Imported food risk statement
Raw milk cheese and staphylococcal enterotoxin

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.

Microbial enterotoxin: Staphylococcal enterotoxin (SE)

Recommendation and rationale
Is SE in raw milk cheese that does not support the growth of pathogenic microorganisms a medium or high risk to public health*: ☐ *Yes* ☑ *No* ☐ *Uncertain, further scientific assessment required* **Rationale:** • SE is a moderate hazard as it generally causes illness of short duration and usually no sequelae • Implementation of control measures on-farm and during the initial stages of cheese making can prevent growth of *Staphylococcus aureus* to high levels that are associated with SE production • Limited epidemiological data for staphylococcal food poisoning attributed to the consumption of this category of cheese • Limited evidence for this category of cheese being contaminated with high levels of *S. aureus* or the presence of SE *Provided that effective through chain controls are in place

General description
Nature of the microbial enterotoxin: *Staphylococcus* spp. are facultative anaerobic Gram-positive, non-spore forming spherical-shaped bacteria. They are commonly found in the environment, humans (nose and skin) and animals. Although several *Staphylococcus* species can produce SEs, including both coagulase-negative and coagulase-positive isolates, the majority of staphylococcal food poisoning (SFP) is attributed to SE produced by coagulase-positive *S. aureus* (FDA 2012; FSANZ 2013). Growth of *S. aureus* can occur at temperatures between 7 – 48°C, pH of 4.0 – 10.0 and a minimum water activity of 0.83 when other conditions are near optimum. SEs are resistant to heat inactivation and cannot be destroyed by cooking. SEs remain stable under frozen storage (FSANZ 2013).
Adverse health effects: SE is a moderate hazard as it generally causes illness of short duration and usually no sequelae (ICMSF 2002). People of all ages are susceptible to SFP. However, the severity of symptoms may vary depending on the amount of SE consumed and the general health status of individuals. The young and elderly are more likely to

develop more serious symptoms (FSANZ 2013).

SFP is characterized by rapid onset gastroenteritis that appears around three hours after ingestion (normal range of 1 – 6 hours). Common symptoms of SFP include nausea, vomiting, abdominal cramps and diarrhea. Recovery is usually between 1 – 3 days (FSANZ 2013).

People become ill after exposure to very small quantities of SE (less than 1 µg). These levels of toxin are generally observed when *S. aureus* populations exceed 10^5 CFU/g of food (FDA 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:

S. aureus 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).

The initial concentration of *S. aureus* in the raw milk and the opportunity to grow during the start of the fermentation process (influenced by the use of starter cultures) determine whether *S. aureus* can grow to levels that are associated with production of SE, which will remain in the curd/cheese during subsequent stages in the cheese making process (Paulin et al. 2011).

Risk mitigation:

Control of *S. aureus* 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
- Hygiene and 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 the growth of any *S. aureus* present. The food safety control system should address the potential for *S. aureus* to grow to high numbers (>10^4 CFU/g) and monitor accordingly.

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 coagulase positive staphylococci and therefore no compliance data is available from the Imported Food Inspection Scheme of the Australian Department of Agriculture.

There was one notification on the European Commission's Rapid Alert System for Food and Feed (RASFF) for the presence of SE in raw milk cheese from Italy during the period January 2007 – January 2014. However from the description provided in RASFF, it could not be determined if this product would not support the growth of pathogens. There were no notifications for the presence of *S. aureus*. There was an additional notification on RASFF for SE in raw milk cheese from France during this period; however this notification was for a soft cheese (Ostyn et al. 2010). As such this cheese would not meet clause 34 of Standard 4.2.4 of the Code.

There have been no food recalls in Australia due to the presence of SE or *S. aureus* in raw milk cheese from January 2007 – January 2014.

Surveillance information:

SFP is not a notifiable disease in Australia. While it is generally recognised that there may be significant under reporting of SFP due to the short duration of illness and self-limiting symptoms, there was one reported outbreak in Australia in 2012 and two outbreaks reported in 2011. Mixed foods including fried rice and chicken were associated with these outbreaks. Factors that may have contributed to the outbreaks include the role of infected food handlers and temperature abuse of food. In Australia it is estimated that *S. aureus* accounts for 1% of foodborne illness caused by known pathogens (OzFoodNet 2012; FSANZ 2013; Pillsbury et al. 2013).

Illness associated with consumption of raw milk cheese contaminated with SE

A search of the scientific literature via the EBSCO Discovery Service and the US CDC Foodborne Outbreak Online Database during the period 1990 – September 2014, identified there are limited (unpublished) reports of SFP outbreaks associated with consumption of this category of cheese.

- Outbreak in France in 2001, 17 cases of illness epidemiologically linked to consumption of semi-hard raw milk cheese. High levels of *S. aureus* (2.9 x 10^4 CFU/g) and SE were present in the cheese (Kerouanton et al. 2007)
- Outbreak in France in 1998, 10 cases of illness epidemiologically linked to consumption of semi-hard raw milk cheese. High levels of *S. aureus* (5.7 x 10^6 CFU/g) were isolated from the cheese. No SE was detected in the cheese (Kerouanton et al. 2007)
- Outbreak in France in 2002, 43 cases of illness linked to consumption of raw sheep milk cheese. High levels of *S. aureus* (2.8 x 10^5 CFU/g) and SE were present in the cheese. However, from the description provided in the scientific literature it could not be determined if the cheese would not support the growth of pathogens (Kerouanton et al. 2007)

Prevalence of *S. aureus* in raw milk cheese

A literature search with the EBSCO Discovery Service during the period 1990 – September 2014 identified that surveys of this category of cheese have isolated high levels of *S. aureus* from 0 – 76% of samples (Tekinsen and Ozdemir 2006; Brooks et al. 2012). Examples of surveys are listed below:

- Survey in the United States, *S. aureus* was not detected in semi-hard and hard raw milk cheese samples (n=29) at retail (Brooks et al. 2012)
- Survey in Portugal in 2005 – 2006, where *S. aureus* at counts ≥10^4 CFU/g was isolated from 9.5% of hard raw milk cheese samples at retail (n=21) (Almeida et al. 2007)
- Survey in the United Kingdom in 2004, where *S. aureus* at counts ≥10^4 CFU/g was isolated from 0.2% of semi-hard raw milk cheese samples at retail (n=951) (Little et al. 2008)
- Survey in Turkey in 2003, where *S. aureus* at counts >10^4 CFU/g was isolated from 76% of unripened Van otlu cheese samples (semi-hard raw milk cheese) (n=50) at retail. Also, 1 sample had a *S. aureus* count >10^7 CFU/g (Tekinsen and Ozdemir 2006)

Surveys listed below were also identified, however there is large uncertainty in the reported prevalence of high levels of S*. aureus* due to the very limited sample sizes:

- Survey in Belgium, where *S. aureus* at counts >10^4 CFU/g was isolated from 12.5% of semi-hard and hard raw milk cheese samples at retail (n=8). No SE was detected in the raw milk hard cheese sample that had a high *S. aureus* count (De Reu et al. 2002)
- Survey in Italy in 2005 – 2006, where *S. aureus* at counts ≥10^4 CFU/g was cultured from 44.4% of Monte Veronese cheese samples ripened for 3 months (semi-hard to hard cheese made from raw cow milk), and SE genes were detected in 66.7% of samples (n=9), samples were collected from small dairies (Poli 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)
- FSANZ guidelines for the microbiological examination of ready-to-eat food have a satisfactory level for coagulase positive staphylococci of <10^2 CFU/g. Food is deemed potentially hazardous if levels are ≥10^4 CFU/g or staphylococcal enterotoxin is detected
- 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.

Canada, the EU and New Zealand have microbiological criteria for *S. aureus,* coagulase-positive staphylococci and SE, respectively, in cheese made from raw milk (European Commission 2007; Health Canada 2008; NZFSA

2009).

Other considerations
Testing for high levels of coagulase-positive staphylococci is an indicator test for the presence of SE. Quarantine restrictions apply to products under this commodity classification. Refer to the ICON database.

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