

CODEx ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
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Organization

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Agenda Item 8.1

CX/FL 21/46/8 Add.1

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEx COMMITTEE ON FOOD LABELLING

46th Session

Virtual

27 September – 1 October and 7 October 2021

PROPOSED DRAFT REVISION TO THE *GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS* – PROVISIONS RELEVANT TO ALLERGEN LABELLING

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

Comments of Algeria, Argentina, Australia, Brazil, Canada, Chile, Colombia, Costa Rica, Cuba, Ecuador, European Union, Guatemala, Indonesia, Iran, Iraq, Japan, 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	MEMBERS / OBSERVERS
Australia in general supports the direction and proposed draft revisions to the GSLPF as provided in Appendix II, CX/FL 21/46/8. We provide the following specific comments – SEE BELOW	Australia
<p>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).</p> <p>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.</p> <p>Regarding section 4.2.1.4 of the GSLPF (additions, deletions and exemptions to the list of foods and ingredients known to cause hypersensitivity and the clarity of the groupings in that list), we request that the revision of this section be postponed until the publication of the full report of the first meeting of Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens.</p> <p>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.</p>	Brazil
<p>Canada thanks Australia, UK, and the U.S. for chairing the work on Food Allergen Labelling and are pleased to provide the following comments:</p> <p>Item 8.1: Proposed draft revision to the General Standard for the Labelling of Prepackaged Foods – Provisions relevant to allergen labelling</p> <p><u>General Comments:</u></p> <p>Canada has a preference for the work on the GSLPF (Part 1) and the guidance on the use of PAL (Part 2) to continue to be progressed together in the interest of ensuring consistency and recognizing that these two parts are inter-related.</p> <p>For example, Canada notes that the definitions, particularly the definition of food intolerance may need to be amended based on scientific advice from the FAO/WHO expert committee.</p>	Canada
Cuba supports the document submitted on the Proposed Draft Revision of the General Standard for the Labelling of Prepackaged Foods (CXS 1-1985) relevant to the labelling of allergens	Cuba
<p>We would like to thank Australia, the United Kingdom and the United States of America for preparing the Proposed Draft Revision and guideline for consideration at the 46th session of the CCFL, to be held from 26 September to 1 October 2021.</p> <p>We support the progress of this document during the 46th session of the CCFL.</p>	Colombia
We believe that Appendix II is well structured in terms of the subjects of definitions, commonly known terms for the source of food, declared foods and ingredients that are known to cause hypersensitivity	Ecuador
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	MEMBERS / OBSERVERS
The EUMS would like to propose the following modifications to improve further the text– SEE BELOW.	
Iran agrees with the changes made	Iran
Malaysia thanks Australia for preparing this paper. Malaysia has no objection with the proposed draft but with a proposal or consideration for some section which as below	Malaysia
New Zealand supports that throughout this document, where foods and ingredients known to cause hypersensitivity are referred to, that the reference is “foods and ingredients listed in 4.2.1.4”. This will ensure not only consistency but also that any advice received from the FAO/WHO expert group on what should be included in this list is transferred to all other clauses. From the summary report provided by the expert group it appears that not all foods and ingredients that cause hypersensitivity may be included in the list going forward.	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
Peru considers that the work should continue to advance together.	Peru
Uganda is in agreement with the proposals in the appropriate clauses	Uganda
<p>We appreciate the preparation of this document, and the opportunity to provide our comments.</p> <p>In the normative proposal substances that cause hypersensitivity that are not allergens are included</p> <p>PROPOSED DRAFT REVISION OF THE GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS (CXS 1-1985) RELEVANT TO THE LABELLING OF ALLERGENS AND OTHER SUBSTANCES THAT PRODUCE HYPERSENSITIVITY (CXS 1-1985)</p>	Uruguay
We believe that it would be helpful to have guidance for handling multiunit retail containers when allergens are present. Both primary and secondary packaging should disclose allergen presence. We suggest that guidance to this effect could be included in Section 8, like exemptions to be considered on food and ingredients (e.g., highly refined oils)	Philippines
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 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)	ICBA
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
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.	International Special Dietary Food Industries (ISDI)
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

GENERAL COMMENTS	MEMBERS / OBSERVERS
<p>The list under 4.2.1.4 is not aligned with CCFH CODE OF PRACTICE ON FOOD ALLERGEN MANAGEMENT FOR FOOD BUSINESS OPERATORS - CXC 80-2020. The last bullet on sulphite needs to be removed.</p> <p>IDF agrees in principle that using common and well understood terms (words) for the source of foods and ingredients known to cause hypersensitivity will help in consumer understanding.</p> <p>The common and well understood term for the source should be part of the ingredient name, e.g. “milk powder”; or provided in another manner in which this information is clearly provided to consumers, e.g. sodium caseinate (milk); or where there are multiple ingredients from the same source, we propose that having a separate “contains” summary statement should remove the need to specify each ingredient is from that source. This would remove the need to repeat the name of the allergen multiple times in brackets. Therefore, we propose the following modification:</p> <p>4.2.1.5 Declaration of the foods and ingredients listed in section 4.2.1.4 shall be made using commonly known terms for the source of the food and ingredient as part of, or in conjunction with, the relevant ingredient name either in the ingredients list or in the separate statement under section 8.3.2.</p> <p>IDF believes the new section 8.3 is not necessary, as regulations are already in place, taking into account adjustments for small labelling area where necessary. If maintained, more flexibility shall be allowed. More discussion may be necessary on this section.</p> <p>For section 8.3.1, we propose revisions for clarification and to avoid redundancy. The original wording could have been interpreted to mean other text near the ingredients list, thereby preventing the use of the same font elsewhere on the pack. Therefore, we propose specifying “rest of the ingredients list”:</p> <p>8.3.1 The foods and ingredients listed in section 4.2.1.4 shall be declared so as to contrast distinctly from the rest of the ingredients list, such as through the use of font type, style or colour.</p> <p>For section 8.3.1.1, we propose to delete this paragraph as it does not provide additional guidance on top of 8.3.1. There are also overarching requirements for legibility in section 8.1.2 of the GSLPF already.</p>	<p>Diseases Patients’ Associations(EFA)</p> <p>IDF/FIL</p>
<p>FoodDrinkEurope appreciates the opportunity to provide comments on this important revision.</p> <p>We suggest bringing both allergen labelling and precautionary allergen labelling forward concurrently, perhaps within a physical Working Group plenary.</p>	<p>FoodDrinkEurope</p>
SPECIFIC COMMENTS	
SCOPE	
<p>SCOPE The EUMS suggest to extend the scope of the GSLPF to all non-prepacked foods as far as the provision of the information on allergen is concerned. The EUMS believe that consumers with food allergies should be able to make informed and safe choices at all times, including safe choices on non-prepacked foods. In fact, evidence suggests that most food allergy and intolerance incidents can be traced back to non-prepacked food, often served in restaurants or at catering counters. In that context, the EUMS suggest the introduction of the term “food information” to the GSLPF to rather refer to the “provision of food information to consumers” instead of the “labelling of pre-packaged foods”. “Food information” would cover the provision of information of a food made available to the final consumer by means of a label, other accompanying material or verbal communication.</p>	<p>European Union</p>

GENERAL COMMENTS	MEMBERS / OBSERVERS
<p>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.</p>	<p>Australia</p>
<p>The EUMS are of the opinion that clear definitions are important for any future addition and/ deletion from the allergen labelling list and to ensure that the terms are understood by the reader, including food business operators.</p> <p>In that context, the EUMS propose the following new definition for the term “hypersensitivity” to describe immune and non-immune mediated reactions to ingested food. In addition, the EUMS are of the opinion that footnotes should be generally avoided in definitions.</p> <p>“Hypersensitivity” means the repeatable adverse reaction to an allergen or otherwise harmless substance in food that leads to food allergy, food intolerance or coeliac disease (autoimmune adverse reaction to food).</p> <p>Further, the EUMS propose to include the following adapted definition for “food allergy”: “Food allergy” means adverse immune reactions to certain food proteins, which may be immunoglobulin E (IgE) mediated, non-IgE mediated, or a combination of both.</p> <p>Reference to anaphylaxis as included in the definition of food allergy, may imply that all food allergies are associated with anaphylaxis. However, allergy attacks in fact range from mild to more severe (such as life-threatening) cases. In addition, as coeliac disease is not a food allergy, the footnote following “non-IgE mediated” in the definition of food allergy should be removed.</p>	<p>European Union</p>
<p>2. DEFINITION OF TERMS</p>	
<p>While the terms of “hypersensitivity” and “allergen” are used in the GSLPF, “food allergy” and “food intolerance”, which are now to be defined newly, are not used either in the GSFLP or the draft. We suggest that only the terms used in the GSLPF should be defined.</p>	<p>Japan</p>
<p>Allergen Food allergy Food intolerance Hypersensitivity</p> <p>Peru will review these definitions in contrast with other regulations, to provide approval to these terms</p>	<p>Peru</p>
<p>The Philippines supports the adoption of the definition on allergen, food allergy, food intolerance and hypersensitivity including the footnote on coeliac disease. We also propose to seek alignment across CCFL and CCFH documents. We also note that CCFL can give further consideration to these definitions once scientific advice is received from FAO/WHO.</p> <p>We would also like to comment on the Title which emphasize that its “Relevant to allergen labelling”. The document states that it also includes other ingredients (not protein) that cause hypersensitivity, like sulphites as stated in 4.2.1.4. But sulphite is not an allergen. Perhaps an asterisk* may be included in the title or change the title unless this is clear in the scope.</p>	<p>Philippines</p>
<p>Uganda is in agreement with the proposed new terms and definitions in regards to the ongoing revisions of GSLPF.</p>	<p>Uganda</p>

GENERAL COMMENTS	MEMBERS / OBSERVERS
<p>We agree with including the proposed definitions. These will provide clarity on the adverse health effects that are under consideration and may require different risk assessment approaches. They also ensure alignment across CCFL and CCFH documents.</p> <p>It is also important to ensure that terms as defined are consistent with those defined in related documents, in this case the Code of Practice for Allergen Management for Food Business Operators (CXC 80-2020). We also note that CCFL should give further consideration to these definitions once scientific advice is received from FAO/WHO, especially those related to hypersensitivity and food intolerance.</p>	<p>International Confectionery Association(ICA/IOCCC)</p>
<p>We agree with including the proposed definitions. These will provide clarity on the adverse health effects that are currently under consideration and may require different risk assessment approaches. They also ensure alignment across CCFL and CCFH documents.</p> <p>It is also important to ensure that terms as defined are consistent with those defined in related Codex texts, in this case the Code of Practice for Allergen Management for Food Business Operators (CXC 80-2020).</p> <p>CCFL can give further consideration to these definitions, particularly the definition of food intolerance, once scientific advice is received from FAO/WHO.</p>	<p>ICGMA</p>
<p>We agree with including the proposed definitions. These will provide clarity on the adverse health effects that are under consideration and may require different risk assessment approaches. They also ensure alignment across CCFL and CCFH documents.</p> <p>It is also important to ensure that terms as defined are consistent with those defined in related documents, in this case the Code of Practice for Allergen Management for Food Business Operators (CXC 80-2020). We also note that CCFL can give further consideration to these definitions once scientific advice is received from FAO/WHO. Especially the definition of food intolerance would benefit from further consideration.</p>	<p>FoodDrinkEurope</p>
<p>“Allergen”</p>	
<p>Definition of allergen: It is suggested to maintain the definition of Allergens found in the document: Code of Practice on Food Allergen Management for Food Business Operators CXC 80-2020.</p> <p>Namely: “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”.</p>	<p>Argentina</p>
<p>“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 <u>typically</u> a protein which is found in food capable of triggering a response in individuals sensitised to it.</p> <p>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:</p>	<p>Brazil</p>

GENERAL COMMENTS	MEMBERS / OBSERVERS
<p>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;</p> <p>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.</p> <p>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.</p>	
<p>“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 <u>allergic</u> to it.</p> <p>It is possible to be sensitised to a particular allergen without actually being allergic, so Canada suggests that the word “allergic” should replace “sensitized”</p>	Canada
<p>We support the definition of “allergen” in the preliminary draft revision, as it is already defined in “CXC 80-2020: Code of Practice on Food Allergen Management for Food Business Operators”.</p>	Colombia
<p>Indonesia agrees with the definition of “allergen”</p>	Indonesia
<p>“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.</p> <p>New Zealand considers it is premature to confirm the proposed definitions until the advice from the FAO/WHO expert group is received. We particularly do not think it is appropriate to list examples at this point until the list of foods and ingredients at 4.2.1.4 is confirmed.</p> <p>That said, New Zealand are is generally supportive of the definitions proposed. However, in the definition of “allergen” we suggest adding the word “[typically]” in square brackets prior to “a protein”. As pointed out in the agenda paper, there are occasions where an IgE mediated response occurs in relation to something other than a protein. However, for all the foods and ingredients currently listed at 4.2.1.4 it is a protein that causes the IgE mediated response. Whether there is a need for the addition of the word “typically” can be determined once the list at 4.2.1.4 is finalised. 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.</p> <p>“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.</p>	New Zealand

GENERAL COMMENTS	MEMBERS / OBSERVERS
<p>“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 <u>usually</u> a protein which is found in food capable of triggering a response in individuals sensitised to it.</p> <p>While protein is a common cause of allergy, there are studies which found that glycoprotein (e.g. galactose alpha 1,3-galactose) and galacto-oligosaccharides (GOS) could cause allergenic reactions in some individuals.</p> <p>Singapore would like propose the following amendment to the definition for “allergen” so that it is not restricted only to protein in food. The will cater for inclusion of non-protein allergens in future, if needed. With this proposed revision, the Committee will not need to revise the definition in future should it decide to list non-protein food allergens in the future.</p> <ul style="list-style-type: none"> • “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. 	Singapore
<p>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 <u>mainly</u> a protein which is found in food capable of triggering a response in individuals sensitised to it.</p> <p>It is not always a protein.</p>	Uruguay
<p>“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.</p> <ul style="list-style-type: none"> - We propose to add the word “typically” to the definition of an allergen, since not only proteins but also other sources may cause an allergic reaction (i.e. Alpha-Gal found in mammalian meat). While it is not a priority allergen, it demonstrates that other triggers for IgE-mediated food allergies exist beyond proteins. This fact that allergen sources are not limited to proteins should be recognized in this definition, but also be introduced in the Code of Practice on Food Allergen Management for Food Business Operators (CXC 80-2020). - EFA encourages Codex to establish definitions that highlight the clear differences between food allergies (IgE-mediated and non-IgE-mediated) and food intolerances as non-IgE-mediated food hypersensitivities. From our patient perspective, we believe the definitions should serve to help distinguish between the different diseases. The purpose of this framework for allergen labelling within GSLPF should be addressed to apply only to food allergies (IgE-mediated and non-IgE-mediated including Coeliac Disease). This should be clearly emphasized in the text. Our proposal is in line with both the recommendation of the ad hoc joint FAO/WHO expert consultation on Risk Assessment of Food Allergens (1st report – issued in May 2021) as well as with the Code of Practice CXC 80-2020 (Section II, 2.1 Scope, page 5: <p>“This Code does not cover hypersensitivities with a non-immunological aetiology such as lactose intolerance and sulphite sensitivity. Food intolerance adverse reactions usually result from a non-immune mediated reaction to food, such as a lack of an enzyme to process foods effectively (e.g. the absence or deficit of lactase in those with lactose intolerance). While intolerances are not explicitly mentioned in the following text, some of the controls described here could be applied to protect those with food intolerances.”</p>	EFA
<p>“Food allergy”</p>	

GENERAL COMMENTS	MEMBERS / OBSERVERS
<p>“Food allergy” means a medical condition in which the individual develops adverse immune reactions to certain food proteins, which may be immunoglobulin E (IgE) mediated and associated with anaphylaxis, non-IgE mediated¹, or a combination of both.</p> <p>This definition seems to be describing an “allergic reaction” to food, rather than “food allergy”. Canada suggests some additional text that specifies that a food allergy is a medical condition that affects some people which is triggered by exposure to specific proteins. Non-IgE mediated food allergy should not include celiac disease, which is a different medical condition, and should not be considered a food allergy. The CXC 80-2020 document referenced for the definition of celiac disease refers to celiac disease as a hypersensitivity and not a non-IgE mediated food allergy. Canada suggests adjustments to the definition of hypersensitivity (below) to ensure celiac disease is included.</p>	Canada
<p>“Food allergy” means adverse immune reactions to certain food proteins, which may be immunoglobulin E (IgE) mediated and associated with mediated anaphylaxis, non-IgE mediated¹, or a combination of both.</p>	European Union
<p>In relation to our comments on definition of “allergen”, Singapore would like to propose the following amendments to the definition for “food allergy”:</p> <ul style="list-style-type: none"> • “Food allergy” means adverse immune reactions to certain food proteins[constituents], which may be immunoglobulin E (IgE) mediated and associated with anaphylaxis, non-IgE mediated¹, or a combination of both. <p>“Food allergy” means adverse immune reactions to certain food proteins[constituents], which may be immunoglobulin E (IgE) mediated and associated with anaphylaxis, non-IgE mediated¹, or a combination of both.</p>	Singapore
<p>“Food allergy” means adverse immune reactions to certain food proteins, which may be immunoglobulin E (IgE) mediated and associated with [footnote 1] anaphylaxis, non-IgE mediated², non-IgE mediated or a combination of both.Footnote 1: See CXC 80-2020: IgE-mediated symptoms typically develop within minutes to 1-2 hours of ingesting the food. Non-IgE-mediated and mixed IgE- and non-IgE-mediated food allergies present with their symptoms several hours after the ingestion of the food. Symptoms of IgE-mediated food allergy may include itching around the mouth, hives, swelling of lips and eyes, difficulties in breathing, drop in blood pressure, diarrhoea and, in its most severe form, anaphylaxis; and may result in death.¹, or a combination of both.</p> <p>We offer the following edits to both simplify the definitions and align with the approach taken by CCFH in CXC 80-2020.</p>	USA
<p>By “food allergy means adverse immune reactions mainly to certain food proteins, which may be immunoglobulin E (IgE) mediated by and associated with anaphylaxis, not IgE mediated¹, or a combination of both.</p> <p>It is suggested to add after, it is “<u>mainly</u>” a protein</p>	Uruguay
<p>“Hypersensitivity”</p>	
<p>“Hypersensitivity” means the repeatable adverse reaction to an allergen or other substance in food associated with IgE mediated food allergy, non-IgE mediated food allergy¹, celiac disease or food intolerance (i.e. sulphites, lactose).</p> <p>In line with comments on the definition of “food allergy”, Canada recommends that hypersensitivity should include celiac disease, but not under “non-IgE mediated food allergy”.</p>	Canada
<p>Regarding "hypersensitivity", "food allergy" and "food intolerance", we agree with the proposed definition, as they are consistent with the European Food Safety Authority (EFSA) scientific opinion on " Evaluation of allergenic "</p>	Colombia

GENERAL COMMENTS	MEMBERS / OBSERVERS
<p>"Hypersensitivity" means the repeatable adverse reaction to an allergen or other otherwise harmless substance in food associated with IgE mediated that leads to food allergy, non-IgE mediated food allergy/intolerance or coeliac disease (autoimmune adverse reaction to food)¹, or food intolerance (i.e. sulphites, lactose).</p>	European Union
<p>We also note the addition of the examples of food intolerance to the definition of "hypersensitivity". As stated above we consider the use of examples needs to wait for the advice of the FAO/WHO expert group. However, we suggest that should examples be included once this advice is received that these examples are more appropriately placed in the definition of "food intolerance".</p>	New Zealand
<p>By "hypersensitivity" is meant the repeatable, exaggerated adverse reaction to an allergen or other substance in food associated with an IgE-mediated food allergy, non-IgE1-mediated food allergy, or food intolerance (i.e., sulphites, lactose).</p>	Uruguay
<p>"Hypersensitivity" means the repeatable adverse reaction to an allergen or other substance in food associated with IgE mediated food allergy, non-IgE mediated food allergy¹, or food intolerance (i.e. sulphites, lactose). <u>resulting from a food allergy or a food intolerance.</u></p> <p>ICGA supports the definitions for food allergy and food intolerance as drafted.</p> <p>In reviewing the definition of hypersensitivity, we understand that it corresponds to the addition of "Food Allergy" and "Food Intolerance". ICGA would therefore like to suggest a mere simplification of the definition of hypersensitivity as follows: ["Hypersensitivity" means the repeatable adverse reaction resulting from a food allergy or a food intolerance.] The phrase "to an allergen or other substance in food associated with IgE mediated food allergy, non-IgE mediated food allergy¹, or food intolerance (i.e. sulphites, lactose)" could then be deleted.</p>	ICGA
<p>More clarity is needed on what is considered an other substance.</p>	ICA/IOCCC
<p>2. MANDATORY LABELLING OF PREPACKAGED FOODS</p>	
<p>Costa Rica would like to request the Committee to clarify whether this guidance would apply to allergen claims made with a declaration of "contains", alternately or in addition to the claims in the list of ingredients</p> <p>In addition, we would like to propose a revised wording (in the second sentence) to improve readability.</p> <p>Where a compound ingredient (for which a name has been established in a Codex standard or in national legislation) constitutes less than 5% of the food or is a food additive that does not fulfil a technological function in the finished product, it does not need to be declared in the list of ingredients [unless listed in section 4.2.1.4].</p>	Costa Rica
<p>Ingredients obtained through biotechnology</p> <p>The EUMS agree that the section 4.2.2 of the GSLPF on ingredients obtained through biotechnology requires no change in relation to allergen labelling.</p>	European Union
<p>The Philippines agrees to the statement including 4.2.1.4 to ensure that foods and ingredients are always declared even at less than 5% as they can still pose a risk to consumers.</p>	Philippines
<p>ICGMA agrees that for consistency and to clearly inform consumers about the presence of these foods and ingredients, the common name for the source of the allergen should be provided, especially in case where there may be ambiguity</p>	ICGMA
<p>4.2.1.3</p>	

GENERAL COMMENTS	MEMBERS / OBSERVERS
<p>4.2.1.3 Where an ingredient is itself the product of two or more ingredients, such a compound ingredient may be declared, as such, in the list of ingredients, provided that it is immediately accompanied by a list, in brackets, of its ingredients in descending order of proportion (m/m). Where a compound ingredient (for which a name has been established in a Codex standard or in national legislation) constitutes less than 5% of the food, the ingredients, other than [those those listed in section 4.2.1.4 and]and food additives which serve a technological function in the finished product, need not be declared.</p> <p>Brazil agrees with the proposed amendment in section 4.2.1.4. Small amounts of allergens can result in serious adverse reactions for people suffering from food allergy and should be always declared when present in compound ingredients. Thus, Brazil suggests the deletion of the square brackets around the new text proposed for section 4.2.1.3.</p>	Brazil
<p>As this information is linked to food safety, we support the amendment to section 4.2.1.3 of the General Standard for the Labelling of Prepackaged Foods (GSLPF) as mentioned in the proposed draft.</p> <p>We support transparent communications with the consumer to ensure food safety and enable consumer choice</p>	Colombia
<p>The EUMS agree with the amendment of section 4.2.1.3 of the GSLPF so that the declaration of foods and ingredients in section 4.2.1.4 applies to all compound ingredients, including those that constitute less than 5% of the food. The EUMS consider that severe allergic reactions can be caused at very low level for certain consumer groups. In that context, the EUMS support the need to always declare information on the presence of food allergens, including compound ingredients, as long as the substance in question is present in the final food and no scientifically established threshold for individual substances is set.</p>	European Union
<p>We request that the Committee clarify whether this guidance would apply to allergen declarations made with a “contains” statement alternatively or in addition to declarations in the list of ingredients.</p> <p>Additionally, we propose revised wording (in the second sentence) for improved readability.</p>	Guatemala
<p>Indonesia agrees with the proposed text in section 4.2.1.3.</p>	Indonesia
<p>Singapore agrees with the inclusion of the text in square brackets.</p>	Singapore
<p>In principle, this section relates to the amount of the food or ingredients known to cause hypersensitivity present in the food therefore we propose to wait for the outcome of the expert consultation.</p>	Thailand
<p>4.2.1.3 Where an ingredient is itself the product of two or more ingredients, such a compound ingredient may be declared, as such, in the list of ingredients, provided that it is immediately accompanied by a list, in brackets, of its ingredients in descending order of proportion (m/m). Where a compound ingredient (for which a name has been established in a Codex standard or in national legislation) constitutes less than 5% of the food, the ingredients, other than [those listed in section 4.2.1.4 and] food additives which serve a technological function in the finished product, need not be declared.</p> <p>We propose to establish a labelling requirement for compound ingredients, in alignment with the information for each of the other components of pre-packaged foods. Given the rise in other non-priority food allergens (i.e. allergy to legumes, to insects) and the significant number of individuals who are allergic to unusual ingredients like fruit and spices, such an indication would enable consumers with food allergies to better protect themselves.</p> <p>Following the suggestion of the ad hoc FAO/WHO expert consultation to develop a watch-list for these allergens, EFA holds that it should be possible to identify them in food products, independently of their percentage in the food. In fact, food allergens can elicit allergic reactions in even small amounts, and that is the reason why they must be declared. EFA therefore recommends to remove the 5% rule to enable patients to identify all ingredients used in a food product.</p>	EFA

GENERAL COMMENTS	MEMBERS / OBSERVERS
<p>4.2.1.3 Where an ingredient is itself the product of two or more ingredients, such a compound ingredient may be declared, as such, in the list of ingredients, provided that it is immediately accompanied by a list, in brackets, of its ingredients in descending order of proportion (m/m). Where a compound ingredient (for which a name has been established in a Codex standard or in national legislation has been legally established) constitutes less than 5% of the food, the ingredients, other than [those listed in section 4.2.1.4 and] food additives which serve a technological function in the finished product, need not be declared.</p> <p>ICGA supports the addition of the reference to the section 4.2.1.4 in the square brackets. Square brackets could be deleted and the proposed text retained.</p> <p>ICGA further suggests that the reference to “national legislation” be avoided and the phrase “for which a name has been established in a Codex standard or in national legislation” be reworded as “for which a name has been legally established.” (i.e. the words “in a Codex standard or in national legislation” can be deleted).</p> <p>ICGA finally further notes that ingredients derived from allergenic sources that trigger hypersensitivity should be declared on the label of the prepackaged food and highlighted as described in new Section 8, unless they are below a limit in the finished product or are specifically exempted from mandatory allergen labelling. It further emphasizes the important of scientific consultation regarding dose-response. Given this, it would be helpful therefore, for the document to address the concept and handling of “non-allergenic” derivatives (e.g. starch hydrolysates from wheat).</p>	<p>ICGA</p>
<p>ICA supports the addition that allergens/foods listed in 4.2.1.4 always be declared even when present in compound ingredients below 5%. We note that ingredients derived from allergenic sources that contain an allergen (e.g., gluten) and those intentionally added that may trigger a food intolerance (e.g., sulfites) should be declared on product and highlighted as described in Section 8, unless they are below a nationally defined limit in the finished product or are specifically exempt in national provisions due to lack of allergenic protein. This emphasizes the important of scientific consultation regarding dose response.</p> <p>Given this, it would be helpful therefore, for this document address the concept and handling of “non-allergenic” derivatives.</p>	<p>ICA/IOCCC</p>
<p>4.2.1.3 Where an ingredient is itself the product of two or more ingredients, such a compound ingredient may be declared, as such, in the list of ingredients, provided that it is immediately accompanied by a list, in brackets, of its ingredients in descending order of proportion (m/m). Where a compound ingredient (for which a name has been established in a Codex standard or in national legislation) constitutes less than 5% of the food, food or is a food additive that does not serve a technological function in the ingredients finished product, other than it need not be declared in the ingredient list [unless it is [those those listed in section 4.2.1.4 and]4] food additives which serve a technological function in the finished product, need not be declared.</p> <p>We request the following edits to improve readability. We also request that Committee to clarify whether this guidance would apply to allergen declarations made with a “contains” statement alternatively or in addition to declarations in the list of ingredients.</p>	<p>Food Industry Asia (FIA)</p>
<p>We suggest the following text change.</p> <p>4.2.1.3 Where an ingredient is itself the product of two or more ingredients, such a compound ingredient may be declared, as such, in the list of ingredients, provided that it is immediately accompanied by a list, in brackets, of its ingredients in descending order of proportion (m/m). Where a compound ingredient (for which a name has been established in a Codex standard or in national legislation) constitutes less than 5% of the food or is a food additive that does not serve a technological function in the finished product, it need not be declared in the ingredient list [unless it is those listed in Section 4.2.1.4 and].</p> <p>Rationale</p>	<p>IFU</p>

GENERAL COMMENTS	MEMBERS / OBSERVERS
<p>We request that the Committee clarify whether this guidance would apply to allergen declarations made with a “contains” statement alternatively or in addition to declarations in the list of ingredients.</p>	
<p>4.2.1.3 Where an ingredient is itself the product of two or more ingredients, such a compound ingredient may be declared, as such, in the list of ingredients, provided that it is immediately accompanied by a list, in brackets, of its ingredients in descending order of proportion (m/m). Where a compound ingredient (for which a name has been established in a Codex standard or in national legislation) constitutes less than 5% of the food, food or is a food additive that does not serve a technological function in the ingredients finished product, other than it need not be declared in the ingredient list [those unless it is listed in section Section 4.2.1.4 and]4.] food additives which serve a technological function in the finished product, need not be declared.</p> <p>We request that the Committee clarify whether this guidance would apply to allergen declarations made with a “contains” statement alternatively or in addition to declarations in the list of ingredients. Additionally, we propose revised wording (in the second sentence) for improved readability.</p>	ICGMA
<p>4.2.1.3 Where an ingredient is itself the product of two or more ingredients, such a compound ingredient may be declared, as such, in the list of ingredients, provided that it is immediately accompanied by a list, in brackets, of its ingredients in descending order of proportion (m/m). Where a compound ingredient (for which a name has been established in a Codex standard or in national legislation) constitutes less than 5% of the foodfood or is a food additive that does not serve a technological function in the finished product, the ingredients, other than it need not be declared in the ingredient list [unless it is [those listed in section Section 4.2.1.4 and]4.] food additives which serve a technological function in the finished product, need not be declared.</p> <p>ICBA requests that the Committee clarify whether this guidance would apply to allergen declarations made with a “contains” statement alternatively or in addition to declarations in the list of ingredients.</p> <p>Additionally, ICBA proposes revised wording (in the second sentence) for improved readability.</p>	ICBA
<p>4.2.1.3 Where an ingredient is itself the product of two or more ingredients, such a compound ingredient may be declared, as such, in the list of ingredients, provided that it is immediately accompanied by a list, in brackets, of its ingredients in descending order of proportion (m/m). Where a compound ingredient (for which a name has been established in a Codex standard or in national legislation) constitutes less than 5% of the food, the except for those ingredients, other than [those listed in section 4.2.1.4 and]and food additives which that serve a technological function in the finished product, these compound ingredients need not be declared..</p> <p>We support the amendment to section 4.2.1.3 of the GSLPF so that the declaration of foods and ingredients in section 4.2.1.4 apply to all compound ingredients including those that constitute less than 5% of the food.</p> <p>We note that all ingredients derived from allergenic sources that contain an allergen (e.g., gluten) and those intentionally added that may trigger a food intolerance (e.g., sulfites) should be declared on-product and highlighted as described in Section 8, unless they are below a nationally defined limit in the finished product or are specifically exempt in national provisions due to lack of allergenic protein. The 5% presence threshold in Section 4.2.1.3. applies broadly to all ingredients and was not intended to apply to a presence threshold for allergens per se.</p> <p>See underlined suggestions above.</p>	FoodDrinkEurope
[4.2.1.4]	
Algeria proposes the following:	Algeria

GENERAL COMMENTS	MEMBERS / OBSERVERS
<ul style="list-style-type: none"> • To insert a title in point 4.2.1.4 as follows: insert a title in point 4.2.1.4 as follows: "List of foodstuffs and food ingredients causing allergies or intolerances"; • Complete this list as follows: • Cereals containing gluten, namely wheat, barley, oats, spelt, kamut or their hybridized strains, and products based on these cereals, with the exception of: <ul style="list-style-type: none"> a) Wheat-based glucose syrups, including dextrose; b) Wheat-based maltodextrins; c) Barley-based glucose syrups; d) Cereals used for the manufacture of alcoholic distillates, including ethyl alcohol of agricultural origin; • Crustaceans and crustacean products; • Eggs and egg products; • Fish and fish products, except for: <ul style="list-style-type: none"> a) Fish gelatin used as a carrier for vitamin or carotenoid preparations; b) Fish gelatin or isinglass used as a clarifying agent in beer and wine; • Peanuts and peanut products; • Soybeans and soybean products, with the exception of: <ul style="list-style-type: none"> (a) Fully refined soybean oil and fat; (b) Natural mixed tocopherols (E306), natural D-alpha-tocopherol derived from soybeans; (c) Phytosterols and phytosterol esters derived from soybean vegetable oils, vegetable stanol ester produced from sterols derived from soybean vegetable oils; • Milk and milk-based products (including lactose), with the exception of: <ul style="list-style-type: none"> (a) When used in the manufacture of alcoholic distillates, including ethyl alcohol of agricultural origin; (b) Lactitol; • Nuts, namely: almonds (<i>Amygdalus communis</i> L.), hazelnuts (<i>Corylus avellana</i>), walnuts (<i>Juglans regia</i>), cashews (<i>Anacardium occidentale</i>), pecans (<i>Carya illinoensis</i> (Wangenh.) K. Koch), Macadamia or Queensland nuts (<i>Macadamia ternifolia</i>), and products based on these fruits, except nuts used for the manufacture of alcoholic distillates, including ethyl alcohol of agricultural origin; • Celery and celery products; • Mustard and mustard products; • Sesame seeds and sesame seed products; • Sulfur dioxide and sulfites in concentrations of more than 10mg/kg or 10 mg/L in terms of total SO₂ for products offered ready-to-eat or reconstituted according to the manufacturer's instructions; • Lupin and lupin products; • Molluscan shellfish and shellfish products. • Insert this list in an annex of the CXS 1 - 1985 Standard. 	

GENERAL COMMENTS	MEMBERS / OBSERVERS
Brazil request that this section 4.2.1.4 be kept in square brackets until the full report of the first meeting of Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens is available.	Brazil
<p>[[4.2.1.4 The following foods and ingredients are known to cause hypersensitivity and shall always be declared:<u>declared when protein from these foods, or sulphites, is part of the formulation of the product.</u>²</p> <p>Comment for the first 7 bullets:</p> <p>Canada suggests that the wording “X and X products” in the list of foods and ingredients known to cause hypersensitivity may be inconsistent with the definition of food allergy unless this is clarified further. The definition of food allergy mentions that it is proteins from specific food allergens that trigger allergic reactions. This means that some products of an allergen which no longer contain protein or contain a negligible amount of protein (such as highly refined oil or enzyme preparations that contain residual protein in a negligible amount that is too small to pose a health risk) should not be included under 4.2.1.4.</p> <p>Canada suggests adding the words “when protein from these foods, or sulphites, is part of the formulation of the product” after “shall always be declared”.</p>	Canada
Please, add some fruit like banana.	Iraq
Malaysia has no objection on the proposed draft. Malaysia is of the view that the recommendations by FAO/WHO and their scientific advice should be adopted in GSLPF.	Malaysia
May we request to separate peanut from soybeans and products of these. These are two separate foods/ingredients. We would also like to request to provide examples under crustaceans.	Philippines
An exemption should apply for certain ingredients that do not cause any reaction, due to their manufacturing process (e.g. wheat glucose syrup, fish gelatine, etc.)	Switzerland
<p>After consideration of the Summary and Conclusions of ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens Part 1, of which proposed to change the current list of the foods and ingredients are known to cause hypersensitivity, we have the following views:</p> <ul style="list-style-type: none"> - this list should be retained to be the list of the food and ingredients known to cause hypersensitivity, i.e. include both foods those cause allergy and food intolerance - the proposed addition of "sesame" needs to be carefully discussed - Consideration should be taken to possible exempting foods, which have been highly refined until the protein that causes an allergenic reaction is eliminated, from the labelling of such allergen. 	Thailand
<p>The United States would support starting a discussion as part of CCFL46 regarding updating Section 4.2.1.4 based on the recommendations from the FAO/WHO expert committee (2021). Please see this report:</p> <p>https://cdn.who.int/media/docs/default-source/food-safety/jemra/1st-allergen-summary-report-10may2021.pdf?sfvrsn=c505375a_7</p> <p>The United States notes based on the summary report that there will be a need to discuss how to differentiate between tree nuts and related products and also how to best approach substances causing sensitivities in light of no new risk assessment information.</p>	USA

GENERAL COMMENTS	MEMBERS / OBSERVERS
<p>The U.S. also notes that in the second report of the FAO/WHO expert committee (2021) threshold values for the priority allergens have been recommended. The Committee may wish to discuss how these threshold values might apply to declarations of priority allergens in highly processed foods, process aids, or carry-over food additives is warranted.</p> <p>That document can be found here: http://www.fao.org/3/cb6388en/cb6388en.pdf</p>	
4.2.1.4	
<p>4.2.1.4 The following foods and ingredients are known to cause <u>hypersensitivity (IgE and non-IgE mediated) food allergies and</u> shall always be declared:²</p>	EFA
<p>This list in 4.2.1.4 generally should be amended based on the work and recommendations by the expert committee on food allergens. The Committee should address the FAO/WHO expert Committee's conclusions that "only foods or ingredients that cause immune-mediated hypersensitivities such as IgE-mediated food allergies and coeliac disease should be included on the list of foods and ingredients included in section 4.2.1.4 of the GSLPF. Thus, it was recommended that foods or ingredients such as lactose, sulphite, and food additives which cause food intolerances rather than immune-mediated responses, should be excluded from this list."</p> <p>ICA notes that CCFL has historically foreseen that such a review shall be performed by JECFA according to footnote #2. It may be useful to seek FAO and WHO and JECFA secretariat views on the pertinence to reword or even keep Footnote 2 in that regard.</p>	ICA
<p>ICGA notes that a dedicated Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens have discussed and made recommendations in their executive summaries published in May and August 2021.</p> <p>ICGA notes also that CCFL had historically foreseen that such a review would be performed by JECFA according to footnote #2. Perhaps, the wording of footnote #2 should be adapted to refer to "relevant FAO/WHO scientific advice" to broaden it from the current reference to JECFA which does not seem appropriate any longer.</p>	ICGA
<p>Will need to be updated based on FAO/WHO Committee's conclusions</p>	ICA
<p>We view that exemptions are appropriate when components are below a defined limit (e.g. sulphite, gluten), or are exempt due to lack of protein (e.g. highly refined oil). The GSLPF does not currently list such exemptions.</p> <p>We encourage an internationally harmonised exemption list and recommend consideration of existing exemptions in country regulations. We note that the CCFH has already requested FAO/WHO to convene an expert consultation to provide scientific advice on threshold levels for priority allergens (terms of reference in REP19/FH, para 56). Guidance from FAO/WHO on threshold levels can also help inform what exemptions are appropriate.</p> <p>Given that the Committee is still awaiting the assessment of the FAO/WHO expert panel, we recommend that the text to be discussed and considered once the Committee has received the advice of the expert panel.</p>	FIA
<p>IFT supports the Appendix II list of ingredients in 4.2.1.4 as ones that shall always be global priority declared allergens or intolerances, with the exception of oats, which we believe should be moved to an individual country-based level as called for in the Joint FAO/WHO Expert Consultation report. In addition, IFT recommends inclusion of sesame to the global priority list based on the Joint FAO/WHO Expert Consultation report. IFT believes further reference is necessary to highlight other known allergen ingredients based on ongoing scientific risk assessments, so as to take into account further priority ingredients on lists established in some countries and regions, such as mustard, celery and others identified in the Joint FAO/WHO Expert Consultation report. This would help serve as a watch list and raise global awareness of wider potential allergenicity concerns.</p>	IFT

GENERAL COMMENTS	MEMBERS / OBSERVERS
<p>Cereals containing gluten; i.e., wheat, rye, barley, oats, spelt or their hybridized strains and products of these</p>	
<p>Cereals containing gluten: in agreement with the ad hoc joint FAO/WHO expert consultation on Risk Assessment of Food Allergens (1st report) the three main species (wheat, rye, and barley) should be listed and their hybridized strains included.</p> <p>Cereals containing gluten; i.e., wheat, rye, barley, oats, spelt or and their hybridized strains and products of these</p>	EFA
<p>Cereals containing gluten; i.e., wheat<u>wheat and other Triticum species, rye</u>rye and other Secale species, barley<u>barley and other Hordeum species, [oats], spelt or [spelt] and</u> their hybridized strains and products of these<u>these [(unless specifically exempted by a recognized authoritative body on a case-by-case basis)]</u>;</p> <p>ICGA notes that the list of known ingredients causing hypersensitivity included in CXS 1 (2018 version) requires some update since its first adoption in 1985.</p> <p>ICGA notes that the conclusions of ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens are very straight forward for CCFL consideration: “The Expert Committee determined that only foods or ingredients that cause immune-mediated hypersensitivities such as IgE-mediated food allergies and coeliac disease should be included on the list of foods and ingredients included in section 4.2.1.4 of the GSLPF. Thus, it was recommended that foods or ingredients such as lactose, sulphite, and food additives which cause food intolerances rather than immune-mediated responses, should be excluded from this list. »</p> <p>The expert consultation also concluded that:</p> <p>« Based on systematic and thorough assessments which used all three criteria (prevalence, severity and potency), the Committee recommended that the following should be listed as priority allergens: Cereals containing gluten (i.e., wheat and other Triticum species, rye and other Secale species, barley and other Hordeum species and their hybridized strains), crustacea, eggs, fish, milk, peanuts, sesame, specific tree nuts (almond, cashew, hazelnut, pecan, pistachio and walnut). Due to the lack of data on prevalence, severity and/or potency, or due to regional consumption of some foods, the Committee recommended that some of the allergens, such as buckwheat, celery, lupin, mustard, oats, soybean and tree nuts (Brazil nut, macadamia, pine nuts), should not be listed as global priority allergens but may be considered for inclusion on priority allergen lists in individual countries. Since current dietary trends include an increased consumption of plant-based foods and diets consisting of alternative protein sources, it was recommended that pulses, insects and other foods such as kiwi fruits be included in a “watch list” and evaluated for the priority allergen list when data on prevalence, severity and potency become available.</p> <p>Finally, the Expert Committee recommended that foods and ingredients derived from the list of foods known to cause immune-mediated hypersensitivities should be evaluated on a case-by-case basis for exclusion from declaration on ingredient lists and/or on food packaging. »</p> <p>See expert consultations executive summaries at 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)</p> <p>ICGA does not support the recommendation to defer the discussion on mandatory labelling of buckwheat, celery, lupin, mustard, oats, soybean and tree nuts (Brazil nut, macadamia, pine nuts) to individual countries or regions. ICGA believes the Codex Alimentarius Commission and CCFL are the place where such discussions should be held, based on the advice of that FAO/WHO expert consultation and Codex member and observer inputs.</p> <p>Based on the above recommendations, ICGA suggests that CCFL46 considers the enclosed tracked changes to the list of allergens covered by mandatory labelling in section 4.2.1.4 of CXS 1 (latest version: 2018) for future discussions:</p>	ICGA

GENERAL COMMENTS	MEMBERS / OBSERVERS
Crustacea and products of these	
<u>Crustacea</u> Crustacea , <u>[Insects]</u> , <u>[Molluscs]</u> , and products of these;	ICGA
Peanuts, soybeans and products of these	
<p>Peanuts, soybeans <u>Peanuts</u> and products of these; <u>peanut products</u>; • <u>Soybeans and soy products</u></p> <ul style="list-style-type: none"> - As a patients organisation, EFA strongly recommends that soy remains in the list of priority allergens, because soy is capable to elicit anaphylactic reactions (not only as exercised induced anaphylaxis) and is prevalent in many European countries as well as in other countries of the world. With regards to potency, the reference dose for soy established by the VITAL 3.0 (ED01) is below the reference dose for foods still considered to be priority allergens, such as fish, wheat, and shrimps, which suggests a greater potency of soy. Our main concern is that soy, widely used as a substitute for children with cow’s milk allergy, will not be recognized as potentially harmful if it is taken off the list of priority allergens. Finally, our concern is not only related to IgE mediated soy allergy, but also to Food Protein Induced Enterocolitis Syndrome (FPIES), where soy is one of the most common eliciting allergens. - Peanuts and soybeans should be listed separately. 	EFA
Peanuts, soybeans <u>[sesame]</u> , <u>[soybeans]</u> and products of these <u>these [(unless specifically exempted by a recognized authoritative scientific body on a case-by-case basis)]</u> ;	ICGA
Recommend separating out soybeans from peanuts	ICA
IFT considers that the scientific output from the Joint FAO/WHO Expert Consultation report could be useful in defining exemptions from allergen/hypersensitivity declarations listed in 4.2.1.4 when foods/food ingredients derived from those items have been processed in a manner in which allergenic components have been removed or rendered non-allergenic. Many regulatory frameworks have established exemptions for food ingredients, such as refined vegetable oils, and it would be beneficial to leverage the output of the Expert Consultation report to align on harmonized exemptions.	IFT
Milk and milk products (lactose included)	
Milk and milk products (lactose included) <u>[(excluding] lactose [included]]</u> ;	ICGA
Tree nuts and nut products	
<p><u>Tree nuts and nut products; and</u></p> <p>Canada suggests that the term “tree nuts” should be defined for clarity and consistency of application.</p>	Canada
<p>Tree nuts and nut products; and: <u>Sesame and sesame products</u></p> <ul style="list-style-type: none"> - We support the recommendation of adding sesame to the list of priority allergens. 	EFA
<p>Specific tree-ree nuts and nut products; and <u>(i.e. almond, cashew, hazelnut, pecan, pistachio and walnut, [Brazil nut, macadamia, pine nuts]) and products of these [(unless specifically exempted by a recognized authoritative scientific body on a case-by-case basis)]</u> .</p> <p>With regards to the definition of tree nuts, it should be also made clear that “coconuts and products thereof” are not included in the above list, although botanically speaking a “tree nut”.</p>	ICGA
Sulphite in concentrations of 10 mg/kg or more.]	

GENERAL COMMENTS	MEMBERS / OBSERVERS
<p>-Sulphite in concentrations of 10 mg/kg or more:</p> <p>The following wording modification is proposed: "Sulphur dioxide and sulphites at concentrations above 10 mg/kg or 10 mg/litre in terms of the total SO₂, to be calculated for ready-to-drink or reconstituted products in accordance with manufacturers' instructions."</p> <p>Argentina's position: It is proposed that the text regarding sulfites be modified according to EU Regulation 1169/2011 to be calculated as total SO₂ (products ready for consumption or reconstituted according to the preparation instructions on the container).</p>	<p>Argentina</p>
<p>- In line with our recommendation on the definition of an allergen, and therefore to include only foods and ingredients that are known to cause IgE and non-IgE-mediated food allergies, EFA suggests deleting sulphite in concentrations of 10mg/ kg or more from the list. (The rule as such to label sulphite in concentrations of 10mg/ kg or more does not need to be affected. However, it should not be part of the allergen labelling).</p> <p>Sulphite in concentrations of 10 mg/kg or more.]</p>	<p>EFA</p>
<p>Sulphite in concentrations of 10 mg/kg or more.]</p> <p>With regards to sulphites, should the CCFL disagree to take that reference out of the list, then it should be expressed as total sulfur dioxide and calculated in the product as consumed, according to the instructions of preparation by the manufacturer.</p>	<p>ICGA</p>
<p>NEW 4.2.1.5</p>	
<p>Uganda is in agreement with the proposed new text as captured under 4.2.1.5 as well as with renumbering of the proceeding relevant subclauses</p>	<p>Uganda</p>
<p>We further suggest that the following substances be considered for an exemption to be reviewed by the ad hoc FAO/WHO Expert Consultation:</p> <ul style="list-style-type: none"> - (a) wheat-based glucose syrups including dextrose and wheat-based maltodextrins ; and their products thereof, in so far as the process that they have undergone is not likely to increase the level of allergenicity assessed by [based on relevant FAO/WHO scientific advice] for the relevant product from which they originated; (b) glucose syrups based on barley; (c) cereals used for making alcoholic distillates including ethyl alcohol of agricultural origin. - fish gelatine used as carrier for vitamin or carotenoid preparations; (b) fish gelatine or Isinglass used as fining agent in beer and wine; - (a) fully refined soybean oil and fat and their products thereof, in so far as the process that they have undergone is not likely to increase the level of allergenicity assessed by [based on relevant FAO/WHO scientific advice] for the relevant product from which they originated; (b) natural mixed tocopherols (E306), natural D-alpha tocopherol, natural D- alpha tocopherol acetate, and natural D-alpha tocopherol succinate from soybean sources; (c) vegetable oils derived phytosterols and phytosterol esters from soybean sources; and (d) plant stanol ester produced from vegetable oil sterols from soybean sources; - whey used for making alcoholic distillates including ethyl alcohol of agricultural origin; (b) lactitol; - nuts used for making alcoholic distillates including ethyl alcohol of agricultural origin. <p>CCFL46 shall thoroughly discuss the ad hoc FAO/WHO Expert Consultation recommendations on:</p> <ul style="list-style-type: none"> - Celery and products of these; - Mustard and products of these; - Lupin and products of these; 	<p>ICGA</p>

GENERAL COMMENTS	MEMBERS / OBSERVERS
<p>- Pulses and products of these.</p> <p>Some fruits, like kiwi, strawberry, and kern fruits, like peach or apricots that may also trigger some hypersensitivity reactions in some individuals.</p> <p>We suggest that CCFL46 should also seek the advice of CCFH and the ad hoc FAO/WHO expert consultation for further guidance and scientific inputs prior to endorse any change to that section 4.2.1.4. in square brackets.</p>	
<p>ICA is supportive of this language. We support the use of commonly known terms for the source of the food and ingredient as part of, or in conjunction with, the relevant ingredient name where there is potential for ambiguity.</p>	ICA
[4.2.1.5]	
<p>Argentina's position: Agrees with the text proposed as item 4.2.1.5</p>	Argentina
<p>Australia supports inclusion of this new section. Consumer behaviour evidence supports the use of consistent, common and known terms (words) for the source of the food and ingredient known to cause hypersensitivity.</p>	Australia
<p>Brazil agrees with the new section 4.2.1.5. The use of commonly known terms for the source of the food and ingredient known to cause hypersensitivity will improve consumers understanding and use of allergen statements. This provision 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. Thus, Brazil suggests the deletion of the square brackets around the new text proposed for section 4.2.1.5.</p>	Brazil
<p>The term "commonly known" is better than the term "well understood" but may still be open to interpretation. Canada suggests that 'commonly known terms' may need to be further defined. For example, one country may consider "cheese" to be a commonly known term for the source of milk protein, while another country may require the word "milk" to appear on the label, even if cheese is listed as an ingredient.</p> <p>Canada suggests trying to link this back to the names listed in 4.2.1.4 (the words "milk", "egg", "peanuts", "soybeans" should appear on the label when an ingredient containing protein from one of these food allergens is present in a product), with the recognition that specific common names are required for ingredients from groups like fish, crustaceans and tree nuts (you can't declare "tree nuts" in the list of ingredients, you must declare the specific tree nut(s) that are present).</p>	Canada
<p>Chile would like clarification of several aspects arising from the phrase "commonly known terms for the food source". In this regard, it is not clear to us by whom are they known, for example, by consumers in the country of destination of the food, or known by consumers in the country of origin of the food, or by the competent authorities of each country. Additionally, we would like to make it clear that "commonly known terms for the food source" can vary between countries or between regions. This is especially noticeable for the case of tree nuts, a term that in many countries is not recognized by consumers, added to the fact that this category is not harmonized worldwide, as there are countries that recognize some foods as tree nuts and other countries not, such as the case of coconuts.</p> <p>For Chile, it is important that, within the list, exceptions be considered for foods or ingredients that have been subjected to technological processes that eliminate the allergen, taking into account evidence to support this elimination.</p>	Chile
<p>We agree with paragraph 4.2.1.5 as proposed in the Proposed Draft document.</p> <p>We support transparent communications with the consumer to ensure food safety and enable consumer choice.</p>	Colombia
<p>The EUMS agree with specifying the use of common terms for the source of the food and ingredient known to cause hypersensitivity, aligned with the relevant ingredient name for declarations on prepacked foods. The EUMS welcome this</p>	European Union

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<p>provision in particular in light of the opinion that food information regarding allergens needs to be harmonised to avoid consumer misunderstanding and misuse. Hence, to clearly indicate the terminology (or wording) to be used with regard to allergen labelling, this terminology (or wording) should be as simple as possible in order to allow the consumer to identify immediately the presence of one of the substances listed in section 4.2.1.4 of the GSLPF. In this context, the EUMS agree with the proposition that allergen information must be clear to understand and that substances must be indicated in the list of ingredients with a clear reference to their name as listed therein (e.g. eggs, fish, milk etc.).</p>	
<p>New Zealand supports the intent of 4.2.1.5 in that we support the foods and ingredients listed in 4.2.1.4 being identified in the ingredients list by terms that are well known to consumers. We provide the above edits for increased clarity.</p> <p>New Zealand considers that once the list of foods and ingredients at 4.2.1.4 is finalised it would be useful to provide a list of the “commonly known terms” to be used for the foods and ingredients listed at 4.2.1.4.</p> <p>The text would then read:</p> <p>[4.2.1.5 Declaration of the foods and ingredients listed in section 4.2.1.4 shall be made using commonly known terms that enable the consumer to identify the foods and ingredients on the list as part of, or in conjunction with, the relevant ingredient name.]</p>	New Zealand
<p>The Philippines agrees to the use of the term ‘commonly known’ instead of ‘well understood.’ The commonly known term for the source should be part of the ingredient name, e.g., “milk powder”; or provided in another manner in which this information is clearly provided to consumers, e.g., sodium caseinate (milk); or where there are multiple ingredients from the same source, we propose that having a separate “Contains” summary statement should remove the need to specify each ingredient is from that source.</p> <p>Therefore, we propose the following modification:</p> <p>4.2.1.5 Declaration of the foods and ingredients listed in section</p> <p>4.2.1.4 shall be made using commonly known terms for the source of the food and ingredient as part of, or in conjunction with, the relevant ingredient name either in the ingredients list or in the separate statement under section 8.3.2.</p>	Philippines
<p>Singapore generally agrees with the inclusion of the new 4.2.1.5 to have clarity for ingredients that are sourced from food listed in section 4.2.1.4 to be declared.</p> <p>However, Singapore is mindful of over declaration which might unnecessarily restrict dietary choices of consumers with food allergy, especially if the ingredients are highly refined (e.g. food additive from ingredients known to cause allergy) such that the allergenic components may no longer be present in the final food product.</p> <p>Hence, Singapore would propose for CCFL to deliberate further on this new text after the report on threshold levels in foods of the priority allergens, is made available.</p>	Singapore
<p>We agree with this addition as it makes the allergen labelling clearer, therefore the brackets can be removed.</p>	Thailand
<p>It is suggested that the footnote should be deleted as it generates confusion.</p> <p>1 Includes coeliac disease which is a serious lifelong illness where the body’s immune system attacks its own tissues when gluten is consumed. This causes damage to the lining of the gut and results in the inability of the body to properly absorb nutrients from food.</p>	Uruguay

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<p>We agree. Some examples:</p> <ul style="list-style-type: none"> - Casein (milk), whey protein (milk). - Gluten containing cereals need to be listed with their species: wheat, barley or rye. - Tree nuts need to be listed with their species: i. e. hazelnut, pistachio, cashew, walnut, pekan nut, almond. 	EFA
ICGA supports the proposal	ICGA
<p>We support the use of commonly known terms for the source of the food and ingredient as part of, or in conjunction with, the relevant ingredient name where there is a potential for ambiguity. Using commonly understood terms to indicate the source of the food and ingredient as part of or in addition to the ingredient name will help ensure consumers can easily recognize those foods and ingredients (identified in Section 4.2.1.4) which may cause hypersensitivity.</p>	ICGMA
<p>We support the use of commonly known terms for the source of the food and ingredient as part of, or in conjunction with, the relevant ingredient name where there is potential for ambiguity. Using commonly understood terms to indicate the source of the food and ingredient as part of or in addition to the ingredient name will help the consumer more easily recognize those foods and ingredients (identified in 4.2.1.4) which may cause hypersensitivity.</p>	FoodDrinkEurope
4.2.3.1 [...]	
<p>-Item 4.2.3.1. [Except for those ingredients listed in section 4.2.1.4, and unless a general class name would be more informative, the following class names may be used. In all cases, the food and ingredients listed in section 4.2.1.4 must be declared in accordance with section 4.2.1.5.]</p> <p>Position of Argentina: We agree with amending Section 4.2.3.1 regarding the ingredients that are listed in Section 4.2.1.4. and the generic names, taking into account that, when the Spanish translation is made, "tree nuts" should be translated as "<i>frutas secas</i>", ("dried fruits"), and "fish and fish products" as "<i>pescado y derivados</i>" ("fish and derivatives") and not as "<i>productos pesqueros</i>", ("fishery products"), which we would understand as a more comprehensive term.</p> <p><i>[T. N. This comment regarding the Spanish translation refers to the Spanish version only]</i></p>	Argentina
<p>Consistent with our comments on new section 4.2.1.5, Australia supports the proposed changes to section 4.2.3.1 so that the proposed new section 4.2.1.5 applies to class names.</p>	Australia
<p>Brazil agrees with the amendments in section 4.2.1.5 and suggests the deletion of the square brackets.</p>	Brazil
<p>This section should be amended based on the final decision on section 4.2.1.5 to align these 2 sections.</p>	Colombia
<p>The EUMS welcome the amendment of defining when and how permitted class names associated with the declaration of the foods and ingredients known to cause hypersensitivity could be used. The EUMS consider that the substances listed in section 4.2.1.4 have to be declared at all times. For this purpose, the EUMS welcome the provision that in all cases, the food and ingredients listed in section 4.2.1.4 must be declared in accordance with section 4.2.1.5 by using common and well-understood terms for the source of the food and ingredient as part of, or in conjunction with, the relevant ingredient name. In that context, the EUMS agree that in cases, where a name clearly refers to one of the allergens listed in section 4.2.1.4 of the GSLPF, such name should be allowed for the purpose of declaring the allergens. Similarly, when a class name of section 4.2.3 would be more informative than the name mentioned in the list of section 4.2.1.4 of the GSLPF, such name should be allowed to declare the allergen in question.</p>	European Union
<p>Indonesia agrees with the proposed text in section 4.2.3.1</p>	Indonesia

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<p>New Zealand considers there are two concepts covered in 4.2.3.1 and suggests the intent would be clearer if the concepts were uncoupled and presented as two separate clauses.</p> <p>The text would then read:</p> <p>4.2.3.1 [Unless a general class name would be more informative, the following class names may be used. 4.2.3.2 In all cases, the food and ingredients listed in section 4.2.1.4 must be declared in accordance with section 4.2.1.5.]</p>	New Zealand
<p>For 4.2.3.1, the Philippines supports the proposed amendment of 4.2.3.1 to improve clarity for consumers and in setting more specific class naming requirements.</p>	Philippines
<p>Singapore generally agrees with the inclusion of the text in square brackets, but would propose for CCFL to deliberate further after the report on threshold levels in foods of the priority allergens, is made available</p>	Singapore
<p>We agree with this modification as it makes this requirement clearer.</p>	Thailand
<p>Uganda is in agreement with the proposed deletions and restructuring of the new text as captured in 4.2.3.1</p>	Uganda
<p>We agree.</p>	EFA
<p>We suggest finalizing the amendments of Section 4.2.3.1 after reaching an agreement on Section 4.2.1.4.</p>	ICGMA
<p>We suggest finalising the amendment of section 4.2.3.1 after reaching an agreement on section 4.2.1.4.</p>	FoodDrinkEurope
<p>4.2.4</p>	
<p>Processing Aids and Carry-Over of Food Additives</p> <p>The Philippines agrees with the recommendation in square bracket wherein exemption will not apply to food additive and processing aids that contains allergen as there is still risk to consumers.</p>	Philippines
<p>4.2.4.2</p>	
<p>-ITEM 4.2.4.2. A food additive carried over into foods at a level less than that required to achieve a technological function, and processing aids, are exempted from declaration in the list of ingredients. The exemption does not apply to food additive and processing aids [that contain or are derived from the foods and ingredients] listed in section 4.2.1.4.</p> <p>Argentina's position: We are in agreement with the modification of item 4.2.4.2. However, a change in the wording order is proposed as follows:</p> <p>"4.2.4.2. Food additives carried over into foods at a level less than that required to achieve a technological function, and processing aids, are exempted from declaration in the list of ingredients. This exemption does not apply to food additive and processing aids [that contain or are derived from the foods and ingredients] listed in section 4.2.1.4 [that contain or are derived from the foods and ingredients]"</p>	Argentina
<p>For clarity we support inclusion of reference to Section 8 to ensure the declaration applies to both a statement of ingredients as well as the separate 'contains' statement (if used). Therefore we suggest editing this point to the following:</p> <p>4.2.4.2 A food additive carried over into foods at a level less than that required to achieve a technological function, and processing aids, are exempted from declaration in the list of ingredients. The exemption does not apply to food additive and</p>	Australia

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processing aids [that contain or are derived from the foods and ingredients] listed in section 4.2.1.4 and declared consistent with Section 8.	
<p>4.2.4.2 A food additive carried over into foods at a level less than that required to achieve a technological function, and processing aids, are exempted from declaration in the list of ingredients. The exemption does not apply to food additive and processing aids [that contain or are derived from the foods and ingredients] listed in section 4.2.1.4. <u>4.2.4.2.1 When the manufacturing process guarantees the absence of the processing aids derived from the foods and ingredients listed in section 4.2.1.4 in the final product, the processing aids are exempted from declaration in the list of ingredients.</u></p> <p>According to the definition of processing aids in section 2 of the GSLPF, these substances could be completely removed from the final product. Thus, Brazil suggests adding a new section to make it clear that the requirement for the declaration of processing aids that are derived from the foods and ingredients listed in section 4.2.1.4 would not apply when the manufacturing process guarantees that the processing aids is completely removed from the final product.</p> <p>4.2.4.2 A food additive carried over into foods at a level less than that required to achieve a technological function, and processing aids, are exempted from declaration in the list of ingredients. The exemption does not apply to food additive and processing aids [that that contain or are derived from the foods and ingredients]ingredients listed in section 4.2.1.4.</p> <p>Brazil agrees with the amendments in section 4.2.4.2 and suggests the deletion of the square brackets.</p>	Brazil
<p>4.2.4.2 A food additive carried over into foods at a level less than that required to achieve a technological function, and processing aids, are exempted from declaration in the list of ingredients. The exemption does not apply to food additive and processing aids [that contain or are derived from the foods and or ingredients] listed in section 4.2.1.4.</p> <p>Since the foods and ingredients listed in 4.2.1.4 are listed as “ x and x products” Canada suggests that there is no need to say “or are derived from” in the square brackets. It is sufficient to say [that contain the foods or ingredients]</p>	Canada
We support the amendment proposed in this section.	Colombia
<p>Costa Rica would like clarification as to whether the guidance in section 4.2.4.2 applies to the "contains" statement, as well as to or instead of the list of ingredients.</p> <p>As it has been requested to the FAO/WHO expert panel to address possible labelling exemptions for highly refined food-derived ingredients and ingredients recommended for inclusion in 4.2.1.4, in this regard, when the panel report becomes available, we would respectfully request that the Committee consider updating section 4.2.4.2 to clarify that foods or ingredients may be exempted from the mandatory declaration provided they meet the specific exemption criteria recommended by the panel.</p>	Costa Rica
The EUMS agree the amendment of section 4.2.4.2 to clarify that the exemption does not apply to food additives and processing aids that contain or are derived from the foods and ingredients listed in 4.2.1.4. The proposed amendment enhances clarity of labelling obligations regarding processing aids and carry-over of food additives in the list of ingredients. The EUMS also suggest retaining the text in the square brackets.	European Union
<p>We request clarification on whether the guidance in 4.2.4.2 applies to the “contains” statement as well as or instead of the list of ingredients.</p> <p>We would also note that the FAO/WHO expert panel has been asked to address potential labelling exemptions for highly refined ingredients derived from foods and ingredients recommended for inclusion in 4.2.1.4.</p> <p>When the panel’s report is available, we respectfully request that the Committee consider updating 4.2.4.2 to clarify that foods or</p>	Guatemala

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ingredients can be exempted from mandatory declaration provided they meet the specified criteria for exemption recommended by the panel.	
Indonesia agrees with the proposed text in section 4.2.4.2	Indonesia
Malaysia is of the view that the recommendation and scientific advice from FAO/WHO should be adopted in GSLPF.	Malaysia
Singapore generally agrees with the inclusion of the text in square brackets, but would propose for CCFL to deliberate further after the report on threshold levels in foods of the priority allergens, is made available.	Singapore
In principle, we do not object to the modification. However, consideration of the practical aspect of this requirement should be carefully taken as the food additive and processing aids derived from the foods and ingredients may not anymore have the protein that can cause an allergenic reaction. To test that would be expensive and some countries like Thailand may not have access to such testing methods.	Thailand
Uganda is taking a keen interest on this matter aware of the on-going discussions by FAO/WHO	Uganda
We agree.	EFA
<p>4.2.4.2 A food additive carried over into foods at a level less than that required to achieve a technological function, and processing aids, are exempted from declaration in the list of ingredients. The exemption does not apply to food additive and processing aids [that contain or are derived from the foods and ingredients] listed in section 4.2.1.44 which are present in the pre-packaged food.</p> <p>In order to avoid any misunderstanding to the extent to which the use of a processing aid in an upstream processing of an ingredient could carry over, we suggest adding at the end of the paragraph the phrase “when they are present in or directly used during the manufacture of the final prepackaged food” or a similar phrase.</p> <p>ICA also believes that clarity on specific situations where carry-over additive or processing aid does not present a risk to allergic consumers is needed. For example, processing aids that are derived from allergens (e.g. highly refined oils) but do not present risk to allergic consumers (for example due to lack of protein). We suggest that text could be added to clarify that additives/processing aids can be exempted provided that they meet the criteria for exclusion from the requirement for labelling of the food source (currently found in WHO TRS 896 (2000)), but to be updated based on the relevant outcome of the current FAO/WHO expert consultation.</p>	ICA
<p>We request the Committee clarify whether this guidance would apply to allergen declarations made with a “contains” statement alternatively or in addition to declarations in the list of ingredients.</p> <p>FIA notes that the FAO/WHO expert panel has been asked to address potential labelling exemptions for highly refined ingredients derived from food and ingredients recommended for inclusion in 4.2.1.4.</p> <p>When the panel’s report is available, we respectfully request that the Committee consider updating 4.2.4.2 to clarify that foods or ingredients can be exempted from mandatory declaration provided they meet the specified criteria for exemption recommended by the panel.</p>	FIA
<p>We request clarification on whether the guidance in 4.2.4.2 applies to the “contains” statement as well as or instead of the list of ingredients.</p> <p>We would also note that the FAO/WHO expert panel has been asked to address potential labelling exemptions for highly refined ingredients derived from foods and ingredients recommended for inclusion in 4.2.1.4.</p> <p>When the panel’s report is available, we request that the Committee consider updating 4.2.4.2 to clarify that foods or ingredients</p>	IFU

GENERAL COMMENTS	MEMBERS / OBSERVERS
<p>can be exempted from mandatory declaration provided they meet the specified criteria for exemption recommended by the panel.</p>	
<p>We agree with the proposal to amend Section 4.2.4.2. to clarify the exemption applying to processing aids and the carry-over of food additives. All allergen containing processing aids and carry-over from additives should not be exempt. All materials derived from allergens intentionally present, whether considered as an 'ingredient' or not for labelling purposes, should be declared in product labelling, unless they are below a defined limit in the finished product (e.g., sulphite, gluten) or are specially exempt in national provisions due to lack of allergenic protein.</p> <p>For further precision we request clarification on whether the guidance in 4.2.4.2 applies to the "contains" statement as well as or instead of the list of ingredients.</p> <p>We also note that the FAO/WHO expert panel has been asked to address potential labelling exemptions for highly refined ingredients derived from foods and ingredients recommended for inclusion in 4.2.1.4.</p> <p>When the panel's report is available, we respectfully request that the Committee consider updating 4.2.4.2 to clarify that foods or ingredients can be exempted from mandatory declaration provided they meet the specified criteria for exemption recommended by the panel.</p>	<p>ICGMA</p>
<p>ICBA requests clarification on whether the guidance in 4.2.4.2 applies to the "contains" statement as well as or instead of the list of ingredients.</p> <p>ICBA also notes that the FAO/WHO expert panel has been asked to address potential labelling exemptions for highly refined ingredients derived from foods and ingredients recommended for inclusion in 4.2.1.4.</p> <p>When the panel's report is available, we respectfully request that the Committee consider updating 4.2.4.2 to clarify that foods or ingredients can be exempted from mandatory declaration provided they meet the specified criteria for exemption recommended by the panel.</p>	<p>ICBA</p>
<p>We agree with the proposal to amend section 4.2.4.2 to clarify the exemption applying to processing aids and the carry-over of food additives. Allergen containing processing aids and carry over from additives should not be exempted. All materials derived from allergens intentionally present, whether considered as an 'ingredient' or not for labelling purposes, should be declared in product labelling, unless they are below a defined limit in the finished product (e.g. sulphite, gluten) or are specifically exempt in national provisions due to lack of allergenic protein.</p> <p>Note: We also would like to reiterate that we believe reference should be made to the ongoing FAO/WHO expert consultation on the application of a risk-based approach to the labelling of unintended presence of allergens.</p>	<p>FoodDrinkEurope</p>
<p>6. EXEMPTIONS FROM MANDATORY LABELLING REQUIREMENTS</p>	
<p>Algeria proposes to replace the 10 cm² area with 20 cm².</p>	<p>Algeria</p>
<p>Argentina's Position: Agrees with the modification of item 6, about including the sentence in square brackets.</p>	<p>Argentina</p>
<p>With the exception of spices and herbs, small units, where the largest surface area is less than 10 cm², may be exempted from the requirements of paragraphs 4.2 and 4.6 to 4.8. [This exemption does not apply to the declaration of foods and ingredients listed in section 4.2.1.4.]</p> <p>Brazil agrees with the amendments in section 6 and suggests the deletion of the square brackets.</p>	<p>Brazil</p>

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<p>We support the amendment proposed in this section. The study of alternative means for the labeling of allergens in small packages is suggested.</p> <p>Colombia has the following concern:</p> <p>Is the exemption proposed in this paragraph also to include the food additive and processing aids mentioned in number 4.2.4.2?</p> <p>There are technical challenges with small packages that can cause a higher risk to allergic consumers due to readability and visibility and, therefore, alternative means should be allowed to communicate this mandatory information, such as collars or flaps on shelf packages</p>	<p>Colombia</p>
<p>Costa Rica agrees with the proposal to amend Section 6 of the GSLPF to remove the exemption from Section 4.2.1.4, as the health risk associated with foods and ingredients known to cause hypersensitivity persists regardless of the size of the food container.</p> <p>However, in certain categories of foods that have very small containers, alternatives should be considered to present the information and guarantee the reading by the consumer and meet the objective of informing.</p>	<p>Costa Rica</p>
<p>The EUMS agree with the removal of the exemption from declaring foods and ingredients listed in section 4.2.1.4 as it currently applies to small units. The EUMS consider that the health risk associated with foods and ingredients known to cause hypersensitivity is the same regardless of the surface area of the food packaging, and therefore the information on the presence of allergens in foods should be provided at all times. The level of consumer protection cannot be lower in the case of small packages. However, in the EU it is possible to provide the information on the presence of allergens in foods, in case of small packages, by using smaller font size. In the EU, in case of packaging or containers of which the largest surface has an area of less than 80 cm², the x-height (as defined in Annex IV of the Regulation (EU) No 1169/2011 on the provision of food information to consumers) of the font size on the packaging shall be equal to or greater than 0.9 mm.</p>	<p>European Union</p>
<p>Indonesia agrees with the proposed text in section 6</p>	<p>Indonesia</p>
<p>The Philippines agrees that the exemption shall not apply to the declaration of foods and ingredients listed in Section 4.2.1.4. We would like to propose an alternative statement to ensure that consumers are well-informed:</p> <p>"In cases where package size prevents display of full ingredient line plus any other allergen labeling in retail unit, the secondary packaging should clearly indicate allergen labeling".</p>	<p>Philippines</p>
<p>Singapore agrees with the inclusion of the text in square brackets.</p>	<p>Singapore</p>
<p>We are in agreement with this exemption in principle as it provides consumer protection. However, we are in doubt of the practical aspect of this requirement.</p>	<p>Thailand</p>
<p>Uganda is in agreement with the new proposed text as captured in under clause 6 since it clarifies on consumer safety</p>	<p>Uganda</p>
<p>We agree.</p>	<p>EFA</p>
<p>ICGA supports that addition.</p>	<p>ICGA</p>
<p>With the exception of spices and herbs, small units, where the largest surface area is less than 10 cm², may be exempted from the requirements of paragraphs 4.2 and 4.6 to 4.8. [This exemption does not apply to the declaration of foods and ingredients listed in section 4.2.1.44 unless demonstrated to meet criteria specified in Annex 4 of Evaluation of certain food additives and contaminants. (WHO TRS 896, 2000)].</p>	<p>ICA</p>

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<p>With the exception of spices and herbs, small units, where the largest surface area is less than 10 cm², may be exempted from the requirements of paragraphs 4.2 and 4.6 to 4.8. [This exemption does not apply to the declaration of foods and ingredients listed in section 4.2.1.4.]- unless demonstrated to meet criteria specified in Annex 4 of Evaluation of certain additives and contaminants. (WHO TRS896, 2000)]</p> <p>We support the proposal to remove the exemption from declaring food and ingredients listed in Section 4.2.1.4 with some suggested changes.</p> <p>The lack of declaration of food allergens presents a food safety risk to consumers who require this information. We believe that allergen labelling should be mandatory and on primary packaging, including small packaging where specific requirements are needed.</p>	ICGMA
<p>We agree with the proposal to remove the exemption from declaring foods and ingredients listed in section 4.2.1.4 as it currently applies to small units.</p>	FoodDrinkEurope
8. PRESENTATION OF MANDATORY INFORMATION	
<ul style="list-style-type: none"> • Allergens must be clearly declared on the food label, whether they are present as ingredients or components of ingredients; • Add the following statements: • If packaged foods contain priority food allergens, gluten sources or added sulfites, they must be declared at least once in the ingredient list; • When a food allergen or a gluten source can be found unintentionally in the food, despite the use of good manufacturing practices, a statement must refer to the presence of the allergens: such as: cross-contamination: • In case of cross-contamination: "may contain x" and to refer to the food allergen concerned; • For products that are pre-packaged and when the product is offered for cutting and in case of the presence of an allergen, the seller must indicate in a visible manner and in the immediate proximity of the sales name of the food the presence of allergens in order to immediately inform the consumer. 	Algeria
<p>Australia supports these new provisions as the consumer behaviour evidence supports allergen information on prepackaged food needing to be presented clearly and consistently to better assist consumers with food allergy.</p>	Australia
<p>We support the inclusion of these specific provisions for the presentation of foods and ingredients that are known to cause hypersensitivity.</p> <p>Adjustments are suggested to numerals: 8.3.1, 8.3.1.1, 8.3.2. and 8.3.2.1 in the following rows of this table.</p>	Colombia
<p>Though we have no objection to the concept of Section 8, the description seems too detailed. We would like to suggest making it rather general, so that it can be applied according to the situation of each country and product, and also considering the balance with the present Section 8.</p>	Japan
<p>The Philippines agrees to statements 8.3. to 8.3.4 with following editorial changes:</p> <p>The sub provision of 8.3 states how the foods and ingredients should be declared. Suggest that the word "declared" be revised to "Declaration of" and written as:</p> <p>8.3 Declaration of foods and ingredients known to cause hypersensitivity".</p>	Philippines

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<p>For section 8.3.2, we propose the following changes to allow for flexibility in labeling while still providing the necessary information:</p> <p>8.3.2 In place of or in addition to the declaration of allergens through the list of ingredients, the foods and ingredients listed in section 4.2.1.4 may be declared in a separate statement, which shall be placed near and within the same field of view as the list of ingredients.</p>	
<p>Malaysia has no objection on the addition of NEW proposed draft on mandatory information for declared foods and ingredients known to cause hypersensitivity.</p>	Malaysia
<p>Uganda is in agreement with the proposed new texts as captured under clause 8</p>	Uganda
<p>EFA agrees with all the below-mentioned aspects to clarify and emphasize allergen labelling and make it clearer, easier, and more understandable for consumers with food allergies and those providing food to them.</p> <p>We urge using only the term “food allergy” (comprising IgE and non-IgE-mediated food allergies), thus discriminating other food hypersensitivities in the approach to define allergen labelling. This recommendation is consistent with the CCFH Code of Practice CXC 80-2020, as well as with the recommendation in the 1st report of the ad hoc joint FAO/WHO expert consultation on Risk Assessment of Food Allergens.</p>	EFA
<p>We view that it would be helpful to have guidance for handling multiunit retail containers when allergens are present. Both primary and secondary packaging should disclose allergen presence. We suggest that this section may be the most appropriate place to address this.</p>	FIA
<p>In section 8, Presentation of Mandatory Information, ISDI considers that the key objective is the provision of information to consumers and that the Codex Standard should reflect all possible approaches that countries may choose to implement in order to effectively deliver this information.</p>	ISDI
<p>It would be helpful to have guidance for handling multiunit retail containers when allergens are present. Both primary and secondary packaging should disclose allergen presence. We recommend that such guidance be included in Section 8 of Appendix II.</p>	IFU
<p>We agree with including specific provisions for the presentation of declarations of foods and ingredients known to cause hypersensitivity in Section 8 (Presentation of mandatory information) in the GSLPF.</p> <p>Global harmonisation in the way foods and ingredients known to cause hypersensitivity are labelled is key. The presence of allergens used as ingredients should be made immediately visible to consumers. Notwithstanding, some flexibility is required to allow countries to choose the labelling approach that best suits their consumers’ needs. As such, there should be a requirement for highlighting the presence of allergens, with examples proposed on how that might be achieved, but national flexibility should also be highlighted.</p>	ICGMA
<p>ICA members agree with including basic parameters to provide guidance on presentation of this information as posted in section 8. This will help to facilitate global harmonization to the extent possible. However, this section should be recognized as an area that has differences regionally. We support allowing flexibility for countries to choose the labelling approach that best suits their consumers’ needs [see redline edit].</p> <p>ICA would like to emphasize our support for the inclusion of 8.3.3. ICA supports list of ingredients being the primary means of communication for foods and ingredients known to cause hypersensitivity. However, for products that are exempt from providing ingredient statements, it is important to provide a mechanism to ensure allergen information is provided. To provide flexibility, it should be permissible to use a secondary means of communication either voluntarily in addition to the primary means, or as an</p>	ICA

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<p>alternative to the primary method when it is not suitable. ICA therefore, supports language that allows for the continued use of allergen declarations as part of the list of ingredients, but also allows for a secondary means of allergen declarations such as use of a “Contains” statement.</p>	
<p>We agree with including specific provisions for the presentation of declarations of foods and ingredients known to cause hypersensitivity in Section 8 (Presentation of mandatory information) in the GSLPF. Global harmonisation in the way foods and ingredients known to cause hypersensitivity are labelled is key. The presence of allergens used as ingredients should be made immediately visible to consumers. Notwithstanding, some flexibility is required to allow countries to choose the labelling approach that best suits their consumers’ needs. As such, there should be a requirement for highlighting the presence of allergens, with examples proposed on how that might be achieved, but national flexibility should also be highlighted.</p>	FoodDrinkEurope
8.3	
Algeria proposes to correct title 8.3 as follows: "Declared foods and ingredients known to cause food allergy or intolerance."	Algeria
Argentina Position: We agree with the inclusion of item 8.	Argentina
<p>This addition makes the presentation of foods and ingredients known to cause hypersensitivity clearer. However, we are concerned about the small packaged food since having additional information on allergen onto the very limited surface area is very challenging. We are of the opinion that such a package may not fully follow the requirements listed in 8.3, only certain requirements should be applicable to a small package.</p>	Thailand
<p>8.3.1 1 The foods and ingredients listed in section 4.2.1.4 shall be declared in a separate statement, which shall be placed near and within the same field of view as the list of ingredients.</p> <p>8.3.1.1 This statement shall commence with the word ‘Contains’ (or equivalent word) and declare all foods and ingredients known to cause hypersensitivity in the food using commonly known terms for the source of the food and ingredient.</p> <p>8.3.1.2 The foods and ingredients listed in section 4.2.1.4 shall be declared so as to contrast distinctly from surrounding text, such as through the use of font type, style or colour.</p> <p>8.3.1.3 The font type, style and a minimum font size as well as the use of upper and lower case letters should be considered by competent authorities to ensure legibility of declarations about foods and ingredients known to cause hypersensitivity.</p> <p>Regarding Section 8.3, and in light of the report of the International Social Science Liaison Group (Consumers and Allergen Labeling: A Literature Review of Consumer Response to Allergen Declarations and Precautionary Allergen Labeling, October 2020), the United States recommends greater emphasis be placed on the use of the “contains” statement to capture all food allergens to be declared in one place rather than depend on consumers to consult the ingredient statement.</p> <p>The United States has offered edits to the text to reflect this recommendation.</p>	USA
8.3 Declared foods and ingredients known to cause <u>hypersensitivity</u>food allergies.	EFA
Inclusion of the term hypersensitivity should be updated based on changes to 4.2.1.4 based off of recommendations from the Expert Committee	ICA
8.3.1	

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<p>Australia supports ensuring the legibility provisions are sufficient for allergen labelling and propose inclusion of also requiring declarations to contrast distinctly with not only the surrounding text but also with the background. Therefore, we suggest editing to the following:</p> <p>8.3.1 The foods and ingredients listed in section 4.2.1.4 shall be declared so as to contrast distinctly from surrounding text and background, such as through the use of font type, style or colour.</p>	<p>Australia</p>
<p>8.3.1 The foods and ingredients listed in section 4.2.1.4 shall be declared so as to contrast distinctly from surrounding text, such as through the use of font type, style or colour.</p> <p>Canada suggests removing 8.3.1, which would require allergens to be bolded, underlined or otherwise “contrast distinctly” in the list of ingredients on the product label. There are country specific requirements that may not allow the use of the differences suggested on their labels (such as different colors or fonts in the list of ingredients). Canada suggests that this aspect of allergen labelling should be left up to individual countries to decide, and has included the wording “or other ways of making the foods and ingredients listed in 4.2.1.4 contrast with surrounding text” in 8.3.1.1 below.</p>	<p>Canada</p>
<p>8.3.1 The foods and ingredients listed in section 4.2.1.4 shall be declared so as to contrast distinctly from <u>surrounding text, from the list of ingredients</u> such as through the use of font type, style or colour.</p> <p>Chile proposed deleting the sentence “from the surrounding text” and changing it to the sentence “from list of ingredients”, as it could in our view give more clarity to future users of the standard.</p>	<p>Chile</p>
<p>8.3.1 The foods and ingredients listed in section 4.2.1.4 shall be declared so as to contrast distinctly from <u>surrounding text, from the rest of ingredients in the list</u> such as through the use <u>the modification of the</u> font type, style or colour</p> <p>To make the text clearer and avoid ambiguity for the reader.</p>	<p>Colombia</p>
<p>In order to streamline the text, it is suggested that subparagraphs 8.3.1 and 8.3.1.1 should be revised as indicated.</p> <p>In addition, cases should be considered where a "contains" statement is used in place of or in addition to the ingredient list statement. If the guidance also applies to the "contains" statement, this should be explicitly stated.</p>	<p>Costa Rica</p>
<p>To streamline the text, we suggest revising 8.3.1 and 8.3.1.1 as indicated.</p> <p>Moreover, consideration should be given to the cases in which a “contains” statement is used instead of or in addition to the declaration in the list of ingredients. If the guidance also applies to the “contains” statement, this should be explicitly stated.</p>	<p>Guatemala</p>
<p>Indonesia agrees with the proposed text in section 8.3.1</p>	<p>Indonesia</p>
<p>New Zealand supports the inclusion of 8.3.1. We suggest the addition of 'in the list of ingredients and any statement that meets 8.3.2' following the word 'declared' to ensure it is clear that the presentation requirements pertain to both declarations made in the ingredients list and any statements made under 8.3.2.</p> <p>The text would then read:</p> <p>8.3.1 The foods and ingredients listed in section 4.2.1.4 shall be declared in the list of ingredients and any statement that meets 8.3.2 so as to contrast distinctly from surrounding text, such as through the use of font type, style or colour.</p>	<p>New Zealand</p>

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remove the following part (such as through the use of font type, style or colour.) 8.3.1 The foods and ingredients listed in section 4.2.1.4 shall be declared so as to contrast distinctly from surrounding text.	Saudi Arabia
<p>8.3.1-1 <u>The foods and ingredients listed in section 4.2.1.4 shall be declared in a separate statement, which shall be placed near and within the same field of view as the list of ingredients. 8.3.1.1 This statement shall commence with the word ‘Contains’ (or equivalent word) and declare all foods and ingredients known to cause hypersensitivity in the food using commonly known terms for the source of the food and ingredient.8.3.1.2 The foods and ingredients listed in section 4.2.1.4 shall be declared so as to contrast distinctly from surrounding text, such as through the use of font type, style or colour.8.3.1.3 The font type, style and a minimum font size as well as the use of upper and lower case letters should be considered by competent authorities to ensure legibility of declarations about foods and ingredients known to cause hypersensitivity.</u></p> <p>Regarding Section 8.3, and in light of the report of the International Social Science Liaison Group (Consumers and Allergen Labeling: A Literature Review of Consumer Response to Allergen Declarations and Precautionary Allergen Labeling, October 2020), the United States recommends greater emphasis be placed on the use of the “contains” statement to capture all food allergens to be declared in one place rather than depend on consumers to consult the ingredient statement.</p> <p>The United States has offered edits to the text to reflect this recommendation.</p>	USA
ICGA supports the addition.	ICGA
8.3.1 The foods and ingredients listed in section 4.2.1.4 shall <u>may</u> be declared so as to contrast distinctly from surrounding text, such as through the use of font type, style or colour.	ICA
<p>8.3.1 The foods and ingredients listed in section 4.2.1.4 <u>[in the list of ingredients and any statement that meets 8.3.2]</u> shall be declared so as to contrast distinctly from surrounding text, such as through the use of font type, style or colour.</p> <p>Consideration should be given to the cases in which a “contains” statement is used instead of or in addition to the declaration in the list of ingredients related to 4.2.1.3 and 4.2.4.2. If the guidance also applies to the “contains” statement, this should be explicitly stated. We suggest the consideration on the square bracket text as one way to address this point.</p>	FIA
<p>8.3.1 The foods and ingredients listed in section 4.2.1.4 shall be declared so as to contrast distinctly from <u>surrounding text</u>the rest of the ingredient list, such as through the use of font type, style or colour.</p> <p>For clarification and to avoid redundancy, ISDI proposes to revise the text.</p>	ISDI
<p>We suggest the following text change.</p> <p>8.3.1 The foods and ingredients listed in section 4.2.1.4 shall be declared so as to contrast distinctly from surrounding text.</p>	IFU
<p>8.3.1 The foods and ingredients listed in section 4.2.1.4 shall be declared so as to contrast distinctly from surrounding text, <u>such as through the use of font type, style or colour.</u></p> <p>To streamline the text, we suggest revising 8.3.1 and 8.3.1.1 as indicated.</p> <p>Moreover, consideration should be given to the cases in which a “contains” statement is used instead of or in addition to the declaration in the list of ingredients. If the guidance also applies to the “contains” statement, this should be explicitly stated.</p>	ICGMA
8.3.1 The foods and ingredients listed in section 4.2.1.4 shall be declared so as to contrast distinctly from surrounding text, <u>such as through the use of font type, style or colour.</u>	ICBA

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<p>To streamline the text, ICBA suggests revising 8.3.1 and 8.3.1.1 as indicated.</p> <p>Moreover, consideration should be given to the cases in which a “contains” statement is used instead of or in addition to the declaration in the list of ingredients. If the guidance also applies to the “contains” statement, this should be explicitly stated.</p>	
<p>8.3.1.1</p>	
<p>45</p> <p>The intent of 8.3.1.1 is to only capture the foods and ingredients known to cause hypersensitivity as listed in 4.2.1.4. However this could be interpreted to be wider than those listed in 4.2.1.4. So for clarity we have proposed a change to the following:</p> <p>8.3.1.1 The font type, style and a minimum font size as well as the use of upper and lower case letters should be considered by competent authorities to ensure legibility of declarations about foods and ingredients listed in section 4.2.1.4.</p>	<p>Australia</p>
<p>8.3.1.1 The font type, <u>style style, colour</u> and a minimum font size as well as the use of upper and lower case letters <u>or other ways of making the foods and ingredients listed in 4.2.1.4 contrast with surrounding text</u> should be considered by competent authorities to ensure legibility of declarations about foods and ingredients known to cause hypersensitivity.</p> <p>Canada suggests that any legibility requirement should also apply to any separate “Contains” statement from 8.3.2 below.</p>	<p>Canada</p>
<p>8.3.1.1 The font type, style and a minimum font size as well as the use of upper and lower case letters should be considered by competent authorities to ensure legibility of declarations about foods and ingredients known to cause hypersensitivity.</p> <p>It does not provide any additional guidance compared to what was already mentioned in section 8.3.1. Colombia calls on the Codex to encourage competent authorities to harmonize requirements or recognize requirements established by other authorities as long as the differentiating purpose of allergen information is fulfilled.</p> <p>Indonesia agrees with the proposed text in section 8.3.1.1</p>	<p>Colombia</p>
<p>Indonesia agrees with the proposed text in section 8.3.1.1</p>	<p>Indonesia</p>
<p>What about small packaged products? We think it would be better to mention products with small packaging too</p>	<p>Iran</p>
<p>New Zealand proposes deleting 8.3.1.1. We do not see that 8.3.1.1. provides any additional guidance over that provided by 8.3.1. We consider that general legibility requirements in 8.1.2 of the GSLPF would apply:</p> <p>(8.1.2 Statements required to appear on the label by virtue of this standard or any other Codex standards shall be clear, prominent, indelible and readily legible by the consumer under normal conditions of purchase and use.)</p>	<p>New Zealand</p>
<p>remove the following part : (should be considered by competent authorities to ensure legibility of declarations about foods and ingredients known to cause hypersensitivity.) 8.3.1.1 Legibility of declarations shall be ensured by the use of distinct font type, style, colour and/or a minimum font size as well as the use of upper- and lower-case letters</p>	<p>Saudi Arabia</p>
<p>8.3.1.1 The font type, style and a minimum font size as well as the use of upper and lower case letters should be considered by competent authorities to ensure legibility of declarations about foods and ingredients known to cause hypersensitivity.</p> <p>This text has been incorporated above.</p>	<p>USA</p>
<p>8.3.1.1 The font type, style and a minimum font size as well as the use of upper and lower case letters should be considered by competent authorities to ensure legibility of declarations about foods and ingredients known to cause hypersensitivity <u>food allergies</u></p>	<p>EFA</p>

GENERAL COMMENTS	MEMBERS / OBSERVERS
<p>8.3.1.1 The font type, style and a minimum font size as well as the use of upper and lower case letters should be considered by competent authorities <u>[to delete: by competent authorities]</u> to ensure legibility of declarations about foods and ingredients known to cause hypersensitivity.</p> <p>ICGA supports the addition. As it is implicit that countries may define further harmonized rules, the reference to “by competent authorities” may be deleted. That requirement may also be directed to food business operators directly from the Codex standard. So, this recommendation is generic.</p>	ICGA
<p>8.3.1.1 The font type, style and a minimum font size as well as the use of upper and lower case letters should be considered by competent authorities to ensure legibility of declarations about foods and ingredients known to cause hypersensitivity.</p> <p>We propose the deletion of section 8.3.1.1 as it does not provide additional information compared to section 8.3.1.</p>	FIA
<p>8.3.1.1 The font type, style and a minimum font size as well as the use of upper and lower case letters should be considered by competent authorities to ensure legibility of declarations about foods and ingredients known to cause hypersensitivity.</p> <p>8.3.1.1, ISDI proposes to delete this paragraph as it does not provide additional guidance to that already provided in 8.3.1.</p>	ISDI
<p>We suggest the following text.</p> <p>8.3.1.1 Legibility of declarations shall be ensured by the use of distinct font type, style, colour and/or a minimum font size as well as the use of upper- and lower- case letters.</p> <p>Rationale</p> <p>It is recommended that Points 8.3.1 and 8.3.1.1 be revised to streamline the text as noted above.</p> <p>The Committee should consider cases in which a “contains” statement is used instead of or in addition to the declaration in the list of ingredients. If the guidance also applies to the “contains” statement, this should be explicitly stated.</p>	IFU
<p>8.3.1.1 <u>The Legibility of declarations shall/may be ensured by the use of distinct font type, style and style, colour and/or a minimum font size as well as the use of upper and lower case letters should be considered by competent authorities to ensure legibility of declarations about foods and ingredients known to cause hypersensitivity.letters.</u></p> <p>To streamline the text, we suggest revising 8.3.1 and 8.3.1.1 as indicated.</p> <p>Moreover, consideration should be given to the cases in which a “contains” statement is used instead of or in addition to the declaration in the list of ingredients. If the guidance also applies to the “contains” statement, this should be explicitly stated.</p>	ICGMA
<p>8.3.1.1 <u>The Legibility of declarations shall be ensured by use of distinct font type, style and style, colour and/or a minimum font size as well as the use of upper and lower case letters should be considered by competent authorities to ensure legibility of declarations about foods and ingredients known to cause hypersensitivity.letters.</u></p>	ICBA
<p>8.3.2</p>	
<p>8.3.2 In addition to the list of ingredients, the <u>The</u> foods and ingredients listed in section 4.2.1.4 may be declared in a separate statement, which shall be placed near and within the same field of view as the list of ingredients.</p> <p>Allow flexibility, taking into account the existing regulations of some countries.</p>	Colombia

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<p>The EUMS would like to draw the attention towards the added Section 8.3.2 (and 8.3.2.1) on Presentation of Mandatory Information. The EUMS would like to clarify that it objects to the proposed introduction of a separate statement about allergenic ingredients in addition to the list of ingredients, as the EUMS do not support any use of summary statement with regard to allergens in order to ensure a consistent way of providing information to consumers. In fact, in the EU, it is not possible to repeat voluntarily the allergen information outside the list of ingredients; or using symbols or text boxes (see Recital 47, Article 21(1) read in conjunction with Article 36(1) of the Regulation (EU) No 1169/2011 on the provision of food information to consumers), as different schemes of providing information to consumers may result confusing consumers. Furthermore, the rationale behind objecting to the added Section 8.3.2 is that there is a risk that consumers mix the ingredients and the ones warned about in PAL and may think that everything in the box is PAL and therefore ignore information about allergenic ingredients. Another point is that if 'allergen boxes'/separate statements on allergen labelling are voluntary, consumers may be misled should they think that foods without 'allergen boxes' or separate statements do not contain any allergenic ingredient. Last, it is easier to advise consumers to always read the list of ingredients, if allergenic ingredients are systematically listed and highlighted in the list of ingredients.</p>	<p>European Union</p>
<p>Indonesia agrees with the proposed text in section 8.3.2</p>	<p>Indonesia</p>
<p>New Zealand supports certainty in the placement of declarations of foods and ingredients listed in 4.2.1.4.</p> <p>It is important that consumers know where to look for this information and that it is always in the same place. We strongly support the declaration being in the ingredients list. If this declaration is also to be made elsewhere on the label (as outlined in 8.3.2) we consider this should be mandatory not voluntary. Voluntary permissions for declarations under 8.3.2. would likely result in some foods making such declarations while others would not. This could risk consumers mis-interpreting its absence as meaning there were no allergens present.</p> <p>New Zealand considers that this decision could be made at a national level whether to require or prohibit declarations under 8.3.2</p>	<p>New Zealand</p>
<p>it is very important that the information about food allergens be very clear and understandable to the consumer. The allergens should always be highlighted in the ingredient list. The additional declaration of allergens in a facultative separate statement could be confusing (give the false impression that when there is no separate statement, there is no allergen contained in the food) and could be a source of error when developing the label. Switzerland therefore disagrees with this point 8.3.2</p>	<p>Switzerland</p>
<p>8.3.2 In addition to the list of ingredients, the foods and ingredients listed in section 4.2.1.4 may be declared in a separate statement, which shall be placed near and within the same field of view as the list of ingredients.</p> <p>This text has been incorporated above.</p>	<p>USA</p>
<p>8.3.2 In addition to the list of ingredients, the foods and ingredients listed in section 4.2.1.4 may be declared in a separate statement, which shall be placed <u>near directly following</u> and within the same field of view as the list of ingredients.</p>	<p>EFA</p>
<p>8.3.2 In addition to the list of ingredients, <u>where</u> the foods and ingredients listed in section 4.2.1.4 <u>may be declared in a separate statement are declared, which shall be placed near and within the same field of view as the list of ingredients. they may also be repeated elsewhere on the labelling to draw the attention of the consumer to their presence in the [prepackaged] food, where warranted. [proposal to delete: declared in a separate statement, which shall be placed near and within the same field of view as the list of ingredients].</u></p> <p>ICGA questions the need for duplicative labelling in this regard, given that ingredients will be clearly identified based on specific rules to ensure the contrast. We understand it reflects some jurisdictions' obligations, nevertheless we would suggest rewording</p>	<p>ICGA</p>

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to allow food business operators to repeat the mandatory information provided in the list of ingredients wherever it is deemed appropriate for informing the consumer clearly on a voluntary basis. ICGA suggests the slight edition of the text.	
Consideration should be given to the cases in which a “contains” statement is used instead of or in addition to the declaration in the list of ingredients related to 4.2.1.3 and 4.2.4.2. If the guidance also applies to the “contains” statement, this should be explicitly stated.	FIA
8.3.2 In <u>place of or in</u> addition to the <u>declaration of allergens through the</u> list of ingredients, the foods and ingredients listed in section 4.2.1.4 may be declared in a separate statement, which shall be placed near and within the same field of view as the list of ingredients.	ISDI
<p>8.3.2 In <u>place of or in</u> addition to the <u>declaration of allergens through the</u> list of ingredients, the foods and ingredients listed in section 4.2.1.4 may be declared in a separate statement, which shall be placed near and within the same field of view as the list of ingredients.</p> <p>We believe that consideration should be given to cases in which a “contains” statement is used instead of or in addition to the declaration in the list of ingredients in select instances (4.2.13 and 4.2.42) if the guidance also applies to the “contains” statement, this should be explicitly stated.</p> <p>To strengthen the text, we offer the specified revisions.</p>	ICGMA
8.3.2.1	
<ul style="list-style-type: none"> • Replace the term "hypersensitivity" with "a food allergy or intolerance"; • The term "contains" must indicate all priority allergens, even if they are already listed in the ingredients. 	Algeria
<p>As per our comment on point 8.3.1.1, we have proposed a change to the following:</p> <p>8.3.2.1 This statement shall commence with the word ‘Contains’ (or equivalent word) and declare all foods and ingredients as listed in section 4.2.1.4 in the food using commonly known terms for the source of the food and ingredient.</p>	Australia
<p>8.3.2.1 This statement shall commence with the word ‘Contains’ (or equivalent word) and declare all foods and ingredients known to cause hypersensitivity in the food using commonly known terms for the source of the food <u>and-or</u> ingredient.</p> <p>Canada suggests this should be “or” because the statement can include each source declaration once but doesn’t have to declare the same food allergen multiple times even if multiple ingredients contribute the same allergen.</p> <p>As with the comment for 4.2.1.5, Canada recommends that “commonly known terms” be defined or explained more clearly.</p>	Canada
<p>8.3.2.1 <u>This-In case that a separate</u> statement <u>is used, this statement</u> shall commence with the word ‘Contains’ (or equivalent word) and declare all foods and ingredients known to cause hypersensitivity in the food using commonly known terms for the source of the food and ingredient.</p>	Colombia
Indonesia agrees with the proposed text in section 8.3.2.1	Indonesia
<p>New Zealand supports the intent of 8.3.2.1 but offers these edits to improve consistency of language and clarity.</p> <ol style="list-style-type: none"> 1. delete the words 'known to cause hypersensitivity' and replace with 'listed in 4.2.1.4'. 2. delete the words 'the source of' 	New Zealand

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<p>3. add the words 'as per 4.2.1.5' to the end of the sentence.</p> <p>The text would then read:</p> <p>8.3.2.1 This statement shall commence with the word 'Contains' (or equivalent word) and declare all foods and ingredients listed in 4.2.1.4 in the food using commonly known terms for the food and ingredient as per 4.2.1.5.</p>	
<p>8.3.2.1 This statement shall commence with the word 'Contains' (or equivalent word) and declare all foods and ingredients known to cause hypersensitivity in the food using commonly known terms for the source of the food and ingredient.</p> <p>This text has been incorporated above.</p>	USA
<p>8.3.2.1 This statement shall commence with the word 'Contains' (or equivalent word) and declare all foods and ingredients known to cause <u>hypersensitivity-food allergies</u> in the food using commonly known terms for the source of the food and ingredient</p>	EFA
<p>8.3.3</p>	
<p>8.3.3 Where a food is exempt from declaring a list of ingredients, the foods and ingredients listed in section 4.2.1.4 shall be declared, such as in a statement made in accordance with <u>section sections 8.3.1 and 8.3.2.1</u>.</p> <p>Brazil fully supports the new section 8. We understand that these amendments would help national authorities developing measures on the labelling of foods and ingredients known to cause hypersensitivity that are clear, objective and easily understood by consumers.</p> <p>The new provisions are 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. We suggest the inclusion of a cross reference to section 8.3.1 in the section 8.3.3 to guarantee the adequate presentation of the statement.</p>	Brazil
<p>8.3.3 Where a food is exempt from declaring a list of ingredients, <u>and no list of ingredients has been provided voluntarily</u>, the foods and ingredients listed in section 4.2.1.4 shall be declared, such as in a statement made in accordance with section 8.3.2.1.</p> <p>Canada suggests this clarification to address situations where exempt foods carry a list of ingredients voluntarily.</p> <p>Alternative wording for consideration :</p> <p>Where no list of ingredients is provided on the label because the food is exempt from declaring a list of ingredients, the foods and ingredients listed in section 4.2.1.4 shall be declared, such as in a statement made in accordance with section 8.3.2.1.</p>	Canada
<p>8.3.3 Where a food is exempt from declaring a list of ingredients, the foods and ingredients listed in section 4.2.1.4 shall be declared, such as in a statement made in accordance with section 8.3.2.1. <u>Foods with very small containers, in which the declaration as described in point 8.3.2.1 cannot be included, this information shall be placed on the larger packaging containing them.</u></p> <p>Chile recognizes the existence of very small containers in which the declaration "contains (any ingredient or food that causes hypersensitivity)" cannot be placed. In this regard, we recommend including a sentence that acknowledges this fact, such as "very small containers, in which the declaration as described in point 8.3.2.1 cannot be included, this information must be put on the larger packaging containing them".</p>	Chile
<p>Indonesia considers that the text in section 8.3.3 should be referred to section 6 to make it clearer:</p>	Indonesia

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<p>8.3.3 Where a food is exempt from declaring a list of ingredients, <u>set out in Section 6</u>, the foods and ingredients listed in section 4.2.1.4 shall be declared, such as in a statement made in accordance with section 8.3.2.1.</p>	
<p>New Zealand considers that our proposed edit to 8.3.2.1 would also ensure that when a food is exempt from an ingredients list the declaration of foods and ingredients listed in 4.2.1.4 would be required to be made using commonly understood terms and so as to contrast with surrounding text. If our suggested edit at 8.3.2.1 is not taken up, we suggest adding the words 'in accordance with 4.2.1.5,' after the word 'declared' to ensure it is clear that the declaration must use the commonly known terms for the source of the food and ingredient.</p> <p>The text would then read:</p> <p>8.3.3 Where a food is exempt from declaring a list of ingredients, the foods and ingredients listed in section 4.2.1.4 shall be declared in accordance with 4.2.1.5, such as in a statement made in accordance with section 8.3.2.1.</p>	<p>New Zealand</p>
<p>Singapore agrees with the inclusion of section 8.3.3.</p>	<p>Singapore</p>
<p>8.3.3-2 Where a food is exempt from declaring a list of ingredients, the foods and ingredients listed in section 4.2.1.4 shall be declared, such as in a statement made in accordance with section 8.3.21.1.</p> <p>Fixing the paragraph number and cross reference due to the edits above.</p>	<p>USA</p>
<p>8.3.4</p>	
<p>As per our comment on point 8.3.1.1, we have proposed a change to the following:</p> <p>8.3.4 For single ingredient foods, section 8.3.3 does not apply where the foods and ingredients listed in section 4.2.1.4 are declared as part of, or in conjunction with, the name of the food in accordance with section 4.2.1.5.</p>	<p>Australia</p>
<p>8.3.4 For single ingredient foods, section 8.3.3 does not apply where foods and ingredients known to cause hypersensitivity are declared as part of, or in conjunction with, the name of the food in accordance with section 4.2.1.5.</p> <p>As previously mentioned, Brazil fully supports the new section 8 with the rationale presented.</p> <p>In addition, we suggest an amendment to section 8.3.4 to indicate that section 8 does not apply instead of only section 8.3.3.</p>	<p>Brazil</p>
<p>Indonesia considers that the text in section 8.3.4 should be further clarified on how information of allergen in product with single ingredient can be delivered to the consumer</p>	<p>Indonesia</p>
<p>As per our General Comment, New Zealand supports 8.3.4 referring to “foods and ingredients listed in 4.2.1.4” rather than ‘foods and ingredients known to cause hypersensitivity’.</p> <p>The text would then read:</p> <p>8.3.4 For single ingredient foods, section 8.3.3 does not apply where foods and ingredients listed in 4.2.1.4 are declared as part of, or in conjunction with, the name of the food in accordance with section 4.2.1.5</p>	<p>New Zealand</p>
<p>Singapore agrees with the inclusion of section 8.3.4.</p>	<p>Singapore</p>
<p>8.3.4-3 For single ingredient foods, section 8.3.3-1 does not apply where foods and ingredients known to cause hypersensitivity are declared as part of, or in conjunction with, the name of the food in accordance with section 4.2.1.5.</p> <p>Fixing the paragraph number and cross reference due to the edits above.</p>	<p>USA</p>

GENERAL COMMENTS	MEMBERS / OBSERVERS
8.3.4 For single ingredient foods, section 8.3.3 does not apply where foods and ingredients known to cause <u>hypersensitivity food allergies</u> are declared as part of, or in conjunction with, the name of the food in accordance with section 4.2.1.5.	EFA