Imported food risk statement
Raw milk cheese and Shiga toxin-producing *Escherichia coli*

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: Shiga toxin-producing *Escherichia coli* (STEC)

Recommendation and rationale
Is STEC 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:** • Human illness has been associated with raw milk cheese contaminated with STEC and infection with STEC can have severe consequences • Ruminants are the main animal reservoir for STEC • The production of raw milk cheese lacks a process that would reliably inactivate STEC • International surveillance and compliance data have shown detections of STEC in raw milk cheese

General description
Nature of the microorganism: *E. coli* are facultative anaerobic, Gram-negative, rod-shaped bacteria. They are found in warm-blooded animals and humans as part of the normal intestinal flora (FSANZ 2013). The majority of *E. coli* are harmless, however some have acquired specific virulence attributes, such as Shiga toxin-producing *E. coli* (STEC), which can cause severe diarrheal disease in humans (FDA 2012). Major foodborne pathogenic STEC strains include O26, O45, O103, O111, O121, O145, O157 (FDA 2012) and O104 (ECDC/EFSA 2011). The major animal reservoir of STEC is ruminants. STEC can also colonise other animals and birds, although the incidence of STEC is lower than in ruminants (FSANZ 2013; Meng et al. 2013). Growth of *E. coli* can occur at temperatures between 7 – 46°C, pH of 4.4 – 10.0 and a minimum water activity of 0.95 when other conditions are near optimum. Some STEC strains are able to survive at pH 2.5 – 3.0 for over 4 hours. STEC is able to survive frozen storage at -20°C, however, it is readily inactivated by cooking (FSANZ 2013; Meng et al. 2013).
Adverse health effects: STEC is a severe hazard as it can cause life threatening illness or substantial chronic sequelae (ICMSF 2002). People of all ages are susceptible to infection with STEC. However, the young and the elderly are more susceptible and are more likely to develop serious symptoms (FSANZ 2013).

Symptoms include diarrhoea, abdominal pain, vomiting and fever. The onset of illness is typically 3 – 8 days after infection and most patients recover within 10 days of the initial onset of symptoms. Acute STEC infections (haemorrhagic colitis) are characterised by severe abdominal cramps and bloody diarrhoea. In some cases, patients develop haemolytic uraemic syndrome (HUS) which can lead to kidney failure. HUS can also have neurological effects and cause seizures, stroke and coma. Approximately 3 – 7% of haemorrhagic colitis cases develop HUS. The fatality rate of HUS is 3 – 5% (FDA 2012; FSANZ 2013).

It is generally accepted that very low levels (10 – 100 cells) of STEC can cause illness. However, depending on the food matrix and strain of STEC, illness may occur at exposure to even lower levels of STEC (FSANZ 2003; 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:

STEC 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 STEC 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 STEC 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.

Compliance history:

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 75 generic *E. coli* tests applied to Roquefort cheese (semi-hard raw milk cheese) from France there were 5 fails (*E. coli* levels >10 CFU/g), a 6.7% failure rate.

There have been four notifications on the European Commission's Rapid Alert System for Food and Feed (RASFF) for the presence of STEC in raw milk cheese which would not support the growth of pathogens during the period January 2007 – January 2014. The notifications were for Roquefort cheese from France, and Swiss and semi-hard cheese from Switzerland. During this time period there have also been an additional five notifications for STEC in raw milk cheese from France and two notifications for excessive levels of generic *E. coli* in raw milk cheese from Austria and France (the generic *E. coli* levels ranged from 1.5×10^6 – 8.6×10^7 CFU/g). However from the description provided in RASFF, it could not be determined if these products would not support the growth of pathogens. Notifications for raw milk cheese that would support the growth of pathogens, such as soft cheese, have been excluded.

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

Surveillance information:

Infection with STEC is a notifiable disease in all Australian states and territories with a reported incidence rate in 2013 of 0.8 cases per 100,000 population (179 cases), which includes both foodborne and non-foodborne cases. This is an increase from the previous five year mean of 0.5 cases per 100,000 population per year (ranging from 0.4 – 0.6 cases per 100,000 population per year). The most common STEC serotype identified in Australia in 2010 was O157 (58.8% of cases), O111 was the next most common serotype. There was 1 case of STEC-associated HUS reported in Australia in 2010 (FSANZ 2013; NNDSS 2014).

Illness associated with consumption of raw milk cheese contaminated with STEC

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 a number of reported STEC outbreaks associated with consumption of this category of cheese. Examples are listed below:

- Outbreak in the United States in 2010, 41 cases of illness linked to consumption of aged raw milk Gouda cheese (semi-hard cheese) contaminated with STEC O157:H7. Deficient sanitation practices and insufficient cheese curing times may have contributed to the outbreak (McCollum et al. 2012)
- Outbreak in Canada in 2002-2003, 13 cases of illness linked to consumption of raw milk Gouda cheese (semi-hard cheese) contaminated with STEC O157:H7. The implicated cheese was found to be contaminated with STEC O157:H7 104 days after production, despite having met regulated microbiological and aging requirements (Honish et al. 2005; FSANZ 2009)
- Outbreak in the United Kingdom in 1999, 2 cases of illness linked to consumption of raw milk Cotherstone cheese (semi-hard cheese) contaminated with *E. coli* O157:H7 (Baylis 2009)

Prevalence of STEC 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 detected STEC in 0 – 19.9% of samples (Vernozy-Rozand et al. 2005; Brooks et al. 2012). Examples of surveys are listed below:

- Survey in the United States, STEC was not detected in raw milk hard and semi-hard cheese samples (n=29) at retail (Brooks et al. 2012)
- Survey in Switzerland in 2006-2008, where STEC was detected in 5.4% of raw milk hard and semi-hard cheese samples (n=1,422) collected from producers (Zweifel et al. 2010)
- Survey in France, where STEC was detected in 19.9% of raw milk hard cheese samples (n=272) at retail (Vernozy-Rozand et al. 2005)

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)
- 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 have microbiological criteria for *E. coli* in cheese made from unpasteurised milk (Health Canada 2008).

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

References

ABS (2014) Australian health survey: Nutrition first results - Foods and nutrients, 2011-12. Australian Bureau of Statistics, Canberra. http://www.abs.gov.au/ausstats/abs@.nsf/Lookup/4364.0.55.007main+features22011-12. Accessed 20 February 2015

Baylis CL (2009) Raw milk and raw milk cheese as vehicles for infection by Verocytotoxin-producing *Escherichia coli*. International Journal of Dairy Technology 62(3):293–307

Brooks JC, Martinez B, Stratton J, Bianchini A, Krokstrom R, Hutkins R (2012) Survey of raw milk cheese for microbiological quality and prevalence of foodborne pathogens. Food Microbiology 31:154–158

Codex (2003) General principles of food hygiene (CAC/RCP 1 - 1969). Codex Alimentarius Commission, Geneva

Codex (2004) Code of hygienic practice for milk and milk products (CAC/RCP 57 - 2004). Codex Alimentarius Commission, Geneva

DOHA (2008) 2007 Australian national children's nutrition and physical activity survey - Main findings. Department of Health and Ageing, Canberra. http://www.health.gov.au/internet/main/publishing.nsf/Content/health-pubhlth-strateg-food-monitoring.htm. Accessed 27 March 2015

ECDC/EFSA (2011) Shiga toxin/verotoxin-producing *Escherichia coli* in humans, food and animals in the EU/EEA, with special reference to the German outbreak strain STEC O104. European Centre for Disease Prevention and Control, Stockholm. http://www.efsa.europa.eu/en/supporting/doc/166e.pdf. Accessed 11 April 2014

FDA (2012) Bad bug book: Foodborne pathogenic microorganisms and natural toxins handbook, 2nd ed. US Food and Drug Administration, Silver Spring. http://www.fda.gov/food/foodborneillnesscontaminants/causesofillnessbadbugbook/default.htm. Accessed 23 July 2015

FSANZ (2003) Review of processing requirements for uncooked comminuted fermented meat (UCFM) products. Food Standards Australia New Zealand, Canberra. http://www.foodstandards.gov.au/code/proposals/documents/P251%20UCFM%20FAR.pdf. Accessed 18 July 2013

FSANZ (2009) Microbiological risk assessment of raw milk cheese. Food Standards Australia New Zealand, Canberra. http://www.foodstandards.gov.au/code/proposals/documents/P1007%20PPPS%20for%20raw%20milk%201AR%20SD3%20Cheese%20Risk%20Assessment.pdf. Accessed 19 November 2014

FSANZ (2013) Agents of foodborne illness. 2nd ed, Food Standards Australia New Zealand, Canberra. http://www.foodstandards.gov.au/publications/Documents/FSANZ_FoodborneIllness_2013_WEB.pdf. Accessed 4 September 2013

Health Canada (2008) Health products and food branch (HPFB) - Standards and guidelines for microbiological safety of food - An interpretive summary. In: Compendium of Analytical Methods, Volume 1. Health Canada, Ottawa,

Honish L, Predy G, Hislop N, Chui L, Kowalewska-Grochowska K, Trottier L, Kreplin C, Zazulak I (2005) An outbreak of *E. coli* O157:H7 hemorrhagic colitis associated with unpasteurized Gouda cheese. Canadian Journal of Public Health 96(3):182–184

ICMSF (2002) Selection of cases and attributes plans. Ch 8 In: Microorganisms in food 7: Microbiological testing in food safety management. Kluwer Academic/Plenum publishers, London, p. 145–172

ICMSF (2011) Milk and dairy products. Ch 23 In: Microorganisms in food 8: Use of data for assessing process control and product acceptance. Springer, New York, p. 305–327

McCollum JT, Williams NJ, Beam SW, Cosgrove S, Ettestad PJ, Ghosh TS, Kimura AC, Nguyen L, Stroida SG, Vogt RL, Watkins AK, Weiss JR, Williams IT, Cronquist AB (2012) Multistate outbreak of *Escherichia coli* O157:H7 infections assoicated with in-store sampling of an aged raw-milk Gouda cheese, 2010. Journal of Food Protection 75(10):1759–1765

Meng J, LeJeune JT, Zhao T, Doyle MP (2013) Enterohemorrhagic *Escherichia coli*. Ch 12 In: Doyle MP, Beuchat LR (eds) Food microbiology: Fundamentals and frontiers. 4th ed, ASM Press, Washington D.C., p. 287–309

NNDSS (2014) Notifications for all disease by State & Territory and year. National Notifiable Disease Surveillance System, Department of Health and Ageing, Canberra. http://www9.health.gov.au/cda/source/rpt_2_sel.cfm. Accessed 20 November 2014

Vernozy-Rozand C, Montet MP, Berardin M, Bavai C, Beutin L (2005) Isolation and characterization of Shiga toxin-producing *Escherchia coli* strains from raw milk cheeses in France. Letters in Applied Microbiology 41:235–241

Zweifel C, Giezendanner N, Corti S, Krause G, Beutin L, Danuser J, Stephan R (2010) Characteristics of shiga toxin-producing *Escherchia coli* isolated from Swiss raw milk cheese within a 3-year monitoring program. Journal of Food Protection 73(1):88–91