May Contain Statements on a Food Label

Precautionary Allergen Labelling (PAL), commonly seen as "May Contain" or "May Be Present" statements, is used to alert consumers when a manufacturer cannot guarantee that a food is free from unintended gluten cross contact. This contamination can occur at any stage of the food supply chain, including farming, harvesting, storage, transport, manufacturing, processing, or packaging.

Coeliac Australia's advice regarding foods carrying a "May Contain" statement has evolved as scientific evidence has improved our understanding of the actual risks posed by trace amounts of gluten. For many years, people with coeliac disease were advised to avoid all products carrying a "May Contain" or "May Be Present" statement because the level of risk was unknown.

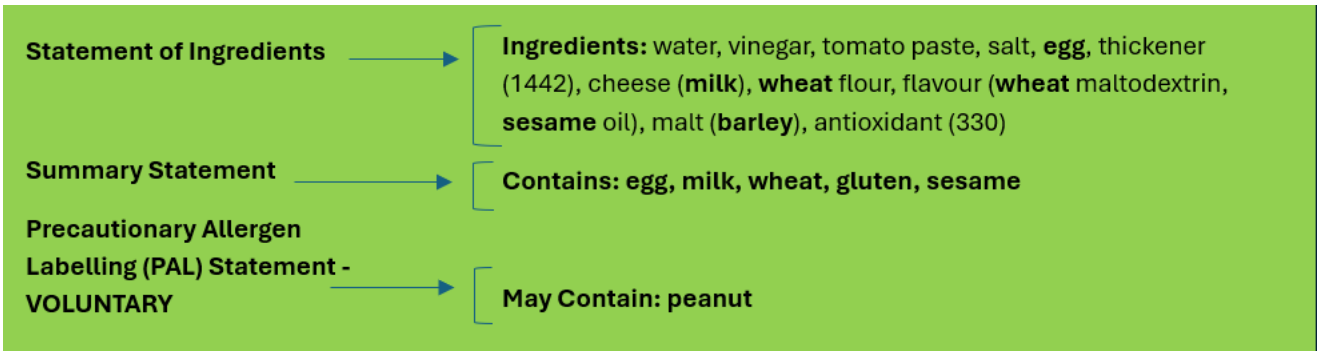
Current advice recognises that the decision to consume foods carrying a "May Contain wheat or gluten" statement is a personal one. Individuals vary in their tolerance to gluten and desire to take risks. Each person needs to consider factors such as their medical history, disease recovery, symptom experiences, lifestyle, and personal preferences when making this decision. What feels acceptable to one person may not feel acceptable to another.

However, while occasional consumption of these products is likely to present a low risk for most people with coeliac disease, **Coeliac Australia does not recommend frequent or daily consumption of foods carrying gluten-related PAL statements.**

What's new with 'May Contain'

In 2026, the World Health Organisation (WHO) and the Food and Agriculture Organisation (FAO) Codex Alimentarius food labelling guidelines, adopted a science-guided Precautionary Labeling quantity for gluten[1], along the same guidelines they put in place for food allergens in 2024.

Before exploring *'May Contain,'* let's first review the 3 relevant sections on food labels that will give you information about the gluten and allergens content of a food



Food Standards Australia New Zealand (FSANZ) is responsible for developing the mandatory regulatory requirements for Plain English Allergen Labelling (PEAL)[2].

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PEAL has mandatory requirements in these two sections of the food label.

1. Statement of Ingredients: MANDATORY

- Every time an ingredient is derived from **wheat, rye, barley or oats** - this will be declared, in **bold**, in the statement of ingredients.
- If there is no mention of wheat, rye, barley or oats in the ingredient list, this means that no ingredient is derived from a gluten-containing grain.
- For other allergens, their common plain English names like wheat, egg, milk, soy, peanut and declaration of individual tree nuts, molluscs and legumes, where applicable, will be **bolded in the statement of ingredients.**

2. "Contains" Summary Statement: MANDATORY

- Mandatory summary statements help us to identify, in one specified line, which allergens are present in a product, including gluten. Check the ingredient statement to see the source of the allergen or gluten words declared there.
- Summary statements will appear as *Contains* or *May be Present* statements: : To make labelling clear and helpful for both those with coeliac disease and those with wheat allergy, the terms 'gluten' and 'wheat' will be declared separately.
    - *Contains **wheat*** is important for those with wheat allergy.
    - *Contains **gluten*** is important for those with coeliac disease

'Contains: Wheat, Gluten'

- Gluten and wheat must be declared separately in the allergen summary statement. **The inclusion of gluten in the allergen summary statement indicates that gluten is present**. Wheat flour contains gluten. The use of wheat flour as an ingredient will stimulate both the inclusion of wheat and gluten in this section of the label.
- These products are not suitable for the gluten free diet.

'Contains: Gluten'

- If an ingredient in the product contains gluten, ***'gluten'*** will be listed in the Allergen Summary Statement: ***'Contains: Gluten'***.
- Rye, barley and oat ingredients will only be identified here using the term **"gluten"**. If **barley** starch in an ingredient, then the Contains summary statement will say ***contains gluten***. You should not see contains barley in this part of the label.
- These products are not suitable for the gluten free diet.

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'Contains: Wheat'

- This indicates that the product contains a wheat derived ingredient, but that the wheat derived ingredient does NOT contain gluten. Wheat-derived dextrose is an example here.
- If you see a declaration of ***'Contains: Wheat'*** (in the absence of 'Contains: Gluten'), the product is suitable.
- This declaration may appear on products that are labelled 'gluten-free'.
- Caution: It is always wise to double check which ingredient in the ingredient list the *Contains **wheat*** declaration came from, to reassure yourself it is a gluten-free wheat-derived ingredient.

Exceptions

Some ingredients that are wheat derived are highly processed, rendering them suitable for the gluten free diet. The following ingredients are suitable for the gluten free diet, even though they are wheat derived.

To see the exceptions and more practical examples of this on labels, please access our label reading document here.

3. Precautionary Allergen Labelling PAL: VOLUNTARY May Contain or May Be Present

Precautionary allergen labelling refers to statements such as "May Contain" or "May Be Present" that are used when there is a possibility of unintended allergen cross-contact during food production.

PAL statements are **voluntary statements** made by food businesses and are not regulated by the FSANZ Food Standards Code. **The Allergen Bureau (AB) provides industry guidance**[3] and developed and administers the voluntary **VITAL®** (Voluntary Incidental Trace Allergen Labelling) program. This VITAL® risk-assessment program was introduced in 2007. It provides manufacturers with a consistent, science-based method for assessing allergen cross-contact risks and deciding when precautionary allergen statements are warranted.

"May Contain" changes for food allergies in 2024:

The **2024 update (VITAL® 4.0)**[3] moved the VITAL® PAL system towards the recommendations of the WHO/FAO expert committee, now aligning VITAL® with the emerging Codex approach to science-based PAL. The 2024 guidelines recommend that a "May Contain" or PAL statement for wheat and other food allergens only be declared on a label, when the quantity of the allergen in a standard serving size of that food, reaches an **eliciting dose (ED)** that reflects a threshold where only the most sensitive 5% may react, (ED05), meaning 95% will not react.

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For **wheat allergy** concerns, the Codex/VITAL® framework uses a **5 mg Reference Dose of total wheat protein per eating occasion**; when a risk assessment indicates that unintended cross-contact exceeds this action level of 5mg, a PAL statement such as **"May be present: wheat"** is generated. VITAL® 4.0 was implemented in August 2024 for wheat and other allergens and is explicitly based on the FAO/WHO ED05 Reference Doses whose levels vary according to the specific allergen.

Gluten was not included in this 2024 review. **Meetings by world leaders in coeliac disease and food allergen analyses, addressed this gap in 2025.**

What's new and what does this mean for Australia?

In 2026 the 49th Session of the Codex Committee on Food Labelling (CCFL49) delivered an updated international guidance on precautionary allergen labelling including, for the first time, a science-based reference dose for cereals containing gluten.

Until now, there has been no internationally agreed approach for assessing the risk of gluten cross-contact specifically for people with coeliac disease.

The new guidance is based on extensive scientific work undertaken by experts from the WHO, FAO, food regulators, and members of the International Society for the Study of Celiac Disease (ISSCD) Gluten Safety and Standards Committee. Coeliac Australia joined coeliac organisations from around the world in supporting the development and adoption of this important standard.

A key feature of the new guidance is the introduction of a reference dose of 4 milligrams of gluten per serving of food. The new Codex guidance has now been incorporated into Australia's VITAL® Program[4] and can be used by food manufacturers and regulators to determine whether a precautionary warning for gluten is needed.

The reference dose was developed using scientific modelling to help ensure that a person's total gluten exposure from multiple foods consumed throughout the day is unlikely to exceed 10 mg of gluten, which is considered safe for most people with coeliac disease.

The goal of the updated guidance is not to increase the number of warning labels. Rather, **it aims to make precautionary statements more meaningful, consistent and evidence-based.** It should indicate a quantified and assessed risk rather than simply a theoretical possibility of contamination. Over time, it may reduce the use of vague statements such as "processed in a facility that also processes wheat" or "made on shared equipment with wheat," which can create confusion for consumers. It may also reduce unnecessary warning labels where the actual risk is extremely low or non existent.

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Examples: how this might work in practical terms

If ingredients have come into the manufacturer with a "May Contain gluten" statement or the environment may impart a risk for gluten cross contact. The manufacturer tests the final product serving size and can take either action below.

Action Level 1: when the cross-contact allergen is present in a standard serving of food, at an amount **equal to or less than the Reference Dose (≤4 mg gluten) → PAL is not required**.

Action Level 2: when the cross-contact allergen is present in a standard serving of food, at an amount **greater than the Reference Dose (>4 mg gluten) → PAL is required**.

4mg gluten or less per serve **No PAL**

If you make a gluten free apple pie (~600g) and the 1tsp of cinnamon used had a "May Contain gluten" statement on the bottle.

If the cinnamon had 100 ppm gluten
1 x 150g slice = 0.075 mg gluten

If this was a commercial product:- because the 150g serving size had less than 4mg of gluten, the product would not need to show a "May Contain" PAL statement.

more than 4 mg of gluten per serve **PAL**

A 500g pizza is gluten free by ingredient but carries a "May Contain gluten" statement. A serving size is 1 slice of pizza (about 60g)

If the gluten concentration was 100 ppm
1 x 60g slice = 6mg gluten

Because the standard serving size has more than 4mg of gluten this would require a "May Contain" PAL statement.

Note:

Importantly, this is **not** a new definition of "gluten-free" and does not change existing food standards for foods labelled gluten free. In Australia, foods labelled gluten-free must still have no detectable gluten, while internationally, gluten-free foods could contain up to or less than 20 parts per million (ppm) of gluten. **PAL statements should not appear on foods labelled gluten free**. Rather, this aims to improve the consistency and meaningfulness of PAL statements on foods not labelled gluten free, but are gluten free by ingredient, by ensuring a PAL statement is based on measurable risk.

Neither the Codex guidance nor the Australian VITAL® program is mandatory. Adoption by manufacturers is voluntary, and implementation across the food industry will take time. Consumers may notice the phrase "May Be Present" on some products, which is the preferred wording used within the VITAL® program and may indicate in Australia that a formal risk assessment has been undertaken.

Coeliac Australia will continue to monitor developments in this area and provide updated guidance as new evidence and industry practices emerge.

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What is the CURRENT risk with "May Contain" statements?

We have no Australia-specific data that has measured the general cross contact levels of gluten in Australian products.

In 2022, research[5] published in Denmark examined 128 foods that were not labelled gluten free but were gluten free by ingredient. Some products carried a "May Contain" statement, while others did not. The study found that:

- 95% of products contained less than 20 parts per million (ppm) of gluten, which is the international threshold for safe gluten-free foods.
- In 76% of products, gluten was not detected (< 5 ppm gluten)
- In the 5% with gluten levels greater than 20 ppm, 5 were between 20.5-39.8 ppm of gluten and one outlier measured at 421 ppm.

These findings suggest that the risk of consuming clinically significant amounts of gluten from such foods is generally low.

While Coeliac Australia cannot conclude that there is no risk with current labels, the evidence does indicate that PAL statements are often used more broadly than the measured level of risk may warrant and therefore advises that consuming foods with a gluten-related PAL is each person's own decision to make. While occasional consumption of these products is likely to present a low risk for most people with coeliac disease, Coeliac Australia suggests limiting frequent or daily consumption of foods carrying gluten-related PAL statements.

References:

1. *Joint FAO/WHO food standards programme Codex Alimentarius commission Forty-ninth Session: https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-714-49%252F%25E2%2598%2585Final%252520report%252FREP26_FLe.pdf*

2. *Plain English Allergen Labelling: https://www.foodstandards.gov.au/food-standards-code/proposals/P1044PlainEnglishAllergenLabelling?*

3. *VITAL resources: https://vital.allergenbureau.net/vital-resources/?*

4. *VITAL 2026: Best_Practice_Labelling_Guide_F4.pdf*

5. *Sisse Nygaard Rasmussen, Håkan Vigre, Charlotte Bernhard Madsen. Risk of consuming products with or without precautionary wheat or gluten labelling for persons with coeliac disease. Food and Chemical Toxicology, Volume 166, 2022,113231, ISSN 0278-6915, https://doi.org/10.1016/j.fct.2022.113231.*

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