



The Sale of Raw Milk to Consumers: Summary and analysis of submissions on MPI Public Discussion Paper No: 2014/22

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Contents	Page
1 Introduction	2
2 Summary of submissions and MPI analysis	2
2.1 Problem definition	2
2.2 Objectives	4
2.3 Raw milk market	6
2.4 Risks and benefits associated with raw milk	6
2.5 Policy options	9
2.6 Detailed requirements proposed under the policy options	14
2.7 Implementation	18
Appendix 1: Example of an MPI review of literature provided in submissions	20

1 Introduction

The Ministry for Primary Industries (MPI) publicly consulted on policy options for the sale of raw milk to consumers from 27 May to 8 July 2014.¹ The discussion paper included 45 questions that related to the problem definition, the objectives of the review, the raw milk market, risks associated with raw milk, policy options, detailed proposed requirements under the proposed options and implementation.

A total of 1,585 submissions were received:

- 94 percent were from individuals, most of whom identified themselves as consumers of raw milk (hereafter referred to as “consumers”);
- 4 percent were from dairy farmers or other producers, and associated organisations, who stated they sell or are interested in selling raw milk to consumers (hereafter referred to as “raw milk suppliers”);
- 1.7 percent were from dairy processing companies, the food industry and associated organisations (hereafter referred to as “dairy processors”); and
- 0.5 percent were from public health (for example, public health units, academics and health and medical bodies), animal health (for example, a veterinarian body) and an environmental agency (hereafter referred to loosely as “public health”).

2 Summary of submissions and MPI analysis

2.1 PROBLEM DEFINITION

In MPI’s discussion paper on the sale of raw milk to consumers, the problem being addressed was attributed to four main factors: the health risk posed by raw milk; the growing demand for raw milk; an increase in the number of outbreaks of illness associated with the consumption of raw milk; and regulation that is not working efficiently.

- Consumers disagreed with the problem definition. They argued the risks from raw milk consumption were widely over-stated because they considered raw milk produced from healthy animals on healthy farms (using modern farming technology and hygiene practices) to be free from or low in pathogens. Many consumers argued that resources would be better spent on addressing illnesses caused by the consumption of poor-quality or high-risk foods and substances (e.g. high-fat, high-sugar foods, alcohol and tobacco) rather than raw milk. They agreed there is a growing demand for raw milk and asserted their right to choose what to eat and drink. Many maintained that raw milk provides health benefits and were disappointed that these were not canvassed in the discussion paper. Some asserted that dairy processors have had safety issues with processed milk (for example, the whey protein concentrate incident in 2013), and that pasteurised milk can contain hormones, genetically engineered (GE) ingredients, pesticides and other chemicals. Some consumers believed the drive to restrict sales is motivated by a wish to restrict competition in the dairy sector.
- Raw milk suppliers also considered the problem ill-defined. They stated that the problem has been defined according to “raw factory milk” (raw milk that is processed) rather than “raw drinking milk”. They asserted the different milks are produced differently, with the consumption of “raw drinking milk” being lower risk. They therefore considered the risks over-stated in the discussion paper, and noted that pasteurisation has negative effects on some people’s health. They agreed that the demand for raw milk is growing and the rules need updating but argued that the increase in the incidence of illnesses associated with raw milk is due to the consumption of “raw factory milk”.

¹ Refer to the Ministry for Primary Industries paper, *The sale of raw milk to consumers*; MPI Public Discussion Paper No. 2014/22.

- Dairy processors and public health submitters largely concurred with MPI’s problem definition. They agreed that there are significant health risks from consuming raw milk, that consumer demand is growing and resulting in an increase in outbreaks of illness and that the current regulatory regime is ineffective (including in its lack of guidance on how to reduce the risks of consuming raw milk).

MPI comment

Risks from raw milk

MPI does not agree that the risk from raw milk consumption is over-stated. The scientific evidence overwhelmingly demonstrates that pathogens occur in raw milk, no matter how good or hygienic the farming practices, and despite improvements in animal health and milk harvesting techniques. Even healthy animals can carry pathogens that may pass into the milk, and pathogens may come from the farm environment. Even low levels of pathogens may cause illness. The recent increase in the consumption of raw milk has corresponded to an associated increase in illnesses. Young children are at highest risk of becoming ill and of suffering the most severe illnesses.

For further analysis of the risks associated with raw milk consumption, refer to MPI’s comments in section 2.4 of this report.

Claims of health benefits

The totality of the evidence for health benefits from consuming raw milk was reviewed by MPI for the consultation paper and such evidence was found to be scientifically unsubstantiated or inconclusive. MPI notes that claims of health benefits from foods are strictly regulated under the Australia New Zealand Food Standards Code (Standard 1.2.7). There are currently no pre-approved “food–health relationships” specifically about the benefits of raw milk. The food industry, including raw milk suppliers, can self-substantiate certain types of claims of health benefits (called “general level health claims”) but it must do so in accordance with the rigorous scientific substantiation processes established under Standard 1.2.7. Any statements about claimed benefits must also meet the requirements of the Fair Trading Act 1986.

For further analysis of the claimed health benefits from consuming raw milk, refer to MPI’s comments in section 2.4 of this report.

Comparisons to poor-quality foods

MPI does not consider it appropriate to directly compare potential long-term nutritional issues related to the consumption of nutrient-poor diets, or other high-risk foods, with the consumption of a single food that has an immediate microbiological risk and can be life-threatening to infants and young children.

For further analysis of the comparable risks from consuming raw milk and nutritionally deficient or other high-risk foods, see MPI comments under section 2.4.

Comparisons with “raw factory milk” for processing

MPI acknowledges its research was based on “raw factory milk” rather than milk produced specifically for direct human consumption, and agrees that “raw factory milk” might be higher risk compared with “raw drinking milk” that has been produced to the highest standards possible. However, pathogens have been found in raw milk intended for direct human consumption, with associated outbreaks of illnesses, in New Zealand and overseas, including:

- seven confirmed cases of campylobacteriosis in Timaru linked to a farm in March 2014; and
- five confirmed cases of campylobacteriosis spread across the Wellington region in March and June 2014 linked to a farm in the Horowhenua District. In three cases, drinking raw milk was the only risk factor.

Problems with processed milk

Outbreaks of illness associated with pasteurised milk are mainly due to failures in the milk pasteurisation process, or cross-contamination post-pasteurisation. The percentages are small compared with outbreaks related to the consumption of raw milk. This is significant given the relatively small amount of raw milk consumed in New Zealand compared with pasteurised milk.

All hazard and contamination incidents in the dairy processing industry are managed as part of the operator's risk management programme. MPI is not aware of any outbreaks or sporadic cases in New Zealand associated with contamination events for processed products.

There are no GE ingredients in New Zealand pasteurised milk. Milk is extensively tested for pesticide residues and other chemical contaminants. All milk contains natural hormones, the level of which will decrease minimally, if at all, during pasteurisation.

Consumer choice

MPI agrees that adults have a right to choose what they eat and drink. The current rules and proposed policy options allow for choice, while imposing regulation to reduce health risks, just as regulations are imposed on other high-risk foods.

2.2 OBJECTIVES

The discussion paper proposed the following objectives for the policy on sales of raw milk to consumers: maintain access to raw milk; reduce raw milk-related illness; clearly inform consumers of health risks; develop unambiguous law; encourage and monitor compliance; protect New Zealand's international reputation; and regulate consistently with the approach used for other uncooked foods that potentially contain pathogens.

- Consumers agreed with some of MPI's objectives (providing consumer information, developing an unambiguous law and ensuring raw milk is monitored and complied with). While they agreed that access to raw milk should be maintained (including collection from common pick-up points), some argued that access should be further increased. Many considered the objective of reducing illness associated with the consumption of raw milk to be flawed because they do not agree with the scientific evidence. They noted outbreak numbers are low and raw milk is frequently identified in outbreaks as a "risk factor" rather than a "cause" of illness. Some also argued that raw milk should not be regulated in the same way as other uncooked foods such as oysters because they considered the latter to be more inherently dangerous. Many questioned the relevance of New Zealand's international reputation as an objective, given raw milk is not exported. Finally some consumers asserted that an objective should be to avoid excessive regulation and costs.
- Raw milk suppliers mainly agreed with MPI's objectives, noting that sound testing provisions, and monitoring and compliance guidelines would produce high-quality, safe milk, thereby reducing illness. They particularly supported an objective to regulate in a way that is consistent with the approach used for other uncooked food that can potentially contain pathogens. They disagreed, however, with the objective of protecting New Zealand's reputation as a supplier of safe food. They argued that outbreaks attributed to raw milk have had no negative reputational impact, the market is only 0.0025 percent of the milk consumed in New Zealand and dairy processors could easily

distinguish their milk if there were an issue relating to the consumption of raw milk. They also noted that New Zealand's reputation has been substantially affected by pasteurised milk.

- Dairy processors and public health submitters did not agree with maintaining existing access to raw milk. The former group favoured limiting access to rural consumers only, while the latter favoured reducing the current availability. Both groups agreed that a policy priority should be minimising the risk of illness associated with raw milk consumption. Dairy processors agreed that the risk to New Zealand's international reputation is a risk that needs to be addressed.

MPI comment

Access to raw milk

MPI recognises that there is a strong demand for raw milk from consumers in both rural and urban areas. This demand is addressed in the context of needing to find an appropriate balance between allowing some access for informed consumers who seek to consume raw milk, and not allowing widespread availability due to the increased risk to public health.

Reducing illness

MPI notes consumers' argument that raw milk is generally identified as a risk factor for rather than the cause of illness. Absolute confirmation of the cause of individual instances of illness for gastrointestinal disease can be extremely difficult to obtain, particularly if only a single case has occurred or the scale of the outbreak is small. 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 a case of illness is diagnosed and reported, there are many difficulties in attributing it to a particular source, especially in the case of food, where all evidence is either consumed or thrown away due to its short shelf-life.

Similar difficulties arise with proving cause and effect for other foods considered to be risk factors for gastrointestinal illnesses. Hence most outbreaks of foodborne illness are described as "associated with" rather than "caused by". Despite this, there have been outbreaks for which the data were strong enough to prove that raw milk caused the illness.

With reference to the points made by raw milk suppliers concerning the importance of sound testing protocols, MPI agrees that microbiological testing of milk is useful. Testing serves as a monitoring tool that can indicate whether an acceptable level of hygiene has been achieved. MPI has therefore included proposed testing requirements under the proposed policy options. However, testing alone does not ensure the absence of particular pathogens or guarantee food safety.²

Refer to comments under section 2.4 addressing the scientific evidence for the risks of consuming raw milk, including outbreak numbers, and risks from other high-risk or unhealthy foods or substances.

Clear information for consumers

The labelling requirements proposed under the new policy would help to ensure consumers are better informed about the food safety risks and how to minimise them.

² Pathogens present in low numbers or in localised, perhaps clumped, high numbers are unlikely to be detected when testing small samples (e.g. 25ml) from a large vat of milk. In addition, it is unlikely that test results for pathogens would be available from the laboratory within the sales period and correct storage life of the raw milk.

Clear, unambiguous law

The new policy aims to develop a law that is unambiguous, and that encourages compliance and the ability to monitor and act on non-compliance. It would allow for raw milk to be available, but with strict controls and monitoring.

Compliance and monitoring

Any new regulatory regime would be intended to minimise the food safety risks and would therefore have compliance costs for raw milk suppliers. Compliance costs are not intended to be excessive. There may be more costs at the beginning of implementation (for example, for setting up record-keeping systems, or better refrigeration).

New Zealand's international reputation

MPI points out that any adverse event involving a New Zealand dairy product could impact negatively on our reputation with our overseas trading partners. The more the policy for the sale of raw milk is liberalised, the more raw milk consumers are likely to drink and the greater the increase in illnesses is likely to be. Even though raw milk is not exported, at a certain point the increase in illnesses would be picked up by overseas markets who may question our food safety regulatory system and/or may attribute the problem to our wider dairy processing industry. International markets will look unfavourably on New Zealand if policy is implemented that results in an increase in illnesses.

2.3 RAW MILK MARKET

The discussion paper sought information on current practices around selling, buying and consuming raw milk in order to understand the raw milk market in New Zealand.

- Little information was provided on the number of farmers selling raw milk to consumers. Three current suppliers of raw milk indicated that the majority of their customers were from urban areas. Amounts of raw milk sold varied: one supplier sold 15 litres a day; another sold 140 litres per day. One sold up to 5 litres per household a day, while another supplier said 1 to 20 litres were sold to each household per day. The median price charged was \$2.50 per litre.
- Consumers cited health benefits, taste, price (compared with pasteurised milk) and a preference for drinking a natural product as reasons for their choice to drink raw milk. Weekly household usage ranged between 1 and 12 litres, with most around 4 to 8 litres. Most consumers said they lived in urban areas. Consumers indicated that raw milk is sometimes consumed by family members, including babies, pre-schoolers and school-age children, and by elderly family members, pregnant women and people with low immunity, because of the claimed benefits provided by the food.

MPI comment

MPI acknowledges that there is a small but growing group of New Zealanders who wish to drink raw milk, mainly as part of a wider trend towards consuming unprocessed foods. MPI notes the information provided by submitters on the raw milk market, along with information from the online survey on raw milk experiences with buying, selling and consuming raw milk. This information has been taken into account in the development of the proposed policy.

2.4 RISKS AND BENEFITS ASSOCIATED WITH RAW MILK

Submitters commented on MPI's assessment of the food safety and health risks associated with consuming raw milk and its literature review on the effects that pasteurisation has on the nutrition and health benefits of raw milk.

- Many consumers and raw milk suppliers were aware of research showing an increase in foodborne illness associated with drinking raw milk. However, most did not believe raw

milk poses a significant health risk. Many said they understood concerns about potential illnesses, but made a choice to drink raw milk anyway, on the basis that the health benefits outweigh any risks.

- Consumers and raw milk suppliers stated that outbreaks of illness associated with raw milk are very low, particularly when compared with other food products and substances (for example, other uncooked food such as oysters, nutrient-deficient foods, alcohol and tobacco). Some noted that illnesses have occurred from contaminated horticultural produce, which the Food Act 2014 allows to be sold direct to the consumer, without limits on points-of-sale and without requiring, for example, advisory or warning statements. They argued that “raw drinking milk” should not be subject to stricter regulation than that applied to such products. Many considered there was no clear evidence to demonstrate that raw milk is the cause of illness, noting that frequently it is simply identified as a generic risk factor along with other risk factors. Some consumers questioned the validity of scientific studies while others noted the food safety risks were mostly associated with poor handling practices rather than the raw milk itself. A number provided anecdotal evidence or links to research supporting raw milk as a safe food (for example, a presentation by Nadine Ijaz³), and emphasised the superior palatability, digestibility and nutritional value of raw milk compared with pasteurised milk.
- Some dairy processors supported MPI’s scientific assessment but were concerned that the discussion paper did not address other risk factors, such as cross-contamination of milk (from equipment, during transportation or from vending machines) or insufficient refrigeration throughout the life of raw milk.
- Public health submitters also supported MPI’s scientific assessment. They pointed to additional research providing evidence of an increase in raw milk-associated illnesses and were particularly concerned (as were the dairy processors) about the risks to children, the elderly, pregnant women and people with immune deficiencies. The increase in illnesses was linked with increased consumption. Some considered that increased reporting could be contributing to the increase in illness, while others stated that illnesses associated with raw milk are under-reported. Public health submitters questioned the evidence to support pasteurised milk as nutritionally or otherwise inferior to raw milk, noting that many of the claimed benefits of raw milk have not been proven.

MPI comment

Risks associated with the consumption of raw milk

MPI reviewed the literature provided by submitters in support of their comments. Appendix 1 provides a summary of MPI’s response to one reference cited by many submitters (a presentation by Nadine Ijaz) as an illustration of how MPI reviews references.

MPI’s scientific risk assessment, which is consistent with other international analysis, found that raw milk is a high-risk food because of the presence of pathogens. Outbreaks of infectious diseases associated with the consumption of raw milk have occurred in New Zealand and internationally, including in countries that have the strictest production and food safety measures. Raw milk has also been identified as a risk factor for sporadic (one-off) cases of illness.

Provisional foodborne illness data for New Zealand in 2014 show that drinking raw milk was identified as a risk factor in 10 foodborne outbreaks. These outbreaks resulted in 41 illnesses, most of which affected young children. Raw milk consumption was determined to be the

³ Ijaz, N. (2013). Unpasteurised milk: myths and evidence. A presentation to BC Centre for Disease Control, Canada. http://www.bccdc.ca/NR/rdonlyres/00E8757C-99E4-4414-8C54-2C92BB776567/0/RevisedPresentationJuly8RawmilkmythsandevideceNadineIjaz_PROTECTED.pdf

cause of at least three of the outbreaks. Five young children who all consumed raw milk were hospitalised with a pathogen that can be life-threatening (shigatoxin-producing *Escherichia coli* (STEC)).

The 2013 statistics showed that raw milk consumption was the second most frequently identified food risk factor (after poultry consumption) despite low consumption per capita relative to the consumption of pasteurised milk and poultry.

MPI agrees that for most outbreaks, raw milk consumption was not the only risk factor identified: contact with farm animals and consuming untreated water are also frequently mentioned. However, since 2009 the number of outbreaks in which raw milk is a recorded risk factor has been consistently higher than in previous years.

Health benefits

MPI considered all the literature cited by submitters in support of their comments. The literature was initially scanned to determine if it was published:

- as a full scientific report to allow critical evaluation;
- in international peer-reviewed scientific journals; and
- in English, the language of all internationally recognised scientific journals.

Any literature that met these criteria was then critically evaluated to determine whether the evidence presented was sufficient to support the stated claims.

MPI could find no conclusive evidence that raw milk offers additional nutrition or health benefits compared with pasteurised milk. As acknowledged in the discussion paper, some studies indicate that drinking raw milk at an early age may help reduce the risk of asthma, hay fever and eczema – but the evidence is inconclusive. Further research on these issues is being conducted.

Scientific literature suggests that pasteurisation can change the structure of certain milk proteins (mainly whey proteins) but they have little effect on digestibility, their nutritional properties or milk allergenicity. A systematic review found evidence that pasteurisation decreases the concentrations of certain vitamins (e.g. vitamin C and vitamin B₂). However, in the context of the whole diet, the impact on human nutrition is insignificant, because either milk is not an important dietary source of these vitamins or the decrease is minimal. Case-control studies have shown no noticeable difference in lactose intolerance when comparing raw milk with milk that is pasteurised.

It is noted that, in the context of discussing the benefits of whole, unprocessed milk, references to various treatments of milk, such as pasteurisation, homogenisation or sterilisation, are often confused.

Risk relative to nutrient-deficient or other potentially harmful foods or products

The Food Act 1981 and the Animal Products Act 1999 apply strict requirements to the supply of all high-risk food, including warning and advisory statements for allergenic foods.

The risk of illness from the consumption of raw milk is higher than, for example, commercially harvested raw oysters, as there is higher overall exposure to the former. Oysters, unlike milk, are not part of the typical daily diet, and raw milk is sometimes fed to infants. Commercially harvested oysters and other bivalve molluscan shellfish must follow a regulated control scheme, given that they are high risk. Part of this scheme involves controls around harvesting, including only allowing harvesting of oysters when it is considered the

oysters will be safe to eat and routinely monitoring the oysters and the growing areas. Furthermore, there has been extensive publicity about high-risk foods such as shellfish over many years. Consumers are aware of the food safety risks and how to minimise them, including the need for vulnerable groups to avoid certain higher-risk products. Processing to destroy pathogens (for example, canning or other antimicrobial heat treatments) is permitted in certain circumstances such as with some imported oysters.

MPI agrees that the consumption of fresh produce has been associated with illnesses, although this occurs more frequently overseas than in New Zealand. Most outbreaks overseas have been associated with inappropriate production (e.g. use of fresh, or inadequately treated, human or animal waste as a fertiliser, contaminated irrigation or processing water, or failure to use antimicrobials such as in organic seed sprout production). Fresh produce production in New Zealand adheres to codes of good agricultural and hygienic practices that minimise the likelihood of contamination. In addition, unlike raw milk, fresh uncooked produce is usually consumed following some form of preparation, such as washing (with water or antimicrobials) or peeling, which further minimises pathogen contamination. Despite these controls, MPI considers that outbreaks and sporadic cases of illness still occur.⁴

Alcohol and tobacco consumption are controlled through strict regulations (for example, age and point-of-sale restrictions) and through policies that include education.

The Government has many policies across several agencies to support nutrient-dense foods.

Cross-contamination

MPI notes the concerns raised by some dairy processors about cross-contamination that might occur from equipment used to transport raw drinking milk from the farm to distribution centres. However, MPI is not aware of specific evidence that supports these concerns and general food processing sanitation requirements should mitigate these risks.

Subsequent to MPI's analysis of comments submitted by stakeholders on the discussion paper, the Office of the Prime Minister's Chief Science Advisor, Sir Peter Gluckman, at the request of the Minister for Food Safety, undertook a review of MPI's scientific assessment of the risks and benefits of raw milk. The review concluded that there are significant infectious disease risks associated with raw milk and that pasteurisation is an effective method of destroying the pathogens that cause such diseases.

Sir Peter Gluckman's review also found that claimed benefits from consuming raw milk are largely unsubstantiated and that the nutritional and digestive differences between raw and processed milk are not of biological significance. He concluded that the risk:benefit ratio for raw milk is high, particularly among the vulnerable groups. A copy of Sir Peter Gluckman's report can be found at <http://mpi.govt.nz/document-vault/7866>.

2.5 POLICY OPTIONS

The discussion paper proposed policy options for the future sale of raw milk to consumers, after determining certain approaches (prohibition, status quo, non-regulatory control measures, sales at retail outlets and sales at farmers' markets) were not viable options.

⁴ In 2014 there was a *Yersinia* outbreak and produce was implicated in media reports. However, the foodborne route for this outbreak was never identified.

Options not considered viable

- Consumers and raw milk suppliers agreed prohibition is not a viable option given the demand for raw milk and the resulting underground market that would likely develop. Some consumers supported the current situation on the basis that they were picking up raw milk via central collection points. Some people also supported non-regulatory control measures such as a code of practice and sales at retail outlets and farmers' markets. They argued that there would be no health risks from greater availability if suppliers simply complied with existing rules.
- Raw milk suppliers did not support the current situation and they considered self-regulation alone would not be effective. However, they supported a voluntary code of practice, in addition to new rules, as they considered it would help promote higher-quality standards. In general, suppliers did not favour sales through retail outlets or farmers' markets as they thought it would make monitoring and enforcement difficult and costly, and would increase consumers' exposure to raw milk when they were not necessarily well informed about the risks. They argued that the safety of raw milk is best guaranteed through sales direct from farmer to consumer.
- Citing the known risks, dairy processors and public health submitters were largely in favour of prohibiting raw milk sales to ensure consumers only had access to safe (pasteurised) milk supplies. However, many recognised the difficulties of enforcing a prohibition. Both groups agreed with MPI's rejection of retail sales on the basis that they would involve high compliance costs and lead to increased consumption by and exposure to illness for potentially uninformed consumers.

MPI comment

The principle objective in developing policy for the sale of raw milk to consumers is to reinstate an appropriate balance between managing the risks to public health and recognising that there is a strong demand for raw milk from consumers in both rural and urban areas. Prohibition, no-regulation and retail sales will not provide an appropriate balance, for the reasons stated in MPI's discussion paper.

The current situation is not a viable option because of the increasing number of outbreaks of illness associated with raw milk, particularly among children. Current legislation around the sale of raw milk to consumers was drafted in 1981 before internet sales were available. There was never any intention for raw milk to be purchased online and then collected from places other than the farm. The ambiguity in the legislation, combined with a lack of offence provisions, has meant that delivery to collection points has not been tested in the courts. Production requirements have also been unenforceable as their generic nature (a requirement to have a risk management programme) does not suit the food safety risk associated with drinking raw milk. Similarly, labelling provisions do not sufficiently inform consumers of the risks.

While progressing a review of the policy, MPI publicly stated on several occasions (including during consultations) that some suppliers are selling raw milk in ways that were never intended and that raw milk is a high-risk food.

MPI agrees with raw milk suppliers who support regulation and sales direct from farmer to consumer on the basis of their best guaranteeing the safety of raw milk. MPI supports the raw milk industry developing a voluntary code of practice to complement regulation and to increase quality standards beyond the legal requirements.

MPI maintains that sales at farmers' market cannot be justified. Farmers' markets, which vary considerably in their size and food safety culture, would increase the exposure to raw milk for opportunistic buyers.

Options under consideration

- The majority of consumers did not support any of the proposed options (option 1 = farm sales with quantity limits; option 2 = farm sales with no quantity limits; option 3 = farm sales with home delivery and no quantity limits). They considered these options to be impractical, particularly for urban consumers, and likely to restrict sales and limit consumer choice. Many asserted the options were inappropriate as these consumers considered the risk of illness from consuming raw milk to be over-stated and the health benefits under-stated, especially when compared with the approach for nutrient-poor foods. Some argued that all three options would exacerbate food safety risks (for example, through lack of refrigeration during transportation from the farm and when raw milk is home-delivered and left without refrigeration at the doorstep). There was some support for option 3, although many argued this would not meet the current demand for raw milk and would not be financially viable.
- Many raw milk suppliers considered that all three options would be uneconomic and would risk making continued sales unviable for producers: option 1 because of the quantity restrictions, and options 2 and 3 because of the stricter production requirements and compliance and implementation costs. (Some, however, supported option 2 or 3.) Many felt that compliance (for example, when related to the refrigeration requirements under option 3) would be difficult to enforce and would result in increased food safety risks. They acknowledged traceability mechanisms are necessary but considered the requirement to keep detailed records of sales non-workable for those selling via vending machines and self-fill vats. Suppliers also argued that the three options were not pertinent to "raw drinking milk", which they argued is a product different from and safer than milk intended for processing.
- Many dairy processors and public health submitters argued that none of the three options would decrease foodborne illness and that increased access (particularly with option 3) could result in costs to public health and a risk to New Zealand's reputation as a safe supplier of food. They considered pasteurisation the most appropriate method to manage the food safety risks associated with raw milk. While these groups said they preferred prohibition, some acknowledged this was not a feasible option and therefore supported option 1 as the one providing the least access and being the most likely to reduce outbreaks of illness. Some dairy processors were concerned that the quantity limits under option 1 would be difficult to enforce. Some dairy processors and public health submitters advocated that there should not be fewer requirements for farmers supplying small quantities of raw milk as these submitters supported the highest standards possible. Some submitters from both groups considered option 2 would be the most practical way of managing food safety risks, given its more stringent production requirements for farmers supplying 40 litres or more per day and the restriction of sales to the farm only.
- Public health groups were concerned that none of the three options adequately addressed the risks at critical control points (for example, storing and transporting raw milk and sterilisation of milk collection containers). They, like suppliers, were concerned the options were uneconomic and likely to result in high compliance costs.

MPI comment

Consultation shows that there is no policy option that can satisfy all groups of submitters or mitigate all risks.

MPI's response to comments in relation to the risks from consuming raw milk being over-stated and the benefits under-stated (and therefore the proposed options being inappropriate) is addressed in section 2.4 of this report.

Option 1: Farm sales with limits on quantities sold and purchased

Option 1 manages the risks to public health by severely restricting the point-of-sale and the quantities sold. It would therefore likely reduce illnesses associated with consuming raw milk. However, illness would still occur, given that:

- food safety measures are not as extensive as they could be;⁵
- there is a food safety risk with consumers transporting raw milk from farms to their homes. Education around maintaining the cold temperature through iced chilly bins would therefore be essential; and
- illness would likely occur, given strong consumer demand, through:
 - legal consumption – raw milk will always be a high-risk food;
 - consumers circumventing the law – consumers could, for example, enter a cow share agreement even though such an arrangement is onerous;
 - consumers acting illegally.

Since option 1 allows farmers to sell only limited quantities of raw milk, they would have to supplement their incomes from other sources (for example, by primarily selling raw milk to a dairy processor or, if they were on a lifestyle farm, by selling other products). Those who currently sell more than limited quantities of raw milk from the farm only and all farmers who deliver to collection points would have to either close or modify their operations.

MPI acknowledges that keeping detailed records of sale would pose problems for farmers selling raw milk via self-fill vats and vending machines. However, it would ensure the highest level of traceability in the event of milk being found to be contaminated or illnesses occurring.

Option 2: Farm sales with no limits on quantities sold or purchased

As with option 1, option 2 would likely decrease the incidence of illness associated with raw milk. While option 2 allows unlimited amounts of raw milk to be sold to consumers, the public health risks would be managed by severely restricting the point-of-sale and applying greater government oversight, including verification checks of farms selling more than limited quantities of raw milk. Some raw milk suppliers stated in their submission that they were successfully running businesses similar to option 2, implying that this approach is viable.

Option 2, however, provides limited choice for consumers, particularly urban people, because they would be required to collect milk from farms. Also some level of ongoing illness would continue due to the inherent risks associated with raw milk, lower requirements for those selling small amounts of raw milk and illegal consumption. (Consumers, however, may prefer to purchase raw milk from those who are known to comply with the stricter requirements.) Farmers currently delivering via collection points would have to close or modify their operations.

Option 3: Farm sales and home deliveries with no limits on quantities sold or purchased

Option 3 provides greater choice for consumers, particularly urban consumers, than options 1 and 2. The risks to public health are managed by restricting the point-of-sale to ensure exposure is limited to consumers who actively seek out raw milk and are aware of the risks

⁵ Under option 1, dairy farmers selling raw milk to consumers would not have to be independently verified, raw milk would not be tested for pathogens, and farmers would not have to attend training courses on good milk harvesting practices and good agricultural practice. These exemptions were proposed to take into account economic viability.

and how to manage them, and by applying strict controls for farmers selling more than 40 litres (including requirements for home delivery).

Lower requirements for farmers selling small amounts of raw milk would, however, expose those consumers to greater risk of illness. Wider access through home deliveries could also increase the incidence of illness associated with raw milk consumption, either through the inherent risks from drinking raw milk or because the cold temperature may not be maintained if a purchaser is not at home when the milk is delivered. It would therefore be in the farmers' interests not to deliver raw milk unless the purchaser was at home or the purchaser was able to provide a way of maintaining the cold temperature.⁶ Requirements around maximum transport and storage temperature and time will mitigate the risk.

Home deliveries are likely to raise the cost of supplying raw milk compared with deliveries to collection points (and may therefore raise the price). However, they are likely to be cheaper overall (i.e. adding price and travel costs) when compared with collecting raw milk from the farm, especially for consumers living in urban areas. Farmers who are currently providing raw milk via collection points would have to close or modify their operations.

Other approaches advocated

- Both consumers and raw milk suppliers strongly advocated for sales from the farm as in option 2, plus delivery to a common pick-up point by farmers selling 40 litres or more of raw milk per day. This approach was supported on the basis that the consumer pre-orders and pays for the milk and is informed of the health risks and how best to manage them prior to delivery. Submitters considered this approach would:
 - reduce the likelihood of illness, due to increased compliance, stringent production requirements and maintenance of the cold temperature until pick-up;
 - help protect New Zealand's reputation as a supplier of safe food;
 - meet the current demand to buy raw milk in places other than from the farm;
 - provide an easy way for farmers to keep detailed records of sale; and
 - ensure consumers make a well-informed choice.

They noted that the disadvantage of this approach was its inconsistency with the way other uncooked foods that potentially contain pathogens are sold. They considered the costs to consumers would be fewer while there would be new costs for farmers not currently selling via collection points and new costs for government in terms of monitoring compliance.

MPI comment

MPI considers it would be very difficult to control collection points as it would be difficult to define them in a way that:

- clearly distinguishes them from general retail outlets; and
- is not anti-competitive (i.e. it does not arbitrarily restrict sales to one type of retail outlet, to the detriment of others).

If collection points were made explicitly legal, there would be an increase in sales, consumption and resulting illnesses. Farmers who are currently operating to the intent of the law would extend their operations and new operators would likely enter the market, given the financial attractiveness of this approach.

⁶ Many businesses delivering perishable goods to homes endeavour to make such arrangements with the purchaser.

Collection points could easily result in a model similar to retail sales where most New Zealand consumers, whether actively seeking it or not, would be exposed to raw milk via a range of retail outlets (which could include, for example, gourmet supermarkets, organic shops, corner dairies, catering establishments and gyms). This would result in difficulties with compliance (as with the current situation).

Defining clear responsibilities between the farmer and the collection point operator would also be difficult, particularly in relation to hygiene requirements that would need to apply to the design and maintenance of the collection point.

2.6 DETAILED REQUIREMENTS PROPOSED UNDER THE POLICY OPTIONS

Detailed requirements under the various options were proposed in the discussion paper. The requirements included the conditions of sale, measures applying to all dairy farmers supplying raw milk to consumers and additional measures under options 2 and 3 for those supplying 40 litres or more of raw milk per day to consumers.

Standards

There were mixed views among all four submitter groups on whether raw milk sold to consumers should at a minimum meet the same standards as for dairy farmers producing milk for pasteurised dairy products.

- Some consumers and raw milk suppliers considered that raw milk producers should only be required to meet the same standards as for pasteurised dairy products as they were already high. However, the majority of consumers and all raw milk suppliers considered raw milk should be produced to higher standards than pasteurised milk because of the higher (good and bad) bacteria and pathogen content. They noted that raw milk producers already follow rigorous practices resulting in a high-quality, safe product. Some thought a risk management programme (RMP) tailored for raw milk was adequate to ensure high standards while others agreed that a regulated control scheme (RCS) was essential to ensure high production standards across the industry. Some raw milk suppliers questioned the need for tighter time controls on raw milk sold, though most supported tight temperature controls.
- Dairy processors and public health submitters were also split on the question of standards. Some thought that raw milk should be produced to the same standards as other dairy foods. Others thought significantly higher standards, particularly covering milk collection, cooling and testing, were essential to maintain food safety in the absence of pasteurisation. There was support for an RCS, although some thought it had limitations. One public health submitter thought raw milk production should be regulated as a high-risk food under a Food Control Plan under the Food Act 2014. A public health submitter also recommended additional food safety standards, including stringent labelling and warning requirements.

MPI comment

MPI considers a higher standard is necessary for the production of raw milk for human consumption compared with pasteurised milk, given there is no step to eliminate the pathogens.

Most farmers producing raw milk intended for further processing operate under a multi-business RMP operated by the company they supply. A few producers have RMPs based on a template. These RMPs are designed to ensure risks are managed for milk that will be further processed. They are not suitable for applying to raw milk intended for human consumption as they do not include the additional measures that would be required to provide for the safe production of raw milk for human consumption.

An RMP requires farmers to ensure the food product is safe to consume and fit for its intended purpose. MPI does not consider it possible to design an RMP that meets the legal requirements for raw milk intended to be consumed as there is no process to eliminate possible pathogens.

An RCS is a single prescriptive set of risk management measures intended to protect the health of consumers by reducing risk factors as much as reasonably possible. It is used when it is inappropriate or impracticable to manage risk factors under an RMP. It can potentially be provided at lower cost to individual producers than an operator-developed RMP.

Compliance with the Australia New Zealand Food Standards Code is already mandatory for anyone who sells food, including those who sell raw milk to consumers.

An audited Food Control Plan under the Food Act 2014 is not an option on farms. When milking animals, the requirements of the Animal Products Act 1999 apply.

Tuberculosis standards

- Some consumers and raw milk suppliers agreed with the proposed requirement for herds to be free of tuberculosis (TB) for five years. Others thought this too stringent, or questioned the need for any minimum TB-free period. Some argued herds should be TB-free for 10 years.
- Dairy processors and public health submitters generally supported the five-year requirement.
- Consumers, raw milk suppliers and public health submitters had mixed views as to whether raw milk intended to be sold to consumers should only be supplied from TB-free regions, with some arguing it is more important for herds than regions to be TB-free.

MPI comment

The proposal for a 10-year TB-free requirement would disadvantage farms with a long history of being TB-free and would be disproportionate to the risk. MPI agrees that, while raw milk from TB-free areas presents a lower (but not zero) risk, noting that outbreaks in dairy herds have occurred in low-risk areas, it is not justifiable to limit the supply of raw milk intended to be sold to consumers to TB-free areas. MPI prefers that farms should be individually assessed.

Additional guidance for small-scale farmers intending to sell raw milk to consumers

- Many consumers and raw milk suppliers favoured self-regulation and the provision of guidance to small producers rather than strict regulation. However, some consumers noted that small producers represent a higher risk to the industry and therefore regulation was desirable as long as it was affordable and sensible. A number of consumers and all raw milk suppliers were supportive of a voluntary code of practice for suppliers selling less than 40 litres of raw milk a day.
- Dairy processors and public health submitters generally felt that minimum requirements should apply to all producers. They supported the provision of assistance and guidance material to help small-scale producers meet such requirements.

MPI comment

MPI does not support a voluntary code of practice as the only way of ensuring small-scale farmers follow production and food safety requirements. This is because the risk is not solely related to the size of an operation and the volume produced: both small and large producers

may fail to comply with requirements. Also, not all farmers selling raw milk to consumers would commit to or rigorously follow a voluntary code, the control measures may be less stringent than those developed independently by government and sanctions would be difficult to apply without the force of the law. MPI aims to minimise compliance costs while maintaining adequate control of risks.

However, MPI would like to work with raw milk producers on a guideline or code of practice that translates regulatory requirements into practical advice for farmers.

Monitoring, verification and testing

- Most consumers and all raw milk suppliers and dairy processors agreed that the safety of raw milk should be monitored. Various monitoring methods were suggested. One public health submitter argued that monitoring would not provide assurances of the safety of raw milk.
- All groups had mixed views on the appropriate frequency of testing. Within each group, some supported the testing frequency proposed in the discussion paper while others argued for more or less frequent testing. Submitters in all categories referred to the need for testing to be cost-effective.

MPI comment

MPI contends that regular monitoring is an integral part of the risk management framework, intended to demonstrate that the framework is working. The level of monitoring is based on performance. If a problem occurs, the onus should be on the operator to show it has been rectified. Some general monitoring programmes for dairy products already exist – the Independent Verification Programme and the National Chemical Contaminants Programme. Raw milk intended to be sold to consumers will be incorporated into these programmes.

MPI considers that testing is valuable as a guide for managing milk quality. The purpose of testing is to verify good hygienic practices and that systems are operating as intended. However, testing does not guarantee the safety of raw milk. Testing will introduce costs but is necessary to enable the continued sale of raw milk to consumers.

Performance recognition and sanctions

- Consumers and raw milk suppliers agreed that good performance should be recognised. A variety of means was suggested, such as a reduction in or exemption from some of the production, testing or inspection requirements, reduced fees or a (milk or farm) grading scheme.
- The dairy processors and most public health submitters argued there was an expectation of good performance. They considered that, rather than recognising good performance by relaxing compliance requirements, poor performance should be managed by imposing stricter requirements.
- Views were mixed among all four groups on the proposed suspension periods if standards were not met. Most consumers supported the proposed 28-day suspension period following repeated failures to meet standards. However, all raw milk suppliers and some consumers considered this excessive: some were concerned about the wastage that would occur and the inconvenience to consumers unable to obtain raw milk during the suspension period. They preferred an approach that implements performance-based criteria for closure and re-entry. Dairy processors did not support the proposed 28-day suspension period and considered the period should be consistent with the approach for pasteurised products. Some public health submitters supported a 28-day suspension and recommended additional financial sanctions, although one public health submitter questioned the rationale for 28 days' suspension.

MPI comment

MPI will consider submitters' suggestions concerning how good performance might be recognised and how poor performance should be managed.

MPI recognises the significance for farmers and consumers of raw milk being unavailable for sale to consumers during the suspension period. However, in a situation of repeated failures to meet food safety standards, the operator needs to take the time to identify root causes, take remedial action and confirm the action is effective. The proposed 28-day suspension is intended to encourage farmers to take these necessary steps and restore good hygienic practice. MPI intends that any suspension will be concluded by demonstrating compliance with food safety criteria.

MPI will consider the possibility of a non-specified period of suspension. The period of withheld supply would then depend on the time taken to obtain test results, which varies according to the test.

Labelling

- The majority of submissions did not respond specifically to the questions regarding labelling options.
- Of those who did respond, most consumers and raw milk suppliers did not support the mandatory labelling requirements proposed in the discussion paper, though in many cases the reasons for this lack of support were not supplied. Consumers who did supply reasons noted they were already aware of the health risks and were making informed choices to drink raw milk. Suppliers thought that the requirements were not warranted given the comparatively low risk from consuming raw milk. Both groups suggested this information would be better provided outside the physical label (for example, on websites).
- Dairy processors and public health submitters strongly supported the proposed labelling requirements and agreed that providing this information specifically on labels was likely to be the most effective way to inform consumers of the health risks and safe handling practices associated with consuming raw milk. They agreed that labelling should include specific information about pathogens, and some called for more descriptive information about the symptoms associated with those pathogens to be part of the mandated labelling material. Some suggested the importance of backing up labelling requirements with links to a website that contained information about the specific pathogens that could be present in raw milk. There was general support for labels to include a date stamp or use-by date. All dairy processors and public health submitters wanted labels to include a mandatory health warning, aimed especially at vulnerable groups, advice on storage and handling, and identifying information to aid traceability.
- All four groups generally agreed that any mandated labelling requirement should have clear legibility requirements and the overall majority were also in favour of the mandated wording being prescribed to provide consistency. Dairy processors and public health submitters recommended stricter requirements around methods for conveying information to consumers (for example, labels to be fixed to containers and signs attached to vending machines).

MPI comment

MPI notes that the proposed labelling requirements are for the protection of public health and safety and are consistent with the approach used for other high- and medium-risk foods under the Australia New Zealand Food Standards Code. The warning statements are consistent with the statements required in other countries that permit the sale of raw milk to consumers, with

the exception that most countries advise that raw milk should be boiled before consumption. MPI considers that heating to 70°C for one minute sufficiently reduces the risk of illness occurring.

MPI does not consider specific information about symptoms and individual pathogens feasible, given that there would be a mandatory warning statement that the consumption of raw milk could possibly cause illness, especially in vulnerable groups. There are also practical issues with fitting a large amount of text on a label. A detailed statement would also not generally be consistent with statements required in other countries.

Requirements for labelling elements, such as supplier details, legibility and instructions for use and storage (if necessary for health and safety reasons, as is the case for raw milk), are already established under the Australia New Zealand Food Standards Code. However, MPI considers that additional legibility requirements are necessary for signage and when ordering online, as this would ensure greater clarity and consistency.

2.7 IMPLEMENTATION

Submitters offered a range of views on MPI's proposed strategy for implementing any legislative policy changes.

- Consumers recommended cooperation between MPI and the industry in implementing new rules. They emphasised that such rules should be realistic, unambiguous and not overly onerous. They stated that the rules should cover the full supply chain and that a "reasonable" transition period should be provided. They also considered monitoring and enforcement costs should be reasonable. Some suggested that information could be provided on the safety standards used by raw milk suppliers and the test results they were achieving. Consumers were also interested in the promotion of health benefits along with food safety advice.
- Raw milk suppliers reiterated that new rules should provide for continued access to raw milk, including sales by small-scale suppliers.
- The dairy processors wished to see a process for follow-up in the case of non-compliance and tighter hygiene testing requirements. They called for a review following implementation and scope for the introduction of more stringent measures if illnesses continued to increase.
- Public health submitters advocated for clear and unambiguous legislation, with provision for timely enforcement action. They also suggested a need for a higher standard of compliance, monitoring of promotional material claiming health benefits, more rules around home delivery, and clarification of rules for farmers producing both raw milk for sale to consumers and raw milk for processing.

MPI comment

MPI's objective is to develop law that is unambiguous and clearly sets out the obligations of the sellers and buyers of raw milk. MPI intends to engage with targeted industry stakeholders following the Government's decision on the policy to ensure technical requirements arising from the new rules are workable. MPI is still working out a reasonable transition period from 1 March 2016 for farmers already operating to implement the new rules.

The cost of listing an operation to sell raw milk to consumers and the cost of verification will be determined as part of MPI's future cost recovery reviews.

In regard to dairy processors' wish to see a process for follow-up in the case of non-compliance, MPI has a step-up strategy to effectively implement legislative policy changes. This strategy first communicates its expectations and obligations; then it monitors and

inspects, and responds to complaints. This approach determines whether stakeholders need assistance or need reminding of their obligations and the sanctions that apply 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.

It is noted that all information, labelling and advertisements related to nutrition content and health claims on all foods must be substantiated and compliant with the relevant requirements under Standard 1.2.7 of the Australia New Zealand Food Standards Code by 18 January 2016.

Appendix 1: Example of an MPI review of literature provided in submissions

MPI considered all literature cited in submissions. This appendix illustrates, by way of example, MPI's evaluation of one such publication; a presentation⁷ by Nadine Ijaz (2013) to the British Columbia branch of the Centre for Disease Control in Canada. MPI is not aware of any international peer-reviewed scientific publication based on the information provided in the presentation.

The presentation refers to three quantitative microbiological risk assessments (QMRAs) and concludes that these studies provide evidence that unpasteurised milk is a low-risk food.

A preliminary step in carrying out a risk assessment is the identification of hazards, in this case bacterial pathogens, that are important in the matrix, in this case New Zealand raw milk. MPI identified *Campylobacter* and pathogenic strains of *Escherichia coli* as most important when categorising New Zealand raw milk as high risk.

However, two of the QMRAs referred to in Ijaz's presentation did not refer to these important pathogens, but instead described other pathogens that are of lesser concern in New Zealand raw milk, namely *Staphylococcus aureus* (and its enterotoxins) and *Listeria monocytogenes*. Although there is documented evidence that *S. aureus* has been associated with raw milk outbreaks, MPI contends that the risk of illness caused by *S. aureus* toxins in raw milk is low because:

- the toxins in raw milk produce relatively mild diseases;
- not all strains of *S. aureus* produce toxins; and
- the high concentrations of *S. aureus* cells that are required to produce toxins have never been found in New Zealand raw milk.

Similarly, MPI considers the risk of *L. monocytogenes* infection from the consumption of raw milk in New Zealand to be low. Although its prevalence has been shown to be similar to or higher than other pathogens in raw milk surveys, the available data suggest that the number of cells in raw milk at the start of the food chain is < 1 CFU/ml. *L. monocytogenes* can grow in raw milk at refrigeration temperatures but the growth rate is typically slow and is unlikely to reach a dangerous level after five to seven days.

Notwithstanding the lack of applicability of the first two QMRAs, the third examined *Campylobacter* and pathogenic strains of *E. coli*. The purpose of this QMRA was to develop a model to describe the risk of illness associated with these pathogens in raw milk (i.e. the probability of at least one haemolytic uremic syndrome (HUS) case linked to raw milk consumption per year) when sold in vending machines in one province of Northern Italy. It was not to determine the relative risk of raw milk

MPI contends that the risk found in the study should be considered high, given that the geographic area was small (the estimated number of raw milk consumers was 10,000 – 20,000 people) and a survey of consumers found that 60 percent boil their milk. The number of cases per head of remaining population was therefore proportionately greater. In addition, the Italian QMRA only examined cases of HUS associated with *E. coli*, ignoring the less severe and likely more common diarrhoeal infections associated with pathogenic *E. coli*. The actual

⁷ Ijaz, N. (2013). Unpasteurised milk: myths and evidence. A presentation to BC Centre for Disease Control, Canada. http://www.bccdc.ca/NR/rdonlyres/00E8757C-99E4-4414-8C54-2C92BB776567/0/RevisedPresentationJuly8RawmilkmythsandevideceNadineIjaz_PROTECTED.pdf

number of cases of illness associated with *E. coli* per year would therefore be substantially higher than those described in the study.

HUS is a devastating illness, although the mortality rate is low (< 1 percent). About 75 percent of affected children require acute dialysis treatment and approximately 15 percent of HUS cases develop chronic renal failure as a long-term condition. In 2009, a team from Italy's Istituto Superiore di Sanità, in charge of a national registry of HUS cases, reported following a case-control study in which the only food significantly associated with HUS in 60 Italian children who developed the disease was raw milk.

According to the Clinical Director of the Department of Paediatric Nephrology (Starship Children's Hospital) and the Principal Investigator for childhood HUS, three cases of HUS in 2013 were associated with the consumption of raw milk in New Zealand.

The risk of campylobacteriosis was also based on the above assumptions. Epidemiological evidence in New Zealand suggests that the risk of infections from particular strains of *Campylobacter* for consumers of raw milk is high and would, if similar epidemiological procedures were used, result in much higher numbers than those shown in the Italian QMRA. Despite recent improvements, New Zealand still has one of the highest per-capita incidence rates of campylobacteriosis in the world.

Ijaz compared the risk of campylobacteriosis from raw milk with the risk from home-cooked chicken. She also compared the risk of developing HUS from raw milk with home-cooked beef patties. Her conclusion was that raw milk had a notably lower risk than the other foods. Although chicken and beef can be contaminated with *Campylobacter* and *E. coli* in their raw forms, the risks are intended to be primarily managed by cooking to kill any pathogens. In the case of raw milk, there is an intention to consume the food without any heating to eliminate the pathogens.

MPI therefore concluded that the evidence presented by Ijaz in 2013 was either not applicable to New Zealand or not sufficiently robust to support the claims of the various submitters that raw drinking milk is of low risk in New Zealand.