6 September 2021

CODEX COMMITTEE ON FOOD LABELLING
46th Session
Virtual 27 September – 1 October 2021

European Union Comments on

Agenda Item 8:

FOOD ALLERGEN LABELLING (CX/FL 21/46/8)
(Comments at Step 3 - CL 2021/21/OCS-FL)

Mixed Competence
European Union Vote

The European Union and its Member States (EUMS) would like to thank Australia, United Kingdom and the United States of America for the preparation of the document 'CX/FL 21/46/8 – Proposed revisions to the General Standard for the Labelling of Pre-packaged Foods (GSLPF) and guidance on precautionary allergen labelling'.

The EUMS would like to propose the following modifications to improve further the text.

PART 1 – REVIEW OF ALLERGEN LABELLING PROVISIONS IN THE GSLPF

I. Comments on proposed draft revisions to the GSLPF in Appendix II

1. SCOPE

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 pre-packaged 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.

2. DEFINITION OF TERMS

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 propose the following new definition for the term "hypersensitivity" to describe immune and non-immune mediated reactions to ingested food. In addition, the EUMS are of the opinion that footnotes should be generally avoided in definitions.

"Hypersensitivity" means the repeatable adverse reaction to an allergen or ~~other~~ ***otherwise harmless*** *substance in food ~~associated with IgE mediated food allergy, non-IgE mediated food allergy[1], or food intolerance (i.e. sulphites, lactose)~~* ***that leads to food allergy, food intolerance or coeliac disease (autoimmune adverse reaction to food)***.

Further, the EUMS propose to include the following adapted definition for "food allergy":

"Food allergy" means adverse immune reactions to certain food proteins, which may be immunoglobulin E (IgE) mediated ***~~and associated with anaphylaxis~~****, non-IgE mediated[1], or a combination of both.*

Reference to anaphylaxis as included in the definition of food allergy, may imply that all food allergies are associated with anaphylaxis. However, allergy attacks in fact range from mild to more severe (such as life-threatening) cases. In addition, as coeliac disease is not a food allergy, the footnote following "non-IgE mediated" in the definition of food allergy should be removed.

3. MANDATORY LABELLING OF PREPACKAGED FOODS

Compound ingredients

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.

Terminology for declarations

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.).

Ingredients obtained through biotechnology

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.

Ingredients and class names

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.

Processing aids and carry-over of food additives

The EUMS agree the amendment of section 4.2.4.2 to clarify that the exemption does not apply to food additives and processing aids that contain or are derived from the foods and ingredients listed in 4.2.1.4. The proposed amendment enhances clarity of labelling obligations regarding processing aids and carry-over of food additives in the list of ingredients. The EUMS also suggest retaining the text in the square brackets.

Exemption for mandatory labelling requirements

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 Regulation (EU) No 1169/2011 on the provision of food information to consumers) of the font size on the packaging shall be equal to or greater than 0.9 mm.

4. PRESENTATION OF MANDATORY INFORMATION

The EUMS would like to draw the attention towards the added Section 8.3.2 (and 8.3.2.1) on Presentation of Mandatory Information. The EUMS would like to clarify that it objects to the proposed introduction of a separate statement about allergenic ingredients in addition to the

list of ingredients, as the EUMS do not support any use of summary statement with regard to allergens in order to ensure a consistent way of providing information to consumers. In fact, 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 Regulation (EU) No 1169/2011 on the provision of food information to consumers), as different schemes of providing information to consumers may result confusing consumers. Furthermore, the rationale behind objecting to the added Section 8.3.2 is that there is a risk that consumers mix the ingredients and the ones warned about in PAL and may think that everything in the box is PAL and therefore ignore information about allergenic ingredients. Another point is that if 'allergen boxes'/separate statements on allergen labelling are voluntary, consumers may be mislead should they think that foods without 'allergen boxes' or separate statements do not contain any allergenic ingredient. Last, it is easier to advise consumers to always read the list of ingredients, if allergenic ingredients are systematically listed and highlighted in the list of ingredients.

PART 2 – GUIDANCE ON THE USE OF PRECAUTIONARY ALLERGEN OR ADVISORY LABELLING

II. Comments on proposed draft guidance for the use of PAL in Appendix III

5. TITLE OF THE GUIDANCE

The EUMS are in favour of the term "precautionary allergen labelling" which correctly reflects the nature and purpose of the labelling in question. The information on unintentional presence of allergens in food is not intended to advice the consumer but to indicate the allergens that may be present because of a cross-contact.

6. PURPOSE

The EUMS are of the opinion that the purpose of the guidelines must be explicit and reflect the main objectives of the PAL in general.

In addition, the reference to "advisory labelling" should be deleted. Therefore, the EUMS suggest the following wording:

To ensure that precautionary allergen labelling is effective, risk-based and restrictive:

- in providing the consumer with information about a food so that an informed choice of food can be made;

- in providing a means for conveying information about the risk from the unintended presence of allergens in the food that may occur;

To ensure that no precautionary allergen labelling is made without a risk assessment regarding cross-contact and neither without carrying out other appropriate risk management measures.

7. SCOPE

The EUMS believe that, for the reasons of clarity and legal certainty, the scope of PAL should be limited to the substances listed in section 4.2.1.4 of the GSLPF. This list is based on scientific knowledge and contain substances for which there is evidence that they can cause hypersensitivity in individuals. The EUMS also consider that the scope of PAL guidelines should also encompass non-prepacked foods.

Further, The EUMS maintain that it has to be clear that PAL is restricted to situations where effective management practices and controls to prevent or minimize the potential allergen cross-contact, as outlined in the Code of practice for allergen management, are not further possible. Therefore, the EUMS suggest to replace paragraph 2.2 with the New paragraph 2.2. The previous paragraph 2.2, which refers to CXC 80-2020 is deleted, as the reference to CXC 80-2020 is included in the New text.

For that reason, the EUMS propose the following changes to the draft:

> 2.1 These guidelines apply to PAL when used to indicate the possible unintentional presence of allergens **listed in section 4.2.1.4 of the GSLPF**, caused by cross-contact, in prepackaged foods that are within the scope of the *General Standard for the Labelling of Prepackaged Foods* (CXS 1-1985) **and non-prepackaged foods offered to the consumer or for catering purposes**.
>
> ~~2.2 The *Code of Practice on Allergen Management for Food Business Operators* (CXC 80-2020) provides guidance on effective management practices and controls to prevent or minimise the potential for allergen cross-contact.~~
>
> 2.2 **PAL is restricted to situations where unintentional allergen(s) may be present despite implementing effective management practices and controls to prevent or minimise the potential allergen cross-contact as outlined in The Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020).**

8. DEFINITIONS

The EUMS consider that it is preferable to only refer to allergens listed in section 4.2.1.4 of the GSLPF.

In addition, as the purpose and scope of the guidance on PAL already refer to the concept of "*unintentional presence"* of substances in question, the EUMS believe that for the sake of coherence, this element should also be maintained in the definition of PAL.

Therefore, the EUMS propose the following changes:

~~[~~*Precautionary allergen labelling ~~or advisory labelling~~*~~]~~ is a statement indicating the ***unintentional presence of one of the*** allergen(s) ***listed in section 4.2.1.4 of the GSLPF*** that may be present in a food due to allergen cross-contact during the production, manufacture and transport of food, which may occur despite implementing allergen management practices and controls such as in the *Code of Practice on Food Allergen Management for Food Business Operators* (CXC 80-2020) ***and taking all possible mitigation measures.***

9. GENERAL PRINCIPLES

The EUMS believe that the draft general principles merit further clarification. Certain principles previously discussed have been lost and it would be useful that they are re-introduced in these guidelines. The EUMS consider that the use of PAL should only be explored where all possible mitigation measures available to eliminate the likelihood have been exhausted. The EUMS agree that the decision to use PAL should be based on the findings of a risk assessment. Without a proper scientifically-based risk assessment, it is difficult to interpret whether a cross-contact is significant or not.

The EUMS suggest the introduction of a new paragraph 4.1 introducing the general principles and then two subparagraphs 4.1.1 and 4.1.2 setting out the principles, as below:

~~4.1 The decision to use PAL should be based on the findings of a risk assessment which can include, but not limited to, quantitative risk assessment. The use of PAL should be restricted to those situations in which allergen cross-contact cannot be controlled to the extent that the product may present a risk to allergic consumers.~~

4.1 **The decision to use of PAL should be restricted to those situations in which allergen cross-contact cannot be controlled and a risk to consumers has been identified. The following general principles/criteria apply for PAL and the decision to use PAL should only be applied if both of these criteria are fulfilled.**

4.1.1. Unintentional allergen(s) may be present despite implementing effective management practices and controls to prevent or minimize the potential allergen cross-contact as outlined in The Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020).

4.1.2 The findings of a risk assessment show that the allergen(s) from the food is above an established reference dose and might thus cause an adverse reaction in a substantial proportion of allergic consumers. The risk assessment can include, but is not limited to, a quantitative risk assessment. Visually detectable allergens (e.g. pieces of nuts) can be compared to reference doses if chemical analyses and a quantitative risk assessment is not possible.

4.2 PAL that is motivated from the above criteria can help to inform FBOs and consumers on the likelihood that the products might contain an allergen.

~~4.2 PAL should only be used if exposure to the allergen from the food is above an established reference dose. If a reference dose is not established for a particular~~

~~allergen, an estimated reference dose can be used. If a quantitative risk assessment cannot be performed, then PAL should only be applied if any risk of allergen cross contact identified through a risk assessment cannot be removed through risk management actions, such as segregation and cleaning.~~

The EUMS believe that these proposed amendments would fulfil the intentions of the work carried out in 2019 on the Code of Practice on Allergen Management, from which paragraphs 14, 160, 161 linked to Precautionary Allergen Labelling were removed in order to be incorporated in the allergen labelling work[1].

10. CLARITY AND COMPREHENSION OF PAL

They EUMS agree with the approach suggested by the Chairs, i.e. points on the presentation of PAL, wording for PAL and education programs to be addressed once scientific advice is received. The efficiency of PAL can be only achieved if the information in question is clearly understandable for consumers.

III. Other general comments

The EUMS consider that both the revision of provisions relevant to allergen labelling in the GSLPF (Part 1) and the development of the guidance on the use of PAL (Part 2)) are very important. The EUMS believe that these two pieces of work should progress separately, so that they can independently progress and avoid any possible delays related to the publication of related scientific advice at different points in time (e.g. revision of criteria for section 4.2.1.4 of GSLPF, thresholds, and PAL).

Furthermore, the EUMS are in favour of dealing with the revision of the GSLPF and PAL separately. This is also considering that the work with PAL needs to take into account hygiene and food safety aspects as well as the CXC 80-2020. This was also mentioned in Report of the Codex Alimentarius Commission of the Forty-third Session, where the Code of Practice on Food Allergen Management for Food Business Operators was adopted, noting that the Code of Practice could be revised in future following scientific advice from FAO/WHO and completion of the work on guidance on precautionary allergen labelling in CCFL and in the Report of the Codex Alimentarius Commission of the Forty-second Session, where it was noted that CCFH should continue to liaise with CCFL on the issue of precautionary labelling to ensure consistency with the work of CCFL.

The specific location as to where to put the separate document could be considered, once work has progressed further on it.

[1] REP19/FH Appendix III, PROPOSED DRAFT CODE OF PRACTICE ON FOOD ALLERGEN MANAGEMENT FOR FOOD BUSINESS OPERATORS (at step 5)