Supporting document 1

Technical Assessment – Proposal P1007

Primary Production & Processing Requirements for Raw Milk Products

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Introduction

The Code specifies processing requirements for dairy products that essentially require all products (except for a number of cheeses[1]) to have undergone pasteurisation or an equivalent pathogen reduction process. These processing measures have been integral to ensuring the high level of public health and safety associated with dairy products in Australia.

In October 2008, through chain food safety requirements for milk production and processing came into effect in the Code through Standard 4.2.4 – Primary Production and Processing Requirements for Dairy Products. This Standard was developed specifically to cover milk production, transport and processing where pasteurisation is used as a critical control in product manufacture. The second stage of the development of Standard 4.2.4 (Proposal P1007) is to elaborate through chain requirements for the production of raw milk products[2] where it can be established that an acceptable level of public health and safety can be met.

This Technical Assessment presents the scientific basis for the approach taken and risk management decisions made in assessing Proposal P1007. It draws on a number of microbiological risk assessments and other reports undertaken by FSANZ[3]:

- *A Risk Profile of Dairy Products in Australia (FSANZ, 2006)*
- *Microbiological Risk Assessment of Raw Cow Milk (FSANZ, 2009a)*
- *Microbiological Risk Assessment of Raw Goat Milk (FSANZ, 2009b)*
- *Microbiological Risk Assessment of Raw Milk Cheese (FSANZ, 2009c)*
- *Assessment of Potential Health Benefits Associated with Raw Milk (review of cited literature)*
- *Raw Milk Consumer Behaviour and Attitudes Study (Colmar Brunton, 2009)*

The Technical Assessment is structured in two sections. The first section presents a through chain analysis of the microbiological hazards/risks associated with raw milk and identifies primary production and processing factors that impact on pathogen control as well as consumer knowledge, motivations and behaviours in relation to raw milk products.

The second section describes the risk management framework developed for assessing raw milk products and the level of risk determined for each product category, including the additional control measures that would be required for the production of raw milk products. It also provides an assessment of consumer issues that have been raised relating to consumer demand.

[1] Processing requirements for cheese and cheese products allows for some alternative processing measures to pasteurisation which include thermisation in combination with storage, and curd cooking (at >48°C) in combination with storage and a minimum moisture content. A number of specified imported cheeses are also permitted (Roquefort, Emmental, Gruyere, Sbrinz).

[2] For the purpose of this Proposal, **raw milk products** are those which have not undergone pasteurisation or an equivalent pathogen reduction process.

[3] These documents are available on the FSANZ website http://www.foodstandards.gov.au/standardsdevelopment/proposals/proposalp1007primary3953.cfm

SECTION 1: Through Chain Assessment

1. Primary Production

A range of microorganisms may be associated with dairy animals, the environment in which they are kept and the milking equipment used that may result in the contamination of milk. This section on primary production identifies those microbiological hazards of greatest public health concern; the primary production factors that impact on their presence, and the current requirements relating to on farm milk production.

1.1 Microbiological hazards

Pathogens typically associated with raw milk include *Coxiella burnetii*, *Brucella* spp. (*B. abortus* in cattle and *B. melitensis* for goat and sheep milk), *Salmonella* spp., *Yersinia enterocolitica*, *Campylobacter jejuni*, *Listeria monocytogenes*, enterotoxigenic *Staphylococcus aureus* and pathogenic *Escherichia coli*. (ICMS, 1998). Those organisms more frequently associated with human illness linked to the consumption of raw milk and raw milk products are (Jaros *et al.*, 2008):

- *Campylobacter* spp.
- *E. coli* spp.
- *L. monocytogenes*
- *Salmonella* spp.

The prevalence and contamination routes for these hazards are discussed further below.

Other pathogen associations include:

- *Toxoplasma gondii* (in raw goat milk)
- *Burkholderia pseudomallei* (affecting goats and sheep in tropical and sub-tropical regions. Infection, however, is mainly through direct contact of skin wounds and abrasions).
- *Cryptosporidium* spp.

*A characterisa*tion of microbiological hazards associated with dairy products is provided in *A Risk Profile of Dairy Products in Australia* (FSANZ, 2006).

1.1.1 Campylobacter jejuni

Many animals carry *C. jejuni* (responsible for most cases of human campylobacteriosis) as part of their normal intestinal flora with no evidence of illness. The occurrence of *C. jejuni* in dairy animals varies but most studies, primarily in cattle, report less than 50% prevalence[4] in animals tested (FSANZ, 2009a). Studies in sheep (meat production) show a similar occurrence (Wallace, 2003) though an Australian study reported a higher prevalence in cattle than sheep (Bailey *et al*., 2003). In the dairy herds sampled, Campylobacter prevalence ranged from 0 to 24%, with a median prevalence reported of 6%.

Contamination of raw milk by *C. jejuni* may occur as a result of faecal contamination of teats which then contaminate milking equipment and lines during the milking process.

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[4] Prevalence refers to the proportion of animals affected by a disease agent (tested positive) in a particular population at a specific time. It can relate to the number of cases/carriers within a herd or the proportion of herds affected within a study.

C. jejuni has also been reported to have caused mastitis in cows resulting in direct shedding into milk (ICMSF, 1996) although this is rare. There is little Australian data on the prevalence of *C. jejuni* in bulk raw milk but there have been a number of outbreaks of campylobacteriosis in Australia (5 between 1995 and 2004) linked to the consumption of raw milk (OzFoodNet data: 1995-June 2004). International surveys of bulk raw milk (cow) have reported prevalence of *Campylobacter* from 0 to 18.2%.

1.1.2 E. coli *spp*

E. coli are a common part of the intestinal flora of humans and other warm-blooded animals. Of greatest concern for raw milk are pathogenic strains such as enterohaemorrhagic *E. coli* (EHEC[5]) which can cause severe disease in humans and for which the intestinal tract of ruminants (particularly cattle and sheep) are major reservoirs. There have been many studies looking at the prevalence of EHEC (primarily O157:H7) in cattle internationally and in Australia which have reported a range of prevalence from 0 – 20.6% (FSANZ, 2009a). A survey of Australian dairy cattle in 1997-1998 found 1.9% of faecal samples taken on farm to be positive for *E. coli* O157 (Cobbold, 2000) while a survey of sheep for *E. coli* O157 found 0.1% of faecal samples taken on farm to be positive (Djardjevic, 2001).

While *E. coli* mastitis can occur the level is low and intramammary E. coli O157 infections have not been documented. Contamination of raw milk generally occurs as a result of faecal contamination of the animal, particularly the teats, which directly contaminate milk during milking operations. Contamination of *E. coli* O157 in Australian milk (cow) has been reported at 1-3% (FSANZ, 2009a). There are no Australian data on the prevalence of EHEC in goat and sheep milk.

1.1.3 L. monocytogenes

L. monocytogenes is commonly found in the environment and may be present in the intestinal tract of various animal species. Listeriosis in ruminants can result in meningoencephalitis, septicaemia or abortion in pregnant animals though many animals may carry *L. monocytogenes* without any evidence of disease. Clinical disease is more common in small ruminants.

There is seasonal variation in the prevalence of *Listeria* spp, in ruminants with higher levels observed in winter than summer. Epidemiological studies (Knightingale *et al*., 2004; Nightingale *et al*., 2005; Esteban *et al*., 2009) have also shown a difference in prevalence and transmission characteristics between bovine and small ruminant farms. In these studies a significantly higher prevalence of *L. monocytogenes* positive samples has been reported for bovine farms[6] than for small ruminant farms. It is indicated that faecal shedding in cattle is much greater than in small ruminants resulting in bovine farms maintaining a higher prevalence of *L. monocytogenes* through cattle acting as amplifiers of the organism by re-contaminating the environment. on small ruminant farms, a higher prevalence in feedstuffs than faecal samples has been observed indicating feed as a primary transmission route.

While mastitis due to *L. monocytogenes* has been documented it is rare and contamination of raw milk by *L. monocytogenes* results primarily from faecal and environmental contamination. While there is little Australian survey data on the presence of *L. monocytogenes* in raw cow milk, overseas survey data from the last 10 years typically report less than 5% prevalence in raw cow milk (FSANZ, 2009a), though levels as high as 17% have also been reported.

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[5] The term EHEC is commonly used to refer to a subgroup of Shiga Toxin producing *E. coli* (STEC) that cause haemorrhagic disease in humans. Serotypes included in this group are 0157:H7, 026:H11, 0111:H-, 0157:H-.
[6] These include faecal, feed, water and soil samples taken from farms with no listeriosis cases.

Survey data from Europe, Australia and the US on ewes and goats milk indicate contamination from 0 to 3.0% and 0 to 4.0%[7] (Ryser & Marth, 2007).

1.1.4 Salmonella spp.

The natural reservoir of *Salmonella* spp. is in the intestinal tract of warm and cold-blooded vertebrates, including dairy animals. Infected animals may show no evidence of disease and intermittently excrete small to large numbers of the organism in their faeces leading to contamination of the surrounding environment including soil, pasture, streams and lakes. *Salmonella* spp can survive for several months in favourable environmental conditions including faecal matter, moist soil and animal feed.

Salmonella shedding in cattle has been reported to be highly variable. The prevalence in dairy cattle in the US, for example, has been reported as ranging from 2.1 to 27.5%. In Australia, a *Salmonella* spp. prevalence of 6.8% (n=310) has been reported in beef cattle (Fegan *et al.*, 2004). A study of slaughter age animals in Australian dairy, beef and sheep farms found a 17% prevalence of non-Dublin *Salmonella* spp in dairy herds and a 5.5% to 13% prevalence in the beef herds sampled (Vanselow *et al.,* 2007). Prevalence in sheep flocks was reported at 3.5%. This study also estimated an individual animal level prevalence which for the dairy cattle herds sampled was 1.7%.

Contamination of raw milk with *Salmonella* spp. occurs as a result of faecal contamination of the animal, particularly the teats, which directly contaminate milk during milking operations. International data shows prevalence of *Salmonella* spp. in raw cow milk ranging between 0 to 11.8 %. South Australian data obtained during the period 1996 to 2000 shows a contamination rate of 2.7% (n=37) in raw milk, whilst a survey conducted in 2008 in Western Australia reported a prevalence of 7.6% (n=183). Australian data indicates an overall contamination rate of 0.2% for raw goat milk and there have been no reported detections in sheep milk.

1.1.5 S. aureus

Animals carry *S. aureus* on various parts of their bodies, including the udder and teats, where they sometimes cause infection. *S. aureus* is the most important bacterial cause of mastitis (clinical and subclinical) and its presence in milk can be related to the health status of the herd in respect to mastitis. Organisms are shed directly into the milk and numbers can range from <10 to several thousand per mL of milk with occasional counts of 10^5 cfu/mL (Asperger, 2002).

Occurrence of staphylococci are common in raw milk however not all strains are able to produce staphylococcal enterotoxin (responsible for food-borne illness). Strains of *S. aureus* from animal sources are considered less likely to produce enterotoxin than strains from human sources (Stewart, 2003). The rate of enterotoxigenic or coagulase positive *S. aureus* isolates from animals is variable. In a study by Phillips *et al* (2001a, 2001b) of Australian beef and sheep carcasses, the prevalence of coagulase-positive staphylococci was around 24%.

In a Western Australian survey of bulk cow milk undertaken in 2007, 26.8% of samples tested positive for coagulase positive staphylococci (n=183).

1.2 Primary production factors for contamination of raw milk

Contamination of raw milk generally occurs via two means: when microorganisms are shed directly into raw milk from the udder as a result of illness or disease, or through contamination from the external surface of the animal and the milking environment.

[7] Survey data from Australia reported no detections (0%).

The primary production factors (animal, environmental and milking related practices) that impact on these routes of contamination are discussed in *A Risk Profile of Dairy Products in Australia*. The major factors are summarised below.

1.2.1 Animal health

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*).

1.2.1.1 Carrier status

While animals showing clinical signs of disease may be identified and their milk withheld from supply, many animals can be infected by a range of pathogens without any evidence of illness (asymptomatic carriers). As outlined in section 1.1, the prevalence of pathogens is variable and the frequency and amount of pathogen excreted by a carrier varies with the organism, the animal, its husbandry and immune status and the natural history of the disease in that animal species (FSANZ, 2009a). Pathogen shedding may be reduced by managing stress and diet while good agricultural practices (maintaining good farm hygiene, clean water and feed, pest control etc.) can reduce entry and spread.

1.2.1.2 Mastitis

Mastitis is inflammation of the mammary gland, usually caused by bacteria which have entered the teat canal and moved to the udder. Infection can be contagious (spread from infected to uninfected animals) or environmental, occurring as a result of ascending infection through the teat canal by organisms present in urine, faeces, soil and bedding. Infection is commonly subclinical (no visible signs evident in the animal or milk) with large numbers of organisms from the infected udder being shed into the milk.

Good milking and environmental hygiene and appropriate management of animals during lactation and drying off are the primary measures used to control mastitis.

1.2.1.3 Other zoonoses

The zoonotic agents that may be shed directly into milk and of primary concern for dairy herds and human health include *M. bovis* (causative agent of tuberculosis in cattle) and *Brucella* spp. In Australia, *M. bovis* and *Brucella abortus* (agent causing bovine brucellosis) have been eradicated through programs combining vaccination and test and slaughter. Ongoing monitoring and surveillance programs assure that Australia remains free of these zoonoses. *B. melitensis* (major cause of brucellosis in sheep and goats) has never been reported in sheep and goats in Australia. To help prevent these zoonotic agents entering Australia the Australian Quarantine and Inspection Service (AQIS) maintain import requirements on dairy products entering the country (discussed under Section 1.4.1).

Ingestion of contaminated raw milk or raw milk products has also been suggested as a route of transmission of *Coxiella burnetii* however the main route of transmission of this pathogen to humans is through inhalation (e.g. of dust in contaminated environments).

1.2.2 The environment and farm management

Pathogens may originate from the farm environment (feed, water, animal holding areas, milking areas, faeces etc.) and the farm management practices relating to these will impact on entry and spread, and subsequent contamination of raw milk.

1.2.2.1 Feed

The potential for pasture, fermented feeds (e.g. silage) and concentrates to be a potential source of microbial hazards is discussed in *A Risk Profile of Dairy Products in Australia*. Of particular importance to raw milk production is the relationship between the feeding of fermented feeds and the prevalence of *L. monocytogenes*. The occurrence of *L. monocytogenes* in poor quality silage is well documented and it is known that there is a causal relationship between feeding improperly fermented silage (pH 4.0 to 5.0) and the prevalence of listeriosis in ruminants. In a study by Nightingale *et al* (2005) the practices of feeding silage and feeding poor-quality silage were associated with a higher prevalence of faecal shedding of *L. monocytogenes* while animals with access to pasture had a lower rate of shedding.

1.2.2.2 Water

Water for stock drinking is a potential source of contamination. Water sources can become contaminated with cud and/or faecal material, feed etc. and the sediment in water can support bacterial growth and be a reservoir for pathogens. Water trough sediments, for example, have been reported as a reservoir for *E. coli* O157 and possible source of infection for this pathogen (Lejeune *et al.*, 2001). Maintaining areas around drinking points in a good condition and the frequent cleaning of water troughs can help ensure water is of a suitable quality for stock.

Water used in the milking shed may be used for teat cup washing, washing of teats, milking plant flushing and rinsing, milk vat flushing and rinsing etc. If it contains microbiological pathogens the animal being milk is exposed and the milk collected becomes contaminated.

1.2.2.3 Animal holding areas/housing

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, contact with bedding etc. Pathogens that have been associated with intensive housing for cattle include *L. monocytogenes*, *E. coli*, *B. cereus* and *Salmonella*.

If holding areas are poorly designed and maintained the spread pathogens is amplified due to increased soiling of udders and teats with faecal material.

1.2.2.4 Herd size

There is some association between herd size and the prevalence of pathogens including *Salmonella* and *Campylobacter*. In a study by Kabagamb *et al* (2000) large herd sizes (>100 animals) were associated with increased *Salmonella* shedding. This may have been as a result of stress or be related to the differing management practices between large and small herds. Bailey *et al* (2003) identified stocking density as a risk factor for *Campylobacter* shedding in cattle and sheep in Australia.

1.2.3 Milking practices

1.2.3.1 Teat washing and disinfection

The teat surface is the major avenue of entry for microorganisms into raw milk. Pre-milking udder hygiene *e.g.* washing with clean water and drying using hand towels, reduces milk contamination by transient bacteria located on the udder.

Post-milking teat disinfection reduces the resident teat skin bacterial population, which is the main source of infection for the mammary gland. In dairy cattle, the rate of new intramammary infection due to *S. aureus* and *St. agalactiae* is reduced by approximately 50% when post-milking teat disinfection is practiced (Sheldrake & Hoare, 1980).

Additionally, the hands of milking personnel need to be considered as a possible source of microbial contamination of the teat and udder. Good personal hygiene practices need to be employed. Milking equipment also needs to be well maintained, cleaned and sanitised.

1.2.3.1 Milk cooling and storage

At milking, the temperature of milk leaving the animal is approximately 37°C. This temperature is optimum for the growth of many pathogenic microorganisms. At temperatures below 5°C, growth of most pathogenic bacteria is prevented or reduced. Therefore the rapid cooling of milk to and storage at 5°C will minimise the potential growth of micro-organisms. Current industry practice is the cooling of milk to 5°C or less within 3.5 hours from the start of milking.

1.2.4 Milk collection and transport

Inappropriate temperature control of milk during transportation can lead to pathogen growth and so time temperature control during transport is a major consideration. Additionally, transport equipment and containers can be a source of contamination if they have not been adequately cleaned and sanitised or they do not adequately protect milk during transport.

1.4 Current requirements

There are a number of points throughout the milk primary production chain where control measures can be implemented to minimise contamination of raw milk by pathogenic microorganisms. Standard 4.2.4 already specifies a number of food safety requirements for dairy primary production businesses to manage possible hazards:

- implement a documented food safety program (defined in Standard 3.2.1 – Food Safety Programs)

- include controls that manage hazards arising from:

    - inputs (feed, water, chemicals [including veterinary and agricultural chemicals] or other substances used in connection with the primary production of milk)
    - the design, construction, maintenance and operation of premises and equipment
    - milking animals
    - persons involved in milking
    - milking practices

- ensure milk is only sourced from healthy animals

- cool and store milk to prevent or reduce the growth of microbiological hazards

- have pest control and cleaning and sanitising programs

- ensure that persons undertaking primary production activities have appropriate skills and knowledge (competencies)

- have a system to enable the tracing of inputs, milking animals and the milk produced.

These controls have been developed for general hazard management of milk produced for further processing (including pasteurisation or equivalent treatment). When milk is being produced for raw milk products even greater stringency of measures may be required to manage the specific risk factors for the pathogens identified above. The Codex *Code of Hygienic Practice for Milk and Milk products* (Codex, 2004) identifies additional provisions for the production of milk used for raw milk[8] products to reduce the likelihood of hazards occurring during the primary production phase (summarised in Appendix 1). The scope of the Codex Code of Practice however does not extend to the production of raw drinking milk.

Standard 4.2.4 also specifies requirements for dairy transport businesses that include:

- implementing a documented food safety program
- having a cleaning and sanitising program
- use of time temperature controls
- having a system to identify the immediate supplier and immediate recipient
- ensuring persons undertaking transport activities have appropriate skills and knowledge.

1.4.1 Quarantine requirements

DAFF Biosecurity and Biosecurity Australia maintain import requirements for dairy products entering Australia. A quarantine permit must be obtained in order to import dairy products (products containing 10 % or more, by weight, of a dairy product) into Australia. The conditions for import depend on whether the country exporting is free from Foot and Mouth Disease. All consignments must be accompanied by an import permit and a specific sanitary certificate signed by an Official Government Veterinarian of the exporting country.

While these requirements are mainly concerned with the transfer of foot and mouth disease, they effectively require that dairy products are sourced from healthy animals and that there are appropriate controls in place within the country of origin to ensure this. For all dairy products the overarching requirements are:

- The milk or the milk from which the dairy product is made must originate from country/zone recognized by the Office International des Epizooties (OIE) as foot and mouth disease-free, with or without vaccination.

- The animals must be clinically healthy at the time the milk was obtained.

Further detail on the requirements for the importation of dairy products from approved countries is provided at Appendix 2.

[8] Codex defines raw milk as milk which has not been heated beyond 40 °C or undergone any heat treatment that has an equivalent effect.

2. Processing

Microbiological hazards are controlled during dairy processing through the application of a combination of processing control measures. The effectiveness of these will depend on the initial microbial load in the raw milk and how effective primary production measures have been in preventing or minimising the presence and numbers of microbiological hazards. This section on processing identifies those microbiological hazards of most concern for raw milk products; the processing parameters (factors) that impact on their growth or survival, and the current requirements relating to dairy processing.

2.1 Microbiological hazards

Raw milk products may contain a variety of pathogens, derived from the raw milk and the processing environment (e.g. contamination during or post processing). As outlined in Section 1.1, those organisms more frequently associated with human illness linked to the consumption of raw milk products are:

- *Campylobacter* spp.
- *E. coli* spp.
- *L. monocytogenes*
- *Salmonella* spp.

More generally, dairy products are also commonly associated with staphylococcal food poisoning as a result of enterotoxin formation by *S. aureus*. These five pathogens are those that have primarily been assessed in FSANZ risk assessments of raw milk products.

2.1.1 Growth limits

A number of extrinsic and intrinsic parameters affect the growth and survival of microorganisms in food. These include temperature, pH, water activity, available nutrients and presence of antimicrobial compounds. The limits for growth of the pathogens identified above with respect to temperature, pH, and water activity are provided in Table 1.

Table 1: Limits for growth of selected pathogens (ICMSF, 1996)

Micro-organism	Temperature °C			pH			Water activity (min)
	min	optimal	max	min	optimal	max	
Campylobacter	32	42-43	45	4.9	6.5-7.5	9.0	>0.987
E. coli spp	7-8	35-40	44-46	4.4	6-7	9.0	0.95
L. monocytogenes	-0.4	37	45	4.4	7.0	9.4	0.92
Salmonella spp.	5.2	35-43	46.2	3.8	7-7.5	9.5	0.94
S. aureus	7	37	48	4.0	6-7	10	0.83
(toxin production)	10	40-45	48	4.5	7-8	9.6	0.87

The values presented in Table 1 reflect the reported maximums and minimums in the scientific literature and have been established when other parameters were optimal.

As one or more factors become limiting, this influences the other parameters (for example at low pH, the maximum temperature limit for growth may also be much less). Other considerations also include the type of acid present. For example the minimum pH limit reported may be when hydrochloric acid is used as the acidulant but when another acid such as lactic acid is used, the pH limit for growth may be much higher.

2.2 Processing factors

The manufacture of dairy products involves processes or effects conditions (e.g. pH, water activity) that impact on microbial growth or survival. Codex (Codex, 2004) has grouped such measures as microbiocidal or microbiostatic:

Microbiocidal control measures reduce the microbial load, for instance by killing, inactivation or removal. These may be applied during processing as processing steps (e.g. pasteurisation, thermisation) or after processing as intrinsic factors (e.g. ageing).

Microbiostatic control measures prevent, limit or retard the growth of microorganisms by chemical or physical means. These may be applied after milk production, during processing and after processing. They may be extrinsic factors (e.g. temperature) or be built into the product as intrinsic factors (e.g. pH, water activity).

Generally more than one control measure is needed to control microorganisms of concern (e.g. pasteurisation in combination with refrigerated storage). Combinations of measures (hurdles) can also be devised such that specific organisms can be reduced in number or can no longer grow or survive. In this way single microbiostatic control measures (such as pH, water activity, temperature) can be combined to provide a microbiocidal effect.

A discussion of the processing control measures of most relevance to raw milk products is provided below.

2.2.1 Pasteurisation and alternative technologies

Pasteurisation has traditionally been used as the key microbiocidal measure to control pathogenic microorganisms in dairy products through applying heat at a sufficient temperature and time to eliminate specified pathogens. For continuous flow systems, heating to 72 °C for 15 seconds has been validated as the minimum pasteurisation conditions for whole milk (63°C for 30 minutes for batch pasteurisation).

Non thermal technologies (e.g. high-pressure treatment, pulsed electric field, microfiltration etc.) are being investigated as an alternative to pasteurisation but to date have not been developed to a stage where they can replace heat processing as the single process to eliminate pathogens for milk and dairy products.

2.2.2 Thermisation

Thermisation is a heat treatment applied to milk, generally for cheese making, that is of a lower intensity than pasteurisation. It reduces the number of microorganisms but does not eliminate them (a general reduction of 3-4 logs can be expected). Any microorganisms surviving will be heat stressed and become more vulnerable to subsequent microbiological control measures such as ripening. Standard 4.2.4 currently permits a thermisation treatment for cheese production of 62°C for 15 seconds in combination with ripening for 90 days.

2.2.3 Curd cooking

The ‘cooking’ of cheese curd involves the application of heat for technical purposes such as promoting syneresis (expulsion of moisture from the curd). Generally the higher the curd cooking temperature applied, the lower the moisture content of the cheese being produced (the harder the variety). Depending on the temperature used, the heat treatment applied may reduce the level of microorganisms or stresses them to become more susceptible to other microbiological control measures.

2.2.4 Ripening

Ripening or ageing of cheese is defined by Codex as ‘the holding for such time, at such temperature, and under such conditions as will result in the necessary biochemical and physical changes characterising the cheese in question’. When used as a microbiocidal control measure, the combined effects of pH, decreased water activity, antagonistic flora and organic acids are used to influence the microenvironment in and on the food and impact on the composition of the microflora present. The decline of any pathogens present during this time will be influenced by the intrinsic characteristics of the cheese and the temperature of storage.

2.2.5 pH reduction

Fermentation or the addition of organic acids lowers the pH of the food matrix and impacts on the growth and survival of microorganisms. Most bacteria grow poorly at pH values below 5.0 and the effect of declining pH and increasing levels of organic acids can be inhibitory for pathogens. Microorganisms become more sensitive to other microbiological control measures at lower pH (synergy occurs with salt, water activity, lactoperoxidase system, organic acids, and antimicrobial substances).

2.2.6 Water activity

The ability of micro-organisms to grow or survive is largely dependent on available or accessible water in the food. This is referred to as water activity (a_w) expressed as the ratio of water vapour pressure in the food to that of pure water. Water activity can be controlled by:

- concentration, evaporation and drying
- salting (addition of sodium chloride)
- sweetening (addition of sugars).

2.2.7 Temperature and time

Maintaining product at low temperatures limits microbial activity (most microorganisms will not grow at refrigeration temperatures <5°C). When temperatures are lowered below the freezing point of the product not only is growth prevented but some microbiocidal effect may be provided.

Time can be used as a microbiostatic control measure through practices such as applying very short collection/storage periods, limiting the shelf life of products, or immediate processing of raw milk to ensure that all microorganisms present are in the lag phase (and therefore not active and more susceptible to other microbiological control measures).

2.3 Current requirements

Depending on the dairy product being manufactured, a number of microbiocidal and microbiostatic control measures may be implemented to prevent pathogen survival or growth.

Standard 4.2.4 currently specifies that the processing of milk and dairy products (other than cheeses) must include pasteurisation (at 72 °C for 15 seconds) or an equivalent (validated) process. Clause 16 of this standard allows for a combination of other processing factors to be used in the manufacture of cheese including:

- thermisation in combination with ripening
- curd cooking in combination with ripening and water activity (expressed as moisture content).

Overarching these processing requirements is the requirement for dairy processing businesses to control potential food safety hazards by implementing a documented food safety program in addition to complying with the food safety requirements of Standard 3.2.2 and 3.2.3. Standard 3.2.2 – Food Safety Practices and General Requirements sets out specific food handling controls related to receipt, stage, processing, display, packaging, transportation, disposal and recall.

Other requirements of Standard 3.2.2 relate to:

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

Standard 3.2.3 – Food Premises and Equipment sets out the requirements for food premises, fixtures, fittings, equipment and food transport vehicles.

These food safety requirements are generic and additional or more specific control measures may be required for managing the risks associated with raw milk products. For example, the permission for Roquefort cheese in Standard 4.2.4A specifies:

The following matters must be monitored and recorded during cheese production:

(a) *pH during the acidification process; and*
(b) *salt concentration; and*
(c) *moisture content*.

The establishment of microbiological and other processing criteria (e.g. time temperature parameters) for incoming raw milk may also need to be considered. For Roquefort cheese, testing of the raw milk for *L. monocytogenes* is specified.

2.3.1 Microbiological limits

Standard 1.6.1 - Microbiological Limits for Food currently specifies a number of microbiological limits for unpasteurised milk products including unpasteurised milk, butter made from unpasteurised milk and certain raw milk cheeses:

- limits for *Campylobacter*, coliforms, *E. coli*, *L. monocytogenes*, *Salmonella* and Standard Plate Count are specified for unpasteurised milk
- a limit for *Campylobacter* is specified for raw milk unripened cheeses (moisture content >50% with pH >5.0)
- limits for *. monocytogenes* and *Salmonella* are specified for all raw milk cheese
- a limit for *E. coli* is specified for all cheese (including raw milk cheese)

- limits for *Campylobacter*, Coagulase positive staphylococci, coliforms, *E. coli*, *L. monocytogenes*, *Salmonella* and Standard Plate Count are specified for butter made from unpasteurised milk.

These limits will need to be revised in line with the product categories outlined in Section 2.

3. Consumer Awareness and Product Information

Evidence about consumer knowledge, motivations and behaviours plays a fundamental role in the risk analysis process. An enhanced understanding of who consumes raw milk products, why they are consumed and consumer's knowledge of raw milk products can inform approaches to assess and manage the health and safety risks posed by their consumption, particularly in relation to product and consumer information needs.

There is a limited literature base on consumer attitudes, understanding, and consumption behaviour of raw milk products, particularly Australian data. It is recognised, however, that there is a demand for raw milk products in Australia, specifically raw drinking milk and raw milk cheeses, though the extent of this demand is unclear.

In order to gather Australian data, FSANZ commissioned a qualitative consumer study on raw milk behaviour and attitudes[9]. Findings from this survey and the published literature, and information from submissions received on the Discussion Paper for P1007 have provided qualitative data on consumer motivations, behaviours and knowledge in relation to raw milk products, outlined below. A summary of the key findings from the literature and the consumer survey is provided at Appendix 3.

3.1 Consumer motivations

The FSANZ Consumer study identified four raw milk consumer 'segments' based on variations in their motivations for consumption and triggers leading to that consumption:

- opportunists (primary motivation is convenience, low cost and easy access)
- lifestylers (consumption is part of a wider belief system e.g. organic or natural lifestyle)
- nutrition seekers (based on perceived or promoted nutritional benefits of raw milk)
- health concerned (as a response to a particular health concern).

The segments identified are comparable to those that have been reported internationally in the literature where the benefits reported by consumers included, taste, health, nutritional qualities, convenience and cost. The limitations of the consumer study did not permit the relative sizes of the segments to be determined nor to exclude the possibility of other segments not included here.

Another major benefit for participants was knowing the source of the milk they drank, and this was also an essential pre-requisite to consuming raw milk for many participants. They felt closer to the producer of the milk, reporting that they knew what the animals were fed, how they were looked after and other factors that were of interest and relevance to them.

In addition to the research undertaken, a large number of submissions were received on the Discussion Paper for Proposal P1007 that also identified consumer motivations. Many of these respondents wanted access to raw milk products because:

[9] A report *Raw Milk and Consumer Behaviour and Attitudes* was prepared for FSANZ by Colmar Brunton Social Research and is available on the FSANZ website: http://www.foodstandards.gov.au/standardsdevelopment/proposals/proposalp1007primary3953.cfm

- they believe they offer significant health and nutrition benefits (mostly associated with raw bovine drinking milk)
- they have strong views around consumer choice and the right to be able to choose to consume raw milk products instead of conventional pasteurised milk products.

In relation to raw milk cheeses, other or additional motivations were elicited through submissions. The primary motivation for raw milk cheeses related to taste with consumers wanting access to these products because they consider them superior in quality (flavour, texture and taste profile). Additionally, having a greater choice of products available (a wider range of imported and locally produced cheeses) was raised as important.

3.2 Consumer knowledge

Information on consumer knowledge/understanding of the nature of raw milk products and inherent risks associated with them was also gathered through the consumer study. It found that the main sources of information about raw milk are word of mouth and personal experience and observation. Additionally, a range of books and websites were referred to with the Weston A. Price Foundation being the single information source most specifically referenced.

Many participants in the FSANZ consumer study were aware of information promoting the dangers of raw milk. They largely considered this ill-informed at best, and malicious scare-mongering at worst. Consumers considered that the warning labels on ‘pet milk’ and ‘bath milk’ indicating that it was not suitable for human consumption were a legal requirement rather than a legitimate warning. Many of the participants held detailed and specific knowledge and beliefs in relation to health and nutrition (discussed in Section 2 under Assessment of Consumer Issues).

3.2.1 NZFSA Market Research Survey

NZFSA commissioned a market research survey in 2008 to gain information on the public understanding of raw milk products. A particular focus of NZFSA study was to gather data on the effectiveness of NZFSA food safety initiatives on raw milk and raw milk products. The study also collected data on understanding of risks and terminology used on product packaging and in food safety educational materials.

In relation to understanding the term ‘raw milk’, the majority understood it to mean unpasteurised though nearly one third of respondents thought it meant fresh or milk in general. For labelling purposes, ‘unpasteurised’ was identified as a more useful and meaningful term than ‘raw milk’. Around one third of respondents considered unpasteurised milk cheeses/products were as safe to consume as pasteurised products.

3.3 Consumption behaviours

Consumer demand for raw milk products is primarily for raw drinking milk or raw milk cheeses. Consumption behaviours for these products are discussed below.

3.3.1 Raw drinking milk

Currently consumers are able to purchase raw goat milk in several states however there is anecdotal evidence that most demand for raw milk, particularly cow milk, is being met through unlicensed sources such as cow share schemes and the purchase of ‘pet milk’ and ‘bath milk’. This has been confirmed in a number of submissions to the Discussion Paper and the consumer study.

The consumer study reported that consumers of raw cow milk in metropolitan areas mainly sourced their milk through organic/health food shops where it is sold as ‘bath milk’ or ‘pet food’, and through growers or farmers markets. In regional areas these were less common sources, with study participants most commonly sourcing direct supplies of fresh milk from their own animal, from commercial dairies or from small producers. All raw goat milk consumers in the study obtained their milk from their own animals or direct from a small producer.

Some individual submitters to the Discussion Paper indicated that they were accessing raw cow milk by participating in ‘herdshare’ programs. Others stated they were buying ‘cosmetic’ or ‘pet food’ raw milk that is labelled as being not for human consumption. The consumer study suggests that such warning labels on ‘bath milk’ and ‘pet food’ are being disregarded. Over 300 hundred submissions were received from consumers wanting to be able to access raw drinking milk.

Findings from the consumer study and the information provided in submissions substantiate that there is a demand for raw drinking milk, largely from individuals that perceive there are substantial health benefits. As part of the consumer study an online poll was carried out to gauge the prevalence of consumption of unpasteurised milk. The poll suggested that the prevalence of consumption was 0.7% and while this can only be considered indicative it is consistent with other international studies (Colmar Brunton, 2009). For example the prevalence of consumption estimated from food safety surveys in the United States suggests between 1-3% of the population may consume unpasteurised milk (Headrick *et al*., 1997; Altekruse, 1999; Zhang & Penner, 1999).

3.3.2 Raw milk cheese

The specialty cheese[10] market has expanded considerably in Australia over the past 10 to 15 years and consumer interest in artisan cheeses has extended to raw milk cheese (indicated in submissions to FSANZ and through media coverage of this issue). There are currently only a limited number of raw milk cheeses available to consumers in Australia and these are imported products. Submissions received on the Discussion Paper indicate that consumers of specialty cheeses want to be able to access raw milk cheeses produced and traded internationally and support that such products should be able to be made locally.

Specialty cheeses are purchased and consumed differently to bulk produced cheddar and processed cheeses. They generally carry a price premium and are sold and consumed in smaller unit volumes. In the case of the imported raw milk cheeses currently permitted, consumers may pay in excess of $AUD100 per kilo (retail price) for some varieties. Such retail prices may also be achieved for certain specialty pasteurised cheeses, both imported and Australian. Consumers wanting such products may be more likely to be aware of or ask about the characteristics of the cheese they are purchasing, including whether it is made from raw milk.

3.4 Vulnerable groups

Risk management decisions take into account potential risks for the whole population as well as for sub-groups of the population that are at greater risk because of increased exposure or because of their health or immune status. There are population groups that are more susceptible or at greater risk of severe consequences of food-borne illness than the general population primarily because of their immune status. These are termed vulnerable populations and include:

[10] The term specialty cheese is generally used to refer to all cheeses other than bulk cheddar, mozzarella or processed cheese.

- pregnant women
- children aged four years or less
- people aged 70 and over
- those people immunocompromised because of a medical condition or treatments they are taking (including people with HIV/AIDS, cancer, diabetes, liver or kidney disease, transplant recipients).

Risk management strategies for such groups have generally included advice (through fact sheets and technical papers) to avoid certain foods that are at higher risk of containing harmful levels of pathogenic microorganisms such as *L. monocytogenes* because of the severe outcomes, including death, which could result. In assessing the risks associated with raw milk products, the general population as well as vulnerable populations are considered.

Risks associated with raw milk products can be higher for vulnerable groups, particularly for the hazards EHEC and *L. monocytogenes.* Age is the most consistent risk factor for susceptibility to complications resulting from EHEC infection. Such complications include haemolytic uraemic syndrome (HUS) which can result in renal failure and has a case-fatality rate of 3% to 7%. Children less than 5 years and adults older than 65 years are at a greater risk of developing HUS.

Groups with compromised immune systems such as pregnant women and their foetuses, neonates, the elderly, transplant patients, patients on corticosteroid treatments, HIV/AIDS patients and alcoholics are those at risk for invasive listeriosis. Listeriosis may result in septicaemia, meningitis, encephalitis, and intrauterine or cervical infections in pregnant women which may result in spontaneous abortion or still birth. Based on OzFoodNet data from 2002 to 2007 (OzFoodNet, 2008), the case mortality rate in Australia has varied from between 12% to 25%.

Submissions received on the Discussion paper for P1007 indicate that raw drinking milk is being provided to/consumed by vulnerable groups such as young children and pregnant women. The consumer study suggested that unpasteurised milk was fed to infants and children, however unpasteurised goat milk was more likely to be fed to infants and children because of perceived benefits relating to allergies or lactose/digestive issues (discussed in Section 2 under Assessment of Consumer Issues).

3.5 Product information

There should be adequate information available to consumers to ensure food products are handled, displayed, stored and prepared correctly and safely. Labelling of packaged foods is an important means of achieving this but its effectiveness is dependent on a range of factors. The salience of safety (or other) information to the consumer is an important factor influencing the extent to which they respond to it.

Labelling which is specifically directed to addressing health risks includes mandatory warning and advisory statements. Other labelling that is relevant to addressing health and safety risks includes storage and use instructions and date marking.

3.5.1 Mandatory warning and advisory statements

Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations requires warning statements or advisory statements to be used on a food label or in association with the display of the food if the food is not required to bear a label. Warning statements and advisory statements are used for different purposes.

Mandatory warning statements are used where the risk to public safety is potentially life threatening and it can be reasonably assumed that the general population or the specific target group is unaware of the potential safety risk. Currently, the Code only requires a warning statement for food containing royal jelly.

Mandatory advisory statements are used where the general population or a sub-group of the population is exposed to a health and safety risk but the risk is not life threatening, or when guidance about a food is needed to maintain public health and safety. There are currently a number of mandatory advisory statements for foods including unpasteurised milk and liquid milk products (although these are not permitted under current processing requirements). Unpasteurised milk requires a statement to the effect that the product has not been pasteurised.

Jurisdictions that permit the sale of unpasteurised goat milk may require a labelling statement on the product such as 'Caution – this milk is an unpasteurised product and may contain organisms that could be injurious to health'.

3.5.2 Directions for use and storage

Standard 1.2.6 – Directions for Use and Storage requires that either directions for use and/or directions for storage of food is to be included on the label where, for reasons of health and safety, the consumer should be informed of specific requirements. Examples of such directions include 'refrigerate after opening', 'cook thoroughly before consumption' or 'refrigerate at or below 4°C'. Currently directions are required for two specific foods in the standard, bamboo shoots and sweet cassava, to the effect that they should be fully cooked before consumption.

3.5.3 Date marking

Standard 1.2.5 – Date Marking of Food requires food (with some exceptions) to be date marked. A use-by date is required where food should be consumed before a certain date (provided it has been stored in accordance with any stated storage conditions) because of health or safety reasons. This may apply to chilled ready-to-eat foods because of the potential for pathogens (such as *L. monocytogenes*) to be present and grow at refrigeration temperatures to harmful levels before the food has noticeably spoiled.

3.6 Consumer information

To support risk management tools such as labelling or as part of a risk management strategy (e.g. listeria advice to people at risk), information and/or advice to consumers may be provided in the form of fact sheets, technical papers, web-based information or public forums.

Particular information or advice may include:

- information to the community about safe handling and adequate preparation of a product;
- information to at-risk groups about safe eating practices (e.g. listeria advice to people at risk; and/or
- information on how to use food labels effectively.

Consumer information needs will be considered alongside proposed risk management options for raw milk products.

SECTION 2: Product Categorisation and Risk Assessment

1. Risk Management Framework

In order to assess risk management options for raw milk products they have been categorised into one of three categories based on the likelihood that pathogens may be present and the potential public health risk posed. These categories are defined in terms of the effect processing factors and intrinsic characteristics of the final product have on pathogen survival and growth:

Category 1 products are defined as those products where:

- intrinsic characteristics and / or
- processing factors

eliminate pathogens that may have been present in the raw milk.

Category 2 products are defined as those products where:

- intrinsic characteristics and / or
- processing factors

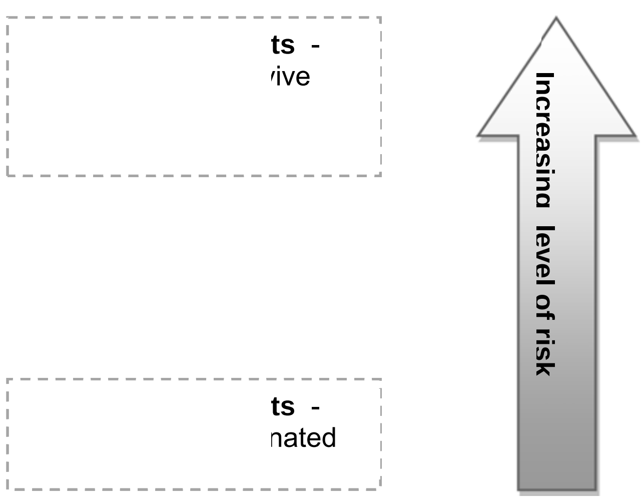
may allow the survival of pathogens that may have been present in the raw milk but do not support the growth of these pathogens.

Category 3 products are defined as those products where:

- intrinsic characteristics and / or
- processing factors

are likely to allow the survival of pathogens that may have been present in the raw milk and may support the growth of these pathogens.

Given the increased potential for pathogens to be present, the food safety risk associated with each category increases from Category 1 to Category 3.



The further refinement of definitions, including the parameters and or processing factors that underpin each category and allow for individual products to be categorised are discussed below. While cheese is the primary raw milk product in international trade and has been the main focus of assessment work, category definitions and outcomes will be developed to apply to other products as appropriate.

2. Category 1

Category 1 products have been defined as those where intrinsic characteristics and/or processing factors eliminate pathogens that may have been present in the raw milk. **Eliminate** means the process[11] will achieve an overall reduction of at least 5 logs[12] (net reduction) of the specified pathogens. Outside of pasteurisation, there are currently two sets of requirements in the Code that would be captured under this definition: thermisation (in combination with storage) for cheese processing and processing requirements very hard grating cheeses. In addition, permissions for Emmental, Gruyere and Sbrinz cheeses were approved based on the processes used being able to eliminate pathogens of concern. These Swiss cheeses and the very hard grating cheeses will be collectively referred to as cooked curd cheeses.

2.1 Thermisation

Standard 4.2.4 allows for a lower heat treatment (than pasteurisation) in combination with a minimum ripening period to be used for the processing of cheese:

> *…by being held at a temperature of no less than 62°C for a period of no less than 15 seconds, and the cheese or cheese product stored at a temperature of no less than 2°C for a period of 90 days from the date of processing;*

The effectiveness of this processing requirement in eliminating pathogens depends on the log reduction provided by the temperature time treatment of the milk in combination with the expected die off during the ripening process. A comparison of the pathogen kill achieved by a range of sub-pasteurisation temperatures (at 16.2 seconds) is provided in Table 2.

The current temperature limit for thermisation in the Code is in the lower range of those used internationally. In New Zealand, for example, the thermisation requirements are 64.5˚C for 16 seconds with storage at not less than 7˚C for no less than 90 days from date of processing. The data presented in Table 2 shows that temperature treatments of 64.5˚C and greater (for 16 seconds) provide a greater than 3 log reduction for all of the pathogens listed. It is proposed that Australian and New Zealand thermisation measures are aligned and the current limits in the Code are amended.

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[11] From the start of production until the product is considered ready for consumption/sale. For example, for a cheese this would mean at the end of the ripening period.
[12] Pasteurisation is generally accepted as being able to achieve at least a 5 log reduction of pathogens and this level of reduction has been used as the benchmark for evaluating raw milk cheese processes in previous assessments (such as for very hard grating cheese).

Table 2[13]: Pathogen kill at thermisation temperatures using a turbulent-flow pasteuriser with a holding time of 16.2 seconds [after Pearce (2003, 2004)*]

Pathogen	**No. of strains used**	**Log-kill at specified temperatures**			
		60°C	**63°C**	**64.5°C**	**66°C**
Listeria monocytogenes	10	No change	1-2	2-3	4-5
E. coli O157:H7	15	2	1-3	>6	na
Yesinia enterocolitica	15	4-5	>5	na	na
Campylobacter spp.	15	4-5	>5	na	na
Salmonella spp.	7	3-5	>5	na	na
Salmonella seftenberg	2	2-3	4	4	5

* Sources of original data cited by Pearce: D'Aoust *et al.* (1987, 1988); Farber *et al.* (1988).

2.2 Cooked curd cheeses

Cooked curd cheeses include those very hard cheese varieties where the curd is heated to elevated temperatures (defined as > 48°C) during processing and include very hard grating cheeses, Swiss Gruyère, Emmental and Sbrinz. The scientific assessments undertaken for cooked curd cheeses manufactured from raw milk established whether a 5 log reduction of the pathogens of concern could be achieved, taking into account initial load, possible growth during milk warming, reduction during curd cooking and during maturation. The assessments concluded that the key microbiocidal control measures for these cheeses were:

- curd cooking
- ripening (in combination with a low moisture environment)

2.2.1 Curd-cooking

Curd-cooking at elevated temperatures has the greatest effect on reducing numbers of pathogens that may be present in the curd.

The maximum temperature for growth for most pathogens is 45-48°C, therefore curd cooking at temperatures 48°C and above will begin to have a lethal effect. Curd cooking at temperatures in excess of 55°C for periods greater than 40 minutes, such as in the manufacture of some extra hard and Swiss cheeses, is sufficient to significantly decrease (> 3 logs) the numbers of pathogens that may be present in raw milk. Any surviving micro-organisms are stressed and become more susceptible to other microbiological control measures (e.g. ripening).

2.2.2 Ripening

Conditions during maturation can result in a combination of hurdles which are sub-optimal for pathogenic bacteria. The combined effects of low pH, high salt, reduced moisture and ripening temperature come into play and promote the die off of pathogens that may be present.

[13] This table is reproduced from the FSANZ publication *Scientific Evaluation of Pasteurisation for Pathogen Reduction in Milk and Milk Products* (2007).
http://www.foodstandards.gov.au/standardsdevelopment/proposals/proposalp1007primary3953.cfm

For very hard grating cheeses, inactivation of pathogens continues throughout ripening (providing the pH is 5.5 or less) and reductions of >5 log occur when ripening extends beyond 3 months regardless of the curd cooking temperature (FSANZ, 2009c). For the Swiss cheeses assessed it was concluded that any surviving pathogens would not survive ripening and storage (>3 log reduction). A minimum storage time for these cheeses was 120 days and moisture content <39%.

2.3 Category 1 parameters

For other dairy products to be considered under Category 1, evidence that the control measures (microbiocidal or microbiostatic) used in production can achieve a 5 log reduction of pathogens would need to be provided. For cheese production, the processing factors and intrinsic characteristics that have been identified in addition to pasteurisation for meeting Category 1 requirements include:

1. Thermisation of milk at 64.5˚C for 16 seconds in combination with a storage period of at least 90 days at no less than 7°C.

2. Curd cooking at elevated temperatures (>48°C) in combination with a storage period of at least 120 days at no less than 10°C. The final product moisture content must be less than 39%.

As the processing factors and product characteristics must provide for a 5 log reduction of pathogens, no additional on farm requirements for raw milk for processing are recommended (i.e. beyond those already required by Standard 4.2.4).

3. Category 2

Category 2 products have been defined as those products where intrinsic characteristics and/or processing factors may allow the survival of pathogens that may have been present in the raw milk but do not support the growth of these pathogens. **Survival** means there should be no net increase from receipt of milk to the end of processing. **No growth** means that there should be no measurable increase (less than log 0.5) of pathogens in the final product to the end of shelf life.

3.1 Roquefort cheese

The Code currently permits one raw milk cheese that fits Category 2 – Roquefort cheese. The safety assessment[14] for this cheese determined that the key processing factors that controlled pathogens were:

- the rapid acidification of the milk during the initial phase of cheese manufacture (i.e. drop in pH from 6.5 to <5.0 within 6 to 8 hours and then to pH 4.8 within 24 hours)
- desiccation of the curd during subsequent processing stages (i.e. a final water activity of approximately 0.92)
- prolonged ripening (i.e. >90 days).

The microbiological status of the incoming raw milk was also a critical factor in this determination, noting that it must meet stringent microbiological testing including no detected levels of *L. monocytogenes*. If pathogens were present at low levels, it was concluded that during the manufacture of Roquefort cheese they would be unlikely to survive or proliferate:

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[14] The scientific evaluation of Roquefort cheese is provided in the Final Assessment Report for Application A499 *To Permit the Sale of Roquefort Cheese*, available on the FSANZ website at: http://www.foodstandards.gov.au/_srcfiles/A499_Roquefort_FAR_FINALv2.pdf#search=%22A499%22

- *B. melitensis*, *C. burnetii* and *C. jejuni* are eliminated during cheese making and maturation
- if low levels of *Salmonella*, EHEC, *Listeria* and *S. aureus* were present in raw milk, conditions during cheese making and maturation make it unlikely they would survive or proliferate
- *L. monocytogenes* is unlikely to grow in Roquefort cheese during maturation and subsequent storage.

The processing factors, including intrinsic characteristics, that could be applicable for Category 2 products generally (cheese and other products) are discussed below.

3.2 Processing factors

3.2.1 Cheese

The ability of pathogens to survive and/or grow in cheese is largely dependent on:

- the extent of acidification by the starter culture
- ripening conditions (in combination with the intrinsic characteristics of the cheese, in particular its salt-in-moisture and pH).

The amount of heat applied at various stages during the manufacture will also impact on levels that may be present. When milk is warmed to setting temperatures[15] between 30 – 35 °C (for example), pathogens that may be present can grow. The curd cooking temperatures that are then used may be microbiocidal (as for hard cooked cheeses), microbiostatic or favourable for growth, noting that the growth of the starter culture and production of lactic acid during this time will become inhibitory.

Taking into account the potential for some growth during the initial phase of manufacture, the combination of controls for Category 2 cheeses must not only limit growth but need to provide for a reduction in levels in order to have no net increase (survival) of pathogens during processing. This reduction is primarily achieved during ripening. The intrinsic characteristic of the final product must then be such that pathogen growth is not supported.

3.2.1.1 Acidification

The production of acid at the appropriate rate and time is critical for the cheese-making process and to ensure the microbiological safety of the final cheese. Acid production and the resultant decrease in pH affects the growth of many non-starter bacteria, including pathogens which may be present in the raw milk. During the first 24 hours (including the early stages of ripening), the production of lactic acid by the starter culture is important in limiting the growth of pathogenic bacteria that may be present.

The use of an active starter culture that achieves a rapid pH drop within the first six hours and total drop within 24 hours of fermentation is a critical control in cheese production. A ‘rule of thumb’ is that the culture should be able to produce acid to achieve pH<5.3 in milk in six hours at 30-37°C (depending on cheese variety) (Fox *et al*, 2004).

3.2.1.2 Ripening

Inhibition of microorganisms during ripening results from the combined effects of pH, decreased water activity (related to salt content), antagonistic flora and organic acids.

[15] For rennet coagulated cheese, milk is warmed before the addition of starter culture and rennet to a temperature and for a time that will optimise the coagulation of the milk and formation of the curd.

These are not static and vary during the ripening period as moisture is lost, salt diffuses through the curd and other biochemical changes occur. Of the factors that influence microbial growth or survival, pH and water activity (represented as salt in moisture) have been identified as the main parameters for determining whether growth or no growth (inhibition) will occur.

pH

The pH of cheese curd after manufacture generally lies within the range 4.5-5.3. For mould and smear ripened cheeses, however, the pH increases during ripening due to the growth of yeasts and moulds. For blue cheeses the pH may increase to 6.0-6.5 during ripening and storage (>90 days) while for surface ripened mould cheeses (such as camembert and brie) the pH increases to around 7.0.

water activity/salt-in-moisture

The concentration of salt-in-moisture has a major effect on the growth of microorganisms in and on cheese. In general, the longer the ripening period the lower the moisture content of the cheese and the resultant water activity due to the salt content. The level of salt used depends on the variety and varies from 0.7-7%. As an example, blue cheeses are among the most heavily salted varieties at around 3-5% NaCl. A blue cheese with salt level of 4.5% will have a corresponding salt-in-moisture level of 10.5%.

For most cheese varieties salt is added after curd formation through brining or dry salting. While salt absorption into the cheese can occur fairly rapidly, salt diffusion in cheese moisture is a slower process. Depending on the variety it may take days or weeks to obtain salt in moisture equilibria throughout the cheese mass.

Predicting pathogen growth based on intrinsic cheese properties

Cheese will have varying intrinsic characteristics depending on its variety and particular manufacturing protocol. One approach to predict whether pathogens will grow or not grow (decrease in numbers) in a cheese is to determine a growth/no growth boundary for pathogens based on the intrinsic properties of the cheese – for example salt in moisture, pH etc using data from the literature and other sources. This approach will be further examined during the assessment of Proposal P1007 to determine appropriate combination of intrinsic parameters for Category 2 cheeses.

3.2.2 Other products

While manufacturing protocols for dairy products other than cheese have not been assessed, there are a number of individual parameters that have been identified as preventing the growth of pathogens[16]:

- water activity below 0.92
- pH below 4.4
- NaCl in solution >10%.

Dairy products with these individual intrinsic characteristics would not support the growth of pathogens. These are extreme limits and, as for cheese, combinations (e.g. pH and water activity) at lower/higher levels may also be inhibitory. Additionally, the manufacturing process used must include appropriate bactericidal or bacteriostatic controls so that there is no net increase of any pathogens during manufacture. For other products to be considered within Category 2, evidence that the production process would not allow for the survival of pathogens and that the final product does not support their growth would need to be provided.

[16] Water activity and pH limits are sourced from ICMSF (1996), based on the most resistant pathogen.

3.3 Raw milk quality

The primary source of contamination in raw milk products is from the raw milk itself. For Category 2 products the raw milk to be used should not have detectable levels[17] of pathogens (as appropriate for each pathogen of concern) to ensure there is no survival by the end of manufacture. This means, as outlined in Section 1.3, that greater stringency of measures would be required during primary production to manage the specific risk factors on farm for raw milk contamination.

3.4 Category 2 parameters

For products to be considered under Category 2, evidence would need to be provided that the production process would not allow for the survival of pathogens and that the final product does not support their growth.

Additionally, raw milk for the production of Category 2 cheeses would be required to meet a higher level of microbiological quality achieved through additional on farm control measures.

For cheeses the processing factors and intrinsic characteristics that have been identified for cheeses to meet Category 2 requirements include:

- the use of an active starter culture to achieve rapid acid production and pH drop
- pH/salt in moisture profile that will not support the growth of pathogens (to be elaborated further in the 2nd Assessment Report following additional work)
- minimum ripening period (e.g. 90 days) and temperature.

4. Category 3

Category 3 products have been defined as those products where intrinsic characteristics and/or processing factors are likely to allow for the survival of pathogens that may have been present in the raw milk and may support the growth of these pathogens. This means that the bactericidal or bacteriostatic controls used during processing would not be sufficiently inhibitory for preventing pathogen survival and the characteristics of the final product (pH, moisture/water activity etc.) would not prevent growth. In effect, the primary control for Category 3 products is the microbiological status of the raw milk for processing.
There are no parameters for defining Category 3 products – they are essentially those dairy products that do not meet the requirements for Category 1 or 2. For cheeses this would include varieties which have a higher moisture and pH profile and can support the growth of pathogens (such as soft mould ripened cheeses). Raw drinking milk is also a Category 3 product.

5. Level of risk associated with product categories

A wide range of microbiological hazards may be associated with raw milk. If these hazards are unmanaged, raw milk poses a high level of risk to public health and safety. Pasteurisation has been the most effective control measure for eliminating pathogens that may be present in raw milk, contributing to the very low level of risk associated with the consumption of dairy products in Australia.

[17] Given the limitations of analytical testing, no detectable level does not mean absence in the entire batch of milk. The processing factors and intrinsic characteristics of Category 2 products should be adequate to control very low levels of contamination.

The framework developed for assessing raw milk products groups them according to key characteristics that will eliminate, reduce or permit growth of pathogens. If processing controls were not in place, products across all Categories would present a high public health and safety risk. In certain cases this level of risk can be reduced to an acceptable level (i.e. low risk) through implementation of specific production and processing controls.

The *Microbiological Risk Assessment of Raw Milk Cheese* has been used to help identify the factors that have the greatest contribution to pathogen control during cheese manufacture and the key parameters for determining pathogen reduction, and conditions for growth and no growth. Risk assessments have also been undertaken for raw goat milk and raw cow milk that highlight the milk production factors that impact on the prevalence of pathogens in raw milk as well as the risk associated with the consumption of raw drinking milk.

5.1 Category 1

Dairy products considered within Category 1 must have undergone processing conditions and/or have intrinsic characteristic that provide for the elimination (≥5 log reduction) of pathogenic microorganisms. By definition the risk presented by such products is very low. A qualitative risk assessment undertaken for raw milk extra hard cheeses and cooked curd Swiss cheeses within the *Microbiological Assessment of Raw Milk Cheese* supports a **very low** risk for both the general and susceptible population groups where production includes:

- curd cooking at high temperatures (>48°C)
- ripening (in combination with a low moisture environment).

5.2 Category 2

The *Microbiological Risk Assessment of Raw Milk Cheese* qualitatively determined the level of risk for a number of selected cheese styles (cheddar, blue, feta, camembert) based on probabilistic modelling. The risk levels determined were very conservative due to the data gaps and assumptions made and cannot be directly ascribed to a product category. What the modelling indicated, however, is the importance of pH and salt in moisture parameters in determining whether pathogens survive or grow and, therefore, the level of risk presented. These parameters will be further investigated to inform the boundary between Category 2 and 3 products. The modelling also indicated the limited information available in published challenge studies on the behaviour of pathogens in cheese.

The key conditions/parameters identified for controlling pathogens in cheeses under Category 2 include:

- the use of milk produced to a stringent level of microbiological quality;
- rapid acidification
- a minimum ripening period and temperature
- an inhibitory pH/salt in moisture profile.

Where such controls can be met the risk to public health is **low,** (as determined in the assessment for Roquefort cheese) for both general and susceptible population groups.

5.3 Category 3

By definition there are no or limited processing factors to prevent survival of pathogens in Category 3 dairy products and their intrinsic characteristics may support pathogen growth. The microbiological status of the raw milk, dependent on the management of risk factors on farm, is therefore a critical control.

The microbiological quality of milk is influenced by a combination of management and control measures along the entire dairy supply chain. The main risk factors identified for raw milk contamination include:

- animal production practices: health status, housing, herd size, feed, water, waste management
- milking practices: mastitis control measures, teat washing and drying, stripping of foremilk, equipment cleaning and maintenance
- chilling and storage, including maintenance of the cold chain.

Implementing practices to reduce the pathogen load in the farm and dairy environment and improving hygienic control over milk harvest may reduce the level and frequency of milk contamination but are not elimination measures. The probabilistic modelling undertaken for the *Microbiological Risk Assessment of Raw Cow Milk* indicates that even when there is low pathogen prevalence in the dairy herd and a low level of bulk milk contamination (below the level of detection) cases of illness from *Campylobacter* spp., EHEC, *Salmonella* spp. and *L. monocytogenes* can be expected. No measures have been identified that would assure 'pathogen free' milk.

Category 3 products present a **medium to high** level of risk (depending on the pathogen) to both general and susceptible population groups because there are no measures to ensure pathogens are not present in bulk milk nor can subsequent handling and processing prevent survival and growth. The severity of illness that results from enterohaemorrhagic *E. coli* infection is a significant contributor to the level of risk for Category 3 products. Additionally, *L. monocytogenes* presents a high risk in these products for vulnerable groups.

6. Control measures

The parameters developed for Category 1 and 2 products reflect a combination of processing measures and product characteristics that are essential to the control of pathogens in these products. For Category 2 products, additional requirements on the raw milk for processing would also be required to ensure microbiological hazards can be managed.

A step-by-step hazard analysis (microbiological) of cheese processing and on-farm milk production has been undertaken to identify more specifically the additional control measures that would be required to support the manufacture of Category 1 and Category 2 raw milk products to provide for a low level of risk. This process has taken into account the primary production and processing factors impacting on pathogen contamination; current requirements in the Code, and additional provisions for raw milk products recommended by Codex. The identified control measures for milk production and processing are provided at Appendix 4 and 5.

Control measures for Category 3 products have not been elaborated as there are no further controls for milk production or processing than those identified for Category 2 products.

6.1 Milk production

The Table in Appendix 4 identifies the control measures and supporting requirements (e.g. skills and knowledge) for raw milk production in relation to those primary production factors identified as impacting on routes of contamination for microbiological pathogens. The measures included in the table consist of baseline control measures (those currently implemented for milk being produced for further processing including pasteurisation) and recommended additional measures for milk being produced for the processing of Category 2 products. No additional controls for milk production are required for Category 1 products.

6.2 Cheese processing

The table in Appendix 5 identifies the control measures required for raw milk cheese processing at key steps in production to prevent or minimise the microbiological hazard or risk presented. The measures included in the table consist of baseline control measures (those that are applicable to cheese production generally) and recommended additional measures for Category 1 and Category 2 products. The key steps in production include:

- raw milk receipt and storage
- milk standardisation
- milk pre-heating/warming
- acidification and coagulation
- curd production
- curd processing
- moulding/pressing
- salting
- ripening/maturation
- packaging
- storage/distribution/retail

While the table has been developed specifically for cheeses, the same controls could apply to any other cultured product, omitting those processing steps which are not relevant.

7. Assessment of Consumer Issues

7.1 Assessment of the potential health benefits associated with raw milk

A large number of submitters to the Discussion Paper stated that there are health benefits associated with the consumption of raw milk that should be taken into account in assessing Proposal P1007 and cited literature to support these claims. The following health benefits and nutritional outcomes were raised:

- There is an association between raw milk consumption and reduced allergy development during childhood.
- There is an association between raw milk consumption and a reduced risk of cardiovascular disease.
- The consumption of raw milk improves growth and development in children.
- Raw milk has a higher vitamin C content than pasteurised milk, and thus protects against scurvy.
- Pasteurisation destroys or decreases the content of vitamin A, B vitamins, vitamin D, and iodine in milk.
- Pasteurisation reduces the availability of folate and/or calcium from milk.

To address the claims made, FSANZ reviewed the literature cited by submitters in support of their comments to determine whether this evidence is of sufficient quality (taking into account study design and methodology; purpose and context of the study; statistical evaluation and epidemiological evidence) to validate the stated health outcomes[18].

The *Assessment of the Potential Health Benefits with Raw Milk* found that the majority of cited literature was insufficient to support the health benefits and nutritional outcomes claimed.

[18] The FSANZ *Assessment of the Potential Health Benefits with Raw Milk* is available on the FSANZ website http://www.foodstandards.gov.au/standardsdevelopment/proposals/proposalp1007primary3953.cfm

The only exception was for the relationship between raw milk consumption and reduced allergy sensitisation during childhood, where a substantial body of well-designed studies was presented. Because these studies were well designed, FSANZ conducted a more thorough review of the science regarding the relationship between raw milk consumption and allergy sensitisation.

7.1.1 Allergy sensitisation

A review of the science showed there is some indication for a weak association between the consumption of raw milk during early childhood and a lower prevalence of allergies later in life. However there are substantial limitations within the evidence base, most notably that the protective associations observed are inconsistent and not always statistically significant. The available evidence also indicates that raw milk consumption is not the only explanation for the reductions in allergy prevalence that have been observed and that other factors associated with a rural lifestyle could explain the observed protection against allergy development. In general, the findings of the studies on allergy sensitisation are consistent with a broader prevailing theory that there is a protective effect from a rural lifestyle.

It is concluded that a specific role for raw milk consumption in the protection against allergy sensitisation has not yet been established in the currently available scientific literature.

7.2 Nutritional claims

A number of submissions made comments that the nutritional profile of raw milk is superior to pasteurised milk. Milk itself is one of the most complete of all foods, containing nearly all the constituents of nutritional importance to humans. Pasteurisation does not impact on the nutritional importance of milk products in the Australian diet. They are the richest source of calcium in the Australian diet and are important contributors to protein, vitamin A, riboflavin, vitamin B_{12}, zinc and iodine.

Results from the 1995 National Nutrition Survey (NNS) showed pasteurised milk to be a major contributor of a variety of nutrients in the Australian diet:

- milk provided the greatest contribution to calcium intake across all population groups, ranging from 29% to 44% of total intake
- milk provided the greatest contribution to phosphorous and riboflavin intake in the population, contributing up to 25% and 30% respectively
- milk was a major contributor to protein, magnesium, zinc, potassium and retinol intakes. The contribution of milk to retinol intake was greatest in children aged 2-11 years, providing up to 27% of retinol intake.

Subsequent work in the 22nd Australian Total Diet Study (ATDS) showed milk to also be a major source of iodine for Australian children & adults. Milk was found to contribute between 35% and 64% of total iodine intake, with the greatest contribution to intake in children aged 2-3 yrs.

The release of the findings of the 2007 Australian National Children's Nutrition and Physical Activity Survey (*Kids Eat Kids Play*) has shown there is no substantial change in the intake of milk and its nutrition contribution in the diets of Australian children since the 1995 Australian and 1997 New Zealand National Nutrition Surveys.

Milk is not a major contributor to vitamin C intake, with other foods (e.g. fruits and vegetables) acting as more important sources of this nutrient.

7.3 Milk allergies and lactose intolerance

A number of submissions and responses to the Consumer Study indicate that many people have a misunderstanding of or misinformation relating to the issue of food allergy and intolerance. For example, there is a belief among some respondents that milk allergy is associated with pasteurised milk and that symptoms reduce or disappear by drinking raw milk. In addition, there is confusion between food allergy and food intolerance and that these are only associated with cow's milk.

7.3.1 Milk allergy

Milk allergy is an immune response where the body's immune system reacts to one or more of the milk proteins. Symptoms may include hives, eczema, face swelling, diarrhoea and noisy breathing. Like other allergens, milk can cause anaphylaxis, a severe and potentially fatal allergic reaction.

Treatment of allergy associated with cow's milk and dairy products involves avoidance or elimination of these foods from the diet. The proteins that may be responsible for triggering an allergic response are a normal constituent of the raw milk. As for other food allergens, heat treatment and other processing does not change the allergen potential of the proteins present. Therefore milk allergic individuals will have an allergic reaction to raw or heat treated milk.

It has been raised that goat milk may be used as a substitute to cow milk in the case of milk allergy. While there are differences in the proteins present in goat and cow milk, most people allergic to cow's milk will also be allergic to goat's milk and similar symptoms will be triggered (ASCIA, 2007)[19]. As allergies can be life threatening, a medical practitioner should be consulted for proper diagnosis and treatment.

7.3.2 Milk intolerance (lactose intolerance)

Some individuals may not be able to tolerate milk and milk products in their diet, which is different from milk allergy. Lactose intolerance is a metabolic disorder resulting from a person's inability to completely digest lactose (the sugar in milk). Symptoms may occur within an hour of ingestion or may take a day or more to develop and include abdominal pain, abdominal swelling, flatulence and diarrhoea. The amount of lactose that can be tolerated before symptoms arise will vary from person to person. Managing lactose intolerance involves establishing the level of lactose that can be tolerated and adjusting the serves consumed of lactose containing foods so that this level is not exceeded. A medical practitioner should be consulted for proper diagnosis and management.

Lactose is present in all milks. Cow milk and goat milk typically have similar levels of lactose and therefore management of lactose intolerance is not simply a matter of substituting one milk type for another. For those with lactose intolerance, the level of lactose consumed needs to be managed from all dairy sources through consuming products with low lactose (such as cheese or lactose modified milks) and/or restricting the number or size of serves of dairy foods consumed.

7.3.2.1 Goat milk digestibility

There is anecdotal evidence that some people find goats milk easier to digest however this is being confused with not causing intolerance or allergy.

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[19] ASCIA is the peak professional body of Allergists and Clinical Immunologists in Australia and New Zealand – Website**:** http://www.allergy.org.au/

Compared to cow milk, goat milk does have lower levels of the protein alpha s1-casein (a protein involved in curd formation), contains smaller fat globules and lacks agglutinin which causes fat globules to cluster together. Collectively these factors may contribute to increased digestibility (the ease and completeness of digestion). Digestibility, however, is a separate issue to milk allergy or lactose intolerance – goat milk, as do all milks, contains lactose and proteins that may be allergenic for some people whether the milk is raw or pasteurised.

Appendix 1 – Codex Code of Hygienic Practice for Milk and Milk Products

Excerpts of additional provisions that specifically apply to the production and processing of milk used for raw milk products[20]:

ANNEX 1: GUIDELINES FOR THE PRIMARY PRODUCTION OF MILK

3.2.1 Areas and Premises for Milk Production

3.2.1.2 Milking area and related facilities

Only potable water can be used in milking areas, product storage areas and other critical areas.

3.2.2 Animal Health

The milk cannot carry unacceptable levels of zoonotic agents. Therefore, the milk shall originate from individual animals:

- that are identifiable such that the health status of each animal can be followed. To this effect:
  - the herd shall be declared to the competent authorities and registered;
  - each animal shall be identified with a steadfast device and registered by the competent authorities.
- that do not show visible impairment of the general state of health and which are not suffering from any infection of the genital tract with discharge, enteritis with diarrhoea and fever, or recognisable inflammation of the udder;
- that do not show any evidence (signs or analytical results) of infectious diseases caused by human pathogens (e.g. Listeriosis) that are transferable to humans through milk including but not limited to such diseases governed by the OIE International Health Code;

that, in relation to brucellosis and tuberculosis, shall comply with the following criteria:

- cows milk shall be obtained from animals belonging to herds that are officially free of tuberculosis and brucellosis in accordance with the relevant chapters of the OIE International Animal Health Code;
- sheep or goat milk shall be obtained from animals belonging to sheep or goat herds that are officially free or free of brucellosis as per the OIE International Animal Health Code;
- when a farm has a herd comprised of more than one species, each species shall comply with sanitary conditions that are mandatory for each particular species;
- if goats are in the same environment with cows, goats shall be monitored for tuberculosis.

[20] The full *Code of Hygienic Practice for Milk and Milk Products* can be accessed through the Codex Alimentarius website www.codexalimentarius.net

In addition, it is necessary that the milk also be checked for other relevant aspects in accordance with point 5.2.3.1 (microbiological and other specifications) which can have an impact on the safety and suitability of raw milk products; these results may provide information regarding the health status of the animals.

In particular, preventive measures are needed to prevent disease including:

- animals of unknown health status shall be separated, before being introduced in the herd, until such time that their health status has been established. During that separation period, milk from those animals shall not be used for the production of milk for the manufacture of raw milk products;

- the owner shall keep a record of relevant information, e.g., results of tests carried out to establish the status of an animal just being introduced, and the identity for each animal either coming or leaving the herd.

3.2.3 General Hygienic Practice

3.2.3.1 Feeding

When using fermented feed, it is necessary that the feed be prepared, stored and used in a manner that will minimise microbial contamination. Particular attention shall be given to compliance with good practices concerning the following aspects:

- the design of silos
- good production practices of silage
- regular check of the quality of the fermented feed (organoleptic inspection or pH).

The owner shall keep a record of relevant information concerning feed.

3.2.4 Hygienic Milking

3.2.4.3 Milking equipment cleaning and disinfection

Only potable water can be used in contact with milking equipment and other milk contact surfaces.

3.3.2 Milk Storage Equipment

Milk tanks and cans can be used only to store milk and milk products.

3.3.3 Premises for, and Storage of, Milk and milk-related Equipment

When milk for further processing is not collected or used within 2 hours after milking, it shall be cooled:

- to a temperature equal to or below 6°C when collected on a daily basis; or
- to a temperature equal to or below 4°C when not collected every day.

Deviations from those temperatures may be acceptable if those deviations will not result in an increased risk of microbiological hazards, have been approved by the manufacturer receiving the milk, have been approved by the competent authority, and the end product will still meet the microbiological criteria established in accordance with 5.2.3.2.

3.3.4.1 Collection, Transport and Delivery Procedures

Milk to be used for the manufacture of raw milk products shall be collected separately. Mixing, or cross-contamination with milk which does not comply with quality (including microbiological) expected for the processing of raw milk products shall not be allowed.

For example:

- organise collection pick-ups in such a way that milk for the manufacture of raw milk products be collected separately; or

- use milk transport tankers with compartments that will allow the separation of the milk for raw milk products from milk to be heat processed combined with the pick-up of milk for raw-milk products before milk for other products.

3.3.4.3 Transport Time and Temperature

The temperature of the milk to be used for the manufacture of raw-milk products shall not exceed 8°C, unless the milk has been collected within 2 hours after milking.

Deviations from this temperature may be acceptable if these deviations will not result in an increased risk of microbiological hazards, have been approved by the manufacturer receiving the milk, have been approved by the competent authority and the end product will still meet the microbiological criteria established in accordance with 5.2.3.2.

ANNEX II: GUIDELINES FOR THE MANAGEMENT OF CONTROL MEASURES DURING AND AFTER PROCESSING

5.1.3 Establishment of Process criteria

It is critical for a dairy farm, when producing milk intended for the manufacture of raw milk product, to comply with the provisions (including the identified additional provisions) detailed in Annex 1 and in section 5.2.3.1 of this Annex, and these activities should be frequently monitored and evaluated for their effective implementation. This evaluation may lead to the identification of needed improvements at the primary production level (practices, equipment, environment, etc.) or in the classification of dairy farms according to their ability to provide milk for the processing of raw milk products.

Any non-compliance detected either at the farm level or at the milk reception of a manufacturing plant should result in immediate action that may affect the farm, the manufacturing establishment or both. For this reason, there should be clear communication between the manufacturer and the farm and, if necessary, technical assistance should be provided to the primary producer by the manufacturer.

5.2.2 Microbiological and Other Specifications

5.2.2.1 Milk

Depending on the hazard analysis performed by the manufacturer and the combination of microbiological control measures applied during and after processing of milk products, specific microbiological criteria regarding pathogens (for example: *Salmonella* spp., *Listeria monocytogenes*) may need to be established.

Appendix 2 – Quarantine Requirements for the Importation of Dairy Products from Approved Countries[21]

1. DAIRY PRODUCTS (OTHER THAN CHEESE AND BUTTER) OF BOVINE ORIGIN FROM APPROVED COUNTRIES

1.1. The milk or the milk from which the dairy product is made must originate from country/zone recognized by the Office International des Epizooties (OIE) as foot and mouth disease-free, with or without vaccination.

1.2 The milk or the milk from which the dairy product is made must originate from a country/zone which meets OIE requirements for freedom from lumpy skin disease, and which is free from buffalo pox.

1.3 The animals must be clinically healthy at the time the milk was obtained.

1.4 The products must be processed in a foot and mouth disease-free country/zone.

1.5 EITHER:

(a) the milk or the milk from which the dairy product was made must originate from a country/zone which meets OIE requirements for freedom from:
- rinderpest (Code Article 2.1.4.2); and
- bovine brucellosis (Code Article 3.2.1.1); and
- bovine tuberculosis (Code Article 3.2.3.1); and
- which is free from Jembrana.

OR

(b) the milk or the milk from which the dairy product was made must be subjected to one of the following heat treatments:
- pasteurisation at 72°C for a minimum of 15 seconds or an equivalent treatment, in terms of phosphatase destruction; or
- pasteurisation at 72°C for a minimum of 15 seconds or an equivalent treatment, in terms of phosphatase destruction; or
- a UHT treatment of 135°C for minimum of 1 second.

1.6 The packaging or immediate container must be stamped with the date of manufacture of the products.

1.7 Dairy products imported under condition 2.1.5(a) shall not be released from quarantine until the conclusion of a period of 30 days from the date of manufacture.

2. DAIRY PRODUCTS (OTHER THAN CHEESE AND BUTTER) OF OVINE/CAPRINE ORIGIN FROM APPROVED COUNTRIES

2.1 The milk or the milk from which the dairy product is made must originate from a country/zone recognized by the Office International des Epizooties (OIE) as foot and mouth disease-free, with or without vaccination.

2.2 The milk or the milk from which the dairy product is made must originate from a country/zone which meets OIE requirements for freedom from sheep pox and goat pox.

[21] Requirements excerpted from the AQIS Import Risk Analysis: Importation of dairy products for human consumption – Final Report http://www.daff.gov.au/ba/ira/final-animal/dairy

2.3 The animals must be clinically healthy at the time the milk was obtained.

2.4 The products must be processed in a foot and mouth disease-free country/zone.

2.5 EITHER:

(a) the milk or the milk from which the dairy product was made originated in a country/zone which meets OIE requirements for freedom from:
- rinderpest (Code Article 2.1.4.2); and
- peste des petis ruminants (Code Article 2.1.5.2); and
- ovine brucellosis (*Brucella melitensis)* (Code Article 3.3.2.1); and
- maedi-visna (Code Article 3.3.5.1); and
- contagious agalactia (Code Article 3.3.3.1); and
- contagious caprine pleuropneumonia (Code Article 3.3.6.2) [caprine products only].

OR

(b) The milk or the milk from which the dairy product was made must be subjected to one of the following heat treatments:
- pasteurisation at 72°C for a minimum of 15 seconds or equivalent treatment, in terms of phosphatase destruction; or
- a UHT treatment of 135°C for a minimum of 1 second.

2.6 The packaging or immediate container of products must be stamped with the date of manufacture.

2.7 Dairy products imported under condition 2.2.5(a) will not be released from quarantine until the conclusion of a period of 30 days from the date of manufacture.

3. DAIRY PRODUCTS (OTHER THAN CHEESE AND BUTTER) OF CAMEL ORIGIN FROM APPROVED COUNTRIES

3.1 The milk or the milk from which the dairy product is made must originate from a country/zone recognized by the Office International des Epizooties (OIE) as foot and mouth disease-free, with or without vaccination.

3.2 The milk or the milk from which the dairy product is made must originate from a country/zone which is free from camel pox.

3.3 The animals must be clinically healthy at the time the milk was obtained.

3.4 The products must be processed in a foot and mouth disease-free country/zone.

3.5 EITHER:

(a) the milk or the milk from which the dairy product was made must originate from a country/zone which meets OIE requirements for freedom from:
- rinderpest (Code Article 2.1.4.2) and
- ovine brucellosis (*Brucella melitensis*) Code Article 3.3.2.1) and
- bovine brucellosis (Code Article 3.2.1.1) and
- bovine tuberculosis (Code Article 3.2.3.1)

OR

(b) The milk or the milk from which the dairy product was made must be subjected to one of the following heat treatments

- pasteurisation at 72°C for a minimum of 15 seconds or equivalent treatment, in terms of
- phosphatase destruction or
- a UHT treatment of 135°C for minimum of 1 second.

3.6 The packaging or immediate container must be stamped with the date of manufacture of the products.

3.7 Dairy products imported under condition 2.3.4(a) will not be released from quarantine until the conclusion of a period of 30 days from the date of manufacture.

4. CHEESE AND BUTTER FROM APPROVED COUNTRIES WHICH ARE FREE OF FOOT AND MOUTH DISEASE

4.1 The milk or the milk from which the cheese or butter is made must originate from a country/zone recognized by the Office International des Epizooties (OIE) as foot and mouth disease-free, with or without vaccination.

4.2 The animals must be clinically healthy at the time the milk was obtained.

4.3 The products must be processed in a foot and mouth disease-free country/zone.

4.4 EITHER:

(a) The milk or the milk from which the cheese or butter was made must be subjected to one of the following heat treatments:
- pasteurisation at 72°C for a minimum of 15 seconds or equivalent treatment, in terms of phosphatase destruction or
- a UHT treatment of 135°C for a minimum of 1 second.

OR

(b) The milk from which the cheese or butter was made was not heat treated as above and the milk or milk from which the cheese or butter was made must originate from country/zone which meets the OIE requirements for freedom from rinderpest in accordance with Code Article 2.1.4.2.

4.5 The packaging or immediate container must be stamped with the date of manufacture of the products.

4.6 Cheese or butter not heat treated in accordance with requirement 2.4.4(a) will not be released from quarantine until the conclusion of a period of 30 days from date of manufacture*.
*[Note: For cheese the date of manufacture is the date the curd was set.]

5. CHEESE FROM APPROVED COUNTRIES AFFECTED BY FOOT AND MOUTH DISEASE

5.1 The milk or the milk from which the cheese is made must originate from a country/zone approved by AQIS for the export of dairy products to Australia.

5.2 The animals must be clinically healthy at the time the milk was obtained.

5.3 EITHER:

(a) The milk from which the cheese was made was pasteurised at a minimum of 72°C for 15 seconds or equivalent treatment, in terms of phosphatase destruction and the cheese has attained a pH of less than 6 and the cheese has aged for 30 days or more.

OR

(b) The cheese has attained a pH of less than 6 and has aged for 120 days or more at a temperature not less than 2°C.

5.4 The packaging or immediate container must be stamped with the date of manufacture of the products.

5.5 Cheese made according to requirement 2.5.3(a) above will not be released from quarantine until a minimum of 30 days after the date of manufacture. Sampling of cheeses prior to release from quarantine to ensure the pH is not above 6 may be required by the Director of Quarantine.

5.6 Cheese made according to requirement 2.5.3(b) above shall not be released from quarantine until a minimum period of 120 days storage at a temperature not less than 2 °C after the date of manufacture. Sampling of cheeses prior to release from quarantine to ensure the pH is not above 6 may be required by the Director of Quarantine.
*[Note: For cheese the date of manufacture is the date the curd was set.]

Appendix 3 – Raw milk product consumption behaviour, knowledge & motivations

1. Introduction

Evidence about consumer's knowledge, motivations and behaviours plays a fundamental role in the risk analysis process used to develop primary production and processing standards. In the case of the Raw Milk Products Primary Production and Processing Standard an enhanced understanding of: (i) who consumes raw milk products; (ii) why they are consumed; and (iii) consumer's knowledge of raw milk products; can inform approaches to assess and manage the health and safety risks posed by the consumption of raw milk products.

Unfortunately there is a poor research base on Australian consumers' knowledge, motivations and behaviours with respect to raw milk products from which to draw conclusions. Accordingly FSANZ commissioned a qualitative consumer study on raw milk behaviour and attitudes to secure some Australian data. The FSANZ consumer study used qualitative methods to develop an in-depth understanding of consumer's attitudes, understanding and consumption behaviours (Colmar Brunton, 2009). The study provided data that enables an informed understanding of the drivers of consumption and the breadth of consumer's motivations. However the study was not designed to provide robust estimates of quantitative consumption behaviour.

In contrast to the FSANZ consumer study a number of international studies have been undertaken that do permit population estimates of consumption behaviour to be determined. A number of food safety behaviour surveys collect data on various behaviours including the consumption of raw milk and milk products (e.g. Headrick et al 1997; Altekruse et al 1999; Zhang & Penner 1999). These can provide data on the prevalence of unpasteurised milk and milk product consumption, and typically permit a socio-demographic profile to be developed of those who consume unpasteurised milk products. However as their focus is food safety in general more detailed information on consumption behaviour (e.g. quantity, frequency), motivations and understanding of risks is generally limited. Furthermore these studies have tended to focus on unpasteurised milk consumption rather than other products prepared from unpasteurised milk.

Another group of studies have specifically focussed on dairy farm workers and owners (e.g. Jayarao et al 2006; Kaylegian et al 2008). These may use representative samples or opportunistic samples of dairy farm workers and their families and typically collect data on consumption behaviour, motivations and understanding. Some studies also collect samples of bulk milk and relate microbiological analyses to demographic and cognitive aspects (e.g. Jayarao et al 2006).

The New Zealand Food Safety Authority (NZFSA) commissioned a study on understanding and awareness of raw milk and raw milk products in 2008. The study targeted 4 distinct groups covering the general public, consumers of raw milk products, trade and health professionals and vulnerable groups. A particular focus of NZFSA study was to gather data on the effectiveness of NZFSA food safety initiatives on raw milk and raw milk products. The study also collected data on understanding of risks and terminology used on product packaging and in food safety educational materials.

This attachment briefly summarises the key findings from the literature with respect to the three key areas:

- who consumes raw milk products
- why they are consumed
- consumers' knowledge of raw milk products.

2. Who consumes raw milk and raw milk products?

There is limited reliable data on the prevalence of unpasteurised milk and milk product consumption. Available data is focussed on the level of unpasteurised (drinking) milk consumption, rather than other products such as raw milks cheeses and yoghurts.

As part of the FSANZ commissioned consumer research an online poll was carried out to gauge the prevalence of consumption of unpasteurised milk. The poll suggested that the prevalence of consumption was 0.7%, while this can only be considered indicative it is consistent with other international studies (Colmar Brunton 2009). For example the prevalence of consumption estimated from food safety surveys in the United States suggests between 1-3% of the population may consume unpasteurised milk (Headrick et al 1997; Altekruse 1999; Zhang & Penner 1999).

Importantly, consumption of unpasteurised drinking milk is not evenly distributed throughout the population but rather particular identifiable groupings tend to be associated with raw milk consumption. For example among dairy farm workers and their families consumption of unpasteurised milk may be as high as 45% (Kaylegian et al 2008; Jayarao 2006), similarly some ethnic cultures also have also demonstrated a higher likelihood of consuming raw milk (Altekruse 1999; Bell 1999).

Analysis of 1995/96 data from a survey carried out in 8 US states suggests that raw milk consumers were more likely to be male, younger, have lower levels of formal education, lower income levels and more likely to be Asian, Pacific Islander or Hispanic than those who did not consume unpasteurised milk (Altekruse 1999). This analysis also found that those who reside in suburban or small town locations were more likely to consume unpasteurised milk than those in rural locations, who in turn were more likely to consume unpasteurised milk than those in urban locations.

No Australian population based surveys of unpasteurised milk or milk product consumption has been located. While no reliable socio-demographic estimates on Australia consumers of raw milk are available the FSANZ study provided evidence that in some cases raw milk is consumed by those with higher vulnerability to food-borne illnesses for example children and including children under the age of 4. The FSANZ study found that some parents do feed unpasteurised milk to infants and children perceiving benefits related to allergies or lactose/digestive issues. The study suggested that goat milk was more likely to be fed to infants and children though some parents also fed their children raw cow milk.

3. Why are raw milk and raw milk products consumed?

The FSANZ consumer study identified four raw milk consumer 'segments' based on variations in their motivations for consumption and triggers leading to that consumption. They were:

- **Opportunists**: typically people who live and/or work in rural areas, especially the dairying community, and for whom the primary motivation is convenience, low cost and easy availability.

- **Lifestylers**: the most emotionally committed segment with individuals who choose to consume organic and natural products (and often other compatible lifestyle choices). Consumption is part of a wider belief system and is not done in isolation.

- **Nutrition seekers**: like the lifestyler segment, the nutrition seeker makes a conscious choice to consume raw milk. The choice is based on an acceptance of the perceived or promoted nutritional benefits of raw milk, often with reference to technical or scientific considerations.

- **Health concerned**: this segment makes a deliberate choice to consume raw milk in actively responding to a health consideration. This segment has much in common with the previous two, though while the previous two are pro-active choices made by individuals, the health concerned segment is more reactive to a specific health concern.

The segments identified are neither definitive nor mutually exclusive. In particular there was considerable overlap with individuals expressing motivations from a number of segments, however for most individuals a dominant segment was observed or could be inferred. The limitations of the study did not permit the relative sizes of the segments to be determined nor to exclude the possibility of other segments not included here.

There are no quantitative Australia data on motivations for consuming unpasteurised milk, however California data from 1994 data indicate that taste (38% of consumers indicated this), health (17%), nutrition (10%) and as it was the only source of milk (10%) (Headrick et al 1997) were the key reported reasons for consuming raw milk. Surveys of dairy farming families indicated that taste and convenience, followed by cost and then nutrition and health aspects motivated their consumption of unpasteurised milk (Kaylegian et al. 2008). Jayarao et al (2006) also found taste and convenience were key motivators in their study of Pennsylvanian farming families.

4. Consumer’s knowledge and understanding of health risks/benefits

The FSANZ consumer study sought to better understand consumer’s knowledge and understanding of the health risks and benefits of raw milk. It was apparent that many participants held detailed and nuanced knowledge and beliefs about raw milk. In many cases these knowledge and beliefs, particularly related to health and nutrition, was in contradiction to generally accepted scientific understandings.

Participants in the research perceived several benefits of raw milk over pasteurised milk. These included cost and availability (for the opportunist segment) and that pasteurisation was detrimental to the nutritional value of the milk. The main benefits participants reported of raw milk were: nutritional content, health, taste and cost. A major benefit was knowing the source of the milk, and this was also an essential pre-requisite to consuming raw milk for many participants. They felt closer to the producer of the milk, reporting that they knew what the animals were fed, how they were looked after and other factors that were of interest and relevance to them.

For consumers of raw cow milk, the benefits were vested very much in the unpasteurised nature of the milk. For consumers of raw goat milk the source of the benefits was less definitive – in particular some of the health benefits sought would be obtained from the consumption of any goat milk, and the choice of raw goat milk was more opportunistic.

Many participants in the FSANZ consumer study were aware of information promoting the dangers of raw milk. They largely considered this ill-informed at best, and malicious scare-mongering at worst. Consumers considered that the warning labels on ‘pet milk’ and ‘bath milk’ indicating that it was not suitable for human consumption were a legal requirement – rather than a legitimate warning.

The main sources of information about raw milk are word of mouth and personal experience and observation. A range of books and websites was referred to – the single information source most specifically referenced was the Weston A. Price Foundation, though this may reflect the origin of the sample used for the study as much as the breadth of information in the community.

Appendix 4 – Hazard table for the production and transport of raw milk intended to be used for Category 2 products

Primary Production Factor	Hazard/Risk Area	Baseline Control Measures currently applied	Recommended Additional Measures for the harvesting and transport of raw milk intended for Category 2 Products
Animal Health	Animals infected with zoonotic pathogens of human health impact	Exclusion of diseased animals (General requirement under Standard 4.2.4 that a dairy primary production business must include control measures in its food safety program that manage hazards in relation to animal health.)	• In the case of clinical disease[22], appropriate veterinary intervention is required. • The milking herd is to be subject to veterinary inspection at an increased frequency. • A suitable identification system to be in place to ensure each individual animal is uniquely identifiable. • Mandatory vaccination programmes may be considered and included as a requirement if deemed appropriate.
		Mastitis management (not a specific requirement under Standard 4.2.4 but should be practiced as part of managing hazards in relation to animal health)	• Operator required to have in place, and adhere to, a programme or procedures for the management of mastitis (for example Countdown Downunder) in conjunction with veterinary advice. • Mandatory annual milking machine testing by a suitably competent person.
		'Skills and knowledge'	• Dairy primary production business must be familiar with, and understand, relevant requirements specific to animal husbandry, feeding and harvesting when supplying milk intended for raw milk products.
Inputs - Water - Silage - Other feed, additives and supplements	Inputs contaminated with pathogens of human health impact	Animal feed and water should be safe and suitable (General requirement under Standard 4.2.4 that a dairy primary production business must include control measures in its food safety program that manage hazards arising from inputs.)	• Advisory information to be provided that milking animals should be supplied with drinking water of a suitable quality to minimise water borne disease transmission. This will include limiting access of animals to unsuitable water. • All feed (including feed additives and supplements) must be of known origin, be traceable back to the source of the feed and be suitable for the milking animals. • No feed waste, poor quality silage, sludge or mouldy feed to be offered.

[22] The clinical and/or pathological manifestation of infection (2007 OIE – Terrestrial Animal Health Code)

Primary Production Factor	**Hazard/Risk Area**	**Baseline Control Measures currently applied**	**Recommended Additional Measures for the harvesting and transport of raw milk intended for Category 2 Products**
			• Feed storage facilities must be appropriate for the feed. Advisory information to be provided. • Particular care must be taken with the production or purchase of fermented feeds. Any fermented feed is to be prepared, stored and used in a manner that minimises microbial contamination. Special consideration to be given to design of silo's or bunkers, production practices for silage, and controlling the quality of the fermented feed including pH or sensory assessment.
Farm dairy	Contamination of milking plant with either pathogens of human health impact or material which supports the survival/growth of such pathogens	(General requirement - food safety program must include control measures that manage hazards arising from the design, construction, maintenance and operation of premises and equipment.)	• Farm Dairy assessments/audits to be carried out more frequently (6 monthly?) • Assessment criteria and checklist to be reviewed once final criteria are agreed
Environment (Housing and races)	Contamination of exterior of udder or teat with pathogens of human health impact	(General requirement - food safety program must include control measures that manage hazards arising from the design, construction, maintenance and operation of premises. Premises include animal holding areas adjacent to milking sheds.)	• Housing, pens and bedding must be designed, maintained and operated in an appropriate manner to minimise pests, contamination of feed and soiling of the udders and teats. • Holding, feeding, loafing and wintering yards or pads must be operated in a manner that minimises soiling of the udder and teats as well as negative impacts on animal health • Races (stock tracks) must be maintained to minimise soiling of the udder and teats • Effluent must be managed to ensure appropriate disposal and minimise exposure to milking animals. Spray irrigation must be under a suitable plan. • Milk to be withheld from animals exposed to areas affected by flooding

Primary Production Factor	Hazard/Risk Area	Baseline Control Measures currently applied	Recommended Additional Measures for the harvesting and transport of raw milk intended for Category 2 Products
	Animal to animal transmission of pathogens of human health impact		• Operator to ensure any housing is operated in a manner that does not pose an increased risk to animal health, that is cleaned as appropriate, has airflow; immediate removal on identification of diseased animals with re-entry only once the condition has been resolved or, in the case of infected[23] animals, when instructed to do so by a Vet or authorised person, for the period instructed.
Milking Plant	Contamination of farm plant and equipment with pathogens of human health impact or material which supports the survival/growth of such pathogens	Cleaning, sanitising and maintenance of premises and equipment	• Pre-milking rinse or sanitising rinse must be undertaken as appropriate for the purpose of the milk (i.e. same as for manufacturing equipment contact surfaces). Drain if necessary following rinse.
Milking Animal	Contamination of udder or teats with pathogens of human health impact or material which supports the survival/growth of such pathogens	Udder and teats should be clean Withholding of milk observed to be abnormal. Milk must be withheld from diseased animals and animals isolated on veterinary instruction	• Teats must be clean and dry: - for bovine wash and dry with single service towel - for goats wipe - for other species clean in the most appropriate manner. • Advisory information on pre-milking teat disinfection to be provided – pending further information. • Mandatory stripping of foremilk[24], observation for abnormalities and withholding of milk from supply. • Animals with milk to be withheld from diseased animals or animals withheld on veterinary inspection are to be segregated in such a way that their milk cannot contaminate the bulk milk.
	Post milking teat canal infection with pathogens of human health impact		• Mandatory protection of teat canal from infection immediately post milking (e.g. teat disinfection)
	Contamination of water with pathogens of human health impact	Water Quality Requirement (requirement for control measures to manage hazards arising from inputs)	• Water to be free of pathogens, i.e. must meet the microbiological standard applicable to potable water or an acceptable alternative

[23] Presence of a pathogenic agent in the host
[24] Drawing foremilk ejects microorganisms which may have entered the teat canal.

Primary Production Factor	Hazard/Risk Area	Baseline Control Measures currently applied	Recommended Additional Measures for the harvesting and transport of raw milk intended for Category 2 Products
	Increase in numbers of microorganisms of concern	Cooling time / temp	• Refer to post harvest below, no additional measures required during milk harvesting
	Transfer of pathogens of human health impact by milk harvesters	Health and hygiene requirements	• Hands and forearms to be kept clean during milking and appropriate hand washing facilities must be available. • Hands must be washed between animals when milking by hand. • Wearing new, clean, latex-type gloves by milking personnel during milking recommended.
Milking Plant	Contamination of milking plant or storage equipment with pathogens of human health impact	Cleaning / sanitizing Current water quality requirements Use of storage equipment	• No additional measure • Water must meet the requirements for use in manufacturing premises i.e. potable water or acceptable alternative • Equipment for storage of raw milk must not be used for any other purpose (e.g. not for storage of calf milk.) When not in use the equipment must be protected from soiling or other contamination.
Storage	Increase in numbers of microorganisms of concern	On farm milk cooling (milk must be cooled and stored at a temperature that prevents or reduces the growth of microbiological hazards). Current industry practice is for milk to be cooled to 5°C or less within 3.5 hours from the start of milking.	• On farm milk cooling to 6°C or below within 2 hrs from the completion of milking (from Codex) • Further cooling to 5°C or less within 3.5 hours from the commencement of milking • Raw milk stored on-farm must be held at or below the nominated temperature limits until removal from the farm silo or until the next milking.[25]
	Cross contamination from non-conforming (for Category 2 purposes) milk.	Provisions for withholding unsuitable milk	• All reasonable steps taken to avoid raw milk not suitable for category two dairy products being collected or used unintentionally for their production. Steps include clearly labelling the bulk milk tank and not storing any material other than category two milk in a bulk milk tank intended for category two raw milk.

[25] Note that the maximum length of time milk can be stored on farm will be determined through compliance with the recommended additional measures at the 'Transfer to Processing Premises' step which states that processing is to commence within 48 hours of the first milking.

Primary Production Factor	Hazard/Risk Area	Baseline Control Measures currently applied	Recommended Additional Measures for the harvesting and transport of raw milk intended for Category 2 Products
Disposal of no-conforming raw milk	Use of milk that is not fit for purpose	Procedures to appropriately dispose of non-conforming milk	• Where non-conforming milk (for Category Two purposes) is shown to conform with general requirements this milk can be diverted to processing
Transfer to Processing Premises	Environmental contamination	Sanitary condition of milk collection vehicles	• As for transport of pasteurised milk • Prevention of contamination with category one milk
	Increase in numbers of microorganisms of concern		• Milk temperature not to exceed 8°C at any point from collection at the farm through to commencement of the manufacturing process (Codex) • Processing to commence within 48 hours of the first milking (Codex)
	Non category two milk which may be contaminated with pathogens of human health impact		• Requirement that milk intended for category two processing must be segregated from milk intended for category one processing. • Milk must only be sourced from a farm dairy registered/licensed to supply raw milk for the manufacture of category two dairy products.

Appendix 5 – Hazard table for the production raw milk cheese at key steps in production

Step	Hazard/risks	Baseline Control Measures[26] (applicable generally to cheese production)	Recommended additional measures for raw milk products	
			Category 1 Products	Category 2 Products
General requirements applicable at all stages of raw milk cheese processing	General cross-contamination	Prevent contamination from environment, premises, equipment, ingredients and people through: • Cleaning and sanitising program • Maintenance program • Health and hygiene requirements		
	Cross-contamination of milk or products from higher risk milk (co-mingling)			(System for) Segregation of milk and dairy materials intended for the manufacture of Category 2 products from Category 1 products. • Prior to processing • During processing
Milk receipt and storage	Presence of pathogenic microorganisms in the raw milk	No measures currently specified – there are industry incoming material requirements such as somatic cell count/total plate count (generally for quality reasons as pasteurisation will eliminate pathogens present)	(No additional measures are currently applied to milk used, as by definition pathogens are eliminated through processing techniques and/or the intrinsic characteristics of the product)	1. Only milk that has been produced in accordance with requirements for raw milk production for Category 2 products can be used 2. Raw milk specifications could include criteria for specific pathogens and/or indicators
	Growth of any pathogenic microorganisms present	Time/temperature controls (storage at 5°C or below)		Processing to commence within 48 hours of milk harvesting. Milk stored at 5°C or below – temperature not to exceed 8°C prior to manufacture
Milk standardisation (if required)	Growth of any pathogenic microorganisms	Time/temperature controls		Specific time/temperature measures may need to be documented, implemented, recorded and verified.
Milk pre-heating/	Growth of any	Minimise time (generally quality rather than		Minimise time for safety purposes-

[26] Baseline Control measures must be: Documented, including non-conformances; implemented; recorded; and verified

Step	Hazard/risks	Baseline Control Measures[26] (applicable generally to cheese production)	Recommended additional measures for raw milk products	
			Category 1 Products	Category 2 Products
warming	pathogenic microorganisms present	safety)		measures may need to be documented, implemented, recorded and verified.
Addition of starter culture / acidification process	Slow or incomplete growth of starter culture could allow for pathogen survival/grow during acidification.	Use of viable, active starter culture (monitored though checking pH drop over time)		1. Commercially sourced starter cultures are preferred but regardless of source they must be pathogen free, and capable of achieving required pH drop in required time 2. pH drop in specified time (if integral to safety)- specific measures may need to be documented, implemented, recorded and verified. 3. Whey or material derived from previous cheesemaking permitted.
	Contamination from starter culture	'approved supplier' or other assurance/testing program*		No additional measures
Coagulation e.g. addition of rennet				
Curd production e.g. cutting, cheddaring				
Curd processing e.g. heating/cooking, stretching, washing	Processing • does not achieve the required level of pathogen reduction • allows pathogen increases beyond the level that subsequent processing steps can eliminate	Specified curd processing steps	Curd processing parameters specified if integral to safety or categorisation of the product: e.g. specified minimum curd cooking temperature.	Curd processing parameters specified if integral to safety - measures may need to be documented, implemented, recorded and verified.
Moulding/pressing	-			
Salting e.g. dry salting/ brine	Insufficient salt content/distribution	Specified salt concentration/contact time		Parameters specified if integral to safety or categorisation of the product

* Controls around assuring the safety of starter cultures to be investigated

Step	Hazard/risks	Baseline Control Measures[26] (applicable generally to cheese production)	Recommended additional measures for raw milk products	
			Category 1 Products	Category 2 Products
immersion. **Note that salting may occur before or after moulding**	achieved allowing for microbial growth during maturation or not providing the necessary pathogen reduction.			(possibly in terms of water activity or minimum salt concentration) - measures may need to be documented, implemented, recorded and verified.
Maturation/ ripening	Growth of pathogenic microorganisms present depending on pH, water activity, presence of inhibitory substances in the cheese, time and temperature of storage etc.	Storage time/temperature controls Water activity and pH of product	Parameters specified if integral to safety or categorisation of the product. These could include: • Minimum storage time and temperature • Specified moisture content (e.g. <39%)	Parameters specified if integral to safety or categorisation of the product. These could include: • Minimum storage time • pH/salt in moisture Measures may need to be documented, implemented, recorded and verified.
	Change in surface conditions during storage (e.g. pH) could promote growth of some pathogens present	Use of specific treatments must not adversely affect the safety of the product	No additional measures	Treatments that may allow pathogen growth will not be permitted
Packaging	General cross-contamination	Approved supplier of packaging materials	No additional measures	No additional measures
Product storage, distribution and retail	Growth of microorganisms	Time/temperature controls	No additional measures	No additional measures
Final product verification	Process failure not identified	Must comply with Standard 1.6.1 – Microbiological Limits for Foods Testing for specific parameters e.g. pH, water activity, salt content	No additional measures	Testing to verify process required on every batch.

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