31 May 2021

European Union Comments on
Codex Circular Letter CL 2021/9/OCS-FL:
Request for comments / information on allergen labelling - revision of the General Standard for the Labelling of Prepackaged Foods
(CXS 1 1985)

Mixed Competence.

European Union Vote.

In response to the request for comments, the European Union and its Member States (EUMS) would like to make the following comments on each of the questions raised.

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?

Proposed answer:

There is no need for further clarification of the scope of the GSLPF.

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.

Proposed answer:

The EUMS agree with the inclusion of specific provisions regarding the presentation of mandatory information for declarations of food and ingredients known to cause hypersensitivity. The EUMS are of the opinion that harmonisation of the presentation of the declaration about allergens in the GSLPF can enhance the understanding of allergen information. Consumers should be able to rely on allergens declarations being understandable and consistent.

In this context, the EUMS welcome the proposal that the allergen information has to be

provided in the list of ingredients, with the allergen name emphasised through a typeset that clearly distinguish it from the rest of list of ingredients. The EUMS suggest further specifying these provisions by establishing means for the clear distinction, such as a minimum font size, style or background colour for the 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.

Proposed answer:

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. In that context, the EUMS consider that "adverse reactions to food" may be a more clear term than "hypersensitivity" to describe immune and non-immune mediated reactions to ingested food. Therefore, the EUMS propose the following new definition:

"Adverse reaction to food means any reproducible adverse effect triggered by an allergen or other otherwise harmless substance in food associated with food allergy, food intolerance or coeliac disease (autoimmune adverse reaction to food)."

Further, to ensure clarity regarding the type of adverse reactions, the EUMS propose to include the following adapted definitions for "allergen", "food allergy" and "food intolerance":

"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~~ ***an allergic reaction in certain individuals through the activation of the immune system****. In the case of foods, ~~it~~ ~~is a protein which is found in food~~* ***the substance is in most cases a (glyco-) protein*** *capable of triggering a response in individuals sensitised to it.*

"Food allergy" means ***(reproducible)*** *adverse immune-mediated reactions to ~~certain food proteins~~* ***foods or components thereof,*** *which may be immunoglobulin E (IgE) mediated, non-IgE mediated, or a combination of both.*

"Food intolerance" means ***(reproducible)*** *adverse reactions to ~~food components~~* ***food or components thereof*** *that occur through* ***known or unknown*** *non-immune mediated mechanisms.*

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.

Proposed answer:

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.

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.

Proposed answer:

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 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.).

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)?

Proposed answer:

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.

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.

Proposed answer:

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.

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)?

Proposed answer:

The EUMS understand the question as amending section 4.2.4.2 to clarify that the exemption does not apply to carry-over of food additives and processing aids derived from substances listed in section 4.2.1.4. In that case, the EUMS agree with the proposed amendment as it enhances clarity of labelling obligations regarding processing aids and carry-over of food additives in the list of ingredients. To enhance clarity, the EUMS suggest deleting the square brackets and retaining the text therein:

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.

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)?

Proposed answer:

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 FIC Regulation) of the font size on the packaging shall be equal to or greater than 0.9 mm.

Question 10

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

Proposed answer:

The EUMS would like to draw the attention towards the newly added Section 8.3.2 on Presentation of Mandatory Information. The EUMS would like to clarify that it does not agree with the proposed introduction of a separate statement in addition to the list of ingredients, as the EUMS do not support any use of summary statement with regard to allergens to ensure a consistent way of providing information to consumers. In fact, different schemes of providing information to consumers may result confusing for consumers. Therefore, 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 FIC Regulation).

Further, 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 prepackaged 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.