

CHECKLIST FOR SUBMITTING PRO FORMA

- Completed pro forma
- Raw milk laboratory reports (microbiological results)
- Starter culture information sheet
- Label of raw milk cheese
- Laboratory results for cheese composition
- Outline of proposed changes to FSP
- Challenge testing data and report (if applicable)
- Additional process information not captured in this form (if applicable)

Completed pro forma with signed declaration and required documents must be attached to your licence application and mailed to:

Attention: Licensing unit

NSW Food Authority

PO Box 6682

SILVERWATER NSW 1811

Food.licensing@dpi.nsw.gov.au

For more information, please contact the Food Authority on 1300 552 406

License application for production of raw milk cheese must be accompanied by a completed pro forma. Applications without a pro forma attached will not be processed.

The technical assessment of a pro forma will be completed once all technical information has been reviewed and applicants will be advised of the outcome in writing.

You must not commence operations until you are informed that your licence application has been processed. If the premises are found to be operating without a licence, enforcement action will be taken.

PRODUCTION OF RAW MILK CHEESE TECHNICAL ASSESSMENT

To manufacture raw milk cheese in NSW, a business must be licensed and have their raw milk cheese process approved by the NSW Food Authority (Food Authority).

This pro forma collects the information required by the Food Authority to approve a raw milk cheese process and assess its compliance against Standard 4.2.4 of the Food Standards Code (the Code).

CONTENTS

CHECKLIST FOR SUBMITTING PRO FORMA	1
1. STANDARD 4.2.4 - RAW MILK CHEESE PRODUCTION	3
a) RAW MILK SUPPLY	4
b) MILK TRANSPORT	7
c) PROCESSING OF MILK FOR RAW MILK CHEESE	7
d) MONITORING	7
2. INFORMATION REQUIRED FOR TECHNICAL ASSESSMENT	8
3. RAW MILK CHEESE DECLARATION	11
4. CHALLENGE TESTING	12

1. STANDARD 4.2.4 - RAW MILK CHEESE PRODUCTION

[Standard 4.2.4](#) of the Code permits the production of a raw milk cheese, but it must be produced in accordance with an approved documented Food Safety Program (FSP).

Divisions 1 to 4 of Standard 4.2.4 are generally applicable while Division 5 sets out additional requirements for raw milk cheese. Food Standards Australia New Zealand (FSANZ) has prepared a supporting document to the requirements of Standard 4.2.4 – [Primary Production & Processing Requirements for Raw Milk Cheese](#).

In NSW, businesses wanting to produce a raw milk cheese must complete a production process pro forma that will be used to assess compliance with Standard 4.2.4. A pro forma is a written description of the steps used by a manufacturer to make a product.

Critical information collected in this pro forma will be entered into the *Raw Milk Cheese Decision Support Tool* to determine if a raw milk cheese complies with Standard 4.2.4.

The *Raw Milk Decision Support Tool* is based on published data and novel research funded by Australian and New Zealand regulatory agencies and developed by the University of Tasmania's Centre for Food Safety and Innovation within the Tasmanian Institute of Agriculture. A copy of this tool can be found at the Food Authority's website.

Essentially a business must:

1. Demonstrate that they can source high quality raw milk that complies with the requirements.
2. Demonstrate that the market ready cheese will not support the growth of pathogenic bacteria, in-particular *Listeria monocytogenes*.
3. Demonstrate that during the process of cheese making (fermentation and maturation) there is no net increase in pathogenic bacteria.

The business' FSP will be audited as part of the approval process to manufacture raw milk cheese, and at least annually thereafter.

The licensing audit and pro forma must demonstrate that the production processes used (raw milk supply, storage and transport conditions, fermentation and maturation) are effective in reducing the risk of foodborne illness to a safe level.

A separate pro forma is required for each different product and process type – that is where the process is significantly different and/or different ingredients are used e.g. different milk suppliers, different type of cheese.

Information provided in this pro forma will be treated in strict confidence.

Once approved, the first five production batches of cheese must be tested to verify that the production process does make a product that complies with the Code. Cheese must be tested for pH, water activity, *Listeria* spp, *E. coli*, *Salmonella* and *S. aureus*. Test results must be forwarded to food.testresults@dpi.nsw.gov.au.

Subsequent batches must be tested per the [Food Safety Scheme Manual](#).

a) RAW MILK SUPPLY

High quality raw milk is an essential ingredient to produce safe raw milk cheese. The milk supply chain - producer, transporter and processor, if there is one, will be audited to confirm that all stages and handling steps comply with requirements outlined in Standard 4.2.4.

[Primary Production & Processing Requirements for Raw Milk Cheese](http://www.dairysafe.vic.gov.au/publications-media/regulations-and-resources/guidelines/337-farmers-checklist-1/file) explains the requirements and establishes milk sanitary standards necessary for raw milk cheese production. A useful checklist for these requirements can be found at <http://www.dairysafe.vic.gov.au/publications-media/regulations-and-resources/guidelines/337-farmers-checklist-1/file>

These guidelines are summarised in Tables 1 & 2. Table 1 explains how compliance with milk sanitary requirements can be demonstrated. Table 2 outlines the recommended monitoring criteria for on farm bulk milk used to make raw milk cheese using a moving window concept. Under a moving window concept the last five batches of milk are compared to determine the microbiological quality of the raw milk. When milk for raw milk cheeses fails these criteria, the milk should be diverted to other uses. This approach provides a practical and cost effective way of continuously checking performance and facilitates early identification of the need for corrective action.

Table 1: Requirements for farmers producing milk for raw milk cheese

Requirement (Std 4.2.4)	Expectation	Limit/evidence	Desk audit	Ongoing auditing
Documented FSP	Documented and validated FSP addressing additional requirements under Std 4.2.4	Required	FSP in place (Including a detailed HACCP process and identification of CCPs)	Yes - Evidence that FSP is in operation
Animal health, identification, and tracing	Producer controls disease through herd management and vaccination	Required	Documented Herd Health Program	Animal treatment records Annual veterinary inspection
	Diseased animals are segregated from herd and not introduced into herd			
	Producer has procedures and practices designed to control mastitis	Mean somatic cell count: Bovine <200,000/ml Other species <10 ⁶ /ml	Documented in FSP	Somatic cell count records (May include data on individual animals)
	Animals identified with non-removable tags	Required	Documented animal id system	Yes - Milking records
	Cows treated with veterinary medicines are identified	Required	Documented in FSP	Yes - Milking records

Requirement (Std 4.2.4)	Expectation	Limit/evidence	Desk audit	Ongoing auditing
Control over inputs	Silage must not be fed to animals milked for milk for raw milk cheese	Required	Documented in FSP: Feed records	Yes - Approved alternative compliance is possible
	Potable water in use for contact surfaces, teats and hands	Town water, treated ground or surface water used	Documented in FSP	Review testing data
Health and hygiene requirements	Procedures covering personal hygiene: hand washing, clothing, illness, covering wounds, etc	Required	Documented in FSP: Hand washing policy, clothing requirements	Yes
Milking practices and milk cooling	Clean and dry teats before milking	Required	Documented in FSP	Yes
	Producer practises good milking hygiene	Total plate count <25,000 cfu/ml	Documented in FSP	TPC records (weekly on bulk milk)
	Producer controls faecal contamination	<i>E. coli</i> <10 cfu/ml Limit 100 cfu/sample (using the moving window concept, refer to Table 2)	Documented in FSP	<i>E. coli</i> records (weekly on bulk milk)
	Producer monitors pathogen status of herd	<ul style="list-style-type: none"> <i>Salmonella</i> ND/25ml <i>L. monocytogenes</i> ND/25 ml; <i>S. aureus</i> <100cfu/ml 	Documented in FSP	Pathogen records (weekly, then monthly if results are good)
	Milk cooled to 6°C within 2 hours of milking, then stored at 5°C (unless used within 2 hours of milking)	Required - Verify alternative compliance arrangements	Documented in FSP	Review milking records
	Clean and sanitise dairy equipment	Required	Documented in FSP	Yes
Control non-conforming product	Separate raw milk cheese milk from other milk	Required	Documented in FSP	Yes

Table 2: Recommended raw milk sanitary requirements (using a moving window concept)

Frequency	Criteria	Compliance		
		Target	Upper limit	Lower limit
		Four or more batches of the last five batches must be below this level	No batch of the last five batches may be above this level	One batch of the last five batches may be above this level but below the upper limit
Weekly	Bulk milk cell count (BMCC)	<200,000 cells/ml for bovines	400,000 cells/ml	200,000 cells/ml
		<1,000,000 cells/ml other species	No upper limit	1,000,000 cells/ml
	Total plate count (TPC)	<25,000 cfu/ml	50,000 cfu/ml	25,000 cfu/ml
	<i>E. coli</i> count	<10 cfu/ml	100 cfu/ml	10 cfu/ml
Routinely	<i>S. aureus</i>	<100 cfu/ml	1000 cfu/ml	100 cfu/ml
	<i>L. monocytogenes</i>	Not detected in 25ml	Not applicable	Not applicable
	<i>Salmonella</i>	Not detected in 25ml	Not applicable	Not applicable
Note1: Milk receival factories or payment laboratories usually report a scan result or individual bacteria count rather than a total plate count.				
Note 2: Over the course of a year, even some high-quality herds might exceed these standards. When this occurs, milk must be diverted to other uses such as pasteurising or for cooked curd cheeses. Herds that exceed these standards more frequently should not be considered for raw milk cheese production until the sanitary issues have been resolved.				
Note 3: Records that demonstrate compliance with milk sanitary requirements over an extended period must be available at audit. At a minimum, weekly records must be provided but results for every pick up should be provided when they are available.				

b) MILK TRANSPORT

Standard 4.2.4 division 5 subdivision 3 establishes requirements for the transport of milk for raw milk cheese production. These requirements are outlined in Table 3.

Table 3: Milk transportation additional and specific requirements

Requirement (Std 4.2.4)	Expectation
Documented Food Safety Plan	Documented and validated FSP addressing additional requirements under Std 4.2.4
Temperature control	Milk must not exceed 8°C at any point between the collection of raw milk from the dairy primary production business that produced it and the delivery of that raw milk to a dairy processing business for processing
Segregation of milk for raw milk cheese	Segregate milk

c) PROCESSING OF MILK FOR RAW MILK CHEESE

Standard 4.2.4 of the Code requires that the FSP includes a wide range of control measures. Some of the control measures relating to cheese processing provide important information for the technical assessment of the raw milk cheese. Compliance with these requirements will be confirmed during audit. Specific control measures as outlined in the Code are:

- starter culture activity
- pH reduction
- salt concentration and moisture content
- fermentation time and temperature
- maturation time and temperature

d) MONITORING

Microbiological verification of the safety of the product is also required. As raw milk cheese will not allow *L. monocytogenes* to grow then according to Schedule 27 of the Code, the limit is <100 cfu/g. However, the target for raw milk cheese is not detected in 25g.

Product to be tested	Test to be conducted	Target
Cheese made from raw milk	Coagulase positive staphylococci	Not exceeding 100 cfu/g
	<i>E. coli</i>	Not exceeding 10 cfu/g
	<i>L. monocytogenes</i>	Not detected in 25 g
	<i>Salmonella</i>	Not detected in 25 g

The frequency of product testing should be high when production first commences and may be reduced when it becomes clear that the process adequately addresses food safety risks and is well controlled.

Batch records will be audited to confirm that appropriate information has been recorded for the specific requirements listed above and that they are consistent with the information provided in this pro forma.

The records must be available for auditors to review and must be kept for 2 years.

2. INFORMATION REQUIRED FOR TECHNICAL ASSESSMENT

The following information is required for a technical assessment of your raw milk cheese process to confirm that the procedure will produce a safe product. Complete information will result in a faster approval turnaround. **Missing information will slow down the approval process and may not allow for a technical assessment.** Most food laboratories will be able to assist in any analytical testing required to complete this pro forma.

COMPANY INFORMATION

Company name:

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License number:

.....

Product name:

.....

Contact person:

.....

Raw milk supplier:

.....

Raw milk supplier licence number:

.....

1. Raw milk cheese characteristics				
1a	Type of cheese	<input type="checkbox"/> Very hard	<input type="checkbox"/> Hard	<input type="checkbox"/> Semi hard
		<input type="checkbox"/> Internal mould ripened	<input type="checkbox"/> Mascarpone	<input type="checkbox"/> Brined
		<input type="checkbox"/> Soft, surface ripened	<input type="checkbox"/> Chevre	<input type="checkbox"/> Cottage/fresh cheese
		<input type="checkbox"/> other please specify		
1b	pH of finished cheese			
1c	Water activity of finished cheese			
	or Measured moisture content of finished cheese (%w/w) and Measured salt content of finished cheese			g/100g g/100g
1d	Lactic acid concentration in the aqueous phase (mM)			mM
	Or measured lactic acid concentration of the cheese (mg/100g) <i>(if lactic acid concentration is only available in mg/100g then moisture content of finished cheese must be provided above in 1c)</i>			mg/100g
1e	Total fat			g/100g

1f	Batch size		kg
2. Milk quality and handling			
2a	Type of milk	<input type="checkbox"/> Cow	<input type="checkbox"/> Buffalo
		<input type="checkbox"/> Sheep	<input type="checkbox"/> Goat
		<input type="checkbox"/> other, please specify	
2b	BMCC (average for last 5 batches of milk)		count/ml
2c	TPC (average for last 5 batches of milk)		cfu/ml
2d	<i>E. coli</i> (latest batch)		cfu/ml
2e	<i>S. aureus</i> (latest batch)		cfu/ml
2f	<i>Salmonella</i> (latest batch) (detected in 25g)	<input type="checkbox"/> yes	<input type="checkbox"/> no
2g	<i>Listeria monocytogenes</i> (latest batch) (detected in 25g)	<input type="checkbox"/> yes	<input type="checkbox"/> no
2h	Has the milk failed any of the criteria listed in Table 2 on page 6 of this pro forma in the last five samples tested. <i>Please attach laboratory reports</i>	<input type="checkbox"/> yes	<input type="checkbox"/> no
2i	Is the milk used to make cheese within two hours of milking	<input type="checkbox"/> yes (go to section 3)	<input type="checkbox"/> no
2j	Temperature of the milk 2 hours after the completion of milking		°C
2k	Temperature of the milk before transport or commencement of cheese making		°C
2l	Length of time milk is held chilled before transport or commencement of cheese making		hours
3. Storage and transport of milk			
3a	Average temperature of the milk during transport		°C
3b	Maximum temperature of the milk during transport		°C
3c	Time elapsed between end of milking and start of cheese production		hours

4. Milk tempering		
4a	Temperature of the milk before tempering	°C
4b	Temperature of the milk prior to the addition of a starter culture	°C
4c	Time taken to reach final temperature	minutes
4d	Holding time at final temperature prior to addition of starter culture	minutes
4e	What is the brand and name of starter culture <i>Please attach starter culture information sheet to this pro forma</i>	
4f	Storage temperature of starter culture e.g. frozen, refrigerated, room temperature	
4g	How is the starter culture reconstituted e.g. tap water, distilled water, time, temperature	
4h	How much starter culture is added per batch	g
5. Fermentation and moulding		
5a	Temperature of the milk during fermentation	°C
5b	Time elapsed from start of fermentation until cutting	hours
5c	Maximum temperature of the cheese making process	°C
5d	Duration of process	hours
5e	pH at cutting	
5f	pH at whey off	
6. Maturation		
6a	Temperature of the maturation/ripening period	°C
6b	Duration of the maturation /ripening period	days

7. Packaging and labelling		
7a	Type of packaging (e.g. individually vacuum packed and loose in cartons, x units in a vacuum pack)	
7b	Description of product on label	
7c	Shelf life	days
7d	Recommended storage conditions on label e.g. store under refrigeration	
7e	How are batches identified e.g. use by, batch number	
7f	Does the product undergo any further processing prior to sale e.g. slicing	
8. Food Safety Program		
8a	To make a raw milk cheese your FSP will need to be updated to reflect the processes and hazards specific to manufacturing raw milk cheese. Please provide an outline of the proposed adjustments to your FSP to comply with Std 4.2.4	

If there is any part of the process that has not been captured by this pro forma (e.g. transportation during processing, use of additional ingredients etc.).

Please attach an outline of these processes to this completed pro forma.

3. RAW MILK CHEESE DECLARATION

I certify that the information detailed in this raw milk cheese process pro forma is an accurate description of the process used for the product specified.

Name (please print)

Position

Signed

Date

4. CHALLENGE TESTING

This section only needs to be completed if the initial application has been rejected. If the *raw milk cheese decision support tool* cannot clearly determine whether the process produces a safe raw milk cheese, then the cheese making process needs to be altered or challenge testing needs to be conducted.

Standard 4.2.4 only permits the production of certain types of cheese – specifically:

- a. those where the finished cheese will not support the growth of pathogenic bacteria, with *L. monocytogenes* usually being the target pathogen
- b. those where no net increase in numbers of pathogenic bacteria occurs following the completion of fermentation and maturation

In many cases the potential for pathogen growth in cheese can be assessed based on the physicochemical nature of the cheese which include pH, water activity, salt-in-moisture and the concentration of lactic acid. Semi-hard to hard and blue vein cheeses are most likely to meet these requirements. In some cases, assessment based on the physicochemical information does not provide a clear outcome. In these cases, the cheese maker might choose to adjust manufacturing conditions or undertake a challenge study. A challenge study is an off-site laboratory trial where bacteria of interest are added at the start of the cheese making process and their numbers are traced through fermentation, maturation and shelf life.

If bacterial pathogens do not grow in the finished cheese, then the information supplied from challenge testing will be used to provide evidence that pathogenic bacteria will not increase during the cheese making process.

For information on raw milk cheese challenge testing please refer to

Challenge testing of Microbiological Safety of Raw Milk Cheese: The Challenge Trial Toolkit'

available at <https://www.mpi.govt.nz/dmsdocument/20621-Challenge-testing-of-microbiological-safety-of-raw-milk-cheeses>

This toolkit provides essential background reading for conducting challenge testing on raw milk cheese as well as providing example protocols.

If challenge testing is required, please provide the following information, complete the tables and attach a challenge testing report to this pro forma.

Location of challenge testing:

Laboratory responsible for challenge testing:

Bacterial strains used:

Point of inoculation:

Challenge testing report attached yes no not applicable

Microbiological change

Record the levels of *E. coli*, *Listeria*, *S. aureus* and *Salmonella* (cfu/g or cfu/ml) at different times during the process, from the tempering of raw milk through to coagulation and maturation. Time points at which to measure will be dependent on process but should be after a significant change in the cheese e.g. after tempering, after fermentation, during cutting, after removal of the whey, after pressing and after maturation.

	Test	Batch 1	Batch 2	Batch 3	Batch 4	Batch 5
Inoculum level	<i>E. coli</i>					
	<i>Listeria</i>					
	<i>S. aureus</i>					
	<i>Salmonella</i>					
	<i>E. coli</i>					
	<i>Listeria</i>					
	<i>S. aureus</i>					
	<i>Salmonella</i>					
	<i>E. coli</i>					
	<i>Listeria</i>					
	<i>S. aureus</i>					
	<i>Salmonella</i>					
	<i>E. coli</i>					
	<i>Listeria</i>					
	<i>S. aureus</i>					
	<i>Salmonella</i>					
	<i>E. coli</i>					
	<i>Listeria</i>					
	<i>S. aureus</i>					
	<i>Salmonella</i>					
End of maturation	<i>E. coli</i>					
	<i>Listeria</i>					
	<i>S. aureus</i>					
	<i>Salmonella</i>					

Change in pH

The change in pH during the cheese making process is an important safety hurdle.

Record the pH at different times during the process, from the addition of the starter culture through to coagulation and maturation. Time points at which to measure will be dependent on process but should be after a significant change in the cheese e.g. after fermentation, during cutting, after removal of the whey, after pressing and after maturation.

For one batch, the lactic acid profile must be recorded. Take and chill a sample at each time period (time period is set by the cheesemaker, a minimum of four time periods are required) and have a laboratory measure the percentage of lactic acid. The lactic acid profile during the cheese making process will assist with assessment of the potential for growth of pathogenic bacteria.

Time	Batch 1 pH lactic acid	Batch 2 pH lactic acid	Batch 3 pH lactic acid	Batch 4 pH lactic acid	Batch 5 pH lactic acid
Starter culture added					
Finished Curd					

Change in salt, moisture and water activity

Record the salt concentration and the moisture content at the start of maturation and the end of maturation. The water activity (aw) of at least one of the batches must be measured to assist with assessment of the potential for growth of pathogenic bacteria.

	Test	Batch 1	Batch 2	Batch 3	Batch 4	Batch 5
Start of maturation	salt					
	moisture					
	aw					
End of maturation	salt					
	moisture					
	aw					

Relative humidity and air movement

If relative humidity and air movement /number of air exchanges are controlled, please also note these criteria.

Criteria	
Relative humidity	
Air movement / exchange	

END OF PRO FORMA