07/10/2024

CODEX COMMITTEE ON FOOD LABELLING (CCFL)

48th Session

Québec City, Canada,
27 October – 1 November 2024

European Union Comments on

Agenda Item 5.2:

Guidelines on the use of precautionary allergen labelling (PAL) (Step 4)

(CX/FL 24/48/5 (Part B) - CL 2024/53-FL)

Mixed Competence
European Union Vote

The European Union and its Member States (EUMS) would like to thank Australia, the United Kingdom, and the United States of America for their efforts in preparing the document 'CX/FL 24/48/5 (Part B) – Proposed Draft Annex to the GSLPF: Guidelines on the Use of Precautionary Allergen Labelling.'

The EUMS would like to offer the following comments on the relevant sections to enhance the text. The EUMS also support CCFL in providing further guidance to the Codex Committee on Food Hygiene (CCFH) on an Unintended Allergen Presence risk assessment. This is aimed at ensuring that the Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020) aligns with the Guidelines on the use of PAL, in view of maintaining consistency across international food safety and labelling standards.

Provided there is agreement on the remaining points for discussion at CCFL48, the EU believes that the text is ready to progress to Step 5.

1. Purpose

The EUMS support the proposed revision of the text in the section on purpose.

2. Scope

The EUMS support the proposed revision of the text in the section on scope.

3. Definition of precautionary allergen labelling

The EUMS support the proposed revision of the text in the section on scope.

4. General Principles

The EUMS support the proposed text in **Principles 4.1 and 4.2**, as presented by the Chairs in Appendix II. The EUMS also support the proposed text in Principle 4.3.

However, the EUMS do not support the changes proposed in **Principle 4.3** by other Codex Members, specifically the allowance of PAL at UAP levels at or below an action level. Such flexibility would compromise the objectivity of PAL usage. The aim of these guidelines is to define and establish clear principles and criteria for the application of PAL, and allowing for such a possibility would not only jeopardise the consistent use of PAL but also undermine the efforts invested in developing these guidelines.

Furthermore, the EUMS support **footnote 6** as it currently appears in the draft Guidelines on PAL (Appendix II). The EUMS do not find it necessary to provide further clarity in that footnote regarding the use of serving or portion sizes in calculating the amount of food. Introducing portion sizes risks introducing significant errors and variability in these calculations. Additionally, portion sizes are not always indicated on labels, they vary across different food products, and it cannot be assumed that consumers consistently consume the exact portion size specified.

With respect to **Principle 4.3.1**, and as raised previously, the EUMS strongly advocate for the inclusion of gluten in the table of reference doses, with a separate indication for gluten The inclusion of gluten in the scope of PAL will be a significant step forward in ensuring that consumers are adequately informed and protected, and for maintaining consistency with the revised General Standard for the Labelling of Prepackaged Foods (GSLPF).

The specific threshold values for gluten merit more extensive discussions and could be fine-tuned at a more appropriate pace, with the input from experts, if necessary.

Upon reflection, the EUMS propose to consider an alternative to the previously suggested 20mg gluten/kg concentration: a reference dose of 4 mg gluten in Table 4.3.1. This reference dose would account for coeliac disease in PAL and consider other gluten-containing cereals beyond wheat. The proposed 4 mg reference dose is based on the wheat protein reference dose which is already in the table (gluten constituting approximately 80% of wheat protein) and is also more coherent with the ‘system’ of the reference doses in the table that form the base for a precautionary allergen labelling, as oppose to an “allergen-free” labelling (that is inherent to the concentration of 20 mg gluten/kg).

While this value is not directly derived from coeliac disease-specific data, it is widely understood that the daily intake of gluten should be as low as possible for consumers with coeliac disease. The reference doses in Table 4.3.1 are designed to protect 95% of allergic consumers, a decision made by the Expert Committee and supported by the vast majority of the eWG. Thus, the EUMS believe that the reference doses should offer similar protection for consumers with coeliac disease as for those with wheat allergies.

Lastly, the EUMS support the proposed text in **Principles 4.3.2 and 4.4.**

5. Presentation of PAL

The EUMS support the proposed revision of the text in the section on presentation.