



Assessment of the microbiological risks associated with the consumption of raw milk

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Abbreviations

ACMFS	Advisory Committee on the Microbiological Safety of Foods (UK)
AHB	Animal health Board
CDC	Centers for Disease Control and Prevention
Codex	Codex Alimentarius Commission
DHB	District Health Boards
ESR	Institute of Environmental Science & Research Ltd
FAO	Food and Agriculture Organization of the United Nations
FDA	United States Food and Drug Administration
FASFC	Comite Scientifique de l'agence federale pour la securite de la chaine alimentaire (Belgian Federal Agency for the Safety of the Food Chain)
FSANZ	Food Standards Australia New Zealand
HUS	Haemolytic ureamic syndrome
ICMSF	International Commission on Microbiological Specifications for Foods
MPI	Ministry for Primary Industry
NNS	National Nutrition Survey
NZFSA	New Zealand Food Safety Authority
RMP	Risk Management Programme
SCC	Somatic Cell Count
STEC	Shiga toxin-producing <i>Escherichia coli</i>
TAC	Total Aerobic Count
TBC	Total bacteria count
WHO	World Health Organization

Executive Summary

This report provides a scientific evaluation of the public health risk associated with the consumption of untreated raw milk (predominantly cows milk) in New Zealand. It covers risks from microbial pathogens only and also reviews milk production and handling practices. Disease burden is estimated under present and alternative New Zealand production and sales circumstances.

Analysis of human epidemiological information from New Zealand is in accord with those in other countries, where outbreaks of campylobacteriosis, salmonellosis and STEC infection associated with raw milk have been reported. Between 2006 and 2012 twenty two outbreaks of illnesses associated with consumption of raw milk were reported in New Zealand. Most of these outbreaks involved children under 15 years old. There have been a number of confirmed outbreaks in New Zealand over this period, but the precise disease burden associated with raw milk remains difficult to estimate due to affected individuals reporting other potential risk factors, inherent difficulties in collecting epidemiologically robust data, and the lack of microbiological confirmation from the food product.

This risk assessment considered primarily domestic information from published and unpublished sources on prevalence and levels of pathogens in raw cow milk and in cattle. Results of international studies were included only in cases when specific New Zealand data were unavailable.

Quantitative risk assessment undertaken during this assessment modelled the following scenarios:

- untreated raw milk consumed in the home after farm-gate sale (with or without use of vending machines);
- raw milk consumed in the home after purchasing milk off-farm (collection points, farm markets);
- raw milk consumed in the home after packaging, distribution and retail sale.

The risk model assumed strict integrity of the supply chain from the farm to the consumer and the same duration from milk production to its consumption, independently of whether the milk was purchased at the farm gates or in a retail store. Only the potential bacterial growth/reduction that might occur along the supply chain was considered in the model (no cross contamination beyond the farm gates is assumed).

The mean predicted numbers of illnesses per 100,000 average servings for various scenarios following consumption of untreated raw milk are:

- 139 cases of campylobacteriosis, 70 cases of STEC, 8 cases of salmonellosis if consumed milk was purchased at the farm gate (urban population, no vending machines);
- 124 cases of campylobacteriosis, 75 cases of STEC, 8 cases of salmonellosis if consumed milk was purchased off-farm;
- 30 cases of campylobacteriosis, 56 cases of STEC, 7 cases of salmonellosis if consumed milk was purchased at retail;
- less than one case of listeriosis in susceptible populations was predicted for each of these scenarios.

Epidemiological evidence indicates that while the mean estimates generated using the median dose-response model under current conditions are similar to those in Italy and less than those from Australia, they are somewhat higher than those that might be actually occurring in New

Zealand. Notwithstanding this, the comparative values generated from the model under different scenarios provide valuable insights on relative risks as follows:

- increased consumption of raw milk corresponds to a proportional increase in the predicted number of illnesses;
- risk of campylobacteriosis for urban population is five times greater than for the population with acquired immunity (such as observed in on-farm residents);
- increased duration of period between production and consumption of raw milk is strongly associated with a rise in the predicted number of illnesses;
- improved on-farm hygiene (eliminating major faecal contamination events) is associated with a greater than 30% decrease in cases of campylobacteriosis and 22% decrease in cases of STEC caused by raw milk consumption;
- use of vending machines reduces the risk of campylobacteriosis by 30% for the farm gate scenario.

The safety of raw milk is influenced by a combination of management and control measures along the entire dairy supply chain and no specific husbandry practices can ensure freedom from pathogens. Control measures applied throughout raw milk procurement activities and during the supply chain to the consumer are primarily aimed at minimising any initial bacterial contamination and subsequent growth but cannot eliminate the presence of pathogens in raw milk.

1 Background

New Zealand raw milk is considered to be of a high hygienic standard. Historically however, the Ministry for Primary Industries (MPI) has deemed raw milk consumption to be unsafe because, unlike pasteurised milk, it has not been subject to heat treatment to kill harmful bacteria e.g. *Campylobacter* spp., pathogenic *Escherichia coli* (*E. coli*) such as shiga toxin producing *E. coli* (STEC), *Listeria monocytogenes* (*L. monocytogenes*), *Mycobacterium bovis* (*M. bovis*), *Salmonella* spp, and *Staphylococcus aureus* (*S. aureus*)¹.

Section 11A of the *Food Act 1981* restricts the sale of raw drinking milk by allowing milk producers (dairy farmers) to sell a maximum of five litres from their farm to people who intend to consume it themselves or give it to their family. This provision is commonly referred to as ‘farm gate sales’ and it acts also as a prohibition on the sale of raw milk for drinking on a larger or more commercial scale.

Under the *Animal Products Act 1999*, raw milk must be harvested and stored in accordance with an approved Risk Management Programme (RMP) that covers risks associated with supplying raw milk for drinking. RMPs that cover the supply of milk for another activity, such as supplying milk to a large processing company for pasteurisation or for making cheese, do not cover or adequately manage the risks associated with farm gate sales.

As of 2012, MPI had not registered any RMPs for raw drinking milk sales. Nevertheless, farm gate sales are occurring and often going beyond farm gates involving purchases through the internet and sales at collection points outside farm gates.

In 2011, MPI consulted on the requirements that allow dairy farmers to sell limited quantities of raw (unpasteurised) drinking milk from their dairy premises direct to consumers. As a result of the consultation MPI is reviewing the current prohibition on the sale of raw drinking milk other than in limited quantities at the farm gate.

MPI will consult on any new regulatory proposals relating to the production and sale of raw drinking milk, including the animal health and hygiene requirements, any limits on the quantity that can be purchased and sold and any proposals for sales of raw milk outside of the farm. In the interim, the current restrictions apply and people can buy up to 5 litres of raw milk from the farm gate for their own personal use or to provide to their family to consume.

To inform any increase in daily limits and the necessity or otherwise of a maximum daily distribution limit for farmers a scientific risk analysis is required. This document seeks to assess the risk to New Zealand consumers of consuming untreated raw milk and to inform MPI of the risks or otherwise of expanding raw drinking milk sales beyond the farm gate. It utilises available scientific data and discusses uncertainty and variability in the conclusions drawn.

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¹ Throughout the document species names, e.g. *Campylobacter* spp and STEC, of organisms are used except where a subspecies, e.g. *Campylobacter jejuni* and *E. coli* O157 has been reported specifically. *Salmonella* spp refers to *Salmonella enterica* subspecies *enterica*, thereby excluding *Typhi*, *Paratyphi* and *Choleraesuis*.

2 Introduction

2.1 DEFINITION OF RAW MILK

For the uses of this assessment, raw milk means 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.

2.2 PURPOSE

The purpose of this assessment is to provide an objective appraisal of the available scientific data on the public health risk associated with the consumption of raw milk in New Zealand and the impact on the risk of widening the availability of raw milk to consumers through commercial outlets.

The assessment has been undertaken to address the following risk management questions:

- What risks does the consumption of raw drinking milk likely pose to New Zealand consumers?
- What are the factors that have the greatest impact on likely risks associated with consumption of raw drinking milk?
- What effect would wider availability of raw drinking milk have on the risk estimates and what options are there for controlling of these risks?

The assessment considers specific microbiological hazards in raw milk, and evaluates epidemiological and other scientific data to determine whether these hazards have presented, or are likely to present, a public health risk. The assessment also aims to identify where in the production and supply chain these hazards may be introduced, decreased or amplified.

2.3 SCOPE

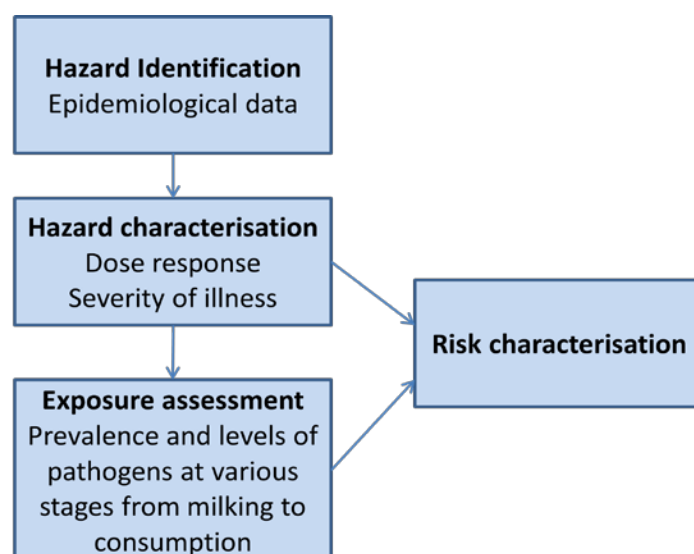
The scope of this risk assessment is to assess the microbiological risk from drinking raw milk for New Zealand consumers and the likely impact of expanding the sale of raw drinking milk beyond the farm gate. This assessment will concentrate on risks associated with consumption of raw cows' milk as scientific data available on microbiological quality and consumption of raw goats' milk in New Zealand are insufficient for a detailed raw goat milk risk assessment. However this issue will be discussed briefly in Appendix 10.2. Consumption of sheep and buffalo raw milk in New Zealand is negligible and therefore risk assessment of these species' milk is not justifiable.

Assessing the risks resulting from consumption of further processed raw milk products, such as yoghurt, kefir or cheese etc., are also outside the scope of this risk appraisal. The cases where processing of raw milk eliminates or dramatically increases the risk of specific microbiological hazards will however be noted.

Evaluation of availability, feasibility and cost of mitigations is out of the scope of this risk assessment.

2.4 APPROACH

The assessment is based upon the Codex Committee on Food Hygiene Principles and Guidelines for the Conduct of Microbiological Risk Assessment (*Codex Alimentarius* Commission, 1999) and includes the following steps.



Risk characterisation utilises the outputs of quantitative modelling which estimate the risk per random daily serve of raw milk to consumers from Shiga toxin producing *Escherichia coli* (STEC), *Listeria monocytogenes*, *Salmonella* spp. and *Campylobacter* spp present in raw milk.

A risk profile for *Mycobacterium bovis* (*M. bovis*) in raw milk is presented in Annex 1. This contains an exposure assessment for the likelihood of unpasteurised cows' milk being contaminated with *M. bovis* when supplied to consumers at the farm gate.

Exposure to Shiga toxin producing STEC, *L. monocytogenes*, *Salmonella* spp. and *Campylobacter* spp has been evaluated semi-quantitatively through the full product pathway from milk collection to milk consumption. Various stages in the supply chain from farm gates to the consumer have been considered to compare the risk under alternative scenarios.

Factors that affect whether, and at what level, pathogens are present in raw milk at the point of consumption are:

- initial microbial composition of milk;
- potential growth or reduction of pathogens after milking; and
- potential cross-contamination during transportation of raw milk, retail or at the consumers' home.

The scientific literature suggests that contamination can occur at any point along the supply chain. However, the literature does not describe the frequency and level of contamination that would inform model inputs for that source of contamination. Consequently, only the potential bacterial growth/reduction that might occur along the supply chain was considered in the risk model (no cross contamination beyond the farm gates is assumed).

3 International risk assessments for raw drinking milk

The safety of raw milk for human consumption has been under scrutiny by many food safety authorities and public health agencies all around the world. An increasing interest in consuming untreated raw milk has stimulated new research aimed at estimating the safety of drinking unpasteurised milk. Several risk assessments have now been prepared by, or for, the competent authority in a number of jurisdictions. Most of the existing risk assessments are country specific (focussed on the pathogens characteristic of that country, or focussing on a specific distribution pathway which is most popular in that country) and so their application to other countries is not straightforward. A summary of the key findings from published risk assessments of human health risks from the consumption of raw milk is presented in Appendix 10.1.

The methods adopted in these international risk assessments will be utilised where appropriate in the assessment of the raw milk associated microbiological risk for New Zealand consumers. Input data from the risks assessments listed in the Table 10.1.1 of Appendix 10.1 will be used to fill data gaps where New Zealand data is not available.

4 Hazard Identification

The biology, pathology, and ecology of all the pathogens considered in this risk assessment have been extensively described in the microbiological literature and in previous risk assessments. MPI has published risk profiles on *M. bovis* and STEC in raw milk which provide summaries of relevant information on the food safety issues associated with these hazard/food combinations.²

This risk assessment will concentrate on analysis of New Zealand epidemiological data. Only a very brief summary of disease outbreaks resulting from the consumption of raw milk from the international literature is presented. Some additional information can be found in the above mentioned risk profiles.

4.1 FOODBORNE ILLNESSES ASSOCIATED WITH DRINKING RAW MILK

The consumption of raw milk has been associated with numerous foodborne illness cases and outbreaks and has resulted in product recalls. Internationally the largest number of such outbreaks has been recorded in the United States (U.S.).

4.1.1 United States of America

A review of dairy-associated outbreaks of human disease during 1993–2006 in U.S. identified 73 outbreaks involving unpasteurised products, resulting in 1,571 cases, 202 hospitalisations, and 2 deaths. Forty three of the 73 outbreaks involved liquid raw milk, accounting for 930 illnesses and 71 hospitalisations (Langer *et al.*, 2012). In a recent study 3.4% of consumers in the US reported drinking raw milk in the previous seven days (Buzby *et al.*, 2013). Furthermore, states that restricted sale of unpasteurised products had fewer outbreaks and illnesses, leading to the recommendation that stronger restrictions and enforcement should be considered (Langer *et al.*, 2012).

4.1.2 Europe

Similar associations between raw milk availability to consumers and outbreaks of foodborne illness have been noted in reports from European countries. In England and Wales, the great majority of milk-borne outbreaks during the eighties were attributed to the consumption of raw milk. In Scotland, a similar situation existed until the sale of unpasteurised milk was prohibited in 1983, leading to a significant drop of the incidence of diseases related to liquid milk consumption; this was further enhanced when supply to farmworkers was prohibited in 1986 (Barrett, 1986; Burt & Wellsted, 1991; Galbraith, Forbes, & Clifford, 1982). In Italy raw milk sales were strictly limited to on-farm until 2005. Thereafter the government permitted raw milk sales through automatic vending devices, a decision that boosted the market and changed milk handling practices along the supply chain. Cases of haemolytic uremic syndrome (HUS) increased significantly. A case-control study of 60 Italian children who developed HUS since 2005, found that the only food associated significantly with the disease was raw milk (Scavia *et al.*, 2009).

² Accessible at http://www.foodsafety.govt.nz/elibrary/industry/Risk_Profile_Mycobacterium-Science_Research.pdf and http://www.foodsafety.govt.nz/elibrary/industry/Risk_Profile_Shiga_Toxin_Producing-Science_Research.pdf

4.1.3 New Zealand

The national notifiable disease surveillance system (EpiSurv), managed by ESR, records data on notifiable diseases and outbreaks reported by public health units. An outbreak is defined as two or more cases linked to a common source, in particular where the common source is exposure at a common event, food or water dispersed in the community, an environmental source, or a source in an institutional setting. In many instances it is difficult to determine the causative exposure for an individual case/outbreak, particularly where multiple risk factors have occurred. A summary of New Zealand outbreaks associated with raw milk consumption and a description of the algorithm to weigh the strength of the link to raw milk, assessed as *suggestive, medium and strong*, is presented in Appendix 10.3

Environmental Science & Research Ltd (ESR) has reported 21 clusters or outbreaks of human illness where raw milk exposure/consumption was recorded as a risk factor between January 2006 and February 2013. An additional cluster of two cases of campylobacteriosis retrospectively linked to consumption of raw drinking milk occurred in Hawkes Bay in 2012 (Dr L. Calder, personal communication, 2013). No clusters/outbreaks associated with pasteurised liquid milk were recorded. Of the 22 cluster/outbreaks, strong evidence for an association with raw milk consumption was found for two campylobacteriosis outbreaks (16 and 9 cases respectively) and for one outbreak of salmonellosis the evidence was very strong (4 cases). For the remaining 19 events, the link with raw milk consumption was suggestive only, due to the presence of other concurrent risk factors and/or lack of pathogen identification.

In addition to the information from outbreaks, some limited national data on sporadic cases of notifiable diseases associated with drinking raw milk have been available for analysis. The exposure information on sporadic cases is not standardised and generally is inconsistent and lacking in detail for a variety of reasons, including single cases of illness not being fully investigated; it is not known whether all District Health Boards (DHBs) ask questions about raw milk consumption and if they do, whether they do so consistently; people who drink raw milk may not report they have done so when they fall ill; the short shelf life of raw milk means that it is very difficult to sample a suspected batch for laboratory analysis and culture.

Available sporadic case data were analysed on a case-by case basis applying evidential criteria outlined in Appendix 10.3. For the period from January 1997 to November 2005 EpiSurv recorded 27 sporadic STEC infections in individuals who reported raw milk consumption with the majority (17) in children aged two years or less. In one sporadic case (a 14 month old child that developed HUS after consumption of raw milk contaminated with *E. coli* O157:H7) implicated raw milk had been microbiologically analysed. The evidence for an association with raw milk was very strong in this case. In all other recorded sporadic cases implicated raw milk was not tested and the evidence for raw milk association has been assessed as medium.

Recently MPI funded a Massey University study for campylobacteriosis in the Manuwatu sentinel site, which allowed targeted surveillance and molecular epidemiology investigations. Analysis of the data collected during 2005-2012 showed a strong positive association between raw milk consumption and infection with a cattle-associated strain of *Campylobacter* (relative risk of approximately 4³) (French, 2012). A significant association ($p < 0.0001$) between raw milk consumption and infection with a cattle-associated genotype was observed, even for those who did not have contact with farm-animals: 54.5% (12/22) of those who consumed

³ Relative risk is the ratio of the probability of the event occurring in the exposed group versus a non-exposed group.

raw milk and had no farm contact were infected with a cattle-associated genotype, compared to 12.9% (53/410) of those who did not drink raw milk and had no reported farm-animal contact. An outbreak (nine cases) of campylobacteriosis associated with a single supplier of raw milk was identified in the Manawatu in 2011 during this study.

The findings of the analysis of epidemiological information from New Zealand reflects those of other countries, where outbreaks of campylobacteriosis, salmonellosis and STEC infection associated with raw milk have been reported.

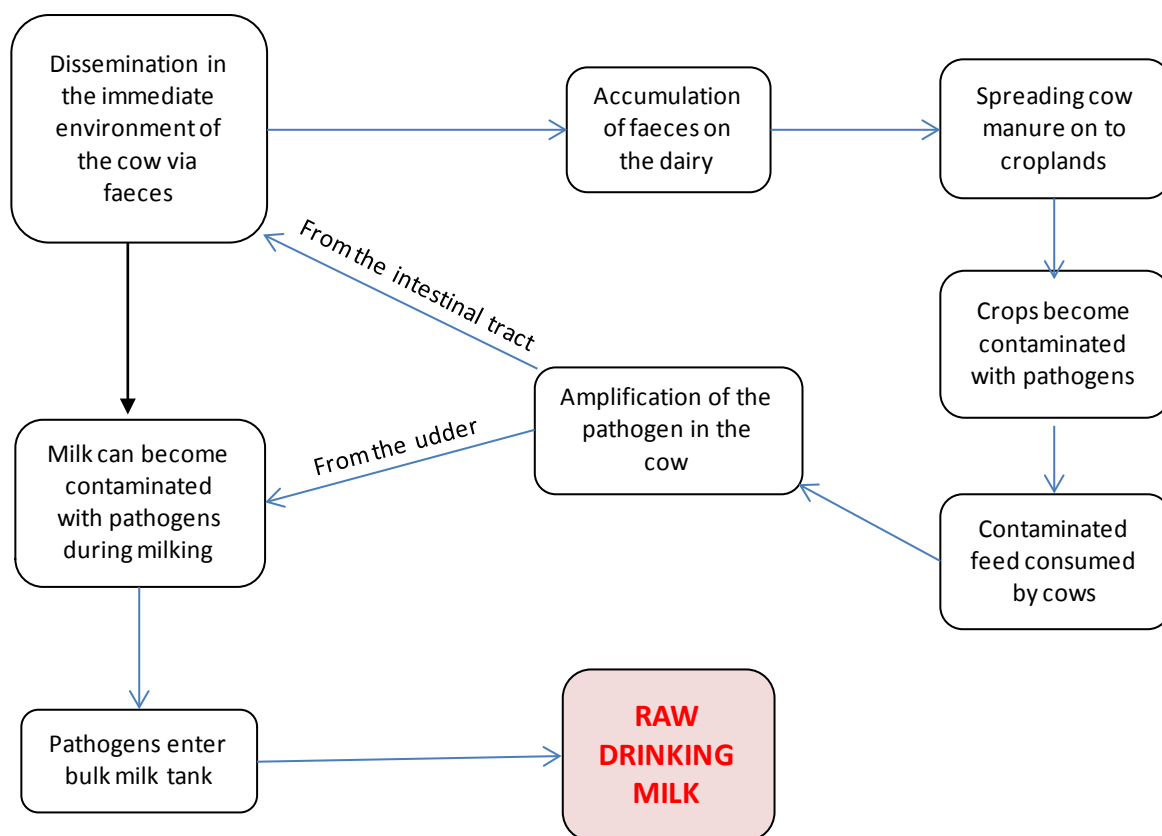
5 Occurrence of pathogens in raw milk

The international literature indicates the occurrence of a number of pathogenic bacteria in raw milk, including: *Bacillus cereus*, *Brucella* spp., *Campylobacter* spp., *Coxiella burnetii*, pathogenic *E. coli*, *L. monocytogenes*, *M. bovis*, *Mycobacterium avium* subsp. *paratuberculosis*, *Salmonella* spp., *S. aureus* and *Yersinia* spp. (Claeys *et al.*, 2013; FSANZ, 2009). Although some of these pathogens, such as *Brucella* and *Coxiella burnetii* (the agent that causes Q fever), are absent from New Zealand, many are present in New Zealand cows including the important agents of the human diseases campylobacteriosis (Moriarty *et al.*, 2008; Rapp *et al.*, 2012; Grinberg *et al.*, 2005), STEC infection (Irshad *et al.*, 2012; Buncic and Avery, 1997) and salmonellosis (Clark *et al.*, 2004; Stevenson, 2012).

5.1 MILK PRODUCTION AND ITS IMPACT ON MILK SAFETY

Most of the human pathogens being assessed can originate from clinically healthy animals from which milk is obtained. Pathogenic bacteria can enter milk from several animal sources including direct passage from blood to the milk, mastitis, and faecal contamination during or after milking; from human skin; and the environment (LeJeune and Rajala-Schultz, 2009). Dairy farms on their own are an important reservoir of foodborne pathogens (e.g. Olver *et al.*, 2005). The relative importance of the various sources of contamination depends on the farming practices and may be different for each of the pathogens. Cycling of the foodborne pathogens in the farm environment is schematically represented in Figure 5.1.

Figure 5.1: Cycling of foodborne pathogens in the dairy farm environment



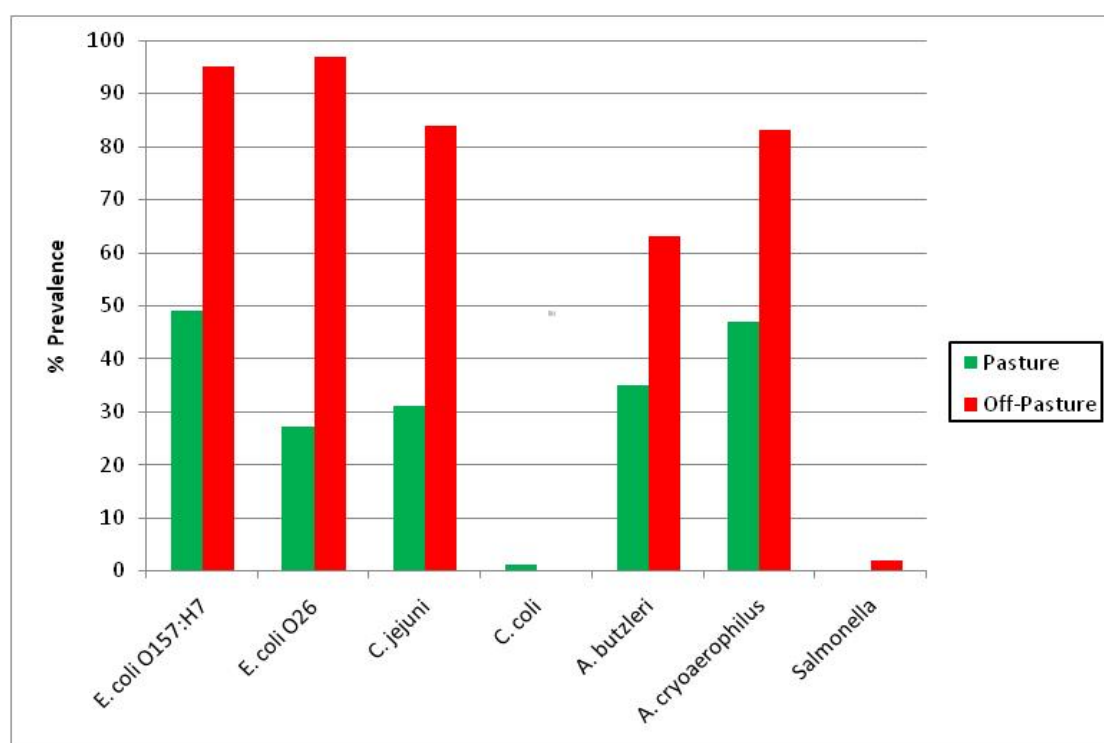
5.1.1 Animal husbandry

Dairy production practices are constantly changing, with a general trend towards management of animals off-pasture.

“Dairy farm practices in New Zealand are evolving in response to growing intensification, in attempts to limit urinary nitrogen deposition on paddocks (which leads to nitrate leaching into waterways), safeguarding soils /pasture in winter and managing animal welfare better. Key changes include growing use of feed pads, stand-off pads and sheltered housing. In these systems cows are much more exposed to faecal contamination, particularly their feet, legs, teats udder and tail. Anecdotal evidence is growing that, similar to northern hemisphere systems, the skin of cows is increasingly contaminated with faecal coliform bacteria. Further, the faeces of cows fed high starch diets such as maize silage contain a much higher coliform content. A likely risk is an increase in coliform mastitis. Thus uncleaned teats at milking and more coliform mastitis will result in an overall increase in faecal coliform bacteria in raw milk. Appropriate management of coliform contamination of teats and raw milk will be increasingly necessary.” (Dr E.Hillerton (DairyNZ), personal communication).

There is also recent evidence that increased contamination of hides of calves with STEC on dairy farms was associated with off-pasture animal management (Cooper *et al.*, 2012). The same authors investigated the impact of off-pasture dairy management systems on the composition of the microflora carried by dairy cull cows, finding that the risk of raw milk contamination is reduced by adherence to an on-pasture dairy management system. Figure 5.2⁴

Figure 5.2: Impact of farming practice on prevalence of pathogens carried by dairy cows



(provided by H.Withers, AgResearch Ltd)

⁴ Non- O157 STEC and *Arcobacter* spp. were recently shown to be present in raw milk (Ertas *et al.*, 2010; Shah *et al.*, 2012; Murphy *et al.*, 2007; Allerberger *et al.*, 2003). As far as MPI is aware New Zealand milk has not been tested for these pathogens.

Poor feeding practices can result in contaminated feed which may increase the transmission and carriage of pathogens; ill health associated with poor nutrition may increase the prevalence of enteric pathogens in a dairy herd. In particular poor silage quality is a potential source of *L. monocytogenes* (Bemrah *et al.*, 1998). Improved control of storage, preparation and distribution of feed can all help to reduce contamination.

The carriage and shedding of specific pathogens, such as STEC in feedlot cattle, have been shown to be influenced by diet, but the effects have varied in magnitude and impact (Callaway *et al.*, 2009). Likewise the association between diet and shedding of *Campylobacter* spp. in dairy cattle remains controversial (Grove-White *et al.*, 2010).

Uncertainty exists as to how differences in milk sourcing practices between small-scale and large-scale producers affects the probability of pathogens being present in the raw milk used for human consumption. For example, pooling milk from many individual cows for larger volumes of milk might increase the probability of having pathogens in any portion of milk sold, but the organism would be diluted. On the other hand, where there are fewer animals the lack of dilution might lead to intermittent high levels of contamination in the smaller volume.

No association between prevalence of pathogenic bacteria or somatic cell count and dairy production type (organic versus conventional) has been identified (Griffiths, 2012 Identification and Assessment of Emerging Issues Associated with Pathogens; Presentation at the IDF Summit, Cape Town).

5.1.2 Animal health

The relationship between bacteria and ill-health in adult dairy cattle is highly variable. *Campylobacter jejuni* is common in healthy cows, but can be associated with abortion in sheep and cattle. There is evidence of the emergence of a virulent strain (ST-8) in the US (Sahin *et al.*, 2012), that has been the cause of raw-milk associated outbreaks; this has yet to be identified in New Zealand. STEC are not recognised as a cause of ill health in adult dairy cows (with the exception of rare sporadic cases of mastitis).

In contrast, *Salmonella* spp. and *L. monocytogenes* are major causes of ill-health in adult dairy cattle (Low *et al.*, 1997), including in New Zealand (Clark *et al.*, 2004; Stevenson, 2012), and may be shed in the faeces of both diseased and unaffected individuals. It follows that the prevention and control of these agents through appropriate herd health management schemes will not only reduce the incidence of clinical disease, but also reduce herd prevalence and faecal shedding in clinically normal animals that may be a source of contamination of raw milk (Ruegg, 2003). For example, previous episodes of clinical salmonellosis in dairy herds have been associated with an increased risk of faecal shedding of *Salmonella* spp. in asymptomatic animals of 4.6 times in the following year (Huston *et al.*, 2002).

If the agent causing subclinical mastitis is one of the pathogens under consideration then controlling mastitis in the herd will have a direct impact on reducing bulk tank contamination. There are sporadic reports of mastitis caused by *Campylobacter* spp. (Hutchinson *et al.*, 1985; Orr *et al.*, 1995), STEC O157 (Lira *et al.*, 2004; Stephan *et al.*, 2002), *L. monocytogenes* (Gitter *et al.*, 1980; Bourry *et al.*, 1995) and *Salmonella* spp. (Knox *et al.*, 1963), but they appear to be uncommon causes of subclinical mastitis. A recent review of the risk and benefits of raw milk did not associate *Campylobacter* spp. or STEC with mastitis (Clayes *et al.*, 2013).

Udder and teat preparation performed as part of mastitis control will also have a direct effect on bulk milk contamination as discussed under ‘milking practices’ below.

5.1.3 Milking practices

Poor, unhygienic milking practices, soiled udders and teats, damaged teats, and poor operator hygiene can all lead to increased contamination of raw milk (Blowey and Edmondson, 2010). A study of 235 dairy herds on Prince Edward Island (PEI) identified pre-milking udder preparation as an important determinant of a range of different bacterial counts in milk (Elmoslemany *et al.*, 2010). The amount of soiling on the teats prior to milking and the method of udder preparation prior to milking were associated with total aerobic count (TAC). In winter months, bulk tanks on farms with cattle with highly faecal contaminated teats prior to pre-milking udder preparation were associated with higher TACs (coefficient 0.26, $p = 0.01$) compared with bulk tanks on farms with lower levels of contamination. This implies a small, albeit statistically significant, increase of 0.26 log in TAC counts associated with this risk factor. This is consistent with other reports from the same authors (Elmoslemany *et al.*, 2009) that show a similar positive association between udder hygiene and bacteria in bulk tank milk, and the view that dirty udders and teats are an important source of environmental bacteria in milk (Pankey, 1989; Murphy and Boor, 2000; Galton *et al.*, 1986; Galton *et al.*, 1984). The association may be attributed to inadequate cleaning of heavily contaminated cattle, due to time pressure (Reneau and Bey, 2007) or the indirect effects of poor udder and teat hygiene on mastitis (Schreiner and Ruegg, 2003).

Teat washing and drying compared to washing but not drying was associated with a five-fold reduction in total bacterial account (TBC) data cited in (Blowey and Edmondson, 2010). Pre-dip and drying with a single use towel was associated with the lowest TBC in the above mentioned PEI study (Elmoslemany *et al.*, 2010) and with reduced risks of *L. monocytogenes* in in-line milk filters (Hassan *et al.*, 2001). The latter study also showed pre-milking examination of abnormal appearance of milk (stripping of foremilk) to be associated with a lower risk. Other studies have also shown an association between reduced bacterial contamination of milk and the use of certain types of pre-milking teat dips and manual drying (Galton *et al.*, 1986; Magnusson *et al.*, 2006).

The implementation of hygiene scoring systems has been advocated as a systematic approach to reducing udder contamination (Ruegg, 2003; Barkema *et al.*, 1998). Clipping udder hair has also been associated with reduced coliform counts (Elmoslemany *et al.*, 2010; Elmoslemany *et al.*, 2009), presumably as a result of reduced contamination of udders and teats (Vissers *et al.*, 2007).

Together, measures to improve milking hygiene appear to offer good opportunities to reduce raw milk contamination, but this requires the adoption of time-consuming practices and attention to detail. The microbiological risk assessment of raw cow’s milk conducted by FSANZ indicated that teat cleaning would reduce the *E. coli* concentrations in raw milk by approximately 1 log (Figure 7 in FSANZ, 2009).

5.1.4 Regular microbiological monitoring of milk production

Testing and removal of pathogen containing lots can result in a lower prevalence of contaminated bulk raw milk. While conventional microbiological monitoring based on culture is too slow to provide a timely indication of bacterial contamination to enable action to be taken before milk is released for sale, the daily use of BactoScan testing (in theory the able to be done within 10 minutes of being received at the laboratory) could provide a rapid, timely

indication of the hygienic status of the milk in bulk tanks on farms. This would allow producers to implement control measures to reduce high results from bulk tanks rather than the current practice of using it as a monitoring scheme with incremental penalties. Testing for the presence of specific pathogens in milk using conventional cultural techniques could be implemented on a sporadic basis to identify farms with repeated contamination; however these failures are more likely to be intermittent and difficult to detect, particularly if only small samples are taken for analysis.

5.1.5 Temperature control of raw milk after milking

Warmer ambient temperatures have been associated with higher bacterial contamination of bulk tank milk, including higher coliform counts (Elmoslemany *et al.*, 2010) highlighting the need for good temperature control during storage of bulk milk. It is important to take into consideration that organisms such as *Listeria* spp. are psychrotrophic and will grow at refrigeration temperatures, and other organisms such as *E. coli* and *Salmonella* spp. can multiply at temperatures of about 8°C. Reducing the temperature of bulk milk to 6+/- 2°C within four hours of commencement of milking and within two hours of completion of milking should help to reduce the risk of pathogen growth.

Another important aspect of the mitigation strategy for reducing the risk of raw milk consumption to human health is ensuring that sale of raw milk commences only after the milk is cooled below 6°C.⁵

5.1.6 Equipment cleaning and maintenance

The PEI study also identified bulk tank cleaning and hygiene as a risk factor for high bacterial counts and identified particular practices that could help to reduce biofilm formation on milking equipment and contamination of raw milk. Manual cleaning, along with lower temperatures and lower frequency of detergent and acid use was associated with increased bacterial contamination of bulk tank milk (Elmoslemany *et al.*, 2010; Elmoslemany *et al.*, 2009). Requirements for cleaning will be critical whenever vending machines are used for raw milk sales, provide further opportunities for minimising biofilm formation.

5.1.7 On-farm waste management

Contaminated animal drinking water and poor management of dairy shed and other effluent can lead to increased pathogen cycling in dairy farms and increased within and between-farm transmission of infectious agents. Studies conducted in New Zealand and elsewhere have shown variable survival rates of pathogens in the farm environment, but also demonstrated the importance of good management of manure and effluent to avoid contamination of waterways (Sinton *et al.*, 2007).

5.2 MICROBIOLOGICAL SURVEYS OF NEW ZEALAND RAW MILK

Two microbiological surveys of raw milk have been conducted recently in New Zealand. In a 2007-2008 study conducted by Fonterra, 297 samples of raw milk from randomly selected farm vats were examined for presence of the non-spore-forming pathogens, *Staphylococcus aureus*, *Escherichia coli* (total count and O157:H7), *Listeria*, *Campylobacter* and *Salmonella* (Hill *et al.*, 2012). More recently in a MPI survey, milk samples were collected 5 times throughout 2011-2012 milking season from each of 80 randomly selected dairy farms and

⁵ Importance of temperature control will be further discussed in the quantitative Risk assessment chapter.

tested for presence of the same pathogens. Both surveys showed similar results for all pathogens, except *Listeria spp.*, which were detected more frequently in the MPI survey. Findings of these two surveys are summarised in Table 5.1

Table 5.1: Prevalence (%) of pathogens in raw milk from New Zealand microbiological surveys

Pathogen	Fonterra (2007-8) Prevalence (95% CI)*	MPI (2011-12) Prevalence (95% CI)†
<i>Campylobacter</i> spp	0.34% (0.01-1.87)	0.58% (0.07-2.10)
<i>E. coli</i> O157:H7	0.00% (0.00-1.24)	0.28% (0.01-1.55)
Non- STEC O157	1.01% (0.21-2.93)	0.28% (0.01-1.55)
<i>Listeria innocua</i>	4.07% (2.12-7.00)	10.08% (7.20-13.60)
<i>Listeria monocytogenes</i>	0.68% (0.08-2.43)	4.09% (2.31-6.65)
<i>Salmonella</i> spp	0.00% (0.00-1.24)	0.00% (0.00-1.03)

*Exact binomial calculated using binom.confint in R package binom

Similar results were presented in an Italian study of raw milk vending machines (Bianchi *et al.*, 2013). Prevalence for the pathogens in question were all within the 95% CI of the New Zealand studies except for *L. monocytogenes* which was higher in New Zealand raw milk. Likewise, in a recent review, the prevalence of these pathogens in raw milk in Europe was similar (Clayes *et al.*, 2012).

Both of the New Zealand studies found high prevalence of *S. aureus* in raw milk. In the MPI survey *S. aureus* was detected in 74.10% of all samples (95% CI 69.2-78.7%.) (Table 5.2).

Table 5.2: Monthly *S. aureus* findings in the MPI raw milk survey and overall in the Fonterra study

	Month					MPI-All	Fonterra
	Jan	Mar	May	Jul	Nov		
Number samples	77	80	55	72	60	344	293
Percent positive (staph detected)	51.9%	83.8%	94.5%	79.2%	65.0%	74.1%	79.9%
95% CI	40.3-63.5%	73.8-91.1%	84.9-98.9%	68.0-87.8%	51.6-76.9%	69.2-78.7%	74.8-84.3%
Count cfu/ml							
<1	48.1%	16.3%	5.5%	20.8%	35.0%	25.9%	20.1%
1-10	37.7%	22.5%	14.5%	23.6%	16.7%	23.8%	11.6%
11-100	13.0%	55.0%	72.7%	45.8%	38.3%	43.6%	29.4%
101-1000	1.3%	6.3%	7.3%	8.3%	10.0%	6.4%	28.3%
>1000	0.0%	0.0%	0.0%	1.4%	0.0%	0.3%	9.6%

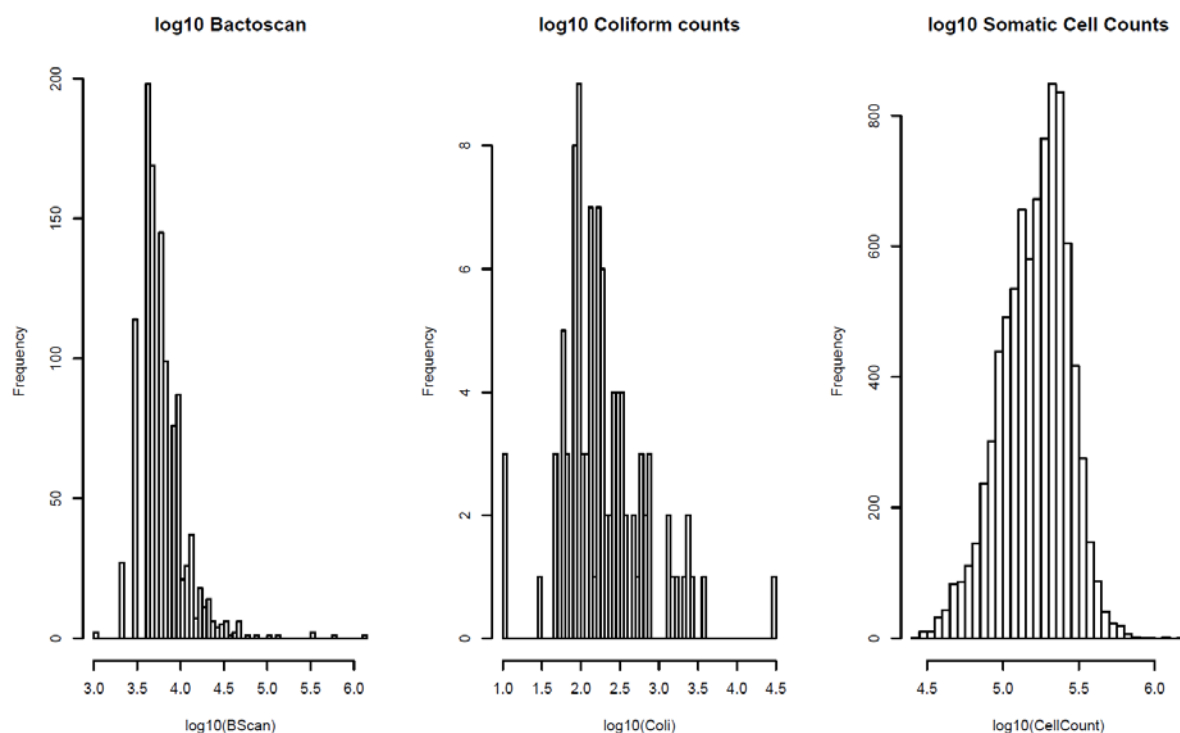
S. aureus is one of the most widespread causative agents of mastitis in dairy herds. This disease involves inflammation of the mammary glands and consequent sporadic shedding of *S. aureus* cells into the raw milk (Barkema *et al.*, 2006). The presence of high numbers of *S. aureus* is indicative of mastitis in a dairy herd.

S. aureus can produce enterotoxin that causes human illness; for toxin production the pathogen concentration needs to exceed 10⁵ cfu/ml. None of the raw milk samples in the Fonterra and MPI studies contained numbers of *S. aureus* approaching this.

The MPI survey also provided daily results of milk quality from the 80 farms (Figure 5.3). A total of 8680 samples were taken providing information for individual bulk tanks on somatic cell counts (SCCs), total TBC using BactoScan, and coliform counts. SCC is an accurate indicator of subclinical mastitis (Rysanek *et al.*, 2009); TBC is a measure of all bacteria present in milk, comprising natural microflora present in milk, mastitis organisms and faecal and environmental contamination (Wallace, 2008); and coliform counts provide information on contamination of milk. The small number of extreme total bacterial counts relate to single isolated 'contamination events', the most marked being a count of 1.4 million cells. This

event corresponded with the 5th largest coliform count (2,200); however the corresponding somatic cell count was close to the population median value.

Figure 5.3: Distributions of Total Viable Bacterial Counts (N=1092), Coliform (N=807) and Somatic Cell Counts (N=8510) in bulk milk tanks from farms (N=80) sampled in the MPI study



Statistical analysis of data collected revealed that:

- There is a strong and significant effect of farm on TBCs and coliform counts. This indicates that there are major differences in the standards of hygiene and/or mastitis control between farms that contribute to the variation in TBCs. After adjusting for SSC (i.e. removing the possible effect of subclinical mastitis), a small number of high TBC 'events' were evident.
- TBCs were negatively correlated with tank volume, which is likely to be a dilution effect.
- TBCs were positively correlated with both coliform counts and somatic cell counts, but the proportion of variation explained was small. The relative contribution of faecal contamination is likely to be greater than the contribution from subclinical mastitis.
- There is significant monthly variation in TBCs and coliform counts: the highest TBCs were observed between March and August, with a peak in the spring calving month of July, whereas the highest coliform counts were in November.

6 Risk Assessment

This quantitative risk assessment only considers: *Campylobacter* spp., *L. monocytogenes*, STEC (with a particular focus on *E. coli* O157), and *Salmonella* spp. because of their likely occurrence in raw milk, their significance to public health in New Zealand and the ability to access suitable data to populate the model⁶. Additionally a semi-quantitative assessment of the risk of contamination of raw milk with *M. bovis* was also performed (see Annex 1).

The biology, pathology and the epidemiology of the above pathogens have been extensively described in the microbiological literature. MPI has published a series of pathogen data sheets which give scientific information about the growth, survival and inactivation of pathogens in foods. They also document their reservoirs and sources of contamination, diseases they cause, and how they can be controlled.⁷

Table 6.1 summarises findings from available epidemiological data and information from NZ bulk milk surveys for the selected microbiological hazards.

Table 6.1: Information on selected microbiological hazards

Organism	Severity of illness*	Implicated in raw milk outbreaks in New Zealand	Detected in raw milk in NZ outbreaks/disease investigation	Can originate from clinically healthy animals	Detected in bulk raw milk in NZ
STEC	severe	✓	✓	✓	✓
<i>L. monocytogenes</i>	severe#			✓	✓
<i>Salmonella</i> spp.	serious	✓	✓	✓	
<i>Campylobacter</i> spp	severe*	✓	✓	✓	✓

Susceptible sub-populations * based on International Commission on Microbiological Specifications for Foods (2002)

6.1 OVERVIEW OF THE MODEL

The quantitative risk assessment is based on an unpublished model for prevalence and concentration of pathogens in raw milk at farm gates developed by Massey University and a model of the supply chain beyond the farm gates written by ESR using the @RISK software (Version 5.7, Palisade Corporation).

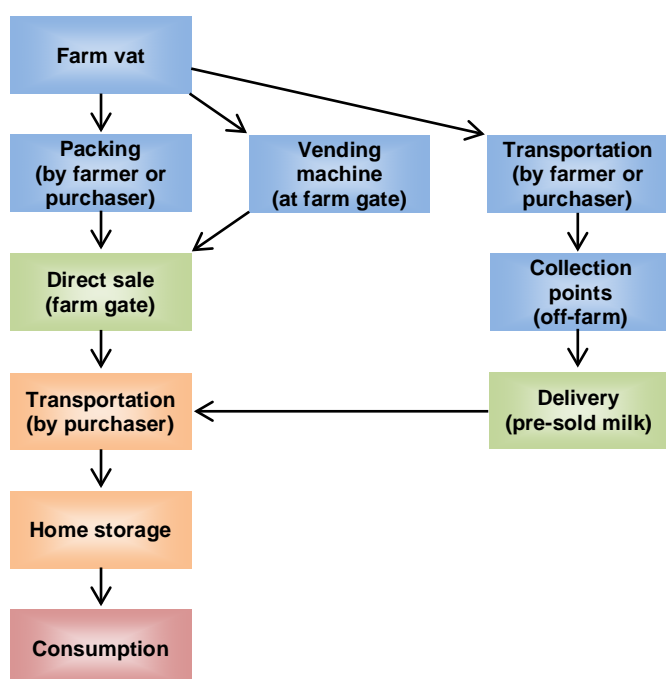
The food chain between the farm gate and the consumer is captured as “pathways”, which are specific channels of purchase, transport, storage, and consumption. The real/projected situation in New Zealand, under current or future legislation, is modelled as “scenarios”. Multiple pathways may operate in a single scenario.

⁶ The same pathogens were identified as the ‘big four’ for raw milk by some international food safety authorities. See, for example <http://www.bccdc.ca/foodhealth/dairy/Raw+Milk.htm> and FSANZ (2009).

⁷ Accessible at: <http://www.foodsafety.govt.nz/science-risk/hazard-data-sheets/pathogen-data-sheets.htm>

There are multiple pathways by which raw milk could reach the consumer. Under current New Zealand legislation (as at 2012) raw milk can be purchased only at the farm gate though in practice there are three pathways currently in existence: direct sales from the farm gate, vending machines located at the farm, and informal distribution via collection points. The latter involves people pre-purchasing the raw milk (e.g. by paying the farmer over the internet), then collecting the milk from the farmer or one of the purchasers at an agreed off-farm location (collection point), usually in an urban region. Figure 6.1 illustrates this “baseline” scenario.

Figure 6.1: Baseline scenario: current pathways in the farm to consumer food chain for raw milk

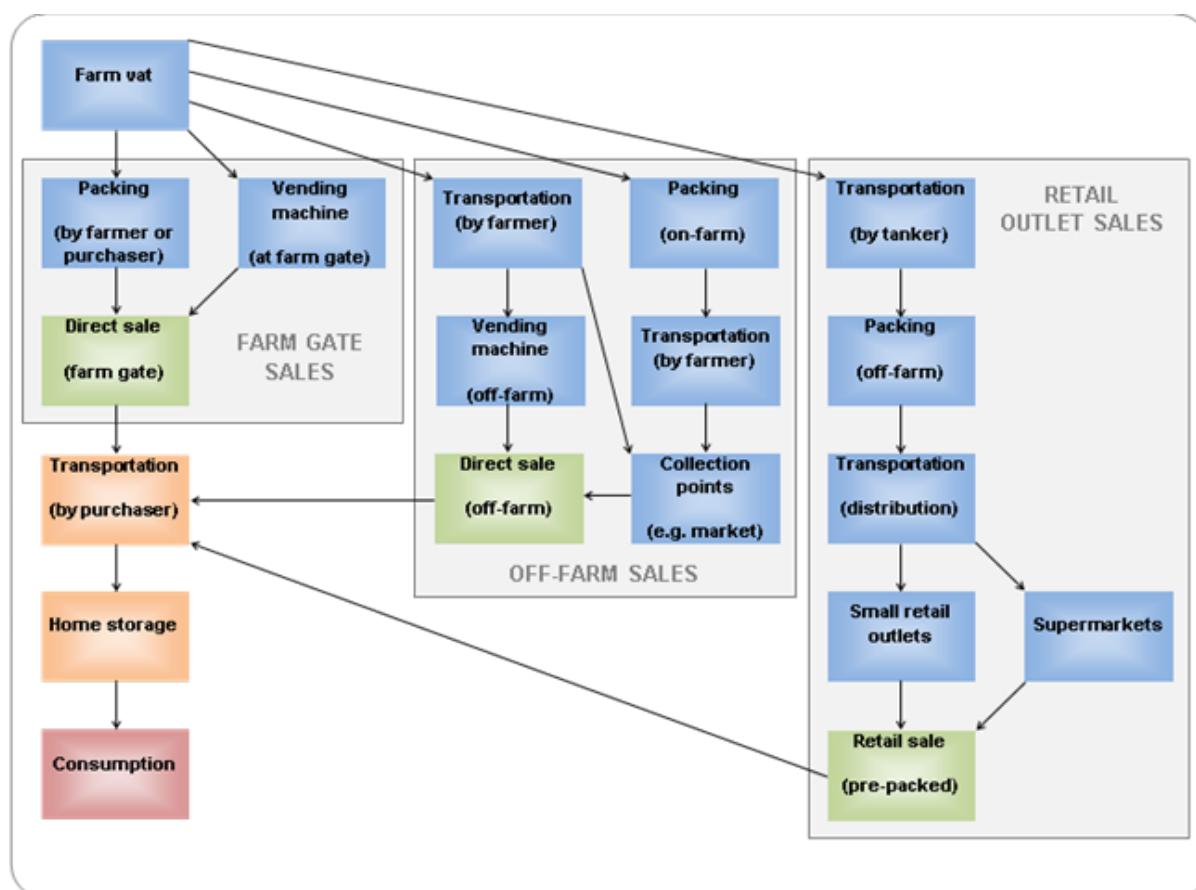


Three scenarios were modelled:

- purchase of raw milk only at the farm (farm gate sales);
- farm gate sales plus purchase of raw milk directly from the farmer at an off-farm collection point or vending machine, which may be located near or within a retail operation (off-farm sales); and
- farm gate sales plus off-farm sales plus purchase of raw milk from a retail outlet such as a convenience store or supermarket (retail outlet sales).

These scenarios are illustrated in Figure 6.2.

Figure 6.2: Modelled scenarios: pathways in the farm to consumer food chain for raw milk

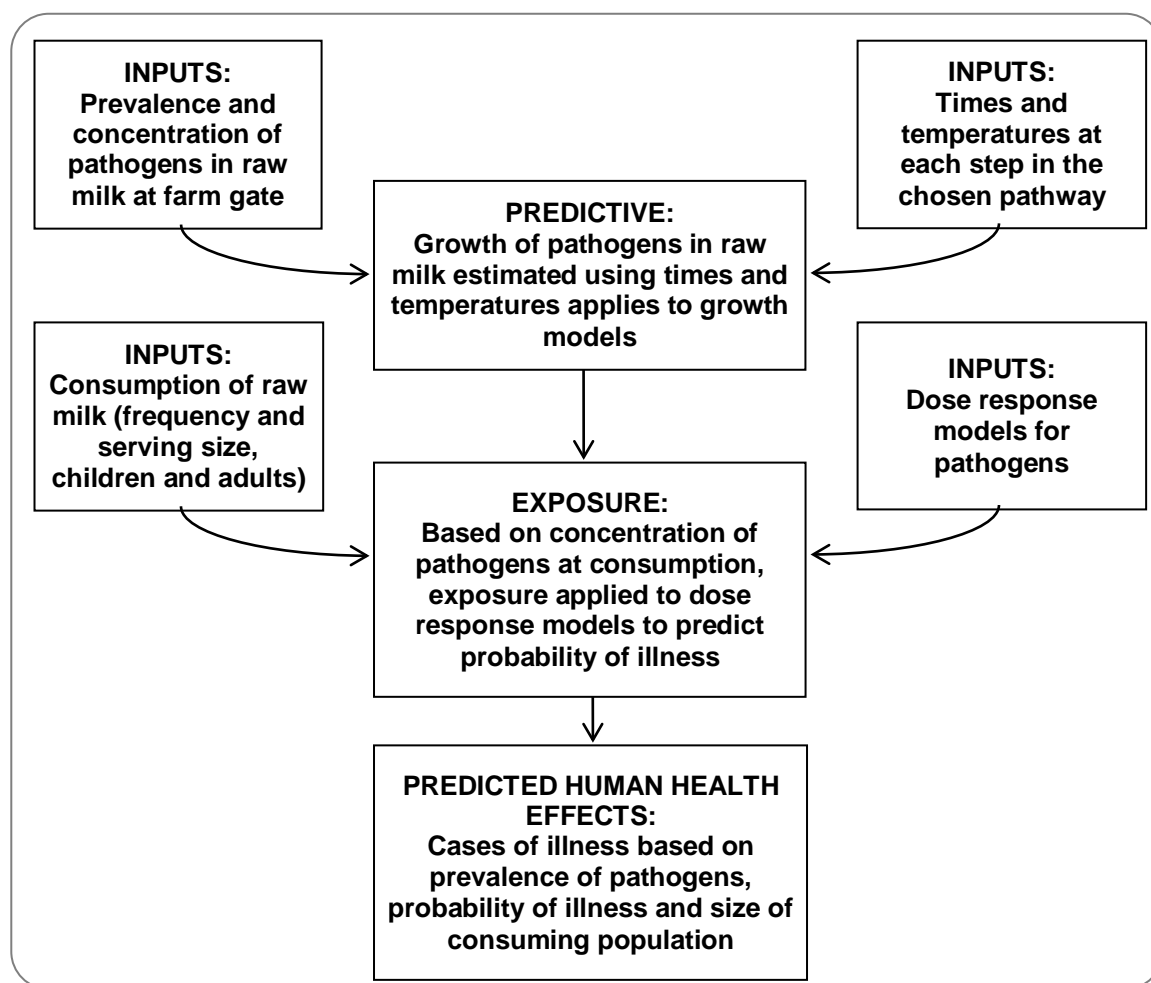


Note that the supply pathway where purchasers collect the milk from the farmer at an agreed off-farm location is assigned to the "off-farm sales"; it is an off-farm collection point that involves an extra transportation step before the purchaser receives the milk. This pathway would not operate if only farm gate sales are allowed.

6.2 MODEL APPROACH AND STRUCTURE

The model calculates the risk for each relevant pathogen separately. From the farm gate to the consumer, the concentration of pathogens in the milk may change due to bacterial growth, which is governed by the temperatures of the milk at each step in the food chain, and the duration of each step. The likely times and temperatures are included in the model as distributions at each step. To predict risk from this series of distributions Monte Carlo simulation is performed. At the end of the food chain, the consumer drinks a serving of raw milk. The number of pathogen cells in that serving (the dose) is determined from the final concentration of pathogens (from the accumulated growth calculated at each step) and the volume of raw milk consumed. A dose-response equation is then used to calculate the probability of illness from that number of cells. The structure of the model is schematically represented in the Figure 6.3.

Figure 6.3: Model Structure



6.3 MODEL INPUTS

6.3.1 Distributions of pathogens in raw milk

For all pathogens it is assumed that some proportion of the TBC distribution is the pathogen in question. This proportion is calculated by deriving the distribution of pathogens within faeces (in cfu/g) of the cows on the farm and combining this with information on whether the farm is positive. If the farm is not positive for the pathogen in question, then a pathogen will not be represented in the TBC. Under the assumption that most of the TBC distribution is derived from faecal material, the number of pathogens is calculated by multiplying the TBC distribution by the proportion found in faecal material.

Based on the recent raw milk survey, TBC was modelled as a mixture of two over dispersed Poisson distributions. The biological rationale is that each farm's TBC distribution is likely to be a mixture of two Poisson distributed counts, the first representing the background contamination inevitable in routine milking (low Poisson), and the second the consequence of a major contamination event⁸ (high Poisson), such as dropping a milking cluster into faecal material.

⁸ Such events may be the most important determinants of outbreaks associated with raw milk.

The sum of all low Poisson distributions, across all farms was modelled using the negative binomial distribution (low negbin), and likewise the high Poisson distributions (high negbin). Thus, the final distribution of counts is presented as a mixture distribution of two negative binomial distributions. These distributions are called ‘background’ and ‘contamination events’ distributions. Parameters, the mean count (μ) and dispersion parameter (r) of the distributions, were determined by analysing total bacterial counts from samples taken during November 2011 – August 2012 from each of 80 farms participating in the MPI study. This resulted in a model of total bacterial counts in New Zealand farms as a mixture distribution of Negbin ($\mu=6.2$, $r=13.3$) with probability 0.929 (background distribution) and Negbin ($\mu=56.7$, $r=0.78$) with probability 0.071 (contamination events distribution).

A pathogen present in a major contamination event is likely to originate from faecal contamination from a single cow. Thus, both the farm and cow needs to be positive, and the proportion of a pathogen within TBC will be determined by the distribution of pathogens within faecal material sampled from a single animal.

Background contamination, on the other hand, assumes that the pathogen is present from many cows mixing either in the tank or in the environment. Thus, the farm needs to be positive, and the proportion of a pathogen within TBC will be determined by the distribution of pathogens within a pooled sample of faecal material sampled from all animals on the farm. With 400 cows assumed on the average farm (DairyNZ, 2011) the central limit theorem gives a normal distribution for the background distribution.

Probabilities of no pathogens ($p(\text{zero})$), pathogen from the background contamination ($p(\text{background})$) or pathogen resulting from a major contamination event ($p(\text{event})$) are calculated as following:

- $p(\text{zero}) = p(\text{farm negative}) + p(\text{farm positive})p(\text{count}=0)$
- $p(\text{background}) = p(\text{farm positive})p(\text{TBC background})p(\text{pooled count} > 0)$
- $p(\text{event}) = p(\text{farm positive})p(\text{TBC event})p(\text{animal count} > 0)$

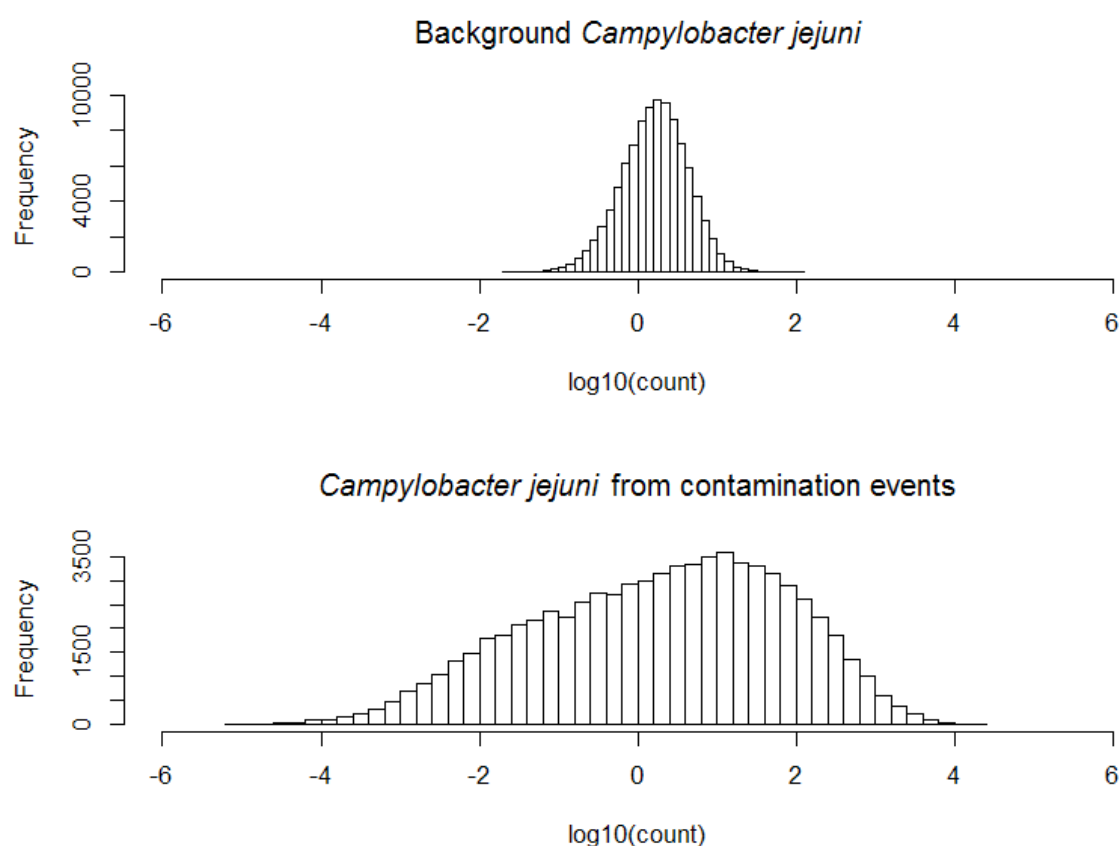
Here the probability of a positive count from an animal $p(\text{animal count} > 0) = 1 - p(\text{animal count} = 0)$. The probability $p(\text{animal}=0)$ of a negative count from an animal is computed by Bayes theorem using probabilities $p(\text{farm positive})$, $p(\text{cow positive}|\text{farm positive})$, $p(\text{counts}|\text{cow positive})$.

As shown above $p(\text{TBC background})$ was estimated to be 0.929 and $p(\text{TBC events})$ to be 0.071 for New Zealand dairy farms. The between farm prevalence and the prevalence and count distributions for individual animals ($p(\text{farm positive})$, $p(\text{cow positive}|\text{farm positive})$, $p(\text{counts}|\text{cow positive})$ respectively) are pathogen specific and were calculated separately for each of the selected pathogens.

Campylobacter spp

The distributions were fitted to New Zealand specific data from Rapp *et al.*, (2012). That resulted in the probability of pathogen being not present, or coming from ‘background’ or ‘events’ as 0.076, 0.883 and 0.041 respectively. The final distributions within ‘background’ and ‘contamination events’ groups are given in Figure 6.4.

Figure 6.4: Simulated counts per litre of *C. jejuni* in bulk milk tanks

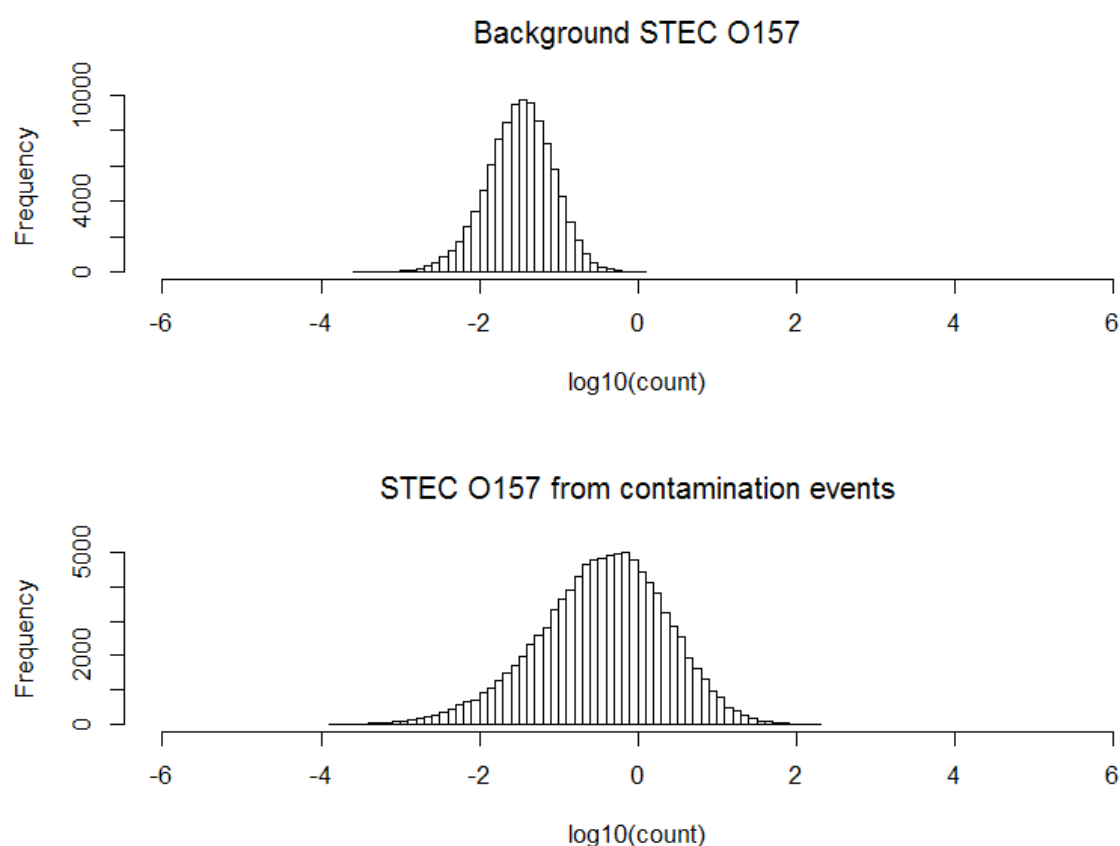


STEC

New Zealand specific prevalence data were fitted to data on adult cows from Jaros *et al.* (personal communication) where 16/134 farms were positive. Given a positive farm, 16/24 animals were positive. A log normal distribution was fitted to count data from a UK based study with 29 positive cows, four of which were higher than 200 cfu/g (Robinson, 2004), cited in (Clough *et al.*, 2009)⁹. That gave the probability of pathogen being not present, belonging to 'background' or 'contamination events' distributions as 0.886, 0.109 and 0.0055 respectively. The final distributions within low and high groups are given in Figure 6.5.

⁹ When New Zealand data were not available international data were assessed to find those most transferrable to the New Zealand context. The main criteria used for this was that the distribution of genotype was comparable, i.e. not dominated by genotypes that NZ does not have. Where multiple applicable sources were found, the choice was made by weighting the data sources on sample size.

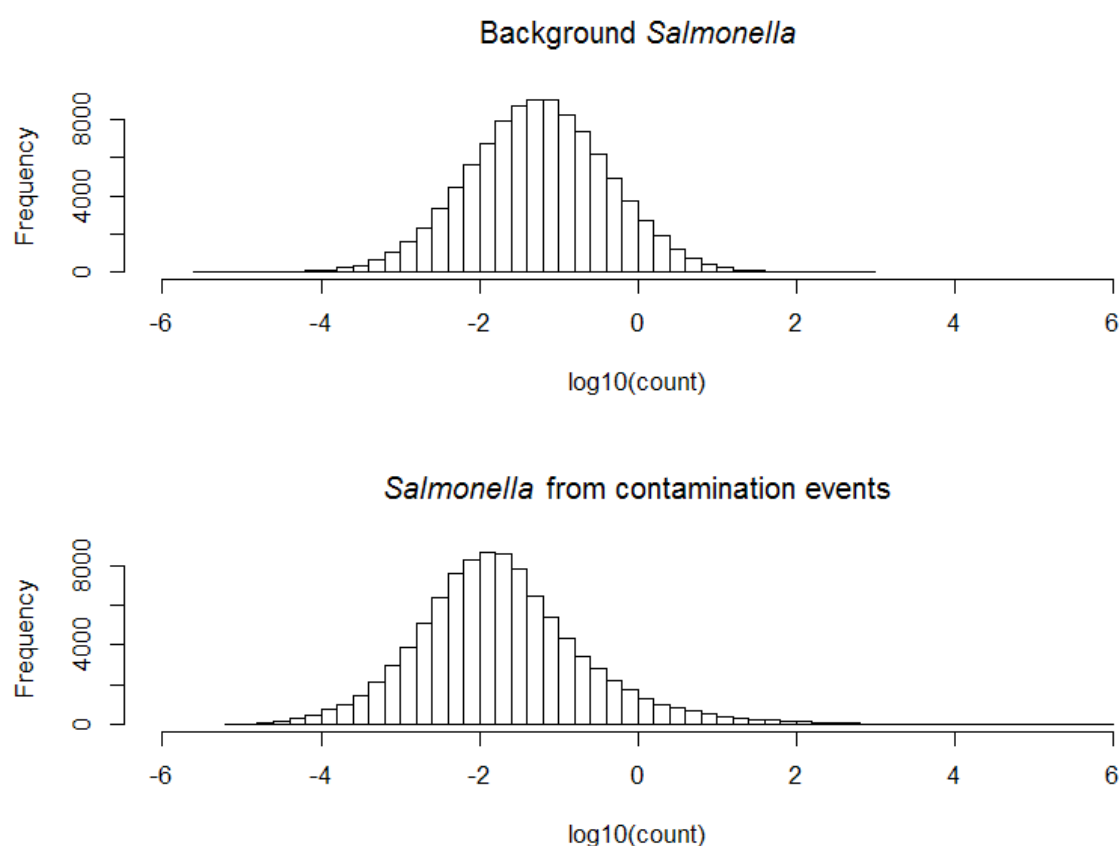
Figure 6.5: Simulated counts per litre of *E. coli* O157 in bulk milk tanks



Salmonella spp.

New Zealand specific prevalence and count data are not available, so *S. Typhimurium* data from a UK study (Kirchner *et al.*, 2012) were used for on-farm prevalence and counts, and a national US study (Ruzante *et al.*, 2010) used for the proportion of positive farms. Prevalence information from multiple farms across multiple visits was available in Kirchner *et al.* and thus all data were used, with a Beta distribution fitted to the individual prevalence, weighted by sample size of each farm/visit pair to estimate prevalence along with uncertainty. That gave the probability of pathogen being not present, or coming from ‘background’ or ‘events’ as 0.581, 0.404 and 0.015 respectively. The final distributions are given in Figure 6.6. Note although the distribution for counts describing the background contamination looks similar to the distribution for Typhimurium counts resulting from a major contamination event, the latter distribution has a higher mean due to the strong right skew.

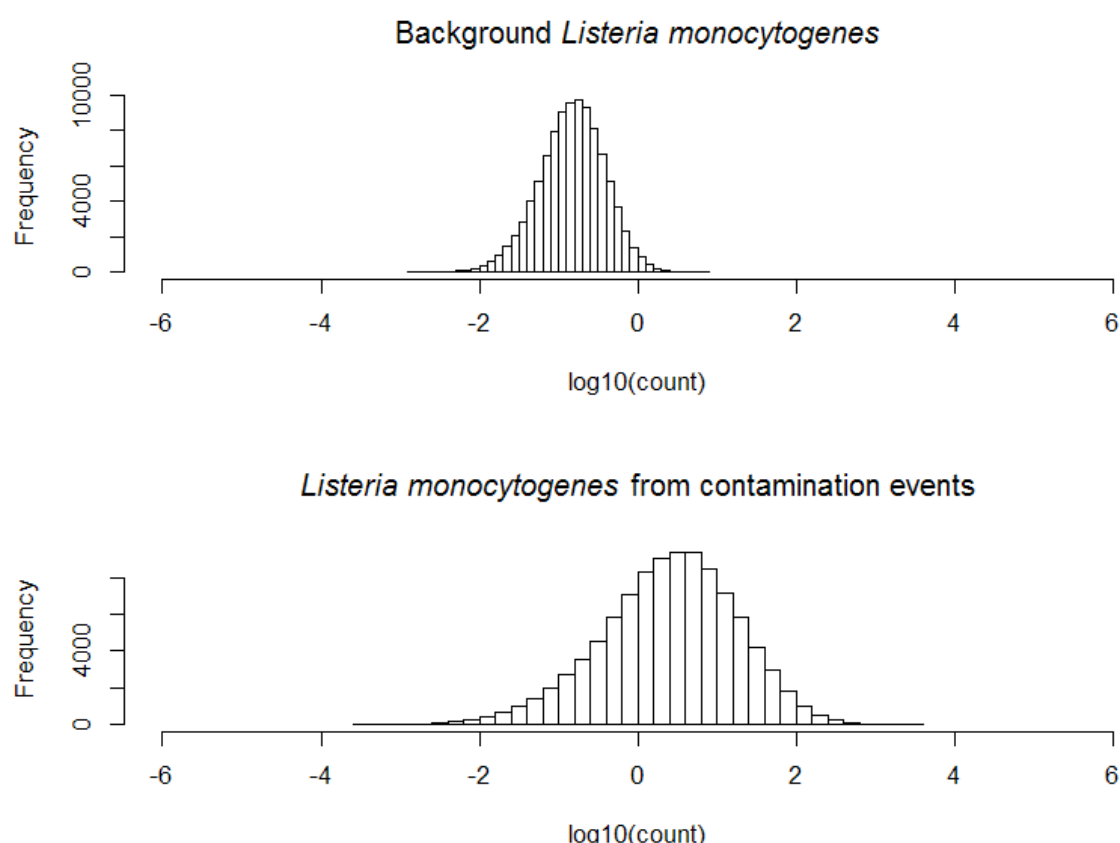
Figure 6.6: Simulated counts per litre of *S. Typhimurium* in bulk milk tanks



L. monocytogenes

New Zealand specific sources for *Listeria* spp. were unavailable, so multiple overseas sources were utilised. Herd prevalence was estimated using data from Esteban *et al.* (2009) where 38/82 herds were positive and Mohammed *et al.* (2009), where 50/50 herds were positive. These studies were chosen as they allowed estimation of both farm prevalence (a range of farms was assessed) and animal prevalence on positive farms (a range of animals on the farm was assessed). A Beta distribution was fitted to these data weighted by sample size. Within herd prevalence was estimated by fitting a Beta distribution to prevalence data from Esteban *et al.*, where 44/182 cows were positive and from Mohammed *et al.* where 608/1,414 were positive. Count data on *Listeria* spp. in faeces is unavailable, and was estimated as normal on the log scale with a mean of 10^3 cfu/g and a standard deviation of half a log. The rationale for these estimates were that they were high enough such that the detection methods would be sensitive (at least 100cfu/g) and low enough so that their absence in the extensive metagenomics analysis of cattle faeces by Dowd *et al.* (2006) would be feasible. That gave the probability of pathogen being not present, or coming from ‘background’ or ‘events’ as 0.348, 0.620 and 0.032 respectively. The final distributions are given in Figure 6.7.

Figure 6.7: Simulated counts per litre of *L. monocytogenes* in bulk milk tanks



For all of the above pathogen count models it is assumed that the pathogen presence is due to faecal contamination. However, this is a particularly major assumption for *L. monocytogenes*, where other environmental sources of contamination (e.g. biofilms on equipment and feed contamination) may also be major contributors to the proportion of this organism in TBCs.

The model of pathogen counts was validated by comparing the estimated probability of detecting a positive bulk tank from a 25 ml sample (the size of sample analysed in the Fonterra and MPI studies) using modelled pathogen concentration in bulk milk samples obtained with the results of the survey described in Table 5.1. The estimates from a simulated survey and both the above studies were consistent for all pathogens except *L. monocytogenes* (see Appendix 10.4). The simulated estimates of *L. monocytogenes* were lower than in the MPI survey. This is likely to be due to an underestimation of concentrations of *L. monocytogenes* in dairy cow faeces and the contribution from poor milking machine hygiene and other sources of contamination.

An alternative approach to modelling the concentration of *L. monocytogenes* was considered which used the prevalence and counts obtained from the MPI raw milk survey. This contamination was modelled using a Beta distribution with parameters $\alpha_1=16$ and $\alpha_2=352$, which is based on 15 positive for *L. monocytogenes* samples out of total 367 samples from milk vats. The counts were randomly sampled from the discrete distribution based on the estimates recorded in the survey.

6.3.2 Time and temperature during transport and storage

Table 10.5.1 in Appendix 10.5 lists the input distributions chosen for parameters relevant to the food chain steps in the model pathways. The choices made reflect the food chain under good refrigerated control; thus the risk assessment assumes the integrity of the supply chain. The overall period from milk production to consumption is limited to the interval during which the milk is organoleptically acceptable for consumption. This means that the pathway with the greatest number of preceding steps to the consumer's home (retail sales) results in the shortest domestic refrigerator storage times.

6.3.3 Growth/inactivation rates

The growth models chosen for this risk assessment are based on information from the scientific literature about the behaviour in milk of the selected pathogens¹⁰.

It is possible that lag in growth would occur due to shifts between holding temperatures. For the pathways considered, it is unlikely that the milk would undergo sudden increases or decreases in temperature, apart from the initial cooling going into the vat at the farm. Any potential growth during the vat cooling period of up to three hours has been ignored (essentially the bacteria are considered to be in lag phase during this initial time). No extra lag in growth was included to account for moving from step to step in the supply chain.

The following minimum growth temperature, °C data from Hudson, 2011, were used in the model for minimum growth temperatures of the selected pathogens:

- *Campylobacter jejuni* 32
- STEC 6
- *L. monocytogenes* -1.5
- *Salmonella* spp. 32

Campylobacter spp.

Given the minimum growth temperature (32°C) for the organism, the only likely outcome is a decline in concentration over time. When held at refrigeration temperatures, the reduction in concentration would be expected to be small, although considerable strain differences have been described in the literature. For example only a 0.2 log reduction was measured in raw milk held at 4°C for four days (Giacometti *et al.*, 2012c). This risk assessment uses a non-linear mixed effects model for the inactivation of *Campylobacter* spp. that has been developed by FSANZ (FSANZ, 2009):

$$\log_{10}N \sim (\beta_0 + a_i) - \exp(\beta_1 + b_i) \text{ time}$$

This model captures the between-strains variability by treating parameters β_0 , a_i , β_1 and b_i as random variables (FSANZ, 2009).

STEC

The growth rate model is based on the model for generation time of *E. coli* O157:H7 growing in broth media (Marks *et al.*, 1988):

¹⁰ If a relevant model for pathogen growth in milk was not identified, growth models for that pathogen growth in broth were checked against available in the literature data and those that fit growth in milk best has been used.

$$\ln(GT) \sim \text{Normal}(\text{mean} = 7.03 - 6.31 \ln(\ln(T)), \text{sd} = 0.16)$$

Predictions of this model are in good agreement with the results from two studies on growth in raw milk ([Heuvelink *et al.*, 1998](#); [Wang *et al.*, 1997](#)).

Salmonella spp.

There are no microbiological growth models available that have been produced in milk. The growth predictions in this risk assessment are based on Gompertz type equations produced for broth cultures (Gibson *et al.*, 1988) and subsequently used in the FSANZ risk assessment of raw cow milk (FSANZ, 2009):

$$\text{Growth rate (log}_{10} \text{ cfu/h)} = BC/e.$$

Based on typical chemical characteristics of the milk C was fixed at 5.97 and

$$\ln B = -7.817 + 0.40 T - 0.0056 T^2.$$

L. monocytogenes

The growth model is a square root model of the maximum specific growth rate with temperature as the only dependent variable and one variable parameter T_{\min} which is the theoretical minimum temperature for growth:

$$\sqrt{\mu_{\max}} = 0.024 (T - T_{\min})$$

Following ([Xanthiakos *et al.*, 2006](#)) the value of T_{\min} was modelled as a normal distribution $N(-2.47, 1.26)$ to allow for variation in growth rates in milk between strains as suggested by Pouillot *et al.*, (2003).

6.3.4 Dose response models

Dose response (a link between the number of pathogenic bacteria ingested and the probability of an individual becoming ill) parameters used were based on the values proposed in other risk assessments and the microbiological literature.

The dose-response relationships were applied to estimate probability of illness due to exposure of a pathogen on a per serving basis.

Campylobacter

A Beta-Poisson model was used to describe probability of infection from an ingested dose:

$$p(\text{infection}|\text{dose}) = 1 - \left(1 + \frac{\text{dose}}{\beta}\right)^{-\alpha}, \text{ where } \alpha = 0.145 \text{ and } \beta = 8.007.$$

To convert the probability of infection to a probability of disease, a standard multiplier of 0.33 was used, similar to the FAO/WHO risk assessment for *Campylobacter* spp. in poultry (WHO/FAO, 2009).

Acquired immunity such as might be obtained through living on a farm exerts a strong influence on the epidemiology of campylobacteriosis (Havelaar *et al.*, 2009). For populations

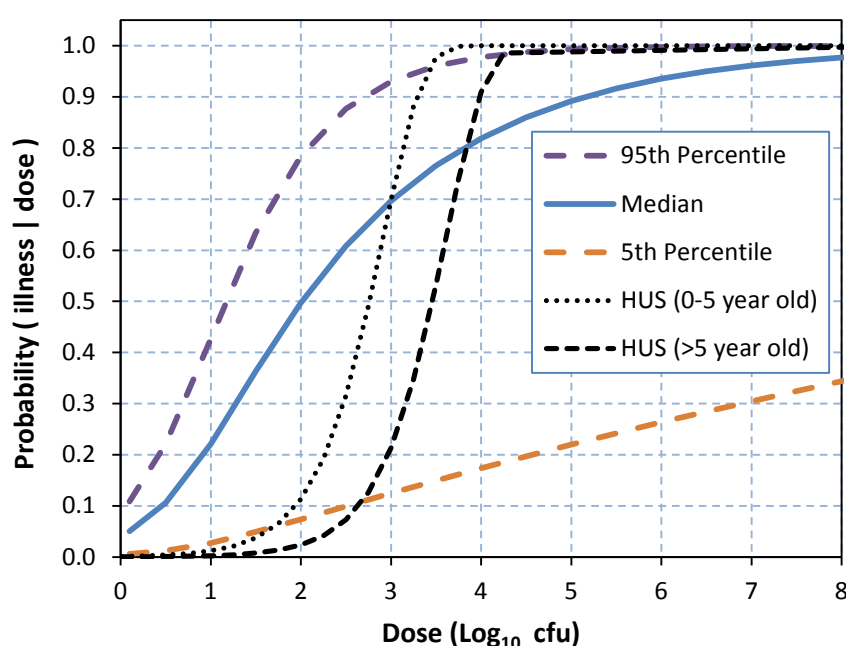
with an increased immunity parameters $\alpha = 0.145$ and $\beta = 50.000$ were used in the dose response model ([McBride and French, 2006](#)).

STEC

The Beta-Poisson dose response for *E. coli* O157 was used in the form $p(\text{illness}|\text{dose}) = 1 - \left(1 + \frac{\text{dose}}{\beta}\right)^{-\alpha}$ with $\alpha = 0.224$ (95%CI 0.025-0.5) and $\beta = 4.88$ ([Strachan et al., 2005](#)).

These dose response curves are shown in Figure 6.8 STEC infection poses the risk of developing the most severe complication - haemolytic uremic syndrome (HUS).

Figure 6.8: Beta-Poisson dose response curves for *E. coli* O157 and exponential dose response curves for HUS



Following [Giacometti et al. \(2012\)](#) the probability of HUS was described as

$$P_{HUS} = 1 - (1 - r)^{\text{dose}}$$

with r equal to 1.2×10^{-3} for the 0-5 year age group and 2.4×10^{-4} for the over five year olds. These probability curves are also shown in Figure 6.8.

Salmonella spp.

A dose response for *Salmonella* spp. has been developed from outbreak data (WHO/FAO, 2002). It is based on the Beta-Poisson model $p(\text{illness}|\text{dose}) = 1 - \left(1 + \frac{\text{dose}}{\beta}\right)^{-\alpha}$ with the parameters $\alpha = 0.1324$ and $\beta = 51.45$.

L. monocytogenes

For *L. monocytogenes*, two groups (susceptible and general populations) have been retained based on the epidemiological evidence highlighting the importance of susceptible populations

and the occurrence of invasive listeriosis. The exponential dose response model for invasive listeriosis was used:

$$P(L) = 1 - e^{-RN}$$

where $P(L)$ is the probability of listeriosis and N = the number of ingested cells (Chen, *et al.*, 2003). Values of the parameter R (5th – 95th percentile) were chosen according to the WHO/FAO risk assessment ([WHO/FAO, 2004](#)):

Susceptible population	1.06×10^{-12} (2.47×10^{-13} - 9.32×10^{-12})
General population	2.37×10^{-14} (3.55×10^{-15} - 2.70×10^{-13})

6.3.5 Milk consumption data

Specific information of the milk consumption patterns of raw drinking milk consumers in New Zealand is not available. For the present study, it has been assumed that milk consumption patterns for this group will be the same as milk consumption patterns for consumers of cold pasteurised milk.

General information on consumption of cold milk by New Zealanders was obtained by analysis of data from the National Nutritional Surveys and is presented in Table 6.2.

Table 6.2: Consumption of cold milk by New Zealanders, from National Nutrition Surveys

	Adult (2009)	Child (2002)
Number of respondents	4721	3275
Number of servings	1902	2425
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
95 th percentile serving size (g)	424.0	387.0

The distribution of cold milk serving sizes for adults and children can be adequately represented by lognormal distributions. The best fit (maximum likelihood estimation) distributions are:

Adults	Lognormal(205.7,153.1)
Children	Lognormal(203.2,122.3).

This individual consumption pattern indicates that a typical 250ml glass of milk is a reasonable approximation of mean cold milk consumption per day. Note that the same was also used in the Australian raw milk assessment to represent a single serving from a bulk milk tank (FSANZ, 2009).

The number of people consuming raw milk in New Zealand is not known. Estimates can be drawn from the National Nutritional surveys and epidemiological studies. Available data on raw milk consuming proportion of the New Zealand population and potential changes in the number of consumers are discussed in Appendix 10.6.

6.4 SIMULATION RESULTS

6.4.1 Comparison of distribution pathways

The model outputs are reported as illnesses following consumption of raw milk purchased from the farm gate; vending machine located on the farm; off-farm collection point; retail outlet.

A summary of the predicted illnesses in New Zealand consumers per 100,000 250 ml servings of raw milk for *Campylobacter* spp, STEC, *Salmonella* spp. and *L. monocytogenes* is presented in Table 6.3. For each pathogen the probability of illness is estimated assuming median dose-response ratios (see section 6.3.4). For *L. monocytogenes* presented estimates describe the probability of illness in susceptible populations only. Median values were calculated based on 20 simulations of 100,000 iterations each. The variability in predictions is indicated by 5th and 95th percentiles. Severity has not been included for the risk estimates.

Table 6.3: Predicted cases of illness per 100,000 servings of raw drinking milk

Pathogen risk per 100,000 servings	Farm gate	Farm gate vending machine	Off-farm sales	Retail
<i>Campylobacter</i> spp.	139.4 (123.2 - 150.7)	98.8 (85.6 - 108.1)	124.7 (112.2 - 130.8)	30.5 (18.5 - 41.7)
<i>Campylobacter</i> spp (acquired immunity)	30.0 (24.8 - 34.2)	20.8 (14.8 - 25.0)	26.3 (21.2 - 29.7)	6.9 (0.6 - 10.2)
STEC	70.5 (66.2 - 75.7)	70.0 (65.9 - 75.1)	75.5 (70.5 - 80.4)	56.3 (53.6 - 60.2)
<i>Salmonella</i> spp.	7.8 (6.3 - 9.3)	7.8 (6.3 - 9.3)	8.4 (6.7 - 10.6)	7.0 (5.4 - 8.0)
<i>L. monocytogenes</i> (susceptible population)	4.13(4.10 - 4.13) x 10 ⁻⁷	4.69(4.68 - 4.71) x 10 ⁻⁷	4.55(4.53- 4.56) x 10 ⁻⁷	9.95(9.88 - 9.98) x 10 ⁻⁷

Similar numbers of predicted illnesses for different pathways reflect that simulations assumed integrity of the supply chain from the farm to the consumer. Each of the simulated ‘farm gates-to-consumer’ pathways includes different number of steps, which are outlined in Figure 6.2. Generally, an increased number of intermediate steps along the supply chain are associated with greater risk of time-temperature abuse. Increased use of machinery and other equipment beyond farm gates is associated with the possibility of cross-contamination, which was not considered in the model. Control measures can be introduced at any step starting from the production of raw milk and up to its purchase by the consumer. Evaluation of availability, feasibility and cost of controls is out of the scope of the risk assessment.

Smaller numbers of predicted illnesses from *Salmonella* spp. and STEC for raw milk purchased at retail premises are due to the assumption that after seven days post-production unused milk is discarded. This assumption means that milk purchased at retail was held for a longer time under controlled refrigeration and less time at the consumer fridge. Under the assumption that packaged raw milk purchased at retail stores was consumed within five days after the consumer brought it home the model predicted increases in numbers of illnesses per 100,000 servings: STEC 71.6 (67.7 - 77.3) and *Salmonella* spp. 7.8 (6.7 - 9.3). This about 20% increase in cases of illnesses for STEC was predicted from the simulations in which the time from milk production to its consumption exceeded seven days in only 2.3% of all iterations and the maximum recorded time for all iterations was 9.36 days.

The highest risk of *Campylobacter* spp. infection is associated with consuming raw milk close to the milking point. The decrease in the number of predicted cases for longer supply chains from the farm gates to the consumer is a result of the inactivation of *Campylobacter* spp. in chilled raw milk.

A greater risk of listeriosis was predicted to be associated with consumption of raw milk obtained from retail as compared with milk purchased at the farm gate. This was due to additional time-temperature combination steps in the retail model, which increased the chances for growth of *L. monocytogenes* in raw milk (in contrast to the other selected pathogens *L. monocytogenes* is a cold-tolerant bacteria that can grow at refrigeration temperatures). Overall, the number of listeriosis cases due to raw drinking milk consumption is predicted to be low. Note, that this assessment assumed a 4.09% prevalence of *L. monocytogenes* based on testing of bulk milk samples collected between November 2011 and August 2012. Sampling from bulk milk tends to underestimate true prevalence, especially for low contamination levels. Estimations of prevalence based on monthly results were variable and in the high prevalence period (May-August 2012) the number of positive samples was about twice the average.

The predicted number of illnesses per serving summarised in Table 6.3 are based on the quantitative model that was designed as a tool to compare different pathways and illustrate the relative importance of different aspects of the food supply chain. Absolute values produced by the model should be treated with caution. For example, the high numbers of illnesses attributed to STEC can be a result of the choice of the dose-response parameters. This effect of the dose-response choice is illustrated by the estimations in Table 6.4.

Table 6.4: Predicted cases of illness per 100,000 servings of raw drinking milk

Farm Gate Sales Pathway	Estimated illness cases per 100,000 servings		
	Median dose response	Lower bound dose response	Upper bound dose response
STEC	70.5 (66.2 - 75.7)	9.5 (7.8 - 10.7)	140.8 (137.3 - 145.9)
<i>Salmonella</i> spp.	7.8 (6.3 - 9.3)	5.3 (3.8 - 8.6)	11.9 (8.8 - 15.6)

Low and upper bounds are as defined in Section 6.3.4.

Similarly, using Chen Lineage I¹¹ instead of the WHO dose-response model, for *L. monocytogenes* the number of predicted illnesses will increase by a factor of 10⁴.

6.4.2 Sensitivity analysis

The sensitivity analysis provides information on how the inputs to the model influence the model outputs. The following specific inputs were considered:

- the temperature of milk when it was purchased/collected from the farm vat;
- the total time from milk production to its consumption;
- initial counts of bacteria of interest in the farm milk vat.

In order to estimate the impact of these factors the quantitative model was run for 100,000 iterations for all of the fixed sets of parameters in the considered range. All simulations below utilised the median values for dose-response parameters.

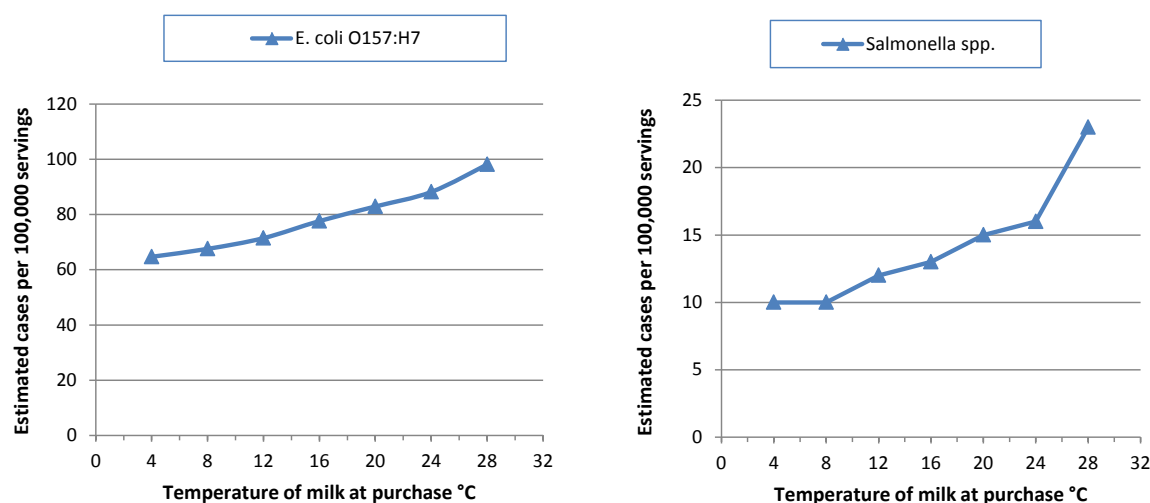
¹¹ Based on molecular subtyping methods *L. monocytogenes* isolates were subdivided into main lineages commonly referred as Chen lineages. Lineage I strains are significantly overrepresented among human listeriosis cases (see e.g. Chen *et al.*, 2006)

6.4.2.1 Temperature of milk on purchase at the farm gate

This analysis used a fixed 250ml serving size, and no growth of pathogen was assumed to occur in the farm vat. The temperature of the milk in the vat was used to set the temperature of the milk at the beginning of the journey home. Each simulation used a fixed milk vat temperature for all iterations. Figure 6.9 shows the relationship between the purchase temperature and the estimated number of cases per 100,000 servings. The estimates have been made for all assessed pathogens except *Campylobacter* spp. The results are shown for STEC and *Salmonella* spp. only. There would be no growth of *Campylobacter* spp. at the considered range of temperatures, moreover the increase of the temperature up to 30°C will increase rates of non-thermal inactivation and, consequently, reduce the risk for *Campylobacter* spp. For *L. monocytogenes* the predicted number illnesses were below 10^{-5} cases per 100,000 servings in all simulations.

The results are shown for the ‘farm gates sale’ pathway. The difference between pathways was lower than random variations between simulations for each pathway.

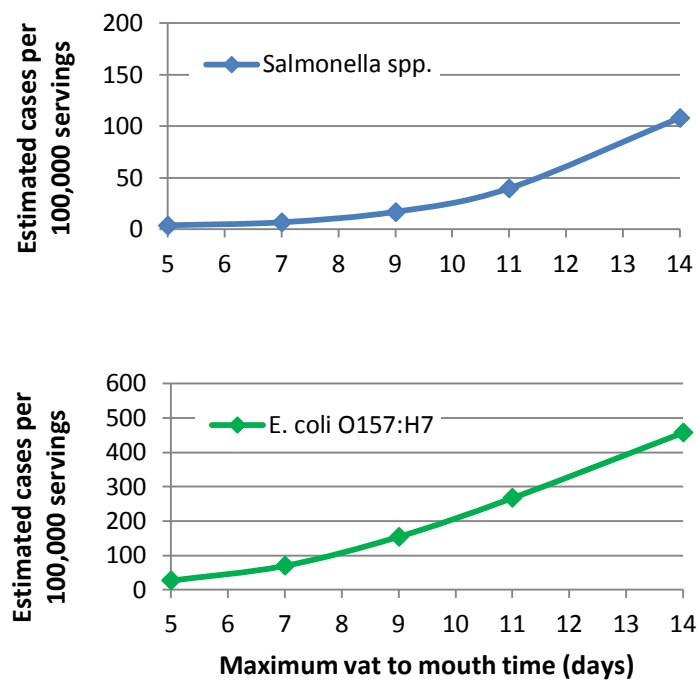
Figure 6.9: Estimates of the risk of illness from STEC and *Salmonella* spp. depending on the temperature of milk purchased from the farm vat



6.4.2.2 Maximum vat to consumption time

A key parameter in the model is the length of time raw milk might be stored before consumption. The model was run using an exhaustion model for the domestic storage with different truncation values (5-14 days) for the maximum allowable vat to consumption time and the results shown in Figure 6.10.

Figure 6.10: Estimate of the risk of illness from STEC or *Salmonella* spp. given the maximum allowable time from farm vat to consumption



The rates of increase in the cases of illness per 100,000 servings are similar for all pathways. Shown are the results of simulations for the ‘retail’ pathway.

6.4.3.3 Pathogen counts in the milk vat

Based on existing data the input concentration of *Campylobacter* spp., STEC and *Salmonella* spp. were modelled as a mixture of two distributions: a distribution of counts representing background/environmental contamination and a distribution with a long upper tail which represents infrequent major faecal contamination events (Section 6.3.1).

Table 6.5 compares the predicted illnesses per 100,000 servings of raw drinking milk estimated using the mixture distribution with the similar estimates that were calculated assuming that only background bacterial contamination is present. This comparison predicted that improved on-farm hygiene is associated with an over 30% decrease in cases of campylobacteriosis caused by raw milk consumption. For STEC the relevant decrease in cases of illnesses is predicted to be around 22%.

Table 6.5: Comparison of the predicted cases of illness per 100,000 servings of raw drinking milk, estimated by using different distributions for bacterial counts in the farm vat

Pathogen	Predicted illnesses per 100,000 servings	
	Mixture distribution with faecal contamination events	Background contamination only
<i>Campylobacter</i> spp. (general population)	139.4 (123.2 – 150.7)	99.8 (86.6 - 107.1)
<i>Campylobacter</i> spp. (acquired immunity)	30.0 (24.8 - 34.2)	16.2 (12.8 - 21.3)
STEC	70.5 (66.2 - 75.7)	54.9 (51.6 - 58.9)
<i>Salmonella</i> spp.	7.8 (6.3 - 9.3)	6.8 (5.5 - 9.3)

6.5 VARIABILITY AND UNCERTAINTY

There is a considerable uncertainty in the dose-response models. Among many types of uncertainty generally recognised in the risk assessments the uncertainty surrounding the parameters of dose-response models dominates all other sources of uncertainty in the risk results.

Variability and uncertainty in input variables have been included in the quantitative model development through the distributions listed in Table 10. 6.1. It covers only a small part of the overall variability of conditions along the supply chain under consideration and uncertainty involved in estimating risk.

Initial concentration of *Campylobacter* spp., STEC and *Salmonella* spp. used in the model include both variability and uncertainty encountered in the development of the distributions for these pathogens in bulk milk. New Zealand specific data were used for *Campylobacter* spp. prevalence and concentration and for prevalence of STEC. New Zealand data for prevalence and concentration of *Salmonella* spp. and for concentration of STEC were unavailable. Inclusion of the international data increased the uncertainty for this input of the model.

Uncertainty and variability for the growth rate equations were not included in this model, as these factors are well defined in the microbiological literature and generally are of little importance due to a limited growth of the pathogens for the considered range of temperatures. The variability in the inactivation rate for *Campylobacter* spp. in raw milk was considered important in evaluating the risk from this pathogen and was included in the quantitative model in the same manner as in FSANZ raw milk risk assessment (FSANZ, 2009).

All absolute values produced in this risk assessment should be considered with some caution. The most important is that estimates of cases of illnesses caused by pathogens present in raw milk were obtained using median dose-responses. Uncertainties in the dose-response models dominate all other sources of uncertainty in the risk assessment. However, impact of these uncertainties on relative risks associated with different pathways and understanding of importance of control measures is low.

7 Discussion

Prior to the introduction of pasteurisation, milk was one of the major sources of severe human infection due to pathogenic bacteria. Therefore pasteurisation is recognised worldwide as one of the public health greatest achievements of the 20th century. Nevertheless, current trend towards ‘consuming natural food’ led to an increasing interest in raw milk consumption.

Existing New Zealand legislation restricts raw milk sales by only allowing milk producers (dairy farmers) to sell a maximum of five litres from their farm to people who intend to consume it within their family. However, other informal options (collection points, internet sales) for buying raw milk are becoming widely used, and the amount of milk purchased by an individual may be exceeding five litres. In the period from September 2010 to October 2012 consumption of raw milk obtained through this limited distribution network was associated with 17 outbreaks of illness. A substantial proportion of the raw milk-associated disease burden falls on children; among these 17 outbreaks, eight (47%) involved children younger than 15 years (information on patients’ ages were unavailable for six outbreaks). In cases of sporadic STEC infection¹² who reported raw milk consumption, 63% (17/27) occurred in children aged two years or less. This is consistent with US epidemiological data where among the 104 raw milk associated outbreaks from 1998-2011 with information on the patients’ ages available, 82% involved at least one person less than 20 years old.

Based on epidemiological evidence, *Campylobacter* spp. and STEC are the pathogens of most concern for raw drinking milk associated illnesses in New Zealand. While *Campylobacter* was most commonly implicated pathogen in raw milk outbreaks, STEC in raw milk are more commonly linked with sporadic cases of illnesses. Surveillance data strongly linked raw milk to a STEC related case of HUS in a New Zealand child. Outbreaks of less severe diseases were associated with *Salmonella* spp. and some other pathogens in raw milk. There are no records of raw milk related illnesses associated with *Listeria* spp. in New Zealand. International data suggest that *Listeria* spp. is of low concern for raw drinking milk, but is the most dangerous pathogen associated with raw milk products that have extended shelf-life. The findings of the analysis of epidemiological information from New Zealand is in accord with those in other countries, where outbreaks of campylobacteriosis, salmonellosis and STEC infection associated with raw milk have been reported.

Drinking raw milk amongst dairy farming households is much more common than in New Zealand households overall. In a 2007 to 2010 survey of New Zealand dairy farmers, 64% (858 / 1337) reported drinking raw milk, while in the national nutrition surveys and relevant epidemiological studies 1-3% of the New Zealand population reported doing so. These findings are similar to the United States where consumption of raw milk amongst farming families was reported as 35% to 60% whilst less than 3% of the general US population consumed raw milk.

Although a much smaller proportion of urban dwellers drink raw milk their absolute number may be higher than of farm dwellers and therefore they are likely to be at most risk of New Zealand’s most commonly notifiable disease reported as associated with a raw milk source, campylobacteriosis. In addition acquired immunity such as might be obtained through living on a farm exerts a strong influence on the epidemiology of this disease. Furthermore, given that the reasons for New Zealanders wanting to purchase raw milk included perceived health benefits, it is likely that raw milk will be consumed by those most at risk from the pathogens of concern.

¹² Available data for sporadic STEC infections cover period from January 1997 to November 2005.

Numerous studies confirm that raw milk produced under even the most hygienic of conditions can still harbour human pathogens. Available data showed that *Campylobacter* spp. is present in 92% of New Zealand farm vats. *E. coli* O157:H7 prevalence of 11% was estimated based on the recent New Zealand data. Although pathogenic microorganisms are present in New Zealand raw bulk milk in low concentration, studies suggests that STEC contamination of raw milk is likely to increase due to the changes in dairy farm practices.

For *Campylobacter* spp. the highest risk of infection is associated with consuming raw milk close to the milking point. The decrease in the number of predicted cases for a longer supply chain from the farm gates to the consumer is a result of the inactivation of *Campylobacter* in chilled raw milk.

A greater risk of listeriosis was predicted to be associated with consumption of raw milk obtained from retail as compared with milk purchased at the farm gate. This was due to additional time-temperature combination steps in the retail model, which increased the chances for growth of *L. monocytogenes* in raw milk.

The predicted numbers of cases of STEC infection and salmonellosis per 100,000 standard servings of raw milk were similar for all distribution pathways. This prediction was made under the assumption of strict integrity of the supply chain from the farm to the consumer and the same duration from milk production to its consumption independently on whether the milk was purchased at the farm gates or in a retail store. It was estimated that increasing maximum duration from milking to consumption from five to seven days is associated with doubling of the predicted number of illnesses. Longer supply chains from the farm gate to the consumers home is associated with a higher risk of time/temperature abuse and possible cross-contamination of the milk. Retail sale assumes longer time to the consumer home and relies on consumer behaviour for not holding milk for extended period.

New Zealand has an effective programme for controlling bovine tuberculosis. As a result of the control measures contamination of raw milk with *M. bovis* is likely to be a very rare event. However, despite the very low probability of excretion of *M. bovis* into milk, there have been reports in recent years, both in New Zealand and overseas of milk as the vehicle for spread of *M. bovis* to other cows in dairy herds. The risk of human *M. bovis* infection acquired from drinking raw milk is unknown in these circumstances but remains a possibility.

Minimising the microbiological risks associated with raw milk is difficult. . Measures to improve animal health and milking hygiene appear to offer opportunities to reduce raw milk contamination, but require the adoption of time-consuming practices and attention to detail. Nevertheless, practices such as teat washing and dipping, foremilk stripping, and good milking hygiene will reduce the number of microorganisms that may enter the milk from environmental sources.

The risk assessment has not identified husbandry practices that can ensure that milk will be free from pathogens. Control measures along raw milk procurement activities and the supply chain to the consumer are aimed at minimising growth and will not eliminate presence of milk borne pathogens. However, strict temperature control along the supply chain and adherence to recommended use-by-dates will reduce risk to raw milk consumers.

With more people exposed to greater volumes of raw milk, the risk that someone will become ill from consuming milk that contains pathogens will increase.

8 Conclusions

Due to the inherent food safety risks associated with raw drinking milk, pasteurisation and adherence to hygienic practices in post- pasteurisation packaging and handling of the milk prior to direct human consumption are the most reliable control measures and thereby the most effective means of protecting public health. Adherence to good hygienic practices during milking and packaging can reduce, but not eliminate, the risk of contamination of drinking milk.

The quantitative risk assessment undertaken for *Campylobacter* spp., *L. monocytogenes*, *Salmonella* spp and STEC demonstrated that access to raw cow drinking milk will result in an appreciable number of cases of illness in New Zealand. The case numbers will vary dependant on where the raw milk is acquired and how it is handled. *Campylobacter* spp presents the greatest risk at the farm gate while risk from *Salmonella* spp and STEC increases further along the supply chain.

The quantitative analysis also determined that:

- increased consumption of raw milk corresponds to a proportional increase in the predicted number of illnesses;
- risk of campylobacteriosis for urban population is five times greater than for the population with acquired immunity (such as observed in on-farm residents);
- increased duration of period between production and consumption of raw milk is strongly associated with a rise in the predicted number of illnesses;
- improved on-farm hygiene (eliminating major faecal contamination events) is associated with a greater than 30% decrease in cases of campylobacteriosis and 22% decrease in cases of STEC caused by raw milk consumption;
- use of vending machines reduces the risk of campylobacteriosis by 30% for the farm gate scenario.

Risk assessment highlighted the importance of an intact refrigeration chain from milk production to consumption and specified use-by-date as risk reduction measures.

The risk assessment has not identified husbandry practices that can ensure that milk will be free from pathogens.

Currently there is no evidence of milk borne transmission of *M. bovis* infection to humans in New Zealand. A number of control measures are available as precautionary measures in this respect if raw milk is increasingly consumed in New Zealand. For example:

- a herd supplying raw milk is not located in a vector risk area;
- clear herd tests for tuberculosis are subject to a minimum number of years;
- there is a maximum period between tuberculin surveillance tests that reflects the latent period (i.e. the period between when a cow becomes infected and reacts to the tuberculin test) and the period between infection and when *M. bovis* is shed in the milk;
- all skin test-positive and skin test-suspect should be subject to intensive post-mortem inspection.

Overall, the risk assessment reaffirmed raw drinking milk as a significant source of risks to human health, especially in regard to STEC and *Campylobacter*. The increased consumption

of raw milk by the wider New Zealand population will increase the number of illnesses if current practices and the consumption profile do not change.

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10 Appendixes

10.1 INTERNATIONAL RISK ASSESSMENTS ASSOCIATED WITH CONSUMPTION OF RAW MILK

Over the past 15 years, microbiological risk assessment has developed into an important tool to support food safety decisions. Its use has been promoted by international bodies such as the World Trade Organization, the Codex Alimentarius, the World Health Organization, and the Food and Agricultural Organization (FAO) of the United Nations because it offers a structured, unified approach to describe changes in the level of pathogens along the supply chain and provides a scientific basis for risk management decisions.

The summary in the table below is restricted to risk assessments of raw drinking milk that follow (or attempt to follow, subject to data availability) the CODEX Guidelines for Microbial Food Safety Risk Assessments (CODEX, 1999).

Pathogen(s) concerned	Food considered	Issuing organisation	Key findings	Reference
<i>Campylobacter</i> , EHEC, <i>Salmonella</i> , <i>L. monocytogenes</i>	Raw cows' milk	FSANZ, Australia	The burden of illness was estimated (cases /100,000 daily servings of mean size) if milk consumed <u>after retail purchase</u> to be <1 case of campylobacteriosis, 97 cases of EHEC infection, 153 cases of salmonellosis, and up to 170 cases of listeriosis in the susceptible sub-population <ul style="list-style-type: none"> estimates change to 19 cases of campylobacteriosis, 16 cases of EHEC infection, 17 cases of salmonellosis, and < 1 case of listeriosis in the susceptible population if milk is consumed from <u>bulk farm milk tank</u> 5 cases of campylobacteriosis, 49 cases of EHEC infection, 55 cases of salmonellosis, and 17cases of listeriosis in the susceptible population <u>after farm gate sale</u>.. 	(FSANZ, 2009)
<i>E. coli</i> O157:H7 (STEC)	Informally marketed unpasteurised milk	Various, East Africa	Low to moderate risk (2-3 STEC infections per 10,000 milk portions consumed, range 0-22) of infection from consuming milk. The risk was mitigated by the prevalent practice of boiling milk prior to consumption.	(Grace <i>et al.</i> , 2008)
<i>L. monocytogenes</i>	Raw milk	Various, USA	Source Population 50th 5th 95th Farm bulk Intermediate 6.6×10^{-7} 2.3×10^{-8} 1.7×10^{-2} Tank Perinatal 2.7×10^{-7} 9.4×10^{-9} 7.0×10^{-3} Elderly 1.4×10^{-6} 4.7×10^{-8} 3.5×10^{-2} Farm Intermediate 3.8×10^{-5} 1.4×10^{-7} 12 Stores Perinatal 1.5×10^{-5} 5.8×10^{-8} 4.8 Elderly 7.8×10^{-5} 2.9×10^{-7} 24 Retail Intermediate 5.1×10^{-5} 2.0×10^{-7} 14 Perinatal 2.1×10^{-5} 8.0×10^{-8} 5.8 Elderly 1.0×10^{-4} 4.0×10^{-7} 29 All values are for cases per year in the populations listed. It was concluded that "Overall, the annual number of listeriosis cases due to raw milk consumption is predicted to be low by this model".	(Latorre <i>et al.</i> , 2011)

Pathogen(s) concerned	Food considered	Issuing organisation	Key findings	Reference
<i>M. bovis</i>	Unpasteurised milk and milk products	ACMSF, UK	Although an increase in the prevalence of <i>M. bovis</i> in cattle had been observed since animal surveillance commenced in 1994, the risk to human health from <i>M. bovis</i> in unpasteurised cows' milk and milk products is very low. The risk to human health from <i>M. bovis</i> in unpasteurised sheep, goat, and buffalo milk and milk products is likely to be very low but due to the lack of data on these species there are more uncertainties associated with this assessment.	(ACMSF, 2011)
Range of pathogens	Raw cows' milk	FASFC, Belgium	Raw milk is considered to be a risk product. Raw milk should be brought to the boil prior to consumption. New delivery mechanisms such as vending machines increase exposure of at risk groups to pathogens present in raw milk, if the consumer does not boil it prior to consumption.	(FASFC, 2011)
Range of pathogens	Raw goats' milk	FSANZ, Australia	The consumption of raw goats' milk poses a risk to public health and safety. Enterohaemorrhagic <i>E. coli</i> poses a high risk to the general population. Enterohaemorrhagic <i>E. coli</i> and <i>T. gondii</i> pose a high risk and <i>L. monocytogenes</i> a moderate risk to susceptible populations. Results on a per serving basis were slightly different; a table of results is presented.	(FSANZ, 2006)
<i>S. aureus</i> and <i>S. aureus</i> enterotoxin A	Raw milk	Various, USA	99.9 th or 99.99 th percentile of servings could contain >10 ⁵ <i>S. aureus</i> /ml, a concentration taken to represent a potential consumer risk. Exposure at the 99.99 th percentile could represent a dose of toxin sufficient to produce an intoxication (94 ng per serving)	(Heidinger <i>et al.</i> , 2009)
STEC, <i>Campylobacter</i>	Raw milk sold in vending machines	Various, Italy	The risk for consumers aged 0-5 years predicted by the model 1-2 cases of campylobacteriosis and 0.02-0.09 cases of HUS per 10,000-20,000 consumers. The risk for consumers >5 years old predicted by the model was 0.1-0.5 cases of HUS per 10,000-20,000 consumers. Strict control of temperature during distribution had a significant effect on predicted rates of disease. This assessment assumed that about 60% of consumes eliminate risk by boiling raw milk before consumption.	(Giacometti <i>et al.</i> , 2012a)
Range of pathogens	Raw milk	Norwegian Scientific Committee for Food Safety	The risk for transmission of <i>E. coli</i> O157:H7 and other STEC, <i>Campylobacter</i> and <i>L. monocytogenes</i> to humans by consumption of raw milk and cream is considered to be high. Additionally, it is noted that the risk that new emerging pathogenic microorganisms may be spread by consumption of raw milk cannot be excluded.	VKM (2006)

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10.2 RAW GOATS' MILK

Generally there is a belief that the probability of faecal contamination of raw goats' milk is slightly less than those of cows' milk due to the anatomical and physiological differences between the two species.

While microbiological hazards in raw goats' milk are not dissimilar to those in raw cows' milk, little is known about the prevalence and concentration of pathogens in the New Zealand domestic raw goats' milk supply. A survey of the microbiological content of New Zealand raw goats' milk was conducted in 2012-2013. The survey was limited to farms supplying goat milk to the Dairy Goat Co-operative, the main processor of raw goat milk in New Zealand. In the samples collected and analysed by the time of this risk assessment *Campylobacter* spp, *Salmonella* spp. or *Escherichia coli* O157 had not been detected. *Listeria monocytogenes* had been detected in one sample out of 40. While these results suggest low levels of microbiological hazards in New Zealand raw goat milk, it should be noted that the Dairy Goat Co-operative produces goat milk based infant formula for export markets and has very high hygiene standards for the milk processed. In contrast to cattle farms, New Zealand goat farms are not included in the TB surveillance programme. It is believed that the TB status of goat herds is similar to that of bovine but the actual prevalence is not known.

Based on the available knowledge of raw milk sales, it is assumed that goats' raw milk consumption is less than 10% of the total raw milk consumed in New Zealand. Anecdotal evidence suggests that raw goat milk is used by New Zealand consumers predominantly for home cheesemaking.

It is concluded that the available information is not sufficient for a formal risk assessment of the risks to public health posed by the consumption, in New Zealand, of raw goats' milk. But the above considerations suggest that the risks are similar to or less than those posed by consumption of raw cows' milk.

The key risk factors affecting the microbiological status of raw goats' milk during primary production, processing and transportation are believed to be similar to the factors summarised in the FSANZ Raw Goat Milk Risk Assessment, which discusses impact of these risk factors on milk safety and suggests some mitigation strategies (FSANZ, 2006).

References

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10.3 FOODBORNE ILLNESS ASSOCIATED WITH CONSUMPTION OF RAW MILK IN NEW ZEALAND

In New Zealand the identification and investigation of clusters of communicable (including potentially foodborne) diseases are the responsibility of the Ministry of Health and its agents, Public Health Services within District Health Boards (DHB) and the Institute of Environmental Science & Research Ltd (ESR). While there are national standards for recording notifiable disease survey findings there are none for investigation practices. For the commoner diseases, such as campylobacteriosis and salmonellosis, these procedures range from some DHBs contacting each case personally to others only investigating those associated with presumptive outbreaks. For the rarer diseases, listeriosis and STEC infection, investigation is regularly in-depth. It is not possible from recorded data to determine which DHBs question cases about raw milk consumption and if this is consistent within a DHB.

10.3.1 Outbreak reports

EpiSurv data from January 2006 – January 2013 included outbreaks where the mode of transmission was foodborne and consumption of unpasteurised milk was identified as a contributing factor to the outbreak, or mention of raw milk was made in either the vehicle/source of common source outbreak or the comments field. There were 21 outbreaks reported. Of the agents involved, 12 were *Campylobacter* spp., three *Cryptosporidia*, three *Salmonella* spp., two *Giardia* spp. and one where multiple pathogens (*Campylobacter*, *Cryptosporidia* and *Giardia*) were isolated from cases. There were 88 associated cases of illnesses, three hospitalisations and no deaths reported. Table 10.3.1 summarises these data. In addition there two notified cases of campylobacteriosis in April and June 2012 that were found retrospectively to be linked by consumption of raw drinking milk in the boarding school of a Hawkes Bay (L Calder, personal communication).

Table 10.3.1: Notified outbreaks where raw milk was identified as a contributing factor

Report Date	Pathogen	DHB	No of Cases	Age range (yrs)	Comments
13/11/2007	Crypto/Campy/Giardia	Southern	6	2-31	Household, father worked on farm
11/07/2008	Campylobacter	Waikato	2	27-31	Prison farm
20/05/2009	Campylobacter	MidCentral	2	NR	Both cases consumed unpasteurised milk, source unknown
17/08/2009	Salmonella	MidCentral	4	6-44	Farm (cattle with Salmonella)
31/08/2009	Campylobacter	Northland	16	5-38	School group farm visit
16/09/2010	Cryptosporidium	Waikato	3	NR	Household
6/10/2010	Campylobacter	Lakes	4	NR	Household on farm, also drank bore water and had contact with farm animals
15/12/2010	Campylobacter	MidCentral	3	NR	Health and Wellness seminar, unpasteurised milk provided
1/11/2010	Giardia	Waikato	3	64-65	Household on farm, also contact with farm animals
22/09/2010	Cryptosporidium	Waikato	2	5-6	Household on farm, also contact with farm animals
8/11/2010	Campylobacter	Waikato	2	68-70	Household, recent farm visit
6/10/2010	Salmonella	Whanganui	2	1-25	Farm (cattle with <i>Salmonella</i>)
18/11/2010	Salmonella	Southern	4	56-87	Family lunch
21/03/2011	Giardia	Waikato	6	1-34	Household, also consumed untreated roof water

Report Date	Pathogen	DHB	No of Cases	Age range (yrs)	Comments
15/04/2011	Campylobacter	Waikato	4	2-4	Household
5/09/2011	Campylobacter	Waikato	4	NR	Household
20/12/2011	Campylobacter	MidCentral	9	NR	Unpasteurised milk purchased from common source (Farm)
26/07/2012	Campylobacter	MidCentral	4	NR	Household
22/08/2012	Campylobacter	Waikato	2	3-7	Household on farm
4/09/2012	Cryptosporidium	Waikato	2	1 - 3	Farm, also contact with sick calves
16/10/2012	Campylobacter	Waikato	5	4 -18	Household on farm, also contact with calves and insufficiently treated groundwater

NR = not reported. Outbreaks highlighted in yellow had strong evidence for being associated with raw milk. The outbreak highlighted in green had very strong evidence for being associated with raw milk. The non-highlighted outbreaks had suggestive evidence for being associated with raw milk. One other outbreak was not recorded in the table but is mentioned in the text above).

Note that in a number of outbreaks cases report consuming raw milk, but have additional risk factors such as animal contact, rural environment, poor water quality or another member of the household being ill.

The following algorithm was used to assess evidence for raw milk-associated outbreaks:

- 1) **Suggestive:** consumption of raw milk was recorded as a contributing factor
- 2) **Medium:** meets the criteria for weak above AND the nature of the clustering of cases in space and/or time was consistent with transmission from raw milk (for example cases report purchasing the raw milk from the same supplier and in the same week)
- 3) **Strong:** EITHER
 - a) meets the criteria for medium above AND the pathogen was identified from an implicated raw milk sample taken during the incubation period of at least one of the outbreak cases, OR
 - b) meets the criteria for medium above AND the identical specific strain of the pathogen from human cases was identified in at least 75% of human cases AND has a milk-producing animal reservoir with a probability of at least 60%. Strain here may mean multilocus sequence type or phage type or other within-pathogen species differentiation methods.
- 4) **Very strong:** meets the criteria for 3.b above AND the identical specific strain of the pathogen from human cases with a milk-animal source was identified in an implicated raw milk sample taken during the incubation period of at least one of the outbreak cases. Strain here may mean multi-locus sequence type or phage type of other within species differentiation methods.

Results of assessment for outbreak data

In 18 of the 21 EpiSurv recorded outbreaks the evidence was suggestive (consumption of raw milk was recorded as a contributing factor) (**Table 10.3.1.**). The three exceptions were

- 1) 17/08/09 where Campylobacter was isolated from a milk sample. This was the largest outbreak and occurred in Northland when 16 people (age range 5 to 38 years) fell ill after consuming raw milk as part of a farm visit. Strong evidence.
- 2) Cluster reported 20/12/11 which was retrospectively identified as an outbreak (9 cases), based on Campylobacter strain type information. This outbreak of campylobacteriosis was associated with a single supplier. Strong evidence.
- 3) 31/08/09 where Salmonella PT 156 was isolated from raw milk and environmental samples. Very strong evidence.

In the Hawkes Bay cluster the evidence was suggestive.

It is important to be aware that a low level of evidence for raw milk as a transmission pathway for gastro-intestinal disease pathogens does not necessarily equate to evidence of no association. For example in the outbreak cases where the standard of evidence was deemed suggestive (19/22) it would have been difficult to meet a higher evidence criterion.

10.3.2 Sporadic cases

Data analysed included individual EpiSurv reports of cases of STEC infection who reported raw milk consumption (1997 – November 2005); summary by DHB of EpiSurv enteric disease reports 1st Jan 2007 – 15th Nov 2012, data supplied by ESR Enteric Reference Laboratory and MidCentral Public Health Unit (PHU) disease notification information,

Assessment of evidence for raw milk-associated sporadic cases was based on the following algorithm:

- 1) **Medium:** consumption of raw milk was recorded as a contributing factor
- 2) **Strong:** EITHER
 - a) meets the criteria for medium above AND the pathogen was identified from an implicated raw milk sample taken during the incubation period of the case, OR
 - b) meets the criteria for medium above AND the specific strain of the pathogen identified from the human case has a milk-producing animal reservoir with a probability of at least 60%. Strain here may mean multi-locus sequence type or phage type or other within-pathogen species differentiation methods.
- 3) **Very strong:** meets the criteria for 3.b above AND the identical specific strain of the pathogen from the human case was identified in an implicated raw milk sample taken during the incubation period of the case. Strain here may mean multi-locus sequence type or phage type of other within species differentiation methods.

Results of assessment for sporadic case data:

- a) EpiSurv reported 27 cases of STEC infections consumed raw milk with the majority (17) in children aged two years or less; five cases did not report either living on a farm, visiting a farm or farm animal contact. The DHB with the highest proportion was Waikato which reported 13 of 140 cases as associated with raw milk (9.3%, 95% CI: 5.5% - 15.2%)
- b) The DHB with the highest proportion of raw milk associated notifications was MidCentral which reported 151 of 2454 cases associated with raw milk (6.2%, 95% CI: 5.3% - 7.23).
- c) Data for MidCentral PHU where raw milk was identified as a risk factor are shown below. These data show a trend of increasing proportion of notifications of campylobacteriosis and salmonellosis over the three year period. However the case numbers are low to enable statistically significant conclusions.

Year	Total cases	Raw milk as risk factor	Percentage of cases
Campylobacteriosis			
2009	234	12	5%
2010	237	11	5%
2011	160	23	14%
Salmonellosis			
2009	31	0	0%
2010	30	1	3%
2011	26	2	8%

In all but one of sporadic cases data the evidence for an association with raw drinking milk is medium. In 2001 HUS case (14 months old boy) the evidence was very strong.

10.4 ASSESSING TRUE PREVALENCE OF SELECTED PATHOGENS IN RAW MILK

In order to assess the true prevalence of pathogens in raw milk (i.e. the probability of a single cell of a pathogen being present in a bulk tank) the estimated probability of detecting a positive bulk tank from a 25 ml sample (the size of sample analysed in both the Fonterra and MPI studies) using simulated pathogen concentration in bulk milk samples was compared with the results of the survey described in Table 5.1. Essentially the MPI study was simulated using the same sample size and volume from the modelled concentration of each pathogen in a large population of bulk tanks. Then the model simulated prevalence estimates with the survey estimates from Fonterra and MPI.

The results for each pathogen are:

Campylobacter spp.

For *Campylobacter jejuni*, the estimated proportion of bulk tanks positive was 92.4% based on simulated bacterial concentrations (i.e. they are predicted to contain at least one viable bacterium in the entire tank). Using the simulated concentrations we estimated that a 25ml milk sample would detect at least one viable bacterium in approximately 6.1% of bulk tanks (i.e. an estimated median prevalence that is considerably lower than the ‘true’ prevalence, but higher than the prevalence estimated in both the MPI (0.58% - red vertical lines, with 95% CI as dashed lines) and Fonterra (0.34% - blue vertical lines) surveys. This is shown in the top graph in Figure 10.4.1. Reducing the sensitivity of the culture method resulted in much lower estimates of bulk tank prevalence that were more similar to the MPI and Fonterra microbiological surveys. For example increasing the minimum number of viable bacteria detected to 2 per 25 ml sample, reduced the estimated median prevalence to 0.88%, and both the survey estimates fell within the simulated prevalence distribution.

STEC

For *E. coli* O157, the estimated proportion of bulk tanks positive was 11.4% based on the simulated bacterial concentrations. Replicating the MPI study and repeatedly sampling 358 x 25ml samples from the simulated bulk tank concentrations resulted in a median prevalence of zero, and only 5% of the simulated surveys identified a single positive farm (i.e. a prevalence of 0.28%). This assumed the test would always detect a single viable bacterium in a 25ml sample, which is consistent with the 100% sensitivity reported in the study conducted by Feldsine *et al.* (1997). This is consistent with the estimates from the Fonterra (0%) and MPI surveys (0.28%) (Figure 10.4.2).

Salmonella spp.

For *Salmonella* spp. the estimated proportion of bulk tanks positive was 41.9% based on the simulated bacterial concentrations. Repeatedly sampling 365 x 25ml samples (i.e. replicating the MPI study) from the simulated bulk tank concentrations resulted in a median prevalence of 0.27%, and 73% of the simulated surveys identified at least one positive farm. However, the estimated prevalence in the simulated surveys was never higher than 1.1%, assuming the test will always detect a single viable bacterium in a 25ml sample. If the limit of detection was increased to at least 2 viable bacteria per 25ml, only 4% of the simulated surveys detected a single positive animal. This is consistent with the zero prevalence estimates from the MPI and Fonterra surveys (Figure 10.4.3).

Figure 10.4.1: Comparison of the estimated proportion of bulk tanks positive for *C. Jejuni* in the MPI and Fonterra surveys with the simulated estimates

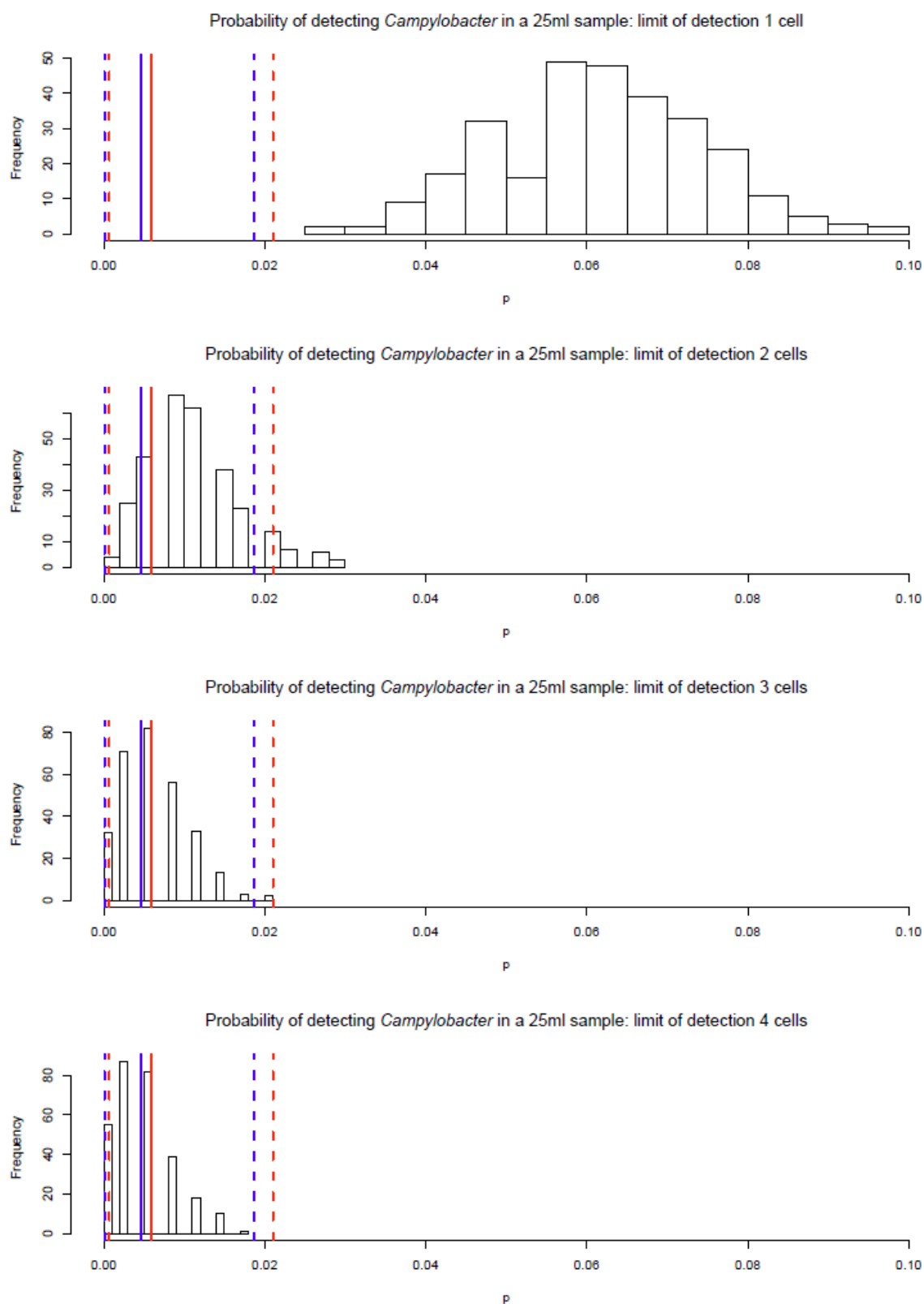


Figure 10.4.2: Comparison of the estimated proportion of bulk tanks positive for *E. coli* O157 in the MPI and Fonterra surveys with the simulated estimates

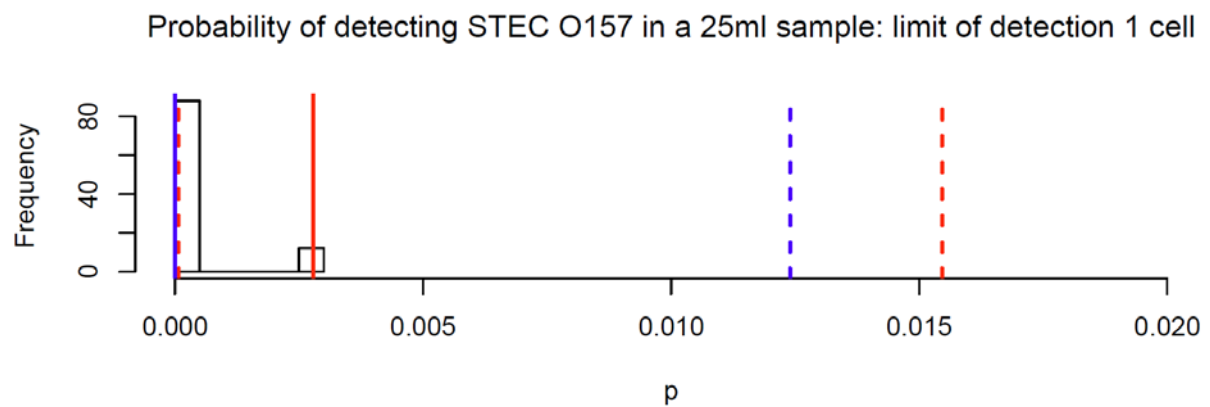
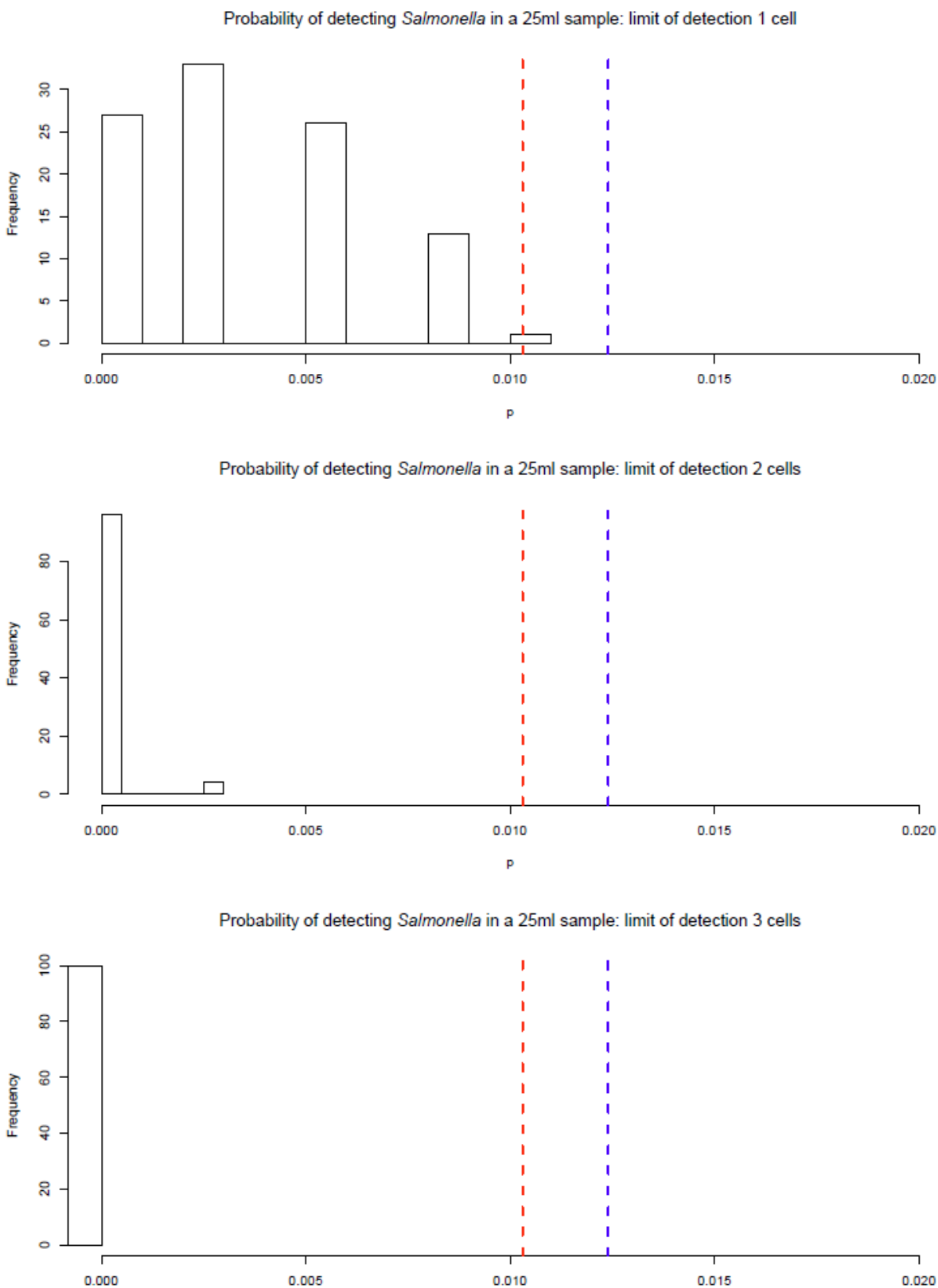


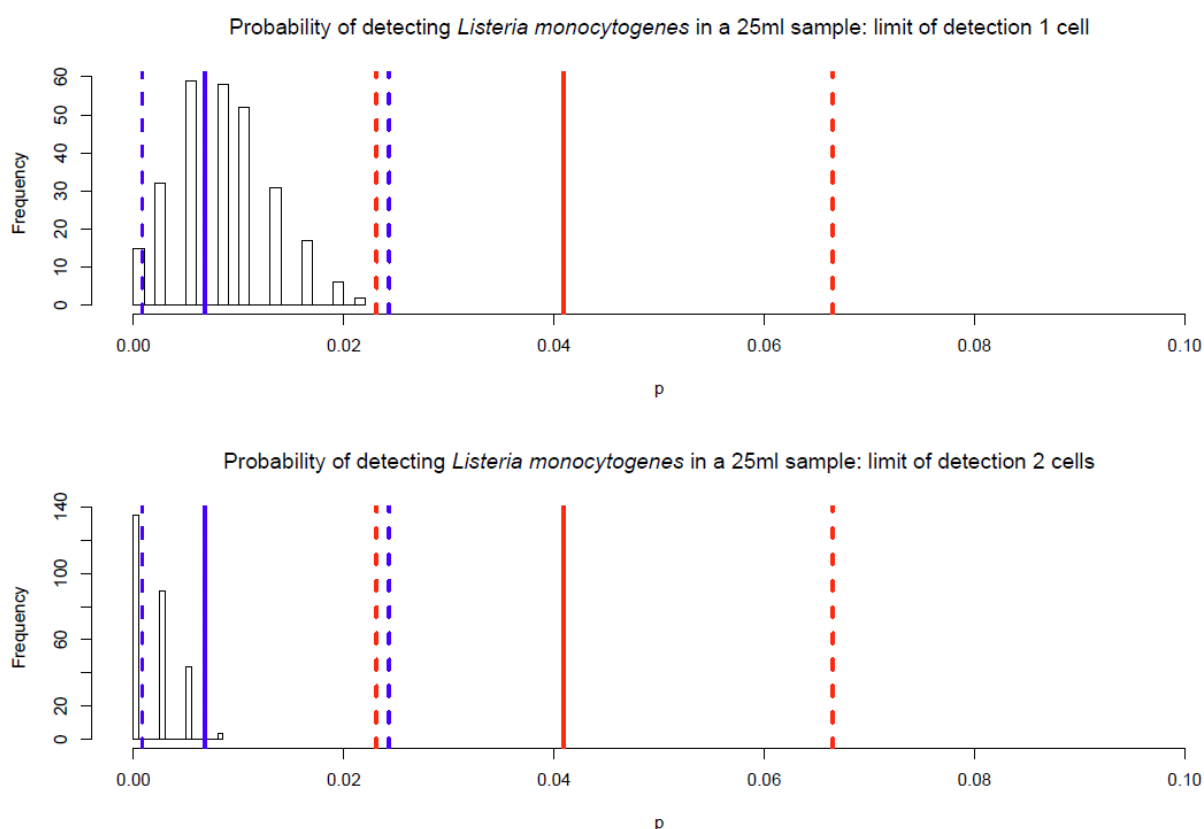
Figure 10.4.3: Comparison of the estimated proportion of bulk tanks positive for *Salmonella* spp. in the MPI and Fonterra surveys with the simulated estimates



L. monocytogenes

For *L. monocytogenes*, the estimated proportion of bulk tanks positive was 65.2% based on our simulated bacterial concentrations. However, repeatedly sampling 367 x 25ml samples (i.e. replicating the MPI study) from the simulated bulk tank concentrations resulted in a median prevalence of 0.8%, assuming the test will detect a single viable bacterium in a 25ml sample, which is consistent with the sensitivity reported in the AOAC study (Hughes *et al.*, 2003). This is consistent with the estimates from the Fonterra (0.68%) survey, but is lower than the MPI survey (4.09%) (Figure 10.4.4.). This is likely to be due to an underestimation of concentrations of *L. monocytogenes* derived from dairy cow faeces and the contribution from poor milking machine hygiene and other sources of contamination.

Figure 10.4.4: Comparison of the estimated proportion of bulk tanks positive for *L. monocytogenes* in the MPI and Fonterra surveys with the simulated estimates



References

Feldsine, P.T., *et al.*, *Visual immunoprecipitate assay (VIP) for detection of enterohemorrhagic Escherichia coli (EHEC) O157:H7 in selected foods: collaborative study*. Journal AOAC International, 1997. 80(3): p. 517-29.

Hughes, D., *et al.*, *Modification of enrichment protocols for TECRA Listeria Visual Immunoassay method 995.22: collaborative study*. Journal AOAC International, 2003. 86(2): p.340-54.

10.5 SUMMARY OF QUANTITATIVE MODEL INPUTS

Distributions chosen for each step in the raw drinking milk supply chain for different distribution pathways are shown in the following table. Notes below the table provide some rationale for the choice of the distributions.

Table 10.5.1: Distributions chosen for model parameters.

Steps in the supply chain	Relevant parameters	Farm gate purchase from vat	Farm gate purchase from vending machine	Off-farm sales (distribution points, farmers markets, vending machines)	Domestic consumption after retail purchase (small retail, supermarket)
Farm Vat Storage: Temperature Logistic	On farm vat storage (temperature) (°C) (Note 1)	Logistic(4.85077, 0.54356). Truncate(0.1,7)	Logistic(4.85077, 0.54356). Truncate(0.1,7)	Logistic(4.85077, 0.54356). Truncate(0.1,7)	Logistic(4.85077, 0.54356). Truncate(0.1,7)
Farm Vat Storage: duration (Uniform)	On farm vat storage (time) (h) (Note 2)	Uniform(1,24)	Uniform(1, 24)	Uniform(1, 24)	Uniform(1, 24)
On farm storage after vat: temperature (Uniform)	On farm vending machine storage (temperature) (°C) (Note 3)	N/A	Uniform(2.5, 4)	N/A	N/A
On far storage after vat: duration (Uniform)	On farm vending machine storage (time) (h) (Note 4)	N/A	Uniform(0.5, 24)	N/A	N/A
Transport off farm to distribution point or factory: temperature (Uniform)	Farmer transport to distribution points (temperature) (°C) (Note 5)	N/A	N/A	On farm vat temp + Uniform(0,2)	N/A
Transport off farm to distribution point or factory: duration (Uniform)	Farmer transport to distribution points (time) (h) (Note 6)	N/A	N/A	Uniform(0.5,3)	N/A
Distribution point or packaging factory: temperature (Normal dbn point)	Distribution point storage (temperature) (°C) (Note 7)	N/A	N/A	Normal(5.2, 2.5) Truncate(1, 10))	N/A
Distribution point or packaging factory: duration (Uniform dbn point)	Distribution point storage (time) (h) (Note 8)	N/A	N/A	Uniform(0.5 ,3)	N/A
Transport off farm to distribution point or factory: temperature (Pert)	Transport to packaging factory (temperature) (°C) (Note 9)	N/A	N/A	N/A	Pert(4,5,6)
Transport off farm to distribution point or factory: duration (Triangle)	Transport to packaging factory (time) (h) (Note 10)	N/A	N/A	N/A	Triang(1,3,6)
Distribution point or packaging factory: temperature (Uniform factory)	Packaging factory storage (temperature) (°C) (Note 11)	N/A	N/A	N/A	Uniform(2,6)
Distribution point or packaging factory: duration (Uniform factory)	Packaging factory storage (time) (h) (Note 12)	N/A	N/A	N/A	Uniform(4,12)
Packaging centre to	Distribution to retail	N/A	N/A	N/A	Pert(1,4,8,7)

Steps in the supply chain	Relevant parameters	Farm gate purchase from vat	Farm gate purchase from vending machine	Off-farm sales (distribution points, farmers markets, vending machines)	Domestic consumption after retail purchase (small retail, supermarket)
retail: temperature (Pert)	(temperature) (°C) (Note 13)				
Packaging centre to retail: duration (Triangle)	Distribution to retail (time) (h) (Note 14)	N/A	N/A	N/A	Triang(1.7,2.1,5.9)
Off farm sales storage: temperature (Normal)	Retail storage temperature (°C) (Note 15)	N/A	N/A	N/A	Normal(4.9, 2.8) truncated at 0 and 6°C
Off farm sales storage: duration (Pert)	Retail storage (time) (h) (Note 16)	N/A	N/A	N/A	Pert(12,48,96)
Transport to home: temperature (Uniform)	Domestic transportation (temperature) (°C) (Note 17)	Uniform(0.3, 2.4) increase per 10 minute period, truncate at 20	Uniform(0.3, 2.4) increase per 10 minute period, truncate at 20	Uniform(0.3, 2.4) increase per 10 minute period, truncate at 20	Uniform(0.3, 2.4) increase per 10 minute period, truncate at 20
Transport to home: duration (Triangle: first two pathways) (Discrete: second two pathways)	Domestic transportation (time) (h) (note 18)	Triang(0.1, 0.5, 1)	Triang(0.1, 0.5, 1)	Discrete({0.25, 0.5, 0.75, 1, 1.25, 1.5, 1.75, 2, 2.25, 2.5, 3, 3.5, 4, 4.5, 5, 5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9, 9.5, 10, 10.5, 11, 11.5, 12, 12.5, 13, 13.5, 14, 14.5, 15, 15.5, 16, 16.5, 17, 17.5, 18, 18.5, 19, 19.5, 20, 20.5, 21, 21.5, 22, 22.5, 23, 23.5, 24, 24.5, 25, 25.5, 26, 26.5, 27, 27.5, 28, 28.5, 29, 29.5, 30, 30.5, 31, 31.5, 32, 32.5, 33, 33.5, 34, 34.5, 35, 35.5, 36, 36.5, 37, 37.5, 38, 38.5, 39, 39.5, 40, 40.5, 41, 41.5, 42, 42.5, 43, 43.5, 44, 44.5, 45, 45.5, 46, 46.5, 47, 47.5, 48, 48.5, 49, 49.5, 50, 50.5, 51, 51.5, 52, 52.5, 53, 53.5, 54, 54.5, 55, 55.5, 56, 56.5, 57, 57.5, 58, 58.5, 59, 59.5, 60, 60.5, 61, 61.5, 62, 62.5, 63, 63.5, 64, 64.5, 65, 65.5, 66, 66.5, 67, 67.5, 68, 68.5, 69, 69.5, 70, 70.5, 71, 71.5, 72, 72.5, 73, 73.5, 74, 74.5, 75, 75.5, 76, 76.5, 77, 77.5, 78, 78.5, 79, 79.5, 80, 80.5, 81, 81.5, 82, 82.5, 83, 83.5, 84, 84.5, 85, 85.5, 86, 86.5, 87, 87.5, 88, 88.5, 89, 89.5, 90, 90.5, 91, 91.5, 92, 92.5, 93, 93.5, 94, 94.5, 95, 95.5, 96, 96.5, 97, 97.5, 98, 98.5, 99, 99.5, 100, 100.5, 101, 101.5, 102, 102.5, 103, 103.5, 104, 104.5, 105, 105.5, 106, 106.5, 107, 107.5, 108, 108.5, 109, 109.5, 110, 110.5, 111, 111.5, 112, 112.5, 113, 113.5, 114, 114.5, 115, 115.5, 116, 116.5, 117, 117.5, 118, 118.5, 119, 119.5, 120, 120.5, 121, 121.5, 122, 122.5, 123, 123.5, 124, 124.5, 125, 125.5, 126, 126.5, 127, 127.5, 128, 128.5, 129, 129.5, 130, 130.5, 131, 131.5, 132, 132.5, 133, 133.5, 134, 134.5, 135, 135.5, 136, 136.5, 137, 137.5, 138, 138.5, 139, 139.5, 140, 140.5, 141, 141.5, 142, 142.5, 143, 143.5, 144, 144.5, 145, 145.5, 146, 146.5, 147, 147.5, 148, 148.5, 149, 149.5, 150, 150.5, 151, 151.5, 152, 152.5, 153, 153.5, 154, 154.5, 155, 155.5, 156, 156.5, 157, 157.5, 158, 158.5, 159, 159.5, 160, 160.5, 161, 161.5, 162, 162.5, 163, 163.5, 164, 164.5, 165, 165.5, 166, 166.5, 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10.6 RAW MILK CONSUMPTION

New Zealand specific data are available from:

- 1997 National Nutrition Survey (1997NNS), including 24HDR and QFFQ responses from 4636 New Zealander adults (15+ years) ([Russell *et al.*, 1999](#)),
- 2002 National Children's Nutrition Survey (2002CNS), including 24HDR and QFFQ responses from 3275 New Zealand children (5-15 years) ([Ministry of Health, 2003](#)), and
- 2009 Adult Nutrition Survey (2009ANS), including 24HDR and limited dietary habit questionnaire responses from 4721 New Zealander adults (15+ years) ([University of Otago and Ministry of Health, 2011](#)).

The surveys oversampled certain population groups, but each respondent was assigned a survey weight to align the survey outputs with the New Zealand population. Although there was no specific 'raw milk' category in the surveys, number of responders reported that they consumed fresh cows' milk', 'vat milk', 'farm milk', 'real milk' and 'cows milk', interpreted as being raw milk consumption.

Based on the data from the NNSs' data it was estimated that 1% of the adult (15+ years) population and 0.5% of the child (1-14 years) population¹³ consume raw drinking milk in any 24 hour period. Using the latest New Zealand population estimates, this equates to 39,656 people (35,500 adults and 4,156 children) consuming raw milk regularly. It is possible that a proportion of these consumers heat treated the raw milk before consumption; a similar Italian study estimated that 60% of raw milk consumers boil milk prior to consumption (cited in *Giacometti *et al.*, 2012*).

A transmission study of *Campylobacter* in the predominantly rural Ashburton region, reported anytime consumption of unpasteurised milk as 9/44 cases (20.5%, 95% CI 9.8-35.3%). (*Baker *et al.*, 2002*). The frequency of raw drinking milk consumption was not investigated.

In a national case-control study of STEC infection carried out in 2011-12, 16/506 controls (3.2%; 95% CI 1.8-5.1 and 5/113 cases (4.4%, 95% CI 1.5-10.0) reported raw milk consumption (Patricia Jaros, Massey University, personal communication). The estimate of those consuming raw milk (3.2% of controls) is higher than that from NNS data (1% of adults). It is plausible that raw milk consumption increased in the three years between the two studied. It has to be noted that the questions in the two studies were formulated differently with the case-control study also capturing raw milk product (cheese, yoghurt) consumption and occasional consumption of raw drinking milk.

It is reasonable to assume that a proportion of the population who consume raw milk are residents of and/or work on dairy farms. A Massey University survey in 2011 found that amongst dairy farmers 64% (858/1337) reported consuming raw milk. The number of people working on dairy farms in 2006 was estimated as 24,795 based on data at the Statistics New Zealand website (NZSCO99 Code 61211 Dairy farmer, dairy farm worker). If 64% of these people consume raw milk then the estimated number of raw milk consumers working on farms in 2006 was 15,869 people.

¹³ For the purpose of the current study, it was assumed that the milk consumption patterns of those aged 1-4 years would be substantially the same as those aged 5-14.

There has only been a small increase in the number of dairy herds since 2006 (11,630 in 2006/07 to 11,798 in 2011/12) but the average number of cows per herd has increased (337 in 2006/07 to 393 in 2011/12), so the number of dairy farm workers will be higher.¹⁴ If it is assumed that each dairy herd is operated by a single household (average size 2.6 people) then there may be 30,675 people living on dairy farms. If 64% of these consume raw milk then the estimated number of raw milk consumers living on farms is 19,632. The number of people working on dairy farms is likely to have increased since 2006 because of expanded herd sizes. Therefore an approximation for people living or working on dairy farms and consuming raw milk of 20,000 is considered reasonable.

These estimates suggest that of the population consuming raw milk (39,656 people based on NNS data) up to half may be people living and/or working on dairy farms. The remainder are likely to be motivated people actively obtaining raw milk for various reasons.

Current legislation restricts raw milk sales to five litres per person only at the farm gate. However an open web-based public survey by Federated Farmers suggests that non-farm gate sales are occurring widely. Of the survey respondents who reported purchasing raw milk, 48 said that they collected raw drinking milk from the farm, while nearly 300 respondents picked it up from a chilled collection point other than the farm gate. If off-farm collection points were prevented, a decrease in the number of raw milk consumers can be expected.

Changes to farm gate sales within the on-farm scenarios, e.g. increased amount (above five litres) per purchase or unlimited volume per purchase, but with a maximum limit per farm per day, are not considered to have strong impact on raw milk consumption. Most people who want to purchase raw milk by this means are able to do so already. On the other hand any changes to farm gate sales (or sales of raw milk in general) will generate media interest, which will increase awareness of raw milk availability among the New Zealand population. There will be people who previously did not consider raw milk as an alternative to pasteurised products and, once aware of raw milk availability, will purchase raw milk. The amount of milk available for purchasing at a farm in any one day is not considered as a limiting factor; market drivers will ensure that demand will not exceed supply (i.e. more farmers will provide the raw milk). This assumes that the cost or effort of meeting regulatory requirements is not a disincentive for farmers to provide raw drinking milk for sale. So, for the on-farm scenarios a modest increase in consumers' number was considered: in the model the number of consumers that do not live or work on farms was doubled. Economic reasons e.g. cost of compliance for the farmer, can significantly change this estimate.

The number of raw milk consumers is expected to increase if farm gate sales continue, but farmers are permitted also to sell raw milk directly to the public via off-farm collection points (off-farm sales). It is not possible to predict the proportion of people who would change from buying raw milk at the farm gate to buying it from a market or vending machines located in an urban area or how many new purchasers will switch from pasteurised to raw milk consumption.

Sales of raw milk through small retail outlets, such as convenience stores or health food stores, and supermarkets are also expected to increase consumption due to availability and easy accessibility of raw milk in urban areas. Consumption pattern of new consumers is unpredictable. It is possible that the increased proportion of the population that try this new product initially will decline later as people return to previous purchasing patterns.

¹⁴ <http://www.dairynz.co.nz/file/fileid/45159> accessed 27 February 2013.

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Annex 1 Evaluation of the likelihood of contamination with *Mycobacterium bovis*

Farm gate supply of unpasteurised cows' milk: an evaluation of the risk of contamination with *Mycobacterium bovis*, March 2013

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List of Technical Terms used in Bovine Tuberculosis Control

Over many years those involved in the control of bovine tuberculosis have adopted a range of technical terms and definitions to describe various aspects of the programme. Some are from the discipline of epidemiology, but others are specific to the New Zealand situation. They are used commonly in this risk analysis. A more extensive list is available in Animal Health Board publications. (AHB (Part A) & (Part B) 2011).

Technical Term	Description
abattoir or slaughter house surveillance	All cattle and deer are subject to post mortem inspection for tuberculosis at slaughter houses. TB reactors are examined more intensively
ancillary test	A diagnostic test applied shortly after a skin test for the purpose of either reducing false positives (improve specificity) or reducing false negatives (improve sensitivity)
area movement control	In some localities there is a high risk of transmission of <i>M. bovis</i> from TB vectors to livestock, and therefore cattle and deer may be required to be tested prior to moving from one farm to another.
Bovigam®	A blood test for <i>M. bovis</i> infection in cattle. It is used in New Zealand as an ancillary test.
bovine tuberculosis	A disease caused by the bacterium <i>Mycobacterium bovis</i> , which can infect humans and a wide range of domestic and wild animals.
caudal fold test	The skin test that is routinely applied to cattle and deer in New Zealand. Tuberculin is injected into the skin fold at the base of the tail in cattle and at the mid-cervical site in deer.
clear herd status	A herd that is considered free of tuberculosis infection. A numeric suffix is added, indicating the number of years the herd has had a clear status; e.g. Clear 1, Clear 5, Clear 10.
granuloma	The typical pathological lesion that is found in tuberculosis infection. During abattoir inspection, carcasses are examined for granulomas.
immune-competent	An animal or human that has a fully functioning immune system.
immune-compromised	An animal or human whose immune system is not fully functional; e.g. in humans during chemotherapy, radiation treatment and with HIV/AIDS infection. In the very young and with advancing age it appears that the immune system has reduced efficiency.
incidence	This is a measure of disease occurrence; it is the number of new cases that occur in a known population over a specified period of time. In this report, the incidence of new infected herds, or breakdowns, is referred to commonly, as a percentage of the population over a period of 12 months.
infected herd	A herd of cattle or deer that includes, or has recently included one or more animals that have been diagnosed as being infected with bovine tuberculosis.
movement control	The legal controls that are placed on an infected or suspect herd to prevent the spread of infection via the movement of cattle and deer from one herd to another.
prevalence	Also a measure of disease occurrence; this is the number of instances of a disease, in a known population, at a designated time, without distinction between old and new cases. The prevalence of <i>M. bovis</i> infected herds is usually reported at a percentage as at 30 June each year.
officially free of bovine tuberculosis	The status of a country or region given a specific prevalence of bovine tuberculosis in herds and animals, as defined by the World Organisation for Animal Health (OIE). It does not mean that <i>M. bovis</i> has been eradicated from the country or region in a biological sense.
sensitivity	The probability that an infected animal will be found positive to a test; e.g. around 85% of animals infected with <i>M. bovis</i> will have a positive skin test.

Technical Term	Description
serial ancillary test	An ancillary test used to reduce false-positive animals. It has the effect of reducing the overall probability of detecting an infected animal; i.e. reduced sensitivity.
skin test	The common diagnostic test for tuberculosis in humans and animals. Tuberculin is injected into the skin. The site is examined for a tissue reaction, especially swelling, two to three days later.
specificity	The probability that an animal free of a disease will not be found positive to a test for that disease. Animals may be sensitised to the <i>Mycobacteria</i> via contact with non-pathogenic members of the genus. They may then react to tests for bovine tuberculosis.
surveillance	The process of determining whether or not bovine tuberculosis infection is present in domestic and wild animals.
surveillance TB testing	The testing of clear herds to confirm freedom from infection with bovine tuberculosis.
suspect animal	An animal for which there are grounds for considering it is infected with <i>M. bovis</i> .
suspended herd status	The status given to a herd with a Clear TB status where there is a suspicion that TB may be present in the herd, or in some circumstances where herd TB testing requirements have not been met.
TB breakdown	Identification of <i>M. bovis</i> infection in a herd that has a "Clear" or "Suspended" status.
TB reactor	An animal that tests positive to a test for bovine tuberculosis and <u>is directed to be slaughtered</u> .
TB vector	Wild animals that carry and transmit bovine tuberculosis to domestic animals. The most likely vector species in New Zealand are possums and ferrets.
test-negative	An animal for which the results of tests for bovine tuberculosis are negative.
test-not negative	An animal which has been tested for bovine tuberculosis and the result is equivocal.
test-positive	An animal for which the results of tests for bovine tuberculosis are positive.
trace back	The process of investigating the movements of animals back from a herd. It is often used during a TB breakdown to find the source of infection.
trace-forward	The process of investigating the movements of animals forward from a herd. It is often used during a TB breakdown to identify herd at risk of infection.
tuberculous animal	An animal considered to be infected with bovine tuberculosis.
vector free area or VFA	A defined geographical area where bovine tuberculosis is not maintained in the wild-life population
vector risk area or VRA	A defined geographical area where bovine tuberculosis is being maintained in the wildlife population as indicated by either epidemiological information from infected cattle and deer herds, or the finding of tuberculosis in wildlife animals that are classed as bovine tuberculosis maintenance hosts

Executive Summary

The purpose of this risk profile is to evaluate the likelihood of unpasteurised cows' milk being contaminated with *Mycobacterium bovis* (*M. bovis*) when supplied to a consumer at the farm gate.

General retail sales of raw (i.e. unpasteurised) milk are currently prohibited in New Zealand, but there is provision for purchase of up to five litres directly from the herd owner (i.e. the "farm gate") if the purchaser intends to drink it him/herself, and/or to supply it to just their family.

The Ministry for Primary Industries is currently reviewing the conditions for the sale of raw milk. This risk assessment is a part of this wider review, which will cover many other potential food safety items.

M. bovis can cause a serious disease in humans. The pathogenicity is similar to the more common cause of tuberculosis, *M. tuberculosis*. Prior to pasteurisation of milk, in children infection of the gut (together with associated organs and tissues) was a common and often serious condition. Latent infection can also occur, with reactivation when the person's immune function is compromised, for example in old age, with chemotherapy treatment and with HIV/AIDS infection.

Pasteurisation of milk has been shown to be a very effective means of destroying *M. bovis* in milk.

Currently, there is no evidence of milk borne transmission of *M. bovis* infection to humans in New Zealand.

The reservoir of *M. bovis* infection in New Zealand is primarily in domestic cattle and deer herds and, in some localities, in wildlife especially possums. Areas where wildlife are infected are termed "vector risk areas"; and where they are not infected "vector free areas". Infection can spread from possums to domestic cattle and deer, complicating the eradication of tuberculosis from livestock. The risks of infection are greater in vector risk areas. Despite this, via a nationally coordinated control strategy (the "National Bovine Tuberculosis Pest Management Strategy"), the incidence in livestock has been reduced to a very low level¹⁵.

Tuberculosis is a slow progressive disease in cattle. The initial or primary lesions are found in the lungs, head and intestine, but, if left undiagnosed, in many cattle it will slowly spread to other organs, possibly including the udder. Once in the udder *M. bovis* can then be shed in the milk. The current bovine tuberculosis control programme in New Zealand minimises this exposure route via regular testing of what are presumed to be tuberculosis-free herds and efficient abattoir surveillance for diseased carcasses. Most infected cattle will be detected and removed from herds in the early phases of the disease. Evidence is presented that when there is an effective control programme, contamination of raw milk is a very uncommon event. However, despite this low probability of excretion of *M. bovis* into milk, in recent years cases have been reported both in New Zealand and overseas where there were serious follow-on human and/or animal health issues.

Outlines of the tuberculosis control programme in New Zealand and the pathogenesis of *M. bovis* infection in cattle are presented. Key risk factors for infection being introduced into

¹⁵ within one to two years it is expected that New Zealand will be accepted internationally as "Officially Free"

herds free of tuberculosis have been identified. It is suggested that if raw milk is being supplied for drinking or processing, conditions of sale based on these should be used to reduce the risk of consumer exposure.

The specific recommendations are as follows:

- Raw milk should be sold in containers that are labelled with a warning about *M. bovis* infection, especially in children and the immune-compromised.
- The herd supplying raw milk is not located in a vector risk area.
- There have been clear herd tests for tuberculosis for 5 or more years (i.e. the herd status is Clear 5 or greater).
- The maximum period between tuberculin surveillance tests is twelve months.
- All skin test-positive and skin test-suspect should be subject to an intensive post-mortem inspection; i.e. no serial ancillary retesting.
- All replacement stock have been grazed only in the vector free area and they truly meet status of Clear 5 or better, as confirmed by trace back using the “National Animal Identification and Tracing” (NAIT) System.
- Following a “not negative” surveillance event (either testing or abattoir) until the herd is confirmed free of infection, raw milk sales are curtailed.

Another condition, that all the neighbouring herds have a tuberculosis clear status, could also be considered. Unlike many other infectious diseases, spread to animals on contiguous properties is not a feature of the epidemiology of *M. bovis*. However, of importance would be that herds supplying raw milk should have adequate containment (i.e. fencing) to prevent mixing of livestock from other farms.

Statement of purpose

The purpose of this risk assessment is to evaluate the risk of unpasteurised cows' milk being contaminated with *Mycobacterium bovis* (*M. bovis*) when supplied to consumers at the farm gate.

Background

Human bovine tuberculosis caused by *M. bovis* was common in the past, although the incidence has declined substantially with the progressive introduction of pasteurisation of milk from the 1930's onwards. In addition, the prevalence of tuberculosis in dairy cattle has been substantially reduced via a nationally coordinated control programme (see Appendix 1). Nevertheless, with raw drinking milk being sold at the farm gate or distributed through alternative channels, albeit outside the law, the health of the consumers of these products may be compromised. Any expansion or relaxation of the conditions for current sales could exacerbate this public health risk.

Hazard Identification

The hazard is the bacterium *M. bovis* in raw milk at the point of availability to a consumer in New Zealand.

M. bovis is the causative agent of “bovine tuberculosis”. It is capable of infecting a wide range of warm blooded animals including humans. Infection in animals can be classified as “maintenance” or “spill-over” (Coleman *et al.*, 2001). In the former circumstance, *M. bovis* is maintained within an animal population independently of other species. The latter is a spill-over of infection from these maintenance species. Among domestic and wild animals the ability to maintain *M. bovis* infection varies considerably. It can be maintained within both domestic cattle and deer herds, and, in New Zealand, within possum¹⁶ populations and sometimes in ferrets. As possums have successfully colonised virtually the whole of New Zealand, cattle-possum (and also deer-possum) contact occurs commonly. In those areas where possums (or ferrets) are infected, *M. bovis* can spread to cattle and deer. This has had profound effect on the ability to eradicate tuberculosis from cattle and deer herds (see Appendix 1).

In developed countries (including New Zealand) another organism, *M. tuberculosis* is by far the most common cause of tuberculosis in humans (Baker *et al.*, 2003; Lopez *et al.*, 2010; Bissielo *et al.*, 2012; Majoor *et al.*, 2011). From an ecological perspective, humans are the maintenance host for *M. tuberculosis*, with *M. bovis* infection being spill-over infection from animal reservoirs. In the absence of immunosuppression, person to person transmission of tuberculosis caused by *M. bovis* is rare (ACMSF, 2011).

In New Zealand during 2009, 245 of the 300 (82%) notifications were culture-positive, and of these only 5 (2%) were *M. bovis* (Lopez *et al.*, 2010). Over three-quarters (83.2%, 253/304) of the TB disease notifications in 2010 were culture positive, of which 250 (98.8%) were due to *M. tuberculosis* and three (1.2%) were due to *M. bovis* (Bissielo *et al.*, 2011). During 2011, *M. bovis* was not isolated from any notified cases Bissielo *et al.*, 2012).

A retrospective study of *M. bovis*-confirmed human cases that had been “officially notified” in New Zealand over the period 1998 to 2002 was conducted by Michael Baker and associates (Baker *et al.*, 2003; Baker *et al.*, 2006). Thirty four cases were identified. Most cases (80%) were over 30 years of age, with a median age of 57 years. Compared with people infected with *M. tuberculosis*, people infected with *M. bovis* were significantly more likely to be male, over 60 years of age, European or Maori, to have been born inside New Zealand rather than migrated here, and to be living in the South Island at the time of diagnosis. The authors concluded that *M. bovis* infection is not increasing despite the reservoir of animal infection in this country. The modes of infection in all but two of these human cases were not established, but the data suggests that transmission via infected milk currently was not a public health issue in New Zealand.

This risk assessment is limited to the presence of *M. bovis* in raw drinking milk. However, it should be noted that contaminated raw milk products are a significant health risk. A recent epidemic of *M. bovis* infection in the United States, in which a child died, was caused by contaminated raw milk cheese (CDC, 2005). In another investigation (Rodwell *et al.*), also in the United States, consumption of imported products made from unpasteurised milk was also thought to be a major source of infection.

¹⁶ *Trichosurus vulpecula*

Hazard Characterisation

Human tuberculosis can be caused by several mycobacterial species including *M. bovis* and *M. tuberculosis*. The pathogenicity of *M. bovis* and *M. tuberculosis* in humans is similar and clinically they are indistinguishable (ACMSF, 2011). The resultant pathology is strongly influenced by the mode of transmission; i.e. in developed countries generally by ingestion of contaminated food¹⁷ with *M. bovis* and by aerosol with *M. tuberculosis*.

Although infection usually involves the lungs (pulmonary tuberculosis) mycobacteria can attack a number of organs in humans (extra-pulmonary tuberculosis). Tuberculosis in immunocompetent individuals is characterised by a slowly developing chronic infection after a long incubation period. Symptoms which can persist for months or years depend on the organ(s) infected. For example the symptoms of intestinal tuberculosis (which can result from direct ingestion of the organism) include fever, chills, weight loss, abdominal pain, diarrhoea, and/or constipation.

By the gastrointestinal route, experimental studies in animals indicate that the infectious dose of *M. bovis* is high, in the region of millions of organisms. The infectious dose via the respiratory route is much less, perhaps as few as, or even less than, 10 to 20 organisms.

Prior to widespread pasteurisation of milk, children tended to suffer much more from extra-pulmonary tuberculosis (Bynum *et al.*, 2012). *“This was related partly to diet— the greater consumption of raw milk— leading to infection with the bovine form of the tubercle bacillus. Acute abdominal tuberculosis killed quickly, but a slow spread from a primary focus in the alimentary tract into the mesenteric and abdominal glands was a more protracted process. Such children would be small, wasted, and suffer from periodic fever. If the tissues lining the abdomen were compromised— tuberculous peritonitis— fluid could flow into the peritoneal cavity, causing significant swelling. The grossly distended abdomen in concert with the otherwise emaciated body made a wretched picture”*.

That children are particularly at risk was highlighted in a recent incident in Ireland. A dairy farming family had been drinking raw *M. bovis* contaminated milk and a four year old child developed clinical tuberculosis (Doran *et al.*, 2009). Continuous antibiotic therapy for a period of 19 months was required.

Infected immunocompetent individuals may not initially display symptoms as their immune systems can control infection. This is referred to as “latent tuberculosis”. At least 10% of those infected subsequently develop “active tuberculosis”. For example in old age persistent mycobacteria may reactivate causing secondary/post-primary/reactivation tuberculosis. Intestinal tuberculosis can occur after reactivation of primary infection.

¹⁷ The mode of transmission of *M. bovis* can be by aerosol as reported in Baker *et al.*'s report and paper [4, 10].

Exposure Assessment

The potential exists for *M. bovis* to be present in unpasteurised milk or milk products if there is *M. bovis* infection in a dairy herd. If the herd happens to be producing raw milk for direct human consumption or for the manufacture of unpasteurised milk products, a public health risk may exist until either infection is detected in the herd by animal testing, slaughterhouse surveillance, or the infected animals are removed for some other reason (e.g. culled for poor production or age). The main risk arises from direct contamination of the milk in the udder, which is most likely when infection becomes disseminated in the animal and a tuberculous mastitis develops.

The post mortem findings in the early phases of tuberculosis control in dairy herds indicate that in many cows *M. bovis* infection progresses to a generalised state (MacFarlane, 1953). Thus, excretion of the organism in milk would have been common prior to the advent of regular animal testing. The current bovine tuberculosis control programme in the New Zealand minimises this exposure route through regular testing of all herds and efficient abattoir surveillance. Most infected cattle should be detected and removed from herds in the early phases of the disease.

The level of tuberculosis in dairy herds in New Zealand is now very low. Despite the complication of wildlife vectors of disease, the control programme has been very successful (see Appendix 1) and a further decrease is likely. In vector free areas less than 10 new herd infections out of a total of approximately 11,350 herds over 12 months are expected. In vector risk areas less than 35 breakdowns out of a total of 2,439 herds are predicted (Livingstone (2011), 2013).

So far this year¹⁸, there have been four dairy herd breakdowns. In one, recrudescence of infection is considered to be the cause. Another involves a complex dairy enterprise made up of three dairy herds. One of the tuberculous animals had been purchased. However, cows are moved between the herds and therefore it is expected that more infected animals will be uncovered. Infection in another herd may possibly be related to prior infection in a neighbour's herd, but the field investigation is still in progress at the time of writing. TB has also been diagnosed in a fourth herd which is currently being investigated. Concerning the current situation, Dr Paul Livingstone¹⁹ commented as follows:

'The number of infected dairy herds in the Vector Free Area of the North Island has increased by 14 since June 2012. Two of the newly infected herds had at least one cow each with TB mastitis. These cows were excreting M. bovis bacteria into the milk which infected calves drinking the milk in both herds. There are reasonable explanations for source of infections in these herds and it is considered unlikely that TB possums were involved. We believe that the infection will be eradicated within the next two years. Tracing forward or back from these new breakdown herds may identify other infected herds'.

The potential for *M. bovis* to be present in the milk of herds considered free of tuberculosis cannot be totally eliminated due to the possible presence of cattle which have become infected between surveillance herd tests and, to a lesser extent, the possible presence of anergic (i.e. infected but skin test negative) cattle. In both cases there is the potential for the animal to develop tuberculous mastitis and for contaminated milk to continue to enter the food supply

¹⁸ the testing year 2012/2013 which starts on 1 July and ends the following year on 30 June.

¹⁹ Manager TB Eradication & Research, Animal Health Board

whilst the herd maintains its official “TB Clear” status. In addition, retesting of skin test-positive or test-suspect animals is a common operational procedure in New Zealand. The effect of this is to lower the probability of identifying an infected animal and thus to increase the risk of milk contamination. Details of the tuberculosis controls in place in New Zealand for “suspect cattle” are given in Appendix 1. However, of note, (and in contrast to the United Kingdom programme) there is no requirement to direct the milk from “not test-negative” animals away from human consumption.

Where there is infection in the herd, either detected or undetected, routes that could lead to contamination of raw milk with *M. bovis* include via faeces and from the environment but the main risk arises from direct contamination of the milk in the udder. Although shedding can occur before the animal tests positive or before clinical signs of infection are apparent, the authors of a recent risk assessment considered this to be an unlikely event in the United Kingdom (ACMSF, 2011). In Northern Ireland, which has an intensive control programme similar to New Zealand, Neill *et al.* considered that this was also the situation (Neill *et al.*, 1994). It is also in accord with observations in New Zealand; in a sample of 424 *M. bovis* infected dairy cows none²⁰ were found to have lesions in the supramammary lymph node which drains the udder (Ryan, 2013).

Clearly, the probability that infection will spread to the udder is a key item in this assessment. There is considerable uncertainty concerning the figure. Collins, in a review published in 2000 (Collins, 2000), quotes the results of survey in the United Kingdom circa 1934 in which 1% of tuberculous cows were found to have infection of the udder. However, this is well before the introduction of the intensive test and slaughter campaign seen nowadays. Some more recent data, also from the United Kingdom, are available (ACMSF, 2011). The pathology of 29,686 *M. bovis* confirmed lesion cases which were slaughtered from 2003 to 2010 is presented; overall 68 (0.23%) had lesions indicative of udder infection (Figure 1). In the New Zealand dataset (Ryan, 2013), although no lesions in the supramammary lymph node were reported, in three cases (0.71%) there was widespread infection; i.e. five or more lesions. In two of these there was evidence of systemic spread and in the third there were many thoracic and gut lesions. There is, therefore, a risk that *M. bovis* had invaded, or would invade, other tissues including the udder and be excreted in the milk.

It is important to note that these “low probability events” do occur, and the consequences can be severe from both a human health and/or animal health perspective. Three cases, one from Ireland and two in New Zealand, have been reported over the last four years as follows.

1. Doran *et al.* (2009) reported such an event in Ireland. People and cattle on a dairy farm became infected following consumption of milk from a seven-year-old cow with tuberculous mastitis. Twenty-five of 28 (89%) calves born during autumn 2004 and spring 2005 were subsequently identified as TB reactors, and five of six family members were positive on the Mantoux21 test. During 2005, milk from this cow had mainly been used to feed calves, and was added only occasionally to the bulk tank. The family collected milk from the bulk milk tank, and consumed it without pasteurisation. Two young children suffered severe health impacts.
2. In New Zealand, in the period 2008 to 2010, multiple herd breakdowns were traced back to a single Waikato herd which was found, subsequently, to contain two tuberculous cows. All of the animals, when calves, had been fed raw whole milk for five months; this was the key event tying together infection in nine other herds (Livingstone *et al.*, 2012). It was not reported if the farmer or his family has consumed raw milk at this time.

²⁰ The 95% upper confidence limit for 0/424 is 0.86%

²¹ a skin test for tuberculosis used in humans

3. In New Zealand, during the current year, a breakdown in a dairy herd was identified in which the source of infection may have been prior disease in a neighbour's herd. At least one cow in this herd had tuberculosis in the udder and this resulted in half of the 100 calves reacting to the TB test (Livingstone (2), 2013).

Whether or not such an “excretor” occurs in a herd would be strongly influenced by the number of infected cows that are present. A subset of data relating to dairy herd breakdowns from the period 1994 to 2004 was extracted from the national TB archive (Ryan, 2013). The number of tuberculous animals found was similar in both vector risk and free areas, with three or less animals in 95% of breakdowns. High prevalence breakdowns occurred infrequently, as indicated in Table 2.

Table 1: Number of lesions in *M. bovis* confirmed dairy cattle, by culls and reactors

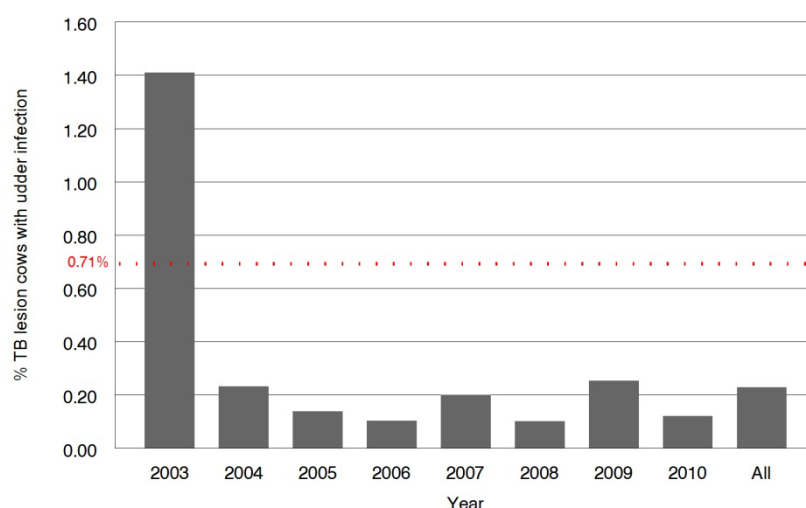
Number of Lesions	Culls	Reactors	Total
1	103	183	286
2	25	61	86
3	12	35	47
4	2	0	2
5	1	0	1
6	0	1	1
10	0	1	1

Table 2: Dairy herd breakdowns in New Zealand, number of tuberculosis animals reported

Number	1	2	3	4	5	6	7	8	9	10	20	30	40	50
Percent	82.0	10.4	2.1	1.2	0.8	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4

Figure 1: Percentage of tuberculous cows with lesions indicative of udder infection, by years

Data from the United Kingdom [8], a figure of 0.71%, the probability used in a model of the NZ situation, is shown



The data presented was incorporated into a stochastic model of the risk of a breakdown²² occurring in which the milk was already contaminated with *M. bovis*. The structure of the

²² It is assumed that milk from a known infected herd would have to be pasteurised.

model is shown in Figure 2. The model scenario consists of a dairy herd, which is free of tuberculosis, either becoming infected or not over one year. The number of tuberculous cows present and the number of these that had developed systemic infection and excreted organisms from the udder is estimated.

During each simulation

1. a herd is randomly allocated to a vector free or vector risk area,
2. whether or not a breakdown occurs is set by a binomial function using the data supplied by Paul Livingstone (Livingstone (1), 2013),
3. if a breakdown occurs the number of tuberculous animals is set as per Table 2, and
4. finally, whether or not an animal excretes *M. bovis* is set by a binomial function with the number derived in 3 above and the probability of udder infection.

A total of 1,000,000 simulations were run, with each simulation representing one herd in one year. This high number of simulations was necessary to accurately estimate the low probability outcomes.

If the probability of udder infection (i.e. 4 above) is set to 0.0023 (0.23%), as per the United Kingdom data, the model indicates that with the current disposition of dairy herds in vector free and risk areas in New Zealand, there is a risk of 1.7×10^{-5} per annum that a “contaminated milk-breakdown” will occur.

In the sample of tuberculous dairy cows from New Zealand herds, the prevalence of animals arguably at high risk of being or developing into milk excretors was 0.71%. Entering this into the model²³, the risk of a “contaminated milk-breakdown” was 4.2×10^{-5} per year. Additional simulations were run to investigate the risk of contaminated milk, for only those herds in the vector free area, and for herds in vector risk areas (Table 3, Figure 3). For the former it was 1.3×10^{-5} per year and the latter 17.5×10^{-5} per year.

These figures are the average for the “population of dairy herds” in the given areas. Within these broad landscapes there may be smaller populations where the risk could be lower or higher. For example, over the last three years the incidence of breakdowns in West Coast dairy herds in the vector risk area averaged 4.3% (Livingstone (1), 2013). When the model was run with this parameter, the output was 63.7×10^{-5} per year (Table 3, Figure 3.).

The model output can also be expressed in terms of the number of “contaminated milk-breakdowns” expected in New Zealand, or in a specific area, over a given period, such as 10 years (Table 3, Figure 4). This measure takes into consideration the number of “herds-at-risk”. Thus, the estimated risk in this group of herds on the West Coast is 49 times that in the group in the vector free area ($63.7/1.3$), but the ratio of “breakdowns with contaminated milk” is only three times greater. This arises because there are only 479 herds in this high risk area, compared to 11,352 in the vector free area.

With additional data concerning the risk factors that leads to herd breakdowns, the model could be used to identify other “sub-populations”, not necessarily in the same area, in which the risk is lower than that estimated. Indeed epidemiological investigations over many years have identified the most important ones and it is suggested that these should be used to formulate conditions of sale of raw milk which will reduce the risk of consumer exposure (see Section 7 and Appendix 1).

²³ Entered into the model as a betapert distribution, with the 95% confidence limits of 3/424 set as the minimum (0.0015) and maximum (0.0205), and the mode as 0.0071.

Finally, and to repeat an important issue, it may be some time before a herd breakdown is “uncovered” by disease control personnel. Over a considerable period, milk could be contaminated while the herd was “Tb Clear”.

Table 3: Outputs from the model of the risk of a dairy breakdown with *M. bovis* contamination of milk

Model Scenario	Risk in terms of breakdown herds with contaminated milk per 100,000 herds	Risk in terms of number breakdown herds with contaminated milk in the area specified in New Zealand over a 10 year period
Current NZ situation, with 82% of dairy herds in vector free areas (n = 11,352) and 18% in vector risk areas (n = 2,439).	4.2	6
Limited to dairy herds in vector free areas (n = 11,352)	1.3	1
Limited to dairy herds in vector risk areas (n = 2,439)	17.5	4
West Coast dairy herds in vector risk areas (n = 479 out of a total of 508)	63.7	3

Figure 2: The structure of the model used to estimate the likelihood of *M. bovis* being excreted into a herd milk

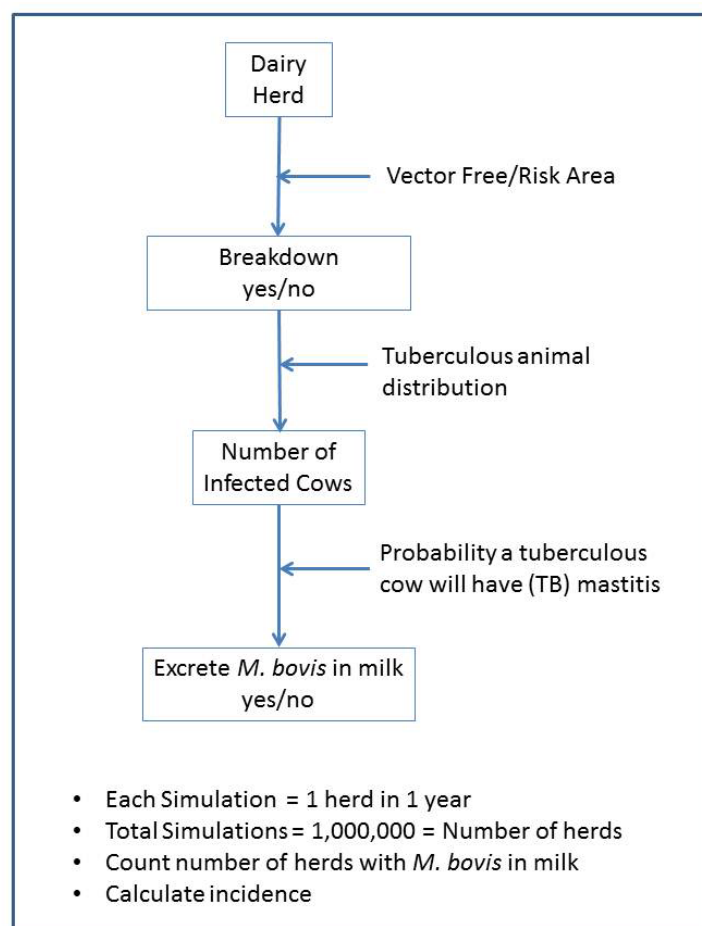


Figure 3: Risk per 100,000 of a breakdown with contaminated milk

Current Vector Free and Risk Areas (VFA + VRA), Vector Free Areas only (VFA), Vector Risk Areas only (VRA) and West Coast dairy herds in Vector Risk Areas

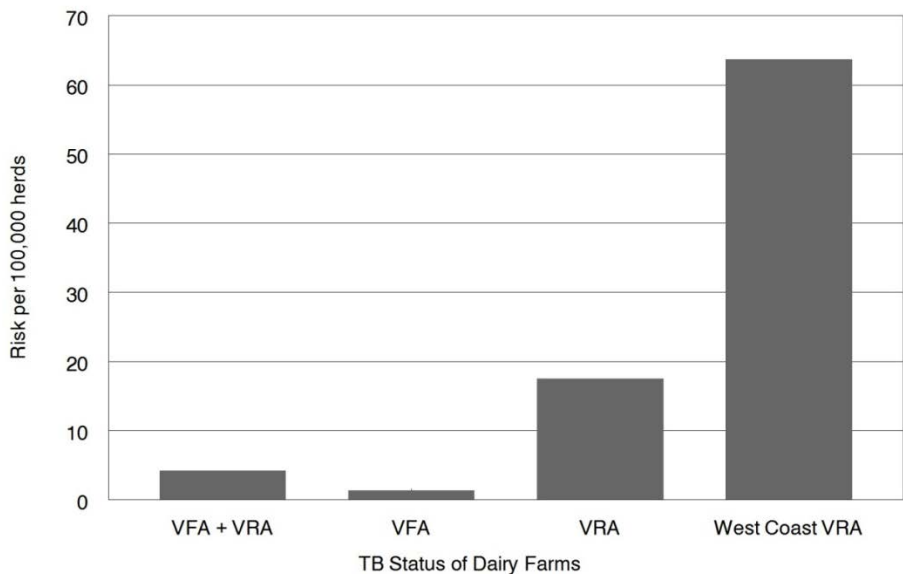
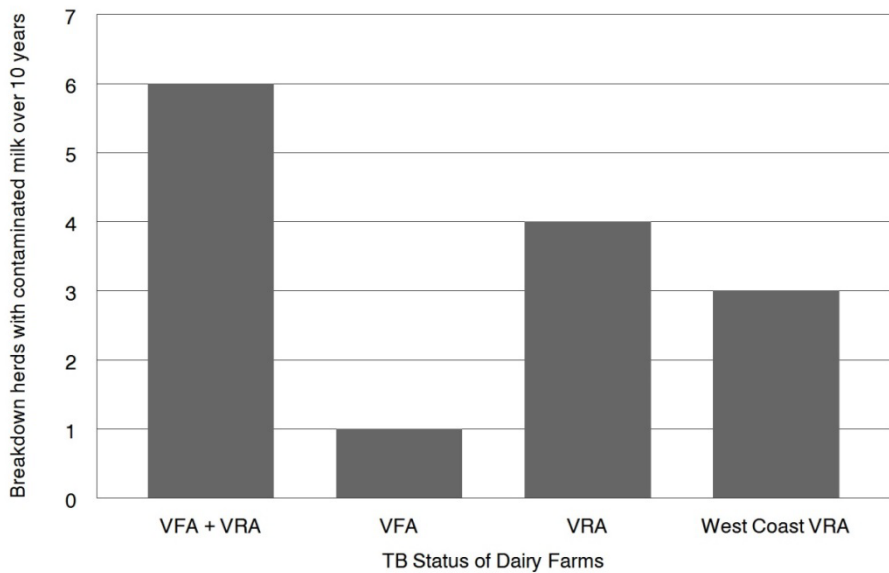


Figure 4: Expected number of breakdown dairy herds with contaminated milk over 10 years

Current Vector Free and Risk Areas (VFA + VRA), Vector Free Areas only (VFA), Vector Risk Areas only (VRA) and West Coast dairy herds in Vector Risk Areas.



Risk Characterisation

Given the current low level of *M. bovis* infection in dairy herds in New Zealand, the likelihood of unpasteurised cows' milk being contaminated with *Mycobacterium bovis* (*M. bovis*) at the farm gate is very low. However, *M. bovis* is a significant human pathogen, especially in children and in the immune-compromised, such as the aged, people undergoing chemotherapy or radiation, HIV infected persons etc.

At this time it is unlikely that *M. bovis* will be eradicated from all possum populations in the immediate future and therefore there will be on-going reinfection of livestock, including dairy cattle. Despite this, the current national control programme (i.e. the "Bovine Tuberculosis Pest Management Strategy") has been very successful and the prevalence of infection in the dairy industry should remain low. However, it seems likely that the risk of new infection associated with vector risk and vector free areas (currently around 26:1) will remain. In some areas, the risk is much higher; e.g. comparing the West Coast vector risk areas and the vector free area, it is around 50:1.

A reasonable risk mitigation policy would therefore be to only allow raw milk sales from dairy herds located in vector free areas.

A major risk factor for a herd to become infected in New Zealand is prior infection (Ryan *et al.*, 1995; Ryan, 2005). To mitigate the risk of transferring infection from one herd to another, a herd status and index based on the time since the herd achieved "Clear" status is in place. Herd owners are encouraged to use this information to avoid introducing infection when purchasing animals. However, a herd can contain up to 25% of lower status introductions before the herd status is downgraded and, thus, it is possible for a low status animal to gain a high status via movement from one herd to another.

A possible risk mitigation policy would therefore to set the minimum status for a herd when supplying raw milk for drinking or processing be Clear 5²⁴.

Further, the somewhat lose control of potentially low TB status cows should not be acceptable where a herd is supplying raw milk for drinking and/or processing. A "National Animal Identification and Tracing System" (NAIT) has recently been introduced and the movements of any replacements since birth will be available. Confirmation that all replacements truly meet the status of the herd (i.e. trace back) could be a condition of supply.

Post mortem data from both New Zealand and the United Kingdom indicates that currently most infected animals are identified and removed from herds prior to the disease progressing to a systemic phase when the udder could be invaded. Early pre-control data indicates that many cattle will progress to generalised tuberculosis over time, and therefore an intensive animal control programme is an important risk mitigation factor. The likely time from infection to the development of a tuberculous mastitis is uncertain, but after natural infection there is good evidence that it would be six or more months (see Appendix 2). In the United Kingdom, it has been a long standing policy to place all dairy herds that are known to sell unpasteurised cows' milk directly to the consumer under an annual TB testing regime (ACMSF, 2011). In Ireland food safety scientists have recommended that these herds should be inspected and tested for tuberculosis every six months (Food Safety Authority of Ireland, 2008).

²⁴ see Annex 1 for the technical justification for "Clear 5"

It would therefore be prudent to set a maximum period between tuberculin surveillance tests for such herds in New Zealand; twelve months appears to be an appropriate maximum period.

There is also the question of retesting of skin test-positive animals. As is described in Appendix 1, serial retesting reduces the overall test sensitivity from around 85% to 75%. Regular negative herd tests would be an important indicator that the herd is free of infection; to reduce the effectiveness would be counterproductive.

We therefore suggest that skin test-positive and test-suspect cows should immediately be declared reactors and post mortemed; i.e. no retesting of animals.

In New Zealand, currently there is no requirement to isolate and re-direct milk from tuberculin skin-test positive animals. Further, there is no requirement for milk from the balance of the herd to be pasteurised (although in New Zealand it would, most likely, be the situation). If the herd is infected then consumers of raw milk may have been exposed. If herds are in the raw milk trade, we believe there would be an expectation by consumers of immediate preventive action.

We therefore suggest that the conditions of supply include provisions to limit potential consumer exposure to *M. bovis* following a “not negative” surveillance episode (either testing or abattoir) until the herd is confirmed free of bovine tuberculosis.

Another condition, that all the neighbouring herds have a tuberculosis clear status, could also be considered. Unlike many other infectious diseases, spread to animals on contiguous properties is not a feature of the epidemiology of *M. bovis*. However, of importance would be that herds supplying raw milk should have adequate containment (i.e. fencing) to prevent mixing of livestock from other farms.

Appendix 1: Tuberculosis Control in Dairy Cattle in New Zealand

Background

Earlier attempts to control tuberculosis in dairy herds that supplied liquid milk to townspeople (i.e. “town supply” herds) are poorly documented. It seems there were sporadic attempts during the first half of the 20th century, but these had no effect on the overall prevalence of the disease. Despite increasing concern about the public health risk, it was not until 1945 that legislation was enacted requiring town supply herds to be subject to tuberculin testing and the compulsory slaughter of test-positive animals (Laing, 1955). By the end of the 1950’s all herds supplying milk to urban areas were under test (O’Hara, 1995).

The history of tuberculosis control in cattle and (later) deer since the introduction of a nationally coordinated programme, circa 1960 – 1965, is better documented (AHB (Part A) 2011; O’Hara, 1995). By 1977 the entire cattle population of eight million animals had been brought under surveillance, either tuberculin testing or abattoir inspection, with follow-up testing or depopulation. Initially the prevalence of infected herds was reduced considerably, but as the programme was extended into some heavily forested areas, the traditional “test and slaughter” programme began to fail (O’Hara, 1995).

That a wild animal reservoir of *M. bovis* infection was responsible for these problems was not at first recognised. However, in 1967 a Ministry of Agriculture and Fisheries (MAF) livestock officer identified the disease in possums (Davidson, 1991) and over the next five years the association became better documented and, finally, accepted as “a causal association”. The first wide scale operations to reduce infected possum populations were carried out in 1972; following these there was a sharp decline in the incidence of tuberculosis in cattle on the treated properties.

Many “problem areas” were gradually identified and an association with infected possums (and in some cases infected ferrets) demonstrated. It became clear that for the programme to be successful, this fundamental difference in the epidemiology of cattle tuberculosis in New Zealand (i.e. both cattle to cattle and possum to cattle transmission) had to be the starting point. The current programme, the so-called “National Bovine Tuberculosis Pest Management Strategy” that is managed by the Animal Health Board contains both elements.

The National Bovine Tuberculosis Pest Management Strategy (PMS)

It is a statutory requirement of the “Pest Management Agency”, in this case the Animal Health Board, to describe both the objectives of the PMS, how these will be met and the key performance indicators.

The objective in the past was to reduce the number of tuberculosis infected cattle and deer herds to a 0.2% annual period prevalence by 2013. At the end of 2011, this objective was achieved (World Organisation for Animal Health, 2013), with infected cattle herds being reduced from a high 1,694 to 65, a 96% decrease (Animal Health Board, 2012). If this is maintained for two more years, New Zealand will be regarded as being “Officially Bovine Tuberculosis Free” by the World Organisation for Animal Health.

Of relevance in this risk assessment, is the tuberculosis status of the national dairy herd. As at June 30, 2012, there were 39 infected dairy herds, a prevalence of 0.28% (39/13,791) (Livingstone (1), 2013). The prevalence in areas considered free of TB possums (i.e. vector free areas) was 0.02% (2/11,352). In the areas where it was considered TB possums were

present (i.e. vector risk areas) the prevalence was 1.52% (37/2,439). Thus, the prevalence ratio was 86.

The number of “newly infected TB Clear” herds, generally called “TB breakdowns”, in dairy herds over the last four years are listed in Table 4.

Table 4 TB breakdowns in dairy herds, by vector area status

Area	2008/09	2009/10	2010/11	2011/12
Vector Free Areas	19	10	9	1
Vector Risk Areas	34	23	30	26
Total	53	33	39	27

In the current year (2012/2013) it is expected that there will be less than 10²⁵ dairy herd breakdowns in vector free areas, and less than 35²⁶ in vector risk areas (Livingstone (2), 2013).

The current PMS objectives, for the period from 2011 to 2026, change the emphasis from reducing the number of infected herds to reducing the area containing *M. bovis* infected possums (AHB (Part A) 2011).

TB Vector Management

Broadly speaking, the goals of this sub-programme are to delineate vector risk areas, reduce the population of vectors (primarily possums), and, over a period of 5 or more years, eradicate TB vectors from the area.

Delineation of vector risk areas involves the assimilation of data from many sources; e.g. herd testing, herd breakdown analysis, surveys of wildlife for *M. bovis* infection. The current vector risk areas are shown in Figure 5.

To control vectors a wide variety of techniques, such as toxic baiting and trapping, are used.

Livestock Disease Management

The goals of this sub-programme are to identify infected herds as quickly as possible, prevent the spread of infection via the movement of animals and to eradicate tuberculosis from infected herds.

Again a variety of methods are used to identify infected herds, but the key ones are periodic “TB testing” of herds and “abattoir surveillance”.

The TB testing programme is based on the risk that herds will become infected, and being in or near to a vector risk area is the main risk factor (Ryan *et al.*, 1995). This spatial data is, therefore, used to establish “TB Disease Control Areas” as shown in Figures 6 and 7. The frequency of herd testing, with or without “pre-movement testing”, varies within each area, as shown.

²⁵ between 5 and 8 expected, i.e. an incidence of between 0.04% and 0.07%

²⁶ between 25 and 35 expected, i.e. an incidence of between 1.03% and 1.44%

Figure 5: Tuberculosis Vector Risk Areas



Another key risk factor is prior infection (Ryan *et al.*, 1995). The sensitivity of animal tests for *M. bovis* are generally rated as moderate; i.e. 80% to 90%. One problem is newly infected animals that have not developed an immune response. Another is “anergy”; this is an uncommon but important phenomenon wherein an animal with disseminated infection is unresponsive to tests based on cellular immunity (e.g. skin testing and the gamma interferon test).

The usual procedure with a clear herd, following the discovery of a skin test-positive animal, is to retest with an ancillary test (AHB (Part B) 2011). As no test is 100% sensitive, the effect of retesting is to lower the overall sensitivity by a factor of 10%, to around 75% (assuming the ancillary test is Bovigam® (Ryan *et al.*, 2000). Clearly, this may compromise early detection of infection.

In 2005, a retrospective analysis was conducted of the period from achieving “Clear” status being a useful risk indicator (Ryan, 2005). Herd index was significantly ($P < 0.05$) inversely associated with the probability of breakdown for the first five years.

For these reasons, an index is attached to the primary herd statuses (i.e. “Clear” or “Infected”). The index is the period in years since the change in status. Low index clear herds (C1) are generally tested more frequently than herds with a C2 or higher status.

Unlike many infectious diseases, such as Foot and Mouth Disease and brucellosis, cattle to cattle transmission of *M. bovis* between neighbouring herds has not figured as an important mechanism of spread. In a large study of breakdowns in vector-free areas, although field staff nominated having an infected herd on a contiguous property was responsible for 4% of breakdowns, it did not emerge as a statistically significant ($P < 0.05$) risk factor (Ryan *et al.*, 1995).

Figure 6: TB Disease Control Area in the North Island

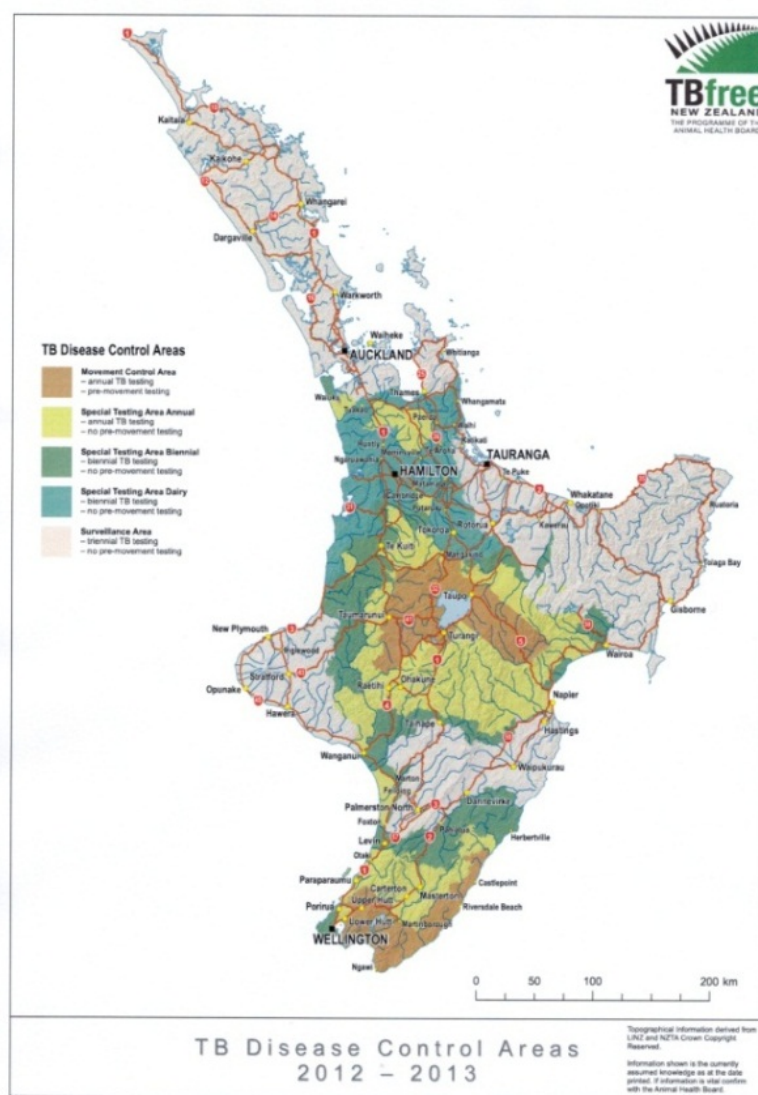
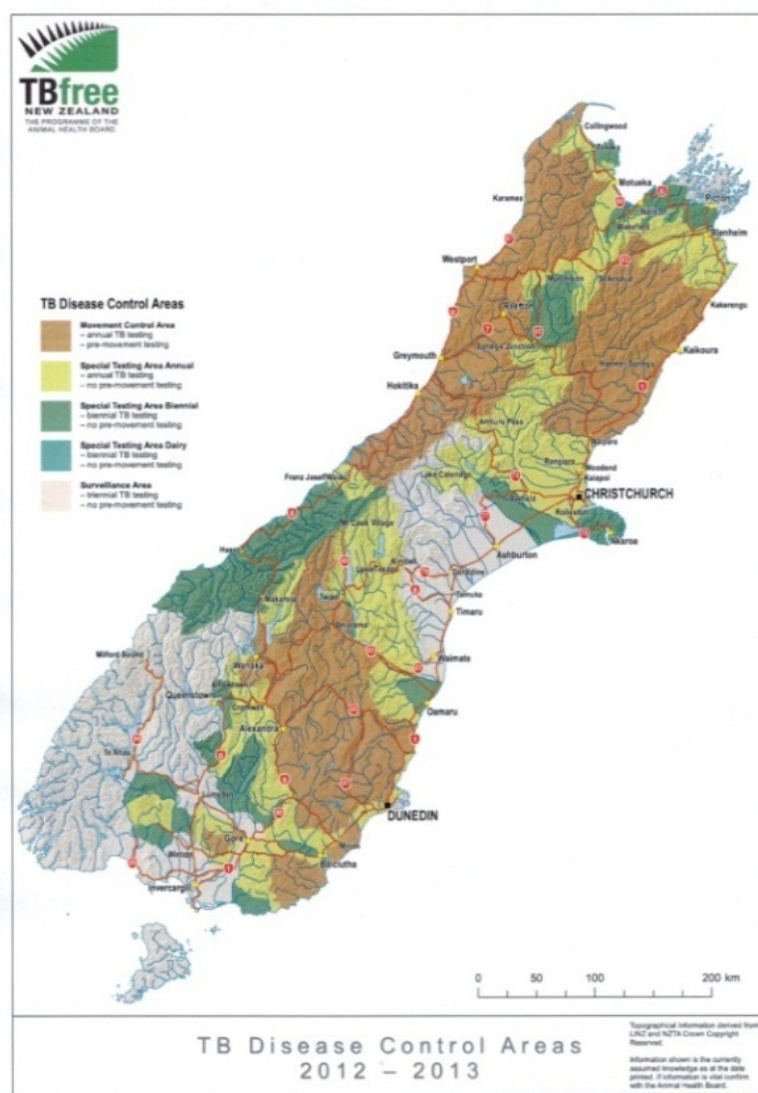


Figure 7: TB Disease Control Area in the South Island



The national dairy herd is dynamic (Ryan *et al.*, 1997). It is common practice for young stock to be grazed on specialist grazing or agistment properties, often mixing with young stock from other herds. Whole herds can be shifted from one property to another. Small numbers of cows are often moved from herd to herd for a variety of management reasons. The Animal Health Board encourages herd owners to check the TB status of the herds when they are considering grazing out or purchasing stock. Of note is that under the New Zealand programme rules, a herd can contain up to 25% of lower status introductions before the herd status is downgraded. Thus, it would be possible for a Clear 10 herd to actually have 25% of the herd derived from, for example, a Clear 3 herd.

In a major study of the causes of breakdowns of herds located in vector free zones, introducing stock from another herd coupled with failing to check the TB status of that herd was found to be an important risk factor (Ryan *et al.*, 1995). However, given the rather loose condition regarding the movement of small number of animals, this key information may not be immediately available.

“Movement Control” is an important part of the disease management programme. This included the usual control of animals leaving an infected herd. Recognising the importance of TB vectors, “area movement control” may also be imposed in high risk area.

There are many other aspects of the disease management programme, such as the management of infected herds. However, these have no relevance to this risk assessment as it is assumed that milk from infected herds would be pasteurised

Comparison with the United Kingdom control programme

There are many similarities between the bovine tuberculosis situation in the United Kingdom and in New Zealand. Both have well developed dairy industries and the basic framework for tuberculosis control is similar. In addition, in both there is the complication of TB vectors. Finally, there is a strong desire by some consumers to have access to raw drinking milk, and raw milk for such things as making cheese. It is therefore useful to compare and contrast the two programmes.

Actions following a test-positive animal

Of relevance to this risk assessment is the required action in the United Kingdom following a positive tuberculin skin test or through routine post-mortem meat inspection (ACMSF, 2011). *“The herd will automatically lose its Officially TB Free (OTF) status. This means that all TB test reactors and any at-risk direct contacts are required to be isolated and are compulsorily removed and slaughtered by the Animal Health and Veterinary Laboratories Agency (AHVLA) in GB. Milk from cows awaiting slaughter is not permitted to go for human consumption. Milk from other animals in the herd must undergo pasteurisation (minimum 72°C for 15s) until herd OTF status is restored”*.

In New Zealand, following a positive skin test, a clear herd status may be suspended, but there is no requirement to isolate test-positive animals and re-direct their milk from human consumption.

Definition of “tuberculous animal”

In the United Kingdom, in most cases a skin test-positive animal would be considered tuberculous (i.e. infected with *M. bovis*).

In New Zealand an animal is considered tuberculous if it has “lesions that are histologically typical of TB, *M. bovis* is cultured or has been identified by PCR, or has been positive to two approved tests, or is test-positive and not met the Animal Health Board standard for a post-mortem examination”.

The most likely effects of this difference is that more clear herds would be considered infected in the United Kingdom, whereas in New Zealand some infected herds would not be identified.

Pre and Post Movement Testing

It is somewhat difficult to compare the movement control rules operating in New Zealand and the United Kingdom. In both there is provision for animals moving from higher risk herds to be pre and post-movement testing, but new rules have been introduced in the United Kingdom concerning where such animals may be moved to. There is also provision for “medium” risk herds to be pre-movement testing.

Appendix 2: The pathogenesis of *M. bovis* infection in cattle

The central issue of this risk assessment is excretion of *M. bovis* in milk. The routes of infection for cattle are either inhalation or ingestion and thus for this to occur systemic infection with invasion of the udder must occur.

The pathogenesis of tuberculosis in animals, especially humans, has been investigated over many decades. A range of susceptibilities has been observed, for example sheep and goats are resistant to infection while in the possum it is a progressive systemic disease with high mortality.

In cattle a primary lesion or focus of infection is established. This lesion together with lesions in the regional lymph nodes is termed the “primary complex”. A classical cellular immune response occurs and resultant lesion is called a tubercle. In many cases the disease does not progress beyond this stage, but in some haematogenous spread to other tissues can occur and this may lead to additional lesions in such organs as the liver, kidney, serous cavities, and the udder (Neill *et al.*, 1994). It appears from experimental results that the age of the animal, route of infection, strain of the organism, and the dose of bacteria will influence the length of time required for the disease to develop (Huchzermeyer *et al.*, 1994). However, under natural infection it is slow moving. Excretion of organisms in nasal mucous is not seen until around 90 days after infection (Neill *et al.*, 1991). Progression to other sites and invasion of the udder would be expected to take considerably longer than this.

In cattle spread from the primary complexes was commonly seen when herds were first brought under test in New Zealand. For example, MacFarlane reported that 49% (184/374) of reactors removed from 46 town supply herds in 1950-1951 had generalised tuberculosis (MacFarlane, 1953). However, when cattle are subject to regular testing, generalised cases are not common. Neill *et al.* reports that in Northern Ireland the number of infected sites was on average 1.2 per animal, and this indicated that infected cattle were removed in the early stages of infection (Neill *et al.*, 1994). In New Zealand, in an abattoir sample of 424 *M. bovis* infected²⁷ dairy cows, the average number of lesions per animal was 1.5; 99% (419/424) had one to three lesions; i.e. in most cases just the primary complexes. Three (0.71%) animals had five or more lesions suggesting systemic spread had occurred or was at risk of occurring (Table 3). No lesions of the supramammary lymph nodes, which drain the udder, were reported in any animals (Ryan, 2013).

Anergy, as a contributor to the moderate sensitivity of cell mediated immunity based tests, has been referred to in section 8.2.2. An unlikely but dangerous scenario is a dairy herd containing a single infected but anergic animal supplying raw milk to consumers. Until infection spreads to other herd members and they developed an immune response or the anergic animal was slaughtered, the herd would retain clear status. In one of the author’s experience (TR), anergic animals are associated with chronic or recurrent infection in herds. There is extensive generalised infection and they are highly infectious. It would be highly unlikely that a herd containing an anergic animal would reach Clear 5 status. Such animals are not common and in a United Kingdom risk assessment this was not considered to be a significant issue (ACMSF, 2011).

²⁷ confirmed by culture

Appendix 3: Sale of raw milk in the United Kingdom

Under the new consolidated EU hygiene rules, which took effect from on 1 January 2006, member states were able to introduce or maintain national rules prohibiting or restricting the placing on the market, within its territory, of raw milk or raw cream intended for direct human consumption. This has removed any uncertainty about the legal basis for national controls in this area. In the period since Devolution, there has been further policy consideration in relation to controls in Scotland and Wales (Food Standards Authority (UK), 2009).

In 2004, Scottish ministers reconfirmed their wish to maintain and extend the ban so that all raw drinking milk and raw cream sales in Scotland would be prohibited. This was introduced by regulation 32 and Schedule 6 of the Food Hygiene (Scotland) Regulations 2005 N0.505 which was later revoked and amended by the Food Hygiene (Scotland) Regulations 2006 N0.3 which came into force on 11 January 2006 and state that : ‘No person shall place on the market raw milk, or raw cream, intended for direct human consumption’. This extends the ban to include sheep, goats, buffalo and any other species farmed for its milk.

In 2000, the Wales Food Advisory Committee (WFAC), concerned that public health evidence supported a ban on raw drinking milk, called for a review of policy options in Wales. Informed by the outcome of a stakeholder consultation, which strongly supported the right of consumers to choose whether or not to consume raw milk or cream, WFAC subsequently concluded that a ban would not be altogether appropriate, given the balance of interest between consumer choice and public health protection. The Welsh Assembly Government then accepted the Agency's advice that the sale of raw drinking milk should be allowed to continue, and agreed to the introduction of an enhanced labelling requirement applying to all raw drinking milk.

This enhanced labelling requirement was given statutory force by the Food Hygiene (Wales) Regulations 2006 which implemented the new EU hygiene regulations and amended the Food Labelling Regulations 1996 in respect of Wales. The regulations, which came into force from 11 January 2006, require, in addition to the existing health warning, the following advice: “The Food Standards Agency strongly advises that it should not be consumed by children, pregnant women, older people or those who are unwell or have chronic illness.” The enhanced labelling requirement in Wales applies to raw milk from cows, sheep, goats and buffaloes.

Policy in respect of England was revisited internally in the Agency in 2002. It was noted that when raw cows' drinking milk policy had last been reviewed in England between 1997 and 1999, the balance of stakeholder opinion had been strongly in favour of the right to informed choice. There was, and still is, no reason to believe this had altered. It was further noted that relatively few people drink raw milk, and that those who do, do so regardless of the existing health warning, which is already clear. Little, if anything, was therefore likely to be gained by requiring the warnings on labels to be increased. Against that background, and taking account of the pattern of raw milk consumption, it was considered that the most balanced approach would be to maintain the existing regulatory requirements, but to revise the Agency's website material. The website now makes the risks associated with consuming raw milk, particularly by vulnerable groups, clear. It also advises that, despite being popular with some people, unpasteurised milk and cream could be harmful.

Current controls: England and Wales

The current controls on the sale of raw cows' drinking milk in hygiene and food labelling regulations are:

- a) the milk may only be sold direct to consumers by registered milk production holdings (at the farm gate or in a farmhouse catering operation) or through milk roundsmen. Sales through other outlets have been banned since 1985 (although sales by the farmer at farmers markets are allowed);
- b) the supplying animals must be from a herd that is officially tuberculosis free, and either brucellosis free or officially brucellosis free;
- c) the production holding, milking premises and dairy, must comply with hygiene rules;
- d) the milk must bear the appropriate health warning;
- e) compliance with a) to d) above is monitored by inspections twice a year; and
- f) the milk is sampled and tested quarterly under the control of the Agency to monitor compliance with standards for total bacterial count and coliforms.

The sale of raw cream:

- a) is not subject to the restrictions at 1a) and d) above;
- b) must comply with all the requirements that apply to milk based products under dairy hygiene rules and microbiological standards;
- c) must be made with milk meeting the herd status criteria described above;
- d) raw cream is not required to carry the health warning; and
- e) compliance with these requirements is, again, monitored at inspections programmed on risk.

Current controls: Scotland

Sales of raw cows' drinking milk and raw cows' cream have been banned in Scotland since 1983. In 2004, Scottish ministers reconfirmed their wish to maintain and extend the ban so that all drinking milk and cream sales in Scotland would be prohibited.

Current controls: Northern Ireland

Northern Ireland has controls similar to those in England and Wales, but there are no known sales in Northern Ireland.

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