

FOOD INDUSTRY GUIDE TO ALLERGEN MANAGEMENT and LABELLING



2007 REVISED EDITION



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|--|----|
| 1. Introduction | 3 |
| 1.1 Statutory Requirements | 3 |
| 1.2 Cross contact allergens | 4 |
| 2. Food Allergies, Coeliac disease and Intolerances | 4 |
| 3. Allergen Management | 5 |
| 3.1 Training and supervision | 6 |
| 3.2 Raw materials | 6 |
| 3.3 Premises | 7 |
| 3.4 Storage and distribution | 7 |
| 3.5 Manufacturing process | 7 |
| 3.6 Rework | 7 |
| 3.7 Filling and packing | 8 |
| 3.8 Equipment and line design | 8 |
| 3.9 Cleaning | 8 |
| 3.10 Formulation and labelling controls | 8 |
| 4. Testing and Analysis of Allergens | 9 |
| 5. Labelling | 9 |
| 5.1 Foods that must be labelled | 9 |
| 5.2 Industry responsibilities | 10 |
| 5.3 Allergen labelling declaration | 10 |
| 5.4 General allergen labelling recommendations | 10 |
| 5.5 Recommended Labelling Format | 11 |
| 5.6 Recommended Labelling Alternatives | 12 |
| 6. Voluntary Incidental Trace Allergen Labelling (VITAL) | 14 |
| 6.1 VITAL | 14 |
| 6.2 VITAL Action Levels for labelling | 15 |
| VITAL Decision Tree | 15 |

Liability Statement

The guidance, procedures and risk management tools contained in this document are intended to provide industry best practice in the management and labelling of allergenic foods and ingredients regulated by the Australia New Zealand Food Standards Code.

The user needs to apply their own skills, knowledge and experience and identify any additional risks associated with the intended consumer group, in applying VITAL to their specific manufacturing environment. If necessary, the user should undertake appropriate training to implement this guidance.

VITAL may be updated over time as further scientific knowledge in relation to allergens and reactions becomes available. It is the responsibility of the user to keep informed of such developments, accessible on the Allergen Bureau website.

The user acknowledges that the Australian Food and Grocery Council, its employees, committee and working group members and agents, accept no liability (including as a result of negligence) for any loss, injury or death that may result from the consumption of a product labelled using VITAL.

1. Introduction

This guide has been prepared by the Australian Food and Grocery Council Allergen Forum and is supported by the New Zealand Food & Grocery Council and replaces the 2002 edition. The Guide is relevant to all sectors of the food industry involved in the supply, handling, production, distribution and sale of foods. It provides recommendations for the production and labelling of foods containing allergenic substances as defined in the Australia New Zealand Food Standards Code ("the Code").

This guide is supported by the Allergen Bureau and by additional resources and information available on the Allergen Bureau website. Please check the Allergen Bureau website for detailed information and the latest updates - (<http://www.allergenbureau.net/>).

This guide provides:

- » an overview of the requirements outlined in the Code regarding food allergens that require labelling
- » an overview of the incidence and symptoms of food allergy and food intolerances and the substances in food that may provoke allergic reactions
- » guidance on the control and management of allergens in the manufacture of foods
- » information on testing for allergens
- » guidelines for declaring mandatory and voluntary allergen information for foods
- » an outline of VITAL (Voluntary Incidental Trace Allergen Labelling).

1.1 Statutory Requirements

Food Standards Australia New Zealand (FSANZ) provides a consolidated version of the Code on their website - (<http://www.foodstandards.gov.au/thecode/foodstandardscode.cfm>).

Standard 1.2.3 of the Code specifies requirements for the mandatory declaration of certain substances and their products. For most packaged foods, the information must appear on the label. In other cases, the information must be shown with the food display or provided to consumers on request.

The substances which must be declared are:

- » cereals containing gluten and their products, namely, wheat, rye, barley, oats, spelt and their hybridised strains other than where these substances are present in beer and spirits standardised in Standards 2.7.2 and 2.7.5 respectively
- » crustacea and their products
- » egg and egg products
- » fish and fish products
- » milk and milk products
- » peanuts and soybeans and their products
- » added sulphites in concentrations of 10 mg/kg or more
- » tree nuts and sesame seeds and their products.

This declaration applies when the listed products are present as:

- » an ingredient; or
- » an ingredient of a compound ingredient; or
- » a food additive or a component of a food additive; or
- » a processing aid or a component of a processing aid.

Schedule 4 to Standard 1.4.2 of the Code specifies that “Tree Nuts” are a food group and lists 16 different species of nuts. FSANZ also provides a user guide on *Warning and Advisory Declarations*, which specifically exempts coconut from the term ‘Tree Nuts’ as they are not considered to be allergenic.

The Code defines “Fish” in Standard 2.2.3 as any of the cold-blooded aquatic vertebrates and aquatic invertebrates such as shellfish or jellyfish, but does not include amphibians and reptiles. As the Table to Clause 4 of Standard 1.2.3 specifically lists Crustacea and their products (i.e. prawns, crabs, crayfish) these need to be specifically labelled for the purpose of the allergen statement, whereas aquatic invertebrates are adequately covered in the summary statement as “Fish”.

Standard 1.2.3 of the Code contains provisions for “mandatory declarations”, “mandatory advisory statements” and “mandatory prescribed statements”, including warning statements. The Code also specifies requirements for legibility under Standard 1.2.9, which sets out how the information should be presented.

1.2 Cross contact allergens

Cross contact allergens occur when a residue or other trace amount of an allergenic substance is unintentionally added into a food not intended to contain that allergenic substance and where such occurrences are sporadic. The guide provides recommendations on precautionary labelling where allergens may be present by cross contact and when indicated by VITAL (Section 5 and Section 6).

2. Food Allergies, Coeliac disease and Intolerances

While food allergies affect a small proportion of the population, an allergic reaction can be life-threatening or fatal. It is generally estimated that 1-2 per cent of the Australian population suffers from a true food allergy. In children this rate rises to between 5 and 8 per cent. Allergies to milk and eggs are often outgrown by 5-7 years of age, while allergies to peanut tend to be life-long and allergies to seafood may not occur until late teens and early adulthood. The Code requires labelling declarations for the eight allergic foods estimated to produce 90% of allergic reactions to foods. However, it is recognised that there are many other foods that may cause an allergic reaction and which are not regulated by the Code for mandatory labelling declarations.

Most food allergens are proteins, and an individual must first be sensitised by exposure to the protein to develop antibodies, which then react to further exposures. Allergenic proteins are usually not denatured under food processing conditions and are relatively resistant to digestion. Allergic reactions to foods are characterised by the rapid release of powerful cellular chemicals such as histamine by the antibodies, which can occur within minutes or up to four hours after ingestion. Food allergies are usually mediated by immunoglobulin E (IgE) antibodies and can be confirmed by a skin-prick test or blood test.

Food allergy symptoms vary in nature and severity between individuals and may include:

- » respiratory problems (rhinitis, asthma, throat swelling)
- » gastrointestinal problems (nausea, vomiting, diarrhoea, abdominal cramping) or
- » skin problems (hives, itching, dermatitis, eczema).

A severe reaction (anaphylaxis) can occur after contact/ingestion with allergens in foods. This can result in a rapid loss of blood pressure, severe obstruction of the airways, a generalised shock reaction and multiple organ failure. This can be fatal if not treated within minutes. While few people with food allergies are at risk of such serious consequences, some deaths have occurred following accidental ingestion of a food containing an allergen to which the individual is sensitive.

Coeliac disease is an autoimmune reaction to dietary gluten. Although Coeliac disease does not result in anaphylaxis, it causes damage to the intestine reducing the ability to absorb nutrients. Symptoms may appear at any time from early childhood to senior years. Treatment requires a strict, life-long gluten-free diet to allow the intestine to recover and to avoid complications.

In contrast to food allergies, food intolerances are generally more common. Reactions are more obviously dose-related, and include non-protein substances in foods. An intolerance reaction to a food may have delayed symptoms, with no observable effect for several hours after eating the food. There are no proven laboratory tests for food intolerances and diagnosis is through the use of an elimination diet. Symptoms can range from mild to severe and may include:

- » hives, eczema, other itchy skin rashes
- » stuffy or runny nose, asthma, frequent colds or ear infections
- » mouth ulcers, reflux, bloating, stomach aches, constipation and / or diarrhoea, incontinence
- » migraines or headaches
- » lack of concentration, anxiety, depression, lethargy, irritability, sleeping difficulties.

3. Allergen Management

Many foods contain ingredients which are known allergens (listed under Section 1.1) and must be labelled according to regulatory requirements in the Code. Food allergens can become part of a food through unintended exposure. This may result from:

- » inadvertent presence in raw materials
- » processing aids (e.g. enzymes)
- » incorrect formulation
- » changes to product scheduling
- » rework
- » insufficient or ineffective cleaning/sanitation procedures
- » in-process cross contact
- » post-process contact.

The recommended approach to allergen risk management is through a Hazard Analysis and Critical Control Point (HACCP) program. This involves evaluating the hazards associated with the whole 'lifecycle' of the product, starting with the production of raw materials and assessing every step of the process through to labelling and packaging of the final product for consumption. The critical points where allergens can be introduced into products during manufacture should be identified, and a system established to monitor these critical control points, to ensure that unintentional cross contact is minimised. The following sets out important areas for consideration, but this is not an exhaustive list and other issues may need consideration depending on the situation.

3.1 Training and supervision

Employee awareness and training is critical to avoid the unintentional or undeclared presence of allergens in products. Training of all staff working within a production facility is essential to control potential sources of food allergen risk. Training should provide an awareness of food allergens and the consequences of unintentional consumption by allergic consumers. Staff should receive training on best practice in allergen management specific to their site, the products they handle and their responsibilities.

Some key areas food companies need to consider when providing training in allergen risk management include:

- » receipt and storage of raw materials
- » avoiding cross contact of non-allergenic ingredients with allergenic materials, or between different allergenic ingredients
- » production scheduling
- » equipment and premises design
- » good manufacturing practices, for example: cleaning procedures, control of rework
- » post-manufacturing controls
- » new product development.

Food companies should have an Allergen Management Policy, and all staff need to be aware of their responsibilities with regard to upholding the policy. Staff should be encouraged to report any suspected breaches to the relevant area supervisor, and to suggest possible improvements. All procedures undertaken for allergen management should be documented and signed by a qualified supervisor. Trained internal compliance auditors should regularly assess these records as part of the company's food safety program.

3.2 Raw materials

Raw materials may contain allergens that are inadvertently present. This may occur at the supplier's site prior to the ingredient reaching your plant or it may occur as a result of cross contact within your manufacturing plant. Suppliers should have good allergen management practices to minimise the risk of cross contact between raw materials.

Allergen information should be provided by the suppliers of each raw material to identify any products that contain allergens, or that are derived from allergenic foods, or have a high likelihood of cross contact with allergenic substances. While some ingredients are easily identified as containing, or derived from, allergens, others are more difficult. It is essential that information is provided by the supplier that verifies whether or not allergens are present. Any change to supplier or suppliers' source should trigger a review of allergen status.

Alternative ingredients should be treated like standard ingredients, with all information necessary provided so the manufacturer can avoid unintentional introduction of allergenic raw materials, or can take into account the need for allergen declarations for alternative ingredients when developing labels.

The AFGC Food Industry Product Information Form (PIF) is available from the Allergen Bureau website to help food companies obtain allergen information from their suppliers in a consistent manner. This form requests information on the food allergens present in the raw material and the potential for cross contact of the material.

Manufacturers should review the information collected on the PIF and consider the potential for inadvertent presence of allergens in materials (see Section 6). Vendor audits can further explore the potential for allergen cross contact.

3.3 Premises

The manufacturing plant, where possible, should be designed to assist in allergen management. Manufacturers producing at more than one site might consider consolidation of products containing like allergens to one location, or create sites free from specific allergens.

Separate production equipment and tools should be used to establish a clear distinction between products containing different allergens and those that do not contain allergens.

3.4 Storage and distribution

Manufacturers should identify all allergenic materials upon receipt at a plant. These should be segregated from non-allergenic materials, and ingredients with different allergens should be segregated from each other. Ingredients should be stored to avoid the potential for spillage onto other ingredients, such as placing allergenic ingredients on shelves below other ingredients.

Materials should be clearly labelled to identify the name of the ingredient, the presence of allergens and specify the type of allergens present. Care must be taken in the storage of finished products to avoid cross contact with raw materials.

3.5 Manufacturing process

To minimise the potential for unintentional allergen cross contact of product, allergen management practices should be part of good manufacturing practices (GMP) and HACCP-based food safety systems, and should be taken into account when these systems are audited.

When ingredients are selected for use in product manufacturing, the ingredients and their product information should be checked against the design criteria to ensure they are suitable for the product to be manufactured. Where possible, a production system should be designed to minimise the potential for cross contact. Monitoring systems should be in place to ensure that cross contact does not occur.

Manufacturers should use dedicated manufacturing tools or equipment for specific allergen-containing products to minimise any chance of cross contact. Production schedules should be organised to process allergen free products at the beginning of the schedule, with allergen containing products run at the end of the production schedule and followed immediately by the cleaning cycle (see Section 3.9). Appropriate scheduling and longer runs can also minimise the potential for allergen cross contact. Clearly defined allergen clean up procedures should be in place on the manufacturing line and in the event of raw material spills.

3.6 Rework

Rework policies and procedures are required to minimise the risk of allergen cross contact. Rework that contains allergenic ingredients should not be included in material that would otherwise be free of that allergen. Rework should be clearly labelled so it can be identified. A procedure for tracking rework through to a finished product is an important element of an allergen risk management program.

3.7 Filling and packing

Controls established for allergen risk minimisation should ensure correct packaging/labels are used for the appropriate product. Care must be taken when variant labels in the same range are used as they may be very similar in colour and graphics. Similarly where blank inners are stored as work in progress for extended periods, special care must be taken to ensure appropriate labelling is applied and different inners are not mixed.

Technological options available to assist in tracking and identifying materials include using internal bar coding, radio frequency identification, or imaging for verification. Appropriate controls such as a simple checklist or match procedure, which are signed off by the responsible production operative, should be in place.

3.8 Equipment and line design

Ease of cleaning should be a consideration when purchasing new equipment and installing or re-laying production lines. Avoiding line crossovers, allowing adequate space for effective cleaning and eliminating “dead legs” and “hang-ups” are important ways to minimise the risk of allergen cross contact. Dust minimisation and/or physical barriers between lines will also reduce the risk of cross contact.

3.9 Cleaning

Documented and validated cleaning procedures are critical for avoiding unintentional allergen cross contact. Adequate time must be allowed for cleaning and verification. Re-cleaning may be required if verification shows initial cleaning has not been adequate. Cleaning short-cuts could lead to product build-up in the manufacturing equipment.

To ensure successful cleaning it is necessary to consider:

- » documented cleaning procedures
- » training of cleaning personnel and operators
- » knowledge of the system to identify hidden or static areas
- » knowledge of the allergen status of the products
- » effective cleaning equipment and supplies
- » dismantling equipment to remove allergen residues
- » cleaning verification e.g. visual inspection, sampling or testing for allergen residues
- » minimise use of air guns and water hoses to avoid distributing allergens within the plant.

3.10 Formulation and labelling controls

Regular internal audits of production systems should be conducted to verify that the product formulation matches the records of ingredient use and that the composition of the final product is accurately reflected in the ingredients specified on the label. Internal audits should also verify the VITAL assessment, even when the precautionary statement is not on a label.

If there is a formulation change, or change to raw material supplier that results in the introduction of new allergenic materials, then existing labels must not be run out.

4. Testing and Analysis of Allergens

Testing for food allergens is a valuable tool when used as part of a risk-based approach to allergen management. Test results can provide assurance and verification of critical controls within a comprehensive risk management program.

The most commonly used analytical method for detecting the presence of food allergens is the Enzyme Linked Immuno Sorbent Assay (ELISA) technique. The sensitivity of ELISA kits currently available is in the low parts per millions (ppm) reporting range.

While there are many benefits to using the ELISA method, there are some limitations to using and interpreting results which must be considered. These may include:

- » protein extraction for analysis
- » effect of food processing
- » protein structure
- » cross reactions
- » availability of kits for different allergens.

It is also important to remember the limitations associated with sampling. As with all food testing methods, results are only representative of the samples tested and cannot be used to categorically prove the absence of allergens in products that have not been tested. This is especially so for particulates.

A number of allergen ELISA test kits are currently available and international research is being conducted to develop alternative or confirmatory methods for the routine detection of allergens in foods. Rapid ELISA test strips for allergen detection are also becoming more widely available and in some instances these may be suitable for allergen screening in-house during production, although these are not as sensitive as current ELISA test kits.

Further information on test methods and interpreting test results when using VITAL is available from the Allergen Bureau website.

5. Labelling

5.1 Foods that must be labelled

Allergen labelling is required on all foods subject to the general labelling requirements of the Code under Chapter 1. The Code is available on the FSANZ website and is subject to change over time. Manufacturers should regularly check the Code for the latest allergen labelling requirements, especially when developing or reprinting labels.

Standard 1.2.1 of the Code provides exemptions to labelling in particular circumstances, taking into account the consumer's access to information from the person who makes the food and their ability to specify ingredients, as well as limitations imposed by the size of packaging. Exemptions are also provided where there are lower expectations for labelling, such as fund raising events.

Where the food is for retail or catering purposes and is exempt from labelling, the required allergen information must either be displayed on, or in connection with the display of the food, or provided to the purchaser upon request.

Standard 1.2.4 of the Code permits the declaration of alternative ingredients. Manufacturers may occasionally substitute one ingredient for another within the same class of foods. The statement of ingredients may list both ingredients in a way which makes it clear that alternative or substitute ingredients are being declared. Where this involves a substance listed in the Table to clause 4 of the Code there must be a declaration on the label that the allergenic substance is present in the food. Labelling should clearly indicate that the product contains one substance or another (e.g. brazil nuts or cashew nuts).

5.2 Industry responsibilities

Manufacturers need to be aware of the nature of the ingredients they use in their products, and whether there are components in compound ingredients, additives and processing aids that may be derived from an allergen. For example, additives, processing aids and vitamins are often mixed with carriers or diluents derived from substances required to be declared. Suppliers of ingredients, additives and processing aids have a responsibility to provide their customers with information on allergens contained in their products.

The current requirement to label applies to any product derived from these allergens irrespective of how highly refined or processed it may be. An example of a material that can be highly processed is wheat, where labelling would apply equally to wheat flour, wheat starch, wheat maltodextrins, glucose and caramel derived from wheat, or grain alcohol.

Manufacturers should assess the need for in-store demonstrators to provide consumer advice about the presence of allergenic ingredients, as consumers often do not have the opportunity to read the label before tasting the product. Consideration should be given to ensuring information is also provided at external outlets in the convenience and trade routes.

5.3 Allergen labelling declaration

The Code states that the substances listed in Section 1.1 of this guide must be declared on the label, but does not specify the format. This guide provides recommended allergen labelling formats for industry to adopt, as detailed below. Alternative labelling options are provided in recognition of constraints due to label size, legibility and other variables, while still promoting overall consistency and clarity of allergen information. In adopting one of these labelling formats industry will assist consumers by providing greater consistency in the presentation, legibility and ease of identifying product allergen information.

5.4 General allergen labelling recommendations

The general labelling recommendations are:

- » all allergen information should be grouped together to be easily identified and not hidden amongst other labelling information
- » product description and representation should provide an accurate expectation of the product and should not be misleading
- » allergens must be declared using plain English terms consistent with the Code
- » legibility requirements are specified in Standard 1.2.9 of the Code. The print size should be big enough to be easily read, preferably at a minimum 1.5mm with sans serif font, and the font colour should contrast distinctly from the background. The use of lower or upper case will depend on the overall presentation of labelling information.

5.5 Recommended Labelling Format

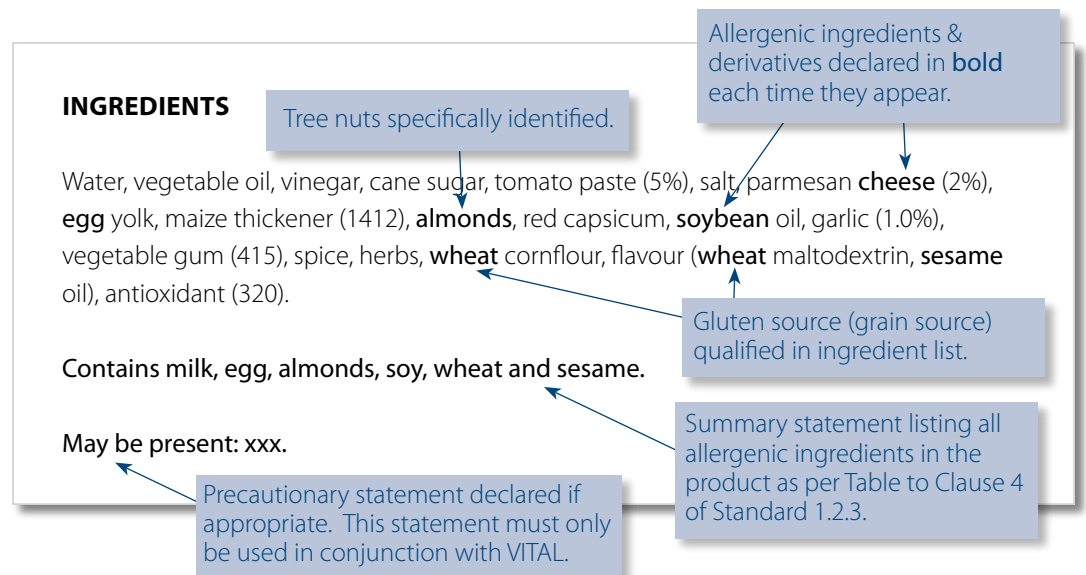
A consistent approach in the presentation of allergen information will help allergic consumers more quickly and easily identify foods of concern, helping to minimise accidental consumption of unsuitable foods. It is desirable that manufacturers adopt the recommended labelling formats.

The recommended format consists of:

- » an ingredient list declaring in bold allergenic substances and their derivatives; and
- » an allergen summary statement; and
- » a precautionary statement.

Allergenic substances are identified in the ingredient list so the information can be easily understood by the consumer. It is also recommended that a standardised summary statement accompany the ingredient list, and if appropriate, a standardised precautionary statement. This precautionary statement must only be used in conjunction with VITAL (Section 6).

RECOMMENDED LABELLING FORMAT EXAMPLE.



Ingredient List

- » All allergens are identified in the ingredient list each time an ingredient containing an allergen is listed.
- » Allergens are declared in bold type each time they appear in the ingredient list.
- » Gluten source (grain source) is qualified in the ingredient list at all times.
- » Declare in bolding the allergenic ingredient/component or qualify in bold the ingredient/component according to the allergenic foods listed in the Table to clause 4 of Standard 1.2.3 in the Code. e.g. Parmesan **cheese** or Parmesan cheese (**milk**).
- » Declare the specific name of the tree nut/s in the ingredient list when added as a direct ingredient, rather than the generic term nuts or tree nuts.
- » Processing aids derived from an allergenic source must declare the allergen in the ingredient list.

Allergen Summary Statement:

- » Declares allergenic foods according to the terms listed in the Table to clause 4 of Standard 1.2.3, in the Code.
- » Declared as '**Contains xxx...**' and appears directly below the ingredient list on a separate line in bold.
- » Uses the same font size as the ingredient list information, or at a minimum print size of 1.5mm.
- » Required for single ingredient foods where the product name does not include the name of the allergen.
- » If there is more than one gluten derived ingredient in the product then the summary statement can be declared by naming each of the source grains or by using the general term 'gluten containing cereals'. If only one gluten derived ingredient is declared in the ingredient list then the summary statement must include the specific name of the source grain.
- » If the product contains tree nuts either the specific name of the tree nut can be declared or the general term 'tree nuts' can be used in the summary statement. The term 'nuts' should not be used at anytime.
- » Processing aids derived from an allergenic source must declare the allergen in the summary statement.

Precautionary Statement

Voluntary statements such as 'may contain xxx', or 'made in a facility that also makes products on the same production line containing xxx' are confusing for allergic consumers and fail to help them understand the risks presented by such products.

To ensure a consistent and clear message is provided to the allergic consumer a simple single precautionary statement should be used, if required, following an assessment using VITAL.

- » The precautionary statement is used in conjunction with VITAL and ONLY when the cross contact allergen is at action level 2 on the VITAL action level grid.
- » The precautionary statement is declared as '**May be present: xxx**', where '**xxx**' lists each of the cross contact allergens present at VITAL Action Level 2.
- » This statement is placed below the summary statement on a separate line in bold.
- » The allergen cross contact statement text must be declared using the same font size as the ingredient list information or at a minimum print size of 1.5mm.

5.6 Recommended Labelling Alternatives

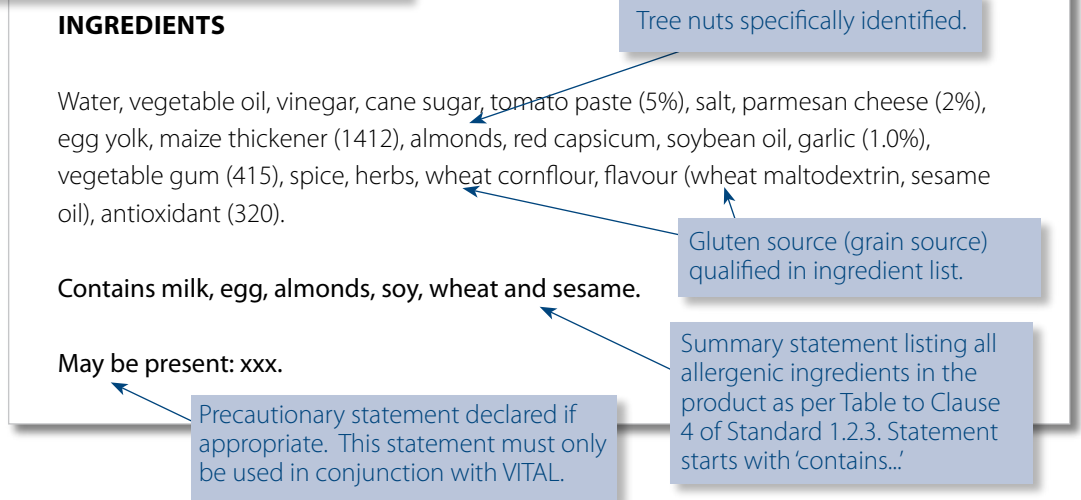
Alternative allergen labelling approaches provide flexibility where label size constraints and other variables do not permit the use of the recommended labelling format, while ensuring the goal of providing accurate consumer information.

Recommended labelling alternatives:

- » bolding and qualifying allergenic substances in the ingredient list is optional when an allergen summary statement is present
- » when an allergen summary statement is not present, allergenic substances are bolded and qualified within the ingredient list.

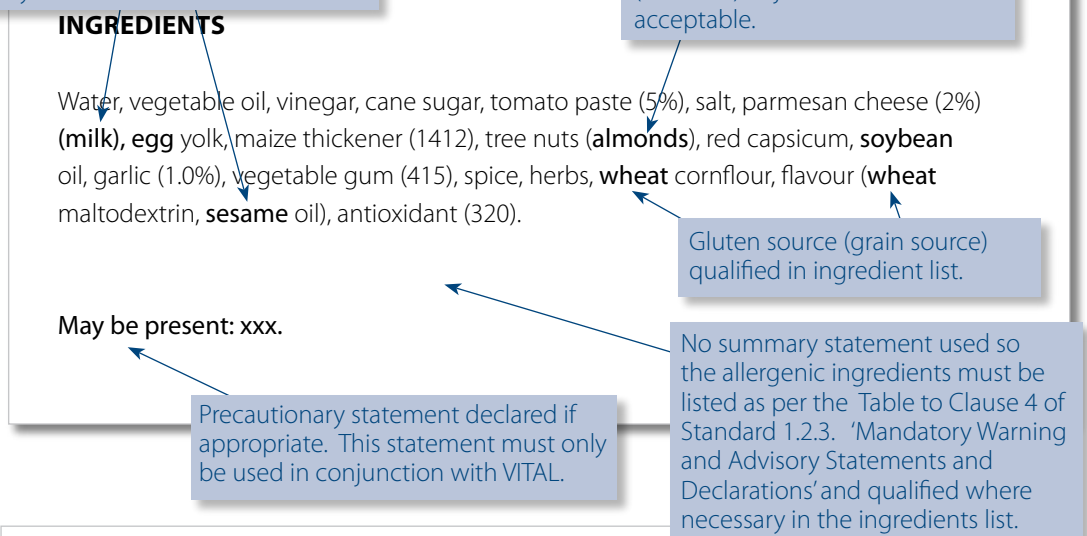
ALTERNATIVE LABELLING FORMAT EXAMPLE 1.

Allergenic ingredients & derivatives declared each time they appear but NOT in bold due to use of summary statement.



ALTERNATIVE LABELLING FORMAT EXAMPLE 2.

Allergenic ingredients & derivatives declared as per Table to Clause 4 of Standard 1.2.3 'Mandatory Warning and Advisory Statements and Declarations.'



Ingredient List Alternatives

- » When an allergen summary statement is used in conjunction with the ingredient list:
 - bolding of the allergens in the ingredient list is optional
 - except in the case of gluten, allergenic ingredients/components do not have to be qualified within the ingredient list as the summary statement would refer to the allergenic terms listed in the Table to clause 4 of Standard 1.2.3.
- » When there is no allergen summary statement following the ingredient list:
 - allergens should be identified in bold in the ingredient list; and
 - where the name of the ingredient is not in the form listed in the Table to clause 4 of Standard 1.2.3 in the Code, the allergenic ingredient/component must be qualified e.g. vegetable oil **(soy)** or **Soybean** oil.

Ingredient List Alternatives Continued

- » A processing aid derived from an allergenic source may be declared according the Table to clause 4 of Standard 1.2.3 in the ingredient list using the following generic statement 'processing aids contain xxx'. The statement should appear on a separate line at the end of the ingredient list.
- » The use of ingredient substitution where one ingredient is allergenic and the other is not e.g. wheat or corn starch, should be avoided where possible. Where unavoidable, the declaration of substitute ingredients should highlight allergenic ingredients such as "sunflower oil or **peanut** oil", or "**wheat** starch or corn starch", or "hydrolysed vegetable protein (corn or **soy**).

Summary Statement Alternatives

- » The summary statement can be declared as 'Ingredients contain...'
- » A summary statement can be omitted as long as the allergenic ingredients are listed and qualified using the terms listed in the Table to clause 4 of Standard 1.2.3 'Mandatory Warning and Advisory Statements and Declarations' in the Code and declared in bold.

Precautionary Statement Alternatives

- » No alternative statements have been suggested as VITAL should be used wherever possible to assess the allergen cross contact risk and to determine if cross contact labelling is required.
- » VITAL can be used for both particulate and readily dispersible substances.

6. Voluntary Incidental Trace Allergen Labelling (VITAL)

Voluntary Incidental Trace Allergen Labelling (VITAL) has been developed to provide a risk based methodology for food producers to use in assessing the impact of allergen cross contact and identify appropriate allergen precautionary labelling.

VITAL uses a three level grid to assist in determining appropriate advisory labelling for residual protein from allergenic substances (refer to Section 1.1) due to unavoidable cross contact. VITAL should be used as part of a HACCP based food safety program and included in auditing assessments for compliance with the HACCP plan.

The following section provides an overview of VITAL. The detailed procedure, including the VITAL action level grid, is available on the Allergen Bureau website. Any business implementing VITAL must refer to the VITAL procedure.

The process should be followed for each allergen that may be present in the final product due to cross contact via ingredients or processing. VITAL is not applicable to ingredients which contain allergenic substances and have been intentionally formulated into the product.

6.1 VITAL

VITAL requires the assessment of likely sources of cross contact allergenic substances from raw materials and the processing environment, an evaluation of the amount present, a review of the ability to reduce the allergenic material from all contributing sources and ongoing monitoring and verification. Particulate and readily dispersible materials are treated differently.

The Decision Tree is a schematic representation of the VITAL. The numbering in the Decision Tree relates directly to the detailed VITAL procedure available from the Allergen Bureau website.

6.2 VITAL Action Levels for labelling

The VITAL action level grid identifies three action levels and is provided on the Allergen Bureau website with more detailed advice on its use. In summary the action levels indicated are:

- » Action Level 1 – Green Zone - precautionary labelling not required
- » Action Level 2 – Yellow Zone - precautionary labelling is required for each relevant allergen using the standard VITAL statement
- » Action Level 3 – Red Zone – significant levels of the allergen are likely to be sporadically present. Labelling of the allergen as an ingredient is required.

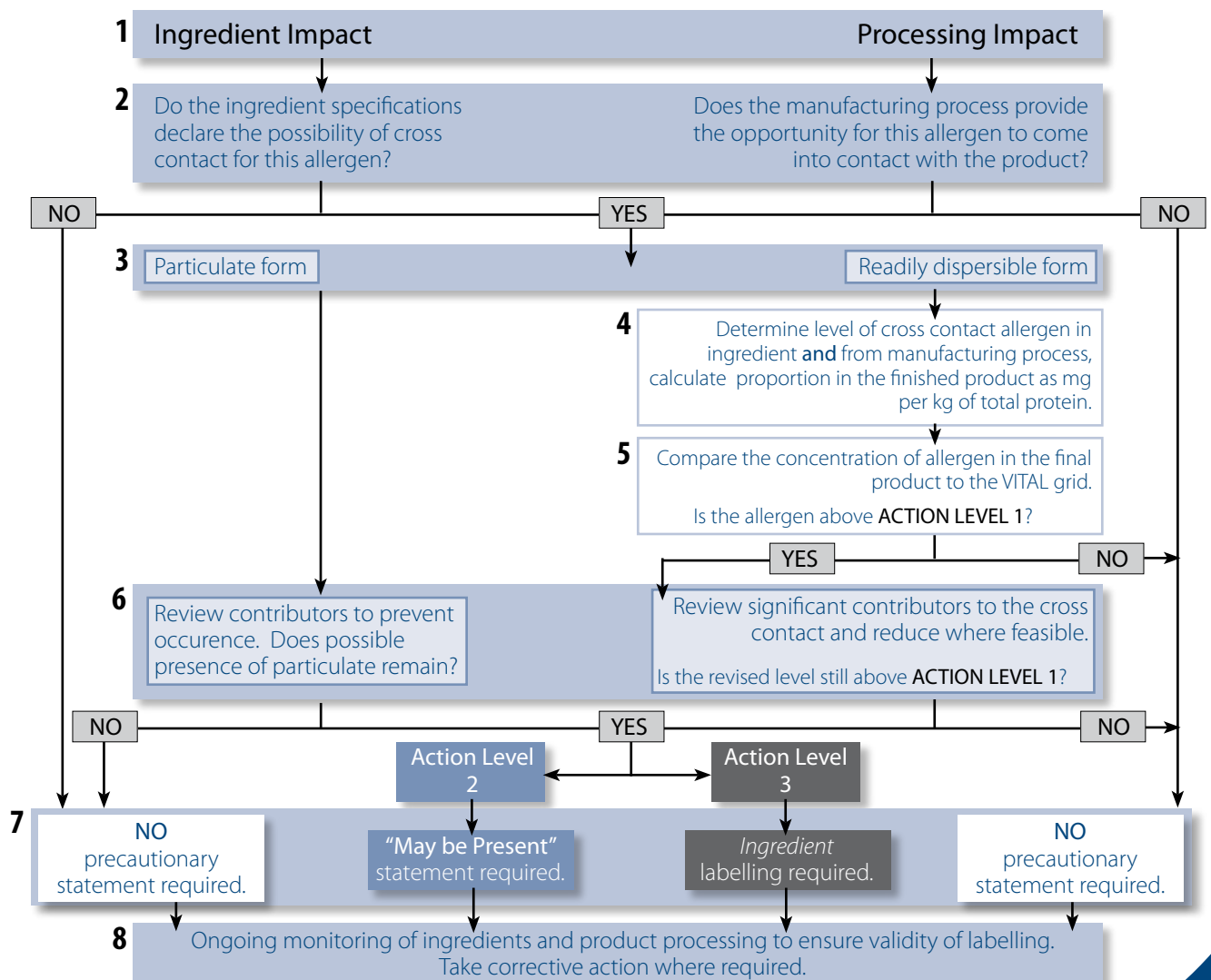
[Reference: "Development of VITAL Allergen Action Levels Grid – Explanatory Notes", Allergen Bureau website.]

The VITAL cross contact statement should only be used where cross contact is:

- » documented using VITAL; and
- » unavoidable; and
- » sporadic.

Precautionary labelling should ONLY be used after a thorough risk assessment. Precautionary statements must NEVER be used as a substitute for good manufacturing practice (GMP) or as a generic disclaimer. Every attempt must be made to eliminate or minimise cross contact by adhering to GMP.

VITAL Decision Tree





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