Precautionary allergen labelling (PAL)
Information for health professionals

Precautionary allergen labelling (PAL) is used to inform food allergic consumers of the possible unintended presence of allergens in food. Food industry uses PAL statements on food labels if they are concerned that a product may be unintentionally contaminated with an allergen due to cross contact within the food supply chain or via processing equipment at the manufacturing plant.

PAL statements such as "may contain traces of XX" are currently unregulated, and therefore are generally unhelpful for consumers. Consumers with food allergy may be confused as to whether a PAL statement means a food is unsafe, and may consult with their trusted health professional for advice. In addition, consumers may erroneously consider a product without a PAL statement for their allergen to be safe. The information below has been developed for health professionals to understand PAL and provide advice to consumers with food allergy.

What actual risk to consumers with food allergy exists from foods with a PAL statement?

The risk to consumers with food allergy is dependent on the following:

1. the amount of allergen contained within the food due to cross contamination
2. the quantity of food with a PAL statement that they consume (higher volume equals higher risk)
3. the threshold level of the food allergen tolerated by the consumer with food allergy[1], and
4. the more foods that contain PAL statements, the less choices consumers with food allergy have and therefore, they are more likely to take risks with products containing PAL statements.

Further, food industry guidance recommends that a risk-based approach should be used to determine if a PAL statement is required and when used, the PAL statement is worded 'May be present: allergen x, allergen y'. However, this guidance is voluntary and inconsistencies in the wording of PAL statements may lead to consumer confusion and uncertainty regarding the safety of the food product.

How common is the use of PAL on food labels?

An Australian study investigated 1355 products with the following results[2]:

- 882 products (65%) had a PAL statement for one or more allergens.
- Tree nuts were the most common allergen listed on PAL statements (36.2%). This was followed by peanuts (34.1%), sesame (27.5%) and egg (22.6%).
- 'May contain traces of …' was the most common type of PAL statement used (392 products; 29.0%).
- 'May be present' was used on 172 products (12.7%). This is the term recommended by the Voluntary Incidental Trace Allergen Labelling (VITAL®) program (see below for more about VITAL®).

A UK survey conducted in 2001 assessed the prevalence of PAL in 232 food items considered to be an 'average' shopping basket and had the following results[3]:

- 69% of cereals and 56% of confectionery items were labelled as containing 'traces' of nuts.

A US survey of over 20,000 unique products found[4]:

- 17% had a PAL statement.

- More than 50% of products within the category of certain convenience foods (e.g. cookies and confectionery items), contained a PAL statement.
- 25 different PAL statements were used, the most common being “may contain…”, “produced on shared equipment…” and “made in the same factory as…”.

In contrast, the absence of a PAL statement may also lead to harm. An Australian survey undertaken in 2018 found that[5]:

- 6.7% of respondents with known allergies self-reported an anaphylaxis to packaged foods where the allergen was not listed as an ingredient.
- Of those reactions:
  - 53.5% were reportedly from foods that did not contain a PAL statement for the suspected trigger food.
  - 8.6% of the foods did not have any PAL statement.

What is VITAL®?

- Voluntary Incidental Trace Allergen Labelling (VITAL®) is a voluntary program developed in Australia and New Zealand that provides a standardised allergen risk assessment process for food industry.
- This is to assist with declaring the possible unintentional presence of allergens in food products by manufacturers. It is based on a quantitative assessment (i.e. how much of the allergen could be in the final product through cross-contact).
- Under VITAL®, a decision to place a PAL statement on the label is where it reaches a level that there is significant chance of an adverse reaction and a precautionary allergen labelling statement is required.
- Products that have undergone the VITAL® process do not currently have a logo on their packaging (although there is a process to do so), although they have a standardised format for the allergen summary statement and PAL statement: (Contains XX; May be present: XX). However, this standardised format does not assure the consumer that the VITAL® process has been used, because foods that have not undergone the VITAL® process can also use this format. Furthermore, if a product does not contain a ‘’May be present’’ PAL statement, the consumer does not know whether a product has been through a stringent VITAL® process or not. When the PAL statement is on a product, consumers have to trust the VITAL® process has been used although the statement is not protected for use only with the VITAL® process.

Given PAL is voluntary, and not all manufacturers use VITAL® as the basis for their PAL decisions, consumers face several different scenarios when reviewing the labels on packaged foods.

1. A PAL statement has been included because of evaluated risk assessment using the validated VITAL® tool indicated there is a significant chance of adverse reaction.
2. A PAL statement has been included because of an evaluated risk assessment using the validated VITAL® tool, however the VITAL® PAL statement has not been used because there is a low chance of adverse reaction.
3. A PAL statement has been included because of a risk assessment using an unvalidated tool.
4. A PAL statement has been used as a coverall statement to “protect” the manufacturer.
5. No PAL statement has been used, but the risk assessment using the validated VITAL® tool, indicates that no PAL statement is required.
6. No PAL statement has been used because of a risk assessment using an unvalidated tool.
7. No PAL statement has been used and no risk assessment has been conducted by the manufacturer. This is particularly challenging as many consumers will assume that if there is no

PAL statement, there is no risk. However, in this case, no risk assessment has been undertaken, hence a risk could still exist.

The current situation makes it impossible for consumers to decide which of the above statements (or lack of statement) they should take notice of. In the scenarios listed above, option 5 is the only situation in which the product would be safe for the consumer, however consumers have no way of knowing that a company's PAL statement is based on scenario 5 or scenario 7. Currently with the VITAL® logo being absent from packaging, scenario 1 is also an issue for consumers as they may assume the risk is the same as scenario 7.

Health professional's knowledge about PAL

Health professionals are often asked for advice about PAL statements and whether foods containing PAL statements are safe[1] to consume. Recently, there has been a growing awareness within the clinical community about the issues surrounding PAL statements[1].

A study undertaken in Australia and the UK found[6]:

- Only 82 (51%) of health professionals knew that PAL is voluntary and unregulated.
  - 51 (32%) thought that all PAL was subject to a standardised risk assessment.
  - 21 (13%) believed that PAL was subject to government regulation.
- Dietitians were better informed than allergy specialists, understanding that PAL statements were voluntary.
- 56% of health professionals had never heard of VITAL® with greater awareness amongst Australian paediatric health professionals.
- PAL was regarded as 'generally helpful' by 69 (43%).
- PAL was believed to be harmful by 40% and the remainder thought PAL was not important.
- 82% believed that PAL 'increased anxiety or abnormal food behaviours'.
- 80% thought that litigation minimisation was the most common reason for PAL statement use.

With regards to current practices[6]:

- 89% of health professionals discussed PAL where the patient had been assessed as being at high risk of anaphylaxis.
- 65% of health professionals discussed PAL where the patient had been assessed as being at low risk of anaphylaxis.
- Only 14% consistently advised patients to avoid foods with PAL statements, with the majority (69%) providing advice depending on the circumstances (Table 1).

TABLE I. Factors influencing the advice provided by health care professionals when advising food-allergic individuals with regard to avoidance of prepacked foods with precautionary allergen labeling (PAL)

	Factors that influence avoidance recommendations	
Answer options	**Percent**	**Count**
Type of allergen named in the PAL (eg, egg, cow's milk, nuts)	47.2%	75
Food to which the patient is allergic	57.9%	92
Type of food (eg, confectionery)	48.4%	77
Age of patient	16.4%	26
History of anaphylaxis	68.6%	109
History of allergic reaction to very small amount of allergen	78.0%	124
Asthma requiring preventer therapy	41.5%	66
Adrenaline autoinjector ownership	25.2%	40
No, I don't recommend avoidance	9.4%	15
Other (please specify)	6.9%	11

Responses to question: "Are your recommendations to avoid foods with precautionary labeling influenced by any of the following? You may select more than one option."

PAL wording

This same study[6] found there was discordance between which PAL statements health professionals believed indicated a real allergen cross-contamination risk, and what they considered was the ideal wording for PAL statements (Figure 1).

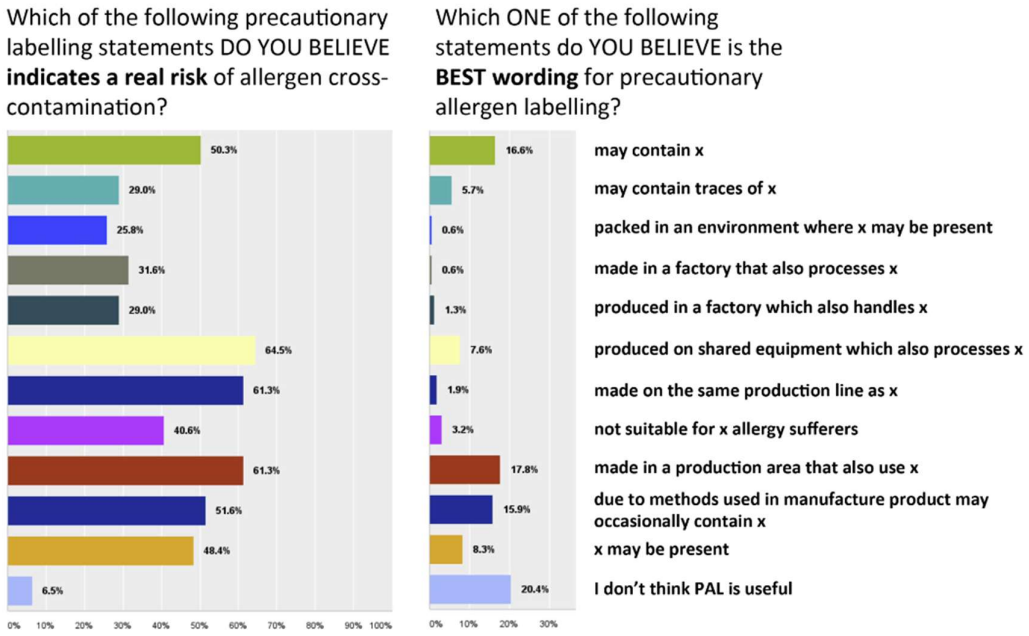

FIGURE 1. Discordance between which statements health care professionals believed indicated a real risk of allergen cross-contamination, and what they considered was the best wording for precautionary allergen labeling (PAL).

A web-based survey of health professionals (dietitians, doctors, allergists and nurses) conducted in the UK in 2013 found[7]:

- 38% of health professionals recommended complete avoidance of foods with PAL statements to nuts (but no nut listed in the ingredients) while 22% advised no avoidance was necessary. The remainder recommended that avoidance was not required under specific circumstances (able to eat if…), related to illness and the type of food. See Figure 2 below.
- Only 12 of 86 health professionals mentioned adrenaline autoinjector availability as being an important factor.
- The statement 'made in a factory where nuts are processed' was considered less important than simpler statements such as 'may contain nuts'.
- Factors resulting in more stringent advice included:
  - asthma (56% recommending complete avoidance)
  - prior anaphylaxis to the allergen in question (79%)
  - prior mild reaction to a tiny amount (71%).
- Advice regarding avoidance of products with PAL statements did not vary significantly where the allergen in question was egg rather than a nut:
  - 41% of health professionals recommended avoidance of items with PAL statements for egg, irrespective of whether the child was able to tolerate egg as an ingredient in baked foods such as cakes.

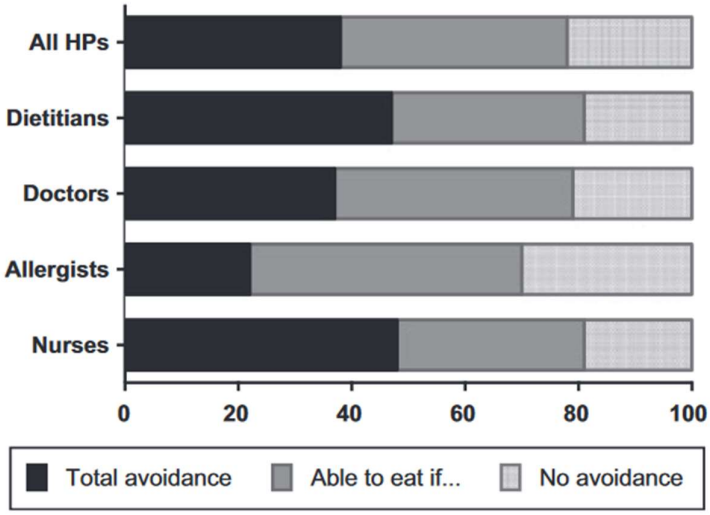

Figure 2 Advice recommended by different health professionals (HPs) with regard to precautionary allergen labelling (PAL) in nut-allergic children.

Key messages for health professionals

- Precautionary allergen labelling (PAL) is used to inform consumers of the possible unintended presence of allergens in packaged food.
- The use of PAL is voluntary and it is unregulated in Australia and New Zealand.
- VITAL® is a program that provides a standardised allergen risk assessment process for food industry.
- There are a range of PAL statements and products containing no PAL statements and they should all be regarded as having the same level of risk. Consumers should be encouraged to contact the manufacturer to check if they use the VITAL process for the particular product they are wanting to consume.

- Manufacturers may change allergen statements including PAL statements on the label, but not change the packaging (e.g. the product may look the same but the allergen information has changed).
- Most food products do not indicate on their packaging that they have been assessed using the VITAL® process (more recently, manufacturers may use the VITAL® mark if they achieve VITAL® certification).
- Industry guidance recommends a standardised format for the PAL statement ('May be present: allergen x, allergen y'). However, this standardised format does not assure the consumer that the VITAL® process has been used. Foods that have not undergone the VITAL® process can also use this format.
- Health professionals should:
  - Remind patients/consumers to read the entire product label, not just the ingredient information, allergy summary statement and PAL statement on each food pack, every time it is purchased.
  - Encourage patients/consumers to contact the manufacturer if they are uncertain about whether the product is safe to consume. They should be encouraged to ask the manufacturer if they use the VITAL® process for the particular food product.
  - Remind patients that if they choose to ignore PAL statements, they need to consider the risk of an allergic reaction which can be impacted by concurrent illness at the time and how much of the food with the PAL statement they eat and any other factors that can exacerbate an allergic reaction (e.g. exercise). If the patient is a child, parental supervision of the child is also required in case an allergic reaction occurs. If the patient is an adult, they should be advised to not eat the food whilst alone.
  - Remind patients that some products are higher risk for cross contamination than others such as sticky products (e.g. nut butters, biscuits, chocolates and ice creams). Other high-risk products include products made by a manufacturer that also makes products containing an allergen.
  - Patients should always have their ASCIA Action Plan and adrenaline injector (if prescribed) with them.

References

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