

Developing a food safety program:  
guidelines for dairy food  
manufacturers

February 2018



## Notes on this guide

This guide provides practical, step-by-step instructions to help you develop a food safety program (FSP). It provides enough information and guidance to assist you to develop a food safety program tailored to your business. It is supported by other DFSV publications such as the *Dairy pathogen manual* and *Hygienic design: guidelines for dairy food manufacturing premises*.

It should be read in conjunction with the *Model food safety program* – a Word document that the licence holder can complete as they assemble the information and draft the program.

Once completed, the FSP will need to be assessed by a Dairy Food Safety Victoria food safety manager to ensure all risks and hazards associated with your business have been identified and assigned monitoring and control measures. It demonstrates your commitment to managing food safety risks, and ensuring your products are safe.

Your FSP will also be subject to periodic Dairy Food Safety Victoria audits to ensure compliance with the documented FSP is being maintained.

Your FSP should be reviewed on a regular basis, and revised any time your business undergoes a major change in process; you introduce new ingredients or new formulations; or where new food safety hazards have been identified.

Always discuss proposed amendments to your FSP with your food safety manager.

## Further information

For further information on food safety or FSPs please contact Dairy Food Safety Victoria. A wide range of food safety information is also available on the Department of Health and Human Services, Food Standards Australia New Zealand, and other websites.

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# Introduction

Consumers of dairy products expect them to be safe and suitable.

A Dairy Food Safety Victoria licensed dairy manufacturing business must have a food safety program (FSP) in place to demonstrate compliance with the Australia New Zealand Food Standards Code (the Code).

The requirements are described in Standard 4.2.4<sup>1</sup> and Standard 3.2.1<sup>2</sup> of the Code.

For example, a dairy manufacturer is required to:

- (a) *identify the potential hazards that may be reasonably expected to occur in all processing and handling operations in the business*
- (b) *identify where during processing and handling operations each hazard identified above can be controlled and the means of control*
- (c) *provide for the systematic monitoring of those controls*
- (d) *provide for corrective action when that hazard is found not to be under control*
- (e) *provide for the regular review of the program by the business to ensure its adequacy*
- (f) *provide for the appropriate records to be kept by the business demonstrating compliance with the food safety program.*

The drafting of a FSP can be a daunting task – but it doesn't need to be. This guide has been prepared to assist you to understand, develop and implement your FSP. It provides a step-by-step guide to preparing your FSP and identifies the documents you need to develop.

While there are many consultants able to assist businesses to write their FSPs, there are significant benefits to doing it yourself. Nobody knows your business operations and processes better than you. Plus, if you do it in-house it will strengthen your food safety knowledge and enable you to demonstrate your commitment to compliance to food safety regulatory requirements.

However, some sections of your FSP may require access to additional specialist technical input because you may not have the in-depth technical knowledge of food safety risks within your business.

It is helpful to think of your FSP as a document that describes the way your business operates. It includes content on what you are manufacturing, where you are making it, who does what and how they have been trained, monitoring activity, actions to be taken before things get out of control, what records are kept, and who will update the program. It tells a story.

There is no rigid design for the way you prepare your FSP, however the companion document to this guideline (**Model food safety program**) provides a common-sense framework which you may use when preparing your documentation.



<sup>1</sup> Standard 4.2.4. <https://www.legislation.gov.au/Details/F2015C00190>

<sup>2</sup> Standard 3.2.1. <http://www.comlaw.gov.au/Series/F2008B00578>

# What is a food safety program?

A FSP is an overarching document that describes your products, how you manufacture them, the hazards that may be associated with these products, and the controls you have in place to manage those hazards and assure food safety.

The FSP contains details of your business, your hazard analysis and critical control point (HACCP) plan, and your pre-requisite programs (PRPs).

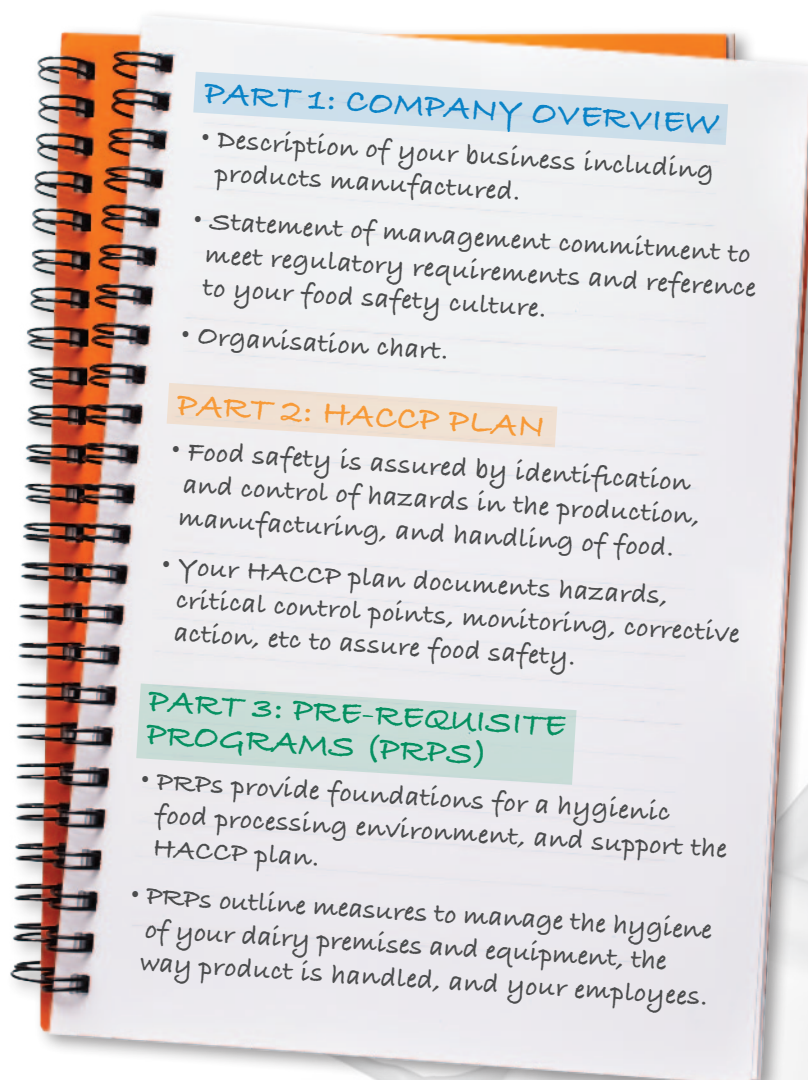
When drafting the FSP, imagine you are telling the story of your business and your food safety objectives.

It is important to identify who keeps the FSP current and keeps records. You need to notify Dairy Food Safety Victoria, in writing, of any changes pertaining to the products manufactured by the business or processes used to

manufacture the products. Such changes need to be accepted prior to commercial implementation to ensure critical control points which could affect public health have been identified and will be managed.

Finally, there are a variety of ways you can document and present your FSP. To ensure the document serves your needs and for ease of auditing (desk and compliance audit by Dairy Food Safety Victoria) you may wish to follow the layout described here. Note that extensive documentation does not necessarily provide a greater assurance of product safety. Be strategic and maintain the optimum (not maximum) paperwork for your FSP. Programs that create paperwork for the sake of documenting everything can be counter-productive.

## Food safety program (FSP)





## Part 1: Company overview



## Part 1: Company overview

The first part of your FSP document should contain a brief overview of your business, and describe the food safety objectives to which the business strives. It should include:

- a description of your business
- a list of the food products your business is manufacturing
- an outline of your objectives
- the scope of your program
- your organisation chart, including key personnel
- a statement of the business's intent and commitment to producing safe and suitable dairy foods.

Everyone in your business has a role in ensuring food safety. Food safety culture comprises a commitment to providing safe food through continuous improvement, including the provision of resources and support to ensure staff have the necessary skills, knowledge and competence to perform their duties. A strong food safety culture means staff understand the importance of safe food and commit to doing whatever it takes to achieve that goal.

### COMPANY COMMITMENT

This food safety program forms the framework of the food safety management system of ***Vic Dairy Products Ltd*** operating from ***14 Burke Avenue, Hawthorn.***

***Vic Dairy Products Ltd*** has considerable experience and expertise in the manufacture of safe and suitable fermented dairy products. It is our policy to ensure that all our manufacturing processes meet the requirements of the *Food Act, 1984*, the *Dairy Act, 2000*, and the Australia New Zealand Food Standards Code as enforced by Dairy Food Safety Victoria.

We promote a strong food safety culture and our employees demonstrate an ongoing commitment to our policies and procedures, ensuring that they are implemented and maintained across all our manufacturing activities.

***Ms Devon Vosges*** is the management representative responsible for oversight of the food safety program. The management representative has the full support of company management to establish, implement and maintain the food safety program and to action any conditions or directives issued by DFSV in order to ensure continued maintenance as a licensee.



## Part 2: HACCP plan





## Part 2: HACCP plan

A HACCP plan identifies hazards associated with dairy products, and assists in identifying and establishing control measures and procedures to reduce or eliminate the hazards at critical control points (CCPs) in the manufacturing process.

To be effective, your HACCP plan needs a detailed analysis of your raw materials and all steps in manufacturing processes, and the establishment of controls at defined CCPs.

HACCP is based upon seven principles:

### 1. Hazard analysis

- Analyse process to determine hazards significant for food safety

### 2. Determine CCPs

- Examine each process step and determine points where control can be applied to prevent or eliminate a food safety hazard or reduce it to an acceptable level

### 3. Critical limits

- Determine the boundary of acceptability and unacceptability and establish critical limits for each CCP

### 4. Monitor CCPs

- Establish a system to monitor control of each CCP by conducting observations or measurements

### 5. Corrective action

- Establish corrective action when monitoring indicates that a CCP is not under control

### 6. Verification

- Establish procedures for verifying the system is working effectively

### 7. Recording

- Document and record all procedures, monitoring and verification activities and corrective actions

A HACCP plan should be developed for each separate manufacturing process. No one size fits all! In fact, the degree of detail in each plan will vary depending on the manufacturer's processing operations. Importantly, you need to prepare a HACCP plan for each separate dairy product or product formulation, as well as for different processes, and keep them up-to-date. The HACCP plan should be reviewed at least annually and changes made when any modification is made to the product, ingredients, equipment, or any step in the process.

## Part 2: HACCP plan

### Developing a HACCP plan

When preparing a HACCP plan, it is important to follow a logical sequence to ensure all aspects of manufacturing are considered. Failure to do this can result in a system that does not accurately reflect the manufacturing process. Table 1 describes the twelve steps for developing a HACCP plan.

**Table 1:** Steps for developing a HACCP plan

<b>Step 1</b>	Assemble HACCP team	
<b>Step 2</b>	Describe product	
<b>Step 3</b>	Identify intended use	
<b>Step 4</b>	Construct flow diagram	
<b>Step 5</b>	On-site confirmation of flow diagram	
<b>Step 6</b>	Hazard analysis – list all potential hazards	(Principle 1)
<b>Step 7</b>	Determine CCPs	(Principle 2)
<b>Step 8</b>	Establish critical limits for each CCP	(Principle 3)
<b>Step 9</b>	Establish monitoring for each CCP	(Principle 4)
<b>Step 10</b>	Establish corrective actions	(Principle 5)
<b>Step 11</b>	Establish verification procedures	(Principle 6)
<b>Step 12</b>	Establish documentation and record keeping	(Principle 7)

It is important to keep records that describe what occurred at each step of developing a HACCP plan.

### Step 1: Assemble HACCP team

Management should assemble a team with the required operational, product, and processing knowledge, and technical and regulatory expertise to prepare and develop the HACCP plan. The creation of multidisciplinary teams is a strongly entrenched aspect of the HACCP system, and results in a better, more comprehensive FSP. Effective HACCP teams interact and share knowledge resulting in positive impacts on food safety.

The necessary expertise may not be available on site in the case of small-scale manufacturers, so outside expertise and advice may be required to develop the HACCP plan.

#### Example of a multidisciplinary team

Team	Name	Position/skill set
Team leader		Quality assurance manager
Member		Microbiologist
Member		Laboratory manager
Member		Production manager
Member		Maintenance manager

## Step 2: Describe product

Prepare a full description of the dairy product/products – including relevant information about the ingredients, the physicochemical properties (e.g. pH, salt concentration, water activity, redox potential) and how each product is prepared, packaged, and stored.

### Example of a product description proforma

<b>Product name</b> (full name of finished product)	Low-fat yoghurt (plain)
<b>Ingredients</b>	Whole milk, skim milk powder, live culture
<b>Composition:</b> Fat total (saturated) Protein Carbohydrate (sugars) Sodium  <b>Physicochemical properties:</b> pH Water activity	4.0% fat (2.0% saturated fat) 9.0% protein 4.0% carbohydrate (2.3% sugars) 30 mg sodium  pH <4.5 $A_w > 0.97$
<b>Processing overview</b>	<ul style="list-style-type: none"><li>• Raw milk mixed with skim milk powder to achieve a total solids concentration of 15% solids</li><li>• Product mix stirred and heated to 88°C and held for five minutes</li><li>• Cooled to 42°C and inoculated with starter culture comprising <i>Lactobacillus bulgaricus</i> and <i>Streptococcus lactis</i></li><li>• Fermented for ~8 hours at 42°C. pH monitored to ensure the final pH is &lt;4.5</li><li>• Cooled to 5°C, transported to filling machine, packaged, labelled, and into cold room at 5°C</li></ul>
<b>Method of preservation</b>	Yoghurt is made from pasteurised milk, and has a pH <4.5 and is stored at refrigeration temperatures (5°C) for the duration of its shelf life
<b>Allergen advice</b>	Contains milk and milk products
<b>Packaging</b>	Packaged and sealed in plastic tubs Volumes: 110ml, 600ml, and 1 litre
<b>Storage conditions</b>	4°C
<b>Shelf life</b>	21 days
<b>Distribution</b>	Warehouse on premises then to supermarkets via wholesaler in refrigerated van

A separate product description is required for each different product line or stock keeping unit (SKU).

There should also be consideration of the allergen status of the product and if it requires allergen statements on the label, or precautionary statements to reflect that the processing facility makes other products that contain allergens e.g. ground nuts, tree nuts, soy products, egg, gluten, sesame products, etc.



## Part 2: HACCP plan

### Step 3: Identify intended use

The intended use of the product should be described, reflecting the expected way the consumer will use the product. It is also important to identify if vulnerable groups will consume the product *e.g.* aged, infants, allergenic consumers.

#### Example of intended use

Product	Low-fat yoghurt (plain)
Intended use	The low-fat product is unsweetened and may be consumed with complementary ingredients such as fruit or nuts May be consumed as a snack, or as an ingredient in dips and sauces
Condition before consumption	Stored refrigerated May be brought to room temperature before consumption
Consumers	General population including the elderly and pregnant women

### Step 4: Construct flow diagram

Prepare a flow diagram to accurately describe the manufacturing process. Ensure all steps are included in the diagram, as well as identify all inputs such as water, ingredients, and packaging. The flow diagram should be revised periodically to ensure it remains current.

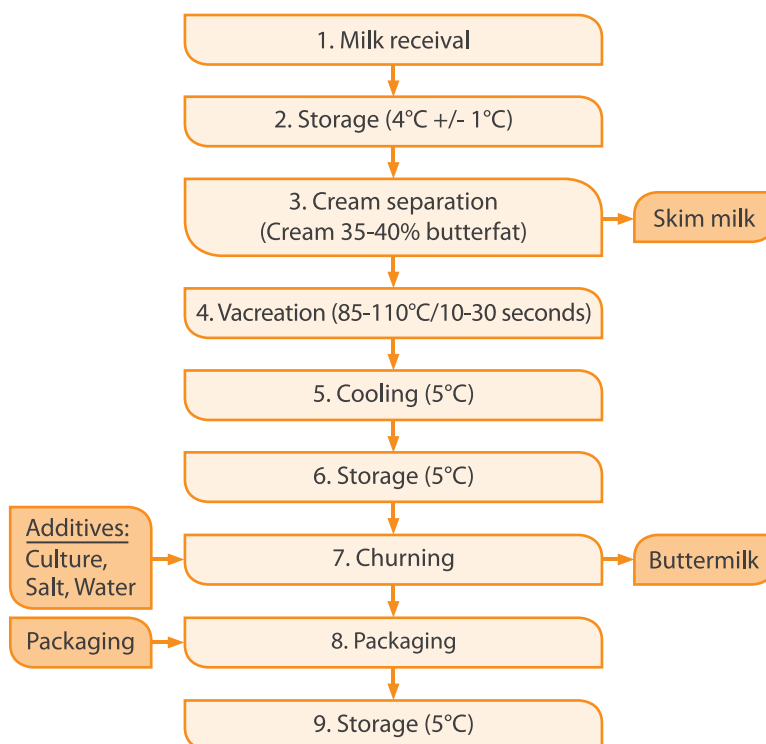


Figure 1: Example of a flow diagram for the manufacture of cultured butter

## Step 5: On-site confirmation of flow diagram

The HACCP team should confirm the accuracy of the flow diagram by observing processing operations during all stages and hours of operation, and amend where necessary. The flow diagram should be reviewed periodically to ensure accuracy.

For start-up manufacturing facilities, the flow diagram presented in the FSP at desk audit will need to be confirmed when production has commenced.

## Step 6: Hazard analysis (principle 1)

The HACCP team should collect and evaluate information in order to identify and document all hazards that may be present in the product. Hazards are agents that may cause illness or injury resulting from ingestion of the food, and can be classified as microbiological, chemical (including allergens), or physical.

Microbiological hazards remain a significant concern in the dairy industry. However, the management of allergens in foods is gaining in prominence, because of severe consequences such as death from anaphylaxis due to food allergy.

### Example of hazards associated with cheddar cheese

Cheddar cheese	Hazard
Microbiological hazards (including bacteria, bacterial toxins, moulds, viruses)	Pathogenic <i>Escherichia coli</i> <i>Salmonella</i> spp. <i>Staphylococcus aureus</i> <i>Listeria monocytogenes</i>
Chemical hazards	Residues of veterinary drugs Environmental contaminants e.g. mycotoxins, heavy metals Cleaning and sanitising chemicals
Physical hazards	Glass Metal Wood fragments Plastic

## Part 2: HACCP plan

The next step is to then conduct a hazard analysis to identify which hazards are of such a nature that their elimination or reduction to acceptable levels is essential to produce safe dairy food. This should include the:

- likely occurrence of the hazard and the consequences or severity of any adverse health effects
- qualitative and/or quantitative evaluation of the presence of hazards
- survival or multiplication of microorganisms of concern
- production or persistence in toxins, chemicals or physical agents
- any conditions leading to the above.

A risk matrix table can be used to assess the likelihood and severity of a hazard – see an example of one form of matrix below.

**Table 2:** Risk ranking matrix

Risk ranking		Consequence (health effect)				
		<i>Insignificant</i>	<i>Minor</i>	<i>Moderate</i>	<i>Serious (incapacitating)</i>	<i>Severe (life threatening)</i>
Likelihood (Risk)	<i>Highly likely</i>	Medium	High	High	Extreme	Extreme
	<i>Likely</i>	Medium	Medium	High	High	Extreme
	<i>Possible</i>	Low	Medium	Medium	High	Extreme
	<i>Unlikely</i>	Low	Medium	Medium	Medium	High
	<i>Rare</i>	Low	Low	Medium	Medium	High



Initially the focus of the HACCP plan should then be on those risks that are considered to be high and extreme. For example, the presence of *Listeria monocytogenes* on a semi-hard cheese would be ranked as a **high** risk (Severe consequence and Unlikely likelihood). However, consideration of how to manage medium risks in the HACCP plan is also essential.



## Step 7: Determine critical control points (principle 2)

The step in the process where a significant hazard is controlled is referred to as a critical control point (CCP). After identifying all significant hazards, it is necessary to identify where they arise and where they can be controlled. Note that more than one control measure may be required to control a specific hazard and more than one hazard may be controlled by a specified control measure.

A CCP can be determined by using a decision tree. In recent years, the introduction of pre-requisite programs has changed our thinking on CCPs. When HACCP was first introduced, manufacturers listed many CCPs because of a lack of pre-requisite programs. Modern HACCP plans are now supported by a detailed set of pre-requisite programs that enable manufacturers to better manage the safety of products and this has reduced the need to have as many CCPs.

Hence, the original Codex decision tree has been modified to include an additional question – is this hazard managed by a pre-requisite program? This means that only the significant hazards which are not managed by pre-requisites continue on through the decision tree to possibly identify CCPs.

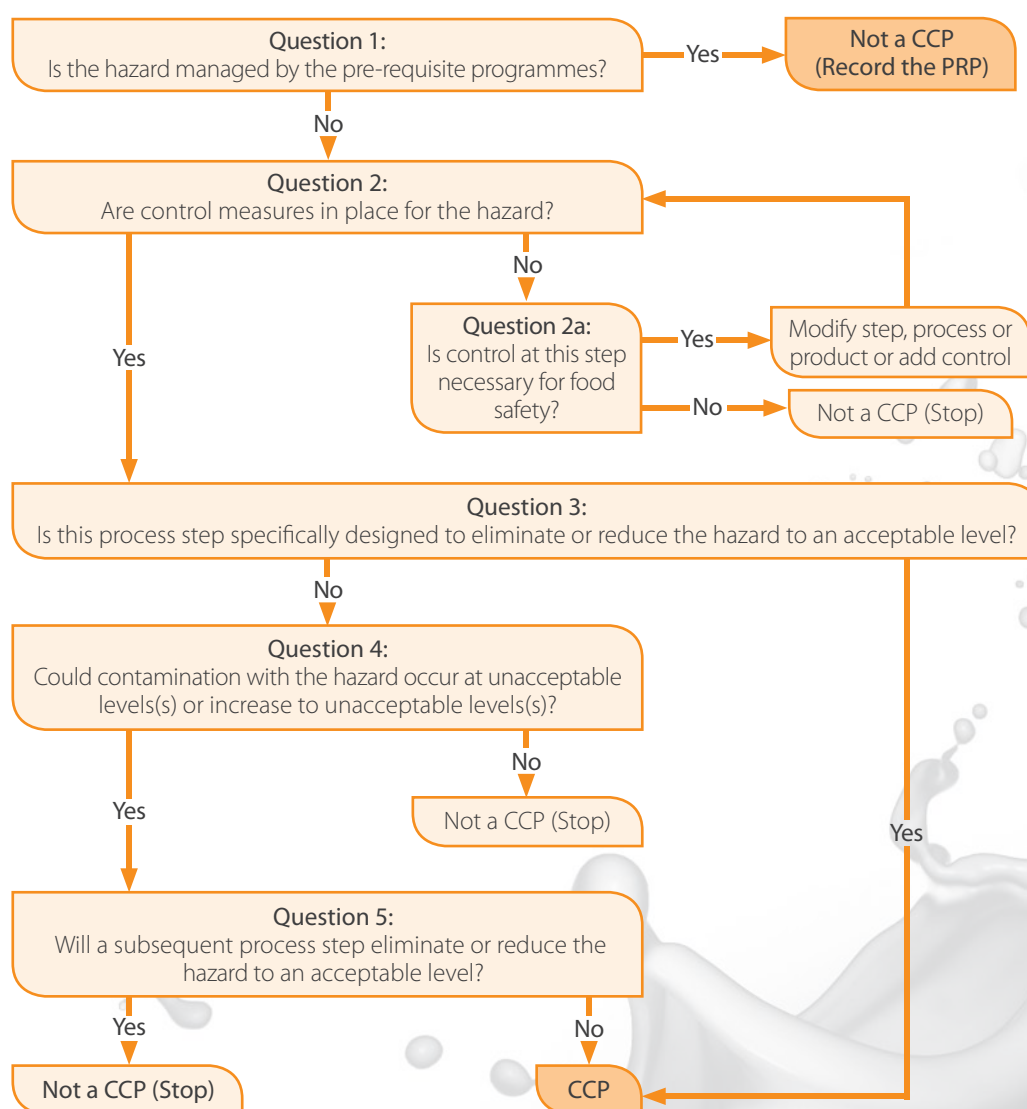


Figure 2: Codex decision tree

## Part 2: HACCP plan

The Codex decision tree enables a manufacturer to identify CCPs and their control measures.

### Example of identifying a CCP for pasteurisation of milk

Process step	Hazard	Control measure	Q1	Q2	Q3	Q4	Q5	CCP
Pasteurisation of milk for market milk	Survival of vegetative bacteria <i>e.g. Salmonella</i> spp., <i>S. aureus</i> , <i>Campylobacter</i> spp., <i>L. monocytogenes</i> , <i>E. coli</i>	Time and temperature of pasteurisation (72°C for 15 seconds)	No	Yes	Yes	-	-	YES

### Example of identifying a CCP for formulation of a dairy dessert

Process step	Hazard	Control measure	Q1	Q2	Q3	Q4	Q5	CCP
Formulation of a flavoured dairy dessert	Growth of selected pathogenic bacteria during product storage <i>e.g. Salmonella</i> spp., <i>S. aureus</i> , <i>Campylobacter</i> spp., <i>L. monocytogenes</i> , <i>E. coli</i>	Addition of sufficient preservative to formulation to prevent growth	No	Yes	No	Yes	No	YES

If a hazard has been identified at a step where control is necessary for food safety, and no control measure exists, then the product or process should be modified to include a control measure.

The decision tree provides a logical reasoning approach for determining CCPs, but it may not be applicable to all situations. Training in how to use the decision tree may be required.



## Step 8: Establish critical limits for each CCP (principle 3)

Once the CCPs have been identified, critical limits for each CCP should be specified and validated where necessary. In some cases, a CCP may have more than one critical limit. Monitoring criteria often include specified limits such as temperature, time, moisture level, acidity/pH, and water activity.

### Example critical limits

Process step	Hazard	Control measure	Critical limits	Monitoring	Corrective action	Records
Pasteurisation of milk for market milk	Survival of vegetative pathogenic bacteria <i>e.g.</i> <i>Salmonella</i> spp., <i>S. aureus</i> , <i>Campylobacter</i> spp., <i>L. monocytogenes</i> , <i>E. coli</i>	Time and temperature of heating (Operates at 74.5°C, and diverts below 74°C)	72°C for 15 seconds	<b>What:</b> Check data recorder temperature recording <b>How:</b> Visual <b>When:</b> Start-up, and every hour until completion of run <b>Who:</b> Operator	If temperature dips below 74°C, check flow diversion value has activated. If not, place product on hold pending assessment Investigate cause of problem	Record data on production make sheet for each shift

Process step	Hazard	Control measure	Critical limits	Monitoring	Corrective action	Records
Formulation of a flavoured dairy dessert	Growth of pathogenic bacteria during product storage <i>e.g.</i> <i>Salmonella</i> spp., <i>S. aureus</i> , <i>Campylobacter</i> spp., <i>L. monocytogenes</i> , <i>E. coli</i>	Incorporation of benzoic acid (700 mg/kg) and nisin (10 mg/kg GMP) in dessert at mixing	<b>Benzoic acid:</b> 350g ACME benzoic acid powder per 500kg mix <b>Nisin:</b> 10g ACME nisin powder per 500kg mix	<b>What:</b> Check addition of correct weight of preservatives at formulation <b>How:</b> Weighed aliquots <b>When:</b> Each batch of mix <b>Who:</b> Operator	Reprocess mix when errors occur during formulation or disposal if out of specification	Addition of volume of preservatives recorded for each batch
			<b>Benzoic acid:</b> 690–700 mg/kg <b>Nisin:</b> 9–10 mg/kg	<b>What:</b> Test final product for level of preservatives <b>How:</b> Sample and test <b>When:</b> Each batch of mix <b>Who:</b> QA manager	Dispose of out-of-specification product	Level of preservative in each batch

An important aspect of identified control measures is the need to validate their effectiveness. Validation involves a process through which evidence is obtained to demonstrate that a food safety control measure achieves the outcome of effectively eliminating or managing a hazard. It focuses on the collection and evaluation of scientific, technical, and observational information to determine whether the measure is capable of achieving its specified purpose *i.e.* hazard control.

For example, a laboratory-based challenge study may be required to demonstrate effective reduction in the number of pathogenic microorganisms during the processing of a new dairy beverage. The study must be designed to simulate industrial processing conditions and demonstrate and document appropriate reduction in pathogens by the specific process *e.g.* achieve a 5-log reduction in *E. coli* in a fortified milk drink.



## Part 2: HACCP plan

### Step 9: Establish a monitoring system for each CCP (principle 4)

Monitoring involves the scheduled measurement or observation of each CCP. Such monitoring determines if there has been a loss of control at a CCP and should provide information in time to make adjustments to ensure that control of the process is maintained and critical limits are not exceeded.

Importantly, effective scrutinising of monitoring data enables the identification of trends, which may indicate a loss of control at a CCP. If monitoring is not continuous, then the amount or frequency of monitoring must be sufficient to ensure the CCP is maintained within control limits.

Monitoring data must be evaluated by a person with appropriate knowledge and authority so they can carry out identified corrective actions when necessary.



Monitoring procedures may be developed by asking questions such as:

- what is going to be monitored?
- how is it going to be monitored?
- where is the monitoring point?
- when is it going to be monitored?
- who is going to monitor it?

Ideally the monitoring of CCPs needs to be in real time in order to quickly respond to any loss of control of a CCP. For example, monitoring the temperature of milk during pasteurisation provides real time data and enables immediate action when the process diverges from predetermined limits. In contrast, measuring the bulk milk cell count of incoming raw milk requires laboratory testing and results are often obtained after raw milk has been comingled and processing has commenced. The documented corrective action must address such situations.

Monitoring should, where possible, employ rapid testing. Physical and chemical measurements are preferred to microbiological testing, because results are generated relatively quickly. This enables the manufacturer to limit the amount of out-of-specification product or respond before a critical limit is breached.

Records and documents associated with monitoring CCPs must be signed by the person(s) doing the monitoring and verified by the responsible supervisor. Records must be legible and traceable/identifiable back to the individual who signed it and distinguishable from others.

## Step 10: Establish corrective actions (principle 5)

Corrective actions must be taken when critical limits at a CCP have been compromised. Corrective actions enable the CCP to be brought back under control, and these actions need to be predetermined when drafting the HACCP plan.

Importantly it is essential to identify the individual who is assigned the responsibility of making corrective actions.

These corrective actions should:

- state how the process is brought back under control
- confirm it is back in control
- identify and isolate any affected product and hold pending a safety evaluation
- document the disposal or reprocessing of all affected product.

Deviations from critical limits and all corrective actions must be documented. Undertaking a root-cause analysis is essential in order to determine what went wrong and why, and this will assist in identifying changes in the food safety plan to prevent recurrence.

## Step 11: Establish verification procedures (principle 6)

While monitoring is a real-time activity, verification occurs after the fact. The objective of verification is to make sure the system is working as designed. Therefore, it is essential that the business undertakes verification activities to determine if the HACCP system is working correctly. Verification procedures may include:

- regular sampling or analysis of product against criteria described in the Dairy Food Safety Victoria **Microbiological testing criteria** guideline
- audit of the HACCP system
- audit of the records and documents kept
- review of the deviations/product disposals/re-processing that has occurred.

Where possible, verification activities should confirm the effectiveness of all elements of the HACCP system and should be conducted regularly.

## Step 12: Establish documentation and record keeping (principle 7)

Efficient and accurate record keeping is essential for the application of a HACCP system. All HACCP procedures should be documented, and the extent of documentation and record keeping should be appropriate to the nature and size of the business.

Documents should include:

- hazard analysis
- CCP determinations
- critical limits/specifications
- specific procedures or methods; including work instructions for monitoring and recording the CCP
- supporting information e.g. validation records, critical limit justification, chemical and microbial test results.

Records kept should include:

- CCP monitoring – validation and verification
- deviations from CCP limits and associated corrective actions
- root cause analysis
- modifications to the HACCP system.

Records need to be retained for four years.



## Part 3: Pre-requisite programs





## Part 3: Pre-requisite programs

### What are pre-requisite programs?

Pre-requisite programs are those practices and conditions needed prior to and during the implementation of HACCP and which are essential for dairy food safety.

PRPs deal with the oversight and day-to-day housekeeping arrangements of a manufacturing facility. In contrast, the HACCP system manages defined hazards associated with specific processes and products.

PRPs are important as they provide the foundation for developing an effective HACCP-based FSP. Typically, they cover the entire dairy manufacturing facility, rather than being specific to an individual process or product.

All PRPs need to be documented, and may also include work instructions for employees in the processing environment. Records which demonstrate the execution of a PRP must be kept to verify their implementation. Your food safety manager will review these records and results during audit, and any other supporting documentation in your FSP to ensure PRPs are being implemented correctly.

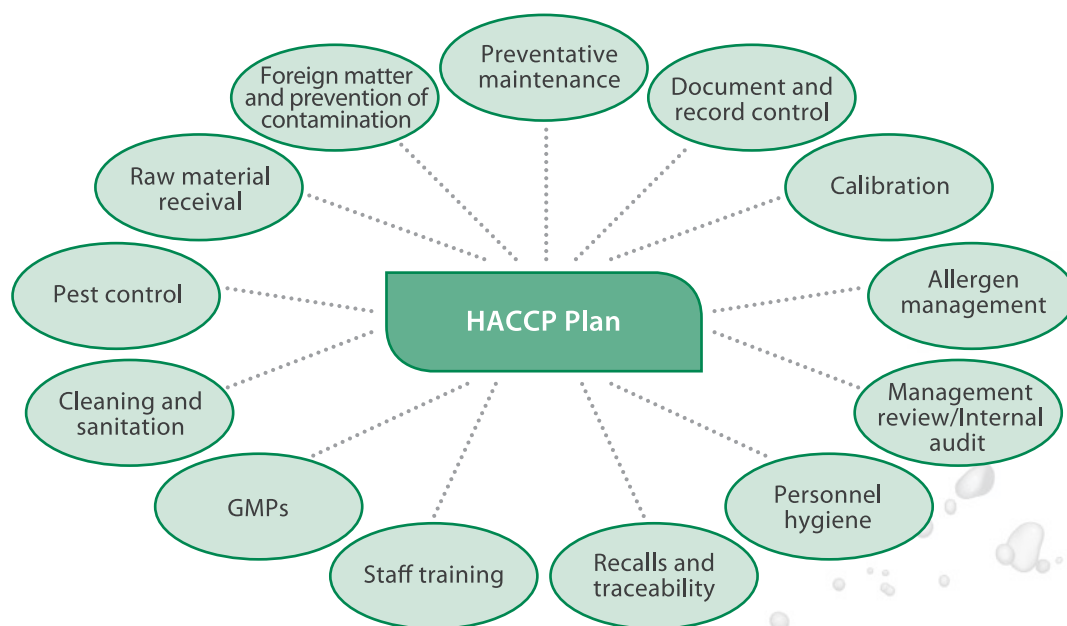


Figure 3: Examples of pre-requisite programs

Other PRPs and/or procedures that a manufacturer may implement include corrective and preventative action, non-conforming product, verification by sampling and testing, product labelling, and water and waste handling and management.

To ensure that each PRP is properly managed, suitably trained personnel should be nominated to have responsibility for managing each program area. The specific responsibilities should be defined in the person's job description. This individual must ensure the program is set up properly and managed on a day-to-day basis. This includes ensuring:

- staff understand their role
- there are documented procedures
- records are properly maintained
- staff have been suitably trained on all procedures and work instructions for which they are responsible.

For each PRP the processor must document how the program will be managed, including roles and responsibilities. There are typically three levels of documentation.

1. The procedure that describes how the program shall be managed and the expectations.
2. Work instructions with step-by-step procedures on how each task is accomplished.
3. Forms used for monitoring, which record the satisfactory completion of an activity.

All of these documents and records should be created and managed through the manufacturer's document control system. The following notes outline the purpose and expectations for selected PRPs.

More comprehensive examples demonstrating the content and layout of PRPs are shown in Appendix 2 and 3. The nature and content of each PRP will be influenced by the size and complexity of the business.

## Part 3: Pre-requisite programs

### A. Raw material receival

#### *(a) Purpose*

The goal is to ensure all raw materials, ingredients, processing aids, and packaging meet incoming material specifications, including food safety requirements.

#### *(b) Expectations*

Incoming raw materials are routinely inspected to ensure their conformance with specifications. This may include review of certificates of analysis for ingredients, temperature monitoring, packaging integrity, label compliance or testing of raw milk at time of receival.

The program includes:

- recording and reporting requirements
- who is assigned (job title) to sample and test raw materials
- instructions for testing incoming raw materials
- identification and disposition of non-conforming raw materials.

### B. Pest control

#### *(a) Purpose*

A pest control program is designed to exclude pests such as insects, rodents, and birds from the plant. The program assists the plant in maintaining a pest-free environment, and is typically carried out through a commercial contractor or by a designated employee.

#### *(b) Expectations*

The pest control program should include:

- an identified position responsible for managing the program – and involve a reputable pest control company (unless handled internally)
- a secure store for all pest control substances and equipment and a register of approved chemicals/bait including:
  - name of chemical and area of application
  - material safety data sheet (MSDS) for all substances and sample labels
- a pest control device map, frequency of inspection, monitoring logs, trend charts, and contractor recommendations
- corrective actions.

See DFSV's Technical information note on pest control programs.

### C. Cleaning and sanitation

#### *(a) Purpose*

The goal of the program is to maintain a clean and sanitary environment for the production of food of the highest safety and quality.

#### *(b) Expectations*

Document how cleaning and sanitation is to be carried out across the entire processing facility, including processing areas, equipment, and the environment.

This will include:

- who is assigned (person/position) to manage the cleaning and sanitation program
- detailed cleaning and sanitising instructions for each piece of equipment or area (instructions should include chemicals used, concentrations, and temperatures)
- an approved cleaning and sanitising chemical list and areas and equipment
- a cleaning schedule that defines frequency for each piece of equipment and area
- records to be kept.

Typically work instructions will be prepared to describe how each piece of equipment should be cleaned, how verification activities would be conducted e.g. visual inspection ATP swabs, or microbial swabs.

See DFSV's Technical information note on cleaning and sanitising.



## D. Good manufacturing practice (GMP)

### *(a) Purpose*

GMPs aid in the delivery, maintenance, and operation of all manufacturing processes and the environment in the plant and assure safe products are produced consistently. GMPs encompass a wide range of food safety procedures and apply to personnel, maintenance staff, contractors, and visitors.

### *(b) Expectations*

GMPs cover aspects of:

- personnel hygiene and hand washing
- limiting personnel access to sensitive production areas
- the use of airlocks, clothing changes, and footbaths
- procedures in place to exclude or restrict employees who show or who are diagnosed with symptoms of an infectious or communicable illness or wounds that could be a source of microbial contamination
- employee clothing and practices:
  - protective clothing *e.g.* uniforms, footwear, hairnets, beard guards, gloves, and earplugs
  - eating, drinking, and smoking rules
  - jewellery – wearing earrings, body piercings, rings, watches, necklaces, and bracelets
  - personal items such as mobile phones
- facilities and grounds:
  - storage of personal effects and food items
  - use of locker rooms
  - daily housekeeping
  - plant surrounds and housekeeping.

## E. Staff training

### *(a) Purpose*

Employee training is designed to ensure all employees understand the scope and responsibilities of the roles they perform, thereby ensuring they meet regulatory requirements and food safety goals.

### *(b) Expectations*

Appropriate training should be presented to any new employee and then repeated to all employees on a regular basis. A training record should be completed and maintained on file for each employee.

As a minimum, persons who supervise food handling operations must have knowledge and skills in food safety and food hygiene corresponding to their work activities. Likewise, quality assurance personnel and

those responsible for monitoring and controlling CCPs should have received training in HACCP from a registered training provider.

You must provide adequate resources to ensure these requirements are met. Investing in training will also help to retain competent and responsible staff.

See DFSV's Technical information note on competency and training.

## F. Recalls and traceability

### *(a) Purpose*

The food recall program should cover the procedures, records, and staff responsibilities needed to recall a non-conforming product. The goal is to protect consumers from a product safety failure by removing all implicated products from distribution channels in a timely manner, once a product recall or withdrawal is initiated.

### *(b) Expectations*

The program should include:

- the FSANZ food industry recall protocol and the procedures to follow in the event that it is necessary to recall a food
- an assigned position responsible for managing a food recall incident
- a scheduled mock recall performed (forwards to the customer and backwards to the raw materials) at least annually to demonstrate that lot traceability and recovery can be achieved in a recall situation, and include:
  - scope of the recall *e.g.* product type, lot information, personnel involved
  - recall and notification procedures
  - inventory/shipment and processing records
  - hold area procedures and product disposition guidelines
  - contact information for customers and regulatory agencies
  - a review of outcomes, including any improvements to the process.

See DFSV's Technical information note on product identification and traceability.

## Part 3: Pre-requisite programs

### G. Personal hygiene

#### *(a) Purpose*

Personal hygiene can have a major impact on product safety, with poor hygiene by food workers contributing to outbreaks of foodborne illness. By practicing good personal hygiene, workers positively impact on the sanitary condition of the dairy premises and product safety.

#### *(b) Expectations*

Staff need to be informed of the importance of personal hygiene in producing safe and suitable dairy products and their role in protecting public health. This is particularly important when processing involves manual handling of food.

Staff facilities and toilets must be:

- adequate for the number of employees in the premises
- maintained in a sanitary condition and in good repair
- employing self-closing doors and not opening into the food processing areas
- adequately ventilated.



### H. Management review/internal audits

#### *(a) Purpose*

The review is to ensure the FSP is meeting its objective of controlling all potential food safety hazards.

#### *(b) Expectations*

A management review of the entire FSP should be undertaken and reported annually (at a minimum), and always after a critical incident has occurred. It is not unusual to conduct rolling audits of selected PRPs, as well as the HACCP system.

See DFSV's Technical information note on internal audits and verification of food safety programs.

### I. Allergen management

#### *(a) Purpose*

The allergen management program should ensure all processes and the plant have been evaluated to mitigate the risk of allergen-related food safety incidents.

#### *(b) Expectations*

The management of allergens in food products is a critically important issue. The potential for allergens to be found in a dairy food may be identified as a hazard and covered as a CCP in the HACCP plan rather than through a separate allergen PRP.

The program should include:

- an assigned position responsible for the allergen management program
- annual employee training on allergen awareness
- identifying and managing zones where allergen contamination may be a problem
- consideration of key areas in the plant:
  - segregation, storage, and labelling of raw materials, ingredients, and processing aids that contain allergens
  - scheduling of processing activity involving allergens
  - packaging and labelling – preventing potential mislabelling of finished products
  - validation of cleaning activity, and ongoing verification of effectiveness
  - verification through product testing.

See DFSV's information on allergen management.

AFGC, Food industry guide to allergen management and labelling (2007).



## J. Calibration

### *(a) Purpose*

All monitoring and measuring equipment used in the processing facility needs to be periodically calibrated to ensure its accuracy and must include equipment used to measure a CCP.

### *(b) Expectations*

The program should include:

- a register of all monitoring and measuring equipment and a schedule for calibration
- records of calibration activity by qualified personnel (internal and external) including for existing, new, or back-up instruments
- appropriate action taken on out-of-specification instruments and equipment.

Where monitoring equipment is found to be out of calibration, consideration needs to be given to reviewing any product that has been manufactured for its conformance with food safety requirements.

See DFSV's Technical information note on calibration.

## K. Document and record control

### *(a) Purpose*

Document and record control ensures current and accurate information is recorded and stored for future analysis and auditing.

### *(b) Expectations*

The program should ensure:

- effective document and record keeping practices are maintained
- documents and records are sufficient to demonstrate compliance with your FSP and regulatory requirements are met
- documents and records are easily retrievable when required
- documents include the issue status *i.e.* date or version number, to ensure that the current version is used
- document retention times are defined and documents and records are adequately secured.

## L. Preventative maintenance

### *(a) Purpose*

A preventative maintenance program is designed to ensure processing equipment is properly inspected, prepared, and maintained to ensure the on-going production of safe food.

### *(b) Expectations*

The program should include:

- an assigned position responsible for the management and oversight of the program
- a preventative maintenance schedule with specific details on frequencies, verification, and actions required
- tracking of equipment undergoing maintenance and temporary repairs
- a tools and parts control and reconciliation program – including a cleaning and sanitation step and inspection before equipment is put back into production
- records of preventative maintenance.

See DFSV's Technical information note on maintenance programs.

## M. Foreign material and prevention of contamination

### *(a) Purpose*

Control measures designed to ensure the facility minimises the risk of foreign or extraneous material contaminating dairy food products.

### *(b) Expectations*

The program should include:

- strategies and processes to prevent product contamination with glass, plastics, rubber, metal fragments, ceramics, wood, and other foreign matter
- installation and monitoring of filters, magnets, and foreign matter detectors
- identification and registration of all glass, rubber, brittle plastics, and ceramics in production areas and consider replacement with suitable alternatives if practical
- regular review of the register
- product isolation and clean-up procedures for when detections occur
- oversight of process controls:
  - installation, oversight and calibration of vision systems and detectors.

See DFSV's Technical information note on detection of extraneous matter.

## Putting your food safety program together

Below is a high-level overview of the process you can follow to develop your FSP. Full details about each component are contained in the appendices.

	<p>Collecting and developing the information</p>	<ul style="list-style-type: none"> <li>• Assemble your team.</li> <li>• Determine the food safety obligations of your business</li> <li>• Establish the tasks you need to perform to prepare the FSP – if necessary, engage a food safety expert.</li> <li>• Undertake the 12 steps for developing a HACCP plan – including describing product composition(s) and attributes, identifying all the microbiological, chemical, and physical hazards you may encounter, and identifying your target consumers.</li> <li>• Identify and develop all the PRPs that will underpin your HACCP plan and provide sufficient information and detail so that someone can follow these procedures without prior knowledge.</li> </ul>
	<p>Document your food safety program</p>	<ul style="list-style-type: none"> <li>• Prepare a document that provides details of your business, which: <ul style="list-style-type: none"> <li>◦ describes your food products, processes, and procedures</li> <li>◦ identifies hazards and the risks they present</li> <li>◦ determines critical control points</li> <li>◦ describes how you validate critical control points</li> <li>◦ outlines monitoring activity</li> <li>◦ determines verification testing</li> <li>◦ defines appropriate corrective actions.</li> </ul> </li> <li>• Describe how and where you will record monitoring data and the way you will review the effectiveness of the program.</li> <li>• Describe how you will undertake root cause analyses in the event of process failures and how you will revise your FSP.</li> </ul>
	<p>Review of your food safety program</p>	<ul style="list-style-type: none"> <li>• Submit program to Dairy Food Safety Victoria for desk audit.</li> <li>• Amend as required after feedback from Dairy Food Safety Victoria.</li> <li>• Audit on site.</li> </ul>

## How long does it take to develop your FSP?

The time required to develop, document, and implement a FSP is influenced by the size and complexity of the dairy processing facility and the resources available to put the program in place.

The time to fully develop and document the program may take from 1–3 months to a year.

## Where can I find additional information?

Information on FSPs, HACCP, and pre-requisite programs can be found on a number of websites. These include the Dairy Food Safety Victoria website and:

**Victorian Department of Health and Human Services**

<https://www2.health.vic.gov.au/public-health/food-safety>

**Food Standards Australia New Zealand**

<http://www.foodstandards.gov.au/industry/safetystandards/programs/Pages/default.aspx>

**NSW Department of Primary Industries Food Authority**

<http://www.foodauthority.nsw.gov.au/ip/food-safety-programs-haccp>

**Australian Institute of Food Safety**

<https://www.foodsafety.com.au/resources/articles/food-safety-programs-an-overview>

**HACCP Mentor**

<https://haccpmentor.com/>

### Other important references include:

**Australia New Zealand Food Standards Code**

<http://www.foodstandards.gov.au/code/Pages/default.aspx>

**Codex Alimentarius Commission, General Principles of Food Hygiene CAC/RCP 1-1969, Rev. 4-2003.**

**ANNEX - Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application**

<https://tinyurl.com/y7gbckm7>

***Dairy Act 2000* (VIC)**

[http://www.austlii.edu.au/au/legis/vic/consol\\_act/da200073/](http://www.austlii.edu.au/au/legis/vic/consol_act/da200073/)

***Food Act 1984* (VIC)**

[http://www.austlii.edu.au/au/legis/vic/consol\\_act/fa198457/](http://www.austlii.edu.au/au/legis/vic/consol_act/fa198457/)

**Food Standards Australia New Zealand, Food Industry Recall Protocol –**

**A guide to writing a food recall plan and conducting a food recall. 7th Edition, June 2014.**

<http://www.foodstandards.gov.au/industry/foodrecalls/firp/Pages/default.aspx>

**Export Control (Milk and Milk Products) Orders 2005**

<https://www.legislation.gov.au/Details/F2007C00778>

# APPENDIX 1: Glossary

## Calibration

Process of comparing an instrument's accuracy to known standards.

## Cleaning

The removal of soil, food residue, dirt, grease or other objectionable material that may cause contamination of dairy food.

## Contaminant

Any biological or chemical agent, foreign matter, or other substances not intentionally added to food which may compromise dairy food safety or is not intended or expected to be present.

## Contamination

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

## Dairy food

As defined in the *Dairy Act 2000* (Victoria). Dairy food means (a) milk and liquid milk products; (b) dried milk and dried milk products; (c) condensed milks; (d) cream and cream products; (e) butter, butter products, dairy blend and dairy spreads; (f) cheese and cheese products; (g) yoghurt and yoghurt products; (h) ice cream, reduced fat ice cream and low fat ice cream; (ha) colostrum and products derived from colostrum; (i) any other product or class of products declared by a determination to be dairy food – but does not include any product or class of product declared by a determination not to be dairy food.

## Disinfection

The reduction, by means of chemical agents and/or physical methods, of the number of microorganisms in the environment to a level that does not compromise dairy food safety.

## Duty of care

A common law concept that refers to the responsibilities of organisations to provide people with an adequate level of protection against harm and all reasonable foreseeable risk of injury.

## Food allergen

A food ingredient or their components that can cause allergic reactions including anaphylaxis. Food allergens include peanuts, tree nuts, milk, eggs, sesame seeds, fish and shellfish, soy, wheat, and lupin.

## Food safety program

A written document describing how a food business ensures the food it manufactures or handles is safe for human consumption. The program 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 control limits.

## Food safety supervisor

A person who has the knowledge to recognise, prevent, and alleviate food hazards in a food business; has a statement of attainment from a registered training provider that confirms competency in food safety; and has the ability and authority to supervise individuals who handle food at the premises.

## Food Standards Australia New Zealand (FSANZ)

Government agency responsible for developing and administering the Australia New Zealand Food Standards Code. The Code contains standards and regulatory requirements in areas such as microbial limits, additives, food safety, labelling, genetically modified foods, and primary production and processing for dairy foods.

## Hazard

A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect in humans.

## Hazard Analysis and Critical Control Point (HACCP)

A system which identifies, evaluates, and controls hazards associated with food safety.

## Manufacture

Includes the preparation and processing of a foodstuff.

## Non-conformance

Where equipment, product or management practices do not meet minimum food safety outcomes, or where a requirement of a food safety program has not been complied with.

## Potable water

Water that is acceptable for human consumption.

## Procedure/protocol

A documented sequence of actions that describe how a process is conducted.

## Sanitisation

The process of making something sanitary, as by cleaning followed by disinfecting.

## 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

The application of tests, procedures, and other methods, in addition to monitoring to determine compliance with the FSP.



## APPENDIX 2: Pre-requisite program example – Calibration

### PURPOSE

This document describes procedures for the calibration and standardisation of all instruments and equipment used for testing and measurement activities in the dairy processing plant.

### SCOPE

The procedure covers all instruments and equipment on site requiring periodic calibration. The calibration will be undertaken by quality assurance personnel, and will confirm the continual accuracy of measuring instrument and equipment. Alternatively, equipment may be sent to an approved contracted calibration laboratory.

All equipment requiring calibration is listed on the Calibration master list (P10L).

### DEFINITIONS

Calibration: to determine, check, or rectify the graduation of any instrument giving quantitative measurements.

Standardisation: to bring to, or make of, an established standard size, weight, quality, or strength.

### METHODOLOGY

#### 1. Record keeping

Each piece of monitoring and testing equipment which requires calibration has its results filed in the *Calibration master list* (held in the quality assurance (QA) office). The file contains information on the characteristics of equipment: description, range of measurement, and accuracy.

#### 2. Calibration

All items listed on the *Calibration master list* are calibrated as per work instructions. The work instructions are based on information sourced from the manufacturer's handbook, NATA or industry standards. These manuals and handbooks are retained on site in the QA laboratory.

As each item of equipment is calibrated it is identified as having been calibrated, with a calibration sticker which details the date, calibration period, and person who carried out the calibration.

Where equipment is calibrated externally, the quality assurance manager liaises with the external contractor and organises dates and times for calibration according to a predetermined schedule. Certificates of calibration are retained on the *Calibration master list*. Examples of test equipment calibrated by external contractors includes scales, pressure, and thermal measuring devices.

Information contained in calibration certificates includes:

- Report No.
- Date of calibration
- Calibration result (status of equipment), method of calibration, and degree of variance and any maintenance required
- Date of next upcoming calibration
- Name/signature of technician.

Where any monitoring equipment has been damaged or mishandled, it is to be re-calibrated immediately, and the re-calibration date recorded on the List.

#### 3. Out of use equipment

Equipment that is no longer required or cannot be calibrated should be removed from the processing environment and identified with an uncalibrated sticker to prevent accidental use.

## APPENDIX 2: Pre-requisite program example – Calibration

### 4. New equipment

All new items of monitoring equipment should be entered into the *Calibration master list*.

### MONITORING

Who	Instrument/equipment	How	When	Record
Quality assurance manager	Weighing scales	Standard weights	Weekly	
	Temperature probe – Pasteuriser	Standard thermometer	6-monthly	
	pH meter	Buffers	Daily	
	Thermometer – Incubator	Standard thermometer	Monthly	
	Thermometer – Laboratory	Standard thermometer	Monthly	
	Laboratory scales	Standard weights	Monthly	
	Standard thermometer	NATA accredited laboratory	Annually	

### CORRECTIVE ACTION

When an instrument is found to be out of calibration it should be recalibrated and/or removed.

Consideration must also be given to the status of dairy products that have been processed on equipment with out-of-calibration monitoring devices. Action needs to be taken to verify that the product produced does not pose a food safety risk. Where non-conforming product is identified, the non-conforming product procedure must be followed.

### RESPONSIBILITIES

#### 1. Factory manager

- Ensure sufficient resources are provided for the effective implementation of calibration activities.

#### 2. Quality assurance manager

- Ensure quality assurance personnel have training in calibration procedures and only calibrated equipment is in use.
- Audit this program annually.
- Determine corrective action when equipment is found to be uncalibrated.
- Ensure *Calibration master list* is maintained.
- Undertake periodic calibration of testing and measurement equipment.

## RECORDS

### 1. Records

Form title	Document No.
Calibration master list	P10L
Calibration record	P10R
Calibrated sticker	
Uncalibrated sticker	

\* Records retained for four years

### 2. Work instructions

Document title	Document No.
Calibrating pH meters	
Calibrating a thermometer-digital	
Use of thermocouple in pasteuriser trials	

## VERIFICATION

Verification activities will ensure that the activities required by this procedure have been undertaken, are effective, have been recorded, and that corrective and preventative action has been taken where appropriate.

## REFERENCES

NATA Technical Note 21. Calibration and Electrode performance checks

NATA Technical Note 13. User Checks of Balance Calibration.

NATA Technical Note 19. Liquid in Glass Thermometers – Selection, Use and Calibration Checks.





## APPENDIX 3: Pre-requisite program example – Allergen control

### PURPOSE

This document describes procedures for the management of food allergens in the dairy processing plant and their listing on product labels.

### SCOPE

The procedure covers the identification and management of food allergens on site. Quality assurance personnel play a critical role in overseeing the identification, management and labelling of products that contain or may contain allergens.

All allergens present in the dairy processing facility will be listed on the *Food allergen ingredient form* (A10L).

### DEFINITIONS

<b>Cross contact allergens:</b>	Allergens that occur when a residue or other trace amount of an allergenic substance is unintentionally present in a food that is not intended to contain that allergenic substance and where such incidences are sporadic.
<b>Food allergen:</b>	Naturally-occurring proteins in foods or derivatives of them that cause abnormal immune responses – currently there are ten allergens described in the Food Standards Code (peanuts, tree nuts, milk, eggs, sesame seeds, fish, shellfish, soy, cereals containing gluten, and lupins).
<b>Precautionary allergen statements:</b>	Voluntary statements about the potential presence of cross contact allergens in a food. They are not regulated by the Food Standards Code, but should be used in conjunction with a VITAL assessment.
<b>VITAL:</b>	Voluntary Incidental Trace Allergen Labelling program is a standardised allergen risk assessment process for the food industry.
<b>Validated cleaning procedure:</b>	A cleaning procedure which has been repeatedly proven to be capable of removing relevant allergens from processing equipment.

### METHODOLOGY

#### 1. Food allergen ingredient analysis

Each ingredient used in the premises will be subjected to an allergen-specific hazard analysis by quality assurance personnel. Details of each ingredient in which an allergen is present will be listed on the *Food allergen ingredient list* (P9L). Product information forms (PIFs) and the Allergen Bureau guide: *Unexpected allergens in food* may be used to assist in identifying ingredients that contain allergens.

## APPENDIX 3: Pre-requisite program example – Allergen control

### 2. Product line allergen assessment

Based on the information in the *Food allergen ingredient list* (P9L), for each production line:

- identify which products contain allergens either as, or in, ingredients.
- identify which products do not contain allergens as, or in, ingredients.
- construct a scheduling matrix to ensure that products which contain allergens are manufactured after those that do not **OR** where products which contain unique allergens are made on the same line and changeovers cannot be avoided, ensure that a validated cleaning procedure is scheduled between any products containing different allergens.
- document the scheduling matrix, collate details of the assessment in the *Product line food allergen assessment form* (P9A) and ensure that all staff are trained in its use.

For each product, undertake a VITAL risk assessment to assess the risk of an allergen being unintentionally present due to cross contact. If the result of the VITAL assessment indicates that a precautionary label is required (Action level 2), a 'may be present' statement will be included on the label.

Quarterly audits of products will be conducted to verify that the product formulation matches the records of ingredient use and that the composition of the final product is accurately reflected in the ingredients specified on the label.

### 3. Food allergen labelling and verification

Dairy products that contain allergens as, or in ingredients will be labelled as '**contains xxx...**'; and this will appear directly below the ingredient list on the label, on a separate line in bold.

Labels will be checked at the commencement of each production run to ensure the correct labels with the appropriate allergen declarations are in use.

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

### 4. Allergen cleaning procedure

The appropriate, designated cleaning procedure will follow each production and packaging run. Post cleaning, production lines and packaging equipment will be screened for the presence of residues of relevant allergens and will be conducted at least monthly as a verification activity. Plus, product testing will also be performed.

## MONITORING

Who	Instrument/equipment	How	When	Record
Quality assurance manager	Food allergen ingredient list	Visual	Each batch	
	Product line allergen assessment	Review formulation	6-monthly	
	Food allergen labelling	Visual check labels	Each batch	
	Allergen cleaning procedure	Visual and swabbing	End of run	

## CORRECTIVE ACTION

When label verification demonstrates a non-conforming product, it will be isolated pending further evaluation and root-cause analysis.

When production lines and packaging equipment are found to contain allergen residues after cleaning, the lines will be stopped pending a full allergen clean and verification testing. In such cases a review of the cleaning process will be initiated.

## RESPONSIBILITIES

### 1. Factory manager

- Ensure sufficient resources are provided for the effective implementation of all allergen management activities.

### 2. Quality assurance manager

- Ensure quality assurance personnel have training in VITAL, allergen identification, and labelling.
- Audit the allergen control program annually.
- Verify the efficacy of cleaning programs to remove allergens from the production environment.
- Initiate corrective action when there is evidence of use of an incorrect label or the presence of an undeclared allergen due to cross-contact.
- Ensure records and forms are maintained.

## RECORDS

### 1. Records

Form title	Document No.
Food allergen ingredient form	P9L
Product line allergen assessment	P9A
Food allergen label verification	P9LV

\* Records retained for four years

### 2. Work instructions

Document title	Document No.
VITAL assessment of allergens	
Verification of cleaning regimes for allergens	

## VERIFICATION

Verification activities will ensure that the activities required by this procedure have been undertaken, are effective, have been recorded, and that corrective and preventative action has been taken where appropriate.

## REFERENCES

AFGC (2007). *Food Industry Guide to Allergen Management and Labelling*. (Australian Food and Grocery Council, Barton, ACT).

<https://www.afgc.org.au/wp-content/uploads/AFGC-Allergen-Management-and-Labelling-Guide.pdf>

Allergen Bureau (2011). *Unexpected allergens in food*.

<http://allergenbureau.net/wp-content/uploads/2013/12/Unexpected-Allergens-in-Food-18-April-2011.pdf>

## APPENDIX 3: Pre-requisite program example – Allergen control

### Food allergen ingredient list (A10L)

Products:

Issue date:

Supersedes:

Food allergens in ingredient formulation or in precautionary labelling

Raw material	Supplier	Egg	Milk	Soy	Wheat	Tree nut	Peanut	Fish	Shellfish	Sesame	Lupin	Precautionary labelling

### Product line food allergen assessment form (A10A)

Products:

Issue date:

Supersedes:

Raw material	Supplier	Egg	Milk	Soy	Wheat	Tree nut	Peanut	Fish	Shellfish	Sesame	Lupin



## Food allergen label verification form (A10LV)

Products:

---

Issue date:

---

Supersedes:

---

Product	Allergen statement
	Contains:
	Contains:
	Contains:
	Contains:
	Contains:
	May contain
	May contain

EXAMPLE ONLY







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