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Haumaru Kai Aotearoa

Update to the assessment of the microbiological risks associated with the consumption of raw milk

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1 Introduction

In 2013 MPI completed an assessment of the microbiological risks associated with the consumption of raw milk. That document reaffirmed raw drinking milk as a significant source of risk to human health, especially in regard to food poisoning caused by Shiga toxin producing *E.coli* (STEC) and *Campylobacter* (MPI, 2014).

The purpose of this update is to assess whether the risk to New Zealand consumers associated with drinking raw (unpasteurised) milk has changed since 2013. The present report outlines currently available information related to the microbiological risks associated with consumption of raw drinking milk (RDM) in New Zealand. The data presented in this report cover the period of 2014-2018.

The data available suggest that the main microbiological hazards present in raw milk in New Zealand have not changed since completion of the 2013 risk assessment. No information was identified that would change description of pathogens potentially present in raw milk, their survival or growth characteristics. Likewise, no additional impacts of the identified hazards on human health or changes in dose-response relationships were described in the 2014-2018 scientific literature.

Hence the approach has been to assess the following:

- whether there has been a noticeable change in human illness associated with RDM consumption in New Zealand
- whether there has been a change in the profile of vulnerable groups becoming ill
- whether the main aetiological agents involved have changed

A summary of key findings from human health risk assessments for the consumption of raw milk, prepared by, or for, the competent authority in a number of international jurisdictions and published between 2014-2018, is presented in Appendix 9.1.

2 Human illness associated with raw drinking milk

Data on human illness were sourced from EpiSurv, the national disease surveillance system that is managed by the Institute of Environmental Science & Research (ESR). Information on notifiable diseases and outbreaks is entered into EpiSurv by public health units (PHUs).

From the beginning of 2014 to the end of November 2018 there were twenty five reported outbreaks[1] involving 112 cases of human illness associated with consumption of raw milk (Table 1). Outbreaks of campylobacteriosis associated with raw milk represent 38.6% of all potentially foodborne outbreaks of campylobacteriosis in New Zealand, and raw milk was the only food identified in outbreaks of STEC infection.

Notified cases of illness and reported outbreaks represent only a subset of all the cases and outbreaks that occur in New Zealand each year. Many sick individuals do not visit a doctor or otherwise come to the attention of the medical system[2]. Outbreaks are more likely to be reported if they involve unusual pathogens, notifiable diseases, a large number of cases or a well-defined setting. The differing availability of resources among PHUs may also impact outbreak investigation and reporting at a regional level. By using EpiSurv data as indicators, we are assuming that they are representative of all the cases of notifiable diseases that occur.

[1] Outbreak is reported when two or more cases of a specific disease or health-related condition linked to a common source, in particular, where the common source is exposure at a common event, or food or water dispersed in a community, an environmental source or a source in an institutional setting; OR a community-wide or person-to-person outbreak; OR any other situation where the outbreak investigation or control measures are being used or considered.

[2] Description of New Zealand notification system and reasons for large number of cases being underreported can be found in Lake *et al* (2010). Additional information is also presented in https://www.mpi.govt.nz/dmsdocument/12675/direct .

Table 1. Notified outbreaks where raw milk was identified as a contributing factor

Report Date	Pathogen	DHB	No of Cases	Age range (yrs)	Comments*
31/01/2014	Giardia	MidCentral	5	2-57	Exposure to raw milk, untreated water; animal contact; contact with infected person
24/03/2014	Campylobacter	South Canterbury	7	1-34	Raw milk the only identified risk factor
27/03/2014	STEC (E.coli O157:H7)	Waitemata	5	<1-29	Household outbreak; likely source is raw milk
10/04/2014	Salmonella	Waikato	3	13-42	Variety of risk factors
8/04/2014	STEC (E.coli O157:H7)/ Campylobacter	South Canterbury	5	7-9	School trip to dairy farm, where students consumed raw milk
5/05/2014	Campylobacter	MidCentral	6	1-56	Raw milk implicated
26/08/2014	Campylobacter	MidCentral	4	1-36	Household outbreak; transmission was believed to be person-to-person
1/09/2014	Campylobacter	Bay of Plenty	2	6-8	The family purchases raw milk daily; week prior to illness children had contact with animals
8/09/2014	STEC (E.coli O157:H7)	Waikato	2	1-2	Raw milk consumption, also water and zoonotic risk factors
15/09/2014	Campylobacter	South Canterbury	2	24-54	Consumed untreated milk from particular source
16/08/2015	Campylobacter	Bay of Plenty	4	2-25	Household outbreak; likely source is raw milk
5/10/2015	Cryptosporidium	Waikato	11	1-54	Cases consumed raw milk from the same raw milk producer
17/10/2015	Campylobacter	Northland	3	4-29	Cases consumed raw milk from the same raw milk producer
23/12/2015	Campylobacter	MidCentral	11	10-14	A group of 15 students attended a farm type camp, raw milk was consumed by some cases straight from a cow or on the morning cereal
2/02/2016	STEC (E.coli O157:H7)	Auckland	11	2-13	Cases consumed raw milk from the same raw milk producer
30/05/2016	Campylobacter	MidCentral	4	15-50	Cases consumed raw milk purchased from the same raw milk producer
26/08/2016	Campylobacter/ Giardia	MidCentral	7	5-75	Cases consumed raw milk purchased from the same raw milk producer
25/10/2016	Campylobacter	Southern	2	3-6	Cases consumed raw milk when staying with family on a dairy farm
14/12/2016	Campylobacter/ Giardia	Nelson Marlborough	5	1-74	Cases consumed raw milk purchased from the same raw milk producer
20/06/2017	Campylobacter	Hawke's Bay	3	35-65	Cases consumed raw milk purchased from the same raw milk producer
21/03/2018	Campylobacter	MidCentral	2	35-52	Cases consumed raw milk purchased from the same raw milk producer
16/05/2018	Campylobacter	Waikato	2	44-77	At least one case consumed raw milk provided for breakfast and hot drinks.
28/06/2018	Campylobacter	Nelson Marlborough	4	51-74	Cases consumed raw milk purchased from the same raw milk producer
11/10/2018	Campylobacter	Southern	2	13-49	Cases were exposed on farm, consumed raw milk and untreated drinking water
12/10/2018	Campylobacter	Southern	3	3-9	Index case consumed raw milk then infected siblings once ill

*Comments are restricted by the information provided to MPI by ESR and do not cover all data collected by PHUs.

Each PHU records data on each outbreak on a standardised outbreak form within EpiSurv. The records were analysed by the ESR Health Intelligence group based on available epidemiological and laboratory evidence. Raw milk was confirmed to be the vehicle/source in seventeen outbreaks: eleven outbreaks of campylobacteriosis; two outbreaks of STEC infection; one outbreak of cryptosporidiosis; three outbreaks were caused by more than one pathogen (*Campylobacter* and STEC in one outbreak, *Campylobacter* and *Giardia* in two others). These seventeen outbreaks involved 81 cases. Table 2 shows how these cases are distributed by types of infections and by age groups (where age information was available). Outbreaks of STEC infection involve the highest proportion of young children among all cases, about one third of these children were under four years old.

Table 2. Number of enteric or STEC cases associated with outbreaks with raw milk identified as a vehicle by age group, January 2014–November 2018[a]

Condition	≤16 year age group	%[b]	>16 year age group	%[b]	Unknown age[c]	Total
Campylobacteriosis	15	35.7	27	64.3	2	44
STEC	9	90.0	1	10.0	11	21
Cryptosporidiosis and giardiasis	4	30.8	9	69.2	3	16
Total cases with known age	28	43.1	37	56.9	16	81

[a] Notifications for 2018 include data reported from January to 30 November 2018 only

[b] Proportion of total cases with age recorded

[c] Age was not available for outbreak cases without individual notifications linked to the outbreak report form in EpiSurv

Table 2 includes only cases linked to outbreaks where raw milk was identified as a vehicle or a suspected or confirmed source contributing to the outbreak.

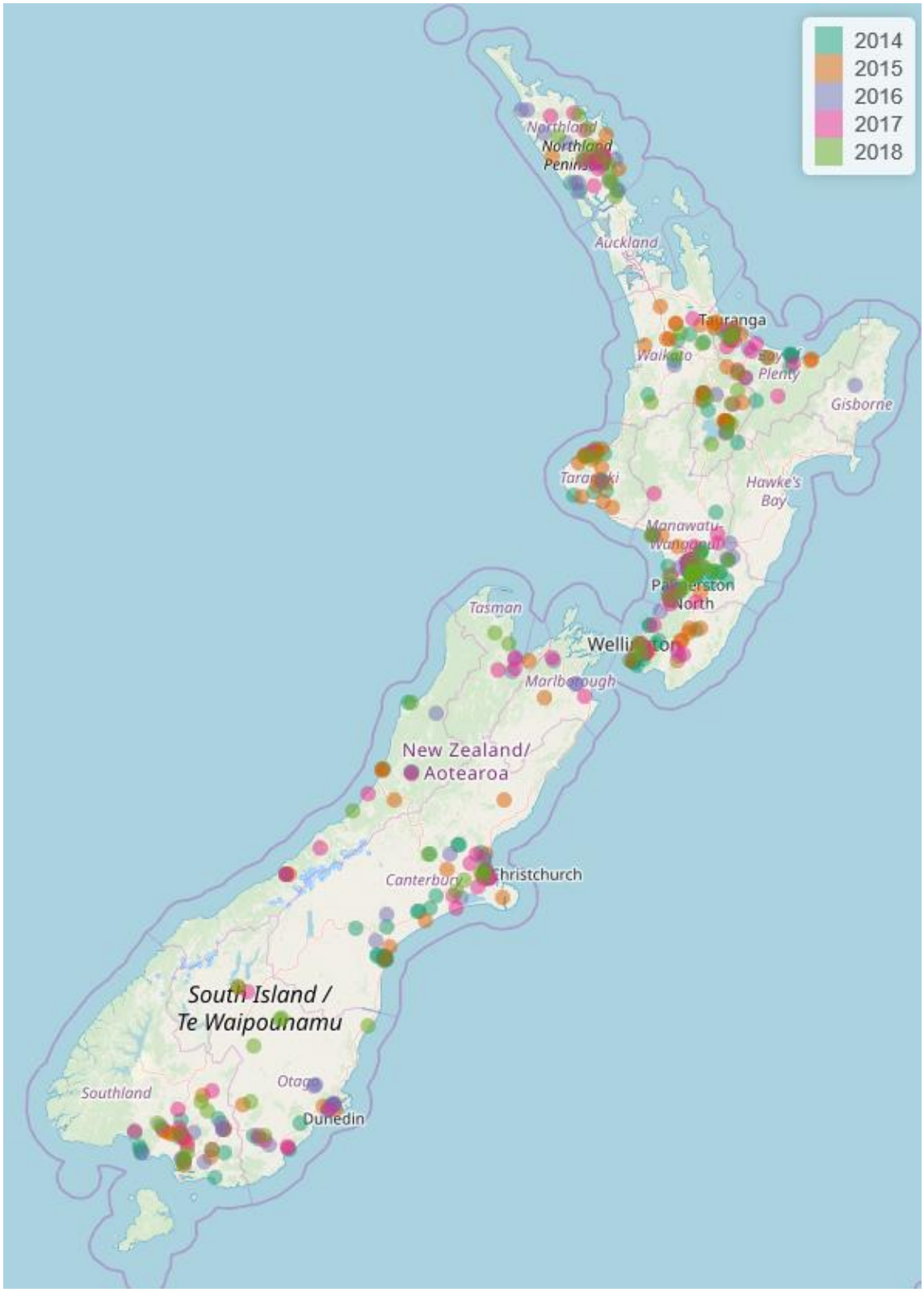
In addition to the information from outbreaks, some limited national data on sporadic cases of notifiable diseases associated with drinking raw milk have been available for analysis. The exposure information on sporadic cases is generally lacking in detail for a variety of reasons, including single cases of illness not being fully investigated and people who drink raw milk may not report they have done so when they fall ill. The enteric disease case report form used from January 2014 to 28 February 2016 did not have a specific question regarding raw milk as a risk factor. A large proportion of campylobacteriosis and STEC cases had no information on risk factors. This is due to the differences in investigation, follow-up practices and available resources among PHUs. For example, there is a high proportion of cases in the Auckland region with missing risk factor information as individual cases are not routinely followed up. These limitations affected distribution of the reported cases of enteric infection shown in Figures 1 and 2. Note, that only cases with raw milk identified as the confirmed or probable cause of illness have been mapped. As expected, majority cases are notified in the main milk production regions. The number of notifications of raw milk associated cases of campylobacteriosis is more than twice as high as notifications for all other enteric illnesses combined. This is why only cases of campylobacteriosis are shown in the separate figure. For all other raw milk associated enteric diseases the highest number of notifications is for cryptosporidiosis, followed by salmonellosis, yersiniosis and giardiasis.

For the period from January 2014 to November 2018 EpiSurv recorded 111 sporadic STEC infections in individuals who reported raw milk consumption with the majority (66) being children under 16 years. A high proportion of these cases were hospitalised[3] (17% among adults and 29% among children). Nine cases (eight children under 8 years and one elderly person) developed haemolytic uremic syndrome (HUS), a life-threatening complication of STEC infections. Of children with HUS, 12–30% will have severe chronic sequelae, including renal and cerebral impairment. The geographical distribution of STEC case associated with raw milk consumption is shown in Figure 3.

This analysis concentrated only on New Zealand epidemiological data. A summary of disease outbreaks resulting from the consumption of raw milk from the international literature is presented in Appendix 9.2.

[3] Data on hospitalisation and HUS was obtained from EpiSurv. These rely on the completion of the relevant fields by PHUs and may be under-reported

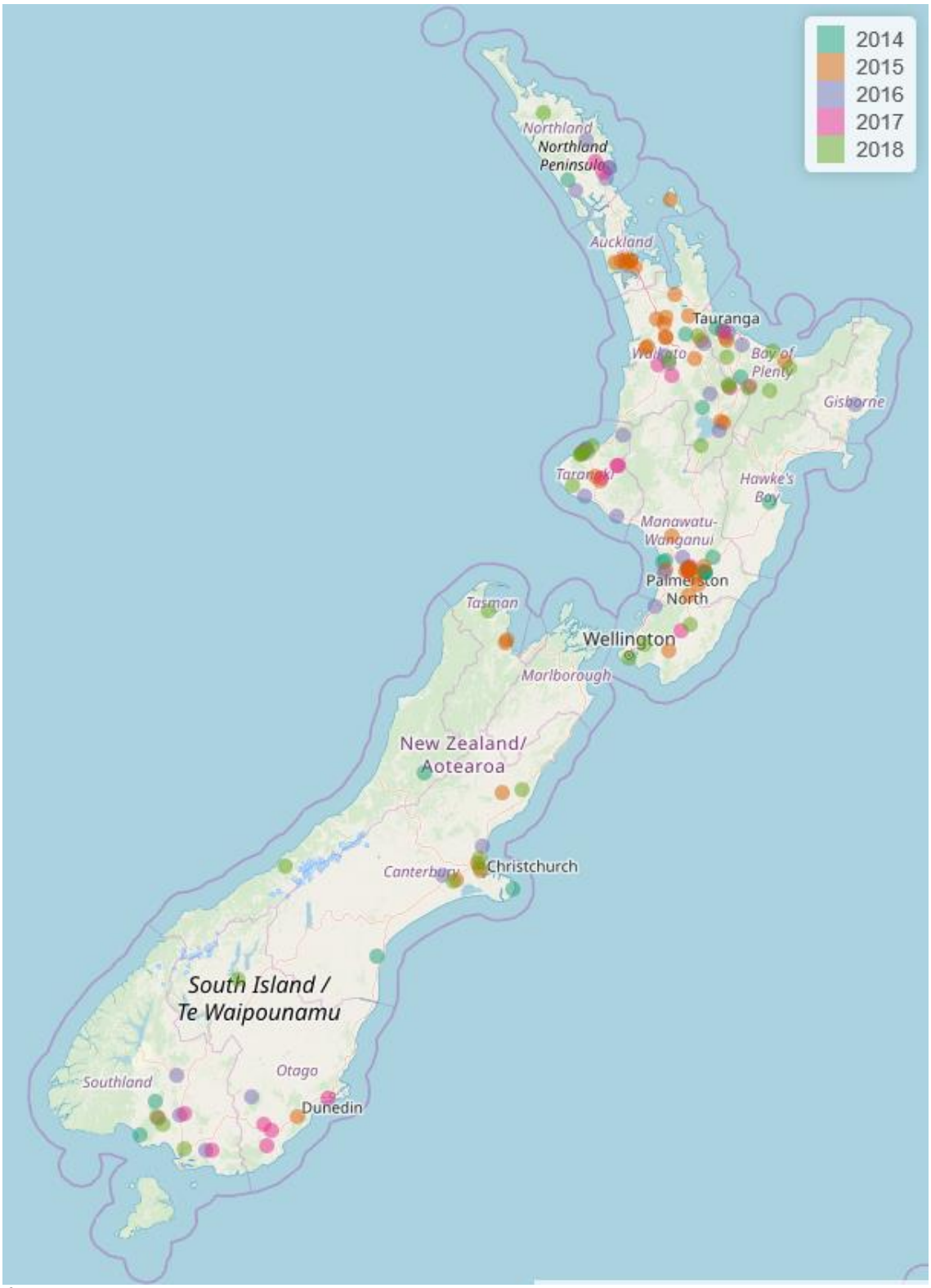
Figure 1. Distribution of campylobacteriosis cases with raw milk recorded as a probable or confirmed cause of illness, January 2014–November 2018[a] [b]



[a] Notifications for 2018 include data reported from January to 30 November 2018 only

[b] Cases with multiple risk factors and a low level of evidence for raw milk as a transmission pathway for campylobacteriosis are not shown.

Figure 2. Distribution of cryptosporidiosis, giardiasis, salmonellosis, and yersiniosis cases with raw milk recorded as a probable or confirmed cause of illness, January 2014–November 2018[a] [b]



[a] Notifications for 2018 include data reported from January to 30 November 2018 only

[b] Cases with multiple risk factors and the low level of evidence for raw milk as a transmission pathway for gastro-intestinal disease pathogens are not shown

Figure 3. Distribution of VTEC/STEC cases with raw milk recorded as a risk factor, January 2014–November 2018[a]

[a] Notifications for 2018 include data reported from January to 30 November 2018 only

3 Microbiological status of raw drinking milk

Although no surveys of the microbiological safety and quality of raw milk were undertaken between 2014 and 2018 to investigate, some data on the presence and levels of pathogens and hygiene indicators in raw milk are available for milk produced under the Regulated Control Scheme (RCS). Dairy farm operators registered to produce RCS raw milk for the purpose of sale routinely take samples of raw milk and send them for microbiological analysis. Bovine milk, produced by farmers following all RCS requirements (MPI, 2016), is considered acceptable for direct human consumption if results of microbiological tests satisfy the criteria listed in Table 3.

Table 3

Microbiological parameter	**Limits**
Salmonella spp.	absent in 5 x 25 ml
Listeria monocytogenes	absent in 5 x 25 ml
Campylobacter spp.	absent in 5 x 25 ml
Coagulase Positive *Staphylococci*	Not exceeding 100cfu/ml
Bacillus cereus	Not exceeding 100cfu/ml
Escherichia coli (*E.coli*)	Not exceeding 3cfu/ml
Total coliforms	Not exceeding 100cfu/ml
Aerobic Plate Counts (APC)	Not exceeding 20,000cfu/ml
Somatic Cell Count (SCC)	Not exceeding 160,000 cell/ml

MPI is notified of unsatisfactory results due presence of pathogens or elevated Aerobic Plate Counts (APC) and/or coliforms. In the period **from November 2016 to February 2019** MPI was notified about presence of pathogens on 18 occasions. The details are shown in Table 4. Although the number of samples supplied for testing by all RDM producers is not known, it was estimated that detections listed in Table 4 came out of at least 1200 samples for each pathogen.

Table 4

Microbiological food safety indicator	**Number of reported detections**
Pathogenic *Listeria*	2
Campylobacter spp.	10
Escherichia coli (*E.coli*)	6

Unacceptable levels of *E.coli* in these samples ranged from 13 to 94 cfu/ml.

On twelve occasions elevated to unacceptable levels of hygiene and/or animal health indicators were detected in milk samples. The details are shown in Table 5. All entries in Tables 4 and 5 are related to samples of the RCS milk collected on different days.

Table 5

Microbiological hygiene indicators	**Number of reported unacceptable results**	**Range of elevated levels**
Total coliforms	7	152-23,800 cfu/ml
Aerobic Plate Counts (APC)	2	280,000-1,441,000 cfu/ml
Somatic Cell Count (SCC)	3	505,000-875,000 cells/ml

While elevated levels of coliforms suggest faecal contamination of the milk and a possibility of pathogens being present, generally APC and coliforms have poor predictive value for identifying food safety concern in raw milk. In the recent survey in England (Willis *et al*., 2017) for 75.9% of the samples contaminated with pathogens, the corresponding hygiene indicator tests produced satisfactory results.

In addition to samples routinely collected by RCS raw milk suppliers, occasionally samples of raw milk are taken during investigation of public health incidents associated with consumption of RDM. Thus, the *Campylobacter jejuni* strain found in leftovers of raw milk was indistinguishable from *Campylobacter jejuni* isolated from two cases of campylobacteriosis linked to consumption of that

milk. On another occasion, in investigation of raw milk linked outbreak of *E.coli* infection the same strain of *E.coli* O157:H7 was isolated from the milk and all cases involved in the outbreak.

Microbiological data obtained from routine testing by RCS raw milk producers do not represent the microbiological status of all raw milk that New Zealand consumers drink. People might drink milk from their family or friends' farms as well as farms where they work. Some raw drinking milk is sold illegally by unregistered producers. RDM produced outside of RCS is not tested for presence of pathogenic micro-organisms. Microbiological criteria for raw milk intended for direct human consumption are stricter than for milk intended for further processing. The relatively low numbers of hygiene and/or animal health indicators that were above RCS criteria indicated that loading of pathogenic micro-organisms in RCS milk is lower than typical for non-RCS raw milk.

4 Risk of milk contamination with *Mycobacterium bovis*

All recommended in the 2013 risk assessment specific risk management controls are in place for bovine tuberculosis (caused by *Mycobacterium bovis*). Control of *Mycobacterium bovis* (TB) is managed by TBfree New Zealand (OSPRI), whose primary objective is to reduce the number of infected herds and to prevent TB vector free areas becoming vector risk areas. The status of a vector area is determined by the prevalence of wild animals there that are considered a source of infection.

The potential exists for *Mycobacterium bovis* to be present in unpasteurised milk or milk products if there is *Mycobacterium bovis* infection in a dairy herd. In 2018 due to the efficient control measures the number of infected dairy herds, as well as number of Tb-infected cows, decreased more than twice in comparison with 2014[4]. This means that the likelihood of exposure to TB due to presence of *Mycobacterium bovis* in unpasteurised milk has reduced since 2014.

The National Operational TB Plan[5] intends to achieve complete freedom from TB in livestock by 2026. Consequently, a continuing decrease leading up to complete elimination of exposure to bovine TB through consumption of raw milk is likely.

Notably at the time of writing this report, all registered RCS raw milk producers were located in TB vector free areas.

5 Impacts of farm practices and consumer behaviour

The impacts of farm practices and consumer behaviour on microbiological risk associated with consumption of raw milk were estimated from the differences in numbers of predicted illnesses following consumption of milk produced and handled under a range of scenarios. The baseline scenario assumes that:

- milk producers adhere to good hygiene practices and strictly follow requirements of the Regulated Control Scheme introduced in 2016 (MPI, 2016)
- raw milk consumers handle milk according to food safety advice published on the MPI website and drink product before its 'use-by' date. https://www.mpi.govt.nz/food-safety/food-safety-for-consumers/is-it-safe-to-eat/raw-milk/.

[4] OSPRI 2018 Annual Report https://ospri.co.nz/assets/Uploads/Documents/OSPRI-Annual-Report-201718.pdf

[5] https://ospri.co.nz/assets/Uploads/Documents/National-Operational-Plan.pdf

- there were no major contamination events during milking and pathogen presence in milk at farm gates is limited to a background level that cannot be eliminated by farming practices

To inform the impact of farm practices and consumer behaviour on microbiological risk simulation a modelling technique developed in Marshall *et al.* (2016) was used to estimate prevalence and concentration of pathogens in raw milk. For each pathogen the probability of illness is estimated assuming median dose-response ratios similarly to the previous assessment of microbiological risks associated with consumption of raw milk (MPI, 2014). The possibility of cross-contamination in the supply chain from the farm to the consumer was excluded. The details of the model are presented in Appendix 9.3.

A summary of the predicted illnesses in New Zealand consumers per 100,000 250 ml servings of raw milk for *Campylobacter*, STEC, *Salmonella* is presented in Table 6. The contamination scenario shows results of a simulation assuming that number of pathogens in milk is predominantly from background contamination, with a major contamination event occurring in a small proportion of milking sessions (4.1% for *Campylobacter*; 0.5% for STEC; 1.4% for *Salmonella* spp.). Median values were calculated based on 20 simulations of 100,000 iterations each. The variability in predictions is indicated by 5th and 95th percentiles (numbers in brackets).

Table 6. Predicted cases of illness in New Zealand consumers of raw drinking milk with baseline and contamination events scenarios

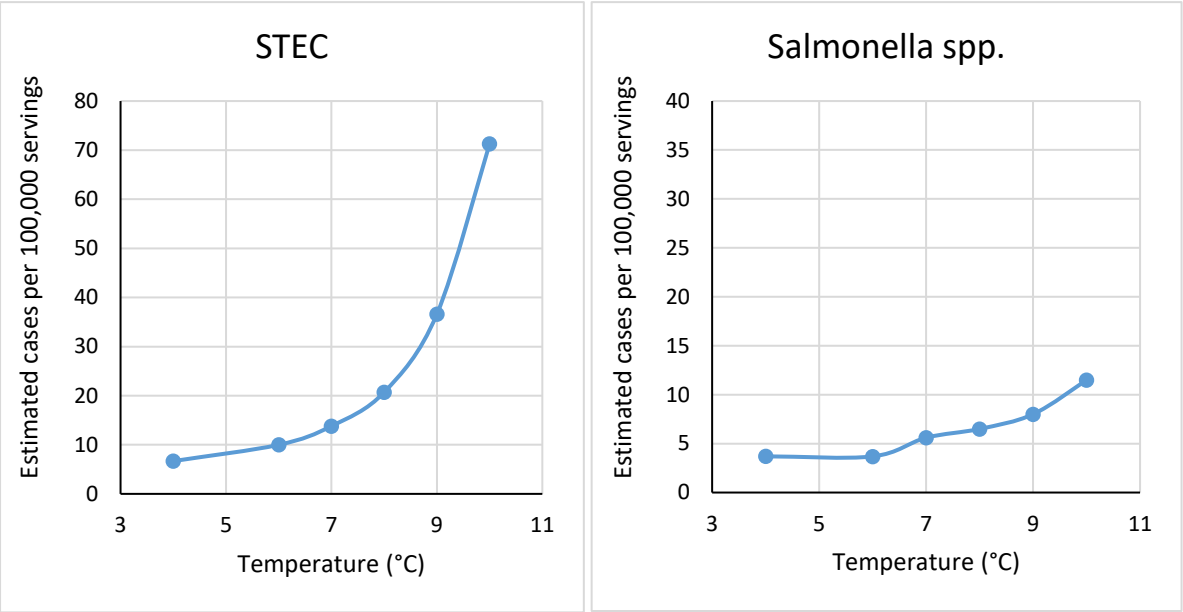
Pathogen	Predicted cases of illness per 100,000 servings of raw drinking milk	
	Baseline scenario	Contamination scenario
Campylobacter spp.	94 (79 - 104)	133 (116 - 150)
*Campylobacter (acquired immunity)**	15 (11 - 23)	30 (22 - 39)
STEC	7 (6 - 8)	13 (11 - 15)
Salmonella	4 (1 - 6)	4 (2 - 7)

*Acquired immunity such as might be obtained through growing up on a farm

The modelling shows that, although the risk of developing illness following consumption of raw milk cannot be eliminated, drinking raw milk produced under a Regulated Control Scheme (RCS) can reduce the risk of campylobacteriosis by 30% and almost halve the risk of STEC infection.

Another example of impact of deviation from RCS requirements is illustrated by simulations of impact of increased temperature of milk storage at the production premises. RCS raw milk must be maintained at a temperature at or below 6 ºC at all times between initial cooling and delivery to a consumer. Increased temperatures will led to an increase of risk of illness following consumption of the milk as it is illustrated in figure 4.

Figure 4. Estimates of the risk of illness from STEC and *Salmonella* spp. depending on the temperature of milk purchased from the farm vat



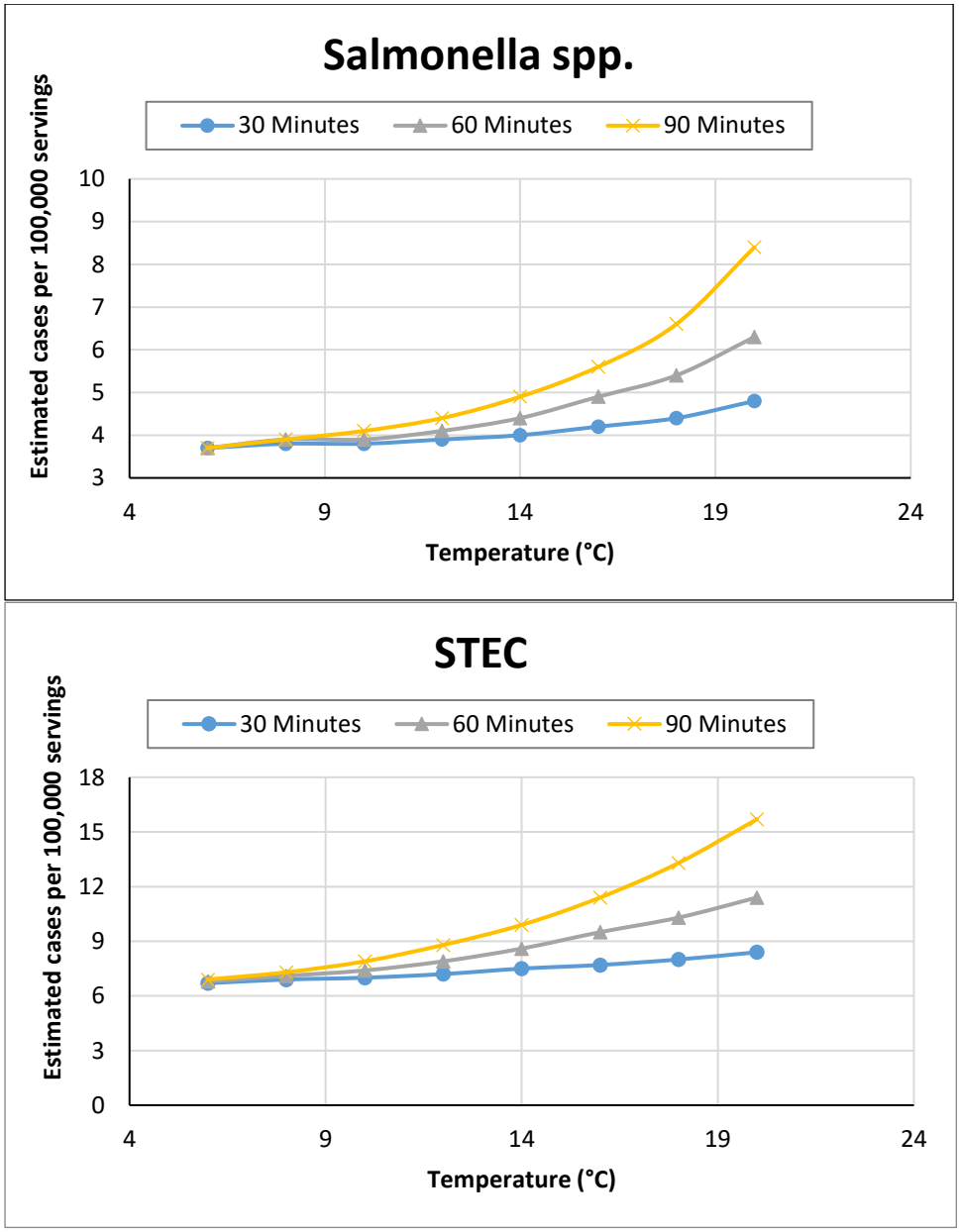
Notably, the difference in risk resulting from milk maintained between 4 ºC and 6 ºC was not higher than random variations between simulations for each of the temperatures at that range. A statistically significant increase in risk appeared only when the temperature increased to above 7 ºC.

The risk of developing campylobacteriosis after consuming raw milk does not depend on temperature changes during milk production and handling as *Campylobacter* does not grow at temperatures less than 32°C.

Temperature control also plays an important role at the consumer part of the supply chain. Figure 5 illustrates the effect of temperature and time in transport in a consumer's vehicle. Simulations were run for three different time durations (30 minutes, 60 minutes and 90 minutes) from the moment of bottled milk leaving farm chilled storage to being placed into home storage fridge. It was assumed that at the start of transportation milk temperature was 6 ºC and the milk was rapidly cooled in the consumer fridge, the temperature of which was within the recommended range 2-4ºC. All other parameters in the simulations were the same as in the baseline scenario. The risk of illness resulting from raw milk consumption will increase if more than one parameter deviates from the criteria required for milk production and/or recommended for milk handling by consumers.

Additional examples of the impact of consumers' behaviour on the risk of raw milk consumption are given in Appendix 9.3.

Figure 5. Estimates of the risk of illness from STEC and *Salmonella* spp. depending on the temperature and time in transport in a consumer's vehicle



6 Discussion

Food safety and human health authorities worldwide recognise that raw milk consumption poses a very serious and avoidable health risk. Nonetheless, raw milk drinkers are passionate about their right to drink raw milk.

Current New Zealand legislations allow consumer choice to be exercised, while using stringent controls, consumer education, and monitoring to protect public health. The Raw Milk for Sale to Consumers Regulations 2015 (the Regulations) have been fully operational since 1 November 2016 and it is too early to estimate whether the introduced measures have reduced the rates of human illness associated with consumption of raw milk.

Aside from raw drinking milk produced according to the Regulations other informal options of accessing raw drinking milk are used by consumers. These may include particular arrangements with milk producers designed to bypass strict requirements of the Regulations as well as obtaining raw milk from family or friends' farms. Milk obtained through unregulated distribution networks as well as domestic consumption of raw milk in dairy farming households contributes to outbreaks of illness demonstrably associated with consumption of raw milk.

In the period from January 2014 to November 2018 there were twenty five reported outbreaks of illness associated with consumption of raw milk, in seventeen of which raw milk was confirmed to be the vehicle/source. The rates of reported serious illness attributable to raw milk consumption peaked in 2014. However, only a small percentage of serious illness attributable to raw milk consumption is officially reported, making it difficult to identify trends from available epidemiological data. Establishing robust causation from the consumption of raw milk to an outbreak is complicated by the short shelf-life of raw milk and the time elapsed from drinking a potentially contaminated milk until both a clinical diagnosis and a positive diagnostic laboratory result[6].

Similar to the previous assessment (MPI, 2014) *Campylobacter* spp. and STEC are identified as the pathogens of most concern for raw drinking milk associated illnesses in New Zealand. These pathogens were responsible for outbreaks of foodborne illness with strong links to raw milk consumption that were confirmed both microbiologically and epidemiologically. In New Zealand raw milk is the only food confirmed as a cause of foodborne STEC infection in humans. According to the surveillance data raw milk consumption is implicated in outbreaks of foodborne campylobacteriosis more often than any other food. While campylobacteriosis is the most common raw milk-borne illness, STEC infections are associated with the most severe sequelae. Since 2014 to 2018 surveillance data linked raw milk to eight STEC related cases of HUS in New Zealand.

Cases of raw milk-borne infections were reported in all main milking regions of New Zealand. After campylobacteriosis and STEC infection the disease with the next highest number of notifications was cryptosporidiosis, followed by salmonellosis, yersiniosis and giardiasis.

As in the previous reporting period, a substantial proportion of the raw milk associated disease burden falls on children. 82% of outbreaks strongly associated with raw milk consumption involved children younger than 15 years. Some of these children were under one year old. In outbreaks of STEC infection associated with raw milk 90% of involved cases were children. Seven out of eight cases who developed raw milk associated HUS were young children.

Data on presence of pathogens in New Zealand raw milk were available only for the period from November 2016 and were limited to milk produced by suppliers registered under the RCS . RCS milk is likely to represent a fraction of New Zealand raw milk that is produced under the strictest hygienic conditions. Presence of pathogenic bacteria in such milk confirms the conclusion of the previous assessment (MPI, 2014) that although reduction of pathogens in raw milk is possible, they cannot be eliminated completely and growth takes place when conditions are suitable. This is in-line with numerous international studies affirming that raw milk produced under even the most hygienic of conditions can still harbour human pathogens.

[6] Detailed analysis of issues related to investigation of foodborne outbreaks in New Zealand can be found in https://www.mpi.govt.nz/dmsdocument/12675/direct

Husbandry practices and measures along the raw milk supply chain to the consumer are aimed at minimising growth but will not eliminate presence of milk-borne pathogens. Predictive modelling was employed to estimate impact of post procurement activities on potential microbial load in raw milk at time of consumption. Quantitative risk assessment highlighted the impact of consumer behaviour on safety of raw milk. Strict temperature control along the chain from purchasing to consuming the milk and adherence to recommended use-by-dates will reduce risk to raw milk consumers.

7 Conclusions

This update reaffirmed the conclusion of the 2013 Risk Assessment that due to the inherent food safety risks associated with raw drinking milk, pasteurisation is the most reliable control measures and thereby the most effective means of protecting public health. Adherence to good hygienic practices during milking, packaging and storage can reduce, but not eliminate, the risk of contamination of raw drinking milk.

Campylobacter and STEC are still the main aetiological agents for which there is a demonstrable link between drinking raw milk and human illness in New Zealand.

Current control measures for bovine TB further reduced risk of milk-borne transmission of *M. bovis* infection to humans in New Zealand.

Most of the outbreaks in 2014-2018 as well as sporadic cases of milk-borne infections involved children. Data on other vulnerable groups associated with milk-borne illness were not routinely collected.

There is no evidence of a significant increase in consumption of raw milk in New Zealand. In the current regulatory environment raw milk producers run relatively small businesses and their product is usually geographically limited to the local consumer. However, it remains the conclusion that raw milk is a high risk product for a consumer, the risk associated with consumption of RDM produced under a RSC, on a population basis, is considered to be medium (outbreaks of illness happen regularly, but do not involve many people).

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9 Appendices

9.1 SUMMARY OF INTERNATIONAL ASSESSMENTS OF RISKS ASSOCIATED WITH CONSUMPTION OF RAW MILK 2014-2018.

The summary in the table below is restricted to published in the scientific literature 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). Different formats might be adopted by risk assessments published by international bodies such as the EFSA or national food safety authorities such as FSA (Great Britain) or AECOSAN (Spain).

Pathogen(s) concerned	Food considered	Issuing organisation	Key findings	Reference
Range of pathogens	Raw drinking milk (cow)	European Food Safety Authority (EFSA)	Currently available evidence was assessed and it was determined that raw drinking milk within the EU contains a range of pathogens (hazards) and there is strong evidence of a link between raw milk containing these hazards and the development of human illness following consumption. Because EU-specific data are limited a quantitative risk assessment was not performed. No single step was identified which would significantly reduce risk relative to a baseline of expected good practice.	(EFSA, 2015)
Range of pathogens	Raw drinking milk (cow)	Scientific Committee of the Spanish Agency for Consumer Affairs, Food Safety and Nutrition (AECOSAN)	The Committee considers that raw milk may carry pathogenic microorganisms and the risk could be reduced, but not eliminated, through extreme hygiene practices. Pasteurisation is the only effective method that guarantees the elimination and control of pathogenic microorganisms in this foodstuff and its derivatives.	(AECOSAN,2015)
Salmonella, L. monocytogenes	Raw milk sold in vending machines	Various, Italy	Depending on the dose-response model used, consumer habits and storage scenario, the expected number of cases of salmonellosis per year per 1.08×10^8 210 ml servings predicted by the quantitative risk assessment ranged from 839 cases at best to 980,128 cases at worst among consumers of milk from vending machines in seven regions of Italy. Listeriosis is unlikely to be caused by raw milk consumption. The assessment emphasized that boiling milk before drinking is a simple yet effective tool to protect consumers against the risk of illness inherent in the consumption of raw milk.	(Giacometti *et al*., 2015a)
Campylobacter	Raw milk sold in vending machines	Various, Italy	Time-temperature scenarios, consumer habits (boiling of milk) and two dose-response relationships were modelled	(Giacometti *et al*., 2015b)

			to determine the expected number of campylobacteriosis cases per year, with comparison of 'sensitive' (≤5 or 6 years) to all other consumers. Using the Black et al (1988) dose response model and assuming 5.57% of consumers ≤5 years it is estimated a range of 97.9 to 396.1 cases/100,000 population/year in that age group depending on the proportion of consumers boiling the milk prior to consumption. For consumers >5 years of age the estimated range was 80.6 to 326.2 cases/100,000 population/year. These estimates assumed that from 57% to 84% of consumers boil raw milk before consumption.	
Staphylococcal Enterotoxin A	Raw drinking milk (cow)	Various, Italy	The output of the assessment was an estimate of the probability of an exposure to the minimal dose of toxins sufficient to be harmful to humans. Assuming that 67% of consumers boil raw milk the risk of such an exposure was estimated to be very low. It was stressed that milk handling by consumers (storage time and temperature, heat treatment) has a crucial effect on the final output.	(Crotta *et al*., 2016)
Escherichia coli O157	Raw milk vending machines	Various, Italy	Milk storage and consumer habits (boiling of milk) were modelled, with consumer habitats having the strongest influence in the sensitivity analysis. Depending on the percentage of consumers that do not boil their milk, the estimated number of HUS cases per year ranged from <1 case if 99% of consumers boil their milk, to a maximum of 19.37 cases in 1-2 year olds if only 80% of the consumers boil their milk. The assessment used data collected from vending machines over a 7 year period (2008-2014). STEC O157:H7 was detected in 0.15% of annual official raw milk samples.	(Giacometti *et al*., 2017)
Shiga toxin-producing *E. coli* (STEC)	Bulk milk sold from producer to consumer	South Africa (published by an international risk assessment team)	For producer-distributor bulk milk (PDBM) the estimated mean STEC level was 0.12 CFU/mL for raw milk. The model predicted that for every 100,000 servings of raw milk a median of 52 ((0.68, 1.3 x 10^5) HUS cases in consumers ≤5 years of age, and 3.2 ((0.04, 1.5 x 10^4) HUS cases >5 years. Assumption that 33% of consumers' drink milk without boiling or insufficiently treated despite warnings to boil all raw milk prior to consumption. Time taken to sell PDBM at the producer-distributor outlet and the serving volume were the	(Ntuli *et al*., 2018)

			factors with the greatest influence on the probability of becoming ill.	
Range of pathogens	Raw drinking milk	Advisory Committee on Microbiological safety of Food (ACMSF), UK (England, Wales, Northern Ireland)	The number of raw drinking milk outbreaks and RDM producers has increased since July 2015 in the UK. Hazardous results (presence or elevated levels of pathogens) are associated with approximately 1% of routine RDM samples evaluated. A qualitative risk assessment was performed. In conclusion the report states "the risk for the subpopulation that consume RDM is currently considered to be medium (occurs regularly) with medium uncertainty." It was noted that in the last three years the microbiological risk associated with consumption of raw drinking milk has increased due to greater levels of exposure.	(ACMFS, 2018)

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9.2 SUMMARY OF OUTBREAKS OF ILLNESS ASSOCIATED WITH CONSUMPTION OF RAW MILK REPORTED INTERNATIONALLY 2014-2018

Reports of outbreaks published since 2014 have been retrieved from the scientific literature and summarised in the table below.

CAUSATIVE PATHOGEN	COUNTRY	YEAR	No. CASES[1]	HOSPITALISATIONS (DEATHS, SEQUELAE)	RAW MILK TYPE; WHERE OBTAINED	EVIDENCE LINKING RAW MILK TO CASES[2]	REFERENCE
Campylobacteriosis							
C. jejuni	Sweden	2014	8 C 3 P	NR[3]	Cow; farm visit	Epidemiology; matching strains (PFGE, WGS) from cases and faeces from dairy cows at implicated farm	(Lahti *et al.*, 2017)
C. jejuni	USA (Utah)	2014	59 C 40 P[4]	10 (1 died)	Cow; on-farm sales	Epidemiology; matching strains (PFGE, WGS) from cases and milk	(Davis *et al.*, 2016; Oakeson *et al.*, 2018)
C. jejuni	USA (California)	2015	7 C 1 P	2	Cow; retail[5]	Epidemiology; matching strains (PFGE) from cases, milk and cream	(CDPH, 2015a)
C. jejuni	USA (California)	2015	5 C 1 P	1	Goat; retail[5]	Epidemiology; matching strains (PFGE) from cases, milk and faeces from goats at implicated farm	(CDPH, 2015b)
C. jejuni	England	2016	16 C 53 P	0	Cow; on-farm vending machine	Epidemiology; matching strains (WGS) from cases and milk	(ACMSF, 2018; Aird, 2017)
C. jejuni	USA (Colorado)	2016	12 C 5 P	1	Cow; on-farm sales (herdshare)	Epidemiology; matching strains (PFGE) from cases and milk	(Burakoff *et al.*, 2018)
Campylobacter spp.	England	2017	4 C	0	Cow	Epidemiology; matching strains from case and milk	(ACMSF, 2018)

CAUSATIVE PATHOGEN	COUNTRY	YEAR	No. CASES[1]	HOSPITALISATIONS (DEATHS, SEQUELAE)	RAW MILK TYPE; WHERE OBTAINED	EVIDENCE LINKING RAW MILK TO CASES[2]	REFERENCE
Cryptosporidiasis							
C. parvum	USA (Idaho)	2014	9[6]	1	Goat; retail	Epidemiology; same *C. parvum* subtype isolated from 3 primary cases and 3 secondary cases[7]	(Rosenthal *et al.*, 2015)
C. parvum	USA (New Mexico)	2016	6 C 1 P	NR	Cow	Epidemiology; same *C. parvum* subtype isolated from 2 cases	(Doman *et al.*, 2017)
Listeriosis							
L. monocytogenes	*US*	2014	2	2 (1 died)	Cow; chocolate milk, purchased from farm	Epidemiology; matching strains (WGS) from cases, milk from implicated farm[8]	(USCDC, 2016)
STEC infection							
E. coli O157 (sorbitol fermenting)	Finland	2012	8 C[9]	6 (4 HUS)	Cow; farm visit	Epidemiology[10]; matching strains (serotype virulence markers, phage type, PFGE, phylogenetics) from cases, faeces from cattle and farm environment	(Jaakkonen *et al.*, 2017)
E. coli O157:H7 and *E. coli* O101:H33	Russia	2013	64	62 (6 HUS, 1 died)	Cow; vending machines	Epidemiology; matching strains (virulence markers, MLST, WGS) from cases and milk	(Onishchenko *et al.*, 2015)[11]
E. coli O157	England	2014	9 C	2 (2 HUS)	Cow; on-farm sales	Epidemiology; matching strains (WGS) from cases and faeces from dairy cows at implicated farm	(Butcher *et al.*, 2016)
E. coli O157	England	2017	7 C	5	Cow	Epidemiology; matching strains from case, milk and animals	(ACMSF, 2018)
E. coli O103:H2 (*stx* positive)	Germany	2017	39	4	Cow; milk delivered by farm for guests' breakfast at	Epidemiology; matching strains (PFGE, WGS) from cases, faeces from calves and environment of implicated farm	(Mylius *et al.*, 2018)

CAUSATIVE PATHOGEN	COUNTRY	YEAR	No. CASES[1]	HOSPITALISATIONS (DEATHS, SEQUELAE)	RAW MILK TYPE; WHERE OBTAINED	EVIDENCE LINKING RAW MILK TO CASES[2]	REFERENCE
					hotel in Austria		
Yersiniosis							
Yersinia pseudo-tuberculosis	Finland	2014	41 C 2 P[12]	NR	Cow; retail	Epidemiology; matching strains (PFGE, MLVA) from cases, milk and milk filter at implicated farm[13]	(Pärn *et al.*, 2015)
Mixed infection							
STEC *Cryptosporidium*	Australia (Victoria)	2014	4[14]	2 (2 HUS, 1 died)[14]	Cow; sold at retail as 'bath milk'	Epidemiology[14]	(Jamieson, 2016; OzFoodNet, 2017)
C. jejuni, non-O157 STEC	USA (Wisconsin)	2014	29 C[15] 9 P	10	Cow; provided by a farm for a shared meal	Epidemiology; matching strains (PFGE) from cases and faeces from dairy cows at implicated farm	(Anonymous, 2014)

Notes to the table

1 C, confirmed (pathogen isolated from clinical sample); P, probable (epidemiological link with outbreak). Cases are assigned C or P where this information has been reported.

2 PFGE, pulsed-field gel electrophoresis; WGS, whole genome sequencing; MLVA, Multiple-Locus Variable number tandem repeat Analysis. "matching strains" indicates that the results from these tests show that the isolates were matching.

3 NR, not reported.

4 A further seven cases were identified in a second outbreak associated with this dairy.

5 Both outbreaks were from milk supplied by the same farm. An outbreak in 2012 was also associated with milk from this farm, affecting 22 people. Samples of raw milk tested positive for *E. coli* O157:H7, *E. coli* non-O157 and *C. jejuni*.

6 Four were primary cases (consumed milk), five were secondary cases (person-to-person transmission from primary cases).

7 Initial PCR tests detected *Cryptosporidium* in nine milk samples but confirmation tests were negative. False-positives were likely caused by amplification of goat DNA.

8 The WGS was conducted on an isolate from chocolate milk produced by the farm during November 2015 and compared retrospectively with isolates from the two cases.

9 This includes three secondary cases.

10 The epidemiological investigation included a case-case study to separate animal contact from milk consumption.

11 Information interpreted from article in Russian.

12 There were possibly an additional 12 cases (total 55 cases) that were not involved in the case control study.

13 The epidemiological investigation included a case-control study. Prior to this outbreak but still during 2014, five people who had consumed this producer's raw milk had fallen ill with campylobacteriosis. At that time, *Campylobacter* was not detected in the raw milk so only epidemiological evidence was available.

14 Two cases were infected by *Cryptosporidium*, one by STEC and one by both pathogens. The two HUS cases (and two cryptosporidiosis cases) were notified during October. Another HUS case had been notified earlier in 2014 and reported consuming the same brand of raw milk. The 2016 coroner's enquiry into the death concluded that the child's death was most likely linked to the consumption of unpasteurised milk. The report also revealed that STEC were isolated from one milk sample of the same brand consumed by the outbreak cases, but this sample was taken during November.

15 Three cases were also infected by non-O157 STEC.

Outbreaks included in the above table are restricted to outbreaks caused by pathogens of significance for New Zealand are summarised in the table. Reports of raw milk related outbreaks that were caused by *Brucella* spp, *Coxiella burnetii*, Tick-borne encephalitis virus and *Toxoplasma gondii* (pathogens that are not routinely present in New Zealand dairy farm environment) are not included in the table.

Peer-reviewed outbreak reports in the scientific literature represent a proportion of reported outbreaks linked to raw milk. Numerous press releases from regulatory or public health agencies and the lay press are also available. For example, the Program for Monitoring Emerging Diseases (ProMED) reports an additional three US outbreaks linked to raw milk consumption during 2018, which prompted product recalls[7].

Data on outbreaks associated with raw milk recorded in the US Centers for Disease Control and Prevention National Outbreak Reporting System (NORS) have been analysed in studies published since 2014. A recent paper by Whitehead and Lake (Whitehead and Lake, 2018) summarises data from NORS for the period 2005–2016. There were 152 outbreaks and 1,735 outbreak-associated cases attributed to unpasteurised fluid milk during this period, resulting in 176 hospitalisations and two deaths.

In addition to the five Great Britain outbreaks listed in the Table, there were two outbreaks reported during 2017, but the details were insufficient to include them in the table. Both were outbreaks of campylobacteriosis with raw cows' milk being the implicated vehicle of infection (ACMSF, 2018):

- South West England, 5 confirmed cases, epidemiological evidence.
- Wales, 18 cases (9 confirmed), microbiological and epidemiological evidence.

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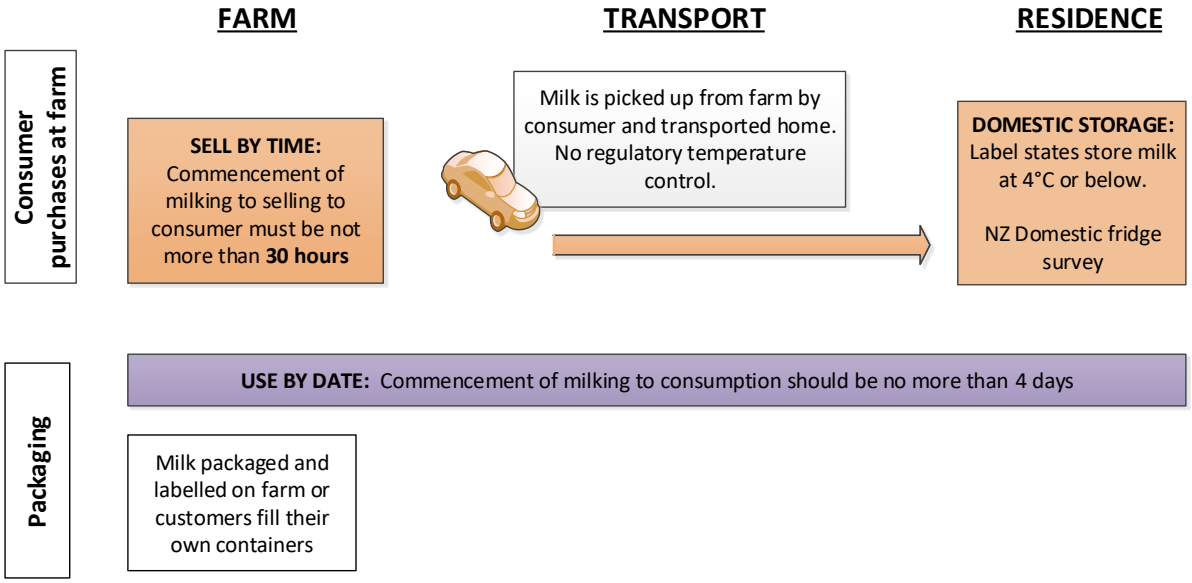
9.3 MODELLING IMPACTS OF FARM PRACTICES AND CONSUMER BEHAVIOUR ON MICROBIOLOGICAL RISK ASSOCIATED WITH CONSUMPTION OF RAW MILK

The impacts of farm practices and consumer behaviour on microbiological risk associated with consumption of raw milk were estimated by differences in number of predicted illnesses following consumption of milk produced and handled under a range of scenarios.
The modelled pathway from milk production to consumption is illustrated in Figure 6

Figure 6. Food chain for raw milk from production to consumption



The input parameters (constants and distributions) for the baseline scenario are specified as follows:

- Farm storage temperature ~ logistic(location=4.85077, scale=0.54356) truncated at min=0.1 and max=6.0
- Duration of milk in farm storage ~ uniform(minimum=1,maximum=30)
- Temperature over transport home set to the same as farm storage for dispensing (vending machine or pre-packaged) which is set to farm vat temperature.
  Duration of transport home ~ triangle(minimum=0.1,most likely=0.5,maximum=1)
- Fridge temperature ~ normal(mean=3.2,sd=2.5) truncated at min=1 and max=4
  Fridge duration until used up ~ pert(0,60,120)
  Time milk spent in fridge before consumption of a single serve ~ uniform(minimum=0, maximum=min(Fridge duration until use, 96-Duration of transport home - duration of milk in farm vat)).
- The temperature of the milk in the fridge is assumed to be at a constant temperature equal to the fridge temperature. This is a simplifying assumption as opening the fridge door, addition of foods, fridge cooling cycle will all possibly effect the air temperature in the fridge.

Similar to the Section 5 pathogen growth/inactivation models and their parameters, as well as dose-response models, are the same as in the 2013 MPI Risk Assessment (MPI, 2014); prevalence and concentration of pathogens in raw milk are described by distributions developed in Marshall *et a*l (2016). The baseline scenario considers only low level background concentrations, assuming no contamination events.

The variability in the model parameters is captured by running the model for 100,000 iterations and for each iteration sampling from distributions for the inherently variable model parameters, such as

storage temperatures and durations. This provides one simulation of the model and one estimate of the risk per pathogen. Using 100,000 iterations to estimate the risk in each simulation ensures the risk estimate has converged to a stable value for the simulation.

A total of 20 model simulations have been run, with each simulation using a different starting seed value for the random number generator used to sample the parameter distributions. Each simulation will produce a slightly different estimate of risk, due to the different values sampled from the parameter distributions in each simulation. Repeating the model simulation provides information on how sensitive the model outputs are to the choice of input value (seed) to the distribution sampling code and therefore, information on between simulation variability.

Table 7 provides the number of estimated cases (baseline scenario) per 100,000 servings for each pathogen along with the 95% credible interval (represented by the columns lower bound CI and upper bound CI). The estimated number of cases is calculated as the mean of the risk estimates for the 20 simulations, and the lower and upper bounds are 2.5th and 97.5th percentiles for the 20 simulations.

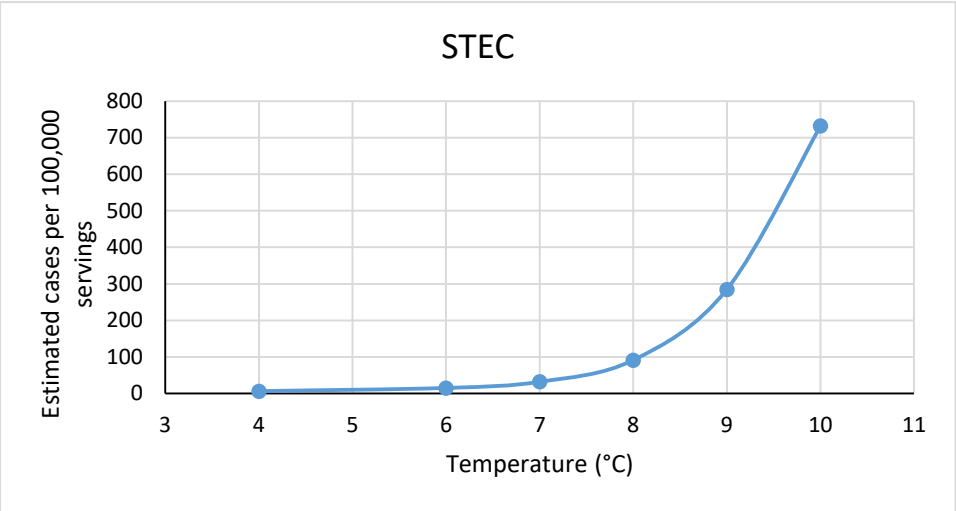
Table 7. Predicted cases of illness per 100,000 servings of raw drinking milk

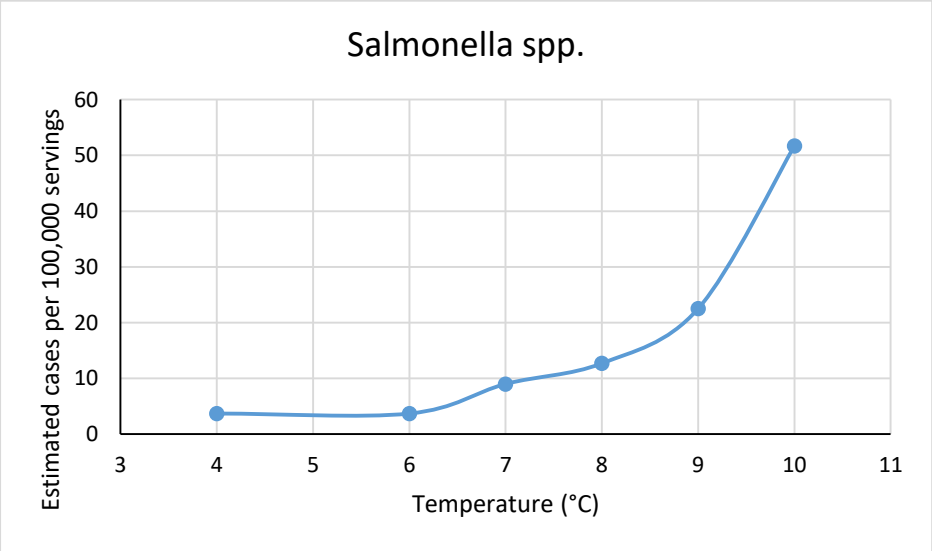
Pathogen	Estimated cases per 100,000, per serving	Simulation Variability Lower bound CI	Simulation Variability Upper Bound CI
Campylobacter	93.7	78.8	104.4
Campylobacter (acquired immunity)	15.1	10.6	22.7
STEC	6.7	5.7	7.9
Salmonella	3.7	1.5	5.9
L. monocytogenes (susceptible population)	8.17E-06	8.14E-06	8.21E-06

Further consideration is restricted to impact of deviations from the baseline scenario on risk of campylobacteriosis, salmonellosis and STEC infection. Risk of raw milk related listeriosis is very low even for the susceptible population.

In addition to the scenarios presented in Section 5 the effect of elevated temperature in the consumer home fridge has been explored. Figure 7 shows the mean of estimated illness cases per 100,000 servings. A total of 20 simulations were run for each of the following fridge temperatures 4,6,7,8,9 and 10 °C. All other parameters in the model are left as specified in the baseline model. Each simulation is also run for a total of 100,000 iterations.

Figure 7. : **Estimates of the risk of illness from STEC and *Salmonella* spp. depending on the temperature at which the milk is stored in the consumer fridge**





There is no allowance for time for the milk temperature to equilibrate to fridge temperature, given the extended time stored in the fridge and milk is likely to be stored in relatively small quantities, this not expected to influence the overall trends in the results.

Similarly, the effect of leaving milk out of refrigeration in the consumer home was explored. It was shown that consuming milk after exposing it to room temperature (20-22^{o}C) for 30 minutes increases risk of related salmonellosis by 29% and STEC infection by 37%.

Combination of different time-temperature abuses of raw milk before its consumption will lead to further increase in risk of developing an associated illness.