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CONSULTATION QUESTIONS

Responses from EFA - European Federation of Allergy and Airways Diseases Patients' Association

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Question 1

Does the scope of the GSLPF need clarifying as it applies to 'food for catering purposes' for the purpose of declaring foods and ingredients known to cause hypersensitivity (see Section 1.1 of Appendix I)? Please provide reasons for your response.

If yes, then how should the scope of the GSLPF as it applies to 'food for catering purposes' be clarified for the purpose of declaring foods and ingredients known to cause hypersensitivity?

Answer: Yes, there is a need for clarification to respond to consumers with food allergies about the presence of foods and ingredients that cause hypersensitivities in all foods, independently if those foods and ingredients are prepackaged (for consumers directly or for catering purposes) or for non-prepacked food. Moreover, every food manufacturer in the food chain needs this information to ensure, firstly, that operators providing food for allergic patients – such as caterers, restaurants, schools, hospitals – and, secondly, operators selling products business to business (B2B) including online markets, inform correctly on foods and ingredients that can cause hypersensitivities.

Even if the GSLPF focuses on prepacked food (as its name indicates), its scope should be extended to all options for food provision in the food chain, in case of foods and ingredients that cause food hypersensitivities. This comprises information on prepacked and non-prepacked food for consumers and catering purposes, but also in the B2B segment as well as in e-commerce.

We recommend integrating the broader scope for mandatory allergen information to the above-mentioned scenarios in a separate section for foods and ingredients that cause hypersensitivities, and as a sub-point under the scope of the GSLPF. Our argument supporting this distinction within the text is that we consider sufficiently relevant for consumers and food operators the fact that enforcing information of foods and ingredients causing hypersensitivities can avoid allergic reactions that can be potentially life-threatening.

Question 2

Do you 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 (see Sections 1.2 and 4 in Appendix I)? Please provide reasons for your response.

Answer: Information on food and ingredients causing allergies should not be restricted only to the ingredients list of prepacked food, but rather accompany all commercialised foods. Therefore, the declaration should apply to labelling in a broader way while ensuring that this option does not soften current labelling rules that require ingredients, and specifically allergens, to be listed on the actual package. With this, EFA wishes to ensure that any change on the presentation of declarations of foods and ingredients including allergen information must be listed in the actual product, besides other optional means such as websites or packing slips.

EFA agrees to the proposal to add a specific section that deals with the presentation of mandatory declaration of foods and ingredients known to cause hypersensitivity.

In the EU, most of the proposed aspects for presentation of mandatory information on foods and ingredients that cause hypersensitivities have been in place for 7 years now. The feedback we as the organisation representing food allergy patients in Europe have received on differentiated labelling for

allergens in foods is very positive. Using highlighted text, bigger fonts or bold formatting is reported as very helpful for consumers with food allergies and their carers, as it guides them to better identify allergens in food. Having similar allergen labelling provisions as the ones set by the EU Food Information to Consumers Regulation into the Codex GSLPF would ensure a broader application and standardisation of allergen labelling methods across the world, which would improve safe mobility and also awareness of food allergies worldwide.

We also recommend to group together in the same place all ingredient and additional allergen information such as “contains...” or “may contain...” statements, to ensure that consumers can easily find and read this information when making food choices.

Finally but not least important, we request Codex to clarify that the scope for information on foods and ingredients that cause hypersensitivity is also applicable to unpackaged food. We recommend in this context to substitute the term “Information” by the term “declaration”.

Question 3

Do you agree with including definitions for ‘hypersensitivity’, ‘allergen’, ‘food allergy’ and ‘food intolerance’ in the GSLPF (see Section 2.2 of Appendix I)? Please provide reasons for your response.

If yes, then please provide comments on these proposed definitions.

***“Hypersensitivity”** means the repeatable adverse reaction to an allergen or other substance in food associated with food allergy, food intolerance or Coeliac disease.*

Answer: As outlined in our last submission, we do not support the definition of “hypersensitivity” as it is too broad and potentially misleading. From our perspective, we recommend to avoid such an overarching term that summarizes very different diseases.

It is the broadest definition possible. There should be an indication/ distinction between the different diseases based on severity of symptoms / public health significance – see specific answers below.

***“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 sensitized to it.*

Answer: We do not agree with the proposed definition.

“Allergen” as well as “Food allergy” should indicate an ingredient’ potential to cause anaphylaxis, which is a life-threatening reaction, medically documented. Such a mention is of outmost importance as it indicates the uniqueness of “Food allergy” and distinguishes it from non-immune mediated food hypersensitivities/food intolerances. We consider that the definition of “Allergens” and “Food allergies” should follow the same rationale of the definition of “Coeliac disease” which includes the physical or medical consequences of the disease, beyond merely considering the underlying mechanism.

We also recommend to complete the mention to protein as a trigger of allergic reactions with the word “**typically**”, because not only proteins but also sugars can be allergens, like Alpha-Gal in red meat.

In summary, we suggest adding the following text (in bold) to the definition:

***“Allergen”** means an otherwise harmless substance capable of triggering a response that starts in the immune system and results in an allergic reaction, **that can cause anaphylaxis and result in a life-threatening allergic reaction** in certain individuals. In the case of foods, it **typically** is a protein which is found in food capable of triggering a response in individuals sensitized to it.*

***“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.*

Answer: We do not agree.

The definition of “Food allergy” must indicate that this reaction can result in anaphylaxis and can cause a life-threatening reaction in order to distinguish it from non-immune mediated food hypersensitivities/food intolerance (see answer to “Allergen”).

We suggest adding the following text (in bold) to the definition:

“Food allergy” means an adverse immune reaction to certain food proteins, which may be immunoglobulin E (IgE) mediated, non-IgE mediated, or a combination of both *and can cause anaphylaxis and result in a life-threatening allergic reaction.*

“Food intolerance” means adverse reactions to food components that occur through non-immunological mechanisms.

Answer: We do not agree as this represents the broadest possible definition.

There should be an indication regarding the difference between „Food intolerance“ and „Food allergy“ that refers not only to the underlying mechanism, but also to the medical consequences. While it is of course necessary to inform patients with food intolerance about the presence of their trigger in food, there should be an indication in the GSLPF to inform food manufacturers, who are not familiar with the medical aspects, about the different scope of the diseases, as it has been suggested in the proposed text for Coeliac Disease.

We suggest to refer to the term that is used in medical nomenclature: „non-Immune mediated food hypersensitivity“ instead of „Food Intolerance“.

Question 4

Do you agree with amending 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 (see Section 3.1 of Appendix I)? Please provide reasons for your response.

Answer: Yes, EFA agrees. Food Allergens can elicit allergic reactions in even small amounts. When a compound ingredient, that constitutes less than 5% of the food, contains a food allergen listed in section 4.2.1.4., it must be indicated to consumers with food allergies in order to enable them to protect themselves.

From our perspective, all ingredients, regardless of quantity, should be required to be labelled. Although the majority of allergic reactions occur to common allergens, there is a significant number of individuals who are allergic to more unusual ingredients such as fruit and spices that do not need to be listed when they are present at less than 5% of the total proportion of the ingredients. Eating any packaged food poses a significant danger to these individuals unless they have enquired with the manufacturer about allergen content. Even if the consumer has enquired the manufacturer about allergen content, the manufacturer is under no obligation to reveal the ingredients of their product.

Question 5

Do you agree with specifying the use of common and well understood terms (words) for the source of the food and ingredient known to cause hypersensitivity as part of, or in conjunction with, the relevant ingredient name when declarations are made on prepackaged foods (see Section 3.2 of Appendix I)? Please provide reasons for your response.

Answer: Yes, we agree with additional aspects (see text in bold below). We agree and support that allergen information must be clear and easy to understand. The names of ingredients sometimes do not identify their source or it is not obvious which food they are derived from e.g. tofu from soy, whey-powder from milk, bulgur from wheat. When a product derived from an allergenic food listed under 4.2.1.4. does not contain the allergen in its name, it is most helpful to consumers with food allergies and their carers (and food manufacturers as well), to have the allergen listed in simple, plain language with a reference

to the common name or source in order to identify the allergen e.g. tofu (soy), whey-protein (milk). Furthermore, this new aspect makes it much easier for consumers with food allergies, who work or travel abroad, to protect themselves, because they just need to learn one term (name) for each allergen in a different language instead of a complicated list of names that are used for products derived from the foods listed under 4.2.1.4.

However, it should be stated more precisely and clearly **HOW** this could be achieved. In our opinion, common and well understood terms for the source of the food and ingredient should directly **use the name of the allergen listed under 4.2.1.4** and should be in **direct** conjunction with the relevant ingredient name.

In order to indicate, how the reference to the allergen should be applied, it is helpful to add examples (see below).

We suggest the following additions to the text (see in underlined)

4.2.1.5 Declaration of the foods and ingredients listed in section 4.2.1.4 shall be made using the common and well understood terms for the source of the food and ingredient listed under 4.2.1.4 as part of, or in direct conjunction with, the relevant ingredient name e.g. tofu (soy), whey-protein (milk).

Question 6

Do you agree that section 4.2.2 of the GSLPF requires no change in relation to allergen labelling (see Section 3.3 of Appendix I)?

Answer: Yes, we agree with the section and encourage to consider current challenges arising from biotechnology. Novel foods might pose a risk to consumers with food allergies according to allergens that are present in both the known allergens listed in section 4.2.1.4 and the novel food e.g. mealworm as novel food can elicit allergic reactions in consumers with shrimp allergy. Therefore, allergen labelling with regards to novel food should be included in the GSLPF.

Question 7

Do you agree with the proposal to amend to section 4.2.3.1 in relation to the ingredients listed in section 4.2.1.4 and class names (See Section 3.4 of Appendix I)? Please provide reasons for your response.

Answer: yes, we agree.

Consistent terminology and wording is key when informing about foods and ingredients listed in section 4.2.1.4, that can cause food hypersensitivities. Therefore, the framework set in section 4.2.1.5. for the declaration of food and ingredients listed in section 4.2.1.4 should be the first reference, and should also apply to class names.

Question 8

Do you 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 (see Section 3.5 of Appendix I)?

Answer: Yes, we agree.

It is important that to clarify that food additives and processing aids that contain or are derived from foods and ingredients in section 4.2.1.4 are not exempt from declaration in the ingredients list.

Question 9

Do you 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 (see Section 3.6 of Appendix I)?

Answer: Yes, we agree.

The exemption of ingredient information on small units should not apply to food listed in section 4.2.1.4. Health risks associated with foods and ingredients known to cause food allergy is the same regardless of the surface area of the package containing a food. All products must provide declarations of foods and ingredients known to cause hypersensitivity no matter the size of the package. If the surface area did not permit a detailed ingredient list, an allergen summary statement would be acceptable e.g. Contains (list of major allergens).

Question 10

Do you have any other comments about the proposed approach or proposed revisions in Appendix II?

Answer:

- EFA reiterates that we do not support the proposed definition of hypersensitivity and strongly request to delineate between food allergy, Coeliac Disease and food intolerance. The consequences of an exposure to food allergen for people with food allergy needs to be clearly outlined as it has already been done for Coeliac Disease. The term hypersensitivity, which is used to collectively speak to three very different food health needs, dilutes the importance and severity of some conditions over others. People already think those with food allergy are "sensitive" and use this term to encompass a potentially life-threatening condition which does not assist in communicating dietary issues.
- We recommend to clearly include e-commerce/internet sales and deliveries for all food products (pre-packaged and non-prepackaged) in requirements for ingredient/allergen disclosure, such as the ingredient list, "contains statements" (if used) and PAL statements (if used). More consumers are purchasing food online and need complete and accurate information in order to make informed, safe food choices.
- As a patient organization representing consumers with food allergies, EFA requests to participate in the Codex work around consumers' understanding of allergen labelling and advisory statements. Our organization is the voice of over 200 millions people living with allergy and airways diseases in Europe and federates patients groups working on food allergy in the region and globally. Please advise how we can work together with the ISSLG as key stakeholders in this work.