



# **GUIDELINES**

FOR THE SAFE  
MANUFACTURE OF  
DAIRY PRODUCTS



**DAIRYSAFE**  
Leaders in dairy food safety

## **Published by:**

The Dairy Authority of South Australia (trading as 'Dairysafe'), South Australia ABN 36 767 901 242

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## Glossary of terms and abbreviations

<b>Ambient temperature</b>	Temperature of the air around you or the product
<b>Allergens</b>	Chemical components of foods which cause adverse health reactions in susceptible consumers
<b>Anaerobic</b>	The absence of oxygen, a state which can exist in canned and vacuum-packed products
<b>Biofilm</b>	A mixture of microorganisms and their excretory products that builds up in food processing equipment
<b>CCP</b>	Critical Control Point. A point, procedure, operation or stage in a process at which a hazard is prevented, eliminated or reduced to an acceptable level
<b>CFU</b>	Colony Forming Unit, an estimate of viable number of bacteria
<b>CL</b>	Critical Limit – a criterion which separates acceptability from unacceptability
<b>Cold chain</b>	The process of maintaining foods under refrigeration, in either a chilled or frozen state, during storage, distribution and marketing
<b>Contaminant</b>	Something which may make food unsafe or unwholesome. Examples of contaminants are microorganisms, chemical residues or foreign matter
<b>Controlling authority</b>	The Commonwealth, State or Territory authority which is responsible for the enforcement of dairy food safety standards
<b>CP</b>	Control Point
<b>DFSV</b>	Dairy Food Safety Victoria
<b>ESL</b>	Extended Shelf Life
<b>FSP</b>	Food Safety Plan
<b>GMP</b>	Good Manufacturing Practice
<b>HACCP</b>	Hazard Analysis Critical Control Point is the system which identifies and controls those hazards which pose a significant risk to food safety
<b>Hazard</b>	A biological, chemical or physical agent which may compromise or affect food safety
<b>Log</b>	Logarithm — used to express microbial counts e.g. log 2 is 100, log 3 is 1,000
<b>Microbial count</b>	The number of microorganisms living in or on a food product



<b>Microbiological limits</b>	The maximum number of microorganisms specified for a food product
<b>Microorganisms</b>	Viruses, yeasts, moulds and bacteria
<b>MAP</b>	Modified Atmosphere Packaging. Enclosure of product in high gas barrier film, in which the gas environment around the product has been changed by removing all the air from pack and flushing it with a gas mixture of varying concentrations of oxygen, carbon dioxide and nitrogen. Vacuum packaging where, most of the air is removed before sealing the pack, is sometimes included in MAP
<b>NATA</b>	National Association of Testing Authorities
<b>Pathogen</b>	A microorganism which causes illness
<b>pH</b>	A measure of acidity or alkalinity
<b>PPPS 4.2.4</b>	Primary Production and Processing Standard for Dairy Products
<b>PRP</b>	Pre-requisite program
<b>QCP</b>	Quality Control Points
<b>QUAT</b>	Quaternary ammonium compounds
<b>RCP</b>	Regulatory Control Point
<b>RTE</b>	Ready to eat
<b>Shelf life</b>	Length of time that a commodity may be stored without becoming unfit for use or consumption, due to loss of quality, the presence of undesirable chemicals, toxins, or growth of pathogens
<b>Spoilage bacteria</b>	Bacteria which limit the shelf life of foods by producing objectionable odours, colours or slime
<b>SSOP</b>	Sanitation Standard Operating Procedures
<b>Syneresis</b>	The expulsion of whey from curd
<b>Toxin</b>	A chemical that can cause illness. Toxins may be produced in food by bacteria and moulds
<b>Validate, validation</b>	The process of obtaining evidence to demonstrate that hazards in a food process are controlled
<b>Verify, verification</b>	Means applying methods, procedures, tests and other evaluations in addition to monitoring to determine whether a requirement is complied with or a matter is met



## Purpose

The dairy industry manufactures a wide range of heat-treated, fermented, liquid, curd-based and dried products, using milk from cattle, sheep, goats, buffalo and camels. Shelf lives vary widely, from a few days for pasteurised milk to months for ripened cheeses and years for powders. Products such as powders and long-life milks may be stored at room (ambient) temperature but products such as milks, cheeses and yoghurts must be chilled. All dairy products are ready-to-eat (RTE) foods.

Manufacture of dairy products involves many risk factors, summed up by Food Standards Australia New Zealand (FSANZ) *Risk Profile of Dairy Products in Australia*:

*'Dairy products containing elevated levels of fat or solids such as ice-cream mixes, cream and yoghurt, warrant higher time/temperature combinations than those currently specified in the Australia New Zealand Food Standards Code (the Code) to compensate for the protective effect of fat and solids on microorganisms. Post-pasteurisation contamination, however, is an ongoing management issue for manufacturers in the provision of safe dairy products. Contamination may result from the environment, including equipment, personnel or contamination of finished product with raw materials. Rigorous control over hygiene, cleaning and sanitation, and product handling is therefore necessary to ensure safety of the final product post-heat treatment.'*

These Guidelines aim to:

1. Update you on hazards and risks in the products you manufacture
2. Suggest ways you can reduce risk to your customers
3. Supply scientific backing for your Food Safety Plan (FSP)
4. Provide background information so you meet the regulatory and customer requirements for the safe manufacture of all your products.

The Guidelines were drafted by Dr John Sumner in cooperation with Dairysafe staff and benefited greatly from technical inputs from Don Sandman, Quality Assurance Manager, Tasmanian Dairy Industry Authority, and Steve Rice, ex Dairy Authority of South Australia CEO. Dairysafe would also like to acknowledge the contributions by Safe Food Queensland, Dairy Food Safety Victoria (DFSV) and SA Health (Health Regulation and Protection).

## Acknowledgments

Many processors assisted in the development of these Guidelines and Dairysafe is grateful to: Dan & Krystyna McCaul, Alexandrina Cheese Company; Kym Masters, Section 28, Woodside; Nick Hutchinson & Douglas Pollnitz, Fleurieu Milk Company, Myponga; Rebecca Flavell, Udder Delights Australia Pty Ltd, Lobethal; Megan Cottrell, Paris Creek Farms Organic Dairy; Dean Burgess, La Casa del Formaggio, Adelaide; Kris Lloyd, Woodside Cheese Wrights, Woodside.

Further development of the Guidelines took place following comments and advice from the 59 participants of 35 dairy businesses who attended four industry sessions.

Dairysafe would also like to acknowledge the generosity and leadership provided by DFSV for allowing access to their library of technical documents, several of which are incorporated in these Guidelines. In addition, much of the data and analysis in the Guidelines is owed to FSANZ's: *A Risk Profile of Dairy Products in Australia* (FSANZ, 2006), FSANZ's Recall website and the NSW Food Authority's: *Food Safety Risk Assessment of NSW Food Safety Schemes* (NSWFA).

## Purpose

The Guidelines for the Safe Manufacture of Dairy Products are intended as a reference for existing dairy processing businesses and also for those wanting to establish a dairy processing business.

The Guidelines provide essential food safety information detailing the food safety hazards and risks associated with dairy products, dairy microbiology and testing, hazard sheets for target bacteria, how to control target bacteria in your dairy process, process control, your food safety program, cleaning and good manufacturing processes.

There are two parts to the Guidelines: Part 1 detailing what you need to know about the safety of dairy products and Part 2 covering process control in their manufacture.

## What you need to do after reading these Guidelines

Review your food safety program: processes, work instructions and monitoring forms. Only you can do this for your individual operation and for approval by your controlling authority.

If starting from scratch, set out how to meet all the provisions of the *Australia New Zealand Food Standards Code* and other relevant standards. You need to do this before your regulator will approve your FSP.

These include:

- Standard 1.2 - Labelling and other information requirements (ingredients, allergens, date marking)

- Standard 1.3.1 - Food Additives

- Standard 1.3.3 - Processing Aids

- Standard 1.6.1 - Microbiological Limits in Food (Schedule 27)

- Standard 3.1.1 - Interpretation and Application

- Standard 3.2.1 - Food Safety Programs

- Standard 3.2.2 - Food Safety Practices and General Requirements

- Standard 3.2.3 - Food Premises and Equipment

- Standard 4.2.4 – Primary Production and Processing Standard for Dairy Products

- Australian Standard AS 3993 - Equipment for the pasteurisation of milk and other liquid dairy products— Continuous-flow systems

The Standards can be downloaded from the FSANZ website, [www.foodstandards.gov.au](http://www.foodstandards.gov.au).

# Part 1: What you need to know about safety of dairy products

1. Hazards and risks in dairy products
2. Introduction to dairy microbiology
3. Hazard sheets for target bacteria and how to control them in dairy processing
4. Microbiological testing for process control



# I. Hazards and risks in dairy products

## Purpose

You have an FSP in which you manage hazards and risks in your Hazard Analysis Critical Control Point (HACCP) plan, the first task of which is to identify hazards and risks. Once you've done that you can set about managing those hazards so you make products that are safe for your customers.

In this section we identify two major categories of hazards that confront you in your process: biological hazards that cause illness (bacteria etc) and an important group of chemical hazards (allergens). Then we talk about risk and how to make simple risk assessments for each of your processes and products.

## Hazard identification

The definition of hazard is: *A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.*

We can identify the hazards that you'll have to manage from two sources of information:

- i. Hazards which have caused food poisoning outbreaks when present in dairy products (This information is available from the NSW Food Authority's *Food Safety Scheme Risk Assessment*, FSANZ's *A Risk Profile of Dairy Products in Australia* and Quarterly Reports on the OzFoodNet website.)
- ii. Hazards which have caused companies to recall dairy products (This information is available on the FSANZ website and is summarised in Appendix 1.)

## Hazards causing food poisoning

Here are some of the outbreaks of food poisoning caused by consuming dairy foods containing dangerous bacteria.

State	Year	Pathogen	Product	Cases	Deaths
Queensland	1992	<i>Campylobacter &amp; Salmonella</i>	Raw milk	4	-
Tasmania	1993	<i>Campylobacter</i>	Raw milk	21	-
WA	1998	<i>Campylobacter</i>	Raw milk	9	-
SA	1998	<i>Salmonella</i>	Gelato	102	-
SA	1999	<i>Salmonella</i>	Raw milk	12	-
SA	2000	<i>Campylobacter</i>	Raw milk	12	-
NSW	2000	<i>Salmonella</i>	Fried ice cream	41	-
Victoria	2000	<i>Campylobacter</i>	Raw milk	25	-
SA	2001	<i>Salmonella</i>	Custard tarts	16	-
WA	2001	<i>Salmonella</i>	Ice cream and sponge	50	-
Queensland	2001	<i>Cryptosporidium</i>	Raw milk	38	-
Victoria	2002	<i>Salmonella</i>	Cream cakes	10	-
SA	2002	<i>Salmonella</i>	Cream cakes	22	-
NSW	2002	<i>Salmonella</i>	Cream cakes	29	-
SA	2003	<i>Salmonella</i>	Cheesecake	6	-
SA	2003	<i>Campylobacter</i>	Raw milk	14	-
Victoria	2003	<i>Campylobacter</i>	Raw milk	13	-

State	Year	Pathogen	Product	Cases	Deaths
Queensland	2004	<i>Salmonella</i>	Custard tarts	5	-
SA	2004	<i>Salmonella</i>	Cream filled cakes	13	-
NSW	2004	<i>Salmonella</i>	Custard	43	-
SA	2006	<i>Salmonella</i>	Feta	6	-
NSW	2007	<i>Salmonella</i>	Fried ice cream	12	-
NSW	2008	<i>Salmonella</i>	Raw milk cheese/ cream cake	27	-
NSW	2009	<i>Salmonella</i>	Fried ice cream	33	-
WA	2009	<i>Salmonella</i>	Fried ice cream	7	-
SA	2009	<i>Salmonella</i>	Fried ice cream	10	-
Queensland	2010	<i>Salmonella</i>	Fried ice cream	3	-
NSW	2010	<i>Salmonella</i>	Fried ice cream	14	-
Queensland	2010	<i>Staph. aureus</i>	Milkshake	6	-
NSW	2011	<i>Salmonella</i>	Fried ice cream	6	-
NT	2011	<i>Salmonella</i>	Banana smoothies	3	-
National	2012	<i>Listeria monocytogenes</i>	Soft cheeses	34	7
Victoria	2015	Pathogenic <i>E. coli</i>	Raw milk	5	1
SA	2017	<i>Cryptosporidium</i>	Raw milk	5	-

It's clear that raw milk consumption caused a large proportion of the outbreaks with *Campylobacter*, *Salmonella* and pathogenic *E. coli* implicated. You'll need to prevent hazards associated with raw milk coming through to your final products. (We'll cover this in later sections.)

Another aspect is the large number of outbreaks caused by fried ice cream, of which we've only included a handful. In each case, the ice cream contained *Salmonella* brought in by raw eggs and highlights the potential dangers of adding ingredients of doubtful food-safety status to pasteurised milk products.

### Hazard severity

It's a fact of life for dairy manufacturers that the udders of all milk animals are directly beneath the anus and are therefore liable to faecal contamination of disease-causing bacteria that cause illness in consumers.

The International Commission on Microbiological Specifications for Foods (ICMSF), a gathering of the smartest microbiologists, describes the severity of illness according to three categories: Moderate, Serious and Severe in the table below.

Severity	Description
Moderate	Not usually life threatening, no complications, normally short duration, symptoms are self-limiting, can have severe discomfort
Serious	Incapacitating but not life threatening, complications infrequent, moderate duration
Severe	Life threatening, substantial complications or long duration

In the table below are listed the disease-causing bacteria regularly found in raw milk. Fortunately, almost all are eliminated by pasteurising, which makes your heat treatment equipment central to your FSP. However, the spore former *Bacillus cereus* is an exception. It survives pasteurising and you need good temperature control to prevent it growing to a dangerous level (you can read more in the Hazard Sheet section).

Whether you have a heat exchanger or a batch pasteuriser, this is where the food safety rubber hits the road—the kill step. Knock out all these dangerous bacteria and then keep them out for the remainder of your process.

Below are the hazards most likely to affect your business. You can find more about them in later sections, particularly how to control them.

Organism	Illness	Severity of illness	Survives pasteurising
<i>Bacillus cereus</i>	Gastroenteritis	Moderate	Yes
<i>Campylobacter</i>	Gastroenteritis	Serious	No
<i>Corynebacterium</i>	Diphtheria	Serious	No
<i>Coxiella burnetii</i>	Q fever	Serious	No
<i>Cronobacter sakazakii</i>	Meningitis in premature infants	Severe	No
Pathogenic <i>E. coli</i>	Gastroenteritis, bloody diarrhoea, Haemolytic Uraemic Syndrome (HUS)	Severe	No
<i>L. monocytogenes</i>	Listeriosis	Severe	No
<i>Mycobacterium bovis</i>	Tuberculosis	Severe	No
<i>Salmonella</i>	Gastroenteritis, typhoid fever	Serious	No
<i>Shigella</i>	Dysentery	Serious	No
<i>Staphylococcus aureus</i>	Emetic intoxication	Moderate	No
<i>Streptococcus</i>	Scarlet fever/sore throat	Serious	No
<i>Yersinia enterocolitica</i>	Gastroenteritis	Serious	No

While pasteurisation is effective at knocking out most pathogens found in raw milk, there are some pathogens that, if they find their way back into the dairy products, may lead to very severe illness, disability and even death.

*L. monocytogenes* is of particular concern in dairy manufacturing as it is a common environmental organism that can become lodged in the facility. Unlike most pathogens, it grows well at refrigeration temperatures (it can harbour in refrigeration units) and has opportunities to grow in cheeses matured for several weeks, depending on the water activity or pH of the cheese. This is why it is mostly associated with soft cheeses, mould-ripened cheeses and dairy dips and desserts (high water activity and pH >4.5).

The presence of *E. coli* in pasteurised product can be an indicator that it has found its way into a post-heating stage, was present as a biofilm in pipework downstream from the pasteuriser or that pasteurisation has been ineffective.

## Hazards causing product recalls

As well as biological hazards, chemical and physical hazards can also cause injury and, if they are found to be present, result in a recall of all affected product.

Allergens have become a significant issue for food businesses (manufacturers, importers and food service) and we cover them later in this section.

The FSANZ website records all recalls and following is a list of dairy recalls from January 1999–January 2019, sorted according to product category so you can see which hazards are most likely to occur in your business. The company names, which can be accessed from the FSANZ website, show that recalls affect businesses both large and small.

## Recalls of Ultra High Temperature (UHT) milks

Given the very high process temperatures (>120°C) what can possibly survive and cause spoilage? Well, bacteria can't but enzymes they produced in raw milk can survive the UHT process and gradually cause gelling, souring and off flavours/odours during storage – of product spoilage not product safety concern.

## Recalls of chilled milk and cream

FSANZ recall data show that milk products were recalled on 33 occasions over the period 1999–2019 for the full range of hazards:

- > physical – synthetic fibres found their way into bottles of finished milk for one recall
- > chemical – on seven occasions cleaning solutions, such as caustic or sanitiser, still in the bottling line
- > microbiological – There were 16 recalls for coliforms and *E. coli* in pasteurised products indicating ineffective pasteurisation or a biofilm in pipework downstream from the pasteuriser  
*Listeria* caused six recalls – the pathogen is present in the environment and was brought into the plant  
Two unpasteurised products were recalled for faecal contaminants – *Salmonella* and the parasite *Cryptosporidium*.

## Recalls of hard cheeses

The 18 recalls for hard cheeses involved a full range of hazards:

- > physical – plastic and metal caused four recalls
- > chemical – undeclared allergen finding its way into grating cheese caused one recall
- > microbiological – eight recalls were for *Listeria* contamination and five for *E. coli*/*Salmonella* contamination.

## Recalls of soft cheeses

Of the 31 recalls, more than 75% were for the presence of the faecal organisms (*E. coli* and *Salmonella*) and *Listeria*, the remainder involving labelling defects, foreign matter and *S. aureus*.

## Recalls of mould-ripened cheeses

Of the 14 recalls of mould-ripened soft cheeses, *Listeria* caused eight. Brought into the cheese plant from the environment, it grows well at refrigeration temperatures and has opportunities to grow in cheeses matured for several weeks.

In other recalls, *E. coli* has obviously found its way into a post-heating stage or the pasteurisation has been ineffective.

## Recalls of yoghurt

Of the 13 recalls for yoghurts, eight indicate a recurring problem with packaging, such as pieces falling into product at opening or resealing, or mislabelling.

The faecal indicator *E. coli* was involved in five recalls.

## Recalls of dairy dips and desserts

Of the eight recalls of dairy dips and desserts, *L. monocytogenes* was responsible for four, with labelling problems (two) and spoilage being responsible for the other recalls.

## Recalls of ice cream and dairy desserts

Of the five recalls of ice cream, labelling problems due to undeclared allergens caused three recalls, with foreign matter and sanitiser left in the lines each causing one recall.



## Allergens

### The problem

Allergens play a significant role in food recalls and pose a significant safety threat to consumers. Here is background information and suggestions on how to manage allergens.

The Allergen Bureau ([www.allergenbureau.net](http://www.allergenbureau.net)) estimates 4–8% of children and 1–2% of adults have a food allergy. When people eat food containing an allergen to which they are sensitive, symptoms range from mild to severe and affect the:

- > respiratory tract (wheezing, asthma)
- > gut (nausea, vomiting diarrhoea)
- > skin (hives, eczema, itching).

By far the most serious condition is anaphylaxis—blood pressure drops, breathing is restricted and the victim goes into shock; some people die of anaphylactic shock.

### Allergen groups

The most common allergic reactions are to the protein components of foods like wheat (gluten), soy and peanuts. So, oils and fibre from these foods have a very limited risk to initiating a reaction but may contain traces of protein depending on the process used. You're in the dairy business and your products are well known to be damaging to consumers who are lactose intolerant, but some people are also allergic to casein and the whey components of milk, and these have caused serious anaphylaxis reactions in Australia, including death. Other allergenic ingredients may enter dairy products, such as egg products in ice cream, egg lysozyme in cheese and soy lecithin in powders.

FSANZ lists 11 allergens that MUST be declared in Standard 1.2.3 (4) – mandatory declaration of certain foods or substances in foods:

Keep a register of all the allergens you have on the premises and your suppliers can help with this. Your register can be a simple list like the one below, backed up by technical information from your ingredient supplier. This will enable you to answer any questions from concerned customers.

Allergen	Present
Milk and dairy products	Yes/No
Eggs and egg products	Yes/No
Peanuts and peanut products	Yes/No
Tree nuts and their products	Yes/No
Sesame and sesame products	Yes/No
Soy and soy products	Yes/No
Crustaceans	Yes/No
Fish	Yes/No
Added sulphites in concentrations of 10 mg/kg or more	Yes/No
Cereals containing gluten (wheat, rye, barley, oats and spelt and their hybridised strains)	Yes/No
Lupins	Yes/No

Regulators have legislated (Clause 4 of Standard 1.2.3) to have producers list allergenic ingredients on the label with appropriate warnings for at-risk consumers. You need to include the segregation of these foods and ingredients in your GMPs and include the risks in the HACCP plan. Check package labels and suppliers regularly to detect any ingredient changes of your inputs and make suppliers inform you of formulation changes before releasing products that could put the consumers and your business at risk.

## Managing the problem

The list of allergens continues to increase as new foods and ingredients are developed. An example is edible insects, many of which are allergenic, including silkworm, mealworm, caterpillars, locusts, grasshoppers, cicadas and bees because they contain chitin.

To minimise the potential for incidental contamination of products with allergens, you can reduce the risk of undeclared allergens by:

- › including allergens in HACCP plans
- › including allergens as part of GMP assessments
- › segregating allergens during storage
- › using production planning to run allergenic products last or cleaning and sanitising between allergenic and non-allergenic products to avoid cross-contamination
- › supplier reviews (scheduled, and also when changing suppliers or when a supplier changes their ingredients)
- › review of substitute ingredients prior to use
- › label reviews (of your products and incoming goods)
- › final product checks (product matches the label prior to dispatch)
- › review of latest recalls due to undeclared allergens.

This is not an exhaustive list, and each business will have to assess their specific risks.

Fortunately, there are excellent resources you can call on. DFSV has *'A guide to managing allergens in the food industry'* and *'Allergen management for dairy food manufacturers'*.

## Further reading

You can read more about allergens in:

- › The Food Standards Code (<http://www.foodstandards.gov.au/code/Pages/default.aspx>)
- › FSANZ food allergen portal (<http://www.foodstandards.gov.au/consumer/foodallergies/foodallergenportal/Pages/default.aspx>)

The Allergen Bureau website has extensive information (<http://allergenbureau.net/>):

- › Food Industry Guide to the Voluntary Incidental Trace Allergen Labelling (VITAL®) Program
- › Unexpected Allergens in Food
- › Food Industry Guide to Allergen Management and Labelling
- › Food allergen analysis
- › VITAL® Training
- › VITAL® Best Practice Labelling Guide.

## Antibiotics

Antibiotics have been used to treat serious bacterial diseases in Australian livestock for more than 60 years. They offer great benefits to industry and food production but also present risks to human health, food production and markets (domestic/export) that must be managed, but they also represent a chemical food safety hazard.

The prevalence of residues in milk is extremely low—of milk samples tested in 2016-2017, no residues were detected above the relevant Australian Maximum Residue Level as specified in the Food Standards Code. These results are evidence that the Australian dairy industry's approach to

agricultural and veterinary chemical usage is responsible, effective and in accordance with good agricultural practice. It also demonstrates that the food safety programs adopted by the dairy industry are successful in managing potential residue contaminations.

At the farm and processor level, a risk-based monitoring program for antibiotic residues in milk can include one or more of the following along the milk supply chain:

- > milk vat testing
- > milk tanker testing
- > silo testing at dairy processor
- > finished product testing.

Farmers must have a system in place to identify treated livestock.

Processors must consider antibiotics within their HACCP plan and have a monitoring program to verify that the controls applied to manage the hazard of antibiotic residues in milk are effective.

## Risk – what is it?

Risk is made up of two parts: the likelihood that something bad (a hazard) will happen, plus the severity the hazard will have on us.

There are important terms associated with risk—like assessment, management and mitigation. Let's spell out what they mean.

### Risk assessment

Worried about getting involved in a car crash? Probably not. When we buckle up we never think we'll have an accident because we know the likelihood of it happening is so small. But, for about 25 Australians each week, that hazard does occur, and the severity of the hazard is extreme.

### Risk mitigation and management



Once we've assessed the risk we can reduce (mitigate) it. Driving interstate to see relatives at Christmas? If you get the car serviced, start early, stop regularly to refresh, change drivers, arrive before dark – now you're thinking about risk, and you're also managing and reducing it.

## Who is most at risk?

If you produce a batch of product that contains dangerous microbes, how vulnerable are your customers? Fortunately, the majority of us are relatively resistant to pathogens because we have a range of natural body defence systems that:

- > kill pathogens in the stomach (the acidity is high, similar pH as battery acid)
- > prevent pathogens attaching to the intestine where they can set up home and damage us
- > reduce the likelihood that an infection will progress to become an illness.

However, many Australians are not so fortunate and are vulnerable to food infections because they have lowered immune systems: young, old, pregnant and immune-compromised (YOPIs).

### Susceptible populations and proportions in Australian society (Australian Bureau of Statistics data)

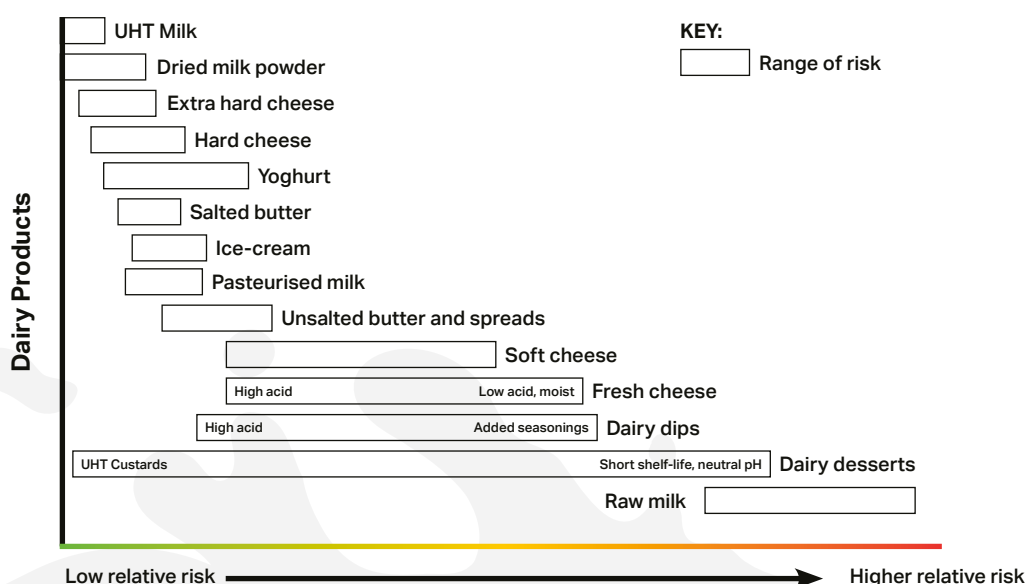
Population	Individuals	Percentage
Pregnancies	300,000	1.3
Neonates	330,000	1.4
Children 1–5	1,500,000	6.3
Elderly >65	3,500,000	14.6
Diabetes	1,700,000	7.1
Cancer Patients	400,000	1.7

Put all these categories together and you can see that vulnerable people make up more than 20% of your customers, and they are at the highest risk from consuming one of your products if it contains a hazard.

You can read more about each hazard in the hazard sheets (Section 3, Part 1).

## Risks in dairy processing

Your business risk varies depending on what you manufacture. There are low, medium and high-risk dairy products which Australia's standard-setting organisation, FSANZ, has arranged according to relative risk. Products range from low (milk powder, UHT milks, hard cheeses), through medium (salted butter, ice cream and pasteurised milk), to high risk (fresh cheeses, mould-ripened cheeses and dairy desserts). But, as you can see from the chart below taken from FSANZ (2006), it's quite possible to make high-risk products safely if you know what you're doing.



## Risk assessment tools

### Simple guess tool

When you develop your HACCP plan you need to include a simple risk assessment, such as in the HACCP Control Worksheet shown below. For every hazard, some people make an estimate of risk by inserting high, medium or low under 'Severity of hazard' and 'Likelihood of hazard occurring'. A problem is that we often just make a guess at answering these two questions about risk.

## Hazard Control Worksheet

Process step	HAZARD		RISK		CONTROL OF HAZARD
	Identification	What can go wrong	Severity of hazard	Likelihood of hazard occurring	
	BIOLOGICAL				
	CHEMICAL				
	PHYSICAL				

### Matrix tool

The tool often used to estimate severity and likelihood involves a matrix such as the one below. You pick out a number for SEVERITY and a letter for LIKELIHOOD and see if the risk is in the red zone. But this involves some guesswork. For example, how likely is the hazard to occur, and neither 'Product recall' nor 'Customer complaint' tell you anything about how severe the hazard is.

Hazard severity		Hazard likelihood	
1	Fatality	A	Common and repeated (day)
2	Serious illness	B	Known to occur (week)
3	Product recall	C	Could occur (month)
4	Customer complaint	D	Not expected to occur
5	Not significant	E	Practically impossible

		LIKELIHOOD				
		A	B	C	D	E
SEVERITY	1	1	2	4	7	11
	2	3	5	8	12	16
	3	6	9	13	17	20
	4	10	14	18	21	23
	5	15	19	22	24	25

### CSIRO tool

A very useful risk assessment tool was developed by Food Science Australia where you answer six questions to come up with a risk assessment. When you put all the answers together you can make a risk rating based on knowing about your process and the hazards you're trying to manage.

Here's one way to go about getting the answers to the questions in the tool.

1. **Severity** of the hazard can be obtained from the table in the previous section.
2. **Likelihood** that the hazard will be present in the final product can be determined from surveys undertaken by DFSV and Dairy Australia. We list them in the pathogen:product risk assessments in Part 2. You can also make a judgement based on whether there have been recalls for the pathogen.
3. **Growth required** to reach an infective dose is determined by assessing whether the storage conditions will allow growth. You'll find this information in the hazard sheets. For example, *Listeria* can grow under refrigeration and, if the product has long shelf life, it may reach an infective dose.

4. **Effect of processing** takes into account the extent to which product is heated e.g. pasteurising *versus* Extended Shelf Life (ESL) and UHT heat treatments obviously kill different groups of bacteria. Also, take into account whether other ingredients are added after the heating step and whether environmental organisms such as *Listeria* can get in.
5. **Consumer cooking step** – dairy products are almost always consumed RTE so no further kill step is involved.
6. **Epidemiological links** – has the pathogen:product pairing caused outbreaks of food poisoning in Australia or anywhere else in the world? If it hasn't then there are no epidemiological links. Also, recalls tell you important epi information.

<b>Product</b>	
Hazard	
1. Severity	
2. Likelihood	
3. Growth required to reach infective dose	
4. Effect of processing	
5. Consumer cooking step	
6. Epidemiological links	
Rating	

In Part 2, we include qualitative risk assessments for several product:pathogen pairings, chosen because businesses are required to test for these pathogens in these products.

All the justifications for each of the inputs to the assessment are explained and, if over the course of time any of the inputs change, the assessment can be updated.

Product	Pathogen
Pasteurised milk and cream	<i>L. monocytogenes</i>
Mould-ripened cheese	<i>L. monocytogenes</i>
Mould-ripened cheese	<i>S. aureus</i>
Butter	<i>S. aureus</i>
Butter	<i>L. monocytogenes</i>
Butter with post-process inclusions	<i>Salmonella</i>
Ice cream	<i>L. monocytogenes</i>
Ice cream with raw egg inclusions	<i>L. monocytogenes</i>
Yoghurt with post-process inclusions	<i>Salmonella, S. aureus</i>
Dairy dips and desserts	<i>L. monocytogenes</i>
Dairy dips and desserts with post-process inclusions	<i>Salmonella, S. aureus</i>
Dairy powders	<i>Salmonella</i>
Dairy powders	<i>S. aureus, B. cereus</i>
Dairy powders	<i>Cronobacter sakazakii</i>

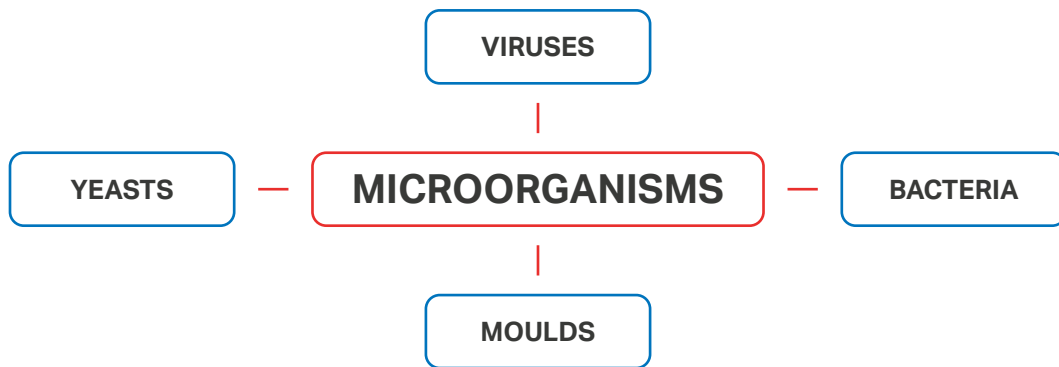
## 2. Introduction to dairy microbiology

### Introduction

Microbiology is about living things (organisms) that are so small they can be seen only with a microscope and are called microorganisms. We also have other names for them such as bugs, germs and microbes.

To get an idea of their size, imagine a metre ruler. If we made bacteria form a queue one behind the other, we'd get about a million of them in that metre-long queue. Viruses are even smaller, and we could have about a billion of those lined up in the same queue.

There are four groups of microorganisms: viruses, bacteria, yeasts and moulds, and all are extremely important in dairy processing.

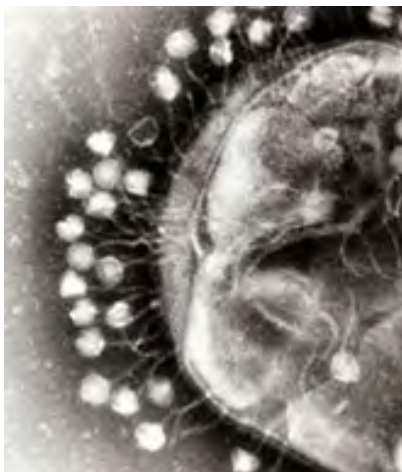


### Viruses

Viruses are very streamlined microorganisms and, because they're made up of only two types of chemicals, there's debate over whether they are actually living things. They're actually parasites and come to life only when they colonise another living thing, like us. When we get a cold or flu it's because a virus enters our body and takes it over, forcing our cells to become virus factories and make more and more viruses. Eventually, our body's immune system will kick in and we can recover.

In the dairy industry, viruses are important for two reasons:

1. Food handlers can become infected with Hepatitis A or Norovirus. These viruses live in our gut and are excreted when we go the toilet. Poor hand hygiene can see them passed onto food and then on to customers.
2. Viruses known as bacteriophage (phage for short) have long plagued cheese making by infecting starter bacteria. So, instead of the starters converting lactose to lactic acid and forming a curd, they produce billions more viruses and acidity increases either slowly or not at all (dead vat).



*An electron micrograph of bacteriophages attached to a bacterial cell.*



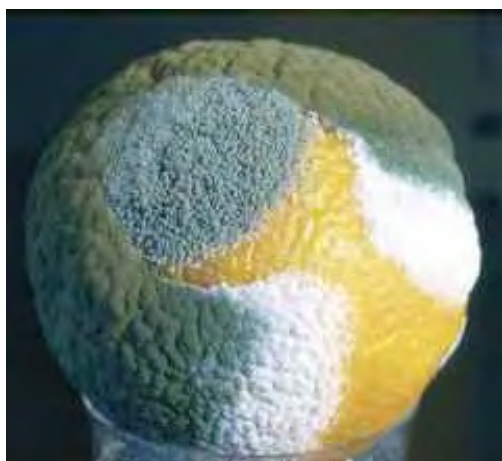
## Yeasts

Yeasts are round or oval cells which multiply by budding, the small buds growing rapidly to full size and then making their own buds. Yeasts are capable of fermenting sugar to alcohol (brewers' yeast) and gas (bakers' yeast). In the dairy industry, they can spoil liquid products like cream and yoghurt, producing off odour, and form spots on the surface.

## Moulds

Moulds have two parts to their body: a fine threadlike skeleton called mycelium and round coloured bodies called spores. Spores are easily moved by air currents that spread the mould to colonise wide areas.

While they have a valuable role in ripening of cheeses like brie, camembert and gorgonzola, moulds can also colonise the exterior of hard cheeses. Some moulds produce toxins called mycotoxins. Fortunately, these are rare and have not been associated with cheeses, so it's safe to trim the mould off hard cheeses.

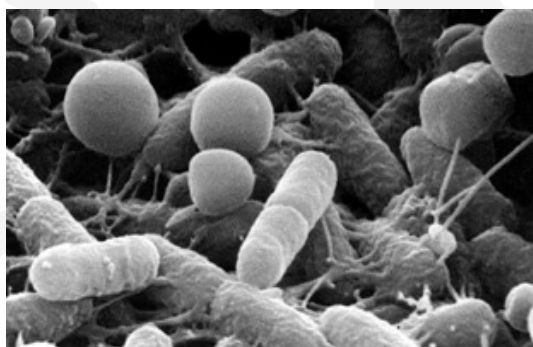


*Orange showing three different strains of the penicillin mould; some of these are toxic.*

(Ref: <http://www.rebresearch.com/blog/allergic-to-penicillin/>)

## Bacteria

Bacteria can exist in two forms: vegetative cells and spores. Vegetative cells are active and grow. Spores are not active but are much more resistant to damage from heat or chemicals such as sanitisers. Spores are produced to protect the cell from harsh conditions and for dispersal. When conditions become more favourable, or when the spores find themselves in a better environment, they break out (germinate) and become active and start to grow again. One spore-forming bacterium, *Bacillus cereus*, is important in the dairy industry because it can spoil product and also cause illness.



*Most bacteria are either rod shaped or round*

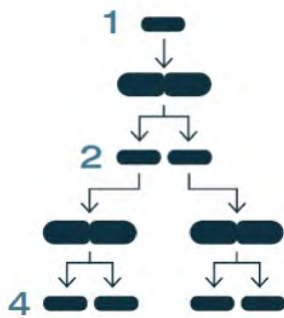
Bacteria are divided into two groups based on their appearance under the microscope. In order to see them it's necessary to add a stain to their cells, otherwise light passes through them and they're invisible. In 1884, the Danish microbiologist Christian Gram discovered that bacteria behave

differently when they are stained. Some retain the stain inside their walls and appear purple under the microscope, while others lose the stain and appear pink. He called the purple group Gram-positive and the pink group Gram-negative.

The two groups are very different in their ability to withstand heat and cleaning chemicals, with Gram-negatives being easier to kill than Gram-positives.

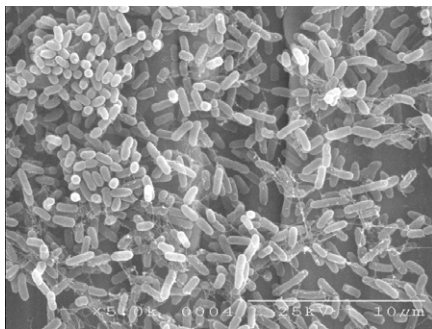
### Bacterial growth

Bacteria growth is very simple. They increase their size then divide into two, and you can see some of them doing this in the image above. This simple growth process doubles the population and, given good conditions, one bacterium will multiply to 1,000,000 in less than seven hours. When they do this, they generate off odours and flavours and may make milk clot.



*Bacteria grow by doubling.  
Your processes are aimed at  
stopping or slowing this growth.*

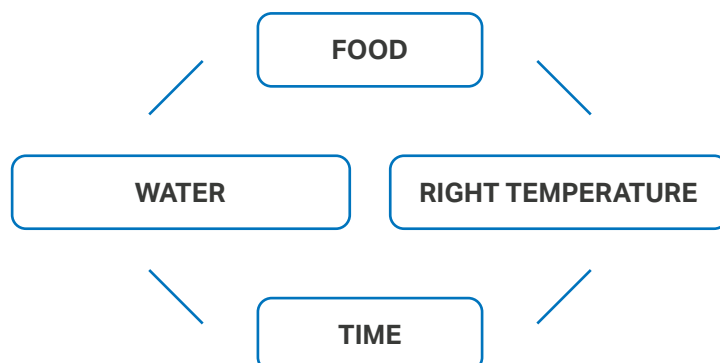
Their size means bacteria can lodge in crevices such as in joints, behind O-rings and in dead spots in milk lines, where they grow very quickly to high numbers. If you transferred a small bit of the gunk that builds up behind an O-ring onto a microscope slide this is what you'd see – wall-to-wall bacteria that keep 'bleeding' into product.



*The result of bacterial  
growth in a milk line.*

### What do bacteria need to grow?

Milk contains protein, vitamins and sugars, and is a nutritious food for bacteria. All they need is four factors (food, water, right temperature and time) and they'll grow quickly to big populations.



A major part of your job as a dairy processor is to make life difficult for them by taking away as many of these factors as possible.

**Temperature** is a major control for bacteria, and, in the dairy industry, three groups are important depending on where they can grow:

- › **Psychrotrophs** grow well at refrigeration temperatures and the shelf life of pasteurised milk depends on how quickly psychrotrophs like *Pseudomonas* can grow to high numbers and cause off odours and clotting. The temperature of product affects the time required for bacteria to divide and double their population. For example, in milk at 4°C, *Pseudomonas* doubles its population every 5.5 hours; in your home fridge at 8°C, its doubling time shortens to every 3.0 hours and shelf life is reduced by about 40%.
- › *Listeria* is psychrotrophic and will increase its numbers in products with long shelf lives, such as ripened cheeses.
- › **Mesophiles** grow well at ambient temperatures and in the gut of warm-blooded animals. Mesophiles can't grow at refrigeration temperatures, which is a primary control for *Salmonella* and pathogenic *E. coli*.
- › **Thermophiles** grow well at temperatures where most bacteria are killed. Thermophiles like *Streptococcus thermophilus* are used in yoghurt manufacture to increase the viscosity and 'set' the product.
- › On the downside, thermophiles can set up home in warm parts of heat exchangers and evaporators and can leak bacteria into final products, for which reason milk powders sometimes have to meet a micro limit for thermophiles.

	Growth range	Fastest growth	Target bacteria
Psychrotrophs	-5 to 20°C	12 to 15°C	<i>L. monocytogenes</i> , <i>B. cereus</i> , <i>Pseudomonas</i>
Mesophiles	7 to 45°C	25 to 37°C	<i>Salmonella</i> , <i>E. coli</i> , <i>Staphylococcus</i>
Thermophiles	40 to 70°C	55°C	<i>Bacillus</i> , <i>Streptococcus</i>

There's an additional group, specific to the dairy industry, called thermodurics. These are bacteria that have high heat resistance, can survive pasteurising but then grow just like mesophiles. They can build up in milk stone, which is why you use a periodic acid wash in your cleaning regime.

**Water** is a key nutrient for microbial growth and the dairy industry uses two main strategies to make water unavailable to bacteria:

- › Removal – by evaporation and drying, as in powder plants, or by curd formation and syneresis in cheese making.
- › Adding salt and changing water to brine, as in cheese and butter manufacture. In brine, the water is 'tied up' by the salt and is not available to the bacteria. There is a technical term called 'water activity ( $a_w$ )' which describes how much water is tied up. Milk has a high water activity ( $a_w = 1.0$ ), cheddar is 0.91–0.95, parmesan is 0.87–0.91 and sweetened condensed milk is 0.80–0.87. The lower the water activity, the less able bacteria are able to grow.

### Further reading

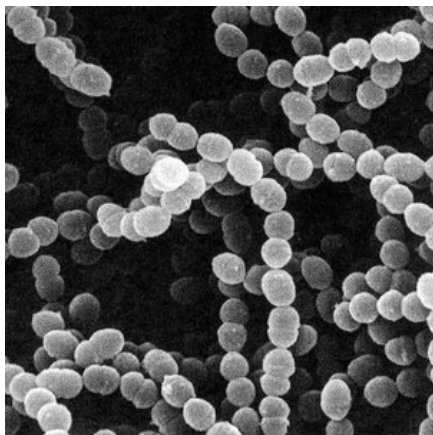
The DFSV Technical Information note: *Water activity and its relevance* is highly recommended. (Accessed at <https://www.dairysafe.vic.gov.au/publications-media/technical-information-notes/product/409-water-activity/file>.)

**Acidity** also affects the ability of bacteria to grow. Acidity is usually expressed as the pH of a product and ranges from pH=0 (extremely acidic) via pH=7 (neutral) to pH=14 (very alkaline). Most microbes prefer products with a neutral pH like milk and, in fermented dairy products like cheese and yoghurt with a pH <4.5, moulds are favoured to grow as they are more tolerant of acid conditions.

Bacteria are of great importance in the dairy industry for both the right and the wrong reasons, which means there are 'good' and 'bad' bacteria.

### Good bacteria

Bacteria are indispensable for making many types of cheese and are added as starter cultures, usually in large numbers (more than 1 million per mL of milk), and grow to even larger numbers, around 100 million per gram of product. Starters consume lactose in milk as an energy source to help them grow, converting it to lactic acid, which increases the acidity of the milk (and lowers the pH) to form a curd.



*Lactococcus, starter culture.  
Several species are used in  
cheese manufacture.*

Some starters convert lactose to lactic acid and very little else. They're called Homofermentative starters and are used to make cheeses such as cheddar.

Other starters convert lactose to lactic acid plus a range of other breakdown products, including gases. They're called Heterofermentative starters and are used to make cheeses with a more open texture, such as gouda and Emmenthal.

Other bacteria are important for ripening/maturing cheese. These are usually lactic acid bacteria, such as *Lactobacillus*.

Good bacteria are also useful because they restrict or inhibit growth of 'bad' bacteria. First, their huge population makes it difficult for competing bacteria to grow. Second, they release various chemicals called bacteriocins that limit growth of bad bacteria.

### Bad bacteria – spoilers

Bad bacteria are those that spoil dairy products or cause illness among consumers of dairy products.

Spoilage bacteria grow well in milk under refrigeration and begin this process on-farm. They use the milk as food and send their enzymes out into the food to break it down (called extracellular enzymes). These enzymes are very stable. They survive pasteurising and can spoil final products:

- > ripened liquid products, e.g. buttermilk, will have rancid odours/flavours because enzymes called lipases (made by bacteria in raw milk) break down fat.
- > yield of cheese is reduced if enzymes called proteases (made by bacteria in raw milk) break down casein, thereby reducing the volume of curd.

- > proteases (made by bacteria in raw milk) also cause UHT products to thicken and gel during storage at ambient temperature.
- > *Bacillus cereus* produces enzymes that split fat and cause 'bitty cream' when milk is added to tea or coffee.

### Bad bacteria – poisoners (pathogens)

A number of disease-causing (pathogenic) bacteria have been involved in illness from dairy products. Some come from the udders of animals with either clinical or subclinical mastitis, others are present in the animal's faeces or in the environment.

Bacteria make consumers ill in two ways.

1. Some produce chemicals called toxins that are poisonous to humans and which they release into the food as they grow. The toxin causes food poisoning, particularly vomiting, usually between 2–6 hours after eating the product. For example, the *S. aureus* toxin is heat resistant and cannot be destroyed by cooking and can induce vomiting within 3–6 hours of eating a contaminated food.
2. Other bacteria cause illness by growing within our gut, usually between 24–48 hours, after they've grown to numbers high enough to cause illness. *L. monocytogenes* is an exception and it may take several weeks for the illness to develop.

There are several target bacteria that can cause illness from consumption of dairy products. Some originate in the cow's udder, others get into the milk from the environment.

Organism	Shed directly into milk*	Contaminant of raw milk**	Survives pasteurising?	Severity of illness
<i>Bacillus cereus</i>	No	Yes	Yes	Moderate
<i>Campylobacter</i>	No	Yes	No	Serious
<i>Corynebacterium</i>	Yes	Yes	No	Serious
<i>Coxiella burnetii</i>	Yes	Yes	No	Serious
<i>Cronobacter sakazakii</i>	No	Yes	No	Severe
Pathogenic <i>E. coli</i>	No	Yes	No	Severe
<i>Listeria monocytogenes</i>	Yes	Yes	No	Severe
<i>Salmonella</i>	No	Yes	No	Serious
<i>Staphylococcus aureus</i>	Yes	Yes	No	Moderate

\* Enters via udder; mastitis

\*\* Enters via faeces or environment

Bacteria that cause disease in consumers are called pathogenic bacteria or pathogens, and those with a history of causing illness from consumption of dairy products include:

- > *Salmonella*
- > Pathogenic *Escherichia coli*
- > *Staphylococcus aureus*
- > *Listeria monocytogenes*
- > *Campylobacter*
- > *Bacillus cereus*
- > *Cronobacter sakazakii*.

In the next section, we develop a Hazard Sheet for each of these pathogens. Find out where they live, what makes them tick and how to control them in the dairy process.

### 3. Hazard sheets for target bacteria and how to control them in dairy processing

During processing, we need to control microbes that can spoil or poison dairy products. There are a few key microbes that are of primary concern – all bacteria and all potential pathogens, with the exception of one spoilage bacterium, *Pseudomonas*.

These bacteria are your targets and their control starts on-farm.

For each of them, we'll construct a Hazard Sheet with the following information:

1. Name and address – who they are and where do they enter the dairy process
2. Impact – what effect do they have on quality and safety of products
3. Epidemiology – have they been involved in any food poisonings
4. Infectious dose – how many of them will make us ill or spoil the product
5. What makes them tick – growth conditions that help them and hinder them
6. How can we control them by either inactivating or killing them
7. Risk rating in dairy products.

#### Target microorganisms for dairy processors

##### Spoilage

- > *Pseudomonas*

##### Pathogenic

- > *Salmonella*
- > Pathogenic *Escherichia coli*
- > *L. monocytogenes*
- > *Staphylococcus aureus*
- > *Campylobacter*
- > *Bacillus cereus*
- > *Cronobacter*



## Hazard sheet *Pseudomonas*

*Pseudomonas* is a Gram-negative rod that lives in the soil and in watercourses. It has many species, many of which are psychrotrophic and can grow steadily in the fridge. Pseudomonads get into milk in the dairy shed, with levels of contamination depending on degree of cleanliness of the udder, the standard of hygiene during milk collection and the water quality.

### Impact

Pseudomonads and their relatives are very good at spoiling protein foods by breaking down protein into shorter chain molecules that cause bitter tastes and, eventually, smells associated with rotting flesh.

When they are in raw milk, pseudomonads get their nutrition by sending enzymes outside their body to break down the big milk proteins into bite-sized chunks that they can bring back through the cell wall and eat. These are called extracellular enzymes and they are very heat stable, so persist through dairying processes, even UHT treatment.

### Spoilage levels

We measure levels of bacteria in foods in terms of colony forming units/gram of food. In pasteurised milk, *Pseudomonas* can get in after the heating stage and grow in the fridge to send the milk sour or clot it.

### Growth of *Pseudomonas*

Conditions under which *Pseudomonas* grows indicates why they multiply well in raw and pasteurised milk (pH around 7 and water activity around 1.0) and why they won't grow in cheese (low water activity and pH).

Conditions	Minimum	Optimum	Maximum
Temperature (°C)	0	25-35	40
pH	5	7	9.5
$a_w$	0.94	0.99	>0.99

It's their ability to grow at refrigeration temperatures that makes them so hazardous to milk quality and shelf life—even a small increase in temperature sees them speed up their growth. In a milk vat running at 4°C, pseudomonads can double their population every 5.5 hours, so collection after 24 hours on-farm will see them double almost 4 times – that's a 10-fold increase in population.

### Killing of *Pseudomonas*

The bacterium is easily killed by heating—just a few seconds at temperatures around 60°C is sufficient—so pasteurising temperatures and times will always give a massive overkill for pseudomonads and other Gram-negative spoilers.

### Relevance for dairy products manufacture

**In UHT processing,** pseudomonads are killed by pasteurising, but their enzymes are heat stable and even survive the extreme heat process (about 140°C for 3–5 seconds). So, although UHT product is commercially sterile, extracellular enzymes can chew away at it during storage: proteases break down proteins and lipases break down fats. Proteases bring about changes to UHT milks by causing an increase in viscosity and eventually a gel, to a custard consistency.

**In cheese processing,** if extracellular enzymes split the casein molecules into peptides, you'll have a reduced yield of curd and peptides can cause bitterness in cheddar.



**In pasteurised milk**, the shelf life is greatly affected by pseudomonads and temperature. Check out the predicted shelf life at different temperatures when there is just one *Pseudomonas* in each mL of the product.

Storage temperature (°C)	Time to spoilage (days)
0	23
2	14.5
4	10
6	7.3
8	5.6
10	4.4

### Control in dairy processing

Good dairy hygiene and keeping the temperature of raw milk as low as possible on-farm, during transport to processing and during storage prior to processing will take care of extracellular enzyme problems with gelling of UHT milks and cheese yields.

Temperature and plant hygiene are also the basis for keeping pseudomonads to very low levels in pasteurised milk so that customers get a full shelf life without adverse taste or smell.

## Hazard sheet *Salmonella*

The *Salmonella* bacterium is named after Dr Salmon who discovered it around 1880. We now know there are several thousand types of *Salmonella*, most of which cause illness in humans. Some types cause mild gastroenteritis. Others cause much more severe infections which can be fatal, such as typhoid fever caused by *S. Typhi*. *Salmonella* is normally found in the gut of animals and birds and is therefore sometimes found in milk.

### Impact and epidemiology

*Salmonella* in dairy products has caused several outbreaks of illness in Australia. Some examples are given in the table below based on information from the FSANZ Dairy Risk Assessment, which was used in developing the Primary Production and Processing Standard (PPPS), Standard 4.2.4.

As mentioned earlier in this section, many of the outbreaks are in the food service sector where mishandling of dairy products or the addition of other ingredients, such as eggs, were the root cause.

State	Year	Product	Cases
Queensland	1992	Raw milk	4
SA	1998	Gelati	102
SA	1999	Raw milk	12
NSW	2000	Fried ice cream	41
SA	2001	Custard tarts	16
WA	2001	Ice cream and sponge	38
Victoria	2002	Cream cakes	10
SA	2002	Cream cakes	22
NSW	2002	Cream cakes	29
SA	2003	Cheesecake	6
Queensland	2004	Custard tarts	5
SA	2004	Cream-filled cakes	13
NSW	2004	Custard	43

As well as these illnesses, there have been numerous recalls of product because of *Salmonella* contamination and you can pick up on these in Appendix 1.

### Infectious dose

How many *Salmonella* cells are needed to cause illness? Early studies indicated at least 100,000 were needed to cause gastroenteritis (i.e. infection of the intestine leading to abdominal pain and, often, diarrhoea) in healthy adults. More recently, as few as 100 organisms caused illness when eaten in contaminated chocolates. Fatty foods can protect bacteria against the acidity of the stomach as they pass through to the intestine.

Gastroenteritis usually lasts 4–7 days, after which symptoms subside. Sometimes the illness is more prolonged and, in a small number of cases, may proceed to infections of the blood (septicaemia) or cause arthritis.

One type, *Salmonella Typhi*, causes typhoid fever—a very serious illness—and, when/if they recover, people may find that they still carry the typhoid germ in their intestine and shed it in their faeces. These people are typhoid carriers and are a great danger if they work as a food handler.

### Growth of *Salmonella*

*Salmonella* grows over a wide range of environmental conditions of temperature, pH and water activity commonly found in the dairy industry. The tolerance ranges for these factors are shown in the table below.

Conditions	Minimum	Optimum	Maximum
Temperature (°C)	7	35-43	45
pH	3.8	7-7.5	9.5
$a_w$	0.94	0.99	>0.99

You can see it will grow well in dairy products with a neutral pH and high  $a_w$  like milk, ice cream and cream-based cakes. To get to an infectious dose, the temperature must be relatively warm as *Salmonella* is unable to grow at refrigeration temperatures.

### Killing of *Salmonella*

*Salmonella* is a Gram-negative bacterium and so is inactivated quickly at temperatures around 65°C. For example, suppose raw milk has a count of 1 million *Salmonella*/mL (which it never would; this is just an extreme example), after bringing the temperature to 65°C for 30 seconds, less than one would remain alive. This shows the effectiveness of the heating process on Gram-negative bacteria and is the basis for the commercial process of thermisation which is discussed in a later section.

In other ways *Salmonella* is a good survivor, especially in dry conditions, and one type (*S. Senftenberg*) can survive long periods in milk powders.

### Control in dairy processing

*Salmonella* is a target organism for all dairy processes because it can be a contaminant in raw milk, almost always being introduced from faeces during milking.

Control of *Salmonella* and other pathogens starts in the dairy shed with maintaining hygiene of equipment and the udder plus reducing the temperature of raw milk in the storage tank in line with regulatory requirements of ANZDAC: *Guidelines for Food Safety – Dairy Farms*. The guideline specifies cooling it to no warmer than 5°C within 3.5 hours from the start of milking and maintaining it no warmer than this.

There are alternative requirements for cooling and storing milk to be used for making raw milk products in the guide that accompanies PPPS 4.2.4. These are onerous and you should read the document in full.

In the processing plant heat treatment is the primary control, plus ensuring no recontamination of pasteurised milk.

## Hazard sheet Pathogenic *Escherichia coli* (STEC)

*Escherichia coli* is named after Dr Escherich who first isolated it in 1885. The organism grows in the gut of all warm-blooded animals and large numbers are excreted in the faeces. Most forms of *E. coli* are harmless and may even contribute to our health. These harmless *E. coli* are called generic *E. coli*. One gram of our faeces may contain 10 million generic *E. coli*. When we find *E. coli* in foods it may be an indication of faecal contamination (poor hygiene) from contaminated water, soil or hands.

Importantly, there are also pathogenic types of *E. coli* and they have caused severe food poisoning outbreaks, including causing deaths. They are called Shiga Toxic *E. coli* (STEC) and have become dangerous after picking up genes from other bacteria, including one called *Shigella*.

### Impact and epidemiology

In Australia, STECs are best known for a terrible outbreak in South Australia in 1995 caused by consumption of mettwurst. Around 150 people became ill and for 22 children the illness was very severe and one died. Many of those who did not die have lifelong complications from the infection, including permanent kidney damage requiring ongoing treatment or a kidney transplant.

More recently there was an outbreak in Victoria when children consumed raw milk sold as bath milk.

State	Year	Product	Cases	Deaths
Victoria	2015	Raw milk	5	1

### Infectious dose from STEC

The infectious dose of pathogenic *E. coli* for healthy adults is probably thousands to tens of thousands of cells. The symptoms are gastroenteritis which clears up in a few days. However, for those who are at risk, like the very young and very old, the infectious dose is lower, less than 100 cells can lead to severe illness.

### Illnesses caused by STEC

STECs have become dangerous because they have acquired genes allowing them to attach to our intestines and cause bloody diarrhoea. This is the first stage of STEC illness and is much less serious than what happens if the illness progresses.

- > Haemolytic Uraemic Syndrome (HUS) where STEC toxins cause kidney damage
- > Brain damage caused by blood clots

For survivors of STEC illness, the treatment and care is often needed for their lifetime

John Doherty, the lawyer for the SA children who developed HUS, reminds us that all 23 were afflicted with endless hospital visits and a list of ailments that is horrific.

*'One child developed diabetes, others had organ transplants and blood transfusions.'*

*'The tragedy of this is that these injuries can't just be fixed, these kids will suffer from these conditions for the rest of their lives' (Doherty, 2014).*

Another mettwurst victim was five months old when he contracted HUS and has had an endless series of hospital visits and organ transplants. His mother reflects that her Medicare card had been swiped 1300 times in 17 years and hopes her remaining kidney will keep going - she donated one to her son, who will need at least two or three more kidneys in his lifetime (Fewster, 2011).

### Growth of STEC

Like *Salmonella*, STECs grow over a range of temperature, pH and water activity commonly found in the dairy industry.

Conditions	Minimum	Optimum	Maximum
Temperature (°C)	7	35-40	46
pH	4.4	6-7	9.0
$a_w$	0.95	0.99	>0.99

### Killing of STEC

Like *Salmonella*, pathogenic *E. coli* are vulnerable to heat and at thermising temperatures around 65°C they die very quickly.

### Control in dairy processing

The Victorian incident occurred because raw milk was sold and consumed. There was no kill step for the pathogenic *E. coli*, which indicates the importance and effectiveness of pasteurisation.

### References

- Doherty, F. (2014). A look back at Garibaldi: a preventable epidemic. University of SA (October 13, 2014). Retrieved November 13, 2016 from [www.ontherecord-unisa.com.au](http://www.ontherecord-unisa.com.au).
- Fewster, S. (2011). Garibaldi victims finally paid, bringing saga to an end. The Advertiser, November 23, 2011.

## Hazard sheet *Listeria monocytogenes*

*L. monocytogenes* has been known for over 70 years as a pathogen of small animals. It was named in recognition of Lord Lister who pioneered antiseptic surgery – methods for preventing wounds becoming infected during surgical operations. During the 1980s, *L. monocytogenes* became known as a food-borne pathogen as a result of several very large outbreaks, some involving scores of deaths. Among the species of *Listeria*, the only pathogenic species is *L. monocytogenes*.

### Impact and epidemiology

*L. monocytogenes* has caused a number of serious outbreaks of food poisoning from dairy products in several countries around the world with various product types implicated including a large outbreak in the USA from pasteurised milk. Nothing was found at the factory to indicate why a product that is normally 100% safe should have failed, but many processors increased their pasteurisation temperature and holding time.

Country	Year	Product	Cases	Deaths
USA	1985	Pasteurised milk	49	14
France	1995	Raw milk cheese	20	-
Switzerland	1995	Soft cheese*	57	16
USA	1997	Chocolate milk	40	-
Finland	1999	Butter	25	6
USA	2000	Mexican cheese*	13	5
UK	2003	Butter	17	-
Canada	2002	Raw milk cheese	17	-
Sweden	2003	Farm fresh cheese*	15	-

\* Raw milk used

In Australia, there has been a large outbreak of listeriosis from mould-ripened cheeses.

State	Year	Product	Cases	Deaths
National	2013	Soft mould-ripened cheeses	34	7*

\* Includes one miscarriage

### Infectious dose

For most people, more than a million *L. monocytogenes* must be swallowed before they become ill, usually with 2–4 days of gastroenteritis. For vulnerable consumers, the infectious dose may be less than 10,000 organisms. In these consumers, the illness progresses sometimes from flu-like symptoms to meningitis (infection in the brain) or to septicaemia (blood poisoning) and the illness may take several weeks to develop.

As can be seen from the tables above, when people become ill a significant proportion (20–30%) die. These consumers tend to be elderly people, pregnant women and their foetus or newborn baby and people whose immune system is low or compromised e.g. because they had antibiotics or cancer treatment, post-transplant drug therapy or because their liver is damaged.

Regulators and food standards have set a 'zero tolerance' for RTE foods which support the growth of *L. monocytogenes* because in long shelf life products there is the potential to grow to an infectious level. Zero tolerance is very difficult to achieve in practice. *L. monocytogenes* is a robust organism that lives in food factories and also grows steadily in many long shelf life refrigerated foods.

### Growth of *L. monocytogenes*

*L. monocytogenes* grows over a wide range of environmental conditions commonly found in meat and dairy products and processing plants and operations, though it grows only slowly, if at all, when the pH of the product is low.

Conditions	Minimum	Optimum	Maximum
Temperature (°C)	-0.4	37	45
pH	4.4	7	9.4
$a_w$	0.92	0.99	>0.99

There are three reasons why *L. monocytogenes* is a very robust organism in the dairy environment. First, it can grow in refrigeration storage; secondly, it is salt tolerant and, thirdly, it grows well in vacuum packs. It becomes a problem in ripened soft cheeses because moulds break down proteins to amines, which give ripened cheeses their distinctive odours. However, amines are basic compounds that raise the pH of the cheese and give *Listeria* a competitive advantage. In harder cheeses it doesn't have this advantage because the pH remains low.

### Killing of *L. monocytogenes*

*L. monocytogenes* is not particularly heat resistant and batch or continuous pasteurising are both designed to reduce population levels by many millions in every mL of milk to less than one cell.

### Control in dairy processing

In the list of outbreaks above, all the products went through a heat process that was enough to eliminate even huge populations of *L. monocytogenes* in the product. So how did these products become contaminated?

*L. monocytogenes* is common in the environment and can enter food premises in many ways, including on the hands, clothing and boots of workers, for which reason dairy factories making soft, ripened cheeses have strict entry requirements.

The most critical situation for a food plant, however, is if *L. monocytogenes* sets up permanent residence in equipment which contacts pasteurised food. And, if the organism sets up permanent residence in some hard-to-clean area, it may be impossible to prevent recontamination of product without radical action like whole of equipment pasteurisation e.g. heating the process room to >40°C during a long weekend.

### References

The DFSV Technical Information note: *Listeria monocytogenes* – management in dairy factories is highly recommended (Accessed at <https://www.dairysafe.vic.gov.au/technical-notes-science/premises/232-l-mono-technical-information-note-1>)



## Hazard sheet *Staphylococcus aureus*

Under the microscope the Gram-positive *Staphylococcus* looks like clusters of grapes, and colonies of the most common type, *S. aureus*, have a yellow colour seen in boils and pimples, leading to its common name 'Golden Staph'.

It's usually associated with people and is carried by around 20–30% of healthy adults, usually in the nose, mouth, ears and warm places such as the armpits.

It is important in the dairy business because it's a common form of bovine mastitis.

### Impact

Historically, *Staphylococcus aureus* has caused many outbreaks of food poisoning from cream-based products because of its tolerance of low water activity. More recently, however, the organism has been less involved in food poisonings, probably because of better refrigeration.

State	Year	Product	Cases
Queensland	2010	Milk shake	6

Some typical overseas outbreaks include:

Country	Year	Product	Cases
France	1983	Ewe milk cheese	20
Thailand	1990	Eclairs	400
France	1995	Raw goats milk cheese	Unknown
USA	1995	Whipped butter blend	29
Japan	2010	Low fat milk	38

### Infectious dose

While growing, *S. aureus* makes a toxin that is released into the food (or other environment) in which it's growing. High numbers of *S. aureus*, at least 1,000,000 per gram, are needed before food becomes toxic; its effects are rapid—usually 2–6 hours after eating the toxic food victims experience nausea, vomiting, diarrhoea and abdominal pain. Fortunately, the illness usually subsides within 2 days.

### Growth of *S. aureus*

The bacterium grows at similar temperatures to *Salmonella* and so is controlled by refrigeration. Unlike *Salmonella*, however, it tolerates high levels of salt and can grow in concentrations as high as 20%. It grows relatively slowly and so usually becomes overgrown by other, faster growing bacteria in the food so that foods often spoil before *S. aureus* grows sufficiently to produce high levels of the toxin. In the table below, parameters for toxin production are shown in brackets, indicating that toxin is produced over a narrower range of temperature, pH and water activity, compared with growth.

Conditions	Minimum	Optimum	Maximum
Temperature (°C)	7 (10)	37 (40-45)	48
pH	4.0 (4.5)	6-7 (7-8)	10 (9.6)
$a_w$	0.83 (0.87)	0.99	>0.99

### **Killing of *S. aureus***

*S. aureus* is relatively easy to kill by pasteurisation. Importantly, however, its toxin is extremely heat stable and no heat treatment used in food processing will eliminate it. In other words, any toxin *S. aureus* makes in raw milk will survive through to final products.

### **Control in dairy processing**

*Staphylococcus aureus* live on up to 20–30% of healthy adults in their noses, ears and mouths but without causing them any harm. It is also found on the skin, particularly in warm moist places such as under the arms and in the perineum. This means that food handlers can transfer the bacterium when they handle food. This is why regulations do not allow bare hands to contact foods that have already received their heat treatment and are now ready to eat.

Mastitic cows may have large numbers of *S. aureus* in the udder and in abscesses. Active refrigeration at the dairy followed by effective cold-chain handling will prevent the organism multiplying to levels where toxin might become a problem for the dairy manufacturer.

## Hazard sheet *Campylobacter*

*Campylobacter* are Gram-negative, S-shaped rods which have a corkscrew-like motion. They are the number one cause of foodborne illness in Australia with more than 31,000 cases per annum. It is a faecal organism of most warm-blooded animals and enters water supplies and the food chain by faecal contamination.

### Impact

The main cause of *Campylobacter* illness is considered to be poultry though, as may be seen from the table below, it has been implicated in several outbreaks of illness following raw milk consumption.

State	Year	Cases
Queensland	1992	4
Tasmania	1993	21
WA	1998	9
SA	1999	12
SA	2000	Not known
Vic	2000	~25
Vic	2003	13

### Infectious dose

The infective dose for *Campylobacter* infection is very low—as few as 100 cells—with an incubation period usually 2–5 days and an illness (campylobacteriosis) generally lasting around a week. Victims suffer fever, diarrhoea, nausea and vomiting, plus abdominal pains so acute that appendicitis is sometimes suspected.

Occasionally symptoms progress to reactive arthritis and Guillain-Barré Syndrome, where victims lose muscular strength.

### Growth of *Campylobacter*

*Campylobacter* grows under an unusually narrow set of conditions, especially for temperature and water activity. It's a thermophile, growing over a narrow range, and stops growing at 32°C, and it can't withstand much salt in its environment.

Conditions	Minimum	Optimum	Maximum
Temperature (°C)	32	42-43	45
pH	4.9	6.5-7.5	9.0
$a_w$	0.98	0.99	>0.99

Its optimum growth temperature is almost identical with that of birds, which explains its involvement in poultry-based illness, but it has also caused illness through consumption of pasteurised milk. In the UK, for many years the practice was to deliver bottled milk with a foil cap to the doorstep, a practice that led to birds pecking the foil and drinking the milk, contaminating it as they did so. The low infective dose was sufficient to cause substantial cases of campylobacteriosis.

### Killing of *Campylobacter*

As a Gram-negative bacterium, *Campylobacter* is not heat resistant and is easily killed by pasteurising. It is also sensitive to refrigeration and dies when stored at chill and frozen temperatures.

### Control in dairy processing

*Campylobacter* is present in 1–6% of raw milk samples so its elimination must be achieved via pasteurising. It is also a cause of mastitis and can be present in the milk stream; control is via udder and teat care.

## Hazard sheet *Bacillus cereus*

*Bacillus cereus* is a Gram-positive spore former and is common in the environment (soil and plants) and can be present on the udder. The spore is heat resistant and can survive pasteurising, even though this kills the vegetative cell surrounding the spore. Later, when conditions are favourable, the spore can germinate and form a vegetative cell, which will then grow at a rate depending on temperature and the food within which it finds itself.

Because it's a spore former, it can survive into milk powders and be present in infant formulae, the fear being that if the bottled milk is kept warm for long enough toxin will be formed.

### Impact

*B. cereus* cause two forms of illness after consumption of food: vomiting (emetic illness) caused by a toxin made by cells growing in the food and diarrhoea caused when the bacterium grows in the intestine and forms another form of toxin. Emetic illness occurs soon after ingesting the food (1–5 hours), while diarrhoea takes 8–16 hours to occur. Both illnesses are mild for most people and last only 1–2 days.

The organism has been responsible for many outbreaks caused by poor storage of boiled rice allowing growth and toxin production, and then incorporation into fried rice.

There have been relatively few outbreaks from dairy products globally and none recorded from dairy products in Australia.

Country	Year	Product	Cases
UK	1977	Milk powder	Unknown
Chile	1984	Infant formula	35
Thailand	1990	Macaroni cheese	400
USA	1994	Hot chocolate	23

### Infectious dose

It is generally accepted that high numbers (greater than 100,000 cells/g food) are needed for toxin formation to occur.

### Growth of *B. cereus*

Some types of *B. cereus* are psychrotrophic and can grow in pasteurised milk, although it is not a good competitor and Gram-negative spoilers like *Pseudomonas* will outgrow it.

Conditions	Minimum	Optimum	Maximum
Temperature (°C)	7	30-37	45-50
pH	5	7-7.5	9
$a_w$	0.94	0.99	>0.99

### Killing of *B. cereus*

The spores are tolerant of pasteurising temperatures and may occur in dairy powders.

### Control in dairy processing

Control is needed at the raw milk stage to prevent formation of toxin and also spores which will survive heat treatment into final products.

## Hazard sheet *Cronobacter sakazakii*

*Cronobacter* (it used to be called *Enterobacter*) *sakazakii* is a Gram-negative rod that occurs in the environment and is able to survive in dairy powder environments. It has a long history of causing problems with infant formulations.

### Impact

The organism can cause severe illness such as meningitis (inflammation of the brain), leading to permanent damage, with a high fatality rate for infants. Other illnesses occur by damage to the intestines, spinal fluid, blood and respiratory tracts.

Country	Year	Cases	Deaths
Iceland	1989	3	1
USA	1989	4	-
USA	1990	Unknown	-
Israel	1999	Unknown	-
USA	2001	1	1
Belgium	2001	12	2
USA	2002	11	1
Switzerland	2002	11	-
New Zealand	2004	4	1
France	2004	9	2
USA	2008	2	-

### Infectious dose

Newborns are especially vulnerable because their gut flora lacks competitive bacteria to offset *Cronobacter* and their immune system is also immature. The infective dose is very low, with around 1,000 cells being sufficient to cause infection.

### Growth of *Cronobacter*

Conditions under which *Cronobacter* grows are similar to other Gram-negative organisms.

Conditions	Minimum	Optimum	Maximum
Temperature (°C)	6	35-43	46
pH	5	7-7.5	9
$a_w$	0.95	0.99	>0.99

### Killing of *Cronobacter*

The bacterium is killed by evaporation and spray drying temperatures but, if it enters products post-process, it is able to survive for long periods in dried foods such as dairy powders.

### Control in dairy processing

Although killed by pasteurising, *Cronobacter* has some factors that allow it to colonise dairy environments by being resistant to drying and able to grow up to 46°C. It needs water in order to grow, making control of condensation in drying and filling areas important.

A survey of five Australian dairy factories isolated *Cronobacter* from more than 30% of samples, with the greatest occurrence (81%) being from a milk powder area during shutdown.

In the home, *Cronobacter* can grow rapidly in reconstituted milk held at warm temperatures.

## 4. Microbiological testing

There are numerous bacteria, both spoilage and pathogenic (disease-causing), that need to be controlled in your business. There are several stages in your operation that you need to know about how successful you are at controlling them:

1. after cleaning and sanitising the plant
2. in raw bulk milk
3. during the process
4. in finished products.

In this section we focus on the testing needed to give you confidence that your incoming raw materials and process parameters will consistently result in finished products of acceptable hygienic quality.

### Microbiological testing – pluses and minuses

Microbiological testing is a useful tool in monitoring your process because it can tell you whether certain bacteria are present and, in some cases, how many are in the product.

The bad news is that micro testing is not cheap and you probably have a 2–3 day wait before you get the result. Also, counting bacteria in foods is not very accurate and most food microbiologists would consider a count of 10,000/mL milk to be very similar to one of 50,000/mL.

For these reasons we always look for information which is as real time as possible and use it to replace micro testing.

### Sampling – lots to think about

In 1959, the Pillsbury Company received a call from the Quartermaster Food and Container Institute of the US Armed Forces asking: *'Can Pillsbury produce foods for consumption in the zero gravity of space capsules?'* The answer was yes but, to increase the certainty that no pathogens would be present, the sampling rate was so high that only a small portion of very expensive space food remained for the astronauts after the lab had done its job.

It's history now that HACCP was invented to cut down on micro testing and it also stimulated microbiologists to do the maths on how many samples are needed to pick up a pathogen like *Salmonella*, *Cronobacter* or *Listeria* in a dairy product. We'll cover this later.

### How frequently should I test my products?

If you're a manufacturer, you and your regulator will want to have confidence in your products and here are some principles:

1. If you're starting up with a new product, it makes sense to test a number of early batches (for example, at a minimum, the first five batches that you manufacture).
2. Once approved, you must test at least at the minimum frequency which demonstrates ongoing process control, as identified by your risk analysis or any guideline document provided by your regulator.
3. If, over time, you can demonstrate a very high standard of product hygiene, you have strong supporting evidence to reduce the frequency of testing, or the suite of organisms.

However, your customers may have specific testing requirements that need to be met.

## Sampling and your business's risk profile

Key questions for working out your testing program include:

1. How often should I test?
2. How many samples should I take?
3. Which organisms should I test for?

To answer these questions, think about the risk profile of your business and read the sections on *Hazards and Risks* and on individual dairy products (see later in Part 2), where you'll find a risk rating for each pathogen:product pairing.

Now you know where you sit on the risk scale, consider another factor affecting risk: your volume of production. As an example, think about manufacture of soft, mould-ripened cheeses - products with a long shelf life. The hazard is *L. monocytogenes*, a pathogen that grows steadily in the fridge and can reach an infective dose for vulnerable consumers.

*Question: Who has the higher risk – a manufacturer making 5,000kg/day or one that makes 50kg/week (all made on one day), assuming both manufacturers have systems to minimise the opportunity for Listeria to get into the final product?*

*Answer: The large manufacturer because there are many more of their units in the marketplace leading to a greater chance that a vulnerable person will consume the product.*

So, a large manufacturer will need to have a much more intensive sampling program to:

1. monitor the end-of-day clean down
2. monitor food contact surfaces during production
3. test final product for *L. monocytogenes*.

This is an example of the way you need to think about testing and to develop a regime for the frequency of testing for each of your product types.

## Which micro tests are useful for product testing?

### Pathogen testing

We worry about pathogens like *Salmonella* and *Listeria* in dairy products and sometimes find it reassuring when the laboratory reports that they were not detected in the sample we submitted.

We shouldn't be overconfident, however, because pathogens are difficult to find in solid dairy products as they often aren't spread homogeneously through the lot and the sample units you choose may not contain them.

Kornacki (2006) states: '*Finished product testing cannot be relied upon as the sole determinant of a Listeria-free product. No amount of finished product sampling and testing short of assaying the entire product with a perfect method can guarantee that the product is Listeria-free. Finding a problem through finished product testing is likely in situations where the incidence of product contamination is high.*'

The statement cites trying to find *Listeria* as an example but the comments apply equally to all pathogens, and, in the table below, Kornicki supplies the sample numbers you need to take to be confident of finding the pathogen, if it is present in the lot of production.



Here's an example. Suppose you had a day's production of milk powder and you want to test for *Salmonella*, and let's assume that it's only present in a tiny proportion of the lot – let's say 0.1% is contaminated.

#### Number of units in a batch to be tested to detect one or more positive *Salmonella* in the production lot

Percent positive	Number of samples to be tested		
	90% confidence	95% confidence	99% confidence
1	230	299	461
0.1	2303	2996	4605

You need over 4,600 samples to be 99% certain of finding one *Salmonella* bacterium – you can't afford that. Ironically, if the product is more contaminated you need fewer samples to be confident of finding it.

However, if a customer or your controlling authority includes pathogens in their specifications, you'll need to sample according to their instructions—it's a cost of doing business.

#### Testing for indicator bacteria

Indicator bacteria are useful organisms to have in a testing program because you get a result more quickly and more cheaply than testing for a pathogen. The main indicator tests are:

- › **Total bacterial count** (also known as Total Plate Count, TPC; Total Viable Count, TVC; Standard Plate Count, SPC and Aerobic Plate Count, APC). This count is an indicator of the general population of bacteria in a product or on a food contact surface and the result is usually expressed as the number of colony forming units (cfu) per gram of product or per cm<sup>2</sup> of food contact surface.
- › **Coliform count** indicates a wide range of bacteria, some of which come from the faeces of animals, others from the environment. It's a commonly used test in the dairy industry and its presence in pasteurised milk indicates either ineffective temperature:time or post-process contamination due to a pasteuriser leak or a breakdown in hygiene at packaging. Pasteurised milk should be Coliform-free.
- › ***Escherichia coli* (*E. coli*)** is a member of the Coliform group but originates only in faeces and potentially can indicate faecal pathogens like *Salmonella*. *E. coli* can set up in a production line—in a valve or a dead spot—where it will grow and 'bleed' into product passing through the line.

As with Coliforms, pasteurised milk should be free of *E. coli*.

The FSANZ Compendium of Microbiological Criteria for Food includes recommendations on what to look for when testing for indicator organisms in dairy processing: <https://www.foodstandards.gov.au/publications/Pages/Compendium-of-Microbiological-Criteria-for-Food.aspx>.

#### What should I test to support process control?

There are three stages when some information is useful:

1. Raw bulk milk
2. Pasteurised milk
3. Final products

## Raw milk testing

After the udder, warm raw milk is cooled quite slowly in an agitated vat, stored without insulation then pumped and sloshed around into a tanker—all good conditions for *Pseudomonas* and its relatives to grow.

The bacterial count of the raw milk that enters your storage vat is important as it affects shelf life of pasteurised milks and also yield of curd.

*Pseudomonas* and its relatives are picked up in a Total Count, which is a useful indicator of how hygienically the milk has been drawn, cooled and transported.

You'll also want to know whether any of the herd are suffering subclinical mastitis, and a test for somatic cells is worth doing.

Target limits for raw bulk milk are:

Total plate count	<50,000 cfu / mL
Somatic cell count	<400,000 cells / mL

### How often should you test raw milk?

If you're a large manufacturer you'll probably test a sample from every supplier tanker after every collection and you'll be in regular feedback with them about the quality of the raw material they're supplying.

If you're a small manufacturer you will need confidence in your supplier and if you're starting with a new supplier, it makes sense to test a number of early batches (say the first five batches of raw milk delivered) then revert to monthly if it meets your specifications.

## Pasteurised products

The temperatures and time of both Low Temperature Long Time (LTLT) (batch) and High Temperature Short Time (HTST) (continuous) pasteurising are designed to eliminate all pathogenic and almost all spoilage bacteria (thermodurics may survive). But check out *Hazards and Risks* and you'll see that, of the 120 recalls of dairy products, bacteria in the final product were the cause in almost 70% of the cases with Coliforms, *E. coli* and *Listeria* foremost.

How these bacteria ended up in a final product made from pasteurised milk is a question for the manufacturer, and the list of possibilities isn't short:

1. Temperature and time regime not delivered
2. Leakage between raw and heated sides in the plate heat exchanger
3. Bacteria surviving in the foamy headspace of a batch pasteuriser or drips entering when the equipment is opened
4. Contamination at the filler
5. Contamination in the lines.

Whatever the cause, the investigations may take some time—see *Good Manufacturing Practices (GMPs)* for more information—but one test can tell you whether your pasteuriser is the problem or whether it's downstream: the Phosphatase test. The test is based on the fact that the enzyme alkaline phosphatase is present in raw milk and is destroyed by a correct pasteurisation operation. It's a real time verification tool routinely used in dairy processing.

Pasteurisation is the primary CCP in dairy processing and is monitored by the operator against temperature (as indicated) and time, plus flow rates and divert data in the case of HTST pasteurisers.

Further verification is possible by using a Coliform Test, which requires at least two days, by which time product will probably be on the market.

### **Finished product testing**

The Compendium of Microbiological Criteria for Food presents criteria for the level of each pathogen and indicator organism in RTE foods which conforms with a Satisfactory, Marginal or Unsatisfactory rating. You are able to compare your test results with these criteria and follow the actions specified for Marginal and Unsatisfactory results.

### **Reference**

Kornacki, J. (2006). Detecting sources of *Listeria monocytogenes* in the Ready-To-Eat processing environment. Accessed at <https://www.researchgate.net/publication>.

## Part 2:

# Process control in manufacture of dairy products

1. Your FSP – what you need to include in it
2. Standard Sanitation Operating Procedures – cleaning the dairy plant
3. GMPs – doing the unit operations correctly using appropriate equipment and techniques

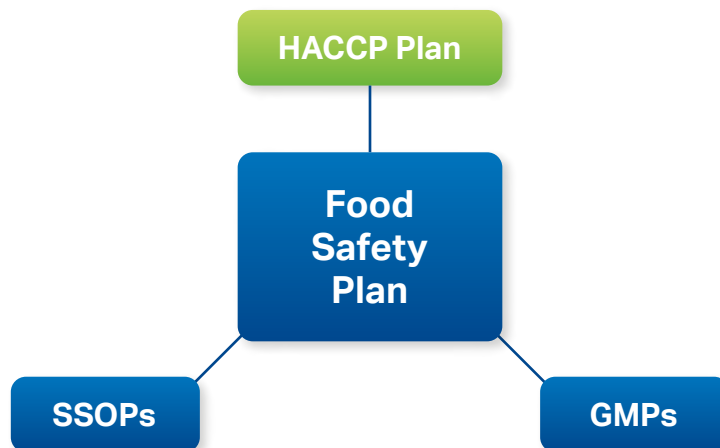


# I. Your Food Safety Plan (FSP)

## – What you need to include in it

An effective FSP needs three elements:

1. HACCP plan
2. GMPs
3. Standard Sanitation Operating Procedures (SSOPs)



### Pre-requisite programs

Pre-requisite programs underpin the FSP. They contain all the steps and procedures that control the operations within the food business, together with the documents needed and the records that have to be kept. Often divided into SSOPs and GMPs, these programs include:

- > Premises, both inside and outside, properly constructed, lit and ventilated and supplied with toilets and hand wash stations
- > A potable water supply
- > Premises cleaned at various stages during the process
- > Transport vehicles properly constructed and kept clean
- > Training of staff with the skills and knowledge sufficient to do their tasks
- > A recall program
- > A maintenance schedule
- > Calibration of equipment
- > Pest control
- > Approved suppliers.

Only when you have these pre-requisite programs set up can you operate an FSP.

### HACCP plan

The HACCP plan controls food safety hazards at all stages of food production—it's a hazard management system. It's based on a series of steps developed by the Codex Alimentarius Commission in its publication *Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application*.

The purpose of the hazard analysis is to develop a list of hazards of such significance that they are reasonably likely to cause injury or illness if not effectively controlled. Hazards that are not reasonably likely to occur would not require further consideration within a HACCP plan.

The steps follow the following course:

- Step 1: HACCP team roles and responsibilities
- Step 2: Description of each product type and packaging format
- Step 3: Intended use of each product
- Step 4: Process flow diagram
- Step 5: Verify the flow diagram
- Step 6: Identify all hazards
- Step 7: Determine Critical Control Points (CCPs)
- Step 8: Establish Critical Limits (CLs) for each CCP
- Step 9: Set up a monitoring and checking system at each CCP
- Step 10: Establish Corrective Actions
- Step 11: Establish a verification system
- Step 12: Maintain records

To construct a HACCP plan, hazard control worksheets, which describe how hazards are controlled at each stage of the process, need to be developed. Some worksheets include a form of risk rating based on the likelihood of a hazard occurring and its severity when it does, but you already have risk ratings for hazards in your hazard sheets and may be able to use a simpler version such as the one below.

Process step	Hazard	What can go wrong	Hazard control
	BIOLOGICAL		
	CHEMICAL		
	PHYSICAL		

## Critical Control Points (CCPs)

CCPs are vital steps in the process and are the ones that keep your customers and your business safe. They require rigorous monitoring to ensure the process is controlled and does not breach CLs—criteria that separate acceptability from unacceptability.

CCPs are monitored using a HACCP audit table such as the one below.

Critical Operation	Hazard	Critical Limit	Monitoring				Corrective Action	Records	Verification
			What	How	When	Who			

For an operation to fulfil the definition for a CCP it must achieve one of the following:

1. prevent the hazard, or
2. eliminate the hazard from the product, or
3. reduce the hazard to an acceptable level.

As well as CCPs, there are Regulatory Control Points (RCPs) which are 'must do' controls specified in Standards and Regulations.

There are also Control Points (CPs), which reduce the level of pathogens but don't do the job as completely as a CCP.

## CPs, RCPs and CCPs in dairy processing

There are a number of unit operations in dairy processing that are either CPs or RCPs and/or CCPs:

1. Active chilling
2. Chilled storage
3. Heating
4. Salting
5. Acidification
6. Water removal

Let's consider each of these aspects thinking only in terms of food safety—quality is also important but food safety is the main game here.

### 1. Active chilling

Active chilling is when refrigeration is applied to remove heat from a warm product and reduce its temperature to one where most pathogens cannot grow.

**Active chilling on-farm** involves removal of heat from milk expressed warm from the udder at 38–39°C. The PPPS 4.2.4 is a non-prescriptive standard and doesn't specify how quickly milk must be cooled but the guidelines to the Standard specify cooling to no warmer than 5°C within 3.5 hours from the start of milking and maintaining it no warmer than this.

Sometimes the temperature of milk will be warmer than 5°C when the tanker arrives for pick up. The decision whether to accept the milk is the responsibility of the processor and procedures in the FSP must be followed. You can read more about cooling milk in Dairysafe's Bulletin #2 (February 2019) available on the website. There are also links to more information on accepting milk warmer than 5°C.

There are alternative requirements for cooling and storing milk for raw milk products in the guide that accompanies PPPS 4.2.4. These are onerous and you should read the document in full.

**Active chilling after pasteurisation** involves cooling milk from much higher temperatures (see the text in section 3 Heating, below) either to storage (5°C or colder) or for immediate further processing, where the required temperature will vary according to the process.

### 2. Chill storage

The period of milk storage may vary up to 24 hours or more, depending on your processing schedule. The warmest temperature recommended for storage is 5°C, though from your hazard sheets you can see *L. monocytogenes* will grow steadily at this temperature, as will the spoiler, *Pseudomonas*.

#### Is active chilling or storage a CCP?

To answer this question let's think of the long list of hazards in raw milk cited in the previous sections: *Hazards and Risks* and in *Introduction to Dairy Microbiology* and answer whether active chilling or storage:

- > prevents these hazards – **No**, they are already in the milk
- > eliminates them – **No**, they're still there in the chilled milk, just waiting for a better temperature to start growing again
- > reduces them to an acceptable level – **No**, their numbers are the same and *L. monocytogenes* can actually increase during storage.



### 3. Heating

In the guide that accompanies the PPPS 4.2.4 for dairy products, several heating regimes are listed based on a minimum temperature of:

- > 48°C or warmer for cooking curd
- > 62°C for no less than 15 seconds
- > 63°C for a minimum of 30 minutes
- > 64.5°C for no less than 16 seconds
- > 72°C for a minimum of 15 seconds
- > 120–125°C for a few seconds
- > 132°C for 1–2 seconds.

Let's clarify how each of these heating regimes is used, their roles in food safety and whether they are CPs or CCPs.

**48°C or warmer** for cooking curd is used in the manufacture of cheese which will have a moisture content of less than 36%, after being stored at a temperature of no less than 10°C for a period of no less than 6 months from the date of processing. The temperature:time component on its own is **not** a CCP because it doesn't prevent, eliminate or reduce pathogens to an acceptable level, but in tandem with the long ripening period and low moisture content, pathogens are reduced to an acceptable level.

**62°C for 15 seconds** is also known as thermisation and its main function is to reduce the population of Gram-negative spoilers like *Pseudomonas* in milk. The process is used when the incoming bacterial load is high or when the milk must be stored for a few days before further processing. Thermisation knocks out bacteria that produce extracellular enzymes that reduce yield of curd and also spoil UHT milk.

Thermisation is **not** a CCP because it doesn't prevent, eliminate or reduce pathogens to an acceptable level. It's a CP.

**63°C for 30 minutes** is LTLT heat treatment, used in conjunction with batch pasteurisation and was important in reducing illnesses caused by consumption of raw milk. Before LTLT pasteurisation, typhoid fever and tuberculosis were illnesses associated with raw milk and these illnesses were still with us until the late 1940s when municipalities began regulating pasteurisation.

Over the years, the temperature:time relations for LTLT pasteurisation have been amended as new pathogens emerged but the current regime (63°C/30 minutes) is a CCP because it **eliminates** all pathogens likely to occur in raw milk.

**64.5°C for 16 seconds** is a regime used in manufacture of cheeses made from milk that has not been pasteurised (raw milk cheeses). The process is similar to thermisation—it is **not** a CCP and must be linked with stringent requirements such as heating curd to 48°C or warmer, holding cheeses at specified temperatures and times and specifying a very low moisture content.

**72°C for 15 seconds** is HTST heat treatment used with continuous pasteurisers. Like LTLT pasteurising, it's a CCP because it **eliminates** all pathogens likely to be in the raw milk. There are a number of CLs and operational settings such as:

- > Temperature:time – 72°C/15s eliminates all vegetative pathogens, even when/if they were present at very high numbers in the raw milk. Some processors run at a higher temperature and longer time when the viscosity of the raw product is higher e.g. cream.
- > It is possible to use alternative temperatures and times providing equivalent lethality; the guide to PPPS 4.2.4 contains a table of alternative temperatures and times for a range of products.

- › Diversion set point – the basis of HTST is that every particle of the milk receives the target temperature and, if the temperature in the pasteuriser falls, the milk is diverted to raw milk until the target temperature is regained. So the divert set point is higher than that of the target temperature and the divert valve and alarm are triggered below the set point.
- › Flow rate – for each product, the maximum flow rate (e.g. 3,000L/h) is validated so that milk receives the target temperature for the correct holding time. If the maximum rate is exceeded an alarm is triggered.

When any of the above CLs are breached the problem is eliminated because milk is prevented from entering the pasteurised line.

**120–125°C for a few seconds** is a heating regime used in the manufacture of ESL milk. It eliminates all vegetative cells, so thermotolerant, psychrotrophic and pathogenic organisms are controlled prior to packaging, which is usually aseptic. ESL milks are stored under refrigeration and have shelf lives of 4–6 weeks. The ESL process is a CCP because it **eliminates** all pathogens likely to be in raw milk.

**132°C for 1–2 seconds** – the heating regime for production of UHT milks results in the product being commercially sterile and capable of storage at non-refrigerated temperatures for several months. Occasionally, a spore former may survive and grow causing souring of the milk without a swelling of the pack, called flat sour spoilage. The other spoilage problem associated with UHT milk is spoilage caused by extracellular enzymes produced in the raw milk. These enzymes survive the UHT process and, over time, cause increase in viscosity of the milk leading to gel formation, called age gelation.

The UHT process is a CCP because it **eliminates** all pathogens likely to be in raw milk.

#### 4. Salting

Salt dissolved in water forms brine, which slows or prevents the growth of bacteria and moulds.

**Salting in butter making.** Butter is an emulsion of water in oil comprising fat (80%), water (16%), salt (2%) and lactose/protein (2%). In the butter process, cream is pasteurised around 80°C under reduced pressure in a vacreator to remove off flavours and then agitated violently (churned) to break up the fat and distribute the water as tiny droplets. The salt dissolves only in the water phase; its concentration rises to 12.5%, giving a low water activity (around 0.94) which stops the growth of many pathogens and Gram-negative spoilers. The size of the droplets is critical, with 3 micrometres (µm) being optimal as this limits the ability of bacteria to get into the droplet and grow.

There are several key stages in butter manufacture but which are CCPs?

Pasteurising at 80°C is a CCP because it **eliminates** all hazards likely to be in the raw cream but salting butter is a CP.

**Salting in cheese making,** either by brining or addition of salt, lowers the water activity of the curd to 0.96, which is inhibitory for many pathogens and Gram-negative spoilers but not for *L. monocytogenes*, making salting of cheese a CP.

#### 5. Acidification

When the pH of milk is lowered to 4.6 casein molecules are destabilised and a curd is formed. Acidification may be by direct addition of acid or by generating lactic acid with starter cultures. Curd can also be formed by addition of a coagulating agent, such as rennet, but this does not provide a fall in pH.

The final pH of 4.5 or below is inhibitory to many pathogens and is enhanced by a second hurdle

in salted cheeses with low water activity, allowing ripening/maturing of cheeses for several months (cheddar is typically ripened for up to 9 months at around 7°C).

Acidification doesn't prevent, eliminate or reduce pathogens to an acceptable level and so it a CP.

## 6. Water removal

Water is a key nutrient and is removed by cutting, heating and pressing curd, by evaporation of concentrated milks and by drying of dairy powders.

**Removal of water from cheese curd** occurs when the curd is cut, when it is heated and when it is pressed, and water is further made unavailable if salt is added. The low water activity, low pH and low maturing temperature are hurdles for many pathogens, as are the huge population of starter and ripening bacteria.

But water removal in cheese manufacture is a CP, as described above under acidification.

**Evaporation of water** is the basis of evaporated and sweetened condensed milks. There are several heating stages, beginning with pasteurisation of milk, a CCP that **eliminates** all pathogens reasonably like to occur, then progressing through several phases running under vacuum (which lowers the boiling point of water) and progressively remove water. The total solids of evaporated milk is at least 28% and higher in sweetened condensed milk after sugar is added, making the water activity too low for bacterial pathogens to grow.

**Drying** to produce dairy powders involves an evaporation process as described above, so a CCP is at the pasteurisation stage, **eliminating** all pathogens likely to be in raw milk. Milk exits the evaporators with very high solids (45–50% depending on the fat content) and is dried to a low moisture content (2–3%) and water activity around 0.3. Most milk powder is manufactured by spray drying, where concentrated milk is atomised at around 120°C into fine droplets which dry as they fall in a large chamber.

As it enters the packing room, milk powder is commercially sterile and stringent precautions are needed to prevent pathogens entering the final product, given the use of milk powder in infant formulae and in disaster relief.

## Summary

Operation	Operation	CCP, RCP or CP
Continuous pasteurisation	72°C/15s	CCP/RCP
Batch pasteurisation	63°C/30min	CCP/RCP
ESL	120–125°C/few seconds	CCP
UHT	132°C/1–2s	CCP
Thermisation	62°C/15s	CP/RCP
Pre-heating cheese milk	64.5°C/16s	CP/RCP
Salt addition to butter	2% salt = 12.5% in water phase	CP
Salt addition to cheese curd	As necessary	CP
Cooking curd	48°C or warmer	CP/RCP
Evaporation	70°C – 45°C	CCP
Spray drying	121°C	CCP

## Further reading

You can read more about pasteurisers in two Technical Information notes from DFSV:

*High temperature-short time pasteurisation of milk*

*Heat treatment alternatives to high temperature-short time pasteurisation of milk*

(Accessed at <http://www.dairysafe.vic.gov.au/technical-notes/product/228-htst-pasteurisation-1> and <https://www.dairysafe.vic.gov.au/publications-media/technical-information-notes/product/246-dfsv-info-note-heat-treatment-alternatives-1/file> respectively.)

## 2. Standard Sanitation Operating Procedures - Cleaning the dairy plant

How you keep your operation clean during the processing day and how you clean it at the end of processing is an integral part of your FSP—without a clean plant you can't operate your HACCP plan effectively.



### When cleaning goes wrong

The largest outbreak of food poisoning associated with a dairy product occurred in the USA when ice cream caused 224,000 illnesses due to *Salmonella*. The outbreak was traced to a milk tanker that delivered pre-mix to the ice cream plant. Its previous load had been raw egg pulp and it hadn't been cleaned properly before the ice cream mix was loaded.

### Elements of a cleaning program

There are two distinct parts:

1. Cleaning – removal of all soils from equipment and working surfaces
2. Sanitising – inactivation of any microbes remaining on or in equipment.

### How to clean the dairy plant

There are three ways to do this depending on the size of your establishment:

#### 1. Dry cleaning

This is obviously done without the hose by scraping, brushing, wiping or vacuuming product and soils from floors and equipment. It can be done throughout the processing day (part of 'clean-as-you-go') and is the first stage in end-of-day cleaning. Dry cleaning is especially important in powder plants.

Equipment needed: Brushes, scrapers, dustpans and squeegees, plus a safe, clean place to locate them. Colour coding is useful if equipment needs to be located only in a specific place e.g. a powder packing area.

#### 2. Manual cleaning

Some equipment needs taking to pieces before you can clean it. After disassembly you'll need to remove soils in a bath of cleaning solution.

Equipment needed: At small scale plants this is 'bucket-and-brush' cleaning but in medium and large plants you'll see mobile spray units delivering cleaning solution as a foam which clings to the equipment and facilitates soil removal by brush.

### 3. Cleaning-in-place (CIP)

Some pieces of equipment can be cleaned by passing cleaning solutions through the internals of pieces of equipment such as heat exchangers, evaporators and vats, involving little disassembly.

Equipment needed: Bulk cleaning solutions, often with a permanent ring main system to link with individual pieces of equipment, coupled with software programs to deliver validated cleaning times and solution temperatures. Cleaning is enhanced by spray balls and other equipment designed to deliver agitation to hard-to-get parts of equipment.

## Soils in the dairy and cleaning solutions needed to remove them

Protein, fat and calcium are components of milk that form soils during the processing day, and for each of which there is a chemical which can dissolve and remove them.

Soil	Chemical which removes it
Protein	Chlorine
Fat	Alkali (caustic)
Calcium	Acid

The most commonly used cleaning solution (detergent) is a chlorinated alkali (based on caustic soda and sodium hypochlorite, hypo), which will remove fat and protein, providing it receives sufficient contact time and is delivered in a water solution at the right temperature. Very hot solutions can cause 'bake-on' and cleaning solutions are usually delivered at warm (40–50°C) temperatures.

Build-up of calcium causes 'milk stone' on equipment such as vats and heat exchangers and is removed by an acid wash usually after set periods of running, rather than every day. Milk stone can hide thermophilic bacteria and protect them from cleaning solutions.

The key cleaning component is water. It forms >99% of all cleaning solutions and your cleaning supplier will need to know the pH of your water supply, especially if you live in a hard water area. For this reason, the supplier may recommend additions to your detergent to improve its effectiveness, such as surfactants, builders and water conditioners. And water isn't cheap so the less you use the better.

## Sanitisers

A sanitiser is a chemical that reduces the level of microbial contamination on the surfaces of food equipment. To qualify as a sanitiser the chemical must kill 99.999% of *E. coli* and *S. aureus* in 30 seconds at 25°C—this is done as a laboratory test.

There are eight classes of sanitiser:

1. Chlorine (usually Sodium Hypochlorite – Hypo)
2. Chlorine Dioxide
3. Iodine (usually called Iodophore)
4. Quaternary Ammonium Compounds (QUATs) – note that some markets do not allow use of QUATs) – and they kill starter bacteria
5. Acid sanitisers

6. Organic acids (such as Acetic Acid)
7. Peroxyacetic acids
8. Phenols

Some of the above are used in the dairy industry, such as Chlorine, Iodine, QUAT and Peroxyacetic acid. They all have advantages and disadvantages that you need to consider after discussing with your cleaning supplier.

## Delivering cleaning solutions

You need to follow five steps when you clean the plant at end of processing:

1. dry clean – remove as much soil as possible from equipment, floors and walls
2. rinse equipment and surfaces with cold water
3. deliver detergent solution either with manual and/or CIP to equipment
4. rinse with water
5. deliver sanitiser solution either with manual and/or CIP to equipment.



Source – Dairy Food Safety Victoria Technical Information Note, Developing a cleaning and sanitising program, June 2015

Applying cleaning solutions is usually done with low pressure and low volume foaming wands. High-pressure pumps only blast soils and solutions all over the plant, creating aerosols and cross contaminating premises. Typically, detergents are foamed onto surfaces and left for around 15 minutes (contact time) while the chemical reactions take place so that all the soil reacts with the detergent. Sanitisers are also foamed and left for the correct contact time needed for bacterial inactivation.

## Having a cleaning plan and people trained to follow it

Your cleaners need a written plan plus training on how to carry it out and to have sufficient time for the job, especially on equipment that have long run times like pasteurisers and evaporators.

Chemical safety is also important:

- › For large operations chemicals need to be stored in a lockable room or caged area that is protected by bunds (low walls) to contain leaks; small to medium food businesses will need a lockable room.



- › Staff need training on using cleaning chemicals safely and what to do if they have an accident.
- › They also need personal protection equipment and have the material data safety sheet (MSDS) available.

## Choosing systems and cleaning solutions

Reputable suppliers of cleaning chemicals are as much concerned with setting their customers up properly as they are with selling drums of soap. Producers can expect a number of 'add-ons' from chemical suppliers such as:

- › training the cleaning crew, both in technique and Work Health & Safety (concentrated cleaning chemicals are dangerous)
- › trialling cleaning solutions and reporting on their effectiveness
- › providing work instructions on how to clean different equipment and areas
- › working out a cleaning budget
- › assessing the effectiveness of the cleandown.

These services can be valuable where you don't have resources to deliver a staff training program and where you haven't the capacity to verify the effectiveness of the cleaning regime. The additional service may also provide the information you need to be confident your chemical usage (costs) are spot-on for your needs. The expertly drafted work instructions would be valuable where the cleaning product hasn't instructions that fit your processing system and equipment.

## Some dos and don'ts

- › Don't use porous and absorbent items like rags or wooden handled tools—they harbour bacteria.
- › Do use separate brushes for product and non-product surfaces—colour-coded is good e.g. red means only use for floor waste, green is used for surfaces that may come into contact with product.
- › Do sanitise brushes and store them correctly between use.
- › Do sanitise brushes and cloths used to smear surface ripened cheeses.
- › Do use low pressure:low volume cleaning systems to minimise splashing and aerosols.
- › Do store hoses on reels or racks.
- › Do have a look up at the blowers in the cool room to ensure they are not dusty or dripping water.
- › Always do a 'pre-op' inspection before work is started. Have a good look to see surfaces and equipment are clean and, if they aren't, do a clean down and sanitise. This will slow operations so, if this is the case, find out why it wasn't done properly first time around.

## How well did we do?

You've cleaned your plant and you've paid for your cleaners, cleaning chemicals and water. Now you need to know whether the job's been done right.

Here's how:

1. Walk around and look for any remaining soils and look at stainless equipment like vats: if you see a rainbow-like sheen, that's protein that hasn't been removed—you're not delivering the right chemicals.
2. Assess whether there's any organic material left—if there is, the job's not done properly. You can do this in real time by investing in:

- › swabs which tell you whether protein remains
  - › an Adenosine Triphosphate (ATP) bioluminescence kit which tells you whether microbes, fat, protein or sugar remains
3. You can swab for microbes and send it to a laboratory for a bacterial count and wait two or more days for the result.
  4. When you get the result make sure you document it so your auditor can assess the effectiveness of your cleaning system, and you also give your cleaners feedback on how well they went.

Prerequisites for a successful cleaning program include having a plant that is properly designed for cleaning and product flow and then monitoring the plant environment to determine whether your cleaners have done the job properly.

There are several excellent technical documents from DFSV:

- › *Hygienic design: guidelines for dairy food manufacturing premises*
- › *Building construction guidelines for dairy manufacturers*
- › *Developing a cleaning and sanitising program*

(Accessed at <http://www.dairysafe.vic.gov.au/publications-media/technical-information-notes/premises>)

## Environmental monitoring

As well as ensuring your premises are clean, you are required to monitor whether you are keeping them free of pathogens like *Salmonella* and *L. monocytogenes*. As part of your FSP, you have agreed a regime for testing your premises with your controlling authority—frequency and location of testing, with your premises divided into zones which you identify as:

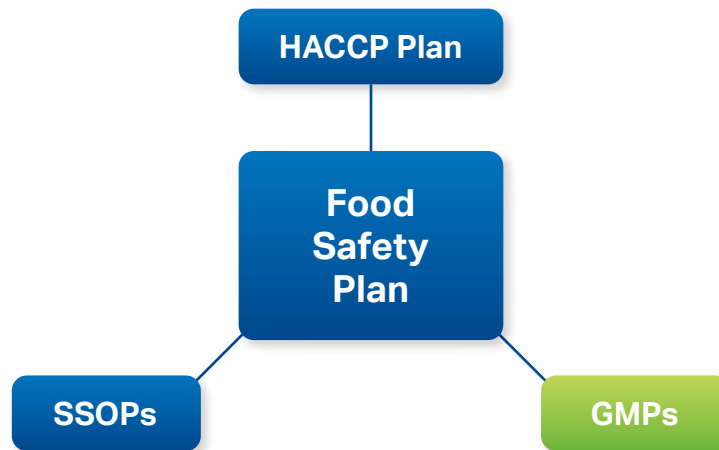
- Zone A: Product contact surfaces
- Zone B: Surfaces that don't contact product but are close to them
- Zone C: Distant surfaces from product contact
- Zone D: Surfaces outside the processing area

If your monitoring program detects either *Salmonella* or *Listeria*, you're into Corrective Action, part of which will involve a clearance program for any product affected by the monitoring result.

You can read more about environmental monitoring in the DFSV documents: *Environmental monitoring in the dairy industry* and *Dairy pathogen manual*.

## 3. Good Manufacturing Practices (GMPs)

GMPs are the procedures and the equipment you use to conform with the standards and guidelines stipulated by your controlling authority. They underpin your FSP.



There are literally hundreds of GMPs that are specific for each individual operation e.g. how you add starters and calcium to your cheese vat, is the vat open or closed, do you cut curd when the pH has reached a particular value or do you rely on the clock?

There are obviously too many to deal with in guidelines that cater industry-wide so, in this section, we concentrate only on those GMPs that are at the forefront of food safety:

- > Calibration
- > Receiving and storing raw materials
- > Allergens and product labelling
- > Pasteurising
- > Detecting foreign matter

### 1. Calibration

You rely on instruments and equipment to measure key unit operations of your business:

- > thermometers record heating and cooling operations
- > scales record weights and volumes of final products
- > other equipment like your pH meter tells you whether curd formation is occurring correctly.

A calibration schedule and methodology will be a component of your FSP and calibration could also be considered as part of your PRP.

### 2. Receiving and storing raw materials

Every dairy processor receives liquid milk or cream either raw or pasteurised and chilled to 5°C or colder. An alternative for cheese makers with their own flock is an approved arrangement with your controlling authority to use milk immediately, without chilling.

Degradation of raw milk in storage is a factor of how quickly *Pseudomonas* grows and produces heat-stable enzymes and is temperature and time dependent.

Manufacturers of dairy desserts and dips need to store a number of ingredients such as milk powder, protein concentrates, flavours, colours, sweeteners, herbs/spices, fruits and dehydrated vegetables in dry storage.

### 3. Allergens and product labelling

Consumers are allergic to a range of foods, including dairy products, and can manage their condition only with the aid of the product label. In the section *Hazards and Risks*, we recorded several recalls of dairy products where the label did not declare the allergen. Allergens are covered in some detail, with the recommendation that you read two excellent DFSV documents: *A guide to managing allergens in the food industry* and *Allergen management for dairy food manufacturers*.

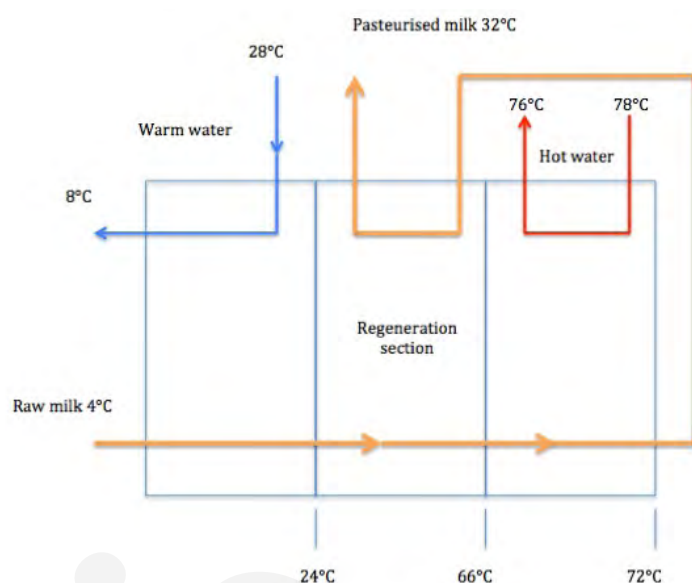
Standard 1.2.3 – Information requirements – warning statements, advisory statements and declarations outlines all the requirements for allergen labelling.

### 4. Pasteurising

Pasteurisation, whether HTST or LTLT, is the primary food safety step in dairy processing and requires equipment to be designed properly and operated by a competent person who also records key parameters.

#### HTST continuous pasteurisers

There is an Australian Standard (AS 3993): *Equipment for the pasteurisation of milk and other liquid dairy products - Continuous-flow systems* that sets out key design features important in ensuring that every particle of milk receives the prescribed heat treatment.



Among the design features needed for successful continuous pasteurising are:

- > **Holding tube** must have a continuous upward slope or, if a holding section is installed, the designated temperature:time regime must be certified by an approved person.
- > **Raw milk balance tank** must prevent entry of extraneous matter into the tank, air being drawn into the pasteuriser and minimise formation of froth.
- > **Temperature probes** must be located to demonstrate that the correct temperature has been achieved at the end of the holding tube.
- > **Indicating thermometer** accurate to +/- 0.5°C must be installed to permit comparison with the temperature chart recorder.
- > **Divert valve(s)** must be located and functional to divert milk that has not achieved pasteurisation at the end of the holding tube.

- › **Operation and monitoring of pressure differential** to ensure no recontamination of pasteurised milk due to a leak in the plate (not applicable for double plate heat exchangers).
- › **Flow meter** to monitor flow rate through the pasteuriser.
- › **Continuous monitoring recording device** for time, temperature and diversion events.

Daily monitoring by the operator includes:

- › correlation between indicating thermometer and chart recorder
- › divert valves and alarms operating and recording
- › pressure differential recording.

Pasteurising is a CCP because it eliminates all target pathogens and there are CLs:

Temperature:time	72°C/15s (or as stipulated in your FSP)
Flowrate	Maximum flowrate XL/h (as stipulated in your FSP)
Divert valve	Reaction time <Xs (as stipulated in your FSP)
Holding tube	Divert to supply tank if temperature falls below X°C (as stipulated in your FSP)

### LTLT batch pasteurisers

The design of batch pasteurisers is important, as is their capability to handle the number of pasteurising and cleaning cycles required on days of maximum production.

Important design aspects of batch pasteurisers include:

- › **Vessel must be enclosed** to ensure product and headspace meet the specified temperature and to prevent contamination from condensate or extraneous matter.
- › **Vat agitation** should ensure uniform product temperature.
- › **Dead spots** where products may not receive effective heat treatment must be absent.
- › **Indicating thermometer** is needed to monitor temperature during processing.
- › **Continuous recording device** (such as a data logger) is needed.
- › **Head space thermometer** or recording device is needed.

## 5. Detecting foreign matter

Foreign matter is a hazard reasonably likely to occur and your equipment and procedures are documented in your FSP.

### Further reading

Useful documents from DFSV include:

- › *Calibration of monitoring equipment*
- › *Metal detection*
- › *X-ray detection of extraneous matter*

(Accessed at <http://www.dairysafe.vic.gov.au/technical-notes/premises/481-calibration-of-monitoring-equipment-1>, <http://www.dairysafe.vic.gov.au/technical-notes/premises/287-tin-metal-detection-web> and <http://www.dairysafe.vic.gov.au/technical-notes/premises/288-tin-x-ray-web> respectively)

## Raw milk

Raw milk consumption is becoming increasingly popular—it can be sold legally in New Zealand, many countries in Europe and several States in the USA. Promoters of raw milk consumption claim health benefits associated with its nutritional, digestibility and immune qualities, and in Appendix 2 we present these claims and the response of the New Zealand Chief Scientific Adviser.

In this document we present evidence of significant illness caused by raw milk consumption together with reference material citing the evidence.

### Raw milk and disease in history

The link between raw milk consumption and disease is longstanding. The ICMSF leads its section on the topic with: *'The literature is replete with accounts of outbreaks due to the consumption of raw milk. Before the widespread use of pasteurisation in the 1930s, milk and dairy products were a major vehicle for transmission of human disease such as typhoid fever, diphtheria, septic sore throat, tuberculosis and brucellosis'* (ICMSF, 2005).

Milking equipment and dairy workers are also sources of transmission of disease. The Victorian typhoid epidemic in 1943 is typical. As the Moorabbin News (March 19, 1943) reported, there were 400 people ill with typhoid and 20 dead from consumption of raw milk contaminated by a typhoid carrier at the dairy farm. Dr Scholes, Medical Superintendent, Queen's Memorial Infectious Diseases Hospital, Fairfield, stated: *'... the great lesson of the outbreak is that it is not safe to drink raw milk'*.

Fortunately, LTLT treatment of milk (pasteurisation) was introduced into Australia in the 1940s, followed soon after by HTST pasteurisation, reducing significantly the burden of disease associated with raw milk.

### Hazards in raw milk

Unfortunately, in all dairy animals (cows, sheep, goats, buffalo) the anus is positioned above the udders (the sewage outfall is above the spigots), making faecal contamination during milking a common occurrence, even in the most hygienic operations. Also, dangerous bacteria can be present in the udders of sub-mastitic cows (FSANZ, 2009).

Raw milk contains serious hazards to human health, and Australia's food poisoning statistics identify pathogens causing outbreaks of food poisoning from raw milk consumption.

#### Outbreaks of food poisoning from raw milk consumption in Australia

State	Year	Pathogen	Cases	Deaths
Queensland	1992	<i>Campylobacter &amp; Salmonella</i>	4	-
Tasmania	1993	<i>Campylobacter</i>	21	-
WA	1998	<i>Campylobacter</i>	9	-
SA	1999	<i>Salmonella</i>	12	-
SA	2000	<i>Campylobacter</i>	Not known	-
Victoria	2000	<i>Campylobacter</i>	~25	-
Queensland	2001	<i>Cryptosporidium</i>	38	-
Victoria	2003	<i>Campylobacter</i>	13	-
SA	2003	<i>Campylobacter</i>	5	-
Victoria	2104	<i>Cryptosporidium</i>	5	-
Victoria	2015	Pathogenic <i>E. coli</i>	5	1

## How serious are the illnesses caused by raw milk?

- › *Listeria* causes meningitis which kills in 20–30% of cases; the foetus is particularly vulnerable.
- › *Salmonella* and *Campylobacter* can cause long-term diarrhoea and can progress to serious conditions such as arthritis and Guillen Barré Syndrome (severe muscle weakness leading to death in 7.5% of cases).
- › In recent times, some *E. coli* have become dangerous because they have acquired genes allowing them to attach to our intestines and cause bloody diarrhoea.
- › They can also make a toxin (Shiga toxin) that can disable our kidneys by causing HUS.
- › In turn, HUS can also cause small blood clots to enter the brain, heart or kidneys, an illness with a mortality rate in the elderly as high as 50% (FDA, 1992).

## Who are most vulnerable to bacteria in raw milk?

Victims of disease caused by raw milk consumption generally suffer from lowered immune systems – they are the young, old, pregnant and immunocompromised (YOPIs), who together form more than 20% of our population (ABS, 2019).

In New Zealand, the Ministry of Primary Industry (MPI) state that between 2009 and 2015 there were 41 outbreaks of illness where consuming raw milk was a risk factor (MPI, 2016). Of these:

- › 90% involved children, ranging in age from 1 to 16 years.
- › In 2014, six people who had consumed raw milk were hospitalised with *E. coli* infections. Five of the six were children, two of whom developed serious, life-threatening complications.
- › In 2015, five children and one elderly patient who had consumed raw milk were hospitalised with *E. coli* infections. One child and the elderly patient developed serious, life-threatening complications.

## How risky is raw milk?

There have been a number of risk assessments of raw milk consumption and the findings are summarised below.

### Australia (FSANZ, 2006)

A risk profile of dairy products in Australia (FSANZ, 2006) concluded that:

- › Unpasteurised dairy products are the most common cause of internationally reported dairy-associated outbreaks of illness (43.4%).
- › Over 22.8% of outbreaks were attributed to unpasteurised cows' milk and 11.8% of outbreaks were attributed to unpasteurised cheese produced from raw cows' milk.
- › Pasteurised dairy milk products in Australia are extremely safe products.

### New Zealand

A risk assessment commissioned by the NZ government (Hudson *et al.* 2014) concluded that:

- › Current evidence suggests the risk of *Campylobacter* infection for consumers of raw cows' milk in New Zealand is high.
- › The risk will be greatest for milk obtained and consumed closest to the point of milking.
- › There is a risk of exposure to *Campylobacter* from goats' milk.
- › There are insufficient data to evaluate the risk from raw milk from sheep and buffalo.



## USA

Recent risk assessments undertaken in the USA established that:

- › From 1998 through 2011, a total of 148 outbreaks were associated with the consumption of raw milk products, resulting in 2,384 illnesses, 284 hospitalizations, and 2 deaths (CDC, 2013).
- › The incidence of reported outbreaks associated with raw dairy products was around 150 times greater, per unit of product consumed, than the incidence involving pasteurised dairy products (Langer *et al.* 2012).
- › It is estimated that up to 20,502 Minnesotans (residents of a state allowing purchase of raw milk) may have become ill with enteric pathogens after consuming raw milk (Robinson *et al.* 2014).

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## Manufacture of pasteurised milk and cream

Pasteurised milks and cream are products from which hazards have been eliminated by a heating stage that is both a CCP and an RCP.

- > Microbiological hazards – bacterial pathogens (*Salmonella*, *E. coli*, *L. monocytogenes*, *S. aureus*, *C. sakazakii*, *B. cereus*), viral pathogens (Hepatitis A and Norovirus) and parasites (*Cryptosporidium*)
- > Chemical hazards include cleaning/sanitising residues and agricultural chemicals such as antibiotics
- > Physical hazards – foreign matter such as glass, metal, plastic, packaging materials.

### CPs, RCPs, CCPs, GMPs

**LTLT** heat treatment (63°C for 30 minutes or an equivalent thermal process) is used in conjunction with batch pasteurisation and is a CCP (and RCP) because it **eliminates** all pathogens likely to occur in raw milk.

**HTST** heat treatment (72°C for 15 seconds) is used with continuous pasteurisers and is a CCP (and RCP) because it **eliminates** all pathogens likely to be in the raw milk.

**ESL** heat treatment (120–125°C for a few seconds) is a CCP because it **eliminates** all pathogens likely to be in raw milk and increases refrigerated shelf life to 4–6 weeks.

**UHT** heat treatment (130–140°C for 1-2 seconds) is a CCP (and RCP) because it **eliminates** all pathogens likely to be in raw milk and also results in the product being commercially sterile and capable of storage at non-refrigerated temperatures for several months.

Operation	CP/CCP/RCP/GMP
Raw milk check for antibiotics	CCP/RCP
Standardise milk	GMP
Homogenisation	GMP
Pasteurising/ESL/UHT	CCP/RCP
Cooling	CP
Packaging	GMP
Cooling and storage	CP/RCP

## Food safety problems with pasteurised milk and cream

### UHT milks

As may be seen from FSANZ recall data below, occasionally a spore former may survive and grow, causing souring of the milk without swelling the pack—flat sour spoilage. The other spoilage problem associated with UHT milk is spoilage cause by extracellular enzymes produced by *Pseudomonas* and its relatives in the raw milk. These enzymes survive the UHT process and, over time, cause increase in viscosity of the milk leading to gel formation, so-called age gelation.

	Product	Cause
2011	UHT Skim milk	Spoilage
2005	UHT flavoured Milk	Sensory - taint
2003	UHT milk	Chemical
2000	UHT milk	Contamination
2000	UHT milk	Spoilage

## Chilled milk and cream

The temperatures and time of both LTLT (batch) and HTST (continuous) pasteurising are designed to eliminate all pathogenic and almost all spoilage bacteria (thermodurics may survive).

While there have not been food poisoning outbreaks in Australia, there have been many recalls of pasteurised milk and cream (see Appendix 1), of which those recalled over the past five years are presented below.

	Product	Cause
2019	Milk	<i>E. coli</i>
2019	Kefir	<i>E. coli</i>
2017	Raw cow's milk	<i>Cryptosporidium</i>
2017	Milk and cream	<i>E. coli</i>
2016	White milk	<i>Coliforms</i>
2016	Flavoured milk	<i>Coliforms</i>
2016	Flavoured milk	<i>Coliforms</i>
2016	Flavoured milk	<i>Coliforms</i>
2014	Full cream milk	<i>E. coli</i>

## Risk assessment *Listeria monocytogenes* in pasteurised milk and cream

### Epidemiology

While there have been no outbreaks in Australia, there have been a small number of documented outbreaks in the USA and Canada where pasteurised milk products caused listeriosis, each of which is examined below.

Country	Year	Product	Cases	Deaths	Reference
USA	1985	Pasteurised milk	49	14	Doyle <i>et al.</i> 1997
USA	1997	Chocolate milk	40	-	Dalton <i>et al.</i> 1997
USA	2007	Coffee milk	6	4*	Weisbecker, 2015
Canada	2015-16	Chocolate milk	34	-	Hanson <i>et al.</i> 2109

\* includes one stillbirth

Investigations of the flavoured milk outbreaks point to the problem of keeping *Listeria* out of your plant, and of preventing it from setting up home (making a biofilm) in lines and pumps. Here are some locations where *Listeria* was detected in the plants that made the flavoured milk leading to the listeriosis outbreaks:

- > post-pasteurisation pump on the chocolate milk line and on non-food contact surface
- > drain, non-food contact areas in coffee milk packaging area.

The pasteurised white milk outbreak was unusual in that the pasteurising cycle was normal and was adequate for killing *Listeria*. In 1985, Bradshaw *et al.* showed that 71.7°C for 15s could kill 1,000,000,000,000,000 cells of *Listeria*. So what caused the problem where 49 people were seriously ill and 14 died?

The initial investigation showed that the milk came from herds in which some cows were suffering from listeriosis and secreting the pathogen into their milk. A second investigation showed that *Listeria* were protected during pasteurisation because they were enclosed in white blood cells and were able to survive 73.9°C for 16.4s.

### Epidemiology Australia

- > Australians probably consume pasteurised milk on several billion occasions each year.
- > There have been no reported food poisoning incidents from *Listeria* in pasteurised milk or cream products.

### Likelihood of presence in pasteurised milk

- > There have been no recalls for *Listeria* in pasteurised milk and cream.
- > In Dairy Australia surveys in 2002–04, *L. monocytogenes* was not detected in 2,403 samples of pasteurised milk.
- > In a Dairy Food Safety Victoria survey in 2002–03, *L. monocytogenes* was not detected in 19 samples of pasteurised milk.

### Growth required to infective dose

The infective dose varies greatly between that for healthy individuals and the 20%+ who are vulnerable. In the 2007 chocolate milk outbreak in the USA, the victims were three men aged 75–87 years old (who all died), two pregnant women (who survived) and one baby (stillborn).

In refrigerated pasteurised milk, *L. monocytogenes* can grow steadily and will increase its population by 10-fold every 5–7 days (depending on the refrigerator temperature).

### Effect of processing

Both heating regimes in Standard 4.2.4 are adequate to kill all *Listeria* in raw milk from cows that are not suffering from listeriosis.

Preventing entry of *Listeria* post pasteurisation is critical. There have been recalls for Coliforms and *E. coli* (see above) that may indicate post-pasteurisation causes.

### Consumer cooking step

Milk is often consumed without any heating.

### Epidemiological links

None in Australia despite many years of manufacturing pasteurised milk and cream products.

### Risk rating

Product	Packaged pasteurised milk and cream
Hazard	<i>L. monocytogenes</i>
Severity	Severe
Likelihood	Common in the environment
Growth required to reach infective dose	Yes, but not great for vulnerable consumers
Effect of processing	Pasteurisation eliminates <i>Listeria</i> but post-process contamination possible
Consumer heating step	None
Epidemiological links	None
Rating	Extremely low

## References

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## Manufacture of cheese

Globally the number of different cheeses is probably in the thousands, but one way of categorising them is by their moisture content:

- > **Soft, unripened cheeses** (often called 'fresh' cheeses) – curd formation is via acidification, with no starters or rennet used (cottage, quark, ricotta) and some may be brined (mascarpone, feta).
- > **Stretched-curd cheeses** (mozzarella, bocconcini, haloumi) – the curd is heated then kneaded and pulled into threads.
- > **Mould-ripened cheeses** (brie, camembert) – made with starter culture, rennet and mould culture to ripen from the exterior to the interior. Cheeses like gorgonzola are pierced (kneaded) with a blue mould that ripens the interior.
- > **Washed-rind cheeses** (Limburger, Munster) – the rind is washed in brine containing bacteria and/or yeasts to give a typical smeared red colour and a pungent odour when mature.
- > **Semi-hard cheeses** (cheddar, edam, colby) – the curd is pressed and milled, salted and pressed into hoops. Flavour development progresses up to 12–24 months.
- > **Eye cheeses** (Emmental, gouda, Swiss) – have a looser texture due to formation of small bubbles ('eyes') produced by gas-producing bacteria.
- > **Hard cheeses** (parmesan, pecorino, romano) – have very low moisture content as the curd is cut very fine and then cooked to maximise removal of whey. Maturing may take up to 36 months and the cheeses are often used for grating.

Most of the above cheeses are made using pasteurised milk but, in Europe, some hard cheeses have traditionally been made from unpasteurised milk and their manufacture has now become regulated in Australia.

### Cheeses made from unpasteurised milk

Although raw milk cannot be sold in Australia for human consumption, it can be used for manufacture of cheese under strictly defined circumstances as set out in Standard 4.2.4:

- > Milk cooling and storage – cooled to 6°C or colder within 2 hours of being drawn, unless processing begins within 2 hours of drawing; stored at 5°C or colder unless processing begins within 2 hours of milking.
- > Milk heated to 64.5°C or warmer for 16 seconds or longer and the cheese stored at 7°C or warmer for a period of 90 days or longer from the date of processing.  
Or
- > The curd produced from unpasteurised milk is heated to 48°C or warmer and the cheese has a moisture content of <39% after being stored at 10°C or warmer for a period of 120 days or longer from the date of processing.

### CPs, RCPs, CCPs, GMPs

Neither of the heating regimes specified: a minimum of 62°C/15s, 64.5°C/16s (which are thermisation processes) or 48°C is a CCP because pathogens are not eliminated or reduced to an acceptable level but, because they are written into the Standard, they become RCPs.

Similarly, the storage conditions that specify temperature, time and water activity are RCPs.

The science behind manufacture of cheese made from unpasteurised milk is that if the conditions in the cheese (salt, moisture, pH) prevent their growth, pathogens will gradually die as their metabolism becomes more and more unbalanced.

The validation parameters cited in the Standard have been set after regulators considered all the scientific information on how pathogens grow and die in various cheeses.

Standard 4.2.4 includes specific requirements to control food safety hazards for raw milk cheeses including:

- › Prior to the commencement of its processing, milk for raw milk cheese must be monitored to ensure its suitability.
- › The level of pathogenic microorganisms in a raw milk cheese must not exceed the level of pathogenic microorganisms in the milk from which the product was made as at the commencement of the processing of that milk.
- › A raw milk cheese must not support the growth of pathogenic microorganisms.

You can read an excellent summary in *Challenge Testing of Microbiological Safety of Raw Milk Cheeses: The Challenge Trial Toolkit* prepared for the NZ Ministry of Agriculture and Forestry by Prof Tom Ross at the University of Tasmania. <https://www.mpi.govt.nz/dmsdocument/20621/direct>

## Cheeses made from pasteurised milk

As may be seen from the introduction, there are a huge number of cheeses made from pasteurised milk, which vary according to:

- › milk animal – cow, sheep, goat, buffalo, camel
- › curd formation by acidification, use of starters, rennet
- › addition of salt
- › method of ripening – washing curd, addition of bacterial, yeast or mould cultures
- › duration of ripening – degree of hardness.

You can read a comprehensive summary of each key property of each cheese category in a Dairy Australia document: <http://www.legendairy.com.au/cheese>.

## CPs, RCPs, CCPs, GMPs

Your FSP plan for your specific cheese making operation will identify CPs and CCPs including the following:

Operation	CP/CCP/RCP/GMP
Raw milk check for antibiotics	CCP/RCP
Standardisation	GMP
Pasteurising	CCP/RCP
Cooling	CP
Culture addition	GMP
Rennet addition	GMP
Curd formation	GMP
Drain whey	GMP
Salting	GMP
Moulding, pressing	GMP
Foreign matter detection	CCP
Maturation/ripening	GMP
Packaging	GMP
Refrigerated storage	RCP



## Food safety problems with cheeses

One way of focusing on problems occurring with cheese products is to identify pathogens involved in outbreaks of food poisoning and recalls.

### Food poisoning outbreaks in Australia and overseas

Some typical outbreaks are presented below

Country	Year	Pathogen	Product	Cases	Deaths
France	1983	<i>S. aureus</i>	Ewe milk cheese	20	-
France	1995	<i>S. aureus</i>	Raw goats milk cheese	Unknown	-
France	1995	<i>L. monocytogenes</i>	Raw milk cheese	20	-
Switzerland	1995	<i>L. monocytogenes</i>	Soft cheese*	57	16
USA	2000	<i>L. monocytogenes</i>	Mexican cheese*	13	5
Canada	2002	<i>L. monocytogenes</i>	Raw milk cheese	17	-
Sweden	2003	<i>L. monocytogenes</i>	Farm fresh cheese*	15	-
Australia	2013	<i>L. monocytogenes</i>	Soft ripened cheeses	34	7**

\* Raw milk also used    \*\* Includes one abortion

### Recalls in Australia

Of the more than 120 recalls listed on the FSANZ website, 50% are for recalls of cheese, with the vast majority caused by microbiological contamination – you can see a complete listing in Appendix 1.

	Number of recalls			
	Microbiological	Chemical	Physical	Allergen
Hard cheese	13	1	4	1
Soft cheeses	28	0	3*	0
Mould-ripened	14	0	0	0
Total	55	1	7	1

\* Includes one labelling defect

A breakdown of microbiological recalls indicates the overwhelming involvement of *Listeria* and *E. coli*, plus recalls also for *Salmonella* and *S. aureus*.

	Number of recalls			
	<i>Listeria</i>	<i>Salmonella</i>	<i>E. coli</i>	<i>S. aureus</i>
Hard cheese	8	1	4	0
Soft cheeses	11	1	15	1
Mould-ripened	8	0	6	0
Total	27	2	25	1

It's possible *S. aureus* was recalled because an operator handled warm curd with bare hands. *Listeria* and *E. coli* are present in raw milk and the former is also present in the environment.

Their presence in final products could be from:

1. inadequate heat treatment
2. cross-contamination during processing
3. post-process contamination in lines and/or the packaging machine.

Your task is now to investigate the cause, and a number of documents published by DFSV offer advice on how to do this:

- > *Environmental monitoring in the dairy industry*
- > *Listeria monocytogenes – management in dairy factories*

(Accessed at <http://www.dairysafe.vic.gov.au/publications-media/technical-information-notes/premises.>)

## Risk assessment *L. monocytogenes* in cheese

### Epidemiology Australia

There has been one reported food poisoning incident from *Listeria* in cheese.

### Likelihood of presence in cheese

- › Over the period 1999–2019, there have been 27 recalls for *Listeria* in hard, soft and mould-ripened cheeses (see above).
- › In a Dairy Australia survey in 2003–04, *L. monocytogenes* was detected in 1/2437 (0.04%) of cheese samples.
- › In Dairy Food Safety Victoria surveys in 2002–04, *L. monocytogenes* was detected in 8/381 (2.0%) of high moisture and 8/185 (4.3%) of low-moisture cheese samples.

### Growth required to infective dose

The infective dose varies greatly between that for healthy individuals and the 20%+ of us who are vulnerable. In the 2012–13 soft cheese outbreak, the victims were predominantly aged and one foetus was aborted.

In most semi-hard and hard cheeses, *L. monocytogenes* will grow only slowly because of low pH and water activity and, in very low-moisture cheeses, it will gradually die. However, in mould-ripened cheeses its growth is promoted in areas of mould growth. This is because moulds break down protein to amines, which raise the pH and make conditions more favourable for growth of *Listeria*.

### Effect of processing

Both heating regimes in Standard 4.2.4 are adequate to kill all *Listeria* in raw milk from cows that are not suffering from listeriosis.

Preventing entry of *Listeria* post pasteurisation is critical—it is an environmental organism and can enter the ripening areas unless entrances are well managed.

### Consumer cooking step

Cheese is almost always consumed RTE.

### Epidemiological links

There are strong epidemiological links (see table above).

### Risk rating

Product	Mould-ripened cheese
Hazard	<i>L. monocytogenes</i>
Severity	Severe
Likelihood	Common in the environment
Growth required to reach infective dose	Yes, but not great for vulnerable consumers
Effect of processing	Pasteurisation eliminates <i>Listeria</i> but post-process contamination possible
Consumer heating step	None
Epidemiological links	Yes
Rating	High

## Risk assessment *S. aureus* in cheese

### Epidemiology Australia

There have been no reported food poisoning incidents from *S. aureus* in cheese for more than 20 years.

### Likelihood of presence in cheese

- > Over the period 1999–2019, there has been 1 recall for *S. aureus* in soft cheese.
- > In a Dairy Australia survey in 2003–04, *S. aureus* was detected in 0/5039 cheese samples.
- > In Dairy Food Safety Victoria surveys in 2002–04, *S. aureus* was detected in 9/381 (2.3%) of high moisture and 3/185 (1.6%) of low-moisture cheese samples.

### Growth required to infective dose

*S. aureus* produces a toxin and, when its population exceeds 1,000,000/g, the toxin may be sufficient to cause illness.

The organism is salt tolerant but won't produce toxin when the temperature is <10°C. It's also a poor competitor and won't thrive against the high populations of lactic acid bacteria in cheese—often >10,000,000/g cheese.

### Effect of processing

*S. aureus* may be present in raw milk from mastitic cows, and both heating regimes in Standard 4.2.4 are adequate to kill it. The toxin is heat stable and isn't killed by pasteurising, which makes the on-farm chill cycle important.

The main point of entry is contamination from food handlers, 20–30% of whom carry *S. aureus* on their hands and in their noses, ears and mouth. Handling of warm curd provides potential for growth of *S. aureus*, but low pH and presence of huge numbers of starter culture competitors will inhibit its growth.

### Consumer cooking step

Cheese is almost always consumed RTE.

### Epidemiological links

There are no epidemiological links (see tables above).

### Risk rating

Product	Mould-ripened cheese
Hazard	<i>S. aureus</i>
Severity	Moderate
Likelihood	Common on food handlers (20-30% carry it on their skin)
Growth required to reach infective dose	High population increase needed
Effect of processing	Pasteurisation eliminates <i>S. aureus</i> but curd handling may introduce organism
Consumer heating step	None
Epidemiological links	None
Rating	Extremely low

## Manufacture of butter

Butter is a high-fat spread made by churning pasteurised cream into an emulsion of water in oil—the fat content of cream (about 35%) being concentrated to around 80%; butter also contains water (16%), salt (2%) and lactose/protein (2%).

In the butter process, cream is pasteurised around 80°C under reduced pressure in a vacreator to remove off flavours and is then agitated violently (churned) to break up the fat and distribute the water as tiny droplets.

Cultured butter is made by adding a lactic acid starter culture and storing overnight for ripening, prior to pasteurising.

### CPs, RCPs, CCPs, GMPs

- › Pasteurising is a CCP/RCP because it inactivates all vegetative bacteria and pathogens. Spore formers and thermotolerants survive and have the potential to grow in poorly worked butter.
- › Churning distributes the water phase through the oil phase as droplets. In well-worked butter droplets, ideally around 3 micrometres (µm) in diameter are produced. Micro droplets limit the ability of bacteria, which are usually 1–3 µm in diameter to grow, even if they do manage to get into a water droplet. Churning is a CP.
- › Salt (3%) dissolves only in the water phase where the concentration rises to 12.5% (water activity around 0.94), stopping the growth of many pathogens and Gram-negative spoilers, and is a CP.
- › Refrigerated storage of butter prevents growth of some pathogens but doesn't prevent, eliminate or reduce them to an acceptable level so is a CP.

Operation	CP/CCP/RCP/GMP
Raw milk receipt	CP
Separation	GMP
Pasteurising	CCP/RCP
Cooling and storage	CP
Churning	GMP
Draining/washing	GMP
Salt addition	GMP
Packaging	GMP
Foreign matter detection	CCP
Refrigerated Storage	CP/RCP

### Food safety problems with butter

Butter, especially salted butter, is an extremely safe product with no recalls listed on the FSANZ website and no food poisonings identified in Australia.

Overseas, there have been two outbreaks of listeriosis. The Finnish outbreak was studied in great detail because it involved hospital patients, and there were complete records of their food intake. Salted butter supplied in small (7g) individual packs was found to be the cause. Cream was pasteurised at 90°C for 30s, salt and water were added and the butter churned, packed and stored under refrigeration.

Country	Year	Pathogen	Product	Cases	Deaths
Finland	1999	<i>L. monocytogenes</i>	Butter	25	6
UK	2003	<i>L. monocytogenes</i>	Butter	17	-

*Listeria* is salt tolerant and can grow at refrigeration temperatures and, in the factory investigation, was found to be living in drains beneath a conveyor and the packing machine. *Listeria* from the factory had the same 'fingerprint' as that which made 25 hospital patients ill and killed six of them.

## Risk assessment *S. aureus* in butter

### Epidemiology Australia

There have been no reported food poisoning incidents from *S. aureus* in butter in Australia.

### Likelihood of presence in butter

- > Over the period 1999–2019, there have been no recalls of butter (see above).
- > In a Dairy Australia survey in 2003–04, *S. aureus* was detected in 0/66 butter samples.
- > Dairy Food Safety Victoria surveys in 2002–04 did not include butter in its sampling program.

### Growth required to infective dose

*S. aureus* produces a toxin and, when its population reaches 100,000/g, the toxin may be sufficient to cause illness.

The organism is salt tolerant and is not inhibited by the high concentration in the water droplets of the water-in-oil emulsion that is butter. However, its growth form is grape-like clusters that are too large to get into water droplets of butter. It is also unable to grow at refrigeration temperatures.



### Effect of processing

*S. aureus* may be present in raw milk from mastitic cows, and both heating regimes in Standard 4.2.4 are adequate to kill it. The toxin is heat stable and isn't killed by pasteurising, which makes the on-farm chill cycle important.

### Consumer cooking step

Butter is almost always consumed RTE.

## Epidemiological links

There are no epidemiological links (see table above).

## Risk rating

Product	Butter
Hazard	<i>S. aureus</i>
Severity	Moderate
Likelihood	Common on food handlers (20–30% carry it on their skin)
Growth required to reach infective dose	High population increase needed
Effect of processing	Pasteurisation eliminates <i>S. aureus</i>
Consumer heating step	None
Epidemiological links	None
Rating	Extremely low

## Risk assessment *L. monocytogenes* in butter

### Epidemiology Australia

There have been no reported food poisoning incidents from *L. monocytogenes* in butter in Australia, but there have been two outbreaks in Europe (see above).

### Likelihood of presence in butter milk

- › Over the period 1999–2019, there have been no recalls of butter.
- › The Dairy Australia and Dairy Food Safety Victoria surveys in 2002–04 did not include butter in its sampling program.

### Growth required to infective dose

*L. monocytogenes* is salt tolerant and is not inhibited by the high concentration (12.5%) in water droplets of the water-in-oil emulsion that is butter. It is also able to grow at refrigeration temperatures. However, *Listeria* is unlikely to be able to multiply in water droplets of well-worked butter, purely because it's too big to get in the droplet.

Management of entry points and personnel clothing are important in preventing its entry.

### Effect of processing

Both heating regimes in Standard 4.2.4 are adequate to kill *L. monocytogenes*.

### Consumer cooking step

Butter is almost always consumed RTE.

### Epidemiological links

There are no epidemiological links in Australia.

### Risk rating



Product	Butter
Hazard	<i>L. monocytogenes</i>
Severity	Severe
Likelihood	Environmental organism
Growth required to reach infective dose	High population increase needed
Effect of processing	Pasteurisation eliminates <i>L. monocytogenes</i>
Consumer heating step	None
Epidemiological links	None
Rating	Extremely low

## Risk assessment *Salmonella* in butter with post-process inclusions

### Epidemiology Australia

There have been no reported food poisoning incidents from *Salmonella* in butter with post-process inclusions in Australia or overseas.

### Likelihood of presence in butter with inclusions

- > Over the period 1999–2019, there have been no recalls of butter.
- > The Dairy Australia and Dairy Food Safety Victoria surveys in 2002–04 did not include butter in its sampling program.

### Growth required to infective dose

*Salmonella* is not salt tolerant and is not able to grow at refrigeration temperatures.

### Effect of processing

Both heating regimes in Standard 4.2.4 are adequate to kill *Salmonella*.

### Consumer cooking step

Butter is almost always consumed RTE.

### Epidemiological links

There are no epidemiological links.

### Risk rating

Product	Butter
Hazard	<i>Salmonella</i>
Severity	Serious
Likelihood	Unlikely
Growth required to reach infective dose	High population increase needed
Effect of processing	Pasteurisation eliminates <i>Salmonella</i>
Consumer heating step	None
Epidemiological links	None
Rating	Extremely low

## Manufacture of ice cream

An important factor in the sensory quality of ice cream is its fat content, with cream, butter and milk fat providing the smooth creamy mouth feel. Sugar, eggs, flavourings and modifying agents (stabilisers and emulsifiers) are also added.

The mixture is homogenised under pressure to produce the required texture by producing fat globules of uniform size. The mixture is pasteurised at 80–85°C for 15 seconds, cooled and stored to allow fat to solidify and viscosity to increase; other ingredients such as nuts are added.

The mixture is frozen at -7°C and beaten to incorporate air into the mix and increase the volume—called 'overrun'—by up to 100%.

### CPs, RCPs, CCPs, GMPs

Operation	CP/CCP/RCP/GMP
Assemble ingredients	GMP
Homogenisation	GMP
Pasteurising	CCP/RCP
Cooling and storage	CP
Addition of flavourings etc	GMP
Ageing	GMP
Freezing	CP
Aeration ('beating')	GMP
Foreign matter detection	CCP
Packaging	GMP
Refrigerated Storage	CP/RCP

### Food safety problems with ice cream

Ice cream caused the largest outbreak of food poisoning associated with a dairy product in the USA where there were 224,000 illnesses due to *Salmonella*. The outbreak was traced to a milk tanker that delivered pre-mix to the ice cream plant. Its previous load had been raw egg pulp and it hadn't been cleaned properly before the ice cream mix was added.

In Australia there was a spate of food poisonings from fried ice cream where the same *Salmonella* contamination entered the product from raw eggs added after pasteurisation.

#### Food poisonings from ice creams in Australia

State	Year	Pathogen	Product	Cases
SA	1998	<i>Salmonella</i>	Gelato	102
NSW	2000	<i>Salmonella</i>	Fried ice cream	41
NSW	2007	<i>Salmonella</i>	Fried ice cream	12
NSW	2009	<i>Salmonella</i>	Fried ice cream	33
WA	2009	<i>Salmonella</i>	Fried ice cream	7
SA	2009	<i>Salmonella</i>	Fried ice cream	10
Queensland	2010	<i>Salmonella</i>	Fried ice cream	3
NSW	2010	<i>Salmonella</i>	Fried ice cream	14
NSW	2011	<i>Salmonella</i>	Fried ice cream	6

## Australian recalls of ice cream

Recalls listed on the FSANZ website are confined to presence of undeclared allergens, foreign matter and chemicals left in the line after cleaning.

	Product	Cause
2015	Ice cream	Allergen (soy)
2015	Ice cream	Allergen (egg)
2003	Ice desserts	Allergen (dairy)
2000	Ice cream	Glass
1999	Ice cream	Sanitiser

## Risk assessment *L. monocytogenes* in ice cream

### Epidemiology Australia

- › There have been no reported food poisoning incidents from *L. monocytogenes* in ice cream in Australia.
- › In the USA in 2015, there was an outbreak of listeriosis from ice cream in which three of the five victims died. Investigations showed that persistent *Listeria* biofilms in ice cream machinery was the cause, with the contamination so severe that the biofilm in one machine could not be eradicated and the machine was decommissioned.

### Likelihood of presence in ice cream

- › Over the period 1999–2019, there have been no recalls of ice cream for *L. monocytogenes* (see above).
- › In a Dairy Australia survey in 2003–04, *L. monocytogenes* was detected in 0/4 ice cream samples.
- › In Dairy Food Safety Victoria surveys in 2002–04, *L. monocytogenes* was detected in 0/148 ice cream samples.

### Growth required to infective dose

*L. monocytogenes* is unable to grow at freezer temperatures but will survive.

### Effect of processing

Both heating regimes in Standard 4.2.4 are adequate to kill *L. monocytogenes*.

### Consumer cooking step

Ice cream is almost always consumed RTE.

### Epidemiological links

There are no epidemiological links (see table above).

### Risk rating

Product	Ice cream
Hazard	<i>L. monocytogenes</i>
Severity	Severe

Product	Ice cream
Likelihood	Environmental organism
Growth required to reach infective dose	No growth possible
Effect of processing	Pasteurisation eliminates <i>L. monocytogenes</i>
Consumer heating step	None
Epidemiological links	None
Rating	Extremely low

## Risk assessment *Salmonella* in ice cream with post-process inclusions

### Epidemiology Australia and overseas

There have been several food poisoning incidents from *Salmonella* in fried ice cream in Australia and many similar incidents overseas, with the ice cream often cited in the media as the cause of the problem, rather the use of post-process inclusions.

### Likelihood of presence in ice cream with inclusions

- › In a Dairy Australia survey in 2003–04, *Salmonella* was detected in 0/4 ice cream samples.
- › In Dairy Food Safety Victoria surveys in 2002–04, *Salmonella* was detected in 0/148 ice cream samples.

### Growth required to infective dose

*Salmonella* is unable to grow at freezer temperatures but will survive.

### Effect of processing

Both heating regimes cited in Standard 4.2.4 are adequate to kill *Salmonella* in raw milk. The problem arises when raw egg containing *Salmonella* is added to ice cream e.g. in the batter of fried ice cream.

### Consumer cooking step

Ice cream is almost always consumed RTE.

### Epidemiological links

There are strong epidemiological links (see table above), though it should be emphasised again that the problem is not with the ice cream, but with the use of raw eggs in fried ice cream.

### Risk rating

Product	Ice cream with raw egg inclusion
Hazard	<i>Salmonella</i>
Severity	Serious
Likelihood	Likely in raw eggs
Growth required to reach infective dose	No growth possible in frozen state
Effect of processing	Pasteurisation eliminates <i>Salmonella</i> but is added with raw eggs
Consumer heating step	None
Epidemiological links	Yes
Rating	High

## Manufacture of yoghurt

Yoghurt is produced in many countries and is one of a family of fermented milks. Milk solids are increased to 14–16% and the milk, to which thickeners and sugar are added, is homogenised and pasteurised at 90–95°C for 5–10 minutes. After cooling, starter cultures *Lactobacillus delbrueckii* subspecies *bulgaricus* and *Streptococcus thermophilus* are inoculated and the milk incubated either at 42–44°C for 3–4 hours (short set) or at 37–38°C overnight (long set) to produce a smooth, viscous curd.

Additional cultures with claimed probiotic qualities may also be added e.g. *Lactobacillus acidophilus* and *Bifidobacterium*.

The mix is cooled and flavour, colour and fruit may be added before filling into containers. Milk may also be filled, fermented and cooled in its container (pot set).

Acidity build up results in a final pH around 4.3, preventing growth of all pathogens, though yeasts and mould can grow and cause spoilage.

### CPs, RCPs, CCPs, GMPs

Operation	CP/CCP/RCP/GMP
Standardise and assemble ingredients	GMP
Homogenisation	GMP
Pasteurising	CCP/RCP
Cooling	CP
Addition of starter cultures	CP
Incubation/acidification	CP
Cooling	CP
Addition of flavours, fruit	GMP
Foreign matter detection	CCP
Packaging	GMP
Refrigerated Storage	CP/RCP

### Food safety problems with yoghurt

The FSANZ recall website records that most of the problems with yoghurt have been with packaging, particularly mislabelling, and parts of the opening/closing mechanism breaking into the product or having the potential to choke children.

Contamination with *E. coli* has also warranted recalls, possibly indicating post-process contamination via biofilms in lines or packaging machines, or via contaminated fruit or flavours.

	Product	Cause
2017	Various yoghurts	Packaging
2017	Yoghurt	Packaging
2017	Various yoghurts	Packaging
2017	Various yoghurts	Packaging
2016	Various yoghurts	<i>E. coli</i>
2016	Various yoghurts	<i>E. coli</i>
2013	Yoghurt	<i>E. coli</i>
2013	Various yoghurts	Foreign matter - plastic

	Product	Cause
2012	Yoghurt	<i>E. coli</i>
2010	Yoghurts for toddlers	Foreign matter - plastic
2008	Yoghurt	Foreign matter - plastic
2007	Yoghurt	Foreign matter - metal
2004	Various yoghurts	<i>E. coli</i>

## Risk assessment *Salmonella* and *S. aureus* in yoghurt with post-process inclusions

### Epidemiology Australia and overseas

There have been no reported food poisoning incidents from *Salmonella* or *S. aureus* in yoghurt in Australia or overseas.

### Likelihood of presence in yoghurt with inclusions

- › Over the period 1999–2019, there have been no recalls of yoghurt for *Salmonella* or *S. aureus* (see above).
- › In a Dairy Australia survey in 2003–04, *Salmonella* and *S. aureus* were not detected in any of 28 yoghurt samples.
- › In Dairy Food Safety Victoria surveys in 2002–04, *Salmonella* was detected in 0/7 yoghurt samples; no samples were tested for *S. aureus*.

### Growth required to infective dose

*Salmonella* and *S. aureus* are unable to grow at refrigeration temperatures or at the low pH of yoghurt.

### Effect of processing

Both heating regimes in Standard 4.2.4 are adequate to kill *Salmonella* and *S. aureus* in raw milk.

### Consumer cooking step

Yoghurt is almost always consumed RTE.

### Epidemiological links

There are no epidemiological links (see table above).

### Risk rating

Product	Yoghurt with post-process inclusions
Hazard	<i>Salmonella</i> and <i>S. aureus</i>
Severity	Serious ( <i>Salmonella</i> ) Moderate ( <i>S. aureus</i> )
Likelihood	Very low
Growth required to reach infective dose	No growth possible at refrigeration temperature and low pH
Effect of processing	Pasteurisation eliminates <i>Salmonella</i> and <i>S. aureus</i>
Consumer heating step	None
Epidemiological links	None
Rating	Extremely low

## Manufacture of dairy dips and desserts

Dairy dips are made from a variety of dairy bases: yoghurt, cream cheese and sour cream, to which a range of spices, herbs, flavourings and dehydrated vegetables may be added, often after the pasteurisation step.

Dairy desserts such as mousse, crème fraiche, custards and puddings are made from milk and cream, and may also contain a range of functional ingredients such as sweeteners, emulsifiers, flavours and colours, plus probiotic bacteria. Other ingredients such as fruit may be added after the pasteurising step.

### CPs, RCPs, CCPs, GMPs

Operation	CP/CCP/RCP/GMP
Assemble and blend ingredients	GMP
Pasteurising, retort or UHT	CCP/RCP
Cooling	CP
Addition of ingredients (flavours, chocolate)	GMP
Blend ingredients	GMP
Homogenisation	GMP
Whipping, freezing	GMP
Blend ingredients (fruit)	GMP
Foreign matter detection	CCP
Packaging	GMP
Refrigerated Storage	CP/RCP

### Food safety problems with dairy desserts and dips

There are no recorded food poisoning outbreaks associated with dairy desserts and dairy dips but there have been recalls.

	Product	Cause
2014	Raspberry dessert	Allergen (dairy)
2102	Snack packs	Foreign matter - plastic
2009	Custard	<i>L. monocytogenes</i>
2009	Dessert	<i>L. monocytogenes</i>
2007	Dairy snacks	Labelling defective
2004	Custard	Spoilage defects
2003	Hummus	<i>L. monocytogenes</i>
2001	Custard	<i>Listeria</i>



## Risk assessment *L. monocytogenes* in dairy dips, desserts with pH >4.5 or <4.5 with or without inclusions post-process

### Epidemiology Australia

There have been no reported food poisoning incidents from *L. monocytogenes* in dairy dips and desserts in Australia or overseas.

### Likelihood of presence in desserts or dairy dips

- › Over the period 1999–2019, there have been three recalls of desserts and one for dairy dips for *L. monocytogenes* (see above).
- › In Dairy Food Safety Victoria surveys in 2002–04, *L. monocytogenes* was detected in 3/65 (4.6%) of dairy dips and 0/18 dairy dessert samples.
- › No testing was undertaken for *L. monocytogenes* in dairy dips and desserts in Dairy Australia surveys of 2003–04.

### Growth required to infective dose

*L. monocytogenes* is able to grow in dairy dips and desserts at refrigeration temperatures.

### Effect of processing

Both heating regimes in Standard 4.2.4 are adequate to kill *L. monocytogenes*.

Preventing entry of *Listeria* post pasteurisation is critical and it can enter the finished product areas unless entrances are well managed.

The DFSV Technical Information note: *Listeria monocytogenes – management in dairy factories* is highly recommended (Accessed at <https://www.dairysafe.vic.gov.au/technical-notes-science/premises/232-l-mono-technical-information-note-1.>)

### Consumer cooking step

Dips and desserts are almost always consumed RTE.

### Epidemiological links

There are some epidemiological links via recalls (see table above).

### Risk rating

Product	Dairy dips and desserts
Hazard	<i>L. monocytogenes</i>
Severity	Severe
Likelihood	Environmental organism
Growth required to reach infective dose	Growth is possible especially in products with long shelf lives
Effect of processing	Pasteurisation eliminates <i>L. monocytogenes</i> but post-process contamination possible
Consumer heating step	None
Epidemiological links	Yes
Rating	Moderately high

## Risk assessment *Salmonella* and *S. aureus* in dairy dips and desserts of pH >4.5 or <4.5 with or without inclusions post-process

### Epidemiology Australia and overseas

There have been no reported food poisoning incidents from *Salmonella* or *S. aureus* in dairy dips and desserts in Australia or overseas.

### Likelihood of presence in desserts or dairy dips

- › Over the period 1999–2019, there have been no recalls of dips or desserts for *Salmonella* or *S. aureus* (see above).
- › In a Dairy Australia survey in 2003–04, *Salmonella* was detected in 0/4 samples and *S. aureus* in 0/27 dairy dessert samples; *S. aureus* was detected in 0/50 samples of dairy dips. No tests were done for *Salmonella* in dairy dips.
- › In Dairy Food Safety Victoria surveys in 2002–04, *Salmonella* and *S. aureus* were not detected in 65 dairy dips or in 18 dairy dessert samples.

### Growth required to infective dose

*Salmonella* and *S. aureus* are unable to grow at refrigeration temperatures and the pH may also be inhibitory. *Salmonella* will survive refrigeration, as will any *S. aureus* toxin produced during processing.

### Effect of processing

Both heating regimes in Standard 4.2.4 are adequate to kill *Salmonella* and *S. aureus* in raw milk, but herbs, fruits and vegetables may be added post pasteurisation.

### Consumer cooking step

Dips and desserts are almost always consumed RTE.

### Epidemiological links

There are some epidemiological links via recalls (see tables above).

### Risk rating

Product	Dairy dips and desserts
Hazard	<i>Salmonella</i> and <i>S. aureus</i>
Severity	Serious ( <i>Salmonella</i> ) Moderate ( <i>S. aureus</i> )
Likelihood	Very low
Growth required to reach infective dose	No growth possible at refrigeration temperature and low pH
Effect of processing	Pasteurisation eliminates <i>Salmonella</i> and <i>S. aureus</i> but inclusions may not be pasteurised
Consumer heating step	None
Epidemiological links	None
Rating	Low

## Manufacture of dairy powders

Dairy powders are produced by evaporating milk and then drying (usually by spray drying) the concentrate. Evaporators have several stages (phases) through which pasteurised milk is passed under vacuum at 60–70°C in the early stage to 45–50°C in later stages, concentrating milk from about 8–12% solids on entry to 45–50% at the spray dryer. There, concentrated milk is passed through an atomiser at 115–120°C which effectively removes pathogenic bacteria.

Some evaporator stages are favourable to the growth of thermophilic bacteria that can increase rapidly over the processing day (up to 18 hours), forming a biofilm that bleeds thermophiles into the dried powder.

Powders typically have a moisture content of 2–3% and a water activity around 0.3, though this can increase because powder is hygroscopic.

### CPs, RCPs, CCPs, GMPs

Operation	CP/CCP/RCP/GMP
Standardise milk	GMP
Pasteurisation	CCP/RCP
Preheat	GMP
Evaporation	CCP/RCP
Spray drying	CCP
Storage	CP
Packaging	GMP
Foreign matter detection	CCP
Storage	GMP

### Problems with dairy powders

Australia has had only one food poisoning outbreak in which milk powder used in infant formulae was the cause. In 1977, seventeen infants contracted salmonellosis from milk powder produced in northern Victoria when cracks in the drying tower allowed *Salmonella* to colonise the insulation and to bleed into the powder as it descended to the floor of the dryer.

There have been numerous outbreaks globally associated with milk powders with *Cronobacter* (formerly *Enterobacter*) *sakazakii* and *Salmonella* the causes.

Country	Year	Pathogen	Cases	Deaths
Iceland	1989	<i>Cronobacter</i>	3	1
USA	1989	<i>Cronobacter</i>	4	-
USA	1990	<i>Cronobacter</i>	Unknown	-
Israel	1999	<i>Cronobacter</i>	Unknown	-
Korea	2000	<i>Salmonella</i>	30	-
USA	2001	<i>Cronobacter</i>	1	1
Belgium	2001	<i>Cronobacter</i>	12	2
USA	2002	<i>Cronobacter</i>	11	1
Switzerland	2002	<i>Cronobacter</i>	11	-
New Zealand	2004	<i>Cronobacter</i>	4	1
France	2005	<i>Salmonella</i>	104	-

Country	Year	Pathogen	Cases	Deaths
Spain	2008	<i>Salmonella</i>	23	-
France	2008	<i>Salmonella</i>	6	-
USA	2008	<i>Cronobacter</i>	2	-

In 2018, the French dairy manufacturer, Lactalis, recalled over 12 million baby food items from 83 countries following suspected contamination with *Salmonella*.

## Risk assessment *Salmonella* in dairy powders

### Epidemiology Australia and overseas

There have been numerous food poisoning incidents from *Salmonella* in dairy powders overseas and one in Australia in 1977.

### Likelihood of presence in dairy powders

- › Over the period 1999–2019, there have been no recalls of dairy powders.
- › In a Dairy Australia survey in 2003–04, *Salmonella* was detected in 1/3852 (0.02%) samples of dairy powders.
- › In a Dairy Food Safety Victoria surveys in 2002–03, *Salmonella* was not detected in 33 samples of dairy powders.

### Growth required to infective dose

*Salmonella* is unable to grow in low-moisture powders.

### Effect of processing

Heating regimes used in evaporation and spray drying are sufficient to kill *Salmonella* in raw milk, but *Salmonella* may enter post pasteurisation.

### Consumer cooking step

Dairy powders are consumed after reconstitution that usually contains pasteurisation or addition of hot water.

### Epidemiological links

There are some epidemiological links via food poisonings overseas but none in Australia for more than 40 years (see table above).

### Risk rating

Product	Dairy powders
Hazard	<i>Salmonella</i>
Severity	Serious
Likelihood	Very low
Growth required to reach infective dose	No growth possible in dried powder
Effect of processing	Evaporation and spray drying eliminates <i>Salmonella</i>
Consumer heating step	Usually
Epidemiological links	None
Rating	Low

## Risk assessment *S. aureus* and *B. cereus* in dairy powders

### Epidemiology Australia and overseas

There have been no food poisoning incidents from *S. aureus* or *B. cereus* in dairy powders in Australia or overseas, except for a suspected incident in the UK in 1997 and one in Chile in 1984 for *B. cereus*; there have been no overseas reports involving *S. aureus*.

### Likelihood of presence in dairy powders

- › Over the period 1999–2019, there have been no recalls of dairy powders.
- › In a Dairy Australia survey in 2003–04, *S. aureus* was detected in 2/976 (0.2%) samples and *Bacillus* spp were detected in 5/250 (2%) of samples of dairy powders.
- › In a Dairy Food Safety Victoria survey in 2002–03, *S. aureus* was not detected in 33 samples of dairy powders.

### Growth required to infective dose

*S. aureus* and *B. cereus* are unable to grow in low moisture powders.

### Effect of processing

Heating regimes used in evaporation and spray drying are sufficient to kill *S. aureus* and *B. cereus* in raw milk.

### Consumer cooking step

Dairy powders are consumed after reconstitution that usually contains pasteurisation or addition of hot water.

### Epidemiological links

There are no epidemiological links in Australia.

### Risk rating

Product	Dairy powders
Hazard	<i>S. aureus</i> , <i>B. cereus</i>
Severity	Moderate
Likelihood	Very low
Growth required to reach infective dose	No growth possible in dried powder
Effect of processing	Evaporation and spray drying eliminates both pathogens
Consumer heating step	Usually
Epidemiological links	None
Rating	Low

## Risk assessment *Cronobacter sakazakii* in dairy powders

### Epidemiology Australia and overseas

There have been no food poisoning incidents from *C. sakazakii* in dairy powders in Australia but there have been numerous overseas reports.

### Likelihood of presence in dairy powders

- › Over the period 1999–2019, there have been no recalls of dairy powders.
- › A survey of five Australian dairy factories isolated *Cronobacter* from more than 30% of product and environmental samples, with the greatest occurrence of the latter (81%) being from a milk powder area during shutdown (Craven *et al.* 2010).

### Growth required to infective dose

*Cronobacter* can survive but is unable to grow in low-moisture powders.

### Effect of processing

Heating regimes used in evaporation and spray drying are sufficient to kill *Cronobacter* in raw milk.

### Consumer cooking step

Dairy powders are consumed after reconstitution that usually contains pasteurisation or addition of hot water. In the home, *Cronobacter* can grow rapidly in reconstituted milk kept at warm temperatures.

### Epidemiological links

There are no epidemiological links in Australia.

### Risk rating

Product	Dairy powders
Hazard	<i>Cronobacter</i>
Severity	Severe
Likelihood	Low
Growth required to reach infective dose	No growth possible in dried powder
Effect of processing	Evaporation and spray drying eliminates <i>Cronobacter</i>
Consumer cooking step	Reconstitution usually involves hot water
Epidemiological links	None in Australia, many overseas
Rating	High

Craven, H. *et al.* (2010). Distribution, prevalence and persistence of *Cronobacter* (*Enterobacter sakazakii*) in the non-processing and processing environments of five milk powder factories. *Journal of Applied Microbiology*, 109:1044-1052.

## Appendix I: Recalls of dairy products 1999-2019 (FSANZ Recall website)

### UHT milk

	Product	Cause
2011	UHT Skim milk	Spoilage
2005	UHT flavoured Milk	Sensory - taint
2003	UHT milk	Chemical
2000	UHT milk	Contamination
2000	UHT milk	Spoilage

### Chilled milk and cream

	Product	Cause
2019	Milk	<i>E. coli</i>
2019	Kefir	<i>E. coli</i>
2017	Raw cow's milk	<i>Cryptosporidium</i>
2017	Milk and cream	<i>E. coli</i>
2016	Milk	Coliforms
2016	Flavoured milk	Coliforms
2016	Milk	Coliforms
2016	Milk	Coliforms
2014	Milk	<i>E. coli</i>
2014	Various milks	<i>E. coli</i>
2013	Full cream milk	<i>L. monocytogenes</i>
2012	Sour cream	<i>E. coli</i>
2012	Milk	<i>L. monocytogenes</i>
2012	Cream	Foreign matter - fibre
2011	Milks	Chemical
2011	Milk	Chemical
2011	Cream	<i>E. coli</i>
2009	Milk	<i>E. coli</i>
2008	Unpasteurised frozen goat milk	<i>Salmonella</i>
2007	Milk	Chemical
2007	Milk	Chemical
2006	Milk products	Microbiological
2006	Cream	<i>E. coli</i>
2005	Fresh milk	Chemical
2005	Skinny milk	Chemical
2004	Cream	<i>E. coli</i>
2001	Flavoured milk	<i>Listeria</i>
2001	Milk	Caustic
2001	Milk	Allergen



	Product	Cause
1999	Milk	<i>L. monocytogenes</i>
1999	Flavoured milk	<i>Listeria</i>
1999	Milk	Coliforms
1999	Cream	<i>L. monocytogenes</i>

## Hard cheeses

	Product	Cause
2017	Parmesan grated	Allergen (egg)
2014	Various cheeses	<i>L. monocytogenes</i>
2014	Tulum cheese	<i>L. monocytogenes</i>
2014	Various cheeses	<i>L. monocytogenes</i>
2011	Cheese	Foreign matter - metal
2010	Various cheeses	<i>Listeria</i>
2009	Smoked cheese	<i>E. coli</i>
2008	Various cheeses	<i>L. monocytogenes</i>
2007	Cheese	<i>E. coli</i>
2007	Cheese	Foreign matter - plastic
2007	Cheese	<i>Salmonella</i>
2006	Goat Cheese	<i>L. monocytogenes</i>
2006	Cheese	<i>L. monocytogenes</i>
2005	Cheese	Foreign matter - plastic
2002	Cheese	<i>E. coli</i>
2002	Cheese	<i>E. coli</i>
2000	Cheese	<i>Listeria</i>
2000	Cheese	Foreign matter - plastic

## Soft cheeses

	Product	Cause
2018	Feta	<i>E. coli</i>
2018	Feta	Labelling defective
2017	Ricotta	<i>E. coli</i>
2016	Feta	<i>E. coli</i>
2016	Feta	<i>E. coli</i>
2015	Goat feta	<i>E. coli</i>
2014	Paneer	<i>L. monocytogenes</i>
2013	Feta	<i>E. coli</i>
2012	Feta	<i>E. coli</i>
2012	Cheese in brine	<i>Listeria</i> and <i>E. coli</i>
2011	Feta	<i>E. coli</i>
2010	Mozzarella	<i>Salmonella</i>
2010	Cottage cheese	Inadequate pasteurisation
2008	Mozzarella	<i>L. monocytogenes</i>

	Product	Cause
2008	Feta	<i>L. monocytogenes</i>
2006	Cottage cheese	Foreign matter - metal
2005	Cheese	<i>E. coli</i>
2005	Bocconcini	<i>L. monocytogenes</i>
2004	Haloumi	<i>S. aureus</i>
2003	Feta	<i>E. coli</i>
2003	Bocconcini	<i>E. coli</i>
2002	Feta	<i>L. monocytogenes</i>
2002	Feta	<i>L. monocytogenes</i>
2002	Fresh cheese	<i>L. monocytogenes</i>
2002	Feta	<i>Listeria</i>
2001	Feta	<i>E. coli</i>
2001	Ricotta	<i>Listeria</i>
2001	Feta	<i>E. coli</i>
2000	Fresh cheese	Metal
1999	Ricotta	<i>L. monocytogenes</i>
1999	Feta	Coliforms

## Mould-ripened cheeses

	Product	Cause
2018	Various cheeses	<i>E. coli</i>
2018	Washed-rind cheese	<i>E. coli</i>
2018	White-mould cheeses	<i>L. monocytogenes</i>
2016	Velvet cheese	<i>E. coli</i>
2014	Brie cheese	<i>E. coli</i>
2014	Blue cheese	<i>L. monocytogenes</i>
2013	Gorgonzola	<i>L. monocytogenes</i>
2013	Duetto cheese	<i>L. monocytogenes</i>
2013	Soft cheeses	<i>L. monocytogenes</i>
2009	Soft cheeses	<i>E. coli</i>
2009	Soft cheeses	<i>L. monocytogenes</i>
2009	Desserts	<i>L. monocytogenes</i>
2009	Various cheeses	<i>E. coli</i>
2005	Cheese	<i>L. monocytogenes</i>

## Yoghurt

	Product	Cause
2017	Various yoghurts	Packaging
2017	Yoghurt	Packaging
2017	Various yoghurts	Packaging
2017	Various yoghurts	Packaging
2016	Various yoghurts	<i>E. coli</i>

	Product	Cause
2016	Various yoghurts	<i>E. coli</i>
2013	Yoghurt	<i>E. coli</i>
2013	Various yoghurts	Foreign matter - plastic
2012	Yoghurt	<i>E. coli</i>
2010	Yoghurts for toddlers	Foreign matter - plastic
2008	Yoghurt	Foreign matter - plastic
2007	Yoghurt	Foreign matter - metal
2004	Various yoghurts	<i>E. coli</i>

## Recalls of ice cream

Labelling problems dominate recalls of ice cream due to undeclared allergens.

	Product	Cause
2015	Ice cream	Allergen (soy)
2015	Ice cream	Allergen (egg)
2003	Ice desserts	Allergen (dairy)
2003	Ice cream	Glass
1999	Ice cream	Sanitiser

## Recalls of dairy desserts and dips

Recalls of dairy desserts and dips include *L. monocytogenes*, foreign matter, labelling problems and undeclared allergens.

	Product	Cause
2014	Raspberry dessert	Allergen (dairy)
2102	Snack packs	Foreign matter - plastic
2009	Custard	<i>L. monocytogenes</i>
2009	Dessert	<i>L. monocytogenes</i>
2007	Dairy snacks	Labelling defective
2004	Custard	Spoilage defects
2003	Hummus	<i>L. monocytogenes</i>
2001	Custard	<i>Listeria</i>

## Appendix 2: Raw milk

### – Health benefit claims and response

In 2015, New Zealand's Chief Scientific Adviser headed an independent review of the evidence surrounding benefits of raw milk (Gluckman, 2015). His findings are summarised here and a link is provided to the review.

#### **Claim 1: Raw milk has a higher nutritional value than pasteurised milk**

Chief Scientific Adviser's response: Pasteurising has no significant impact on the digestibility or nutritional value of milk.

#### **Claim 2: People with lactose intolerance can drink raw milk**

Chief Scientific Adviser's response: Lactose intolerant participants in a case-controlled study reported symptoms after consuming both raw and pasteurised milk, with no difference in severity of symptoms.

#### **Claim 3: Pasteurisation inactivates beneficial antimicrobial systems and enzymes**

Chief Scientific Adviser's response: Antimicrobial enzymes hardly exist in raw milk and there is no evidence for milk enzymes enhancing human digestion.

#### **Claim 4: Raw milk helps development of strong immune system and prevents allergies**

Chief Scientific Adviser's response: There is no study that supports this claim. Studies quoted by promoters are confounded by presence of other factors in addition to raw milk.

#### **References**

Gluckman, P. (2015). Review of evidence for health benefits of raw milk consumption. Office of the Prime Minister's Chief Scientific Adviser, Auckland, New Zealand. Retrieved January 21, 2019 from [www.pmcsa.org.nz](http://www.pmcsa.org.nz).





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