Ministry for Primary Industries
Manatū Ahu Matua

The sale of raw milk to consumers

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Growing and Protecting New Zealand

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1 Consultation

This document sets out policy options for the sale of raw milk to consumers. The Ministry for Primary Industries (MPI) invites all interested parties to make written submissions on the issues raised and options presented in this consultation document. MPI is particularly interested in receiving feedback on the practical implementation of each option.

1.1 How to make a submission

The closing date for submissions is 5:00pm 8 July 2014.

MPI encourages individuals and organisations to make all or part of their submission by clicking on "https://www.surveymonkey.com/s/RawMilkSubmission" and responding to questions. We hope this will make the submission process easier and help ensure the accuracy of submissions.

MPI will consider all relevant material made in submissions. You are welcome to provide information that is additional to the questions we are asking, via the above link.

You may also choose not to use the link and send in a submission in your own format. If you choose to do this, please mail your submission to:

Consultation on raw milk sales
Food Policy Team
Ministry for Primary Industries
PO Box 2526
Wellington 6104
New Zealand

Or for hand delivery: Pastoral House, 25 The Terrace, Wellington

Or email it to: rawdrinking.milk@mpi.govt.nz

Please include your name and address on your submission. If you are making comments on behalf of an organisation, also include your title, the name of the organisation and whether your submission represents the whole organisation or a section of it.

Please make sure your comments can be clearly read as a number of copies will be made to help with analysis. Please also state the number of the question you are answering; or if you are making a general comment, state the number of the section your comments are referring to.

1.2 Official Information Act 1982

Under the Official Information Act 1982 (OIA) information held by MPI is to be made available to requestors unless there are grounds for withholding it. The grounds for withholding information are outlined in the OIA.

If you are making a submission you may wish to indicate any grounds for withholding some information contained in your submission. Reasons for withholding information could include that the information is commercially sensitive, or you wish personal information such as names or contact details to be withheld. An automatic confidentiality disclaimer from your

information technology (IT) system will not be considered as grounds for withholding information if an OIA request is made.

MPI will take your indications into account when determining whether or not to release requested information. Any decision to withhold information requested under the OIA may be reviewed by the Ombudsman.

1.3 Process after submissions

Once the consultation period has closed MPI will analyse submissions and make recommendations to the Minister for Food Safety. A summary of submissions and analysis will be sent to all submitters and posted on the MPI website.

Changes to legislation will be required to implement any policy change and will require Ministerial and parliamentary oversight.

2 Executive summary

Problem
The consumption of raw milk is causing some people to get sick, but the amount being drunk appears to be increasing. The existing law is unclear and this has led to some confusion about the rules that apply.

Raw milk
Raw milk is untreated milk that typically comes from cows, goats, or sheep. This means it has not been pasteurised and nothing has been added or removed. Pasteurisation is a process that kills harmful bacteria (pathogens) by heating milk to a specific temperature for a set period of time. MPI is interested in reducing the foodborne illness that results from drinking unpasteurised milk –called 'raw milk' in this paper.

The law
In New Zealand, people are legally allowed to buy limited amounts of raw milk (up to five litres at any one time) from the farm, for themselves and their family. The law also has general rules that apply to the production and supply of raw milk sold to consumers. The existing legislation is outdated and hard to interpret and enforce.

Previous consultation
MPI consulted on the sale of raw milk to consumers in 2011. People and organisations expressed very diverse and strong opinions. The submissions indicated that there is some demand for raw drinking milk. Some consumers wanted to buy raw milk at places other than the farm and in larger volumes than are currently allowed. Many people considered raw milk nutritionally better than pasteurised milk and able to help reduce symptoms that relate to conditions such as lactose intolerance, heart disease, asthma and other allergies. Consumers expected raw milk to be collected from healthy animals, tested, and refrigerated.

However, dairy processors, a representative group of dairy farmers, district health boards, and scientists were concerned about the food safety risks. They stated that pathogens such as *Escherichia coli*, *Campylobacter* and *Salmonella* can intermittently occur in raw milk in sufficient amounts to cause illness, even when farming and food safety practices are excellent. They are most concerned for the health of infants, children, older adults, pregnant women and those with low immunity because studies show these groups of people are the most likely to get ill from drinking raw milk and to suffer the most severe symptoms. Some also raised concerns about the potential impact of any illness outbreaks on New Zealand's reputation as a supplier of safe food. These submitters supported pasteurisation, or measures that minimise the risks of raw milk and limit its sales.

Illness
Data for 2013 shows that raw milk was a reported risk factor in outbreaks[1] of foodborne illness. There were eight reported outbreaks, affecting 33 people, where the consumption of raw milk was identified as one of the risk factors. In addition, two children younger than five years old who were hospitalised with serious renal problems had consumed raw milk.

For most outbreaks raw milk consumption is not the only risk factor identified; contact with farm animals and consuming untreated water are also often mentioned. However, since 2009

[1] A foodborne outbreak is when two or more people get the same illness from the same contaminated food or drink. Not all foodborne illness is reported.

the numbers of outbreaks where raw milk consumption is a recorded risk factor have been consistently higher than in previous years.

Nutrition and health effects when raw milk is pasteurised

A review of the scientific literature showed that pasteurisation does not substantially change the nutritional value of raw milk. Also, scientists have not confirmed any specific health benefits from the consumption of raw milk. A few studies suggest that drinking raw milk at an early age, along with other factors, may help reduce the risk of developing asthma, hay fever, or eczema but the science is not conclusive because of a lack of data and the absence of a biological reason why raw milk could help protect against these conditions.

Options for future sales of raw milk to consumers

All policy options for the sale of raw milk to consumers were considered. MPI undertook a thorough analysis of all potential options before eliminating approaches that were considered unlikely to meet the policy objectives of reducing foodborne illness, improving consumer understanding of the risks, maintaining access, ensuring the law is clear and can be enforced, and protecting New Zealand's reputation as a supplier of safe food.

Options not proceeded with because they would not adequately meet the policy objectives include: prohibition; the status quo; non-regulatory control measures; sale at retail outlets; and sale at farmers' markets.

Following analysis, we consider the following are viable options.

Option 1: Sales only from the dairy farm direct to consumers with restrictions on the quantity a farm dairy operator (dairy farmer) could sell each day (less than 40 litres per day) and the amount a consumer could purchase (6 litres per day). Forty litres is roughly equivalent to milking one to two cows non-intensively. Dairy farmers would have to meet baseline production requirements to sell raw milk to consumers. Additional labelling requirements would apply.

Option 2: Sales only from the dairy farm direct to consumers and with no quantity limits provided strict requirements are followed. There would be two levels of requirements depending on how much raw milk is sold per day. All dairy farmers would have to meet baseline production requirements but those selling 40 litres or more per day would have to comply with additional, more-stringent requirements. Additional labelling requirements would apply.

Option 3: Sales from the dairy farm as for option 2, plus home deliveries by the dairy farmer directly to the consumer only. Additional food safety requirements would be required for the home delivery component. Home deliveries would only occur if the purchaser pre-orders, delivery is to their place of residence, and the milk is not on-sold.

Your views

MPI is seeking comment from individuals and organisations on the options and any other matters in this document. See page 1 on how to make a submission. We are seeking feedback on the details around all of the options. Such feedback will assist MPI's analysis and improve the policy outcome even if your preferred option is not the one finally chosen.

3 The problem

MPI is concerned about the foodborne illness that results from drinking milk that is not heat treated. Pasteurisation is the process that eliminates harmful bacteria (pathogens) through a specific heat treatment (72°C for 15 seconds). In this paper, unpasteurised milk is called raw milk [see section 6.1 for the definition we are using].

The principal problem is that drinking raw milk is causing some people to get sick, especially infants and young children. The Government has a responsibility to manage food safety risks associated with all food that is sold, so that people do not get sick and to keep costs to the taxpayer as low as possible.

The recorded outbreaks of illness where raw milk consumption is identified as a risk factor have been consistently higher since 2009. In 2013, in illness outbreaks reported as foodborne – where a food was specified - raw milk was one of the most frequently identified risk factors (second only to poultry consumption), despite relatively low consumption per capita. Despite the health risks, it appears that consumption of raw milk is increasing.

MPI considers the problem is caused by a number of factors:

- New Zealand raw milk intermittently contains pathogens that can cause very severe illness. No level of control measures will eliminate the risk as the milk has not been processed to destroy harmful pathogens that may be present.
- A growing trend in New Zealand to drink raw milk. Some consumers consider that there are health benefits or may not be aware of the risks.
- The laws that govern the sale of raw milk to consumers are not working efficiently and were only intended for rural people unable to access pasteurised milk. Some rules are difficult to interpret and some are hard to enforce. Previous consultation on raw milk sales indicated that people who consume raw milk do not consider the laws are serving their needs.
- Clear rules are needed on the practices dairy farmers can use to minimise the risk of pathogens occurring in raw milk, and on information that describes to consumers the risks associated with raw milk and how best to reduce them.

As a consequence of these factors, the following are likely to be contributing to outbreaks of illness:

- poor animal health, hygiene, and food safety measures being practised by some dairy farmers;
- consumers not heat treating raw milk to kill any pathogens that may be present;
- consumption of raw milk by vulnerable groups such as infants, children, the elderly, pregnant women and those with weakened immune systems;
- consumption of raw milk by urban people (with lower immunity compared with rural people); and
- insufficient inspection of farms selling raw milk for drinking.

Question

1. Do you agree with the way that the problem with the current situation has been described? If not, why not?

4 Scope of this review

This consultation document examines options for the future sale of raw milk to consumers. It focuses on the safety risks and implications of raw milk consumption; that is, whether people are at risk of becoming ill when they drink raw (unpasteurised) milk. If they are, then how big is the health risk and what is the best way to minimise the risks when some people want to drink it?

Raw milk products such as raw milk cheese, yoghurt, and butter are not covered in this consultation. Requirements placed on people producing and selling raw milk products are in other parts of food legislation.

This consultation relates to the sale of raw milk from all milking animals. Scientific analysis has, however, mainly concentrated on risks associated with consuming raw cows' milk. Limited scientific data available on raw goats' milk in New Zealand suggest that the risks of consuming raw goats' milk are similar to those for cows' milk. The consumption of sheep and buffalo raw milk is believed to be negligible and does not justify additional scientific assessment.

This review's focus is the sale of raw milk to consumers. What people do with it in their own homes is not regulated by food legislation as long as the raw milk is not traded or sold to anyone else.

5 The objectives

The objectives for the policy on sales of raw milk to consumers are to:

- reduce illness related to the consumption of raw milk;
- maintain existing access to raw milk;
- ensure consumers receive accurate, easy to understand information on the health risks of consuming raw milk;
- develop law that is unambiguous, and clearly sets out the obligations of buyer and sellers of raw milk;
- encourage compliance and have the ability to monitor and act on non-compliance;
- protect New Zealand's reputation as a supplier of safe food;
- regulate in a way that is consistent with the approach used for other uncooked foods that can potentially contain pathogens.

Question

2. Have all of the objectives been identified? If not, what other objectives should MPI use to assess policy options?

6 Background

6.1 Raw milk

Raw milk is milk from all milking animals, such as cows, goats, sheep, and buffalo. It has not been altered in any way. It has not been pasteurised, homogenised, dried or frozen, and nothing has been added to it or removed from it.

MPI is only concerned about the foodborne illness that results from milk that is not heat treated (for example by pasteurisation). Pasteurisation is the process that eliminates harmful bacteria (pathogens) through a specific heat treatment (72°C for 15 seconds). In this paper, therefore, the term raw milk relates to unpasteurised milk.

Homogenisation is a different process that breaks up the fat globules in milk so the fat is distributed uniformly throughout. This process prevents the cream layer from separating out of the rest of the milk. There is no foodborne illness risk resulting from homogenisation.

All liquid milk sold in New Zealand is heat treated to a standard equivalent to or greater than pasteurisation, with the exception of the limited quantities of raw milk sold direct from a farmer to consumers at the farm. These limited sales are sometimes referred to as "farm gate" sales.

6.2 Previous MPI work on the sale of raw milk to consumers

In October 2011 MPI sought public input on options that continued to restrict sales of raw milk by only allowing them from the farm and in limited quantity.[2] Our preferred option was to allow dairy farmers to sell up to six litres of raw milk each day to a consumer for their own or their family's consumption. Under this option the farmer would not have been permitted to sell more than 120 litres of raw milk per day. Additionally, dairy farmers would have been exempt from operating under a risk management programme but would have been required to meet certain animal health, hygiene, and food safety requirements including keeping records of sales.

The consultation resulted in 1,685 submissions and indicated the level of interest in the policy for raw milk sales.[3] The consumers, and dairy farmers who sold raw milk, strongly:

- supported the continuation of sales;
- supported sales in places other than the farm;
- supported collection of milk by people other than the consumer;
- supported the purchase of more than six litres of milk at a time;
- pointed to the relatively low number of outbreaks as evidence of low risk; and
- expressed their right to choose to drink/provide raw milk.

However, dairy processors, a representative group of dairy farmers, district health boards, and scientists expressed strong concerns about the high risk raw milk posed to public health and reiterated that heat treatment is the only way to kill pathogens. These submitters supported stringent controls on sale if prohibition was not the preferred policy. Dairy processors were concerned about the dairy industry's domestic and global reputation in the event of a serious outbreak of foodborne illness occurring.

[2] Ministry for Primary Industries. Proposals for continuing to legally provide for farm gate sales of raw drinking milk. http://www.foodsafety.govt.nz/elibrary/industry/farm-gate-raw-milk-sales/. Accessed 11 April 2014.
[3] Ministry for Primary Industries. Summary of Submissions on the Proposals for Continuing to Legally Provide for Farm Gate Sales of Raw Drinking Milk. http://www.foodsafety.govt.nz/elibrary/industry/farm-gate-raw-milk-sales/2012-12-summary-submissions-raw-milk.pdf . Accessed 11 April 2014.

7 Current situation

7.1 New Zealand legislation

Three pieces of legislation govern the supply of raw milk to consumers: – the Food Act 1981, Animal Products Act 1999, and Australia New Zealand Food Standards Code.

7.1.1 Food Act 1981

Section 11A of the Food Act 1981 allows milk processors (dairy farmers) to sell up to five litres of raw milk at any one time from their dairy premises (farms) to people wanting to consume it themselves or give it to their family. Dairy farmers must also comply with other general requirements in the Food Act.[4]

Sales from the farm direct to consumers (commonly known as "farm gate sales") were introduced into legislation when pasteurisation of milk for town supply became compulsory around the 1940s. The two reasons for this were:

- to ensure farm workers and people living in rural areas had access to milk at a time when commercially bottled pasteurised milk was not available in isolated areas. Milk was purchased on a "buyer-beware" basis with consumers responsible for managing the food safety risks. The original intention of farm gate sales was to provide raw milk for drinking, not for processing into cheese, so the limit of 1 gallon (and later 5 litres) was considered to be adequate even for large households; and
- to restrict widespread sales of raw milk. The rationale was that making raw milk available to all consumers would expose the community to potential foodborne illnesses to an unacceptable extent.

Problems occur with interpreting section 11A, including for example how many times a day an individual may purchase up to five litres of raw milk. Also the Food Act was developed before internet sales were available and therefore the Act does not take into consideration sales that occur via this method.

7.1.2 Animal Products Act 1999

Raw milk is an animal product, so its production is covered under the Animal Products Act 1999. The Animal Products Act (APA) and legislation made under it require that all animal products, including ingredients, must be fit for their intended purpose.

With few exceptions the APA requires dairy farmers to operate under a risk management programme (RMP) that is specifically designed for the food they produce. A RMP is a written programme that identifies and manages the food safety risks to "ensure" that the product is fit for the intended purpose. Domestic market RMPs are verified regularly, generally on an annual basis.

The RMP requirements apply to all dairy farmers who are producing raw milk, regardless of whether they own one cow or have a large commercial herd. The requirements apply to any person in a cowshare agreement who physically milks the cow.

[4] Section 9(4) (the prevention of the sale of food that is "unsound or unfit for human consumption or contaminated") and section 11AA (contravention of the Act when it is known that a sale will create a risk to human health) of the Food Act are relevant general requirements.

Most dairy farms in New Zealand operate under RMPs that are owned and operated by large dairy processors. These RMPs are specific to the dairy processor's operations and so the procedures only cover the milk the dairy processor intends to use. The dairy processor is responsible for the entire programme working effectively, including instructing the dairy farmer on how to operate.

Dairy farmers selling raw milk to consumers must operate under a RMP that specifically covers this activity. The RMPs that cover the supply of milk for another activity, such as supplying milk to a large processing company for pasteurisation or making dairy products, do not cover or adequately manage the risks associated with farm gate sales of raw milk.

A RMP must set out how the relevant process ensures safety for consumers. No-one selling raw milk to consumers has a registered RMP for this activity. There is no acceptable way of ensuring raw milk doesn't contain pathogens, apart from heat treatment. MPI has therefore not actively enforced the RMP requirement for dairy farmers producing and selling raw milk directly to consumers.

7.1.3 Australia New Zealand Food Standards Code

The Australia New Zealand Food Standards Code (Food Standards Code) is a set of food standards for both New Zealand and Australia. Microbiological limits and labelling requirements under this Code apply to raw milk.

In most circumstances raw milk sold to consumers is exempt from general labelling requirements because it is packaged at the farm, often in the presence of the purchaser. However, the name of the food, directions for its storage and use, and a mandatory advisory statement (which may be verbal) to the effect that the product has not been pasteurised, must be provided to the consumer. The dairy farmer must also comply with any other applicable requirements in the Food Standards Code, including requirements around making nutritional and health benefit claims if these are made.

The way the above information must be provided to the consumer is specific for each labelling requirement. For instance, the mandatory advisory statement must be "displayed on or in connection with the display of the food" (including when it is dispensed from a vending machine) "or provided to the purchaser on request".

Given the food safety risks, MPI considers the above requirements are insufficient to warn consumers about the health risks associated with drinking raw milk and how best to minimise them.

7.2 Raw milk market

7.2.1 Dairy farmers supplying raw milk to consumers

The raw milk industry is relatively small compared to the rest of the dairy industry. It is difficult to gauge the size of the raw milk industry because many suppliers do not advertise very widely (or at all) and no-one is currently registered with MPI for this activity.

However, MPI has some recent information from the Raw Milk Producers Association (the Association), set up by 35 producers in 2013. In April 2014 the Association advised us that it has 54 members. Its President estimated that there are at least that number again of dairy farmers producing raw milk for sale to consumers but who are not members of the Association.

The Association's numbers suggest an increase in producers since 2011, when a Federated Farmers internet survey[5] and a MPI audit identified 34 and 35 producers respectively. This apparent growth is consistent with a number of recent media reports that refer to newly-established suppliers.

MPI does not currently have reliable data on the volume of raw milk sold. Indicatively, seven of the 34 Federated Farmers survey respondents in 2011 reported selling more than 300 litres per week.[6]

MPI is asking dairy farmers to indicate whether they sell raw milk direct to consumers, how much they currently sell, and their likely intentions under the options presented. MPI will use this information to assist with the policy analysis.

Question

3. Do you have any evidence about the numbers of farmers supplying raw milk to consumers or the volume of raw milk supplied?

Questions for dairy farmers selling / considering selling raw milk to consumers

4. Do you currently sell or are you considering selling raw milk to consumers?

5. If you sell raw milk to consumers:
- on average, what volume of raw milk do you sell to consumers each day?
- what price per litre do you charge consumers?
- are you meeting the demand from consumers?
- what proportion of your sales is to urban consumers?
- do you know how many people buy your raw milk once a week or more? If so, please state how many.

7.2.2 Consumers

MPI has the following data on the incidence of raw milk drinkers:

- A MPI commissioned telephone survey of 1,010 New Zealand adults in April 2014 showed that 5% of respondents currently consume raw milk. Over half (57%) stated they had drunk it (at some time).
- Using national nutrition survey data from 1997-2009 MPI estimated that about 1% of the New Zealand population consumed raw milk regularly at the time of the surveys and that up to half of those consumers were probably living and/or working on dairy farms (refer to the consultation website Attachment 1 Appendix 10.6).
- A national case-control study of *Shiga-toxin producing Escherichia coli* infection carried out from 2011-2012 found that 16/506 controls (3.2%; 95% CI 1.8-5.1%) reported raw milk consumption[7].

MPI's consultation in 2011 indicated that some people who are interested in natural and unprocessed foods are increasingly seeking out raw milk. These people stated a particular interest in their personal and family health, and the environment. Some people also preferred

[5] Federated Farmers sent a questionnaire to 5,500 email addresses. For eight days, it also publicly invited viewers of its website to respond to the survey. Four hundred and sixty four responses were received. A summary of the data was included in Federated Farmers' submission to MPI's October 2011 consultation on raw milk.
[6] These seven producers reported selling 300, 600, 600, 1000, 1200, 3000 and 3700 litres per week.
[7] Jaros P, Cookson A, Campbell D, Besser T, Shringi S, Mackereth G, Lim E, Lopez L, Dufour M, Marshall J, Baker M, Hathaway S, Prattley D, French N. (2013) A prospective case-control and molecular epidemiological study of human cases of Shiga toxin-producing *Escherichia coli* in New Zealand. *BMC Infectious Diseases*; 13(1): 450.

the taste of raw milk compared with pasteurised milk, while others said they buy it when it is cheaper than processed milk.

Submissions in 2011 indicated that many raw milk consumers are now from urban areas. To avoid visits to farms, some consumers have formed raw milk clubs. After ordering the milk, the farmer or one of the members of the club delivers the milk to a collection point such as an organic food store, a farmers' market, or someone's fridge. This was not the intent of the law.

In addition a number of consumers want to make raw milk cheese or kefir[8] for themselves and/or their families. These consumers told us that 5 litres are not enough to make a reasonably sized cheese.

The 2014 telephone survey of adult New Zealanders found that just over a quarter of respondents (26%) were 'quite interested' or 'very interested' in drinking or using raw milk while 71% were 'not that interested' or 'not at all interested'. When asked to rate how safe raw milk is on a scale of 1 to 10 where 1 was extremely unsafe and 10 was extremely safe, the mean value was 6.[9] Eighty-nine percent of respondents who drank raw milk thought it was very safe (a rating of 8-10).

As part of this consultation we are asking consumers to indicate whether they currently buy raw milk, how much they currently buy, and their likely intentions under the options presented. MPI will use this information to update our data on current demand for raw milk, to assist with the policy analysis.

Question

6. Do you have any further evidence on the incidence of people drinking raw milk in New Zealand?

Questions for people who buy, or want to buy, raw milk

7. If you buy raw milk, who consumes it?
- are they people in your immediate household?
- how old are the people who drink the raw milk you buy?
- are you, or is anyone you provide raw milk to, pregnant or have low immunity?

8. Why do you buy (or want to buy) raw milk?

9. If you have not bought raw milk but are thinking of doing so, who would consume it?

10. How much raw milk would you like to buy at any one time?

11. Do you work or live on a farm, in a rural community but not on a farm, or in an urban area?

12. Where do you collect your raw milk from?

[8] A fermented milk drink made with a starter culture of yeast and bacteria.
[9] A quarter of respondents rated it from 1 to 4, just over a quarter (26%) rated it 5 or 6 and 42% rated it from 7 to 10.

7.3 Outbreaks of illness in New Zealand

7.3.1 Outbreaks[10]

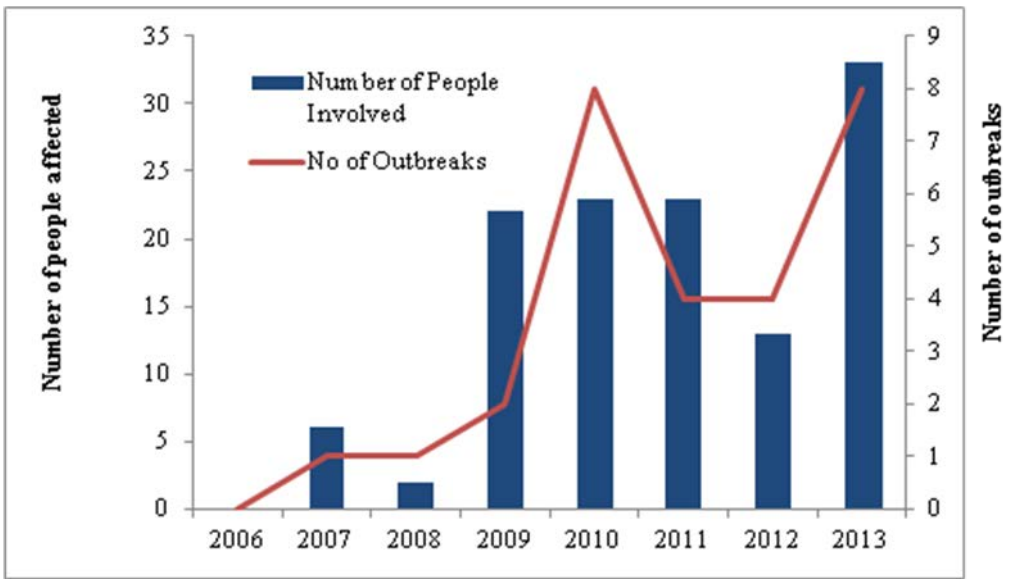
Data on reported outbreaks of disease is collected on behalf of the Ministry of Health by the Institute of Environmental Science and Research. Data for 2013 shows that raw milk is a reported risk factor in outbreaks of foodborne illness. There were eight reported outbreaks, affecting 33 people, where the consumption of raw milk was identified as one of the risk factors. All outbreaks where people's ages were recorded included children younger than five years old.

For most foodborne illnesses (whether they be outbreaks or one-off cases) the consumption of an individual food such as raw milk is not the only risk factor identified; for raw milk, contact with farm animals and consuming untreated water are also often mentioned.

However, since 2009 the number of outbreaks with raw milk consumption as a recorded risk factor has been consistently higher than in previous years, as shown in Figure 1 (below), even though consumption per capita is low. Vulnerable groups such as young children, pregnant women, and older people are most at risk of becoming ill from bacteria that may be present in raw milk and of suffering the most severe symptoms.

During the three-year period 2007-09 there were five reported outbreaks where consumption of raw milk was identified as a risk factor; in comparison, 16 outbreaks recorded drinking raw milk as a risk factor in the three years from 2010 to 2012.

Figure 1: Reported outbreaks of illness from 2006-2013 where raw milk consumption was identified as a risk factor.



Of the reported outbreaks in 2012 where a food was identified as a risk factor, dairy products and grains/beans were the commonest food categories; each category was associated with eight outbreaks. Four of the eight outbreaks for dairy products were associated with raw milk consumption. In 2013 in outbreaks reported as foodborne – where a food was specified - raw

[10] A foodborne outbreak is when two or more people get the same illness from the same contaminated food or drink. Not all foodborne illness is reported.

milk consumption was the second most-frequently identified risk factor (second only to poultry consumption) despite relatively low consumption per capita.

7.3.2 One-off cases

Raw milk has been identified as a risk factor for sporadic (one-off) cases of illness in addition to outbreaks. Determining the cause of illness for sporadic cases is difficult. People with acute gastrointestinal illness are generally unlikely to seek medical attention so will not be investigated or reported and subsequently recorded in surveillance data. Even if diagnosed and reported, there are many difficulties in attributing a one-off case of illness to a particular source, especially in the case of food with a short shelf-life.

However, data from 2013 identified raw milk as a risk factor for some sporadic cases of illness, some of which were severe. In 2013 two children younger than five years old were hospitalised with serious renal problems. Both had consumed raw milk.

7.3.3 Pathogens and resulting health problems

Campylobacter and pathogenic *Escherichia coli* (*E. coli*) are of most concern in New Zealand raw milk. Infection with *Campylobacter* typically lasts a week and can result in muscle pain, headache and fever, diarrhoea, abdominal pain, and nausea. In some cases it can lead to chronic health problems such as reactive arthritis and Guillain-Barré syndrome.[11] Infection with pathogenic strains of *E. coli* can cause severe bloody diarrhoea and in some cases kidney failure in otherwise healthy people, particularly young children.

Outbreaks of less severe diseases are also associated with *Salmonella* and other pathogens found in raw milk. The risk of developing tuberculosis in New Zealand from drinking raw milk is very low but cannot be disregarded, given that bovine tuberculosis is still present in this country. There are currently no specific tuberculosis requirements for raw drinking milk that is sold to consumers. However, for raw milk products the law requires that bovine animals must be clear of tuberculosis for at least five years and testing must be done each season. MPI considers the same or similar level of requirements should apply to all raw milk intended for sale to consumers.

7.3.4 Minimising the risk of disease

Bacteria that cause food poisoning often do not produce changes in foods that would warn consumers that the food is not fit for consumption. There is no way of telling by taste, sight, or smell that raw milk contains pathogens. MPI advises consumers that the only way to make raw milk safe to drink is to heat treat it to kill any potential pathogens.

7.3.5 International outbreaks

Internationally there are many well-documented outbreaks of foodborne illness caused by raw milk consumption. The US Centers for Disease Control and Prevention reported that from 1993 to 2006 unpasteurised dairy products (which are principally raw drinking milk, raw milk cheeses, and raw milk yoghurts) were 150 times more likely to cause disease outbreaks and result in 13 times more hospitalisations than illnesses involving pasteurised dairy products.[12] Nearly half of the outbreaks associated with unpasteurised dairy products were due to people drinking raw milk.

[11] Guillain-Barré syndrome is a disorder in which the body's immune system attacks part of the peripheral nervous system. It can result in paralysis.
[12] Langer, A.J., Ayers, T., Grass, J., et al. (2012) Nonpasteurised dairy products, disease outbreaks, and state laws – United States, 1993-2006. *Emerging Infectious Diseases* 18(3): 385-391.

Consumer loyalty to a particular trusted producer of raw milk is no guarantee of protection from illness. The Centers for Disease Control and Prevention warn that serious illness can still occur from raw milk even if one producer has been used for a long time without any previous health consequences.

Questions

13. Were you aware that research has shown that outbreaks of illness associated with drinking raw milk have increased in the past few years?

14. Do you agree with the representation of foodborne illnesses associated with drinking raw milk provided above? If not, please provide evidence to support your views.

15. Overall, do you agree with the way that the current situation has been described? If not, how would you describe it? What other factors should be considered?

8 Assessment of evidence

8.1 Risk assessment

8.1.1 Risks

In 2013 MPI undertook a scientific assessment of the risks associated with drinking raw milk. The work was done in collaboration with Massey University and the Institute of Environmental Science and Research, and the study was independently peer reviewed. A summary of the report is provided in Appendix 1 of this document and the full report can be found on the consultation website as Attachment 1.

The report included a record of outbreaks of illness associated with raw milk in New Zealand from 2007 to 2012. The data has been updated and summarised in section 7.3 above. The study clearly indicated that vulnerable people such as young children are more likely to develop illness from drinking raw milk and to suffer the most serious symptoms that can result in hospitalisation.

Every human pathogen that may be associated with cows, milk handlers, or the farm environment may be an accidental contaminant of milk. The study demonstrated that good husbandry practices, on-farm hygiene, and equipment cleaning can substantially reduce the risk of illnesses from drinking raw milk. However, there are no husbandry practices that would guarantee raw milk would be free from pathogens.

The risk of illness increases as the number of people drinking raw milk goes up. This risk cannot be eliminated even when the milk is appropriately refrigerated by the farmer and kept at the right temperature until it is drunk. Also, the risk of illness increases as the time between milking and consumption increases. It is safest to drink raw milk within four days of milking.

Scientists estimate that urban people are five times more likely to develop illness from *Campylobacter* compared with people with acquired immunity (such as those who live on farms).

8.1.2 Effects of pasteurisation on raw milk

MPI reviewed the scientific literature on the effects pasteurisation has on the beneficial properties of raw milk (refer to Attachment 2 on the consultation website). Studies provided by submitters to the 2011 consultation were included in the review if they were published in internationally recognised peer reviewed scientific journals.

Our review concluded that pasteurising milk does not substantially change its nutritional value for humans. Heating raw milk over 90°C (which is considerably higher than the 72°C required for pasteurisation) does, however, change the composition and reduce enzymes that have health benefits.

Pasteurisation does not change the fat structure of raw milk. The fat structure is often changed to prevent the cream layer from separating out of the milk. Homogenisation is the process that achieves this separation and is completely independent from pasteurisation. Some medical researchers consider that the smaller, agitated milk fat molecules that result from homogenisation may bind more easily to the walls of the arteries and potentially lead to heart disease. Experimental evidence failed to substantiate, and in many cases refuted, this theory. Non-homogenised pasteurised milk can be purchased in New Zealand supermarkets if

consumers prefer the fat structure not to be changed. Alternatively, consumers can pasteurise raw milk at home without altering the fat structure.

Lactose-intolerant people have lower levels of lactase, an enzyme needed to digest lactose. All dairy milk contains lactose. Prolonged heat at temperatures higher than pasteurisation can convert the lactose present in the raw milk to a more soluble easily-absorbed form. No significant changes have been found between the consumption of raw milk and pasteurised milk in lactose-intolerant people.

The MPI review also found little evidence of good bacteria or other components in raw milk effectively destroying pathogens to prevent illness or protect a consumer from major diseases.

Some studies indicate that drinking raw milk at an early age, along with other factors, may help reduce the risk of developing asthma, hay fever, and eczema. The science is not conclusive, particularly because it is not known how raw milk could have a protective effect. Research is currently being conducted in many countries including New Zealand to investigate this matter further. The association between consuming whole (not skim) milk and a decreased incidence of hay fever and asthma is in line with recent studies that indicate a protective effect of foods rich in fatty acids. Pasteurisation does not change milk fat content.

A summary of the effects of pasteurisation on the beneficial properties of raw milk is attached in Appendix 2 of this document.

Questions

16. Were you aware of the health risks described in this section?

17. Do you have any further evidence on the risks associated with drinking raw milk?

18. Do you have any further evidence on the effects pasteurisation has on the beneficial properties of raw milk?

8.2 International approaches

Other similar countries are grappling with the same raw milk issues as New Zealand; namely, some raw milk sales have been traditionally allowed despite evidence of risks and sales are increasing because drinking raw milk is now becoming popular with some urban people.

No consensus has been reached internationally on how best to protect people's health while also providing for consumer choice. Scotland, Canada, Australia[13] and a little under half the states in the United States of America[14] prohibit sales.

Others allow the sale of raw milk to consumers but place restrictions by:

- only permitting farm gate sales (for example in January 2014 13 USA states allowed sales from the farm direct to the consumer);
- only permitting raw milk sales that are direct from the farmer to the consumer (for example, in England, Wales, and Northern Ireland raw milk can be sold direct from the

[13] Despite the general prohibition, raw milk can be sold to consumers if there is an applicable law in a state or territory. No state or territory allows cows' milk to be sold because it is deemed too high a risk. Four Australian states, however, permit the sale of goats' milk.

[14] Despite this, the US Food and Drug Administration has a clear position against the sale of raw milk and prohibits trade across state boundaries.

farm premises, in a farmhouse catering operation, at a farmer's market, and from a vehicle used as a shop premise);

- permitting farm gate sales and only allowing sales in certain retail outlets (for example, in Germany, France, and in January 2014 13 USA states).

Analysis of US data from 1993 to 2006 by the Centers for Disease Control and Prevention shows that most outbreaks (75%) associated with unpasteurised dairy products (including raw milk) occurred in the US states that allowed sales to consumers.[15]

It is difficult to compare the different regulatory measures used by countries against outbreaks of illness because many variables contribute to outbreaks. These variables include:

- the number of people consuming raw milk per capita;
- the microbiological profile of milk within a country;
- the specific control measures used on the farm;
- the specific control measures that apply when selling raw milk off the farm;
- the degree to which control measures are monitored and complied with;
- the degree to which control measures are enforced;
- a country's history with raw milk and people's attitudes and behaviours;
- people's attitude towards reporting illnesses. Reporting is likely to be low when a substance is banned; and
- the surveillance system, including the degree to which investigations seek information about the consumption of raw milk.

See Appendix 3 of this document for a summary of international regulations.

[15] Langer, A.J., Ayers, T., Grass, J., et al. (2012) Non-pasteurised dairy products, disease outbreaks, and state laws – United States, 1993-2006. *Emerging Infectious Diseases* 18(3): 385-391.

9 Potential options considered but not proceeded with

All policy options relating to the sale of raw milk to consumers, from prohibition to non-regulatory approaches, were considered. MPI undertook a thorough analysis of all potential options before eliminating approaches that were considered unlikely to satisfy the policy objectives.

9.1 Prohibition – a ban on sales of raw milk to consumers

Under prohibition, only milk that is pasteurised would be able to be sold. The difficulty in effectively implementing a prohibition led us to consider it would not be a viable option.

The main advantage with an outright ban would be that illness related to drinking raw milk would significantly decrease. This would protect New Zealand's reputation for safe food, and reduce costs to the healthcare system and to work productivity (fewer sick days off work). We would also be more in line with Australia's policy.

Prohibition would be easy for compliance officers to interpret. However, it would be inconsistent with the approach used for other high-risk foods, where food safety risks are managed through regulations and consumers are given information to allow them to make an informed choice (for example, some shellfish).

There would be no consumer choice under a ban. Existing operations would not be maintained; there would be no recognition of New Zealand's tradition for some raw milk sales to consumers, nor of the desire of some people to make products from raw milk (for example, cheeses). Some countries that have a total ban have reported people circumventing the law by, for example, selling it under a different title such as 'raw milk for pets'. Compliance action and vigorous enforcement would therefore be needed to ensure raw milk was no longer sold direct to consumers. This would impose a cost on government.

MPI considers that an underground market would likely result, given New Zealand's tradition for raw milk sales. Without regulatory control measures it is likely that illnesses would still occur. People would be unlikely to report that they had consumed raw milk if they became ill for fear of prosecution, so illness associated with drinking raw milk would likely be undetected.

Dairy farmers who currently sell raw milk to dairy processors[16] would not be substantially affected by a ban on sales to consumers. However, dairy farmers who sell raw milk only to consumers would either have to sell it to a dairy processor, discontinue supply, or set up appropriate systems to process the milk (for example, pasteurise it or make dairy products). Dairy processors will often set minimum supply volumes for processing (which can be 10,000 kilograms of milk solids per year).

9.2 Status quo

MPI does not consider retaining the current situation is viable because a main objective is to reduce illness related to raw milk consumption and recent data suggest this is increasing. Many reasons why more outbreaks are being recorded are outlined in this document. They indicate that doing nothing will lead to outbreaks continuing to increase.

[16] Dairy processors alter the state of raw milk by pasteurising it and making dairy products. Fonterra is the largest dairy processor in New Zealand.

Two recent outbreaks of illness in the Timaru area during March and April 2014 were reported in the media. They highlight the risks associated with drinking raw milk, particularly because they involved children. They underscore the need for new policy on the sale of raw milk to consumers.

9.3 Non-regulatory control measures

A non-regulatory approach was considered as an alternative to specifying rules in regulations. For instance, a voluntary code of practice could be developed to assure customers that dairy farmers are operating to a set of prescribed control measures that minimise the risk of illness. The code could be developed by industry or by government, or a combination of both, and administered by industry. Government could apply additional measures such as consumer education, and could independently monitor and review how effectively the code was operating. In 2013 the Raw Milk Producers' Association stated that they planned to develop such a code.[17]

We rejected self-regulation as the sole safety control measure on the basis that the risk of raw milk-associated illness outbreaks would likely increase. We understand it is in the industry's interest to make sure their customers do not get sick. However, MPI considers it likely that not all dairy farmers selling raw milk to consumers would commit to, or rigorously follow, a voluntary code if developed by industry alone. The control measures may also be less stringent than those developed independently by government, and sanctions could be difficult to apply without the force of the law.

In particular, some farmers who sell raw milk may prefer an approach that allows widespread sales of raw milk to consumers. MPI does not consider this is appropriate for raw milk sold to consumers in New Zealand (see below). Also, under self-regulation there may be resistance to labelling measures that inform consumers of the risks, advise consumers to pasteurise the milk, or recommend certain groups of the population do not consume raw milk.

No other food that poses a similar risk to raw milk is controlled by self-regulation in New Zealand.

9.4 Sale at retail outlets

MPI rejected allowing third parties such as supermarkets and organic produce shops to sell raw milk even though stringent measures could be imposed. We consider the potential number of people who would then have access to raw milk presents too great a health risk, given our scientific assessment predicts that foodborne illnesses would increase. For instance, MPI's scientific assessment found that even when raw milk is handled correctly throughout the retail chain, 56 cases of *Escherichia coli* infection are predicted for every 100,000 glasses of raw milk drunk (see Attachment 1 on the consultation website). A risk assessment by Food Standards Australia New Zealand predicted similar numbers for raw cows' milk and concluded that sales to consumers should be (and are) prohibited in Australia.[18]

Limiting consumer exposure by permitting retail sales to occur only at organic produce or health food stores, for example, would be anti-competitive. It could be argued that

[17] http://www.stuff.co.nz/business/farming/dairy/9076972/Rising-demand-for-raw-milk-puts-pressure-on-suppliers 23 August 2013

[18] Food Standards Australia New Zealand (2009). *Microbiological Risk Assessment of Raw Cow Milk*. Food Standards Australia New Zealand, Australia. http://www.foodstandards.gov.au/code/proposals/documents/P1007%20PPPS%20for%20raw%20milk%201AR%20SD1%20Cow%20milk%20Risk%20Assessment.pdf Accessed 11 April 2014.

supermarkets are in a better position to maintain the cold temperature required for raw milk and to receive and sell it quickly.

Although a few countries provide for sales via retail outlets, their situations are likely to be different from New Zealand as outlined in section 8.2. For instance relatively few people drink raw milk in France. In a northern part of Italy a survey found that over half of the respondents who buy raw milk boil it before drinking it.[19] In Germany very few retailers are licensed to sell raw milk to consumers because the control measures are very onerous. Nevertheless several raw milk-related outbreaks involving large numbers of people have been reported in the past decade in Germany.

9.5 Sale at farmers' markets

MPI also considered allowing sales that were pre-ordered by the consumer and provided direct from the farmer to the consumer at a farmers' market. Farmers' markets can be very large retail operations. This means large numbers of people who are not aware of the different food safety risks of consuming raw milk could become opportunistic buyers. As stated above, increased exposure is predicted to increase the likelihood of illnesses occurring. It is likely that many people would be able to easily purchase raw milk at a farmers' market without understanding the product risks.

We note that raw milk is allowed to be sold in England, Wales, and Northern Ireland at farmers' markets. The rules there are stringent, including registration with government, regular inspections, and penalties for non-compliance. Data from producers indicates that only 7% of raw milk sales are from farmers' markets.[20] MPI cannot assume the level of sales via a farmers' market in New Zealand would be equally low, and there could be significant costs for compliance and enforcement.

An important objective is to reduce foodborne illness related to drinking raw milk. Widening the conditions of sale to this extent and therefore increasing the number of consumers drinking raw milk is not considered justifiable for New Zealand at the present time.

Questions

19. Do you agree with the approach MPI has taken in rejecting non-viable options for the sale of raw milk to consumers? If not, why not?

20. What evidence or rationale can you provide to support the notion that outbreaks of illness associated with drinking raw milk would reduce under the rejected options?

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

[20] United Kingdom Food Standards Agency (2014). Impact assessment on the review of the controls governing the sale and marketing of unpasteurised, or raw drinking milk and raw cream (RDM) in England, Wales and Northern Ireland. United Kingdom Food Standards Agency, London http://multimedia.food.gov.uk/multimedia/pdfs/consultation/rawmilk-pack-england.pdf. Accessed 11 April 2014.

10 Options under consideration

This section discusses the three options under consideration:

Option 1: sales only from the farm to consumers with restrictions on the quantity a dairy farmer could sell each day and the amount a consumer could purchase;

Option 2: sales only from the farm directly to consumers, and no quantity limits, provided strict requirements are followed;

Option 3: sales from the farm as under option 2, plus home deliveries by the farmer directly to the consumer only.

All options are expected to meet all of the objectives to some extent.

All options propose amending current legislation to clarify obligations and requirements, and improve compliance. The level of requirements under each proposed option increases in line with the increased access of consumers to raw drinking milk.

10.1 Option 1: sales only from the farm to consumers with restrictions on the quantity a dairy farmer could sell each day and the amount a consumer could purchase

Under option 1, dairy farmers would only be allowed to sell limited quantities (for example, 40 litres per day[21]) of raw milk from the farm direct to consumers. Consumers would be allowed to purchase up to six litres per day for their, and their household's, consumption.

MPI would exempt dairy farmers from the requirement to operate under a Risk Management Programme (RMP). Instead they would have to comply with universal requirements in a regulated control scheme (RCS) under the Animal Products Act. A RCS provides for situations where it is inappropriate or impractical to manage risk factors under a RMP.

Unlike a RMP, the Animal Products Act does not require the RCS to "ensure" that the product is fit for the intended purpose. It imposes risk management measures intended to protect the health of consumers by reducing risk factors as much as reasonably possible. A single RCS is imposed on all operators rather than allowing operators to develop individual RMPs that may lack consistency.

Production requirements for dairy farmers under this option would not be too onerous because the dairy farmer could only sell low volumes of raw milk to consumers each day. The baseline requirements would be to:

- meet animal health and husbandry, hygiene and food safety measures;
- register their business details with MPI;
- keep records of sales;
- meet general requirements in the APA, Food Act and Food Standards Code, including those that cover food safety; and
- provide more information around the risks in the form of labelling.

Sections 11.2.1 and 11.3 below provide details on the specific requirements being proposed.

[21] Forty litres per day is estimated to be equivalent to milking one to two cows non-intensively.

MPI would also provide dairy farmers with guidance on further ways to reduce food safety risks (see section 11.2.2).

In some instances the baseline requirements proposed for producing raw milk are more onerous (for example herds must be free of tuberculosis for at least five years, and milk must be sold within 24 hours) than the requirements for milk intended to be pasteurised. The reason is that unlike pasteurised milk, raw milk will potentially contain harmful pathogens.

10.1.1 Advantages

The main advantage would be a reduction in foodborne illness compared to the current situation as fewer people would be able to buy raw milk and therefore fewer people would potentially get sick.

Baseline production and sales requirements and obligations would be clear, with penalties for breaches.

Labelling requirements would help ensure full information on health risks is provided and reduce misleading information being circulated.

New Zealand's reputation as a supplier of safe food would also be protected.

10.1.2 Disadvantages

This option would not maintain consumers' existing access to raw milk as it would only allow dairy farmers selling less than 40 litres per day to operate. It may not provide access to enough raw milk for those consumers who wish to make cheeses at home.

An illegal market and more unreported foodborne illness could potentially result. Illegal sales from places other than the farm gate would be hard to identify, presenting a challenge to enforcement.

Compliance officers could have difficulty ensuring dairy farmers were only selling the limited amounts allowed, which might encourage non-compliance. In addition, this option is not consistent with the approach used for other high-risk foods, where there are no limits on the quantity that can be sold.

10.1.3 Economic costs

Dairy farmers would face some increased operating costs due to the control measures that would apply under the RCS (refer Appendix 5 of this document). In addition there would be a one-off fee of approximately $140 to register their business details with MPI and an annual renewal fee of $70.

Costs are not expected to change much for farmers who already sell raw milk both to processors and to consumers. However dairy farmers who sell raw milk to consumers only, and currently supply more than 40 litres per day, would have to change their operations in some way and therefore would incur some cost.

Consumers, particularly people from urban areas, could face costs if they do not pre-order their raw milk; otherwise they could travel to the farm only to discover that the dairy farmer had already sold her/his limit for the day.

10.2 Option 2: sales only from the farm to consumers and no quantity limits, provided strict requirements are followed

This option would allow dairy farmers to supply raw milk from the farm direct to the consumer in whatever quantities they wish. The milk would have to be collected by the purchaser from the farm. There would be no restriction on the amount of milk a consumer could buy, although the milk would not be allowed to be on-sold to another person or organisation.

This option builds on from option 1 in terms of the production requirements that would be set.

Under this option, dairy farms supplying 40 litres or more of raw milk per day would have to comply with additional animal health and husbandry, farm dairy design, hygiene and food safety requirements (see section 11.2.3.1 for details). These requirements are similar to those that are applied to milk produced for the manufacture of raw milk products. They would provide additional measures to those required for milk that is intended to be pasteurised by, for instance, requiring pathogen testing.

10.2.1 Advantages

This option would reduce the likelihood of foodborne illness compared to the current situation and therefore help protect New Zealand's reputation as a supplier of safe food while extending current consumer access to raw milk.

This option would place stringent requirements on raw milk production in the same way that stringent requirements are placed on other raw foods that potentially contain pathogens, to reduce the risk of illness.

Sales and production requirements would be clear and enforceable. MPI expects that assessment of dairy operations and checking compliance would be relatively straight forward as dairy farmers would have to follow a prescribed list of requirements. This approach would encourage compliance because dairy farmers who do not consistently meet the requirements would have to close that part of their business.

Consumers of raw milk would be able to purchase the quantity of milk they require, including amounts needed to make raw milk cheeses, and would be assured that safety measures to reduce the risk of foodborne illness have been followed and checked. They would also be informed about health risks through additional labelling provisions.

10.2.2 Disadvantages

Despite a predicted decrease in foodborne illness due to stringent controls being imposed, there would still be a level of health risk because dairy farmers could sell unlimited amounts without heat treating the milk to ensure its safety.

The proposed restrictions on the sale of raw milk are not consistent with how we regulate the sale of other raw foods that potentially contain pathogens.

10.2.3 Economic costs

There would be increased costs for dairy farmers due to the control measures that would apply under the RCS (see Appendix 5 of this document), particularly for those supplying 40 litres or more per day. These include costs associated with farm dairy assessments and testing

for pathogens. The likely result is a shift towards larger operators.[22] Dairy farmers may be able to pass on their increased costs to consumers.

Consumers who are currently part of a raw milk club and have their milk collected by others may face increased travel costs (but as noted earlier, this practice is against the intent of the existing law).

Government would incur the cost of amending legislation. There would also be costs associated with ensuring compliance and communicating the changes to dairy farmers, farm dairy assessors, and consumers. Compliance costs would include monitoring dairy farmers selling less than 40 litres per day (and therefore only meeting baseline production requirements) to check they are not exceeding the volume limit without meeting the additional production requirements.

New costs to the economy would be offset by reduced healthcare costs and increased work productivity due to a predicted decrease in outbreaks of illness and sick days off work.

10.3 Option 3: sales from farm as for option 2, plus home deliveries

Option 3 extends option 2 by allowing dairy farmers selling 40 litres or more of raw milk per day to deliver raw milk directly to a consumer's place of residence, provided the consumer has pre-ordered the milk and has been informed of the health risks prior to the delivery. Additional requirements for home deliveries would be imposed in the RCS to make sure that the milk is packaged, transported, and delivered to a high standard (see section 11.2.3.2 for details). Like options 1 and 2, the farmer would have to register their business details with MPI and keep records of sales.

10.3.1 Advantages

The current demand by some consumers to buy raw milk in places other than from the farm would be met.

Pre-ordering raw milk for home deliveries would provide an easy way for dairy farmers to keep records of customers' names, addresses, and the volume and frequency of milk ordered.

The additional requirements imposed on home deliveries would help manage risks to consumers and, as for the other options, dairy farmers who do not consistently meet the requirements would have to close that part of their business.

This option places stringent requirements on the production of raw milk for drinking, in the same way that stringent requirements are placed on the sale of other raw foods that potentially contain pathogens.

The labelling requirements would prevent misinformation from being circulated and help ensure full information on health risks was being provided to consumers.

There may potentially be a small positive environmental impact due to fewer consumers driving to farms.

[22] "Large" operations for raw milk would be much smaller than "large" operations that produce milk for further processing because the requirements to keep the milk as safe as possible would be intensive and time consuming.

10.3.2 Disadvantages

Despite the proposed hygiene and safety controls for home deliveries, the increased access would increase the number of people drinking raw milk. This is likely to increase the risk of illness and may impact on New Zealand's reputation as a supplier of safe food.

There is also a risk that:

- sales may occur in ways other than intended. For example, homes getting deliveries could become de facto collection points. This would present challenges for monitoring compliance.
- refrigeration during transport may not always be maintained; and
- refrigeration may not be maintained if a purchaser is not at home when their raw milk is delivered.

This option is not consistent with the way we regulate the sale of other raw foods that potentially contain pathogens.

10.3.3 Economic costs

As home deliveries would be a new option for dairy farmers, those who opted to deliver to homes would face initial set up costs, such as the purchase of a refrigerated truck and assessments to ensure the relevant transportation, distribution, and home delivery requirements were being followed.

There could be fewer costs to consumers who do not need to go to farms or other retail outlets, although dairy farmers are likely to pass any increased production costs on to consumers.

Government would face some additional costs to those outlined under option 2, such as the costs to inform dairy farmers about how to minimise foodborne risks during home deliveries and costs to educate consumers on the importance of maintaining the cold temperature once the milk has been delivered. There would be further costs associated with monitoring compliance to ensure that raw milk:

- is not sold if it was not pre-ordered before the farmer left the farm;
- is not delivered to or by a third party;
- is kept at the required temperature during transportation to homes.

Questions

21. Do you agree with the advantages, disadvantages and costs that MPI has described under each option? If not, why not? Can you support your position with evidence?

22. Do you support any of the proposed options? If yes, which options do you support?

23. If you do not support any of the proposed options, please explain why not. What alternative approach do you support? What evidence or rationale can you provide to support the notion that outbreaks of illness associated with raw milk would reduce under your approach?

24. Is there any other evidence MPI should examine to inform further analysis?

11 Detail on proposed requirements under the options

MPI would appreciate receiving your views on the detailed requirements proposed in this section, whether or not you support a specific option. This will allow a fuller analysis of each option.

11.1 Conditions of sale

If new conditions of sale are required as is proposed, dairy farmers ("farm dairy operators" under the Animal Products Act) would have to comply with the requirements set out below.

Dairy farmers would be allowed to sell and supply quantities of raw milk, provided:

- the farmer supplies the milk from the dairy farm (namely, the property on which the farmer's farm dairy where the milk was harvested is situated) or, under option 3, delivers to the purchaser's place of residence. Home deliveries do not include drop-off points for multiple purchasers;
- the purchaser collects the milk in person from the farm dairy (unless the milk is delivered to their home under option 3). The milk would not be allowed to be collected from other premises or places such as local stores or farmers' markets; and
- the milk is sold only to people who are purchasing it for their own or their household's consumption. Purchasers would not be allowed to sell their milk to another person or organisation.

Dairy farmers would also have to comply with other general requirements in the Food Act[23] and with the requirements in the Food Standards Code (refer section 7.1.3).

11.2 Producing and processing raw milk

At present dairy farmers are required to operate under a RMP for raw milk sold to consumers. We propose to exempt these dairy farmers from this requirement.

Instead, we propose imposing a RCS by way of regulations under section 166 of the Animal Products Act. The RCS would be supplemented by specifications and other detailed requirements set by the Director-General.

The RCS and supplementary specifications would include:

(a) requirements that apply to all dairy farmers supplying raw milk from the farm to consumers; and

(b) additional requirements that apply **only** to dairy farmers supplying 40 litres or more of raw milk to consumers, on any day (under options 2 and 3).

11.2.1 Measures applying to all dairy farmers supplying raw drinking milk to consumers

MPI proposes that all dairy farmers intending to sell raw milk to consumers must:

i. be listed with MPI under the proposed RCS. The list would be open for public inspection so consumers would know where to buy milk. The list would include the name and address of the dairy farmer, a description of the property where the milk is

[23] Section 9(4) (the prevention of the sale of food that is "unsound or unfit for human consumption or contaminated") and section 11AA (contravention of the Act when it is known that a sale will create a risk to human health) of the Food Act are relevant general requirements.

supplied from, and other matters such as date of listing. The farmer would apply to register their details with MPI and this would cost around $140. After that an annual renewal fee of around $70 would be required in order for MPI to maintain the list;

ii. ensure that raw milk sold directly to consumers meets all specified food safety criteria;

iii. follow NZCP1: *Code of practice for the design and operation of farm dairies* for all areas that apply to a particular dairy farm situation;

iv. apply tighter time and temperature controls than NZCP1 on milk cooling and milk storage:
   a. immediately after milking cool to 18°C or cooler; and
   b. cool to 6°C or cooler within 2 hours of completion of milking and within 4 hours of commencement of milking;

v. ensure that raw milk sold to consumers is only supplied:
   a. from healthy milking animals that are kept on the property;
   b. within 24 hours from harvesting; and
   c. after the milk has been cooled to 6°C or cooler; and
   d. from herds (other than sheep and goats) that have not had any tuberculous animals for at least the previous five years; that is, have a minimum herd status of C5. Animals must be tested for tuberculosis each season. Animals can only be introduced if they come from herds with a status of C5 or better;

vi. make a representative raw milk sample available to MPI on request, and at short notice, for monitoring purposes;

vii. have a system in place that enables a record to be kept of:
   a. who the farmer has supplied raw drinking milk to and their contact details;
   b. how much was supplied (ie. collected);
   c. when it was collected; and
   d. which milking(s) it came from.

   This information would be required for traceability purposes should anything occur that would require purchasers to be contacted. The records would be required to be kept for four years; and

viii. inform MPI if a failure is identified by the dairy farmer.

Questions

25. As a minimum, should dairy farmers who are producing raw drinking milk be expected to meet the same standards as dairy farmers producing milk for pasteurised dairy products? If not, why not?

26. Is five years a long enough period of time to require a herd to be tuberculosis-free?

27. Should raw drinking milk only be supplied from tuberculosis-free regions?

11.2.2 Guidance for dairy farmers under option 1 and dairy farmers supplying less than 40 litres per day to consumers (equivalent to milking one to two cows for raw milk sales to consumers) under options 2 and 3

In addition to the legal requirements applying to all dairy farmers supplying raw drinking milk, MPI intends to provide the following guidance to dairy farmers intending to supply raw milk under option 1 and to dairy farmers supplying less than 40 litres raw milk per day to consumers under options 2 and 3:

i. farm dairy operators and milk harvesters should complete training in good milk harvesting practice (eg Ag-ITO Licence to Milk) and good agricultural practice;

ii. farm dairy operators should follow MPI guidelines for milk harvesting practice, dairy hygiene, milking animal health, and milk cooling, storage and packaging;

iii. independent farm dairy assessments (inspections) should be undertaken to confirm that suitable hygiene standards are being maintained;

iv. annual veterinary visits should be arranged to confirm the health status of the animals, preferably in conjunction with the veterinary medicine consultation;

v. raw drinking milk should be monitored periodically for hygiene indicators such as aerobic plate count, total coliforms, and somatic cell counts;

vi. raw drinking milk should not to be offered for sale when any hygiene indicators exceed thresholds;

vii. dairy farmers should have a written procedure that identifies the controls in place to ensure that only limited quantities of raw drinking milk will be supplied; and

viii. records should be kept to show that standards are being maintained.

Dairy farmers could consider using the guidelines to develop and administer their own industry code of practice. This approach would provide their customers with some assurance that they are operating to a certain level of food safety.

Question

28. Is it sufficient to only provide guidance to small producers rather than setting requirements?

Questions to dairy farmers who sell or intend to sell less than 40 litres of raw milk per day to consumers

29. Would you be interested in developing a code of practice to help provide assurance to your customers? If so, how could development of such a code be initiated? If you are not interested, why not?

11.2.3 Additional measures under options 2 and 3 applying to dairy farmers supplying 40 litres or more of raw milk per day to consumers

11.2.3.1 For raw milk sold at the farm

The following additional measures are proposed for dairy farmers intending to supply raw drinking milk in quantities of 40 litres or more per day under options 2 and 3:

i. Farm dairy operator competence

   a. farm dairy operators must complete training in good milk harvesting practice (e.g. Ag ITO Licence to Milk) and should complete training in good agricultural practice; and

   b. farm dairy operators must be familiar with requirements for the harvesting and supply of raw drinking milk and must understand the requirements for dairy hygiene and mastitis management.

   The general principle is that dairy farmers should understand what needs to be done and are competent in getting it done.

ii. Animal health
   a. records must be kept of the animals in the herd or flock producing raw drinking milk intended for supply, and all animals to be uniquely identifiable in some manner;
   b. controls on the use of veterinary medicines must be followed and any use recorded; and
   c. colostrum and milk that is abnormal or unwholesome must not be offered for sale as drinking milk.

iii. Location, facilities, services and equipment
The same requirements that apply to the harvesting of milk for general supply and for raw milk products will be applied via the RCS. Examples are:
- farm dairy water quality;
- equipment standards; and
- protection from physical hazards such as glass, pathogens and chemical contamination.

iv. Operation
   a. milking practices to be hygienic, with teats cleaned, sanitised and wiped immediately before milking; and
   b. milking plant and dairy environment to be kept in a suitably hygienic state, including all milking equipment and any bottling or dispensing equipment.

v. Milk cooling
   a. milk is to be stored at 6°C or cooler; and
   b. the temperature of milk shall not exceed 6°C at any point until the product is physically receipted by the purchaser (in their hands).

vi. Acceptance standards
   a. more stringent limits to be specified for hygiene indicators; and
   b. specified limits for pathogens, chemical residues and contaminants consistent with the limits that apply to all other dairy products.

Questions

30. Do you agree that raw drinking milk should be of a higher quality standard, based on hygiene indicators, than raw milk intended for pasteurised dairy products?

31. Do you agree that raw drinking milk should meet the same food safety standards as all other dairy products? If not, why not?

vii. Monitoring and verification
   a. dairy farmers must arrange for the farm dairy to be assessed (inspected) twice a year and for veterinary visits twice a year. This is consistent with the required frequency for raw milk products. Dairy inspections confirm that standards are being maintained, and veterinary visits confirm that animals are healthy;
   b. assessments are to include any milk dispensing equipment used; and
   c. raw drinking milk is to be tested for hygiene indicators at least as often as raw milk for pasteurised dairy products, and tested for pathogens at specified frequencies (see Appendix 4 of this document).

Independent verification audits by a third party would not be required.

Questions

32. Should MPI monitor the safety of raw drinking milk periodically as proposed?

33. Do you agree with the frequency of testing for hygiene indicators and pathogens as outlined in Appendix 4 of this document?

34. Should there be recognition for good performance? If so, then how should it be demonstrated?

viii. Failure to meet standards

a. farm dairy operators must report any failure to meet specified food safety criteria to MPI as well as any failure to follow the RCS;

b. dairy farmers must test the milk for specified pathogens if hygiene indicator thresholds are exceeded;

c. the supply of raw drinking milk must be temporarily suspended following a failure to comply with the food safety criteria applicable to raw drinking milk. For example:

- following the first failure in 12 months - all raw drinking milk must be withheld from supply until three consecutive days have been shown to comply;
- following any further failure within 12 months - all raw drinking milk must be withheld from supply for 28 days;

d. MPI would delist any farm (remove approval) incurring excessive food safety failures; and

e. farm dairy operators must have a documented procedure to deal with any failures to maintain required temperature during distribution to the purchaser (ie disposal as a non-conforming product).

In addition to self-monitoring by dairy farmers, MPI may undertake surveys (sampling and testing) and audits from time to time to confirm that acceptable standards are being maintained.

Questions

35. Are the proposed suspension periods sufficient to encourage dairy farmers to ensure their milk consistently meets food safety standards?

36. Do you have any specific comments on the additional proposed measures, above?

11.2.3.2 For home deliveries of raw milk under option 3

The following additional measures are proposed for the home delivery component under option 3 (that is, dairy farmers delivering raw milk to a purchaser's home):

i. Milk is to be transported at 6°C or cooler;

ii. Distribution. The same requirements that apply to the transport of milk for further processing will be applied via the RCS. Examples are:

a. hygiene requirements
b. equipment design operation and cleaning requirements
c. bottling and packaging machines assessments by a recognised person

iii. Home deliveries may be permitted provided that - until the purchaser physically accepts the milk – it is:

- protected from physical, chemical and pathogen contamination; and
- maintained at a temperature not exceeding 6°C.

11.3 Labelling of raw milk

MPI proposes specific labelling requirements for raw milk sold, in addition to the general labelling requirements specified in the Food Standards Code. This approach would enable consumers to be better informed about the food safety risks from drinking raw milk and how to minimise them. Accordingly, we recommend that the following information should be provided to consumers:

i. "The product may contain bacteria that can cause illness" (or "the product has not been heat treated and may therefore contain organisms harmful to health");

ii. "It is recommended that the milk is heated to 70°C for one minute before consuming"; and

iii. "If the product is not heated:
   - the product is not suitable for young children, pregnant women, frail elderly and people with weakened immunity;
   - the product should be consumed by [date]", where the date is four days after the milk has been harvested.

MPI also proposes that such information must be provided to the consumer, either:

i. on a label; or

ii. displayed in connection with the raw milk; or

iii. displayed on or in connection with a vending machine that dispenses raw milk; or

iv. a combination of the above.

Standard 1.2.9 of the Food Standards Code requires labels to be in the English language, legible and prominent. They must be a distinct contrast to the background and any warning statement must be in a particular font size. With respect to raw milk clause 2 of Standard 1.2.1 would provide an exemption to Standard 1.2.9 as the food would be made and packaged on the premises from which it is sold. MPI therefore proposes that additional requirements are needed to apply these conditions to the sale of raw milk to consumers.

Standard 1.2.6 of the Food Standards Code requires labels to include directions for the use and storage of the food. Labels should therefore indicate to consumers that raw milk should be kept refrigerated.

Questions

37. Do you agree with each of the proposed mandatory requirements listed above? If not, why not

38. Should there be specific information on the main pathogens that could be present in raw milk?

39. Is any other labelling information required?

40. Should the exact words be prescribed?

41. Should there be specific legibility requirements (for example, prescribe font type and font size)?

42. Do you agree with the proposed ways that dairy farmers must provide the mandatory information to consumers?

43. Are there any other requirements in relation to labelling that MPI should consider?

12 Implementation

If the policy approved by Cabinet is different to the status quo, legislative change will be required.

MPI has a strategy to effectively implement legislative policy changes. The first step is to communicate our expectations and obligations. We then monitor and inspect, and respond to complaints. This determines whether stakeholders need assistance or need reminding of their obligations and the sanctions that occur when legislation is not followed. The third step is to use a range of tools such as warnings, food recalls, infringement notices, and suspension of operations to ensure compliance. Finally, enforced compliance via prosecution can be undertaken.

To help with implementation MPI intends to work with representatives of stakeholder groups with an interest in raw milk sales to consumers.

12.1 Conditions of sale

MPI will inform interested dairy farmers and consumers about any changes to sale conditions. MPI would contact dairy farmers through their listings (as required under the RCS) if new production requirements are to be made. Media releases would be issued to inform consumers. Ongoing information about raw milk would also be provided to consumers.

12.2 Production and processing requirements

All options propose exempting dairy farmers from the requirement to operate under a RMP and imposing a RCS under the Animal Products Act.

MPI proposes a three-month transition period after the new legislation is passed so that dairy farmers have time to adjust to the new rules. After that period all dairy farmers would have to comply with the new requirements.

MPI would hold workshops to explain the new requirements to dairy farmers selling, or interested in selling, raw milk to consumers. MPI may also provide farm dairy assessors with guidance.

MPI would inform people who consume raw milk that dairy farmers should be following the RCS. We would do this by writing letters to the consumers who make submissions to this consultation as well as through media communications.

12.3 Labelling requirements

If new labelling requirements are approved we will inform dairy farmers about these. Similarly any guidance provided to farm dairy assessors about regulatory change would include the new labelling requirements. Consumers would be informed via media releases.

Questions:

44. Do you have any comment to make on the proposed implementation of any changes to raw milk sales to consumers?

45. Do you consider any particular stakeholder group would represent your interests in the future implementation of raw milk policy?

13 Monitoring, evaluation and review

Following the development of new legislation MPI would continue to monitor outbreaks of foodborne illness associated with consuming raw milk, as recorded by the Institute of Environmental Science and Research. This data would provide an indication of how new requirements were operating.

To understand the data MPI would also need to know about market growth, dairy farmers' practices, and consumers' attitudes to, understanding of, and behaviour towards raw milk consumption. MPI would therefore keep records of complaints and investigations, follow media related articles, and liaise with representative bodies such as Federated Farmers, the Raw Milk Producers' Association, district health boards, and consumer-related groups.

MPI proposes that it reviews how effectively the legislative changes are working three years after all changes had been made. The review would likely include a microbiological study that examines samples of raw milk from randomly selected farms supplying raw milk to consumers. MPI would test the milk to determine the type and number of pathogens it contained, and then consider these results along with an analysis of the recorded outbreaks of foodborne illness associated with raw milk over the past 10 years, other monitoring data (as described above) and any relevant scientific research literature.

MPI would also consider conducting a study on consumers' attitudes, understanding and consumption behaviour to help better understand the drivers of consumption and the breadth of consumer motivation, depending on the need. If the results of all other data implied that foodborne illnesses had significantly reduced and the market was operating well, there would be no need for such a study.

Summary of the assessment of the microbiological risk associated with the consumption of raw milk

The assessment of the microbiological risks associated with raw (predominantly cows') milk (refer to Attachment 1 on the consultation website):

- provided an objective evaluation of the available information on the public health risk associated with consuming untreated raw milk in New Zealand;
- reviewed milk production and handling practices;
- modelled the likelihood of illnesses associated with key pathogens; and
- estimated the disease burden that may occur under present and alternative New Zealand production and sales circumstances.

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, farmers' markets); and
- 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 was assumed).

The quantitative risk assessment undertaken for *Campylobacter* spp., *Listeria monocytogenes*, *Salmonella* spp. and Shiga toxin-producing *Escherichia coli* O157 (STEC) demonstrated that wide access to raw cows' drinking milk will result in an appreciable number of cases of illness in New Zealand. The case numbers will vary depending 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; and
- 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 guarantee 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 the presence of milk-borne pathogens.

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.

Overall, the risk assessment reaffirmed raw drinking milk as a high risk food. The risk for illnesses caused by transmission of STEC and *Campylobacter* to humans through consumption of raw milk is considered to be high, and the risk of developing milk-borne diseases is especially high for children and other vulnerable groups of people. 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.

Summary of the assessment of the effects of pasteurisation on claimed nutrition and health benefits of raw milk

The following table is a summary of the claimed benefits of raw milk compared to pasteurised milk and the conclusions derived from a review of the scientific literature. Refer to Attachment 2 on the consultation website for the full literature review.

Claimed benefit of raw milk	Conclusions drawn from the scientific evidence available
Higher nutritional value	*Proteins and amino acids* • Heating modifies structure of some (mainly whey) proteins but has little effect on digestibility and nutritional properties of milk proteins. • Effects on amino acids negligible. *Vitamins* • Effect of pasteurisation on the vitamin content of milk is very low from a nutritive point of view. Only heat sensitive vitamins are affected by the pasteurisation process, with small decreases observed in the vitamin B2, B12, C and folate content of pasteurised milk, but concentrations of these vitamins are naturally low in milk. *Minerals* • Pasteurisation does not affect mineral stability, milk mineral content, or mineral bioavailability. *Fat* • Pasteurisation has no negative effect.
Can be consumed by people with lactose intolerance	A case-control study, evaluating lactose intolerance and raw milk, did not show any significant difference in the frequency or duration of symptoms
Antimicrobial systems and enzymes	Raw milk may contain the following antimicrobial factors • *Lactic acid bacteria and bacteriocins* eg, *Nisin* – Growth, hence, production of *nisin* too low to result in a positive effect under refrigerated conditions and only effective against gram positive pathogens. Pasteurisation can kill lactic bacteria, but does not destroy bacteriocins already present in the milk. • *Lactoferrin* – Concentration is too low in mature bovine milk to be effective and pasteurisation causes no loss of antimicrobial activity of lactoferrin. • *Lysozyme* – Concentration is usually low and lysozyme is heat stable and is not destroyed by pasteurisation. • *Lactoperoxidase* – Lactoperoxidase is heat stable and is not destroyed by pasteurisation. • *Xanthine oxidase* - is the most heat stable milk fat globule membrane enzyme. *Enzymes* Pasteurisation inactivates enzymes like protease and lipase but these enzymes have no physiological role in human digestion. Pasteurisation may lower the activity of some enzymes minimally, but their activity is limited anyway at refrigeration temperatures used to store raw milk

Claimed benefit of raw milk	Conclusions drawn from the scientific evidence available
Enhances the immune system	Concentration of bovine immunoglobulins is too low to be of physiological significance and pasteurisation has no or low impact on their level.
Prevents the development of asthma, allergies, and atopic diseases	Epidemiological evidence suggests some protective role of unprocessed cow's milk consumption on the development of asthma, hay fever and atopic sensitization. The consumption of whole (not skim) milk was associated with a decreased prevalence of hay fever and asthma. This is in line with recent studies that indicate a protective effect of foods rich in fatty acids. Physical structure of milk fat can be changed by homogenisation, but not by pasteurisation.

International regulations on the sale of raw milk to consumers

This section briefly summarises the regulatory status of raw milk in overseas jurisdictions.[24] The focus is on selected developed countries, and the summary is not comprehensive (it should not be assumed that countries not listed do not have controls).

Australia

Standard 4.2.4[25] of the Australia New Zealand Food Standards Code (which only applies in Australia) specifies processing requirements for milk and dairy products that dairy processing businesses must comply with. Clause 15 of Standard 4.2.4 requires milk that is to be sold as liquid milk or used in the manufacture of dairy products (excluding cheese) is to be pasteurised (or equivalently processed).

However, Standard 4.2.4, Clause 15 also states that this requirement holds "unless an applicable law of a state or territory otherwise expressly provides." A review of legislation for individual Australian states indicated that in some states (New South Wales, Queensland, South Australia and Western Australia) the sale of raw goats' milk is permitted. This permission is subject to producers having a documented food safety programme or plan. The product must be labelled as unpasteurised. No Australian state or territory permits the sale of raw cows' milk for drinking purposes. It is not illegal for someone to drink raw cows' milk from cows that they own.

Standard 1.6.1 of the Australia New Zealand Food Standards Code sets the microbiological limits for unpasteurised milk for retail sale (Table A3.1).[26]

Table A3.1: Australia New Zealand Food Standards Code, Standard 1.6.1 microbiological limits for unpasteurised milk for retail sale

Microorganism	n	c	m	M
Campylobacter/25 ml	5	0	0	
Coliforms/ml	5	1	10^2	10^3
Escherichia coli/ml	5	1	3	9
Listeria monocytogenes/25 ml	5	0	0	
Salmonella/25 ml	5	0	0	
Standard plate count at 30°C/ml	5	1	25,000	250,000

Notes:
n = the minimum number of sample units that must be examined from a lot of food.
c = the maximum allowable number of sample units exceeding m.
m = the acceptable microbiological level in a sample unit.
M = the level, when exceeded in one or more samples, that would cause the lot to be rejected.

In 2008-2012, a review and consultation process (Proposal P1007[27]) examined multiple issues concerned with raw milk and raw milk products, including whether controls over the sale of raw milk should be nationally consistent. Changes to Standard 4.2.4 were made in May 2012, but these only affected Clause 16 relating to cheese manufacture from raw milk (hard, curd

[24] MPI is grateful to the Institute of Environmental Science Research for collating this information.
[25] Australia New Zealand Food Standards Code – Standard 4.3.4 – Primary Production and Processing Standard for Dairy Products (Australia Only) http://www.comlaw.gov.au/Series/F2012L00294. Accessed 14 January 2014.
[26] Australia New Zealand Food Standards Code – Standard 1.6.1 – Microbiological Limits for Food. http://www.comlaw.gov.au/Details/F2012C00862. Accessed 14 January 2014
[27] Food Standards Australia New Zealand Proposal P1007 – Primary Production & Processing Requirements For Raw Milk Products. http://www.foodstandards.gov.au/code/proposals/Pages/proposalp1007primary3953.aspx. Accessed 14 January 2014.

cooked cheeses).. The requirements for milk sold as liquid milk were unchanged, as P1007 concluded that raw drinking milk presented too high a risk to consider any permission in the Code.

The approval report for P1007 stated that the exemption in Standard 4.2.4 that allows for state or territory laws to provide otherwise in relation to pasteurised milk would be further considered. In September 2012, Proposal P1022[28] was prepared, which will consider permissions for the production and sale of additional raw milk products. The call for submissions on Proposal P1022 says that Food Standards Australia New Zealand (FSANZ) has given the matter of the exemption in Standard 4.2.4 further consideration and concluded that the exemption will not be assessed by FSANZ at this stage. State and territory laws will continue to provide for the sale of unpasteurised milk. Submissions on Proposal P1022 closed on 10 January 2014.

European Union (EU)

According to Regulation (EC) 853/2004 (laying down specific hygiene rules for the hygiene of foodstuffs),[29] EU member states are able to establish or maintain national rules prohibiting or restricting the placing on the market, within its territory, raw milk intended for direct human consumption. Regulation (EC) 853/2004 also sets microbiological standards for raw milk that apply if EU member states have not set their own standards:

- raw cows' milk: plate count at 30°C ≤100,000 CFU/ml; somatic cell count ≤400,000/ml
- raw milk from other species: plate count at 30°C ≤1,500,000 CFU/ml.

Within the EU

United Kingdom

An overview of raw milk controls in the United Kingdom is provided in a paper prepared in 2012 for the United Kingdom Food Standards Agency (UKFSA) (Gleadle, 2012).

The Food Hygiene (Scotland) Regulations 2006 state that no person shall place on the market raw milk intended for direct human consumption.[30]

In England,[31] Wales,[32] and Northern Ireland[33] it appears that sales of raw cows' milk are permitted with restrictions specified by the UKFSA. Sales of other types of raw milk (sheep, goat, buffalo milk) are not subject to these restrictions but may be controlled by a local food authority. The restrictions on the sale of raw cows' milk essentially allow only sales from farm gates, farm catering, milk rounds and farmers' markets (the regulations do not address internet sales or vending machines). In England and Northern Ireland all raw milk products except buffalo milk must be labelled as not heat treated and therefore may contain organisms harmful to health. This labelling applies to all raw milk sold in Wales.

[28] Food standards Australia New Zealand Proposal P1022 – Primary Production and Processing requirements for Approved Raw Milk Products http://www.foodstandards.gov.au/code/proposals/Pages/proposalp1022primary5627.aspx Accessed 14 January 2014
[29] European Union (2004) Regulation (EC) No 853/2004 of the European Parliament and of the Council http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:139:0055:0205:EN:PDF Accessed 14 January 2014
[30] The Food Hygiene (Scotland) Regulations 2006 http://www.legislation.gov.uk/ssi/2006/3/contents/made Accessed 14 January 2014
[31] The Food Safety and Hygiene (England) Regulations http://www.legislation.gov.uk/uksi/2013/2996/pdfs/uksi_20132996_en.pdf Accessed 14 January 2014
[32] The Food Hygiene (Wales) Regulations 2013 http://www.legislation.gov.uk/wsi/2006/31/contents/made accessed 14 January 2014
[33] The Food Hygiene Regulations (Northern Ireland) 2006 http://www.legislation.gov.uk/nisr/2006/3/contents/made Accessed 14 January 2014

All raw milk sold must also meet microbiological standards (plate count at 30°C ≤20,000 CFU/ml; coliforms <100 CFU/ml), milk production holdings must be registered, and the supplying animals must be tuberculosis and/or brucellosis free.

In March 2012 the UKFSA Board agreed for the Director of Food Safety to launch a public consultation on the current regulatory controls over raw milk. The consultation is to cover milk from all animal species, the language in health warnings on raw milk, and to consider management of food safety risks in the light of controls in other parts of the food chain (eg, bovine tuberculosis) (UKFSA, 2012). The consultation launched in England, Northern Ireland and Wales in January 2014.[34]

Republic of Ireland

According to the website of the Food Safety Authority of Ireland (FSAI)[35] sales of raw milk in Ireland appear to be permitted provided the products are labelled as "raw milk", and the origin must be stated if it is not bovine. Premises selling raw milk must be registered and approved, and general European Community hygiene regulations and specific microbiological standards (plate count, somatic cell count) must be met. It appears that some of these regulations do not apply to producers who directly supply small quantities of primary products either to the final consumer or to local retail establishments directly supplying the final consumer. While allowing sales of raw milk, the FSAI advises against consumption of this product.[36]

Italy

In Italy, the sale of raw milk from vending machines is allowed, provided they are registered and only filled with milk from a single farm on a daily basis, and the milk is kept at between 0-4°C (Bucchini, 2012; Giacometti et al., 2012). If the vending machine fills bottles the bottle must carry the label "unpasteurised raw milk". All raw milk sold must be labelled "to be used only after boiling" (and for on-farm sales, the warning is to be given verbally). An expiry date of three days after delivery to the consumer is required. The EU microbiological standards for plate count and somatic cell count should be met alongside the following standards (Amagliani et al., 2012):

- *L. monocytogenes*, *Salmonella* spp., *E. coli* O157 and thermotolerant *Campylobacter* spp. all absent in five 25mL samples.
- *Staphylococcus aureus* (per mL) n = 5, m= 500, M= 2000, c = 2.

Germany

European Community law has applied in Germany since January 2006, including the three hygiene regulations that apply to raw milk and its production (EC 852/2004, EC 853/2004 and EC 854/2004).[37] There are two classifications of raw milk in Germany. Raw milk ("rohmilch") must only be sold from the farm by the producer directly to the consumer, and the farmer must display a sign on their tank stating the product is raw milk and that it must be boiled before consumption. "Vorzugsmilch" (certified milk) is unpasteurised milk that has been produced and handled according to higher standards than those required for normal milk production including a monthly testing regime. Vorzugsmilch must be packaged for sale through retail outlets and must be labelled as "raw milk – store at a maximum of 8°C,

[34] United Kingdom Food Standards Authority (10 September 2013) Proposed Consultation http://www.food.gov.uk/multimedia/webpage/propconsult Accessed 14 January 2014
[35] Food Safety Authority of Ireland (3 September 2010) General Hygiene Provisions http://www.fsai.ie/legislation/food_legislation/milk_and_milk_products.html and *a Compendium of Food Law in Ireland* (2008) http://www.fsai.ie/assets/0/86/204/d1e0f1d9-ef79-46d8-bbb5-62265b2a2034.pdf Accessed 14 January 2014
[36] Food Safety Authority of Ireland (2009) *Heath risks from unpasteurised milk.* General factsheet series. Available from http://www.fsai.ie. Accessed 14 January 2014
[37] Federal Institute for Risk Assessment (BfR) Food Hygiene http://www.bfr.bund.de/en/food_hygiene-54339.html Accessed 14 January 2014

consume up to [date]", where the date is 96 hours after milk collection (Tschischkale, 2011).[38,39]

France

The 1984 and 1985 rules governing the sale of raw milk in France (Maillot, 1998) were repealed through a decree of 13 July 2012, which sets out the conditions of production and placing on the market raw milk from cows, small ruminants and solipeds (eg, donkeys).[40,41] Raw milk can be supplied to consumers from the farm or via vending machines, distributers or cooperatives. Raw milk must be labelled with the words "raw milk, keep at +4°C maximum" and "boil before consumption for sensitive people (young children, pregnant women and people with weakened immune systems)", and carry a deadline for consumption that is three days after production.

Suppliers must be registered and their products must conform with the following microbiological criteria.

- All milk (throughout shelf-life): *L. monocytogenes* ≤100 CFU/ml in five samples, *Salmonella* spp. absent in five 25 ml samples.
- Cows' milk: *E. coli* n=5, c=2, m=10 CFU/ml, M=100 CFU/ml; aerobic plate count ≤50,000 CFU/ml.
- Milk from animals other than cows: *E. coli* n=5, c=2, m=10 CFU/ml, M=100 CFU/ml; aerobic plate count at 30°C ≤500,000 CFU/ml.

United States

At a federal level the UA Food and Drug Administration Code of Federal Regulations Title 21. Sec. 1240.61 (Mandatory pasteurization for all milk and milk products in final package form intended for direct human consumption) prohibits the interstate sale of unpasteurised milk (USFDA, 2012).

Within individual states, legislation governing raw milk sales is more varied. According to a 2013 publication by the National Conference of State Legislatures, it is at least technically possible to legally sell or distribute raw milk for human consumption in 30 states (National Conference of State Legislatures, 2013).

States that permit the sale of raw milk in retail stores are:
Arizona, California, Connecticut, Idaho, Maine, New Hampshire, New Mexico, Nevada, Pennsylvania, South Carolina, Utah, Washington

States that allow the sale of raw milk on the farm include:
Arkansas*, Illinois, Kansas, Kentucky*, Massachusetts, Minnesota, Mississippi*, Nebraska, New York, Oklahoma, Rhode Island*, Texas, Wisconsin

(*Arkansas, Kentucky, Mississippi and Rhode Island restrict sales to goat milk, with Kentucky and Rhode Island requiring a prescription from a physician).

There are some further restrictions in the amounts and types of milk, as well as microbiological standards that apply in different states. For example in four states (Minnesota,

[38] http://www.gesetze-im-internet.de/tier-lmhv/anlage_9_53.html Accessed 14 January 2014
[39] http://www.laves.niedersachsen.de/portal/live.php?navigation_id=20111&article_id=73874&_psmand=23 Accessed 14 January 2014
[40] http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000026208547&dateTexte=&categorieLien=id Accessed 14 January 2014
[41] http://agriculture.gouv.fr/IMG/pdf/DGALN20128271Z_cle8b3544.pdf Accessed 14 January 2014

Wisconsin, Oklahoma, Illinois) sales are restricted to only incidental occurrences (i.e., occasional; not as regular course of business; no advertising) (National Association of State Departments of Agriculture, 2011).

States allowing the sale of raw milk at farmers' markets or through other avenues:
Colorado, Missouri, Oregon, South Dakota, Vermont.

The remaining states prohibit the sale of raw milk:
Alabama, Alaska, Delaware, Florida, Georgia, Hawaii, Indiana, Iowa, Louisiana, Maryland, Michigan, Montana, New Jersey, North Carolina, North Dakota, Ohio, Tennessee, Virginia, West Virginia, Wyoming.

Some states have recently changed or are considering changing raw milk legislation. Until recently, South Dakota allowed farmers to sell raw milk at farmers' markets but not in retail stores, provided they met the same standards as pasteurised milk. From 11 December 2013 South Dakota's five licensed raw milk dairies will be able to sell their products on the farm or through home delivery as long as they are properly labelled.[42] However, the requirement for coliform levels to be less than 10 per millilitre is considered difficult to achieve. In Wisconsin, in early 2014 the State Senate will consider legislation that would permit on-farm sale of raw milk and raw milk products beyond the currently permitted "incidental sales".[43]

In some states where raw milk sales are prohibited, so-called "share" agreements (cowshare, herdshare and so on) can be set up.[44] These arrangements involve ownership of an animal by one or more non-farmers, and payment of the farmer for hosting the animal. The milk is then obtained without a specific payment. In some states, such as Wisconsin and Florida, such arrangements are illegal. Other states, such as Colorado, Idaho, Indiana, and Washington, explicitly allow such arrangements (National Conference of State Legislatures, 2013).

Canada

The Canadian Food and Drug Regulations do not permit the sale of raw milk (B.08.002.2, Consolidation Food and Drug Regulations C.R.C., c. 870) (Government of Canada, 2013).

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[42] *Food Safety News* (2013) South Dakota's New Raw Milk Rules Effective Date Dec.11 http://www.foodsafetynews.com/2013/12/south-dakotas-new-raw-milk-rules-take-effect-on-dec-11/ accessed 14 January 2014

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Proposed hygiene and pathogen standards for unlimited supply of raw milk

The following are proposed acceptance standards for dairy farmers intending to sell 40 litres or more per day of raw milk directly to consumers

Table A4.1: Proposed hygiene testing requirements

Parameter	Frequency of tests (days)
Aerobic plate count	10
Somatic cell counts	10
Inhibitory substances	10

Table A4.2: Proposed pathogen testing requirements

Parameter	Frequency of tests (days)
Escherichia coli	15
Listeria monocytogenes	15
Salmonella	15
Campylobacter	15

Farmers' compliance costs for the proposed options

The proposed regulated control scheme (RCS) and supplementary specifications (see section 10 of the consultation document) include:

1. requirements that apply to all dairy farmers supplying raw milk from the farm to consumers; and
2. additional requirements that apply only to dairy farmers supplying 40 litres or more of raw milk to consumers, on any day (under options 2 and 3).

Requirements for all farmers

Compliance costs likely to be faced by all farmers who sell raw drinking milk to consumers are listed in Table 1 below. In addition, farmers would also need to spend time to familiarise themselves with the requirements and determine what changes they need to make to their current systems and practices.

Table 1: requirements for all farmers who sell raw milk

Requirement	**Potential cost**
Registration as raw milk supplier with MPI	Initial fee $140 Annual renewal fee $70
Comply with the Animal Products (Dairy) Regulations 2005	Costs will depend on how compliant the farmer currently is with these regulations.
Follow the NZCP1: Code of practice for the design and operation of farm dairies	Costs will depend on how compliant individual farmers are with NZCP1 currently.
Apply tighter time and temperature controls on milk cooling and storage	Could mean some suppliers need to upgrade their refrigeration facilities. Costs will depend on current refrigeration facilities.
Record keeping for who milk was sold to, amount, collection time, which milking	MPI is unsure if any suppliers currently keep records at this level of detail. The costs would include system set up and ongoing data collection and management.
Label milk in accordance with the Food Act 1981 and any regulations under this Act.	Costs will depend on whether the farmer currently sells their raw drinking milk in labelled containers or allows customers to use their own containers. They will also depend on the information currently included on labels for raw drinking milk by particular farmers.
Animals must be tested for tuberculosis each season	Farmers may incur testing costs if their animals would not otherwise be due for routine testing, which varies from yearly to three-yearly.

Additional requirements for farmers selling more than 40 litres per day (under options 2 and 3)

MPI is proposing that farmers selling more than 40 litres per day will be required to follow the requirements in Table 2 below. Table 2 lists the associated compliance costs. The proposed changes are likely to increase costs for producers who do not already follow similar procedures. This may also lead to a price increase by some producers.

Farms that also supply milk to a dairy processor who does some testing of the milk (such as for APC and SCC) will not need to do additional testing to comply with this requirement. They will, however, need to maintain records that prove this testing has been undertaken.

Table 2: additional requirements for farmers who sell more than 40 litres per day

Requirement	**Potential cost**
Complete training in good milk harvesting practice and good agricultural practice and familiarity with requirements for harvesting and supply of raw drinking milk	AgITO Licence to Milk Fees: Stage 1 $250 Stage 2 $290 Mastitis Management $490 Additional costs include class, assignment, assessment, and travel time.
Animal health records, controls on use of veterinary medicines and no sale of colostrum or abnormal milk	System set up and maintenance of records to verify compliance and storage of these records.
Comply with requirements for general supply of milk via a regulated control scheme for raw milk for drinking	Initial registration $300 Initial inspection $1000 Also ongoing registration and inspection fees
Milking practices to be hygienic, teats must be cleaned, sanitised and wiped immediately prior to milking. Milking and processing equipment to be kept suitable hygienic	Costs include additional milking time per cow and additional cleaning materials. The proposal could also increase cleaning times for milking equipment.
Stringent hygiene indicators and specified limits for pathogens, chemical residue and contaminants	The testing regime and some estimated costs are below in Tables 3-6.
Veterinary inspections of all animals twice per year	Costs would depend on the number of animals being inspected and the how far the veterinarian needs to travel.
Farm dairy assessment twice each year by suitably qualified person	$350 per assessment
Failure to meet standards must be reported to MPI. Specific pathogens must be tested for more frequently if hygiene indicators thresholds are exceeded	Time to report the failure to meet standards to MPI and additional testing costs if suspension of supply is required until sufficient compliant tests have obtained and normal supply can resume.

Estimated costs of proposed hygiene and pathogen testing

Tables 3 and 4 below provide estimated testing costs for high volume farmers who do not currently supply a dairy processing company. The estimates assume that the farmer milks for around 260 [45] days per year. Total hygiene and pathogen testing costs for this option are estimated at $2,034 per year.

Table 3: hygiene testing cost estimates for farmers who sell more than 40 litres per day

Parameter	Frequency of tests (days)	Number of tests per year	Estimate cost per test (MilkTestNZ)	Total cost per test type per year
APC	10	27	$2	$54
SCC	10	27	$1	$27
Inhibitory substances	10	27	$2	$54
Total				**$135**

Table 4: pathogen testing costs estimate for farmers who sell more than 40 litres per day

Parameter	Frequency of tests (days)	Number of tests per year	Estimated cost per test (MilkTestNZ)	Total cost per test type per year
E.Coli	15	18	$17.50	$315
L. Monocytogenes	15	18	$25	$450
Salmonella	15	18	$25	$450
Campylobacter	15	18	$38	$684
Total				**$1,899**

Three different scenarios have been evaluated for courier costs for test samples, using the standard user rates for Fastway Couriers on their web site as at 20 May 2014[46]. All scenarios assume that Milk Test NZ in Hamilton is being used to do the testing. Charges will also vary between different courier companies.

The analysis assumes that the samples are sent to laboratories for testing in a small chilly bin, so each sample involves two courier trips – one to send the sample to the laboratory and one to return the chilly bin to the farmer. Costs for containers for the samples have not been estimated as some laboratories include sample containers in their testing costs and others do not. The analysis assumes a 30 ml sample of milk will be required for the hygiene testing and that a 500 ml sample of milk will be required for the pathogen testing. Costs have not been included for chilly bins to use to keep the samples cool while they are in transit.

Courier costs are estimated to vary between $439.40 if the farm is based close to the testing facility and $839.80 if the farm is at the other end of New Zealand to the testing facility.

[45] From Dairy New Zealand, Livestock Improvement Corporation 'New Zealand Dairy Statistics 2011-12' the average days in milk production for the years 2009/10 to 2012/13 give an overall average of 267. These reports are available from http://www.dairynz.co.nz/page/pageid/2145866855/New_Zealand_Dairy_Statistics

[46] Fastway Courier's standard pricing is available at http://www.fastway.co.nz/pricing/courier-rates

Table 5: courier cost estimates for hygiene and pathogen testing

Scenario	Costs	Total courier cost per sample	Annual cost (assuming testing every 15 days so 18 tests per season)
Farm in rural Waikato	$5.60 each way plus $3.85 rural delivery charge for return trip for up to 25 kg one day service	$15.05	$439.40
Farm in rural area near Wellington	$11.95 each way plus $3.85 rural delivery charge for return trip for up to 10 kg next day service	$27.75	$795.00
Farm in rural area near Balclutha	If package up to 5 kg: $12.75 each way plus $3.85 rural delivery charge for return trip 2 day service If package 6-10 kg: $20.55 each way plus $3.85 rural delivery charge for return trip 2 day service	$29.35 $45.85	$839.80

Table 6 below estimates the total cost of the proposed testing regime for this option depending on where the farm is located in relation to the testing facility. The estimated cost varies between $2,473 and $2,874 per year.

Table 6: estimated total testing and courier costs for hygiene and pathogen testing

Scenario	Estimated Cost Hygiene testing	Estimated Cost Pathogen testing	Estimated Courier cost	Estimated Total annual cost
Farm in rural Waikato	$135.00	$1,899.00	$439.40	$2,473.00
Farm in rural area near Wellington	$135.00	$1,899.00	$795.00	$2,829.00
Farm in rural area near Balclutha	$135.00	$1,899.00	$839.80	$2,874.00