RESPONSE FORM
Codex Committee on Food Labelling
EWG on Precautionary Allergen Labelling

1st Consultation Paper

Please provide a response using this form and post it on the Codex Forum EWG on Precautionary Allergen Labelling by **30 May 2025**

Name of Member Country/Organization: Allergy & Anaphylaxis Australia

Question 1:
Which of the following versions of Section 4.3 do you support? Please rank the options in order of preference (first being the highest preference and last being the lowest). EWG Members should consider this choice in light of the agreed 4.1 and 4.2, as well as the proposed amendment to Section 4.3.2 (Question 2 below) which would allow competent authorities the ability to set alternative reference doses based on national risk.

A. PAL shall only be used when it is demonstrated that unintended food allergen presence cannot be mitigated to a level at or below the action level[3] for a food allergen based on the reference doses in the table at 4.3.1.
B. PAL should only be used when it is demonstrated that unintended food allergen presence cannot be mitigated to a level at or below the action level[3] for a food allergen based on the reference doses in the table at 4.3.1.
C. PAL shall be used when it is demonstrated that unintended food allergen presence cannot be mitigated to a level at or below the action level[3] for a food allergen based on the reference doses in the table at 4.3.1.
D. PAL should be used when it is demonstrated that unintended food allergen presence cannot be mitigated to a level at or below the action level[3] for a food allergen based on the reference doses in the table at 4.3.1.
E. (Alternative proposed text) When it is demonstrated that unintended food allergen presence cannot be mitigated to a level at or below the action level[3] for a food allergen based on the reference doses in the table at 4.3.1, PAL should be used.
F. (Alternative proposed text) Only when it is demonstrated that unintended food allergen presence cannot be mitigated to a level at or below the action level[3] for a food allergen based on the reference doses in the table at 4.3.1, PAL should be used.

Footnote 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 quantity that can reasonably be expected to be consumed on a single eating occasion preferably using the 50th percentile.

Please provide your ranked preferences: A, C, B, F, D, E

Please provide reasons for your answer:

A&AA supports the use of 'shall only' so PAL is a requirement rather than a recommendation and not used indiscriminately. A standardised risk assessment should be mandated, so that products with a PAL are accepted as a higher risk product and people can have greater confidence in products without a PAL.

A&AA is concerned that the wording is difficult to interpret. We have spoken to key stakeholders who also found the text confusing. It would be clearer if the terminology was consistent with the expert Scientific Committee and Dr Paul Turner who states in his publication, 'Time to ACT-UP: Update of precautionary allergen labelling (PAL).' It states: '' If the degree of unintended allergen presence (UAP) is greater than the "reference dose" (RfD) for that allergen, then a PAL statement should be applied."

Question 2:
Do you support amending 4.3.2 to include flexibility for competent authorities to determine whether a reference dose is sufficiently protective for their population, as follows?

4.3.2 Where a reference dose is not established for a particular food allergen in the table to 4.3.1 above, **or when competent authorities determine based on a risk assessment[4] that the reference dose is not sufficiently protective for the regional/national population,** ~~regional or national~~ **competent** authorities can establish a reference dose consistent with recognized principles[5] for the purposes of determining an action level.**]**

Footnote 4: FAO and WHO (2023). *Risk assessment of food allergens – Part 3: Review and establish precautionary labelling in foods of the priority allergens (Sections 3.3.1 to 3.3.6 provide guidance for the risk assessment of unintended food allergen presence).* https://doi.org/10.4060/cc6081en
Footnote 5: 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.

☒YES
☐NO

Please provide reasons for your answer:

A&AA agrees that where a reference dose is not established for a particular allergen or the reference dose is not sufficiently protective for the population, competent authorities can establish a reference dose. This data should be accepted as a reflection of local influences and should be reviewed on a regular basis as more information on allergic reactions is provided. Competent 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. However, A&AA is not clear what local factors could influence a competent authority's decision to use ED05 or other safety values as a reference dose.

Question 3:
Do you support section 4.4 as follows?

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

☒YES
☐NO

Please provide reasons for your answer:
A&AA strongly supports 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 do 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 the 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 4:
Do you support section 5 as proposed by the Chairs to align it with the corresponding section of the revisions to provisions relevant to allergen labelling in the GSLPF?

5. PRESENTATION OF PAL

5.1 Section 8.1.1, 8.1.2 and 8.1.3 and 8.2 of the *General Standard for the labelling of pre-packaged foods*

(CXS 1-1985) apply to PAL labelling.

5.2 PAL ~~should~~ **shall** appear as a separate statement directly under or in close proximity to 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~~ **declare the** allergenic food(s) using the specified names for the foods and ingredients as listed in sections 4.2.1.4 and where applicable 4.2.1.5 of the General Standard for the labelling of pre-packaged foods (CXS 1-1985).

5.2.2 A PAL statement shall **be declared in a clear and distinct manner such as through the use of** ~~contrast distinctly from surrounding text such as through the same~~ font type, style or colour **that contrasts from the surrounding text** ~~used for declarations~~ in accordance with section 8.3.1 of the General Standard for the labelling of pre- packaged foods (CXS 1-1985).

☒YES
☐NO

Please provide reasons for your answer:

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

5.2 A&AA is unclear why (when present) is included at the end of the sentence. Should it read: When a PAL statement is present, it shall appear as a separate statement directly under or in close proximity to the ingredient list?

'When present' at the end of the sentence suggests it is referring to the ingredient list. We are not aware of cases where there would not be an ingredient list, but a PAL is required.

5.2.1 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.

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'.

5.2.2 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.

Question 5:
Does your country have questions related to food allergen qualitative risk assessment that the Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens should consider addressing in their meetings on qualitative risk assessment and on reference dose(s) (RfDs) for cereals containing gluten or gluten?

☒YES
☐NO

Please provide the questions and reasons for your answer:

A&AA is unclear how a reference dose for cereals containing gluten or gluten will be beneficial to consumers with coeliac disease.

In Australia, packaged food is required to be gluten free to be suitable for people with coeliac disease. That is, there should be no detectable gluten. Therefore, a product that has undergone a risk assessment and deemed not to require a PAL statement because the gluten is below the Action Level, is not necessarily suitable for a consumer with coeliac disease (in Australia) unless there is no detectable gluten, and it states that it is 'gluten free'.

People with IgE mediated food allergy to wheat need to be considered, as people with wheat allergy rely on the term gluten free and the product not containing wheat. It should be ensured that the Action level for gluten is appropriate for both people with coeliac disease and people with wheat allergy.