Ministry for Primary Industries
Manatū Ahu Matua

Guidance Document

# Dairy Pathogen Management

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# Title

Guidance Document: Dairy Pathogen Management

# About this document

This guidance document applies primarily to risk management programme (RMP) operators and dairy manufacturers who are developing dairy pathogen management for the processing of dairy material or dairy products. The principles outlined are also applicable to dairy manufacturers operating under a food control plan and to other food manufacturers.

# Document history

| Version Date | Section(s) Changed | Change(s) Description |
|---|---|---|
| May 2006 | | Original draft |
| October 2024 | All | New format. Updated sections. Complete review to align with the APN: Production, Supply and Processing |

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# Disclaimer

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# Contents

# 1 Purpose

(1) This guidance supports regulatory requirements and provides guidance to assist dairy manufacturers with meeting the requirements of the Animal Products Act 1999, the Animal Products Regulations 2021 and the Animal Products Notice: Production, Supply and Processing (PSP Notice) that relate to the control, management and monitoring of pathogens and hygiene indicator organisms.

(2) While written with dairy manufacture in mind, the principles set out in this guidance will be relevant to many other food businesses.

## Background

(1) Previous experience tells us that contamination of manufactured foods typically occurs during the manufacturing process. This could be from the processing environment, from inadequate process control, or from inadequate control of inputs. Effective management of pathogens relies heavily on controlling pathogens in the processing environment, by ensuring appropriate process controls are in place, and by establishing appropriate procurement practices.

(2) This guidance provides guidance to manufacturers for pathogen management to assist with meeting regulatory requirements and implementing good manufacturing practices.

(3) Pathogen management will normally be a pre-requisite programme supporting the Hazard Analysis and Critical Control Point (HACCP) plan and will be either included in the risk management programme (RMP) or referenced by the RMP.

(4) Pathogen management is an integral part of food safety and is a vital component of an effective risk management programme and will ideally shape decisions during the design of a manufacturing premises.

(5) The PSP Notice requires all dairy manufacturers operating under an RMP to have certain procedures in place related to sampling and testing plans, and for the management of pathogens in dairy products and in the environment.

(6) Pathogen management is an ongoing activity and needs to be adequately resourced to be effective. Capturing the information collected over time enables manufacturers to understand their own situation along with the microbial ecology of their processing environment.

## How to use this document

(1) This guidance provides information that dairy manufacturers should note as soon as possible. However, it's not practical for this guidance to present an exhaustive list of procedures and control measures. Each processing operation is unique, and manufacturers will need to evaluate their own operation to establish the pathogen management procedures that are most appropriate.

(2) It is recommended to read this whole document before the design of processing premises, and before drafting or amending dairy pathogen management procedures.

## Scope

(1) This guidance is focused on various management practices that collectively help dairy manufacturers minimise the presence of pathogens relevant to human health and animal health in dairy products.

(2) The guidance includes steps from design and construction through to the release of manufactured dairy products, and includes consideration of equipment and environmental monitoring, procurement and receipt of inputs, processing considerations, and monitoring. This guidance document also includes considerations for sampling plans, sampling techniques and analytical testing.

(3) This guidance is not directly relevant to dairy processors operating under the Animal Products Raw Milk for Sale to Consumers Regulations 2015, but the considerations for maintaining hygienic processing conditions outlined in this guidance will be relevant.

(4) While this guidance will be relevant to manufacturers of raw milk products, it does not attempt to address all microbiological considerations that need to be made by manufacturers of unpasteurised products (thermised cheese and raw milk products). Additionally, the sampling and testing examples given in this document relate to pasteurised products unless noted otherwise.

# Who should read this document?

(1) This guidance is primarily intended to assist businesses who carry out the manufacture of dairy materials and dairy products for human consumption under a risk management programme, and as such should be read by:

a) dairy manufacturers;
b) RMP operators, covering dairy manufacture;
c) dairy RMP evaluators, and Dairy Premises and Equipment evaluators;
d) dairy RMP verifiers; and
e) laboratories.

(2) However other food businesses are likely to find aspects of this guidance of value and applicable to their own situation.

# Definitions

(1) The following terms are used in this guidance document:

**Act** means the Animal Products Act 1999

**control (verb**) means to take all necessary actions to ensure and maintain compliance with criteria established in the RMP

**control (noun)** means the state wherein correct procedures are being followed and criteria are being met

**control measure** means any action and activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level

**critical control point (CCP)** means a point at which it is essential to use processes or procedures to control the hazard (whether by preventing or eliminating it, or reducing it to an acceptable level)

**critical limit** means a criterion, observable or measurable, relating to a control measure at a critical control point that separates acceptability from unacceptability of animal material or animal product

**Disposal Notice** means the Animal Products Notice: Disposal of Non-conforming Dairy Material or Dairy Product

**dry area** means any area where dry ingredients or dry relevant products:

a) are or may be exposed to the processing environment; and
b) will not subsequently be heat treated.

**facilities** means a place, amenity, or equipment provided for a particular purpose and includes water supply, refrigeration, heating, ventilation, vacuum, air conditioning, treatment and filtration, supply of gases, lighting, effluent disposal, waste disposal and sanitary arrangements

**Food Standards Code** means the current joint food standards code established under the Australia–New Zealand Joint Food Standards Agreement

**Infant Formula Notice** means the Animal Products Notice: Manufacture of Dairy Based Infant Formula Products and Formulated Supplementary Foods for Young Children

**NZFS** means New Zealand Food Safety, a business unit under the Ministry for Primary Industries

**outcome** means the expected level of control of a hazard or risk factor relating to food processed under an RMP

**pathogen** means a human or animal disease-causing organism

**procedure** means instructions that are documented and followed by the operator

**process** includes manufacture, treat, preserve, pack, label, transport, and store

**processing aid** has the meaning given to it in Standard 1.3.3 of the Food Standards Code

**process control step** means, for the purposes of this guidance document, a microbiological process control step

**PSP Notice** means the Animal Product Notice: Production, Supply and Processing

**raw product** means, for the purposes of this guidance document, food material, including ingredients and additives, prior to any bactericidal critical control point in the process

**Regulations** means the Animal Products Regulations 2021

**relevant product means:**

a) dairy based infant formula for infants aged up to 6 months;
b) dairy based follow-on formula for infants aged 6 months to 12 months;
c) dairy based formulated supplementary food for children aged between 12 months to 36 months; and
d) any dairy material or dairy product intended for use in any of those products (unless it will comprise less than 5% of the final product).

**RMP** means a registered risk management programme

**suitably skilled person** means a person who, in the opinion of the relevant processor or operator, is skilled in a particular activity or task through training, experience, or qualifications

**wet area** means any area where liquid dairy material or liquid dairy product is processed.

(2) Any other term or expression defined in the Act, Regulations, PSP Notice, Infant Formula Notice or Disposal Notice that is used, but not defined, in this document has the same meanings as in the Act, Regulations or those Notices.

# 2 Dairy pathogen management overview

(1) Pathogen management refers to all the things that need to be assessed and addressed by dairy manufacturers and RMP operators. Pathogen management preferably follows a systematic approach, starting at the initial concept and design of manufacturing processes to ensure that processing facilities will be suitably hygienic for the dairy products that are to be manufactured.

(2) There are a number of components to pathogen management and the documented pathogen management plan, some of which include:

a) appropriate premises location and design;
b) construction materials and equipment design;
c) pathways for people, ingredients, packaging, product and other things that may cross paths;
d) operational control measures to maintain hygiene standards while allowing for the entry and exit of people, products and other things;
e) procurement controls (supplier programmes, inwards goods acceptance and monitoring, etc);
f) cleaning, sanitation and maintenance programmes and procedures;
g) monitoring of the manufacturing process environment and equipment hygiene;
h) in-process checks to ensure the process functions as intended;
i) final product sampling and testing (extending beyond microbiological testing to include composition and packaging integrity); and
j) responding to unexpected and unfavourable findings.

(3) This guidance document provides relevant prompts that manufacturers should consider as they develop their own comprehensive pathogen management procedures (referred to as the pathogen management plan in this guidance), tailored to their situation. It will also help address many of the required procedures, and the recommended steps to follow as the procedures are developed.

# 3 Regulatory requirements to be met

(1) The following are relevant and set out either the outcomes that must be met or the procedures that are required by RMP operators of dairy manufacturers:

a) Animal Products Act 1999 (particularly sections 16 and 17);
b) Animal Products Regulations 2021;
c) Animal Products Notice: Production, Supply and Processing (PSP Notice), particularly sections D1 and D3; and
d) Animal Products Notice: Disposal of Non-conforming Dairy Material and Dairy Product (Disposal Notice).

(2) Additional requirements relevant to pathogen management are set out in Notices that apply to specific products, processes or markets, including:

a) Animal Products Notice: Raw Milk Products;
b) Animal Products Notice: Manufacture of Dairy Based Infant Formula Products and Formulated Supplementary Foods for Young Children (Infant Formula Notice); and
c) Overseas Market Access Requirements (OMARs)

# 4 Useful resources

(1) This is a list of useful resources

a) MPI/NZFS publications - see www.mpi.govt.nz.
b) Consultants and/or industry experts Hiring a food consultant | NZ Government (mpi.govt.nz).
c) Operational Guideline: Design and Construction of Dairy Premises and Equipment.
d) Bad Bug Book (Second Edition) | US FDA.
e) Guidance Document: How to Determine the Shelf life of Food.

f) ICMSF | International Commission on Microbiological Specifications for Foods (ICMSF).
g) EHEDG: Guidelines | The European Hygienic Engineering & Design Group (EHEDG) is a source of information regarding process equipment.
h) 3A Sanitary Standards - note this resource comes at a cost.
i) Guidance for the Control of *Listeria monocytogenes* in Ready-to-eat Foods:

   i) Part 1: Listeria Management and Glossary;
   ii) Part 2: Good Operating Practices;
   iii) Part 3: Monitoring Activities; and
   iv) Part 4: Corrective Actions.

j) *Listeria* factsheets:

   i) *Listeria monocytogenes* and ready-to-eat foods;
   ii) *Listeria* control measures;
   iii) cleaning and sanitising;
   iv) environmental testing for *Listeria*; and
   v) testing product for *Listeria monocytogenes*.

k) Listeria guidance for the food industry | NZ Government.
l) NZFS Microbial Pathogen Data Sheets (scroll down to "Pathogen data sheets").
m) Compendium of Microbiological Criteria for Food.
n) Codex Alimentarius Code of Hygienic Practice for Milk and Milk Products CAC/RCP 57-2004.
o) Predictive modelling programmes such as Combase (before use consult a technical specialist).
p) Controlling pathogens in dairy processing environments – guidance for the US dairy industry.
q) Handbook of Hygiene Control in the Food Industry 2nd edition (notably Chapter 44 Surface sampling and the detection of contamination).
r) The Management of *Cronobacter* in Powdered Infant Formula Manufacturing and/or Dairy Processing Plants in New Zealand.

# 5 Dairy pathogen management plan development

(1) In order to control pathogens effectively within dairy manufacturing environments, dairy manufacturers must have and comply with:

a) procedures for managing pathogens within the manufacturing environments and for monitoring the effectiveness of these procedures (see subclause (4) for exceptions to this);
b) procedures for monitoring the effectiveness of all other systems, pre-requisite programmes, procedures, and control measures identified in the HACCP plan, or elsewhere within the RMP, that are relevant to environmental hygiene; and
c) a sampling and testing plan when testing under the RMP (see clauses D1.12, D1.13 and D3.6 of the PSP Notice).

(2) To meet the requirements of clause D3.4 of the PSP Notice, the procedures must describe:

a) what is to be monitored;
b) how monitoring will be undertaken so that it will provide an effective early warning:

   i) of microbial contamination within the manufacturing environment; and
   ii) when exposed material and food contact surfaces are at risk of contamination unless corrective action is taken.

c) the locations from which samples will be obtained, and the type of samples;
d) how acceptable findings are distinguished from unacceptable findings for each parameter tested; and
e) the steps to be followed in the event of an unacceptable finding, which must include:

   i) increased surveillance of appropriate areas, surfaces, or things that may be a source of contamination;

ii) how investigations into the cause will be undertaken, who will be involved and the procedures that ensure that identified corrective and preventative actions are taken to remedy the situation without undue delay;
iii) when surveillance can return to normal frequency and coverage; and
iv) who must be notified.

(3) The procedures must:

a) provide for the monitoring of manufacturing environments and adjacent areas, manufacturing processes, equipment and other relevant items to confirm that pathogens are effectively controlled within manufacturing areas;
b) ensure that the opportunities for pathogens to gain entry to the manufacturing areas, processes, raw materials or dairy products are appropriately minimised;
c) ensure adequate control of movements into manufacturing areas by people, equipment, consumables, packaging and other raw materials and other things, as appropriate to the nature of the processing undertaken;
d) ensure that materials that may be introduced into critical hygiene areas are identified, and ensuring they are handled to avoid contamination of the processing environment;
e) in relation to sampling, set out:

i) how to determine which sampling points will be sampled, and when;
ii) how sampling bias is to be avoided, especially the dates and times that samples will be collected (this will not be relevant for samples and swabs intended to be collected pre-startup and post cleaning);
iii) how samples are to be managed and controlled, including sub-sampling and compositing along with associated labelling and records; and
iv) requirements for the handling, storage, dispatch or delivery of samples to the relevant laboratory.

f) ensure there is no use or introduction of wood within critical hygiene areas except in situations where:

i) its use is essential;
ii) no reasonable alternative is available;
iii) the HACCP plan identifies the relevant hazards of significance and how these are controlled; and
iv) procedures are in place that are suitable and have been validated as adequate.

(4) Despite subclause (1)(a), a dairy manufacturer is not required to have procedures for managing environmental pathogens if the manufacturer:

a) only relabels packaged dairy material or dairy product, or repacks packaged dairy material or dairy product into new outer packaging;
b) has procedures in place that describe the process and ensure that:

i) no dairy material or dairy product will be exposed; and
ii) the integrity of the inner packaging will not be compromised.

c) maintains an adequate level of hygiene within the processing area of the premises.

(5) In developing the above procedures, manufacturers should:

a) assign responsibility to a suitably skilled person for maintaining and administering the pathogen management plan or environmental pathogen monitoring plan;
b) design procedures to provide an early warning should a hygiene breach occur within the manufacturing environment;
c) consider increasing surveillance for new or modified processes or premises, or when a breach of hygiene and entry controls occur. This should include consideration of:

i) relevant processing areas and adjacent areas;
ii) dairy material, dairy product and inputs;

iii) product contact surfaces post heat treatment that may be exposed; and
iv) any other equipment, facilities or items that may be a source of contamination.

(6) The environmental monitoring programme must consider monitoring of the following if the Infant Formula Notice applies, and should be considered by all manufacturers:

a) pressure differentials, and relative humidity in the case of dry areas;
b) air quality (by using, for instance, exposure plates for relevant hygiene indicators); and
c) product contact surfaces and non-contact surfaces (by, for instance, taking swabs, dust samples and powder residue samples from a selection of different surfaces (both contact and non-contact) throughout the whole high hygiene area at different times). This is covered under section 9.2.3 of this guidance.

(7) The purpose of monitoring the manufacturing environment is to identify hygiene or control failures as soon as possible to avoid the environment becoming a source of product contamination. Manufacturers sometimes confuse this with confirming the effectiveness of cleaning, which is equally important, but requires quite different design consideration with monitoring after cleaning where environmental monitoring should routinely occur prior to cleaning.

(8) In developing the procedures for managing pathogens, manufacturers should bring together the following resources:

a) premises diagrams (e.g. RMP boundary, drainage, airflow and ventilation plans);
b) initial pathway diagrams for the movement of people, product, inputs, waste and other relevant things (e.g. trolleys) throughout each manufacturing area;
c) process flow(s) (e.g. inputs, process steps and outputs);
d) product description(s) (e.g. intended consumer and regulatory requirements);
e) HACCP plan (where available);
f) any relevant and available pathogen history of the premises (e.g. trend analysis); and
g) personnel that have a variety of skills and experience with the product, process, raw materials or pathogens.

(9) Using these resources and various considerations highlighted in this guidance, including the sampling plan examples in Appendix 2, will assist in the development of effective procedures. Appendix 6 provides a self-assessment checklist to help manufacturers confirm that their procedures are complete.

(10) Records should be kept of the considerations that were made in designing the Pathogen Management Plan and Environmental Pathogen Management Plan, along with the rationale for the procedures and monitoring adopted. Records should also include those aspects that were considered but not adopted and why. This will help inform future reviews so that others can have a clear understanding of the programme/plan design.

## 5.1 Pathogens of relevance to product or process

(1) For both the HACCP Plan and the Environmental Pathogen Management Plan, consider pathogens known to cause foodborne illnesses and that may occur in the dairy products. These are the hazards to be considered for dairy product.

(2) Appendix 1 sets out the pathogens and indicator organisms that are likely to be relevant to certain common products or processes. Table 3: Microbiological limits for dairy product for human consumption in the PSP Notice also highlights the pathogens most likely to be relevant, though not all the pathogens or indicator organisms identified will be relevant to all processes and products. The resources identified in section 4 will also assist in identifying the pathogens of relevance to various dairy products and processes.

(3) Consider the following questions:

a) are pathogens likely to be introduced through inputs, during processing, or from people or the processing environment?

b) can these pathogens grow or survive in the product?
c) do these pathogens present a risk to the intended consumer groups?

(4) Identify the target organisms for the product(s). Table A.3 in Appendix 1 provides information related to typical dairy products that will assist.

(5) Document the things that have been considered to justify the inclusion or exclusion of each pathogen or indicator organism.

## 5.2 Process zones

(1) Processing areas can be divided or defined based on:

a) functional use of the area and the nature or processing undertaken; and
b) the potential exposure of dairy material and dairy products to pathogens and risk factors following heat treatment, microbiological control or equivalent CCPs.

(2) Zoning is useful in that each zone will be managed according to the risk of product contamination. This allows the manufacturer to apply a more intense focus on zones of higher risk. This will then influence design and operational considerations including air movement and positive pressure differentials, and the entry and exit points for:

a) people;
b) equipment;
c) inputs;
d) dairy material and product;
e) pallets, crates and bins;
f) tools;
g) cleaning items;
h) vehicles/forklifts; and
i) other items.

(3) Manufacturers should assign a zone to every area within the site/premises based on the nature of the activities undertaken. The following is an example of how zones may be established:

a) **zone 1** encompasses the **outside** environment of the processing area;
b) **zone 2** encompasses those **inside** areas where product will not be exposed (standard hygiene area). For example, stores, or where there is exposed raw product (e.g. prior to a microbiocidal critical control point, such as raw milk prior to pasteurisation):

    i) These areas will act as a **buffer** between the outside environment or other high-risk areas and the critical hygiene area (zone 3) or higher hygiene/high care areas (zone 4), however they are not “buffer areas” as specified in the Infant Formula Notice.

c) **zone 3** encompasses those **inside** areas where product, particularly product after a microbiocidal critical control point, and product contact surfaces may be exposed to the processing general environment (critical hygiene areas); and
d) **zone 4** encompasses higher hygiene or high care areas that warrant additional protection from the environment, people and anything that is introduced into the area. Typically, these are areas where dairy material, product or inputs will be exposed, they will not undergo a further pathogen reduction step such as pasteurisation, and the final product is intended for specified populations (e.g. blending and packing infant formula products).

(4) It is generally considered that the risk of contaminating food within a processing area is highest at the points of exposure to the processing environment or when there may be contact or manual handling of the product. The risk then reduces with distance from these points. However, this assumption depends heavily on the manufacturing processes and procedures including cleaning methods (e.g. use of water or cleaning solutions under high pressure may re-contaminate all exposed surfaces).

(5) Pathway mapping will also assist by clarifying how freely pathogens may flow between areas. In conjunction with pathway mapping, the identifying zones and the management considerations for each zone should influence the design and construction of the manufacturing premises.

(6) Zoning should also consider buffer areas between zones for everything and everyone entering or exiting a higher hygiene zone.

(7) 'Zones' implies physical separation between areas, and most commonly this will be the only way to achieve effective separation between zones. Where physical separation of areas is not possible, controls should be identified to ensure incompatible activities are somehow segregated (e.g. by space, hygiene/work area management techniques designated equipment and operators, or cleaning). Consider ventilation, air movement and air pressure differentials and drainage/waste movement between areas. In some cases the effectiveness of separation requires validation.

(8) If different zones are identified or desired within a physical area, there should be appropriate controls in place to control the pathogen transfer pathways between the different zones. Generally the effective separation of these zones will need to be validated. If validation cannot confirm that the separation is effective, then the manufacturer should either:

a) reconsider whether separate zones are required; or
b) implement physical separation

(9) Maintain documents detailing the justification for the zoning applied to each area of the premises.

## 5.3 Pathway mapping

(1) Pathway mapping is a useful technique that assists manufacturers to identify points of high risk within processing areas post heat treatment.

(2) Through pathway mapping the manufacturer will be able to preferentially identify sites for environmental sampling. Pathway maps will also assist in root cause analysis investigations in the case of unfavourable environmental results.

(3) As well as pathway mapping (5.3.1) and determining high risk points within an area (5.3.2), it is recommended that potential pathogen harbourage sites are also mapped (5.3.3) along with sites associated with historic unfavourable results (5.3.4). During the pathway mapping exercise, senior management should be advised if:

a) the mapping exercise identifies flows that are unnecessary or that introduce unnecessary risk of product becoming contaminated, or
b) harbourage sites are identified that can be rectified through better design, maintenance or other means.

### 5.3.1 Determine and map pathway flows

(1) Determining the high-risk points within a processing area starts with identifying how people and items (inputs, product, waste, equipment and tools etc) flow through an area. These flows should be recorded on an appropriate floor plan/schematic to produce a pathway map. This exercise will require a mapping team with personnel familiar with all activities that occur within the area along with an engineering representative or person familiar with the ventilation and drainage systems.

(2) To capture the various flows within the area it is recommended that the mapping team work through the following process. For a large room with multiple processing areas or zones, repeat this exercise for each area/zone:

a) starting with product flows, work through Table 1 to identify the various flows within the area/zone;
b) focus on the routine daily activity flows and those that occur multiple times a week. Avoid dwelling on unscheduled/non-routine activities that may or may not occur, and that should have separate controls; and

c) record each different flow type using a suitable scheme. Table 1 provides an example:

**Table 1: Flow coding scheme example**

| COLOUR | DESCRIPTION |
|---|---|
| | Product |
| | People |
| | Raw Materials (exc. water) |
| | Water |
| | Compressed Air |
| | Waste |
| | Air |
| | Harbourage areas |
| * | Exposed Product/alternate flow intersect |

d) circle points where inputs or product will be or may be exposed, including intrusive sampling, or where raw material/product contact surfaces may be exposed;
e) as part of assessing the pathways, consider buffer zones, airlocks and entry points for the manufacturing area;
f) undertake a final reality check by spending time within the area where there is good visibility of the equipment, entrances/exits and activities that occur in the area. If the flows or activities don't align with the draft pathway map then either the pathway map or the current physical process flow need to be adjusted; and
g) this exercise should be repeated whenever there is a significant change to the building structure, services, equipment, process or people movement.

**Table 2: Pathway mapping process example**

| CATEGORY | PROMPT | DESCRIPTION |
|---|---|---|
| **Product Flows** *(e.g. product, outputs)* | Identify the start of the process | Find the point where the product enters the area/zone. Include buffer zones, airlocks and entry points in the assessment. |
| | Determine flow through the area | Trace product through the process within the area and identify major processing equipment.<br>**Circle on the pathway map any points where product or a product contact surface is exposed to the environment** |
| | Identify the end of the process | Find the point where the product exits the room/area. |
| | Identify any output streams | Find the point where different product streams may branch off as secondary product streams. |
| **Traffic Flows** *(e.g. people & equipment movement)* | Trace movement during manufacture | Trace the movement of people & equipment (e.g. forklifts/pallet jacks/trolleys) during manufacture. This includes the patterns they travel for routine checks during manufacture, to operate the plant, and to bring in necessary raw materials. Include buffer zones, airlocks and entry points in the assessment.<br>**Highlight on the pathway map any areas where personnel sample or physically handle product, or common touch points such as door handles** |

| CATEGORY | PROMPT | DESCRIPTION |
|---|---|---|
| | Trace movement during cleaning | Trace the movement of people & equipment (e.g. vacuum cleaners) during cleaning. This includes the patterns they travel, the areas they clean, the types of cleaning they may do (e.g. compressed air blow downs in packing).<br>**Highlight on the pathway map any equipment points that need to be dismantled for cleaning** |
| | Trace movement during plant checks | Trace the movement of people during routine weekly/monthly plant checks. This includes any housekeeping activities or routine maintenance that may occur. |
| **Input Flows** *(e.g. movement of inputs, chemicals, services)* | Trace movement of inputs | Trace the movement of inputs (packaging and anything to be added during processing) from entry into the area through to use. Include buffer zones, airlocks and entry points in the assessment**.**<br>**Circle on the pathway map any point where inputs are exposed to the environment** |
| | Trace services | Identify where services (including water, compressed air and steam) enter the area and trace their distribution and points of use.<br>**Highlight on the pathway map any points where utilities are exposed to the environment while manufacturing product** |
| | Trace | Find the areas where manufacturing solid waste.<br>**Circle on the pathway map any areas where waste is stored** |
| **Waste Flows** *(e.g. solid waste & drains)* | Identify drainage points | Identify any drains (e.g. drainage channels, floor drains, downpipes) and trace the movement of water or liquid wastes within the area and through to its exit.<br>**Circle on the pathway map any floor drains**. |
| | Identify waste movement and storage | Identify flow of waste material (e.g. sifter overs, dust collector fines, damaged packages) through to its exit, including storage.<br>**Highlight on the pathway map rubbish containers and any temporary storage points** |
| **Air Flows** | Identify air flows | Identify the air inlets and the air outlets in the area, confirm positive pressure (if HVAC operating) and trace the flow of air (to help determine the direction of air flow, hold a piece of paper up and look at the direction its blowing). If air direction can't be confirmed, assume that the air flows over all surfaces within the area.<br>Consider any openings to higher or lower hygiene zones including doors, input entry and product exit, openings, or vents that the air may flow in or out.<br>**Highlight on the pathway map any areas where air flows may intersect other flows** |

### 5.3.2 Determine high risk points

(1) The points circled from clause 5.3.1(2)(d) above are automatically high-risk points.

(2) If a different flow (other than ventilation air) intersects one of the circled points from clause 5.3.1(2)(d) (exposed input, product or product contact surface) then this will be a critical risk point and should be indicated as such e.g. highlight with a star. The only exception would be situations where there is a robust and valid preventative control measure in place (e.g. sanitising ingredient outer packaging or UV tunnel).

(3) Next, on the pathway map highlight any points where multiple differing flows intersect. These points are of medium interest but are necessary to be aware of when investigating the root cause of an unfavourable result. Intersect points create the opportunity for pathogens to flow in multiple directions through the processing area. Careful analysis of the flows and intersect points will enable a more robust root cause analysis to be undertaken.

### 5.3.3 Determine harbourage sites

(1) Once flows have been described, conduct a final inspection of the area to identify points or equipment that are known or likely harbourage sites.

(2) Harbourage sites are places where microorganisms can live and grow. They usually provide suitable conditions for microbial growth (e.g. water, food, temperature) and are shielded from routine cleaning and sanitation.

(3) Harbourage sites are generally hard to clean areas, for example:

a) cracks, crevices, chips and cavities (think of floors, walls, coving and flashing);
b) areas of damage in buildings or to equipment (especially after equipment has been removed or replaced);
c) obsolete or decommissioned equipment within the area;
d) dead ends within equipment;
e) equipment with known design flaws (e.g. hollow support structures, conveyer belt rollers, air intake filters);
f) safety barriers, cages and other protection around equipment; and
g) bearings, gear housing, and other moving or electrical parts enclosed to protect staff particularly in wet environments.

(4) Some examples for the target microorganisms mentioned in clause 5.3.3(2) include:

a) Listeria - hollow rollers on conveyors, gasket materials around doors, hollow support structures, grease inside bearings, condensate and drains; and
b) Salmonella/*Cronobacter* - floor/wall joints, sifter tailings, vacuum cleaner, dust collector, air intakes filters.

(5) Update the pathway map with any identified harbourage sites, e.g. by use of a box or similar to highlight the area.

### 5.3.4 Review historic findings for the area

(1) Review historic data and investigations to determine whether any sites within the area have had multiple unfavourable environmental results, and:

a) if any harbourage sites within the area have been identified from repeated unfavourable findings then these should be added to the pathway map;
b) for sites within the area that have had repeated unfavourable findings and that occur where flows intersect, elevate the site to indicate that it is a point of high risk;
c) for sites within the area that have had repeated unfavourable findings and neither a. or b. apply, indicate as high risk using an alternative highlighting method. Although such sites should already have been thoroughly investigated, undertake another walk through the area to ensure that nothing has been missed in terms of flows or potential harbourage sites; and
d) appropriate remedial action has been taken and confirmed as resolved through testing over time.

(2) Sites identified in clause 5.3.4(1) do not need to be added to the pathway map if the root cause has already been identified and confirmed as resolved through follow-up testing over time.

## 5.4 Assess risk to process or product

(1) If a source of bacterial contamination exists within a processing area, bacterial numbers will increase rapidly when:

a) the temperature is suitable;
b) there is enough time (i.e. between cleaning); and
c) nutrients and water are present.

(2) Understanding these concepts is an important tool in the development of effective control measures, and knowing where control needs to be applied.

(3) Consider each of the relevant pathogens and each potential source to determine the likelihood of in-process or product contamination. This assessment should only be carried out by a suitably skilled person, though a team is likely to be required to draw on processing and microbiological knowledge. If in doubt, or if internal expertise is limited, manufacturers should seek suitably competent technical advice from external sources such as consultants, associations or other businesses.

(4) To support the RMP procedures and to aid future reviews, manufacturers should document:

a) the process used to assess risk to product;
b) the skills and knowledge of the team; and
c) the factors considered and the justification for decisions made such as sampling sites, sample numbers and frequency of sampling.

(5) Ensure the following are considered as part of the risk assessment for the Dairy Pathogen Management Plan:

a) HACCP;
b) pre-requisite programmes and Good Hygiene Practice; and
c) design and construction of equipment and facilities.

# 6 Technical considerations for achieving an effective pathogen management plan

(1) This section assists dairy manufacturers in considering a range of factors that will influence development of an effective Pathogen Management Plan that is relevant to the nature of processing and products that they manufacture.

(2) Manufacturers should review sections 6.1 and 6.2 in conjunction with the Operational Guideline: Design and Construction of Dairy Premises and Equipment to facilitate good hygienic premises design.

## 6.1 Buildings

### 6.1.1 Requirements

(1) Manufacturers will need to demonstrate that their premises, buildings and facilities meet the minimum requirements for their type(s) of manufacturing activities.

(2) Minimum requirements may be defined by legislation or industry guidance (e.g. Territorial Authority (council) building codes, Food Act 2014 and Animal Products Act 1999).

### 6.1.2 Site and building location

(1) It is important to assess the impact that the location and external environment might have on food safety and maintaining the required hygiene status of the manufacturing environment throughout the year. In doing so, manufacturers should consider:

a) proximity to sources of pathogen contamination (e.g. landfill, water treatment stations, pathogen lab, adjacent manufacturers, spray irrigation of effluent, dust and airborne contaminants);
b) movement of vehicles on and off-site;
c) waste disposal (e.g. general rubbish and process waste), positioning, access, spill containment, and frequency of removal; and
d) environmental factors such as flood risk.

### 6.1.3 Building design

(1) Good building design is essential for effective pathogen control. Consider whether:

a) building integrity ensures there are no water leaks;
b) windows and doors are tight fitting and kept closed to exclude insects, pests and dust (which may carry bacteria);
c) there is direct access to the outside environment;
d) floor, wall and ceiling materials are non-porous, will withstand cleaning compounds and are easily cleaned;
e) floors are well drained to prevent ponding;
f) drains are away from the packaging area and well screened and trapped - especially where they pass through a wall;
g) raw products are received in an area separate from processing and packaging areas;
h) processing areas flow naturally from raw or unprocessed food to final product;
i) amenities (e.g. toilets, changing areas, canteens) are located so people moving to and from these areas do not cause cross-contamination between processing areas;
j) temperature is controlled in areas where such temperature control is necessary;
k) ventilation and air transport systems are appropriate;
l) microbiology laboratories are physically separated from the processing building; and
m) waste storage areas are isolated so that leaking or spilled material cannot be tracked around the site and back into the processing areas.

### 6.1.4 Floors and drains

(1) Assume that the floor and drains are always contaminated. These surfaces are likely to be contaminated from:

a) foot and vehicle traffic, or from contaminated material falling on to the floor; and
b) almost everything on the floor will find its way into the drain.

(2) Dairy manufacturers should develop a procedure for handling any equipment or product that falls on to the floor, e.g. equipment should be cleaned and sanitised before reuse, and product should be discarded.

(3) Manufacturers should consider the following for floors and drains and ensure any issues are appropriately managed:

a) eliminate ponding of water at the design and construction stage, with correct fall to drains;
b) eliminate water leaks;
c) eliminate cracks and holes;
d) pipe waste directly into the drain;
e) ensure that drains have adequate capacity;
f) drain traps should be located outside;
g) drain traps should be cleaned regularly;
h) make floors as smooth as safety will allow;
i) clean floors daily in dry areas;
j) sanitise floors and drains daily in wet areas;
k) use dedicated cleaning equipment; and
l) clean and rinse using low pressure hosing.

### 6.1.5 Walls and Ceilings

(1) Walls and ceilings should be made of materials that can be easily cleaned and sanitised, with:

a) non-absorbent materials;
b) no holes or cracks;
c) no unflushed openings; and
d) no sills or high ledges.

(2) The join between wall and floor should be coved and sealed to minimise the build-up of water or other residues.

(3) All protrusions should be flashed and sealed.

## 6.2 Equipment

### 6.2.1 Equipment selection and design

(1) All equipment should be designed for easy cleaning and disinfection, made of non-absorbent material and meet the recommendations set out in the Operational Guideline: Design and Construction of Dairy Premises and Equipment.

(2) Equipment should:

a) utilise stainless steel for contact surfaces wherever possible (with no pitting and with hygienic welds that are ground and polished);
b) have no dead ends or hollow box sections that can trap food residues and contaminants and be difficult to clean;
c) have no sandwiched surfaces; and
d) be free draining (including pipes and all sections).

(3) Conveyor belts have proven to be ideal places for pathogens to lodge and grow, especially belts with absorbent material, such as nylon reinforcing on the lower surface or running through the middle of the fabric. Conveyor belts should:

a) be made of hygienic, easily cleaned material;
b) positioned to prevent contamination and off the floor;
c) never be allowed to touch the floor;
d) be made of non-absorbent material; and
e) have rollers that are completely sealed unless product is packaged.

(4) Some equipment will need to be dismantled each day, so that all surfaces can be adequately cleaned and sanitised.

(5) Boltholes and rivets will allow liquids to pass from one surface to another. Their positioning needs to be carefully considered when equipment is designed and built. It is recommended that rivets are not used in critical hygiene areas as they cannot be effectively cleaned. Ensure that bolts or boltholes are not positioned on or above any product contact surface.

(6) Procedures should identify all equipment that requires manual or out of place cleaning and sanitising.

### 6.2.2 Equipment maintenance

(1) Maintenance will normally be carried out by maintenance personnel. It is important to ensure that:

a) contractor induction is undertaken in a way that is appropriate for the processing activities and zone concerned;
b) the activities of maintenance personnel are managed in a way that will not cause contamination of the processing area, processing activities and product;
c) there is adequate clean-up upon completion of any maintenance work; and
d) there is sign-off by a suitably skilled person that:

i) processing equipment has been returned to a state suitable for processing activities and that manufacture can resume (if it was suspended); and
ii) potentially affected dairy material, dairy product or other input has been identified and is being managed in accordance with RMP procedures, or as waste, or as non-conforming dairy material/product.

(2) Detailed records for the above need to be kept for all maintenance that may have an adverse effect on processing or the processing environment.

### 6.2.3 Access restrictions

(1) The normal access restrictions and controls that apply to all other people on site should also apply to site visitors and contractors (refer to Section 6.4 Controlled Access).

### 6.2.4 Timing of maintenance

(1) All routine maintenance should be timed to occur between processing runs so that full clean up, including flushing lines, cleaning and sanitising, can be completed before processing resumes.

(2) Intrusive maintenance that cannot be programmed between processing runs should be timed to occur when there is a break in processing, if possible, so that:

a) product is not being processed at the time; and
b) any foreign matter can be removed, and the plant cleaned and sanitised before processing recommences.

(3) As with breakdowns (see clause 6.2.5), if intrusive maintenance is undertaken while processing is in progress, a suitably skilled person will need to determine whether the process or product may have been compromised. If this is the case, then product may need to be managed as potentially non-conforming (i.e. non-conforming until it can be determined that it has not been adversely affected).

(4) Maintenance that will not have any adverse effect on product or processing may be undertaken while the plant is running provided that:

a) it is controlled and recorded;
b) full hygiene controls will be applied (people, tools etc) and maintained within the area; and
c) any risk factors associated with the work is managed to ensure contamination of product will not occur (including dust, fumes and aerosols).

### 6.2.5 Breakdowns

(1) Breakdowns within the manufacturing environments that require immediate attention should (as appropriate for the equipment concerned), be followed by the flushing, cleaning and sanitising of those parts of the plant that have been worked upon.

(2) Product which is in-process at the time of the breakdown may be at risk from:

a) contamination from people, equipment or the environment during repairs; or
b) temperature abuse.

(3) Product which is in-process will need to be assessed by a suitably skilled person to determine whether it is, or may be, non-conforming. The manufacturer should have:

a) procedures for assessing conformance by suitably skilled persons;
b) procedures for the management and disposition of product that is identified as potentially non-conforming;
c) a list of suitably skilled people; and
d) documented the skills, knowledge and experience required by suitably skilled people.

### 6.2.6 Redundant equipment

(1) It is best practice to remove all redundant equipment.

(2) Care needs to be taken when removing any redundant equipment or items in zone 3 and 4 areas to ensure that it doesn't contaminate other equipment or the environment. This includes items such as HVAC systems.

(3) Equipment in the manufacturing area that is no longer in use (and has not been removed) should be maintained as if it were in use so that it doesn't harbour pathogens.

## 6.3 Services

(1) Consider the impact that services may have on processes and the processing environment, in particular:

a) the potential to allow entry of pathogens, introduce pathogens or promote their growth (e.g. direct or indirect contact of services with product or product contact surfaces); and
b) how any impact may be minimised.

(2) Refer to the Operational Guideline: Design and Construction of Dairy Premises and Equipment for information on services and maintaining the hygiene integrity of critical hygiene areas.

### 6.3.1 Water

(1) Water used within processing areas must be suitable for the intended use and must meet the water requirements set out in the PSP Notice section C subpart 4.

(2) If there is any chance that water will come into contact with food or food contact surfaces (directly or indirectly) it will need to be effectively treated (for example by chlorination, ultraviolet (UV), ozone, or filtration) and monitored. The nature of the treatment will depend on the particular use of the water and the water use criteria that has been established by the processor.

(3) Water stored on-site needs to be protected from contamination (e.g. in covered holding tanks or covered header tanks).

(4) Water quality should be checked at regular intervals at point of use (e.g. turbidity, free available chlorine, total coliforms or *E coli*).

(5) Hoses should be kept off the floor when not in use and never let hose nozzles touch the floor. (Always assume that the floor is a source of microbiological contamination).

(6) Frayed hoses should be replaced.

(7) Equipment that generates aerosols, such as pumps, or washing equipment, should be well shielded to prevent aerosols spreading throughout the processing area.

(8) Eliminate leaks from hoses, taps, drains, steam lines, condensate pipes or any other source (to deprive pathogens of the moisture needed for growth).

(9) Avoid the use of water at high pressure within the general processing environment. Use of high-pressure water and water blasters to clean floors and equipment have been identified as the root cause of pathogen events.

### 6.3.2 Compressed air and gases

(1) Any air or gases that will come into contact will need to be sufficiently filtered to prevent contamination. This also applies when using compressed air within the manufacturing environment. Care should be taken when using compressed air as part of the cleaning programme as pathogens can be inadvertently spread more widely within the area.

### 6.3.3 Ventilation systems and pressure differentials

(1) It is desirable that food processing operations operate at a positive air pressure with respect to the outside environment, to prevent contamination due to unfiltered air, dust, taints and contaminants entering the manufacturing area from outside the manufacturing environment.

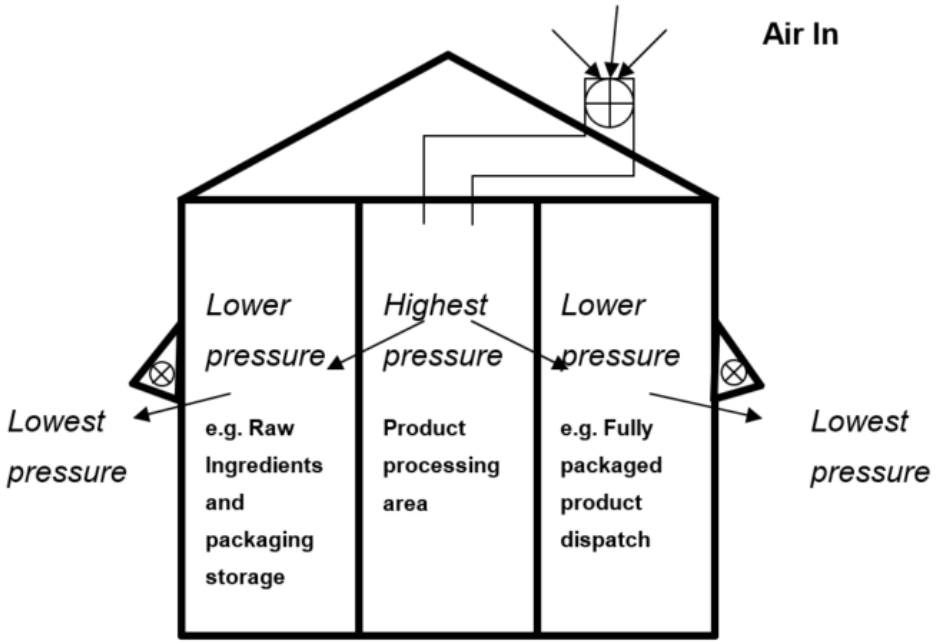
(2) Critical hygiene areas should be at a higher pressure than areas where inputs requiring a pathogen reduction treatment are handled or stored. For more sensitive manufacturing areas, it may be necessary to have multiple zones with each operating at successively higher pressure.

(3) Positive air pressure can be achieved by forcing clean, filtered air into the processing area. Refer to Figure 1.

(4) The volume of incoming air should be greater than the volume removed by exhaust vents and extractor fans to maintain a positive pressure in the processing area.

(5) Condensation on walls and ceilings is an indication that the ventilation system is inadequate.

**Figure 1: Pressure differential**




### 6.3.4 Air filtration systems

(1) Consider whether air needs to be filtered to remove contaminating particles.

(2) Where air filtration is included in the Pathogen Management Plan there should be a documented filter maintenance programme in place, with records kept of all filter maintenance carried out.

(3) Filters will need to be frequently checked, cleaned and replaced as necessary.

(4) Air intakes should be upwind from the prevailing wind, exhaust vents, inwards goods and rubbish disposal sites.

### 6.3.5 Temperature and humidity

(1) Heating, ventilation and air conditioning systems should be capable of maintaining critical temperature and relative humidity levels within the processing environment.

(2) The RMP should specify the actions to be taken if temperature or humidity controls fail to be applied. In situations where these controls are critical, such as humidity level in dry environments, this may need to include increased testing of potentially affected product and the affected processing environment.

### 6.3.6 Cooling systems

(1) Condensation can provide a moisture source that may allow pathogens to multiply. It is essential that all drainage ducting from air-handlers and condensers is piped directly into the drains and not on to the floor or ground.

(2) Special consideration will be required for dry processing environments, as it is critical that absolutely no moisture is present in the environment. Routine visual inspections of the processing area (especially areas around entry/exit points, windows, vents, and lighting) should be included undertaken as part of, or in conjunction with, environmental monitoring.

(3) Cooling towers can produce aerosols and should be considered as a potential source of contamination.

## 6.4 Controlled access

(1) The processing area is a common source of contamination for processed foods. For this reason, it is vital to ensure that the processing area is always protected from contamination.

(2) Effective Pathogen Management procedures will identify and control pathogen transfer pathways between zones.

(3) Physical controls may be necessary at the boundaries of zones. The nature of the controls will be determined by the product, the intended consumer, and the type of processing undertaken.

(4) For entry into a higher hygiene area and exit from a higher hygiene area, a buffer may be required where items (e.g. packaged ingredients, packaging, tools, consumables etc) can be prepared for entry to a higher hygiene zone. The buffer area will provide a degree of hygiene control as things move in and out of higher hygiene zones. Preparation may range from simply minimising exposure of the higher hygiene zone to lower hygiene zones environment or may include sanitising exterior surfaces, removal of outer packaging or preparation for other forms of control (e.g. UV tunnel).

(5) Items that require rapid entry into, or exit from, a higher hygiene zone should do so through appropriately controlled access points. These may use air pressure, air curtains, air flushing, UV or other techniques to ensure that items don't introduce contaminants, and that the processing environment is always protected.

### 6.4.1 People

(1) People (this refers to staff, visitors and contractors) entering the processing area should understand the role personal hygiene has in food safety e.g. the potential for contamination of product, equipment or the environment.

(2) Access to processing areas should be restricted to the people who need to be there, and who have undergone the appropriate induction and training.

(3) Entry into higher hygiene areas (critical hygiene areas, high hygiene areas and high care areas) should be via some form of buffer area, such as a redline boot and clothing exchange with handwashing and sanitising facilities. Effective separation between zones is essential when:

a) manufacturing products intended for specific populations, or
b) product may be exposed and there will be no further pathogen reduction step in the process.

### 6.4.2 People health

(1) People entering a processing area should be free of illness, or symptoms, that could put product (and ultimately the end consumer) at risk.

(2) Part C2 of the PSP Notice sets out criteria that apply to people health.

(3) For illnesses of concern, refer to Table 2.4 (Pathogen or Disease-Specific Exclusion and Clearance Criteria for People at Increased Risk of Transmitting an Infection to Others) in Appendix 2 of the current edition of the Te Whatu Ora Communicable Disease Control Manual.

### 6.4.3 Handwashing and sanitising

(1) Handwashing facilities should include a dedicated sink (piped directly into the drains), warm water, soap and suitable hand drying materials (e.g. paper towels). These facilities should be maintained in a clean and tidy condition.

(2) Staff members should know when it is appropriate to wash their hands, this includes:

a) before starting work;
b) before and after work breaks;
c) after going to the toilet;
d) before and after working with raw product;
e) before and after working with raw product contact surfaces;
f) after rubbish removal; and
g) before and after cleaning operations.

(3) Hand sanitising or disinfection facilities may also be provided. These can provide some additional protection, but only if appropriate hand washing has been carried out first.

### 6.4.4 Watches, rings, other jewellery and cosmetics

(1) Watches, rings and other jewellery cannot be adequately cleaned and so are potential sources of contamination.

(2) Consider the risk jewellery presents to the process and whether it is appropriate to implement a jewellery policy outlining which jewellery items can or cannot be worn in processing areas.

(3) Plain wedding bands (i.e. no stone) may be acceptable, if they cannot be easily dislodged and can be effectively cleaned in the same manner as hands. Devices (e.g. medical alert necklaces) or cultural gifts (e.g. taonga necklace) may be acceptable if they are securely worn under clothing, though again this will depend on the nature of the processing activity and potential contamination risk.

(4) Manufacturers should consider their policy on false eyelashes and fingernails, other cosmetic additions and cosmetics and toiletries for personal use. This will assess the potential for contamination of product, inputs or food contact surfaces given the nature of processing that will be undertaken.

### 6.4.5 Eating, drinking and smoking.

(1) There are some activities that should not be carried out in the processing environment, such as eating and drinking.

(2) Food or drink items may carry in additional pathogen contaminants, so should not generally be taken into processing areas.

(3) Smoking and vaping should be restricted to designated areas that are away from processing areas where dairy material, product or inputs might be adversely affected.

### 6.4.6 Protective clothing

(1) As part of the risk assessment, manufacturers will have determined whether protective clothing must be worn to protect the processing environment from contaminants on clothing, footwear or hair.

(2) If required, any protective clothing policy applies to all personnel (e.g. visitors and contractors).

(3) Protective clothing may include:

a) overalls;
b) hairnets, hats, beard masks;
c) boots;

d) safety glasses and ear protection;
e) aprons; and
f) gloves.

(4) Cleaned overalls and other protective clothing (e.g. boots, aprons) should be stored appropriately to minimise cross-contamination between clean and dirty items.

(5) The wearer should keep protective clothing as clean as practically possible. Consideration should be given to the potential for transfer of contamination via protective clothing (e.g. during movement between zones, during change of activities).

### 6.4.7 Gloves

(1) Gloves may be worn to protect hands and to prevent bacteria on skin from contaminating the product.

(2) Gloved hands should be washed and sanitised during normal work.

(3) Disposable gloves should be replaced regularly (e.g. when they become soiled or damaged, after breaks, between zones or activities).

(4) Multi-use gloves should be washed and sanitised at regular intervals and stored in a hygienic manner when not in use.

### 6.4.8 Boot exchanges and or footbaths

(1) Boot exchanges are the preferred barrier between zones and are essential for entry into dry areas where control of moisture on the floor is important to prevent pathogen growth. However, if the risk assessment has determined that a footbath is necessary then it should:

a) be wide enough that people cannot avoid stepping into it;
b) be a 50-70mm constant depth;
c) contain suitable sanitiser at recommended strength; and
d) be changed at least daily and either changed at regular frequencies throughout the day or the sanitiser strength checked throughout the day.

### 6.4.9 Equipment and materials

(1) Consideration should be given to the impact that the movement of equipment and materials may have on the potential for pathogens to contaminate other processing equipment or the processing environment. This extends to:

a) equipment, materials and other items entering a higher hygiene zone (assume everything entering the processing area is contaminated and steps are taken to decontaminate and sanitise);
b) equipment, materials and other items exiting a higher hygiene zone (removing fixed equipment may dislodge soil that harbours pathogens); and
c) equipment that is usually in a fixed position and is being moved within a critical hygiene area or high hygiene/high care area.

(2) Specific consideration should be given to the following:

a) transfer systems:

i) large equipment, pallets, bins etc passed through an air lock (noting the recommended restriction on wood and other absorbent materials other than packaging under section 7.3);
ii) small items (e.g. conveyers) with air curtains or similar; and
iii) forklifts.

b) removal of outer packaging before entry into processing areas;
c) cleaning or sanitising incoming goods or containers;
d) restriction of vehicle movements;
e) appropriate storage of equipment, materials, ingredients and final product;

f) restriction of access of certain materials, either into the processing area or between areas (e.g. wood, porous materials, cleaning equipment, high risk foods, or tools); and
g) use of separate equipment for raw and processed product, including:

i) bins, crates;
ii) knives, utensils;
iii) conveyors;
iv) trolleys;
v) tables;
vi) cleaning equipment; and
vii) tools.

h) colour coding as a method to identify portable equipment and utensils (e.g. knives, cleaning equipment) for exclusive use in a particular hygiene zone, or processing area, to distinguish between equipment and utensils used in lower hygiene zones vs higher hygiene zones.

### 6.4.10 Additional considerations for dry processing environments

(1) The priority for dry processing areas is to keep the area absolutely dry at all times.

(2) Consideration should be given to the following:

a) ceiling space;
b) under floor space;
c) coving, flashings and wall cavities. All openings into zone 3 or 4 areas should be effectively covered and sealed or, in the case of permanent openings for the rapid entry of items such as cans, there should be some form of biocidal control between the zones (e.g. UV tunnel);
d) building integrity issues such as water leaks, roof leaks, gaps under doors etc. Consider whether these are (or should be) part of a routine premises' inspection;
e) scaffolding (temporary for maintenance and permanent, controlled entry, sanitised, completely dry within any framing or piping);
f) fire suppression systems and sprinkler heads (location and leaks);
g) cracks and crevices on any surfaces;
h) trolleys;
i) location of eye wash, safety shower and hand sanitising stations; and
j) control and monitoring of relative humidity always, whether actively processing or not.

### 6.4.11 Alterations, unused equipment and unused processing areas

(1) When looking to make alterations or changes to premises, processing areas, equipment or services there are a number of factors that will need to be considered. This will require planning in advance to minimise the impact of the proposed changes, including:

a) significant and minor amendments;
b) introducing new equipment;
c) removing equipment;
d) unused equipment; and
e) unused processing areas.

(2) Consider the nature of the work involved, whether the hygiene envelope created by the RMP will be breached, and whether the intention is to undertake work while any of the area is processing.

(3) Any unused equipment within a manufacturing area must be cleaned and maintained as if it were in service to avoid it harbouring pathogens. This also applies to unused areas within the wider manufacturing area.

# 7 Cleaning, sanitisation and housekeeping

(1) Consideration should be given to the internal environment and routine activities that may affect the presence, movement or growth of pathogens.

(2) Routine 'housekeeping' activities do impact pathogen control and are an important consideration.

(3) The chemicals used for cleaning, sanitising and maintaining processing areas and equipment are classified as maintenance compounds. This also includes the compounds used to treat water on-site and compounds used for pest management. NZFS maintains a list of Approved Dairy Maintenance Compounds, which is available on the MPI website. This list identifies the intended use for each compound and any special conditions associated with its approval, such as the requirement to follow label instructions and to rinse surfaces after use. Manufacturers may opt to use alternatives but will need to assess the suitability of each compound and keep a record of their assessment.

## 7.1 Cleaning

(1) Cleaning refers to the physical removal of soil from surfaces, including milkfat, protein and mineral deposits. Sanitising refers to the inactivation of bacteria on cleaned surfaces (typically present due to post cleaning contamination) and the ongoing protection of cleaned surfaces until processing recommences.

### 7.1.1 What needs to be cleaned?

(1) The overarching requirement is that food contact surfaces need to be clean, and the processing environment sufficiently hygienic for the nature of processing undertaken.

(2) For wet areas, all equipment and processing area surfaces will need to be adequately cleaned and should be sanitised on a regular basis. Particular attention should be given to areas where materials may accumulate and present a pathogen risk, such as:

a) waste;
b) accumulation areas;
c) drains;
d) fat traps; and
e) water traps.

(3) For dry areas:

a) food contact surfaces will need to be cleaned. Typically, this will be a dry clean using suitable material to flush residual powder from contact surfaces;
b) the processing area will need to be cleaned regularly to remove any accumulated powder;
c) vacuum cleaners or central vacuum systems will need special consideration, including how the environment will be protected; and
d) there will be times that the processing area needs to be taken out of service for a more intensive clean, and procedures should address this.

### 7.1.2 Cleaning procedures

(1) Before a formal cleaning programme can be developed, manufacturers will need to know the standard operating procedures for the process, processing equipment and processing areas.

(2) Every step in the process will need a clearly specified cleaning and sanitising programme. This should state:

a) what has to be cleaned;
b) with what;
c) how;
d) when and/or how frequently;

e) by who; and
f) how the effectiveness of cleaning will be monitored or assessed.

(3) Cleaning procedures should also be in place to cover items not directly related to processing, including electrical boxes, power cables and plugs.

(4) Procedures should make it clear which things need to be cleaned out of place and how this will be done.

(5) Supervision and records of cleaning and sanitising operations will provide a high level of assurance that they have been carried out correctly. This could include checklists for operators to indicate areas cleaned, and pre-processing peer inspections to visually assess cleanliness of processing areas and equipment.

(6) Environmental monitoring for hygiene indicators, such as coliforms, Enterobacteriaceae, aerobic plate count, or, for equipment and surfaces in wet areas, ATP (Adenosine triphosphate, an indicator of the biological material present) can assist in determining whether the cleaning systems are effective. Note that environmental monitoring is covered under section 9.2.

(7) Cleaning procedures should follow the instructions provided by the chemical manufacturer and equipment supplier. NZFS also provides conditions for use of registered maintenance compounds (including cleaning chemicals), refer to the Dairy Maintenance Compound Register.

(8) A typical wet cleaning procedure would include:

a) preclean:

i) removal of loose food residue, soil etc; and
ii) initial rinsing.

b) clean – solution A:

i) for cleaning in place (CIP) this may be an alkali or acid; and
ii) for manual cleaning, this may use a detergent and might be the only cleaning step.

c) drain and rinse:

i) ideally drain or air purge then rinse. For CIP this may not be feasible; and
ii) the purpose is to remove residues of the first cleaning solution so that the next cleaning solution or the sanitiser won't be adversely affected.

d) clean – solution B:

i) for some equipment such as membranes there may be a soak associated with one of the cleaning steps.

e) drain and rinse;
f) sanitise and drain;
g) final rinse; and
h) dry – drying times and methods will need to be validated for dry processing areas to ensure that all equipment is thoroughly dry, and all moisture has been removed from the area before processing resumes. This includes assessment for drier and bag house dry out times.

(9) A typical dry clean CIP procedure may include:

a) preclean for dislodging powder that may have accumulated in the plant and using a vacuum system (preferably portable) to remove powder from the environment;
b) an initial flush or purge to remove residual powder;
c) polishing clean e.g. using a sugar such as dextrose;
d) flush with powder when processing resumes; and
e) a more intense (deeper) clean to remove allergens or when pathogens have been detected in material that has gone through the plant.

(10) Equipment and processing areas should be routinely inspected and should not become soiled to a degree that requires high pressure sprayers or water blasters.

(11) A variety of chemical cleaning compounds are available that are formulated to remove fats and grease, protein and minerals when used at the correct temperature and pH (and, in the case of CIP, with sufficient contact time and turbulence).

(12) Use of water under pressure is suitable when the processing area is out of production (e.g. winter shutdown), provided that all equipment and surfaces in the area (including ceilings, windows, doors, floors etc) will be completely cleaned, sanitised and dried before processing recommences.

(13) In dry areas, use of compressed air is likely to be used to dislodge powder during cleaning. Care should be taken to minimise the transfer of powder within the area.

### 7.1.3 Cleaning frequencies

(1) Typically processing areas and equipment will need to be cleaned and, for wet areas, sanitised at least daily. Remember that bacteria can grow rapidly under the right conditions so mid-shift cleaning may be necessary.

(2) Many items in the processing area will need to be regularly cleaned and sanitised to maintain suitable hygiene.

(3) Consider whether the processing area will be washed down before breaks or whether product remains in-process over breaks. Manufacturers may consider it better practice for staff to stagger breaks or to ensure that a batch of product has been fully processed before starting a break.

(4) Some items or areas tend to be overlooked. These also need to be included in a regular programme of cleaning and sanitising. Examples include:

a) chillers;
b) freezers;
c) light fittings;
d) doors or doorways;
e) switches;
f) computer keyboards and keypads;
g) forklifts; and
h) soap dispensers.

### 7.1.4 Cleaning equipment

(1) Cleaning equipment should be handled and managed in a way that it doesn't become a breeding ground for bacteria and source of contamination.

(2) Separate cleaning equipment should be used in each hygiene zone to ensure that cross-contamination between zones cannot occur. Colour coding of cleaning equipment, or other identification techniques, will assist in confirming that the right equipment is in the right hygiene zone. Ensure that relative cross-contamination risks between the following have been considered when establishing cleaning programmes:

a) inside vs outside;
b) raw product areas vs process areas; and
c) product contact vs non-product contact.

(3) Equipment used to clean the floor and drains should be dedicated to this task and not be used for any other purpose.

(4) Use only easily cleaned, non-absorbent cleaning equipment:

a) plastic brushes;
b) nylon bristles; and
c) rubber squeegees.

(5) Do not use cleaning equipment with wooden handles, wooden heads or fibrous bristles, as these porous materials can harbour pathogens.

(6) In wet areas, clean and sanitise all cleaning equipment after every use.

(7) Ensure that all cleaning equipment is stored in such a manner that it will not pose any risk to the processing operation, and so that the cleaning equipment is protected from environmental contamination.

(8) Store all cleaned cleaning equipment in a well separated area or room.

(9) Do not clean the processing environment using high pressure water sprayers or water blasters. High pressure cleaning creates aerosols that can spread bacteria throughout the processing area. Use other cleaning options whenever possible (e.g. use of appropriate cleaning compounds, low pressure and high volume, brushing).

## 7.2 Sanitising

(1) Surfaces need to be cleaned before sanitising. Sanitising will only be effective if the surface being sanitised has already been thoroughly cleaned to remove all product or other residue (e.g. milkfat, oil, protein and minerals).

(2) Special consideration will be required when sanitising equipment used to handle powders in dry environments. Sanitising using alcohol or other liquid without removing powder residue will be less effective.

(3) Sanitisers should only be used at the concentration recommended by the manufacturer and be allowed to stay in contact with the surface for the recommended time.

(4) Increasing the concentration of the sanitiser will not compensate for inadequate cleaning, and sanitisers are not a substitute for poor cleaning. The role of the sanitiser is to maintain plant hygiene from the time of cleaning through to processing recommencing.

(5) Consider whether specific areas will require special attention and may need to be cleaned and sanitised “out of place” to ensure effective contact with the entire surface.

(6) Fast acting sanitisers may be necessary for sanitising the plant prior to short breaks. Slower acting sanitisers may be suitable for longer breaks, such as overnight. In both cases food contact surfaces should be rinsed free of the sanitiser prior to processing re-commencing.

(7) With very few exceptions, sanitisers should be flushed from food contact surfaces prior to processing re-commencing. This is to avoid product being contaminated with sanitiser residue. Some sanitisers may contain compounds that:

a) are considered to be contaminants if they carry through into dairy products;
b) react with food components and form compounds that are undesirable and are considered to be contaminants; and
c) produce taints, and some may affect the manufacturing process if present at high levels.

(8) While maintaining the hygienic state of equipment and facilities is critical, manufacturers should consider the guidance on chlorates in dairy products and the appropriate use of sanitisers and disinfectants used for water treatment and to sanitise food contact surfaces, equipment and processing areas. Prudent use will ensure adequate hygiene is maintained and that any carryover of chemical residues into product is minimised.

## 7.3 Control of absorbent materials

(1) Pathogens, particularly *Listeria monocytogenes*, will survive and grow in any absorbent material including;

a) wood;
b) foam;
c) cloths;
d) scourers;
e) cardboard;
f) rope;
g) nylon fabric; and
h) conveyor fabric.

(2) These materials cannot be effectively sanitised, and any found in processing areas should be replaced with sanitary, easily cleaned, non-absorbent alternatives.

(3) It may be useful to include a regular check of processing areas for absorbent materials, documenting any found and corrective action taken.

(4) Using wooden shelving for cheese maturation presents an increased risk of *Listeria monocytogenes* and is strongly discouraged. Where wooden shelves are used, the cheesemaker must have cleaning and sanitising procedures that have been validated as adequate for an absorbent surface.

(5) Wood, including wooden pallets and wood associated with packaging, should only be permitted in manufacturing areas when an appropriate validation confirms adequate control of pathogens, notably *Listeria monocytogenes*. Also note that wood and other absorbent materials permitted in the manufacturing area will need to be included in regular environmental monitoring for listeria species.

## 7.4 Waste control

(1) Every food business produces waste and will store it temporarily before disposal. This poses some potential problems:

a) food waste will attract pests that are likely to be carrying pathogens;
b) food waste can be an ideal growth medium for bacteria, including pathogens; and
c) pathogens may grow on discarded materials such as packaging, e.g. cardboard boxes or crates, particularly if it is wet.

(2) An offensive odour around stored waste is likely to be due to bacterial growth and indicates an increased risk of pathogens. Waste should be removed at a frequency that ensures that this will not occur in or near manufacturing facilities, and waste storage should have been considered when determining the location and design of the premises.

(3) The management of waste for on-site laboratories undertaking microbiological testing will need particular care. All waste that might contain pathogens should be sterilised prior to disposal, with the treated waste removed from the premises frequently.

(4) Within the manufacturing areas, waste should be collected and held in covered bins/containers or closed bags until removed. Lids of bins/containers should have hands free operation, or a sanitising station should be located in the immediate vicinity so that hands can be sanitised immediately after use.

### 7.4.1 Recommended waste control guidelines

(1) **Inside**:

a) wherever possible, waste should be discarded as it is produced/recovered into labelled bins and located in designated areas;
b) clearly differentiate waste bins from product bins;
c) waste bins used in food preparation areas should be emptied and cleaned at least daily, and more frequently if the nature of the waste may attract pests, be the source of odour, or contaminate the environment in any way;
d) dispose of all packaging used for raw food materials immediately after opening; and

e) do not reuse any input packaging.

(2) **Outside**:

a) locate bulk waste bins away from food preparation and storage areas;
b) store wet waste in metal or plastic containers with tight-fitting lids;
c) wet waste should be removed from the premises every working day;
d) clean bins regularly to prevent build-up of pathogen-containing residues;
e) wash bins in a well-drained yard area;
f) store dry waste in enclosed containers; and
g) yard areas should be kept clean and tidy.

## 7.5 Pest management

(1) Pathogens may be carried into the environment by animals such as insects, birds and rodents. Manufacturers need to consider the access controls that apply to people and items, and also consider access controls for pests. This will mean aligning the pest management procedures with the pathogen management procedures and ensuring that there are no gaps to the monitoring and control measures that need to be applied.

## 7.6 Drying dry processing areas

(1) Following wet cleaning and sanitising within dry environments, other than spot sanitising with alcohol which must be allowed to evaporate completely, the whole processing area and all equipment within the processing area must be allowed to dry out thoroughly before processing recommences.

(2) Operators should establish and validate drying times (required when processing under the Infant Formula Notice) and embed the times and any associated criteria, checks and considerations into the manufacturer's procedures.

(3) A failure to completely dry the equipment and environment will enable pathogens, such as salmonella and *Cronobacter*, to survive, grow and enter product in a sporadic manner.

# 8 Process control

(1) In developing the RMP, operators are expected to:

a) identify each manufacturing process step where some form of control over pathogens can be established;
b) define the nature of control in procedures (i.e. by way of a CCP or Pre-requisite Programme (PRP)); and
c) ensure that effective control is always maintained at these steps.

(2) For most operators, process controls will be determined during the development of the HACCP plan.

(3) A CCP is a process designed to eliminate, or at least significantly reduce to an acceptable level, the total number of pathogens and contaminating bacteria (e.g. heat treatment). A process control PRP is intended to reduce the total number of pathogens and contaminating bacteria or to minimise their growth, for example heat, pressure, pH, or addition of salt or sugar to reduce water activity of the product, chilling/freezing or modified atmosphere.

(4) For each process control step identified the operating criteria will need to be clearly set out or referenced in procedures. For example, a heat treatment will require a heat treatment plan that meets the criteria set out in the PSP Notice. This will include various parameters including minimum (divert) time and temperature, maximum particle (filter) size, minimum/maximum flow rate, start-up procedures, the records to be kept, the frequency and how they will be recorded and checked.

(5) When process control steps are identified as critical control points (in a HACCP plan) they must be documented, confirmed as valid, checked regularly (monitored) and periodically verified by the manufacturer or RMP operator.

(6) Where several 'hurdles' are required for appropriate control, but each individually does not meet the requirement for a CCP. Manufacturers should document the hurdles used and ensure that each hurdle is regularly checked and verified by the operator with records or logs kept in much the same way as a CCP. In some cases, several hurdles may, collectively, be considered a CCP when they will consistently achieve an equivalent outcome.

## 8.1 Prior to processing

(1) Operators are expected to have procedures for re-starting processing activities after:

a) planned maintenance (including restarting after a seasonal shutdown) or temporary withdrawal from service;
b) relatively short, planned breaks with environmental controls maintained, for example no processing during weekends, but access and relevant ventilation, humidity and temperature controls in force; or
c) an unanticipated interruption in which the integrity of the processing environment may have been compromised, for example when people or things have not followed the required controls when moving in or out of a processing zone e.g. after a fire alarm has activated.

(2) For each restart situation, the procedures should identify all steps to be taken to ensure that the processing equipment and environment will be fit for purpose when processing recommences. This will range from extensive cleaning, sanitising and thorough drying for dry areas through to (for b) inspection and review to confirm that controls were maintained. In all cases consideration should be given to more intense sampling and testing of the first dairy material/product processed after restarting.

(3) Manufacturers should have procedures for the procurement and receipt of inputs. The procedures should identify preferred suppliers and any steps to be taken before accepting inputs for processing. In association with the preferred supplier programme, manufacturers should have a clear understanding of the microbiological specifications or assurances given by the supplier and undertake periodic checks. More extensive checks may be necessary as part of any related root cause analysis. While

audit of raw material suppliers is ideal, this will not be an option in many cases, in which case the manufacturers own monitoring checks, tests and records become the basis for supplier confidence.

(4) Raw or processed materials should be stored appropriately (e.g. chilled or frozen as soon as possible after receipt or kept in a dry and clean environment).

(5) Processing of chilled raw milk and other chilled inputs should commence as soon as possible after receipt (minimising delays). Other inputs will need to be used within any Expiry or Use by Date and will need to be used within a Best Before date unless a shelf-life assessment has determined otherwise.

(6) For inputs that will be consumed over time once opened, the operator's procedures should make it clear how the material is to be handled, stored (including storage conditions) and the last day for use. The input instructions may state the time to consume once opened, or operators may need to make their own determination.

(7) Unnecessary handling of materials prior to processing should be minimised.

## 8.2 During processing

(1) Appropriate time and temperature combinations should be determined for each operation.

(2) When control of the temperature and/or relative humidity within the processing environment is critical, these should be carefully controlled to achieve the desired result and be recorded at an appropriate frequency.

(3) Nothing is to be moved from the floor to product contact surfaces, and packaging, containers, bins and equipment used in processing area(s) are to be kept off the floor during processing and storage.

(4) It should be assumed that anything that has been in contact with the floor is contaminated, including hands and gloves.

(5) Anything that falls on the floor and that is to be reused will need to be cleaned and sanitised before reuse (e.g. scoops) and gloves need to be cleaned or changed.

## 8.3 During storage

(1) Products should be stored appropriately (e.g. chilled or frozen as soon as possible after processing or kept in a clean dry environment). This will minimise the likelihood of pathogen growth in product.

(2) The temperature of chillers and freezers used for product storage should be monitored and controlled constantly.

(3) If the rate of cooling or freezing will also influence the likelihood of significant pathogen growth, the manufacturer should treat this as a manufacturing step rather than a storage activity.

(4) Keep product contact surfaces, such as spiral belts, racks or shelves clean and sanitary. Product contact surfaces in chillers and freezers will accumulate product residues if not cleaned regularly.

(5) It is important to control the temperature during storage of high moisture foods as some pathogens and spoilage organisms may continue to grow, although at a slower rate, at refrigeration temperatures.

## 8.4 Alkaline phosphatase testing

(1) If it is intended that product will be released and may be consumed prior to micro results being available (e.g. liquid milk intended for the domestic market), then it is likely that alkaline phosphatase testing (or an acceptable alternative) will be needed to confirm that pasteurisation conditions have been achieved and no cross contamination has occurred. This testing should be done on milk immediately after pasteurising. It is not required when the product microbiological results (per the sampling and testing plan) will be available before the product leaves the manufacturers control.

(2) Refer to the MPI Alkaline Phosphatase Testing Guidance for more information.

## 8.5 Rework

(1) Rework should be subject to similar controls as other inputs to ensure that they are and remain suitable for the intended use. The RMP will need to address any special considerations related to rework, such as:

a) product or material that is intended to be added back into product that will not undergo a heat treatment;
b) removal of packaging and preparation for rework;
c) the reason that the product or material needs to be reworked; and
d) the potential to contaminate the processing environment.

(2) The RMP will also need to have procedures for the rework of product that is non-conforming for microbiological reasons (e.g. under a product disposal approval) in order to undertake rework. These procedures will need to ensure that cross contamination of product or the manufacturing environment will not occur. Similarly, the activity should be included as a process step in the HACCP Plan with consideration given to the introduction of hazards and control of risk factors.

(3) An approval for rework (further processing) of dairy material or product under a product disposition does not override the requirement for the activity to be covered within the RMP.

## 8.6 Management of inputs

### 8.6.1 Procurement of inputs

(1) Every dairy manufacturer should:

a) set out in the RMP the acceptance criteria to be used in the selection of inputs and the suppliers of those inputs;
b) ensure that a list is kept of accepted suppliers of inputs and the inputs they supply along with a record of the way the suitability of each supplier was confirmed; and
c) ensure that procurement records are kept for each input, showing the intended use of the input and its critical specifications.

(2) To confirm the suitability of inputs, dairy manufacturers should review any associated reports from laboratories accredited to ISO/IEC 17025, certificates of analysis, and declarations from other dairy manufacturers or suppliers of inputs.

(3) Any certificates of analysis, supplier declarations or assurances, or any other documented safeguards used by suppliers to confirm that inputs meet requirements should be retained by the dairy manufacturer to support the dairy manufacturer's determination of suitability.

(4) Dairy manufacturers should ensure that suppliers will consistently supply inputs that are suitable for the intended use. For this purpose, dairy manufacturers should hold relevant information on each supplier of inputs, such as that obtained by carrying out supplier audits, reviewing audits of suppliers by third parties, reviewing equivalent endorsements, or any other appropriate process.

(5) If a supplier fails to meet the dairy manufacturer's acceptance criteria for the input supplied, the dairy manufacturer should:

a) raise the issue with the supplier and record the outcome; and
b) if the acceptance criteria continues not to be met, deem the supplier to no longer be suitably qualified for the input concerned.

(6) If a supplier is not the person who manufactured the input, the dairy manufacturer should take steps to ensure that:

a) they know who the original dairy manufacturer of the input is; or

b) they are satisfied the supplier has reliable and robust systems in place to ensure the integrity of inputs.

### 8.6.2 Input acceptance

(1) The RMP should set out the procedure for recording the following in relation to the receipt of inputs:

a) the input received and the quantity;
c) who supplied it; and
d) when it was received at the premises.

(2) Every RMP should set out the procedures for checking that:

a) inputs are only accepted from suppliers on the list of accepted input suppliers referred to in sections 8.1(3) and 8.6.1(1)a);
b) the integrity of each input consignment has been maintained and its outer packaging has not been compromised; and
c) all inputs used for relevant product meet the dairy manufacturer's acceptance criteria and are fit for purpose.

(3) If an input is received from a supplier with a problem that might adversely affect relevant product (such as having the potential to cause contamination, or having its composition misrepresented), the RMP operator advise the verifier without delay if the problem with the input could reasonably be expected to:

a) result in relevant product being non-conforming; and
b) affect other dairy manufacturers receiving the product for use in relevant product.

(4) This notification is to enable MPI to be advised and to take steps to minimise the impact on other dairy processors who may be affected. The advice does not affect product conformance provided that the affected input has not been used.

(5) Dairy manufacturers should:

a) identify in the RMP which testing of inputs they will undertake, and at what point the testing will occur; and
b) regularly compare their own test results with any supplier statements concerning the inputs.

### 8.6.3 Storage and unpacking of inputs

(1) Inputs used to manufacture relevant product should be:

a) clearly identifiable at all times;
b) stored away from things that might cause contamination or that might adversely affect the input or its packaging;
c) stored in a place and manner that protects the input from contamination and deterioration;
d) stored in a place and manner that protects the packaging of inputs from damage and deterioration; and
e) adequately spaced to permit inspection during storage.

(2) Inputs should not be stored in buffer zones but may be kept in buffer zones temporarily pending use.

(3) The removal of outer packaging (if any) from inputs, and the decontamination of inputs, should occur in a buffer or transitional area before the input enters a higher hygiene zone, unless:

a) the manufacturer has in place a procedure that has been validated in accordance with Regulation 34; and
b) the RMP operator holds validation information that shows the procedure is as effective at preventing the introduction of pathogens or other contaminants into higher hygiene zones as the removal of outer packaging from inputs and decontamination of inputs before their entry into a high hygiene area.

(4) As far as practicable, the following should be stored apart from each other, in a manner that minimises the risk of cross-contamination and ensures that one thing is not mistaken for another:

a) packaging materials;
b) bulk dairy material;
c) ingredients in concentrated form;
d) maintenance compounds; and
e) chemicals not for use as ingredients.

### 8.6.4 Ingredient shelf life

(1) For each ingredient, the dairy manufacturer should know and record:

a) its shelf life while in its package; and
b) its shelf life once its package is open (i.e. the shelf life of the unpackaged ingredient).

(2) If a final product has a shelf life that takes it beyond the shelf life of an ingredient (as at the time it is incorporated) the dairy manufacturer should document the justification for the shelf life applied to the product.

### 8.6.5 Ingredient management

(1) The RMP should set out procedures to ensure that any ingredient that will not be further heat treated meets the microbiological limits that apply to the relevant product in which it is used, unless the RMP specifies an alternative microbial limit for that ingredient.

(2) Ingredients that will not be subsequently heat treated should always be prepared in an area managed as a higher hygiene zone (zone 3 or 4).

### 8.6.6 Disposal of unused inputs

(1) Any input that does not meet its acceptance criteria or is otherwise unwanted should be clearly identified and stored in a manner that prevents its inadvertent use. A record should be kept detailing the nature of the acceptance failure and the fate of the affected input.

# 9 Monitoring and surveillance

(1) The PSP Notice sets out requirements for sampling and testing (D1.12 and D1.13), environmental monitoring/surveillance (clause D3.4) and final product testing (D3.6). Other product specific Notices, such as the Infant Formula Notice and Raw Milk Products Notice, contain additional criteria and points to consider.

## 9.1 Sampling and testing plans

(1) Information to help with development of pathogen management plans and sampling and testing plans is provided in the appendices, for instance:

a) Appendix 1 – Pathogens and Indicator Organisms of Relevance;
b) Appendix 2 – Sampling and Testing Plan Examples; and
c) Appendix 4 – Useful Analytical Techniques.

(2) Appendix 2 sets out examples of sampling plans relevant for smaller manufacturers. These examples are intended to help illustrate the pathogens and indicator organisms relevant to different products and processes, and to also indicate minimum testing frequencies. While these generic plans indicate the nature of sampling and testing expected, there may be reasons why these plans are not appropriate for a particular manufacturer, due to the nature of processing, ingredients, product and the potential presence of uncontrolled hazards.

(3) In developing an appropriate sampling and testing plan, manufacturers intending to export should also consider:

a) OMAR requirements; and

b) country specific requirements, as advised by the importer.

# 9.2 Environmental monitoring/surveillance

(1) The environmental monitoring programme provides confirmation that the processing environment is at the required hygiene state, and that pathogen control systems in place are operating as intended. Monitoring final product, the manufacturing environment and other forms of monitoring such as in-process are not control measures but are vital tools to assess the effectiveness of control measures. Monitoring of inputs such as ingredients and packaging may be control measures in their own right if applied as such.

## 9.2.1 General considerations

(1) Contamination of product from the processing environment is a common source of contamination for processed foods. For this reason, it is critical to ensure that the processing environment is always protected from contamination.

(2) Monitoring of the processing environment (along with final product and the process itself) provides the processor with an assurance that the control measures are effective. However, environmental monitoring for pathogens is not a critical control point. RMP operators should ensure that their programme is clear whether or not the monitoring is linked to operator defined limits.

(3) Each manufacturing premises is required to have environmental monitoring procedures (refer to PSP Notice clause D3.4). These procedures will include:

a) sampling responsibilities;
b) site plan showing sampling sites;
c) what is to be sampled and tested and how (sampling and sample handling procedures);
d) minimum sample numbers and the frequency of sampling;
e) what samples are to be tested for; and
f) required follow-up actions.

(4) The environmental pathogen management plan/procedures should include:

a) how to determine sampling points;
b) how samples are obtained; and
c) the handling and dispatch or delivery of samples to the relevant laboratory.

(5) Additional information on swabbing and the use of swabbing as part of the environmental pathogen monitoring is set out in Appendix 5.

(6) The selection of suitable sample sites will be based upon the perceived risk to the product or process. Processing areas should be maintained in a sanitary condition, though the hygiene standard will differ according to the nature of the process and material at the various stages of processing (raw milk storage and processing vs the processing of treated product).

(7) Contamination may be brought into processing areas (e.g. on items such as raw ingredients, packaging, water, equipment, tools or personnel). Pathogens may also enter the process environment in other ways (e.g. via pests, roof leaks and other breaches of the processing environment, or openings to lower hygiene zones).

(8) During the development of pre-requisite programmes (good operating practices, good hygienic practices) or the HACCP Plan, the control measures necessary to prevent entry of microbiological contaminants should be considered. Consequently, the sampling plan for the environmental surveillance programme should be developed to confirm the effectiveness of these controls. As part of this development consider all points of entry and exit including buffer zones and airlocks.

(9) Manufacturers should undertake pathway mapping as it will help clarify the points where exposed product may intersect with risk factors, and how the various risk sectors may intersect and where.

Refer to Section 5.3 Pathway Mapping for information to assist with the selection of sampling sites for monitoring the environment.

(10) When establishing the sampling plan, be prepared to apply flexibility and collect additional samples when the circumstances dictate, such as when new equipment is installed or existing equipment is returned to service, following interruptions or loss of hygiene envelope integrity (e.g. suspected redline breaches).

(11) When considering the collection of additional samples, the sampler should have access to a suitably skilled person who can determine whether additional samples are required, and if so, how extensive. This will be heavily influenced by the nature of processing and the known microbiological ecology of the manufacturing area concerned. Manufacturers may opt to wet clean and sanitise in situations of doubt (e.g. possible redline breach) and this would negate the need for additional samples.

(12) In general, and using the zones described in section 5.2, surveillance is likely to include:

a) **zone 2** - **inside** standard hygiene areas where product is not normally exposed (e.g. stores), areas where there is exposed raw product that will receive a microbiocidal CCP (e.g. raw milk prior to pasteurisation), and corridors immediately adjacent to zone 3 hygiene areas. These areas often act as a **buffer** between the outside environment and zone 3, and as such the primary focus should be on the entry pathways to zone 3;
b) **zone 3** - **inside** areas where material (including ingredients), particularly after a microbiocidal critical control point, is processed and may be exposed (critical hygiene areas);
c) **zone 4 – inside** areas that require a higher level of hygiene due to the nature of the processing and/or product; and
d) **designated buffer areas** between the above zones.

(13) Sampling from zone 1 is not likely to be necessary or useful though there may be exceptions based on the site design, assessed risk and ability to control pathogen within the area concerned.

### 9.2.2 Zone 2

(1) Examples of suitable sampling sites include:

a) stores used to hold inputs;
b) product stores;
c) floors near zone 3 entry points;
d) zone 3 buffer zones, air locks and other entry/exit points (people, packaging, product, tools, services etc);
e) service areas; and
f) wet areas.

(2) Samples may be in the form of swabs, wet material or dry material (e.g. sweepings, scrapings, rubbish).

### 9.2.3 Zone 3

(1) It is important to know that this environment is free from contamination at all times.

(2) Examples of suitable sampling sites include:

a) processing areas;
b) packaging areas;
c) chillers or freezers;
d) forklifts, trolleys or other forms of conveyance;
e) drains (higher probability of harbouring pathogens);
f) floors;
g) cleaning equipment;
h) walls or ledges;
i) hard to clean equipment;
j) wet areas;

k) product contact surfaces located in zone 3, especially filling heads and points where dry product may accumulate, though these will often be in zone 4;
l) benches;
m) conveying systems or belts;
n) areas close to filling heads;
o) utensils (e.g. knives);
p) gloves;
q) shelving;
r) packaging material;
s) bins or footbaths (consider monitoring footbath sanitiser strength routinely);
t) entry/exit points from a lower zone for people, packaging, product, tools, samples, services etc, including designated buffer areas; and
u) higher zone entry points (if applicable).

(3) Samples may be in the form of swabs, wet material or dry material (scrapings, product residues).

### 9.2.4 Zone 4

(1) The sampling sites to consider will be similar to those for zone 3.

### 9.2.5 Sample collection

(1) The purpose of the environmental surveillance programme is to test the effectiveness of pathogen control measures. It is in the best interests of the business to maximise the effectiveness of the surveillance programme.

(2) As a general rule, the bigger the sample taken, the more likely there will be an environmental contamination detection.

(3) Samples may be obtained in various forms, such as:

a) wet or dry swabs;
b) wet material or dry material (e.g. scrapings, sweepings, sifter overs, residue from vacuum systems or other product residues); and
c) airborne contaminants (e.g. exposure plates).

(4) Swabbing is an important mechanism for gathering environmental samples, particularly in areas where there is not enough loose material to collect. Refer to Appendix 5 for more detailed information on swabbing, including how to swab and what to test for.

(5) Samples such as swabs may be taken and cultured to identify the bacterial load or specific pathogens, or they may be used to rapidly assess hygiene, for example ATP.

(6) Procedures for sampling should identify:

a) how to collect the samples, for example:

i) what, when and how to swab e.g. aseptic technique, direction and swab rotation, area to cover for consistency, number of passes;
ii) whether any special action is required, such as neutralising any antimicrobial agent that may be present;
iii) when and how to composite samples (if applicable);
iv) only suitably trained personnel to collect samples; and
v) how to randomise samples (e.g. sampler should swab random sites in specified areas and note the site clearly on the sample submission form).

b) how to handle sampling equipment and containers, as well as collected samples, including:

i) how to label the swab (e.g. zone, location, date, and time);
ii) how to complete any laboratory sample submission form;
iii) any sample temperature controls (e.g. refrigerate after collection without delay); and

iv) how the sample will be stored until courier pick-up and maximum storage times prior to dispatch (e.g. to be received by the laboratory within 24 hours of sampling).

c) sampling frequencies, locations and how to randomise sampling to minimise bias;
d) target organisms or parameter (e.g. *Listeria monocytogenes*, *Salmonella* spp., *Cronobacter* spp., Enterobacteriaceae, APC, etc);
e) operator defined action limits and alert triggers for all target organisms or parameters that are measured (e.g. not detected/swab); and
f) training and competency requirements;

(7) The RMP indicates the need to include sampling procedures when sampling for testing, including samples for Environmental Pathogen Management, input/ingredient monitoring and final product testing.

(8) A Swabbing for *Listeria* video has been developed to assist RMP operators on how to collect environmental samples from the processing area for *Listeria* testing.

(9) Ensure the following is sampled:

a) product contact surfaces;
b) in-process sampling;
c) after intrusive maintenance;
d) new or recommissioning idle equipment;
e) personnel protective equipment or hands;
f) product packaging; and
g) in the case of a breach, the redline.

(10) Ensure procedures are in place for sampling when the plant is not in operation, such as weekends or the off-season, and after interruptions such as routine or unplanned maintenance.

(11) Procedures within the RMP should specify the actions to be taken if alert triggers or operator defined action limits are exceeded (escalation procedures), as well as the criteria to be met in order to revert back to routine monitoring (de-escalation).

### 9.2.6 Sampling in a dry environment

(1) In dry process environments there will be a strong focus on keeping microbiological contamination out of the processing area, especially for zone 3 and above. As well as actively monitoring the barriers to entry, including intended entry/exit points, there should be robust controls to ensure adequate air quality and pressure at all times, appropriate temperatures and relative humidity levels at all times, even when not processing, and to prevent the entry of moisture.

(2) Cleaning programmes differ from those of wet processing, and there is a greater reliance on maintaining a dry, hygienic environment at all times.

(3) Sampling plans should take these factors into account and monitor points of greatest weakness as well as random points within the environment. The timing of sampling should aim to assess the hygiene status when there is no processing as well as while processing is underway.

(4) In many situations it is not practical or desirable to monitor product contact surfaces while processing is in progress. For some processing areas, it is not desirable to break open a plant/equipment that is forming an enclosed, hygienic envelope. It's recommended that processors undertake product contact surface monitoring (e.g. swabs) when the plant is dismantled for other reasons, such as periodic removal of residual powder build-up or cleaning out of place.

(5) If it is necessary to take swabs of product contact surfaces within the dry process environment, consider the use and effectiveness of dry swabs. If wet swabs are used, the area swabbed should subsequently be wiped with an alcohol sanitiser and allowed to dry.

(6) Because some level of residual powder can be expected to hang in the powder handling lines, sampling plans should consider this and how it can be shown that this powder will not affect product (e.g. via flushing of lines at start-up and when restarting after an interruption).

(7) Salmonella will be the primary pathogen of interest in dry environments, along with pathogens that might be introduced through ingredients.

(8) Manufacturers of infant formula (i.e. for infants 0 to 6 months of age) will also need to confirm that the product is free from *Cronobacter*. Enterobacteriaceae is commonly chosen as the target organism for monitoring dry environments as it can provide a more sensitive early warning. However, the RMP needs to be clear on the actions to be taken if unfavourable Enterobacteriaceae results are obtained with the default assumption that all of the detected organisms may be *Cronobacter*.

### 9.2.7 Sampling frequency

(1) The frequency of environmental sampling will be influenced by:

a) the nature of premises and processing;
b) adequacy of hygiene controls between zones;
c) the intended consumer (specific populations/vulnerable population vs general population);
d) intrinsic characteristics of the product;
e) historic performance; and
f) the scale of production.

(2) As routine environmental monitoring is intended to give confidence that products will not be affected by the environment, the more frequent the testing the greater the confidence. This becomes an important consideration when things go wrong and product is found to contain a pathogen at an unacceptable level. A lack of environmental test data may mean that more product needs to be classified as potentially non-conforming. This in turn may result in the recall of more product than would otherwise be the case.

(3) Historical performance and ongoing trends will help to indicate whether the frequency of monitoring is adequate.

(4) Appendix 2 provides some examples of sampling frequency that may be suitable for small dairy manufacturers, though this will depend on the nature of the manufacturing facilities and whether other processing activities occur.

### 9.2.8 Compositing samples

(1) Compositing is the combining of a number of subsamples to form a larger, composite sample prior to testing. Composite samples may be prepared by the manufacturer or, subject to certain NZFS criteria, the laboratory. This can reduce test costs and enable more extensive monitoring to be undertaken. At the same time, compositing samples does come with some limitations.

(2) Before forming a composite, it is important to consult the laboratory that will undertake testing to determine the maximum size of a composite, and the maximum number of samples intended to make up the composite. In some situations, it may be preferable for the laboratory to form the composite sample, as they will have appropriate facilities for aseptic handling of samples, and they can identify the makeup of the composite on their test report. However, this won't be an option when proportional samplers are being used to collect samples, and operators are responsible for ensuring that samples are truly proportional and that the portion(s) collected for testing are representative.

(3) The Sampling Conditions column in Table 3 of the PSP Notice provides additional information to assist operators, verifiers, and NZFS, especially in relation to collecting samples and will guide the forming of composites.

(4) While there are some advantages in testing composite samples, manufacturers need to be aware that there are also some limitations and in some situations the testing of composite samples may not be appropriate. For example, one disadvantage of compositing is that further traceback work will have to be undertaken to isolate a contamination point when a composite is positive, resulting in a longer timeframe required to isolate the problem. However, for companies with effective controls and a good surveillance history, compositing is a cost-effective option.

(5) In some cases, Table 3 of the PSP Notice presents information on the minimum number of sample increments that should form a composite. However, it may be that a manufacturer will form multiple composites per batch or production run. This is permitted and the sampling conditions will help to guide how such composites are formed.

(6) As an example, the sampling conditions for *Cronobacter* refer to 30 x10g samples or a composite comprising at least 30 samples across the production run. In this case 3 composites, each comprising 10x10g taken across one third of the production run is acceptable. This will provide at least 30 subsamples of at least 10g from across the run being tested.

(7) Compositing using gauze swabs is a particularly effective way of sampling large areas.

(8) Compositing rules include:

a) only composite samples within a zone (do not mix samples from different zones);
b) do not composite wet samples with dry samples;
c) do not include swabs that smell of sanitiser in a composite; and
d) document the sample sites (e.g. location, date and time) for all areas that make up a composite.

(9) The rules and justification for compositing samples should be documented in the Pathogen Management Plan or the Sampling and Testing Plan. It is important that manufacturers understand the benefits and limitations of composite samples.

### 9.2.9 Trend analysis

(1) The results from environmental monitoring should be actively reviewed and assessed for both conformance with the alert triggers and actions limits that have been established and documented, as well as trends indicated by the data.

(2) Results will need to be recorded in a way that supports review and observation of trends, for example via entry into a spreadsheet or database. For very small manufacturers manual systems will suffice, but it is recommended that the results are recorded as well as plotted on a graph for each sample type and area.

(3) When the trend data indicates that environmental controls are deteriorating or weakening over time it is important that appropriate remedial action is taken. The approach will be similar to that for any investigation/root cause analysis and will include consideration of things outside the direct control of the manufacturer such as seasonal effects as well as those within the manufacturers control.

(4) Having a clear understanding of historical data will support a more rapid and effective root cause analysis and recall determination should a product pathogen non-conformance occur.

## 9.3 Response to environmental monitoring detections

(1) Just as selection of sample sites is based on the potential for contamination of material during processing, pre-determined corrective actions when pathogens are isolated should correspond to the risk of product being affected.

(2) Procedures should be included in the RMP that specify the actions to be taken in the event of unfavourable environmental sample results. These actions will differ according to the purpose of failure (early alert trigger vs a pathogen in zone 3 or 4). Having the actions specified and evaluated gives certainty with respect to the immediate actions expected.

(3) If the RMP applies the environmental monitoring thresholds as operator defined limits then any breach of a limit will need to satisfy the requirements set out in Regulations and PSP notice, including obligations for verifier notification. If the environmental monitoring thresholds are not set as operator defined limits then verifier notification is not required (provided the RMP details the actions to be taken), however advising the verifier as an FYI is generally to the manufacturers advantage.

(4) The following are suggested actions in response to isolation of pathogens from each of the hygiene zones.

### 9.3.1 Positive results from zone 2

(1) Positive results from zone 2 are to be expected from time to time. These provide manufacturers with:

a) confidence that the sample site selection is probably adequate; and
b) knowledge with which to manage the situation.

(2) Trends combined with root cause analysis will help to develop appropriate corrective/preventative actions.

### 9.3.2 Recommended actions for positive results in zone 2

(1) Positive pathogen results and elevated indicator results in zone 2 serve as an early warning. That is, pathogens are, or may be, in the general environment, but not yet in the zone 3 critical hygiene areas.

(2) The response to elevated results for general hygiene indicators (e.g. APC and ATP) will typically involve more intense cleaning and review of traffic movement, the RMP controls, and anything which might have changed or contributed.

(3) The response to pathogen detections will typically include increased monitoring within the zone 2 environment to confirm that a suitable level of hygiene has been reinstated, and increased testing within the adjacent zone 3 environment and the entry points to zone 3.

(4) Resample in order to pinpoint the source of contamination, but before this occurs:

a) review trends for past failures in the area and root cause analysis findings; and

b) review the pathway map(s) for the area. This will help to show possible movement of pathogens within the manufacturing environment and help guide sampling so that the probable source can be identified.

(5) Reassess:

a) relevant controls associated with zone 2, including physical inspection of the area to confirm that the controls are working as intended;
b) access restrictions to zone 3;
c) zone 3 sampling points and results at or near entry points from zone 2 including buffer zones and airlocks;
d) cleaning and sanitising programmes;
e) manufacturing and product handling procedures in the area, as well as any protections on entry to zone 3 (de-bagging, sanitising, UV etc); and
f) corrective/preventative actions to be taken.

(6) It would be prudent to intensify sampling in zone 3 to ensure that zone 3 barriers have not been breached. As an example, double the routine environmental sampling with a focus on entry points. Sampling might then return to routine levels once samples taken over the following 4-7 days (while the area is in production) came back as clear. Typically, when day 4 results are received there will be another 3 days or more of samples to be tested. The testing of these should continue as part of the increased testing.

(7) Clean and sanitise the affected area, if appropriate, to minimise the risk of contamination spreading.

(8) Resample the affected area, and adjacent areas, until confident that the source of contamination has been eliminated. Generally, this means documenting the required escalation (frequency, sampling points) and the trigger to be met to de-escalate (noting the examples in (6) above).

### 9.3.3 Positive results from zone 3

(1) Positive results in zone 3 mean that the zone 1 and zone 2 barriers may have been breached and contamination has entered the critical hygiene area.

(2) Depending upon the location of the finding and the actual source and flow within the area, it is possible that product may be affected. The frequency of product sampling and testing should be reviewed. The default position being that product sampling rates are increased, unless the manufacturer can justify why product is unlikely to be affected.

(3) When increased sampling and testing occur, the expectations are that:

a) every batch is tested from the point of the last relevant negative test result for product; and
b) for each batch or daily production run, sufficient sampling is undertaken to be confident that no contamination has occurred. For example, by use of a statistical approach (e.g. International Commission on Microbiological Specifications for Foods). Refer to section 9.5 for recommended actions (including sampling) in the case of product positive results.

### 9.3.4 Recommended actions for positive results in zone 3

(1) Sources of contamination in critical hygiene areas will not always be isolated in one discrete area. It may be necessary to look further for sources of contamination, particularly focusing on areas that do not form part of the normal monitoring programme.

(2) The objectives of follow-up actions are to:

a) identify the locations and extent of contamination within the zone;
b) identify the source (root cause);
c) determine the extent of the problem, including:

i) potential product contamination; and
ii) contamination of the environment.

d) eliminate the contamination within the zone (e.g. clean and sanitise);
e) eliminate the root cause; and
f) take steps to prevent any re-occurrence.

(3) Specific follow-up actions include undertaking the following:

a) a root cause analysis to determine the source of contamination (refer to section 10.1);
b) a review of the pathway map(s) to identify a possible source and the probable spread within the processing environment. This will help inform sampling site selection for more intense sampling;
c) a review of trends related to environmental monitoring, in-process testing or final product testing;
d) immediate and more intense testing of the processing environment, particularly around the site of the positive finding before cleaning and sanitising the affected area. This should also consider the possible source of the pathogen and the probable movement within the processing area. The default approach for increased testing should be set out in an RMP procedure, though the actual situation will influence the approach taken;
e) review of the relevant controls associated with zone 3, including physical inspection of the area to confirm that the controls are sufficient and working as intended;
f) cleaning and sanitising of the affected area or, if appropriate, the whole zone 3 area;
g) more intense ongoing (post cleaning) monitoring of the affected area, adjacent areas, and any areas indicated by way of the pathway map as being potentially affected in order to pinpoint the source of contamination. This increased monitoring needs to continue until the manufacturer is confident that the source of contamination has been eliminated and the area has been returned to the hygienic state necessary for the nature of processing. Generally, the default escalation (frequency, sampling points) and the trigger to be met to de-escalate will be set out in the relevant RMP procedures;
h) increased testing of product. The appropriate testing intensity will be guided by the location of the affected sampling site and the potential for product to be affected. This will include consideration of the pathway maps, potential movement of pathogens within the processing environment, and initial findings coming from the root cause analysis. In the absence of a probable root cause, increased testing of product should typically go back to the time of the last clear environmental result for the sampling site concerned;

i) more intense sampling in zone 4 (if relevant) to ensure that zone 4 barriers have not been breached, especially around the entry points such as clothing exchange, buffer areas and airlocks;
j) a return to routine monitoring should be described in RMP procedures, for example when there have been no positive or unfavourable results over 4-7 sample collection days (while the area is in production). Typically, when day 4 results are received there will be a further 3 days or more of samples at various stages of dispatch and testing. The testing of these should continue as part of the increased testing;
k) testing composite environmental samples is generally not recommended in the case of a traceback unless there is a clear understanding of the limitations of a composite and the likely need to resample. Testing a composite of product samples is suitable for presence/ absence purposes but has serious limitations for enumeration tests (quantitative tests that produce a count) that the manufacturer needs to understand. Composites may be appropriate as a monitoring tool when the acceptable limit is adjusted in proportion to the number of samples that form the composite, for example if there are 5 samples in a composite, reduce the acceptable limit by a factor of 5. Generally, the use of composited samples for enumeration tests should be used for monitoring purposes to add to the manufacturer's confidence rather than the sole means of confirming conformance to a regulatory limit.
l) reassess:

    i) all access restrictions from zone 2 into zone 3, and (if relevant) from zone 3 into zone 4;
    ii) housekeeping, cleaning and sanitising programmes;
    iii) controls in place to assess the microbiological suitability of ingredients;
    iv) manufacturing and product handling procedures; and
    v) sanitary design of equipment.

m) if product is not available for testing, manufacturers should contact their recognised agency or regulator;

n) finally:

    i) confirm the corrective/preventative actions to be taken; and
    ii) follow-up to ensure that the corrective/preventative actions have been completed as intended. Unfortunately, it is not uncommon for manufacturers to fail to adequately implement all required corrective and preventative measures to address the findings of the root cause analysis.

### 9.3.5 Positive results from zone 4

(1) Positive results in zone 4 suggest that either:

a) zone 2 and 3 barriers may have been breached and that product may be contaminated; or
b) the microbiological contaminant has been introduced via an ingredient, which has affected the processing environment and means that product is likely to also be contaminated.

(2) Depending on the nature of the positive result, enhanced testing of product may be necessary to confirm that conformance standards (i.e. D1.2 of the PSP Notice plus any other relevant standards or operator defined limits) have been met.

(3) Enhanced testing will be expected if the finding involves a pathogen relevant to the product(s) being processed. The guidance under clause 9.3.4 will typically apply, though the general expectation will be more intense follow-up monitoring (escalation) and for longer than would normally be the case for zone 3 (e.g. 7-10 days before returning to routine monitoring levels). However, this will depend on the findings from the root cause analysis, and whether the area and equipment can be effectively cleaned and sanitised.

# 9.4 Product testing

(1) Final product testing is not a pathogen control measure but is an important tool in confirming that the manufacturing activities are fit for purpose, performing as intended, and consistently deliver conforming product.

(2) While routine testing at an individual batch level is unlikely to give a reasonable level of statistical confidence of conformance, over time the test results will provide the manufacturer with adequate confidence assuming favourable results.

(3) Final product testing should not be considered as a CCP, or a pathogen control measure. However, it may form part of a CCP (e.g. raw milk products utilising multiple process hurdles) and will commonly form part of the monitoring to confirm that a CCP is performing as intended.

(4) The PSP Notice requires manufacturers to have a sampling and testing plan and sets out minimum requirements for the plan (refer D1.12, D1.13, and D3.6).

(5) In addition to the recommendations in clause 9.7, manufacturers should discuss their testing requirements with the relevant laboratory so that:

a) appropriate test methods are used;
b) samples are submitted in a manner acceptable to the laboratory (which may include sample age and temperature, sample size and sample containers); and
c) the lab is aware of the purpose of the testing and any specific instructions or actions to be taken if results exceed nominated limits e.g. who to contact and how, and whether to provide alerts for presumptive positive product results or presumptive positive environmental results, etc.

## 9.4.1 Sampling and testing plans

(1) In designing the sampling and testing plan for final product, manufacturers need to consider:

a) the nature of the process (UHT with aseptic packing vs traditional cheesemaking with manual handling and direct contact between product and personnel; processes with single lines vs multiple lines or filling heads);
b) the pathogens of primary concern and indicator organisms that help identify process control failures;
c) at which point product contamination is most likely to occur e.g. at start-up or after an interruption, and after intrusive maintenance; and
d) what samples can be obtained. For liquid products the sample may be a packaged consumer ready item, while for powder a sample may be taken immediately before sealing the package (e.g. manual or by autosampler).

(2) All manufacturers, other than those that simply label or repack without exposing product in any way, should be testing their product at regular intervals. The less frequent the routine testing is the more testing will be required if a product failure occurs, or the more product will be subject to recall.

(3) Table 3 of the PSP Notice sets the conformance criteria (the microbiological limits) that apply. RMP operators will determine the appropriate minimum routine sampling and testing frequency across a production run to give confidence that the relevant microbiological limit will be met. The expectation is that a sample drawn from any packaged dairy material or product will meet the micro limits.

(4) Dairy manufacturers are not required to test strictly in accordance with Table 3, but are expected to:

a) adopt a sampling and testing plan that gives confidence that the Table 3 criteria will be met; or
b) have determined that testing for the parameter concerned is not relevant for their product and process, and retain a record of the justification.

(5) Establishing the sampling and testing plan will require several factors to be considered, including:

a) testing identified as necessary during development or review of the HACCP Plan and prerequisite programmes (not all pathogens or indicator organisms will be relevant to all products);
b) conformance history (if an existing process);
c) the nature of processing, opportunity for contamination to occur, and product characteristics;
d) raw materials, supplier approval programme, raw material receipt procedures;
e) whether raw materials from a mix of batches will be used;
f) intensity and routine findings from monitoring of the manufacturing environment;
g) the intended consumer;
h) the level of statistical confidence desired vs the level achieved; and
i) any market specific requirements that apply.

(6) Manufacturers need to determine the sampling and testing frequencies necessary to be confident that every product item will conform with microbiological limits specified in Table 3 of the PSP Notice as well as any export limits or operator defined limits. This means that for routine monitoring the number of samples per batch or per 24-hour production period may be less than that indicated in Table 3 (with justification) or may need to be greater than that indicated.

(7) The expectation is that manufacturers and RMP operators will test for relevant pathogens, toxins and indicator organisms at sufficient frequency to demonstrate conformance with adequate confidence. For some pathogens, such as *Cronobacter*, testing at a lower frequency than that indicated in Table 3 may be difficult to justify and would rely on robust testing of inputs, processing equipment and the environment.

(8) For a new operator or an operator implementing a new process, the sampling frequencies for pathogens and indicators relevant to the product are likely to align with the Sampling Conditions column in Table 3, or run at a higher rate until sufficient information has been gathered to amend the sampling and testing plan.

(9) While statistical sampling plans may be adopted, these generally require a large number of samples across a batch, or (for presence/absence testing), so a large number of subsamples will be required to form a composite sample. Statistically based sampling plans, while ideal, may not be practical for small manufacturers.

(10) Escalation of testing frequencies will typically need to be increased significantly following unfavourable results. This increased testing will be expected for the affected product batch as well as prior batches which may have been affected, and subsequent batches until it can be confidently determined (through testing and root cause analysis) that no further product batches are affected. The RMP should be clear on the increased testing rates. Associated with this, the plan should also set the trigger to re-instate the routine testing regime, which is likely to be a combination of a minimum number of subsequent conforming batches, a root cause being identified, and remedial actions having been taken.

(11) When product failures occur, MPI may require more extensive testing than that set out in Table 3. The extent of testing will depend on the microbiological limit concerned, the extent of the failure and recent performance. Sampling at n=30 and n=60 across a batch is often necessary to confirm the extent of a problem and ensure all affected product has been identified.

(12) Table 3 now includes limits set on the basis of a 24-hour production run[1] rather than on a per lot or batch basis. This is to recognise that in some situations a lot may extend well beyond the “typically 24 hours” previously expected. Manufacturers will determine the appropriate sampling rate and should document the considerations and justification for the sampling and testing of dairy material and product. This will consider various factors, such as whether the process is new or a trend history

[1] For clarity, a 24-hour production run means continuous processing within a 24-hour window. It doesn’t mean the cumulative sum of processing time. Processing 6 hours per day for 4 consecutive days is considered to be 4 x 24-hour production runs.

exists, the nature and frequency of environmental and food contact surface monitoring, and situations where a production run extends beyond 24-hours continuous processing or is subject to interruption.

(13) When the 24-hour production run period is exceeded by a small margin, pro rata testing may be appropriate for a continuous process, taking into account the overrun period as a proportion of the routine production period minus interruptions and breaks. For other situations the sampling and testing should be proportional to typical production run periods. In all cases sampling may need to be adjusted based on the nature of the specific situation, such as:

a) additional start of run and end of run samples;
b) length of time that processing equipment may have been idle;
c) where required, processing environment conditions confirmed to be maintained continuously (e.g. red line access, temperature, relative humidity, positive pressure differential);
d) the raw material batches used, and whether these are the same for the whole dairy product batch; and
e) the routine sampling frequency that has been determined to be required across a production run to give confidence that the relevant microbiological limits will be met.

(14) Appendix 2 of this guidance provides examples that may assist smaller manufacturers.

(15) Having considered the items highlighted above, the manufacturer should design a sampling regime that is most likely to identify microbiological contamination of the material/product should contamination occur.

(16) If a product failure occurs, it is important to have sampling and testing escalation parameters included in the RMP (refer to sections 9.3 and 9.5).

(17) In situations where a sample is sent to a third party for sub-sampling or compositing, and the third-party is not covered by the manufacturers RMP, the RMP operator should ensure that the sample is handled in accordance with good laboratory practice. For these situations the third-party's activities should be under the scope of a relevant ISO accreditation to ensure that sample integrity is maintained.

(18) RMP procedures should clarify who (by name or position) is responsible for each aspect of sampling, sample handling and dispatch.

### 9.4.2 Two-class and three-class attributes sampling plans

(1) Sampling plans for the microbiological sampling and testing of food products are generally described as two- or three-class attributes sampling plans.

(2) A three-class attributes plan specifies:

a) two microbiological limits: "m" and "M";
b) the number of samples to test across the batch ("n");
c) the maximum limit that no samples can exceed ("M"); and
d) the maximum number of samples that can exceed "m", noted as count "c".

(3) Key points for a three-class plan:

a) "m" is the upper limit for good operating practice;
b) "M" is the maximum allowable result for any sample;
c) a batch is considered conforming if:

i) no more than "c" samples exceed "m"; and
ii) no samples exceed "M".

(4) For some pathogens, "m" may equal "M", meaning all samples (n) must meet the limit specified.

(5) By comparison, under a two-class attributes plan:

a) samples are taken from a lot and tested against a single microbiological limit (m = M); and
b) if any result exceeds the limit, the lot is considered non-conforming.

(6) For detailed information on sampling plans refer to Microbiological sampling plans – Statistical aspects*.

## 9.5 Recommended actions for dairy product positive results

(1) If dairy material or dairy product exceed, or is suspected to exceed, regulatory or operator defined microbiological limits then:

a) it must be managed in accordance with the procedures set out in the RMP, or if there are no documented procedures for the nature of the failure then it must be treated as non-conforming;
b) non-conforming dairy material and dairy product must be managed in accordance with the RMP, the PSP Notice (refer to C6 and D3.8 and D3.11) and the Disposal Notice. Typically, the RMP operator will need to notify the verifier of the non-conformance;
c) a root cause analysis (investigation), traceback/trace forward will be required along with undertaking corrective and preventative actions;
d) the RMP should detail the nature of increased (escalated) product testing in response to any failure to meet a microbiological limit. Acting fast to implement additional testing and lock down potentially affected product will help minimise the impact of the non-conformance. The RMP procedures should consider the following:

i) for larger product batches, additional testing across the product batch with the non-conforming result to quantify the extent of the contamination;
ii) additional testing of all product manufactured about the same time (same day +/- 1 day) and in the same area or that share common equipment or lines post heat treatment (e.g. packing lines). This will help quantify the extent of the contamination and inform the root cause analysis;
iii) the root cause analysis will assist in identifying additional product that may be affected, for example due common ingredients, processing equipment, manufacturing environment, packaging or people. Increased testing will typically be required for each batch/production day for all product that may be affected, as if the non-conformance had occurred in that product;
iv) in addition to increased sampling and testing of affected and potentially affected product made about the same time, previous production of affected and potentially affected product will typically require additional testing to confirm conformance. Generally, this will go back to the last conforming result for the parameter concerned in each product. Manufacturers may be able to justify an alternative period, for example due to limited product shelf life or root cause analysis findings. If routine testing is sufficiently extensive then increased testing may not be necessary;
v) environmental monitoring should be increased for the manufacturing areas identified by the root cause analysis as a potential or that might have been adversely affected. As an example, the root cause analysis might identify an ingredient used in a dry process as the probable cause. In turn this ingredient may have become distributed within the manufacturing environment;
vi) increased testing will need to continue until the root cause analysis and the test results give confidence that the product (and all other products manufactured) is not affected. As a guide, assume that clear results from product and environmental samples will be required for the 7 batches or production days following the day of the non-conformance. This may need to be extended if the product type that incurred the non-conforming result is only manufactured intermittently;
vii) the intensity of testing will depend on the pathogen concerned, the intended consumer, product batch size, range of other potentially affected products, and the nature of contamination (one off, intermittent, extensive). As a default, expect that 60 samples across a batch may be required, though usually for presence/absence tests these samples can be formed into composites to reduce testing costs (e.g. 6 composite samples

containing 10 samples each). The laboratory will be able to advise on sample size and compositing requirements; and

viii) it is advisable to discuss the intended sampling plan with the RMP verifier before committing to the sampling and testing plan.

e) the root cause analysis is intended to identify the likely source or cause of the failure. This information will then determine whether other dairy material or product may be affected and which may also need to be deemed non-conforming or subject to particular controls under the RMP;

f) in considering corrective actions following the root cause analysis, the manufacturer should reassess the environmental sampling programme, access restrictions and processing procedures to determine possible causes of the product contamination, and, for repeat events of a similar nature, reassess the pathogen management plan;

g) in most cases the RMP verifier will need to be notified of the event (refer Regulation 36 and PSP Notice Part D1 Subpart 3);

h) as the root cause analysis and tracing activities narrow down the material/product that may be or is affected, the RMP verifier should be notified accordingly; and

i) testing of final product can return to routine levels in accordance with the RMP procedures, or once the manufacturer is confident that the root cause of contamination has been identified and rectified. Confirmation will typically require clear test results over 7 production days.

(2) Operator defined microbiological limits may be set to provide an early alert and may specify the particular actions to be taken. Where these clearly apply, it may not be necessary to notify the RMP verifier provided that the required RMP actions are taken immediately, and appropriate records are kept.

(3) In situations where dairy material or dairy product is suspected to be non-conforming, the RMP may already specify the particular actions to be taken to control the material/product and confirm whether it is conforming or non-conforming. Where this situation clearly applies (and meets the requirements of the PSP Notice and the Disposal Notice) it may not be necessary to notify the RMP verifier provided that the required RMP actions are taken immediately, and appropriate records are kept.

(4) Every RMP must include procedures for recalling product from market should this be necessary.

(5) All dairy material or product in store that is potentially non-conforming must be separated from other product. Clearly label the product to indicate its status (e.g. physical or effective electronic hold).

(6) Product disposition options should be outlined in the RMP, aligning where practical to those provided in the Disposal Notice. Note that the Disposal Notice provides for the manufacturer, in accordance with the RMP, to dispose of dairy material/product in certain situations. The Disposal Notice provides options for the streamlined release by the verifier subject to certain criteria being met for some events. In most other cases approval for disposition will be required from NZFS (refer to the Disposal Notice clause 2.1).

## 9.6 Sample collection, handling and transport

(1) This section provides additional guidance to support the specific sampling information covered.

(2) The proper handling of samples from collection through to delivery to the testing laboratory is critical if the test results are to be relied upon. All too often manufacturers hold the laboratory responsible for unsatisfactory results or identify the manufacturers own failure to maintain samples in suitable condition as the root cause of unsatisfactory results.

(3) The manufacturers sampling responsibilities include the use of automated sampling devices and their operation, calibration, maintenance and suitability for obtaining reliable samples. This requires procedures that are complete and clear.

(4) If a root cause analysis indicates an issue with sample collection, a sampling device or sample handling then it is expected that appropriate corrective action will be taken, and that a review will be

extended to all similar equipment and procedures for sample collection, sample handling and sampling devices.

(5) Generally, samples for microbiological analysis should be stored and transported at a temperature not exceeding 5°C (without freezing). However dried products are best kept at ambient temperatures, and some samples may need to be held at the manufacturers recommended temperature. In all cases the procedures should be clear regarding the temperature and any other specific sample handling criteria.

## 9.7 Testing laboratories

(1) Within either a Pathogen Management Plan or the Sampling and Testing Plan, identify:

a) the testing laboratories to be used along with their contact details, ISO/IEC 17025 accreditation status or MPI recognised laboratory status for the intended samples and testing;
b) the specific test methods for each sample type;
c) which samples will be sent to which laboratory;
d) the situations under which an alternate laboratory may be used, for instance testing over and above that required by the RMP may not need to be sent to the lab identified in c); and
e) who the laboratory will contact regarding any testing issues, presumptive or positive results and how this will be done (e.g. via phone or email), along with a back-up contact. This information will need to be included on the laboratories sample submission form unless notified separately and confirmed by the laboratory.

(2) There are requirements regarding the qualifications of laboratories that are intended to be used for environmental samples, water samples and dairy product samples set out in the PSP Notice (D1.13). These requirements need to be reviewed when developing or amending either the Pathogen Management or the Sampling and Testing Plans.

(3) Selecting an appropriately qualified laboratory and the appropriate test method is the responsibility of the RMP operator, though MPI recognised laboratories and IANZ accredited laboratories do have their own specific requirements that they must meet and will assist operators to select the most appropriate test method for their purposes.

(4) Occasionally a processor may question laboratory test results. In such cases the processor should contact the testing laboratory to discuss any concerns they may have. From a regulatory perspective, test results continue to apply unless the laboratory withdraws the result. Processors are welcome to undertake further testing or retest a sample to further their understanding of an unsatisfactory result, and this may assist in sub-lotting (refer to the Disposal Notice for more on sub-lotting). However, in all cases the original result will continue to be deemed valid and apply unless withdrawn by the laboratory (e.g. by way of an amended test report). Processors should be mindful that if analytical test accuracy is called into question, the uncertainty will apply equally to favourable results as well as unfavourable results.

# 10 Conformance failures

## 10.1 Root cause analysis

(1) Root cause analysis is a systematic review of an event or failure (e.g. unfavourable test result) to determine the most likely true root cause (or causes). This includes consideration of all relevant factors that might have contributed to the failure, so that effective corrective actions can be taken to prevent a future occurrence.

(2) PSP Notice clause D3.11 outlines the need to initiate an investigation to determine the root cause of failures and identify corrective actions.

(3) With each unfavourable product or processing environment finding for pathogens, hygiene indicator organisms or from another hygiene indicator tests it's important to understand the source and the factors that contribute to the finding. Each failure should be investigated to:

a) determine the root cause;
b) facilitate a full and effective traceback, trace forward and, if required, recall;
c) enable all potentially affected dairy material or dairy product to be identified and managed appropriately (in conjunction with tracing back and forward);
d) enable appropriate immediate corrective actions to be taken; and
e) enable new controls to be introduced or existing controls supplemented as well as longer term preventative measures to be taken.

(4) The following are intended to serve as a series of prompts for consideration by the team as they undertake their analysis/investigation. Manufacturers will have a number of more relevant things to be considered that relate to their situation, and these should be included in the root cause analysis procedures:

a) Assemble a multi-disciplinary team
The team, should consist of people with relevant knowledge and experience in the areas that may need to be considered as the root cause analysis proceeds. Consider including specialists for food safety/quality, CIP, packing/packaging, production, Lab, procurement, engineering. Also include process operators familiar with day-to-day procedures (as opposed to documented procedures);
b) Assign a team lead
The team lead will be responsible for driving the root cause analysis process. They should have a level of authority that is relevant to the issue under review so that the team will be given appropriate co-operation and freedom to investigate all relevant aspects;
c) Define the problem and root cause analysis scope
The nature of the failure should be described in sufficient detail so that the team is clear on the issue. In doing so there should be clarity regarding which things are or are not within scope of the teams investigation;
d) Identify the initial areas worthy of investigation or analysis by considering each of the following (these should be adapted to suit the nature of the premises, product and processing):

i) Machine:

1) design (hygienic faults/weaknesses, deadends, product accumulation points, cracks, rough surfaces and welds etc);
2) equipment maintenance (leaks, rubberware, faults or deterioration);
3) process records; and
4) physical inspections.

ii) Method:

1) walk through the process and compare with HACCP process flow;
2) sampling procedures and environment;
3) test methods to assist deeper investigations such as whole genome sequencing (refer to Appendix 4);
4) cleaning effectiveness especially CIP (poor equipment design, components requiring out of place cleaning); and
5) equipment and facility drying times (dry areas).

iii) Material:

1) inputs and packaging;
2) specifications, preferred supplier programme, and controls/checks for receipt of material;
3) services (gases, vacuum etc);
4) cleaning tools;
5) trolleys; and

6) things moving in and out of processing areas (including areas for preparing of minor ingredients).

iv) People:

1) staff activities (hygiene controls);
2) contractor activities; and
3) food safety culture.

v) Environment:

1) site floor plans and pathway maps vs actual layout (walk through);
2) ventilation, airflow, humidity, temperature;
3) drainage, ponding of water;
4) storage conditions;
5) entry breaches (people, inputs, packaging and other items);
6) zoning (appropriateness); and
7) environmental monitoring programme (design suitability, results, physical inspections, intensity of follow-up monitoring).

vi) Measurements:

1) Calibrations;
2) suitability of measurements – are they appropriate; and
3) monitoring.

e) Assign team member responsibilities
Assign analysis/investigation responsibilities to team members with relevant knowledge or experience;

f) Facilitate a dynamic process
The process needs to be dynamic so that as the investigation continues. The wider team should review findings as they come to hand and collectively determine how best to respond to the information and what it may infer. The initial list of things worthy of consideration under (d) will likely grow as information comes to hand; and

g) Prepare a report
The report should clearly identify the probable root cause or causes if these have been established, and most importantly set out the corrective actions required to prevent any repeat occurrence. For each corrective action there should be clear timeframes for completion and the responsible person identified. It is also important that the person identified has the authority to undertake the corrective action and agrees to the action.

(5) In some cases, it will not be possible to identify the root cause, but the nature of the analysis/investigation and the areas that have been covered should be clearly described for future reference. Each failure serves as a lesson and provides an opportunity to strengthen the pathogen management plan or the wider RMP or food safety plan. The goal is to prevent future failures by having a clear understanding of the microbial ecology of the manufacturing environment and the cause of past failures. This same approach is equally relevant to procedural failures.

(6) Procedures should include the following:

a) review pathway maps and compare with environmental sampling sites;
b) identify sampling sites for pre-clean sampling and areas and equipment to clean and sanitise (consider entry/exit points, buffer zones, airlocks and neighbouring areas);
c) initiate traceback sampling (e.g. sampling sites determined from a) and b));take pre-clean samples and swabs;
d) clean and sanitise the area (e.g. record the detergent and sanitiser used, cleaning parameters and date clean and sanitation performed);
e) repeat traceback swabbing (e.g. daily swabbing post-clean);
f) review traceback results (e.g. trend analysis); and

g) close traceback (e.g. after 4-7 consecutive days of acceptable results – refer to sections 9.3 and 9.5 for more detail).

## 10.2 Root cause analysis report

(1) Completing a root cause analysis report for each failure that is investigated is important as it will formalise corrective actions and responsibilities, and, of equal importance, serve as a reference for any future similar events. The report should be as clear and concise as possible.

(2) The following sets out the recommended format to follow in completing the root cause analysis report:

a) title (sufficient for future reference, including any report reference);
b) date and version;
c) prepared by;
d) root cause analysis team members (who and areas of expertise/responsibility);
e) describe event (what happened and how was the failure identified);
f) describe investigations:

i) what has been considered (e.g. from 10.1(4)d));
ii) what has been investigated (include record reviews e.g. production, maintenance, CIP, use of appropriate test method and laboratory, etc);
iii) review of customer complaints and operator verification reports;
iv) what additional testing has been undertaken as part of the investigation;
v) non-routine events identified;
vi) what tracing (back or forward) or recall, if any, has been undertaken;
vii) what was found; and
viii) anything else of note from the investigation.

g) describe actions taken in response to the event:

i) notifications (senior management, verifier, etc);
ii) what has been done, how and when (additional to 10.2(2)f)iii) and v); and
iii) contact with internal or external parties (e.g. lab, suppliers of inputs or consumables etc).

h) scope of problem:

i) details of product deemed affected or potentially affected following investigation;
ii) what other product and processes might be affected;
iii) confirm how product that may be affected is being managed (noting regulatory requirements related to the management of non-conforming product); and
iv) identify product that has been disposed of in accordance with the Disposal notice.

i) outcomes:

i) aspects of the root cause analysis investigations that weren't able to be completed and why;
ii) conclusions of the root cause analysis investigations;
iii) confirmation of probable root cause, causes or the absence of a probable source; and
iv) corrective actions which should include the required actions, clear timeframes for completion and the responsible person who should have appropriate authority to ensure the corrective actions will be completed. The actions should be regularly updated with progress, especially when capex is required or completion will take longer than 3 months.

j) next steps (planned actions in addition to the corrective actions, if any); and
k) relevant data, information, test reports and other supporting reports.

## 10.3 Tracing backward and forward

(1) Tracing is generally undertaken in conjunction with root cause analysis and involves:

a) starting with a specific batch or lot of dairy material or product that is or maybe non-conforming (e.g. from the manufacturers own testing of dairy material or product, third party testing of product, or complaints of illness);
b) tracing back through the manufacturing process(es) to identify all of the inputs that have or may have gone into a product;
c) following root cause analysis as described in section 10.1, determining the input or inputs which may have contributed to the non-conformance (material and lot or sublot); and
d) tracing forward from each input that is a known source or is suspected to be the source and identifying all products that may contain the input.

(2) Having effective tracing procedures is vital so that timely action can be taken to identify potentially affected products and initiate a recall if required. Also, for dairy manufacturers (and other animal product businesses) there are requirements set out in the Regulations.

(3) Whether product identified as potentially affected from an event is non-conforming will depend on a number of factors. A suitably skilled person will be required to review the information gathered so that they can make conformance determinations.

(4) Procedures for tracing backward and forwards should be documented in the RMP and available for use under the Pathogen Management Plan. These procedures should consider the actions to take when a presumptive or positive pathogen detection is reported by the testing laboratory, or any failure to meet a regulatory or operator defined microbiological limit.

(5) Under the Regulations manufacturers may be required to undertake regular mock recall exercises, and under the PSP Notice there may be requirements for tracing exercises.

# 11 Training, competency and capability

(1) Personnel must be competent to undertake their specific roles and tasks unless under direct supervision. This includes all aspects relevant to pathogen management and includes training for people involved in sampling and the handling of samples. This is important to ensure that test results are meaningful and to ensure that processing area(s), product contact surfaces and products will not be contaminated.

(2) Personnel involved in processing product or entering areas used to process product, should have an understanding appropriate to their roles and tasks. It is also important that personnel have an appreciation for food safety and why control measures are required. This should include promoting awareness of:

a) the risks posed by pathogens in the products manufactured to customers and consumers;
b) the pathogens relevant to the process, likely sources of contamination, harbourage sites and transmission routes to processing areas and products;
c) the specific procedures for the roles or tasks for which they are responsible; and
d) training available and any refresher training or awareness opportunities.

# 12 Validation

(1) The pathogen management procedures will need to be validated as part of the overall RMP validation when they are first developed (refer to Regulation 34 and PSP Notice B1.3). Likewise, cleaning and sanitisation procedures and any other related PRP procedures will also require validation.

(2) Validation will involve a suitably skilled person or team reviewing the Pathogen Management Plan to confirm that:

a) procedures and controls are appropriate for the nature of processing undertaken;
b) the sampling and testing plan is appropriate;
c) the planned environmental sampling will provide the manufacturer with an early warning of contamination within processing areas if contamination were to occur; and

d) product sampling and testing will be capable of giving confidence that the RMP controls are working as intended and that product is conforming.

(3) The validation will include an on-site component to walk through the premises to determine whether:

a) higher hygiene zones are protected;
b) control measures are appropriate for the nature of processing, including entry points to higher hygiene zones; and
c) environmental sampling sites are practical and suitable.

(4) If procedures are amended, the amendments will most likely need to be validated and may be considered a significant amendment. For example:

a) reducing the frequency of environmental or product monitoring (significant);
b) amending the pathogens, indicator organisms or parameters monitored for (significant unless the amendment is to supplement existing parameters);
c) changing swab types e.g. from gauze swabs to sponge stick swabs (not significant); and
d) monitoring associated with a new process (significant).

(5) If an amendment to procedures is significant then it will need to be evaluated and registered with NZFS. Typically, like for like changes and increasing the intensity of monitoring will be considered minor. Reducing the intensity of monitoring is more likely to be considered significant unless:

a) the verifier considers it to be minor; or
b) the amendment is consistent with NZFS guidance for a minor amendment and the verifier agrees.

(6) NZFS guidance makes a number of assumptions regarding RMP content and the PRP procedures in place. The guidance will generally apply, but may not be applicable in all situations. If in doubt, the RMP verifier or evaluator will be able to advise whether the changes are significant.

(7) It is also important to note that cleaning programmes will require validation to confirm that they are effective. Existing cleaning systems will require re-validation if validation reports, or suitable validation information is no longer available.

# 13 Records, review and reporting

(1) Maintaining complete and accurate records is essential, both for regulatory compliance and for maintaining effective pathogen management.

(2) The documentation and record keeping systems in place should be appropriate to the nature and size of the operation. Having full and orderly records will be especially important if things go wrong or unfavourable results are obtained. Being able to align all sampling, testing and traceability information quickly will minimise the time that restrictions may apply to product or processing activities.

(3) Manufacturers should:

a) ensure training and competency requirements are documented and that induction and training records are available. Operators in a food business need to be competent for the duties they undertake, but they should also be given an appreciation of food safety and microbiological hazards. Fostering a strong food safety culture will be to the benefit of the food business;
b) ensure the justifications associated with sampling and testing are readily available (including environmental sampling methods, sampling sites, and parameters to be tested as well as final product microbiological parameters and testing frequencies;
c) be able to provide records to show that there is active monitoring for trends in the test results;
d) be able to provide records to show that the effectiveness of the pathogen management plan has been reviewed as part of operator verification, with any deficiencies and their associated corrective actions logged; and
e) maintain records of risk assessments, corrective actions, root cause analysis, preventative actions and confirmation of resolution of issues.

## 13.1 Operator verification

(1) The RMP should specify the frequency for internal verification of the pathogen management procedures by the operator, which should be at least once per season. This may be as part of an overall internal verification of the RMP by the operator or maybe undertaken as a separate exercise.

(2) Operator verification of the pathogen management plan should include:

a) confirming that regulatory requirements are addressed by the procedures;
b) assessing whether the procedures reflect reality;
c) review of procedures, looking for omissions or errors, particularly in light of any changes to the manufacturers' products or processes;
d) observation of sampling sites, operator sampling and their sampling techniques, and sample handling procedures;
e) observation of the controls for each zone, and especially the access points to each higher hygiene zone;
f) review of the RMP change control process to consider whether all risks and impacts of changes on the pathogen management controls and PRPs will be adequately addressed;
g) review of training records;
h) review of any unfavourable environmental or product test results, and for each the associated root cause analysis to determine whether any further corrective/preventative actions are required; and
i) review of findings from past (e.g. previous three seasons) operator verification and from independent verification, and confirmation that any required corrective actions were completed, implemented and continue to be applied. Assess trends to determine problematic areas, seasons, processing types, shifts etc.

(3) Refer to the Guidance Document: Risk Management Programme Manual and Guidance Document: Operator Verification on the MPI website for more information.

## 13.2 Corrective actions and reporting

(1) The PSP Notice D3.11 sets reporting requirements that may apply, or that will apply if the RMP does not address the actions to be taken in the event of unfavourable findings or a failure to undertake monitoring in accordance with the RMP.

(2) The pathogen management procedure should document the steps to be followed in the event of an unacceptable finding, including:

a) increased surveillance of the relevant processing area, adjacent areas, dairy material or dairy product, or product contact surfaces that may be exposed within the relevant processing area, or any other equipment, facilities or items that may be a source of contamination;
b) how investigations into the cause will be undertaken, who will be involved and the procedures that ensure that identified corrective and preventative actions are taken to remedy the situation without undue delay;
c) when surveillance can return to normal frequency and coverage;
d) who is to be notified and when (also consider PSP Notice Subpart 3: Notifying and reporting to verifying agency);
e) how root cause analyses should be done; and
f) who must be involved in response and root cause analyses.

# 14 Food safety culture and awareness

(1) To be successful it is vital that food businesses have a positive food safety culture embedded throughout the organisation. This includes promoting food safety awareness and emphasizing the

importance of pathogen management across all aspects of manufacture. This will enable the manufacturer to design and implement effective pathogen management measures.

(2) The methods for implementing a strong food safety culture will vary to some degree from business to business, but there are some common themes, for instance:

a) build a culture that embraces and promotes food safety awareness starts at the top of the organisation. The CEO and Board of Directors should lead by example so that the focus on food safety flows through staff at all levels;
b) everyone should "walk the talk" without compromise;
c) make the messaging consistent and visible so that everyone in the organisation is aware of the food safety vision and clear on their contribution;
d) ongoing training in food safety across the organisation as relevant, with methods implemented to promote awareness. This will include training and awareness at induction, training on the job to the extent relevant for the activities to be undertaken, and ongoing refresher training;
e) avoid creating an environment where there is a fear of highlighting food safety issues due to consequential actions. Such an environment will encourage failures to be hidden. This can occur despite the best intentions. For example, linking performance targets to food safety outcomes can lead to failures being hidden;

(4) Useful references include:

a) New food safety guide for directors, executives and business owners;
b) Research paper - Food safety culture;
c) Food Standards Australia New Zealand - Food safety culture; and
d) The FSSC 2200 approach to food safety culture.

(3) For those who believe that a food business is not addressing serious food safety breaches, or actively attempting to cover up breaches, there are options for notifying any concerns, for example:

a) for food related concerns contact MPI on freephone 0800 00 83 33 or Make a food complaint; or
b) in the case of serious wrongdoing refer to Protected Disclosures (Protection of Whistleblowers) Act 2022

# 15 Check-back tool

(1) The decision tree in Appendix 7 Check-back Tool can be used as a quick reference tool to clarify whether the key pathogen control measures have been considered, or whether there is a need to revisit and review the pathogen management procedures to provide additional control measures.

# 16 Pathogen management plan examples

(1) Examples of pathogen management procedures, including environmental monitoring and product testing, are included in the NZFS Dairy Products RMP Template for selected products and their associated processes. This template has been updated to meet the Regulations and PSP Notice, and is available on the MPI website.

# Appendix 1 – Pathogens and indicator organisms of relevance

### Table A.1: Pathogens and indicator organisms to consider

| Organism | Reason | Characteristics and Considerations |
|---|---|---|
| *Salmonella spp.* | Regulatory limit | Salmonella can persist for extended periods in low moisture environments (including crevasses and wall cavities). As such, for pasteurised dairy products, *Salmonella spp*. are of particular concern in dried dairy products, dried ingredients and dry processing environments.<br><br>For more information:<br><br>US FDA: Bad Bug Book (second edition)<br><br>Food Standards Australia New Zealand: Compendium of Microbiological Criteria for Food March 2022 (refer Appendix 1) |
| *Listeria monocytogenes* | Regulatory limit | *Listeria monocytogenes* is of most significance in pasteurised dairy products that support growth and that will be exposed during processing or that have non-dairy ingredients added. It will survive and grow within the processing environment where there is moisture and a nutrient source.<br><br>For more information:<br><br>US FDA: Bad Bug Book (second edition)<br><br>Food Standards Australia New Zealand: Compendium of Microbiological Criteria for Food March 2022 (refer to Appendix 1) |
| *Listeria spp.* | Useful target organisms for environmental monitoring | Provides greater sensitivity for environmental monitoring purposes as an alternative to *Listeria monocytogenes*. Will provide an early indication of critical process hygiene control failures.<br><br>For more information:<br><br>Food Standards Australia New Zealand: Compendium of Microbiological Criteria for Food March 2022 (refer to Chapter 6 and Appendix 2) |
| Coagulase Positive Staphylococci | Regulatory limit | Common pathogen in raw milk and under favourable conditions will grow rapidly and may produce toxins prior to heat treatment. Good farm practices, appropriate milk cooling and heat treatment are generally sufficient controls.<br><br>For more information: |

| | | |
|---|---|---|
| | | US FDA: Bad Bug Book (second edition)<br><br>Food Standards Australia New Zealand: Compendium of Microbiological Criteria for Food March 2022 (refer to Appendix 1) |
| *B. cereus* | Regulatory limit | Generally controlled by hygienic milking conditions (e.g. clean teats), regular cleaning during manufacture, avoiding temperature abuse (chilled products) and appropriate equipment and process design to avoid dead-ends and the production of biofilms. May also be introduced via ingredients. Potential for growth when processing delays occur and chilled products are held at higher temperatures for an extended time.<br><br>For more information:<br><br>US FDA: Bad Bug Book (second edition)<br><br>Food Standards Australia New Zealand: Compendium of Microbiological Criteria for Food March 2022 (refer to Appendix 1) |
| *E. coli* | Regulatory limit | Occurs when there is an opportunity for post pasteurisation contamination, for example:<br>- due to manual handing material during processing (handling curd in traditional cheese manufacture);<br>- raw ingredients added post pasteurisation; and<br>- ingredients, dairy material or product exposed to unhygienic conditions (e.g. contact surfaces or environment).<br><br>For more information:<br><br>US FDA: Bad Bug Book (second edition) (refer to pathogenic *E. coli* Group)<br><br>Food Standards Australia New Zealand: Compendium of Microbiological Criteria for Food March 2022 (refer to Appendices 1 and 2) |
| *Cronobacter spp*. | Regulatory limit for infant formula intended for infants 0-6 months | *Cronobacter spp*. is a pathogen of concern when manufacturing infant formula (0-6 months) or ingredients for infant formula that will not undergo subsequent heat treatment.<br><br>*Cronobacter* is of particular concern in dry processing areas as it has been found to survive and grow on surfaces that are not absolutely free of moisture. Following wet cleaning all equipment and the entire processing area must be completely dry before processing recommences. |

| | | |
|---|---|---|
| | | If the manufacturing area will process infant formula (0-6 months) at any time, or ingredients for infant formula that will not undergo subsequent heat treatment, then the environment is expected to be monitored **at all times** for *Cronobacter* (or Enterobacteriaceae). If monitoring for Enterobacteriaceae as an alternative to *Cronobacter spp.,* all positive detections are expected to be treated as *Cronobacter spp.* detections.<br><br>For more information:<br><br>Controlling *Cronobacter spp*. in dairy manufacturing – Fundamental characteristics and practical guidance<br><br>Quantifying the uncertainty of transfer of *Cronobacter spp*. between fomites and floors and touch points in dairy processing plants<br><br>The Management of *Cronobacter* in Powdered Infant Formula Manufacturing and/or Dairy Processing Plants in New Zealand<br><br>FAO/WHO (2004) *Enterobacter sakazakii* and other microorganisms in powdered infant formula: Meeting Report, Microbiological Risk Assessment Series No. 6<br><br>FAO/WHO (2006) *Enterobacter sakazakii* and Salmonella in powdered infant formula: Meeting Report, Microbiological Risk Assessment Series No. 10<br><br>US FDA: Bad Bug Book (second edition) |
| Enterobacteriaceae | Useful target organisms for environmental monitoring | Provides greater sensitivity for environmental monitoring purposes as an alternative to Salmonella, *Cronobacter* and coliforms/STECs. Will provide an early indication of critical process hygiene control failures. When used as an alternative to *Cronobacter,* any detections should be assumed to be due to *Cronobacter*.<br><br>For more information:<br><br>US FDA: Bad Bug Book (second edition)<br><br>Food Standards Australia New Zealand: Compendium of Microbiological Criteria for Food March 2022 (refer to Appendix 2) |
| Alkaline Phosphatase | Supports pasteurisation records | Confirms that pasteurisation conditions have been achieved. To avoid false positive results, testing |

| | | |
|---|---|---|
| | | should be on liquid milk immediately after pasteurisation.<br><br>For more information:<br><br>Cornell University: Alkaline Phosphatase (ALP) Testing for Milk Pasteurization<br><br>EFSA: The use of alkaline phosphatase and possible alternative testing to verify pasteurisation of raw milk, colostrum, dairy and colostrum-based products |

**Table A.2: Pathogens that can generally be excluded from dairy sampling and testing plans**

| Organism | Reason | Additional Considerations |
|---|---|---|
| Campylobacter | Post pasteurisation contamination unlikely. | Fragile pathogen, unlikely to survive dairy processing. |
| STECs | Monitoring for STECs directly unlikely to give adequate confidence of absence. Monitoring for *E. coli* or Enterobacteriaceae will help determine whether hygienic processing conditions are being maintained. | Post pasteurisation contamination is possible, particularly when product is routinely exposed or manually handled (e.g. handling curd during soft cheese manufacture). |
| Anaerobic spore formers | On-farm controls and GMP with regular cleaning during manufacture are typically sufficient. | May cause quality defects (e.g. defects over time in brine salted cheese). |

**Table A.3: Pathogens/Indicator organisms of interest by dairy product[2]**

| Dairy Product | Organism/Parameter | Considerations |
|---|---|---|
| All dairy products | Coagulase Positive Staphylococci | Monitoring may be appropriate for product when:<br>- it is subject to manual handing;<br>- unpasteurised ingredients are added;<br>- temperature abuse has occurred prior to pasteurisation; and<br>- market requirements are particularly tight.<br><br>To be meaningful, sampling is expected to be undertaken at the point during processing |

[2] Specific markets may require testing for additional pathogens or microbiological parameters - refer to relevant Overseas Market Access Requirements

| Dairy Product | Organism/Parameter | Considerations |
|---|---|---|
| | | when numbers are expected to be at their greatest. |
| | Staphylococcal enterotoxin | To be considered when time/temperature abuse of raw milk has occurred. |
| | *B. cereus* | Monitoring may be appropriate for product when:<br>- it is susceptible to growth of *B. cereus*;<br>- ingredients known to introduce aerobic spores are added; and<br>- for chilled product, temperature abuse has occurred e.g. processing delays with product held at ambient or warm temperatures for an extended time. |
| Liquid milk | *Listeria monocytogenes* | Potential presence due to post-pasteurisation contamination will depend on exposure of product to the processing environment and maintaining equipment hygiene. |
| | *E. coli* | Monitoring is appropriate to confirm post-pasteurisation/cross contamination has not occurred and hygienic conditions have been maintained. |
| Cream | *Listeria monocytogenes* | Potential presence may occur through post-pasteurisation contamination e.g. due to unhygienic equipment or exposure of product to the processing environment. |
| | *E. coli* | Monitoring is appropriate to confirm post-pasteurisation/cross contamination has not occurred and hygienic conditions have been maintained. |
| | *B. cereus* | Monitoring may be appropriate for cream products when:<br>- it is susceptible to growth of *B. cereus*;<br>- ingredients known to introduce aerobic spores are added; and<br>- temperature abuse has occurred e.g. processing delays with product held at ambient or warm temperatures for an extended time. |
| UHT products | Aerobic Plate Count (APC) | To confirm commercial sterility, test following pre-incubation of the packaged product at, for example, 30 degree C for 7 days. APC testing may be supported by more frequent ATP testing. |

| Dairy Product | Organism/Parameter | Considerations |
|---|---|---|
| | ATP | Test following a pre-incubation time period and temperature determined to be valid and equivalent to APC testing above. |
| Cheese – soft/firm | *Listeria monocytogenes* | Monitoring typically required due to the high potential for contamination to occur post pasteurisation. |
| | *B. cereus* | Monitoring is appropriate for unripened cheese to confirm that good manufacturing practice has been applied (including hygiene controls and suitable ingredients). Particularly important when processing delays occur, with chilled product held at ambient or warm temperatures for an extended time. |
| | *E. coli* | Monitoring is appropriate to confirm post-pasteurisation/cross contamination has not occurred and hygienic conditions have been maintained. |
| Cheese – hard/very hard | *Listeria monocytogenes* | Potential presence may occur in cheese that supports growth through post-pasteurisation contamination e.g. due to unhygienic equipment, use of wooden shelving (generally not permitted) or insufficient processing environment controls. |
| | *E. coli* | Monitoring is appropriate to confirm post-pasteurisation/cross contamination has not occurred and hygienic conditions have been maintained. |
| Yoghurt | *Salmonella spp.* | Monitoring typically not required if no unpasteurised ingredients added. |
| | *Listeria monocytogenes* | Potential presence may occur through post-pasteurisation contamination e.g. due to unhygienic equipment, exposure to the processing environment or use of raw/ unsuitable ingredients. |
| | *B. cereus* | Monitoring may be appropriate for product when:<br>- it is known to be susceptible to growth of B. cereus;<br>- ingredients are known to introduce aerobic spores; or<br>- temperature abuse has occurred e.g. processing delays with product held at ambient or warm temperatures for an extended time. |
| | *E. coli* | Monitoring is appropriate to confirm post-pasteurisation/cross contamination has not |

| Dairy Product | Organism/Parameter | Considerations |
|---|---|---|
| | | occurred and hygienic conditions have been maintained. |
| Fat products | *Salmonella spp.* | Typically not required. |
| | *Listeria monocytogenes* | Potential presence due to post-pasteurisation contamination will depend on exposure of product to the processing environment, ability to maintain equipment hygiene, and whether the product supports growth. |
| | *E. coli* | Monitoring to confirm post-pasteurisation/cross contamination has not occurred (including via ingredients) and hygienic conditions have been maintained. |
| Dried milks, dried protein products, dry blended products | *Salmonella spp.* | Regular monitoring is appropriate as Salmonella contamination is known to occur within dry environments, dried ingredients and, as a result, in dairy products. |
| Infant formula products | *Salmonella spp.* | Regular monitoring of these pathogens and indicator organisms is important to confirm that critical hygiene conditions have been maintained during processing and that regulatory standards have been met. |
| | *Cronobacter spp.* (if intended for infants 0-6 months) | |
| | *Listeria monocytogenes* | |
| | *B. cereus* | |
| | *E. coli* | |

# Appendix 2 – Sampling and testing plan examples

## A2.1 Product testing regimes for small processors

Table A2.1 sets out examples for microbiological monitoring of final product. These examples are **only relevant for smaller processors manufacturing product for the domestic market** and do not export other than to Australia.

These examples assume that:

a) areas used for the manufacture of the product are only used to manufacture that product (i.e. monitoring for potential cross contamination has not been included);
b) processing is undertaken in suitably hygienic environments with appropriate environmental monitoring in place confirming the absence of pathogens;
c) ingredients are sourced from reputable suppliers;
d) historical results and trends are favourable; and
e) no extraordinary events occur that might impact the product or process such as cooling failures, process interruptions, hygiene breach or failing to follow risk management programme/documented procedures.

In situations that don't meet the above, manufacturers will be guided by their hazard identification and analysis to determine pathogens that are likely to be relevant and require monitoring.

**Table A2.1: Final product testing examples**

| | **Pasteurised Drinking Milk - Note 5** | **Cheese – Firm/hard moisture <39%** | **Cheese – soft (not firm/hard)** |
|---|---|---|---|
| *Salmonella spp.* | Generally, not required. | Generally, not required. Test monthly if adding raw ingredients after the defined heat treatment. | Generally, not required. Test monthly if adding raw ingredients after the defined heat treatment. |
| *L. monocytogenes* | Monthly, reduced if environmental sampling for Listeria species at point of filling/packaging (see Note 1). | Generally, not required when undertaking environmental sampling per Table A2.2. | Monthly. |
| *E. coli* | One batch every 10 calendar days if testing for alkaline phosphatase, unless testing for Total coliforms and applying the *E. coli* limit. Test every batch if not doing phosphatase on each batch. | If testing for alkaline phosphatase on the milk for each batch, test one batch of each cheese type every 10 calendar days (at least one batch of each cheese type every month).<br><br>If not testing for phosphatase, test every batch.<br><br>Samples to be taken prior to maturation or ripening. | If testing for alkaline phosphatase on the milk for each batch, test one batch of each cheese type every 10 calendar days (at least one batch of each cheese type every month).<br><br>If not testing for phosphatase, test every batch.<br><br>Samples to be taken prior to ripening. |

| | **Pasteurised Drinking Milk - Note 5** | **Cheese – Firm/hard moisture <39%** | **Cheese – soft (not firm/hard)** |
|---|---|---|---|
| | | Testing for *E.coli* is not required when testing for Total coliforms and applying the *E. coli* limit. | Testing for *E.coli* is not required when testing for Total coliforms and applying the *E. coli* limit. |
| *S. aureus* | Regular monitoring is generally not required unless there has been a significant adverse event such as a milk cooling failure. | Not required unless there has been a significant milk cooling failure or unusually slow acid development. | Not required unless there has been a significant milk cooling failure or unusually slow acid development. |
| *B. cereus* | Monthly for extended shelf-life milk, especially if it contains ingredients likely to contain elevated spores e.g. cocoa powder. | Not required | Not required |
| Enterobacteriaceae | Not required | Not required | Not required |
| Total Coliforms (as an alternative to *E.coli*) | One batch every 10 calendar days if testing for alkaline phosphatase, unless testing for *E. coli* and applying the *E. coli* limit.<br>Test every batch if not doing phosphatase on each batch.<br>Limit 100/ml (see Note 2). | If testing for alkaline phosphatase on the milk for each batch, test one batch of each cheese type every 10 calendar days (at least one batch of each cheese type every month).<br><br>If not testing for phosphatase, test every batch.<br><br>Samples to be taken prior to maturation or ripening.<br><br>Testing for Total coliforms is not required when testing for *E.coli*. (see Note 2). | If testing for alkaline phosphatase on the milk for each batch, test one batch of each cheese type every 10 calendar days (at least one batch of each cheese type every month).<br><br>If not testing for phosphatase, test every batch.<br><br>Samples to be taken prior to ripening.<br><br>Testing for Total coliforms is not required when testing for *E.coli*. (see Note 2). |
| APC | At least one batch every 10 processing days.<br>See Note 3. | Not required | Not required |
| Alkaline Phosphatase | Every batch (typically start and end of run) | Recommend testing pasteurised milk every heat treatment run (start and end). See Note 4. Optional when testing each batch and all micro results will be available prior to release. | Every heat treatment run (start and end) see Note 4 |

| | **Pasteurised Drinking Milk - Note 5** | **Cheese – Firm/hard moisture <39%** | **Cheese – soft (not firm/hard)** |
|---|---|---|---|
| Other | Sensory testing prior to release | pH or titratable acidity tested during manufacture to confirm acid development.<br>pH, moisture and milkfat tested periodically to confirm firm/hard cheese parameters are met. | |

| | **Yoghurt** | **Ice Cream Mix** |
|---|---|---|
| *Salmonella spp.* | Generally, not required. | Not required. |
| *L. monocytogenes* | Weekly. | Not required. |
| *E. coli* | 2 batches per week unless testing for Total coliforms. | 2 batches per week unless testing for Total coliforms. |
| *S. aureus* | Not required unless there has been a significant milk cooling failure. | Not required. |
| *B. cereus* | Monthly for products with ingredients likely to contain starch or elevated spores. | Not required. |
| Enterobacteriaceae | Not required. | Not required. |
| Total Coliforms | 2 batches per week if not testing for *E. coli*.<br>see Note 2. | 2 batches per week if not testing for *E. coli*.<br>see Note 2. |
| APC | Not required. | Not required. |
| Alkaline Phosphatase | Every heat treatment run (start and end) see Note 4. | Recommended for every heat treatment run (start and end). See Note 4.<br>Optional when testing each batch and all micro results will be available prior to release. |

**Notes**

**Note 1**: Consider sampling to be in conjunction with environmental sampling.

**Note 2**: If Total coliforms exceed action limit the product must be managed as non-conforming as if all coliforms present are *E. coli, unless testing for E. coli* at the same time on the same sample. This may require recalling product based on the Total coliform result.

**Note 3**: Samples should not be composited unless reducing the action limit applied – refer to clause 9.3.4(3)b) for more information. Results exceeding 5,000 cfu/ml indicate a process hygiene failure. The operator is expected to immediately investigate, determine likely root cause and take corrective action. Exceeding 50,000 cfu/ml is a serious process hygiene failure.

**Note 4**: Samples for phosphatase testing should be taken immediately post pasteurisation and before any additional ingredients are added. No testing required for thermised cheese.

**Note 5**: The testing identified is only relevant when ingredients which might contain pathogens are not added after applying the defined heat treatment.

In general, microbiological tests should be on final packaged product unless noted otherwise.

# A2.2 Environmental monitoring regimes for small processors

Table A2.2 sets out examples for microbiological monitoring of the manufacturing environment. These examples are **only relevant for smaller processors manufacturing product for the domestic market** and do not export other than to Australia.

### Table A2.2: Environmental monitoring examples

| | **Liquid Milk** | **Cheese** |
|---|---|---|
| Listeria spp. | Weekly swabs for high-risk locations. | Weekly swabs (monthly for wood in processing areas).<br>Not required if only manufacturing cheese that does not support the growth of listeria. |
| Enterobacteriaceae | Monthly. | Monthly swabs. |
| Other | Weekly ATP swabbing of product contact surfaces after cleaning.<br>APC swabs fortnightly (locations from pathway mapping). | Weekly ATP swabbing of product contact surfaces after cleaning.<br>APC swabs fortnightly (locations from pathway mapping).<br>Yeast and moulds as needed. |

| | **Yoghurt** | **Ice Cream** |
|---|---|---|
| Listeria spp. | Weekly swabs.<br>Not required if only manufacturing yoghurt that does not support the growth of listeria. | Weekly swabs. |
| Enterobacteriaceae | Monthly swabs. | Monthly swabs. |
| Other | Weekly ATP swabbing of product contact surfaces after cleaning.<br>APC swabs fortnightly (locations from pathway mapping).<br>Yeast and moulds as needed. | Weekly ATP swabbing of product contact surfaces after cleaning.<br>APC swabs fortnightly (locations from pathway mapping). |

**Notes**

Sampling/swabbing locations will be determined in conjunction with pathway mapping, knowledge of the equipment, environment, process and cleaning effectiveness, and historic findings. Increased sampling will be necessary following unfavourable results and continued until the root cause has been clearly resolved.

# Appendix 3 – Root cause analysis report example

ABC Dairies ltd

**Title:** Investigation into the Detection of Listeria spp. in the Soft Cheese maturation area

**Company:** ABC Dairies, Terrace Site, RMP ID: DX12

**Date & version:** 17 December 2022, version 1

**Prepared by:** B Holly, Site Quality Lead

**Root Cause Analysis Team:**
Phil – Maintenance
Suzy – Cheese Operations manager
Mick – Lab
Buddy – Site Quality
Jon – Procurement

**Event description:**

On 8 November 2022 ABC Dairies Terrace site received a "detected'' result for Listeria species in a routine environmental swab taken from the Blue Mould maturation room at a location near a drain. The sample had been collected on 4 November 2022.

On preliminary investigation, it was identified that some maintenance work had been carried out on the main drain in the maturation room on 1 November 2022 by an external contractor. The drain was reported to be ineffective in draining water causing water pooling after sanitising the area. The drain had been opened and big lumps of cheese and concrete had been recovered and disposed of. The room had been hosed with water on completion of maintenance work and the cheese maturation area sanitised but not the drain or the area around the drain. This most likely led to the positive Listeria species result in the room.

**Investigation**

(1) What has been considered?

The root cause analysis team have reviewed:

- production records (including maturation room temp and humidity), cleaning records, product test results and environmental results;
- walk through check of the maturation room and equipment (shelving);
- observation of people and product movement in, pout and within the maturation room;
- review of sampler technique;
- review of maintenance records;
- review of red line clothing/boot exchange;
- review of hygiene controls and management of waste; and
- interviews with staff (cheese operators, maintenance, sampling staff).

(2) What has been investigated (include record reviews e.g. production, maintenance, CIP, use of appropriate test method and laboratory, etc)?

See (1) above. Swabbing, sample handling and use of correct test method all confirmed as ok.

(3) Review of customer complaints and operator verification reports

No relevant complaints in the last 6 months. Operator verification report dated April 22 looked at intrusive maintenance procedures and checklists. No issues relevant to this event were noted. No relevant comments on the RMP verification reports in the last 2 years.

(4) What additional testing has been undertaken as part of the investigation?

Increased Lm testing of cheese matured in the room from 1 November until 8 November. This involved batch B10 made on 4 November and batch B11 made on 7 November. In each case 10 samples per batch were taken and submitted for testing. All test results were “no detected” in 25 g.

Follow-up swabbing of the maturation room was undertaken for Listeria species, with a focus at and near the drain. This swabbing was after the clean undertaken on 8 November and continued for 5 days. All results were “not detected”.

(5) Non-routine events identified

Intrusive maintenance by contractor. All procedures related to site induction and permitting of work was completed correctly. No product was present in the maturation room at the time of the work. Investigation has found that following completion of the work the cleaning and sanitising procedures were only partially followed.

(6) What tracing (back or forward) or recall, if any, has been undertaken?

All product was still undergoing maturation and no potentially affected product had been released. No additional forward tracing or recall required.

(7) What was found?

Maintenance work had been carried out on the main drain in the maturation room on 1 November 2022 by an external contractor. The drain was reported to be ineffective in draining water causing water pooling after sanitising the area. The drain had been opened and big lumps of cheese and concrete had been recovered and disposed of. The room had been hosed with water on completion of maintenance work and the cheese maturation area sanitised but not the drain.

(8) Anything else of note from the investigation

Noted that procedures were not followed fully, possibly due to misinterpretation of the processing environment description.

**Initial actions taken**

(1) Quality notified Cheese Operations manager and Senior Leadership team. Verifier advised of the detection and the steps being taken. No exception raised.

(2) Convened the root cause analysis team to oversee the investigation and corrective actions. Confirmed that “response to failure” procedures were being applied for the cheese plant while the root cause analysis was being undertaken. This procedure included additional environmental samples and product samples being tested. The root cause analysis team walked through the area to see the conditions first hand.

(3) Contacted the contractor involved to confirm scope of work and procedures followed while on-site. Confirmed that work was limited to the drain concerned.

**Scope of Problem**

(1) Details of product deemed affected or potentially affected following investigation

No product deemed affected, confirmed by increased product testing

(2) What other product and processes might be affected?

Exposure was limited to the cheese maturation room. No other product affected.

(3) Confirm how product that may be affected is being managed (noting regulatory requirements related to the management of non-conforming product)

Product was placed on hold until results from increased testing were available. No potentially affected product had been released and so no recall required.

(4) Identify product that has been disposed of in accordance with the Disposal notice

No product required disposal. Waste disposed of per RMP and not for consumption.

**Outcomes**

(1) Aspects of the root cause analysis investigations that weren't able to be completed and why.

The root cause analysis team were satisfied that all relevant aspects of the investigation was able to be completed satisfactorily. The team have noted it would be useful for photos to be taken before, during and after any maintenance within critical hygiene areas provided that it is safe to do so and there will be no risk to the process or product. The team acknowledge that for some intrusive maintenance taking photos would not be appropriate. However, in this case photos would have helped the team to understand the state of the drain, the gunk removed, and the state post maintenance. This might aid future investigations.

(2) Conclusions of the root cause analysis investigations

The root cause analysis team were confident that the root cause was a failure to fully sanitise the maturation room, and especially around the drain, following maintenance.

(3) Confirmation of probable root cause, causes or the absence of a probable source around the

Initial evidence indicated that maintenance on a drain and lack of follow-up sanitising was the root cause. This was consistent with the environmental results, including the initial positive the positives in follow-up testing prior to remedial cleaning, and then the absence in all subsequent monitoring. This confirmed while the drain following maintenance was the source, the root cause was the lack of full sanitising within the maturation room following maintenance.

(4) Corrective actions (action, completion date, person responsible, updates, especially when capex is required)

Amend intrusive maintenance procedure and form (Buddy, by 2 Feb 23). The procedure will be updated to:

a) clarify the nature of post maintenance cleaning and sanitising within processing rooms;
b) require two level sign-off that all maintenance and follow-up actions have been completed; and
c) include provision for photos before and after maintenance work.

The form will be updated to include a second signature for sign-off.

**Next Steps**

Site Quality will monitor follow-up cleaning after maintenance in processing areas to ensure amended procedures and checklists are followed.

**Appendix 1 - Test results**

**Environmental samples**

| | Listeria species not detected | Listeria species detected |
|---|---|---|
| Routine environmental samples – July-Oct | 283 | 0 |

| | Listeria species not detected | Listeria species detected |
|---|---|---|
| Routine environmental samples – Nov | 80 | 1 |
| Routine environmental samples – Dec 1-10 | 30 | 0 |
| Traceback and escalation – Nov | 120 | 3 |
| Traceback and escalation – Dec 1-10 | 30 | 0 |
| Total | 543 | 4 |

**Product samples**

| | Listeria monocytogenes not detected | Listeria monocytogenes detected |
|---|---|---|
| Routine final product samples – July-Oct | 267 | 0 |
| Routine final product samples – Nov | 90 | 0 |
| Routine final product samples – Dec 1-10 | 30 | 0 |
| Additional final product – Nov | 45 | 0 |
| Additional final product – Dec 1-10 | 0 | 0 |
| Total | 432 | 0 |

## Appendix 2 – Sampling

Locations for routine and traceback sampling points attached.

# Appendix 4 – Useful analytical techniques

### Table A4.1: Analytical techniques to support pathogen management

| Technique | Description | Consider for: | Pros | Cons |
|---|---|---|---|---|
| Swab (cultured) | Monitoring viable bacteria on surfaces. | Routine monitoring of food contact surfaces and non-contact surfaces in zone 3 and 4 manufacturing areas, plus buffer areas and zone 2 entry to zone 3. | Results are meaningful and can establish trends. | Results are not available in real time. |
| Air/exposure plates | Plates exposed to the processing environment. | Used to measure airborne bacteria for a specific purpose e.g. APC for general air quality, Yeast and Moulds in wet/humid environments. | Useful for pathogens/ indicator organisms in dry high care areas where product for specific populations may be exposed or Yeast and Moulds in cheesemaking. | Results are not available in real time.<br>Colonies developed on plate might require further purification and identification. |
| Adenosine Triphosphate (ATP) | A rapid method that measures ATP in a sample, such as a surface swab. | Rapid assessment of surfaces post cleaning to assess the hygienic status.<br>Testing of UHT milk after incubation to provide rapid confirmation of sterility. | Quick and meaningful.<br>Results available much faster, aiding product release. | If ATP levels are high, sampling for TBC should be used to verify that the level is due to bacterial contamination, and not other organic ATP-contributing material. |
| Polymerase Chain Reaction (PCR) | Rapid detection and confirmation of pathogens. | Pathogen confirmation and typing | Rapid and meaningful<br>High sensitivity | Potentially lower specificity compared to culture |
| Whole genome sequencing (WGS) | Rapid typing and genomic characterisation. | Due to its more advanced ability to differentiate isolates. WGS is a powerful tool for tracing pathogens and pathogen events to determine source linkages. Useful for predicting survival characteristics, resistance to biocides and adaptation within processing environments, product | Generally definitive. Highest specificity and sensitivity, best when other methods cannot differentiate isolates.<br>High discrimination power.<br>Enables a clear determination of association between pathogen | Cost.<br>Time to report result.<br>Analytical capacity.<br>Skilled result interpretation. |

| Technique | Description | Consider for: | Pros | Cons |
|---|---|---|---|---|
| | | shelf life and spoilage potential. | detections or events. | |
| Pulsed-field gel electrophoresis (PFGE) | Confirmation of pathogens. | Pathogen confirmation and typing. | Highly discriminatory. | Labour-intensive with up to 3 to 4 days required to complete. |
| Subtyping tools | Various such as serotyping, ribotyping and matrix-assisted laser desorption/ ionization time-of-flight mass spectrometry. | Alternative options to WGS that assist with pathogen tracing. | Cost (in some cases), often sufficient for routine purposes. Rapidly evolving field worth further investigation. | Less definitive than WGS. |

# Appendix 5 – Information on swabbing

## General

Swabbing surfaces will assist in assessing the hygiene status of the surface being swabbed.

Be clear on the purpose of the swab as this will determine the timing of swabbing. In particular:

- to assess the hygiene status of equipment during processing, swab surfaces during product or immediately following processing and prior to cleaning; and
- to assess the cleanliness of surfaces after cleaning, undertake swabbing after cleaning. If the surface has been sanitised, then the swab diluent will need to be capable of neutralising any sanitiser picked up by the swab. If possible, allow surfaces to drain and dry after sanitising and avoid swabbing a surface immediately after sanitising.

## Preparation for swabbing

- if equipment needs to be disassembled or broken apart to facilitate swabbing, then the swabs should be taken immediately prior to cleaning. Breaking apart equipment that has formed a hygienic envelope should be avoided to minimise the risk of contaminating surfaces;
- use of wet swabs in dry processing areas should be limited to sampling external surfaces, or food contact surfaces only when:
  - the surface can be effectively sanitised following swabbing and allowed to dry (e.g. alcohol wipe); or
  - the food contact surfaces are to be given a wet clean.
- large gauze swabs (50 x 50mm 8-ply), moistened in suitable sterile diluent, are recommended for wet areas as they can cover a large area. Additionally, the use of sterile stainless-steel forceps to hold gauze swabs means that some considerable force can be applied to lift material stuck to surfaces. Procedures should include how to sterilise forceps after each use and ensure no cross contamination of alcohol or sanitiser;
- dry swabbing should be considered for routine swabbing of food contact surfaces in dry areas. While recovery of viable microorganisms may be less than with wet swabs, there is a lower risk of causing contamination due to the swabbing procedure;
- personnel will need to ensure that hands are clean and sanitised, clothing is clean, wear a mask and hair net and follow proper aseptic techniques; and
- as part of planning for the swabbing exercise, ensure the sequence is from high hygiene zones to lower hygiene zones.

## Selection and size of swabbing area

- the environmental pathogen management procedures should make it clear how the surface to be swabbed is to be chosen, and may specify the location due to known point of weakness (hard to clean, accumulation of product, equipment surface, past findings);
- it is important that the person undertaking sampling knows which area is to be swabbed and for what purpose;
- particular consideration should be given to surfaces with rust, corrosion, cracks, crevices, poor/rough welds, decommissioned equipment in the manufacturing area;
- the person undertaking sampling should have discretion to take additional swabs based on observations (visual or odour);
- the surface area to swab will depend on the expected level of hygiene;
- for surfaces (food contact and non-contact) in general manufacturing environments start with 100mm x 100mm as a default for process hygiene tests such as APC and 200mm x 200mm as a default for

pathogens. The swabbing area can be increased or decreased in size depending on the results obtained and the purpose of swabbing (confirming effective cleaning vs assessing the hygienic state of a surface);
- for food contact surfaces in dry areas a larger swab area is likely to be appropriate; and
- procedures should ensure that a surface is only swabbed once on each occasion.

## Swabbing technique

- swabs come in various forms, including sponges, gauze wipes and flexi swabs. For the purposes of this guidance assume that the swab is a commercially available type that is self-contained. An example of wet swabbing:
  - check that the swab is upright and the tip of the swab is in the diluent;
  - label the swab with a unique ID, and separately record the swab ID, location, date, time and person taking the swab;
  - undo the lid, breaking the sterile seal;
  - remove the sterile swab from the tube with diluent and gently press the tip against the inside of the diluent tube to remove excess liquid;
  - place the tip of the swab on one corner of the area to be swabbed and move the swab from side to side across the swab area, rolling the tip of the swab while wiping from side to side until the full swab area has been covered;
  - as a default, 100mm x 100mm is recommended but in some cases a larger area will be appropriate. The size may need to be increased or decreased in order to make the data meaningful when trending results;
  - repeat going up and down;
  - optionally, repeat in diagonal directions taking care to stay within the swabbing zone;
  - in total there will be a minimum of 2 passes (horizontal and vertical) and up to 4;
  - place the swab back into the diluent and secure the lid; and
  - swabs will need to be handled in the same was as any perishable sample, so either test without delay or refrigerate the swabs.
- procedures need to be very clear to ensure consistency between persons taking swabs; and
- if using a template to ensure that a consistent area is covered, take care to ensure that the template doesn't become a source of contamination, or that any disinfection of the template doesn't compromise the reliability of the swab.

## What to test for

The nature of processing will influence what should be tested for. For example:

- following wet cleaning, consider testing for ATP (rapid method, results in real time) or APC (culture method, results delayed) to confirm surfaces are clean;
- during wet processing, consider testing for Listeria species, *E. coli*, Total coliforms or Enterobacteriaceae (note that testing for APC and is not relevant for cheese and yoghurt manufacture, and ATP is only relevant for clean surfaces and sterile products);
- for dry processing, consider Enterobacteriaceae and ATP to support salmonella and, for infant formula manufacturers, *Cronobacter*;
- in some situations, presence/absence (qualitative) testing (with enrichment in some cases) will be appropriate, for example when testing for pathogens that should not be present at any level;
- in other cases, counts of colony forming units per area swabbed (quantitative) will better suit the purposes of testing. For example, when testing for indicator organisms. For quantitative testing the manufacturer will need to establish a pass/fail threshold (or a two tiered approach with an action limit for an initial response and a hard upper limit for a more intense response);
- manufacturers should be flexible and open minded when selecting the most appropriate method for their processing environment; and

- it may be appropriate to consider yeasts and moulds when processing suspectable products.

Refer to Appendix 2 for further information on suggested target organisms for the environmental monitoring of certain manufacturing processes.

# Appendix 6 – Pathogen management plan elements

### Table A6.1: Self-assessment worksheet

| No. | Pathogen Management Plan Requirement<br><br>Systems Considerations | Do you have this? Y / N | Where this can be found |
|---|---|---|---|
| **1.0** | **General** | | |
| 1.1 | Scope of plan is defined | | |
| 1.2 | Regulatory outcomes to be met are identified | | |
| 1.3 | Management commitment to this pathogen management plan | | |
| 1.4 | Responsibilities for the implementation and maintenance of this plan are defined | | |
| 1.5 | Procedures for review of this plan (who and frequency) are defined | | |
| 1.6 | A corrective action system is described within the RMP | | |
| 1.7 | Relevant documents are subject to document control | | |
| 1.8 | A reality check has been undertaken (physical process walkthrough) | | |
| **2.0** | **Risk Assessment** | | |
| 2.1 | Pathogens that could be a risk to your products/processes are identified along the reason why (per HACCP Plan) | | |
| 2.2 | Potential sources of these pathogens have been considered, including:<br>• Vehicles<br>• Waste<br>• Staff, contractors and visitors<br>• Entry and exit points (people and things)<br>• Animals, insects, birds<br>• Ingredients<br>• Water<br>• Air<br>• Equipment<br>• Packaging materials | | |
| 2.3 | Potential pathways of contamination have been mapped (per section 5.3) | | |

| No. | Pathogen Management Plan Requirement | Do you have this? Y / N | Where this can be found |
|---|---|---|---|
| 2.4 | Equipment that is difficult to clean or requires out of place cleaning has been identified | | |
| 2.5 | Parts of the process suitable for pathogen growth have been identified, taking into consideration:<br>• Suitable temperatures<br>• Time between cleaning<br>• Food and moisture availability | | |
| 2.6 | The likelihood of process or product contamination has been determined for each pathogen / source | | |
| 2.7 | Control measures have been identified and implemented as appropriate | | |
| 2.8 | Rationale used for assessing risk has been documented | | |
| **3.0** | **HACCP** | | |
| 3.1 | HACCP assessment for each process | | |
| 3.2 | HACCP team make-up is appropriate | | |
| 3.3 | Flow diagrams are prepared for each main type of food produced | | |
| 3.4 | All hazards relevant to each product have been identified | | |
| 3.5 | Control measures have been identified for all hazards. | | |
| 3.6 | Critical Control points have been identified and validated | | |
| 3.7 | Critical limits have been established | | |
| 3.8 | Monitoring activities have been documented for each critical control point | | |
| 3.9 | Corrective actions have been identified for situations where critical limits are exceeded | | |
| 3.10 | Operator verification actives have been documented | | |
| 3.11 | Pre-requisite programmes have been confirmed as valid | | |
| 3.12 | Procedures for the testing of product and the process environment is in | | |

| No. | Pathogen Management Plan Requirement | Do you have this? Y / N | Where this can be found |
|---|---|---|---|
| | place, with frequencies and limits defined | | |
| **4.0** | **Inputs** | | |
| 4.1 | Approved supplier programme in place | | |
| 4.2 | Specifications for all incoming supplies | | |
| 4.3 | Acceptance criteria for inputs (including dairy material, ingredients, processing aids and packaging) is based upon risk assessment of the inputs and the suppliers | | |
| 4.4 | All incoming goods checked on receipt (condition, identification and labelling, temperature, quantity) and placed into storage as soon as practical or used immediately in the process | | |
| | **Technical Considerations** | | |
| **5.0** | **Buildings** | | |
| 5.1 | Buildings designed to MPI/sanitary guidelines. | | |
| 5.2 | Impact of building location has been considered, including:<br>• Proximity to other high-risk operations (e.g. Landfill, wastewater treatment, pathogen lab, contaminating neighbours)<br>• Movement of vehicles on and off site<br>• Waste disposal (e.g. Location of bins, access for removal, spill containment) | | |
| 5.3 | Building design has considered:<br>• Windows and doors excluding pests<br>• No direct access from critical processing areas to outside<br>• Floor, wall, and ceiling materials are non-porous and easily cleaned<br>• Process flow minimises opportunity for cross-contamination<br>• Amenities located to minimise opportunity for cross-contamination<br>• Temperature control as required<br>• Air systems appropriate<br>• Microbiology laboratories physically separated from processing building | | |

| No. | Pathogen Management Plan Requirement | Do you have this? Y / N | Where this can be found |
|---|---|---|---|
| | • Waste handling areas appropriately designed and located | | |
| 5.4 | Appropriate consideration of floors and drains:<br>• Designed to minimise ponding<br>• Cracks and holes eliminated<br>• Waste is piped directly to drain<br>• Drains have adequate capacity<br>• Drains are trapped<br>• Traps are cleaned regularly<br>• Floors are smooth without being slippery<br>• Floors and drains are cleaned daily<br>• Cleaning equipment used for floors and drains are not used for any other purpose<br>• Low pressure hosing only is used on floors and drains<br>• Product contact equipment is not cleaned on the floor<br>• Product that falls onto the floor is sent to waste | | |
| 5.5 | Walls and ceiling are made of non-absorbent, easily cleaned material:<br>• No holes or cracks<br>• No unflashed openings<br>• No sills or high ledges<br>• Wall/floor junctions are appropriately flashed and sealed | | |
| 5.6 | Equipment is designed and constructed for easy cleaning and disinfection:<br>• Non-absorbent, non-corrosive, e.g. Stainless steel<br>• No hollow box sections<br>• No sandwiched surfaces<br>• Free draining pipes and sections, no dead ends<br>• Components likely to perish or discolour should be regularly replaced | | |
| 5.7 | Conveyor belts:<br>• Are made of hygienic, easily cleaned material<br>• Are non-absorbent<br>• Are never allowed to touch the floor<br>• Have completely sealed rollers | | |

| No. | Pathogen Management Plan Requirement | Do you have this? Y / N | Where this can be found |
|---|---|---|---|
| 5.8 | Equipment that requires out of place (manual) cleaning has been identified | | |
| 5.9 | Repairs and maintenance are planned where possible, and carried out to minimise risk to product:<br>• Maintenance personnel observe normal access restrictions<br>• Timing is appropriate<br>• There is adequate clean-up after maintenance, including removal of waste, cleaning and sanitising of the area<br>• A suitably skilled person confirms that equipment and facilities are in a sufficiently sanitary state for processing to continue<br>• A record is kept of all repairs and maintenance undertaken | | |
| **6.0** | **Services** | | |
| 6.1 | Water meets current regulatory requirements | | |
| 6.2 | Water is treated and handled appropriately:<br>• Storage and reticulation prevent contamination<br>• Quality is checked regularly at point of use<br>• Backflow prevention is in place as needed<br>• Records of water treatment and checks are maintained | | |
| 6.3 | Ventilation air is used to maintain positive air pressure inside the manufacturing areas | | |
| 6.4 | Air pressure is designed to ensure air flows from the highest hygiene zone to the lowest | | |
| 6.5 | Ventilation air is filtered to remove insects and dust | | |
| 6.6 | There is a documented air filter maintenance programme | | |
| 6.7 | Air intakes are up-wind of exhaust vents, cooling towers, inwards goods, and rubbish disposal sites | | |

| No. | Pathogen Management Plan Requirement | Do you have this? Y / N | Where this can be found |
|---|---|---|---|
| 6.8 | Condensate from cooling systems is piped directly into drains | | |
| 6.9 | Food contact gases and compressed air are appropriate, with oil and moisture removed as needed | | |
| **7.0** | **Controlled Access** | | |
| 7.1 | Higher hygiene areas have been adequately differentiated from lower hygiene areas (e.g. zones) | | |
| 7.2 | Transfers between areas are controlled to minimise cross-contamination by, e.g.:<br>• Redline<br>• Protective clothing<br>• Boot exchange<br>• Footbath<br>• Airlock or buffer | | |
| 7.3 | Transfer areas are monitored to ensure that controls are effective | | |
| 7.4 | Access is restricted to those who need to be there | | |
| 7.5 | People entering high or critical hygiene areas are free of illnesses of concern | | |
| 7.6 | People entering the critical hygiene area maintain appropriate level of person hygiene | | |
| 7.7 | Hand washing facilities:<br>• Are appropriately located<br>• Have warm water<br>• Soap<br>• Suitable hand drying material, e.g. paper towels | | |
| 7.8 | Staff wash hands at appropriate times | | |
| 7.9 | Hand sanitation facilities are provided as appropriate | | |
| 7.10 | Jewellery policies are adhered to | | |
| 7.11 | Eating, drinking and smoking do not occur in processing areas | | |
| 7.12 | Protective clothing is worn as appropriate | | |
| 7.13 | Gloves are worn where necessary | | |
| **8.0** | **Cleaning and Wastes** | | |

| No. | Pathogen Management Plan Requirement | Do you have this? Y / N | Where this can be found |
|---|---|---|---|
| 8.1 | A register of cleaning, sanitising and other maintenance compounds is held and kept up to date | | |
| 8.2 | Cleaning and sanitising programmes have been documented:<br>• What has to be cleaned and/or sanitised<br>• By who<br>• What equipment is used<br>• What chemicals are used<br>• When (e.g. for routine clean, deep clean, sanitising, etc)<br>• How (pre-rinsing, dose rate, temperature, CIP flow rates and times) | | |
| 8.3 | A register of cleaning, sanitising and other maintenance compounds is held and kept up to date | | |
| 8.4 | Procedures include how cleaning effectiveness is monitored | | |
| 8.5 | Cleaning programmes include infrequently cleaned (out of the way) items or areas | | |
| 8.6 | Procedures for wet cleaning in dry areas include times to ensure all equipment and facilities are completely dry | | |
| 8.7 | Records of cleaning/sanitising and its effectiveness are maintained | | |
| 8.8 | Frequency of cleaning has been determined based on the nature of processing, the environment, and the material being processed | | |
| 8.9 | Cleaning equipment is coded (e.g. by colour) and dedicated to particular areas or items to avoid cross-contamination | | |
| 8.10 | Cleaning equipment is easily cleaned and sanitised after use (No wooden handles or fibrous bristles) | | |
| 8.11 | High pressure hosing is avoided in manufacturing areas to minimise the spread of contaminated aerosols | | |
| 8.12 | Sanitising occurs only after effective cleaning | | |

| No. | Pathogen Management Plan Requirement | Do you have this? Y / N | Where this can be found |
|---|---|---|---|
| 8.13 | Sanitiser strength and contact times are as per manufacturer instructions | | |
| 8.14 | Absorbent materials such as wood have been removed from processing areas | | |
| 8.15 | Inside waste is stored and handled appropriately:<br>• In dedicated areas<br>• Covered bins with handsfree opening of the lid<br>• Clearly identified bins or bags<br>• Bins emptied and cleaned daily<br>• Input packaging disposed of immediately<br>• Input packaging is not reused | | |
| 8.16 | Outside waste is stored and handled appropriately:<br>• Bulk waste bins away from storage or preparation areas<br>• Wet waste is contained<br>• Bins are cleaned regularly<br>• Bin areas are well drained<br>• Waste areas are clean and tidy | | |
| **9.0** | **Process Control** | | |
| 9.1 | Process control steps have been identified and implemented, e.g. through application of HACCP | | |
| 9.2 | Control ***prior to processing*** minimises risk to product safety:<br>• Appropriate storage (facilities, temperature and time)<br>• Delays avoided<br>• Minimise handling of dairy material | | |
| 9.3 | Control ***during processing*** minimises the risk to product safety:<br>• Time / temperature<br>• Temperature of process environment (and humidity for dry areas) | | |
| 9.4 | Control ***after processing*** minimises the risk to product safety:<br>• Appropriate storage ASAP after processing<br>• Temperature control and monitoring | | |

| No. | Pathogen Management Plan Requirement | Do you have this? Y / N | Where this can be found |
|---|---|---|---|
| | • Housekeeping in storage areas, especially chillers and freezers | | |
| **10.0** | **Monitoring and Surveillance** | | |
| 10.1 | The environmental surveillance programme verifies that pathogen control systems are effective. | | |
| 10.2 | Sampling procedures are documented. | | |
| 10.3 | Environmental surveillance takes into consideration section 10 | | |
| 10.4 | Environmental sample site selection is based on assessed risk (section 10.2) | | |
| 10.5 | Sample size and type is appropriate:<br>• Large gauze swabs<br>• Sweepings<br>• Scrapings<br>• Product residues | | |
| 10.6 | Samplers are trained appropriately:<br>• Aseptic technique<br>• How to swab<br>• Sample handling<br>• Sample selection | | |
| 10.7 | Procedures ensure that samples are appropriately handled, stored and despatched to the laboratory | | |
| 10.8 | Acceptance criteria (pass/fail) has been established for all tests | | |
| 10.9 | Escalation criteria documented in the event of unacceptable test results | | |
| 10.10 | Records are kept of all results and relevant actions taken | | |
| 10.11 | Corrective action procedures include root cause analysis (see section 11) | | |
| 10.12 | Product testing is carried out to verify the effectiveness of control measures and surveillance programme | | |
| 10.13 | Testing laboratories are qualified for the testing they undertake | | |
| 10.14 | The most suitable test methods have determined in consultation with the testing laboratory | | |
| 10.15 | Operator verification procedures include review of control measures for | | |

| No. | Pathogen Management Plan Requirement | Do you have this? Y / N | Where this can be found |
|---|---|---|---|
| | pathogen management, selection of sampling sites (via pathway mapping) and monitoring | | |

# Appendix 7 – Check-back tool

## Decision tree for dairy products that may not undergo a further pathogen reduction step

To be used in conjunction with the HACCP Plan.