

7. How to Manage Allergens

This guide aims to outline the minimum considerations for managing allergens in food products. Every facility, product and process is different, and each vendor must consider their specific circumstances and implement controls as appropriate.

Introduction

Individuals may be allergic or sensitive to certain components in foods. These people rely upon the product labelling for accurate information of the product ingredients so they can make informed judgements on whether they are able to consume the product. The Australia New Zealand Food Standards Code identifies and provides a list of ten substances (nine foods and sulphites) which require specific identification in food products as they are the most common ingredients which cause concerns for allergic and sensitive people. These substances are: Peanuts; Tree Nuts; Soybeans; Milk; Egg; Cereals Containing Gluten (Wheat, Rye, Barley, Oats, Spelt, and their Hybridised Strains); Fish; Crustacea; Sesame Seeds and Added Sulphites in concentrations of 10mg/kg or more. This list is from Standard 1.2.3, Table to Clause 4, and these substances are termed throughout this document as 'allergens'.

The result of an affected individual coming into contact with a food allergen can, at worst case, cause anaphylaxis and be life threatening. The result of a sensitive individual coming into contact with a food to which they have intolerance can cause symptoms such as stomach upsets, headaches, migraines and skin rashes.

Allergen identification and labelling for allergens in direct ingredients

Incorrect labelling of food allergens often results in a consumer product recall due to the adverse health affects food allergens can have on affected customers. It is therefore important to identify, minimise, control and accurately label food allergens. Systems should be routinely challenged and reviewed to ensure the correct product is packed into the correct packaging. Incorrect product or packaging scenarios will likely result in product withdrawal or recall.

A product which is specifically marketed in such a way that it is suitable for a person with a food allergy or sensitivity must be manufactured in a fully validated and documented process that ensures complete absence of the allergen concerned.

Allergens must be identified in a product when they are:

- Present as an ingredient
- Present in any part of any ingredient (i.e. as part of a compound ingredient)
- Used to produce any ingredient (despite how refined or processed the ingredient is)
- Used as a processing aid

Individuals have different reactions to allergen contamination, some have severe reactions at low levels, and others have milder reactions at high levels. If an allergen is intentionally present as an ingredient in a product at any level, it must be labelled.

There are other food allergens in existence which are not required to be labelled under the Australia New Zealand Food Standards Code due to a relatively low prevalence of sensitivity in the population. Sensitive components include chilli peppers and members of the Allium family (garlic, onion, leek, chives, shallots and scallions). Vendors should provide a breakdown of herbs and spices used in their products to assist Woolworths in labelling these sensitive components appropriately. There are also emerging allergens, an example of which is Lupin which may

require specific labelling in the future. Other countries legislate some of the same and some different allergens to those legislated in Australia and New Zealand. Vendors should be aware of these differences when importing ingredients as it may affect how the overseas business manages or declares allergens.

Allergen Management Plan

An Allergen Management Plan is necessary to control allergens with the aim of eliminating unintentional presence in products. Allergen cross-contact management should be based upon risk analysis e.g. HACCP program principles by assessing allergen hazards.

The main areas which need to be considered with controls documented in the Allergen Management Plan are:

1. Number and type of allergens handled on site both directly and indirectly as cross contact – range of products produced.
2. Raw material risk assessment
3. Separation, identification and handling in manufacturing premises, equipment and processes
4. Cleaning to remove allergen residues
5. Process validation and verification
6. Packaging – Cross Contact Allergen Labelling
7. People
8. New product development & reformulation
9. Corrective and preventative actions

1. Number and type of allergens handled on site

If the allergen is intentionally present in every product produced on site, no specific processing controls are required although every product must be labelled as containing the allergen concerned.

If an allergen is intentionally present in some products produced on site, process controls must be developed and validated to ensure this allergen does not cross-contaminate other products not containing the allergen concerned.

If more than one allergen is intentionally contained in some products and not in others, consideration must be given to methods of preventing cross-contact across multiple allergens and products.

If an allergen is present in a raw material as a cross contact based on information from a raw material supplier, the best course of action is to eliminate the cross-contact. This could be done by sourcing from an alternative supplier or working with the supplier to eliminate the cross contact. If it is not possible to eliminate the cross contact, this, together with direct handling of multiple allergens presents the most complex scenario for allergen management.

An allergen risk matrix will assist in identifying where and when allergens are handled both directly and indirectly. In most cases the controls can be simplified where the amount of both direct and indirect allergens handled is minimised. Vendors should work to reduce and remove potential cross contact with allergens where possible by reviewing and limiting the introduction of allergens handled.

2. Raw material risk assessment

Raw ingredient information should be available in a specification format e.g. Product Information Form (PIF) from the raw ingredient supplier. This information should clearly state the allergens intentionally added to the raw ingredient and any potential cross contact allergens. Raw material suppliers should be part of the approved supplier program. Allergens must be reviewed with any changes in the supply of raw materials. Allergen management should be part of the raw material supplier approval process and methods of keeping up to date with changes in allergens handled at the raw material supplier should be implemented.

Unexpected Allergens

Many ingredients, processing aids and additives can be derived from an allergenic food. The list below indicates where allergens could unexpectedly be present in food. The list is not exhaustive and should be used as a guide only.

More information is available in the Allergen Bureau publication 'Unexpected Allergens in Food'. Available from:

<http://www.allergenbureau.net/downloads/vital/Unexpected-Allergens-in-Food-18-April-2011.pdf>

Ingredients (possible allergen)

Baking Powder (Wheat)

Cocoa (Soy or Wheat)

Coconut Milk (Casein – Milk Protein)

Corn Flour (Wheat)

Dextrose, Dextrin (Wheat or Oats)

Gelatine (Sulphites)

Glucose, Glucose Syrup (Wheat or Oats, Sulphites)

Hydrolysed Vegetable Protein (HVP) (Soy, Wheat, Peanut, Sesame)

Icing Sugar (Wheat)

Maltodextrin (Wheat or Oats)

Starch (Wheat, Sulphites)

Sugar (Wheat, Sulphites – particularly in Sugar from China)

Textured Vegetable Protein (TVP) (Soy or Wheat)

Vegetable Oil (Peanut or other Nuts, Sesame or Soy, Antioxidants derived from Soy or Egg)

Vinegar (Milk, Egg or Fish used as fining agents, Wheat, Barley)

Whitener (Wheat or Casein- Milk Protein)

Worcestershire sauce (Fish- Anchovies, Crustacea)

Food Additives (possible allergen)

150a-150d Caramels (Wheat)

160a Carotene (Fish)

306-309 Tocopherols (Soy or Wheat)

322 Lecithin (Soy or Egg)

1100 Amylase (Wheat, Barley or Soy)

1400-1450 Thickeners (Wheat)

Antioxidants (Soy or Egg)

Sweeteners (artificial) – Polyols (Wheat)

3. Separation, identification and handling in manufacturing premises, equipment and processes

An assessment of the facility, machinery, common processes and raw material segregation should be undertaken to identify sources of allergen cross contact hazards in the facility.

Procedures to eliminate or minimise the risk of cross contact should be developed and implemented.

Methods of controlling allergen cross contact include but are not limited to:

- Keeping material with allergens in different or segregated parts of the production facility
- Use of dedicated equipment (including colour coding cleaning equipment)
- Minimising movements of materials
- Scheduling of production runs of products on common equipment. After full cleaning, products without allergens should be scheduled before products with allergens. Contingencies need to be considered and validated, if, for example a product needs to be produced outside of its standard sequence.
- Managing and minimizing re-work to ensure that remaining allergenic material is not re-worked into a product free of that allergen. Rework should be fully identified.
- Consideration of physical location (storage) of allergens on site e.g. products containing allergens could be stored below allergen-free products in multilevel racking or in less traveled areas of warehouses.
- Methods of identifying allergens present on site e.g. colour coding of equipment, personnel clothing, cleaning equipment, storage and processing areas.
- Methods of managing allergen incidents e.g. spills.

4. Cleaning to remove allergen residues

Effective cleaning to remove allergen residues from common equipment is not necessarily the same methodology as cleaning to remove microbiological residues from plant and equipment. Microbiologically clean equipment is not necessarily allergen clean. 'Visually clean' is insufficient as a basis to ensure that allergen carry-over will not occur. If allergen cleaning is insufficient it is likely that a build up of allergen contamination will occur over a period of time which may contaminate product either continuously or in a random manner.

The validation of the cleaning methodology needed for allergen cleans is therefore different than the validation of microbiological cleans. Validation of the cleaning method should include evidence to support the method used i.e. that the level of equipment disassembly and type of chemicals used are capable of removing the allergenic proteins. Ongoing verification of the methodology is also required to ensure the methods used continue to be effective. Specific swabs are available which can be used to test surfaces and equipment for residues of allergenic protein. Product from the process can also be sampled to test for allergen residues. Validation studies may also be carried out using a known 'marker' i.e. known contaminated product and sampling post cleaning.

Cleaning validation also needs to extend to washing of hands and personal protective equipment such as factory clothing and footwear as well as equipment used in the cleaning process. This is because cleaning tools have the potential to move allergens around a facility, and cleaning processes can transfer allergens onto the operator's protective clothing.

Effective cleaning requires:

- Appropriate equipment and energy to assist in cleaning difficult areas.
- Disassembly of equipment for manual cleaning.
- Food-grade chemicals capable of removing allergenic protein residues. Note most sanitisers (including hand sanitisers) do not remove allergenic protein. Extra precaution must be taken when producing organic product.
- Checks to ensure the equipment has been effectively cleaned.

5. Process validation and verification

Testing for allergens can be done either externally by a specialist laboratory or in house by use of a testing kit. The Vendor should seek advice from the supplier or specialist if required and ensure that validation testing is applicable to the worst case allergen scenario encountered in production. Validation work may also include literature and documented studies.

The vendor should be aware that testing simply represents the specific sample taken and does not prove the ongoing absence of an allergen. Testing is very unlikely to detect cross contact particulate allergens which are not spread throughout the batch.

Process verification methods also need to be devised with a frequency and quantity based on risk assessment. Again, testing in isolation is unlikely to identify an issue, but the level of confidence increases with the number of samples and the length of time over which the verification has been implemented. It is not possible to recommend a specific amount of data since this will be a risk-based approach dependent on the varying manufacturing processes and the nature of the food.

6. Packaging – Cross Contact Allergen Labelling

The 'Allergen Advice' statement on packaging (Woolworths 'One Stop Spot') is to include both allergens contained in the product and any cross contact allergens.

Allergens must be identified in a product when:

- there is potential cross contamination and
- the allergen falls above the specific action levels as identified in VITAL (see below)

Voluntary Incidental Trace Allergen Labelling (VITAL)

VITAL is a standardised allergen risk assessment tool for determining labelling of unintentional allergen cross contact. VITAL has been developed by the Allergen Bureau and it requires the assessment of likely sources of cross contact allergenic substances from raw materials and the processing environment. Vendors should be familiar with the VITAL tool and supporting information. Documentation substantiating the VITAL calculation and assessment should be available. Training on the use of VITAL is recommended and is available within Australia and New Zealand. Please contact the Allergen Bureau for further information or visit their website at <http://allergenbureau.net/>

Woolworths requires the use of the VITAL tool for Own Brand pre-packaged products. It should be known that VITAL is not applicable for sulphites or for particulate allergens.

Where the VITAL assessment has been completed the pack can include a 'may be present' statement (if required).

Procedures must be in place to ensure that the correct product is always packed into the correct packaging. Obsolete packaging needs to be isolated and appropriately disposed to prevent inadvertent use.

Where an allergen is considered to require labelling due to unintentional cross contact, Vendors will be expected to provide documented evidence to support the allergen declaration on the packaging. Woolworths will not support allergen cross-contact labelling where this is not justified or is a result of a lack of processing controls.

7. People

All staff should understand the importance and the responsibility of managing allergens.

Communication and training should be in place on allergens, company policies and allergen management procedures. Allergens can be introduced into a facility by people e.g. through staff food, and procedures to manage this should be established and implemented.

8. New product development & reformulation

New products and product reformulation should be developed with allergen-free alternatives where possible but should otherwise minimise allergens used both directly and as cross contact. The introduction of a new allergen into a manufacturing facility should be avoided. When new allergens are required to be introduced the entire allergen management plan should be reviewed and procedures updated and implemented accordingly. This may involve packaging updates, and sufficient time should be allowed for these changes to take place before product commercialisation. Woolworths should be advised if packaging updates are needed and these should be represented in the product specifications.

9. Corrective and preventative actions

Allergen management procedures should be part of the vendor's internal audit and review procedures. Non conformances should be part of the management review and any incidents need to be fully investigated with resulting corrective and preventative measures implemented.