APPENDIX III

RESPONSE FORM

Codex Committee on Food Labelling
Electronic Working Group on Allergen Labelling

1st Consultation Paper

Please provide a response using this form and post on the Codex eWG Allergen Labelling online-forum by **28 March 2024**.

Name of Member Country/Organisation: Allergy & Anaphylaxis Australia (A&AA) _____

Question 1: Do you agree to removing the bracketed text [or substance or processing aid] from the proposed definition for 'food allergen as shown below? ***"Food allergen"*** *means a food or ingredient* ~~*[or substance or processing aid]*~~ *used in food, usually a protein or protein derivative that can elicit IgE-mediated or other specific immune-mediated reactions in susceptible individuals.*	
Yes X☐	No ☐
Please provide reasons for your answer: A&AA agrees with the definition of food allergen, as based on the existing definitions of 'food' and 'ingredient' in the GSLPF, 'substance', 'food additive' and 'processing aid' are already captured.	

Question 2: Do you agree with the proposed text for section 4.2.1.7, including deleting the text in square brackets and the proposed footnote?	
Yes X☐	No ☐
Please provide reasons for your answer: *4.2.1.7 When sulphite is present in a* ***[****ready-to-eat****]*** *food* ***[****or products as reconstituted according to the instructions of the manufacturer****]****, at a total concentration of 10 mg/kg or above, it shall always be declared using the specified name 'sulphite'.* *[8]Sulphite measured as the total concentration of sulphur dioxide (SO_2) and sulphur dioxide equivalents.* A&AA agree with deleting reference to ready-to-eat and reconstituted products. We do not support threshold amounts for sulphite being applied to the final product as consumed as this is not consistent with how other ingredient/nutrition information is provided to consumers. Some consumers are likely to prepare ready-to-eat foods differently to the instructions of the manufacturer, rendering the information inaccurate. A&AA agree with the proposed footnote that defines sulphite.	

Question 3:
Do you agree with the proposed changes to section 4.2.3 and 4.2.3.1 to provide distinction between 'specified name' and specific name?

Yes X☐	No ☐

Please provide reasons for your answer:

4.2.3 *Except for those foods and ingredients as listed in sections 4.2.1.4, 4.2.1.7 and where applicable 4.2.1.5* ***that must be declared using the specified name in addition to or as part of the ingredient name****, ~~a specific name shall be used for~~ ingredients in the list of ingredients* ***shall be declared*** *in accordance with the provisions set out in Section 4.1 (Name of the Food) except that:*

4.2.3.1 *Unless a general class name would be more informative, the following class names may be used. ~~In all cases, the food and ingredients listed in sections 4.2.1.4, 4.2.1.7 and where applicable 4.2.1.5 shall be declared using the specified names listed in those sections~~.*

This question is unclear and 4.1 could not be identified in the relevant document. Please explain further if comment is required.

Question 4:
Do you support providing flexibility by including 'whenever possible' in section 8.3.1 by removing the square brackets?

Yes ☐	No X ☐

Please provide reasons for your answer:

8.3.1 *The foods and ingredients listed in sections 4.2.1.4, 4.2.1.7 and where applicable 4.2.1.5 shall be declared so as to contrast distinctly from the surrounding text* ***[****whenever possible****]****, such as through the use of font type, style or colour.*

A&AA does not support providing flexibility by including 'whenever possible' as we believe that there should be a required standardised approach. It is vital for consumers to have ingredient labels with a clear contrast from surrounding text through the use of font type, style or colour.
For consumer safety, allergen declarations need to stand out from other information on a food label. This assists with critical allergen information being easier to access for consumers who may only quickly visualise the food label.

Question 5:
Of the three options for section 8.3.2, which do you prefer?

Option 1 X☐	Option 2 ☐	Option 3 ☐	Other ☐

Please provide reasons for your answer.
If answering 'Other', please describe your proposed option and explain why you support this.

[8.3.2 *When the foods and ingredients in sections 4.2.1.4, 4.2.1.7 and where applicable 4.2.1.5 are declared in the list of ingredients, they may also be declared in a separate statement, which shall be placed directly under the list of ingredients.*
Bis. *Foods and ingredients in sections 4.2.1.4, 4.2.1.7 and where applicable 4.2.1.5 shall be declared in the list of ingredients or in a separate statement which shall be* ***[****placed directly under****]*** *the list of ingredients or in both. The most appropriate manner to declare these foods and ingredients shall be decided by national competent authorities.*
Ter. *The foods and ingredients listed in sections 4.2.1.4, 4.2.1.7 and where applicable 4.2.1.5 shall be declared so as to contrast distinctly from the surrounding text (such as through the use of font type, style or colour) and/or be declared in a separate statement commence with the word 'contains' (or equivalent word) directly under the list of ingredients.****]***

A&AA strongly supports option 1: When the foods and ingredients in sections 4.2.1.4, 4.2.1.7 and where applicable 4.2.1.5 are declared in the list of ingredients, they may also be declared in a separate statement, which shall be placed directly under the list of ingredients. However, we feel the language should be stronger and say that they SHOULD also be declared in a separate statement to ensure consistency across countries. It is important that we aim for best practice and it is essential for consumers that the ingredient list is the source of truth for food allergen information. The separate statement is a valuable summary to the consumer who may first check the separate statement as a quick confirmation that their (common) food allergen is not included before proceeding with reading the more detailed ingredient list.

A&AA does not believe there should be an option to include the relevant foods and ingredients in the list of ingredients OR in a separate statement as it is important to provide clear and consistent for consumers. This information should be consistent across all countries and not left to national authorities to decide as varied approaches may create a barrier to trade and increase workload for manufacturers who must make their products compliant for all countries importing their product and regulators who have to monitor compliance.

Question 6:

Do you support the Title, Purpose and Scope sections in the proposed draft PAL guidelines?

Yes X☐	No ☐

Please provide reasons for your answer:

GUIDELINES ON THE USE OF PRECAUTIONARY ALLERGEN LABELLING

1. PURPOSE

*To facilitate a consistent and harmonized approach to the effective use of precautionary allergen labelling (PAL) for communicating to consumers with **food** allergy[1] about the risk from the unintended presence of allergens in food due to cross-contact.*

2. SCOPE

*These guidelines apply to PAL when used to indicate the risk from the unintended presence of a **food** allergen(s)[1] caused by cross-contact in prepackaged foods.*

A&AA does not support in full the title: Guidelines on the use of Precautionary Allergen Labelling. While we agree that consumers and industry understand the term, Precautionary Allergen Labelling (PAL), we believe that to ensure PAL is meaningful, accurate and valuable to consumers, it should be mandated and therefore be titled, "Requirements for the use of Precautionary Allergen Labelling."

A&AA generally agree that the purpose is "To facilitate a consistent and harmonised approach to the effective use of PAL for communicating to consumers with food allergy about the risk from the unintentional presence of allergens in food due to cross-contact," however we believe that cross contact/cross contamination should replace just "cross contact". This uses language that is better understood by the community.

A&AA agree with the scope, "These guidelines apply to PAL when used to indicate the risk from the unintended presence of a food allergen(s) caused by cross-contact in pre-packaged food." However, as we believe PAL should be mandatory, the scope should refer to 'requirements' rather than 'guidelines.' Again, we suggest that cross contact/cross contamination should replace just "cross contact".

Question 7:

Do you support the revised definition for PAL and the changes to the definition section in the proposed draft PAL guidelines?

Yes X☐	No ☐

Please provide reasons for your answer:

Precautionary allergen labelling (PAL) is a statement made in the labelling of prepackaged foods to indicate a risk from the unintended presence of a food allergen(s)[1] due to cross-contact[2] that has been identified by a risk assessment.
[1]As defined in the General Standard for the Labelling of Prepackaged Foods (CXS 1-1985).
[2]Allergen cross-contact as defined in Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020).

A&AA agree with the definition, "Precautionary Allergen Labelling is a statement made in the labelling of prepackaged foods to indicate a risk from the unintended presence of a food allergen(s) due to cross-contact," that has been identified by a risk assessment', however, believe that cross-contact/cross contamination should replace just "cross-contact" as this uses language that is better understood by consumers. In addition, we need to capture that it is all ingredients, from paddock to plate, that are part of the risk assessment. This will help consumers understand the challenges for industry.

Question 8:

Do you support the revised wording for Principle 4.1 in the draft PAL guidelines?

Yes X☐	No ☐

Please provide reasons for your answer:

*Effective **allergen** management practices and **including** controls to prevent or minimize the unintended presence of food allergens caused by cross-contact shall be implemented as outlined in the Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020). The use of PAL shall be restricted to those situations in which the unintended presence of an **food** allergen(s) cannot be **prevented or** sufficiently controlled using these allergen management practices **and may result in an exposure above a reference dose**.*

A&AA suggests that the grammar needs to be reviewed with this paragraph to:

*Effective **allergen** management practices, **including** controls to prevent or minimize the unintended presence of food allergens caused by cross-contact, shall be implemented as outlined in the Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020). The use of PAL shall be restricted to those situations in which the unintended presence of a **food** allergen(s) cannot be **prevented or** sufficiently controlled using these allergen management practices **and may result in an exposure above a reference dose**.*

A&AA support that the use PAL be restricted to those situations in which the unintended presence of an allergen(s) cannot be prevented or sufficiently controlled. It should not be used as a blanket statement to absolve food business operators from using good manufacturing practices. A&AA also believes that cross-contact/cross contamination should replace just "cross-contact" as this uses language that is better understood by consumers. A&AA supports PAL being mandatory and therefore believes stronger language is required - replacing ''shall be implemented'' to ''should'' and ''replacing shall be restricted'' to ''should.''

Question 9:

Do you support the revised wording for Principle 4.2 in the draft PAL guidelines?

Yes X☐	No ☐

Please provide reasons for your answer:

The decision to use PAL should be based on the findings of ***an appropriate*** *risk assessment*[3] *which shall include, but is not limited to, quantitative risk assessment* ***of unintended allergen presence to indicate exposure above a reference dose****.*

[3] FAO and WHO (2022). Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens: Part 2: Review and establish threshold levels in foods of the priority allergens. https://doi.org/10.4060/cc2946en.

A&AA agree with principle 4.2 that the decision to use PAL should be based on the findings of a risk assessment which shall include, but is not limited to, quantitative risk assessment of unintended allergen presence to indicate exposure above a reference dose. A&AA believe that risk assessment should be evidence/science based, otherwise it is subjective. If risk assessment is not done quantitatively, using agreed reference doses, accurate and consistent information cannot be conveyed to consumers to allow them to make an informed choice.

This is complex wording used and scientific processes may not be understood by small to medium manufacturers and people from Culturally And Linguistically Diverse (CALD) backgrounds.

Question 10:

Do you support the revised wording for Principle 4.3 and footnote 3 in the draft PAL guidelines?

Yes X☐	No ☐

Please provide reasons for your answer:

PAL shall only be used if the ***unintended allergen*** *presence cannot be* ***mitigated*** *to a level at or below of a protein from an allergen is equal to or above the action level*[3] *for* ***a food*** *allergen* ***based*** *on, using the listed reference dose values in the table at 4.3.1.*

[3] Action level (mg total protein from the allergen / kg food) = Reference dose (mg total protein from the allergen) / Amount of the food (kg). ***The amount of food should be established based on the 50th percentile or population mean for a single eating occasion intake of the food.***

Yes, A&AA agree that PAL should only be used if exposure to an allergen is above the established reference dose for that allergen (ED05) as we support quantitative risk assessment.

This is complex wording used and scientific processes may not be understood by small to medium manufacturers and people from CALD backgrounds.

Question 11: Do you support the use of ED05-based RfDs as recommended by the Expert Committee and provided in the table at Principle 4.3.1?	
Yes X☐	No ☐X
Please provide reasons for your answer: *The Expert Committee recommended ED05-based values because the difference in the public health impact of choosing a more stringent RfD is expected to be negligible in terms of reducing public health risk, and would introduce considerable burdens and limitations for monitoring and potential unintended consequences on the application of PAL or other risk management strategies. This is particularly pertinent with respect to potential limitations to food choice for individuals with IgE-mediated food allergies.* A&AA support the use of ED05-based RfDs rather than the more stringent ED01, as the increased threshold will provide more choice to consumers with minimal impact on the risk to public health. We accept that thresholds are based on levels agreed by the Expert Committee but suggest that they do need review at points in time when more data may become available. This is likely to occur with the high number of oral food challenges that are being undertaken in controlled settings. In addition, the National Allergy Council in Australia is working with government and key stakeholders to create an anaphylaxis register, so it is likely that we will have more information on people that are having anaphylaxis. This will allow us to monitor this space once we move to ED05. It is critical that any easy to understand, transparent education campaign progresses to inform consumers of current challenges, the reasons for change and what to expect.	

Question 12: Do you support Principle 4.3.2 in the draft PAL guidelines?	
Yes X☐	No ☐
Please provide reasons for your answer: *Where a reference dose is not established for a particular **food** allergen by 4.3.1 above, national authorities can establish a reference dose consistent with recognized principles[4] for the purposes of determining an action level.* *[4]FAO and WHO (2022). Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens: Part 2: Review and establish threshold levels in foods of the priority allergens*	

A&AA agree that where a reference dose is not established for a particular allergen, national authorities can establish a reference dose. This data should be accepted as reflective of local influences and should be reviewed on a regular basis as more information on allergic reactions come to hand. National authorities must include clinical immunology/allergy specialists and people with scientific expertise in food allergy. The process and reasoning should be clearly communicated to consumers.

Question 13:

Do you support principle 4.4 in the draft guidelines?

Yes X☐	No ☐

Please provide reasons for your answer:

4.4 PAL should be accompanied by education/information programs to ensure understanding and appropriate use of PAL by consumers, health care providers and food business operators.

A&AA strongly support PAL education/information programs for consumers, health care providers and food business operators.
The experience of A&AA is that many consumers ignore PAL statements because:

- They are voluntary and a product without a PAL statement may be more of a risk than a product with a PAL statement.
- Some manufacturers have a PAL statement on all products, including products that pose very little risk to consumers.
- There is nothing on pack indicating why a PAL has been added or not included/removed.
- Many packaged foods, even those with single ingredients eg. black beans, have a PAL, so food choices are very restricted, even when cooking with basic ingredients.
- Some consumers have been advised to so by their treating doctor or dietitian because of the mistaken belief that manufacturers use a PAL to 'protect themselves from litigation'. This is true in some cases.
-

There is a general lack of understanding that the intention of PAL is to communicate risk of cross-contact/contamination in the production of packaged foods.
Ignoring all PAL statements can increase the risk of allergic reactions, including anaphylaxis.
If PAL is to be meaningful, accurate and effective, it is important that the education messaging is consistent.

Question 14:

Do you agree with the proposed revisions to Section 5 of the PAL Guidelines relating to the presentation of a PAL statement?

Yes X☐	No ☐

Please provide reasons for your answer:

5.1 Section 8.1.1, 8.1.2 and 8.1.3 and 8.2 of the General Standard for the Labelling of Prepackaged Foods (GSLPF) (CXS 1-1985) apply to PAL labelling.

5.2 PAL should appear as a separate statement in the same field of vision as the ingredient list (when present).

5.2.1 A PAL statement shall commence with the words 'May contain' (or equivalent words) and include the identified allergens using the specified names as listed in sections 4.2.1.4 and where applicable 4.2.1.5 of the GSLPF.

5.2.2 A PAL statement shall contrast distinctly from surrounding text such as through the same font type, style or colour used for declarations made in accordance with section 8.3.1 of the GSLPF.

A&AA agree with the proposed revisions to the Guidelines relating to the presentation of a PAL statement.

The presentation of PAL needs to be simple, consistent and clear for consumers. PAL statements should be clearly distinguishable on packet and need to be able to easily be visualised near the list of ingredients and any related allergen statements.

There should be a consistent approach to PAL, including the use of a single PAL statement. It is vital that consumers are presented with a consistent PAL so there is no room for interpretation. We are aware that some consumers and health professionals make assumptions about different PAL statements confer different levels of risk. For example, many believe that ''may contain traces'' is less of a risk than ''may contain'' and ''made on a production line'' is more of a risk than ''may contain''. Furthermore, they believe "made in a facility'' is less of a risk than ''made on a production line'' and ''may contain pieces of peanut'' is more of a risk than ''may contain peanut.''

A&AA is concerned that if the statement ''may contain'' is used, consumers not understanding the changes proposed for PAL, will continue to ignore the statement. Using a statement that has previously not been widely used, such as 'not suitable for people with a X allergy'' may be trusted as being a product of real risk.

Question 15:

Do you support the proposed draft PAL guidelines <u>not</u> including provision for the use of a risk assessment indicator?

Yes ☐	No X ☐

Please provide reasons for your answer:

A&AA believe that a symbol should be included on the label if a risk assessment has been done as otherwise there is no way to communicate to consumers that the product has undergone a risk assessment. We believe that a risk assessment indicator would instil some confidence in consumers, knowing that the product has undergone risk assessment. Currently packaged food without a PAL may be more of a risk than a product with a PAL and consumers have no way of knowing this. If there is use of a symbol, that too must be legislated and not voluntary.

A&AA acknowledges that if there is legislation for the use of PAL, there would be no need for a risk assessment indicator as it would be clear to consumers that all products have undergone the required risk assessment and have been labelled accordingly with or without a PAL statement.