

APPENDIX III

**ANNEX TO
THE GENERAL STANDARD FOR THE LABELLING OF PRE-PACKAGED FOODS (CXS 1-1985):
GUIDELINES ON THE USE OF PRECAUTIONARY ALLERGEN LABELLING**

(For adoption at Step 8)

1. PURPOSE

To facilitate a consistent and harmonized approach to the effective use of precautionary allergen labelling (PAL) for communicating to consumers with food allergy or coeliac disease about the risk from the unintended presence of a food allergen(s) due to cross-contact¹ with allergenic food(s).

2. SCOPE

These guidelines apply to PAL when used in the labelling of pre-packaged foods to indicate the risk from the unintended presence of a food allergen(s) caused by cross-contact with allergenic food(s).

3. DEFINITIONS

For the purpose of these guidelines, the following definition shall be used in conjunction with the definitions in Section 2 of the *General Standard for the labelling of pre-packaged foods* (CXS 1-1985):

“Precautionary allergen labelling” is a statement made in the labelling of pre-packaged foods to indicate a risk from the unintended presence of a food allergen(s) due to cross-contact with an allergenic food(s) that has been identified by a risk assessment.

4. GENERAL PRINCIPLES

- 4.1** Effective food allergen management practices, including controls to prevent or minimize the unintended presence of food allergens caused by cross-contact with allergenic foods, shall be implemented in accordance with the *Code of practice on allergen management for food business operators* (CXC 80-2020). The use of PAL shall be restricted to those situations in which the unintended presence of a food allergen(s) cannot be prevented or controlled using these allergen management practices.
- 4.2** The decision to use PAL should be based on the findings of a risk assessment^{2,3}, which begins with qualitative risk assessment and may be supplemented with quantitative risk assessment of unintended food allergen presence.
- 4.3** PAL shall be used when, following the application of appropriate mitigation measures, it is demonstrated that unintended presence of a food allergen(s) is above the action level⁴ for the allergenic food based on the reference doses in table 1 for IgE-mediated food allergy and table 2 for coeliac disease. PAL should not be used when unintended presence of a food allergen(s) is at or below the action level.

¹ Allergen cross-contact as defined in *Code of practice on allergen management for food business operators* (CXC 80-2020).

² FAO and WHO (2023). *Risk assessment of food allergens – Part 3: Review and establish precautionary labelling in foods of the priority allergens* (Sections 3.3.1 to 3.3.6 provide guidance for the risk assessment of unintended food allergen presence). <https://doi.org/10.4060/cc6081en>

³ FAO and WHO. *Risk Assessment of Food Allergens – Part 6: Guidance for risk assessment*. (in press)

⁴ Action level (mg total protein from the allergenic food / kg food) = Reference dose (mg total protein from the allergenic food) / Amount of the food (kg). The amount of food should be established based on the quantity that can reasonably be expected to be consumed on a single eating occasion preferably using the 50th percentile.

Table 1 References doses for allergenic foods relevant to IgE-mediated food allergy risk analysis

Allergenic food(s) (IgE-mediated food allergy)	Reference dose (RfD) (mg total protein from the allergen)
Almond	1.0
Brazil nut	1.0
Cashew	1.0
Pistachio	1.0
Macadamia	1.0
Pine nut	1.0
Walnut	1.0
Pecan	1.0
Celery	1.0
Mustard	1.0
Peanut	2.0
Egg	2.0
Milk	2.0
Sesame	2.0
Hazelnut	3.0
Wheat	5.0
Fish	5.0
Buckwheat	10.0
Lupin	10.0
Soy	10.0
Crustacea	200.0

Table 2 Reference dose for gluten relevant to coeliac disease risk analysis

Allergenic food(s) (Coeliac disease)	Reference dose (RfD) (mg of total gluten from all relevant sources)
Cereals containing gluten:* <ul style="list-style-type: none"> – wheat and other <i>Triticum</i> species – rye and other <i>Secale</i> species – barley and other <i>Hordeum</i> species and products thereof† 	4.0

† Includes spelt, Khorasan, and other specific cereals containing gluten that are species or hybridized strains under the genus names of *Triticum*, *Secale* and *Hordeum*.

* Oats have been listed in the *General standard for the labelling of prepackaged foods* (CXS 1-1985) as an allergenic food (Section 4.2.1.5). However, no specific RfD for gluten has been established for oats because individuals with coeliac disease may react to the ingestion of oats due to either wheat, barley or rye cross-contact.

- 4.3.1** Where a reference dose is not established for a particular allergenic food in the table 1 above, regional/national authorities can establish a reference dose consistent with recognized principles⁵ for the purposes of determining an action level.
- 4.3.2.** If a PAL statement for cereal(s) containing gluten (wheat, barley, and rye) is necessary, then the term “gluten-free” shall not be used.⁶
- 4.4** PAL shall be complemented by effective education and information programs supported by competent authorities to promote appropriate use of PAL by food business operators and proper understanding by consumers, health care providers and other stakeholders.
- 5. PRESENTATION OF PAL**
- 5.1** Sections 8.1.1, 8.1.2 and 8.1.3 and 8.2 of the *General Standard for the labelling of pre-packaged foods* (CXS 1-1985) apply to PAL labelling.
- 5.2** PAL shall appear as a separate statement directly under or in close proximity to the ingredient list (when present).
- 5.2.1** Where a food is exempt from declaring a list of ingredients, and no list of ingredients is present, PAL shall be declared in a prominent position on the label. Where a separate statement made in accordance with Section 8.3.2.1 of the *General Standard for the labelling of pre-packaged foods* (CXS 1-1985) exists on the label, the PAL statement should appear directly under or in close proximity to the separate statement.
- 5.2.2** A PAL statement shall commence with the words ‘May contain’ (or equivalent words such as ‘may be present’, as determined by the competent authorities) and declare the allergenic food(s) using the specified names for the foods and ingredients as listed in Sections 4.2.1.4 and where applicable 4.2.1.5 of the *General Standard for the labelling of pre-packaged foods* (CXS 1-1985).⁷
- 5.2.3** When gluten is present above the action level and the source of the gluten cannot be verified by risk assessment, the specified names of all cereals containing gluten (i.e. wheat, barley, and rye) shall be included in the PAL statement.⁷
- 5.2.4** A PAL statement shall be declared in a clear and distinct manner such as through the same font type, style or colour that contrast from the surrounding text in accordance with Section 8.3.1 of the *General Standard for the labelling of pre-packaged foods* (CXS 1-1985). Where both a PAL statement and an allergen declaration are present, these shall be declared using the same clear and distinct manner.

⁵ FAO and WHO (2022). Risk Assessment of Food Allergens - Part 2: Review and establish threshold levels in foods of the priority allergens. <https://doi.org/10.4060/cc2946en>.

⁶ “Gluten-free” foods as defined in the *Standard for foods for special dietary use for persons intolerant to gluten* (CXS 118-1979).

⁷ In addition to the specified name of wheat, barley, and rye, the word ‘gluten’ may be used. Where permitted, the words ‘cereals containing gluten’ or ‘gluten’ may be used in place of the specified names barley and rye.