

Manufacturers of raw milk cheese

Qualifying criteria

Under Standard 4.2.4, manufacturers of raw milk cheese will need to meet additional and more stringent requirements than those manufacturing cheese from pasteurised milk. These include only making cheese that will not support the growth of pathogens and managing the cheese making process so there is no net increase in pathogens. The two specific requirements are referred to as qualifying criteria and are described below.

Requirement (Standard 4.2.4)	Comments
A raw milk cheese must not support the growth of pathogenic microorganisms [Standard 4.2.4, Clause 34 (c)]	While a range of pathogens may be present in a raw milk cheese (e.g. Salmonella, pathogenic <i>E. coli</i> , <i>Listeria monocytogenes</i>) the main concern is with those that may grow during storage Under the requirements of the Food Standards Code, perishable and high risk foods must be stored at 4°C, hence the principal pathogen of concern is <i>L. monocytogenes</i>
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 [Standard 4.2.4, Clause 34 (b)]	A range of pathogens may be present in raw milk (e.g. Salmonella, pathogenic <i>E. coli</i> , <i>S. aureus</i> , <i>L.monocytogenes</i>) and during the initial phase of cheesemaking, where the starter culture is added and the milk heated, these organisms may grow. During subsequent cheesemaking steps, draining, salting, and maturation/ripening these organisms may die off

The way manufacturers may demonstrate conformance with these qualifying criteria is demonstrated using the following decision trees (Table 1 and Table 2).

Table 1: Raw milk cheese must not support growth of pathogenic microorganisms

Requirement	Information required	Check	Decision
Raw milk cheese does not support the growth of pathogens	Manufacturer has identified pathogens that may grow in the cheese (finished product under defined storage, marketing, and handling conditions)	<input type="checkbox"/> Yes <input type="checkbox"/> No	Undertaken as part of their HACCP process, and documented in their food safety program If no, have the manufacturer resubmit
	Physico-chemical properties of the cheese prohibit the growth of identified pathogens e.g. <i>L. monocytogenes</i> will not grow at pH <4.4 or a water activity <0.92, or a combination of pH 5.0 and water activity of 0.94	<input type="checkbox"/> Yes <input type="checkbox"/> No	If yes, the manufacturer may be approved conditionally, with the need to: (a) Demonstrate no net increase in pathogens during cheesemaking as documented in their food safety program (FSP), and (b) Provide evidence of the capacity to consistently produce raw milk cheese with these physico-chemical properties as documented in their FSP
	Evidence that a detailed catalogue of raw milk cheese properties inhibit identified pathogens e.g. water activity, salt concentration, pH, redox potential, lactate levels, etc This can be demonstrated by reference to scientific literature for the specific cheese: pathogen combination or using pathogen growth modelling tools e.g. Augustin model, Dalgaard model	<input type="checkbox"/> Yes <input type="checkbox"/> No	If yes, the manufacturer may be approved conditionally, with the need to: (a) Demonstrate no net increase in pathogens during cheesemaking as documented in their FSP, and (b) Provide evidence of the capacity to consistently produce raw milk cheese with these physico-chemical properties as documented in their FSP
	Challenge studies for the specific raw milk cheese using identified pathogens This is achieved by detailed laboratory studies using the raw milk cheese and identified pathogens	<input type="checkbox"/> Yes <input type="checkbox"/> No Manufacture of this cheese from raw milk is prohibited	If yes, the manufacturer may be approved conditionally, with the need to: (a) Demonstrate no net increase in pathogens during cheesemaking as documented in their FSP, and (b) Provide evidence of the capacity to consistently produce raw milk cheese with these physico-chemical properties as documented in their FSP

Table 2: No net increase in level of pathogenic microorganisms in a raw milk cheese

Requirement	Information required	Check	Decision
Level of pathogenic microorganisms in a raw milk cheese must not exceed the level of pathogenic microorganisms in the raw milk	<p>Manufacturer describes how the cheese will be made and describes in detail key processing steps and target cheese attributes <i>i.e.</i> titratable acidity (or pH), salt concentration, moisture in the fat-free-substance (MFFS), maturation conditions (time and temperature), etc</p> <p>Documented in their food safety plan with listing of CCPs and monitoring regime</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<p>If yes, includes a sampling regime to demonstrate compliance.</p> <p>If no, have the manufacturer resubmit</p>
	<p>Production data showing the conditions that prevail during cheesemaking that prevent pathogen growth and achieve the requirement of no increase in pathogen levels between raw milk and final product</p> <p><i>e.g.</i> rapid acidification of raw milk by lactic acid producing starter cultures, combination of pH and salt-in-moisture phase during maturation/ripening that prevents pathogen growth</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<p>If yes, the manufacturer may be approved conditionally, with the need to provide evidence of the capacity to consistently control the manufacture raw milk cheese as documented in their food safety program</p> <p>If no, have the manufacturer provide scientific data such as challenge studies</p>
	<p>Challenge studies for the specific raw milk cheese using identified pathogens</p> <p>This is achieved by detailed laboratory studies using the raw milk cheese and identified pathogens</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No Manufacture of this cheese from raw milk is prohibited	<p>If yes, the manufacturer may be approved conditionally, with the need to provide evidence of the capacity to consistently control the manufacture raw milk cheese as documented in their food safety program</p>

Further details of these requirements are listed in Division 5 (Additional requirements for raw milk cheese) of Standard 4.2.4, and described in Supporting Documents 1, 2 and 3 (FSANZ, 2014).

Additional requirements

Additional requirements for manufacturers of raw milk cheese can be grouped as follows:

Documented food safety program (FSP)	Milk receipt and storage	Control of specific food safety hazards	Microbiological testing of finished product
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Requirement (Standard 4.2.4)	Expectation	Limit/evidence	Desk audit	Ongoing auditing
Documented FSP	Documented and validated FSP addressing additional requirements under 4.2.4	Record data on starter activity, pH reduction, salt and moisture content, storage time and temperature	FSP in place (Including a detailed HACCP process, identification of CCPs, monitoring, and record keeping)	✓ Evidence that FSP is in operation
Milk receipt and storage	Temperature control over raw milk at receipt	Milk for raw milk cheese must not exceed 8°C at any point between collection from producer and delivery to cheese making business	Documented in FSP Receipt records	✓ Milk receipt records Alternative compliance needs to be approved
	Raw milk cheese must not be made from milk that was milked more than 24 hours before processing	Required	Documented in FSP Receipt records	✓ Milk receipt records Alternative compliance needs to be approved
	Milk for raw milk cheese must be kept separate from milk used or intended for other dairy products	Required	Documented in FSP Receipt records	✓ Milk receipt records
Control of specific food safety hazards	Prior to the start of processing, milk for raw milk cheese must be monitored to ensure its suitability	TPC 100,000cfu/ml <i>E. coli</i> <100/ml	Documented in FSP	✓ Testing records
Microbiological testing of finished product	Product meets the microbiological criteria in Standard 1.6.1	<i>E.coli</i> <10 cfu/g <i>Salmonella</i> ND/25g <i>L.monocytogenes</i> ND/25g Staphylococcal enterotoxin ND/25g	Documented in FSP	Pathogen records (weekly initially, then monthly if results are reliably good)

The above are in addition to standing requirements under Standard 4.2.4, which include pre-requisite program requirements such as servicing and maintenance of equipment, calibration of measuring equipment, pest control, cleaning and sanitation, etc.