

Imported food risk statement
Raw milk cheese and *Mycobacterium bovis*

Commodity: Cheese that has not undergone a heat treatment step (such as pasteurisation, thermisation with additional hurdles or high temperature curd cook) during production. A raw milk cheese must not support the growth of pathogenic microorganisms and have no net increase in pathogen levels during the manufacture of the cheese.

Microorganism: *Mycobacterium bovis*

Recommendation and rationale
<p>Is <i>Mycobacterium bovis</i> in raw milk cheese that does not support the growth of pathogenic microorganisms a medium or high risk to public health:</p> <p><input checked="" type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Uncertain, further scientific assessment required</p> <p>Rationale:</p> <ul style="list-style-type: none"> • <i>M. bovis</i> is a zoonotic pathogens and is associated with farming animals from which milk is used to produce raw milk cheese • The production of raw milk cheese lacks a process that would reliably inactivate <i>M. bovis</i> • <i>M. bovis</i> is a severe hazard as it causes illness of long duration and can be life-threatening • Human illness has been associated with raw milk cheese contaminated with <i>M. bovis</i> and international surveillance data have shown detections of <i>M. bovis</i> in raw milk cheese

General description
<p>Nature of the microorganism:</p> <p><i>M. bovis</i> is an aerobic, Gram-positive, non-spore forming, rod-shaped bacteria. It is widely distributed in the environment and is found in soil and water. As the causative agent of bovine tuberculosis, <i>M. bovis</i> causes systemic infections in cattle and other animals, where it initially infects the gastrointestinal tract before spreading to other parts of the body. <i>M. bovis</i> can be shed directly from infected mammary glands into milk and subsequently transmitted to humans via consumption of contaminated raw milk products (FSANZ 2006).</p> <p><i>M. bovis</i> is a very slow growing microaerophilic organism. Growth can occur between 25°C and 45°C, with an optimum growth rate at 37°C. <i>M. bovis</i> survives better under cool conditions (i.e. during winter) and survives dry conditions well. Pasteurisation of milk at 72°C for 15 seconds (or equivalent) is lethal to <i>M. bovis</i> (Lake et al. 2002; FSANZ 2006; Rowe and Donaghy 2008).</p>
<p>Adverse health effects:</p> <p><i>M. bovis</i> is a severe hazard as it causes illness of long duration and can be life-threatening (ICMSF 2002). Children and immunocompromised individuals are more susceptible to <i>M. bovis</i> tuberculosis, and immunocompromised individuals are more susceptible to re-activation of an infection acquired in the past (Lake et al. 2002; Gallivan et al. 2015).</p>

Symptoms associated with *M. bovis* tuberculosis include fever, chills, weight loss, abdominal pain, diarrhoea or constipation. Symptoms of further infection depend on the organs infected. The onset of illness of tuberculosis can be years after infection and even in immunocompromised individuals the incubation period can be several months. Symptoms may last for months or years. In a small proportion of people the infection can prove fatal (Lake et al. 2002; FSANZ 2006; Rowe and Donaghy 2008).

Large quantities of *M. bovis* (10^4 – 10^6 cells or more) appear to be required to cause illness via the oral route (FSANZ 2006).

Consumption patterns:

Raw milk cheese was not identified as being consumed by respondents in the 2007 Australian National Children's Nutrition and Physical Activity Survey (2-16 years) (DOHA 2008). Similarly, the 2011 – 2012 Nutrition and Physical Activity Survey (part of the 2011 – 2013 Australian Health Survey) did not identify any consumers of Roquefort or raw milk cheese specifically (ABS 2014). This indicates the small proportion of consumers of raw milk cheese in the population.

Data sourced from the Australian Bureau of Statistics for 2008 – 2014, indicates Australia imports about 25.5 tonnes of Roquefort cheese (semi-hard raw milk cheese) annually.

Key risk factors:

M. bovis can be a contaminant of milk sourced from infected herds. As raw milk cheese production does not include a process that reliably inactivates pathogens, the microbiological quality of raw milk is critical. Other risk factors include temperature control of the raw milk, acidification process, curd cooking, maturation/ripening, salt concentration, water activity, pH and nitrate (FSANZ 2006; FSANZ 2009).

Risk mitigation:

The primary control for *M. bovis* is that milk used for raw milk cheese processing is only sourced from animals belonging to herds that are officially free of tuberculosis in accordance with the OIE *Terrestrial Animal Health Code*.

The food safety control system in place should ensure the origin of raw milk for processing.

In Australia [Standard 4.2.4 of the Australia New Zealand Food Standards Code](#) (the Code) sets out a number of food safety requirements for primary production and processing of dairy products, including the implementation of documented food safety programs for dairy primary production, collection, transportation and processing. Clause 16 of [Standard 4.2.4](#) includes the requirements for processing of dairy products to make cheese and cheese products.

Division 5 of [Standard 4.2.4](#) includes additional requirements for raw milk cheese. Specifically, clause 34 of [Standard 4.2.4](#) states the requirements to control specific food safety hazards:

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

Additional information can be found in the FSANZ supporting documents for Proposal P1022 – Primary production and processing requirements for raw milk cheese. [Supporting document 1 – Guide to the requirements for raw milk cheese in Standard 4.2.4 – Primary production and processing standard for dairy products \(at Approval\)](#) includes additional explanation and information to support the implementation of requirements for raw milk cheese in Standard 4.2.4. [Supporting document 2 – Guide to the validation of raw milk cheese \(at Approval\)](#) was prepared to assist processors and enforcement agencies with the validation of processing control measures for raw milk cheese. [Supporting document 3 – Scientific information for the assessment of raw milk products – Cheeses \(at Approval\)](#) highlights the scientific information which may be used to develop the evidence to support the production of a raw milk cheese to achieve the food safety

outcomes: (i) the intrinsic physico-chemical characteristics of the raw milk product do not support growth and (ii) controls during processing that result in no net increase in hazard levels during manufacture. Supporting document 3 covers:

- physico-chemical characteristics of retail cheeses
- the utility of predictive equations to determine the likelihood of pathogen growth
- milk and cheese challenge studies to determine the behaviour of pathogens during production and maturation
- information required to demonstrate no net increase in pathogen levels.

Compliance history:

Imported raw milk cheese are not currently required to be tested for *M. bovis* and therefore no compliance data is available from the Imported Food Inspection Scheme of the Australian Department of Agriculture.

There have been no notifications on the European Commission's Rapid Alert System for Food and Feed (RASFF) for *M. bovis* in raw milk cheese from January 2007 – January 2014.

There have been no food recalls in Australia due to the presence of *M. bovis* in raw milk cheese from January 2007 – January 2014.

Surveillance information:

Australia was declared free from bovine tuberculosis in 1997, following an extensive eradication program (FSANZ 2006).

Tuberculosis is a notifiable disease in all Australian states and territories, with a reported incidence rate in 2013 of 5.5 cases per 100,000 population (1,262 cases) with most cases occurring in individuals born overseas. This is a slight reduction from the previous five year mean of 6.0 cases per 100,000 population per year (ranging from 5.7 – 6.2 cases per 100,000 population per year). The proportion of these cases that were caused by *M. bovis* (non-vaccine strain) is very low, 0.2% of cases (2 cases) in 2010 (Health 2010; Australian Mycobacterium Reference Laboratory Network 2013; NNDSS 2014).

Illness associated with consumption of raw milk cheese contaminated with *M. bovis*

A search of the scientific literature via the EBSCO Discovery Service, the US CDC Foodborne Outbreak Online Database and other published literature during the period 1990 – September 2014, identified there are limited reports of *M. bovis* outbreaks associated with consumption of raw milk cheese.

- Outbreak in the United States in 2001-2004, 35 cases of *M. bovis* illness including one fatality linked to consumption of raw milk fresh cheese (Quesco Fresco) illegally imported from Mexico (CDC 2005; FSANZ 2009). However, as this cheese would support the growth of pathogens it would not meet clause 34 of [Standard 4.2.4 of the Code](#)

A case control study in 1997-1998 in the United States found that children with a positive tuberculosis skin test were more likely to have received the Bacillus Calmette-Guérin (BCG) vaccine against tuberculosis, be born in a foreign country and to have consumed raw milk or raw milk cheese compared to controls. However, from the description provided in the scientific literature it could not be determined if the raw milk cheese would not support the growth of pathogens (Besser et al. 2001).

Data on the prevalence of *M. bovis* in raw milk cheese

A literature search with the EBSCO Discovery Service during the period 1990 – September 2014 identified that data on the prevalence of *M. bovis* in raw milk cheese is limited. Only prevalence data in cheese that would support the growth of pathogens could be identified, and as such, these products would not meet clause 34 of [Standard 4.2.4 of the Code](#):

- Survey in Mexico in 2004-2005, where *M. bovis* was detected in 3.2% of raw milk fresh cheese samples (n=95) at retail (Pereira-Suarez et al. 2014)
- Survey at the United States – Mexico border in 2005, where *M. bovis* was detected in 0.5% of soft fresh cheese samples (n=203) collected from travelers, although it was not stated if the cheese had a

heat treatment step during production (Harris et al. 2007)

Other relevant standards or guidelines

- Codex general principles of food hygiene *CAC/RCP 1 – 1969* provides key hygiene controls from primary production through to final consumption (Codex 2003)
- Codex code of hygienic practice for milk and milk products *CAC/RCP 57-2004* covers additional hygienic provisions for the production, processing and handling of milk and milk products (Codex 2004)

Approach by overseas countries

Many countries, such as the European Union, the United States and Canada, have HACCP-based measures in place for production of this commodity.

Other considerations

Quarantine restrictions apply to products under this commodity classification. Refer to the [ICON database](#).

This risk statement was compiled by FSANZ in: July 2015

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