

# Dairy pathogen manual

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# 1. About this document

The Australian dairy industry has a reputation for the manufacture of safe, high quality products that are preferentially chosen around the world. Product safety is achieved by the implementation of through chain HACCP-based food safety programs, which are designed to ensure dairy foods meet the regulatory requirements of our domestic market and, where appropriate, international markets.

This document provides dairy manufacturers with guidance on how to respond when their products or their dairy processing environment are found to be contaminated with pathogens (organisms that can cause disease). These pathogens may be detected through routine product testing, environmental surveillance or from regulatory surveillance programs.

The presence of pathogens such as *Listeria monocytogenes*, *Salmonella spp.*, pathogenic *Escherichia coli*, *Staphylococcus aureus* or other pathogenic organisms in dairy products or dairy processing environments requires rapid and effective action to control and manage affected products, minimise the risks to consumers and correct identified problems to prevent recurrence.

The *Dairy pathogen manual* outlines the expected response to detections of bacterial pathogens (and/or their toxins) associated with dairy products and describes clearance procedures.

Strategies for the management of pathogens in the dairy industry have evolved over the past 25 years. This document describes current approaches and supersedes other pathogen control publications, including:

- *Australian Manual for Control of Listeria in the Dairy Industry, ADASC (July 1999)*
- *Australian Manual for Control of Salmonella in the Dairy Industry, ADASC (July 1999)*
- *National Guidelines-Pathogen Management, Dairy Authorities Technical Advisory Committee (June 2011)*

The *Dairy pathogen manual* supports businesses to meet the requirements of **Standard 4.2.4** (Primary production and processing standard for dairy products), **Standard 1.6.1** and **Schedule 27** (Microbiological limits in food) of the Australia New Zealand Food Standards Code (the Code). It should also be read in conjunction with relevant user guides and additional guideline criteria.

This document:

- references current microbiological limits (Section 2)
- outlines actions to identify the cause of contamination and manage the problem (Section 3)
- describes product clearance programs (Section 4)
- discusses environmental monitoring (Section 5)
- discusses the importance of an organisation's food safety culture (Section 6).

The *Dairy pathogen manual* is published and maintained by Dairy Food Safety Victoria (DFSV). It will be revised from time to time, to reflect ongoing changes to the Code and industry practices and the emergence of any newly identified pathogens.

## 2. Pathogens and microbiological limits

When certain bacterial pathogens and their toxins are present in dairy products, they can lead to foodborne illness. These organisms may originate in the raw milk or they may be introduced via ingredients, people, environmental sources or packaging materials.

To maximise the safety of a dairy product, manufacturers exercise control over incoming raw materials, ingredients, processing operations (including pasteurisation, post-kill step hygiene, manufacturing, handling and storage practices) conditions in their facility and the physico-chemical properties of the product, that is, whether it will support the growth or survival of pathogens.

Table 1 lists pathogens that can be found in milk and dairy products. When evaluated in terms of probability of occurrence and risk to consumers, a smaller group of dairy food and pathogen combinations are relevant to dairy manufacturers. Further information on common agents of foodborne illness may be obtained from a range of sources (FSANZ, 2013 and FDA, 2012).

Microbiological criteria are set when risk assessment has shown that the risk of foodborne illness is unacceptably high.

Standard 1.6.1 and Schedule 27 of the Code establishes microbiological criteria for finished dairy products. Dairy foods that fail these limits may pose a threat to human health and must not be offered for sale. When these limits are exceeded, dairy manufacturers must take corrective action (see Section 3).

**Table 1:** Pathogens found in dairy products

<i>Aeromonas hydrophila</i>	<i>Bacillus cereus</i>	<i>Campylobacter jejuni</i> and <i>C. coli</i>
<i>Clostridium botulinum</i>	<i>Clostridium perfringens</i>	<i>Coxiella burnetii</i>
<i>Cronobacter sakazakii</i>	<i>Cryptosporidium parvum</i>	<i>Mycobacterium bovis</i>
<i>Listeria monocytogenes</i>	<i>E. coli</i> (pathogenic) e.g. STEC	<i>Salmonella spp.</i>
Shigella spp.	<i>Staphylococcus aureus</i>	<i>Yersinia enterocolitica</i>

Standard 1.6.1 and Schedule 27 do not list all potential pathogens or all dairy foods. Furthermore, standards in the Code are periodically reviewed and change over time so manufacturers should always check the current limits. For example, recent changes have established limits for *L. Monocytogenes* in ready-to-eat foods, which includes most dairy products as they are consumed without further preparation.

The *E. coli* limits in the Code are also being examined. While *E. coli* is considered to be pathogenic, unless proven otherwise,

only a subset of *E. coli* strains are pathogenic. Those of most interest in Australia are the shiga toxin-producing *E. coli* (STEC). The most common STEC serotypes reported in Australia are *E. coli* O157, O111, and O26. The presence of *E. coli* in a processed dairy product signals recent exposure of the product to faecal contamination and the potential presence of bona fide human pathogens.

Manufacturers should also refer to the DFSV document *Microbiological testing criteria* which lists testing requirements for finished products.

### 3. Actions to take after a pathogen or toxin is detected

When harmful microorganisms such as *Salmonella spp.*, *L. monocytogenes* (including detections of *Listeria spp.*) and *E. coli* are detected in dairy products above prescribed limits or in a dairy manufacturing environment, the manufacturer must stop production and implement corrective action.

Corrective action includes:

- effectively dealing with the contaminated and at-risk product
- undertaking a root cause analysis to identify the cause
- performing a major clean-up of the operation

- initiating a clearance program which involves high level sampling and testing of subsequent batches of product on the implicated production line
- putting into effect procedures that will prevent future occurrences.

The manufacturer must also notify DFSV.

Table 2 provides a summary of the actions that need to be considered and implemented. Note that some of these actions will occur concurrently. The following sub-sections provide detail for each action.

**Table 2:** Actions required for pathogen (or toxin) detections in product

Actions	Pathogen detected in product	
	Levels above limits in Code	Levels below limits in Code
<b>Immediate action</b>		
3.1 Identify and isolate affected products	✓	Consider†
3.2 Notify DFSV and other relevant authorities	✓	Consider†
3.3 Recall or withdraw contaminated products <sup>π</sup>	Consider†	Consider†
3.4 Halt production and isolate affected process lines <sup>φ</sup>	✓	Consider†
<b>Investigative action to determine cause</b>		
3.5 Review records on affected product	✓	✓
3.6 Test raw materials, in-process materials, and finished product	✓	✓
3.7 Enhanced environmental sampling (Zones A, B, C, and D) <sup>ψ</sup>	✓	✓
3.8 Clean and disinfect, and verify effectiveness	✓	✓
3.9 Identify corrective action and rectify the cause of the incident	✓	✓
<b>Follow-up</b>		
3.10 Disposal of product	✓	Consider†
3.11 Clearance of products	✓	Consider†
3.12 Documentation, records and reporting	✓	✓

**Key:**

\* Actions apply to dairy products containing pathogens exceeding limits in the Code.

It is recommended that these actions also apply for presumptive positive results for *Salmonella spp.* and *Listeria spp.*

✓ Action expected

π The decision to recall can be mandated by the relevant authority, but is usually voluntary (in consultation with the authority)

† When considering and assessing if action should be taken, assess trends, contaminant levels (cfu/gram), and the potential for a pathogen (or toxin) to increase during product shelf-life. Seek guidance from DFSV. A risk assessment may be required.

φ Where manufacture has halted, production should not recommence until clearance by authorities

ψ Enhanced monitoring should occur when pathogens (e.g. *Salmonella spp.*, *L. monocytogenes*, pathogenic *E. coli*, *Cronobacter sakazakii*) are detected in product (Zones are described in Section 5)

### 3.1 Identify and isolate affected products

Once a product is found to be contaminated, it is essential that steps are taken to identify, label, isolate and hold or withdraw the product. This minimises the risk of affected units being mistaken for uncontaminated product and helps prevent the product from being used, sold or further distributed.

- Clearly **label** the contaminated product to show its status (for example, mark with **Quarantine** or **Hold** labels) or otherwise manage the product to eliminate the risk of accidental release or use.
- **Store** contaminated product in a manner that minimises the potential for direct contact or cross-contamination with other products, packaging materials, equipment and surfaces. Where products are not packaged, the contaminated product should be physically segregated from other uncontaminated products.
- Keep the affected product on **hold** to allow time for more information to be gathered about the level of risk posed by the identified food safety hazard, so that appropriate decisions and corrective actions can be implemented.
- Identify, label and hold for testing **other products** processed on the same line or on lines in close proximity to the contaminated line.

### 3.2 Notify relevant authorities

The manufacturer must notify DFSV at the earliest opportunity after learning of product contamination.

Notification must be written confirmation (via email, letter, fax or any other written medium) and received by DFSV within 24 hours. Often a manufacturer will call their Food Safety Manager to immediately inform them of a contamination incident.

Information that needs to be provided includes:

- product implicated
- production codes (Lot or batch number)
- date of manufacture
- microbiological test results
- use by/best before date
- unit size and quantity of product involved
- location of product
- other products that may have been contaminated, such as dairy product(s) produced on the same line prior to or after the detection or product(s) produced in close proximity to the contaminated batch.

If the contaminated product is made in an export registered facility, the Australian Government Department of Agriculture and Water Resources must also be contacted and notified.

Before production recommences on the affected process lines, DFSV must be consulted. DFSV may request additional information to verify the effectiveness of the corrective action and further testing.

### 3.3 Recall or withdraw contaminated products

The action taken will depend on where the contaminated product is.

- If contaminated product has not left the manufacturing site it must be isolated and held (see 3.1).
- If the product is at a storage facility or with wholesalers it should be identified and withdrawn (see 3.1).
- If the product has entered the marketplace, a food recall may be required if there is a reasonable possibility that consumption of the food would cause adverse health consequences or where the product has a serious defect that poses a potential health risk.

The manufacturer responsible for the supply of a food normally initiates food recall action. Any decision to recall is usually made by the manufacturer in consultation with the State Department of Health. However, the Commonwealth Minister responsible for consumer affairs and state and territory food enforcement agencies have the legislative power to order a food recall when a serious public health and safety risk exists.

It is a legal requirement that food manufacturers have in place a 'food recall plan' which must be followed in the event of a recall (Standard 3.2.2–Food Standards Code). FSANZ publishes advice and guidance on how to develop a recall plan and conduct a recall (FSANZ, 2014). Depending on factors such as product composition, contamination levels and volume and extent of distribution, the incident may result in either a trade withdrawal or a consumer recall of the affected product.

In addition to product known to be contaminated, consideration should be given to recalling or withdrawing any other products that may be implicated, such as product processed on the same line or in close proximity to the contaminated line. This should extend back to the last batch of product tested and found to be free of the pathogen (the last clearance point).

### 3.4 Halt production and isolate affected process lines

As soon as possible after notification of a pathogen in a dairy product, the manufacturer should cease production and isolate the affected process line.

This allows for visual inspection of the line and equipment, which can help assess conditions and identify areas that may be the source or harbourage point for pathogens. A critical part of this investigation is dismantling and thoroughly inspecting equipment, looking for niches that are hard to access or not normally visible (see Section 3.7).

Halting production will help minimise the potential spread of the pathogen. Note that some days may have passed between processing the contaminated batch and receipt of the laboratory test results.

At this point, enhanced environmental sampling should also be undertaken to identify the source of the contamination. Associated process lines and areas may also need to be isolated and inspected and environmental sampling completed to determine additional sources of contamination.

When manufacture has been halted, production should not recommence until clearance has been obtained from DFSV.

### 3.5 Review records on affected product

The manufacturer must review and trace-back production and processing records and microbiological test results to identify the possible source, timing and extent of the contamination. It is important to determine whether or not the process was under control and that standard operating procedures were adequate and being followed.

The identification of unusual or atypical conditions or data may assist in determining possible causes or links to contamination.

The manufacturer should consider the following.

- Were there changes to product formulation or ingredient substitutions on that production line during the time of the contamination?
- Was there a loss of control at a critical control point? For example, review pasteurisation records to determine if the target temperature was being met.
- Was there equipment breakdown, plant modifications or maintenance work carried out on, or near, the process line prior to the contamination event?
- Do records show cleaning and sanitation procedures were followed correctly? Was the correct type and concentration of detergent and sanitiser used? Was there a change in methods or chemicals?
- Did environmental monitoring indicate any potential problems or lapses in hygiene?
- Were there new or inexperienced staff on the affected process line at the time of the contamination?
- Were there frequent changes in the speed of the process line or changes in packaging films/containers during or near the time of the contamination?
- Was there any unusual weather event, such as storms or dust?

This information can help determine which product and ingredients may be potentially contaminated and the need for additional microbiological testing to more accurately determine the extent of the contamination.

Identifying a possible cause of the contamination at this stage allows for specific actions to minimise the risk of the problem recurring.

### 3.6 Test raw materials, in-process materials and finished product

Pathogens may be introduced into the processing environment or finished products through raw ingredients, in-process materials or the finished product.

To identify the extent of the contamination, it is essential to test:

- raw materials, such as ingredients, additives and processing aids
- in-process materials, including intermediate products post-pasteurisation
- surrounding batches of finished product back to the last batch of product tested and found to be free of the pathogen (see Section 4)
- packaging materials, including liners, inners, outers and pallet wrapping.

### 3.7 Enhanced environmental sampling

The processing environment is often the source of product contamination. Routine environmental sampling assists in pinpointing sources of contamination and identifying niches where pathogens may potentially reside.

The level of monitoring should be enhanced when pathogens such as *L. monocytogenes*, *Salmonella spp.*, pathogenic *E. coli*, and *Cronobacter sakazakii* are detected in any environmental zones. For example, action should be considered when *E. coli* is detected in Zone A (food contact surfaces), as it reflects poor hygiene control procedures. Similarly, the detection of *Listeria* species in Zone A should also be investigated further, as its presence suggests conditions may be suitable for survival and/or growth of *L. monocytogenes*. For information on zones within manufacturing plants see Section 5.

When an incident occurs, more intensive environmental monitoring is recommended. The number of samples is increased and a wider range of sampling points surveyed. In this situation, pinpointing the contamination source is essential, so the compositing of samples is not advisable.

A more extensive sampling program will include:

- hard-to-reach and clean surfaces and equipment (may require equipment dismantling)
- worn or damaged equipment or equipment that has recently been repaired
- a focus on equipment and surfaces suspected as harbourage points for pathogens that are adjacent to food contact surfaces.

To identify potential sources of contamination, it is important that environmental sampling takes place prior to any cleaning and disinfection action, that is **immediately after production ceases**.

### 3.8 Clean and disinfect and verify effectiveness

When a contaminated product has been identified, a comprehensive cleaning and disinfection program should be initiated. This will involve all processing equipment, utensils and processing zones associated with the product, including the dismantling of equipment and conveyors. Any environmental samples must be taken prior to this cleaning and disinfection process.

At the completion of the cleaning and disinfection program, the cleaned and disinfected area, equipment and utensils should be visually inspected to determine if they are clean and environmental samples (swabs, ATP- adenosine triphosphate measurements) taken to confirm the efficiency of the program. Manufacturers are encouraged to seek guidance and advice from suppliers of cleaning and sanitising agents.

### 3.9 Identify corrective action and rectify the cause of the incident

If the cause of the incident has been identified, corrective action may need to be implemented to minimise the likelihood of recurrence and prevent future contamination. For example, if the cause of the contamination was ineffective cleaning, then the cleaning and disinfection program should be modified then validated to assess its efficacy. The manufacturer's food safety plan must reflect any modifications to operations and procedures, which may include the initiation and documentation of staff training.

### 3.10 Product disposal

Dairy products found to contain pathogens may be reprocessed or destroyed. For example, it may be possible to reprocess contaminated product into animal feed or use in non-food applications. Before reprocessing a contaminated batch, the manufacturer will need written approval from DFSV.

DFSV may also require proof of disposal when product has been dumped.

The following information should be documented for each batch of product scheduled for disposal:

- location of the contaminated product
- quantity, identification and labelling information for the contaminated product
- date and time of proposed disposal
- level of hazard associated with the contaminated product
- intended method of disposal, for example, destruction (by burial in a controlled landfill, heat treatment or burning), reprocessing or use as animal feed etc.
- records of location and method of disposal, for example, photographic evidence, disposal receipt

- level of risks (food safety, occupational health and safety, and security) associated with the proposed disposal method and how the risks will be managed
- conditions and controls for the method of disposal.

For reprocessed product, the following information should be documented (where appropriate):

- specifications
- location and storage details
- quantity, identification and labelling information
- distribution, use and sale information
- microbiological sampling and testing.

### 3.11 Clearance of products

Clearance programs are designed to verify that corrective actions undertaken in response to a pathogen detection have been effective. These programs involve elevated levels of end-product testing after an incident to demonstrate that a food safety program is again under control. Clearance requirements are described in detail in Section 4.

Products under a clearance arrangement should be withheld from distribution and sale until the test results for a batch satisfy microbiological limits in the Code. Manufacturers must ensure that there is an appropriate system for retaining products under a clearance program and for authorising product release when each batch satisfies the criteria.

If product test results for any batches in the clearance program fail to comply with the pathogen levels described in the Code, the regulator will require the program to be recommenced.

Any alternative clearance arrangements to those described in this manual must be submitted in writing to the relevant State regulator for approval.

### 3.12 Documentation, records and reporting

All records, actions, reports and relevant information relating to the contamination incident and investigation are to be kept and made available upon request by the DFSV. This is a requirement under Standard 3.2.1 of the Food Standards Code [section 5(f)].

## 4. Undertaking a clearance program

The detection of pathogens (for example, *Salmonella spp.* or *L. monocytogenes* and other selected microorganisms such as *Listeria spp.*) during routine testing of a batch of dairy product indicates a failure of a manufacturer's food safety program and a potential threat to public health. All product of the same batch/lot number and any product processed on the affected processing line should be considered to be potentially contaminated.

Further production on the affected processing line should only commence following a detailed inspection and analysis of the cause, effective decontamination of the affected line, and the identification and implementation of corrective action.

Once this is completed, a clearance program involving extensive sampling and product testing must commence on subsequent production runs.

The clearance program protocol is based on sampling procedures suggested by the International Commission on Microbiological Specifications for Foods (ICMSF, 2002). The ICMSF recommend that where the hazard is severe and there is likely to be no change before consumption, a sampling plan for lot acceptance requires 30 samples to be tested. Testing must be performed by an accredited laboratory.

The **minimum** clearance program arrangements are as follows:

**30 samples are to be taken per batch from the affected production line at listed intervals.**

Day	Samples
Day 1	30 samples (immediately following comprehensive clean*)
Day 3	30 samples
Day 5	30 samples
Day 12	30 samples

\* First batch after restart, not first batch after contamination event

The 30 samples representing the batch will need to be of sufficient size for the laboratory to take 25 grams (or 25 millilitres) from each. Each sample may be tested individually or composited, for example, six lots of five samples.

For small scale manufacturers the requirement to take 30 samples for testing may be excessive when a small number of units are produced. In these circumstances, the regulator may consider alternative sampling protocols.

A clearance program needs to be completed in full and is only considered to be complete when the results of all tests meet regulatory requirements. If results from any of the four batches fails to comply with the pathogen levels in the Code or indicate unacceptable levels of microorganisms, then DFSV will require the program be recommenced and appropriate product control and incident investigation must be undertaken.

It is recommended that products manufactured on day 1 are held and released when they test negative. Similarly, product made on days 2 and 3, days 4 and 5, and days 6–12 are retained until the results from days 3, 5 and 12 have tested negative, respectively. This may not be practical with short shelf-life products which cannot be held pending release to the market.

Any product from the implicated processing line that was produced prior to the original contamination (day 0) and is still available should also be tested at 30 samples per batch and withheld until cleared. This may include product within the warehouse or retained samples. This will be particularly important where testing is done on a periodic basis rather than on every batch of product. Product should be tested back to the last compliant test result.

It is strongly recommended that all products from other production lines in the same processing area be tested for the contaminant detected on the day of, the day before and the day after the original contamination. DFSV will provide advice on interpreting the above requirements if necessary.

## 5. Environmental monitoring of food processing zones

An important adjunct to product testing in the dairy industry is environmental monitoring. Environmental monitoring assesses the efficacy of cleaning and sanitation programs and scrutinises potential risks from pathogens such as *L. monocytogenes* and *Salmonella spp.*

Detection of a pathogen in the processing environment can be regarded as a warning of potential problems. When this happens, manufacturers need to implement further investigations and take corrective action to prevent contamination from environmental sources spreading to the product.

An environmental sampling plan is implemented to assess whether the hygienic status of the dairy processing environment is effectively under control. The goal is to eliminate potential contamination by pathogens.

In dairy processing environments, sites for environmental monitoring must be selected in a logical and risk-based manner. This is done by dividing the manufacturing plant into four zones, each based on the potential for product contamination if a pathogen were to be present in that zone. This is referred to as the 'zone concept' and requires the manufacturer to define and identify production areas based upon pathways for product contamination as described in Table 3 and as illustrated in Figure 1. The zone of highest risk is classified as Zone A and the lower level of risk is classified as Zone D.

The areas, surfaces, items and equipment in each zone will vary between premises and will depend on the history and experience of each individual manufacturer.

**Table 3:** Descriptions and examples of environmental monitoring zones

Zone	Description	Risk to product	Examples
A	<b>Product contact surfaces</b> Surfaces over or through which product passes during processing (product contact surfaces/direct contact surfaces)	High	Conveyors, tables, racks, holding vats and tanks, utensils, pumps, valves, slicers, freezers, packing/filling machines
B	<b>Non-product contact surfaces in close proximity to product</b> Surfaces that are in close proximity to the flow of product and may indirectly lead to product contamination (non-product contact surfaces/in-direct contact surfaces that are close to product)	High	Conveyors, exterior of processing equipment, refrigeration units, equipment control panels, service lines, equipment/building above exposed product. May also include keypads and door handles
C	<b>Non-product contact surfaces located further away from product</b> Surfaces located further away from the flow of products. These surfaces are less likely to lead to product contamination but may hinder efforts to control pathogens (non-product contact surfaces/in-direct contact surfaces that are further away from product)	Low – provided good manufacturing practice (GMP) establishes control systems	Drains, walls, floors, condensate, hoses, trolleys, pallets, conveyor belts, forklifts, computer keyboards and telephones, switches, etc.
D	<b>Surfaces outside the processing area</b> Surfaces outside of the premises but includes areas through which people, equipment and ingredients may pass	Low	Locker rooms, cafeterias, entry/access ways, pallets and pallets, loading bays, roofs, gutters, waste pits, garbage storage areas

A properly designed environmental monitoring program includes a diagram of the manufacturing site with markers showing routine sampling sites. Selection of sampling sites should be based on the likelihood of revealing contamination by the target pathogen if it were present and the risk to the product. This means looking for hard-to-reach and clean areas, and surfaces where biofilms are likely to form. The choice of sites should be justified and documented in the food safety program.

The results obtained from environmental monitoring (positive and negative) can be plotted on the diagram, and this can be used to identify patterns or trends.

Generally, the larger the number of samples taken the more likely environmental contamination will be detected. To minimise testing costs, it is possible to composite swabs for routine environmental monitoring, although a positive result will implicate a number of sites and require further swabbing. Compositing is not recommended during incident investigations.

When compositing environmental samples:

- only composite samples within a single zone (do not mix samples from different zones)
- do not composite wet with dry samples
- document the sample sites for all areas/points that make up a composite.

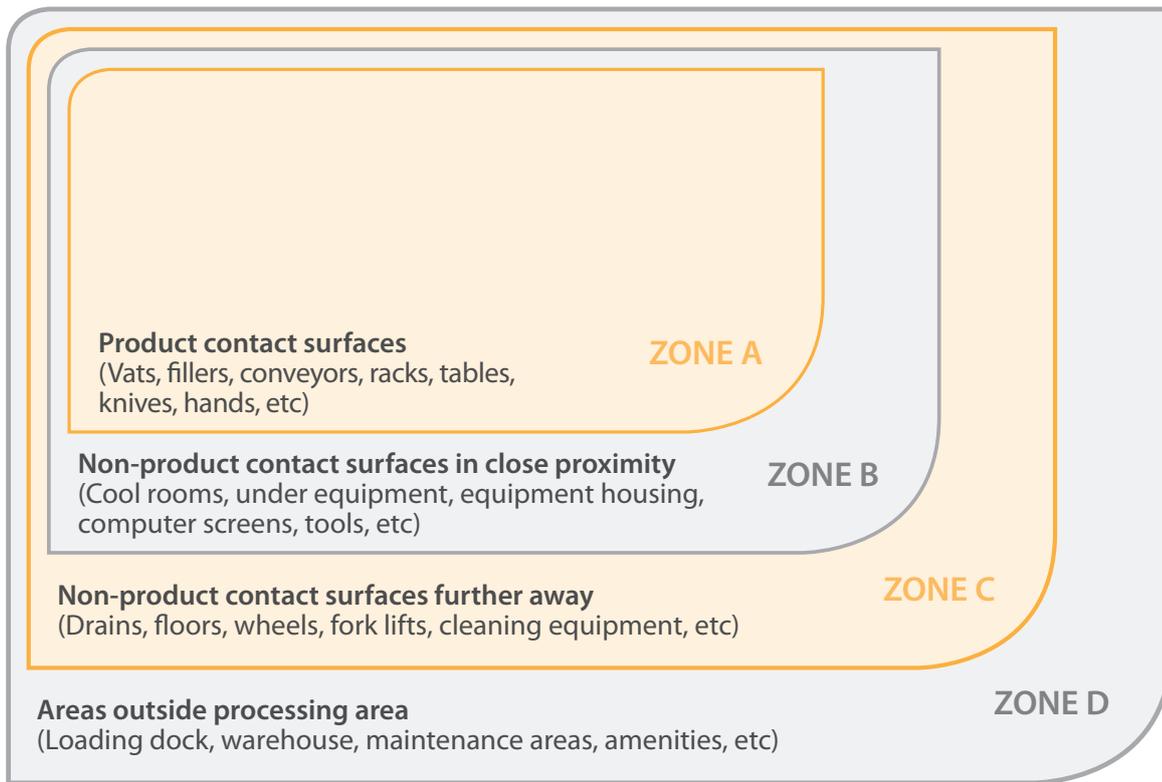
In addition to swab and sponge samples, environmental sampling may include residues from products, materials or surroundings in either dry or wet form, for example, shavings from slicing machines, rubbish or dust from the floor, condensate and liquid residues.

When a pathogen is detected in a zone, the corrective action varies depending upon the proximity of the zone to product. Table 4 describes recommended actions for pathogen detections in the different zones.

**Table 4:** Specific actions recommended for environmental monitoring detections

<b>ZONE A: Product contact surfaces</b>	<b>ZONE B: Non-product contact surfaces in close proximity to product</b>
<ul style="list-style-type: none"> <li>• Consider placing suspect product on hold</li> <li>• Increase sampling to pinpoint contamination sources</li> <li>• Reassess access/entry restrictions to Zone A and review staff hygiene training and knowledge</li> <li>• Review Zone B results and trends to identify any areas that may require control reassessment</li> <li>• Reassess cleaning and sanitising program</li> <li>• Reassess manufacturing and product handling procedures</li> <li>• Review the sanitary design of equipment</li> <li>• Clean and sanitise this zone and any suspect areas</li> <li>• Resample all sites to verify cleaning and sanitising efficacy</li> <li>• Sample and test any batches of product or retention samples of short shelf-life products associated with the area manufactured on the day of, day before, and day after the positive environmental result. Corrective action is needed if any batches are positive. If no product is available the next available batch of product manufactured after the date of the environmental positive should be tested</li> </ul>	<ul style="list-style-type: none"> <li>• Increase sampling to pinpoint contamination sources</li> <li>• Reassess access/entry restrictions to Zone B and review staff hygiene training and knowledge</li> <li>• Review Zone C results and trends to identify any areas that may require control reassessment</li> <li>• Reassess cleaning and sanitising program</li> <li>• Reassess manufacturing and product handling procedures</li> <li>• Review sanitary design of equipment</li> <li>• Check receipt of packaging material</li> <li>• Clean and sanitise this zone and any suspected areas</li> <li>• Resample all sites to verify cleaning and disinfection efficacy</li> </ul>
<b>ZONE C: Non-product contact surfaces located further away from product</b>	<b>ZONE D: Surfaces outside of the processing area</b>
<ul style="list-style-type: none"> <li>• Increase sampling to pinpoint contamination sources</li> <li>• Reassess access/entry restrictions to Zone C and review staff hygiene training and knowledge</li> <li>• Review Zone D results and trends to identify any areas that may require control reassessment</li> <li>• Check pallets and pallets, trolleys and forklifts</li> <li>• Reassess cleaning and disinfection program</li> <li>• Reassess manufacturing and product handling procedures</li> <li>• Clean and disinfect this zone and any suspect areas</li> <li>• Resample all sites to verify cleaning and disinfection efficacy</li> </ul>	<ul style="list-style-type: none"> <li>• Reassess the cleaning and disinfection program for Zone C</li> <li>• Undertake sampling in Zone C to ensure that access/entry controls are intact and effective</li> <li>• Review access/entry restrictions between Zones D and C and reinforce staff training and knowledge</li> </ul>

Figure 1: Zones



## 6. Food safety culture

The management of dairy food safety involves understanding and controlling a range of design and operational issues within the processing facility. Manufacturers need to know how identified contaminants may gain entry into raw materials, the plant and their products, and how processing operations are managed to produce safe products. This is the basis of a food safety management program.

Equally important is the conduct and behaviour of employees within the food processing environment. Influencing and changing human behaviour in the food processing environment so there is a shared set of values that staff follow will enhance the production of safe dairy products. This is a critical part of managing dairy food safety, and is a demonstration of the organisation's food safety culture.

A strong food safety culture is evidenced by all staff (from senior management through to the operator on the production line) understanding the risks associated with the dairy foods they produce, knowing why managing these risks is important and constantly striving to manage those risks in a verifiable manner. It is based on all employees:

- understanding the big picture – that is, food safety is not negotiable
- understanding the goals of the company – striving to produce safe food
- understanding their own responsibility for food safety – where they fit in the picture.

Manufacturers with a suitable food safety culture will have individuals who implement practices that represent the company's goals and can identify where they may be failing. Such businesses can then demonstrate to their staff and customers that they are aware of food safety issues, that they can learn from others' mistakes and that food safety is important to them.

An all-inclusive approach to management of food safety issues involves an effective integration between the food safety culture and the food safety management program.

## 7. Summary

Maintaining a hygienic manufacturing environment is critical to the production of safe and suitable dairy products.

Incursions of pathogens can occur from time to time. Dairy food manufacturers need to be vigilant and prepared to respond in a systematic manner when a problem occurs. This includes early notification to the regulator, identification and isolation

of product, root-cause analysis, effective decontamination and prevention measures, and the implementation of a product clearance program.

The combination of a suitable environmental monitoring program and well trained, competent employees are the best defence for keeping pathogens out of dairy products.

## 8. Bibliography

- Australian Dairy Authorities Standards Committee 1999, *Australian Manual for Control of Listeria*. ADASC
- Australian Dairy Authorities Standards Committee 1999, *Australian Manual for Control of Salmonella*. ADASC
- Australian Dairy Authorities Standards Committee 2000, *Minimum sampling guidelines for dairy products*. ADASC
- Australia New Zealand Food Standards Code 2016. *Standard 1.6.1–Microbiological Limits for Food*.  
Viewed 29 March 2016 <<http://www.comlaw.gov.au/Series/F2015L00411>>
- Australia New Zealand Food Standards Code 2015. *Standard 4.2.4–Primary Production and Processing Standard for Dairy Products*.  
Viewed 29 March 2016 <<http://www.comlaw.gov.au/Series/F2012L00294>>
- Codex Alimentarius Commission 1991. *General Standard for Labelling of Prepackaged Foods. Codex Standard 1-1985*, Revision 1
- Codex Alimentarius Commission 2003. *Recommended International Code of Practice–General Principles of Food Hygiene*.  
CAC/RCP 1-1969, Revision 4
- Dairy Food Safety Victoria 2013. *Microbiological testing of finished dairy products*.  
Viewed 29 March 2016 <<http://www.dairysafe.vic.gov.au/publications-media/regulations-and-resources/technical-information-notes/product/248-microbiological-testing-of-finished-dairy-products-updated-1>>
- Dairy Food Safety Victoria 2014. *Cleaning in place (CIP)*.  
Viewed 29 March 2016 <<http://www.dairysafe.vic.gov.au/publications-media/technical-information-notes/premises/285-tin-cip-web/file>>
- Dairy Food Safety Victoria 2015. *Microbiological testing criteria*.  
Viewed 29 March 2016 <<http://www.dairysafe.vic.gov.au/publications-media/regulations-and-resources/guidelines/347-dfsv-micro-testing-criteria2015web>>
- FSANZ 2013. *Agents of foodborne illness*. 2nd edition. Food Standards Australia New Zealand, Canberra.  
Viewed 29 March 2016 <[http://www.foodstandards.gov.au/publications/Documents/FSANZ\\_Foodbornellness\\_2013\\_WEB.>](http://www.foodstandards.gov.au/publications/Documents/FSANZ_Foodbornellness_2013_WEB.>)
- FSANZ 2014. *Food Industry Recall Protocol–A guide to conducting a food recall and writing a food recall plan* (7th ed).  
Viewed 29 March 2016 <<http://www.foodstandards.gov.au/publications/Documents/FSANZFoodRecallProtocol2014.pdf>>
- International Commission on Microbiological Specifications for Foods 2002. *Microbiological testing in food safety management (Microorganisms in foods 7)*. Kluwer Academic/Plenum Publishers, New York, USA.
- US Food and Drug Administration 2012. *Bad Bug Book*. (2nd ed) USA.  
Viewed 29 March 2016 <<http://www.fda.gov/downloads/Food/FoodbornellnessContaminants/UCM297627.pdf>>
- Yiannas, F. 2009. *Food Safety Culture: Creating a Behavior-Based Food Safety Management System*. Springer, NY

## 9. Abbreviations

ADASC	Australian Dairy Authorities Standards Committee
ATP	Adenosine triphosphate
DFSV	Dairy Food Safety Victoria
FSANZ	Food Standards Australia New Zealand
FSC	Australia New Zealand Food Standards Code
GMP	Good manufacturing practice
HACCP	Hazard analysis and critical control points
ICMSF	International Commission on Microbiological Specifications for Foods
STEC	Shiga-toxin producing <i>Escherichia coli</i>

## 10. Glossary of terms

**Animal feed** – any single material (or multiple materials), whether processed, semi-processed or raw, which is intended to be fed directly to food producing animals.

**Batch/Lot** – a definitive quantity of a commodity produced essentially under the same conditions, for example, up to 24 hours of continuous production of a product, or products from a specific line, or a lesser period of continuous production between the completion of cleaning and disinfecting procedures; the term 'batch' has the same meaning as 'lot'.

**Cleaning** – the removal of soil, food residue, dirt, grease or other objectionable matter. A comprehensive clean would generally indicate a requirement to disassemble, inspect and clean individual manufacturing equipment components.

**Dairy product(s)** – products defined by *Standard 4.2.4 Primary production and processing standard for dairy products of the Australia New Zealand Food Standards Code*, as well as dairy-based dips and dairy-based desserts.

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

**Disposal/Dispose** – to change the purpose/intended use of the product, such as to destroy, reprocess so that the risk is reduced to a safe level, use as animal feed or use in a non-food application.

**Foodborne illness** – any illness resulting from the consumption of contaminated food.

**Food recall** – action to remove from distribution, sale and consumption, food which may pose a health and safety risk to consumers.

**Non-conforming** – product that is suspected or known not to meet regulatory requirements.

**Pathogen** – any microorganism capable of causing foodborne illness.

**Qualitative testing** – laboratory analysis which establishes the presence or absence of a pathogen.

**Quantitative testing** – laboratory analysis which enables the level of pathogens present to be determined.

Routine pathogen sampling and testing programs – routine (regular and ongoing) sampling and testing that is conducted to detect pathogens in dairy products and the processing environment. Routine sampling and testing is seen as an essential element of a dairy manufacturer's food safety program to meet requirements in terms of monitoring and verification.

**Traceback** – process of tracing back through various stages of production and processing to determine the cause of a problem.



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