

Food Industry Guide to
**Allergen Management
and Labelling**





1. Introduction

This Guide has been prepared by the Australian Food and Grocery Council and is supported by the New Zealand Grocery Marketers Association.

This Guide is designed to:

- provide guidance on the control of allergens in the manufacture of food products and the manner in which the presence of allergens, either intentional or through unavoidable cross-transfer from other products, should be communicated to consumers
- advise on the requirements of the joint Australia New Zealand Food Standards Code (the Food Standards Code) on the identification of substances in food that may provoke allergies or other adverse reactions in some people
- assist food companies in providing uniform and understandable labelling information to consumers who may need to be alerted to the presence of certain foods and components

1.1 Scope

The Guide is relevant to all people involved in the handling, production, distribution and sale of foods.

The Guide is intended as supplementary recommendations for the production and labelling of foods with allergenic potential to assist in meeting the requirements of the Food Standards Code. It also provides recommendations on advisory labelling where cross-transfer of allergens is possible.

1.2 Statutory requirements

The Food Standards Code contains a requirement in Standard 1.2.3 for the mandatory declaration in all cases of certain substances and products derived from them. For packaged foods, the information must appear in the label. In other cases, the information must be shown with the food display or provided to consumers on request.

The substances that must be declared are:

- cereals containing gluten and their products, namely, wheat, rye, barley, oats 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
- nuts and sesame seeds and their products
- peanuts and soybeans and their products
- added sulphites in concentrations of 10 mg/kg or more
- royal jelly presented as a food or royal jelly present in a food*
- bee pollen*
- propolis*

**Note: These substances are not normally used as ingredients or components of processed food.*

Food Standards Australia New Zealand (FSANZ), formerly the Australia New Zealand Food Authority, has issued a User Guide to assist in the interpretation of, and compliance with, this Standard. The Guide is available from www.foodstandards.gov.au

Some substances in the above list are not strictly allergens (eg sulphites), but can cause adverse reactions in some people. Similarly, while gluten sensitivity, such as coeliac disease, is mediated in a different manner to most allergies, it also can produce adverse reactions in intolerant individuals. This Guide relates to the management and labelling of these substances. The mandatory identification of these substances is referred to as a "mandatory declaration", as distinct from "mandatory advisory statements" and "mandatory prescribed statements", including warning statements, which are specified in other parts of the Food Standards Code. (Refer to the FSANZ User Guide for an explanation of the differences between these terms).

2. Food Allergy

Food allergies affect a small proportion of the population. However, in some cases, an allergic reaction can be life-threatening or fatal. It is generally estimated that only 1-2 per cent of the Australian population suffers from true food allergy. However, in children this rate rises to between 5 and 8 per cent. Many children have outgrown allergies, such as those to milk and eggs, by the time they have reached 5-7 years of age.

Food allergies need to be distinguished from food intolerances. The latter are generally caused by chemical agents, such as sulphites or certain genetic deficiencies, such as lactose intolerance. True food allergies are an unusual immunological response to the ingestion of the offending food, usually mediated by immunoglobulin E (IgE). Virtually all known 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 resistant to digestion in the intestinal tract. Allergies are characterised by the rapid release of powerful cellular chemicals such as histamine by the antibodies, which cause the symptoms of the allergic reaction within minutes or up to an hour after ingestion.

Symptoms of coeliac disease or related conditions may not appear until about eight hours or more after ingestion.

Symptoms can range from mild to severe, with most individuals suffering from just a few of the many possible symptoms. These can range from:

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

In some cases, a more severe systemic reaction can occur which results in a rapid loss of blood pressure, severe obstruction of the airways, a generalised shock reaction and multiple organ failure. This is known as anaphylactic shock and can be fatal if not treated within minutes. Although only a few people with food allergies are at risk of such serious consequences, there are many documented cases of death resulting from accidental ingestion of an offending food.

It is estimated that about 90 per cent of all food allergies are attributable to eight foods: cows' milk, eggs, fish, crustaceans, peanuts, soybeans, tree nuts* and wheat. However, more than 160 additional foods have been documented as having caused allergies. The frequency and potential severity of reactions to these eight major allergens is one reason why the Food Standards Code requires the food industry to pay particular attention to control and labelling.

* *Note: Tree nuts is a group consisting of almonds, Brazil nuts, cashews, chestnuts, hazelnuts, hickory nuts, macadamia nuts, pecans, pine nuts, pistachios and walnuts. From an allergenic perspective, coconuts and more unusual nuts such as shea nuts or kola nuts are not classed as tree nuts and are rarely allergenic.*

3. Allergen Management

Many foods contain ingredients which are known allergens, however food allergens can become part of a food through unintended exposure. This may result from:

- contamination of raw materials
- accidental misformulation
- changes to product scheduling
- rework
- insufficient or ineffective cleaning/sanitation procedures
- in-process cross contamination
- post-process contamination

Industry awareness is essential to control potential sources of food allergen risk.

Some of the key areas that food companies need to consider to control allergen risk include:

- employee training and supervision
- raw material sourcing and storage
- production scheduling
- equipment and premises design
- manufacturing, eg cleaning procedures, control of rework
- labelling
- post-manufacturing controls

The recommended approach to control the possibility of allergen contamination is through a HACCP (Hazard Analysis and Critical Control Point) program. This involves evaluating the hazards associated with every step of a process from obtaining raw materials through to final product consumption. The critical points during manufacture where allergens can be introduced into products should be identified and a system established to monitor these critical control points to ensure unintentional contamination is being controlled.

3.1 Training and supervision

Employee awareness and training are vital in avoiding contamination of products by allergens. Manufacturers should ensure detailed procedures on control and prevention of allergen contamination are readily available or visible in the manufacturing area, and that employees are made aware of them. The procedures should include information about general practices such as:

- hand contact and the need for hand washing
- clothing requirements
- cleaning procedures
- rework
- waste control
- potential cross contamination situations

To ensure the effectiveness of the implemented procedures, a clear understanding of the definition of an allergen and the consequences of unintentional consumption by allergic consumers is necessary. Employees should be encouraged to report any suspected cross contamination.

Internal compliance to allergen risk control policies and procedures should be assessed regularly by trained auditors.

3.2 Raw materials

Products can become contaminated with allergens through raw materials. When sourcing raw materials, manufacturers should consider the potential for contamination of them prior to their reaching the plant. Suppliers should also address allergen control practices, and vendor audits can be carried out to identify contamination risk. Allergen information should be requested from suppliers to identify any products that may be allergenic or derived from allergenic foods. Some ingredients are very easily identified as potentially allergenic, however some ingredients are not as obvious, so further information may have to be requested from the supplier.

Allergenic raw materials should be identified on intake into the plant and segregated, if possible. They should be clearly identified to avoid accidental contamination of other raw materials.

Manufacturers should identify alternative ingredients suitable as second choices for substitution of an ingredient that may be difficult to consistently source. Alternative ingredients should be treated like standard ingredients, and all the necessary specifications and documentation should be obtained, so the manufacturer can ensure no unintentional introduction of an allergenic raw material occurs.

3.3 Premises

The manufacturing plant, where possible, should be designed to assist in allergen control. Manufacturers producing at more than one site might consider production segregation.

Where this is not possible, separate production equipment and tools should be used to establish a clear distinction between allergen-containing products and allergen-free products.

3.4 Manufacturing process

To minimise the potential for unintentional allergen contamination of allergen-free products, good manufacturing practices and a HACCP-based food safety system should be employed. A HACCP-based system will assist manufacturers by highlighting the areas for potential contamination concern.

If possible, the production system design should minimise the amount of equipment exposed to an allergen. Manufacturers should identify areas, equipment and processes where allergenic ingredients may contaminate allergen-free foods. Monitoring systems should be in place to ensure that contamination is not occurring. It is often necessary to designate specific manufacturing tools or equipment for allergen-containing products to avoid any chance of contamination. Where shared production equipment between allergen-free products and allergen-containing products is unavoidable, allergen-containing products should be run at the end of the shift, immediately before cleaning. Cleaning following the processing of an allergen-containing product is essential. Equipment may need to be disassembled and manually cleaned to ensure hard to clean areas are free of allergen residue. Appropriate scheduling and longer runs can also minimise the potential for allergen contamination and changeovers from one product to another.

3.4.1 Rework

Rework policies and procedures are required to minimise the risk of cross-contamination. Rework that contains allergenic ingredients should only be reworked into the same or similar products. Rework should be correctly labelled so it can be clearly identified. A procedure for tracking rework all the way through to a finished product is an important element of an allergen control system.

3.4.2 Labelling

Controls established for allergen risk minimisation should ensure correct packaging/labels are used for the appropriate product. Variant labels in the same range are often very similar in colour and graphics. Useful controls such as a simple checklist that is signed off by the production operative should be in place.

3.4.3 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 and allowing adequate space for effective cleaning are important ways to minimise the risk of contamination.

3.5 Cleaning

Documented cleaning procedures are essential for avoiding unintentional allergen contamination. Adequate time must be allowed for cleaning. Cleaning short-cuts could lead to potential product build-up in the manufacturing equipment. There are static or hidden areas in many manufacturing lines that need to be identified. Dismantling may be necessary to remove allergen residues.

To ensure successful cleaning it may be necessary to consider:

- documented cleaning procedures
- trained cleaning personnel
- knowledge of the system to identify hidden or static areas
- knowledge of the products
- effective cleaning equipment and supplies
- cleaning verification eg visual inspection, sampling or testing for allergen residues

3.6 Post-manufacturing controls

Products are required by the Food Standards Code to be labelled appropriately. They must clearly indicate the presence of the allergenic material. Label audits of finished product should be conducted to verify that the product formulation matches the ingredients specified on the label. If there is a formulation change and an allergenic material is introduced into the formulation, then there is no case for old label runout—the label must reflect the actual formulation with the allergen indicated, preferably in the ingredient list.

Finished products that contain allergens must be adequately packaged or contained to avoid any possibility of contamination of allergen-free products during storage. Ideally, allergen-containing products should be segregated prior to distribution from the manufacturing site.



4. Testing and Analysis of Allergens

Allergens are determined using ELISA techniques, where the allergen protein is bound to a selective antibody then detected using a second antibody (detector antibody). The lower detection limit of some current ELISA tests is 1-2.5 ppm.

4.1 Suppliers of test kits

The following list of test kits for allergens has been compiled from the AOAC list and other sources. Refer to <http://www.aoac.org/testkits> for the latest list.

Allergen	Neogen Corporation	Tepnel Biosystems	r-Biopharm GmbH	Other
Milk and milk products	Alert® for Milk Veratox® for Milk	BioKits Casein Assay BioKits Whey Protein Assay	RIDASCREEN® Lactoglobulin Assay	Elisa Systems™ Milk Residue
Crustacea and their products				Elisa Systems™ Seafood Residue (Tropomyosin)
Egg and egg products	Alert® for Egg Veratox® for Egg		RIDASCREEN® Ei/Egg Protein Assay	Elisa Systems™ Egg Residue
Fish and fish products				
Cereals containing gluten		BioKits Gluten Assay Kit	RIDASCREEN® Gluten Assay	Diffchamb AB Transia Plate Gluten Assay
Peanut	Alert® for Peanut Veratox® for Peanut	BioKits for Peanut Protein Assay	RIDASCREEN® Peanut Assay	Elisa Systems™ Peanut Residue
Sesame		BioKits for Sesame Protein Assay		Elisa Systems™ Sesame Residue
Soy Protein		BioKits for Soy Protein Assay		Elisa Systems™ Soy Residue
Tree nuts	Alert® for Almond Veratox® for Almond			
Sulphites	Analysed by the Monier Williams method, refer to AOAC Official Method 962.16 (1995) Limit of detection 10 ppm.			

5. Labelling

5.1 Allergenic substances that must be declared

Standard 1.2.3 of the Food Standards Code requires the mandatory declaration of the following allergenic substances in foods:

Cereals containing gluten and their products, namely, wheat, rye, barley, oats and spelt and their hybridised strains (other than when used for the manufacture of beer and spirits)	Peanuts and soybeans and their products
Crustacea and their products	Added sulphites in concentrations of 10 mg/kg or more
Egg and egg products	Royal jelly presented as a food or royal jelly present in a food
Fish and fish products	Bee pollen
Milk and milk products	Propolis
Nuts and sesame seeds and their products*	

*The Food Standards Code currently uses this terminology. Codex standards use the term tree nuts as referred to in Section 2. FSANZ is currently considering adopting the Codex terminology for clarity.

5.2 Extent of declaration

This declaration applies when these listed products are present as:

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



5.3 Foods which must be labelled

This labelling is required on all foods subject to the normal labelling requirements of the Food Standards Code. In addition, where the food is for retail or catering purposes, and is exempt from the normal labelling requirements, 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”.

These normally exempt foods are where the food is:

- other than in a package
- in an inner package contained in an outer package which is labelled*
- made and packaged on the premises from which it is sold
- packaged in the presence of the purchaser
- whole or cut fresh fruit and vegetables except sprouting seeds or similar products in packages that do not obscure the contents
- delivered packaged and ready for consumption at the express order of the purchaser
- sold at fund-raising events

**Note: Inner packages which are individual portion packs require a declaration of the substances listed in 5.1.*

5.4 Complexity of declaration

Manufacturers would generally be aware of the nature of the ingredients they use in their products. However, the extensive nature of the requirements listed in 5.2 places a responsibility on manufacturers to determine all the ingredients/components of compound ingredients, additives and processing aids that they use in their products.

For example, additives, processing aids and vitamins are often mixed with carriers or diluents which may be one of the substances required to be declared, such as wheat starch, lactose or an oil.

Compound ingredients may often contain unexpected substances that must be declared. For example, some Worcestershire sauces may contain anchovies.

Suppliers of compound ingredients, additives, processing aids, etc have a responsibility to provide their customers with information on any of the allergenic ingredients listed in 5.1 contained in their products.

The requirement to label the various allergens and their products is non-discriminatory. It applies to any product derived from these allergens irrespective of how highly refined or changed it might be, or whether it contains the allergen itself or not. Thus, it would apply equally to wheat flour, wheat starch, wheat maltodextrins, glucose and caramel derived from wheat and to mono and diglycerides, other emulsifiers and tocopherols derived from soybean oil.

5.5 Method of declaration

The Food Standards Code merely states that the substances listed in the Table in 5.1 must be declared in the label, but is generally silent on how they are to be declared.

The Food Standards Code does require that when contained in the ingredient list:

- for cereals—if wheat, rye, barley, oats, spelt or a hybridised strain, the specific name of the cereal must be used, not the generic term cereal
- for fats and oils—the specific name peanut, soybean or sesame must be declared, not just the generic term vegetable oil
- for fish—if crustacea, the specific name of the crustacean must be used, not the generic name fish or crustacea, however for fin fish, it would appear that the generic term fish could be used
- for nuts—the specific name of the nut must be used, not the generic term nuts
- for starch—if it is derived from wheat, rye, barley, oats, spelt or a hybrid (eg triticale) the specific name of the cereal must be used, not the generic name starch

It does not give any guidance on how other derivatives of these products must be declared or how the other allergens or their products should be declared.

Obviously, for labelling to be of use to allergy sufferers the specific name of the allergen should be used in conjunction with the name of the ingredient. For example, “wheat maltodextrin” not just “maltodextrin”, or “soy lecithin” not just “lecithin”.

Alternatively, if there is more than one derivative of the same allergen used, a statement at the end of the ingredient list such as “contains wheat” or “contains wheat products” would fulfil the non-specific labelling requirements.

Similarly, where derivatives of allergens are used as carriers or diluents in additives, a statement such as “contains wheat starch” next to the additive name or number could be used. Similarly, a statement of the type described above at the beginning or the end of the ingredient list could be used. A statement at the beginning of the ingredient list is recommended, as it is the first statement visible to the consumer and is unlikely to be missed.

Processing aids are not generally declared in the ingredient list, and when compound ingredients are used at less than 5 per cent. Neither are:

- ingredients of the compound ingredient
- additives present in the compound ingredient if they have no technological function in the final food

In these cases, if:

- the processing aids are made from the allergens or their derivatives
 - the allergens or their derivatives are present in the compound ingredient, additive or processing aid
- then a statement alerting the consumer to the presence or potential presence of the allergen must be made.

A statement such as "contains soy" at the beginning of the ingredient list would fulfil the allergen labelling requirements. However, this may seem unclear to the consumer if there is no reference to soy in the ingredient list.

Where the allergen is used as, or is present in, a processing aid, a statement such as "soy lecithin used to assist in processing" at the beginning of the ingredient list would be a more informative statement for the consumer.

Where the allergen is contained in a compound ingredient but is not required to be declared under the ingredient labelling requirements of Standard 1.2.4, a declaration such as "contains soy lecithin" in brackets after the name of the compound ingredient, in addition to the allergen statement at the beginning of the ingredient list, would again be a more informative way of providing the consumer with information.

An example could be: "wheat flour, sugar, margarine (contains milk), salt, flavour (contains wheat starch)".

A consistent approach to the presentation of allergen information by food manufacturers will help allergy sufferers to identify foods of concern and help to minimise accidental consumption of unsuitable foods. Two suggested ways of doing this are set out below. Although other formats or variations in the style of allergen identification are possible, it is considered desirable for as many manufacturers as possible to adopt consistent formats for the benefit of consumers who need to find this information.

INGREDIENTS

Contains wheat and barley products, soy, fish and milk as indicated in bold type.

Water, minced beef (25%), unbleached **wheat** flour, margarine [vegetable fats and oils, water, salt, skim **milk** powder and **whey** powder, emulsifiers (471, **soybean** lecithin), colour (160a)], shortening, thickener (1422), textured vegetable protein (**soy**), onion, sunflower oil, flavour (contains **wheat** starch), worcestershire sauce (contains **soy, anchovy, malt** vinegar), salt, colour (150), whey powder (**milk**), **soy** flour, raising agents (450,500), emulsifiers (**soy** lecithin, 471, 481), spices, food acid (330).

INGREDIENTS

Water, minced beef (25%), unbleached wheat flour, margarine [vegetable fats and oils, water, salt, skim milk powder and whey powder, emulsifiers (471, soybean lecithin), colour (160a)], shortening, thickener (1422), textured vegetable protein (soy), onion, sunflower oil, flavour (contains wheat starch), worcestershire sauce (contains soy, anchovy, malt vinegar), salt, colour (150), whey powder (milk), soy flour, raising agents (450,500), emulsifiers (soy lecithin, 471, 481), spices, food acid (330).

Contains wheat and barley products, soy, fish and milk.

Note: Where no gluten-containing cereals are present, it is useful to use terminology such as "thickener (1422 from maize)" to indicate the non-allergenic nature of the ingredient to sensitive consumers where this is not otherwise clearly evident.

5.6 May contain statements

For allergy sufferers, statements such as "may contain peanuts" or "may contain soy" are not useful. It runs the double risk of causing allergy sufferers to risk eating the food or conversely cause them to avoid foods which may be perfectly safe.

"May contain" statements should only be considered as a last resort where contamination risk is:

- documented, eg through visual observation, test results or consumer feedback
- uncontrollable
- sporadic and
- potentially hazardous

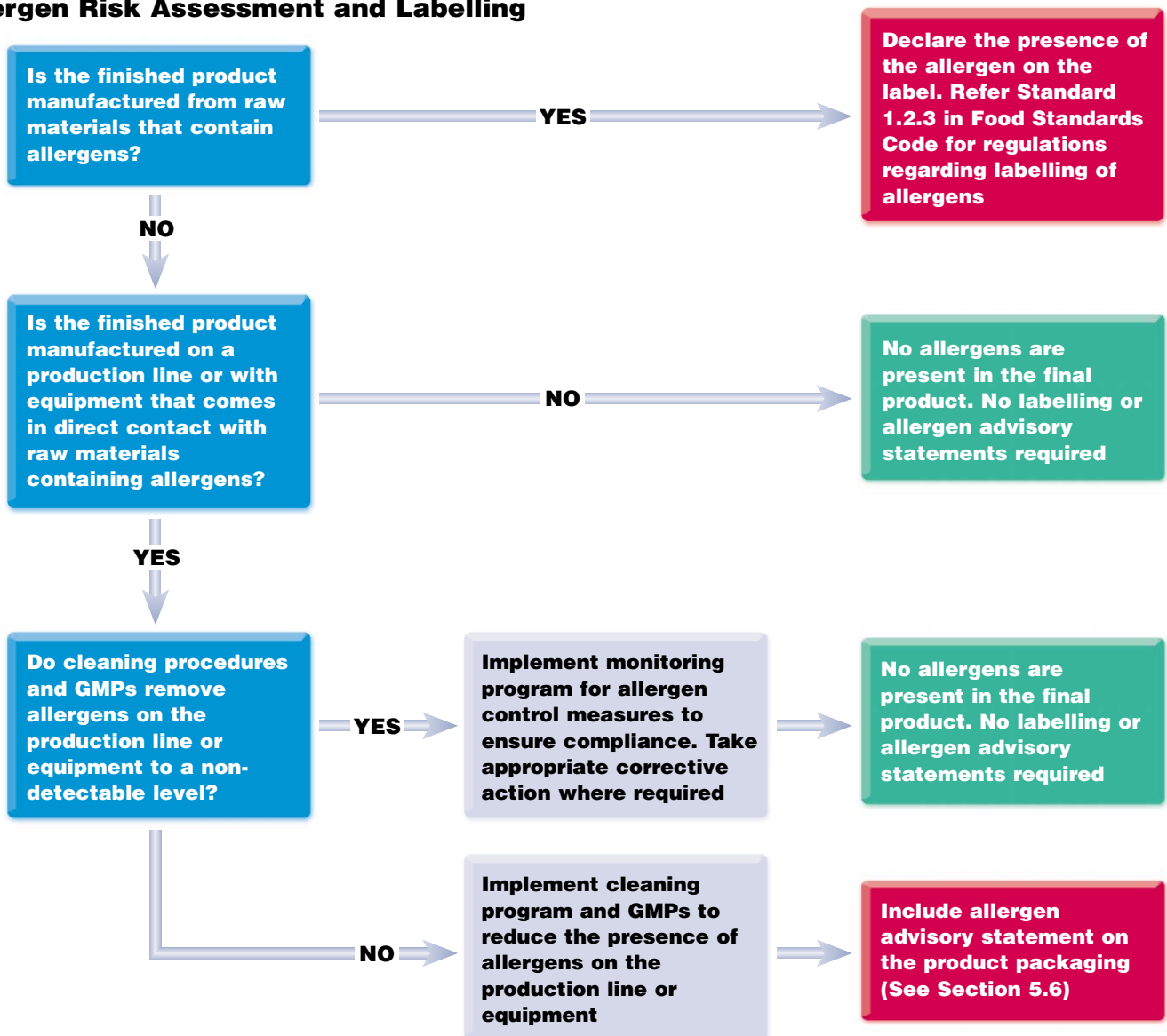
Unless all of these conditions are applicable, "may contain" statements should not be used.

Such statements should never be used as a substitute for good manufacturing practice or to compensate for poor work practices.

The following flowchart provides a step-by-step approach to assessing the need for, and level of, labelling for a food. A risk assessment approach should be used in deciding whether allergen advisory statements are necessary, and the statements themselves should reflect the level of risk. For example, "made on a production line that also produces products containing x" rather than a blanket "may contain x" statement might be considered.



Allergen Risk Assessment and Labelling



5.7 Declaration of alternative ingredients

Standard 1.2.4 – Labelling of Ingredients in the Food Standards Code permits the declaration of alternative ingredients “where the composition of a food may be subject to minor variations by the substitution of an ingredient which performs a similar function”.

Expressions such as “sunflower oil or peanut oil”, or “wheat starch or corn starch”, or “hydrolysed vegetable protein (corn or soy)” in an ingredient list of a product are of limited use to allergy sufferers. They suffer from the same disadvantages as “may contain” labelling and should be avoided wherever possible. Their use should be restricted, using the same considerations as those recommended for “may contain” statements.

5.8 Legibility and clarity

Allergen statements are advisory statements, not “warning statements”, and no minimum type size is prescribed for them. However, the Food Standards Code does require all labelling statements to be “written or set out legibly and prominently such as to afford a distinct contrast to the background”. Notwithstanding this, manufacturers should ensure that the labelling for allergen content stands out from the background and surrounding print, and that it is not concealed by the seal of a flow wrap or by any other part of the package.

6. Review of Guide

This Guide will be reviewed regularly to ensure its advice remains current and relevant, but at least every three years.

Australian Food and Grocery Council ABN 23 068 732 883
 Level 2, Salvation Army Building, 2–4 Brisbane Avenue Barton ACT 2600
 Locked Bag 1, Kingston ACT 2604
Telephone: (02) 6273 1466 **Facsimile:** (02) 6273 1477
Email: afgc@afgc.org.au **Website:** www.afgc.org.au