



Risk Profile: *Listeria monocytogenes* in Raw Milk

MPI Technical Paper No: 2014/16

Prepared for Ministry for Primary Industries
Nicola King, Dr Rob Lake, Peter Cressey, ESR

ISBN No: 978-0-478-43214-5 (online)

ISSN No: 2253-3923 (online)

May 2014

Disclaimer

Every effort has been made to ensure the information in this report is accurate.

MPI does not accept any responsibility or liability whatsoever for any error of fact, omission, interpretation or opinion that may be present, however it may have occurred.

This report or document (“the Report”) is given by the Institute of Environmental Science and Research Limited (“ESR”) solely for the benefit of the Ministry for Primary Industries (“MPI”), Public Health Services Providers and other Third Party Beneficiaries as defined in the Contract between ESR and MPI, and is strictly subject to the conditions laid out in that Contract. Neither ESR nor any of its employees makes any warranty, express or implied, or assumes any legal liability or responsibility for use of the Report or its contents by any other person or organisation.

Requests for further copies should be directed to:

Publications Logistics Officer
Ministry for Primary Industries
PO Box 2526
WELLINGTON 6140

Email: brand@mpi.govt.nz
Telephone: 0800 00 83 33
Facsimile: 04-894 0300

This publication is also available on the Ministry for Primary Industries website at <http://www.mpi.govt.nz/news-resources/publications.aspx>

© Crown Copyright - Ministry for Primary Industries



**RISK PROFILE:
LISTERIA MONOCYTOGENES
IN RAW MILK**

Client report FW13052

By

Nicola King
Dr Rob Lake
Peter Cressey

April 2014



**RISK PROFILE:
LISTERIA MONOCYTOGENES
IN RAW MILK**

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. FW13052

Dr Stephen On
Chief Scientist, Food and Water

Dr Rob Lake
Project Leader

Dr Andrew Hudson
Peer Reviewer

DISCLAIMER

This report or document (“the Report”) is given by the Institute of Environmental Science and Research Limited (“ESR”) solely for the benefit of the Ministry for Primary Industries (“MPI”), Public Health Services Providers and other Third Party Beneficiaries as defined in the Contract between ESR and MPI, and is strictly subject to the conditions laid out in that Contract.

Neither ESR nor any of its employees makes any warranty, express or implied, or assumes any legal liability or responsibility for use of the Report or its contents by any other person or organisation.

GOVERNMENT AGENCY MERGERS AFFECTING THIS DOCUMENT

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.

We also thank Jonathan Watts (MPI) for his advice on listerial mastitis and Andrew McFadden (MPI) for advising on the dairy farmer survey.

CONTENTS

SUMMARY	1
1 INTRODUCTION	3
2 HAZARD AND FOOD.....	4
2.1 The Pathogen: <i>L. monocytogenes</i>	4
2.1.1 Pathogenicity	4
2.2 The Food: Raw Milk	6
2.2.1 Milk production in New Zealand.....	6
2.3 Behaviour of <i>L. monocytogenes</i> in Raw Milk.....	7
2.3.1 Contamination of raw milk by <i>L. monocytogenes</i>	7
2.3.2 Behaviour of <i>L. monocytogenes</i> in raw milk.....	9
2.4 Exposure Assessment.....	11
2.4.1 New Zealand prevalence studies	12
2.4.2 Food consumption: Raw milk.....	13
2.4.3 Potential for growth of <i>L. monocytogenes</i> along the raw milk food chain.....	14
2.5 Data on <i>L. monocytogenes</i> and Raw Milk from Other Countries	15
2.5.1 Prevalence and frequency studies in other countries	15
2.5.2 Raw milk consumption in other countries	16
3 EVALUATION OF ADVERSE HEALTH EFFECTS	17
3.1 Disease Characteristics	17
3.2 Dose Response	17
3.2.1 Invasive listeriosis	18
3.2.2 Non-invasive listeriosis	18
3.3 New Zealand Human Health Surveillance.....	18
3.3.1 Raw milk consumption as a risk factor for <i>L. monocytogenes</i> infection.....	19
3.3.2 <i>L. monocytogenes</i> infection in New Zealand	19
3.3.3 Serotypes	21
3.4 <i>L. monocytogenes</i> Infection Overseas.....	22
4 EVALUATION OF RISK.....	23
4.1 Existing Risk Assessments.....	23
4.1.1 New Zealand risk assessment	23
4.1.2 Risk assessments from other countries	23
4.2 Evaluation of Risk for New Zealand.....	24
4.2.1 Risk associated with raw milk	25
4.2.2 Risks associated with other foods.....	26
4.3 The Burden of <i>L. monocytogenes</i> Infection in New Zealand	27
4.3.1 Burden of disease from raw milk contaminated with <i>L. monocytogenes</i>	27
4.3.2 Burden of disease from all <i>L. monocytogenes</i> infection.....	27
4.4 Summary of Risk	28
4.5 Data Gaps	28
5 AVAILABILITY OF CONTROL MEASURES	30
5.1 Current Control Measures	30
5.2 Current Control Measures	30
5.2.1 Controls in other countries	30
5.3 Additional Options for Risk Management	30
5.3.1 On-farm control options: <i>L. monocytogenes</i>	31
5.3.2 Consumer advice	31

6	REFERENCES	33
7	APPENDIX 1: HAZARD AND FOOD.....	51
7.1	<i>L. monocytogenes</i> in Raw Milk and among Dairy Animals Overseas.....	51
7.1.1	Detection of <i>L. monocytogenes</i> in raw milk overseas	51
7.1.3	<i>L. monocytogenes</i> among dairy animals.....	56
7.1.4	Recalls	58
7.2	Consumption of Raw Milk in Other Countries	58
8	APPENDIX 2: EVALUATION OF ADVERSE HEALTH EFFECTS	60
8.1	Dose Response	60
8.1.1	Invasive listeriosis	60
8.1.2	Non-invasive listeriosis (febrile gastroenteritis).....	61
8.2	<i>L. monocytogenes</i> Infection Overseas.....	62
8.2.1	Incidence.....	62
8.2.2	Outbreaks.....	64
8.2.3	Case control studies investigating raw milk as a risk factor	65
8.3	Risk Assessment and Other Activities Overseas	65
8.3.1	Risk assessments considering raw milk.....	65
8.3.2	Risk assessments considering <i>L. monocytogenes</i> in RTE foods	68
9	APPENDIX 3: CONTROL MEASURES IN OTHER COUNTRIES	70
9.1.1	Australia	70
9.1.2	United Kingdom	70
9.1.3	Republic of Ireland	70
9.1.4	Italy.....	71
9.1.5	France	71
9.1.6	Germany	71
9.1.7	United States of America.....	71

LIST OF TABLES

Table 1:	Characteristics of the four <i>L. monocytogenes</i> lineages	5
Table 2:	Prevalence of <i>L. monocytogenes</i> in two New Zealand surveys of raw cows' milk.	12
Table 3:	Consumption of cold milk by New Zealanders (national nutrition surveys).....	14
Table 4:	Number of reported cases and rates of invasive listeriosis, 1997-2012.....	20
Table 5:	Listeriosis cases that resulted in hospitalisation and death, 1997-2012.....	21
Table 6:	<i>L. monocytogenes</i> serotypes identified by the ESR Special Bacteriology Laboratory, 2003-2012	22
Table 7:	Prevalence of <i>L. monocytogenes</i> in raw cows' milk overseas	52
Table 8:	Counts of <i>L. monocytogenes</i> in raw cows' milk overseas	54
Table 9:	Prevalence of <i>L. monocytogenes</i> in raw goats' milk overseas.....	55
Table 10:	Prevalence of <i>L. monocytogenes</i> in raw sheep milk overseas	55
Table 11:	Prevalence of <i>L. monocytogenes</i> among dairy cows overseas (faecal samples or rectal grabs).....	57
Table 12:	Concentration of <i>L. monocytogenes</i> in foods linked to outbreaks of febrile gastroenteritis.....	62
Table 13:	Reported incidence data for notified cases of listeriosis overseas	62

LIST OF FIGURES

Figure 1:	Growth of <i>L. monocytogenes</i> in raw cows' milk held at 4°C	10
Figure 2:	Reported invasive listeriosis cases by year, 1997-2012.....	20
Figure 3:	Dose response models at median values for R for disease caused by <i>L.</i> <i>monocytogenes</i>	61
Figure 4:	Rates of listeriosis in New Zealand, Australia, the USA and the EU, 1997-2012...	63

GLOSSARY AND ABBREVIATIONS

ANS	The 2009 Adult Nutrition Survey
a_w	Measure of water activity (max = 1.000 = pure distilled water)
ACMSF	Advisory Committee on Microbiological Safety of Foods
CFU	Colony forming unit
CNS	The 2002 National Children's Nutrition Survey
EFSA	European Food Safety Authority
EU	European Union
FAO	Food and Agricultural Organisation of the United Nations
FSANZ	Food Standards Australia New Zealand
MPI	Ministry for Primary Industries
MPN	Most Probable Number
Neonate	A newborn baby during the first 28 days after birth ¹
NNS	The 1997 National Nutrition Survey
NZFSA	New Zealand Food Safety Authority (now MPI)
PCR	Polymerase Chain Reaction
PFGE	Pulsed Field Gel Electrophoresis
pH	Measure of acidity (min = 0 = most acidic; max = 14)
Perinatal	The period from 20 weeks or more gestation to 7 days after birth ¹
RMP	Risk Management Programme (under the <i>Animal Products Act</i> 1999)
RTE	Ready-to-eat
USA	United States of America
USFDA	United States Food and Drug Administration
USDA	United States Department of Agriculture
WHO	World Health Organization

¹ As defined in Ministry of Health (2010).

SUMMARY

This Risk Profile considers *Listeria monocytogenes* in raw milk from cows, sheep, goats and buffaloes. *L. monocytogenes* causes two forms of disease in humans: Invasive listeriosis (“listeriosis”) or non-invasive gastrointestinal listeriosis (“febrile gastroenteritis”). Pregnant women usually recover but *L. monocytogenes* can cross the placental barrier and infect the foetus, resulting in serious outcomes, including stillbirth.

The purpose of this Risk Profile is to critically review information to answer the following risk management question: What is the public health risk from *L. monocytogenes* in raw milk consumed in New Zealand? 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 *L. monocytogenes* infection through consumption of raw milk was low. This Risk Profile also includes relevant information since February 2013, particularly updated human health surveillance data.

L. monocytogenes is naturally present throughout the environment, particularly in soil and on vegetation, and is pathogenic to humans and animals. The main transmission route to humans is via food. *L. monocytogenes* strains vary in their ability to survive in food and cause disease in humans but more work is needed before it is possible to identify strains that will not cause human illness. Presently, all *L. monocytogenes* strains need to be considered pathogenic.

Milk supports the growth of microorganisms and it is impossible to produce sterile raw milk. Raw milk can become contaminated with *L. monocytogenes* from contaminated udders and milking equipment, and animals with listerial mastitis. The prevalence of *L. monocytogenes* in the farming environment is enhanced by faecal shedding from animals infected by *L. monocytogenes* or fed with poor quality silage or baleage. *L. monocytogenes* can form biofilms on the milking equipment and slough off into the milk.

Two surveys of raw cows’ milk for *L. monocytogenes* have been conducted in New Zealand. One survey found a prevalence of 2/295 (0.7%) and the other 15/367 (4.1%). The concentration of *L. monocytogenes* in positive samples was <1 CFU/ml. The single survey of goats’ milk found a prevalence of 2/60 (3.3%). No New Zealand surveys of *L. monocytogenes* in raw milk from sheep or buffaloes were located. The prevalences of *L. monocytogenes* among New Zealand dairy cows, milking goats, milking sheep or buffalo are not known. Studies from overseas indicate that the prevalence of *L. monocytogenes* among dairy animals can be highly variable.

If *L. monocytogenes* is present in raw milk it will be able to grow. The concentration reached primarily depends on the temperatures and holding times of the milk. Studies of growth in raw cows’ milk at 4°C indicate that growth of around 1 log₁₀ takes at least five days, and growth of 2 log₁₀ might be expected by 10 days. The temperature of raw milk can exceed 4°C on multiple occasions throughout its shelf-life, particularly in consumers’ homes, so more growth is likely (e.g. a survey of domestic refrigerators in New Zealand found one third to be operating at a mean temperature above 6°C). Information on storage times for raw milk by consumers is unavailable.

The number of people drinking raw milk in New Zealand is still uncertain. Recent estimates suggest the proportion of the population consuming raw milk is low (1% adults, 0.5% children). People living or working on dairy farms are more likely to consume 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.

Drinking raw milk has not been reported as a risk factor or confirmed as the cause of any reported sporadic cases or outbreaks of *L. monocytogenes* infection in New Zealand, but the listeriosis case report form does not specifically ask about consumption of raw milk so this information is not routinely collected. 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. No case control studies concerning listeriosis have been conducted in New Zealand. There have been no recent reports of listeriosis outbreaks in other countries where drinking raw milk was a risk factor.

The currently available evidence suggests that the risk of *L. monocytogenes* infection for consumers of raw milk in New Zealand is low. Although the prevalence of *L. monocytogenes* has been shown to be similar or higher than other enteric pathogens in raw milk surveys, available concentration data suggest that the number of cells in raw milk at the start of the food chain are <1 CFU/ml. *L. monocytogenes* can grow in raw milk at refrigeration temperatures and, while it is difficult to predict the extent of growth as the times and temperatures of milk storage will vary (particularly after purchase by the consumer), the growth rate is likely to be slow and increases of more than 2 log₁₀ CFU/ml during the shelf life of raw milk (5-7 days) are unlikely. The available dose response models indicate that the estimated number of cells ingested through drinking raw milk has a very low probability of infection.

There are many data gaps and uncertainties in the evidence to evaluate the risk from *L. monocytogenes* in raw milk, particularly the demographics and practices of raw milk consumers in New Zealand. The two surveys of raw cows' milk covered only a small proportion of the large volume of cows' milk produced each year. The available studies of *L. monocytogenes* growth in raw milk are not sufficient to predict with confidence the extent of growth that might occur, particularly given variability between *L. monocytogenes* strains and the absence of growth experiments in milk from sheep, goats and buffaloes. The rate of non-invasive listeriosis (febrile gastroenteritis) is not known for New Zealand.

On a national scale (and on the basis of existing information), the burden of listeriosis from people drinking raw milk contaminated with *L. monocytogenes* is considered to be low relative to other sources of *L. monocytogenes* infection. This is primarily because the size of the population that drinks raw milk is small.

It is important to note that the risk from raw milk products such as cheeses will be higher, due to their longer shelf life and potential for *L. monocytogenes* growth. Raw milk cheeses have been identified as the source of listeriosis outbreaks overseas.

1 INTRODUCTION

This Risk Profile considers *Listeria monocytogenes* in raw milk from cows, sheep, goats and buffaloes. This Risk Profile does not consider products made from raw milk such as cheese or yoghurt.

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

- What is the public health risk from *L. monocytogenes* in raw milk consumed in New Zealand?

Risk Profiles provide scientific information relevant to a food/hazard combination for risk managers and describe potential risk management options (NZFSA, 2010).²

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.

² 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: *L. monocytogenes*

KEY FINDINGS

L. monocytogenes is naturally present throughout the environment, particularly in soil and on vegetation. The main transmission route to humans is via food.

L. monocytogenes strains vary in their ability to survive in food and cause disease in humans but more work is needed before it is possible to identify strains that will not cause human illness. Presently, all *L. monocytogenes* strains need to be considered pathogenic.

Appendix 1 contains additional information on L. monocytogenes.

There are ten species in the genus *Listeria* (Bertsch *et al.*, 2013; Graves *et al.*, 2010; Lang Halter *et al.*, 2013; Leclercq *et al.*, 2010; Orsi *et al.*, 2011). *L. monocytogenes* is the most important pathogen with respect to human health and most scientific studies focus on this species. *L. monocytogenes* is naturally present throughout the environment and is commonly found in soil and on vegetation. The main route of transmission of *L. monocytogenes* to humans is via food, according to a New Zealand expert elicitation process (Cressey and Lake, 2007).

L. monocytogenes causes two forms of listeriosis: Invasive listeriosis (usually just called listeriosis) and non-invasive gastrointestinal listeriosis (also called febrile gastroenteritis). See Section 3 for more information on these diseases.

Serotyping is widely used to subtype *L. monocytogenes* isolates and involves identifying the O (somatic) and H (flagella) antigens. Thirteen serotypes have been identified, which are based on specific combinations of multiple O and H antigens: 1/2a, 1/2b, 1/2c, 3a, 3b, 3c, 4a, 4ab, 4b, 4c, 4d, 4e and 7 (Wiedmann and Evans, 2011). Most New Zealand laboratories refer clinical *Listeria* isolates to the Special Bacteriology Laboratory at ESR, Kenepuru, for serotyping (Nicol *et al.*, 2010). Serotyping information can be supplemented by molecular typing methods to further distinguish isolates (reviewed by (Nightingale, 2010) and (Jadhav *et al.*, 2012)). Macrorestriction analysis followed by pulsed-field gel electrophoresis (PFGE) is a molecular typing method used in New Zealand and is a way of identifying genetic relatedness between isolates of the same serotype. This is important for linking isolates from listeriosis cases to isolates from the suspected source of infection.

Information on the growth, survival, sources and transmission routes of *L. monocytogenes* is summarised in a microbiological data sheet.³

2.1.1 Pathogenicity

There is a growing body of evidence demonstrating that *L. monocytogenes* strains vary in their ability to cause disease in humans. This is important for risk assessment as the risk to humans from contaminated foods therefore depends on the strain of *L. monocytogenes* present. However, it is still not possible to say with any certainty that a particular strain of *L.*

³ http://www.foodsafety.govt.nz/elibrary/industry/Listeria_Monocytogenes-Science_Research.pdf (accessed 10 September 2013).

monocytogenes will, or will not cause human illness. Until further research generates certainty in this area, and standard methods for testing pathogenicity are validated and implemented, all *L. monocytogenes* need to be considered pathogenic.

L. monocytogenes isolates can be grouped according to phylogenetic characteristics. These are called lineages, and there are currently four (I-IV) recognised lineages (Orsi *et al.*, 2011). Molecular analyses are used to determine the lineage of a *L. monocytogenes* isolate. Lineages are closely correlated with serotypes (Table 1) (Nadon *et al.*, 2001).

Table 1: Characteristics of the four *L. monocytogenes* lineages

Lineage	Serotypes	Distribution of isolates
I	1/2b, 3b, 3c, 4b	Various sources; overrepresented among human isolates
II	1/2a, 1/2c, 3a	Various sources; overrepresented among food and food environments as well as natural environments
III and IV	4a, 4b, 4c	Most isolates from ruminants

Note to Table 1: Table is adapted from Orsi *et al.* (2011).

There is epidemiological, phenotypic and molecular evidence to support the hypothesis that lineage I isolates are more capable of causing disease in humans and that lineage II isolates are better adapted to survive in foods and food environments, but both lineages are important for human infection (Orsi *et al.*, 2011). The majority of human listeriosis outbreaks worldwide have been linked to lineage I serotype 4b isolates. Some outbreaks have been caused by lineage I serotype 1/2b isolates and lineage II serotype 1/2a isolates.⁴ Analysis of sporadic cases has revealed some regional variation, e.g. lineage II serotype 1/2a strains appear to be more common among human listeriosis cases in Northern Europe, lineage I strains dominate human listeriosis cases in the United States of America (USA). Lineage III strains have occasionally been isolated from human clinical cases, so these cannot be considered non-pathogenic to humans (Orsi *et al.*, 2011). No reports of Lineage IV strains isolated from human clinical cases were located.

A set of genetic markers to determine whether a strain of *L. monocytogenes* will cause human disease has not yet been identified. One gene that has received particular attention is *inlA*, coding for internalin A, which has a role in enabling *L. monocytogenes* to cross the intestinal barrier. A recent analysis of 1,009 *L. monocytogenes* isolates from human listeriosis cases and ready-to-eat (RTE) foods showed that a greater proportion of isolates from RTE foods carried a truncated form of this gene that makes them less invasive. This suggests that strains of *L. monocytogenes* carrying this mutation are less likely to cause human disease (Van Stelten *et al.*, 2010). However, expression of virulence genes is also influenced by environmental factors, e.g. increased transcription of some virulence genes was observed in four *L. monocytogenes* strains after cold (4°C) and freezing (-20°C) stress (Miladi *et al.*, 2013).

It is important to note that research and debate around lineages continues and the current paradigm is certain to change in the future. The connection between lineages as determined

⁴ Groups of genetically-related strains that have been implicated in geographically and temporally unrelated outbreaks have been assigned to “epidemic clones” (ECs) (Rocha, 2013). These are distinguished by ribotyping or multi-virulence-locus sequence typing (MVLST). Seven ECs have been proposed to date (Lomonaco *et al.*, 2013).

by molecular analyses, the presence and characteristics of virulence genes and genes that enhance survival in different environments, and the actual pathogenicity of isolates, remains to be established.

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.⁵ 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).

⁵ <http://www.villagemilk.co.nz/get-village-milk/> (accessed 13 January 2014).

Dairy goat farms in New Zealand produce milk that is used for making cheese or for processing into infant formula.⁶ 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.⁷

2.3 Behaviour of *L. monocytogenes* in Raw Milk

KEY FINDINGS

Raw milk can become contaminated with *L. monocytogenes* from contaminated udders and milking equipment, and animals with listerial mastitis. The prevalence of *L. monocytogenes* in the farming environment is enhanced by faecal shedding from animals infected by *L. monocytogenes* or fed with poor quality silage or baleage. *L. monocytogenes* can form biofilms on the milking equipment and slough off into the milk.

L. monocytogenes can grow in refrigerated raw cows' milk but growth is slow. At 4°C it takes at least five days for the concentration to increase by 1 log₁₀ CFU/ml. Growth is accelerated when the temperature of raw milk is higher than 4°C, even if this is only for short periods.

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

2.3.1 Contamination of raw milk by *L. monocytogenes*

It is impossible to produce sterile raw milk. Raw milk can become contaminated with *L. monocytogenes* through:

- Contaminated udders or teat canals;
- Mastitic animals; or
- Contaminated milking equipment, cleaning water, workers, and the environment (Leedom, 2006).

The udders and teats of milking animals are contaminated with microorganisms when they come into contact with faeces, urine, feed (e.g. silage) soil, contaminated water and dirty equipment. The udders of housed cows can also become contaminated from contact with bedding materials (e.g. hay, sawdust). *L. monocytogenes* is environmentally ubiquitous but its presence can be enhanced on dairy farms through faecal shedding from animals fed poor quality silage or baleage. An outbreak of listeriosis among livestock will also create an opportunity for *L. monocytogenes* to multiply and be distributed in the farming environment.

L. monocytogenes can be shed in the faecal matter of both clinically-infected animals and asymptomatic carriers. In asymptomatic animals, *L. monocytogenes* is unlikely to colonise the gastrointestinal tract for long periods of time. Rather, the pathogen either passes directly

⁶ 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).

⁷ As ascertained from the websites of various New Zealand sheep milk producers.

through the gastrointestinal tract without infecting the animal, or colonises and multiplies in the gastrointestinal tract for short periods of time (2-4 days) (Ho *et al.*, 2007). This leads to a pattern of intermittent faecal shedding with the animals being re-infected from feed or the farm environment. A study in the USA supported the view that re-infection from the farm environment is more likely than chronic shedding (Borucki *et al.*, 2005). Intermittent shedding was also evident in another study that found 94% (30/32) of cows in one herd excreted *L. monocytogenes* at least once when sampled 33 times over a four-month period, and the daily prevalence ranged 0-100% of cows within the herd (Ho *et al.*, 2007). Reinfection by strains that persist in the farming environment is possible (Muraoka *et al.*, 2003).

L. monocytogenes is a natural contaminant in the plant material used for preparing silage and baleage and will survive and multiply in these foods if they are not fermented properly (Wiedmann and Evans, 2011). Feeding dairy animals with improperly fermented silage or baleage (pH \geq 5.0) can introduce *L. monocytogenes* into herds and has been the cause of listeriosis outbreaks among livestock (Borucki *et al.*, 2005; Clark *et al.*, 2004; Holmes and Brookes, 2006; Nightingale *et al.*, 2004). A longitudinal study of a single dairy cow herd in the USA found a significant relationship between the presence of *L. monocytogenes* in faecal samples from the cows and in the silage they were fed (Ho *et al.*, 2007). Cows were eight times (95% CI: 5-12) more likely to shed *L. monocytogenes* on the days when silage was contaminated with *L. monocytogenes*, and there were significant associations between the strains (ribotypes) of *L. monocytogenes* detected in the faecal and silage samples. A case control study comparing ruminant farms found that feeding high quality silage and access to pasture were protective against ruminant listeriosis (Nightingale *et al.*, 2005). An outbreak of listeriosis among milking sheep was traced to silage containing up to 5 log₁₀ CFU/g *L. monocytogenes* (Wagner *et al.*, 2005). During the outbreak, *L. monocytogenes* was detected in faeces and bulk milk from cattle also fed the silage although the cattle were not clinically infected. *L. monocytogenes* was not detected in raw milk from individual cows, which suggests that the source in the bulk milk was environmental contamination.

Mastitis caused by *L. monocytogenes* infection of the udder has been reported in dairy animals but it appears to be rare. The infection is more commonly reported in sheep and goats than in cows. Bovine mastitis caused by *L. monocytogenes* infection can go undetected as the cows do not necessarily demonstrate any outward signs of infection and the milk can remain visually unchanged (Hunt *et al.*, 2012). Somatic cell counts in contaminated milk may be elevated, but can still fall within acceptable limits. A 23-year survey of dairy cows in Denmark found the overall prevalence of listerial mastitis to be 0.04% (448/1,132,958) among individual cows and 1.2% among herds (36,199 herds were tested) (Jensen *et al.*, 1996). In almost all of the positive herds only one mammary quarter of one cow was infected. When considering only clinically mastitic animals, the proportion of infections caused by *L. monocytogenes* may be high. An Iranian survey found 8% (17/207) of clinically mastitic cows were infected with *L. monocytogenes* (Jamali and Radmehr, 2013).

Listerial mastitis in just one animal can introduce a high number of *L. monocytogenes* cells into the bulk tank milk. For example, *L. monocytogenes* was detected in bulk tank milk from a farm in Ireland during routine testing (Hunt *et al.*, 2012). The milk was the combined product of 180 cows and an investigation found that only one of these cows had one infected mammary quarter (the cow was asymptomatic and milk appeared normal). The concentration of *L. monocytogenes* in milk from the infected quarter was 280 CFU/ml. Similarly, one animal in a flock of 130 sheep had asymptomatic *L. monocytogenes* ovine mastitis; the milk

from the infected udder of this animal contained a mean concentration of 4.6×10^4 CFU/ml *L. monocytogenes* when monitored for 99 days (range 9×10^1 - 3×10^5 CFU/ml), and *L. monocytogenes* was detected in the bulk milk at 5.7×10^3 CFU/ml (Schoder *et al.*, 2003). Shedding of *L. monocytogenes* from an animal with listerial mastitis can also be prolonged. One cow was observed to shed *L. monocytogenes* in her milk for almost three years at levels ranging 10^3 - 10^4 CFU/ml (Farber *et al.*, 1990).

L. monocytogenes can also be transferred into milk from milking equipment that has become contaminated, e.g. through contact with the cows, milkers or contaminated water. Milk containing *L. monocytogenes* also effectively carries the pathogen into the milking system. *L. monocytogenes* are able to attach to the surfaces of milking equipment and the milking environment (e.g. drains) and create dense growths of living cells. Formation of these *L. monocytogenes* biofilms is influenced by the presence of other bacteria that are already attached to surfaces (Flint *et al.*, 2011; Weiler *et al.*, 2013). The ability to form biofilms varies between *L. monocytogenes* strains and is not related to serotype (Weiler *et al.*, 2013). *L. monocytogenes* can form dense growths within a short period of time (e.g. $>4 \log_{10}$ CFU/cm² in 24 hours at 25°C on stainless steel under laboratory conditions (Norwood and Gilmour, 1999)) and when these biofilms form in the milking equipment, cells can break away individually or as clumps and contaminate raw milk. An in-depth analysis of *L. monocytogenes* strains present on a USA farm over several years provided evidence of persistent contamination in milk that probably arose from biofilm formation inside the milking equipment (Latorre *et al.*, 2009; Latorre *et al.*, 2010). Of three strains that were persistent in the milk and milking equipment over time, one demonstrated strong adherence ability *in vitro*, supporting this strain's ability to form biofilms (Latorre *et al.*, 2011b).

2.3.2 Behaviour of *L. monocytogenes* in raw milk

L. monocytogenes can survive and grow in raw cows' milk. Four studies have demonstrated that *L. monocytogenes* can grow in raw cows' milk held at 4°C, but the lag time (time required for cells to adapt to a new environment and start duplicating) and growth rate varied among the isolates used in these studies (Figure 1) (Brouillaud-Delattre *et al.*, 1997; Farber *et al.*, 1990; Giacometti *et al.*, 2012b; Pitt *et al.*, 1999).⁸ Some of this variability will be a result of differences between *L. monocytogenes* strains, the physiological state of the inoculum (which is a consequence of how it was treated prior to inoculation), the counting method (different solid agars were used for enumeration in each of the four studies) and the properties of the raw milk (particularly the presence of other bacteria).⁹

The lag times were in the range 3-7 days, except in the study by Pitt *et al.* (1999) where growth was observed after two days. The reason for this difference was not identified; Pitt *et al.* (1999) used a culture that had been frozen, thawed and inoculated into the milk, rather than a fresh inoculum, and it would be expected that this approach would extend the lag time, not reduce it.

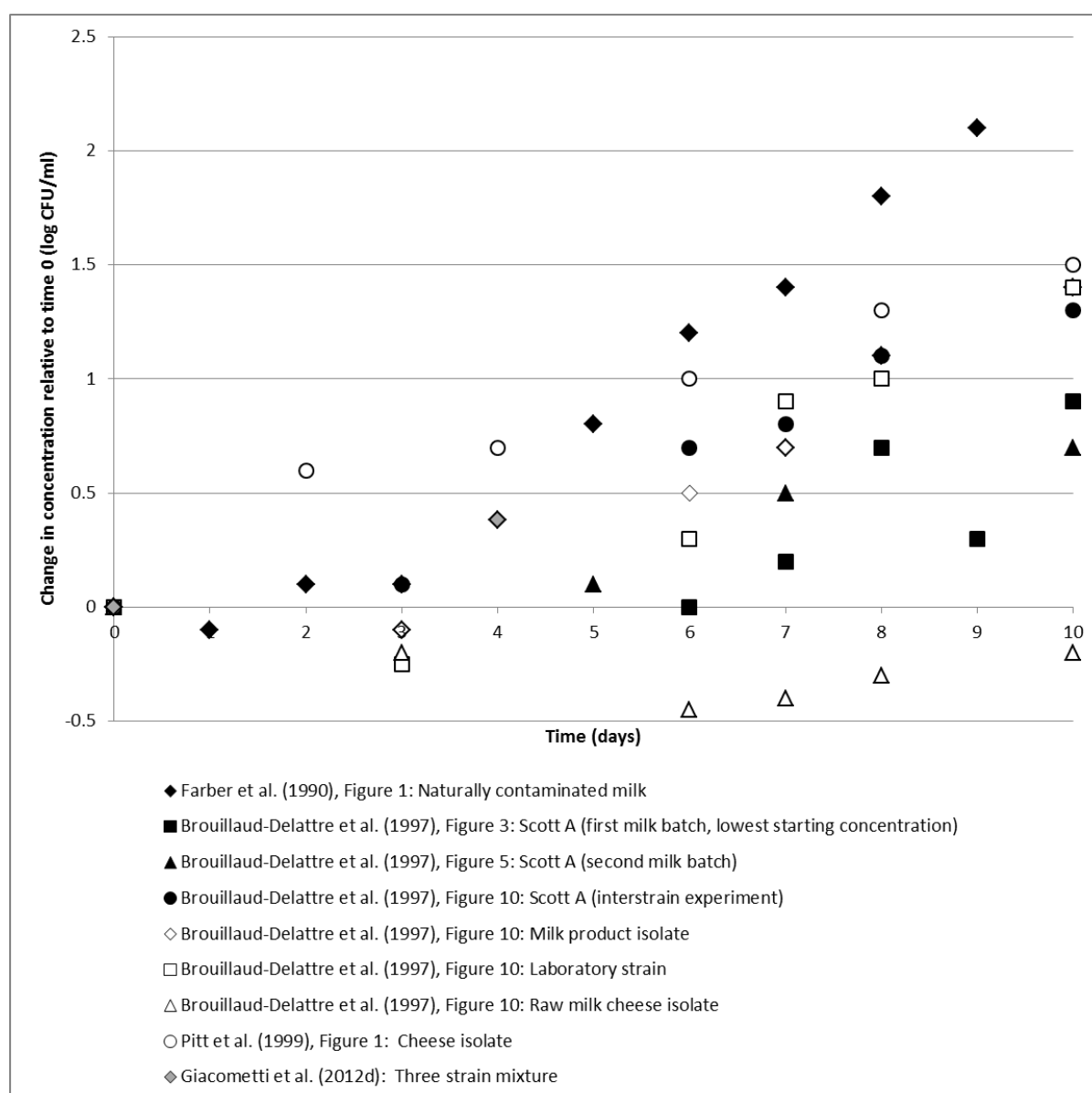
At 4°C none of the isolates exceeded 1 log₁₀ growth before five days. In experiments where growth of *L. monocytogenes* was measured for 9-10 days, growth was less than 2 log₁₀ in all

⁸ Growth in raw milk held at 4°C was not observed in two additional studies, possibly due to an extended lag phase (Wenzel and Marth, 1990) or cellular damage (Northolt *et al.*, 1988).

⁹ Even the same strain used repeatedly in the same laboratory did not behave the same way each time: See results from Brouillaud-Delattre *et al.* (1997) in Figure 1 using *L. monocytogenes* Scott A.

but one experiment. The study by Farber *et al.* (1990) might be considered the best representation of growth at 4°C because this used raw milk from a cow with listerial mastitis (the milk was naturally contaminated with *L. monocytogenes* at a concentration of about 4 log₁₀ CFU/ml). The lag time ranged 3-5 days across three replicates. The average generation time was calculated as 25.3 hours in this study, which is shorter than the generation time of 70 hours as calculated by Giacometti *et al.* (2012d). It is possible that *L. monocytogenes* naturally contaminating milk has a shorter lag time and faster growth rate than inoculated isolates of *L. monocytogenes*, but more work is needed to evaluate this. *L. monocytogenes* causing mastitis is likely to be well-adapted to growth in raw milk, so observing such growth, while more realistic than artificial inoculation, might be considered a worst-case scenario.

Figure 1: Growth of *L. monocytogenes* in raw cows' milk held at 4°C



Note to Figure 1: Plotted values are approximated from graphs in papers or actual values when these were provided. Readers should consult the original references to view the graphs from which these data were sourced.

A prediction can be generated from the study of Farber *et al.* (1990). Given a lag time of three days, a generation time of 25.3 hours and a starting concentration of 1 CFU/ml, the concentration of *L. monocytogenes* in raw milk held at 4°C would reach 10 CFU/ml after the sixth day and 100 CFU/ml at around 10 days. This assumes a constant storage temperature of 4°C. Periods at higher temperatures will allow *L. monocytogenes* to grow faster. The following studies in raw cows' milk suggest that growth may not be that much faster at 7°C compared with 4°C (although there are concerns about these results), but growth is encouraged at higher temperatures occurring in the raw milk food chain:

- At 7°C, the concentration of a *L. monocytogenes* isolate (originally from cheese) in raw milk increased by 1 log₁₀ after about five days, and by around 2 log₁₀ in 10 days, but no lag phase was observed (see earlier comments) (Pitt *et al.*, 1999).
- At 7°C the concentration of four isolates of *L. monocytogenes* (three from cheese) increased by about 1 log₁₀ after seven days but the lag phase in these studies appeared to be extended, possibly due to cellular damage (Northolt *et al.*, 1988).
- Using raw milk naturally contaminated with *L. monocytogenes*, the concentration of *L. monocytogenes* increased by around 1.5 log₁₀ in three days when held at 10°C, and in only two days at 15°C. The average generation time was 10.8 hours at 10°C and 7.4 hours at 15°C (Farber *et al.*, 1990).
- In a variable temperature experiment that simulated the worst temperature profile (as recorded from survey work) for the chain from farm to vending machine to a purchaser's home in Italy (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 of a cocktail of three strains of *L. monocytogenes* increased by 1.1 log₁₀ CFU/ml in raw cows' milk over the total four day period (Giacometti *et al.*, 2012b).

Studies of *L. monocytogenes* growth in pasteurised milk, UHT milk or reconstituted and sterilised milk powder showed similar lag times and growth rates as those observed in raw milk, but the final concentration of *L. monocytogenes* tended to be higher in the treated milks (Alavi *et al.*, 1999; Bovill *et al.*, 2000; Kowalik *et al.*, 2012; Xanthiakos *et al.*, 2006).

The results reported above were from experiments based on a few strains of *L. monocytogenes* and should not be considered necessarily representative of a whole lineage or the whole *L. monocytogenes* species. There is growing evidence to demonstrate variety among *L. monocytogenes* strains in terms of their ability to survive and grow in different environments (Lianou and Koutsoumanis, 2013). Growth studies should use a large number of strains, representative of overall strain variability (Pouillot *et al.*, 2003). A set of 46 *L. monocytogenes* isolates representing diversity and outbreak strains has been proposed for use in *L. monocytogenes* studies (Fugett *et al.*, 2006).

2.4 Exposure Assessment

KEY FINDINGS

L. monocytogenes was detected in two surveys of raw cows' milk from farm vats in New Zealand at prevalences of 0.7% and 4.1%. However, the concentration of *L. monocytogenes* in the positive samples was low (range 0.047-0.36 CFU/ml). A survey of raw goats' milk (n = 60) found a prevalence of 3.3%. No surveys of *L. monocytogenes* in milk produced in New Zealand from sheep or buffaloes were located. No surveys of the prevalence of *L. monocytogenes* among New Zealand dairy cows, milking goats, milking sheep or buffaloes

were located.

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.

If *L. monocytogenes* is present in raw milk it will be able to grow. It is difficult to predict the extent of growth as the times and temperatures applied to the milk along its shelf-life will vary, but assuming a low starting concentration (as found in the New Zealand surveys) and a five-day shelf-life, the available dose response models indicate that the estimated number of cells ingested through drinking raw milk has a very low probability of infection.

2.4.1 New Zealand prevalence studies

2.4.1.1 *Prevalence of L. monocytogenes in raw milk*

L. monocytogenes was detected in two recent microbiological surveys of raw cows' milk from farm vats (Table 2). The serotypes of these isolates were not reported. 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.

Table 2: Prevalence of *L. monocytogenes* in two New Zealand surveys of raw cows' milk

Raw milk survey	Survey period	Sample source	Prevalence of <i>L. monocytogenes</i> *	Reference
Fonterra study	April 2007-May 2008	Farm vats, 290 dairy farms	2/295 (0.7%)	(Hill <i>et al.</i> , 2012)
MPI study	November 2011-August 2012	Farm vats, 80 dairy farms	15/367 (4.1%)	(MPI, 2013; Soboleva <i>et al.</i> , 2013)

* Limit of detection 0.04 CFU/ml.

In the MPI study the positive samples came from 12/80 (12.5%) of the farms from which samples were obtained.

The concentration of *L. monocytogenes* in both positive samples from the 2007/08 study was estimated 0.25 MPN/ml. In the 2011/12 study, the concentrations of *L. monocytogenes* in the positive samples ranged from 0.047-0.36 MPN/ml.

No surveys on the prevalence of *L. monocytogenes* in milk produced in New Zealand from sheep or buffaloes were located. A MPI survey of raw goats' milk in 2012/13 detected *Listeria* spp. in 4/60 samples (6.6%), and *L. monocytogenes* was identified in two of these (3.3%). 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 *L. monocytogenes* among dairy animals

No studies of the prevalence of *L. monocytogenes* among dairy animals in New Zealand were located.

The MPI Surveillance and Incursion Investigation Group (Animals) receive sick animal data from Gribbles and New Zealand Veterinary Pathology laboratories. For the period 2003 to July 2013 this database did not contain any reports of listerial mastitis. However, due to changes in reporting requirements over this period this does not necessarily mean that no cases were detected (Jonathan Watts, MPI, pers. comm. September 2013). *L. monocytogenes* is not a notifiable organism for animal health (MPI, 2010).

2.4.2 Food consumption: Raw milk

ESR has extensively analysed data from three 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 National Nutrition Survey (NNS; 4,636 people aged 15+ years) (Russell *et al.*, 1999);
- 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 "mostly" using raw milk.

Another recent estimate was provided by a national case-control study of Shiga toxin-producing *Escherichia coli* infection carried out during 2011/12. 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 3. In the absence of specific data for raw milk servings (size and frequency of consumption), these data can be used as an indicator.

Table 3: 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 *L. monocytogenes* 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 above refrigeration temperatures, and the temperature will rise again if new milk is added from subsequent milkings. There are no studies of *L. monocytogenes* growth under a temperature profile similar to cooling milk, but *L. monocytogenes* is able to grow at all of the temperatures milk will be held at, including refrigeration. The amount of growth is primarily determined by the temperatures and holding times before consumption. The final concentration will also depend on the strains of *L. monocytogenes* present, as the available data indicate that growth rates vary between strains.

Studies of *L. monocytogenes* growth in raw milk at 4°C indicate that growth of around 1 log₁₀ takes at least five days, and growth of 2 log₁₀ might be expected by 10 days (Section 2.3.2). The temperature of raw milk can exceed 4°C on multiple occasions throughout its shelf-life, particularly in consumers' homes, so more growth is likely. A survey of domestic refrigerators in New Zealand found one third (43/127; 34%) to be operating at a mean temperature above 6°C (Gilbert *et al.*, 2007). Studies show that at 7°C, *L. monocytogenes* can grow just over 1 log₁₀ in five days, though the time to achieve this growth may be shortened if the bacteria are already in exponential phase when storage of the raw milk in consumers' homes begins. There are no data on storage times for raw milk held in consumers' homes.

It is difficult to predict the extent of *L. monocytogenes* growth as the times and temperatures applied to the milk along its shelf-life will vary (particularly after purchase by the consumer). Assuming 1 CFU/ml (higher than that measured in New Zealand surveys), *L. monocytogenes* may grow to 10 CFU/ml in five days; based on dose response relationships described in Appendix 2, the probability of such a serving of 250 ml causing illness in a susceptible person is only 2.7×10^{-9} .¹⁰ Gross temperature abuse will encourage *L. monocytogenes* to grow to much higher concentrations but the concurrent growth of spoilage bacteria will result in a product that would not be consumed.

2.5 Data on *L. monocytogenes* and Raw Milk from Other Countries

KEY FINDINGS

Recent overseas prevalence values for *L. monocytogenes* in raw cows' milk collected at the farm ranged from not detected to 20% (the prevalence values for New Zealand raw milk are within this range). *L. monocytogenes* was not often detected in raw milk from sheep, goats or buffaloes but fewer studies are available on these types of milk. The concentration of *L. monocytogenes* in raw cows' milk was usually <10 CFU/ml, but higher concentrations have been reported (e.g. 105 CFU/ml at one farm, >1,000 CFU/g at retail).

The prevalence of *L. monocytogenes* among dairy animals overseas is highly variable (from not detected to 72% based on faecal samples). This variability reflects seasonal differences and the apparently transient nature of *L. monocytogenes* colonisation of the gastrointestinal tract of asymptomatic animals. A similar pattern would be expected in New Zealand.

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

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 comparative purposes and to augment limited New Zealand data, it is important to note that dairy farming methods in New Zealand are different to those in many 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 because they are predominantly fed on pasture (Hill *et al.*, 2012). Factors such as housing conditions and feed supply can affect the prevalence of pathogenic microorganisms among dairy animals (see Section 2.3.1).

2.5.1.1 *L. monocytogenes* in raw milk

L. monocytogenes was detected in raw cows' milk from farm vats at prevalence values ranging from not detected to 20% (see Appendix 1, Table 8). A recent paper has reported a prevalence range of 2.2-10.2% for *L. monocytogenes* in European raw milk (Claeys *et al.*, 2013). Some data were available on the concentration of *L. monocytogenes* in raw cows' milk (Appendix 1, Table 9). While the concentration in most of the positive samples was <10 CFU/ml, some samples contained higher concentrations (105 CFU/ml in a French study

¹⁰ Calculated from $P=1-e^{-RN}$ where $R=1.06 \times 10^{-12}$ and $N=2,500$ (FAO/WHO 2004a).

(Meyer-Broseta *et al.*, 2003), >1,000 CFU/g in a single sample in an Estonian survey of raw milk near the end of shelf-life (Kramarenko *et al.*, 2013)).

A small number of studies of *L. monocytogenes* prevalence in milk from goats and sheep are available (Appendix 1, Tables 10 and 11). These show that *L. monocytogenes* is not often detected in milk from these species. When *L. monocytogenes* was detected in sheep or goats' milk the prevalence was $\leq 2\%$. No concentration data were available.

L. monocytogenes was only detected in one out of five surveys of buffaloes' milk.

2.5.1.2 *L. monocytogenes* among dairy animals

There are not many studies of the prevalence of *L. monocytogenes* among dairy animals. Those that were located (six on dairy cows, one on dairy sheep) showed high variability in the in-herd prevalence (up to 72%, as tested by faecal or rectal samples). Longitudinal studies show that the in-herd prevalence can vary over time from no animals to all animals in the herd shedding *L. monocytogenes* (Ho *et al.*, 2007; Latorre *et al.*, 2011b). Consequently prevalence values from a single faecal sample are only a snapshot at the time of testing.

2.5.2 Raw milk consumption in other countries

Estimates for the proportions of the populations drinking raw milk in other developed countries are low (up to 3%), irrespective of the legal status of raw milk sales (Buzby *et al.*, 2013; Giacometti *et al.*, 2012a). The proportion of people living or working on dairy farms and consuming raw milk is higher in most surveys (up to 60% has been reported), which is similar to the situation in New Zealand (Oliver *et al.*, 2009; Nesbitt *et al.*, 2009).

3 EVALUATION OF ADVERSE HEALTH EFFECTS

3.1 Disease Characteristics

KEY FINDINGS

L. monocytogenes causes two forms of listeriosis: Invasive listeriosis (“listeriosis”) and non-invasive gastrointestinal listeriosis (“febrile gastroenteritis”).

Healthy people rarely develop invasive listeriosis (“listeriosis”). High risk groups for listeriosis are pregnant women and their foetuses, neonates, the elderly and immunocompromised people. Pre-existing gastrointestinal problems may be a risk factor for non-invasive listeriosis.

In invasive listeriosis, the most serious form of the disease, ingested *L. monocytogenes* cells penetrate the intestinal tissue and become exposed to phagocytic cells of the immune system. A portion of the *L. monocytogenes* cells survive and multiply within the host phagocytes. They then move throughout the host via blood or the lymphatic system.

Healthy people rarely develop listeriosis and it is generally recognised that there are some higher risk groups in the population (Sutherland *et al.*, 2003). High risk groups for listeriosis include pregnant women and their foetuses, neonates, the elderly and people with a compromised immune system (e.g. those with cardiovascular disease, congestive heart failure, diabetes, liver cirrhosis, cancer, organ transplants or HIV/AIDS infections). People taking antacids also increase their risk of listeriosis by increasing the pH of gastric fluid, which better enables *L. monocytogenes* to survive gastric passage (Cotter and Hill, 2003). Pregnant women usually recover but *L. monocytogenes* can cross the placental barrier and infect the foetus, resulting in miscarriage, stillbirth or premature delivery of an infant with perinatal septicaemia (a severe infection that can lead to death or permanent mental retardation) (Ryser, 2011).

The incubation period for listeriosis can be long (1-90 days). A recent study has attempted to provide more accurate data on this incubation period (Goulet *et al.*, 2013). Based on 37 cases, the median incubation period was eight days (range: 1–67 days). The researchers found that the incubation period differed significantly between the clinical forms of the disease. A longer incubation period was observed for pregnancy-associated cases (median 27.5 days; range: 17–67 days).

The non-invasive form of listeriosis was recognised during the 1990s. A study in Nova Scotia suggested that pre-existing gastrointestinal problems such as irritable bowel syndrome and inflammatory bowel disease may be a risk factor for this febrile gastroenteritis (Schlech *et al.*, 2005).

3.2 Dose Response

KEY FINDINGS

The presence of *L. monocytogenes* in food at a concentration of <100 CFU/g carries a very low probability of causing disease.

Appendix 2 contains detail on dose response.

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.

3.2.1 Invasive listeriosis

No listeriosis outbreaks were located where a point estimate could be calculated with certainty. Analysis of animal trial and outbreak data for the dose response relationship of listeriosis has produced models for both high and low risk populations. While the only completely safe dose of *L. monocytogenes* is zero, even for healthy people, the models indicate that the probability of invasive disease following exposure to even moderate levels of cells is very low. Most listeriosis cases are due to consumption of RTE foods able to support growth of *L. monocytogenes* and containing levels markedly above 100 CFU/g (Chen *et al.*, 2003; EFSA, 2007).

3.2.2 Non-invasive listeriosis

Dose response data for febrile gastroenteritis caused by *L. monocytogenes* infection are limited to point estimates from outbreaks. Consumption of more than 6 log₁₀ *L. monocytogenes* cells appears to be required to cause febrile gastroenteritis at a high attack rate. It is possible that foods contaminated with lower numbers of *L. monocytogenes* may also infrequently cause non-invasive listeriosis.

3.3 New Zealand Human Health Surveillance

KEY FINDINGS

Drinking raw milk has not been reported as a risk factor or confirmed as the cause of any reported sporadic cases or outbreaks of *L. monocytogenes* infection, but the listeriosis case report form does not specifically ask about consumption of raw milk. No New Zealand case control studies concerning listeriosis have been conducted.

The annual rate of reported listeriosis cases has remained stable for the last 15 years (0.5-0.7 per 100,000) and five outbreaks have been reported since 1992. Both perinatal and non-perinatal cases are reported each year, with the latter making up the majority. Having an underlying illness is a risk factor for listeriosis in non-perinatal cases. Reported rates for more susceptible population groups are higher, e.g. in 2012 the estimated perinatal infection rate was 3.2/100,000 and the estimated rate for people aged 70 years and older was 3.1/100,000.

The clinical outcomes are often serious. Hospitalisation rates each year are high (85% or more), and 27 non-perinatal and 33 perinatal deaths have been reported between 1997 and 2012 (overall mortality rate of 16%).

Febrile gastroenteritis from *L. monocytogenes* infection would only be notified in New Zealand when there was a suspected common cause, so there are no data on infection rates (one outbreak was reported). It is not normal practice for clinical laboratories to examine faecal specimens from cases of gastrointestinal disease for the presence of *Listeria* spp., and the characteristics of this form of *L. monocytogenes* infection means that normally healthy people are unlikely to seek medical attention.

3.3.1 Raw milk consumption as a risk factor for *L. monocytogenes* infection

3.3.1.1 *Sporadic cases*

Drinking raw milk was not reported as a risk factor in any of the listeriosis cases reported to EpiSurv for the period January 2006 to December 2013. The listeriosis case report form does not specifically ask about consumption of raw milk so this information is not routinely collected.

3.3.1.2 *Outbreaks*

None of the five listeriosis outbreaks reported in New Zealand between 1992 and 2013 implicated raw milk.

3.3.1.3 *Case control studies*

No case control studies concerning listeriosis have been conducted in New Zealand.

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 between consumption of raw milk and raw milk products and infection from *L. monocytogenes* (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 only examined randomised control trials, cohort, case-control and cross-sectional studies, and outbreak investigations with a denominator. The researchers noted that the prolonged incubation period of listeriosis makes it very difficult to prove temporality when using a case-control study design.

3.3.2 *L. monocytogenes* infection in New Zealand

Detection of cases with *L. monocytogenes* infection in New Zealand is biased towards detecting cases of invasive listeriosis because laboratories do not normally test faecal samples for *Listeria* spp. as part of a standard faecal screen. Most laboratories only test faecal samples for *Listeria* spp. if requested or if other information indicates that *L. monocytogenes* infection is a risk (e.g. the patient is pregnant) (Nicol *et al.*, 2010).¹¹ So while it appears that febrile gastroenteritis is a rare cause of human disease, this condition might be responsible for a proportion of undiagnosed sporadic gastrointestinal disease reported each year. Moreover, febrile gastroenteritis usually has a short duration (1-3 days) and does not lead to serious complications in healthy people, so normally health patients are unlikely to seek medical attention and thus remain unreported. Febrile gastroenteritis cases are more likely to be detected if they are part of an outbreak.

Table 4 lists listeriosis notification data from the EpiSurv database for the period 1997-2012 and preliminary EpiSurv data show 19 reported listeriosis cases for 2013. Figure 2 displays these notified listeriosis cases as proportions identified as perinatal or non-perinatal. The

¹¹ Laboratories usually test specimens from sterile sites (e.g. blood, cerebral spinal fluid, amniotic fluid) for *Listeria* spp.

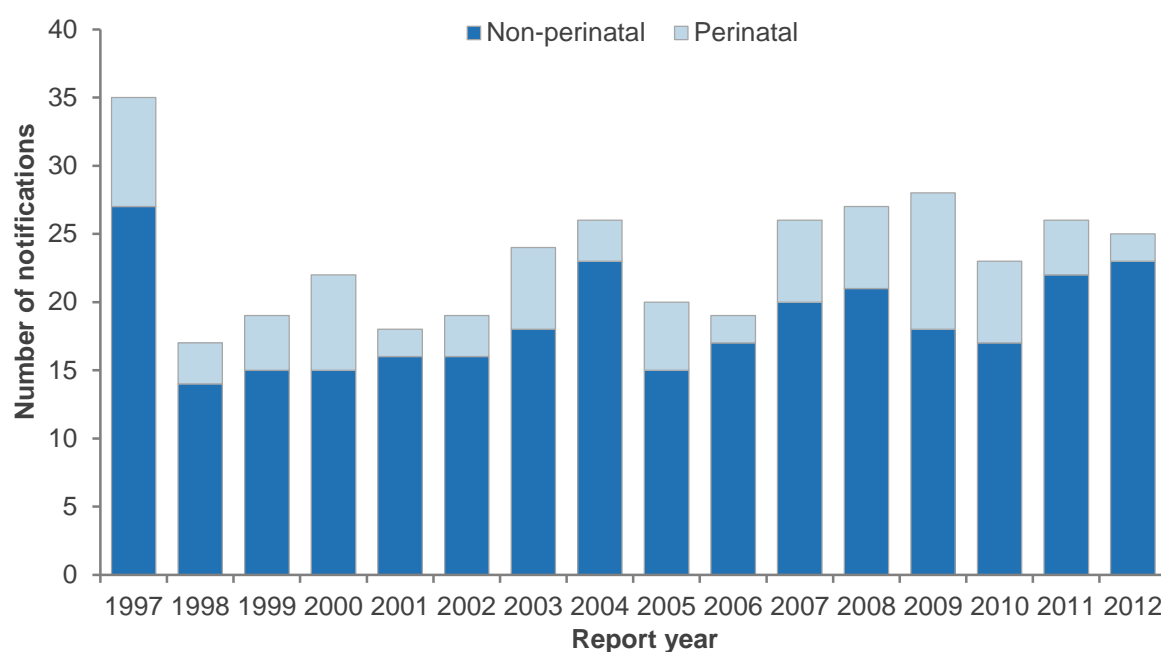
notification rate for listeriosis has been stable, ranging from 0.4 to 0.7 per 100,000 except for 0.9 per 100,000 in 1997.

Table 4: Number of reported cases and rates of invasive listeriosis, 1997-2012

Year	Listeriosis cases	Rate (cases/100,000)
1997	35	0.9
1998	17	0.5
1999	19	0.5
2000	22	0.6
2001	18	0.5
2002	19	0.5
2003	24	0.6
2004	26	0.7
2005	20	0.5
2006	19	0.5
2007	26	0.6
2008	27	0.6
2009	28	0.6
2010	23	0.5
2011	26	0.6
2012	25	0.6

Note to Table 4: Rate data for 1997 to 2008 are from (Gilbert *et al.*, 2009). Case and rate data for 2011 and 2012 are from (ESR, 2012) and (ESR, 2013), respectively. All other data are from (Lim *et al.*, 2011).

Figure 2: Reported invasive listeriosis cases by year, 1997-2012



Note to Figure 2: Figure is from (Lopez *et al.*, 2013).

New Zealand notification data support the assertion that pregnant women and their foetuses, the elderly, and people with an underlying illness are at greater risk. In 2012, 13/23 (57%) non-perinatal cases were aged 70 years and over. In the same year, 16/23 (70%) non-perinatal cases had an underlying illness such as cancer, autoimmune disease, Crohn's disease, renal failure or other chronic illness (ESR, 2013). Between 2008 and 2012 the risk factor most commonly associated with listeriosis each year was having an underlying illness. Receiving immunosuppressive drugs and admission to hospital for treatment of another illness were also commonly reported risk factors (Lopez *et al.*, 2013).

While the number of reported listeriosis cases is small compared to other notifiable diseases, the clinical outcomes are often severe. Where hospitalisation status was recorded, 85% or more listeriosis cases were admitted to hospital each year between 1997 and 2012 (Table 5). Listeriosis is often only diagnosed once patients are admitted to hospital. Between 1997 and 2012, 27 non-perinatal listeriosis cases died, and infection with *Listeria* spp. caused the death of 33 foetuses/neonates (Table 5). All four of the non-perinatal fatalities in 2012 were aged 60 or older.

Table 5: Listeriosis cases that resulted in hospitalisation and death, 1997-2012

Year	Number of cases	Number hospitalised (%)*	Number of deaths (% infections resulting in death)		Reference
			Non-perinatal	Perinatal	
1997	35	33/33 (100)	2 (7)	6 (75)	(ESR, 1998)
1998	17	16/16 (100)	0	0	(Perks <i>et al.</i> , 1999)
1999	19	18/19 (95)	1 (7)	2 (50)	(Kieft <i>et al.</i> , 2000)
2000	22	22/22 (100)	2 (13)	4 (57)	(Lopez <i>et al.</i> , 2001)
2001	18	17/18 (94)	1 (6)	1 (50)	(Sneyd <i>et al.</i> , 2002)
2002	19	13/13 (100)	0 (0)	3 (100)	(Sneyd and Baker, 2003)
2003	24	22/22 (100)	2 (11)	2 (33)	(ESR, 2004)
2004	26	25/26 (96)	3 (13)	2 (67)	(ESR, 2005)
2005	20	13/15 (87)	1 (7)	0	(ESR, 2006)
2006	19	16/17 (94)	0	1 (50)	(ESR, 2007)
2007	26	19/19 (100)	2 (10)	2 (33)	(ESR, 2008)
2008	27	17/20 (85)	3 (14)	2 (33)	(ESR, 2009)
2009	28	17/18 (94)	2 (11)	2 (20)	(ESR, 2010)
2010	23	15/17 (88)	3 (18)	4 (67)	(ESR, 2011)
2011	26	22/22 (100)	1 (5)	0	(ESR, 2012)
2012	23	22/23 (96)	4 (17)	2 (100)	(ESR, 2013)

* Hospitalisation is not always reported. The denominator is the number of cases for which hospitalisation was recorded. Hospitalisation may not be reported for perinatal cases.

3.3.3 Serotypes

ESR's Special Bacteriology Laboratory tests *L. monocytogenes* isolates sent from public health laboratories to see whether they are serotype 4 or 1/2. They do not test for other serotypes. In the last ten years all *L. monocytogenes* isolates received at the laboratory were serotypes 4 and 1/2 (Table 6).

Table 6: *L. monocytogenes* serotypes identified by the ESR Special Bacteriology Laboratory, 2003-2012

Year	Total isolates serotyped	Number typed as serotype 4 (%)	Number typed as serotype 1/2 (%)
2003	24	14 (58)	10 (42)
2004	24	18 (75)	6 (25)
2005	19	14 (74)	5 (26)
2006	20	12 (60)	8 (40)
2007	26	16 (62)	10 (39)
2008	23	16 (70)	7 (30)
2009	29	25 (86)	4 (14)
2010	22	16 (73)	6 (27)
2011	26	15 (58)	11 (42)
2012	25	12 (48)	13 (52)

Note to Table 6: See Table 5 for references.

3.4 *L. monocytogenes* Infection Overseas

KEY FINDINGS

There have been no recent reports of overseas listeriosis outbreaks where drinking raw milk was a risk factor. Raw milk was considered a risk factor for listeriosis in two case control studies but odds ratios could not be calculated because the controls did not report consumption of raw milk.

The rates of listeriosis reported by other countries are comparable to that reported in New Zealand. Hospitalisation rates overseas are high, as are mortality rates (e.g. 13% for the EU and 19% for the USA in 2011).

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 concluding that the risk of *L. monocytogenes* infection from drinking raw cows' milk is low.

Risk assessments produced in other countries all conclude that there is some risk of *L. monocytogenes* infection from drinking raw milk. Based on cases per serving in susceptible populations, the findings from the New Zealand risk assessment were more aligned with that of a USA quantitative risk assessment than an Australian quantitative risk assessment, which predicted a much higher number of listeriosis cases than predicted for New Zealand. All three models predicted increased risk as the supply chain lengthened.

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 *L. monocytogenes* (and other pathogenic microorganisms).

The risk assessment concluded that the risk of *L. monocytogenes* infection through consumption of raw milk was low. However, MPI noted that these predictions were based on prevalence generated through a small New Zealand survey; the survey may have underestimated *L. monocytogenes* prevalence in raw milk because the testing regime may not detect *L. monocytogenes* at a low concentration (<1 CFU/25 ml) and prevalence appears to be influenced by seasons (higher in winter months). MPI also noted that the dose response input strongly influences the outcome.

4.1.2 Risk assessments from other countries

Risk assessments for *L. monocytogenes* in raw milk have been published for Australia, the USA, the UK, Norway, and Belgium (see Appendix 2, Section 8.3.1). In summary:

- Australia (raw cows' milk (modelling), raw goats' milk (qualitative)): The cows' milk model did not predict any listeriosis cases among the "healthy" population if raw milk was consumed, but found that the risk of *L. monocytogenes* infection for the susceptible population increased as the supply chain lengthened. The number of listeriosis cases among the susceptible population was calculated using three different parameter values for the probability of illness, so the mean predicted cases of listeriosis among the susceptible population per 100,000 daily serves of raw milk ranged <1-0.2 when milk was consumed from farm bulk milk tanks, 0.1-17 when milk was consumed after farm gate sales and 0.7-170 when milk was consumed after retail purchase (in contrast to the New Zealand quantitative model, the Australian model allowed the retail food chain to be longer than the farm gate chain). The goats' milk assessment rated the risk to public health and safety from *L. monocytogenes* in raw goats' milk as "very low" for the general population and "high" for the susceptible population.

- USA (modelling): There was a risk of *L. monocytogenes* infection if raw milk was consumed. The risk increased as the supply chain lengthened. For milk purchased from a farm bulk tank, the median probability of listeriosis per serving ranged from 1.1×10^{-13} to 1.8×10^{-15} for two susceptible populations (perinatal and elderly).
- UK (revision of evidence): Maintained the view that there were significant risks to human health from consumption of raw drinking milk.
- Norway (raw cows' milk and cream): The risk associated with *L. monocytogenes* in raw cows' milk and cream was considered high but there were considerable data gaps (including a lack of prevalence data for *L. monocytogenes* in raw milk).
- Belgium: *L. monocytogenes* was potentially present in raw milk but other pathogenic bacteria posed a greater risk.

Risk assessments have also been conducted that consider *L. monocytogenes* in RTE foods. Raw milk was only specifically assessed as one type of RTE food in the USA assessment. In summary:

- USA (quantitative risk assessment): Considered raw milk as a separate food group ranked alongside 22 other RTE foods. On a per serving basis, raw milk was ranked 4th highest ("high risk"). On a per annum basis, raw milk was ranked 7th ("moderate risk") because of the low number of annual servings. The risk per serving values for susceptible subpopulations were higher than for the general population, but the number of cases per annum were lower.
- FAO/WHO (quantitative risk assessment): The model predicted that nearly all listeriosis cases were the result of eating high numbers of *L. monocytogenes*.
- EU (scientific opinion): Most listeriosis cases were due to consumption of RTE foods able to support *L. monocytogenes* growth and containing concentrations well above 100 CFU/g.

4.2 Evaluation of Risk for New Zealand

KEY FINDINGS

The currently available evidence suggests that the risk of *L. monocytogenes* infection for consumers of raw milk is low. Although the prevalence of *L. monocytogenes* has been shown to be similar or higher than other enteric pathogens in raw milk surveys, available concentration data suggests that the numbers are low (<1 CFU/ml). Although *L. monocytogenes* can grow in raw milk at refrigeration temperatures, the rate is slow and increases of more than 2 log₁₀ CFU/ml during the shelf life of raw milk (5-7 days) are unlikely. The available dose response models indicate that high concentrations of cells are needed to create significant risk of infection (e.g. a single dose of 2,500 cells provides a probability of infection of 2.7×10^{-9} in a susceptible person).

Drinking raw milk has not been reported as a risk factor or confirmed as the cause of any reported sporadic cases or outbreaks of *L. monocytogenes* infection in New Zealand.

This evaluation of risk is based on currently available data and agrees with the findings of the MPI risk assessment, but there are considerable data gaps and uncertainties.

4.2.1 Risk associated with raw milk

The risk of *L. monocytogenes* infection for consumers of raw milk is considered low. This is based on the following:

1. Two surveys of raw cows' milk in New Zealand have found prevalences of *L. monocytogenes* of 0.7% and 4.1% and the concentration of *L. monocytogenes* in positive samples was <1 CFU/ml or <1 MPN/ml. One survey of goats' milk found a prevalence of 3.3%. Overseas surveys of sheep and buffaloes' milk indicate that *L. monocytogenes* can contaminate these milks, but possibly less often than milk from cows. Thus there is a risk of exposure to raw milk contaminated with *L. monocytogenes*, but the concentration of cells is likely to be low.
2. *L. monocytogenes* is able to grow in raw milk, even at 4°C. It is difficult to predict the extent of growth as the times and temperatures applied to the milk during its shelf-life will vary. Growth of 1 log₁₀ over five days would not be unexpected, but growth of more than 2 log₁₀ during this period would be unlikely unless serious temperature abuse occurred (which also causes milk spoilage). Assuming a low starting concentration (as found in the New Zealand surveys) and a five-day shelf-life, the available dose response models indicate that the estimated number of cells ingested through drinking raw milk has a very low probability of infection.
3. Drinking raw milk has not been reported as a risk factor or confirmed as the cause of any reported sporadic cases or outbreaks of *L. monocytogenes* infection in New Zealand. There have also been no recent reports of listeriosis outbreaks in other countries that were caused by consumption of raw milk.

This evaluation of risk is based on currently available data and agrees with the findings of the MPI risk assessment (MPI, 2013). However, this evaluation must be considered with the following in mind:

- The two surveys of raw cows' milk covered only a small proportion of the large volume of cows' milk produced each year.
- Overseas surveys of raw milk have shown that raw milk can contain concentrations of *L. monocytogenes* higher than those measured in the New Zealand surveys.
- Studies of *L. monocytogenes* growth in raw milk to date are not sufficient to predict with confidence the extent of growth that might occur, particularly given variability between strains and the absence of growth experiments in milk from sheep, goats and buffaloes.
- The risk of illness from raw milk contaminated with *L. monocytogenes* increases with extended product life, particularly when milk is stored longer (e.g. 5-10 days) in consumer refrigerators where cool temperatures are less likely to be maintained. If the legislation regarding raw milk sales were to change to permit retail sales, this extended chill-chain will increase the opportunities for *L. monocytogenes* growth.
- The listeriosis cases reported to the New Zealand health surveillance system do not include any cases or outbreaks linked to raw milk consumption but this does not mean that raw milk has not caused listeriosis in New Zealand. 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. Moreover, the rate of non-invasive listeriosis (febrile gastroenteritis) is not known for New Zealand,

although raw milk would need to be highly temperature abused (which will cause spoilage) or highly contaminated to achieve the concentration of *L. monocytogenes* thought to be necessary to cause this form of the disease.

Other data gaps important for assessment of risk are summarised in section 4.5.

It is important to note that the risk from raw milk products such as cheeses will be higher, due to their longer shelf life and potential for *L. monocytogenes* growth. Raw milk cheeses have been identified as the source of listeriosis outbreaks overseas.

4.2.2 Risks associated with other foods

Foods that pose a high risk for causing listeriosis have the following properties (ILSI Research Foundation/Risk Science Institute expert panel on *Listeria monocytogenes* in foods, 2005):

- Have the potential for contamination with *L. monocytogenes*;
- Support the growth of *L. monocytogenes* to high numbers;
- Are RTE;
- Require refrigeration; and
- Are stored for an extended period of time.

Listeriosis is considered to be primarily a foodborne disease and RTE foods are considered high risk because many of these foods support the growth of *L. monocytogenes*, even when stored under refrigeration.

Smoked mussels and RTE meats have caused outbreaks of listeriosis in New Zealand, and feta cheese was confirmed as the cause of one sporadic non-perinatal listeriosis case in 2010. No other foods have been confirmed as vehicles for any other sporadic listeriosis cases between 2000 and 2012. A recent analysis of 503 *L. monocytogenes* isolates from foods, food contact surfaces and clinical cases in New Zealand found that one particular PFGE type was detected in clinical cases from 1999 to 2013 but had not been detected in foods. The transmission route may be an as-yet unidentified food (Hudson and Gilpin, 2013).

RTE meats (including fish) and dairy products are important vehicles of infection. In 2008, a listeriosis outbreak in Canada was caused by RTE meats and resulted in 58 confirmed cases and caused 22 deaths (Weatherill, 2009). Numerous outbreaks have been caused by consumption of cheeses, including cheeses made from raw milk (FDA/Health Canada, 2012; FSANZ, 2009b). The importance of these foods is emphasised by a number of studies:

- A USA risk ranking exercise ranked deli meats, unheated frankfurters, pate and meat spreads, unpasteurised fluid milk, smoked seafood and cooked RTE crustaceans as high risk (per serving basis) (FDA/USDA, 2003).
- An attribution exercise based on *L. monocytogenes* surveillance data from England and Wales concluded that the most important food sources were multicomponent foods (sandwiches and prepacked mixed salad vegetables), finfish and beef (Little *et al.*, 2010). Beef, milk and milk products, and finfish were important sources of infection for pregnancy-associated cases.

- An attribution exercise using USA outbreak data found that 6/14 (43%) listeriosis outbreaks that could be attributed to a single commodity were attributed to the commodity group ‘dairy’ (which will include milk, cheese and other dairy products) (Gould *et al.*, 2013). Five outbreaks were attributed to ‘poultry’ and the remaining three to ‘beef’, ‘pork’ and ‘sprout’. The analysis identified *Listeria* and ‘poultry’ as the pathogen-commodity pair responsible for the most deaths (16) of all pathogen-commodity pairs.
- A case control study of listeriosis cases in Australia found the only food-related risk factor was consumption of camembert by non-perinatal cases (OR 4.7, 95% CI 1.1-20.6) (Dalton *et al.*, 2011).

A variety of other foods have also been implicated in outbreaks of listeriosis. These include pasteurised milk, cantaloupe, sandwiches, diced celery and imitation crab meat (CDC, 2012a; Cumming *et al.*, 2008; Farber *et al.*, 2000; Gaul *et al.*, 2013; Shetty *et al.*, 2009). Produce outbreaks are often linked to poor growing or storage conditions, or environmental cross-contamination after processing.

4.3 The Burden of *L. monocytogenes* Infection in New Zealand

KEY FINDINGS

On a national scale (and on the basis of existing information), the burden of listeriosis from people drinking raw milk contaminated with *L. monocytogenes* is considered to be low relative to other sources of *L. monocytogenes* infection primarily because the size of the population drinking raw milk is small. The burden of disease from all foodborne listeriosis in New Zealand is fourth on a ranked list of six enteric foodborne diseases, a position largely determined by the high mortality rate.

4.3.1 Burden of disease from raw milk contaminated with *L. monocytogenes*

On a national scale (and on the basis of existing information), the burden of disease from raw milk contaminated with *L. monocytogenes* is low relative to other sources of *L. monocytogenes* infection because:

- Currently the size of the consuming population is thought to be 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 (Jaros *et al.*, 2013);
- Drinking raw milk was not reported as a risk factor in any of the listeriosis cases reported to EpiSurv for the period 2006-2012; and
- Drinking raw milk has never been confirmed as a vehicle of infection in outbreaks of *L. monocytogenes* infection.

4.3.2 Burden of disease from all *L. monocytogenes* infection

It has been estimated by expert consultation that 85% (minimum 78%, maximum 92%) of listeriosis incidence is due to foodborne transmission (Lake *et al.*, 2010). A recent analysis of

the burden of foodborne disease in disability adjusted life years (DALYs) used data from 2011 and multipliers from recent studies to estimate cases not reported to the health system (Cressey, 2012). The total burden of disease from listeriosis and sequelae was calculated as 188 DALYs, with 160 DALYs (5th-95th percentile 31-305) being foodborne. For comparison, the next largest DALYs estimate for foodborne-associated disease was for STEC infection (200, 5th-95th percentile 1.5-783), followed by campylobacteriosis (587, 5th-95th percentile 425-781) and norovirus infection (873, 5th-95th percentile 675-1083). The DALYs estimate for foodborne listeriosis was higher than that of salmonellosis and yersiniosis. The annual rate of listeriosis is currently lower than all of these diseases (e.g. the 2012 salmonellosis rate was 24.5 per 100,000 (ESR, 2013)) but the DALY value for listeriosis is elevated by the high proportion of fatalities. For most foodborne diseases the burden due to morbidity is the greater part of the burden of disease estimate. For perinatal listeriosis, mortality accounts for more than 99% of the DALY estimate.

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), listeriosis accounted for \$15.2 million (9%), reflecting the high cost of patient care and the risk of premature death. This estimate was similar to those for salmonellosis (\$15.4m) and STEC infection (\$14.6m).

These estimates cover all potential food vehicles. There are no separate estimates for transmission of *L. monocytogenes* via raw milk.

The health burden for non-invasive listeriosis (febrile gastroenteritis) has not been estimated for New Zealand or other countries.

4.4 Summary of Risk

KEY FINDINGS

L. monocytogenes can contaminate raw milk in New Zealand and the absence of pasteurisation means that there is no control measure that will eliminate *L. monocytogenes* from this food. The existing information suggests that the risk of listeriosis is low for individual New Zealanders who consume raw milk. This is chiefly because the probability of infection from the predicted number of cells in raw milk contaminated with *L. monocytogenes* is low, even for susceptible people. The risk increases with increased milk storage time.

4.5 Data Gaps

KEY FINDINGS

There are many data gaps identified in this report that impact on the risk from *L. monocytogenes* in raw milk. New data on the amount of raw milk consumed in New Zealand, the behaviour of *L. monocytogenes* in raw milk under appropriate temperature profiles and the storage times for raw milk in consumers' homes will improve the exposure assessment.

Data gaps identified in this report are:

- The ability to predict the risk of infection based on the strain of *L. monocytogenes*;
- The behaviour of a range of *L. monocytogenes* isolates (representing strain variability) in raw milk;
- The behaviour of *L. monocytogenes* in milk from sheep, buffaloes, or goats;
- The behaviour of *L. monocytogenes* in raw milk under a temperature profile similar to milk cooling in farm dairy vats;
- Survival of *L. monocytogenes* in frozen raw milk;
- The prevalence of *L. monocytogenes* in raw milk from sheep and buffaloes;
- The concentration of *L. monocytogenes* in raw milk other than cows' milk;
- The prevalence of *L. monocytogenes* among dairy animals in New Zealand (as an indicator of the potential for milk contamination);
- The amount of raw milk consumed in New Zealand;
- The proportion of the population drinking raw milk in New Zealand and the demographics of this population; and
- Storage times for raw milk in consumers' homes.

Moreover, the current dose models lack critical information (see Appendix 2, Section 8.1) so prediction of infection is difficult.

5 AVAILABILITY OF CONTROL MEASURES

5.1 Current 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.

5.2 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.

5.2.1 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.

5.3 Additional Options for Risk Management

The absence of a pathogen elimination step for raw milk means that control measures for reducing the risk of *L. monocytogenes* contamination must be implemented by the raw milk producer. MPI has reviewed on-farm control options for managing pathogenic microorganisms and did not identify any animal husbandry practices which guarantee that milk will be free from pathogens (MPI, 2013). Measures to improve animal health and milking hygiene can reduce microbiological contamination of raw milk. Some additional information on on-farm controls is included below.

5.3.1 On-farm control options: *L. monocytogenes*

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.¹² Nevertheless, mastitis control will reduce the risk from this occasional source of pathogen contamination, and a number of management tools are available via the Dairy NZ website.

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.¹³ 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.

5.3.2 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

¹² <http://www.dairynz.co.nz/file/fileid/27234> accessed 20 March 2014.

¹³ <http://www.fooss.dk/industry-solution/products/bactoscan-fc> accessed 21 March 2013

producers and consumers, and implementing the use of warning labels on raw milk packaging.

MPI has published advice to consumers on the safety of raw milk.¹⁴ 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”.

¹⁴ <http://www.foodsmart.govt.nz/food-safety/high-risk-foods/raw-milk/> accessed 13 May 2013

6 REFERENCES

Abbas BA, Jaber GM. (2012) Occurrence of *Listeria monocytogenes* in raw milk of ruminants in Basrah province. Iraqi Journal of Veterinary Sciences; 26(1): 47-51.

ACMSF. (2011a) Health risks to consumers associated with unpasteurised milk and unpasteurised cream for direct human consumption. Advisory Committee on the Microbiological Safety of Foods. Report Number ACM/1008. Accessed at: Available from: <http://www.food.gov.uk/multimedia/pdfs/committee/acm1008rawmilk.pdf>. Accessed: 12 December 2012.

ACMSF. (2011b) Advisory Committee on the Microbiological Safety of Foods, Minutes: 20 January 2011. Accessed at: <http://acmsf.food.gov.uk/acmsfmeets/acmsf2011/acmsf200111/acmsfmin200111>. Accessed: 18 February 2014.

Alavi SH, Puri VM, Knabel SJ, Mohtar RH, Whiting RC. (1999) Development and validation of a dynamic growth model for *Listeria monocytogenes* in fluid whole milk. Journal of Food Protection; 62(2): 170-176.

Albarracín YC, Poutou RP, Carrascal AC. (2008) *Listeria* spp. and *L. monocytogenes* in raw goat's milk. La Revista MVZ Córdoba; 13(2): 1326-1332.

Allerberger F, Guggenbichler JP. (1989) Listeriosis in Austria - report of an outbreak in 1986. Acta Microbiologica Hungarica; 36(2-3): 149-152.

Amigo L, Fontecha J. (2011) Milk: Goat Milk. In: JW Fuquay (eds). Encyclopedia of Dairy Sciences (Second Edition). San Diego: Academic Press.

Angot J-L. (2012) Note de service DGAL/SDSSA/N2012-8271 24 Décembre 2012. Paris: Ministère de L'Agriculture, de L'Agroalimentaire et de la Forêt.

Anonymous. (1999) Microbiological survey of unpasteurised sheep, goats' and buffaloes' milk. London: Food Standards Agency.

Arnold GJ, Coble J. (1995) Incidence of *Listeria* species in foods in NSW. Food Australia; 47(2): 71-75.

Aureli P, Fiorucci G, Caroli D, Marchiaro G, Novara O, Leone L, Salmaso S. (2000) An outbreak of febrile gastroenteritis associated with corn contaminated by *Listeria monocytogenes*. New England Journal of Medicine; 342(17): 1236-1241.

Australian Government. (2013) National Notifiable Diseases Surveillance System. Accessed at: <http://www9.health.gov.au/cda/source/cda-index.cfm>. Accessed: 9 September 2013.

Bertsch D, Rau J, Eugster MR, Haug MC, Lawson PA, Lacroix C, Meile L. (2013) *Listeria fleischmannii* sp. nov., isolated from cheese. International Journal of Systematic and Evolutionary Microbiology; 63(Pt 2): 526-532.

Bianchi D, Barbaro A, Gallina S, Vitale N, Chiavacci L, Caramelli M, Decastelli L. (2013) Monitoring of foodborne pathogenic bacteria in vending machine raw milk in Piedmont, Italy. *Food Control*; 32: 435-439.

Borucki MK, Gay CC, Reynolds J, McElwain KL, Kim SH, Call DR, Knowles DP. (2005) Genetic diversity of *Listeria monocytogenes* strains from a high-prevalence dairy farm. *Applied and Environmental Microbiology*; 71(10): 5893-5899.

Bouazza F, Hassikou R, Ohmani F, Hmnamouchi J, Ennadir J, Qasmaoui A, Mennane Z, Charof R, Khedid K. (2012) Hygienic quality of raw milk at Sardi breed of sheep in Morocco. *African Journal of Microbiology Research*; 6(11): 2768-2772.

Bovill R, Bew J, Cook N, D'Agostino M, Wilkinson N, Baranyi J. (2000) Predictions of growth for *Listeria monocytogenes* and *Salmonella* during fluctuating temperature. *International Journal of Food Microbiology*; 59: 157-165.

Brouillaud-Delattre A, Marie M, Collette C, Mattei C, Lahellec C. (1997) Predictive microbiology of dairy products: Influence of biological factors affecting growth of *Listeria monocytogenes*. *Journal of the Association of Official Analytical Chemists*; 80(4): 913-919.

Bucchini L. (2012) Italy's experience liberalizing raw milk sales: Can't put the genie back in the bottle. Accessed at: <http://www.foodsafetynews.com/2012/04/italys-experience-with-liberalizing-raw-milk-sales-cant-put-the-genie-back-in-the-bottle/>. Accessed: 11th December.

Buzby JC, Gould LH, Kendall ME, Jones TF, Robinson T, Blayney DP. (2013) Characteristics of consumers of unpasteurized milk in the United States. *Journal of Consumer Affairs*; 47(1): 153-166.

Carrique-Mas J, Hökeberg I, Andersson Y, Arneborn M, Tham W, Danielsson-Tham M, Osterman B, Leffler M, Steen M, Eriksson E, Hedin G, Giesecke J. (2003) Febrile gastroenteritis after eating on-farm manufactured fresh cheese - an outbreak of listeriosis? *Epidemiology and Infection*; 130(1): 79-86.

Cartwright EJ, Jackson KA, Johnson SD, Graves LM, Silk BJ, Mahon BE. (2013) Listeriosis outbreaks and associated food vehicles, United States, 1998-2008. *Emerging Infectious Diseases*; 19(1): 1-9; quiz 184.

CDC. (2007) Foodborne Active Surveillance Network (FoodNet) Population Survey: Atlas of Exposures, 2006-2007. Atlanta, Georgia: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention.

CDC. (2012a) Multistate outbreak of listeriosis linked to whole cantaloupes from Jensen Farms, Colorado. Accessed at: Available from: <http://www.cdc.gov/listeria/outbreaks/cantaloupes-jensen-farms/index.html>. Accessed: 25 September 2013.

CDC. (2012b) Foodborne Diseases Active Surveillance Network (FoodNet): FoodNet surveillance report for 2011. Atlanta, Georgia: U.S. Department of Health and Human Services, CDC.

CDC. (2013) Foodborne Diseases Active Surveillance Network (FoodNet). Table 2a FoodNet–Number of Laboratory–Confirmed Infections by Year 2012. Accessed at: Available from: <http://www.cdc.gov/foodnet/data/trends/tables/2012/table2a-b.html#table-2b>. Accessed: 1 October 2013.

Chandio TH, Soomro AH, Bhutto MB, Dewani P, Shah G. (2007) Occurrence of *Listeria monocytogenes* in bovine milk in Hyderabad, Pakistan. *Annals of Microbiology*; 57(3): 341-344.

Chen Y, Ross WH, Scott VN, Gombas DE. (2003) *Listeria monocytogenes*: low levels equal low risk. *Journal of Food Protection*; 66(4): 570-577.

Chen Y, Ross WH, Gray MJ, Wiedmann M, Whiting RC, Scott VN. (2006) Attributing risk to *Listeria monocytogenes* subgroups: dose response in relation to genetic lineages. *Journal of Food Protection*; 69(2): 335-344.

Claeys WL, Cardoen S, Daube G, De Block J, Dewettinck K, Dierick K, De Zutter L, Huyghebaert A, Imberechts H, Thiange P, Vandenplas Y, Herman L. (2013) Raw or heated cow milk consumption: Review of risks and benefits. *Food Control*; 31: 251-262.

Clark RG, Gill JM, Swanney S. (2004) *Listeria monocytogenes* gastroenteritis in sheep. *New Zealand Veterinary Journal*; 52(1): 46-47.

Costa Sobrinho Pde S, Marcal de Faria CA, Silva Pinheiro J, Goncalves de Almeida H, Vieira Pires C, Silva Santos A. (2012) Bacteriological quality of raw milk used for production of a Brazilian farmstead raw milk cheese. *Foodborne Pathogens and Disease*; 9(2): 138-144.

Cotter PD, Hill C. (2003) Surviving the acid test: Responses of gram-positive bacteria to low pH. *Microbiology and Molecular Biology Reviews*; 67(3): 429-453.

Cressey P, Lake R. (2007) Risk ranking: Estimates of the burden of foodborne disease for New Zealand. Client Report FW0724 for the New Zealand Food Safety Authority. Christchurch: Institute of Environmental Science and Research (ESR) Limited.

Cressey P. (2012) Risk ranking: Updated estimates of the burden of foodborne disease for New Zealand in 2011. Client Report RW12030 for the Ministry for Primary Industries. Christchurch: Institute of Environmental Science and Research (ESR) Limited.

Crump JA, Griffin PM, Angulo FJ. (2002) Bacterial contamination of animal feed and its relationship to human foodborne illness. *Clinical Infectious Diseases*; 35(7): 859-865.

Cumming M, Kludt P, Matyas B, DeMaria A, Stiles T, Han L, Gilchrist M, Neves P, Fitzgibbons E, Condon S. (2008) Outbreak of *Listeria monocytogenes* infections associated with pasteurized milk from a local dairy - Massachusetts, 2007. *Morbidity and Mortality Weekly Report*; 57(40): 1097-1100.

D'Amico DJ, Groves E, Donnelly CW. (2008) Low incidence of foodborne pathogens of concern in raw milk utilized for farmstead cheese production. *Journal of Food Protection*; 71(8): 1580-1589.

D'Amico DJ, Donnelly CW. (2010) Microbiological quality of raw milk used for small-scale artisan cheese production in Vermont: Effect of farm characteristics and practices. *Journal of Dairy Science*; 93(1): 134-147.

Dalton CB, Austin CC, Sobel J, Hayes PS, Bibb WF, Graves LM, Swaminathan B, Proctor ME, Griffin PM. (1997) An outbreak of gastroenteritis and fever due to *Listeria monocytogenes* in milk. *New England Journal of Medicine*; 336(2): 100-105.

Dalton CB, Merritt TD, Unicomb LE, Kirk MD, Stafford RJ, Lalor K, OzFoodNet Working G. (2011) A national case-control study of risk factors for listeriosis in Australia. *Epidemiology and Infection*; 139(3): 437-445.

Dehaumont P. (2012) Arrêté du 13 juillet 2012 relatif aux conditions de production et de mise sur le marché de lait cru de bovinés, de petits ruminants et de solipèdes domestiques remis en l'état au consommateur final NOR: AGRG1229148A. Paris: Ministère de L'Agriculture, de L'Agroalimentaire et de la Forêt.

Department of Health Social Services and Public Safety. (2006) The Food Hygiene Regulations (Northern Ireland) 2006. Schedule 6. Belfast: Northern Ireland Executive.

Doijad S, Barbuddhe SB, Garg S, Kalekar S, Rodrigues J, D'Costa D, Bhosle S, Chakraborty T. (2011) Incidence and genetic variability of *Listeria* species from three milk processing plants. *Food Control*; 22(12): 1900-1904.

EFSA. (2007) Scientific opinion of the Panel on Biological Hazards on a request from the European Commission on Request for updating the former SCVPH opinion on *Listeria monocytogenes* risk related to ready-to-eat foods and scientific advice on different levels of *Listeria monocytogenes* in ready-to-eat foods and the related risk for human illness. *EFSA Journal*; 599: 1-42.

ESR. (1998) Annual surveillance summary 1997. Porirua: ESR.

ESR. (2004) Notifiable and other Diseases in New Zealand. Annual Report 2003. ESR Client Report FW0426. Kenepuru: ESR.

ESR. (2005) Notifiable and other Diseases in New Zealand. Annual Report 2004. ESR Client Report FW0532. Kenepuru: ESR.

ESR. (2006) Notifiable and other Diseases in New Zealand. Annual Report 2005. ESR Client Report FW0621. Kenepuru: ESR.

ESR. (2007) Notifiable and other Diseases in New Zealand. Annual Report 2006. ESR Client Report FW0717. Kenepuru: ESR.

ESR. (2008) Notifiable and other Diseases in New Zealand. Annual Report 2007. ESR Client Report FW08034. Kenepuru: ESR.

ESR. (2009) Notifiable and other Diseases in New Zealand. 2008 Annual Surveillance Report ESR Client Report FW09074. Kenepuru: ESR.

ESR. (2010) Notifiable and other Diseases in New Zealand. 2009 Annual Surveillance Report. ESR Client Report FW10043. Kenepuru: Institute of Environmental Science & Research (ESR) Ltd.

ESR. (2011) Notifiable and other Diseases in New Zealand. Annual Report 2010. ESR Client Report FW11030. Porirua: ESR.

ESR. (2012) Notifiable and other Diseases in New Zealand. Annual Report 2011. ESR Client Report FW12019. Porirua: ESR.

ESR. (2013) Notifiable and other Diseases in New Zealand. Annual Report 2012. ESR Client Report FW13014. Porirua: ESR.

Esteban JI, Oporto B, Aduriz G, Juste RA, Hurtado A. (2009) Faecal shedding and strain diversity of *Listeria monocytogenes* in healthy ruminants and swine in Northern Spain. *BMC Vet Res*; 5: 2.

European Food Safety Authority. (2005) The Community Summary Report on trends and sources of zoonoses, zoonotic agents, antimicrobial resistance and foodborne outbreaks in the European Union in 2004. *EFSA Journal*; 310: 1-275.

European Food Safety Authority, European Centre for Disease Prevention and Control. (2006) The Community Summary Report on trends and sources of zoonoses, zoonotic agents, antimicrobial resistance and foodborne outbreaks in the European Union in 2005. *EFSA Journal*; 94: 1-288.

European Food Safety Authority, European Centre for Disease Prevention and Control. (2007) The Community Summary Report on trends and sources of zoonoses, zoonotic agents, antimicrobial resistance and foodborne outbreaks in the European Union in 2006. *EFSA Journal*; 130: 1-352.

European Food Safety Authority, European Centre for Disease Prevention and Control. (2009) The Community Summary Report on trends and sources of zoonoses, zoonotic agents and food-borne outbreaks in the European Union in 2007. *EFSA Journal*; 223: 1-215.

European Food Safety Authority, European Centre for Disease Prevention and Control. (2010) The Community Summary Report on trends and sources of zoonoses, zoonotic agents and food-borne outbreaks in the European Union in 2008. *EFSA Journal*; 8(1): 1496.

European Food Safety Authority, European Centre for Disease Prevention and Control. (2011) The European Union summary report on trends and sources of zoonoses, zoonotic agents and food-borne outbreaks in 2009. *EFSA Journal*; 9(3): 2090.

European Food Safety Authority, European Centre for Disease Prevention and Control. (2012) The European Union summary report on trends and sources of zoonoses, zoonotic agents and food-borne outbreaks in 2010. *EFSA Journal*; 10(3): 2597.

European Food Safety Authority, European Centre for Disease Prevention and Control. (2013) The European Union summary report on trends and sources of zoonoses, zoonotic agents and food-borne outbreaks in 2011. EFSA Journal; 11(4): 3129.

FAO/WHO. (2004a) Risk assessment of *Listeria monocytogenes* in ready-to-eat foods: Interpretative summary. Rome: Food and Agriculture Organization of the United Nations and World Health Organisation.

FAO/WHO. (2004b) Risk assessment of *Listeria monocytogenes* in ready-to-eat foods: Technical report. Rome: Food and Agriculture Organization of the United Nations and the World Health Organisation.

Farber JM, Sanders GW, Speirs JJ. (1990) Growth of *Listeria monocytogenes* in naturally-contaminated raw milk. Lebensmittel-Wissenschaft & Technologie; 23(3): 252-254.

Farber JM, Daley EM, MacKie MT, Limerick B. (2000) A small outbreak of listeriosis potentially linked to the consumption of imitation crab meat. Letters in Applied Microbiology; 31(2): 100-104.

FASFC. (2011) Advice 15-2011 of the scientific committee of the FASFC on the risk-benefit evaluation of raw cow milk consumption and the effect of heat treatment on these risks and benefits. Brussels, Belgium: Comité Scientifique de l'agence fédérale pour la sécurité de la chaîne alimentaire (Belgian Federal Agency for the Safety of the Food Chain).

FDA. (2012) CFR - Code of Federal Regulations Title 21. Sec. 1240.61 (Mandatory pasteurization for all milk and milk products in final package form intended for direct human consumption). Accessed at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm>. Accessed: 11 April 2013.

FDA/Health Canada. (2012) Joint FDA/Health Canada quantitative risk assessment of the risk of listeriosis from soft-ripened cheese consumption in the United States and Canada: Draft report. Silver Spring, MD: Food and Drug Administration.

FDA/USDA. (2003) Quantitative assessment of relative risk to public health from foodborne *Listeria monocytogenes* among selected categories of ready-to-eat foods. US Food and Drug Administration (Center for Food Safety and Applied Nutrition) and US Department of Agriculture (Food Safety and Inspection Service).

Flint S, Palmer J, Bremer P, Seale B, Brooks J, Lindsay D, Burgess S. (2011) Biofilm formation. In: JW Fuquay (eds). Encyclopedia of Dairy Sciences (Second Edition). San Diego: Academic Press.

Food Standards Agency. (2014a) Impact Assessment on the review of the controls governing the sale and marketing of unpasteurised, or raw drinking milk and raw cream (RDM) in Wales. Accessed at: <http://www.food.gov.uk/news-updates/consultations/consultations-wales/2014/rawmilk-consult-wales>. Accessed: 3 February 2014.

Food Standards Agency. (2014b) Impact Assessment on the review of the controls governing the sale and marketing of unpasteurised, or raw drinking milk and raw cream (RDM) in

Northern Ireland. Accessed at: <http://www.food.gov.uk/news-updates/consultations/consultations-northern-ireland/2014/rawmilk-consult-ni>. Accessed: 3 February 2014.

Food Standards Agency. (2014c) Impact Assessment on the review of the controls governing the sale and marketing of unpasteurised, or raw drinking milk and raw cream (RDM) in England. Accessed at: <http://www.food.gov.uk/news-updates/consultations/consultations-england/2014/rawmilk-consult>. Accessed: 3 February 2014.

Foschino R, Invernizzi A, Barucco R, Stradiotto K. (2002) Microbial composition, including the incidence of pathogens, of goat milk from the Bergamo region of Italy during a lactation year. *Journal of Dairy Research*; 69(2): 213-225.

Fox PF. (2011) Milk: Bovine Milk. In: JW Fuquay (eds). *Encyclopedia of Dairy Sciences* (Second Edition). San Diego: Academic Press.

Frece J, Markov K, Čvek D, Kolarec K, Delaš F. (2010) Comparison of conventional and molecular methods for the routine confirmation of *Listeria monocytogenes* in milk products produced domestically in Croatia. *Journal of Dairy Research*; 77(1): 112-116.

Frye DM, Zweig R, Sturgeon J, Tormey M, LeCavalier M, Lee I, Lawani L, Mascola L. (2002) An outbreak of febrile gastroenteritis associated with delicatessen meat contaminated with *Listeria monocytogenes*. *Clinical Infectious Diseases*; 35(8): 943-949.

FSAI. (2008) A compendium of food law in Ireland. Dublin: Food Safety Authority of Ireland.

FSAI. (2009) Health risks from unpasteurised milk. General Factsheet Series Issue No. 1. Dublin:

FSAI. (2010) Milk and Milk Products: General hygiene provisions. Dublin: Food Safety Authority of Ireland.

FSANZ. (2009a) Microbiological risk assessment of raw goat milk. Canberra: Food Standards Australia New Zealand.

FSANZ. (2009b) Microbiological risk assessment of raw milk cheese. Food Standards Australia New Zealand.

FSANZ. (2009c) Microbiological risk assessment of raw cow milk. Canberra: Food Standards Australia New Zealand.

FSANZ. (2012) Australia New Zealand Food Standards Code - Standard 4.2.4 - Primary production and processing standard for dairy products (Australia only). Version starting 28 June 2012. Canberra: Food Standards Australia New Zealand.

Fugett E, Fortes E, Nnoka C, Wiedmann M. (2006) International Life Sciences Institute North America *Listeria monocytogenes* strain collection: development of standard *Listeria monocytogenes* strain sets for research and validation studies. *Journal of Food Protection*; 69(12): 2929-2938.

Gadiel D. (2010) The economic cost of foodborne disease in New Zealand. Report prepared for the New Zealand Food Safety Authority. Sydney: Applied Economics Pty Ltd.

Gaul LK, Farag NH, Shim T, Kingsley MA, Silk BJ, Hyytia-Trees E. (2013) Hospital-acquired listeriosis outbreak caused by contaminated diced celery -Texas, 2010. *Clinical Infectious Diseases*; 56(1): 20-26.

Gelbicova T, Karpiskova R. (2012) Occurrence and typing of *Listeria monocytogenes* isolated from raw cow's milk collected on farms and from vending machines. *Klinická Mikrobiologie a Infekční Lekarství*; 18(2): 38-42.

German Federal Ministry of Justice. (2007) Anlage 9 Anforderungen an Vorzugsmilch (Appendix 9 Requirements for certified milk). Verordnung über Anforderungen an die Hygiene beim Herstellen, Behandeln und Inverkehrbringen von bestimmten Lebensmitteln tierischen Ursprungs (Regulation on the hygiene requirements for the manufacture, treatment and marketing of certain products of animal origin). Accessed at: http://www.gesetze-im-internet.de/tier-lmhv/anlage_9_53.html. Accessed: 11 April 2013.

Giacometti F, Serraino A, Bonilauri P, Ostanello F, Daminelli P, Finazzi G, Losio MN, Marchetti G, Liuzzo G, Zanoni RG, Rosmini R. (2012a) Quantitative risk assessment of verocytotoxin-producing *Escherichia coli* O157 and *Campylobacter jejuni* related to the consumption of raw milk in a province in northern Italy. *Journal of Food Protection*; 75(11): 2031-2038.

Giacometti F, Serraino A, Finazzi G, Daminelli P, Losio MN, Tamba M, Garigliani A, Mattioli R, Riu R, Zanoni RG. (2012b) Field handling conditions of raw milk sold in vending machines: experimental evaluation of the behaviour of *Listeria monocytogenes*, *Escherichia coli* O157:H7, *Salmonella* Typhimurium and *Campylobacter jejuni*. *Italian Journal of Animal Science*; 11(2): 132-136.

Giacometti F, Bonilauri P, Serraino A, Peli A, Amatiste S, Arrigoni N, Bianchi M, Bilei S, Cascone G, Comin D, Daminelli P, Decastelli L, Fustini M, Mion R, Petruzzelli A, Rosmini R, Rugna G, Tamba M, Tonucci F, Bolzoni G. (2013) Four-year monitoring of foodborne pathogens in raw milk sold by vending machines in Italy. *Journal of Food Protection*; 76(11): 1902-1907.

Gilbert S, Whyte R, Bayne G, Lake R, van der Logt P. (2007) Survey of internal temperatures of New Zealand domestic refrigerators. *British Food Journal*; 109(4): 323-329.

Gilbert S, Lake R, Hudson A, Cressey P. (2009) Risk Profile: *Listeria monocytogenes* in processed ready-to-eat meats. Client Report FW08021 for the New Zealand Food Safety Authority. Christchurch: Institute of Environmental Science & Research (ESR) Ltd.

Gleadle A. (2012) Microbiological safety of raw drinking milk. Paper FSA 12/03/05 presented to the Food Standards Agency Board at their meeting on 20 March 2012. London: Food Standards Agency.

Gould LH, Walsh KA, Vieira AR, Herman K, Williams IT, Hall AJ, Cole D. (2013) Surveillance for foodborne disease outbreaks - United States, 1998-2008. Morbidity and Mortality Weekly Report; 62 Suppl 2: 1-34.

Goulet V, King LA, Vaillant V, de Valk H. (2013) What is the incubation period for listeriosis? BMC Infectious Diseases; 13(1): 11.

Government of Canada. (2013) Food and Drug Regulations. Consolidation current to 9 December 2013. Accessed at: http://laws.justice.gc.ca/PDF/C.R.C.,_c._870.pdf. Accessed: 10 July 2013.

Graves LM, Helsel LO, Steigerwalt AG, Morey RE, Daneshvar MI, Roof SE, Orsi RH, Fortes ED, Milillo SR, den Bakker HC, Wiedmann M, Swaminathan B, Sauders BD. (2010) *Listeria marthii* sp. nov., isolated from the natural environment. International Journal of Systematic and Evolutionary Microbiology; 60: 1280-1288.

Hächler H, Marti G, Giannini P, Lehner A, Jost M, Beck J, Weiss F, Bally B, Jermini M, Stephan R, Baumgartner A. (2013) Outbreak of listeriosis due to imported cooked ham, Switzerland 2011. Euro Surveillance; 18(18): 20469.

Han X, Lee F, Zhang L, Guo M. (2012) Chemical composition of water buffalo milk and its low fat symbiotic yoghurt development. Functional Foods in Health and Disease; 2(4): 86-106.

Hill B, Smythe B, Lindsay D, Shepherd J. (2012) Microbiology of raw milk in New Zealand. International Journal of Food Microbiology; 157(2): 305-308.

Ho AJ, Ivanek R, Grohn YT, Nightingale KK, Wiedmann M. (2007) *Listeria monocytogenes* fecal shedding in dairy cattle shows high levels of day-to-day variation and includes outbreaks and sporadic cases of shedding of specific *L. monocytogenes* subtypes. Preventive Veterinary Medicine; 80(4): 287-305.

Hoelzer K, Chen Y, Dennis S, Evans P, Pouillot R, Silk BJ, Walls I. (2013) New data, strategies, and insights for *Listeria monocytogenes* dose-response models: Summary of an interagency workshop, 2011. Risk Analysis; 33(9): 1568-1581.

Holmes C, Brookes I. (2006) DairyNZ farmfact 1-46. What is high quality pasture silage? Accessed at: <http://www.dairynz.co.nz/file/fileid/36154>. Accessed: 11 February 2014.

Hudson A, Gilpin B. (2013) Typing of *Listeria monocytogenes* isolates from food and construction of a PFGE database. Draft client report FW13031 for the Ministry for Primary Industries. Christchurch: Institute of Environmental Science and Research (ESR) Limited.

Hunt K, Drummond N, Murphy M, Butler F, Buckley J, Jordan K. (2012) A case of bovine raw milk contamination with *Listeria monocytogenes*. Irish Veterinary Journal; 65(1): 13.

ICMSF. (2005) Micro-organisms in foods 6: Microbial ecology of food commodities. Second Edition. New York: Kluwer Academic/Plenum Publishers.

ILSI Research Foundation/Risk Science Institute expert panel on *Listeria monocytogenes* in foods. (2005) Achieving continuous improvement in reductions in foodborne listeriosis - a risk-based approach. *Journal of Food Protection*; 68(9): 1932-1994.

Jackson EE, Erten ES, Maddi N, Graham TE, Larkin JW, Blodgett RJ, Schlessner JE, Reddy RM. (2012) Detection and enumeration of four foodborne pathogens in raw commingled silo milk in the United States. *Journal of Food Protection*; 75(8): 1382-1393.

Jadhav S, Bhawe M, Palombo EA. (2012) Methods used for the detection and subtyping of *Listeria monocytogenes*. *Journal of Microbiological Methods*; 88(3): 327-341.

Jamali H, Radmehr B. (2013) Frequency, virulence genes and antimicrobial resistance of *Listeria* spp. isolated from bovine clinical mastitis. *Veterinary Journal*; 198(2): 541-542.

Jaros P, Cogger N, French N. (2008) A systematic review of the human disease evidence associated with the consumption of raw milk and raw milk cheeses. Palmerston North: Massey University.

Jaros P, Cookson A, Campbell D, Besser T, Shringi S, Mackereth G, Lim E, Lopez L, Dufour M, Marshall J, Baker M, Hathaway S, Prattley D, French N. (2013) A prospective case-control and molecular epidemiological study of human cases of Shiga toxin-producing *Escherichia coli* in New Zealand. *BMC Infectious Diseases*; 13(1): 450.

Jensen A, Frederiksen W, Gerner-Smidt P. (1994) Risk factors for listeriosis in Denmark, 1989-1990. *Scandinavian Journal of Infectious Diseases*; 26(2): 171-178.

Jensen NE, Aarestrup FM, Jensen J, Wegener HC. (1996) *Listeria monocytogenes* in bovine mastitis. Possible implication for human health. *International Journal of Food Microbiology*; 32(1-2): 209-216.

Kieft C, Perks M, Baker M, Galloway Y, Sutherland H. (2000) Annual Surveillance Summary 1999. ESR Client Report FW0059. Porirua: ESR.

Kowalik J, Lobacz A, Tarczyska AS, Ziajka S. (2012) Graphic validation of growth models for *Listeria monocytogenes* in milk during storage. *Milchwissenschaft*; 67(1): 38-42.

Kramarenko T, Roasto M, Meremäe K, Kuningas M, Pölsama P, Elias T. (2013) *Listeria monocytogenes* prevalence and serotype diversity in various foods. *Food Control*; 30(1): 24-29.

Lake RJ, Cressey PJ, Campbell DM, Oakley E. (2010) Risk ranking for foodborne microbial hazards in New Zealand: Burden of disease estimates. *Risk Analysis*; 30(5): 743-752.

Lang Halter E, Neuhaus K, Scherer S. (2013) *Listeria weihenstephanensis* sp. nov., isolated from the water plant *Lemna trisulca* taken from a freshwater pond. *International Journal of Systematic and Evolutionary Microbiology*; 63(Pt 2): 641-647.

Langer AJ, Ayers T, Grass J, Lynch MJ, Angulo FJ, Mahon BE. (2012) Nonpasteurized dairy products, disease outbreaks, and state laws-United States, 1993-2006. *Emerging Infectious Diseases*; 18(3): 385-391.

- Latorre AA, Van Kessel JA, Karns JS, Zurakowski MJ, Pradhan AK, Zadoks RN, Boor KJ, Schukken YH. (2009) Molecular ecology of *Listeria monocytogenes*: evidence for a reservoir in milking equipment on a dairy farm. *Applied and Environmental Microbiology*; 75(5): 1315-1323.
- Latorre AA, Van Kessel JS, Karns JS, Zurakowski MJ, Pradhan AK, Boor KJ, Jayarao BM, Houser BA, Daugherty CS, Schukken YH. (2010) Biofilm in milking equipment on a dairy farm as a potential source of bulk tank milk contamination with *Listeria monocytogenes*. *Journal of Dairy Science*; 93(6): 2792-2802.
- Latorre AA, Pradhan AK, Van Kessel JAS, Karns JS, Boor KJ, Rice DH, Mangione KJ, Grohn YT, Schukken YH. (2011a) Quantitative risk assessment of listeriosis due to consumption of raw milk. *Journal of Food Protection*; 74(8): 1268-1281.
- Latorre AA, Van Kessel JA, Karns JS, Zurakowski MJ, Pradhan AK, Boor KJ, Adolph E, Sukhnanand S, Schukken YH. (2011b) Increased in vitro adherence and on-farm persistence of predominant and persistent *Listeria monocytogenes* strains in the milking system. *Applied and Environmental Microbiology*; 77(11): 3676-3684.
- LAVES. (2013) Milch ab hof und vorzugsmilch – eine gegenüberstellung (Milk from the farm and certified milk - A comparison). Niedersächsisches Landesamt für Verbraucherschutz und Lebensmittelsicherheit (Lower Saxony State Office for Consumer Protection and Food Safety). Accessed at: http://www.laves.niedersachsen.de/portal/live.php?navigation_id=20111&article_id=73874&_psmand=23. Accessed: 11 April 2013.
- Leclercq A, Clermont D, Bizet C, Grimont P, Le Flèche-Matéos A, Roche S, Buchrieser C, Cadet-Daniel V, Le Monnier A, Lecuit M, Allerberger F. (2010) *Listeria rocourtiae* sp. nov. *International Journal of Systematic and Evolutionary Microbiology*; 60: 2210-2214.
- Leedom JM. (2006) Milk of nonhuman origin and infectious diseases in humans. *Clinical Infectious Diseases*; 43(5): 610-615.
- Lianou A, Koutsoumanis KP. (2013) Strain variability of the behavior of foodborne bacterial pathogens: A review. *International Journal of Food Microbiology*; 167(3): 310-321.
- LIC. (2013) New Zealand dairy statistics 2012-13. Hamilton: Livestock Improvement Corporation Limited and DairyNZ.
- Lim E, Lopez L, Cressey P, Pirie R. (2011) Annual report concerning foodborne disease in New Zealand 2010. Christchurch: Institute of Environmental Science & Research (ESR) limited.
- Little CL, Pires SM, Gillespie IA, Grant K, Nichols GL. (2010) Attribution of human *Listeria monocytogenes* infections in England and Wales to ready-to-eat food sources placed on the market: adaptation of the Hald *Salmonella* source attribution model. *Foodborne Pathogens and Disease*; 7(7): 749-756.

Lomonaco S, Verghese B, Gerner-Smidt P, Tarr C, Gladney L, Joseph L, Katz L, Turnsek M, Frace M, Chen Y, Brown E, Meinersmann R, Berrang M, Knabel S. (2013) Novel epidemic clones of *Listeria monocytogenes*, United States, 2011. *Emerging Infectious Diseases*; 19(1): 147-150.

Lopez L, Baker M, Perks M. (2001) Annual surveillance summary 2000. ESR Client Report FW0156. Kenepuru: ESR.

Lopez L, Carey-Smith G, Lim E, Cressey P, Pirie R. (2013) Annual report concerning foodborne disease in New Zealand 2012. Christchurch: Institute of Environmental Science & Research (ESR) limited.

Lyytikäinen O, Autio T, Maijala R, Ruutu P, Honkanen-Buzalski T, Miettinen M, Hatakka M, Mikkola J, Anttila VJ, Johansson T, Rantala L, Aalto T, Korkeala H, Siitonen A. (2000) An outbreak of *Listeria monocytogenes* serotype 3a infections from butter in Finland. *Journal of Infectious Diseases*; 181(5): 1838-1841.

McFadden A, Owen K, McIntyre L, Burton L. (2011) Spatial and temporal trends of Salmonellosis in dairy cattle in New Zealand 2007-2010. A report for the New Zealand Ministry for Primary Industries. Palmerston North: Massey University.

Mead PS, Dunne EF, Graves L, Wiedmann M, Patrick M, Hunter S, Salehi E, Mostashari F, Craig A, Mshar P, Bannerman T, Sauders BD, Hayes P, Dewitt W, Sparling P, Griffin P, Morse D, Slutsker L, Swaminathan B, Listeria Outbreak Working G. (2006) Nationwide outbreak of listeriosis due to contaminated meat. *Epidemiology and Infection*; 134(4): 744-751.

Meyer-Broseta S, Diot A, Bastian S, Riviere J, Cerf O. (2003) Estimation of low bacterial concentration: *Listeria monocytogenes* in raw milk. *International Journal of Food Microbiology*; 80(1): 1-15.

Miettinen MK, Siitonen A, Heiskanen P, Haajanen H, Bjorkroth KJ, Korkeala HJ. (1999) Molecular epidemiology of an outbreak of febrile gastroenteritis caused by *Listeria monocytogenes* in cold-smoked rainbow trout. *Journal of Clinical Microbiology*; 37(7): 2358-2360.

Miladi H, Chaieb K, Snoussi M, Ammar E, Bakhrouf A. (2013) RT-PCR assays for the evaluation of the expression of *Listeria monocytogenes* virulence genes after cold and freezing shock. *African Journal of Microbiology Research*; 7(8): 612-619.

Ministry of Health. (2003) NZ Food NZ Children. Key results of the 2002 National Children's Nutrition Survey. Wellington: Ministry of Health.

Ministry of Health. (2010) Infant and perinatal mortality 2005, 2006 and 2007 (provisional). Wellington: Ministry of Health.

Mohammed HO, Stipetic K, McDonough PL, Gonzalez RN, Nydam DV, Atwill ER. (2009) Identification of potential on-farm sources of *Listeria monocytogenes* in herds of dairy cattle. *American Journal of Veterinary Research*; 70(3): 383-388.

MPI. (2010) Notifiable organisms. Accessed at: <http://www.biosecurity.govt.nz/pests/registers/no>. Accessed: 24 September 2013.

MPI. (2013) Assessment of the microbiological risks associated with the consumption of raw milk. Wellington: Ministry for Primary Industries.

Muraoka W, Gay C, Knowles D, Borucki M. (2003) Prevalence of *Listeria monocytogenes* subtypes in bulk milk of the Pacific Northwest. *Journal of Food Protection*; 66(8): 1413-1419.

Nadon C, Woodward D, Young C, Rodgers F, Wiedmann M. (2001) Correlations between molecular subtyping and serotyping of *Listeria monocytogenes*. *Journal of Clinical Microbiology*; 39(7): 2704–2707.

National Assembly for Wales. (2006) The Food Hygiene (Wales) Regulations 2006. Schedule 6. Senedd: National Assembly for Wales.

National Conference of State Legislatures. (2013) Summary of raw milk statutes and administrative codes. Denver, CO: National Conference of State Legislatures.

Nesbitt A, Majowicz S, Finley R, Marshall B, Pollari F, Sargeant J, Ribble C, Wilson J, Sutler N. (2009) High-risk food consumption and food safety practices in a Canadian community. *Journal of Food Protection*; 72(12): 2575-2586.

NESP. (2013) National Enteric Surveillance Program (NESP) annual summary 2011. Including serotype and phage type tables for 2011, NESP and NML. Ontario: Public Health Agency of Canada.

Newkirk R, Hedberg C, Bender J. (2011) Establishing a milkborne disease outbreak profile: potential food defense implications. *Foodborne Pathogens and Disease*; 8(3): 433-437.

Nicol C, King N, Pirie R, Dufour M. (2010) Diagnostic and public health management practices of foodborne bacterial diseases. Client Report FW10044 for the New Zealand Food Safety Authority. Christchurch: Institute of Environmental Science and Research (ESR) Limited.

Nightingale K. (2010) *Listeria monocytogenes*: Knowledge gained through DNA sequence-based subtyping, implications, and future considerations. *Journal of the AOAC International*; 93(4): 1275-1286.

Nightingale KK, Schukken YH, Nightingale CR, Fortes ED, Ho AJ, Her Z, Grohn YT, McDonough PL, Wiedmann M. (2004) Ecology and transmission of *Listeria monocytogenes* infecting ruminants and in the farm environment. *Applied and Environmental Microbiology*; 70(8): 4458-4467.

Nightingale KK, Fortes ED, Ho AJ, Schukken YH, Grohn YT, Wiedmann M. (2005) Evaluation of farm management practices as risk factors for clinical listeriosis and fecal shedding of *Listeria monocytogenes* in ruminants. *Journal of the American Veterinary Medical Association*; 227(11): 1808-1814.

Northolt M, Beckers H, Vecht U, Toepoel L, Soentoro P, Wisselink H. (1988) *Listeria monocytogenes*: Heat resistance and behaviour during storage of milk and whey and making of Dutch types of cheese. Netherlands Milk and Dairy Journal; 42: 207-219.

Norwood DE, Gilmour A. (1999) Adherence of *Listeria monocytogenes* strains to stainless steel coupons. Journal of Applied Microbiology; 86(4): 576-582.

NZFSA. (2009) Raw Milk Products: A four-part survey on awareness and understanding of raw milk products, November 2008. Wellington: New Zealand Food Safety Authority.

NZFSA. (2010) New Zealand's food safety risk management framework. Wellington: New Zealand Food Safety Authority.

Oliver SP, Boor KJ, Murphy SC, Murinda SE. (2009) Food safety hazards associated with consumption of raw milk. Foodborne Pathogens and Disease; 6(7): 793-806.

Orsi RH, den Bakker HC, Wiedmann M. (2011) *Listeria monocytogenes* lineages: Genomics, evolution, ecology, and phenotypic characteristics. International Journal of Medical Microbiology; 301(2): 79-96.

Paris A, Riboldi E, Salmi F, Bacci C, Bonardi S, Brindani F. (2009) First results on the detection of *Listeria monocytogenes* in raw milk: Comparison of two different analytical methods. Veterinary Research Communications; 33(SUPPL. 1): S253-S255.

Perks M, Galloway Y, Baker M. (1999) Annual Surveillance Summary 1998. Porirua: ESR.

Pichler J, Much P, Kasper S, Fretz R, Auer B, Kathan J, Mann M, Huhulescu S, Ruppitsch W, Pietzka A, Silberbauer K, Neumann C, Gschiel E, de Martin A, Schuetz A, Gindl J, Neugschwandtner E, Allerberger F. (2009) An outbreak of febrile gastroenteritis associated with jellied pork contaminated with *Listeria monocytogenes*. Wiener Klinische Wochenschrift; 121(3-4): 149-156.

Pitt WM, Harden TJ, Hull RR. (1999) Antibacterial activity of raw milk against *Listeria monocytogenes*. Australian Journal of Dairy Technology; 54: 90-93.

Pouillot R, Albert I, Cornu M, Denis J-B. (2003) Estimation of uncertainty and variability in bacterial growth using Bayesian inference. Application to *Listeria monocytogenes*. International Journal of Food Microbiology; 81(2): 87-104.

Pradhan AK, Van Kessel JS, Karns JS, Wolfgang DR, Hovingh E, Nelen KA, Smith JM, Whitlock RH, Fyock T, Ladely S, Fedorka-Cray PJ, Schukken YH. (2009) Dynamics of endemic infectious diseases of animal and human importance on three dairy herds in the northeastern United States. Journal of Dairy Science; 92(4): 1811-1825.

Rahimi E, Momtaz H, Behzadnia A, Baghbadorani ZT. (2014) Incidence of *Listeria* species in bovine, ovine, caprine, camel and water buffalo milk using cultural method and the PCR assay. Asian Pacific Journal of Tropical Disease; 4(1): 50-53.

Ramos M, Juarez M. (2011) Milk: Sheep Milk. In: JW Fuquay (eds). Encyclopedia of Dairy Sciences (Second Edition). San Diego: Academic Press.

Rocha PR, Lomonaco S, Bottero MT, Dalmaso A, Dondo A, Grattarola C, Zuccon F, Iulini B, Knabel SJ, Capucchio MT, Casalone C. (2013) Ruminant rhombencephalitis-associated *Listeria monocytogenes* strains constitute a genetically homogeneous group related to human outbreak strains. *Applied and Environmental Microbiology*; 79(9): 3059-3066.

Rodriguez JL, Gaya P, Medina M, Nuñez M. (1994) Incidence of *Listeria monocytogenes* and other *Listeria* spp. in ewes' raw milk. *Journal of Food Protection*; 57(7): 571-575.

Roos Y. (2011) Water in dairy products: Significance. In: JW Fuquay (eds). *Encyclopedia of Dairy Sciences* (Second Edition) Amsterdam: Academic Press, Elsevier Ltd.

Ross T, Rasmussen S, Fazil A, Paoli G, Sumner J. (2009) Quantitative risk assessment of *Listeria monocytogenes* in ready-to-eat meats in Australia. *International Journal of Food Microbiology*; 131(2-3): 128-137.

Russell DG, Parnell WR, Wilson NC, Faed J, Ferguson E, Herbison P, Horwath C, Nye T, Reid P, Walker R, Wilson B, Tukuitonga C. (1999) *NZ Food: NZ People*. Wellington: Ministry of Health.

Ruusunen M, Salonen M, Pulkkinen H, Huuskonen M, Hellstrom S, Revez J, Hanninen ML, Fredriksson-Ahomaa M, Lindstrom M. (2013) Pathogenic bacteria in Finnish bulk tank milk. *Foodborne Pathogens and Disease*; 10(2): 99-106.

Ryser ET. (2011) Pathogens in milk: *Listeria monocytogenes*. In: JW Fuquay (eds). *Encyclopedia of Dairy Sciences* (Second Edition). San Diego: Academic Press.

Scallan E, Hoekstra R, Angulo F, Tauxe R, Widdowson M-A, Roy S, Jones J, Griffin P. (2011) Foodborne illness acquired in the United States - major pathogens. *Emerging Infectious Diseases*; 17(1): 7-15.

Schlech WF, 3rd, Schlech WFt, Haldane H, Mailman TL, Warhuus M, Crouse N, Haldane DJ. (2005) Does sporadic *Listeria* gastroenteritis exist? A 2-year population-based survey in Nova Scotia, Canada. *Clinical Infectious Diseases*; 41(6): 778-784.

Schoder D, Winter P, Kareem A, Baumgartner W, Wagner M. (2003) A case of sporadic ovine mastitis caused by *Listeria monocytogenes* and its effect on contamination of raw milk and raw-milk cheeses produced in the on-farm dairy. *Journal of Dairy Research*; 70(4): 395-401.

Scottish Parliament. (2006) *The Food Hygiene (Scotland) Regulations 2006*. Schedule 6. Edinburgh: Scottish Executive.

Secretary of State. (2013) *The Food Safety and Hygiene (England) Regulations 2013*. Schedule 6. London: Her Majesty's Government of the United Kingdom.

Seeliger H, Jones D. (1986) Genus *Listeria*. In: P Sneath; N Mair; M Sharpe et al. (eds). *Bergey's Manual of Systematic Bacteriology*. Volume 2. Baltimore: The Williams and Wilkins Co.

Shetty A, McLauchlin J, Grant K, O'Brien D, Howard T, Davies EM. (2009) Outbreak of *Listeria monocytogenes* in an oncology unit associated with sandwiches consumed in hospital. *Journal of Hospital Infection*; 72(4): 332-336.

Silk B, Mahon B, Griffin P, Gould L, Tauxe R, Crim S, Jackson K, Gerner-Smidt P, Herman K, Henao O. (2013) Vital signs: listeria illnesses, deaths, and outbreaks - United States, 2009-2011. *Morbidity and Mortality Weekly Report*; 62: 448-452.

Sindhu JS, Arora S. (2011) Milk: Buffalo milk. In: JW Fuquay (eds). *Encyclopedia of Dairy Sciences* (Second Edition). San Diego: Academic Press.

Sneyd E, Lopez L, Eglinton M, McDowell R, Margolin T. (2002) Annual surveillance summary 2001. ESR Client Report FW0156. Kenepuru: ESR.

Sneyd E, Baker M. (2003) Infectious diseases in New Zealand: 2002 Annual Surveillance Summary. ESR Client Report FW0332. Porirua: ESR.

Soboleva T, French N, Marshall J, Jamieson P. (2013) Microbiology of New Zealand bulk tank milk. *Proceedings of the International Association for Food Protection: European Symposium on Food Safety, 15 May 2013, Marseille, France*. Accessed at: <https://www.foodprotection.org/downloads/library/soboleva.pdf>. Accessed: 17 June 2013.

Soncini G, Valnegri L. (2005) Analysis of bulk goats' milk and milk-filters from Valtellina and Valchiavenna (Lombardy Prealps) for the presence of *Listeria* species. *Small Ruminant Research*; 58: 143-147.

Sutherland PS, Miles DW, Laboyrie DA. (2003) *Listeria monocytogenes*. In: AD Hocking (eds). *Foodborne Microorganisms of Public Health Significance*. Sixth edition. Sydney: Australian Institute of Food Science and Technology Inc.

Swaminathan B, Gerner-Smidt P. (2007) The epidemiology of human listeriosis. *Microbes and Infection*; 9(10): 1236-1243.

Thomas M, Murray RJ, Flockhart L, Pintar K, Pollari F, Fazil A, Nesbitt A, Marshall B. (2013) Estimates of the burden of foodborne illness in Canada for 30 specified pathogens and unspecified agents, circa 2006. *Foodborne Pathogens and Disease*; 10(7): 639-648.

Tschischkale R. (2011) Raw milk hazards and safety; Vorzugsmilch (Grade A raw milk) in Germany. *Proceedings of the International Raw Milk Conference: Raw Milk - Health or Hazard?* Prague, Czech Republic. Accessed at: http://www.slowfood.com/slowcheese/filemanager/bibliografia/Raw_Milk_Paper_Prague_Conference.pdf. Accessed: 19 December 2012.

University of Otago and Ministry of Health. (2011) A Focus on Nutrition: Key findings of the 2008/09 New Zealand Adult Nutrition Survey Wellington: Ministry of Health.

Van Kessel JAS, Karns JS, Lombard JE, Koprak CA. (2011) Prevalence of *Salmonella enterica*, *Listeria monocytogenes*, and *Escherichia coli* virulence factors in bulk tank milk and in-line filters from U.S. dairies. *Journal of Food Protection*; 74(5): 759-768.

Van Stelten A, Simpson JM, Ward TJ, Nightingale KK. (2010) Revelation by single-nucleotide polymorphism genotyping that mutations leading to a premature stop codon in *inlA* are common among *Listeria monocytogenes* isolates from ready-to-eat foods but not human listeriosis cases. *Applied and Environmental Microbiology*; 76(9): 2783-2790.

Vanegas MC, Vásquez E, Martinez AJ, Rueda AM. (2009) Detection of *Listeria monocytogenes* in raw whole milk for human consumption in Colombia by real-time PCR. *Food Control*; 20: 430–432.

Vilar MJ, Pena FJ, Perez I, Dieguez FJ, Sanjuan ML, Rodriguez-Otero JL, Yus E. (2010) Presence of *Listeria*, *Arcobacter*, and *Campylobacter* spp. in dairy farms in Spain. *Berliner Und Munchener Tierarztliche Wochenschrift*; 123(1-2): 58-62.

VKM. (2006) A qualitative assessment of the risks of transmission of microorganisms to humans resulting from the consumption of raw milk and raw cream in Norway. Oslo, Norway: Vitenskapskomiteen for mattrygghet (Norwegian Scientific Committee for Food Safety).

VKM. (2007) Risk associated with consumption of raw milk and colostrum. Oslo, Norway: Vitenskapskomiteen for mattrygghet (Norwegian Scientific Committee for Food Safety).

Waak E, Tham W, Danielsson-Tham ML. (2002) Prevalence and fingerprinting of *Listeria monocytogenes* strains isolated from raw whole milk in farm bulk tanks and in dairy plant receiving tanks. *Applied and Environmental Microbiology*; 68(7): 3366-3370.

Wagner M, Melzner D, Bago Z, Winter P, Egerbacher M, Schilcher F, Zangana A, Schoder D. (2005) Outbreak of clinical listeriosis in sheep: evaluation from possible contamination routes from feed to raw produce and humans. *Journal of Veterinary Medicine B. Infectious Diseases and Veterinary Public Health*; 52(6): 278-283.

Weatherill S. (2009) Report of the independent investigator into the 2008 listeriosis outbreak. Ontario: Government of Canada.

Weiler C, Ifland A, Naumann A, Kleta S, Noll M. (2013) Incorporation of *Listeria monocytogenes* strains in raw milk biofilms. *International Journal of Food Microbiology*; 161(2): 61-68.

Wenzel JM, Marth EH. (1990) Behavior of *Listeria monocytogenes* at 4 and 7°C in raw milk inoculated with a commercial culture of lactic acid bacteria. *Milchwissenschaft-Milk Science International*; 45(12): 772-774.

Wiedmann M, Evans KG. (2011) Diseases of dairy animals: Infectious diseases - Listeriosis. In: JW Fuquay (eds). *Encyclopedia of Dairy Sciences* (Second Edition). San Diego: Academic Press.

Xanthiakos K, Simos D, Angelidis AS, Nychas G-JE, Koutsoumanis K. (2006) Dynamic modeling of *Listeria monocytogenes* growth in pasteurized milk. *Journal of Applied Microbiology*; 100: 1289-1298.

Yilmaz T, Moyer B, MacDonell R, Cordero-Coma M, Gallagher M. (2009) Outbreaks associated with unpasteurized milk and soft cheese: An overview of consumer safety. Food Protection Trends; 29(4): 211-222.

7 APPENDIX 1: HAZARD AND FOOD

Further information on *L. monocytogenes* infection is summarised in a microbiological data sheet that can be accessed from:

http://www.foodsafety.govt.nz/elibrary/industry/Listeria_Monocytogenes-Science_Research.pdf

7.1 *L. monocytogenes* in Raw Milk and among Dairy Animals Overseas

Recent surveys investigating the prevalence of *L. monocytogenes* among dairy animals or in raw milk from countries that are of less relevance to New Zealand for comparative purposes are not included in this Risk Profile except when data are scarce (e.g. sheep and buffaloes' milk). This includes surveys conducted in Asian countries (e.g. China, India), African countries (e.g. Algeria) and Middle Eastern countries.

7.1.1 Detection of *L. monocytogenes* in raw milk overseas

7.1.1.1 *Cows' milk*

FSANZ has summarised 51 studies published between 1972 and 2006 that measured the prevalence and/or concentration of *L. monocytogenes* in raw cows' milk in various countries (see Table 3.5, page 55 of (FSANZ, 2009c)). The prevalence values ranged 0-68%, with a median value of 4%. The USFDA and USDA combined data from 45 prevalence surveys (19,080 raw milk samples, most from cows) published between 1985 and 2001 and calculated the same prevalence value of 4% (FDA/USDA, 2003). More recent studies on cows' milk are listed Table 7. When *L. monocytogenes* was detected, the prevalence values ranged 1-20%, except for one study of samples from milk silos (rather than individual farms) which found a prevalence of 50%.

In addition, EFSA collates data from EU member states on foods tested for *L. monocytogenes*. Of 1,421 raw milk samples tested at farm level during 2011, *L. monocytogenes* was detected in 3.7% (these samples were all taken in Italy and were mainly from raw milk intended for direct human consumption) (European Food Safety Authority and European Centre for Disease Prevention and Control, 2013). In the same year, *L. monocytogenes* was detected in 0.2% of 1,890 samples of raw milk collected at processing plants, and of 1,810 samples of milk tested at retail level, *L. monocytogenes* exceeded 100 CFU/g in 0.1% (the report does not state whether these were samples of raw or pasteurised milk).

Some data are available for the concentration of *L. monocytogenes* in raw cows' milk (Table 8). The concentration in most of the positive samples was <10 CFU/ml, but these studies showed that raw milk can contain higher concentrations (105 CFU/ml was reported in a French study). An Estonian survey of raw milk (all samples assumed to be cows' milk) found that of 230 samples tested near the end of their shelf-life, it was possible to enumerate *L. monocytogenes* in one sample, but the concentration was >1,000 CFU/g in that sample (Kramarenko *et al.*, 2013).

Table 7: Prevalence of *L. monocytogenes* in raw cows' milk overseas

Study location	Study period	Sample source	Number of samples	Prevalence: No. positive (% positive)	Reference
Brazil	NR	6 cheesemakers	155	ND	(Costa Sobrinho Pde <i>et al.</i> , 2012)
Colombia	NR	Local producers	81	13 (16) ¹	(Vanegas <i>et al.</i> , 2009)
Croatia	NR	NR	60	4 (7)	(Frece <i>et al.</i> , 2010)
Czech Republic	NR	Farms Vending machines	346 219	11 (3) 4 (2) ²	(Gelbicova and Karpiskova, 2012)
Estonia	2008-2010	At processing and retail	105 ³	19 (18)	(Kramarenko <i>et al.</i> , 2013)
Finland	2011	183 farms	183	10 (6)	(Ruusunen <i>et al.</i> , 2013)
Italy	2007	3 suppliers	15	1 (7)	(Paris <i>et al.</i> , 2009)
Italy	2009-11	112 farms 131 vending machines	298 320	5 (1.7) 5 (1.6) ⁴	(Bianchi <i>et al.</i> , 2013)
Italy	2008-2011	1,239 vending machines	60,907	83 (0.14) ⁵	(Giacometti <i>et al.</i> , 2013)
Spain	2005	98 farms	98	6 (6)	(Vilar <i>et al.</i> , 2010)
USA	2003-2006	50 farms	137	By PCR: 22 (16) ⁶	(Mohammed <i>et al.</i> , 2009)
USA	2004-2007	1 farm	172	34 (20)	(Latorre <i>et al.</i> , 2009)
USA	2006	5 cheesemakers	62	3 (5) ⁷	(D'Amico <i>et al.</i> , 2008)
USA	2007	536 farms	536	24 (4) ⁸	(Van Kessel <i>et al.</i> , 2011)
USA	2008	12 cheesemakers	45	ND	(D'Amico and Donnelly, 2010)
USA	2009/10	Silos (milk from multiple farms)	184 214	Direct plating: 23 (13) Enrichment: 107 (50)	(Jackson <i>et al.</i> , 2012)

NR, not reported; ND, not detected

(See next page for table notes)

Notes to Table 7:

¹ 21/81 (26%) positive by real-time PCR.

² 13 isolates were serotype 1/2a, two were 1/2b and the remainder was 4b.

³ The type of raw milk was not specified and it is assumed that it is all cows' milk.

⁴ Two of these vending machines were supplied by farms where milk samples also tested positive for *L. monocytogenes*. The serotypes were 1/2a (n = 6) and 4b/4e (n = 4).

⁵ Includes the vending machine results from Bianchi *et al.* (2013).

⁶ When milk from individual cows was tested (30 cows from each of the 50 farms on multiple occasions) the prevalence among cows was 13% (184/1412).

⁷ Two positive samples were from the same farm, sampled at different times.

⁸ While the actual prevalence was 4.5%, the weighted prevalence was calculated at 3.7%. Weighting was necessary to adjust for each dairy operation's probability of selection during sampling and to adjust (post-sampling) for nonresponse. Filter samples were also taken from most of the farms and the *L. monocytogenes* prevalence was 34/519 (6.6%; weighted prevalence 5.1%). There were 13 farms where *L. monocytogenes* was detected in the raw milk but not on the filter. The serotypes of isolates from raw milk are not reported separately, but all *L. monocytogenes* isolates in the study were serotyped as 1/2a, 1/2b or 4b.

Table 8: Counts of *L. monocytogenes* in raw cows' milk overseas

Study location	Study period	Number of samples	Concentration	Reference
Finland	2011	10	ND in 1 ml direct plating (8 samples)* 5 CFU/ml (1 sample) 30 CFU/ml (1 sample)	(Ruusunen <i>et al.</i> , 2013)
France	2000/01	14	ND in 2 ml direct plating (11 samples) 0.5 CFU/ml (1 sample) 5 CFU/ml (1 sample) 105 CFU/ml (1 sample)	(Meyer-Broseta <i>et al.</i> , 2003)
Sweden	1997/8	294	ND in 0.1 ml direct plating (291 samples) <10 CFU/ml (2 samples) 60 CFU/ml (1 sample)	(Waak <i>et al.</i> , 2002)
USA	2006	62	ND in 2 ml direct plating (59 samples) <1 CFU/ml (3 samples)	(D'Amico <i>et al.</i> , 2008)
USA	2009/10	107	MPN/ml: Minimum <0.0055 Mean 0.65 Median 0.092 Maximum 29	(Jackson <i>et al.</i> , 2012)

ND, not detected.

* These samples were positive by enrichment (see Table 7).

7.1.1.2 Goats' milk

FSANZ has summarised six studies published between 1996 and 2001 that measured the prevalence of *L. monocytogenes* in raw goats' milk in various countries (see Table 10 of (FSANZ, 2009a)). The prevalence ranged 0-4%. Results from other studies of the prevalence of *L. monocytogenes* in raw goats' milk are listed in Table 9. These studies indicate that *L. monocytogenes* is not often detected in goats' milk. No data on the concentration of *L. monocytogenes* in raw goats' milk were located.

7.1.1.3 Sheep milk

Only five studies of *L. monocytogenes* in sheep milk were located, and of these, the bacterium was only detected in two studies (Table 10). No data on *L. monocytogenes* concentration were located.

7.1.1.4 Buffaloes' milk

Studies of *L. monocytogenes* in buffaloes' milk are rare. A UK survey (1997-1999) of two producers of buffaloes' milk found 2/8 samples (25%) contained *L. monocytogenes* at a concentration of <10 CFU/ml (Anonymous, 1999). The pathogen was not detected in more recent surveys of buffaloes' milk carried out in India, Iran, Iraq and Pakistan (Abbas and Jaber, 2012; Chandio *et al.*, 2007; Doijad *et al.*, 2011; Rahimi *et al.*, 2014).¹⁵ No other studies were located.

¹⁵ *L. monocytogenes* was detected by PCR in 1/34 raw milk samples from buffaloes in Iran but the organism was not isolated from this positive sample (Rahimi *et al.*, 2014).

Table 9: Prevalence of *L. monocytogenes* in raw goats' milk overseas

Study location	Study period	Sample source	Number of raw milk samples	Prevalence: No. positive (% positive)	Reference
Australia (NSW)	2002	NR	59	ND	(FSANZ, 2009a)
Australia (NSW)	NR	NR	69	9 (1.4)	(Arnold and Coble, 1995)
Colombia	NR	Farms	90	2 (2)	(Albarracín <i>et al.</i> , 2008)
Italy	2002/03	8 farms	96	ND	(Soncini and Valnegri, 2005)
Italy	NR	10 farms (milk for cheesemaking)	60	ND	(Foschino <i>et al.</i> , 2002)
USA	2006	4 cheesemakers	49	ND	(D'Amico <i>et al.</i> , 2008)
USA	2008	5 cheesemakers	25	ND	(D'Amico and Donnelly, 2010)

NR, not reported; ND, not detected

Table 10: Prevalence of *L. monocytogenes* in raw sheep milk overseas

Study location	Study period	Sample source	Number of raw milk samples	Prevalence: No. positive (% positive)	Reference
Iran	2011	25 farms	56	1 (1.8)	(Rahimi <i>et al.</i> , 2014)
Morocco	2010	6 farms	30	ND	(Bouazza <i>et al.</i> , 2012)
Spain	NR	287 farms 17 transport tankers	1,052 136	23 (2)* 25 (18)	(Rodriguez <i>et al.</i> , 1994)
USA	2006	2 cheesemakers	22	ND	(D'Amico <i>et al.</i> , 2008)
USA	2008	4 cheesemakers	15	ND	(D'Amico and Donnelly, 2010)

NR, not reported; ND, not detected

* All positive samples were from only 19 farms. *L. monocytogenes* was not detected in milk produced by 268 (93%) farms.

7.1.3 *L. monocytogenes* among dairy animals

There are only a few surveys of *L. monocytogenes* among dairy animals. Surveys of faecal samples from dairy cows are summarised in Table 11, which shows prevalence to be highly variable. Longitudinal studies show that the in-herd prevalence can vary over time from no cows shedding *L. monocytogenes* to all cows in the herd (Ho *et al.*, 2007; Latorre *et al.*, 2011b). Consequently, prevalence values from a single sampling time are only indicative.

Only one survey was located on the prevalence of *L. monocytogenes* among dairy sheep (Esteban *et al.*, 2009). This study, conducted in Spain during 2003-2005, tested pooled faecal samples from 30 animals from each of 120 herds of dairy sheep and found that *L. monocytogenes* was present among 14% (17/120) of the herds. Faeces from 48-50 individual sheep from each of four positive herds were then tested to discover the prevalence among animals. *L. monocytogenes* was not detected in any of the animals from two of these herds, and the prevalences among animals in the remaining two herds were 2% (1/49) and 4% (2/48). All of the isolates were serotype 4b.

A US case-control study found the prevalence of *L. monocytogenes* among animals on farms where at least one recent case of listeriosis had been detected (case farms) was higher than the prevalence on control farms (28% of 24 case farms vs. 14% of 28 control farms) (Nightingale *et al.*, 2004). This study included herds of dairy cows and herds of goats and sheep (it was not reported whether these were milking herds). When data from case and control farms were pooled, carriage of *L. monocytogenes* among healthy animals was more prevalent in cows than in small ruminants ($P < 0.0001$), which suggests that goats and sheep are less likely to be asymptomatic carriers. This study also found that the diversity of *L. monocytogenes* strains on bovine farms was greater than that observed in small-ruminant farms. Nightingale *et al.* (2004) suggested that small-ruminant farms are characterized by a single or a few strains of *L. monocytogenes* that cause disease in small ruminants, whereas animals on bovine farms are frequently exposed to multiple *L. monocytogenes* subtypes.

Table 11: Prevalence of *L. monocytogenes* among dairy cows overseas (faecal samples or rectal grabs)

Study location	Study period	Sample source	Number of samples	Prevalence: No. positive (%)	Reference
Farm-level studies					
Spain	2003-05	82 herds	82 (pooled sample of 30 animals per herd)	38 (46)	(Esteban <i>et al.</i> , 2009)
Spain	2005	97 herds	97 (pooled sample of 3 animals per herd)	9 (9)	(Vilar <i>et al.</i> , 2010)
Animal-level studies (in-herd prevalence)					
Spain	2003-05	4 dairy herds positive for <i>L. monocytogenes</i> in pooled samples.	Herd A: 46 Herd B: 47 Herd C: 50 Herd D: 39 Total: 182	Herd A: 5 (11) Herd B: 34 (72) Herd C: 3 (6) Herd D: 2 (5) Total: 44 (24) ¹	(Esteban <i>et al.</i> , 2009)
USA	2004	1 herd	825	255 (31) ²	(Ho <i>et al.</i> , 2007)
USA	2006	1 herd	715	51 (7) ³	(Latorre <i>et al.</i> , 2009)
USA	2003-2006	30 cows from each of 50 herds, tested multiple times	1,414	By PCR: 608 (43%) ⁴	(Mohammed <i>et al.</i> , 2009)
USA	2004-2007	All cows from each of three different herds ⁵	Farm A: 327 Farm B: 111 Farm C: 132	Farm A: (4) Farm B: ND Farm C: ND	(Pradhan <i>et al.</i> , 2009)

NR, not reported

¹ All isolates were serotyped as 4b or 1/2a and multiple strains were identified by PFGE.

² Average prevalence. This herd was sampled 33 times over a four-month period (25 animals sampled each time). The prevalence ranged 0-100%.

³ Average prevalence. This herd was sampled eight times during the period 2004-07. The number of samples tested ranged 12-333, prevalence of *L. monocytogenes* ranged 0-26%. When this study was extended for another year, the overall prevalence was 57/935 (6%) (Latorre *et al.*, 2011b).

⁴ At least one cow was positive on each farm at some point between 2003 and 2006.

⁵ This study tested these three herds on multiple occasions, but only once was the entire herd tested (these results are reported in the table). The prevalence ranges across all sampling rounds were: Farm A, ND-25.5%; Farm C, ND-19.2%; *L. monocytogenes* was not detected from any faecal samples collected from cows on Farm B.

7.1.4 Recalls

Recalls are not necessarily linked to human illness, but recall information provides an indication of how often *L. monocytogenes* 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.

7.1.4.1 *European Union*

The Rapid Alert System for Food and Feed portal was used to retrieve recall records regarding pathogenic microorganisms in milk and milk products.¹⁶ There are 32 countries participating in this system (including all EU member states and Lichtenstein, Iceland, Norway and Switzerland). The search retrieved 268 records dating from 1985 to December 2013. There were no recalls issued for raw milk on the basis of contamination with *L. monocytogenes*.

7.1.4.2 *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.

7.1.4.3 *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 December 2013 were scanned for relevant records.¹⁷ No recalls for raw goats' milk were issued during this period.

7.2 **Consumption of Raw Milk in Other Countries**

7.2.1.1 *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 (Buzby *et al.*, 2013). Across all years of the survey, 3.4% (1,004/29,753) of respondents reported 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

¹⁶ <https://webgate.ec.europa.eu/rasff-window/portal/>. Search function parameters entered: Product type: Food; Notification type: Alert; Product category: Milk and milk products; Hazard category: Pathogenic micro-organisms. (Accessed 18 February 2014)

¹⁷ The FSANZ website (<http://www.foodstandards.gov.au/>) only contains recent recalls. The full dataset was kindly provided by FSANZ.

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 unpasteurised milk was significantly more prevalent among rural residents (9.0%) than among urban residents (0.4%, $P < 0.001$).

7.2.1.2 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 Dose Response

Dose response relationships may be described by an estimated “infectious dose” (point estimate), or a curve describing the probability of infection after ingestion of a defined number of cells. There is a trend towards the latter approach, where single hit models assume that any viable microorganism has a non-zero probability of causing infection and illness and acts independently, i.e. ingestion of even one cell still carries a risk of infection (EFSA, 2007). Nevertheless, point estimates from outbreaks can still provide useful information about the doses that caused illness.

8.1.1 Invasive listeriosis

8.1.1.1 *Point estimates from outbreaks*

No outbreaks were located where all critical information necessary to estimate dose was known (i.e. the concentration of *L. monocytogenes* in the food consumed and the amount of food consumed). Three listeriosis outbreaks provide indicators:

- USA, meat frankfurters: The outbreak strain (serotype 4b) was only detected at low concentrations (<0.3 CFU/g) in the recalled product, but product testing also recovered a *L. monocytogenes* strain of serotype 1/2a at concentrations as high as 3,000 CFU/g (Mead *et al.*, 2006).
- Switzerland, ham: Testing of two ham samples found concentrations of 4,800 and 470 CFU/g *L. monocytogenes*, respectively. A point estimate can be calculated as 4.7×10^4 CFU ($470 \text{ CFU/g} \times 100 \text{ g}$) (Hächler *et al.*, 2013).
- Finland, butter, immunocompromised people: Exposure estimated as being between 3-4 \log_{10} CFU, or up to 6 \log_{10} CFU for a highly contaminated sample (Lyytikäinen *et al.*, 2000).

8.1.1.2 *Probability of infection*

Dose response models for *L. monocytogenes* are affected by determinants of virulence between different *L. monocytogenes* strains, differing susceptibilities among humans, the impacts of food matrices, and the reliability of extrapolations to lower average doses (Hoelzer *et al.*, 2013).

A FAO/WHO working group used two single hit models, one for the population with increased susceptibility (supposed to represent 15% to 20% of the total population but 90 to 98% of the cases) and the other for the rest of the population (EFSA, 2007; FAO/WHO, 2004b; Ross *et al.*, 2009).

$$P = 1 - e^{-RN}$$

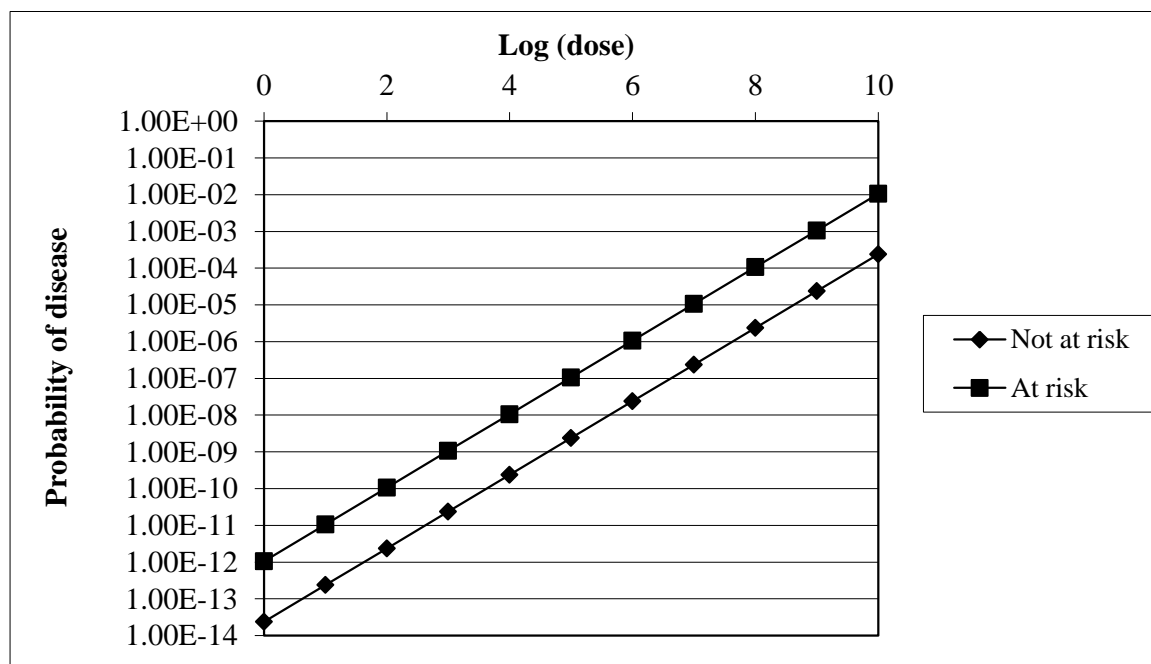
Where:

- P is the probability of invasive listeriosis;
- N is the number of *L. monocytogenes* cells consumed; and

- R is the average probability (recognising variation in pathogen virulence and host susceptibility) that ingestion of a single *L. monocytogenes* cell leads to illness.

The value of R depends on the susceptibility of the population group and is constant for a given population. R values for susceptible groups and the non-immunocompromised populations are given. Figure 3 shows the dose response curves for high and low susceptibility groups.

Figure 3: Dose response models at median values for R for disease caused by *L. monocytogenes*



Note to Figure 3: Information provided by Dr. Tom Ross, University of Tasmania, and is that used in the FAO/WHO *Listeria* quantitative risk assessment (FAO/WHO, 2004b).

There has been considerable discussion about the potential for a relaxation of the zero tolerance approach for *L. monocytogenes* contamination of food adopted by some countries, to a tolerance of up to 100 CFU/g. While the only completely safe dose of *L. monocytogenes* is zero, even for healthy people, the model indicates that the probability of invasive disease following exposure to even moderate levels of cells is very low. Most listeriosis cases are due to consumption of RTE foods able to support growth of *L. monocytogenes* and containing levels markedly above 100 CFU/g (Chen *et al.*, 2003; EFSA, 2007).

8.1.2 Non-invasive listeriosis (febrile gastroenteritis)

8.1.2.1 *Point estimates from outbreaks*

The concentration of *L. monocytogenes* in foods causing six outbreaks of febrile gastroenteritis suggest that very high numbers of cells are required to cause this illness (Table 12). Samples of contaminated RTE meat taken as a result of a series of outbreaks in New Zealand contained concentrations of *L. monocytogenes* that ranged from detected (<100 CFU/g) to 1.8×10^7 (ham, see Table 12) so it is possible that lower doses may cause disease in some people (Sim *et al.*, 2002).

Table 12: Concentration of *L. monocytogenes* in foods linked to outbreaks of febrile gastroenteritis

Food vehicle	Concentration of <i>L. monocytogenes</i> in the food (CFU/g)	Reference
Ham	1.8×10^7	(Sim <i>et al.</i> , 2002)
Cheese	$3.0 \times 10^1 - 6.3 \times 10^7$	(Carrique-Mas <i>et al.</i> , 2003)
Tuna and corn salad	$>10^6$	(Aureli <i>et al.</i> , 2000)
Precooked, sliced turkey	1.6×10^9	(Frye <i>et al.</i> , 2002)
Chocolate milk	$8.8 \times 10^8 - 1.2 \times 10^9$	(Dalton <i>et al.</i> , 1997)
Cold smoked trout	1.9×10^5	(Miettinen <i>et al.</i> , 1999)
Jellied pork	$3 \times 10^3 - 3 \times 10^4$	(Pichler <i>et al.</i> , 2009)

8.1.2.2 Probability of infection

No dose response relationships were located.

8.2 *L. monocytogenes* Infection Overseas

8.2.1 Incidence

Table 13 shows the reported incidence of listeriosis for several countries for the year 2011 (the most recent year for which data were available for all countries). New Zealand's 2011 listeriosis rate of 0.6 per 100,000 is near the higher end of the range of rates listed in Table 13 (range 0.2-0.9; mode = 0.3). Comparisons of listeriosis rates between countries must be made cautiously, as reporting practices may differ.

Table 13: Reported incidence data for notified cases of listeriosis overseas

Country	Year	Incidence (cases/100,000)	No. of notified cases	Ref. ¹
Australia	2010	0.3	71	a
	2011	0.3	70	a
	2012	0.4	93	a
North America				
USA ²	2011	0.3	145	b
Canada	2011	0.4	NR	c
EU countries				
EU notifications	2011	0.3	1,476	d
Austria	2011	0.3	26	d
Belgium	2011	0.6	70	d
Czech Republic	2011	0.3	35	d
Denmark	2011	0.9	49	d
Finland	2011	0.8	43	d
France	2011	0.4	282	d

Country	Year	Incidence (cases/100,000)	No. of notified cases	Ref. ¹
Germany	2011	0.4	330	d
Ireland	2011	0.2	7	d
Netherlands	2011	0.5	87	d
Poland	2011	0.2	62	d
Spain	2011	0.8	91	d
Sweden	2011	0.6	56	d
United Kingdom	2011	0.3	164	d
Non-EU countries				
Iceland	2011	0.3	1	d
Norway	2011	0.4	21	d
Switzerland	2011	0.7	47	d

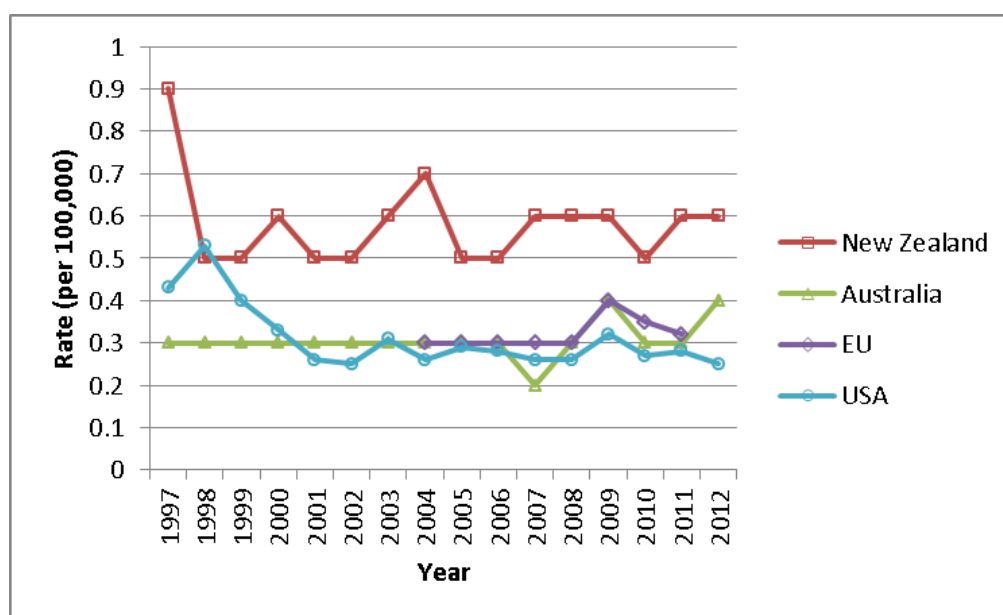
¹ References:

- a. (Australian Government, 2013)
- b. (CDC, 2012b)
- c. (NESP, 2013)
- d. (European Food Safety Authority and European Centre for Disease Prevention and Control, 2013)

² Data is for the 10 sentinel states monitored by FoodNet, not the whole of the USA.

It has been reported that the incidence of sporadic listeriosis has been declining in most industrialised countries (Swaminathan and Gerner-Smidt, 2007). This statement was supported by limited data from 2004 or before. Incidence data for the period 1997-2012 shows that the rates of listeriosis in Australia, the USA and the EU have remained stable over the most recent decade, as has the rate in New Zealand (Figure 4).

Figure 4: Rates of listeriosis in New Zealand, Australia, the USA and the EU, 1997-2012



Note to Figure 4: Data were only available for the EU for the period 2004-2012

References:

- Australia: (Australian Government, 2013)
- USA: (CDC, 2013)

EU: (European Food Safety Authority, 2005; European Food Safety Authority and European Centre for Disease Prevention and Control, 2006; 2007; 2009; 2010; 2011; 2012; 2013)

EFSA lists the reported cases of human listeriosis for 26 EU Member States and 3 Non-Member States for the year 2011 (European Food Safety Authority and European Centre for Disease Prevention and Control, 2013). Sixteen Member States reported hospitalisation status for all or the majority of their cases (representing 44% of all EU cases), and on average, 94% of the cases were hospitalised. In 10 Member States, 100% of cases were hospitalised. Nineteen Member States reported 134 deaths due to listeriosis, of which 46 deaths were reported by France. The EU case fatality rate was 12.7 % among the 1,054 confirmed cases for which this information was reported (71.4 % of all confirmed cases).

In the USA, 93% of cases in the 10 FoodNet sentinel sites were hospitalised during 2011 and 28/145 (19%) cases ended in death (CDC, 2012b).

8.2.1.1 Community level estimates

The number of notified *L. monocytogenes* infections only represents a proportion of total cases, since not all cases will come into contact with public health agencies. Estimates for the annual number of community *L. monocytogenes* infections and annual rates of infection have been published:

- USA: 1,607 (90% CrI: 563-3,193) cases of domestically-acquired *L. monocytogenes* infection, of which 99% were estimated as being foodborne (1,591 cases, 90% CrI: 557-3,161) (Scallan *et al.*, 2011). This was based on surveillance data from 2000 to 2008. Using the 2006 USA population of 299 million, both case numbers correspond to a rate of 0.5 per 100,000.
- Canada: 0.6 cases of domestically-acquired foodborne *L. monocytogenes* infection per 100,000 people per year (Thomas *et al.*, 2013). This estimate was 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.

These estimates are similar to the reported incidence of listeriosis in those countries because the serious health effects caused by listeriosis means that most cases will be notified, so the underreporting and underdiagnosis multipliers are small.

8.2.2 Outbreaks

Raw milk has been implicated in outbreaks of foodborne disease (ACMSF, 2011a; Cartwright *et al.*, 2013; Langer *et al.*, 2012; Newkirk *et al.*, 2011; Silk *et al.*, 2013), but raw milk not been the suspected or confirmed cause of any outbreaks of listeriosis infection since 1986. Raw milk was the cause of a protracted listeriosis outbreak spanning 1949-1957 in Germany involving about 100 cases (Seeliger and Jones, 1986). Raw milk and organically grown vegetables were the suspected causes of 28 cases of listeriosis infection in Austria in 1986 (Allerberger and Guggenbichler, 1989). A sporadic case of listeriosis was linked to raw milk in Denmark (Jensen *et al.*, 1994).

Annual summaries published by EFSA for EU countries do not contain enough detail to show whether any of the reported outbreaks of *L. monocytogenes* infection were caused by consumption of raw milk.

8.2.3 Case control studies investigating raw milk as a risk factor

Two case controls studies were located where raw milk was considered as a possible risk factor for listeriosis but odds ratios could not be calculated because the controls did not report consumption of raw milk:

- Australia: 112 non-perinatal cases and 85 controls, 19 perinatal cases and 12 controls. Consumption of raw or unpasteurised milk in the month prior to specimen collection date was reported by 1/112 non-perinatal cases and 1/19 perinatal cases. None of the controls in either group reported consuming raw milk (Dalton *et al.*, 2011).
- Denmark: 50 listeriosis patients (hospitalised, perinatal and non-perinatal) and 40 matched controls (hospitalised at the same department on the same date as the patient). Consumption of unpasteurised milk during the month prior to the *L. monocytogenes* positive specimen was reported by 11% of patients. None of the controls reported consuming raw milk (Jensen *et al.*, 1994).

8.3 Risk Assessment and Other Activities Overseas

Two risk topics are applicable to *L. monocytogenes* in raw milk: Assessments that consider raw milk and assessments that consider *L. monocytogenes* in RTE foods.

8.3.1 Risk assessments considering raw milk

8.3.1.1 *Australia*

FSANZ published two microbiological risk assessments in 2009, one addressing raw cows' milk and one raw goats' milk (FSANZ, 2009a; c). Both considered the risk of illness from raw milk contaminated with *L. monocytogenes* (as well as other pathogens). Both found that the risk of listeriosis from consumption of raw milk was very low for the general population and high for the susceptible population.

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 susceptible and 'healthy' (non-susceptible) populations. Three dose response R-values were separately modelled for the susceptible population:

- 5.85×10^{-12} as used in the FAO/WHO risk assessment (FAO/WHO, 2004a);
- 1.31×10^{-8} as determined for more virulent strains of *L. monocytogenes* (Chen *et al.*, 2006); and
- 5.01×10^{-11} as determined for less virulent strains of *L. monocytogenes* (Chen *et al.*, 2006).

The time period for the total supply chain was not fixed (unlike the New Zealand model).

There were no predicted cases of listeriosis among the 'healthy' population (based on the FAO/WHO R-value).

The mean predicted cases of listeriosis among the susceptible population per 100,000 daily serves of raw milk ranged between:

- <1-0.2 when milk is consumed from farm bulk milk tanks (single 250 ml serving);
- 0.1-17 when milk is consumed after farm gate sales (includes transport home and storage in domestic refrigerator; serving size distribution based on adult consumption with a mean daily consumption of 397 ml); and
- 0.7-170 when milk is consumed after retail purchase (includes additional packaging, distribution and retail storage components; serving as for farm gate sales).

The upper mean values in the ranges reported above are the outputs from models using the R-value for virulent strains of *L. monocytogenes*, i.e. they assume that all *L. monocytogenes* present in raw milk are highly virulent strains. The increase in the number of illnesses between milk consumed from the farm and milk consumed after retail purchase reflects the extended supply chain and the ability of *L. monocytogenes* to grow at refrigeration temperatures, and the larger serving size. Some assumptions had to be made where data gaps existed. Some important data gaps were the prevalence and concentration of *L. monocytogenes* in Australian dairy cows and raw milk produced in Australia, and raw milk consumption and the demographics of the consuming population in Australia.

The raw goats' milk risk assessment, using qualitative risk rating, rated the risk to public health and safety from *L. monocytogenes* in raw goats' milk as 'very low' for the general population and 'high' for the susceptible population. The risk assessment noted that susceptible populations were likely to consume goats' milk, but the demographics of the consuming population were unknown as were the frequency and amount of consumption. Data on the prevalence and concentration of pathogens in the domestic raw goat milk supply were also scarce.

8.3.1.2 United States of America

One of the objectives of a USA-based risk assessment was to estimate the risk of listeriosis for susceptible raw milk consumers due to the presence of *L. monocytogenes* in raw milk sold by permitted raw milk dealers and for people who consume raw milk on farms (Latorre *et al.*, 2011a). The probability of listeriosis per serving of milk was calculated for 'intermediate' and two susceptible populations (pregnant women and their foetuses or newborns, and the elderly), on the basis of the milk being purchased from the farm bulk tank, from a farm store or from a retail outlet.¹⁸ For milk purchased from a farm bulk tank, the median probability of listeriosis per serving was:

- 1.8×10^{-15} for the 'intermediate' population;
- 1.1×10^{-13} for the perinatal population; and
- 1.8×10^{-14} for the elderly population.

These probabilities increased by 1-2 orders of magnitude when the purchases were made from a farm store or retail outlet due to the longer chill chain giving more opportunity for *L.*

¹⁸ The intermediate group includes susceptible populations not captured in the other two groups, e.g. cancer, AIDS and transplant patients (FDA/USDA, 2003).

monocytogenes growth. These outputs were based on an overall prevalence of 1.2% for *L. monocytogenes* in bulk tank raw milk and assuming that if bulk tank milk contained *L. monocytogenes* it is at a concentration of at least 0.04 CFU/ml (limit of detection for testing a 25 ml sample of milk). The temperature of the home refrigerator had the greatest influence on the probability of listeriosis (e.g. increasing the temperature from 4 to 8°C resulted in an approximately seven-fold increase in the number of predicted listeriosis cases). Overall, the model predicted a low number of annual listeriosis cases due to consumption of raw milk, but the demographics of the raw milk consuming population was an important data gap.

8.3.1.3 United Kingdom

The Advisory Committee on the Microbiological Safety of Foods (ACMSF), who provides 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.

8.3.1.4 Norway

The Norwegian Scientific Committee for Food Safety has published two risk assessments, one considering raw cows' milk and one considering raw milk from other species (sheep, goat, horse and reindeer) (VKM, 2006; 2007). The Committee considered enterohaemorrhagic *Escherichia coli* and *L. monocytogenes* to present the highest risk of all the pathogens that might be present in raw Norwegian milk due to the severity of the diseases they cause. They concluded that the probability for transmission of *L. monocytogenes* through raw milk and cream is relatively high, and acknowledged that although *L. monocytogenes* seldom causes disease in a healthy person the consequences per case can be "dramatic". *L. monocytogenes* was also recognised for its ability to survive and replicate in biofilms within equipment used for production and storage of raw milk. 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.

8.3.1.5 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 *L. monocytogenes* among other pathogens. *L. monocytogenes* was recognised as being potentially present in raw cows' milk, but the committee 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).

8.3.2 Risk assessments considering *L. monocytogenes* in RTE foods

8.3.2.1 USA

A quantitative risk assessment for *L. monocytogenes* in RTE foods consumed by the United States population was published by the USFDA and the USDA in 2003 (FDA/USDA, 2003). The risk assessment considered raw milk as a separate food group, ranked alongside 22 other RTE food groups. On a per serving basis, raw milk was ranked 4th highest (“high risk”, >5 cases per billion servings) in terms of risk, behind deli meats, frankfurters not reheated and pâté and meat spreads. On a per annum basis, raw milk was ranked 7th (“moderate risk”, >1 to 10 cases per annum) because of the low number of annual servings ($\leq 1 \times 10^9$). These findings are based on the assumptions that the contamination frequency is moderate (>2% to <5%), the contamination level at retail is moderate (>0.1% to <0.6% of predicted servings at 3-6 log₁₀ CFU), serving sizes are large (≥ 90 g) and growth of *L. monocytogenes* during refrigerated storage is high (≥ 0.2 log₁₀ CFU/day). The relative risk ranking results of the 23 food types (per annum and per serving) were used in cluster analysis, which ranked raw milk as high risk.

The risk assessment also estimated the number of listeriosis cases per serving and per annum from consumption of raw milk by more vulnerable subpopulations. As expected, the risk per serving values for the perinatal, immunocompromised (“intermediate”, see Section 8.3.1.2) and elderly subpopulations were higher than for the general population, but the number of cases per annum values were lower as a result of the susceptible population groups containing a smaller number of people who consume raw milk less frequently than the general population.

There were plans for this risk assessment to be updated at the time of the preparation of this report.¹⁹

8.3.2.2 FAO/WHO

In 2004 the FAO and WHO jointly published a risk assessment of *L. monocytogenes* in RTE foods (FAO/WHO, 2004a; b). One of the objectives was to estimate the risk of serious illness from *L. monocytogenes* in foods that support its growth, and foods that do not, under specific storage and shelf-life conditions.

Some of the key findings from this risk assessment were:

- Nearly all the listeriosis cases predicted by the model were the result of eating high numbers of *L. monocytogenes* (i.e. consumption of foods that do not meet current standards, whether that is zero-tolerance or 100 CFU/g); and
- Control measures that reduce frequencies of contamination have proportional reductions in rate of illness. Control measures that prevent high levels of contamination at point of consumption would be expected to bring about the greatest reduction in rate of illness.

¹⁹ <https://www.federalregister.gov/articles/2011/04/07/2011-8360/update-of-the-2003-interagency-quantitative-assessment-of-the-relative-risk-to-public-health-from> (accessed 18 February 2014).

8.3.2.3 *European Union*

In 2007 EFSA published a scientific opinion on *L. monocytogenes* in RTE foods, which updated and expanded a previous scientific opinion published by the European Commission, and took the form of a risk assessment (EFSA, 2007). One objective of the updated opinion was to provide scientific advice on different levels of *L. monocytogenes* in RTE foods (absence in 25 g, 100 CFU/g and higher levels) and the related risk for human illness. They found that most listeriosis cases were due to consumption of RTE foods able to support *L. monocytogenes* growth and containing concentrations well above 100 CFU/g, and these foods should be the target of risk management measures. The Panel suggested that, for RTE foods in which *L. monocytogenes* can grow (such as raw milk), applying a zero tolerance for *L. monocytogenes* (absence in 25 g) throughout the shelf life might result in foods being classified as unsatisfactory, although they are of low risk. Alternatively, tolerating 100 CFU/g throughout shelf life means accepting the probability that foods with more than 100 CFU/g will be consumed, since it is impossible to predict with certainty that this level will not be exceeded. The impact on public health would depend on whether concentrations markedly above 100 CFU/g are reached.

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 USDA.