

Supporting document 1

Guide to the requirements for raw milk products in Standard 4.2.4 — Primary Production and Processing Standard for Dairy Products – Proposal P1022

Primary Production & Processing Requirements for Raw Milk Products

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GUIDE TO THE REQUIREMENTS FOR RAW MILK PRODUCTS IN STANDARD 4.2.4 - PRIMARY PRODUCTION AND PROCESSING STANDARD FOR DAIRY PRODUCTS

Introduction

Food safety requirements for the dairy sector are specified in Standard 4.2.4 - Primary Production and Processing Standard for Dairy Products. Standard 4.2.4 sets out requirements for:

- dairy primary production businesses (covering on-farm milk production activities)
- dairy transport businesses (covering the collection and transport of milk and dairy products) and
- dairy processing businesses (covering activities up to, but not including, retail).

Standard 4.2.4 requires these dairy businesses to control the potential food safety hazards associated with their business by implementing a documented food safety program. These existing measures provide the baseline set of requirements for raw milk product manufacture.

A number of additional requirements are specified in Standard 4.2.4¹ for raw milk products to ensure their safe manufacture. These requirements apply to businesses producing, transporting and processing milk for raw milk products.

Standard 4.2.4 also specifies that the processing of milk for raw milk products must ensure:

- no net increase of pathogens
- the characteristics of the final product do not support growth.

The business processing raw milk products must be able to validate that their product meets this requirement and demonstrate that control measures can be implemented consistently to achieve a safe product. An additional document, *Validation of Raw Milk Product Safety*, has been prepared to assist processors and enforcement agencies with validation requirements.

This guide provides additional information on the food safety outcomes to be achieved by the additional requirements for raw milk products in Standard 4.2.4, including appropriate monitoring activities and verification measures.

Note that this draft document precedes the development of draft amendments to Standard 4.2.4 for raw milk products. The additional measures included in this document are those proposed for inclusion in Standard 4.2.4 but the wording may change in line with final drafting of the requirements.

Using the guide

- The text of Standard 4.2.4 requirements for raw milk products is provided in the coloured pages preceding guidance information. [to be included]
- This guide is structured in three sections, covering milk production, collection and transport, and processing of raw milk products.
- Where existing requirements provide the basis for the additional measures for raw milk products, text and information on them precedes discussion of those requirements.
- The additional measures specified in Standard 4.2.4 for raw milk products are highlighted in the guide as shaded boxed text.



Primary production of milk for raw milk products

1. Controlling food safety hazards

Standard 4.2.4 requires dairy primary production businesses generally to control potential food safety hazards by implementing a documented food safety program. General measures that must be covered in the program are specified under clauses 4 to 6 of the Standard. Essentially the food safety program must cover the following elements:

- Animal health
- Inputs
- Premises and equipment
- Health and hygiene
- Milking operations
- Cleaning and Sanitising
- Traceability
- Skills and knowledge

The primary production of milk for raw milk products requires a greater level of control to ensure that the potential for pathogen contamination is minimised. The additional measures that are required to ensure this level of control is met are elaborated below in relation to existing baseline requirements. Supplementary information relating to general dairy requirements is provided as context in which the additional measures for production of milk for raw milk products apply.

2. Animal health

Baseline requirements

A requirement for milking animals in Standard 4.2.4 specifies that control measures implemented on farm must ensure that milk for human consumption is only sourced from healthy animals and a system must be in place that enables the tracing of animals to be milked. To address these requirements the following elements should be covered by the food safety program:

- Milk is only sourced from healthy animals and animals showing signs of infectious disease are segregated and their milk kept from supply and a diagnosis made of the cause.
- A system for livestock identification is in place and all livestock purchases are supported by vendor declarations as to disease status.
- Treated animals are identified; only approved drugs are used, and specified withholding periods observed for all treatments. Adequate treatment records are kept.
- A mastitis control program is implemented.

Additional considerations for raw milk products

The health and disease status of milking animals has a significant impact on the contamination of raw milk due to:

- pathogens being shed in the faeces which then contaminates the animal and the environment:
- pathogens being shed directly into milk as a result of mastitis;

 pathogens being shed directly into milk from other zoonoses (e.g. Brucella spp, Mycobacterium bovis).

Programs in Australia have successfully eradicated bovine brucellosis and bovine tuberculosis and *Brucella melitensis* (cause of brucellosis in sheep and goats) has never been reported in sheep and goats in Australia. Ongoing surveillance and biosecurity requirements ensure ongoing management of these zoonoses (information available from Animal Health Australia [http://www.animalhealthaustralia.com.au/]). Where a raw milk product has been manufactured in another country, evidence should be available to show that the milk was sourced from animals belonging to herds that are officially free of tuberculosis and brucellosis in accordance with the OIE *Terrestrial Animal Health Code*.

Raw milk product requirements

• General animal health and carrier status

Animals found to be carriers of or showing clinical signs of disease transferable to humans through milk must be isolated from the milking herd and veterinary clearance must be obtained before those animals can re-enter the raw milk herd.

Milking animals should show no apparent general animal health problem such as diarrhoea, fever, discharge, udder inflammation or wound to the udder, or produce milk that appears abnormal. Such animals should be removed from the milking herd and not be milked for supply until the problem has been resolved, or veterinary clearance has been obtained. Animals showing unusual behaviour or a significant drop in milk production or appetite should also be monitored carefully.

In the case of botulism and salmonellosis, veterinary and laboratory diagnosis is necessary and the milk must be withheld from supply until a diagnosis is made. Any unusual animal deaths need to be assessed and veterinary involvement sought if not resolved.

[To be developed: section to cover appropriate herd monitoring program to confirm carrier status, specifically for EHEC/STEC]

Significant animal health issues should be advised to the enforcement agency and the business to whom the milk is being supplied. Written records of animal health issues, veterinary visits (e.g. diary, computer, cow records) and veterinary reports should be filed as part of the food safety program records. It would be expected that animals in the milking herd would be subjected to a veterinary inspection at least annually.

Recommended monitoring criteria

Test	Acceptable limit	Corrective Actions		
General health and quality: weekly on farm bulk milk				
Somatic cell count*	 200 000 cells/ml for bovines 1 000 000 cells/ml for other species 			
Total plate count at 30°C for 72 hours	25 000 cfu/ml			
E. coli	<10 cfu/ml	If the <i>E. coli</i> limit is exceeded, further investigation should be required to verify hygiene measures. Cessation of supply for raw milk product manufacture should result if this limit is routinely exceeded, or a level greater than 100cfu/ml is returned. A test result of <10cfu/ml should be required before recommencement of supply.		
Pathogen monitoring: one test per week on farm bulk milk				
S. aureus	<100 cfu/ml	Any test failure for pathogens should result in cessation of supply for raw milk product manufacture and necessitate investigation of hygiene, cleaning or animal health issues and may require a veterinary visit. A clear test should be required before recommencement of supply.		
Salmonella spp.	Not detected in 25ml A positive test may result in animals being tested for Salmonella.			
L. monocytogenes	Not detected in 25ml			

^{*} It is also recommended that dairy primary production businesses monitor individual animal somatic cell counts. A mastitis management program such as Countdown 2020 should be implemented.

• New animal purchases

A system must be in place to ensure that no animals are introduced into the herd until their health status is verified.

New animals should only be sourced from herds with the best assurance of freedom of disease and where good herd management is in place. It is recommended that under existing requirements, signed declarations and assurances for purchased animals would be obtained for the following diseases:

Species	Disease or condition	Management Program
Cattle	Mastitis	Yes
	Salmonella	Yes
	Johne's Disease	Yes
	Clostridia bacteria	Vaccination status
	Leptospirosis	Vaccination status
Sheep	As above for cattle	As above
	Caseous Lymphadenitis (CLA)	Vaccination status
	Footrot	Yes
Goats	As above for cattle	As above
	Footrot	Yes
	Caprine Arthritis Encephalitis (CAE)	Yes
Buffalo	As above for cattle	As above
	Ticks	Consult State Departments for information
Camelids	As above for cattle	As above

A system for the introduction of new animals to the raw milk herd should include a quarantine period. It would be expected that newly purchased animals are quarantined and their milk withheld from supply for raw milk products until their health and carrier status is confirmed following transport. A minimum quarantine period of 4 to 6 weeks from the raw milk herd may be appropriate.

Purchased animals must be individually identified and introduced into the farm stock register. The dairy primary production business needs to keep all records of stock purchases including any documentation relating to tests carried out to verify health and carrier status.

Stock identification

A stock identification system must be used that ensures each individual animal is uniquely identifiable.

The stock identification system used by the dairy primary production business needs to be documented in the food safety program. The system selected by a business producing milk for raw milk products should:

- ensure each individual animal is uniquely identifiable
- be appropriate to the animal species concerned
- be sufficiently robust to ensure that there is a low incidence of loss of tags etc.

If loss of ear tags or alternative identification occurs, this should be recorded. If there are significant losses of tags etc., an alternative system should be considered. Individual animal identification through the National Livestock Identification System (NLIS) may be appropriate.

Individual animal identification numbers should be recorded in a register of the animals in the raw milk herd and a record kept of which animals are in the milking herd when milk is supplied for raw milk products. The dairy primary production business should monitor the milking records to ensure that only animals intended to be in the herd for the supply of raw milk are in the raw milk herd.

The record system used should be permanent, legible, and stored in a manner which protects the records from damage, deterioration or loss.

3. Feed and Water

Baseline requirements

Standard 4.2.4 specifies that control measures must be included in the documented food safety program that manage the potential food safety hazards arising from inputs which include any feed, water and chemicals used in connection with the primary production of milk. To address these requirements it would be expected that the following elements are included in the businesses food safety program:

- Records for purchased stock feeds including vendor declarations
- Management of pasture including records of chemical pasture treatments and effluent management
- Management of chemical and microbiological hazards in conserved fodder
- Records for the use of all agricultural and veterinary chemicals
- Management of water sources (stock water and milking shed water) such that they are fit for purpose.

Raw milk product requirements

Feed

Feed must be prepared, stored and used in a manner that ensures microbial contamination is prevented, eliminated or reduced to an acceptable level. In particular, fermented feeds must be managed to ensure control of *Listeria monocytogenes*.

Feed provided to milking animals should be of suitable quality and of known origin. To ensure this, the following is recommended:

- All sources of feed (paddocks grazed, feed conserved and feed purchased) should be traceable as part of the food safety program. Accurate paddock and purchase records should be kept.
- Feed production and storage facilities should be appropriate for the nature of the feed and not contribute to microbial contamination.
- No feed waste, silage sludge or mouldy feed should be offered to or consumed by milking animals. Spoilt grain must not be fed to animals because of the risk of mycotoxin contamination. Mycotoxin binders should be used as appropriate.
- Animals should not have access to effluent areas. A period of 21 days is recommended between application of effluent to pastures and grazing or, harvesting of feed. Detailed paddock grazing records should be kept as part of the food safety program and should provide details of effluent spreading.

A specific provision is included for fermented feeds such as silage as poor preparation and storage of these feeds can create conditions highly selective for the growth of undesirable microorganisms such as *L. monocytogenes*. This can then provide a source of infection of listeriosis in miking animals.

The preparation and storage of fermented feeds for the raw milk herd should be addressed and documented in the food safety program and cover production practices and storage facilities (including the design of silos or bunkers). The quality of each batch of fermented feed being used should be assessed and recorded, noting sensory assessment (e.g. odour) and pH reduction.

A rapid pH reduction and storage under anaerobic conditions is considered to be essential for the safe production of fermented feeds. Silage testing for pH should be carried out as a good guide to silage fermentation quality. For silages with a dry matter content of less than or equal to 35%, there is a high probability of poor silage if the pH for grass silage is greater than 4.65 and for legume silage if it is greater than 4.8. No silage should be fed with a pH of greater than 5.0. The Dairy Australia and NSW. Department of Primary Industries "Top Fodder, Successful Silage" Manual (2004) provides guidance for safe silage production.

Fermented feed that has not been prepared and stored correctly should not be offered to milking animals. It is recommended that fermented feeds are not offered immediately premilking to reduce spore or bacterial contamination of teat ends.

Water

Water used in milking operations for raw milk products (e.g. in contact with milking equipment, teat washing and handwashing) must be potable.

Potable water is defined in the Code as water acceptable for human consumption. It is essential that water used in the milking shed does not introduce contaminants and result in the contamination of raw milk with microorganisms. The water supply used within the dairy for sanitising and rinsing the milking plant, for washing teats, mixing up of teat dips and hand washing for operators should be potable.

Businesses able to use treated town water can usually assume that the supply is potable. Businesses with untreated water supplied may need to treat the water before use to ensure it is of a suitable microbiological quality.

The food safety program should document what water supply is used in milking operations and any treatments required. Where the supply is not town water, the microbiological quality should be monitored. It is recommended that testing for *E. coli* be undertaken quarterly unless there is a change of water supply or quality problems occur. *E. coli* should be absent in 100ml.

4. Premises and equipment

Baseline requirements

Standard 4.2.4 requires a dairy primary production business to control the potential food safety hazards arising from the design, construction, maintenance and operation of premises and equipment as part of its food safety program. The control measures must include support programs that ensure that premises and equipment are clean and sanitary and that pests are controlled.

Additional considerations for raw milk products

While the baseline requirements for premises and equipment should provide an adequate level of control dairy premises used for production of milk for raw milk products, these premises should be assessed differently. There should be a higher level of attention to cleaning regimes, the servicing of milking machines and other equipment, and premise layout to ensure the potential for contamination is minimised.

Cleaning and sanitising

Dairy primary production businesses are already required to have a cleaning and sanitising program. For those producing milk for raw milk products, the food safety program should document the specific cleaning regime that ensures the outside of milking equipment, railings in the dairy and the milking platform are free of manure and clean. It is important that the milking plant in farm dairies, including the bulk milk tank, is cleaned and sanitised:

- in a manner that minimises the risk that milk may deteriorate or be contaminated;
- with detergents and sanitisers supplied by a reputable chemical supply company, used according to manufacturers' specifications;
- with water of a suitable quality and at the correct temperature (manufacturer's recommendation); and
- a manner that minimises the risk that the detergents and sanitisers used, may contaminate milk.

The cleaning and sanitising systems available involve variations including rinsing with cold water, washing with a detergent in hot water (acid and alkali variations), use of a sanitiser and rinsing or draining. The system used must be effective, appropriate for the farm's circumstances, including cleaning in place system and automation if installed, and as advised by the chemical company.

The effectiveness of the cleaning program should be monitored by regular physical checks of the milking plant and by monitoring microbiological test data (e.g. total plate count and *E. coli*).

Milking machines

Milking machines and milk cooling equipment should be correctly installed, maintained, cleaned and serviced. For businesses producing milk for raw milk products, a more frequent servicing of milking machines and milk cooling and storage equipment should be implemented to ensure milk quality and safety is maintained.

It is recommended that automated (robotic) milking systems and novel milking systems should not to be used for milk intended for raw milk products unless the design has been submitted for assessment by the enforcement agency.

• Housing and environment

Intensive housing of animals may increase the risk of contamination of udders, leading to mastitic infection due to closer proximity of animals, concentration of faeces, and contact with bedding etc. Where housing is used for animals in a raw milk herd, the design, maintenance and operation of housing pens and bedding should be included in the food safety program. It is important that the facility is cleaned, well ventilated and animals are monitored for stress or disease.

The design and maintenance of holding areas can also amplify the spread of pathogens due to increased soiling of udders and teats with faecal material, and overcrowding which can lead to udder damage and animal stress. The food safety program should include how holding yards, feeding yards, loafing yards and feed pads are managed and operated to avoid overcrowding and to minimise the soiling of udders. Raceways, gateways and watering points should be maintained to minimise soiling of the udders.

Raw milk product requirements

Handwashing and toilet facilities

Designated hand washing facilities must be provided and it should be ensured that they are only used for the washing of hands (& arms etc.)

Adequate toilet facilities must be available and suitably located.

It is a requirement that staff milking animals for milk for raw milk products must wash and dry their hands before milking; during milking when soiling occurs; and when milking groups of animals, in between milking each group of animals. To facilitate this it is important that designated, appropriate hand washing facilities are available to milking staff, independent of equipment washing facilities and hoses. Hand basins should be easily accessible.

Milking staff should also have access to toilet facilities that are well maintained so that they are clean and operating properly. The location of the toilet should take into account any likelihood of droplet-borne contamination which could affect the safety of the milk.

5. Health and Hygiene

Baseline requirements

Standard 4.2.4 requires a dairy primary production business to control potential food safety hazards arising from persons involved in milking. This means that the food safety program should document personal hygiene practices such as:

- hand washing policy
- clothing requirements
- policies for personnel suffering from symptoms of foodborne illness
- the need to cover cuts and wounds
- where eating is permitted.

Raw milk product requirements

• General health and hygiene

Division 4 – Health and hygiene requirements of Standard 3.2.2 apply to the production of milk for raw milk products.

The application of Division 4 of Standard 3.2.2 to businesses producing milk for raw milk products highlights that the potential for contamination from persons involved in milking activities should be assessed akin to food handlers in a food business.

The requirements of Division 4 are provided at Attachment 1. These requirements put obligations on both milk handlers (persons undertaking milking activities) and the dairy primary production business to take all reasonable measures to ensure the safety and suitability of the milk is not compromised.

Specific matters to be given attention regarding milking personnel include:

- In relation to the health of milk handlers (subclause 14(1)), persons with a transmissible disease or known to be a carrier of pathogens or parasites should not undertake milking activities.
- In relation to clothing (subclause 15(1)(c) of Standard 3.2.2), clothes worn for milking should be reserved for that activity and changed and cleaned regularly.
- People with scratches and open wounds on the hands or forearms should not undertake milking activities. If this is not possible, the wounds must be completely covered with waterproof dressing.
- In relation to people on the premises (subclause 18(3)), visitors to a dairy farm
 producing milk for raw milk products should be excluded. If necessary, use of singleuse clothing and boots (or other suitable garment) should be provided.

Hand washing

Persons milking animals for milk for raw milk products must wash (with soap or other effective means, and running water) and dry their hands and forearms before milking; regularly during milking when soiling occurs; and when milking groups of animals, in between milking each group.

The hands of personnel undertaking milking activities need to be considered as a possible source of microbial contamination of the teat and udder. Persons milking animals must wash and dry their hands prior to milking and during milking when soiling occurs. Regular washing of hands is also necessary where milking staff are checking animals for mastitis and treating cows. The provision and use of disposable paper towel for hand drying is a preferred option in the milking plant.

If gloves are used, new, clean, latex-type gloves at each should be worn for morning or evening milking and changed where damaged during milking. Gloves should also be cleaned or changed when soiling occurs.

People milking by hand should ensure hands are washed between animals or if gloves are used, changed between animals.

6. Skills and knowledge

Baseline requirements

Standard 4.2.4 specifies that persons undertaking primary production activities must have skills and knowledge of food safety and hygiene matters commensurate with their work activities. The food safety program should identify who has the appropriate authority and control to deliver the required outcomes. Persons undertaking milking activities, applying agricultural chemicals or administering veterinary treatments, should have appropriate competencies and understand how their actions may impact on food safety.

Raw milk product requirements

The dairy primary production business must demonstrate that personnel have the required skills, knowledge and competencies to safely produce milk for raw milk product processing.

Persons undertaking activities related to the production of milk for raw milk products need to fully understand any implications the activities they undertake may have on the microbiological status of the milk.

Dairy primary production businesses producing milk for raw milk products should have skills and knowledge (competencies) in the areas of:

- animal health and herd management;
- safe production of silage and other conserved feed;
- hygienic milking practices;
- microbiological hazards and their control measures (food safety); and
- cleaning and sanitation requirements.

Records that should be kept include:

- how staff have been trained (including staff attending courses and on-the-job training provided
- how competencies are tested.

7. Milking operations

Baseline requirements

Standard 4.2.4 requires a dairy primary production business to control the potential food safety hazards arising from milking practices. To address this general requirement the food safety program should document practices including:

- maintaining good personal hygiene;
- ensuring correct cleaning, sanitising, operation and maintenance of equipment; and
- minimising contamination from the animal.

Under best practice it would be expected that the following milking practices are implemented:

- Animals teats and udders should be checked for injury or damage, heat or swelling and animal behaviour monitored, particularly evidence of udder discomfort or resistance to milking.
- Good milking management should be practised, including gentle handling of animals, avoiding excessive air intake at cup attachment, minimising over-milking, gentle removal of cups and care to avoid cups sucking up faecal or other material.
- Handwashing/glove cleaning or changing as appropriate.
- Inspection of the milk filter after use to check for abnormalities.

Raw milk product requirements

The teats of animals milked for milk for raw milk products must be clean and dry before the animals are milked.

The teat surface is the major avenue of entry for microorganisms into raw milk. Pre-milking udder hygiene reduces milk contamination by transient bacteria located on the udder. Good personal hygiene practices need to be employed during milking and milking equipment needs to be well maintained, cleaned and sanitised.

The udder and teats of each animal to be milked must be checked for cleanliness. If cleaning is necessary the teats should be washed and wiped with a single service towel. After milking, teats should be sanitised with an approved teat spray, ensuring an adequate contact time. The Dairy Australia Countdown 2020 site provides guidance material on appropriate teat disinfection practices.

Trends in the somatic cell count of the herd and individual cows should be monitored.

8. Milk cooling and storage

Baseline requirements

Standard 4.2.4 specifies that milk must be cooled and stored at a temperature that prevents or reduces the growth of microbiological hazards in the milk. This means that the dairy primary production business must document its cooling regime as part of its food safety program and record monitoring, servicing and compliance with the documented cooling requirement. Thermometers and gauges used to record and check milk temperature should be calibrated and records of calibration kept.

Raw milk product requirements

Milk for raw milk products must be cooled to a temperature of 6°C or below within 2 hours of it being milked, unless processing is to commence within 2 hours of it being milked.

Milk for raw milk products must be stored at a temperature of 5°C or below, unless processing is to commence within 2 hours of it being milked.

A prescriptive cooling and storage requirement is specified for the production of milk for raw milk products to provide greater assurance that the potential for growth of any microorganisms present is minimised.

To meet this requirement, dairy primary production businesses producing milk for raw milk products should:

- have milk cooling equipment serviced annually and repaired when any malfunction occurs:
- calibrate vat recording devices every three months and maintain records;
- check the vat temperature prior to milking and assess milk cooling compliance twice daily to ensure the milk is cooled to 6°C or below within 2 hours from the completion of milking. Any abnormality must be recorded along with any corrective action; and
- store milk at 5°C or below.

If existing milk cooling systems are inadequate to meet the milk cooling and storage requirements, equipment upgrading may be necessary. Options include larger vat compressors, improved plate cooling, cooling towers, ice bank systems, glycol systems etc.

9. Integrity of Supply

Raw milk product requirements

A system should be in place to ensure that milk for raw milk products is kept separate from milk used or intended to be used for other dairy products.

The traceability requirements in Standard 4.2.4 require a dairy primary production business to have a system that enables the tracing of animals to be milked and the milk produced. For a dairy primary production business producing milk for raw milk products, a further consideration is the potential for cross contamination between milk for general dairy processing and milk for raw milk products. It is essential that the integrity of milk for raw milk products is maintained and the potential for any cross contamination is minimised.

For dairy primary production businesses which also produce and supply milk for general dairy processing or where non-conforming milk must be managed, a separate system may be required.

The system put in place should consider, for example, milking procedures (such as milking the raw milk herd before other animals) and storage. For storage:

- Bulk milk storage tanks intended for approved raw milk storage should be clearly labelled and not used for any other purpose.
- Bulk milk storage tanks should be kept closed/sealed at all times.
- Raw milk to be used for the manufacture of Category 2 products should be collected separately from milk intended for other Category products/non complying milk.

10. Product withdrawal and disposal

Raw milk product requirements

Milk that has not been produced in accordance with the recommended control measures, or is otherwise not fit for the manufacture of raw milk products, must be withheld and either—

- (a) disposed of appropriately on farm.
- (b) redirected to supply for general dairy processing, provided that the milk meets the requirements in Standard 4.2.4.

It is important that a system is in place that ensures that milk which does not meet the requirements for raw milk products is not supplied for raw milk product manufacture. These procedures and criteria should be documented in the food safety program. Depending on the non-conformance, the milk could be used for the manufacture of pasteurised milk products or must be disposed of.

The use or disposal of non-conforming raw milk should be recorded, including details of date and milk volumes involved. The reason for failure of the milk to meet requirements should be documented and appropriate corrective action taken and recorded.

Collection and transport of milk for raw milk products

1. Controlling food safety hazards

Standard 4.2.4 requires businesses involved in the collection and transport of milk to control potential food safety hazards by implementing a documented food safety program. Measures that must be covered in the program are specified under clauses 8 to 11 and essentially cover cleaning and sanitising of vehicles and equipment; personal hygiene; time and temperature control; skills and knowledge requirements, and traceability. The food safety program should include the following elements:

- Cleaning and sanitation program
- Maintenance program
- Pest control
- Personal hygiene practices
- Health requirements
- Traceability system

The collection and transport of milk for raw milk products requires a greater level of control to ensure that there is no cross-contamination between milk for suitable for raw milk products with that for general dairy processing or temperature abuse. The additional measures that are required to ensure this level of control is met are elaborated below in relation to existing baseline requirements. Supplementary information relating to general dairy requirements is provided as context in which the additional measures for collection and transport of milk for raw milk products apply.

2. Integrity of supply

Raw milk product requirements

Dairy transport businesses that collect and transport milk for raw milk products must have a system to ensure there is no cross-contamination between raw milk for the processing of raw milk products and milk and dairy products that do not conform to raw milk requirements (but may be suitable for general dairy processing).

The collection and transport of milk for raw milk products needs to effectively manage the potential for cross-contamination between milk suitable for raw milk products and milk for general dairy processing. The food safety program should document the system in place that ensures segregation is maintained.

Regardless of whether collection and transport of milk for raw milk products involves vehicles or is small in scale (e.g. transported in small vessels such as buckets), equipment and containers must be able to be effectively cleaned, prevent contamination and the process used be able to segregate milk for raw milk products from milk for general dairy processing. The elements that may need to be addressed in such a system include the following:

 Milk for raw milk products should be collected before collection of any milk for general dairy processing. Once a milk transfer line has been exposed to milk for general dairy processing, it should not be re-used for milk for raw milk products until it has been thoroughly cleaned and sanitised.

- If a farm produces both milk for raw milk products and for general dairy processing, then the former needs to be transferred first with the clean milk transfer lines before the milk for general dairy processing is transferred to a separate compartment on the tanker.
- The use of separate and defined vessels and milk collection equipment for collecting
 milk for raw milk products. The use of a dedicated milk tanker for the collection and
 transport of milk for raw milk products must be used if collecting from multiple farms.
- All hoses, pumps, pipes, sampling equipment and milk contact surfaces must be clean and sanitised before approved milk can be collected.

3. Time temperature controls

Baseline requirements

Standard 4.2.4 requires a dairy transport business to transport dairy products using time and temperature controls that prevent or reduce the growth of microbiological hazards in the product. The food safety program should document how the business will maintain temperature control which may include, for example, organising milk collection times in relation to milking schedules to ensure the temperature of the milk at pick-up is at 5°C or below. The food safety program should also specify how the temperature of the milk will be monitored and recorded.

Requirements for raw milk products

A dairy transport business that collects and transports milk for raw milk products must ensure that the temperature of milk for raw milk products does not exceed 8°C at any point from collection at the farm through to delivery to a dairy processing business for dairy processing (unless collected within 2 hours after milking).

This prescriptive time temperature requirement for the collection and transport of milk for raw milk products requires communication and planning between the primary production business, the transport business and the processing business (noting that milk should be no older than 24 hours before the processing of raw milk products commences). The food safety program should document how this is ensured and records kept of raw milk temperatures and collection times. For example:

- The time of completion of milking should be documented and displayed by the primary production business in a manner that is accessible to transport personnel. The transport business should record the time of completion of milking and the time of collection in addition to the normal records that must be taken at the farm upon collection of milk (e.g. temperature, volume, organoleptic assessment etc.).
- The transport or processing business should validate that the transportation
 procedures used will ensure that milk in the tanker/container will be received by the
 processing business at or below 8°C. The use of automated temperature data-logging
 equipment on a milk tanker with regular calibration checks and downloadable records
 would meet this requirement.

When milk is collected above 8°C, records should clearly document the time from completion of milking, time of collection and delivery.

Deviations from the temperature requirement may be agreed with the processing business if it can be shown that it would not adversely affect the microbiological safety of the end product. This may be reflected in the raw milk product validation and alternative limits specified in the food safety program (discussed under Section 3 Raw milk products manufacture).

4. Health and hygiene

Baseline requirements

Standard 4.2.4 specifies that control measures must be included in the dairy transport business's food safety program that manage hazards arising from persons engaged in the dairy transport business. This should cover the personnel hygiene practices that personnel are expected to follow to avoid contaminating milk or any equipment likely to be in contact with milk. Additionally procedures should be documented to cover when personnel have symptoms of foodborne illness or know that they are suffering from or are carriers of a foodborne disease.

Additional considerations for raw milk products

While there are no additional requirements in relation to health and hygiene requirements for businesses collecting and transporting milk for raw milk products, it is recommended that this area is given additional consideration to minimise the potential for contamination. For example:

- Collection and transport personnel should wear clean clothes, be restricted to the farm
 vat milk storage room and must not enter areas where animals are kept or manure is
 present. If clothing or foot wear is contaminated, there should be procedures in place to
 mitigate potential contamination of the raw milk.
- Collection and transportation personnel should be equipped with a means to sanitise
 hands before touching any equipment or surfaces that may come into contact with the
 approved raw milk.
- Upon delivery, collection and transport personnel should not enter the processing facility and that a procedure is put in place to enable communication with factory staff and delivery of any milk samples for testing.

5. Skills and knowledge

Additional considerations for raw milk products

Standard 4.2.4 specifies that dairy transport business must ensure persons undertaking milk or dairy product collection and transport activities have skills and knowledge commensurate with their work activities. No additional requirements are specified for the skills and knowledge of businesses collecting and transporting milk for raw milk products however it is recommended that transport personnel have competencies to understand and implement practices (e.g. access restrictions, personal attire) that minimise the risk of transferring pathogens to the raw milk. For example:

- aseptic collecting and sampling of farm vat milk
- general hygienic practices relating to collection and transport activities.

This may be delivered through in-house training or accredited training courses.

Processing of raw milk products

1. Controlling food safety hazards

Standard 4.2.4 requires dairy processing businesses to control potential food safety hazards by implementing a documented food safety program. For the manufacture of raw milk products the food safety program should take into account the entire production chain, from raw milk production to collection, transport and processing through to final product. This demonstrates a relationship between the milk producer and the processing business that helps ensure the final product safety is met.

Food Safety Program

On farm control measures

Transport control measures

Processing control measures

Primary Production

Transport

Processing

Additional considerations for developing a food safety program for raw milk products are discussed below

• Product description and characterisation

The food safety program for a raw milk product should clearly describe and characterise the product so that the control measures and parameters required to ensure safety are clearly identified. For cheese the product description should include:

- Product name
- Cheese style (e.g. internal or surface ripened using mould or bacteria [strains specified])
- Processing factors (e.g. lactic fermentation to pH X; dry salted or brined; rind washed during ageing; aged at least D days at temperatures above Y°C)
- Product characteristics (e.g. moisture, salt content, pH [changes over time])
- Ingredient list
- Packaging used
- Shelf life
- Storage, distribution and handling information
- Intended user

Flow diagram of the process

A flow diagram should be included that describes the manufacturing process step-by-step. The key steps for cheese production can generally be described as: warming, addition of starter cultures and or rennet, warming/ripening, curd cutting, removal of whey, hooping, pressing, salting, maturation/ripening. A generic flow diagram outlining major steps in the cheese making process is provided in Figure 1. In addition, the food safety program should document primary production and transport steps.

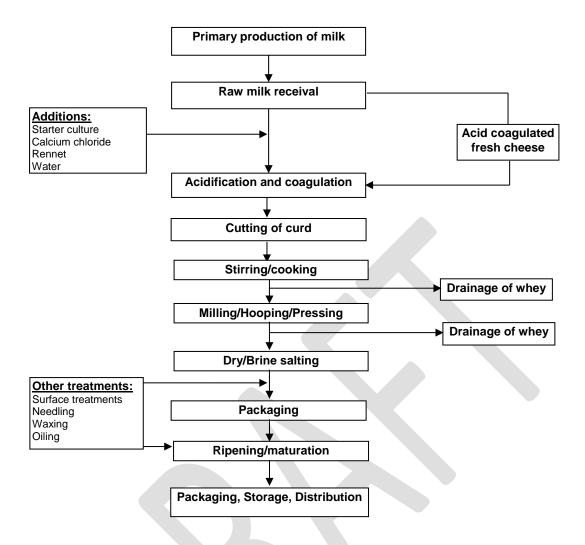


Figure 1. Overview of major steps in the manufacture of cheese

Hazard analysis

Where a business manufactures both heat treated dairy products and raw milk products, the hazard analysis for a raw milk product should identify the potential for cross-contamination between these processes. This should ensure that appropriate systems and procedures are in place so that there is no cross-contamination, both prior and during processing, between milk and dairy materials intended for the processing of raw milk dairy products and those intended for general dairy processing. In particular:

- The milk handling systems for both products should be clearly explained in the food safety program as to how the two milk streams are to be kept separate.
- Consideration should be given to processing raw milk products separately to pasteurised milk products (achieved through either having a separate area or at different times).

The design of the milk receival area and the processing factory should be planned to optimise the capability for segregating the raw milk and pasteurised milk product manufacturing processes.

The personnel access and traffic flow should minimise crossover from low risk to high risk areas and the staff should be sufficiently aware of the importance of adhering to the planned and approved procedures.

Critical control points (CCPs)

Pasteurisation provides the principle critical control point for pathogen control in general dairy processing. The control of pathogens in raw milk product manufacture, however, is achieved through a combination of control measures. These measures would be identified as part of validating the process and should be included in the food safety program as CCPs. Critical limits need to be identified for each CCP as well as how they will be monitored and the corrective actions that will be taken if critical limits are not met. Further discussion on processing factors that would be expected to be identified as CCPs for the purpose of raw milk product manufacture (e.g. acidification, salting, ripening) is provided below under raw milk processing.

2. Food handling controls

Baseline requirements

Standard 3.2.2 Food Safety Practices and General Requirements and Standard 3.2.3 Food Premises and Equipment apply to the processing of dairy products. Standard 3.2.2 specifies process control requirements to be satisfied at each step of the manufacturing process covering receipt, storage, processing, packaging, distribution, disposal and recall.

Other requirements relate to:

- health and hygiene requirements of food handlers
- cleaning, sanitising and maintenance of premises and equipment
- skills and knowledge.

Requirements for raw milk products

Additional requirements for the processing of raw milk products relate to ensuring the integrity of the milk to be used for raw milk processing and the system and temperature controls to support this.

Raw milk receipt

Raw milk products must only be manufactured using raw milk which has been produced and transported in accordance with the specified additional requirements for raw milk products in Standard 4.2.4.

Diary processing businesses processing milk for raw milk products should be able identify the source of each milk shipment that is received onto their premises and have a recording system that captures all required information from each collection of milk from the primary production business. Such information would include:

- unique identifier of the producer
- date and time of collection at the farm
- temperature of the milk immediately prior to collection from the farm vat
- date and time of the completion of milking (provided by the producer)

- the volume of milk collected
- the temperature of the milk upon arrival at the processing premises
- microbiological testing data (from on farm monitoring)
- any other notes concerning the milk or samples taken.

Monitoring criteria

Milk should be sampled and tested prior to the commencement of manufacture according to a documented plan and at a sufficient frequency to ensure food safety criteria are met. Initially it would be expected that a representative sample of each raw milk tank/silo is tested prior to manufacture. Over time sufficient data may be obtained such that a reduced frequency is adequate, depending on the relationship between the dairy primary production business and the processing business and the type of cheese being produced. Recommended tests and acceptable limits for total plate count and *E. coli* are provided below. Monitoring for pathogens, such as *L. monocytogenes* and *Salmonella* should also be considered.

Test	Acceptable limit	
Total plate count at 30°C for 72 hours	100 000 cfu/ml	
E. coli	<100 cfu/ml	

Raw milk exceeding 8°C (at any time) prior to processing must not be used for the manufacture of raw milk products (unless processing of the milk commences within 2 hours after milking or the business can demonstrate that an alternative temperature will not adversely affect the microbiological safety of the raw milk product).

A maximum temperature for milk at receipt is specified to minimise the potential for growth of any pathogens that may be present between milking and processing. The processing business should have records from the transport business that provide evidence that each consignment of raw milk meets the requirements for collection and transport and was maintained at or below 8°C from collection at the farm to delivery at the processing premises.

Evidence may be provided by a continuous temperature-monitoring instrument or rely on a combination of the recorded times and temperatures and a validated protocol on the performance of the container/tank to maintain the milk temperature below 8°C during transportation. For operations where the business both produces raw milk and manufactures raw milk products, records such as a log sheet that records times and temperatures from collection to storage or point of manufacture may suffice.

Deviations from the temperature requirement may be acceptable if it can be shown that it would not adversely affect the microbiological safety of the end product. This may be reflected in the initial product validation and alternative limits specified in the food safety program.

Raw milk should be no older than 24 hours (from the completion of milking) when processing commences, unless the business can demonstrate that an alternative process will not adversely affect the microbiological safety of the raw milk product.

Along with temperature control, restricting the time from milking to the start of manufacture minimises the potential for growth of any pathogens that may be present. Records should be kept that identify when milking was completed for each consignment of raw milk received and when processing commenced. Depending on the type of cheese to be made and its manufacturing protocol, milk older than 24 hours may be suitable to use though it must not exceed 48 hours. This deviation would need to be reflected in the product validation and documented in the food safety program.

Cleaning and sanitising

No additional requirements for cleaning and sanitising are specified for raw milk products however procedures should be examined in relation to maintaining the integrity of the milk for raw milk product manufacture. For example, the business should have a documented unloading procedure that ensures that all associated equipment is clean and sanitised before the milk for raw milk product processing is transferred from the incoming container/tank to the businesses raw milk storage tank/silo which should be clearly labelled as to the contents. Interior surfaces of storage vessels should also be cleaned and sanitised to schedule each time they are emptied.

Raw milk processing

The processing of milk for raw milk products must:

- (a) result in no net increase in the level of pathogenic microorganisms that may be present in the milk at the commencement of processing; and
- (b) ensure that the raw milk product does not support the growth of pathogenic microorganisms.

The processing outcome to be met for a raw milk product (i.e. no net increase of pathogens during processing and no growth in the final product) needs to be delivered through the combination of control measures (hurdles) used during processing. Under food safety program obligations, the business would need to be able to validate and verify that the process used and final product meets the outcome required. An additional document, *Validation of Raw Milk Product Safety*, has been prepared to assist with validation requirements.

The food safety program for each raw milk product should identify the processing factors that impact on microbial growth and inactivation and include these as CCPs. The parameters (critical limits) that must be met and how these are verified (e.g. log sheets / analytical results) should also be specified. In relation to cheese manufacture, specific controls to be included in a business's food safety program should address:

- management of temperatures and time used during all stages of production
- management of acidification/pH reduction
- management of salting
- management of ripening/storage

This information should be recorded for each batch of product, such as in a cheese making log, to show the process is in control. Controls and records relevant to raw milk cheese manufacture are discussed below.

Temperature records

During the cheese making process, particularly the early stages of cheese making, milk and curd will be at temperatures that support the growth of pathogens.

The food safety program should document these stages and specify the temperature and time parameters to be met during production. Temperature records of milk and curd for each batch of raw milk product could include:

- at the time vat heating begins
- at the time starter culture is added
- at the time rennet is added
- at time of curd cutting
- temperature and time of heating/cooking regimen
- at time of draining whey
- at end of pressing or turning unpressed cheeses

Acidification

The food safety program should document the required level of acidification that must be achieved within a specified time and temperature for the type of cheese being produced. Records for each batch of raw milk product manufactured should clearly identify:

- the type and specific strain(s) used (starter and ripening cultures)
- batch details
- the inoculum level
- temperature of milk and time when starter added
- the pH (or titratable acidity)

The pH or titratable acidity should be measured at set/defined intervals to ensure that the starter is active and achieving the desired rate of acid production for that type of cheese and in the time required. This includes:

- at the time the vat heating begins
- at the time when adding rennet
- at the time of draining whey and hooping curds
- at the time of end pressing or turning unpressed curds
- at the time of milling
- at the time of brining

Salting

Depending on the type of cheese to be made, salting may be achieved by adding dry salt to the curds; pressing dry salt to the outside of newly-made cheese; brining cheese in a salt solution, or a combination of dry salting and brining. The salting procedure (level of addition and method of salting) should be documented in the food safety program and validated to ensure that the method of salt addition achieves the required level in the finished product and does not lead to uneven distribution. It is essential that the salt concentration required for safety is achieved in the final product.

The stage at which salting takes place, the amount of salt added or time for brining should be recorded for each production run:

- amount and type of salt added
- time brining begins
- brining time (time cheese is taken out of brine)

The management of brine tanks and maintenance of salt concentrations (% saturation) should also be documented in the food safety program and records kept. Salt concentrations should be monitored routinely (daily may be appropriate) using a hydrometer calibrated in an appropriate scale or a refractometer. The pH of the brine should also be monitored routinely and maintained at a pH value roughly equal to the cheese.

Ripening

Inactivation of pathogens during ripening is achieved through the combined effects of temperature control, pH and water activity. Temperature during ripening will vary depending on the type of cheese being made, stage in the ripening process and time-scale required for ripening the cheese. The food safety program should document the process and the work instructions related to the required maturation/ripening conditions. Records should be kept of actions taken (frequency and method) including:

- maturation temperature checks
- relative humidity checks
- turning of cheeses
- cheese washing or brushing
- spiking/piercing of internal mould ripened cheese.

Other records that may be included:

- batch records including traceability of ripening cultures or other surface treatment ingredients
- log of cheese faults and actions taken
- corrective action instructions.

3. Skills and knowledge

The business must demonstrate that persons undertaking activities related to the processing of milk for raw milk products have the required skills, knowledge and competencies to safely produce raw milk products.

A baseline requirement is that people involved in the handling of raw milk and processing of milk for raw milk products must have sufficient understanding of and skills in food safety and hygiene matters commensurate with their work activities. In order to manufacture raw milk products, a processing business must ensure that staff have demonstrated competencies relevant to the safe processing of milk for raw milk products.

It would be expected that the technical control of the process is under the supervision of a designated operator (e.g. cheese maker) who has the appropriate skills, knowledge and experience in the manufacture of raw milk dairy products. The cheese maker must have relevant experience, qualifications and training as required by the competent authority. Historical evidence (e.g. demonstrated skills and competencies in cheese making or other product manufacture over time) could be taken into account.

The food safety program should specify the competencies required by personnel in order to ensure the safe processing of milk for raw milk products. Records should be kept of relevant experience, qualifications and experience.

4. Process verification

A sampling and testing regime should be in place that includes both microbiological and chemical testing e.g. (salt content, pH, water activity, other as appropriate). The sampling frequency and schedule of tests required should be determined by the processing business in collaboration with the competent authority and documented in the food safety program.

Microbiological sampling and testing

Microbiological monitoring of raw milk products may include testing for both indicators and pathogens. Process hygiene criteria that are applicable to raw milk products is provided in the table below.

Test	Limit
E. coli	<10 (target) If exceeds100 cfu/g further investigation required
Coagulase positive Staphylococci	1000 cfu/g Testing should be undertaken at the time during processing when it would be expected that the number of staphylococci to be highest.
Staphylococcal enterotoxins (if coagulase positive staphylococci exceed 1000 cfu/g)	Not detected (5 x 25g sample)
L. monocytogenes	Not detected (target)
Salmonella	Not detected

The National Guidelines – Pathogen Management (Guidelines for Dairy industry response to pathogen detections in dairy product and the processing environment) document provides additional information on pathogen monitoring, including implementing an environmental monitoring program.

Chemical sampling and testing

Monitoring of critical limits for processing measures identified as CCPs should occur as appropriate throughout the manufacturing process. End product testing to verify pH, salt and moisture characteristics should also be scheduled and documented within the food safety program.

Appendix 1

Standard 3.2.2 Health and Hygiene Requirements

Division 4 - Health and hygiene requirements

Subdivision 1 – Requirements for food handlers

13 General requirement

A food handler must take all reasonable measures not to handle food or surfaces likely to come into contact with food in a way that is likely to compromise the safety and suitability of food.

14 Health of food handlers

- (1) A food handler who has a symptom that indicates the handler may be suffering from a foodborne disease, or knows he or she is suffering from a foodborne disease, or is a carrier of a foodborne disease, must, if at work
 - report that he or she is or may be suffering from the disease, or knows that he or she is carrying the disease, to his or her supervisor, as the case may be;
 - (b) not engage in any handling of food where there is a reasonable likelihood of food contamination as a result of the disease; and
 - (c) if continuing to engage in other work on the food premises take all practicable measures to prevent food from being contaminated as a result of the disease.
- (2) A food handler who suffers from a condition must, if at work
 - if there is a reasonable likelihood of food contamination as a result of suffering the condition – report that he or she is suffering from the condition to his or her supervisor; and
 - (b) if continuing to engage in the handling of food or other work take all practicable measures to prevent food being contaminated as a result of the condition.
- (3) A food handler must notify his or her supervisor if the food handler knows or suspects that he or she may have contaminated food whilst handling food.

15 Hygiene of food handlers

- (1) A food handler must, when engaging in any food handling operation
 - (a) take all practicable measures to ensure his or her body, anything from his or her body, and anything he or she is wearing does not contaminate food or surfaces likely to come into contact with food;
 - (b) take all practicable measures to prevent unnecessary contact with ready-to-eat food;
 - (c) ensure outer clothing is of a level of cleanliness that is appropriate for the handling of food that is being conducted;
 - (d) only use on exposed parts of his or her body bandages and dressings that are completely covered with a waterproofed covering;
 - (e) not eat over unprotected food or surfaces likely to come into contact with food;
 - (f) not sneeze, blow or cough over unprotected food or surfaces likely to come into contact with food;
 - (g) not spit, smoke or use tobacco or similar preparations in areas in which food is handled: and
 - (h) not urinate or defecate except in a toilet.

- (2) A food handler must wash his or her hands in accordance with subclause (4) -
 - (a) whenever his or her hands are likely to be a source of contamination of food;
 - (b) immediately before working with ready-to-eat food after handling raw food; and
 - (c) immediately after using the toilet.
- (3) A food handler must, when engaging in a food handling operation that involves unprotected food or surfaces likely to come into contact with food, wash his or her hands in accordance with subclause (4)
 - (a) before commencing or re-commencing handling food;
 - (b) immediately after smoking, coughing, sneezing, using a handkerchief or disposable tissue, eating, drinking or using tobacco or similar substances; and
 - (c) after touching his or her hair, scalp or a body opening.
- (4) A food handler must, whenever washing his or her hands
 - (a) use the hand washing facilities provided:
 - (b) thoroughly clean his or her hands using soap or other effective means, and warm running water; and
 - (c) thoroughly dry his or her hands on a single use towel or in another way that is not likely to transfer pathogenic microorganisms to the hands.
- (5) A food handler who handles food at temporary food premises does not have to clean his or her hands with warm running water, or comply with paragraph (4)(c), if the appropriate enforcement agency has provided the food business operating from the temporary food premises with approval in writing for this purpose.

Subdivision 2 – Requirements for food businesses

16 Health of persons who handle food – duties of food businesses

- (1) A food business must ensure the following persons do not engage in the handling of food for the food business where there is a reasonable likelihood of food contamination
 - (a) a person known to be suffering from a foodborne disease, or who is a carrier of a foodborne disease; and
 - (b) a person known or reasonably suspected to have a symptom that may indicate he or she is suffering from a foodborne disease.
- (2) A food business must ensure that a person who is known or reasonably suspected to be suffering from a condition and who continues to engage in the handling of food for the food business takes all practicable measures to prevent food contamination.
- (3) A food business may permit a person excluded from handling food in accordance with paragraph (1)(a) to resume handling food only after receiving advice from a medical practitioner that the person no longer is suffering from, or is a carrier of, a foodborne disease.

17 Hygiene of food handlers — duties of food businesses

- (1) Subject to subclause (2), a food business must, for each food premises
 - (a) maintain easily accessible hand washing facilities;
 - (b) maintain, at or near each hand washing facility, a supply of
 - (i) warm running water; and
 - (ii) soap; or
 - (iii) other items that may be used to thoroughly clean hands;

- (c) ensure hand washing facilities are only used for the washing of hands, arms and face: and
- (d) provide, at or near each hand washing facility -
 - (i) single use towels or other means of effectively drying hands that are not likely to transfer pathogenic microorganisms to the hands; and
 - (ii) a container for used towels, if needed.
- (2) Paragraph (1)(c) does not apply in relation to handwashing facilities at food premises that are used principally as a private dwelling if the proprietor of the food business has the approval in writing of the appropriate enforcement agency.
- (3) With the approval in writing of the appropriate enforcement agency, a food business that operates from temporary food premises does not have to comply with any of the requirements of paragraphs (1)(b)(i) or (1)(d) that are specified in the written approval.

18 General duties of food businesses

- (1) A food business must inform all food handlers working for the food business of their health and hygiene obligations under Subdivision 1 of this Division.
- (2) A food business must ensure that any information provided by a food handler in accordance with Subdivision 1 of this Division is not disclosed to any person without the consent of the food handler, except the proprietor or an authorised officer, and that the information is not used for any purpose other than addressing the risk of food contamination.
- (3) A food business must take all practicable measures to ensure all people on the food premises of the food business –
- (a) do not contaminate food;
- (b) do not have unnecessary contact with ready-to-eat food; and
- (c) do not spit, smoke, or use tobacco or similar preparations in areas where there is unprotected food or surfaces likely to come into contact with food.