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# Risk Profile: Shiga Toxin-Producing *Escherichia Coli* in Raw Milk

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Client report FW13026

By

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April 2014

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Prepared for the Ministry for Primary Industries
under project MRP/12/01 - Microbiological Risk Profiles,
as part of an overall contract for scientific services

Client report no. FW13026


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On 1 July 2010, the New Zealand Food Safety Authority (NZFSA) and the Ministry of Agriculture and Forestry (MAF) were amalgamated. On 30 April 2012, MAF was renamed as the Ministry for Primary Industries (MPI).

This Risk Profile uses the names NZFSA and MAF for documents produced during the existence of these organisations.

**ACKNOWLEDGMENTS**

The authors wish to acknowledge the Ministry of Health as owner of the copyright and funders of the 1997 National Nutrition Survey, and the 2002 National Children's Nutrition Survey and the 2009 Adult Nutrition Survey, and to thank them for access to food consumption information (24-hour dietary recall and qualitative food frequency questionnaire) from these surveys.

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## GLOSSARY AND ABBREVIATIONS

| | |
|---|---|
| $a_w$ | Measure of water activity (max = 1.000 = pure distilled water) |
| ACMSF | Advisory Committee on Microbiological Safety of Foods |
| ANS | The 2009 Adult Nutrition Survey |
| CAC | Codex Alimentarius Commission |
| CFU | Colony forming unit |
| CNS | The 2002 National Children's Nutrition Survey |
| EFSA | European Food Safety Authority |
| EHEC | Enterohaemorrhagic *E. coli* |
| EU | European Union |
| FAO | Food and Agricultural Organisation of the United Nations |
| FSANZ | Food Standards Australia New Zealand |
| FSP | Food Safety Programme (under the *Food Act* 1981) |
| HACCP | Hazard Analysis Critical Control Point |
| HC | Haemorrhagic Colitis |
| HUS | Haemolytic Uraemic Syndrome |
| MAF | Ministry of Agriculture and Forestry (now part of MPI) |
| MPI | Ministry for Primary Industries |
| MPN | Most Probable Number |
| NZFSA | New Zealand Food Safety Authority (now part of MPI) |
| PCR | Polymerase Chain Reaction |
| PFGE | Pulsed Field Gel Electrophoresis |
| pH | Measure of acidity (min = 0 = most acidic; max = 14) |
| RMP | Risk Management Programme (under the *Animal Products Act* 1999) |
| STEC | Shiga Toxin-producing *E. coli* |
| US | United States (of America), shortened version often officially used |
| USA | United States of America |
| USDA | United States Department of Agriculture |
| FSIS | Food Safety and Inspection Service (USDA) |
| VTEC | Verocytotoxigenic *E. coli* (synonym of STEC) |

**Additional terminology used in this document:**

| | |
|---|---|
| O157 STEC | *E. coli* that have been serotyped as O157 and confirmed to either carry the Shiga toxin-producing genes or produce Shiga toxin. |

| | |
|---|---|
| non-O157 STEC | *E. coli* that are of serotypes other than O157, and are confirmed to either carry the Shiga toxin-producing genes or produce Shiga toxin. |
| Probable STEC | *E. coli* of serotypes likely to carry the Shiga toxin-producing genes but further work was not carried out to confirm the presence of these genes or the ability of the isolates to produce Shiga toxin, e.g. O157, O26, O45, O103, O111, O121 and O145. The term 'probable STEC' is used where there is a need to group research findings. If specific research is being discussed, then the actual serotype will be named, e.g. *E. coli* O157:H7. |

## SUMMARY

This Risk Profile considers Shiga toxin-producing *Escherichia coli* (STEC) in raw milk from cows, sheep, goats and buffaloes. Infection by STEC in humans usually results in diarrhoea, and a proportion will go on to suffer more serious outcomes including haemorrhagic colitis, haemolytic uraemic syndrome, thrombotic thrombocytopaenic purpura and death.

This document updates the 2007 Risk Profile considering STEC in raw milk. The purpose of this update is to critically review new information to answer the following risk management question: Has the public health risk from STEC in raw milk consumed in New Zealand changed since the 2007 Risk Profile? The Ministry for Primary Industries (MPI) completed an assessment of the microbiological risks associated with raw milk in June 2013. This quantitative risk assessment was based on data up until February 2013 and concluded that the risk of STEC infection through consumption of raw milk was high. This Risk Profile also includes relevant information since February 2013, particularly updated human health surveillance data.

Two surveys of raw cows' milk for STEC with the serotype O157 have been conducted in New Zealand. One survey found a prevalence of *E. coli* O157:H7 of 1/358 (0.3%), while the other did not find any samples positive for *E. coli* O157:H7. No New Zealand surveys of non-O157 STEC in raw cows' milk were located. A number of surveys have quantified STEC carriage of up to 45% in samples from dairy cows in New Zealand.

*E. coli* O157 was not detected in a survey (n = 52) of raw goats' milk. No other New Zealand surveys of STEC in raw milk from goats, sheep or buffaloes were located. The prevalences of STEC among New Zealand milking goats, milking sheep or buffalo are not known. STEC have been detected in raw milk from goats, sheep and buffaloes in other countries.

Refrigerated storage of raw milk may allow STEC to grow slowly if the temperature is high enough (<1 log in 150 hours at 7°C) but at lower temperatures (<5°C) STEC will slowly decline in raw milk. A survey of domestic refrigerators in New Zealand found one third to be operating at a mean temperature above 6°C, suggesting that growth may occur in this proportion of stored milk.

The number of people drinking raw milk in New Zealand is still uncertain. Recent estimates (nutrition surveys in 1997 and 2009 of adults, and in 2002 of children) suggest the proportion of the population drinking raw milk is low (1% adults, 0.5% children). People living or working on dairy farms are more likely to drink raw milk. There are no data on consumption patterns (e.g. serving sizes) for raw milk, although consumption patterns for cold milk could serve as a proxy. The frequency of consumption is likely to depend on how easily consumers can access raw milk supplies.

There has been one case of STEC infection between 1998 and 2012 with a strong link to consumption of raw milk. Raw milk consumption continues to be reported as a risk factor associated with sporadic cases of STEC infection in New Zealand but usually other risk factors are also reported. Consumption of raw milk has been reported as one of several risk factors in three outbreaks of STEC infection between 1998 and November 2013.

The annual rate of reported STEC infection rose from 2006 to 2009, but has been relatively stable since then. The highest age-specific rates of infection continue to be observed in

young children. Up to 43% of cases of STEC infection were hospitalised in the years between 2006 and 2012, and one death was reported in 2009. *E. coli* O157:H7 continues to be the predominant serotype isolated from New Zealand cases of STEC infection. However, New Zealand clinical laboratories do not have consistent protocols and procedures in place for detecting non-O157 STEC and there are no national testing protocols for the isolation of non-O157 STEC.

The 2007 Risk Profile concluded that the risk of STEC infection for raw milk consumers was difficult to assess, given the shortage of raw milk prevalence or animal carriage data. Evidence obtained since 2007 suggests that the risk of STEC infection for consumers of raw milk in New Zealand is high. This is based on the following:

1. Although surveys of raw milk in New Zealand have found a low prevalence of O157 STEC, these surveys took small samples from bulk milk (where low numbers of STEC may be undetectable due to dilution) and covered only a small proportion of the large volume of cows' milk produced each year. Additionally, raw milk was never tested for non-O157 STEC. We consider the data on carriage of *E. coli* O157 and other STEC by dairy cows in New Zealand to indicate substantial potential for contamination.
2. Even a very low concentration of *E. coli* O157 in milk presents a considerable risk of infection, with a typical serving of 250 ml needing only 0.4 CFU/ml to generate a dose of 100 cells resulting in a 50% risk of infection.

Surveillance data linking STEC infection to raw milk consumption consists of raw milk being listed as a risk factor for some sporadic cases and outbreaks, but such a link has not yet been confirmed by finding the same STEC in raw milk samples. This is not unexpected; conclusive evidence for transmission vehicles is rarely obtained from sporadic cases or small outbreaks, mostly because obtaining samples of food consumed by actual cases is difficult. The small proportion of cases and controls consuming raw milk in the case-control study would have provided only limited power to detect any increased risk.

On a national scale (and on the basis of existing information), the burden of disease from raw milk contaminated with STEC is considered to be low because the size of the population drinking raw milk is small. The burden of disease from all foodborne STEC infection in New Zealand is third on a ranked list of six enteric foodborne diseases, based on an estimate from 2011.

Several data gaps have been identified in this report that impact on the evaluation of risk. New data on the amount of raw milk consumed in New Zealand, the prevalence of STEC in raw milk and the behaviour of STEC in raw milk would improve the exposure assessment.

# 1 INTRODUCTION

This document updates the 2007 Risk Profile considering Shiga toxin-producing *Escherichia coli* (STEC) in raw milk (Gilbert *et al.*, 2007a). This Risk Profile does not consider products made from raw milk such as cheese or yoghurt.

This is not a stand-alone document and readers are referred to the 2007 Risk Profile, which can be accessed from: http://foodsafety.govt.nz/science-risk/programmes/hazard-reduction/stec.htm.

The purpose of this update is to critically review new information to answer the following risk management question:

- Has the public health risk from STEC in raw milk consumed in New Zealand changed since the 2007 Risk Profile?

Risk Profiles provide scientific information relevant to a food/hazard combination for risk managers and describe potential risk management options (NZFSA, 2010).[1]

MPI completed an assessment of the microbiological risks associated with raw milk in June 2013 (MPI, 2013). This quantitative risk assessment was based on data up until February 2013. This Risk Profile also includes relevant information since February 2013, particularly updated human health surveillance data.

[1] Risk Profiles commissioned by MPI and its predecessors can be viewed at: http://www.foodsafety.govt.nz.

# 2 HAZARD AND FOOD

## 2.1 The Pathogen: STEC

*KEY FINDINGS*

Since the 2007 Risk Profile, the nomenclature and classification issues around STEC have not been fully resolved.

Serotyping remains an important STEC typing method, but since the 2007 Risk Profile there has been a greater emphasis on virulence genes as indicators of pathogenicity. This has generated more data on non-O157 serotypes through research, food testing and public health surveillance.

However, knowledge of virulence markers for pathogenic STEC is still developing, and it is currently not possible to exclude human health risk from isolates where known markers are not detected. There is no combination of genetic markers that reliably predicts whether an STEC isolate will infect humans or the severity of disease following infection.

Cattle are still considered the major STEC reservoir. A recent review confirms that STEC can survive for extended periods (weeks/months) in faeces, soil and water (Fremaux *et al.*, 2008).

*Appendix 1 contains additional information on STEC.*

### 2.1.1 Nomenclature

The pathotype enterohaemorrhagic *E. coli* (EHEC) is still used occasionally to refer to the subset of STEC that are capable of causing haemorrhagic colitis (HC) and haemolytic uraemic syndrome (HUS). The system of classifying *E. coli* by pathotype (Nataro and Kaper, 1998) has recently been challenged by a foodborne outbreak in Germany during 2011, caused by an enteroaggregative *E. coli* (EAEC) strain (*E. coli* O104:H4) that had acquired the ability to produce Shiga toxin (i.e. had become an STEC) yet did not have any of the other virulence markers typically associated with EHEC (Beutin and Martin, 2012; Clements *et al.*, 2012).

### 2.1.2 Pathogenicity

Some specific serotypes such as *E. coli* O157, O26, O45, O103, O111, O121 and O145, are consistently associated with severe human disease.[2] A 2010 publication reported that more than 200 virulent non-O157 serotypes had been isolated from outbreaks and sporadic cases of HUS and severe diarrhoea in the USA and other countries (Kaspar *et al.*, 2010). Many STEC serotypes have been isolated that have not been associated with human disease, although this does not mean that they are not capable of causing illness. Moreover, the presence of virulence genes varies among isolates sharing the same serotype (see Table 5 in (Lynch *et al.*, 2012) for a useful summary).

Recently more data on the prevalence and characteristics of non-O157 STEC have been generated. Current research shows that detecting multiple genes better discriminates between STEC strains and helps determine the potential for an STEC isolates' ability to cause disease

[2] A colloquial term for O26, O45, O103, O111, O121 and O145 is the "super-six". The term "super-seven" refers to these serotypes plus O157.

(e.g. 41 genes were targeted in a recent molecular-based STEC typing method (Brandt *et al.*, 2011)). However, the documents reviewed for this update usually only targeted *stx* (the Shiga toxin genes) and occasionally *eaeA* and *hlyA/ehxA* (binding and haemolysis of the intestinal cells). Tests for *stx* might only discriminate between *stx1* and *stx2*, but there are now at least three recognised subtypes of the toxin Stx1 (Stx1a, Stx1c and Stx1d) and six subtypes of Stx2 (Stx2a, Stx2c, Stx2d, Stx2e, Stx2f and Stx2g) (Baylis, 2009).

A categorisation scheme that classifies STEC serotypes on the basis of human disease incidence and severity (Karmali et al., 2003) was recently reviewed by the European Food Safety Authority (EFSA) Panel on Biological Hazards over concerns that testing regimes were too focussed on serotypes classified as 'high risk' by this scheme, thus failing to recognise the potential for other serotypes to cause human disease (EFSA, 2013). The Panel concluded that "there is no single or combination of marker(s) that defines a "pathogenic" VTEC." However, the Panel recognised that STEC strains positive for *stx2* and either *eae* or the combination of *aaiC* (secreted protein of EAEC) and *aggR* (plasmid-encoded regulator) were associated with a higher risk of more severe illness than other virulence gene combinations. The Panel noted a new testing standard (released in 2012) that will improve detection of STEC in food, and also proposed a molecular-based classification scheme intended to improve detection of emerging pathogenic STEC. Both of these approaches use a combination of serotyping and detection of virulence genes to predict human health risk (see EFSA (2013) for details), but EFSA acknowledged that the human health risk of STEC isolates that do not possess the target genes or serotypes cannot be inferred.

## 2.2 The Food: Raw milk

*KEY FINDINGS*

MPI defines raw milk as: "milk (secreted by mammals and used as food by human beings) that has not been subjected to any processing intended to alter the quality or composition characteristics of the milk." (MPI, 2013).

Milk supports the growth of microorganisms. It is impossible to produce sterile raw milk and if pathogenic bacteria are among the microorganisms in the milk, there is a risk of illness for people who consume the milk.

The volume of cows' milk produced in New Zealand is increasing. While the exact quantity of cows' milk consumed as raw is not known, some evidence suggests that availability of raw milk to domestic consumers is increasing.

The quantity of raw drinking milk from sheep, goats and buffaloes that is available to domestic consumers is also unknown, but is likely to be lower than cows' milk.

The farm gate is the only point at which raw milk sales are allowed in New Zealand. Raw milk vending machines are now being installed on dairy farms in New Zealand.

Milk is made up of water, protein, fat, lactose, vitamins and minerals, with the types and proportions of each varying with animal breed, feed, age and phase of lactation (Amigo and Fontecha, 2011; Fox, 2011; Ramos and Juarez, 2011; Sindhu and Arora, 2011). Raw milk has a high water activity ($a_w$ = 0.99) and an almost neutral pH (Roos, 2011). Milk is an excellent substrate for the growth of microorganisms (ICMSF, 2005).

### 2.2.1 Milk production in New Zealand

The volume of cows' milk processed by New Zealand dairy companies has increased almost every season for over 30 seasons since 1982/83, to approximately 19 million litres in 2012/13 (LIC, 2013). While the exact quantity of cows' milk consumed as raw is not known, some evidence suggests that availability of raw milk to domestic consumers is increasing.

The farm gate is the only point at which raw milk sales are allowed in New Zealand. Raw milk vending machines are now being installed on dairy farms in New Zealand.[3] Based on news reports about raw milk vending machines, supply for these outlets is provided by small herds (<50 cows). There is also anecdotal evidence for informal distribution networks of raw milk.

There are a few buffalo herds in New Zealand, but the milk from these animals is usually used for producing yoghurt or cheese, because of the higher solids and fat content compared to cows' milk (Han *et al.*, 2012; Sindhu and Arora, 2011).

Dairy goat farms in New Zealand produce milk that is used for making cheese or for processing into infant formula.[4] The availability of raw goats' milk directly to consumers is unknown.

There are a few milking sheep herds in New Zealand, but the milk from these animals is usually used for producing cheese, ice cream or powdered milk.[5]

## 2.3 Behaviour of STEC in Raw Milk

*KEY FINDINGS*

There has been no change to the view that STEC primarily enters the raw milk supply via faecal contamination.

Results from more recent studies on STEC growth in raw milk support the findings of the 2007 Risk Profile, that STEC can grow in raw milk held at 7°C or warmer and will slowly decline in raw milk held at 5°C or less. STEC can survive in frozen milk.

The studies of STEC behaviour all used cows' milk. No studies on the behaviour of STEC in sheep, buffaloes' or goats' milk were located.

### 2.3.1 Contamination of raw milk by STEC

The main route by which STEC enters the milk supply is through faecal contamination. STEC might also enter the milk supply from mastitic cows where the mastitis was caused by *E. coli* rather than the more common causative bacteria (*Staphylococcus*, *Streptococcus*) (Lira *et al.*, 2004).

[3] http://www.villagemilk.co.nz/get-village-milk/ (accessed 13 January 2014).
[4] The Dairy Goat Cooperative receives an annual supply of 20 million litres of goat milk from 30,000 milking goats to produce infant formula (http://www.dgc.co.nz; accessed 21 May 2013).
[5] As ascertained from the websites of various New Zealand sheep milk producers.

### 2.3.2 Behaviour of STEC in raw milk

STEC will grow in raw milk if the temperature is suitable. The 2007 Risk Profile described the results of studies that showed STEC or *E. coli* O157 isolates:

- Multiply in raw milk held at 15°C;
- Survive or multiply in raw milk held at 7 or 8°C; and
- Decline slowly in raw milk held at ≤5°C.

Two recent studies confirm that STEC slowly dies in raw cows' milk at 4°C and can multiply at temperatures ≥7°C (with growth moderated by temperature and the presence of other microorganisms):

- The concentration of *E. coli* O157:H7 in raw cows' milk was reduced by 1.5 $\log_{10}$ CFU/ml after 14 days at 4°C (Alhelfi *et al.*, 2012). At 20°C, the concentration increased by 2.7 $\log_{10}$ CFU/ml in 2 days, but the milk is likely to have spoiled over this period at that temperature.
- The concentration of a cocktail of three strains of *E. coli* O157:H7 in raw cows' milk decreased slightly (by 0.3 $\log_{10}$ CFU/ml) after 4 days at 4°C (Giacometti *et al.*, 2012c). After a variable temperature treatment representing the worst temperature profile for raw milk between the farm and a purchaser's home (7.0°C for 5 h, 11°C for 22.5 h, 30°C for 0.5 h, 12°C for 68 h), the concentration increased by 1.8 $\log_{10}$ CFU/ml.

Based on the results of one study, freezing raw milk can cause STEC to die, but at a very slow rate. When *E. coli* O157 was inoculated into heat-treated (65°C, 30 min) cows' milk and stored at -18°C, a significantly ($P \leq 0.05$) lower concentration of STEC was recovered after 7 days (this reduction was very small, <0.1 $\log_{10}$ CFU/ml) and no further reduction was observed after a further 14 days (Hubáčková and Ryšánek, 2007).

No studies were located on the behaviour of STEC in milk from other animals. The concentration of *E. coli* in raw sheep milk held at 4°C did not change after four days (survival when frozen at -20°C was also noted in this study) (de Garnica et al., 2011). In raw goats' milk held at 4°C, the concentration of *E. coli* did not change after seven days (but increased by 3.9 log under storage at 8°C) (Zapico *et al.*, 1995).

## 2.4 Exposure Assessment

*KEY FINDINGS*

Two surveys of raw milk for O157 STEC have been conducted in New Zealand. One survey found a prevalence of *E. coli* O157:H7 of 1/358 (0.3%), while the other did not find any samples positive for *E. coli* O157:H7. No New Zealand surveys of non-O157 STEC in raw cows' milk were located. A number of surveys have quantified STEC carriage of up to 45% in samples from dairy cows in New Zealand.

*E. coli* O157 was not detected in a survey (n = 52) of raw goats' milk. No surveys of STEC in raw milk from goats, sheep or buffaloes were located. STEC have been detected in faeces from non-milking sheep.

The number of people drinking raw milk in New Zealand is still uncertain. Recent estimates

suggest the proportion of the population drinking raw milk is low (1% adults, 0.5% children). People living or working on dairy farms are more likely to drink raw milk. There are no data on consumption patterns (e.g. serving sizes) for raw milk, although consumption patterns for cold milk could serve as a proxy. The frequency of consumption is likely to depend on how easily consumers can access raw milk supplies.

Refrigerated storage at 7°C may allow slow growth (<1 log in 150 hours) but at lower temperatures (<5°C) STEC will slowly decline in raw milk. A survey of domestic refrigerators in New Zealand found one third to be operating at a mean temperature above 6°C, suggesting that growth may occur in this proportion of stored milk. Information on storage times for raw milk by consumers is unavailable.

### 2.4.1 New Zealand prevalence studies

#### *2.4.1.1 Prevalence of STEC in raw milk*

At the time of preparation of the 2007 Risk Profile there were no published data available for the prevalence or concentration of STEC in raw milk in New Zealand. Two microbiological surveys of raw cows' milk have now been published that included testing for O157 STEC (Table 1).

**Table 1: Prevalence of *E. coli* O157:H7 in two New Zealand surveys of raw cows' milk**

| Raw milk survey | Survey period | Sample source | Prevalence of *E. coli* O157:H7[1] | Reference |
|---|---|---|---|---|
| Fonterra study[2] | April 2007-May 2008 | Farm vats, 290 dairy farms | 0/296[2] | (Hill *et al.*, 2012) |
| MPI study | November 2011-August 2012 | Farm vats, 80 dairy farms | 1/358[3] (0.3%) | (MPI, 2013; Soboleva *et al.*, 2013) |

1 Limit of detection 0.04 CFU/ml.
2 The Fonterra survey did detect non-pathogenic *E. coli* O157 (i.e. non-H7, lacking *stx1*, *stx2*, *eae* and *hlyA* genes) in three (1%) samples.
3 In the MPI survey *E. coli* O157 was detected twice. One isolate was confirmed as *E. coli* O157:H7 (with the *stx2* & *eae* genes); in the other neither *stx*, nor *eaeA* or *hlyA/ehxA* were found.

The one positive sample found in the MPI survey yielded *E. coli* O157:H7 at a concentration of 0.047 MPN/ml. These surveys did not test for non-O157 STEC. It should be noted that the milk sampled during both of these studies was destined for pasteurisation and/or processing into dairy products and was not necessarily also sold by the farmers as raw milk for direct human consumption.

No surveys on the prevalence of STEC in milk produced in New Zealand from sheep or buffaloes were located. A MPI survey of raw goats' milk in 2012/13 did not detect *E. coli* O157 in 52 samples. Samples were taken from farms that supply a major goat milk processor that produces goat milk-based infant formula for export markets (T. Soboleva (MPI), pers. comm., January 2014). The survey involved three samples each from 20 farms that represented around one third of dairy goat farms in New Zealand.

#### *2.4.1.2 Prevalence of STEC among dairy animals*

The 2007 Risk Profile reported results from two published surveys on the prevalence of STEC in New Zealand ruminants. The prevalences were 0.5% (*E. coli* O157:H7 in faecal matter from dairy cows at slaughter), 27% (STEC in faecal swabs from cattle and calves) and 66% (STEC in faecal swabs from sheep and lambs) (Buncic and Avery, 1997; Cookson *et al.*, 2006).

A year-long study from 2005 to 2006 provides further evidence that STEC is present among dairy cows in New Zealand (Moriarty *et al.*, 2008). STEC was detected in 1.3% (2/155) of fresh faecal samples collected from four dairy farms on four occasions (the two positive samples were collected from the same farm at the same collection time). One of these isolates was serotyped as O130:H11 (also possessing the *stx1*, *eaeA* and *hlyA* genes); the second isolate was identified as H38 but the O serogroup could not be typed. Serotype O130:H11 was isolated from a human case of STEC infection in New Zealand in 2008 (Section 3.3.4).

A total of 919 animals from dairy farms (689 bobby calves, 230 older cows and bulls) were tested post-slaughter at plants in both the North and South Islands over a two year period (Patricia Jaros, Massey University, personal communication, August 2013). From these animals, enrichment broths from 180 were PCR-positive for O157, and 19/180 were confirmed for O157 STEC by culture/PCR. This equals an O157 STEC prevalence of 2.1% (19/919) among dairy animals. These animals originated from 655 dairy farms. Converting the data to indicate farm prevalence, 65 were PCR-positive for O157 of which 15 were confirmed positive for O157 STEC by culture isolation and PCR. This is equals an O157 STEC prevalence of 2.3% (15/655) among dairy farms.

A study of super-7 prevalence among 33 cows and their calves on one dairy farm detected, by enrichment and PCR, both *stx* and *eae* in 45% (15/33) of cow faecal samples (Withers, 2013). As identified by PCR all of the super 7 serotypes except for O111 were present.

No other recent studies on the prevalence of STEC in samples from dairy cows were located, but a study of New Zealand bobby calves at slaughter found that *E. coli* O157 was detected in calves from 47/197 (24%) dairy farms using PCR (Irshad *et al.*, 2012).[6] The researchers were only able to culture 10 isolates, which were all STEC.

The detected prevalence will vary depending on the method used (PCR- vs. cultural-based, see Section 7.2), so the variability between studies is not unexpected. On the basis of the studies reported above it is not possible to say what the prevalence among dairy animals in New Zealand might be, but it can be concluded that STEC are present among dairy cows in New Zealand, and potentially other dairy animals.

### 2.4.2 Food consumption: Raw milk

The 2007 Risk Profile presented data from the 1997 National Nutrition Survey (NNS) (Russell *et al.*, 1999). These data were for all milk consumption, as raw milk consumption was not explicitly considered in the NNS. The consumption frequency and serving sizes for raw milk were considered to be the same as consumption of any milk.

[6] Bobby calves are the unwanted offspring of dairy cows and are usually slaughtered very young (<2 weeks old).

Since the 2007 Risk Profile, ESR has extensively analysed data from the NNS and two more recent New Zealand nutrition surveys to estimate raw milk consumption. A summary of the results is presented here.

The three data sets analysed were:

- The 1997 NNS (4,636 people aged 15+ years);
- The 2002 National Children's Nutrition Survey (CNS; 3,275 people aged 5-15 years) (Ministry of Health, 2003); and
- The 2009 Adult Nutrition Survey (ANS; 4,721 people aged 15+ years) (University of Otago and Ministry of Health, 2011).

#### *2.4.2.1 Number of people consuming raw milk in New Zealand*

People were not specifically asked about consumption of raw milk. The following estimates are made from the available data:

- NNS: 1.0% (95% CI 0.8-1.4%) of the adult population consumed "fresh cows' milk" as one of the categories included under "other" type of milk.
- CNS: 0.5% (95% CI 0.3-0.8%) of the child population consumed "vat milk", "farm milk", "real milk" and "cows' milk".
- ANS: An upper bound of 1.1% of the adult population reported consuming "other" types of milk, which will include raw milk.

Another recent estimate was provided by a national case-control study of STEC infection carried out from 2011-2012. It was found that 16/506 controls (3.2%; 95% CI 1.8-5.1%) reported raw milk consumption, which is higher than the estimates from nutrition surveys (Jaros *et al.*, 2013). The difference might be real and reflect an increase in raw milk consumption since the 2009 ANS, or may be high because the question asked in the case-control study also captured people who consume raw milk products.

People who live or work on dairy farms are more likely to consume raw milk, as shown by a Massey University survey in 2011 which found that 64% (858/1,337) of dairy farmers reported consuming raw milk (McFadden *et al.*, 2011).

There is also anecdotal evidence that raw milk availability is increasing. Raw cow and goat milk are advertised on auction and other websites and raw milk vending machines are now operating in some areas.

#### *2.4.2.2 Raw milk servings*

The ANS and CNS data were analysed to extract consumption patterns for all milk, and then this was partitioned into servings considered to be cold milk only, by removing servings where the milk was thermally treated in some way, e.g. added to hot beverages, used to prepare porridge or added to cooking. A summary of the results is presented in Table 2. In the absence of specific data for raw milk servings (size and frequency of consumption), these data can be used as an indicator.

**Table 2: Consumption of cold milk by New Zealanders (national nutrition surveys)**

| Statistic | Adult (2009 ANS) | Child (2002 CNS) |
|---|---|---|
| Number of respondents | 4,721 | 3,275 |
| Number of servings | 1,902 | 2,425 |
| Number of consumers (percentage of total respondents) | 1,653 (35.0%) | 1,778 (54.3%) |
| Servings/consumer/day (average) | 1.1 | 1.4 |
| Consumer mean (g/person/day) | 231.9 | 273.4 |
| Mean serving size (g) | 201.5 | 200.5 |
| Median serving size (g) | 169.6 | 194.0 |
| 95th percentile serving size (g) | 424.0 | 387.0 |

### 2.4.3 Potential for growth of STEC along the raw milk food chain

Assuming that the milking system on a farm will cool and then store raw milk at refrigeration temperatures, there will be a period of time during the cooling period (possibly 2-3 hours, plus total milking time) when the temperature of the milk is high enough to permit STEC growth. The temperature will rise again if new milk is added from subsequent milkings. There are no studies of STEC growth under a temperature profile similar to cooling milk.

As described in Section 2.3.2, STEC will not grow in raw milk at ≤5°C, and growth is very slow at temperatures from 5-7°C.

There are no data on storage times for raw milk held in consumers' homes. A survey of domestic refrigerators in New Zealand found one third (43/127; 34%) to be operating at a mean temperature above 6°C, suggesting that growth may occur in this proportion of stored milk (Gilbert *et al.*, 2007b).

## 2.5 Data on STEC and Raw Milk from Other Countries

*KEY FINDINGS*

Recent prevalence data for STEC in raw milk in other countries is consistent with overseas data reported in the 2007 Risk Profile and new data available for New Zealand. Most studies using cultural methods report low prevalences (<1%) while PCR detects much higher prevalences (up to 50%). STEC have been detected in raw milk from cows, goats, sheep and buffaloes in other countries. Data on the concentration of STEC in raw milk are still very scarce.

The prevalence of STEC or probable STEC (e.g. *E. coli* O157) among dairy animals overseas remains generally low (<10%) but higher prevalences (up to 61%) have been reported. This variability is consistent with studies in New Zealand, and may reflect seasonal differences.

New Zealand estimates on raw milk consumption are similar to estimates made in other developed countries (up to 3% of the population, with people living or working on dairy farms being more likely to consume raw milk).

*Appendix 1 contains detailed data summarised in this section.*

### 2.5.1 Prevalence and frequency studies in other countries

While data collected in other countries are useful for supplementing or comparing to New Zealand data, it is important to note that dairy farming methods in New Zealand are different to those in other countries. For example, dairy herds in New Zealand are much larger than those generally seen in the EU, larger volumes of milk are processed, and New Zealand dairy herds are generally not housed and are predominantly fed on pasture (Hill *et al.*, 2012). Factors such as housing conditions and food supply can affect the prevalence of pathogenic microorganisms among dairy animals. For example, a recent review of the effect of feed on the shedding of *E. coli* O157:H7 by cattle cited several studies showing increased shedding by cattle fed grains rather than forage, however the authors stressed that the effects of feed on shedding levels are not consistent (Callaway *et al.*, 2009).

#### *2.5.1.1 STEC in raw milk*

The 2007 Risk Profile presented the results from surveys of raw milk reported between 1991 and 2005. These results showed the prevalence of STEC (or probable STEC, e.g. O157) to be generally low (<5%, many not detected), with a few exceptions. Generalising these results is difficult because the surveys were carried out for different purposes (e.g. outbreak investigations, surveys targeting specific producers), targeted different *E. coli* (e.g. O157 only, STEC) and varied in the number of samples that were tested (range 23-610).

For the same reason, the results of more recent surveys of raw milk in Australia, and European and North American countries (Table 7, Appendix 1) are also difficult to generalise, but the data indicate that prevalences continue to be low in raw milk from cows, sheep, goats and buffaloes:

- The prevalence of probable STEC in milk samples as tested by cultural methods ranged from not detected to 10% (this higher value was associated with samples collected from farms where hygiene was poor).
- Most of the studies that tested for specific serotypes that were probably STEC (e.g. O157) did not detect the target serotypes.

In addition, Dairy Australia has commented that *E. coli* O157 in Australian raw cows' milk has been detected at prevalence values ranging 1-3% (FSANZ, 2009a), and a recent review used data from a number of studies to generate a prevalence range of 0-5.7% for STEC in raw milk in Europe (Claeys *et al.*, 2013).

Where testing was based on PCR, the prevalences for STEC were much higher (up to 50% for one batch of samples). However, PCR testing only indicates the potential presence of STEC. A short discussion on the issues associated with current culture-based and PCR-based test methods is included in Appendix 1.

Data on the concentration of STEC in raw milk are still very scarce. The one study reported in the 2007 Risk Profile and the information reported in Appendix 1 both suggest the concentration could be low. Surveys rely on sample enrichment to improve detection and rarely do researchers carry out quantification.

#### *2.5.1.2 STEC among dairy animals*

Data in the 2007 Risk Profile showed the prevalence of *E. coli* O157:H7 or STEC in animal faeces to be generally below 10%. Studies published since (see Section 7.2.2, Appendix 1) showed similar results when cultural methods were applied. Some studies have found higher prevalences among dairy animals (e.g. 37% for buffaloes in Brazil), or when prevalence is reported on a herd basis (e.g. 61% of dairy cow herds positive for *E. coli* O157 in a Belgian study (Cobbold *et al.*, 2008)). PCR methods are now more commonly used and these tend to produce consistently high prevalence data (prevalences of >50% among dairy animals have been reported when PCR testing was applied). However, PCR testing does not confirm the presence of infectious STEC.

### 2.5.2 Raw milk consumption in other countries

The 2007 Risk Profile did not specifically include information on raw milk consumption by people in other countries. Where data have been located, estimates for the proportions of the populations consuming raw milk are low (up to 3%), irrespective of the legal status of raw milk sales. The proportion of people living or working on dairy farms that consume raw milk is much higher (up to 60% has been reported), which is similar to the situation in New Zealand.

# 3 EVALUATION OF ADVERSE HEALTH EFFECTS

## 3.1 Disease Characteristics

*KEY FINDINGS*

Infection by STEC in humans usually results in diarrhoea, and a proportion will go on to suffer more serious outcomes including haemorrhagic colitis (HC), haemolytic uraemic syndrome (HUS), thrombotic thrombocytopaenic purpura (TTP) and death (Desmarchelier and Fegan, 2003).

New information from overseas shows that the number of cases of STEC infection that develop HUS may be higher than previously estimated (10% vs. 4% in the 2007 Risk Profile). Infection with O157 STEC is more likely to result in the development of severe illness compared with infection by non-O157 STEC.

New information has been published on HUS, which is a serious sequela of STEC infection (HUS can also be caused by infection by *Shigella dysenteriae* type 1). A recently-published systematic review of published case-control studies on HUS found that 61% of HUS cases may be attributable to a previous infection with STEC (Walker *et al.*, 2012). In a recent analysis of STEC cases in the EU, 10% developed HUS (EFSA, 2013). An analysis of ten years' of epidemiological data in the USA found that bloody diarrhoea, hospitalisation, and HUS were more common in patients infected by O157 STEC than in patients infected by non-O157 STEC (Hadler *et al.*, 2011). However, the 2011 outbreak of STEC infection caused by *E. coli* O104:H4 (see Section 2.1.1) demonstrated that non-O157 isolates are capable of causing serious illness; of 3,816 cases in this outbreak, 845 developed HUS and 54 died (European Food Safety Authority and European Centre for Disease Prevention and Control, 2013).

## 3.2 Dose Response

*KEY FINDINGS*

There is no known safe level of exposure for ingestion of *E. coli* O157:H7. Based on a model derived from outbreak data, a dose of 100 cells provides a median 50% probability of infection, while 10 cells provides a median 20% probability of infection (Strachan *et al.*, 2005). Dose-response data are for *E. coli* O157 specifically; dose response models for non-O157 STEC have not yet been established.

Dose response information is presented as an estimated number of cells that have caused infection (point estimate) or the probability of infection by exposure to differing numbers of cells. As reported in the 2007 Risk Profile, there is a trend towards the latter approach.

### 3.2.1 Point estimates from outbreaks

No new point estimates were located. An investigation of a 2005 outbreak of *E. coli* O157:H7 infection in the USA caused by contaminated raw milk found that the risk of illness increased with an increasing number of cups of milk consumed daily, but the concentration of *E. coli* O157:H7 in the milk consumed in this outbreak was not reported (Bhat *et al.*, 2007; Denny *et al.*, 2008).

There are few data on which to base a dose-response relationship for non-O157 STEC. A summary of available information was prepared for a USDA Risk Profile on non-O157 STEC (FSIS, 2012). This report commented that the minimum dose estimates for STEC serogroups O111 and O145 appeared to be comparable to minimum dose estimates for *E. coli* O157:H7.

### 3.2.2 Probability of infection

A paper examining beta-Poisson dose response models for *E. coli* O157:H7 was published in 2005 (Strachan *et al.*, 2005). The data were derived from eight outbreaks of *E. coli* O157 infection in the UK, USA, and Japan. The best fit was found for the exact beta-Poisson with beta-binomial likelihood model, which provided a curve which estimated that a dose of 100 cells provides a median 50% probability of infection, while 10 cells provides a median 20% probability of infection. More recently, a dose-response model specifically for the sequela HUS from *E. coli* O157 infection was published (Giacometti *et al.*, 2012a).

## 3.3 New Zealand Human Health Surveillance

*KEY FINDINGS*

There has been one case of STEC infection between 1998 and 2012 with a strong link to consumption of raw milk. Raw milk consumption continues to be reported as a risk factor associated with sporadic cases of STEC infection in New Zealand but usually other risk factors are also reported. People with STEC infection are not always asked whether they had consumed raw milk in the week before becoming ill so exposure to this risk factor is not always reported.

Raw milk has not been confirmed as the source of any outbreaks of STEC infection in New Zealand. Consumption of raw milk has been reported as one of several risk factors in three outbreaks of STEC infection between 1998 and November 2013.

Food associated risk factors, including drinking raw milk or drinking treated milk, were not identified as risk factors for STEC infection in a recent case control study.

The annual rate of reported STEC infection rose from 2006 to 2009, but has been relatively stable since then. The highest age-specific rates of infection continue to be observed in young children. Up to 43% of cases of STEC infection were hospitalised in the years 2006 to 2012, and one death was reported in 2009.

*E. coli* O157:H7 continues to be the predominant serotype isolated from New Zealand cases of STEC infection. However, New Zealand clinical laboratories do not have consistent protocols and procedures in place for detecting non-O157 STEC and there are no national testing protocols for the isolation of non-O157 STEC. Because of this, cases of non-O157 STEC infection are likely to be underreported.

### 3.3.1 Raw milk consumption as a risk factor for STEC infection

An analysis of outbreak data and sporadic cases has been reported in MPI's raw milk risk assessment (MPI, 2013). This section provides more detail on STEC infections associated with raw milk between January 2006 and November 2013, and outbreak data up to November 2013.

#### *3.3.1.1 Sporadic cases*

Consumption of raw milk is considered a risk factor for STEC infection if the milk was consumed by the case in the week prior to illness. From 2006 to 2012 there were 897 cases of STEC infection reported to New Zealand's notifiable diseases database, EpiSurv. Of these, 579 cases (65%) were asked whether they had consumed raw milk or products made from raw milk, and 49/579 (8%) had (Table 3).[7] Note that some of these cases may have consumed raw milk products and not raw milk. Available data were not enough to confirm raw milk as the single source of illness for any STEC cases notified between 2006 and 2012. From January to end of November 2013 there were 209 notified cases of STEC infection, and of those who were asked, 15/128 (11.7%) of cases reported consumption of raw milk or raw milk products as a risk factor.

It is rare for the source of STEC infection to be identified for sporadic cases, particularly since many STEC cases live on farms where they may have been exposed to STEC from a variety of sources (e.g. contact with animals, faecal matter in the environment, contaminated drinking water).

There has only been one case of STEC infection with a strong link to consumption of raw milk. This is the same case cited in the 2007 Risk Profile, of a 14 month old boy in Canterbury who developed HUS in 2001 as a result of ingesting raw milk from bowls served to cats on a farm (an indistinguishable strain was isolated from both the child and the raw milk).

#### *3.3.1.2 Outbreaks*

Between January 2006 and November 2013 there were 28 outbreaks or clusters of human illness where raw milk exposure was recorded as a risk factor, but STEC was listed as a causative agent in only one of these outbreaks, which was reported in August 2013 (P. Cressey, ESR, pers. comm.). STEC and *Campylobacter* were detected in a clinical sample from the index case in this outbreak but only *Campylobacter* was detected a sample from the other case linked to this outbreak. Raw milk was only one of several risk factors reported (others were untreated water, farm exposure to animal faeces, exposure to infected person) and the source of infection was not confirmed. The 2007 Risk Profile reported that consumption of raw milk was a risk factor for two STEC outbreaks between 1998 and 2005.

#### *3.3.1.3 Case control studies*

A prospective case-control and molecular epidemiological study of human cases of STEC infection in New Zealand was conducted from July 2011 to July 2012, involving 113 cases and 506 controls (Jaros *et al.*, 2013). The difference between the proportions of cases and controls that reported drinking raw milk (4.4% cases, 3.2% controls) did not reach statistical significance. Statistically significant risk factors were "cattle present in meshblock", "contact with animal manure", and "contact with recreational waters".

A systematic review of the international scientific literature up to August 2008 by New Zealand scientists found there was moderate evidence available to support a causal link

[7] The VTEC/STEC case report form includes a question about consumption of raw milk or products made from raw milk. See http://www.surv.esr.cri.nz/episurv/CaseReportForms/VTEC-Aug2007.pdf (accessed 22 October 2013).

between consumption of raw milk and raw milk products and infection from *E. coli* spp. (raw milk was not considered separately) (Jaros *et al.*, 2008). This conclusion was based on seven published studies, of which only three considered raw milk. The review was restricted to randomised control trials, cohort, case-control and cross-sectional studies, and outbreak investigations with a denominator.

**Table 3: Notified cases of STEC infection in New Zealand, 2006-2012, and consumption of raw milk or raw milk products as a risk factor**

| Year | Total No. cases | Hospitalisations | | No. reported paediatric cases of HUS | Rates of STEC infection per 100,000 | | | Consumption of raw milk or products from raw milk | | References |
|---|---|---|---|---|---|---|---|---|---|---|
| | | No. cases with known hospitalisation status (% of total cases) | No. hospitalised (% of cases with known hospitalisation status) | | All cases | Cases aged <1 year | Cases aged 1-4 years | No. cases asked if they had consumed these foods (% of total cases) | No. of cases that did consume these foods (% of cases that were asked) | |
| 2006 | 87 | 86 (99) | 23 (27) | 12 | 2.1 | 10.2 | 16.7 | 60 (69) | 5 (8) | (ESR, 2007b; Pirie *et al.*, 2008) |
| 2007 | 100 | 96 (96) | 27 (28) | 4 | 2.4 | 19.4 | 18.2 | 62 (62) | 2 (3) | (ESR, 2008a; Williman *et al.*, 2008) |
| 2008 | 128 | 105 (82) | 37 (35) | 3 | 3.0 | 7.8 | 16.5 | 66 (52) | 9 (14) | (ESR, 2009b; Williman *et al.*, 2009) |
| 2009 | 143 | 118 (83) | 38 (32) | 4 | 3.3 | 14.3 | 21.9 | 74 (52) | 4 (5) | (ESR, 2010a; Lim *et al.*, 2010) |
| 2010 | 138 | 113 (82) | 38 (34) | 4 | 3.2 | 14.1 | 25.8 | 88 (64) | 13 (15) | (ESR, 2011a; Lim *et al.*, 2011) |
| 2011 | 154 | 133 (86) | 57 (43) | 6 | 3.5 | 14.4 | 23.8 | 111 (72) | 7 (6) | (ESR, 2012a; Lim *et al.*, 2012) |
| 2012 | 147 | 133 (91) | 44 (33) | 3 | 3.3 | 14.9 | 22.7 | 118 (80) | 9 (8) | (ESR, 2013a; Lopez *et al.*, 2013) |

### 3.3.2 STEC infection in New Zealand

The annual rate of reported STEC infection rose from 2006 to 2009, but has been relatively stable since then. The 2007 Risk Profile showed that the rates (per 100,000 population) of STEC infection increased from 1.3 in 1998 to 2.5 in 2005, with the exception of 2003 where the rate was 2.8 per 100,000. The rate of notified STEC infection has continued to rise, although not consistently year on year, with the rate being between 3.0 and 3.5 per 100,000 since 2008 (Table 3). Changing laboratory protocols will only account for a small part of this rate increase, since a survey of New Zealand clinical laboratories in 2010 found that most had not changed their isolation method since 2006 (Nicol *et al.*, 2010). Importantly, laboratory methods are biased toward detecting *E. coli* O157, so cases of non-O157 STEC infection are likely to be underreported in public health surveillance data (see Section 3.3.4).

The 2007 Risk Profile reported that STEC infection can affect any age group but most often causes disease in children aged four years or less. This pattern continues to hold for the period 2006 to 2012. The rate per 100,000 was elevated each year in very young children (Table 3); with a few exceptions, annual rates for the other age groups were usually around 1-2 per 100,000 (rates were slightly elevated in some years for the 5-9, 60-69 and/or 70+ age groups). Notification rates for very young children are affected by the fact that parents are more likely to seek medical advice for infants than older children.

There were regional differences in annual rates. Notably, the Waikato District Health Board region was among those with the highest rates every year. As reported in the 2007 Risk Profile, the high rates in the Waikato region may be associated with the high number of cattle in the district.[8] Notification rates tend to follow a seasonal pattern with peaks in late summer/autumn and spring. The annual rates of STEC infection between 2006 and 2012 were generally similar for males and females.

A large number of STEC cases go unreported each year. An estimate of the total number of reported and unreported cases of gastroenteritis caused by STEC infection for 2005 was 340 (95% CI 180-620) cases per year (Cressey and Lake, 2007). A subsequent estimate of 2,830 cases (95% CI 120-10,500) was calculated using alternative multipliers from overseas studies (to adjust reported cases to total cases) and notification data from 2011 (Cressey, 2012). Roughly, this means that for every case that is reported, 17 are not. This is equivalent to a rate of 70.8 per 100,000, which is higher than a recent Australian estimate, but similar to recent estimates for the USA and Canada (see Appendix 2).[9] The author of the 2012 document stressed that there was a high level of uncertainty in the multipliers (as reflected in the confidence intervals for the estimated number of cases).

While the number of reported STEC cases is small compared to other notifiable diseases, the clinical outcomes are often severe. For the period 2006-2012, the hospitalisation status was known for over 80% of STEC cases each year, and the proportion of these cases hospitalised per year was in the range 28-43% (Table 3). One death was reported in 2009, which is the first death reported since 1998.

[8] Statistics for the 2011/12 year showed that the Waikato region contained almost a quarter (24.6%) of all New Zealand's dairy cows (LIC, 2012).. The next highest was the Taranaki region (10%).
[9] Rate per 100,000 calculated using the estimated New Zealand resident population mean for the year ending 2011 of 4,407,400 (http://www.stats.govt.nz/infoshare accessed 7 August 2013).

Between 2003 and 2012, the number of hospitalised cases of HUS ranged from 20 to 39 per year (Lopez *et al.*, 2013). These data do not specify whether STEC was the primary cause of HUS.

### 3.3.3 Reported outbreaks

Outbreaks of STEC infection continue to make up only a small proportion of the total reported outbreaks and outbreak-associated cases each year in New Zealand (Table 4; note that percentages in this table are reported for all enteric outbreaks, not all outbreaks as was reported in the 2007 Risk Profile). Only 4/27 of the outbreaks of STEC infection between 2006 and 2012 were reported as foodborne and no food was confirmed as the vehicle of infection for any of these outbreaks.

**Table 4: Reported outbreaks of STEC infection in New Zealand and information on those reported as foodborne (2006-2012)**

| Year | No. STEC outbreaks (% all reported enteric outbreaks)* | No. cases associated with STEC outbreaks (% all cases associated with enteric outbreaks) | Hospitalisations | | No. foodborne STEC outbreaks | Food(s) implicated (level of evidence) | References |
|---|---|---|---|---|---|---|---|
| | | | No. cases where hospitalisation status known (No. outbreaks) | No. cases hospitalised | | | |
| 2006 | 5 (1.0) | 16 (0.3) | 16 (5/5) | 0 | 0 | N/A | (ESR, 2007a; Pirie *et al.*, 2008) |
| 2007 | 6 (1.3) | 13 (0.2) | 13 (6/6) | 4 | 2 | 4 confirmed cases. No food vehicle implicated. | (ESR, 2008b; Williman *et al.*, 2008) |
| 2008 | 4 (0.9) | 25 (0.4) | 25 (4/4) | 4 | 1 | 14 cases. Vehicle not confirmed. | (ESR, 2009a; Williman *et al.*, 2009) |
| 2009 | 4 (0.7) | 15 (0.1) | 8 (1/4) | 0 | 0 | N/A | (ESR, 2010b; Lim *et al.*, 2010) |
| 2010 | 5 (0.9) | 12 (0.2) | 5 (2/5) | 1 | 1 | 3 cases. Suspected vehicle was undercooked chicken | (ESR, 2011b; Lim *et al.*, 2011) |
| 2011 | 2 (0.4) | 7 (0.1) | 7 (2/2) | 1 | 0 | N/A | (ESR, 2012b; Lim *et al.*, 2012) |
| 2012 | 1 (0.2) | 3 (<0.1) | 1 (1/1) | 0 | 0 | N/A | (ESR, 2013b; Lopez *et al.*, 2013) |

* From 2006 to 2008 outbreaks were reported as VTEC/STEC. In 2009 outbreaks were reported as *E. coli* O157, in 2010 and 2011 outbreaks were reported as *E. coli* O157:H7, and in 2012 outbreaks were reported as VTEC/STEC. Outbreaks caused by non-O157 STEC may not be detected (see Section 3.3.4).

### 3.3.4 Serotypes

The 2007 Risk Profile reported that *E. coli* O157:H7 was the predominant serotype isolated from STEC cases (91% of isolates from human cases). This pattern has continued, although the proportion of non-O157 isolates associated with human disease is increasing (Table 5). The dominance of isolates with the O157 serotype is most likely a consequence of laboratory procedures, which are biased toward detection of this serotype. A 2010 survey found that New Zealand clinical laboratories did not have consistent protocols and procedures in place for detecting non-O157 STEC and that there were no national testing protocols for the isolation of non-O157 STEC in New Zealand (Nicol *et al.*, 2010).

**Table 5: STEC serotypes identified by ESR's Enteric Reference Laboratory, 2008-2012[1]**

| Year | 2006 | 2007 | 2008 | 2009 | 2010 | 2011 | 2012 | Total |
|---|---|---|---|---|---|---|---|---|
| No. STEC isolates serotyped | 86 | 97 | 120 | 145 | 128 | 153 | 142 | 871 |
| **No. isolates of each serotype (% of all isolates serotyped for that year)** | | | | | | | | |
| ***E. coli* O157:H7[2]** | **80 (93)** | **96 (99)** | **118 (98)** | **137 (94)** | **115 (90)** | **139 (91)** | **119 (84)** | **804 (92)** |
| **Non-O157** | **6 (7)** | **1 (1)** | **2 (2)** | **8 (6)** | **13 (10)** | **14 (9)** | **23 (16)** | **67 (8)** |
| O26:H11 | 0 | 0 | 0 | 1 | 0 | 1 | 1 | 3 (0.3) |
| O68:HNM | 0 | 0 | 0 | 0 | 1 | 0 | 1 | 2 (0.2) |
| O84:H2 | 0 | 0 | 0 | 0 | 1 | 2 | 0 | 3 (0.3) |
| O84:HNM | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 2 (0.2) |
| O103:H2 | 0 | 0 | 0 | 1 | 0 | 1 | 0 | 2 (0.2) |
| O103:H25 | 1 | 0 | 0 | 1 | 0 | 0 | 0 | 2 (0.2) |
| O128:H2 | 2 | 0 | 0 | 0 | 1 | 2 | 0 | 5 (0.6) |
| O146:H21 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 2 (0.2) |
| O176:HNM | 1 | 0 | 1 | 0 | 2 | 1 | 1 | 6 (0.7) |
| ONT:H2 | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 2 (0.2) |
| ONT:H11 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 2 (0.2) |
| ONT:HNM | 0 | 0 | 0 | 3 | 0 | 0 | 9 | 12 (1.4) |
| Other serotypes[3] | 2 | 1 | 1 | 2 | 7 | 4 | 7 | 24 (2.8) |

[1] References as for (Table 3).
[2] No other O157 serotypes were isolated.
[3] Single isolates of the following serotypes:
2006: O111:H21, O91:H21
2007: O177:HNM
2008: O130:H11
2009: O22:H16, O174:H21
2010: ONT:H21, ONT:H23, ORough:HNT, ORough:H7, O77:HNM, O123:H8, ONT:HRough
2011: O123:HNM, O131:HRough, O178:H23, ORough:H2
2012: O26:H7, O38:H26, O128:HNM, O146:HRough, O176:HRough, O180:HNM, ONT:H7

## 3.4 STEC Infection Overseas

*KEY FINDINGS*

Similarly to New Zealand, the rate of STEC infection per 100,000 has increased for Australia, many countries in the EU, and the USA since the previous Risk Profile. Rates for 2011 ranged between 0.1 and 6.8 per 100,000 but most countries had rates lower than New Zealand, including Australia. The proportion of isolates serotyped as being non-O157 STEC has increased for most countries, which is similar to the situation in New Zealand. Of note is that only 59% of STEC isolates serotyped in Australia are O157.

Two recent case control studies found consumption of raw milk was a risk factor for STEC infection in very young children (Germany) and for the development of HUS in children (Italy).

Recent outbreaks of STEC infection have been linked to raw cows' milk and raw goats' milk in other countries.

*Appendix 2 contains detailed data summarised in this section.*

# 4 EVALUATION OF RISK

## 4.1 Existing Risk Assessments

*KEY FINDINGS*

MPI has completed a risk assessment that concluded that the risk of STEC infection from consumption of raw cows' milk is high.

This finding is supported by recent risk assessments in other countries.

*Appendix 2 contains detailed data summarised in this section.*

### 4.1.1 New Zealand risk assessment

MPI has completed a microbiological risk assessment for the consumption of raw milk in New Zealand (MPI, 2013). The assessment focussed on raw cows' milk and used quantitative modelling to estimate the risk per random daily serve of raw milk to consumers from STEC (and other pathogenic microorganisms).

The risk assessment concluded that the risk for transmission of STEC to humans through consumption of raw milk is considered to be high, and the risk of developing milkborne diseases especially high for children and other vulnerable groups of people.

### 4.1.2 Risk assessments from other countries

Risk assessments for STEC in raw milk have been published for Australia, the UK, Italy, Norway, and Belgium (see Appendix 2, Section 8.2). In summary:

- Australia (raw cows' milk (modelling), raw goats' milk (qualitative)): The risk of EHEC infection if raw cows' milk was consumed increased according to the length of the supply chain (unlike the New Zealand model, the time period for the total supply chain was not fixed). Three scenarios (for children and adults separately) were modelled: 250 ml servings direct from the farm bulk milk tank, farm gate sales including transport and domestic storage (and higher serving sizes from nutritional surveys), and retail sales (which also included packaging, distribution and retail storage). The mean predicted cases of illness from EHEC infection per 100,000 daily serves of raw milk were 17 children and 17 adults (farm bulk milk tanks), 49 children and 38 adults (farm gate sales), and 96 children and 78 adults (retail sales).
- UK (revision of evidence): Maintained the view that there were significant risks to human health from consumption of raw drinking milk.
- Italy (modelling of the risk of HUS): Raw milk consumption carried a risk of HUS, moderated by the assumption that 57% of consumers boiled the milk before consuming.
- Norway (raw cows' milk and cream): The risk associated with *E. coli* O157:H7 and other EHEC in raw cows' milk and cream was high (based on low infectious dose and potentially severe consequences).
- Belgium: Pathogenic *E. coli* were among the main bacteria that can be transmitted through raw milk to humans.

## 4.2 Evaluation of Risk for New Zealand

*KEY FINDINGS*

The 2007 Risk Profile concluded that the risk of STEC infection for raw milk consumers was difficult to assess, given the shortage of raw milk prevalence or animal carriage data. Evidence obtained since 2007 suggests that the risk of STEC infection for consumers of raw milk in New Zealand is high. This is based on the following:

1. Although two surveys of raw milk in New Zealand have found a low or nil prevalence of O157 STEC, these surveys took small samples from bulk milk (where low numbers of STEC may be undetectable due to dilution) and covered only a small proportion of the large volume of cows' milk produced each year. Additionally, neither survey tested for non-O157 STEC. We consider the data on carriage of *E. coli* O157 and other STEC by dairy cows in New Zealand to indicate substantial potential for contamination.
2. Even a very low concentration of *E. coli* O157 in milk presents a considerable risk of infection, with a typical serving of 250 ml needing only 0.4 CFU/ml to generate a dose of 100 cells resulting in 50% risk of infection.

Surveillance data linking STEC infection to raw milk consumption consists of raw milk being listed as a risk factor for some sporadic cases and outbreaks, but such a link has not yet been confirmed by finding the same STEC in raw milk samples. This is not unexpected; conclusive evidence for transmission vehicles is rarely obtained from sporadic cases or small outbreaks, mostly because obtaining samples of food consumed by actual cases is difficult.

### 4.2.1 Risk associated with raw milk

The 2007 Risk Profile concluded that the risk of STEC infection for raw milk consumers was difficult to assess, given the shortage of raw milk prevalence or animal carriage data. The document also noted major data gaps including the size of the raw milk consuming population and frequency of consumption. Data from two surveys of O157 STEC in raw milk are now available, but information on non-O157 in raw milk and raw milk consumption by New Zealanders remains limited.

Evidence obtained since 2007 suggests that the risk of STEC infection for consumers of raw milk in New Zealand is high. This is based on the following:

1. Although two surveys of raw milk in New Zealand have found a low or nil prevalence of O157 STEC, these surveys took small samples from bulk milk (where low numbers of STEC may be undetectable due to dilution) and covered only a small proportion of the large volume of cows' milk produced each year. Additionally, neither survey tested for non-O157 STEC. We consider the data on carriage of *E. coli* O157 and other STEC by dairy cows in New Zealand to indicate substantial potential for contamination.
2. Even a very low concentration of *E. coli* O157 in milk presents a considerable risk of infection, with a typical serving of 250 ml needing only 0.4 CFU/ml to generate a dose of 100 cells resulting in 50% risk of infection.

This evaluation of risk is made on the basis of currently available data and agrees with the findings of the MPI risk assessment (MPI, 2013). Data gaps identified in this document are summarised in Section 4.5.

Surveillance data linking STEC infection to raw milk consumption consists of raw milk being listed as a risk factor for some sporadic cases and outbreaks, but such a link has not yet been confirmed by finding the same STEC in raw milk samples. This is not unexpected; conclusive evidence for transmission vehicles is rarely obtained from sporadic cases or small outbreaks, mostly because obtaining samples of food consumed by actual cases is difficult. The small proportion of cases and controls consuming raw milk in the case-control study would have provided only limited power to detect any increased risk.

Children are particularly at risk as they are more susceptible to infection (and are more likely to experience serious health outcomes). For raw milk consumers living or working in rural areas, the risk of STEC infection from contact with animals or their faecal matter is also important.

### 4.2.2 Risks associated with other foods

In New Zealand, no foods have been confirmed as the cause of outbreaks of STEC infection (Table 4) and a recent case-control study found no evidence to suggest that sporadic STEC cases in New Zealand were associated with exposure to STEC-contaminated food products (Jaros *et al.*, 2013). This makes it difficult to ascertain the role of other foods as vehicles of STEC infection in New Zealand relative to raw milk.

As stated in the 2007 Risk Profile, the main vehicle implicated in foodborne outbreaks of STEC infection overseas has been red meat, particularly undercooked hamburger meat. A recent analysis of foodborne outbreaks reported in the USA between 1998 and 2008 found that of the 133 outbreaks of STEC infection that could be attributed to a single food commodity, 58% (78 outbreaks) were attributed to the commodity group 'beef'. The next highest proportion was 'leafy vegetables' (22 outbreaks, 17%) then the commodity group 'dairy' (11 outbreaks, 8%), which will include milk, cheese and other dairy products (Gould *et al.*, 2013b). Beef was consistently the most reported food commodity over time. However, this analysis included outbreaks where the food was not necessarily confirmed by laboratory or strong epidemiological information, and also focussed on O157 STEC.[10]

A wide range of foods have now been implicated in outbreaks of O157 and non-O157 STEC infection in other countries. Examples include spinach, sprouts, cookie dough, rice cakes, crab meat, lettuce and ice cream made from pasteurised milk (Buchholz *et al.*, 2011; De Schrijver *et al.*, 2008; Matulkova *et al.*, 2012; Nabae *et al.*, 2012; Neil *et al.*, 2012; Slayton *et al.*, 2013; Wendel *et al.*, 2009). These reports confirm that STEC infections can arise through a range of foods and suggest that the proportion of cases attributed to beef may not be as high as currently thought. Knowledge in this area will increase as laboratory testing for non-O157 STEC becomes more widespread.

[10] In an analysis of foodborne outbreaks in the USA for 2009 and 2010, none of the three outbreaks caused by enterotoxigenic *E. coli* could be attributed to a single food commodity .

## 4.3 The Burden of STEC Infection in New Zealand

*KEY FINDINGS*

On a national scale (and on the basis of existing information), the burden of disease from raw milk contaminated with STEC is considered to be low because the size of the population drinking raw milk is small. The burden of disease from foodborne STEC infection in New Zealand is third on a ranked list of six enteric foodborne diseases, based on an estimate from 2011.

### 4.3.1 Burden of disease from raw milk contaminated with STEC

On a national scale (and on the basis of existing information), the burden of disease from raw milk contaminated with STEC is considered to be low because currently the size of the consuming population is small. An estimated 1% of adults and 0.5% of children in the New Zealand population consume raw milk in any one day, although a case control study suggested that consumption of raw milk in New Zealand may have increased since 2007.

### 4.3.2 Burden of disease from all STEC infection

The 2007 Risk Profile reported the results of the cost of foodborne STEC infection in New Zealand ($507,000) that was published in 2000. More recent estimates have been published.

An estimate of the burden of foodborne disease in disability adjusted life years (DALYs) was initially published using data principally from 2005 (Lake *et al.*, 2010), then revised using data from 2011 and multipliers from more recent overseas studies to estimate cases not reported to the health system (Cressey, 2012). The most recent study calculated the total burden of disease from STEC infection and sequelae as 505 DALYs, with 200 DALYs ($5^{th}$-$95^{th}$ percentile 1.5-783) being foodborne. For comparison, higher DALY burden of foodborne disease estimates were for norovirus infection (873, $5^{th}$-$95^{th}$ percentile 675-1083) and campylobacteriosis (587, $5^{th}$-$95^{th}$ percentile 425-781)). The DALY estimate for foodborne STEC infection was higher than that of foodborne listeriosis, salmonellosis and yersiniosis. However, the author stressed the high level of uncertainty associated with the DALY estimates for STEC infections.

An estimate of the total economic cost to New Zealand of six foodborne diseases has been published (Gadiel, 2010). This estimate converted the individual burden in DALYs to an economic value and was based on data from 2009. Of the estimated total cost ($161.9m), STEC infection accounted for $14.6 million (11%), reflecting the associated risk of its rare but severe complications and premature death. This estimate was similar to those for salmonellosis ($15.4m) and listeriosis ($15.2m), but all three were below estimates for norovirus infection ($50.1m) and campylobacteriosis ($36.0m), and well above the estimate for yersiniosis ($1.9m).

## 4.4 Summary of Risk

*KEY FINDINGS*

STEC can contaminate raw milk in New Zealand and the absence of pasteurisation means that there is no control measure that will eliminate STEC from this food. The risk of STEC infection is high for individual New Zealanders who consume raw milk.

## 4.5 Data Gaps

*KEY FINDINGS*

Some data gaps have been addressed but there are still many data gaps identified in this report that impact on the evaluation of risk. New data on the amount of raw milk consumed in New Zealand, the prevalence of STEC in raw milk and the behaviour of STEC in raw milk would improve the exposure assessment.

The data gaps identified in the 2007 Risk Profile and updated commentary on these are presented in Table 6.

**Table 6: Data gaps**

| Data gap identified in 2007 Risk Profile | Commentary |
|---|---|
| Consumption data for raw milk in New Zealand | Data on the number of people consuming raw milk can be estimated from various sources, but information on frequency and serving sizes is unavailable, and can only be assumed to be the same as pasteurised milk. |
| Prevalence of STEC carriage by dairy cattle in New Zealand | Some new prevalence data are available (testing of deposited faecal matter on dairy farms and bobby calves at slaughter (Section 2.4.1.1). These, and previous studies, show that prevalence values are highly variable and depend on the sampling and testing method. Overseas studies show seasonality to also be important. Because of such variability and unpredictability, data on prevalence and concentration in raw milk are more valuable for risk assessment. |
| Prevalence of STEC in raw milk in New Zealand | The prevalence of *E. coli* O157:H7 in raw cows' milk in New Zealand has been evaluated through two recent surveys (Section 2.4.1.1). |
| Identification of the principal human infection pathways for STEC in New Zealand | A case control study has been undertaken to investigate risk factors associated with sporadic STEC infections in humans in New Zealand (Section 3.3.1.3). |

Continuing and additional data gaps identified in this report that impact on the risk are:

- The ability to predict infection and severity of disease from STEC genetic markers;
- Dose response for non-O157 STEC;
- The amount of raw milk consumed in New Zealand;

- The proportion of the population consuming raw milk in New Zealand and the demographics of this population;
- The prevalence of non-O157 STEC in raw cows' milk;
- The prevalence of STEC in raw milk from goats, sheep and buffaloes;
- The concentration of STEC in raw milk;
- Storage temperatures for vats holding raw milk;
- Storage times for raw milk in consumers' homes, and the influence of spoilage on consumption;
- The behaviour of STEC in milk from sheep, buffaloes, or goats;
- The behaviour of STEC in raw milk under a temperature profile similar to milk cooling in farm dairy vats; and
- The behaviour of STEC in raw milk at temperatures between 5 and 7°C.

# 5 AVAILABILITY OF CONTROL MEASURES

*KEY FINDINGS*

Under current legislation, a milk producer may sell raw milk to any person if it is sold at the producer's dairy premises and in a quantity not exceeding 5 litres at any one time, and the person intends the milk for consumption by the person or the person's family.

There are no on-farm practices that can guarantee that milk will be free from pathogens but there are practices that will reduce opportunities for milk contamination.

Consumer advice on raw milk is available.

## 5.1 Current Control Measures

The rules for the production and sale of raw milk are set by the *Animal Products Act 1999* and Section 11A of the *Food Act 1981*. MPI has stated how these rules apply to raw milk for direct human consumption in their risk assessment (MPI, 2013). In short:

- A milk producer may sell raw milk to any person if it is sold at the producer's dairy premises and in a quantity not exceeding 5 litres at any one time, and the person intends the milk for consumption by the person or the person's family.
- All milk producers must operate under a registered Risk Management Programme (RMP). If a dairy farmer produces milk primarily for direct human consumption then the RMP must adequately manage risks, and it is the farmer's responsibility to see that it does. If a dairy farmer primarily supplies milk for another use (e.g. for pasteurisation), then the RMP will not necessarily manage the risks to consumers who buy small volumes of this milk for drinking raw.

### 5.1.1 Controls in other countries

Sales of raw milk for direct human consumption are prohibited in Scotland and Canada (Gleadle, 2012; Government of Canada, 2013; Scottish Parliament, 2006). Appendix 3 contains information on controls in some European countries and the states of Australia and the USA where the sale of raw milk is permitted. Several countries also require labels instructing consumers to boil the raw milk before consumption.

## 5.2 Additional Options for Risk Management

### 5.2.1 On-farm control options: STEC

Control options to reduce the risk of contamination of raw milk by pathogens and other faecal bacteria have been examined as part of the risk assessment process conducted by MPI (MPI, 2013).

Mastitis caused by the human pathogens *Campylobacter* spp., STEC and *L. monocytogenes* appears to be uncommon, and these bacteria are not mentioned in a review of mastitis control prepared for Dairy NZ.[11] Nevertheless, mastitis control will reduce the risk from this

[11] http://www.dairynz.co.nz/file/fileid/27234 accessed 20 March 2014.

occasional source of pathogen contamination, and a number of management tools are available via the Dairy NZ website.

On-farm procedures that prevent faecal contamination of the milk supply will reduce the risk of STEC contaminating raw milk. The detection and elimination of STEC super-shedders from a herd is a potential control option, but one that is labour-intensive and expensive. For this approach to be effective it would require high-level veterinary supervision and on-going surveillance of individual animals in a herd (FSANZ, 2009a). Cattle vaccines are available in the USA and Canada for *E. coli* O157 (Matthews *et al.*, 2013).

Changes in dairy production practices are occurring in New Zealand, particularly the increasing use of feed pads, stand-off pads, and sheltered housing. These practices increase the potential for faecal contamination of the udder and teats. This makes hygiene controls at milking more important. Such controls can include pre-milking teat dips, cleaning and drying of teats before milking, stripping of foremilk and clipping of udder hair. These measures are time consuming, which would be a barrier for implementation. Effective equipment cleaning is another aspect of milking hygiene which can reduce the risk of contamination of raw milk, through control of the formation of biofilms.

Contaminated supplementary feed may increase the risk of carriage and shedding of pathogens by livestock (Crump et al., 2002). It is important that feed is properly treated to eliminate pathogens.

The potential for microbiological testing to be a component of risk management for raw milk will be limited by the time required to conduct such testing. A rapid test such as that offered by the Bactoscan instrument (less than 10 minutes) could be used for microbiological monitoring of bacterial numbers that would be an indicator of faecal contamination events.[12] This could enable diversion of milk with high bacterial counts (potentially from a faecal contamination event) to pasteurisation. The cost of such an instrument and consumables could be a barrier to its use by individual farms.

A 2008 social study on raw milk products found that the term “raw milk” was not well understood, and for labelling purposes, the term “unpasteurised milk” was favoured over “raw milk” and “non-heat treated milk” (NZFSA, 2009). Consumer education to more clearly define categories of milk may help risk communication.

### 5.2.2 Consumer advice

The authors of a review of US consumer safety in relation to raw milk and raw milk cheeses debated some of the options for risk management (Yilmaz *et al.*, 2009). They argued that imposing an outright ban on all sales of raw milk would require too much time and resources to enforce, and may not be completely effective at preventing illegal sales. This is supported by the FoodNet-based study of raw milk consumption in the United States, where the probability of raw milk consumption was not related to the legal status of sales in individual states (Buzby *et al.*, 2013). Yilmaz *et al*. (2009) recommended providing education to dairy producers and consumers, and implementing the use of warning labels on raw milk packaging.

[12] http://www.foss.dk/industry-solution/products/bactoscan-fc accessed 21 March 2013

MPI has published advice to consumers on the safety of raw milk.[13] The advice includes instructing consumers to "keep raw milk under refrigeration (4°C or less) and discard if it has spent more than two hours at room temperature".

[13] http://www.foodsmart.govt.nz/food-safety/high-risk-foods/raw-milk/ accessed 13 May 2013

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# 7 APPENDIX 1: HAZARD AND FOOD

## 7.1 STEC

General information on the growth, survival and inactivation of *E. coli* O157 and non-O157 STEC are presented in the 2007 Risk Profile and microbiological datasheets available from: http://www.foodsafety.govt.nz/science-risk/hazard-data-sheets/pathogen-data-sheets.htm

New information has been published on the effectiveness of pasteurisation for STEC inactivation.

The most commonly used standards for pasteurising raw milk are the low temperature long time (LTLT) (62.8°C for 30 minutes) method (also known as the "holding method" or "batch method"), and the high temperature short time method (HTST) (71.1°C for a minimum of 15 seconds). Ultra-high temperature pasteurisation involves heating to at least 135°C for 1 second (Ryser, 2011). HTST is most commonly used for milk products in New Zealand.

A review published by FSANZ in 2007 collated data on the effect of pasteurisation on pathogenic strains of *E. coli* (Juffs and Deeth, 2007). The review concluded that *E. coli* O157:H7 is destroyed by both batch and HTST pasteurisation, with a wide margin of safety. Estimates of the level of destruction of *E. coli* O157:H7 and some other pathogenic strains of *E. coli* by a thermisation treatment of 62°C for 15 seconds (sub-pasteurisation) vary widely, e.g. from <1D kill to a 5D kill. Variables include the strain of *E. coli* present, the type and composition of milk, the numbers of the organisms present and the source of the reference data used to estimate kill. A recent study investigating the effect of different thermisation treatments on nine strains of *E. coli* (four STEC) also detected wide variability in heat resistance (D-values at 65°C ranged from 3 to 93 seconds; the D-value at 70°C of the most heat resistant strain was 4.2 seconds) (Peng *et al.*, 2013).

A recent New Zealand study demonstrated variability in heat resistance between 30 *E. coli* strains, and then evaluated the effectiveness of different pasteurisation regimes on the most heat resistant strain of *E. coli* (for safety reasons they selected the most heat-resistant non-pathogenic strain, O157:H42, a meat isolate) (Pearce *et al.*, 2012). With a constant holding time of 15 seconds, the concentration of this strain in milk was observed to significantly decrease at 62°C and above. The strain was almost completely eliminated after heating at 65°C (a 7-log reduction), supporting the conclusion of Juffs and Deeth (2007). Currently there are no published data that suggest that non-O157 STEC have greater heat resistance than O157 (Mathusa *et al.*, 2010).

## 7.2 STEC in Raw Milk and among Dairy Animals Overseas

There are recent surveys reported in the scientific literature that investigate the prevalence of STEC among dairy animals or in raw milk from farms in African, Asian, and Middle Eastern countries. The results of these studies have not been reported here since they were considered of less relevance to New Zealand for comparative purposes. A recent review summarises prevalence studies in other countries (Farrokh *et al.*, 2013).

The methods used to produce the data reported in this section vary between studies. This Risk Profile does not review testing methods, but readers should note the following:

- PCR-based methods are designed to detect the presence of virulence genes (e.g. *stx*) or genes that can indicate serotype, usually in an enriched sample. Should these target genes be detected, they only indicate that a sample is potentially STEC-positive. For example, if *eae* and *stx* are both present in a sample, there is no way to know whether these genes were present in a single cell or multiple cells. The genes for stx are also encoded in bacteriophages and can be found independent from *E. coli* in free phage particles. The prevalence of PCR-positive samples is usually much higher than the prevalence found by culture-based methods.
- Culture-based methods can fail to isolate (and therefore confirm) STEC, particularly non-O157 STEC. Success rates for PCR-positive samples have been between 10 and 50%.

A recent overview has been published (Bosilevac, 2013) that discusses the current issues around testing for STEC. There is no standard method for detecting non-O157 STEC and a recent review (Farrokh *et al.*, 2013) discusses different methods.

### 7.2.1 Detection of STEC in raw milk overseas

The 2007 Risk Profile presented the results from surveys of raw milk reported between 1991 and 2005. These results showed the prevalence of STEC (or probable STEC, e.g. O157) to be generally low (<5%, many not detected), with a few exceptions. Generalising these results is difficult because the surveys were carried out for different purposes (e.g. outbreak investigations, surveys targeting specific producers), targeted different *E. coli* (e.g. O157 only, STEC) and varied in the number of samples that were tested (range 23-610).

The results of more recent surveys of raw milk in Australia, and European and North American countries are presented in Table 7. In addition, EFSA collates data from EU member states on foods tested for STEC. Four member states provided data on raw cows' milk intended for human consumption for the year 2011 (European Food Safety Authority and European Centre for Disease Prevention and Control, 2013):

- Belgium: 1/39 (2.6%) farm-level samples positive for O157 STEC;
- Germany: 1/94 (1.1%) samples at processing level positive for STEC, 3/57 (5.3%) samples at retail positive for STEC;
- Hungary: STEC not detected in 102 samples at farm level; and
- Slovenia: STEC not detected in 128 samples.

During the years 2007 to 2010, EFSA also received 24 data sets from eight countries for raw milk tested for STEC (European Food Safety Authority and European Centre for Disease Prevention and Control, 2012). Of the 24 surveys, STEC was not detected in 14, and the prevalences for the other 10 surveys ranged from 0.6 to 17.6 (Table VT9, page 172).

All of the surveys in Table 7 focussed on prevalence, and quantitative data are rare. One survey where researchers analysed raw milk samples for the concentration of STEC (e.g. *E. coli* O157:H7) or probable STEC reported low concentrations. In this study, 159 raw ewes' milk samples were collected from three cheese factories in Spain over the course of a year and *E. coli* O157:H7 was detected in 29 samples at a mean concentration of 0.22 MPN/ml (Caro *et al.*, 2011). The concentration in samples taken in summer was higher (O157:H7

detected in 13/42 samples at a mean concentration of 0.5 MPN/ml). *E. coli* O111 was detected in 13/159 samples at a mean concentration of 0.03 MPN/ml. Another survey, of *E. coli* O157 and O26 in raw cows' milk taken from tankers, reported concentrations of <0.3 MPN/ml in 3/5 positive samples, while 2/5 positive samples had concentration of 1.4 MPN/ml (Trevisani *et al.*, 2013).

**Table 7: Prevalence of STEC or probable STEC in raw milk overseas**

| Study location | Study period | Target *E. coli* | Samples | Prevalence: Number positive (% positive) | Reference |
|---|---|---|---|---|---|
| **STEC – detection using cultural methods** | | | | | |
| Germany (Bavaria) | 2004 | STEC | 209 raw cows' milk (4 farms) | ND | (Messelhäusser *et al.*, 2008) |
| Greece | 2002-2005 | O157 STEC | 950 raw cows' milk<br>460 goats' milk<br>595 sheep milk | 7 (0.7)[1]<br>2 (0.4)<br>3 (0.5) | (Solomakos *et al.*, 2009) |
| Greece | NR | O157:H7 STEC | 116 (87 sheep milk, 29 goat milk) | 11 (10)[2] | (Zdragas *et al.*, 2009) |
| Finland | 2011 | STEC | 183 raw cows' milk (183 farms) | 5 (3) | (Ruusunen *et al.*, 2013) |
| Italy (Lazio and Apulia regions) | 2006/07 | O26 STEC | 160 raw water buffaloes milk | 1 (0.6) | (Lorusso *et al.*, 2009) |
| Italy (Emilia-Romagna Region) | 2010 | O157:H7 STEC | 99 raw cows' milk (vending machines supplied by 33 farms) | 1 (1) | (Giacometti *et al.*, 2012b) |
| Italy (Marche region) | NR | STEC | 85 bulk tank bovine milk | 1 (1.2%) | (Petruzzelli *et al.*, 2013) |
| US (Washington State) | 2002-2004 | Non-O157 STEC | 531 raw cows' milk | 17 (3)[3] | (Cobbold *et al.*, 2008) |
| **STEC – detection using PCR** | | | | | |
| France | 1997/98 | STEC | 205 raw cows' milk | 43 (21)[4] | (Madic *et al.*, 2009; Perelle *et al.*, 2007) |
| Ireland | 2007/08 | STEC | Raw cows' milk (60 farms):<br>Summer (60 samples)<br>Winter (60 samples) | <br>30 (50)[5]<br>13 (22)[5] | (Lynch *et al.*, 2012) |
| Italy (Marche region) | NR | STEC | 85 bulk tank bovine milk | 8 (9.4%) | (Petruzzelli *et al.*, 2013) |
| US (multi-State) | 2002 | STEC | 859 raw cows' milk | 70 (8)[6] | (Karns *et al.*, 2007) |
| US (multi-State) | 2007 | STEC | 533 raw cows' milk | 78 (15 WP)[7] | (Van Kessel *et al.*, 2011) |
| **Probable STEC – detection using cultural methods** | | | | | |
| Australia (Queensland) | 2001-2006 | O157:H7 | 34 raw goats' milk, frozen (3 farms)[8] | ND | (Eglezos *et al.*, 2008) |

| Study location | Study period | Target *E. coli* | Samples | Prevalence: Number positive (% positive) | Reference |
|---|---|---|---|---|---|
| Australia (Western Australia) | 2007 | EHEC | 183 raw cows' milk | ND | (FSANZ, 2009a) |
| Italy | 2009/10 | O157 | 27 raw cows' milk | ND | (Amagliani *et al.*, 2012) |
| Italy (Piedmont region) | 2009/10 | O157 | Raw cows' milk:<br>107 bulk tank<br>104 vending machine | <br>ND<br>ND | (Bianchi *et al.*, 2013) |
| | 2010 | O157 | Raw cows' milk:<br>92 bulk tank<br>113 vending machine | <br>ND<br>1 (0.9%) – strain was not STEC | |
| | 2011 | O157 | Raw cows' milk:<br>99 bulk tank<br>103 vending machine | <br>ND<br>ND | |
| Spain | NR | O157, O111 | 159 raw ewes' milk (3 cheese factories over a year) | O157: 29 (18)<br>O111: 31 (8) | (Caro *et al.*, 2011) |
| US (Vermont State) | 2006 | O157:H7 | From farms supplying milk for artisan cheese-making:<br>67 raw cows' milk (5 farms)<br>49 raw goats' milk (4 farms)<br>22 raw sheep milk (2 farms) | <br>ND<br>1 (2)<br>ND | (D'Amico *et al.*, 2008) |
| US (Vermont State) | 2008 | O157:H7 | From farms supplying milk for artisan cheese-making:<br>45 raw cows' milk (12 farms)<br>25 raw goats' milk (5 farms)<br>15 raw sheep milk (4 farms) | <br>ND<br>ND<br>ND | (D'Amico and Donnelly, 2010) |

ND, Not detected

[1] In addition, 14 cows' milk, 1 goat milk and 2 sheep milk samples were positive for non-STEC O157.

[2] The authors stressed that the hygienic conditions on these farms was generally poor.

[3] 110/531 (21%) of the samples were *stx*-positive by PCR, but only 17 (3%) by culture. Based on PCR detection of *stx*, it appears that the proportion of STEC-positive samples was higher during winter months than during summer (26% vs. 9%), but there was no difference in prevalence based on culture methods (both 3%). Some of the serotypes isolated have been associated with human disease: O128, O108 and O160.

[4] Number positive for one or both *stx* genes, as detected by PCR of raw milk enrichments, not cultural methods. Of the 43 PCR-positive samples, the scientists only attempted cultural methods on seven samples that possibly contained the serotype O91 (the object of this research was to detect the clinically significant serotype O91:H21). Only one isolate was obtained (O91:H-).

[5] Number positive for one or both *stx* genes, as detected by PCR of raw milk enrichments, not cultural methods. Of the 43 PCR-positive samples, further PCR methods detected genes that indicated the presence of serotypes O26 (3 samples), O103 (4 samples), O145 (22 samples) and O157 (1 sample). Isolation by cultural methods was only attempted on one raw milk sample, but the authors do not report the result separate from other samples tested by cultural methods.

[6] Number positive for one or both *stx* genes, as detected by PCR of raw milk enrichments, not cultural methods. Of the 70 PCR-positive samples, 36 were also PCR-positive for *tir*, an indicator for the potential presence of *E. coli* O157:H7. Further PCR analysis of these 36 samples indicated that only two samples potentially contained *E. coli* O157:H7, and a culture was only isolated from one of these.

[7] Number positive for one or both *stx* genes, as detected by PCR of raw milk enrichments, not cultural methods. Results are presented as weighted prevalence (WP) which accounts for farms that are sampled more than once and non-response. The combination of *stx2*, *eaeA*, and γ-*tir*, indicating the potential presence of *E. coli* O157:H7 was detected in 5 (1.1% WP) samples.

[8] The method does not specify how long the samples were frozen for before testing, but the information provided suggests it is not a long period of time (perhaps a few days). It has been found that freezing milk for three days at -18°C does not affect the concentration of STEC (Hubáčková and Ryšánek, 2007), but the organism can decline during longer periods of frozen storage (7 days or longer). The majority of raw goats' milk is marketed in Queensland in the frozen state (Eglezos *et al.*, 2008).

### 7.2.2 STEC among dairy animals

The 2007 Risk Profile found that the prevalence of *E. coli* O157:H7 or STEC among animals was low (<2%) in most studies published between 1991 and 2005. The results of more recent surveys of STEC or probable STEC (e.g. *E. coli* O157) in European and North and South American countries are presented in Table 8 and Table 9.

The prevalence of *E. coli* O157 across herds of dairy cows ranged from 8 to 61% of the herds tested (Table 8). This indicates that *E. coli* O157 can be widespread among farms producing raw milk. Only one study was located that analysed for the presence of O157 STEC (8%, The Netherlands) and one that analysed for non-O157 STEC (21%, Spain). Prevalences among dairy cows were similar to those in the 2007 Risk Profile when only considering studies detecting STEC or probable STEC using cultural methods. Prevalences are higher when PCR methods are used.

Three studies were located that analysed the prevalence of STEC or probable STEC among buffaloes (Table 9). Only one study evaluated STEC (prevalence 37%, Brazil).

In Northern Spain, 122 herds of dairy sheep were tested for the presence of *E. coli* O157:H7, and the prevalence was 8.7% (95% CI: 4.2-13.2) (Oporto *et al.*, 2008).[14] In the same study, within-herd prevalence was also investigated by testing individual animals (279 sheep) within six of the sheep herds that were positive for *E. coli* O157:H7. All animals were negative in two sheep herds, and the prevalence for the other four herds ranged from 2.0% to 20.8%. The mean within-herd prevalence of excretion of *E. coli* O157:H7 was 7.3%.

No studies were located that analysed the presence of STEC among dairy goats. A survey of 214 goats in The Netherlands during 2011 did not detect STEC (European Food Safety Authority and European Centre for Disease Prevention and Control, 2013). The STEC prevalence among 76 goats tested in Germany during 2010 was 12%, and in 2007, prevalences of 6% and 2% were detected among goat herds in Germany and Portugal, respectively (European Food Safety Authority and European Centre for Disease Prevention and Control, 2012).

In a longitudinal study of STEC shedding by 133 dairy cows on six farms in Germany, researchers found that the presence of "super-shedders" in the herds was a significant risk factor ($p<0.001$) for shedding of STEC by dairy cattle (Menrath *et al.*, 2010).[15] The inner-herd prevalences, as detected by PCR, were 11.1% to 32.3%. Over the course of the study, 18 cows remained *stx*-negative, and 14 were identified as super-shedders. A recent study has proposed that super-shedding cows (dairy and non-dairy) contribute significantly to human infection with *E. coli* O157 (Matthews *et al.*, 2013).[16]

[14] The analysis method was altered during the study so the overall prevalence was calculated using an adjustment factor that accounted for the different sensitivities of the methods. The actual numbers of positive herds were 3/94 by VIDAS and 5/28 by IMS.

[15] For this research, a "super-shedder" was defined as a cow for which at least half of their faecal samples and equal or more than four consecutive samples were *stx*-positive.

[16] For this research, a super-shedder (or high shedder) was defined as cow who's faeces contained >1,300 CFU/g *E. coli* O157.

**Table 8: Prevalence of STEC or probable STEC among dairy cows overseas**

| Country | Study period | Target *E. coli* | Samples | Prevalence: No. positive (% positive) | Reference |
|---|---|---|---|---|---|
| **Farm-level studies** | | | | | |
| Belgium | 2007 | O157[1] | 49 farms (overshoes) | 30 (61) | (Cobbaut *et al.*, 2009) |
| Norway | 2002 | O157 | 50 dairy herds | 0[2] | (LeJeune *et al.*, 2006) |
| Spain | NR | O157:H7, non-O157 STEC | 82 dairy herds | O157:H7:<br>7.0% (95% CI: 1.7-12.3)[3]<br>Non-O157 STEC: 17 (21) | (Oporto *et al.*, 2008) |
| The Netherlands | 1996-2005 | O157 STEC | 1051 dairy herds | 8.0% | (Berends *et al.*, 2008) |
| USA | 2002 | O157 | 50 dairy herds | 4 (8)[4] | (LeJeune *et al.*, 2006) |
| USA | 2007-2009 | O157 | 149 farms (cow pats) | 35 (24)[5] | (Cernicchiaro *et al.*, 2012) |
| **Animal-level studies** | | | | | |
| Argentina | 2006/07 | STEC<br>O157 STEC | Rectal swabs (5 farms):<br>1440 dairy cows over four seasons<br>252 dairy calves in autumn and spring | STEC (tested by PCR):<br>540 (38) – cows[6]<br>108 (43) – calves[6]<br>O157 STEC (tested by culture):<br>3 (0.2) – cows<br>2 (0.8) – calves | (Fernández *et al.*, 2009) |
| Ireland | 2006-2009 | O157, O26, O103, O111, O145 | 600 faeces | 6 (1)[7] | (Teagasc, 2011) |
| Ireland | 2007/08 | STEC | 600 faecal swabs (60 farms):<br>Summer (300 samples)<br>Winter (300 samples) | Tested by PCR:<br>229 (76) – summer[8]<br>157 (52) – winter[8] | (Lynch *et al.*, 2012) |
| USA | 2001/02 | STEC | 2,362 faecal samples (28 farms) | Tested by PCR:<br>107 (5)[9] | (Cho *et al.*, 2006) |
| USA | 2002 | O157 | 750 (50 herds) | 5 (0.7) | (LeJeune *et al.*, 2006) |
| USA | NR (2-year period) | O157:H7 | 333 rectal grabs (1 farm) | 9 (3) | (Jeong *et al.*, 2013) |

NR, not reported
[1] Isolates were also tested for *stx* genes but the results were not presented separately for dairy animals.
[2] The *stx* gene was detected by PCR in samples from one or more animals in 50/50 farms (100%; 95% CI: 94-100).
[3] The analysis method was altered during the study so the overall prevalence was calculated using an adjustment factor that accounted for the different sensitivities of the methods. The actual numbers of positive herds were 2/77 by VIDAS and 2/5 by IMS.
[4] The *stx* gene was detected by PCR in samples from one or more animals in 19/50 farms (70%; 95% CI: 56-81).
[5] A total of 86 of 8940 (1%) bovine faecal samples tested positive for E. coli O157; 70/86 (81%) positive samples were collected in summer and 19% (16/86) were collected during fall.
[6] Higher proportion cows positive in spring and summer; higher proportion calves positive in spring.
[7] 63% of samples were positive by PCR. The isolates were O157, O26 and O103.
[8] Number positive for one or both stx genes, as detected by PCR of enrichments, not cultural methods. Of the 386 PCR-positive samples, further PCR methods detected genes that indicated the presence of serotypes O26 (37 samples), O103 (125 samples), O145 (244 samples) and O157 (18 samples). Isolation by cultural methods was attempted on 277 samples, but the authors do not report the results separate from other sample types tested by cultural methods.
[9] 21 (75%) of the dairy farms had at least one STEC-positive sample.

**Table 9: Prevalence of STEC or probable STEC among dairy buffaloes overseas**

| Country | Study period | Target *E. coli* | Samples | Prevalence: No. positive (% positive) | Reference |
|---|---|---|---|---|---|
| **Farm level studies** | | | | | |
| Italy | NR | O26 | 48 pooled faeces | 4 (8)[1] | (Astarita *et al.*, 2007) as cited in (Lorusso *et al.*, 2009) |
| **Animal level studies** | | | | | |
| Turkey | 2002/03 | O157:H7 | 300 faecal samples:<br>158 research institute<br>142 private farms | 11 (4)[2]<br>10 (6) – Institute<br>1 (0.7) – Farms | (Şeker and Yardımcı, 2008) |
| Brazil | NR | STEC | 100 faecal swabs (9 farms) | 37 (37)[3] | (Oliveira *et al.*, 2007) |

NR, not reported
[1] All isolates produced enterohaemolysin.
[2] None of the isolates produced enterohaemolysin. The buffaloes at the research institute were grain fed and those on private farms were hay fed.
[3] The on-farm prevalence of STEC ranged from 0 to 64% depending on the farm. Of the 20 distinct serotypes identified, more than 50% corresponded to serotypes associated with human diseases.

### 7.2.3 Recalls

Recalls were not reported in the 2007 Risk Profile. Recalls are not necessarily linked to human illness, but recall information provides an indication of how often STEC are detected in raw drinking milk sold for direct human consumption. Recall information is only relevant for countries where the sale of raw milk for direct human consumption is legal.

#### *7.2.3.1 European Union*

The Rapid Alert System for Food and Feed portal was used to retrieve recall records from January 2007 to 31 March 2013.[17] There are 32 countries participating in this system (including all EU member states and Lichtenstein, Iceland, Norway and Switzerland). The search retrieved 101 records, of which only nine were for products contaminated with *E. coli* or STEC. Raw milk was not identified in any of these recalls, although one record does not state whether the contaminated milk was raw or pasteurised.

#### *7.2.3.2 United States*

The regulations for the sale of raw milk vary between States and recalls are issued by appropriate State Departments, so there is no centralised database available for retrieving data. Raw milk recalls have been issued recently as a result of STEC contamination (e.g. (Anonymous, 2011a; b; 2013b).

#### *7.2.3.3 Australia*

Raw cows' milk is not permitted for sale in Australia, but raw goats' milk is allowed to be sold in some Australian states. All food recalls recorded by FSANZ from 2000 to May 2013 were scanned for relevant records.[18] No recalls for raw goats' milk were issued during this period.

## 7.3 Consumption of Raw Milk in Other Countries

#### *7.3.1.1 North America*

The US Foodborne Diseases Active Surveillance Network (FoodNet) monitors foodborne illness in 10 sentinel States, covering 15% of USA's population. FoodNet's activities include surveys of the people living in these areas. In a 2006/07 survey, a total of 17,372 people were asked whether they had consumed any unpasteurised milk in the past seven days, and 528 (3%) had (CDC, 2007). Estimates for the proportion of farming families and farm workers who consume raw milk range from 35 to 60% (Oliver *et al.*, 2009).

A more recent analysis combined results from the 2006/07 FoodNet survey (above) and from two other FoodNet surveys carried out in 1998/99 and 2002/03, to determine the characteristics of raw milk consumers in the USA by multivariate analysis (Buzby *et al.*, 2013). Across all years of the survey, 3.4% (1,004/29,753) of respondents reported

[17] https://webgate.ec.europa.eu/rasff-window/portal/. Search function parameters entered: Notified between 01/01/2007 and 31/03/2013; Product type: Food; Notification type: Alert; Product category: Milk and milk products; Hazard category: Pathogenic micro-organisms.

[18] The FSANZ website (http://www.foodstandards.gov.au/) only contains recent recalls. The full dataset was kindly provided by FSANZ.

consuming unpasteurised milk at some point in the previous seven days. Of those who reported consuming raw milk, only 6.5% lived on a farm and 14.8% lived in a rural area. Just under half of raw milk consumers (44.9%) lived in a State where all sales of unpasteurised milk were prohibited (some States permitted cow shares).

In Canada, a sample of 2,332 residents of the Waterloo Region (Ontario) participated in a telephone survey of food consumption and food safety during 2005/06 (Nesbitt *et al.*, 2009). Seventeen (0.7%) respondents reported consuming raw milk in the seven days prior to being questioned. Drinking unpasteurized milk was significantly more prevalent among rural residents (9.0%) than among urban residents (0.4%, P<0.001). Raw milk is not permitted for sale in Canada.

#### *7.3.1.2 Italy*

A quantitative risk assessment focussed on one province of the Emilia Romagna Region in Italy estimated 1-2% of the population were consumers of raw milk from vending machines (10,577-21,154 people of a population of 995,000) (Giacometti *et al.*, 2012a). From a consumer survey, Giacometti *et al*. (2012a) found that 57% of consumers boiled the raw milk before consumption, so the estimated proportion of the population consuming raw milk is 0.5-0.9% (4,548-9,0963 people).

# 8 APPENDIX 2: EVALUATION OF ADVERSE HEALTH EFFECTS

## 8.1 STEC Infection Overseas

### 8.1.1 Incidence

The 2007 Risk Profile presented incidence data for STEC infection for Australia, and European and North American countries, most for the year 2004. The most recent incidence data are given in Table 10, with New Zealand data provided for comparative purposes. The rate per 100,000 has increased for most of these countries, as has the proportion of isolates serotyped as being non-O157.

The 2007 Risk Profile discussed how non-O157 serotypes are increasingly being reported as the cause of human disease in a number of countries. Reported cases of non-O157 STEC infection appear to be increasing, but this is not necessarily due to increasing infections; recognition of non-O157 STEC infection as a notifiable disease and increased laboratory testing for these organisms in diarrheal patients means that non-O157 STEC infection is now more likely to be reported (Mathusa *et al.*, 2010). In the United States, the number of reported non-O157 STEC infections increased from an incidence of 0.12 per 100,000 population in 2000 to 0.95 per 100,000 in 2010; while the rate of O157 STEC infections decreased from 2.17 to 0.95 per 100,000 (Gould *et al.*, 2013a). In Australia the rate of STEC infection is higher for South Australia because laboratories in this State routinely test all bloody stools by PCR for the *stx* genes as part of diagnosis (OzFoodNet, 2012). Data presented in Table 10 show the proportion of serotyped isolates that are non-O157 STEC, which varies between countries. It is beyond the scope of this Risk Profile to investigate the extent to which these differences are a result of different laboratory testing protocols.

**Table 10: Reported incidence data for STEC infections by country**

| Country | Year | Incidence (per 100,000) | Change since 2007 Risk Profile | Serotyped isolates | | | Ref.* |
|---|---|---|---|---|---|---|---|
| | | | | Number | % O157 | % other STEC | |
| New Zealand | 2011 | 3.5 | ↑ | 153 | 91 | 9 | a |
| | 2010 | 3.2 | ↑ | 128 | 90 | 10 | b |
| Australia | 2011 | 0.4 | ↑ | NR | NR | NR | c |
| | 2010 | 0.4 | ↑ | 51 | 59 | 41 | d |
| **European countries** | | | | | | | |
| EU[1] | 2011 | 1.9 | ↑ | 4,506 | 48 | 52 | e |
| Austria | 2011 | 1.4 | ↑ | 103 | 29 | 71 | |
| Belgium | 2011 | 0.9 | ↑ | 86 | 76 | 24 | |
| Czech Republic | 2011 | 0.1 | ↓ | 7 | 43 | 57 | |
| Denmark | 2011 | 3.9 | ↑ | 204 | 13 | 87 | |
| Finland | 2011 | 0.5 | ↑ | NR | NR | NR | |
| France | 2011 | 0.3 | NR | 157 | 50 | 50 | |
| Germany[1] | 2011 | 6.8 | ↑ | 1591 | 9 | 91 | |
| Ireland | 2011 | 6.1 | ↑ | 269 | 74 | 26 | |

| Country | Year | Incidence (per 100,000) | Change since 2007 Risk Profile | Serotyped isolates | | | Ref.* |
|---|---|---|---|---|---|---|---|
| | | | | Number | % O157 | % other STEC | |
| Italy | 2011 | 0.1 | NR | 39 | 36 | 64 | |
| Netherlands | 2011 | 5.1 | ↑ | 242 | 27 | 73 | |
| Norway | 2011 | 1.0 | ↑ | NR | NR | NR | |
| Poland | 2011 | <0.1 | ↓ | 5 | 40 | 60 | |
| Spain | 2011 | <0.1 | NR | 20 | 80 | 20 | |
| Sweden | 2011 | 5.0 | NR | 247 | 25 | 75 | |
| Switzerland | 2011 | 0.9 | NR | NR | NR | NR | |
| United Kingdom | 2011 | 2.4 | ↑ | 1,492 | 99 | 1 | |
| **North American countries** | | | | | | | |
| Canada | 2011 | 1.4[2] | ↓ | 527 | 91 | 9 | f |
| USA[3] | 2011 | 1.0 | ↑ | 911 | 51 | 49 | g |

NR, Not Reported

*Table notes:*

[1] EU values based on data from 26 Member States. In 2011 there was a large outbreak of *E. coli* O104:H4 infection that affected more than 3,816 people in Germany and additional cases in 15 other countries (particularly France, Denmark and The Netherlands), so the total number of cases reported for the EU in 2011 (9,485) was much higher than that reported in 2010 (3,656). The total number of confirmed cases in Germany during 2011 (5,558) was also much higher than for 2010 (955), and similarly France (221 in 2011, 103 in 2010). Of the 1,591 STEC isolates serotyped in Germany, O104 accounted for 59%; this value was 24% (1,064/4,506) for the EU total.

2 Rate is for O157 STEC only. Rate for non-O157 STEC has been in the range 0.12 to 0.41 per 100,000 over a ten-year period (2001-2011; NESP 2013, page 16).

[3] Data is for the 10 sentinel states monitored by FoodNet, not the whole of the USA. Rate of 1.0 is for O157 STEC (rate for non-O157 STEC is 1.1). A rate of 1.8 per 100,000 has been reported for all STEC infections for the whole of the USA for the year 2010 (CDC, 2012a).

** References:*

a. (Lim *et al.*, 2012)
b. (Lim *et al.*, 2011)
c. (Department of Health and Aging, 2013)
d. (OzFoodNet, 2012)
e. (European Food Safety Authority and European Centre for Disease Prevention and Control, 2013)
f. (NESP, 2013)
g. (CDC, 2012b)

### *8.1.1.1 Community level estimates*

The number of notified STEC infections only represents a proportion of total cases, as not all cases will come into contact with public health agencies. New estimates for the annual number of community STEC infections and annual rates of infection have been published:

- Australia: 4,420 cases (95% Credible Interval (CrI): 2,407-10,196), or a rate of 23 (95% CrI: 13-54) per 100,000 people (Hall *et al.*, 2008). This was based on notified cases from 2000 through 2004.
- USA: 93,094 (90% CrI: 26,046-219,676) domestically-acquired O157 STEC cases and 138,063 (90% CrI: 14,080-350,891) domestically-acquired non-O157 STEC cases (Scallan *et al.*, 2011). This was based on surveillance data from 2000 to 2008. Using the

2006 USA population of 299 million, this produces rates per 100,000 of 31 for O157 STEC infection and 46 for non-O157 STEC infection. Rates per 100,000 for domestically-acquired foodborne STEC infections were 21 for O157 STEC infection and 38 for non-O157 STEC infection. These data are from active surveillance through the FoodNet system and indicate that in that the USA the rates of O157 STEC infection are similar to those for non-O157 STEC.

- Canada: 39 cases of domestically-acquired O157 STEC infection per 100,000 people and 63 cases of non-O157 STEC infection per 100,000 people (Thomas *et al.*, 2013). These estimates were based on surveillance data from 2000 to 2010 plus relevant international literature, and were produced through a modelling approach that accounted for underreporting and underdiagnosis.

Estimates for the true incidence of O157 and non-O157 STEC have also been produced for the EU but these were not converted to population-based rates of infection so are difficult to compare with the results from other countries (see Table 8, page 20 in EFSA (2013) for details). The ratio is about 130 cases of unreported STEC infection for every one reported case.

### 8.1.2 Outbreaks

The 2007 Risk Profile listed 14 outbreaks of STEC infection in other countries where raw/unpasteurised milk was the implicated vehicle. Table 11 lists 19 outbreaks reported from 2007 onwards. Outbreaks may have occurred in countries other than the USA but data are less readily accessible, e.g. Annual summaries published by EFSA for EU countries do not contain enough detail to show whether any of the outbreaks of pathogenic *E. coli* infection were caused by consumption of raw milk.[19]

A 2010 report published by the ACMSF included data on all foodborne intestinal infectious disease outbreaks in England and Wales from 1992 to 2009 (ACMSF, 2011a). It was noted that from 2003 to 2009 there were no reported outbreaks linked to raw drinking milk or cream produced from raw milk (from 1992 to 2002 there were 20 outbreaks linked to raw drinking milk or raw cream).

A review published in 2011 has summarised outbreaks of disease in the US between 1990 and 2006 linked to consumption of fluid milk (Newkirk *et al.*, 2011). There were 83 reported outbreaks, of which 46 (55%) were associated with consumption of raw milk and caused 974 (27%) of the total cases (3,621) reported for all milkborne outbreaks. Of these 46 raw milk outbreaks, *E. coli* (presumably pathogenic) was identified as the causative pathogen in six (13%). Notably, a later review of data from the same source (CDC) but for a slightly shorter period (1993 to 2006) reported that outbreaks involving raw milk represented 82% (46/56) of the total fluid milk outbreaks (Langer *et al.*, 2012). In the absence of directly comparable results, this suggests that raw milk outbreaks are being increasingly reported; a graph presented by Newkirk *et al*. (2011) (Figure 1) lends support to this hypothesis. Langer *et al.* (2012) also reported that States that restricted the sale of raw milk products had fewer outbreaks and illnesses.

[19] http://www.efsa.europa.eu/en/zoonosesscdocs/zoonosescomsumrep.htm (accessed 11 June 2013).

**Table 11: Overseas outbreaks of STEC infection where raw milk was an implicated vehicle (reported from 2007 onwards)**

| Country | Year | No. cases[1] | Hospitalisations, sequelae and age of hospitalised cases (where known) | Ages of non-hospitalised cases (where known) | Product | Exposure | Serotype | Reference |
|---|---|---|---|---|---|---|---|---|
| Finland | 2012 | 5 | 1 hospitalisation (4 year old) | 1 year old | Cows' milk | Farm gate | NR | (Anonymous, 2012c) |
| Germany | 2013 | 45 | 2 hospitalisations with HUS | 6-10 years old | Cows' milk | School visit to dairy farm | O157:H7 | (Kirchner *et al.*, 2013) |
| USA (TN) | 2013 | 9 | 5 hospitalisations (3 HUS) | All <7 years | Cows' milk | Cow share | NR | http://www.foodsafetynews.com/2013/11/tn-raw-milk-dairy-linked-to-e-coli-outbreak-reboots-business/ and http://www.foodsafetynews.com/2013/11/raw-milk-dairy-linked-to-e-coli-outbreak-through-tests/ |
| USA (WI) | 2013 | 3 | Hospitalisation not reported | 3 year old | Cows' milk | (to be confirmed)[2] | O157:H7 | (Anonymous, 2013a) |
| USA (OR) | 2012 | 11 C<br>8 P | 5 hospitalisations, all children (4 acute kidney failure[3], aged 1, 3, 13 and 14 years old) | NR | Cows' milk | Herd share | O157:H7 | (Anonymous, 2012b; Shyng and McIntyre, 2013) |
| USA (MO) | 2012 | 13 | 1 hospitalisation (1 HUS, a child) | NR | Cows' milk | NR | O157:H7 | (Shyng and McIntyre, 2013) |
| USA (CA) | 2011 | 5 | 3 hospitalisations (all children) | All children | Cows' milk | Retailed milk | O157:H7 | (Anonymous, 2012a) |
| USA (WA) | 2011 | 3 | 1 hospitalisation (1 HUS, a child) | All children | Cows' milk | Farm gate or retail | O157:H7 | (Shyng and McIntyre, 2013) |
| USA (CO) | 2010 | 30[4] | 2 hospitalisations (both children) | NR | Goats' milk | Goat share | O157:H7 | (CDC, 2013; Shyng and McIntyre, 2013) |
| USA (MN) | 2010 | 8 | 4 hospitalisations (2 toddlers, 1 school-aged child, 1 adult aged in 70s) | 1 school-aged child | Cows' milk | Farm gate or milk club | O157:H7 | (Anonymous, 2010a; b; Shyng and McIntyre, 2013) |
| USA (TN) | 2010 | 3 | No hospitalisations | NR | Cows' milk | NR | O157:H7 | (CDC, 2013) |
| USA | 2010 | 6 | No hospitalisations | NR | Cows' milk | NR | O26:H11 | (CDC, 2013) |

| Country | Year | No. cases[1] | Hospitalisations, sequelae and age of hospitalised cases (where known) | Ages of non-hospitalised cases (where known) | Product | Exposure | Serotype | Reference |
|---|---|---|---|---|---|---|---|---|
| (WA) | | | | | | | | |
| USA (WA) | 2010 | 2 | 1 hospitalisation | NR | Cows' milk | NR | O157:H7 | (CDC, 2013) |
| USA (WA) | 2009 | 3 | No hospitalisations | NR | Cows' milk | NR | O121; O157:H7 | (CDC, 2013) |
| USA (CT) | 2008 | 7 C<br>7 P | 5 hospitalisations, 1 adult, 4 children (3 HUS, all children) | NR[5] | Cows' milk | Farm gate or retail | O157:NM | (Guh *et al.*, 2010) |
| USA (MO) | 2008 | 4 | 2 hospitalisations | NR | Goats' milk | NR | NR | (CDC, 2013) |
| USA (VT) | 2008 | 6 | 3 hospitalisations | NR | Cows' milk | NR | NR | (CDC, 2013) |
| USA (CA) | 2006 | 6 | 3 hospitalisations, all children[6] (2 HUS) | All children[6] | Cows' milk | Retail | O157:H7 | (Schneider *et al.*, 2008) |
| USA (WA) | 2005 | 8 C<br>10 P | 5 hospitalisations, all aged 1-13 years (4 HUS) | NR[7] | Cows' milk | Cow share | O157:H7 | (Bhat *et al.*, 2007; Denny *et al.*, 2008) |

NR, not reported

[1] C, confirmed; P, probable.

[2] The report indicated that the outbreak cause was still under investigation but that officials suspected raw milk as the vehicle of infection.

[3] Acute kidney failure is one of the symptoms of HUS

[4] Some of these cases also sick with campylobacteriosis (the report does not distinguish cases by aetiology)

[5] Ages of non-hospitalised patients were not reported separately. Age range of all 14 cases was 1-81 years, median age 5 years (10 were aged <18 years).

[6] Age range of all 6 cases was 6-18 years, median age 8 years.

[7] Ages of non-hospitalised patients were not reported separately. Age range of all 18 cases was 1-47 years, median age 9 years.

### 8.1.3 Case control studies investigating raw milk as a risk factor

Two case control studies that considered consumption of raw milk as a risk factor have been published since the 2007 Risk Profile.

Scientists in Germany undertook a case control study to identify risk factors for sporadic illness associated with STEC infection, regardless of serogroup (Werber *et al.*, 2007). The study was based on 202 cases identified between 2001 and 2003, and 202 controls pair-matched to cases by age group. Non-O157 strains accounted for 85% of STEC isolated from cases. Elevated odds ratios (OR) were found as follows:

- Children <3 years of age (101 case-control pairs), by multivariate analysis: Having touched a ruminant (OR 9.3), having consumed raw milk (OR 6.9), or having played in a sandbox (OR 2.6). The 95% confidence interval (CI) for consuming raw milk was 1.0-47.9. Consumption of raw milk was reported by 9 (9.1%) of cases and 2 (2.0%) of controls.
- Children aged 3-9 years (44 case-control pairs), by univariate analysis (multivariate analysis was not possible): Having played in a sandbox (OR 9.0) and to have swum in unchlorinated water (OR 3.8). Raw milk was not a risk factor. Consumption of raw milk was only reported by one case.
- People aged 10+ years (57 case-control pairs), by multivariate analysis: Consumption of lamb meat (OR 14.1) and consumption of any of the raw fermented spreadable sausages (OR 3.2). Consumption of raw milk was reported by 2 (3.6%) of cases and 1 (1.8%) of controls, and was not considered a risk factor by univariate analysis (OR 2.0, 95% CI: 0.2-22.1).

Thus consumption of raw milk was only found to be an important risk factor for very young children, although even for this age group other transmission routes exist.

Early results have been reported for a case control study in Italy that, at the time, involved 60 HUS patients (aged 8 months to 15 years) and 157 control subjects (Scavia *et al.*, 2009). After multivariate analysis, the highest statistically significant odds ratio was for consumption of raw milk (odds ratio, 8.3; 95% CI: 1.3–51.7). This was the only food significantly associated with HUS.

A case control study investigating risk factors for STEC infection in Australia has recently been published, but the researchers did not ask participants about raw milk consumption (McPherson *et al.*, 2009).

## 8.2 Risk Assessment and Other Activities Overseas

The 2007 Risk Profile reported on risk assessments and other activities for Ireland, South Australia and Scotland. Risk assessments and risk-related activities published for Australia, the United Kingdom, Italy, Norway and Belgium have since been published.

### 8.2.1 Australia

FSANZ published two microbiological risk assessments in 2009, one addressing raw cows' milk and one raw goats' milk (FSANZ, 2009a; b). Both considered the risk of illness from raw milk contaminated with EHEC (as well as other pathogens). Both found that there was a risk of EHEC infection if raw milk was consumed.

The raw cows' milk risk assessment included quantitative microbiological modelling to predict the number of illnesses per 100,000 daily servings of raw milk for children and adults. Three scenarios (for children and adults separately) were modelled (unlike the New Zealand model, the time period for the total supply chain was not fixed). The mean predicted cases of illness from EHEC infection per 100,000 daily serves of raw milk were:

- 17 children and 17 adults when milk is consumed directly from farm bulk milk tanks (250ml serving size);
- 49 children and 38 adults when milk is consumed after farm gate sales (includes transport home and storage in domestic refrigerator, and also an empirical serving size distribution (with a mean for children and adults of 536 ml and 397 ml respectively); and
- 97 children and 78 adults when milk is consumed after retail purchase (includes additional packaging, distribution and retail storage components; serving sizes as for farm gate sales).

The higher number of predicted child cases in the farm gate and retail sales scenarios reflect the larger volume consumed by this age group. Some assumptions had to be made where data gaps existed. Some important data gaps were the prevalence and concentration of pathogens in Australian dairy cows and raw milk produced in Australia, and raw milk consumption and the demographics of the consuming population in Australia (consumption volumes were based on data for pasteurised milk).

The raw goats' milk risk assessment found, by qualitative risk rating, that EHEC was the hazard of most concern for the general population from the consumption of raw goat milk produced in Australia. Data for this assessment were scarce. Particular data gaps identified were the prevalence and concentration of pathogens in the domestic raw goat milk supply, the frequency and amount of consumption and the demographics of the consuming population.

### 8.2.2 United Kingdom

The Advisory Committee on the Microbiological Safety of Foods (ACMSF), who provide scientific advice to the UK Food Standards Agency (UKFSA), has considered the risks associated with raw drinking milk on several occasions in the past, and most recently in 2011. On all occasions the ACMSF concluded that there were significant risks to human health from consumption of raw drinking milk and stressed the importance of pasteurisation to ensure food safety (ACMSF, 2011a; b). The UKFSA recently completed a wider review that included new scientific and surveillance information since the 2011 review, and in January 2014 launched public consultations in England, Wales and Northern Ireland on the controls governing the sale and marketing of raw drinking milk and raw cream in these countries (Food Standards Agency, 2014a; b; c). One objective of these consultations is to harmonise raw milk labelling rules.

In 2006, scientists from the UK and New Zealand published a qualitative exposure assessment for STEC *E. coli* O157:H7 in pasteurised milk containers at the point of retail (Clough *et al.*, 2006). The study utilised UK-specific data where possible, and supplemented this with expert opinion. The first part of this assessment is relevant to this Risk Profile, as it assessed the probability of milk becoming contaminated with STEC *E. coli* O157:H7, and the probability of this pathogen growing during storage in the bulk tank. The authors' concluded that the probability that the bulk tank is contaminated with STEC *E. coli* O157:H7 is likely to be low to moderate, and when such contamination is present, the concentration of this pathogen is likely to be low. They also concluded that the probability of growth in the bulk tank is low (provided temperature guidelines are adhered to), and the extent of growth, should it occur, is likely to be low.

### 8.2.3 Italy

A quantitative risk assessment was developed to describe the risk of HUS linked to consumption of raw milk sold in vending machines in Northern Italy (Giacometti *et al.*, 2012a). The assessment focussed on *E. coli* O157:H7 as the causative pathogen for HUS and encompassed the whole food chain from the farm to the consumer. The model also considered two storage scenarios where the milk was kept at optimal temperature (4°C) throughout the food chain or kept at variable (worst-case) temperatures as identified through another study (see (Giacometti *et al.*, 2012c)). The model predicted the number of HUS cases per 10,000-20,000 consumers, per year, linked to consumption of raw milk as:

- 0.09 cases in the 0-5 year age group under the worst storage scenario;
- 0.02 cases in the 0-5 year age group under the best storage scenario;
- 0.5 cases in the >5 year age group for the worst storage scenario; and
- 0.1 cases in the >5-year age group for the best storage scenario.

It is important to note that the model took into account that 57% of consumers boiled the raw milk before consumption. While the authors also accounted for insufficient heat treatment (e.g. microwaving, insufficient boiling), removal of this module would increase the number of predicted cases.

### 8.2.4 Norway

The Norwegian Scientific Committee for Food Safety has published two risk assessments, one considering raw cows' milk and one considering of raw milk from other species (sheep, goat, horse and reindeer) (VKM, 2006; 2007). The Committee found the occurrence of *E. coli* O157:H7 and other EHEC to be very low in cows in Norway, so the risk of exposure through raw cows' milk (and cream) was low. However, they considered the risk associated with *E. coli* O157:H7 and other EHEC in raw cows' milk and cream as high on the basis of the low infectious dose and the potentially severe consequences for the individual infected. The Committee considered that the risks from consumption of raw milk from other animals was not significantly different from the risks from consumption of raw cows' milk. However it should be noted that there were little to no data on pathogen prevalence and milk consumption to support this conclusion.

### 8.2.5 Belgium

In 2011 the Scientific Committee for the Belgian Federal Agency for the Safety of the Food Chain (FASFC) published a risk-benefit evaluation of raw cow milk consumption (FASFC, 2011). The committee considered pathogenic *E. coli* among other pathogens. They concluded that *Salmonella*, *Campylobacter jejuni*/*coli* and pathogenic *E. coli* were the main bacteria that can be transmitted through raw milk to humans (these conclusions were based on wider European data because there was a lack of data specific to Belgium).

# 9 APPENDIX 3: CONTROL MEASURES IN OTHER COUNTRIES

This section provides a summary of controls in some European countries and the states of Australia and the USA where the sale of raw milk is permitted.

### 9.1.1 Australia

At the federal level, Clause 15 of the Australia New Zealand Food Standards Code Standard 4.2.4 (which only applies in Australia) requires milk that is to be sold as liquid milk or used in the manufacture of dairy products (excluding cheese) to be pasteurised (or equivalently processed) "unless an applicable law of a State or Territory otherwise expressly provides." (FSANZ, 2012).

A review of legislation for individual Australian states indicated that in some states (New South Wales, Queensland, South Australia, and Western Australia) the sale of raw goats' milk is permitted. This permission is subject to producers having a documented food safety programme or plan. The product must be labelled as unpasteurised.

### 9.1.2 United Kingdom

The Food Hygiene (Scotland) Regulations 2006 state that no person shall place on the market raw milk intended for direct human consumption.[20] In England, Wales, and Northern Ireland it appears that sales of raw cows' milk are permitted with restrictions specified by the UKFSA, whereas sales of other types of raw milk (sheep, goat, buffalo milk) are not subject to these restrictions but may be controlled by a local food authority (Department of Health Social Services and Public Safety, 2006; Gleadle, 2012; National Assembly for Wales, 2006; Secretary of State, 2013). The restrictions on the sale of raw cows' milk essentially allow only sales directly from the farmer to consumers (i.e. from farm gates, farm catering operations, from a vehicle used as a shop premises, and by a farmer at farmers markets).

In England and Northern Ireland all raw milk products except buffalo milk must be labelled as not heat-treated and therefore may contain organisms harmful to health. This labelling applies to all raw milk sold in Wales (Gleadle, 2012).

### 9.1.3 Republic of Ireland

According to the website of the Food Safety Authority of Ireland (FSAI) sales of raw milk in Ireland appear to be permitted provided the products are labelled as "raw milk", and the origin must be stated if it is not bovine (FSAI, 2008; 2010). Premises selling raw milk must be registered and approved, and general EC hygiene regulations and specific microbiological standards (plate count, somatic cell count) must be met. It appears that some of these regulations do not apply to producers who directly supply small quantities of primary products either to the final consumer or to local retail establishments directly supplying the final consumer. While allowing sales of raw milk, the FSAI advise against consumption of this product (FSAI, 2009).

[20] http://www.legislation.gov.uk/ssi/2006/3/contents/made

### 9.1.4 Italy

The sale of raw milk is permitted in Italy, but its use in catering premises, including school cafeterias, is prohibited. In 2007 the Italian Government permitted the sale of raw milk via vending machines and by 2012, around 1,400 machines were in operation (Bucchini, 2012; Giacometti *et al.*, 2012a). The vending machines must be registered, only filled with milk from a single farm on a daily basis, and the milk kept at 0-4°C. If the vending machine fills bottles, the bottle must carry the label "unpasteurised raw milk". All raw milk sold must be labelled "to be used only after boiling" (for on-farm sales, the warning is to be given verbally, and it must appear on the front of vending machines). An expiry date of three days after delivery to the consumer is required.

### 9.1.5 France

Raw milk must be labelled with the words "raw milk, keep at +4°C maximum" and "boil before consumption for sensitive people (young children, pregnant women and people with weakened immune systems)", and carry a deadline for consumption that is three days after production (Angot, 2012; Dehaumont, 2012). Suppliers must be registered.

### 9.1.6 Germany

There are two classifications of raw milk in Germany. Raw milk ("rohmilch") must only be sold from the farm by the producer directly to the consumer, and the farmer must display a sign on their tank stating the product is raw milk and that it must be boiled before consumption. "Vorzugsmilch" (certified milk) is unpasteurised milk that has been produced and handled according to higher standards than those required for normal milk production including a monthly testing regime. Vorzugsmilch must be packaged for sale through retail outlets and must be labelled as "raw milk – store at a maximum of 8°C, consume up to [date]", where the date is 96 hours after milk collection (German Federal Ministry of Justice, 2007; LAVES, 2013; Tschischkale, 2011).

### 9.1.7 United States of America

All milk sold interstate must be pasteurised, but individual States are responsible for setting their own legislation for the sale of raw milk (FDA, 2012). It is at least technically possible to legally sell or distribute raw milk for human consumption in 30 states (National Conference of State Legislatures, 2013). Overall regulation for the USA dairy industry is the responsibility of the USFDA.