

CODEX COMMITTEE ON FOOD LABELLING
47th Session
Ottawa, Canada, 15 – 19 May 2023

European Union Comments on

Agenda Item 5.2:
Proposed draft Guidance on Precautionary Allergen Labelling
(CX/FL 23/47/5 (Part B)- CL 2023/06-FL Appendix III)

Mixed Competence
European Union Vote

1. Codex members and observers are invited to submit comments on:
 - (i) the proposed draft guidelines for the use of PAL in Appendix III of [CX/FL 23/47/5](#), including:
 - a. the proposed location as an annex to the GSLPF (i.e. whether the guidelines should be incorporated as an annex to the GSLPF to ensure consistency with the GSLPF) ; and
 - b. the need to seek advice on standardised analytical methods and sampling from CCMAS (i.e. whether there is agreement to seek advice on appropriate methods for undertaking risk assessments, taking into account information provided within FAO/WHO scientific advice reports)
 - (ii) whether to provide any advice to CCFH to ensure consistency with the *Code of Practice on Allergen Management for Food Business Operators* (CXC 80-2020).

The European Union and its Member States (EUMS) would like to thank Australia, the United Kingdom and the United States of America for the preparation of the document 'CX/FL 23/47/5 – Proposed draft annex to the GSLPF: Guidelines on the use of precautionary allergen labelling.

The EUMS support the proposed location as annex to the GSLPF, as long as the revision of the GSLPF and the draft PAL guidelines do not delay each other.

The EUMS support the need to seek advice on standardised analytical methods and sampling from CCMAS.

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

APPENDIX III

PROPOSED DRAFT ANNEX TO THE GSLPF:
GUIDELINES ON THE USE OF PRECAUTIONARY ALLERGEN LABELLING
(FOR COMMENT AT STEP 3 THROUGH CL 2023/06/OCS-FL)

1. PURPOSE

The EUMS agree with the proposed text for the purpose of the guidelines.

2. SCOPE

The EUMS consider that it is not needed to specifically refer to “pre-packaged foods” in the text of the scope, since the PAL guidelines are annexed to the GSLPF text. The EUMS also consider the footnote redundant, as these guidelines will be part of the General Standard for the Labelling of Prepackaged Foods (CXS 1-1985).

In the light of the above, the EUMS propose the following modifications to the text of the scope of the PAL guidelines:

“These guidelines apply to PAL when used to indicate the risk from the unintended presence of allergens caused by cross-contact ~~in prepackaged¹ foods.~~”

3. DEFINITIONS

The EUMS support the terms included and the definitions provided for this section.

4. GENERAL PRINCIPLES

Principle 4.1: The EUMS support principle 4.1.

Principle 4.2:

The EUMS support principle 4.2 with an editorial modification:

“The decision to use PAL ~~should~~**shall** be based on the findings of a risk assessment which shall include, but is not limited to, quantitative risk assessment.”

Principle 4.3:

The EUMS support principle 4.3 with a modification:

“PAL shall only be used if the presence of a protein from an allergen is equal to or above the action level¹ for this allergen **in a specific food**, using the listed reference dose values in 4.3.1.”

Principle 4.3.1: References doses

The EUMS have the following question in relation to the Reference doses:

The reference doses in the table are written as total mg protein from the allergen.

- Gluten constitutes approximately 80 % of the wheat proteins. For this reason, the EUMS propose that a footnote is added to the table for the entry “*wheat*” stating: “**Gluten constitutes approximately 80% of the wheat proteins**”.
- How shall walnut (and pecan) and cashew (and pistachio) be expressed? The analytical methods to walnut and cashew might cross-react to pecan and pistachio respectively. In addition, this cross-reactivity might also be found among allergic consumers. Thus, the total amount from walnut/pecan and cashew/pistachio respectively might be best to use in the calculations? Should the wording be walnut (including pecan) and cashew (including pistachio)?
- How were the confidence intervals for the ED05 considered when the reference doses were set? The EUMS find the explanations for fish and crustaceae (page 89-90 [Risk assessment of food allergens: part 2: review and establish threshold levels in foods for the priority allergens: meeting report \(who.int\)](#)) justifiable but wonder regarding e.g. the tree nuts.

Principle 4.3.2:

The EUMS propose two editorial modifications:

“Where a reference dose is not established for a particular allergen by [section 4.3.1](#) above, national **or regional** authorities can establish a reference dose consistent with recognized principles¹ for the purposes of determining an action level.”

Principle 4.4: The EUMS support principle 4.4

5. PRESENTATION OF PAL

Section 5.2:

The EUMS have serious concerns if sections 8.3.2 and 8.3.2.1 are maintained in the GSLPF. The EU insists that the use of many separate statements on the label to indicate the presence of allergens in the final product (allergen labelling) and the potential presence of allergens (PAL) will be overloading consumers with information and will not actually train/educate them to always look at the list of ingredients to ensure the absence of any allergens in food.

Section 5.2.1:

Both the ISSLG literature review and Expert Committee Part 3 Summary and conclusions indicate a consistent and harmonised approach to PAL including a single PAL statement is important for communicating to consumers with food allergy about the risk from unintended allergen presence.

For this reason, the EUMS question the need for the addition of ‘*or equivalent words*’, as this could allow for deviations from the commonly agreed statement ‘may contain’. For this reason, the EUMS propose to delete this reference.

“A PAL statement shall commence with the words ‘May contain’ ~~(or equivalent words)~~ and include the identified allergens using the specified names as listed in sections 4.2.1.4 and where applicable 4.2.1.5 of the GSLPF.”