

### Imported food risk statement

#### Raw milk cheese in which growth of *Listeria monocytogenes* will not occur

**Commodity:** Cheese that has not undergone a heat treatment step (such as pasteurisation, thermisation with additional hurdles or high temperature curd cook) during production and in which growth of *Listeria monocytogenes* will not occur. Examples of this type of product include cheese prepared from raw (unpasteurised) milk that have physico-chemical characteristics (e.g. low pH and water activity) that limit growth of *L. monocytogenes*, such as Roquefort cheese. A raw milk cheese must have no net increase in pathogen levels during the manufacture of the cheese.

**Microorganism:** *Listeria monocytogenes*

Recommendation and rationale
<p>Is <i>L. monocytogenes</i> in raw milk cheese in which growth of the organism will not occur a medium or high risk to public health:</p> <p><input type="checkbox"/> Yes</p> <p><input checked="" type="checkbox"/> No</p> <p><input type="checkbox"/> Uncertain, further scientific assessment required</p> <p><b>Rationale:</b></p> <ul style="list-style-type: none"> <li>• There is limited evidence of listeriosis attributed to this category of cheese</li> <li>• While production of raw milk cheese lacks a process that would reliably inactivate <i>L. monocytogenes</i>, growth of <i>L. monocytogenes</i> will not occur due to the physico-chemical characteristics of these products</li> <li>• There is limited compliance or surveillance data showing detection of <i>L. monocytogenes</i> in this category of cheese. Where <i>L. monocytogenes</i> was enumerated the levels were &lt;100 CFU/g</li> </ul>

General description
<p><b>Nature of the microorganism:</b></p> <p><i>L. monocytogenes</i> is a Gram-positive, non-spore forming rod-shaped bacterium that can grow in both aerobic and anaerobic conditions. It is found throughout the environment and has been isolated from domestic and wild animals, birds, soil, vegetation, fodder and wet areas of food processing environments (FSANZ 2013).</p> <p>A distinguishing feature of <i>L. monocytogenes</i> is its ability to grow at refrigeration temperatures. Growth can occur at temperatures between 1.5 – 45.0°C, pH of 4.0 – 9.6 and a minimum water activity of 0.90 when other conditions are near optimum. Temperatures above 50°C are lethal to <i>L. monocytogenes</i>, however, it is able to survive frozen storage at -18°C (ICMSF 1996; FSANZ 2013).</p>
<p><b>Adverse health effects:</b></p> <p>For susceptible populations <i>L. monocytogenes</i> is a severe hazard as it can cause life threatening illness (ICMSF 2002). People at risk of invasive listeriosis include pregnant women and their foetuses, newborn babies, the elderly and immunocompromised individuals (such as cancer, transplant and HIV/AIDS patients). Less frequently reported, but also at a greater risk, are patients with diabetes, asthma, cirrhosis and ulcerative</p>

colitis (FSANZ 2013).

In pregnant women invasive listeriosis can cause spontaneous abortion, stillbirth or neonatal infection. Influenza-like symptoms, fever, and gastrointestinal symptoms can also occur in the mother. In immunocompromised individuals and the elderly invasive listeriosis can cause potentially fatal bacterial meningitis with symptoms of fever, malaise, ataxia and altered mental status. The onset of illness of invasive listeriosis generally ranges from 3 days to 3 months after infection. Invasive listeriosis has a fatality rate of 15 – 30% (FDA 2012; FSANZ 2013).

Nearly all cases of listeriosis in susceptible people result from the consumption of high numbers of the pathogen (Chen et al. 2003; FAO/WHO 2004). However, in some foods growth of *L. monocytogenes* can occur, enabling high levels of *L. monocytogenes* to be achieved that may lead to illness.

Exposure to *L. monocytogenes* has minimal impact on the general healthy population. If illness does occur it is often mild and may be mistaken for a viral infection or flu (FSANZ 2012).

**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:**

*L. monocytogenes* 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 2009).

**Risk mitigation:**

Control of *L. monocytogenes* is achieved through on farm and processing measures.

The food safety control system(s) should verify:

For primary production:

- Animal health measures are in place that ensure milk is only sourced from healthy animals which can be individually identified
- Milking hygiene controls are in place to minimise contamination during milking, cooling, storage and transport
- Time and temperature controls are in place during milk handling, storage and transport

For processing:

- The origin of the raw milk for processing can be ensured including verification that primary production controls are met
- The combination of control measures should effectively control any *L. monocytogenes* present. These measures should address the following processing factors:
  - Starter culture activity and pH reduction
  - Salt concentration and moisture content
  - Storage time and temperature

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:

- Prior to the commencement of its processing, milk for raw milk cheese must be monitored to ensure its suitability.
- 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.
- 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.

[Standard 1.6.1 of the Code](#) has a microbiological limit for *L. monocytogenes* in ready-to-eat (RTE) food in which growth of *L. monocytogenes* will not occur of  $n=5, c=0, m=10^2$  CFU/g.

Clause 6 of [Standard 1.6.1 of the Code](#) states that, for the purposes of the Schedule, growth of *L. monocytogenes* will not occur in a RTE food if:

- the food has a pH less than 4.4 regardless of water activity; or
- the food has a water activity less than 0.92 regardless of pH; or
- the food has a pH less than 5.0 in combination with a water activity of less than 0.94; or
- the food has a refrigerated shelf life no greater than 5 days; or
- the food is frozen (including foods consumed frozen and those intended to be thawed immediately before consumption); or
- it can be validated that the level of *L. monocytogenes* will not increase by greater than 0.5 log CFU/g over the food's stated shelf life.

It is considered likely that growth of *L. monocytogenes* will not occur in RTE foods consumed frozen and those intended to be thawed just before consumption (to be eaten cold or re-heated). However, final use of the frozen product and instructions for use should be taken into consideration, for example product intended to be thawed and chilled for retail sale (where growth of *L. monocytogenes* can occur).

Additional information can be found in the FSANZ document [Guidance on the application of microbiological criteria for \*Listeria monocytogenes\* in RTE food](#).

Public information for vulnerable populations to avoid consumption of RTE food in which growth of *L. monocytogenes* can occur is available on various government websites [including FSANZ's website](#).

**Compliance history:**

For the purposes of this assessment, it was considered likely that growth of *L. monocytogenes* will not occur in hard and semi-hard cheeses. The imported food compliance data sourced from the Imported Food Inspection Scheme of the Australian Department of Agriculture for January 2007 – January 2014 showed that of the 84 *L. monocytogenes* tests applied to Roquefort cheese (semi-hard raw milk cheese) from France there was 1 fail, a 1.2% failure rate (based on detection of the presence of *L. monocytogenes*, the levels were not enumerated).

There have been two notifications on the European Commission's Rapid Alert System for Food and Feed (RASFF) for the presence of *L. monocytogenes* in raw milk Raclette (semi-hard cheese) from France and Emmentaler cheese (hard raw milk cheese) from Germany with raw material from the Netherlands during the period January 2007 – January 2014. Among the notified products the counts of *L. monocytogenes* were all <100 CFU/g. There have been 19 notifications from multiple countries for the presence of *L. monocytogenes* in raw milk cheese where it is uncertain whether growth of *L. monocytogenes* will not occur. Some of these raw milk cheese notifications may belong in this category of cheese, however, the description provided in RASFF did not provide enough information to determine this.

There have been no food recalls in Australia due to the presence of *L. monocytogenes* in this category of cheese from January 2007 – January 2014.

**Surveillance information:**

Listeriosis is a notifiable disease in all Australian states and territories with a notification rate in 2013 of 0.3 cases per 100,000 population (76 cases). This is the same as the previous five year mean of 0.3 cases per 100,000 population per year (ranging from 0.3 – 0.4 cases per 100,000 population per year) (NNDSS 2014).

**Illness associated with consumption of raw milk cheese in which growth of pathogens will not occur contaminated with *L. monocytogenes***

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 listeriosis outbreaks associated with consumption of this category of cheese:

- Outbreak in the United States, 15 cases of illness including 1 fatality linked to consumption of raw milk blue-veined cheese, however, from the description provided in the scientific literature it could not be determined if growth of *L. monocytogenes* would not occur in the product (CDC 2013; CDC 2014)
- Outbreak in Canada in 2002, 17 cases of illness linked to consumption of raw milk cheese from a particular factory. The outbreak strain of *L. monocytogenes* was isolated from soft (likely that growth of *L. monocytogenes* can occur) and semi-hard (likely that growth of *L. monocytogenes* will not occur) raw milk cheeses produced at the same factory, although it was not stated which type(s) of cheese caused the outbreak (PHAC 2003; FSANZ 2009)

**Prevalence of *L. monocytogenes* in raw milk cheese in which growth of pathogens will not occur**

A literature search with the EBSCO Discovery Service during the period 1990 – September 2014 and other published literature identified that surveys of this category of cheese have detected *L. monocytogenes* in 0 – 4.8% of samples (Colak et al. 2007; Brooks et al. 2012). Examples of surveys are listed below:

- Survey in the United States, *L. monocytogenes* was not detected in raw milk hard and semi-hard cheese samples (n=29) at retail (Brooks et al. 2012)
- Survey in Spain, *L. monocytogenes* was not detected in raw Idiazabal cheese samples (semi-hard cheese) (n=51) at retail (Arrese and Arroyo-Izaga 2012)
- Survey in Turkey in 2004 – 2005, *L. monocytogenes* was detected in 4.8% of raw Tulum cheese samples (semi-hard cheese) (n=250) at retail, although the level was not reported (Colak et al. 2007; FSANZ 2009)

### 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)
- Codex guidelines on the application of general principles of food hygiene to the control of *L. monocytogenes* in foods *CAC/GL 61 – 2007* (Codex 2007) states:
  - For ready-to-eat foods in which growth of *L. monocytogenes* can occur the microbiological criterion for *L. monocytogenes* is n=5, c=0, m=absence in 25g
  - For ready-to-eat foods in which growth of *L. monocytogenes* cannot occur the microbiological criterion for *L. monocytogenes* is n=5, c=0, m=100 CFU/g
- There are *E. coli* limits in [Standard 1.6.1 of the Code](#) for all cheeses. Generic *E. coli* is used as an indicator of process hygiene (ICMSF 2011)

### 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](#).

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