expert panel. Costa Rica recommends that the text be placed in square brackets and considered once the Committee has received the advice of the panel of experts.	**Costa Rica**
4.1 The decision to use of PAL should be ~~based on~~ restricted to those situations in which allergen cross-contact cannot be controlled and a risk to consumers has been identified. The following general principles/criteria apply for PAL and the decision to use PAL should only be applied if both of these criteria are fulfilled.4.1.1. Unintentional allergen(s) may be present despite implementing effective management practices and controls to prevent or minimize the potential allergen cross-contact as outlined in The Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020).4.1.2 The findings of a risk assessment ~~which~~ show that the allergen(s) from the food is above an established reference dose and might thus cause an adverse reaction in a substantial proportion of allergic consumers. The risk assessment can include, but is not limited to, a quantitative risk assessment. ~~The use~~ Visually detectable allergens (e.g. pieces of ~~PAL should~~ nuts) can be ~~restricted~~ compared to ~~those situations in which allergen cross-contact cannot be controlled to the extent that the product may present~~ reference doses if chemical analyses and a quantitative risk ~~to allergic consumers~~assessment is not possible.	**European Union**
We support a risk-based approach. However, we believe that it is premature to evaluate 4.1 and 4.2 given that the Committee is still awaiting the assessment of the FAO/WHO expert panel. We recommend that the text be placed in square brackets and considered once the Committee has received the advice of the expert panel.	**Guatemala**
New Zealand supports 4.1 but suggests the words 'that the product may present' are deleted and repaced with 'needed to mitigate'. for increased clarity. The text would then read: 4.1 The decision to use PAL should be based on the findings of a risk assessment which can include, but is not limited to, quantitative risk assessment. The use of PAL should be restricted to those situations in which allergen cross-contact cannot be controlled to the extent needed to mitigate a risk to allergic consumers .	**New Zealand**
Singapore agrees with the proposed principle.	**Singapore**

GENERAL COMMENTS	MEMBER/OBSERVER
4.1 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. The use of PAL should be restricted to those situations in which allergen cross-contact with other substances that produce hypersensitivity cannot be controlled to the extent that the product may present a risk to ~~allergic consumers~~ consumers. Same as previous point	**Uruguay**
4.1 The decision to use PAL should be based on the findings of a risk assessment which can include, but is not limited to, quantitative risk assessment. The use of PAL should be restricted to those situations in which allergen cross-contact cannot be controlled to the extent that the product may present a risk to allergic consumers.	**USA**
- The draft text of the previous version said: "The decision to use PAL should be based on findings of a quantitative risk assessment" (QRA) We note that the current version limits substantially the importance of QRA. In EFA's opinion, QRA is just one (important) part of a greater allergen management strategy. Qualitative measures as such as allergen management frameworks have to be considered too. The significance of a quantification of unintended allergen presence in a product should be the basis. If it is offered as an option, the more risk averse FBOs will still have the option to use PAL, even if the product does not pose a risk to allergic consumers. On the other hand – less risk adverse FBO may choose not to label despite a health risk. 4.1 The decision to use PAL should be based on the findings of a risk assessment which ~~can~~ should include, but not limited to, quantitative risk assessment. The use of PAL should be restricted to those situations in which allergen cross-contact cannot be controlled to the extent that the product may present a health risk to allergic consumers.	**EFA**
4.1 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~~assessment [***, including the use of appropriate reference doses***]. The use of PAL should be restricted to those situations in which allergen cross-contact cannot be controlled to the extent that the product may present a risk to allergic consumers. ICGA supports the principle in 4.1. as we strongly believe in risk-based decisions derived from a scientific quantitative risk assessment which may also include the use of appropriate reference doses. As a preventive strategy cannot always be efficiently implemented, PAL should be applied for a risk communication purpose to food allergic consumer. When a product is bearing a PAL and the allergen of concern is detected, then the product may not be necessarily viewed as harmful to health and thus the product will not have to be taken off the market. As such, the inclusion of the words "including the use of appropriate reference doses", after "risk assessment", may be useful.	**ICGA**
4.1 The decision to use PAL should be based on the findings of a ~~risk assessment~~ [risk assessment] which can include, but not limited to, quantitative risk assessment. The use of PAL should be restricted to those situations in which allergen cross-contact cannot be controlled to the extent that the product may present a risk to allergic consumers. Committee waiting assessment of FAO/WHO panel recommend text to be put in brackets	**ICA**
4.1 [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. The use of PAL should be restricted to those situations in which allergen cross-contact cannot be controlled to the extent that the product may present a risk to allergic consumers. While we support a risk-based approach, we believe that it is premature to evaluate 4.1 and 4.2 given that the Committee is still awaiting the assessment of the FAO/WHO expert panel. We recommend that the text be placed in square brackets and considered once the Committee has received the advice of the expert panel	**FIA**

GENERAL COMMENTS	MEMBER/OBSERVER
4.1 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. The use of PAL should be restricted to those situations in which allergen cross-contact cannot be controlled to the extent ~~that the product may present a~~ needed to manage the risk posed to allergic consumers. ISDI is also concerned that the wording of 4.1 under general principles is not clear and recommends that it is reconsidered.	**ISDI**
IFT supports the language in Appendix III, Section 4 on the General Principles of PAL in which a scientific based risk assessment should serve as the basis of PAL.	**IFT**
We support a risk-based approach. However, we believe that it is premature to evaluate 4.1 and 4.2 given that the Committee is still awaiting the assessment of the FAO/WHO expert panel. We recommend that the text be placed in square brackets and considered once the Committee has received the advice of the expert panel.	**ICGMA**
[4.1 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. The use of PAL should be restricted to those situations in which allergen cross-contact cannot be controlled to the extent that the product may present a risk to allergic consumers.] We support a risk-based approach. However, we believe that it is premature to evaluate 4.1 and 4.2 given that the Committee is still awaiting the assessment of the FAO/WHO expert panel. We recommend that the text be placed in square brackets and considered once the Committee has received the advice of the expert panel.	**ICBA**
4.2	
[4.2 PAL should only be used if exposure to the allergen from the food is above an established reference dose. If a reference dose is not established for a particular allergen, an estimated reference dose can be used. If a quantitative risk assessment cannot be performed, then PAL should only be applied if any risk of allergen-cross contact identified through a risk assessment cannot be removed through risk management actions, such as segregation and cleaning.] As already mentioned, Brazil requests that section 4 be kept in square brackets until the full report of the Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens is available. As stated before, we have several concerns about the proposed principles.	**Brazil**
4.2 ~~PAL should only~~ The product would be ~~used~~ considered to present a risk to allergic consumers if exposure to the allergen from the food is possible (or may be present) above an established reference dose. If a reference dose is not established for a particular allergen, an estimated reference dose can be used. If a quantitative risk assessment cannot be performed, then PAL should only be applied if any risk of allergen-cross contact identified ~~through risk~~ despite implementing allergen management ~~actions, such as segregation~~ practices and ~~cleaning~~controls such as in the Code of Practice on Food Allergen Management for Food Business Operators (CXC 80-2020). Canada notes with cross contact/PAL, the allergen is not always present, and usually not present homogeneously (there can be significant variability within the same lot of product). For this reason Canada suggests that the use of PAL should not be tied to the presence of the allergen in the food or exposure to the allergen, but instead should consider the possible presence or possible exposure.	**Canada**

GENERAL COMMENTS	MEMBER/OBSERVER
Canada notes that the terms “established reference dose” and “estimated reference dose” may need to be defined or further explained. Particularly with regards to “estimated reference dose” Canada is not clear on what is being suggested here. Canada suggests that it should be clarified that an estimated reference dose is not something at the discretion of individual FBO’s. Canada suggests that without more specificity, “cannot be removed” may be open to interpretation. While the general principle is sound, further details will be needed and it may be helpful to link this concept to the Code of Practice or otherwise clarify what efforts at control are expected of food manufacturers before resorting to PAL. Canada has also suggested edits to the last sentence to account for wording recommended to be removed from the “precautionary allergen labelling” definition. Canada suggests that the second general principal be restructured. Since the first principal indicates that the use of PAL should be restricted to those situations in which allergen cross contact cannot be controlled sufficiently that there is a risk to allergic consumers, the second principal can be used to specify when or under what circumstances the food/product would be considered to present a risk to consumers.	
4.2 PAL ~~should only be used if exposure to the allergen~~ that is motivated from the ~~food is~~ above ~~an established reference dose. If a reference dose is not established for a particular allergen, an estimated reference dose~~ criteria can ~~be used. If a quantitative risk assessment cannot be performed, then PAL should only be applied if any risk of allergen-cross contact identified through a risk assessment cannot be removed through risk management actions, such as segregation~~ help to inform FBOs and ~~cleaning~~consumers on the likelihood that the products might contain an allergen.	**European Union**
The EUMS believe that these proposed amendments would fulfil the intentions of the work carried out in 2019 on the Code of Practice on Allergen Management, from which paragraphs 14, 160, 161 linked to Precautionary Allergen Labelling were removed in order to be incorporated in the allergen labelling work [REP19/FH Appendix III, PROPOSED DRAFT CODE OF PRACTICE ON FOOD ALLERGEN MANAGEMENT FOR FOOD BUSINESS OPERATORS (at step 5)].	
New Zealand reserves comment on 4.2 until advice from the FAO/WHO expert group is received on foods and ingredients to be listed in 4.2.1.4 and thresholds (if any) to be applied to these.	**New Zealand**
4.2 PAL should only be used if exposure to the allergen from the food is above an established reference dose. If a reference dose is not established for a particular allergen, an estimated reference dose can be used. If a quantitative risk assessment cannot be performed, then PAL should only be applied, unless this declaration is made in a volunteer manner, if any risk of allergen-cross contact identified through a risk assessment cannot be removed through risk management actions, such as segregation and cleaning must leave the possibility that the PAL can be used voluntarily	**Peru**
4.2 PAL should only be used if exposure to the allergen from the food is above an established reference dose, according to annex X. If a reference dose is not established for a particular allergen, an estimated reference dose can be used. If a quantitative risk assessment cannot be performed, then PAL should only be applied if any risk of allergen-cross contact identified through a risk assessment cannot be removed through risk management actions, such as segregation and cleaning. Indicate in an annex which are the reference doses	**Peru**
Singapore would propose for section 4.2 to be further discussed after the report on threshold levels in foods of the priority allergens is made available.	**Singapore**
4.2 PAL should only be used based on reference dose limits established through risk assessment if exposure to the allergen from the food is above an established reference dose. If a reference dose is not established for a particular allergen, an estimated reference dose can be used. If ~~a quantitative~~ reference dose limits established through risk assessment cannot be ~~performed~~determined, then PAL	**USA**

GENERAL COMMENTS	MEMBER/OBSERVER
should only be applied if any risk of ~~allergen-cross contact~~ allergen cross-contact identified through a risk assessment cannot be removed through risk management actions, such as segregation and cleaning. The United States offers the following edits to Section 4.2 to be consistent with the establishment of threshold values through risk assessment as the basis for determining the use of PAL statements. As noted in our earlier comment, please refer to the second report of the FAO/WHO expert committee (2021) where threshold values for the priority allergens have been recommended. That document can be found here: http://www.fao.org/3/cb6388en/cb6388en.pdf	
4.2 PAL should only be used if exposure to the allergen from the food is above an established reference dose. If a reference dose is not established for a particular allergen, or other substances that produce hypersensitivity, an estimated reference dose can be used. If a quantitative risk assessment cannot be performed, then PAL should only be applied if any risk of allergen-cross contact identified through a risk assessment cannot be removed through risk management actions, such as segregation and cleaning cleanliness, the correction is for consistency with what is declared. We also express that we share the concerns of the members of the electronic working group regarding the establishment of reference thresholds. More information is expected from the FAO/WHO expert group	**Uruguay**
4.2 PAL should only be used if exposure to the allergen from the food is above an established reference dose. If a reference dose is not established for a particular allergen, an estimated reference dose can be used. If a quantitative risk assessment cannot be performed, then PAL should only be applied if ~~any~~ the risk of allergen-cross contact identified through a risk assessment cannot be removed through risk management actions, such as segregation and cleaning. - There needs to be more clarification on the sentence "If a reference dose is not established for a particular allergen, an estimated reference dose be used." How will estimates be evaluated to determine the safety of consumers with that food allergy? The use of the word "any" in the context of "any risk of cross-contact" is not acceptable because 1) it does not reflect the relevance for health for allergic consumers and 2) it might lead to a wider and unnecessary use of PAL. We encourage Codex to be clearer and stressed that not "any risk of cross contact" should lead to the application of PAL, but rather only a risk that is likely to have an adverse health impact to consumers with food allergies. Our proposal should be included in Purpose, Scope, Definitions and General Principles	**EFA**
ICGA believes that the wording of 4.2 may need to be further worked out in the light of the outcome of the ad hoc FAO/WHO expert consultation on risk assessment of food allergens (see ICGA earlier comments on new paragraph 2.3)	**ICGA**
4.2 PAL should only be used if exposure to the allergen from the food is above an established reference ~~dose. If a reference~~ dose ~~is not established for a particular allergen, an estimated reference dose can be used~~[or range]. If a quantitative risk assessment cannot be performed, then PAL should only be applied ~~if any~~ if risk of allergen-cross contact identified through a risk assessment cannot be removed through risk management actions, such as segregation and cleaning. On 4.2, further detail should wait for the consultation on reference doses to be concluded fully and detailed documents are published. Until then, we believe 4.2 is too premature in the process and may even cause confusion. Recommend that the guidance not recommend estimating a reference dose if one does not exist Recommend removal of the term "any" to specify that this does not mean zero risk	**ICA**
4.2 PAL should only be used if exposure to the allergen from the food is above an established reference dose. If a reference dose is not established for a particular allergen, an estimated reference dose can be used. If a quantitative risk assessment cannot be	**FIA**

GENERAL COMMENTS	MEMBER/OBSERVER
performed, then PAL should only be applied if any risk of allergen-cross contact identified through a risk assessment cannot be removed through risk management actions, such as segregation and cleaning.] While we support a risk-based approach, we believe that it is premature to evaluate 4.1 and 4.2 given that the Committee is still awaiting the assessment of the FAO/WHO expert panel. We recommend that the text be placed in square brackets and considered once the Committee has received the advice of the expert panel	
Brand loyalty impacts consumer purchasing behavior, particularly repetitive purchase of a given product or brand (see references on Brand Loyalty). IFT recommends that the Codex implementation guidance on PAL consider consumers' brand loyalty purchasing behavior. For example: a.) Brand loyal consumers may not check the ingredient list of a product they typically consume, that has been reformulated to include an allergenic or hypersensitive component (e.g., the product is reformulated and includes a dairy protein ingredient). Merely listing the ingredient on the ingredient lists in such cases may not be enough to inform consumers about the change, i.e., the presence of an allergenic ingredient. In such instances, additional methods, such as providing information on the Front-of-pack label to alert/inform brand loyal consumers is needed. b.) In cases where multiple production facilities for a product, where one or more, but not all facilities have exposure to an allergenic component, IFT recommends that Codex consider PAL on all such branded product, as if the allergenic component is present, since brand loyal consumers again will not likely be reviewing the back label of a product they consider as "safe". Also, due to supply chain changes or consumer travel, these consumers might encounter a product from one of the facilities where PAL would normally be required by Codex PAL guidance. Brand Loyalty References of Interest: - Consumers with food allergies: A growing market remains underserved - McKinsey - Greater Food Brand Loyalty is Linked to Food Transparency (nutrifusion.com) - Brand Loyalty is not habitual (researchgate.net)	**IFT**
We support a risk-based approach. However, we believe that it is premature to evaluate 4.1 and 4.2 given that the Committee is still awaiting the assessment of the FAO/WHO expert panel. We recommend that the text be placed in square brackets and considered once the Committee has received the advice of the expert panel.	**ICGMA**
We support a risk-based approach. However, we believe that it is premature to evaluate 4.1 and 4.2 given that the Committee is still awaiting the assessment of the FAO/WHO expert panel. We recommend that the text be placed in square brackets and considered once the Committee has received the advice of the expert panel.]	**ICBA**
5. PRESENTATION OF PAL	
Australia supports the inclusion of this section based on the available consumer evidence and noting the FAO/WHO expert advice on PAL is yet to be received. Similar to the inclusion of provisions on the presentation of allergen information into the GSLPF, provisions on the presentation of PAL will promote consistency and clarity of information for consumers.	**Australia**
The EUMS agree with the approach suggested by the Chairs, i.e. points on the presentation of PAL, wording for PAL and education programs to be addressed once scientific advice is received. The efficiency of PAL can be only achieved if the information in question is clearly understandable for consumers.	**European Union**

GENERAL COMMENTS	MEMBER/OBSERVER
We suggest that location be within the same field of view as the list of ingredients and allergen declaration. Iso, we propose not to put a restrictive provision on the placement / format of precautionary statement in the label	**Philippines**
We do not object to the list of information to be included in this section. Nevertheless, the consumer education programme should be left for the countries to design thus not necessary to be included here.	**Thailand**
ICA notes the importance of reflecting consumer understanding (especially food allergy consumers) in the development of the PAL guidelines. Not only should PAL be based off a risk based approach but should be established in a way to best build consumer trust. • In addition, ICA suggest the following to be considered when discussing presentation of PAL: • PAL is a statement separate from the list of ingredients. • Wording of PAL should be uniform. • Allergens listed in PAL should have to be declared under a name making a clear reference to the specific type when possible, instead of group names like cereals, gluten, nuts, fish.	**ICA**
FREE-FROM Claims: IFT recommends that Codex consider whether to include "Free-From" allergen claims in these guidelines. Ideally, "Free-From" claims are not required if an allergenic ingredient is not listed and PAL is not necessary for a product. However, in reality, "Free-From" claims, such as 'Peanut-Free Facility' are used in some food products in some regions for additional assurances to those consumers who are concerned about allergens. IFT believes such claims may proliferate and that this is the appropriate time to add guidelines related to "Free-From" claims to ensure harmonization across countries who choose to include such claims.	**IFT**
ICGA notes the importance of reflecting consumer understanding (especially food allergy consumers) in the development of the PAL guidelines. Not only PAL should be based on a risk-based approach, but it should be established in the best possible way to build consumer trust and food business operator's adhesion. In addition, ICGA suggests the following to be considered when discussing presentation of PAL: • PAL is a statement separate from the list of ingredients. • Wording of PAL should be uniform. • Allergens listed in PAL should have to be declared under a name making a clear reference to the specific type when possible, instead of group names like cereals, gluten, nuts, fish.	**ICGA**
We recommend a consistent approach including provisions relating to the location, format and presentation is critical to consumer understanding.	**ICGMA**