



# Proposals for continuing to legally provide for farm gate sales of raw drinking milk

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# 1 Introduction

## 1.1 PURPOSE OF THIS DOCUMENT

This document discusses options for continuing to provide for the legal sale of raw (untreated) drinking milk from the farm gate. Options cover current requirements set by section 11A of the Food Act 1981 (the Food Act) and the Animal Products Act 1999 (Animal Products Act).

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

Dairy farmers undertaking farm gate sales are also required to operate under a risk management programme (RMP) under the Animal Products Act.

## 1.2 SCOPE OF PROPOSALS

This document focuses on proposals for continuing to provide for farm gate sales of raw milk from all milking animals that is intended to be sold for human consumption. The proposals have implications for all dairy farmers from large farms that supply milk to dairy manufacturers to people with a lifestyle property that milk only one or a few animals.

There is no proposal to prohibit the sale of all raw drinking milk. Farm gate sales of raw milk are a long standing tradition and current and previous Ministers for Food Safety have stated that they will be provided for into the future, in some form.

Options consulted on in this document do not include providing for the sale of raw milk for drinking on a more commercial scale. The Ministry of Agriculture and Forestry (MAF) acknowledges that there is interest in the wider availability of raw drinking milk but this is a different activity from farm gate sales of raw milk. Providing for commercial scale sale of raw drinking milk was considered and consulted upon in 2008 and 2009 when the New Zealand Food Safety Authority<sup>1</sup> (NZFSA) was developing the framework and standards for raw milk products. Issues around allowing or providing for the commercial scale sale of raw drinking milk are associated with a much greater level of risk and are more complex than farm gate sales. Providing for the sale of raw milk for drinking on a more commercial scale is not considered appropriate at this time.

Some people may be aware that MAF is reviewing the Dairy Industry Restructuring (Raw Milk) Regulations 2001 made under the Dairy Industry Restructuring Act 2001 and has recently finished consultation on possible improvements to the current working of the Regulations. These Regulations enable independent dairy processors to purchase a limited amount of raw milk directly from Fonterra and set the default sale price for that milk. These issues are not related to the review of farm gate sales of raw milk.

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<sup>1</sup> NZFSA was merged with the Ministry of Agriculture and Forestry on 1 July 2010.

### 1.3 REASONS FOR REVIEW OF FARM GATE SALES

There are several reasons for reviewing the current requirements including issues with the requirement for dairy farmers to have an RMP for farm gate sales of raw drinking milk, and the interpretation and enforcement of section 11A of the Food Act.

A further reason is that the Food Bill is currently intentionally silent on farm gate sales of raw milk. If the Food Bill is passed into law the Food Act will be repealed and consequently when the new Food Act comes into force, there will no longer be provisions for limited farm gate sales of raw milk or a prohibition on all other sales of raw milk for drinking in an Act. The current and previous Ministers for Food Safety have made commitments that farm gate sales of raw drinking milk will continue to be provided for in the law if the Food Act is repealed and that there will be no gap between any new requirements and revocation of the Act.

Given it is not currently considered appropriate to provide for commercial scale sale of raw milk, MAF proposes to maintain the legal prohibition in regulations or standards under the proposed new food regime that will be established by the Food Bill.

## 2 Consultation

Written submissions on the issues raised and options presented in the consultation paper are invited from all interested parties. MAF is particularly interested in feedback on the feasibility of the preferred option in section 6.

The closing date for submissions is 5 December 2011.

Submissions should be sent to:

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PO Box 2526  
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New Zealand

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Please include your name and address on your submission. If you are making comments on behalf of an organisation, also include your title and the name of the organisation.

Please make sure your comments can be clearly read as a number of copies may be made of your submission.

Submissions backed by evidence and argument will carry more weight than statements of opinion.

### 2.1 OFFICIAL INFORMATION ACT

The Official Information Act 1982 (OIA) states that information is to be made available unless there are grounds for withholding it. The grounds for withholding information are outlined in the OIA. Submitters may wish to indicate any grounds for withholding information contained in their submission. Reasons for withholding information could include that information is commercially sensitive or that the submitters wish personal information such as names or contact details to be withheld. MAF will take such indications into account when determining whether or not to release information. Any decision to withhold information requested under the OIA may be reviewed by the Ombudsman.

### 2.2 PROCESS AFTER SUBMISSIONS

Once the consultation period has closed, MAF 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 MAF's website.

Changes to legislation will be required to implement the determined outcome. Legislative changes will depend on the passage of the Food Bill, which is currently before Parliament. MAF will consult on details of proposed changes to legislation, including regulations under the Animal Products Act 1999 and regulations under the proposed new Food Act. Information on the timing of this consultation will be posted on MAF's website sent to interested parties.

## 3 Background to the proposal

### 3.1 WHAT IS RAW MILK?

Raw milk is milk harvested from a milking animal that has not undergone any heat treatment (e.g. pasteurisation) or other treatment that destroys or inhibits the growth of organisms that cause disease. It includes the milk from all milking animals, including cows, goats, sheep and buffalo.

Raw milk is sometimes referred to as ‘unpasteurised milk’ but unpasteurised milk may have been subject to other treatments, for example, milk that is subject to ultra-heat treatment (UHT), so this document uses the term ‘raw milk’ because it is a more accurate term.

All liquid milk sold in New Zealand is pasteurised or heat treated to a microbiological standard that is equivalent or greater than pasteurisation, with the exception of the limited quantities of raw milk that can be sold direct from farmer to consumer from the farm for personal consumption.

### 3.2 FOOD SAFETY RISKS ASSOCIATED WITH RAW DRINKING MILK

Raw milk is a high risk food product because of the potential for it to contain a number of organisms that cause disease. Unlike pasteurised milk there is no heat step to kill any harmful pathogens that might be present in the raw product.

Pathogenic bacteria have been identified as a major hazard in raw milk. Raw milk can become contaminated by bacteria from an infected animal’s udder or from faeces and other contaminants in the farm environment during milking or storage. While modern hygiene practices can reduce bacterial contamination of the milk, they cannot eliminate it. Farm milk is always susceptible to contamination and it is inevitable that bacterial pathogens, even at a low level, will always be present.

Pathogenic bacteria in raw milk can cause serious illness. If infected, some people can develop symptoms that are chronic, severe, or even life-threatening. Outbreaks of foodborne diseases such as salmonellosis, campylobacteriosis, *Escherichia coli* (*E. coli*) O157:H7 infection and tuberculosis have been linked to drinking raw milk. Many of these outbreaks have involved serious illnesses and deaths. Vulnerable consumers, such as the young, elderly, pregnant and immuno-compromised, are at greatest risk from infection.

While most outbreaks of disease associated with raw drinking milk have occurred overseas, several have occurred in New Zealand. For example, in August 2009 a campylobacteriosis outbreak was associated with consumption of raw milk by primary school children visiting a dairy farm near Whangarei<sup>2</sup>. The lower number of documented outbreaks in New Zealand might reflect our smaller population and that the sale of raw drinking milk is limited by the farm gate sale restriction. There is also likely to be under-reporting for short term less severe illnesses because people are less likely to visit their doctor when ill and if an individual case of food borne illness is reported, it can be difficult to trace the source.

#### Consumer choice

Bacteria that cause food poisoning do not generally produce changes in foods that would warn consumers that the food is not fit to eat. There is, therefore, no way of telling by taste, sight

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<sup>2</sup> For a summary of this outbreak see: [http://www.surv.esr.cri.nz/PDF\\_surveillance/NZPHSR/2010/NZPHSR2010March.pdf](http://www.surv.esr.cri.nz/PDF_surveillance/NZPHSR/2010/NZPHSR2010March.pdf)



or smell that raw milk contains pathogens. MAF advises consumers that the only way of eliminating the risk of food borne illness from raw milk is to avoid drinking it or heat treat it to kill pathogens.

While MAF does not recommend drinking raw milk, if consumers choose to drink it MAF recommends they minimise the risk of food borne illness by ensuring:

- Raw milk is kept under refrigeration (4°C or less)
- Raw milk that has spent more than two hours at room temperature is discarded, and
- Vulnerable consumers should avoid this food as they are at greatest risk from infection.

See Appendix 1 for more information on hazards associated with consumption of raw milk.

### 3.3 ORIGIN AND INTENT OF LAW ABOUT FARM GATE SALES

#### Limited sale of raw milk direct from farmer to consumer

The farm gate sale provisions are intended to maintain the traditional right of consumers to purchase raw milk for drinking, while restricting the quantity and way raw milk can be sold in order to protect the community from potential food borne illness on an unacceptable scale.

Farm gate sales and the five litre rule (originally the one-gallon rule) were introduced into legislation when pasteurisation of milk for town supply became compulsory in the 1950s. The original farm gate sale restriction was included in the Milk Regulations 1956 and limited consumers to purchasing up to one gallon at a time from a dairy farmer's premises. The restriction was introduced for two reasons:

- 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 more isolated areas and most homes did not have fridges or freezers to store milk for longer periods. Consumers were responsible for managing the food safety risks associated with consuming raw milk, and so purchased it on a 'buyer beware' basis. MAF understands that it was routine practice for raw milk to be boiled to maximise its shelf life, which would have killed harmful pathogens; and
- To prevent sales of raw drinking milk on a scale greater than provided for by the farm gate sale provisions. Such sales were considered unacceptable because making raw drinking milk widely available would expose the community to potential food borne illness on an unacceptable scale. This is for two reasons: greater numbers of people would be consuming the milk increasing the likelihood of a food borne illness outbreak; and the risk of food borne illness is further increased as transporting and storing large quantities of milk increases the risk of the milk containing higher levels of pathogens.

It is for these reasons that a prohibition was included in legislation and still exists in the Food Act.

#### Other risk management requirements

In the 1990s new legislation – the Dairy Industry (Regulations) 1990 – was introduced requiring dairy farmers to operate under a MAF approved Product Safety Programme (PSP) for the harvesting of milk. While this requirement also applied to farm gate sales of raw milk, it was recognised at the time that development of an appropriate PSP covering raw drinking milk would be very difficult because there is no practical or cost effective way of managing contamination of raw milk with pathogenic bacteria so that it is safe to consume. No PSPs were received for the purpose of supplying raw milk for farm gate sales and MAF did not enforce this requirement.

The incorporation of dairy legislation into the Animal Products Act in 2005 replaced the requirement for a PSP with the requirement for dairy farmers to operate under a registered RMP for harvesting milk. This included farmers undertaking farm gate sales of raw milk. Again MAF recognised that developing an acceptable RMP for harvesting and storage of raw milk for farm gate sales was very difficult, and there are no registered RMPs for farm gate sales of raw milk. MAF has not enforced this requirement.

### 3.4 CURRENT LEGAL REQUIREMENTS IN NEW ZEALAND

#### Food Act 1981

Section 11A of the Food Act allows for dairy farmers to sell up to five litres of raw milk from their dairy farms to people wanting to consume it themselves or give it to their family. These sales are commonly referred to as 'farm gate sales' and the restriction on the quantity that can be sold as the 'five litre rule'. The intention of section 11A has always been to provide only for limited sales of raw milk direct from farmer to consumer, with the consumer responsible for managing the food safety risks associated with consuming raw milk, i.e. on a 'buyer beware' basis. Section 11A is included in Appendix 2.

#### Animal Products Act 1999

Raw drinking milk is an animal product and its production is covered under the Animal Products Act, which manages risks to human health arising from the production and processing of animal material. The Animal Products Act and legislation made under this Act requires that all animal products, including ingredients, are fit for their intended purpose.

Under the Animal Products Act all farm dairy operators or dairy farmers must have a registered RMP for the activity of harvesting milk and it must cover all intended uses for the milk harvested. The requirement for dairy farmers who are selling milk to operate under some form of a risk management programme has been in place for nearly 10 years (firstly as a PSP, and more recently as an RMP). RMPs describe strategies for mitigating food safety risks associated with harvesting, storing and supplying milk to dairy processors. The RMP requirements for harvesting milk apply to all dairy farmers, regardless of whether they own one cow or have a large commercial herd.

Most dairy farms in New Zealand operate under multi-business<sup>3</sup> farm dairy RMPs that are owned and operated by larger dairy processors. Such companies require the dairy farms that are contracted to supply them with milk to operate under the processing company's multi-business farm dairy RMP. These RMPs are specific to the dairy manufacturer's operations and so the procedures will only cover the milk the dairy manufacturer intends to use and will take into account transport and processing procedures. The dairy manufacturer is responsible for the entire programme working effectively and will provide instructions to the farmer – the farmer may not even be aware they are operating under a farm dairy RMP.

Dairy farmers undertaking farm gate sales of raw milk are legally required to operate under an RMP that specifically covers this activity – an RMP that covers supply of milk for another activity e.g. supplying milk to a large processing company for pasteurisation or making cheese, does not cover or adequately manage the risks associated with farm gate sales.

#### Food Standards Code

New Zealand and Australia have a joint food standards setting system under an Agreement between the Government of Australia and the Government of New Zealand. This has resulted

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<sup>3</sup> Multi-business RMPs are provided for by section 17A of the APA.

in the Australia New Zealand Food Standards Code (the Code). The Code, which is developed and published by Food Standards Australia New Zealand (FSANZ), is a set of food standards for both New Zealand and Australia. MAF works alongside FSANZ to ensure that the standards they develop for both countries reflect New Zealand's requirements. MAF is responsible for implementing and enforcing the Code in New Zealand. MAF is responsible for developing and implementing New Zealand's food legislation for food safety, primary production, and maximum residue levels for agriculture and veterinary chemicals.

The Code primarily sets food standards for labelling and composition but also includes some limits for chemical and microbiological hazards. Standards in the Code that apply to raw drinking milk sold in New Zealand include:

- Microbiological limits: Standard 1.6.1 sets microbiological criteria for a range of foods including raw milk for retail sale. Limits are set for a range of microbiological pathogens, including *Campylobacter*, *E. coli*, *Listeria monocytogenes* (*L. monocytogenes*) and *Salmonella*.
- Labelling requirements: Raw milk sold at the farm gate is exempt from the requirement to "bear a label" because the "food is made and packaged on the premises from which it is sold", or the "food is packaged in the presence of the purchaser" (Standard 1.2.1 sub clause 2.1). However, the following labelling information must be provided to the consumer in another manner, for example accompanying the food, displayed on or in connection with the food or provided to the consumer on request (Standard 1.2.1 sub clause 2.2):
  - The name of the food (Standard 1.2.2 clause 1)
  - Directions for storage and use that explain to the consumer how to store and use the food where warranted for health or safety reasons (Standard 1.2.6)
  - A mandatory advisory statement to the effect that the product has not been pasteurised (Standard 1.2.3 clause 2). Mandatory advisory statements are used when consumption of a food exposes the general population or a population subgroup to a health and safety risk, or where guidance about a food is needed to maintain public health and safety.

The Code is available on FSANZ's website at:

<http://www.foodstandards.gov.au/foodstandards/foodstandardscode.cfm>

### 3.5 REGULATION OF RAW MILK PRODUCTS

In the last few years there have been changes to the requirements for selling and exporting products made from raw milk. In July 2008 government consulted upon a framework to enable the production, export and wider importation of unpasteurised or raw milk products. In October 2009 standards were introduced to implement the framework.

Farm gate sales of raw milk were excluded from the scope of the framework and standards for raw milk products because they are a long standing tradition and current and previous Ministers for Food Safety have stated that they will be provided for into the future, in some form. However, raw drinking milk on a more commercial scale was included in the framework for unpasteurised or raw milk products and was categorised as 'Category 3: Unpasteurised milk products not able to be produced in New Zealand'. Category 3 covers raw or unpasteurised milk products with an unacceptable or unknown level of risk.

Section 5.2 discusses some of the reasons why removing all restrictions on the sale of raw drinking milk on any scale is not considered acceptable at this time. Appendix 4 summarises submissions made during consultation on the framework and standards. Information on the framework and standards for unpasteurised or raw milk products can be found on MAF's website at: <http://www.foodsafety.govt.nz/industry/sectors/dairy/unpasteurised-milk-products/>

### 3.6 APPROACH TO MANAGEMENT OF OTHER HIGHER RISK FOODS

There are several situations where the production and processing of higher-risk foods for sale are minimally regulated both under the Animal Products Act and the Food Bill. The principles used to determine whether and how to regulate these activities are consistent with the original intent of farm gate sales of raw milk. For example, egg producers are exempt from operating under an RMP where they produce eggs from 100 or fewer female birds and sell direct to the consumer. In determining this exemption the following factors were considered:

- The number of people that could be affected by a potential food borne illness is limited by the quantity of birds, and therefore eggs sold, and the requirement to sell direct from the farmer to the consumer.
- Consumption is on a ‘buyer beware’ basis because activities are not subject to the Animal Products Act’s risk management systems, so no assurances can be given by the regulator as to the safety of the product regardless of whether or not it is sold

### 3.7 THE APPROACHES OF OTHER COUNTRIES TO RAW DRINKING MILK

The regulation of the sale of raw drinking milk varies across the world. Some countries have complete bans (for example Canada) while others have partial bans that do not restrict the purchase of raw milk bought directly from the farmer (examples include some states within Australia and the United States (US)). Many European countries have a tradition of producing a wide range of unpasteurised and raw milk products (particularly cheeses) and are more liberal in their management of raw drinking milk.

Some countries with partial bans are facing the same issues as New Zealand with raw drinking milk being provided as a long standing tradition despite scientific evidence of the risks. MAF considered other countries approaches when developing options for continuing to legally provide for farm gate sales of raw drinking milk. The approaches taken by Australia, the US and the United Kingdom are summarised in Appendix 3.

## 4 Current issues with provisions for farm gate sales

There are a number of issues relating to farm gate sales of raw milk that need assessing. These include the requirement for dairy farmers to have an RMP and the interpretation and enforcement of section 11A of the Food Act. These issues are discussed in the sections below.

### 4.1 REQUIREMENT FOR RISK MANAGEMENT PROGRAMME (RMP)

While the Animal Products Act requires that any person harvesting raw milk for farm gate sales operates under a registered RMP no such RMP has ever been submitted to NZFSA or MAF and so there are no registered RMPs for farm gate sales. This is a reflection of the considerable food safety risks associated with raw drinking milk and the difficulty in assessing and addressing these.

MAF is not aware of any practical or cost effective way of managing the food safety risks associated with raw drinking milk and so it is unlikely that a suitably validated RMP would be developed for evaluation and approval. Even if a suitable programme were able to be developed, validated and approved, requirements that would be necessary to manage the risks are likely to be so stringent that they would be very expensive to implement. MAF has not actively enforced the RMP requirement for this reason.

### 4.2 INTERPRETATION AND ENFORCEMENT OF SECTION 11A OF THE FOOD ACT 1981

Some of the wording of section 11A of the Food Act is ambiguous, which has led over time to it being interpreted in ways that conflict with its original intention. For example, the limit of five litres is unclear because the current wording ‘at any one time’ could be interpreted as the same person being able to purchase several amounts of raw milk over the course of a day as long as each purchase did not exceed five litres each time. This was not the intention when section 11A was drafted.

Section 11A also does not limit the total amount of milk a dairy farmer can sell in a specified time period, which could provide an opportunity for farm gate sales to occur on a large, more commercial scale. Again, this was not the intention when section 11A was drafted.

Advances in technology mean that consumers no longer have to go to the farm to pay for raw milk and can purchase it via the internet and phone. Payment by internet or phone could legally be interpreted as meeting the requirements of section 11A. However, while the wording of section 11A requires the act of ‘sale’ to occur at the premises, the intention was to require consumers to physically go to the farm dairy (the place where animals are milked and where milk is stored or treated) to collect their milk.

MAF has become increasingly aware of non-compliant activities that do not meet the requirements of section 11A of the Food Act or the intent of this section. These activities include ‘raw milk clubs’ where consumers order and buy milk from a dairy farmer over the internet or phone, and the farmer then has the milk delivered to a pick up point from which consumers collect their purchase. This activity does not meet the original intention of farm gate sales, which required consumers to physically go to the dairy premises to pay for and collect the milk. Visiting the dairy farm provides the consumer with an opportunity to assess the hygiene of the farm dairy they are purchasing raw milk from. The activity of delivering the raw milk to a point off the farm also exposes the consumer to greater likelihood of food

borne illness as there are additional risks associated with transporting raw milk and storing it off the farm.

### 4.3 CHANGE IN CONSUMERS AND DEMAND FOR RAW MILK

Since section 11A was introduced, there have been some changes in the profile of consumers of raw milk. Many of these consumers are no longer those for whom farm gate sales were originally intended.

Fewer people live in isolated rural areas and those that do are able to transport or store pasteurised milk in the fridge and/or freezer. MAF does not know the extent to which dairy farmers still drink their own raw milk and supply it to their sharemilkers and other workers, but farms are now large scale businesses and it is assumed this and other factors (awareness of food safety, concerns about fat consumption and low fat milk options) may have changed their consumption practices too.

While there has been a decrease in consumption of raw drinking milk among traditional consumers of this product, there is increasing demand from people who want to consume raw drinking milk because of an interest in natural and unprocessed foods, perceived health benefits, and/or its taste. MAF is aware that there is an increased demand from consumers who live in urban areas and that these consumers may not be as aware of farming practices and the risks associated with consuming raw milk.

Some consumers want to make raw milk cheese for themselves and/or their families. However, five litres is not enough to make a reasonable sized cheese; about 10 litres is needed to make approximately one kilogram of cheese. The original intention of farm gate sales was to provide raw milk for drinking, not for processing into cheese, and the limit of one gallon and later five litres, was considered to be adequate for even larger households.

## 5 Options for farm gate sales of raw milk

### 5.1 OPTIONS CONSIDERED BY MAF

In considering what form farm gate sales should take in the future, MAF considered three options.

#### Option 1: Maintain the current legal position

Maintaining the current legal position would be to:

- Continue the conditions of sale for farm gate sales currently contained in section 11A of the Food Act; and
- Require dairy farmers to operate under a registered RMP that specifically manages the risks for farm gate sales of raw milk.

#### Option 2: Make limited amendments to conditions of sale and retain the requirement for an RMP

The farm gate sale requirements would be amended to address the current issues with section 11A of the Food Act and to better reflect the intent of limited sale of raw milk from farmer to consumer. Proposed amendments are described under the heading ‘Limited conditions of sale’ in section 6.1 Amended Farm Gate Sale Requirements. The requirement for dairy farmers undertaking raw milk farm gate sales to operate under a registered RMP that covers the risks associated with this activity would be retained.

#### Option 3: Make limited amendments to conditions of sale, exempt farmers from the requirement to operate under an RMP, and require that dairy farmers meet certain animal health and hygiene requirements (MAF’s preferred option)

The farm gate sale requirements would be amended to address the current issues with section 11A of the Food Act and to better reflect the intent of limited sale of raw milk from farmer to consumer, with the consumer being responsible for managing the food safety risks. Dairy farmers undertaking farm gate sales would be exempt from the requirement to operate under a registered RMP for that activity but would be required to meet some animal health and hygiene requirements and keep records of who they sell raw milk to. Option 3 is MAF’s preferred option and is further described in section 6.

### 5.2 OPTIONS OUTSIDE THE SCOPE OF THIS REVIEW

#### Preventing all sales of raw drinking milk

Preventing all sales of raw drinking milk, including farm gate sales, is not considered in the scope of this review. There are implications in continuing to provide for farm gate sales of raw milk including a likelihood that there will continue to be some cases of food borne illness given raw milk is a high risk product. However, prohibiting all sales of raw drinking milk is not a viable option given the long standing right of farmers and those in rural areas to farm gate sales and the commitment made by the current and previous Ministers for Food Safety that such sales would continue to be provided for.

#### Removing all restrictions on sale of raw milk

The option of removing restrictions on sale of raw drinking milk on any scale was not analysed as part of this review. Revocation of section 11A the Food Act will have the effect of lifting this prohibition and allowing sales on any scale. It is for this reason that taking no action is not considered with other options.

MAF acknowledges that there is interest in the wider availability of raw drinking milk but this is a different activity from farm gate sales. Issues around allowing or providing for the commercial scale sale of raw drinking milk are complex and associated with a much greater level of risk. MAF does not consider it currently possible to safely produce and process raw drinking milk on a commercial scale and would have great difficulty processing any applications for registration of an RMP covering raw drinking milk.

There have been numerous letters to Ministers for Food Safety over the years asking for the sale of raw drinking milk to continue with some consumers and farmers wanting it to be made more widely available. The response from Ministers has been that the legal provision for farm gate sales would not change as this is a long-standing right for farmers and the limiting provisions of farm gate sales ensured the risks to public health were minimised.

**Other reviews that considered sale of raw drinking milk**

During 2008 and 2009 NZFSA developed a framework and standards for raw milk products. The work specifically excluded farm gate sales but did cover wider scale sale of raw drinking milk. Consultation on the framework and standards resulted in submissions that both supported raw drinking milk being made widely available and opposed all sales. The decision was that commercial scale sale of raw drinking milk was an unacceptably high risk activity given current science and technology and could not occur in New Zealand. Appendix 4 includes a summary of the different views of people and organisations that made submissions on raw drinking milk.

**5.3 ANALYSIS OF OPTIONS**

The advantages and disadvantages of each of the options are summarised in the table below. The options were evaluated against the following criteria:

1. Continues to provide for farm gate sales of raw milk as originally intended
2. Ensures there is no increase in the risk of food borne illness from drinking raw milk
3. Ensures there is no increase in costs to dairy farmers
4. Requirements are clear and impose the minimum regulation necessary
5. Must be enforceable.

<b>Option 1:</b> Maintain the current legal position (retain provisions in section 11A of the Food Act and require farmers to operate under a registered RMP for this activity)	
<b>Advantages</b>	<b>Disadvantages</b>
<ul style="list-style-type: none"> <li>• Legislation would continue to provide for farm gate sales.</li> <li>• Continuing to limit the availability of raw drinking milk would ensure there was no increase in the risk of food borne illness</li> <li>• Requiring dairy farmers to have an RMP that covers farm gate sales would:             <ul style="list-style-type: none"> <li>○ Ensure risks associated with raw drinking milk are closely managed, reducing the likelihood of a food</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• The current ambiguity around requirements will remain, making enforcement of conditions of sale difficult; however, the enforcement of the RMP requirement would shut down all current farm gate sales of raw drinking milk.</li> <li>• Farm gate sales of raw milk may be shut down for the foreseeable future because the requirement to operate under a registered RMP is not viable for the following reasons:             <ul style="list-style-type: none"> <li>○ MAF is not aware of any practical or</li> </ul> </li> </ul>



<p>borne illness</p> <ul style="list-style-type: none"> <li>○ Ensure MAF was aware of who was selling raw drinking milk, which would assist with enforcement and traceability in the event of a food borne illness outbreak.</li> </ul>	<p>cost effective way of managing the food safety risks associated with raw drinking milk and so it is unlikely that a suitably validated RMP would be developed for evaluation and approval.</p> <ul style="list-style-type: none"> <li>○ Even if a suitable programme were able to be developed, validated and approved, requirements that would be necessary to manage the risks are likely to be so stringent that they would be impractical and impose significant costs. The cost of implementation would not be viable, particularly given the limit on sales of raw drinking milk.</li> </ul>
<p><b>Option 2:</b> Make limited amendments to conditions of sale and retain the requirement for an RMP.</p>	
<p><b>Advantages</b></p>	<p><b>Disadvantages</b></p>
<ul style="list-style-type: none"> <li>• Continues to provide for farm gate sales of raw milk as originally intended.</li> <li>• Continuing to limit the availability of raw drinking milk would ensure there was no increase in the risk of food borne illness.</li> <li>• Clarifying the inconsistencies with section 11A of the Food Act and the intent of the requirement would make the requirements more enforceable and ensure more risky activities such as delivery of raw milk to pick up points off the dairy farm, no longer continued.</li> <li>• Requiring dairy farmers to have an RMP that covers farm gate sales would: <ul style="list-style-type: none"> <li>○ Ensure risks associated with raw drinking milk are closely managed, reducing the likelihood of a food borne illness</li> <li>○ Ensure MAF was aware of who was selling raw drinking milk, which would assist with enforcement and traceability in the event of a food borne illness outbreak.</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• Current non-compliant activities such as ‘raw milk clubs’ do not meet the original intent and will not be legal under this option, which limits consumer choice.</li> <li>• Enforcement of the RMP requirement would shut down all current farm gate sales of raw drinking milk.</li> <li>• Farm gate sales of raw milk may be shut down for the foreseeable future because the requirement to operate under a registered RMP for this activity is not viable for the reasons outlined under the analysis of option 1.</li> </ul>

**Option 3 (MAF's preferred option):** Make limited amendments to conditions of sale, exempt farmers from the requirement to operate under an RMP, and require that dairy farmers meet certain animal health and hygiene requirements.

Advantages	Disadvantages
<ul style="list-style-type: none"> <li>• Continues to provide for farm gate sales of raw milk as originally intended.</li> <li>• Continuing to limit the availability of raw drinking milk and better enforcing the new requirements would ensure there was no increase in the risk of food borne illness.</li> <li>• Clarifying the inconsistencies with section 11A and the intent of the requirement would make the requirements more enforceable and ensure more risky activities such as delivery of raw milk to pick up points off the dairy farm, no longer continued.</li> <li>• Removal of RMP requirement:             <ul style="list-style-type: none"> <li>○ Is a simple, clear rule that would resolve current compliance issues.</li> <li>○ Acknowledges that MAF does not consider it possible to manage all the risks associated with raw drinking milk and consumers purchase it on a 'buyer beware' basis.</li> </ul> </li> <li>• Requiring dairy farmers undertaking farm gate sales to meet some animal health and farm hygiene requirements will set clear food safety expectations and provide another level of protection for consumers.</li> </ul>	<ul style="list-style-type: none"> <li>• Current non-compliant activities such as 'raw milk clubs' do not meet the original intent and will not be legal under this option, which limits consumer choice.</li> <li>• MAF will have little regulatory oversight of what is a high risk product, particularly where a dairy farmer does not hold an RMP for other milk harvesting activities.</li> </ul>

## 6 Recommended option

MAF's preferred option for providing for future farm gate sales would be Option 3: Make limited amendments to conditions of sale, exempt farmers from the requirement to operate under an RMP, and require that dairy farmers meet certain animal health and hygiene requirements. MAF considers this option to best meet the criteria outlined at the beginning of Section 5.5 and balances the consumers' right to choose to drink raw milk against the need to protect public health.

The preferred proposed option is described and discussed in the next two chapters.

### 6.1 AMENDED FARM GATE SALE REQUIREMENTS

MAF proposes the following requirements apply to future sales of raw drinking milk at the farm gate. These safeguards would ensure that there is limited exposure of the New Zealand public to raw drinking milk, however, there may still be a risk to individual consumers who purchase milk on a 'buyer beware' basis.

#### Limited conditions of sale:

- Only dairy farmers would be allowed to sell their own raw milk and only directly to people that are purchasing it for their own consumption or for their family or household to consume. Raw milk will not be allowed to be on-sold to anyone or provided to anyone other than the purchaser's family.
- Dairy farmers would be restricted to selling a maximum of:
  - Six litres of raw milk per day to an individual wanting to consume it themselves or provide it to their family or household. Milk is commonly sold in two litre containers and so the six litre limit is more practical than five litres.
  - 120 litres of raw milk in total per day which would be, for example, the milk from approximately six milking cows or 24 milking goats. Assuming one customer purchases the maximum of six litres per day, this limit would provide a dairy farmer with 20 customers per day.
- Ordering and payment of raw milk can occur via the phone, internet or other such means. However, all raw milk purchased must be collected by the individual who will consume it or provide it to their family or household from the place where the animals producing the milk are milked i.e. the farm dairy. This reflects the intent, where customers are buying raw milk on a 'buyer beware' basis and are therefore responsible for making decisions on the level of risk.
- Milk will not be allowed to be sold or distributed from other premises or in other contexts e.g. at local stores or farmers markets. Transportation and storage of milk off the farm adds a new level of complexity and increases the risk of contamination and growth of pathogens.

#### Animal health and hygiene requirements:

- Only dairy farmers with TB free herds will be able to sell raw drinking milk
- Dairy farmers harvesting raw milk for drinking will be required to follow hygienic milking practices such as washing teats before milking
- Equipment used to store and dispense raw drinking milk to consumers must be clean
- Raw milk would only be able to be sold in clean containers to prevent contamination with pathogenic bacteria
- Milk that is stored more than a certain period of time (e.g. two hours) before it is sold to the consumer would be required to be kept at an appropriate temperature (e.g. at or below 6 degrees Celsius or less).

- Dairy farmers would be required to keep records of who they sell raw milk to, how much was sold to each person, and when the sale occurred. This would allow for enforcement of the limits on volume able to be sold and for trace-back if the farmer identifies any problems with the raw milk or there is a food borne illness outbreak.

#### Other risk management practices:

MAF will develop guidance material on the risks associated with raw milk and how to mitigate them and make this available to farmers selling raw milk at the farm gate and to consumers purchasing this product. This will include advising farmers of labelling requirements in the Code and what they could do to meet these requirements.

## 6.2 EXEMPTION FROM REQUIREMENT TO OPERATE UNDER A REGISTERED RMP FOR FARM GATE SALES

All dairy farmers undertaking raw milk farm gate sales would be exempt from the requirement to operate under an RMP for this activity. They would still be subject to the general requirements of the Animal Products Act and the proposed Food Act and any regulations and relevant specifications made under these Acts. Raw milk sold at the farm gate would continue to be required to meet the standards in the Code. As a result, such farmers would be required to ensure the raw milk they harvest and sell is safe and suitable and is appropriately labelled. Farmers selling raw milk at the farm gate would be accountable for any food borne illness outbreaks and could be prosecuted.

Any exemption from the requirement to operate under an RMP is required under section 9 of the Animal Products Act to be on the basis of there being other sufficient safeguards in place to minimise any risk to human health. Risks would be managed through the limitations on sale, animal health and hygiene requirements, and guidance material for farmers and consumers as described in section 6.1.

This option recognises that MAF is not aware of any practical or cost effective way of managing the food safety risks associated with raw drinking milk. As a result, it is unlikely that a suitably validated RMP would be developed for evaluation and approval, or if a suitable programme were able to be developed, validated and approved, requirements that would be necessary to manage the risks are likely to be so stringent that they would be impractical and very expensive to implement. This option also reflects the original intent of the provisions for farm gate sales, where consumers are responsible for making decisions about the risks. MAF proposes to continue the legal prohibition on sale of raw drinking milk on a scale greater than provided for by farm gate sales. This could be reviewed should new technology and/or information become available that shows raw drinking milk can be produced safely on a commercial scale.

Farmers' compliance with any new requirements such as the proposed animal health and hygiene requirements will not be subject to routine external verification. Enforcement would instead focus on intermittent surveys and spot checks, and responding to complaints received. MAF would be obliged to investigate if there was a complaint or foodborne illness outbreak.

## 6.3 CONTINUING THE LEGAL PROHIBITION ON COMMERCIAL SCALE SALE

MAF intends to continue the legal prohibition on sale of raw drinking milk on a scale greater than provided for by farm gate sales. This will be reviewed should new technology and/or information become available that shows raw drinking milk can be produced safely on a commercial scale.

# Appendix 1: Hazards associated with raw drinking milk

## SOME PATHOGENS THAT ARE OF PARTICULAR CONCERN IN RAW MILK

An intensive search of the international literature shows that raw milk is often contaminated with pathogens. While the prevalence of major pathogens in the raw milk recorded internationally varies significantly, most of the studies showed a low, but persistent percentage of contamination by pathogens like *Listeria monocytogenes* (*L. monocytogenes*) and pathogenic *Escherichia coli* (*E. coli*) O157. Prevalence of *Staphylococcus aureus* usually exceeds 50%.

In 2007 to 2008 a survey was carried out by Fonterra, in collaboration with NZFSA, to quantify the levels of key non-spore forming pathogens in raw milk in New Zealand. The survey included *Campylobacter* species, pathogenic *E. coli* species, *L. monocytogenes*, *Listeria innocua*, *Salmonella* species and *Staphylococcus aureus*. The frequency and level of all these pathogens in New Zealand raw milk were consistent with other international studies.

The following are brief descriptions of three of the pathogens that are of particular concern in raw milk.

*L. monocytogenes* is a bacterium that is of particular concern for vulnerable consumers, including pregnant women, elderly people who are frail, people with weakened immune systems, and the very young. Pregnant women infected with *L. monocytogenes* may not suffer symptoms of listeriosis, but their unborn child may become infected resulting in miscarriage, stillbirth, or illness or death of the newborn.

Enterohemorrhagic *E. coli* (EHEC) infection has been linked to haemolytic uremic syndrome (HUS), a condition that can cause kidney failure and death. If infected with EHEC, young children are particularly susceptible to contracting HUS.

*Mycobacterium bovis* (*M. bovis*) causes bovine tuberculosis (TB), which is one of New Zealand's most serious animal health problems affecting domestic cattle and deer herds throughout the country. *M. bovis* is endemic in possums in New Zealand and possums are considered to be the principal vector for cattle and deer infections. *M. bovis* also causes TB in humans, which is an illness that can have serious consequences including disability and death. People become infected mainly through the consumption of raw milk or by handling infected animals or carcasses. In the developing world TB caused by *M. bovis* still causes thousands of human deaths annually. In the developed world the risk is greatly reduced because of high standards of meat hygiene and milk pasteurisation.

New Zealand has had a compulsory, national TB eradication campaign operating in cattle herds since 1970 and in deer herds since 1990. Most cattle and deer herds are tested regularly to confirm they are free of TB. While many of New Zealand's international trading partners have attained TB free status<sup>4</sup> New Zealand continues to have a low level of bovine tuberculosis infection.

## FARM CONTROLS AND HAZARDS IN RAW DRINKING MILK IN NEW ZEALAND

All raw milk that is harvested for sale in New Zealand must be produced under a registered farm dairy RMP that sets out how the dairy farmer will identify and control hazards and other

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<sup>4</sup> The international standard for TB freedom is reached when 99.8% of domestic cattle and deer herds have been free of bovine TB for three years. This figure has been set by the Office Internationale Epizooties (World Organisation for Animal Health).

risk factors when harvesting and storing raw milk to ensure it is fit for purpose. However, currently all farm dairy RMPs that are registered are for supply of raw milk to dairy processors for further processing, and all dairy processors pasteurise drinking milk intended to be sold for human consumption. These farm dairy RMPs are designed to reduce the likelihood and levels of hazards present in the raw milk by requiring controls in place to ensure animals are healthy and that good hygienic practices are followed during harvesting and storage of the raw milk.

Despite great improvements in animal health, farm hygiene and refrigeration, farm dairy RMPs are designed to minimise the presence of microbiological pathogens, not eliminate them, and ensure any pathogens present in the raw milk will be at levels that can be destroyed during pasteurisation of milk for drinking. The dairy environment is inherently difficult to keep clean and while adherence to good hygienic practices during milking can reduce the risk of contamination, pathogens are not eliminated from the raw milk. Also, there are some animal diseases can result in contamination of milk with pathogens where the farmer may have no way of knowing the animal is infected as it seems well, but the risks are mitigated through subsequent heat treatment of the milk.

At present there is a lack of information on the levels of microbiological pathogens in raw milk in New Zealand, particularly data for individual farms and from farms that do not supply larger dairy processors. However, a number of studies are underway and being planned.

More information on pathogens that can potentially be present in raw milk in New Zealand and potential risk factors for the presence of these pathogens can be found in the following report which was commissioned by NZFSA in 2008 to inform development of the framework and standards for raw milk products.

[http://www.foodsafety.govt.nz/elibrary/industry/Consideration\\_Farm-Identifies\\_Known.pdf](http://www.foodsafety.govt.nz/elibrary/industry/Consideration_Farm-Identifies_Known.pdf)

## Appendix 2: Section 11A of Food Act 1981

### *11A Restriction on selling raw milk*

- (1) Except as provided in subsections (2) and (3) of this section, no person shall sell, resell, or buy any raw milk.
- (2) A dairy farmer may sell raw milk to any person if—
- (a) It is sold—
    - (i) At the farmer's dairy premises; and
    - (ii) In a quantity not exceeding five litres at any one time; and
  - (b) The person intends the milk for consumption by the person or the person's family;—  
and the person may buy it accordingly.
- (3) A dairy farmer may sell raw milk to a dairy processor (as defined in section 4(1) of the Animal Products Act 1999) who—
- (a) purchases the milk for processing for sale or export; and
  - (b) is a person who—
    - (i) carries out the processing under a risk management programme registered (or deemed to be registered) under the Animal Products Act 1999 or under a food safety programme (as defined in section 4(1) of that Act); or
    - (ii) carries out processing of a kind that is exempt under section 9 of that Act from the requirement for a risk management programme; or
    - (iii) is a person or business who, by section 79 of the Animal Products (Ancillary and Transitional Provisions) Act 1999, is at the time of the sale excused from the requirement to operate under a registered risk management programme or a food safety programme.
- (4) This section is subject to section 9<sup>5</sup>.

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<sup>5</sup> Section 9 of the Food Act 1981 refers to general requirements related to sale of food

## Appendix 3: Examples of other countries approaches to regulating the sale of raw drinking milk

### AUSTRALIA

Australian legislative requirements for the production of dairy products are set out in the Code, which requires that milk and liquid milk products made in Australia must be pasteurised (or undergo an equivalent treatment) ‘unless an applicable law of a State or Territory otherwise expressly provides’. Production of raw drinking goat milk for sale for human consumption is permitted in four States - New South Wales, Queensland, South Australia and Western Australia. This is contradictory to the intent of the Council of Australian Governments (COAG) Food Regulation Agreement in that there is inconsistent regulation of raw goat milk across Australia.

On 19 August 2011 FSANZ released for public consultation *Proposal P1007 Primary Production & Processing Requirements for Raw Milk Products 2<sup>nd</sup> Assessment Report*. This proposal rules out changes to the ban on selling raw milk for drinking because it presents too high a risk to public health to be permitted. FSANZ also intends to review the standard that allows production of raw goat milk for sale for human consumption. FSANZ notes that most submissions were from people wanting access to raw milk, which they saw as healthier, but it rejects the claimed health benefits as outcomes for risk assessments of raw milk indicate that raw milk for drinking presents “too high a risk to public health to be permitted”

### UNITED STATES

In the US, the production of raw milk products is regulated by individual states, some of which allow for the manufacture and sale of such products. The sale of raw drinking milk is legal in 26 of the 50 states in the USA. Raw milk regulations differ between states but can contain requirements such as warning labels, licensing, restriction of sales to the farm gate or to individuals who have a signed prescription from a physician, and limits on the period that raw milk can be sold from the time when a farmer fills a milk container. Federal law bans the movement between states of all locally manufactured or imported raw milk products, except for certain cheeses which must be aged for a minimum of 60 days at a set temperature.

The U.S. Food and Drug Administration (FDA) and Centres for Disease Control and Prevention (CDC) both advise consumers not to consume raw milk with the FDA advising that “raw milk should not be consumed by anyone, at any time, for any reason”.

### UNITED KINGDOM

The Government has assessed the public health risks and proposed a ban on the sale of raw cows' drinking milk in England, Wales and Northern Ireland three times since 1984, most recently in 1997. Each time, the Government decided not to give effect to its proposal in the face of consumer opposition. Farmers also resisted a ban. On each occasion additional measures to protect consumers were introduced. Examples of current controls include effectively restricting sales of raw cows' drinking milk to the farm gate, introducing health warning labelling and increasing the frequency of inspection and microbiological sample testing of raw cows' drinking milk at registered production holdings.

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



sales of raw cows' milk and cream was introduced in 1983 following a number of milk-related illnesses and 12 potentially associated deaths. The introduction of the ban resulted in a marked decline in milk-related illness, which has been maintained in subsequent years.

## Appendix 4: Submissions related to raw milk on proposed framework and standards for raw milk products

During the development of the framework and standards for raw milk products submissions were received that both supported and opposed the sale of raw drinking milk. The groups and their arguments are summarised below.

### DEMAND FOR COMMERCIAL SCALE SALE OF RAW DRINKING MILK

Six submissions were received from consumers stating they would like to see raw drinking milk become more readily available, in addition to other raw milk products. A consumer interest group commented that it was disappointed that the framework did not allow for the sale of raw milk for drinking, even though farmers would be able to make cheeses from raw milk. One individual submitter stated that there was no indication to show why raw drinking milk produced under proper hygienic conditions is deemed to pose an unacceptable risk.

### INDUSTRY CONCERNS

Larger New Zealand dairy processors outlined their concerns at raw milk products being made more widely available. Concerns included the potential for a foodborne illness outbreak to damage the reputation of the entire New Zealand dairy industry resulting in problems for New Zealand's exports of milk products. Dairy makes a very strong direct contribution to the NZ economy. The dairy sector directly accounts for 2.8% of GDP, or \$5 billion and dairy exports were \$10.4 billion in calendar year 2009, accounting for around 26% of New Zealand's total goods exports.

The concerns raised by this sector of industry included that any implementation of a regulatory framework for raw milk products should be based on scientific assessment of the risks so these can be carefully managed, as any food safety incident involving the sale of raw milk could affect New Zealand's reputation overseas as a safe and nutritious farmer of food.

### CONCERNS ABOUT RISK TO PUBLIC HEALTH

Submissions were received from a group of academics who did not support the proposed framework and favoured maintenance of the status quo, i.e. pasteurisation of milk and milk products manufactured and sold in New Zealand. These submitters referred to NZFSA's mandate to protect consumers and expressed concerns that the proposed legislation would put an unnecessary burden on the consumer to make the right choice from a food safety perspective. The submitters stated that risk management should favour the elimination of risks wherever possible, as is occurring internationally.