RESPONSE FORM

Codex Committee on Food Labelling
Electronic Working Group on Allergen Labelling

Second Consultation Paper October 2022

Please provide comments using this response sheet and post on the **online platform** by **9 December 2022**

Note: Only one response per Codex Member or Codex Observer is permitted.

Request for comments on Part 1 – Revision of the GSLPF

The EWG are asked to provide comments on the proposed draft revisions to the GSLPF as discussed in Part 1 of the consultation paper. This includes providing comments on the proposed definitions at Section 2 of Part 1.

The European Federation of Allergy and Airways Diseases Patients' Associations (EFA) is the EU-wide umbrella organisation representing the voice of more than 200 million of allergy, asthma, and chronic obstructive pulmonary disease (COPD) patients in Europe.
EFA's responses to the CCFL consultations have been prepared in close collaboration with the EFA Food Allergy Working Group.

Comments on Part 1:

Regarding the proposed draft revisions of the GSLPF (CXS 1-1985), EFA would like to comment the following:

- Regarding **oats**, while the EU does not consider oats as a primary allergen, EFA supports the proposal of the Chairs to include oats in a separate list of regional allergens, as it is possible that oat allergy is more prevalent among non-EU population, therefore requiring consideration at a regional level.

- On **lactose**, EFA supports the recommendation of the Chairs to remove lactose from the list of priority allergens, as it should not be considered as a single allergen. However, as lactose and milk are often confused, EFA stresses to grant special attention to lactose-free products containing milk proteins because lactose-free dairy products are safe to consume for lactose-intolerant consumers but they are not suitable for consumers allergic to milk and, depending on the production method, also not for people with galactosemia.
  Clarification on the suitability of specific "milk containing products" for lactose-intolerant people can be provided by additional information, besides the list of ingredients. A lactose-free claim is commonly used on food products for this purpose. However, criteria on lactose thresholds, conditions and possible additional labelling for lactose-free claims are not defined within any Codex Alimentarius standard. Therefore, we suggest defining criteria for a lactose-free claim within Codex Standard GSLPF or a stand-alone standard similar to the Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten.
  In addition to other benefits, such a standard would also help filling the existing gap of education among food producers, consumers, and regulators.

- EFA applauds the proposed approach of including **specific names** for the declaration of food and ingredients in both the priority allergens' list and the regional allergen lists. As indicated in our response to the 1st consultation, we very much welcome the provision to add the common/species name next to the specific name in certain cases e.g. fish and crustacea, as it will facilitate the identification of the allergens by allergic consumers. We think it is imperative to apply this principle also other types of allergens, such as tree nuts, egg and milk.
  In addition, EFA stresses that the GSLPF must add group names also for gluten-containing cereals e.g. wheat (gluten), as well as extra examples to table for often misinterpreted ingredients, as follows:
  - Spelt (wheat, gluten)
  - Gluten-free wheat starch (wheat)
  - Wheat starch (wheat, gluten)
  - Lactose (milk)
  - Cheese (milk)
  - Whey powder (milk)
  - Shrimp (crustacea)

  On the one hand, and particularly for **shrimps**, EFA thinks that it should not be labelled as ['shrimp' or 'crustacea'], as the proposed approach suggests, but as ['shrimp (crustacea)']. The same applies for fish, as the names of some fish species e.g. tilapia might not be very popular, and therefore it is more helpful to include both the name and the reference e.g. "Tilapia (Fish)".
  On the other hand, in the case of **nuts,** EFA advises using of the name of the specific nut and not the overarching name 'nut'. This recommendation arises because allergy to nuts is hugely diverse and the ingredients are commonly used. Therefore, it would be easier and less choice-restrictive for allergic consumers to recognise the specific nut type. Moreover, using the overarching name 'nut' might lead to its indiscriminate use also within the Precautionary Allergen Labelling, a scenario that must definitely be avoided from a patient's allergen eviction perspective.

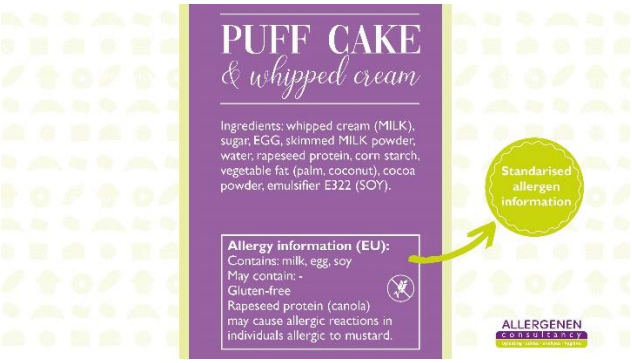
- Regarding section 8.3, EFA acknowledges the difficulty of the debate, as the use of **summary statements** in the package labelling provides with both advantages and disadvantages. However, we think that the allergy patient community has a lot to gain by 'Contains…' statements, based on the following considerations:
  - They are convenient for the consumer for a quick screening of allergenic ingredients (they spare patients from going through the whole list of ingredients, which is a time burden for people with food allergy)
  - They provide a place for additional explanation about allergens: e.g. if gluten-free made wheat starch is used as an ingredient, it would only appear as wheat starch (bolded or in capital letters).
  - They also provide opportunity to standardize allergen information on the label. If implemented, then the symbol to indicate that a Qualitative Risk Assessment (QRA) has been performed would not be necessary anymore (see Question 9 in the consultation on the proposed PAL guidelines).

  Also, summary statements are useful as long as they are fully consistent with the ingredients' list. In addition, the use of summary statements must be based on mandatory education for food business operators, to ensure that the statements are placed in a way that enables allergic consumers to get the information they need.

To be even more effective, EFA proposes to establish a unified **'allergy statement'** referring not only to the list of ingredients but also Precautionary Allergen Labelling (where applicable) and other allergen-related information of the food product, all in one place.

Below you can find an example of a 'allergy statement' that includes all allergen-related information. With PAL:

And without PAL:



- Regarding **definitions**, EFA finds that the difference between "Hypersensitivity" and "Food Allergy" is not clear. Given the scope of the current list, the definition of food allergy covers both IgE and non-IgE mediated immune reactions to food – that means IgE mediated food allergy and coeliac disease. Therefore, the proposed definition for food allergy is accurate and term "hypersensitivity" should be erased in the text of the GSLPF 4.2.1.4. Hypersensitivity could be only referred to indicate a broader range of adverse reactions to food after ingestion e.g. those including adverse reactions to sulphite, which are not immune-mediated and therefore they do not constitute food allergy.

Request for comments on Part 2 – Proposed draft PAL guidelines

Please provide responses to the following questions about the PAL guidelines.

Question 1: Do you support the Chair's proposal for the title, purpose, and scope?	
Yes ☒	No ☐

Please provide reasons for your answer:

- EFA applauds the removal of 'advisory' from the **title** and agrees with the proposed revised title: 'Guidelines for the use of Precautionary Allergen Labelling'
- EFA agrees with the proposed text on the **purpose**. However, we would welcome further clarification on what 'production' means in this context, by offering an explicit definition. At any rate, we suggest to slightly change the wording of the purpose as follows:
  *'To facilitate a consistent and harmonized approach to the effective use of precautionary allergen labelling (PAL) for communicating to consumers with food allergy about the risk from the unintended presence of allergens in food due to cross-contact during the **whole** production **process** of food'*
- As regards the **scope**, EFA stresses that consumers with food allergy must have access to all food information to make informed food choices, including for prepacked and non-prepacked food. However, we acknowledge that the provision of PAL-related information and the undertaking of a Quantitative Risk Assessment might be difficult for the non-prepacked food sector, such as restaurants or bakeries, for two specific reasons: firstly, because of lack of knowledge among food business operator (FBOs), a majority of which are small businesses, on issues around cross-contact; and secondly, because this might trigger side-effects such as the use of 'blanket statements' on allergens by FBOs, leading to the exclusion of allergic patients from their establishments. Therefore, EFA suggests that PAL information on potential allergen cross-contact in the non-prepacked sector must in any case be available upon request by the consumer with food allergies.

Question 2:
Do you support the Chair's proposal for the definitions of 'allergen' and 'precautionary allergen labelling'?

Yes ☒	No ☐

Please provide reasons for your answer:

- EFA supports the proposed **definition for 'allergen'.**
- EFA agrees with the proposed **definition for 'precautionary allergen labelling',** but reiterates that PAL information must be available, on demand, also in the non-prepacked sector.

Question 3:
Do you support the inclusion of the new revised principle 4.1?

Yes ☒	No ☐

Please provide reasons for your answer:

While in principle EFA agrees with the meaning of principle 4.1, EFA considers it is important to include a clear statement that the use of PAL is not voluntary **but mandatory**. In order to emphasize this, the words "should" should be replace by "must" in both sentences, as follows:
*'4.1 Effective management practices and controls to prevent or minimize the unintended presence of allergens caused by cross-contact **must** be implemented as outlined in the*

*Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020). The use of PAL **must** be restricted to those situations in which the unintended presence of an allergen(s) cannot be controlled.'*

Question 4: Do you support the revised wording of principle 4.2?	
Yes ☒	No ☐
Please provide reasons for your answer: Here too, EFA agrees with the proposal but stresses the need to make PAL a **mandatory procedure**, and therefore "should" should be replaced by "must", as follows: *'4.2 The decision to use PAL **must** be based on the findings of a risk assessment which shall include, but is not limited to, quantitative risk assessment.'* In addition, a preference for quantitative risk assessment should be expressed in the principle, including other options. For example: *'The decision to use PAL must be based on the finding of a risk assessment**, which shall be quantitative but is not limited to QRA'**.*	

Question 5: Do you support the including in section 4.3.1 of the draft guideline the established reference doses (RfD) based on ED05 as recommended by the Expert Committee?	
Yes ☒	No ☐
Please provide reasons for your answer: In general, EFA agrees with the concept of reference doses for QRA and specifically EFA supports the recommendations of the Expert Committee for ED05. This approach will protect the vast majority of consumers with food allergies and provide food manufacturers with values they can use to perform their risk assessment, which will be a huge step forward for a meaningful and consistent use of PAL (which is much preferred than having no guidance on thresholds as an alternative option). In the EU legal context, this will also serve comply with the law (the EU General Food Law, Regulation 178/2002), which stipulates that food without PAL should be safe for everybody. Regrettably, we do know that this is not always the case. If a product does not include PAL, this does not mean healthy for anyone, not only ED01 consumers. Moreover, EFA would like to note that the wording of allergens in table 4.3.1 is not in line with paragraph 4.2.1.4, which risks excluding some species. To improve the clarity, EFA suggests applying the following changes in the table: - Sorting allergens in the same order as in paragraph 4.2.1.4 - Replace shrimp with crustacea - Replace wheat with cereals containing gluten - List each nut in a separate line - Use plural forms where used as such in 4.2.1.4 (e.g. peanuts) A mechanism for revision/updating of the table should be established. Furthermore, as reference doses might be confused by limits to produce foods with a free-from claim, such as gluten-free, lactose-free or other allergens and substances, it is	

imperative to clarify the difference between PAL and 'free-from' statements by adding a new paragraph to the Guidance. The use of 'free-from' statements is a wholly different category of assessment, as it implies that the highest level of control and analysis of the food have been implemented. Therefore, it would be extremely helpful to have a clear definition of what 'free-from' entails to avoid cases where a product bears both a 'free-from' and a PAL statement for the very same ingredient, which leads to confusion and lack of safety.
Finally, reference can be made to Codex Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten, a suggested new Standard for Foods for Special Dietary Use for Persons Intolerant to Lactose and other free-from claims.

Question 6:
Do you support principle 4.4 which allows national authorities to determine reference doses for the regional list of allergens in section 4.2.1.5 of the proposed revised GSLPF?

Yes ☒	No ☐

Please provide reasons for your answer:

From the perspective of food allergy patients, EFA highly welcomes the recognition of regional differences by Codex, and supports this approach through the implementation of section 4.2.1.5. However, EFA recommends emphasising that the use of QRA and PAL also applies for regional allergens as well, and therefore a reference dose should be determined also regional allergens.
EFA reiterates its proposal for an 'allergy statement' (stated in Comments to Part 1) that will integrate PAL statements based on the reference doses that will be determined, as well as other allergen-related information applied at regional level.

Question 7:
Do you support including location and format aspects in the principles for the presentation of PAL?

Yes ☐	No ☒

Please provide reasons for your answer:

EFA stresses that PAL should not only be in the "same field of vision", which gives the opportunity to place it anywhere on the same side of the package of a prepacked food. This might result in overseeing a statement – or as recently happened during the EU emergency labelling changes due to the war in Ukraine: PAL statements occurring in the field for the "best before…" date at the opposite end of the package – even though on the same side.
A second and even more ambiguous scenario, which also happened, is when there is a PAL statement already present under the ingredient list and the field for the "best before…" date is used to provide an additional PAL statement.

Therefore, the location of the PAL statement should be better defined and include the following aspects:

- PAL must appear "under the ingredient list" or "in direct conjunction to the ingredient list".
- If a food does not have an ingredient list, it must be placed under the "Contains-Statement" indication the presence of allergens.

- There should also be an additional indication that a PAL statement is only allowed in one location on a package. EFA proposes the following wording: **"PAL must appear as a separate statement under the ingredient list or the "Contains"-Statement indicating the presence of allergens. There must be only one PAL statement per food item and it should contrast distinctly from surrounding text, such as through the use of font type, style or colour**"

Obviously, these location and format principles should also be applied with EFA's proposal for a unified **'allergy statement',** which shall refer not only to the list of ingredients but also to a potential PAL and other allergen-related information of the food product (as referred to in Comments to Part 1).

Question 8:
Which option for a single statement for PAL do you prefer and why?
Option 1 – 'Not suitable for people with a x allergy' or 'Not suitable for x allergy'
Option 2 – 'May contain x'
Option 3 – 'May be present: x'

Option 1 ☐	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.

One long lasting call of EFA is that food manufacturers must provide clear information on their products, so that consumers are not left in a position of uncertainty regarding buying or not buying a food. Based on this principle and within the current circumstances it is not possible for EFA to choose the "right" preferred option based on the considerations below:

- **Option 1: 'Not suitable for people with a x allergy'** – Consumer research has shown that this statement for unintended allergen presence prevents consumers with food allergy from buying and eating a product. The wording takes the "decision" away from the consumer – which might be seen both as an advantage or disadvantage. However, many consumers are able to tolerate more allergen than the reference dose, making the product suitable for them. Therefore, using option 1 restricts their food choices and might even erode the value of the warning, leading to limited reliability eventually. Moreover, 'Not suitable for people with a x allergy' can be confusing for consumers as they might expect all allergens listed in this type of statement, but it currently does not list allergens intentionally added. For example, a hazelnut paste contains only hazelnuts as an ingredient but there is a risk on cross-contact of peanut. If the PAL lists "Not suitable for people with a peanut allergy'" it is confusing as it is also not suitable for people with a hazelnut allergy.
- **Option 2: 'May contain x'** – This option is not ideal either, as it does not help food allergy consumers distinguish the food product that has undergone risk assessment from the one that has not. Moreover, this option is currently overused and linked to lack of transparency and consumer credibility. Besides, it would be difficult to distinguish between the previous 'may contain' statements with the new ones based on ED05.
- **Option 3: 'May be present: x'** – This option is also problematic, as it would present translation difficulties, as it would be challenging to convey the same meaning in other languages.

EFA acknowledges that all three options have advantages too. This is exactly why we strongly believe that this is a topic where Codex must broadly consult the people to whom this information is addressed: the food allergy community. Consulting food allergy patients and carers would not only help determine the preferred wording for PAL but could also improve trust on the use of PAL overall, which should be the main objective. One major element that can help achieve this objective is making PAL mandatory.

Finally, EFA encourages that PAL wording, as many other parameters of PAL, should be accompanied with an educational aspect. All the wording options put forward should be clearly explained to all the involved stakeholders: consumers, healthcare professionals, food manufacturers, food authorities etc.

Question 9:
Do you support the inclusion of a principle on the need to indicate on the label (e.g. through the use of a symbol) that a risk assessment has been undertaken?

Yes ☐	No ☐

Please provide reasons for your answer:

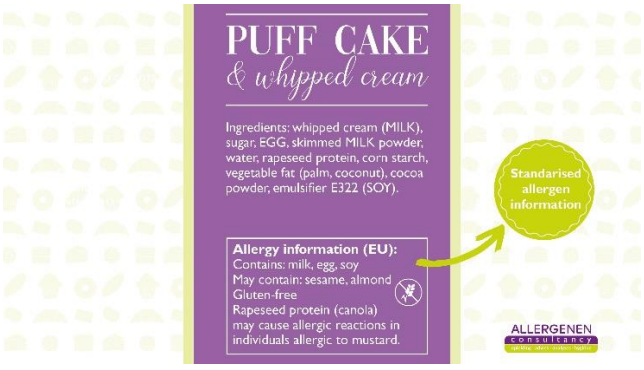
As mentioned above, EFA holds that the use of PAL and the reference to the supporting QRA must become mandatory information in prepacked food, which would make the use of a symbol unnecessary. However, if Codex does not opt for a mandatory PAL, the use of symbols must comply with certain requirements:

- Symbols must be jointly agreed-on, harmonised and standardised to ensure recognition by consumers and avoid different manufacturers using different symbols
- Symbols must include statements about the method through which the food manufacturer arrived to this decision e.g. *'The use of this symbol is supported by quantitative/qualitative risk assessment performed by the manufacturer'*

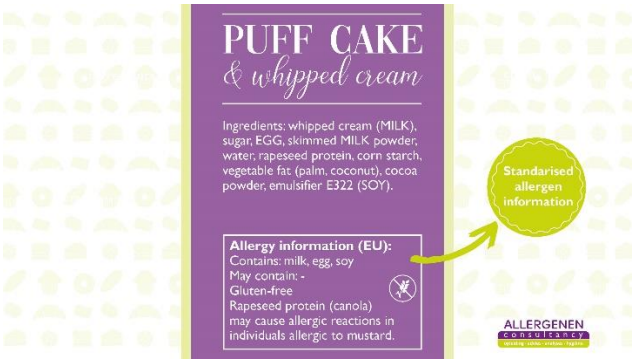
Both EFA and the global food allergy patient community should be consulted for the definition of such a unified symbol to prevent negative side-effects.

In addition, a symbol is not the only possible type of communication on use of QRA on a label while other options have not been investigated yet. Those options should also be considered before the introduction of any symbol.

Below you can find an example of a 'allergy statement' that includes all allergen-related information. With PAL:



And without PAL:



In light of the considerations above, EFA would prefer to not choose among the options 'Yes' or 'No' in this question.

Question 10:
Do you agree with the proposed principle on education to ensure understanding about PAL by consumers, health care providers and food business operators?

Yes ☒	No ☐

Please provide reasons for your answer:

EFA cannot stress enough the importance of education of all involved actors on allergen labelling e.g. consumers, healthcare professionals, food business operators, food inspectors etc on issues around allergen labelling. Education to FBOs must be made compulsory to be consistent with mandatory PAL, especially in the context of this guideline, through mandatory training courses in allergen risk assessment.

Question 11:
Do you support the Chairs' proposal to incorporate the draft PAL guideline as an annex to the GSLPF?

Yes ☒	No ☐

Please provide reasons for your answer:

EFA agrees with the Chairs' proposal to incorporate the draft PAL guideline as an annex to the GSLPF.