Dairy Food Safety Victoria

A guide to managing allergens in the dairy industry

August 2018

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Content

Introduction

Dairy manufacturers have a responsibility to manage allergens in their products so that consumers with food allergies are protected. Failure to adequately control the presence of allergens in dairy food or to correctly label products can present a serious risk to public health, and lead to expensive food recalls.

What is food allergy?

Food allergy occurs when the body's immune system reacts by producing antibodies to substances (allergens) in a food which are usually harmless to most consumers. These substances are generally heat stable proteins. When antibodies are produced to these substances and react with cells in the body, an allergic reaction takes place producing symptoms which can range from mild to severe.

Allergic reactions occur quickly, with mild to moderate symptoms including hives, stomach pain and vomiting. More severe symptoms include difficulty breathing, swelling of the tongue, wheezing, dizziness and collapse. Anaphylaxis is the most severe form of allergic reaction and can be life threatening.

Food allergy can affect anyone but is more commonly seen in children and can be as high as 10 per cent of children up to one year of age[1]. Allergies to cow's milk, eggs and peanuts are the most common allergies in children.

Food allergy currently has no cure, so the only choice is for affected consumers to avoid consuming foods containing substances to which they are allergic. Therefore, they rely on being able to clearly identify products which contain allergens.

Allergy versus intolerance

Not all adverse reactions to food are due to food allergy. Many consumers experience less severe symptoms related to food intolerances.

For example, lactose intolerance occurs in people with an inability to digest the carbohydrate lactose due to reduced levels of the enzyme lactase. This condition can cause significant discomfort but is not life threatening.

In contrast, milk allergy is related to the proteins in dairy products and can cause severe life-threatening reactions. There have been a number of severe allergic reactions in Australia associated with the consumption of coconut products containing undeclared milk protein.

Coeliac disease is a chronic autoimmune disease triggered by gluten, a group of proteins found in wheat, rye, barley, oats and other grains. Coeliac disease is severe but is not associated with anaphylaxis and sudden death.

Correct food labelling enables consumers affected by an intolerance, disease or allergy to make informed consumption choices.

DFSV expects:

Food allergens must be controlled through every stage of food manufacture and a documented allergen management plan (AMP) should form an integral part of a dairy manufacturer's food safety program.

Manufacturers need to demonstrate that they understand their obligations and have effectively validated and verified their AMP. Compliance with Standard 1.2.3 – **Information requirements – warning statements, advisory statements and declarations** of the Australia New Zealand Food Standards Code (the Code) will be assessed by DFSV food safety managers at audit.

As a minimum, manufacturers are required to demonstrate that they address the points raised in this guideline and can present records to demonstrate the effectiveness of allergen control measures.

Overview

Food allergen facts

1. Most food allergies are caused by peanuts, milk, and eggs but also include tree nuts, soy, wheat, sesame, shellfish, and fish.
2. Allergy is one of the fastest growing chronic conditions in Australia affecting up to 10% of children and 2–3% of adults.
3. 4.1 million Australians have at least one allergic disease.
4. Food-induced anaphylaxis has doubled in the last 10 years and 10% of infants now have a food allergy.
5. Hospital admissions for anaphylaxis have increased four-fold in the last 20 years.
6. Undeclared allergens are the most common reason for food recalls in Australia.

Dairy manufacturer responsibilities

1 RAW MATERIALS AND INGREDIENTS
Know the allergen status of your raw materials and ingredients

2 DAIRY MANUFACTURING
Identify and map allergens and manage your entire manufacturing environment

3 PRODUCT LABELLING
Declare allergens on food labels

Regulatory requirements

To assist allergic consumers, Standard 1.2.3 of the Code mandates that the presence of certain substances in a food must be declared on the label. Allergens that must be declared are any of the following foods, and include ingredients, compound ingredients, additives or processing aids derived from them.

Table 1: Allergens that must be declared

Cereals containing gluten	Soybeans
Crustacea	Sesame seeds
Egg	Tree nuts (other than coconut)
Fish	Lupin
Milk	Sulphites: not greater than 10 mg/kg for added sulphites
Peanuts	

Ingredients added to dairy food formulations, such as yoghurt, dairy dips and desserts, may contain many of these allergens.

There are some exemptions in the Code for highly processed ingredients as listed in Section 4 of Standard 1.2.3.

Where a food is not required to bear a label, this information must be shown with the food displayed, or provided to consumers on request.

Standard 1.2.7 and Schedule 4 – **Nutrition, health and related claims** and Standard 1.2.8 – **Nutrition information requirements** provide further information regarding requirements for gluten and lactose free claims.

Recalls

Food allergen-related recalls are the most commonly reported and have a significant impact on both food producers and customer confidence. Over the period 2008–2017, 37 per cent of all Australian recalls were due to the presence of undeclared allergens, with undeclared dairy the most common, followed by peanut.

Analysis of international food recalls shows most are associated with inclusion of the wrong ingredient, incomplete labelling of a product, or the wrong product placed in a package. This trend indicates failures in good manufacturing practice (GMP) and the need for improvements in preventative controls.

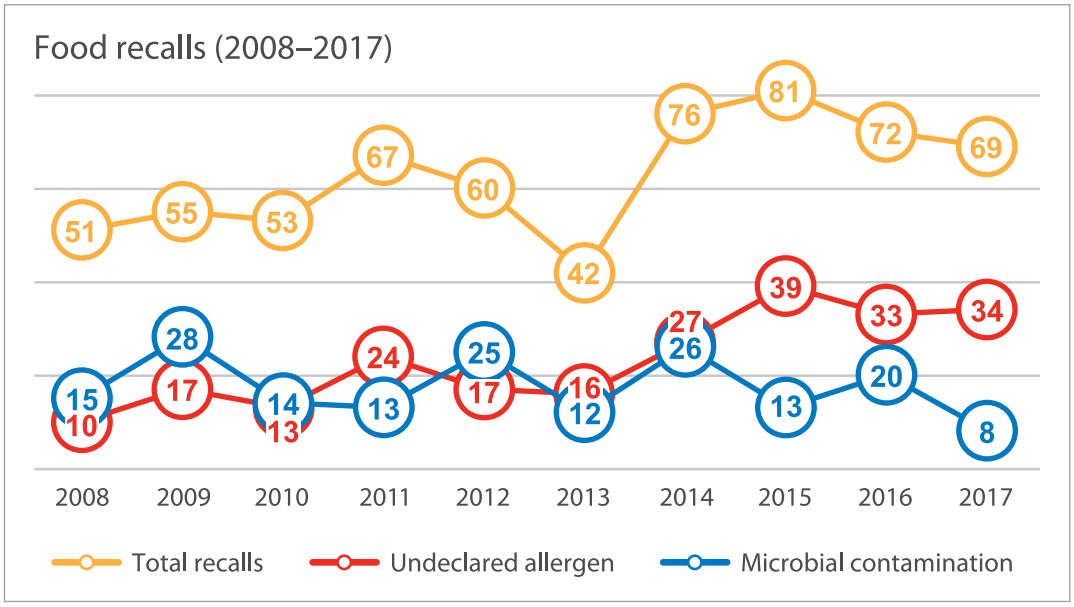


Figure 1: Australian food recalls 2008–2017 (as reported by Food Standards Australia New Zealand)

Allergen management for the dairy industry

To enable allergic consumers to avoid consuming foods containing undeclared allergens, food manufacturers need to ensure products do not inadvertently contain allergenic ingredients and are correctly labelled. Manufacturers achieve this by documenting their policy on allergen management, and developing and complying with an AMP within their food safety program.

Allergen alert: Manufacturer's responsibilities

Food manufacturers have a responsibility to manage the unintentional presence of food allergens, including:

- implementing an effective AMP
- training staff in food allergen risks, management and communication
- providing clear and accurate information on the allergen status of your product.

The potential for allergens to be found in a dairy food may be identified as a hazard and covered as a critical control point in the food safety program or through a separate allergen pre-requisite program.

The unintentional presence of allergens in product may occur as a result of a range of management failures, including:

- unexpected presence in raw materials or ingredients
- mismanagement of raw ingredients
- accidental miss-formulation of a product
- incorrect or incomplete labelling
- cross-contact: including during manufacture, due to equipment design, through poor cleaning, as a result of airborne particles, during rework, or through operator error.

Allergen alert: Cross-contact

- Cross-contact occurs when an allergen or allergenic ingredient unintentionally makes contact with another food, environmental surface, or piece of equipment and crosses over into a food or surface that doesn't contain the allergen.

Developing your AMP

The development of an AMP involves a basic set of principles, which apply regardless of the size of the manufacturing premises. Systems need to be in place to effectively manage allergens, and it starts by identifying the allergen profile of all incoming raw materials and ingredients and extends all the way until the finished product is packaged and labelled.

Allergen management in its simplest form involves:

- identifying and mapping all allergens on the site (including milk)
- controlling the presence of allergens in food as either unintentional contaminants or through cross-contact
- communicating the risk to the consumer through accurate labelling.

Assemble an allergen management team

In a process similar to establishing a team to develop the Hazard Analysis and Critical Control Point (HACCP) plan for your food safety program, assemble a multi-disciplinary team to oversee the process of identifying and managing allergens on your site. The members of the team should know the physical environment, the product formulations, and understand the manufacturing and packaging operations.

Identify allergens on site

Identify all allergens that may be introduced onto the site through:

- raw materials and ingredients (including compound ingredients)
- processing aids and additives
- packaging materials.

All allergens listed in Standard 1.2.3 need to be controlled. The form they are in will affect their storage and handling, the equipment used for their handling, and cleaning processes. For example, milk may be present on site as liquid milk, whey protein concentrate, or as skim milk powder, while almonds may come as whole nuts, slivers, paste, meal or flour. A fine powder is more likely to spread as airborne particles if not handled appropriately, while a paste may be easy to store but is likely to be viscous and hard to remove when cleaning contact surfaces in the production environment.

The team should also identify any allergen introduced via a raw material or ingredient through cross-contact. This should be reported by the supplier as a quantitative amount *e.g.* 2 ppm soy protein present in a flavour from cross-contact. Raw materials that come with a cross-contact or precautionary statement (*e.g.* soy present because of cross-contact) are not acceptable. Where a supplier only provides a cross-contact statement on a raw material or premix, it should be investigated further to determine whether the cross-contact can be reduced, removed, or fully quantified.

It is important to also consider how much of the allergenic protein is present. Ingredients with a high level of protein, such as milk powder or egg, pose a significantly higher risk if cross-contact occurs. Hence, mechanisms for controlling the risk need to be more stringent.

This information is then used to develop an ingredient matrix, which lists the ingredient, the supplier, where it is stored, the allergens present as ingredients and any allergens present through cross-contact. If possible, include the form of the allergen (liquid, solid, powder) and the level of allergenic protein, if known.

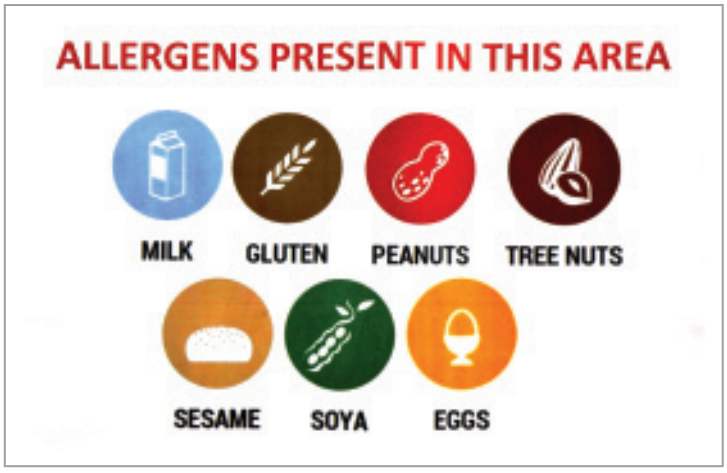


Table 2: Ingredient register (location and allergen)

Ingredient	Supplier	Form	Crustacea	Egg	Fish	Gluten	Lupin	Milk	Peanuts	Soy	Sesame	Tree nuts	Storage
Stabiliser	Smith's stabilisers	Powder	A	A	A	A	A	A	A	P	A	A	Warehouse Bay 2
Milk	Daisy's dairy	Liquid	A	A	A	A	A	P	A	A	A	A	Silo
Skim milk powder	Kurtins ingredients	Powder	A	A	A	A	A	P	A	CC	A	A	Warehouse Bay 21
Soy protein isolate	Kurtins ingredients	Powder	A	A	A	A	A	A	A	P	A	A	Warehouse Bay 6
Tapioca starch	Sam's starch	Powder	A	A	A	CC Wheat	A	A	A	A	A	A	Warehouse Bay 4
Caramel swirl	Ron's ripples	Liquid	A	A	A	A	A	P	A	A	A	A	Chiller 1
Macadamia swirl	Ron's ripples	Liquid	A	A	A	A	A	A	CC	A	A	P–Mac CC–Alm	Chiller 2

Key: **A** = absent **P** = present **CC** = cross-contact **Alm** = almond **Mac** = macadamia

Allergen mapping

Mapping the location and movement of allergens across a manufacturing site provides a clear and comprehensive picture of areas where there is potential for cross-contact and this assists in identifying control measures to mitigate the risk.

Mapping steps

1. Walk the manufacturing line with the team.
2. Draft a site floor plan.
3. Overlay this with a process flow chart which identifies each step along the processing line, the equipment, the allergens that may be introduced along the line, and key cross-contact points.

Mapping should commence from receipt of raw materials and ingredients, and map all on-site manufacturing processes, including labelling of the finished product. Existing food safety programs already capture much of this information and these can be used to inform both the mapping process and the AMP.

This site produces dairy and soy yoghurt products. There is a segregated process for preparing dairy and soy yoghurts, however there is a single shared inline mixer tank and filler unit for the addition of flavours. Flavours are procured externally and made up on site in a shared mixer.

The dairy yoghurt has a soy-based stabiliser. The soy yoghurt is not labelled as dairy-free however the dairy needs to be controlled and excluded from cross-contact impact in the soy yoghurt. The caramel swirl contains milk and is only used in the dairy yoghurt while the macadamia swirl is used in both.

The warehouse and formulation room require allergen management procedures to reduce cross-contact. Plus, the use of the shared equipment *e.g.* flavour mixer, inline mixer and filler present a cross-contact risk which needs to be investigated, risk assessed, and controlled.

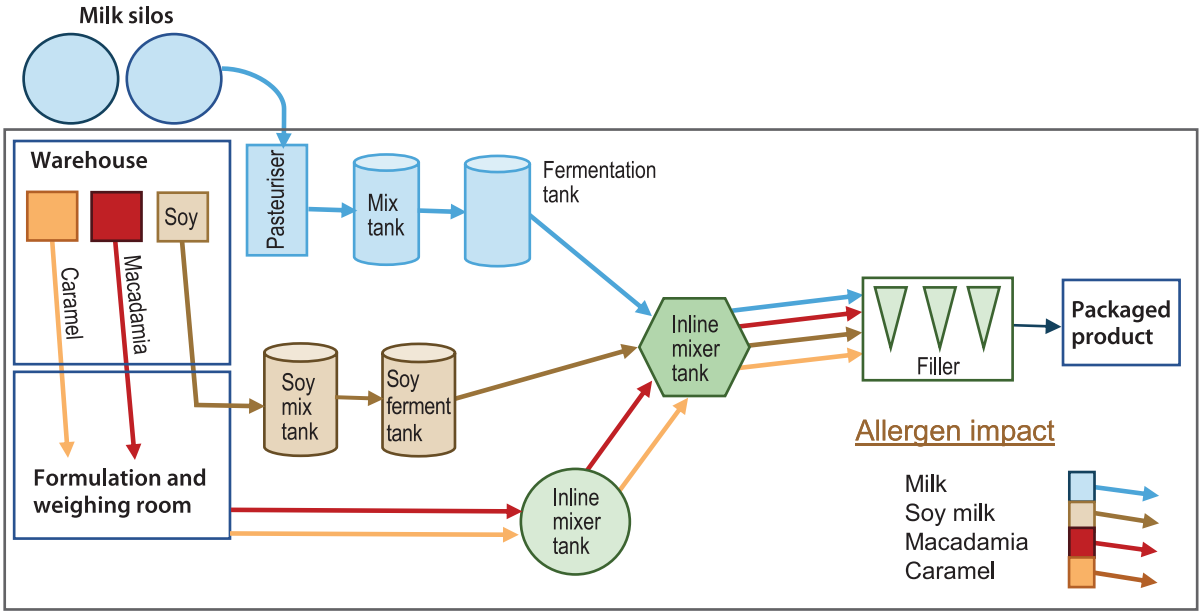


Figure 2: Allergen map

Controlling raw materials and ingredients

With a growing awareness around the risk of inadvertent contamination of ingredients with allergens, food fraud, or substitution, it is essential to ensure the allergen profile of your raw materials and ingredients is known and accurate. Regular testing of ingredients can be used to verify the allergen profile as documented in the supplier's certificate of analysis.

Supplier approval

Knowing what allergens are present in raw materials and ingredients is a critical first step. All suppliers to a manufacturing site should be identified as approved suppliers and have a regularly audited food safety program in place.

Suppliers should retain records of the way they manage allergens and provide certificates of analysis showing the allergen profile of all supplied raw materials and ingredients.

Allergen alert: Certificate of analysis

A certificate of analysis is a document which represents the certified concentration of components in an ingredient, as well as its microbiological and allergen status.

Management and storage of ingredients

Clearly identify all ingredients containing allergens when they arrive on your site. The product information form (PIF)[2] provides compositional information related to raw materials and ingredients and information regarding allergen and allergen cross-contact. The manufacturer should also review the ingredient specification and the certificate of analysis for allergens on receival of ingredients.

Store ingredients containing allergens in designated and dedicated bins, bays or holding areas, and labelled with a clear visual identification system (such as colour coding or tagging). Ensure all paperwork or electronic records; work in progress (WIP) and rework; specification sheets and finished product records are retained.

Allergen alert:

Special care must be taken with ingredients containing dairy if non-dairy products are also manufactured on your site.

Where designated bays or dedicated storage areas are not available, storage of like-with-like is the best approach. Store non-allergenic material above allergenic material to reduce risks from spills. Where an electronic warehouse management system is in place, check sensors regularly to ensure the system is correctly identifying allergenic ingredients and allocating their storage correctly.

Before substituting any ingredients, ensure the allergenic ingredients and cross-contact risks are the same. The same ingredient from different suppliers may have different cross-contact risks.

To minimise the risk of cross-contact:

- dispose of ingredients received in damaged or open packaging
- use pallet covers to prevent cross-contact from fine powders in the warehouse areas
- dust or clean down, re-cover, or re-wrap bags or boxes removed from pallets for staging or production preparation before returning to the warehouse
- examine the type of packaging used, as some packaging contains wheat-based release agents or may have allergen-derived oiled liners.

It is important that warehouse staff are fully trained in protocols and procedures for handling allergenic ingredients and that an allergen spill procedure is in place with dedicated tools and equipment for clean-up and disposal.

Food allergens can be present in many food ingredients and are not always obvious from their name.[3] Manufacturing staff should be made aware of alternative names, for example ingredients labelled as sodium caseinate, whey protein concentrate, milk protein hydrolysate, lactoglobulin, or lactalbumin all contain milk protein.

Table 3: Examples of hidden names for allergens

Allergen	Ingredients listed below may indicate the presence of an allergen
Milk	Milk, casein, calcium caseinate, lactalbumin, lactoglobulin, lactose, milk powder, whey powder, whey protein concentrate
Tree nuts	Almonds, Brazil nuts, cashews, chestnuts, ginkgo nuts, hazelnuts, macadamia nuts, nut butters, nut milks, pecans, pine nuts, pistachio nuts, walnuts
Egg	Albumin, dried egg solids, egg white, lecithin, lysozyme, ovalbumin, ovoglobulin
Soy	Bean curd, edamame, hydrolysed soy protein, hydrolysed vegetable protein, soy albumin, soy lecithin, soy sauce, teriyaki sauce, tofu
Cereals containing gluten	Barley, cous cous, dextrin, farina, malt, MSG, rye, semolina, soy sauce, spelt, triticale, various flours, wheat

Segregation during manufacture

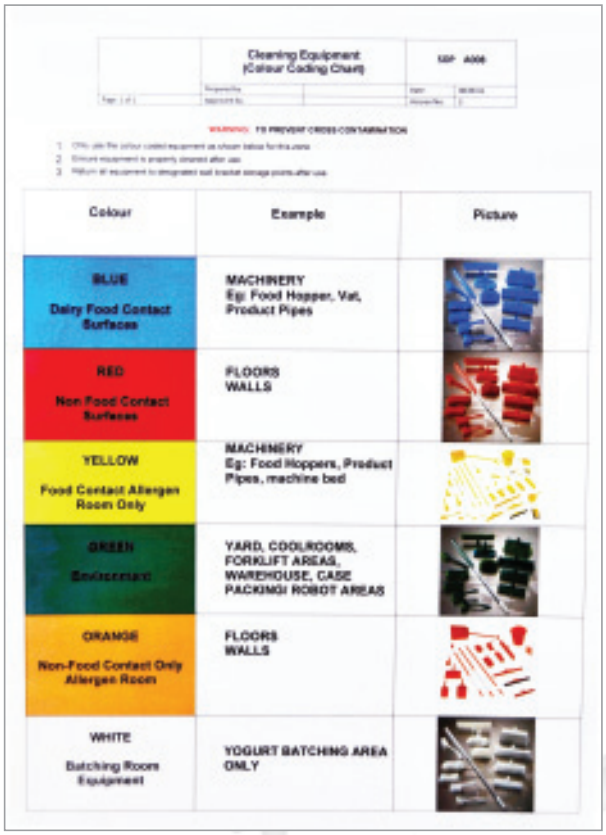
Separate equipment, processing, and packaging lines; staff; and cleaning procedures contribute significantly to allergen control. Where possible, use dedicated lines to segregate allergen and non-allergen containing food products.

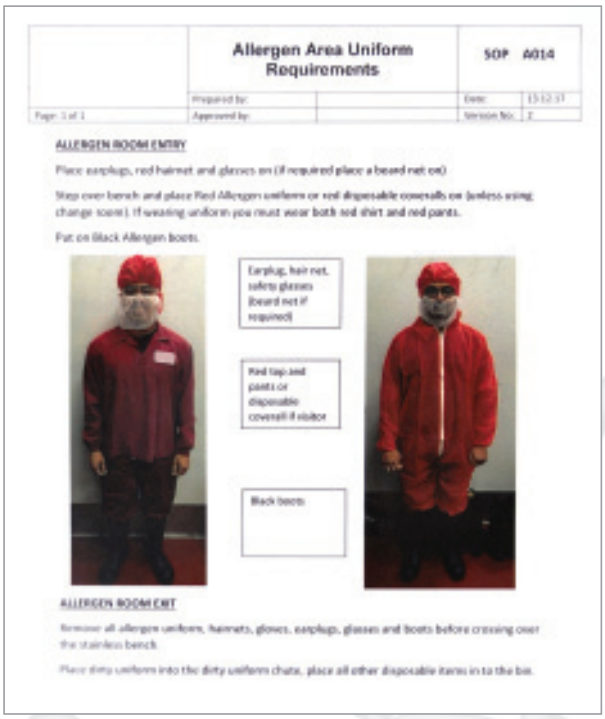
If your site has an 'allergen-free' area or a controlled production environment where segregated production takes place, you must provide:

- separate storage areas for the ingredients
- separate controlled room entry
- dedicated change rooms
- dedicated equipment and cleaning utensils
- area- or operator-specific personal protective equipment (PPE).

The PPE may be as simple as a different coloured uniform or include a full range of protective equipment set aside for a specific production line or product. This colour coding or other visual identification system should be used consistently throughout the site from raw material to finished product. Always ensure staff have received adequate instructions on the use of PPE so it doesn't contribute to cross-contact and is stored and disposed of separately. Dedicated line-specific tools and monitored maintenance programs also help reduce cross-contact.

The use of separate lines, even if adjacent, or placing physical barriers (such as shield covers or catch pans) will reduce the risk from spillage or cross-contact but it is important to have evidence to demonstrate that separation and control mechanisms are effective.





In-progress work

Appropriate management of in-progress products or work in progress blends is critical to ensure the correct products are produced, and ingredients waiting to be staged and/or processed are neither exposed to cross-contact nor made up into incorrect formulations. Cross-contact risks can be reduced by:

- segregation of ingredients and products
- visual identification systems
- appropriate handling.

As part of GMP, any utensils or containers used for allergenic ingredients or product should be emptied, cleaned and dried as soon as possible to reduce the risk of cross-contact.

Sites where allergenic ingredients are added

Where practical, isolate allergen addition points and dedicate re-feed systems. If allergens are added at the end of a processing line, fewer parts of the process line and equipment will require intensive cleaning to remove residues.

It is important to have control or lock out procedures for access to equipment that uses or supplies allergenic ingredients to ensure that the equipment isn't used in another area of production without appropriate cleaning. The allergen spill protocol should also be applied here with dedicated clean-up equipment and disposal process.

Site design and modifications

New production facilities should be designed, constructed and equipped with due consideration for the management of allergens, and include barriers or manufacturing zones that physically segregate allergen and non-allergen containing food products.

Pre-existing premises may need to be modified to ensure all equipment, regardless of age, is fit for purpose, can be effectively cleaned and maintained, and able to produce safe food, as required under Standard 3.2.3 of the Code. Equipment designed to be disassembled and/or easily cleaned is also ideal for allergen management.

A register of each item of equipment, its maintenance program, and any known issues will help prepare the allergen map and the documentation of cross-contact risks. Where possible, limit or eliminate cross-over of conveyor lines carrying allergenic ingredients or product. Alternatively, use shielding or cover systems to limit spillage or dropping of unsealed product from overhead conveyor lines. For further guidance, see the DFSV publication *Hygienic design: guidelines for dairy food manufacturing premises*.[4]

Scheduling manufacturing

Separating allergen and non-allergenic products using scheduling is a practical allergen control strategy. This includes:

- processing and packaging non-allergenic products prior to those containing allergenic ingredients
- batch production of allergen containing products to reduce cleaning problems and downtime
- beginning with products with less allergenic ingredients or easier to clean allergens through to those with highest allergen levels
- extended runs of allergenic products, if possible, to minimise changeovers.

Automated scheduling systems and batch sequencing systems are highly dependent on the correct information being available, so monitoring the system and checking for compliance with the AMP is essential. Similarly, the success of scheduling for allergen control is based on an effective, validated cleaning procedure and evidence it has taken place.

Where push through product or purging is used to act as a buffer between allergenic and non-allergenic product or as a cost-effective cleaning process, it is important to accurately determine the amount of push through necessary to remove allergenic product. Any product or ingredient used for this purpose needs to be strictly monitored, labelled appropriately and its use controlled *e.g.* as rework or discarded.

Reformulation

Establish a process to manage reformulation that ensures product is handled appropriately, that any equipment impact is considered, and labels match the reformulated product. The AMP should be reviewed and any changes documented. Records for materials and ingredient lists must reflect the current status of the product and outdated packaging and labels removed and disposed of. Keep details of the original labelling for traceability purposes.

Rework

Clearly designate any allergenic and non-allergenic rework and have systems in place to ensure 'like-into-like'. This could include the use of colour tags, containers, plastic liners or bar coding to identify allergen containing products consistent with the site's visual identification system. Ensure the rework process is documented, transparent and traceable. Document the type of rework, the quantities involved, and where it is redirected to.

Labelling and packaging

To provide appropriate warning to consumers of the presence or possible presence of an allergen in a product, all allergenic ingredients must be listed legibly and prominently on the product label. Incorrect labelling of product is a significant cause of allergen related recalls and has been responsible for a number of allergic consumer reactions to packaged food.[5]

Under Clause 4, Standard 1.2.4 **Ingredients to be listed by common, descriptive or generic name**, of the Code, ingredients must be declared using either:

- their common name
- a name that describes the true nature of the ingredient, or
- a generic name as listed in Schedule 10 of the Code. If the generic name is used, the presence of the allergen must still be clearly declared. As an example, milk is used in the manufacture of cheese and yoghurt and therefore must be on the label.

> **INGREDIENTS: MILK**, SKIM **MILK** POWDER, CULTURE (*S. thermophilus* and *L. bulgaricus*), THICKENERS (401, 412), STABILISER (**SOY** LECITHIN)
>
> **CONTAINS MILK AND SOY**
>
> **MAY BE PRESENT: TREE NUTS** (MACADAMIA)

While not a requirement of the Code, bolding the allergen in the ingredient list makes it easier for allergic consumers to make the correct choice of product and is recommended as best practice.

The AMP should also include a process for checking label artwork, approving label changeovers, and visual checking of labelled product, in addition to other food safety or sensory checks. Whether the process is a simple label count, or an automated label match system tied in with an image-based inspection system, the effectiveness must be monitored and verified to ensure it is functioning effectively and avoids incorrect labelling.

Clean, unused packaging and labels must be stored away from allergenic ingredients to prevent cross-contact prior to use. Any unused items should be removed from the production area once processing is completed to prevent them being accidentally used for the wrong product.

Allergen alert: Are you a global customer?

If you source or supply food or ingredients into the global market you need to be aware that some countries have different regulations and may require declarations for a range of allergens which differ to those specified in Australia.

The definitions for the allergens may also differ, so careful checking of the country's regulations regarding intentional and unintentional allergens is important. For example, the European Union requires declaration of the presence of the allergens celery, mustard and molluscs.[6]

Ensure robust controls are in place in the AMP if an **allergen-free** label is being considered, as the risk for the target consumer is significant.

Precautionary labelling

'May contain', 'made on the same line', or 'may be present' are all forms of precautionary statements sometimes used on food labels. Such statements should only be used when there is evidence that a cross-contact risk exists and should not be used as a substitute for appropriate allergen management.

These are voluntary statements made by food manufacturers and are not regulated by the Code.

They should only be applied when the cross-contact risk is:

- documented *e.g.* through visual observation, test results or consumer feedback
- uncontrollable
- sporadic
- potentially hazardous.

VITAL® 2.0 and precautionary labelling

The Allergen Bureau's VITAL (Voluntary Incidental Trace Allergen Labelling) program is a standardised allergen risk assessment process for the food industry.[7] This science-based systematic approach reviews the allergen status of ingredients and the processing conditions and advises a labelling outcome that summarises the allergens present as ingredients and from cross-contact.

Where food allergens are present due to cross-contact, use of the VITAL program enables a decision to be made regarding precautionary statements.

The VITAL procedure is set out in the *Food Industry Guide to the Voluntary Incidental Trace Allergen Labelling (VITAL)' Program* and it is essential that staff using the VITAL tool are trained in how to use it.[8]

Allergen alert: Precautionary statements

Application of precautionary statements should be the result of risk assessment and supported by evidence.

Cleaning validation and verification

Removal of food residues or soil is an essential part of plant hygiene and is particularly important in allergen control. Proteinaceous soils containing allergens can be hard to remove from food contact surfaces, so the best mechanism to remove them from surfaces is by physical cleaning (sweeping, brushing, and vacuuming) followed by rinsing, and washing with cleaning agents.

Alkaline detergents are commonly used to remove proteinaceous soils. However, always check with your detergent supplier as to the most effective cleaning agents, temperatures, concentration, and contact time. As with microbiological contamination, methods that remove the allergen but spread food particles across surfaces, such as high-pressure hoses and compressed air should be avoided or used with a high degree of care.

The effectiveness of both manual and cleaning-in-place (CIP) systems need to be validated. Cleaning tools, cloths, sponges, and cleaning solutions should be single use, designated for foods with specific allergen profiles, or easily cleaned to reduce the potential for cross-contact. Also, be aware that recirculated CIP solutions may contain allergens.

Validation and verification of control measures are crucial steps in your AMP. Visual inspection on its own is insufficient as the surfaces may appear clean but low levels of allergen may still be present. Validated and effectively implemented cleaning programs are one of the most important control processes to support an AMP and manage cross-contact risk.

Validation

Validation of the effectiveness of a cleaning protocol provides evidence that the cleaning process will remove the allergen and reduce the potential for cross-contact. The allergen map is an important tool in identifying cross-contact points, guiding development of the cleaning protocol, and pinpointing sampling sites to collect evidence to validate the efficacy of the cleaning protocol. (See Appendix 1 for an example of the validation process). Use a combination of surface swabs and in-line samples to assist with monitoring cleaning and cross-contact points.

Allergen alert: Cleaning validation

Validation of the effectiveness of a cleaning protocol provides evidence that the cleaning process removes all traces of an allergen and reduces the potential for cross-contact.

Validation should be specific to the allergen and process, as allergens will behave quite differently in different formulations and on different surfaces.

Once the cleaning protocol is shown to be effective it should be repeated three times to demonstrate a consistently acceptable outcome. The protocol must be documented and revalidated regularly (at least annually) or if any substantial change occurs. Ensure all staff responsible for cleaning understand and comply with the protocol and document outcomes.

Once a cleaning validation has been performed for each allergen on each production line, a cleaning matrix can be documented. This will outline the cleaning requirements for product changeovers.

Verification

Cleaning verification involves checking and reporting on the efficacy of cleaning procedures following each day's production and ahead of the processing and packaging of non-allergenic foods.

Environmental monitoring is one aspect of verification and involves monitoring the effectiveness of a cleaning program. Details of environmental monitoring are described in Appendix 2.

The food manufacturing facility produces four product formulations: vanilla, caramel swirl, caramel choc, and double choc. Vanilla contains no allergens, while the remaining three contain different allergen combinations. Depending on the scheduling of processing, the cleaning protocol will vary:

(1) Prior to start-up, confirm the cleanliness of the processing line by visual check and review the monitoring results from the previous day.

(2) If the sequence of processing is vanilla, caramel swirl, caramel choc, and double choc, then only a flush is required between batches. If caramel swirl is processed before a changeover to vanilla, a full allergen clean is necessary, then a flush before processing caramel choc. A full allergen clean is necessary prior to the production of vanilla flavour product.

(3) To verify cleaning, collect five samples across a run of vanilla every fifth batch and submit for external analysis for the presence of milk, gluten, and egg.

Food product	Vanilla	Caramel swirl	Caramel choc	Double choc
Vanilla **(No allergens)**		Cleaning procedure 1* (Flush)	Cleaning procedure 1 (Flush)	Cleaning procedure 1 (Flush)
Caramel swirl **(Contains milk)**	Cleaning procedure 2** (Allergen clean)		Cleaning procedure 1 (Flush)	Cleaning procedure 1 (Flush)
Caramel choc **(Contains milk and gluten)**	Cleaning procedure 2 (Allergen Clean)	Cleaning procedure 2 (Allergen clean)		Cleaning procedure 1 (Flush)
Double choc **(Contains milk, gluten, and egg)**	Cleaning procedure 2 (Allergen clean)	Cleaning procedure 2 (Allergen clean)	Cleaning procedure 2 (Allergen clean)	

* **Cleaning procedure 1:** Visual check, rinse and flush

** **Cleaning procedure 2** (Allergen clean): Visual check, rinse, flush, and wash, then check for residues of milk/gluten/egg using validated lateral flow devices (LFD's) and swabs

Table 4: Example of a basic cleaning matrix

Analysis of allergens

Tests used in allergen analysis range from non-specific methods (*e.g.* ATP test swabs, protein swabs) to antibody-based screening lateral flow devices (LFDs), and quantitative methods such as ELISA (Enzyme-Linked Immunosorbent Assay), PCR (Polymerase Chain Reaction), and LC–MS (Liquid Chromatography Mass Spectrometry).

Non-specific methods involve swabbing and are often used for verifying cleaning procedures and indicate general hygiene. They are neither specific for an allergen residue, nor representative of the allergen load. Swabbing in general is qualitative (presence/absence) and can only be used in easily reached areas. Importantly, these methods may be affected by the presence of sanitisers and surfactants on surfaces and fail to identify potential issues associated with hang-up points (locations where food residues may accumulate) or within closed systems.

LFDs can be used qualitatively or semi-quantitatively to determine whether an allergen is present. LFDs are typically dipstick tests which provide a visible indication of the presence of an allergen. They are useful tools for manufacturers to check surfaces between product runs to be sure they are clean. LFDs are not reliable for testing products or ingredients unless they have been validated for each ingredient or product.

In contrast, ELISA detection methods can be used for validation and verification, and for assessing the status of raw materials and finished products. ELISA methods can detect the specific allergen of concern at low levels, however they may not detect all proteins implicated in food allergy and can be affected by the processing and nature of the food being tested.

This presents challenges when deciding whether to use a test kit or send samples to a commercial laboratory with expertise in allergen analysis. Choosing the correct type of analysis and test can be complex, particularly as a single test result should not be considered in isolation.

Allergen alert: Analysis

Only a fully validated method such as ELISA, should be used for verifying the allergen status of a finished product.

Further information on allergen analysis and testing limitations can be found in the *Food Industry Guide to the Voluntary Incidental Trace Allergen Labelling (VITAL) Program Version 2.0* and in Appendix 3.

Sampling

Cross-contact allergens may be distributed to a food intermittently, so even an extensive sampling program may not detect all cross-contact allergens.

The number of samples should take into account the type of potential cross-contact, and involve different time points within a batch, multiple batches, and possibly different production runs. Samples must not be composited.

To have confidence in the results, it is important to have a robust sampling plan which considers:

- the nature of the allergen (*i.e.* free-flowing liquid, paste, meal, whole or segmented nuts)
- the nature of the process (*e.g.* single continuous flow, multiple depositor heads, complex heat exchange columns, all of which will impact the distribution of any cross-contact allergen)
- the consequences if the presence of an unintentional allergen is not detected (*i.e.* consumers likely to eat the product)
- labelling claims stating, 'free from'.

Maintenance

Preventative maintenance is important in allergen management. Routine checks of washers, valves, rubbers, pumps, access and sampling points helps identify potential niches where allergenic material can be trapped.

Maintenance and repair teams must receive allergen training and be mindful of the risks of cross-contact presented by their tools. Where possible, maintenance crews should have designated, tagged, and colour-coded equipment. If equipment is shared, there must be validated and documented cleaning processes, with results recorded.

Maintenance of any dust collection, extraction or ducting systems, or filter and collection systems need to be carefully managed to prevent spillage or cross-contact, and only performed when production has ceased and equipment is covered.

Product development

When developing new food products, personnel need to understand and consider the implications of introducing new allergenic ingredients onto a site. The site should have a plan in place to manage the storage and handling of trial ingredients; the production and appropriate labelling of any trial products; and allow for downtime for additional cleaning. All staff should be made aware of any changed protocols due to the trial of new products.

Similarly, those involved in developing or implementing a marketing plan for a new product should understand and consider the implications for allergic consumers to ensure appropriate promotion and labelling of the product.

Training

The establishment of a site culture which supports the effective management of allergen risks requires training for all staff, including management and administrative personnel.

Allergen training should:

- be an essential part of the staff training pre-requisite program in the food safety program
- include casual and seasonal staff and visitors to the site
- address basic information on food allergy, regulations, allergen management, site- and role-specific control measures and the importance of correct labelling
- be updated as changes take place in regulations and site processes.

Allergen alert: Training

Staff who understand and appreciate the importance of allergen management will be more engaged and cooperative, and often suggest practical solutions to the challenges of allergen management.

Verification of your AMP

Verification of the performance of your AMP in your food safety program ensures the plan is working as designed. It is an ongoing requirement and should be conducted regularly.

It will typically include periodic sampling and testing of final products for the presence of undeclared allergens, reviews of process controls, tracking of process control data, audit of records and documents, reviews of deviations from the plan during processing, and the extent to which documented corrective action has been implemented.

Be prepared

Despite everyone's best efforts, things can go wrong. Managing the unintentional presence of allergens in a food requires being prepared and having a response plan which can be rapidly executed if required.

The plan should include an investigation stage, potential corrective actions, and a list of critical contacts, and be linked to the business' food recall procedure if a recall becomes necessary. If a recall is not warranted, options may include re-labelling, reworking, or disposal.

The DFSV *Dairy pathogen manual* identifies actions to take when a pathogen or toxin is found in a dairy product.[9] The same steps apply when managing the unintentional presence of an allergen in a dairy food.

Table 5: Steps to be taken to manage unintentional presence of an allergen in a food

Immediate action	Identify and isolate affected products
	Notify DFSV and other relevant authorities
	Recall or withdraw contaminated products
	Halt production and isolate affected process lines
Investigative action to determine cause	Review records of affected product
	Test raw materials, in-process materials, and finished product
	Enhance environmental sampling (Zones A, B, C, and D)
	Clean and verify effectiveness
	Identify corrective action and rectify the cause of the incident
Follow-up	Disposal of product
	Clearance of products
	Documentation, records and reporting

Allergen alert: Recall plan

As defined in the Code, all food manufacturers, importers and wholesale suppliers must have a written food recall plan, as described in Clause 12, Standard 3.2.2 – Food Safety Practices and General Requirements. The plan should cover the procedures, records, and staff responsibilities a business needs to have in place for a food recall. It should be kept up-to-date and be relevant for each manufacturer's operations.

Conclusions

The unintentional presence of allergens in dairy products presents a major risk to your business and to consumers. Managing the risks requires constant vigilance by you and your staff. It is essential that you:

- know your raw materials and the allergen risks associated with ingredients
- know your process and consider the elements that need to be assessed and addressed to support allergen management, including cross-contact risks
- isolate allergen containing ingredients and products, and use dedicated equipment, processing and packaging lines, and staff where possible
- schedule the production of both allergen and non-allergen containing product to reduce the risk of cross-contact
- label your product appropriately to comply with all regulations and to best inform the consumer
- educate staff concerning food allergy and allergen management at your site
- integrate all allergen management and control procedures within your food safety program
- regularly review and verify your AMP.

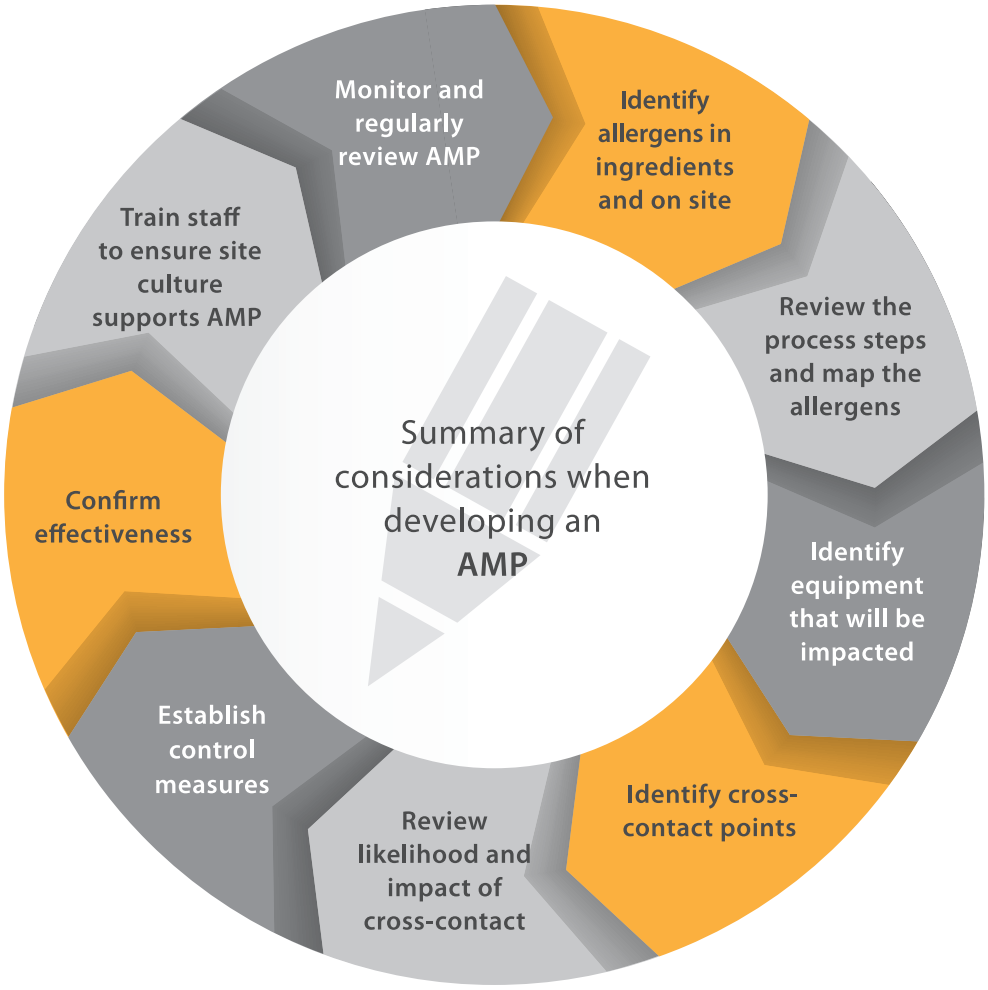


Figure 3: Summary of considerations when developing an AMP

Appendix 1: Allergen cleaning validation

An essential step when developing an AMP is to validate the effectiveness of allergen cleaning procedures. Ideally, the validation should be completed before the food safety program becomes operational.

When you have developed a proposed allergen-specific cleaning procedure, identify relevant sampling sites and proceed to validate the effectiveness of cleaning as follows:

(1) Run a product containing the allergen of concern through the product line *e.g.* egg.

(2) Before undertaking any cleaning, swab those areas identified as potential cross-contact sites on the product line. Focus on those hard to clean areas which may trap product residues. This enables the identification of swabbing sites as valid cross-contact points. It also establishes whether the allergen can be detected.

(3) Clean the product line according to the proposed cleaning procedure.

(4) Once the line and equipment has been cleaned, repeat the swabbing process. Always swab adjacent to the initial swab site, not the exact same area, as the original swabbing may have removed some of the allergen.

(5) Run a new product which does not contain the allergen of interest *i.e.* a non-egg product through the product line and collect samples of the finished product.

(6) Analyse samples (finished product and swabs) using a method appropriate for the specific allergen of concern (*e.g.* fully quantitative ELISA method for egg).

Where a reliable analysis is not available for the allergen of concern, use another allergen in its place to assess the effectiveness of the cleaning procedure. Non-specific methods such as ATP or protein swabs are not appropriate for allergen cleaning validation purposes.

(7) If the swabs and samples are free from the specific allergen this indicates the cleaning procedure is effective. It should then be repeated to provide a minimum of three sets of validation results. If the procedure is found to be ineffective, further development of the allergen cleaning procedure will be necessary.

Establishing an appropriate validation procedure can be complex and should be considered carefully. Collaborate with a reliable testing laboratory or analyst prior to undertaking cleaning validation trials to ensure the sampling and testing methods are appropriate.

Sampling

- As a guide, take a minimum of five samples of finished product.
- The number of samples should reflect the size of the production run or batch, the nature of the process, and whether the allergen is likely to be evenly distributed (homogeneously) or irregular and unevenly distributed (non-homogeneous product).
- If the cross-contact is likely to be irregular or unevenly distributed, or the allergen is present as a particulate, take a larger number of finished product samples.
- Analyse samples individually, do not composite.

Appendix 2: Environmental monitoring for allergens

Environmental monitoring provides evidence that your AMP is effective. Sampling sites should be selected in conjunction with the existing monitoring programs using the allergen map and risk assessment.

Divide the site into zones based on production pathways, the potential risk of cross-contact and its impact. Food contact surfaces are the highest risk and are classified as Zone A. Zones B, C, and D will generally be non-contact surfaces that could contribute to cross-contact via food handlers, equipment, and air or water circulation.

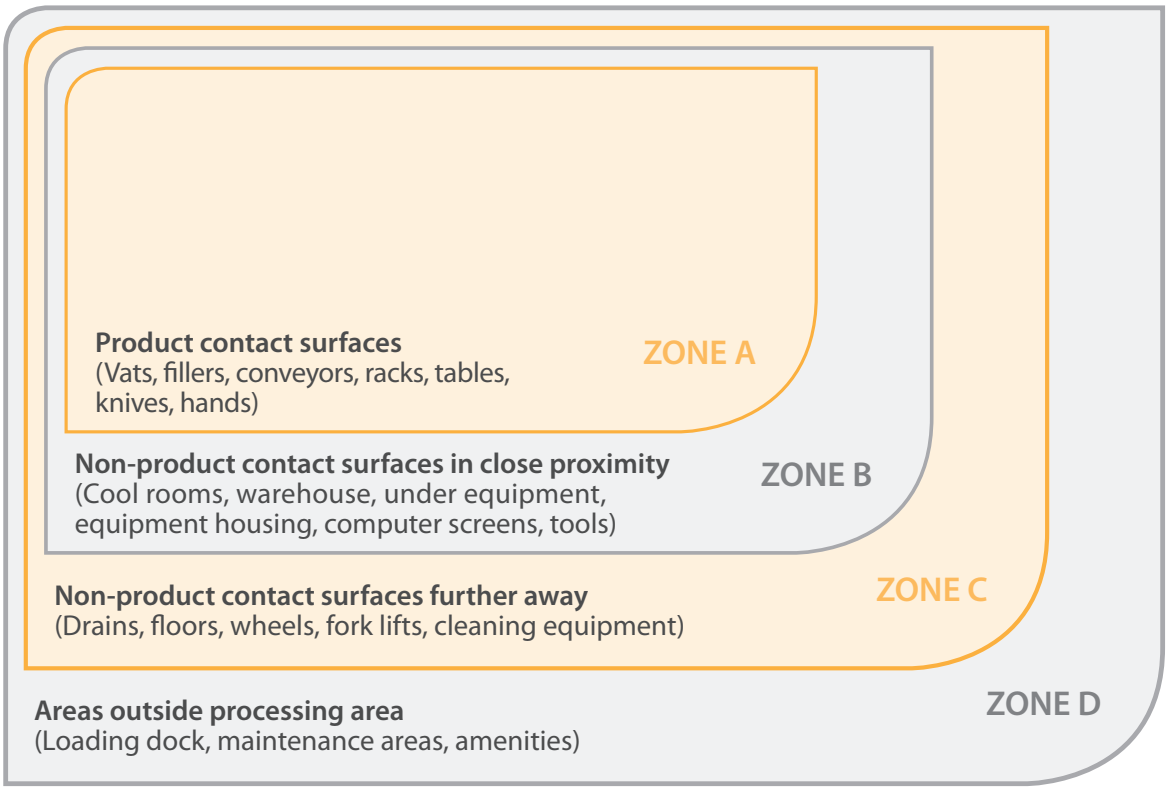


Figure 4: Allergen monitoring zones

Zoning allows manufacturers to prioritise monitoring (Table 6), and the review and trending of test results can help identify patterns or highlight unexpected sources of allergen cross-contact.

The number and location of the swabs taken will be specific to each site and facility and should be related to the risks identified by the site. The larger the sample number, the greater the potential to identify poorly cleaned areas or cross-contact sites. Where possible, samples should be taken from a range of equipment and different surface types for allergen analysis. ATP or protein swabs are not suitable for environmental monitoring, and compositing of swab samples is not appropriate.

The program should be re-examined if:

- there is a critical change at the site such as new equipment or cleaning procedure
- a new allergen/or new form of an existing allergen is introduced
- product results indicate the presence of an unexpected allergen
- a customer complaint is received.

Table 6: Zones and frequency of monitoring

Zone	Description	Risk	Example	Frequency and details
A	Product contact surfaces where the product has direct contact with surfaces which may contribute to allergen cross-contact	High	Conveyors, belts, vats, pumps, hoppers, mixers, packing/filling machines, delivery hoses	• Multiple samples from a range of sites • Allergen-specific swabs based on products produced • Monitor frequently **This type of monitoring can form part of the verification of cleaning procedures**
B	Non-product contact surfaces in close proximity, which may be exposed to allergens, through contact or airflow	Medium	Conveyors, equipment exteriors, air vents, piping, cleaning and wash-up areas, warehouses, WIP storage areas, coolers. chillers, freezers	• Representative samples, on a rotational basis (*i.e.* rotate the site or the allergen) • Allergen-specific swabs based on production • Monitor monthly **This type of monitoring can form part of the verification of cleaning procedures**
C	Non-product contact surfaces located further from direct product contact	Low	Walls, floors, hoses, forklifts, pallets, pallet jacks	• Rotate sampling of sites and allergens to consider all surfaces and allergens handled • Monitor every three months
D	Surfaces external to the production areas and/or premises	Low	Change rooms, entry access, raw material receipt, shipping areas	• Multiple sites where risk is identified as highest • Rotate sampling of sites and allergens to consider all surfaces and allergens handled • Initially establish a base line and then monitor annually to confirm control

Environmental monitoring is used to assess the effectiveness of the AMP within a dairy manufacturing facility. With a validated cleaning procedure in place, and allergen management controls in position, such monitoring enables ongoing verification of allergen controls.

Appendix 3: Laboratories and analysis

The analytical testing of raw materials and ingredients, in-line swabs, and finished product for the presence of identified allergens is a critical aspect of a manufacturer's AMP.

The results from such analyses verify the effectiveness of documented allergen management practices and provide assurance that the AMP is being followed.

Laboratory analysis for allergens is undertaken for a variety of reasons, including:

- as a screening tool for raw materials and ingredients *e.g.* verifying the certificate of analysis (provided by an approved supplier)
- to confirm raw material and ingredient storage and handling practices are effective
- to assist in allergen mapping, and to substantiate allergen risk assessments
- to validate allergen control processes and investigate control failures
- to assist in verifying 'free from' claims on the label
- to confirm the allergen status of finished products
- to assess the effectiveness of cleaning protocols
- to investigate customer complaints.

When deciding on the laboratory and test methods to use, consider the following.

Laboratory requirements

The laboratory should have:

- National Association of Testing Authorities (NATA) or equivalent accreditation in the field of allergen analysis
- demonstrated specific expertise in the field of allergen analysis using externally validated analysis methods where possible
- participated in appropriate proficiency programs, and achieved acceptable performance to verify ability to accurately perform the analysis
- performed appropriate quality control of methods and have a laboratory investigation protocol for outlying results
- verified the performance of test kits as suitable for the product submitted, or can provide external evidence that the sample is suitable for analysis
- provided clear details about the method and the reporting units provided in the results. Results may be reported as either parts per million protein or parts per million of the food *e.g.* peanut analysis may be reported as 2.6 ppm protein or 10 ppm total peanut.

Test method requirements

Whether using an external laboratory or performing in-house analysis it is important to choose test methods or kits:

- from a company with an established history and record of performance
- where the performance of the method has been peer reviewed, published or approved by an international body *e.g.* AOAC, or has external validation data to support performance
- that have a history of performing well in proficiency programs
- that are sufficiently sensitive, specific and robust and will detect the allergen of interest
- that detect the correct form of the allergen *e.g.* detect beta lactoglobulin where the ingredient is whey powder, or casein if the ingredient is sodium caseinate. (If the product contains both casein and whey, a total milk kit may be appropriate).

Appendix 4: Case studies

Case study 1

Company Y produces dairy-based yoghurt products and has decided to manufacture a coconut-based yoghurt as an alternative market offering. They begin production of coconut-based yoghurts using the same equipment as is used for the dairy yoghurt and have assumed that standard cleaning practices will be sufficient to remove milk residues. No allergen cleaning validation is performed. The new coconut product does not carry a 'free from' claim, nor does it declare milk or possible cross-contact with milk on its label.

Soon after production commences they receive a complaint from a milk allergic consumer. Analysis is performed on the customer's sample and it shows levels (greater than 100 ppm) of milk protein. Analysis of the company's retained samples indicate that milk is present. Further analysis of other batches shows a variable level of milk protein, so it is clear that significant cross-contact has occurred.

Investigation at the site raises concerns that the standard cleaning protocol is not sufficient to remove milk from the line and confirms that cleaning validation has not been performed. The company initiates a voluntary recall and all production of coconut-based yoghurt ceases while a cleaning validation takes place.

With the addition of a variable flushing cycle and agitation, and push through of first run coconut product, the new cleaning protocol is validated as being effective and production of the coconut-based, non-dairy yoghurt recommences. The site also institutes an allergen hold and release program for the coconut yoghurt.

Learnings: Always validate cleaning programs and undertake verification activities on a regular basis.

Case study 2

Five weeks after initiating major changes to cleaning and verification activities, Company Y again finds milk protein in their coconut-yoghurt products and processing stops. Site records and the verification program are reviewed and records of visual checks, cleaning, monitoring and control processes show no apparent cause for the detections.

An analysis of raw materials used in the production of the coconut-based yoghurt shows milk protein in the coconut powder used as the base for the yoghurt. Further investigation of the coconut powder shows that while the brand is the same, the packaging is slightly different. This deviation was identified at receipt however it was not considered significant as the powder had come from the same ingredient supplier, a trading house.

Follow-up with the trading house established that increased demand meant they had to source a larger supply of coconut powder, and their international merchant had provided a similar but not identical powder. The trading house had not confirmed the allergen status of the replacement powder nor had they notified Company Y or provided an updated PIF.

Discussions with the trading house and their international supplier identified that the supplier provides two forms of coconut powder, one dairy free and the other containing sodium caseinate as an emulsifier. The trading house advised that they had not considered this was an issue as the second powder was less expensive and the company producing the yoghurt was known to be a dairy-based facility.

The company changed suppliers, requested certificates of analysis for milk from the new supplier for each batch of coconut powder, initiated a vigorous PIF review program to ensure there were no other unidentified risks, reviewed their ingredient receipting protocol, updated the training of all staff, and continued its positive release program for the coconut yoghurt.

Learnings: Ingredients can be a source of allergens. Always review incoming raw materials and ingredients for the potential presence of undeclared allergens. Regularly check there has been no unadvised changes to the formulation of supplied ingredients.

Glossary

Allergen: naturally-occurring proteins that cause abnormal immune responses in allergenic individuals affecting various organs in the body and causing a range of symptoms.

Allergen management plan (AMP): a documented system that identifies, controls, educates and communicates the risk presented by food allergens from raw materials to finished products.

Allergen profile: the allergens expected to be present in an ingredient or food.

Anaphylaxis: severe, life-threatening, generalised or systemic hypersensitivity reaction in an individual sensitised to a substance such as an allergen.

Certificate of analysis (COA): document issued by a laboratory indicating that a particular batch of product has been analysed for a specific substance, by a defined method, and has given a specified result.

Cleaning: removal of soil, food residue, dirt, grease or other objectionable material that may contaminate food.

Cleaning validation (allergen): a process to determine that the proposed cleaning procedure will effectively remove or reduce the presence of an allergen in a process line or piece of equipment to an acceptable level.

Contamination: introduction or presence of a contaminant in the dairy food or dairy food environment.

Cross-contact: occurs where an allergen or allergenic ingredient unintentionally makes contact with another food, environmental surface, or piece of equipment, and crosses over into a food that doesn't contain the allergen.

Food allergen: food ingredient or food components that can cause allergic reactions, including anaphylaxis.

Food intolerance: hypersensitive reaction which is non-allergic, causing similar symptoms to a food allergy, but generally less serious and often limited to digestive problems *e.g.* lactose intolerance.

Food safety program: document that identifies potential hazards, describes how such hazards can be controlled/monitored, and defines appropriate corrective action when a control measure is found to be outside acceptable limits.

ELISA: enzyme-linked immunosorbent assay is a highly sensitive and specific technique that uses antibodies and colour change to accurately measure the amount of a substance in a sample *e.g.* allergen.

Good manufacturing practices (GMP): operational conditions and requirements necessary to enable a food business to ensure hygiene during food processing and to produce food safely.

Hang up point: location on a manufacturing line where food residue may accumulate instead of flowing through freely.

Hazard Analysis and Critical Control Point (HACCP): system which identifies, evaluates, and controls hazards associated with food safety.

ppm: reporting units for quantitative allergen analysis *i.e.* parts per million (milligrams per kilogram).

Precautionary allergen statements: voluntary statements used on food labels advising consumers of the potential presence of allergens in a food *i.e.* from cross-contact.

Push through: practice of pushing through an ingredient, product, or flush solution to purge residue of a previous product.

Standard operating procedure (SOP): written document or instruction detailing all steps and activities of a process.

Sulphites: may be naturally occurring substances, or added to ingredients, foods, and drinks as preservatives. They can cause severe reactions in sensitive individuals.

Validation: obtaining evidence that a control measure or combination of control measures, if properly implemented, is capable of controlling the hazard to a specified outcome.

Verify/verification: application of tests, procedures, and other methods, in addition to monitoring to determine compliance with the food safety program.

VITAL®: Voluntary Incidental Trace Allergen Labelling program is a standardised allergen risk assessment process.

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