



Food Authority



A model for assessing allergen labelling compliance

Food Allergen Management Symposium

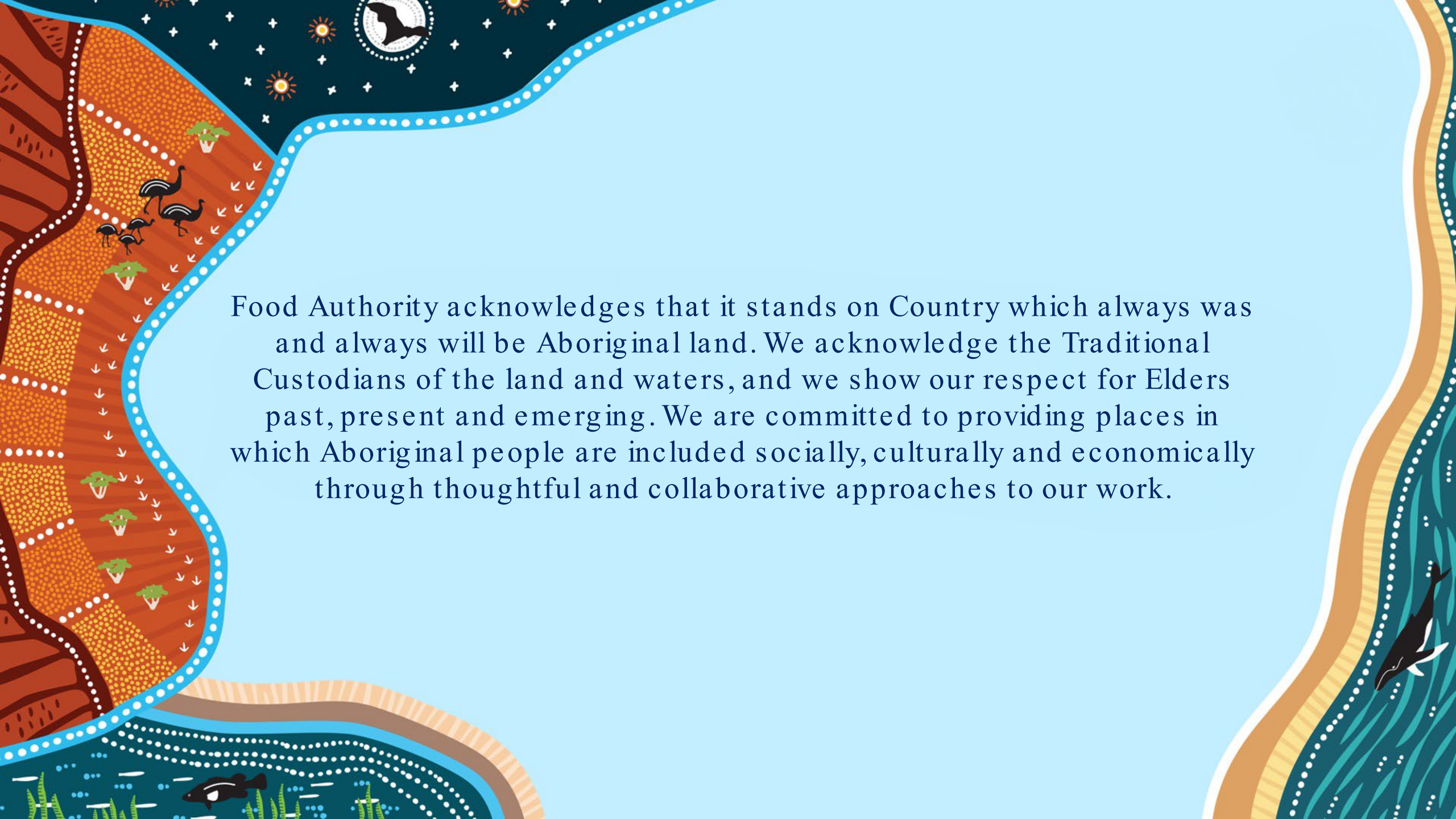
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Overview

1. Allergen risk management and the objective of allergen labelling
2. Allergen labelling requirements –packaged retail products
3. Consumer concerns –complaints received
4. Proposed model for assessing labelling compliance





Food Authority acknowledges that it stands on Country which always was and always will be Aboriginal land. We acknowledge the Traditional Custodians of the land and waters, and we show our respect for Elders past, present and emerging. We are committed to providing places in which Aboriginal people are included socially, culturally and economically through thoughtful and collaborative approaches to our work.

Characteristics of allergen risk

For consumers – exposure risk	For industry – presence risk
Risk can change over time	Presence varies depending on how allergen cross-contact occurs
Risk can vary depending on individual circumstances	Multiple facilities can supply ingredients for, or produce, a particular product
Unique to each person	Rely on others to provide information needed for risk assessment



May contain

A chance a single peanut is present in a baked good

or

A single peanut may have been milled into an ingredient used to make 100 baked goods



Exposure

One slice of pizza or eight slices of pizza

Amount of allergen consumed over time alters risk.

Knowledge of thresholds constitutes a critical requirement to assessing the risk from allergens Their establishment ... is thus essential to evidence-based application of risk management and mitigation strategies, such as precautionary allergen labelling (PAL).

FAO and WHO. 2022. Risk assessment of food allergens –Part 2: Review and establish threshold levels in foods for the priority allergens. Meeting Report. Food Safety and Quality Series No. 15. Rome.

<https://doi.org/10.4060/cc2946en> at p. XV

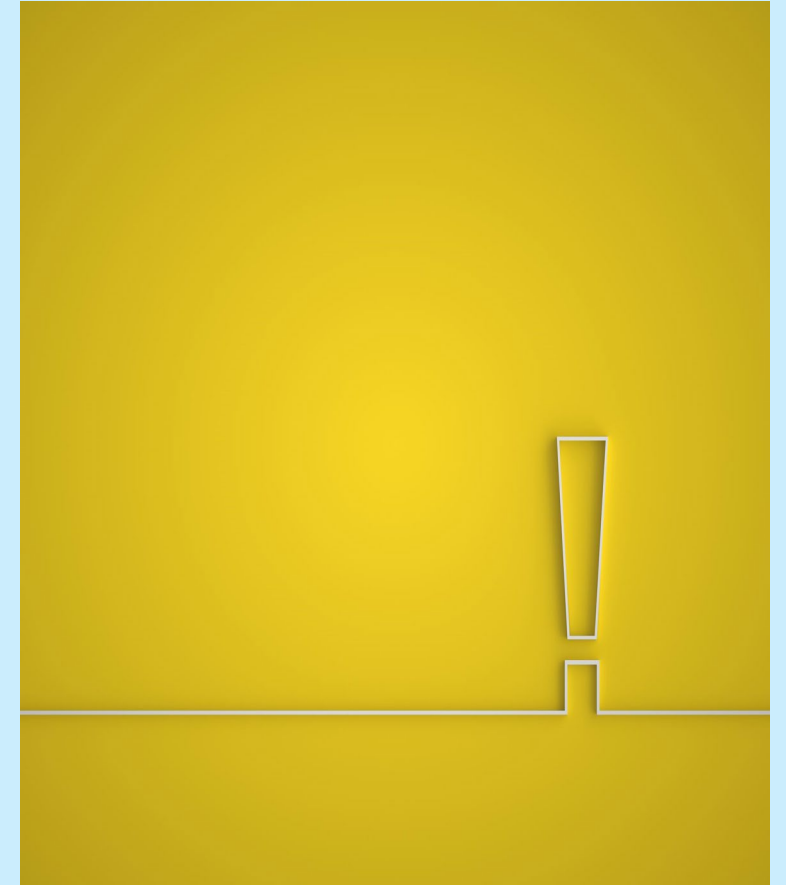
Establishing a threshold

What was the objective of the WHO/FAO committee?

“to minimise, to where further refinement does not meaningfully reduce health impact, the probability of any clinically relevant objective allergic response , as defined by dose -distribution modelling of minimum eliciting doses (MEDs) and supported by data regarding severity of symptoms in the likely range of envisioned Reference Doses (RfD).”

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Labelling requirements

What is the regulatory objective?

- Protect the health and safety of consumers by reducing risks related to food;
- Enable consumers to make informed choices about food



<https://www.foodregulation.gov.au/resources/publications/overarching-strategic-statement-food-regulatory-system> at p 4

Managing allergen risk



Essential elements :

- Communication
- Food safety culture
- Systems and processes

foodauthority.nsw.gov.au/sites/default/files/2023-02/managing-food-allergen-risk.pdf

Food business obligations – Suppliers

- Minimising the risk of unintentional allergen contamination:

Ingredient selection and production processes

- Providing clear and accurate allergen information

Risk assessment and product labelling

Empowers the consumer to make a risk assessment



Food Suppliers

Food suppliers manage food allergen risk by:

- Implementing an effective allergen management strategy
- Minimising the risk of unintentional allergen contamination
- Providing clear and accurate allergen information
- Training staff in food allergen risk management and communication

Allergen information – Std 1.2.3



Ingredient list	<p>Must list ingredients and identify common allergens:</p> <p>Ingredients Wheaten cornflower (Wheat)</p>
Summary statement	<p>Must list common allergens if present:</p> <p>Contains: wheat, gluten</p>
Set format	<p>A prescribed format must be followed: location, size, language etc</p>

Ingredients

Water, vegetable oil, vinegar, sugar, tomato paste, capsicum, salt, egg yolk, thickener (1412), almonds, parmesan cheese (milk), garlic, wheat flour, flavour (wheat maltodextrin, sesame oil), antioxidant (320).

Contains: egg, almond, milk, wheat, gluten, sesame.

PAL statements and other information provided to consumers - Model food provisions (MFP)

**False description
s14 MFP**

“May contain milk and peanuts –also labelled dairy free”

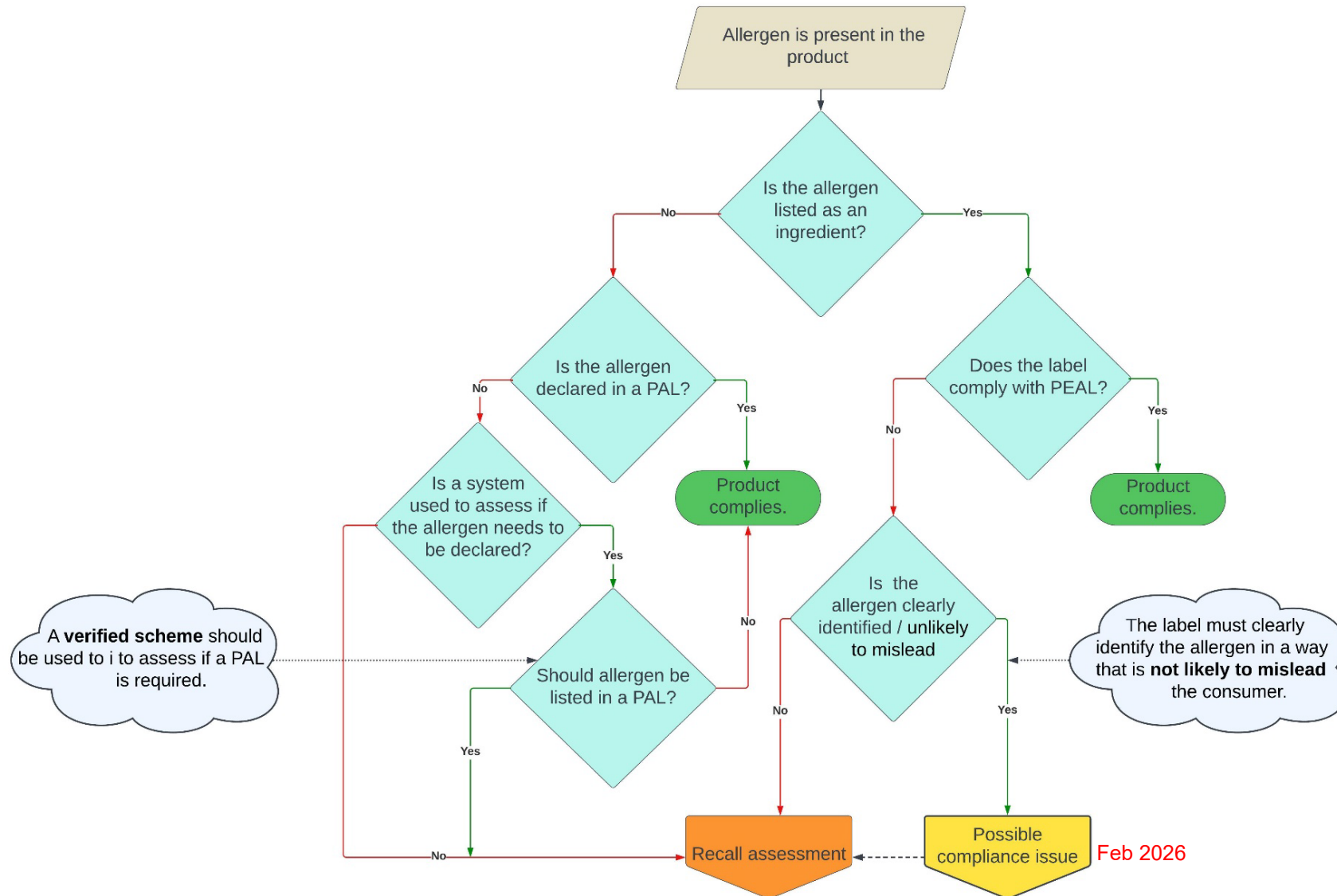
“May contains *traces* of almonds”

“Made in a facility that also handles wheat, eggs, dairy, peanuts, fish, soy, watermelon, crustaceans and tree nuts”

**Comply with
purchaser's demands
s15 MFP**

If you order an allergen free meal you should receive an allergen free meal

Draft allergen labelling assessment model



Overriding question: Has the allergen risk been managed in accordance with the objectives of the Food Act and Food Standards Code

PAL risk assessment

Does the business use a recognised system for assessing the risk of any unintended allergens that may be present?

Does the system use threshold levels for "priority" allergens established by the FAO and WHO expert committee?

That is, does the system set a level above which an allergen needs to be listed in a PAL statement to protect consumers?

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Unintended dairy

Report – single child reaction – EpiPen®prescribed

- ‘Severe allergy to cow’s milk’
- Vomiting while eating one serve of the food
- Hives 15 to 20 minutes later
- EpiPen® was not required -treated with anti - histamines
- Not hospitalised



Unintended dairy

Product – baked good



- Sold in 100g packs with a serving size of 8g
- Milk not an intentionally added ingredient
- Milk not listed in a PAL
- No 'Dairy free' claim
- **Casein** detected at **1.9 ppm**
- Beta-lactoglobulin and total milk were reported at <LOQ, that is, <0.1 and <2.5 ppm respectively

Unintended dairy

Exposure dose

- The child consumed < 1 serve (8g) and exposed to < 0.015mg of casein
- Assuming the child consumed the entire 100g of product (12 serves), they would have been exposed to up to 0.19mg of casein

Risk assessment

- The level of unintended allergen present is less than the ED01 risk level
- Risk to consumers is not significant (WHO/FAO principles)
- Business used VITAL® to decide whether a PAL statement is required

Decision

- Monitor for similar complaints

Unintended peanut

Report – multiple reports of reactions to a chocolate bar

- Multiple patchy reports, some mentioning other social media reports
- Allegation of undeclared peanut
- Range of products mentioned



Unintended peanut

Product – chocolate bar



- Sold individually
- Peanut not an intentionally added ingredient
- PAL–“May contain peanut”
- No ‘Peanut free’ claim
- **Peanut detected**

Unintended peanut

Exposure dose

- Label clearly states that peanut allergen may be present
- Level will depend on source of unintended contamination
- Investigation found contamination level likely to vary
- Widely distributed product

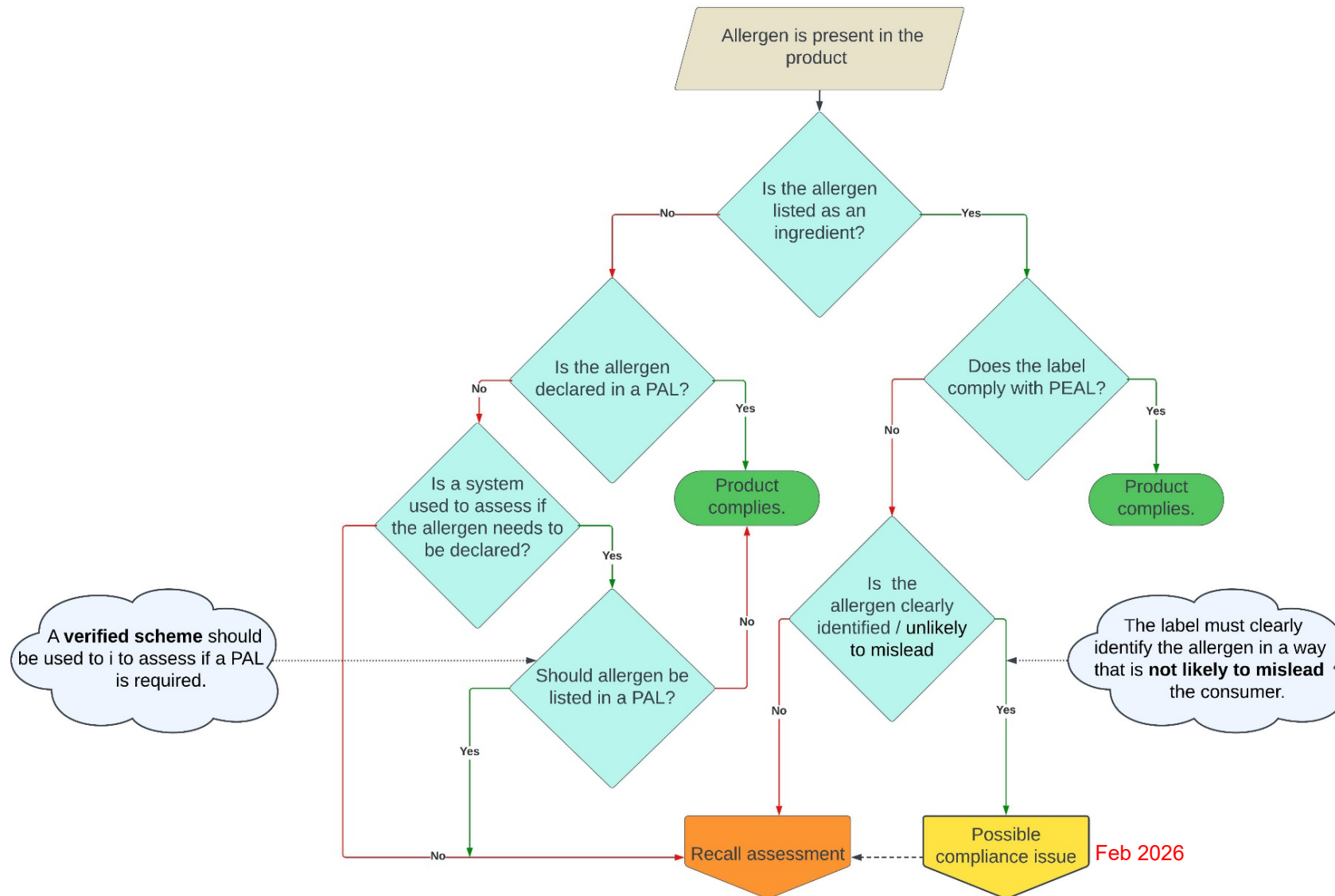
Risk assessment

- The level of unintended allergen present is greater than the ED01 and ED05 risk level
- There is a risk to consumers (WHO/FAO principles) if peanut is not declared in a PAL
- Peanut is declared in a PAL

Decision

- No compliance issue but consumers are ignoring the PAL statement

Draft Recall assessment model



Overriding question: Has the allergen risk been managed in accordance with the objectives of the Food Act and Food Standards Code

False description?

“A person must not sell food that they **ought reasonably know** is falsely described and **is likely to cause physical harm** to a consumer of the food who relies on the description.”

False description includes, where food is not of the nature or substance represented by the manner in which it is packaged, labelled or offered for sale. E.g. labelled allergen “free” when it contains the allergen.



Is a PAL required?

- There is no requirement to include a PAL statement on a label BUT
- A verified scheme designed to manage allergen hazards can be used to determine whether unintended allergens pose a risk to consumers
- E.g. For exposure dose levels see-VITAL 4.0 Summary and FAQs at www.allergenbureau.net/vital-4-0-update

Example

- A supplier receives an undeclared allergen complaint
- Product is not labelled with a PAL statement
- The level exceeds the ED05 and could pose a risk to an allergic consumer
- Once a supplier becomes aware of a risk to allergic consumers it may be committing an offence if it fails to act
- A recall assessment is required

Recall assessment

- The flowchart identifies when a recall is likely
- Question to be answered is whether, because the allergen[s] present in the food are not clearly declared on the product label, the food will or is likely to cause physical harm to an allergic consumer who relies on the label when deciding to consume the food
- In some cases, a compliant product may pose a risk, and a recall assessment is required, even though the product is correctly labelled

Consider

- How the product will, or is likely to, cause physical harm to an allergic consumer who relies on the label?
- How much product (product) is in the market
- The product shelf life
- The target consumer
- Where the product is sold
- Whether the product is exported interstate or overseas

