Regulation of raw drinking milk and the role of veterinarians

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Abstract

Raw drinking milk is a high risk food because it does not undergo a pasteurisation step. Pasteurisation is the most effective risk management tool for eliminating microbiological risk in dairy material and products. Internationally, legislation on the sale of raw drinking milk varies significantly. The New Zealand government has completed a review of the policy for raw drinking milk resulting in a new regulatory framework for production and sale. Evidence based policy and scientific assessment of microbiological risk, on-farm hygiene and animal health was used to assist the risk management process. The regulatory framework came into effect on 1 March 2016 to coincide with the transitional provisions of the Food Act 2014. Raw milk producers will be registered under a Regulated Control Scheme to manage risks associated with production and processing of raw milk.

Introduction

Context

Raw drinking milk is liquid milk from dairy animals that does not undergo a heat treatment step and does not have anything added or removed from it. Raw milk is considered a high risk food product, as the only way to eliminate the microbiological hazards in the milk is via a kill step such as pasteurisation.

Consuming raw milk has long been a tradition for rural New Zealanders, dating back to the 1800s, when the New Zealand dairy industry was first established. In recent years, the sale of raw milk at the farm gate has been limited to five litres by Section 11A of the Food Act 1981, however this legislation lacked provisions for enforcement. The original intent of the raw milk legislation was to allow for continued access to milk for the rural community. More recently, with a rise in raw milk demand from urban consumers, and a decrease in returns for dairy farmers, producers have been interpreting the legislation in ways the government did not envisage when drafting. This has led to producers using creative ways to sell raw milk at the farm gate in an effort to supplement farm incomes (MAF 2011).

Driven by consumer lobbying, an opportunity to review legislation within an impending food bill, and the implementation of a regulatory framework for raw milk products, the Ministry for Primary Industries (MPI) launched a review of raw drinking milk policy. This review utilised the risk profiles and analyses from the raw milk products policy review. The objective of the review was to address gaps in the existing regulatory framework, and the confusion resulting from allowing sale under the Food Act 1981, whilst requiring a Risk Management Programme (RMP) under the Animal Products Act 1999.

Previous setting

The regulatory framework for national raw milk was introduced in the late 1940s, with the creation of the Milk Act 1944 (Gilmour 1992). Pasteurisation of town milk supplies was made compulsory in the 1950s and the one gallon (five litre rule) for the farm gate sale of raw milk was introduced in the Milk Regulations 1956 (MAF 2011), and later introduced into Section 11A of the Food Act 1981. This was to allow farm workers access to milk, as pasteurised milk was not readily available in some isolated areas, and to prevent sales of raw drinking milk on a commercial scale.

The introduction of the Dairy Industry Regulations 1990 (MAF 2011, Flynn C 1999) under the Dairy Industry Act 1952 saw the requirement for all dairy processors and dairy farmers producing and harvesting milk to have Ministry of Agriculture and Fisheries (MAF) approved Product Safety Programmes (PSPs). This requirement included dairy farmers harvesting milk for sale at the farm gate. MAF did not receive any applications for PSPs for the purpose of supplying raw milk for farm gate sales, but didn't actively enforce the requirement since it was recognised that there was no cost effective way of developing a PSP for small scale producers.

When the dairy industry legislation was brought across into the Animal Products Act 1999 (APA) in 2005, PSPs were replaced with RMPs. MAF again recognised the difficulties of enforcing RMPs for the harvesting and sale of raw milk at the farm gate, so continued to not actively enforce the requirement. The Food Amendment Act 1996 included a provision to repeal Section 11A by Order in Council (section 8). At the time, the Ministry of Health, then responsible for the Food Act 1981, considered that the provisions of the Food Act 1981 didn't adequately address the risk associated with raw milk sale and consumption. Repeal by Order in Council never eventuated. The eventual impending repeal of the Food Act 1981 as a result of the Food Act 2014 meant there would no longer be a provision to permit the sale of raw milk at the farm gate after 29 February 2016, and provided the government with an opportunity to consider a new regulatory framework.

Consumer demand

In recent years, the consumer profile of those who drink raw milk has changed, with fewer people living in isolated rural areas, and pasteurised milk available in all areas of the country. There are greater numbers of consumers in urban areas, and a decrease in consumption from rural purchasers (MAF 2011).

The recent increase in raw milk consumption can be attributed to attitude changes; such as an increasing trend towards natural and unprocessed foods, preference in the taste of unaltered full fat milk and the perceived health benefits. Consumers have a belief that the ability to purchase raw milk is a personal freedom, and they accept the risk to health associated with consumption, although many believe that the likelihood of becoming ill is low and are not fully informed of the consequences. Consumers note that not all raw milk has the same risk, since risk is influenced by hygiene and food safety practices on the farm and in home kitchens (MPI 2015a).

International setting

Legislation providing for the sale of raw drinking milk varies significantly internationally from prohibition through to limited requirements on sale. In the Western world, the risks associated with drinking raw milk are well documented with scientific evidence providing sound rationale for the legislative tools used. However consumer demand means that legislation is not always effectively implemented, particularly in the instance of prohibition.

International standards for raw milk products are included in the Codex Alimentarius, *Code of Hygienic Practice for Milk and Milk Products* (Codex Alimentarius Food Standards 2004). This standard provides for raw milk products but specifically excludes raw drinking milk.

Australia permits the production and sale of raw milk cheeses that do not support the growth of pathogens, however the situation for raw drinking milk differs on a state by state basis. Raw goat milk sale is permitted in four states (New South Wales, Queensland, South Australia and Western Australia), however the sale of raw milk for other species of dairy animals such as cows and sheep is not currently permitted (MPI 2011).

In the United States the sale of raw milk is regulated at state level, with a federal ban on the movement of raw milk between states. Of the states that allow raw milk for sale to consumers, there are varying regulations covering labelling, restrictions on sales and processing requirements.

Canada has a complete ban on the sale of raw drinking milk.

The EU has a long history and tradition associated with products such as raw milk cheeses and raw drinking milk, so has a liberal regulatory framework for production and sale within each member state (MAF 2014).

Within the UK, Scotland has a complete ban on raw drinking milk and raw milk products that was extended in 1983 from a previous ban on cow's milk to all dairy species. England, Wales and Northern Ireland do not currently have a ban, however increasing levels of restriction have been put in place, such as on farm sales, labelling, and microbiological testing (MAF 2014).

Raw milk products policy

The pre-cursor to New Zealand's raw milk products and raw drinking milk policies was a request from the French Government in 2004 to allow the importation of Roquefort raw sheep milk cheese (NZFSA 2008). This prompted the New Zealand government to undertake a risk assessment of Roquefort in 2007, amend food import standards and explore wider policy options for importing and manufacturing raw milk products.

Following these amendments, a decision was made that future case-by-case risk assessments on individual cheeses considered for import approval was not a practical risk management measure. NZFSA released discussion papers in 2008 and 2009 defining raw milk product categories, outlining the proposed scope of a raw milk products regulatory framework, and describing policy options and technical requirements under consideration (NZFSA 2008, NZFSA 2009). NZFSA acknowledged that there was increasing consumer demand for raw milk cheeses, and an opportunity to

develop domestic and export markets for raw milk products. The raw milk products policy review excluded raw drinking milk, and there was no intention of addressing raw drinking milk policy at the time. The *Animal Products (Raw Milk Products Specifications) Notice 2009* was published in 2009, and an accompanying document, the *Code of Practice: Additional Measures for Raw Milk Products* was published in 2010 to provide guidance on how to meet the new requirements.

Food safety risks

Risk finding summary

To inform the development of regulatory frameworks for raw milk products and raw drinking milk, a portfolio of risk assessment activities were undertaken. The findings from these activities were used by risk managers to inform the risk management process, ensuring risks from raw milk products were managed and risks from raw drinking milk were well understood.

The risk assessment findings identified key microorganisms of concern for raw milk consumption, assessed perceived health benefits associated with raw milk, and identified key control points on farm and along the supply chain where interventions to reduce the risk could be applied. While these measures couldn't guarantee an absence of pathogens, they were considered to provide reasonable and practical risk management in the face of consumer demand in order to provide New Zealanders access to raw milk.

Hazards of concern

The microorganisms of most concern for raw milk consumption were identified by MPI and the dairy industry to be *Campylobacter* spp., *E. coli* STEC (Shiga Toxin producing *Escherichia coli*), *Listeria monocytogenes* (*L. monocytogenes*), *Mycobacterium bovis* (*M. bovis*), *Salmonella* spp. and *Staphylococcus aureus* (*S. aureus*) (MPI 2013a).

For *Campylobacter* spp. (particularly *C. jejuni* and *C. coli*), the minimum growth temperature is recognised to be 32°C (Hudson 2011). *C. jejuni* and *C. coli* will not grow at refrigeration or storage temperatures below 4°C (Hudson *et al.* 2014) and microbial load will decrease over time if this temperature is sustained, however this is species dependent. The rate of illnesses per 100,000 servings of raw milk at the farm gate is predicted to be 139.4, and 124.7 for off farm sales, suggesting that consumers would be at higher risk of infection from these pathogens when consumption is at a point closer to when milking occurred (MPI 2013a).

E. coli STEC, particularly serotype O157:H7, are commonly associated with sporadic cases of illness from raw milk consumption rather than in outbreaks. Infection of humans with *E. coli* STEC can result in Haemolytic Uremic Syndrome (HUS), leading to renal failure and death (Gilbert S 2007). The rate of illnesses for *E. coli* STEC per 100,000 servings of raw milk at the farm gate is predicted to be 70.5, and 75.5 for off farm sales (MPI 2013a). With a minimum growth temperature of 8°C (Hudson A 2011), if *E. coli* STEC is present in the raw milk there is a chance of continued growth during shelf life, in particular when refrigeration is insufficient in on-farm systems, during transportation, or in home kitchens.

L. monocytogenes is viewed as a hazard of lower concern in relation to consumption of raw milk, and New Zealand cases of raw milk related listeriosis are estimated to be low (MPI 2013a). However *L. monocytogenes* is of particular significance to vulnerable populations due to its opportunistic nature and is the pathogen of most concern for long shelf life raw milk products. The rate of illnesses for vulnerable populations per 100,000 servings of raw milk at the farm gate is predicted to be 4.13, and 4.55 for off farm sale (MPI 2013a). *L. monocytogenes* has a minimum growth temperature of -1.5°C (Hudson 2011), allowing it to grow at refrigeration temperatures.

Contamination of raw milk with *M. bovis* is thought to be a very rare occurrence in New Zealand and overseas (MPI 2013a). Tuberculosis transmission from drinking milk was common up until the 1930s when pasteurisation became more prevalent. Today there is no evidence of milk borne transmission of *M. bovis* infections to humans in New Zealand, as a result of pasteurisation and an effective national on farm monitoring and control strategy. The potential for exposure must be considered in the absence of such risk mitigations.

Health benefits

Consumers often express belief in health benefits derived from the consumption of raw milk. These health benefits have been summarised into four broad claims (MPI 2013b):

- Claim 1: Raw milk has a higher nutritional value than pasteurised milk.
- Claim 2: People with lactose intolerance can drink raw milk.
- Claim 3: Pasteurisation destroys/inactivates beneficial antimicrobial systems and enzymes.
- Claim 4: Consuming raw milk helps the development of a strong immune system and prevents the development of allergies, asthma and atopy. People with these conditions will have worse symptoms if they drink pasteurised milk.

A comparison of the nutrient content (proteins, fat, carbohydrates, vitamins and minerals) of pasteurised milk and raw milk suggests that pasteurisation has little effect on milk nutrient composition, and absorption and utilisation by the body were found to have little to no impact from pasteurisation (Weeks *et al.* 1985, Zurera-Cosano *et al.* 1994, Efigenia *et al.* 1997, Claeys *et al.* 2012). The effect on vitamins is varied, as vitamin B1 and B6 concentrations showed no significant effect, while vitamins B2, C and folate showed a significant decrease, however due to the low concentration of vitamin C and folate in milk, this has minimal impact on an individual's diet. The effect on vitamin A, E and B12 was unable to be quantified due to significant variabilities in study results (McDonald L *et al.* 2011).

Lactose is metabolised into glucose and galactose by the enzyme lactase (beta-galactosidise) (MPI 2013b). Lactase producing bacteria can be present in raw milk, however their growth is inhibited by refrigeration temperatures, thus preventing lactase production. The physiological effect of lactase from these bacteria on consumers is very limited (Claeys *et al.* 2012).

Pasteurisation does not significantly reduce the biological activity of antimicrobial systems present in raw milk (MPI 2013b). Antimicrobial systems include enzymes (lactoperoxidase, lysozyme, xanthine oxidase), and proteins (lactoferrin, bacteriocins) (Arauz *et al.* 2009, Griffiths 2010, Thomas *et al.* 2000). Pasteurisation has little effect on these heat-stable enzymes, so reduction in concentration and activity in raw milk is minimised (Andrews *et al.* 1987, Fox and Kelly 2006, LeJeune *et al.* 2009, Kussendrager

and van Hooijdonk 2010). Lactoferrin is not affected by heat treatments lower than 85°C for 10 minutes (Conesa *et al.* 2010). Bacteriocin producing bacteria present in raw milk are often destroyed during pasteurisation, however any bacteriocins produced prior will survive the heat treatment step. These bacteriocins tend to be effective only against gram-negative bacteria (Boziaris and Adams 1999, Arauz *et al.* 2009). The enzymes and proteins present in raw milk that display antimicrobial properties are at concentrations too low to eliminate pathogens, and their activity is reduced by refrigeration temperatures (Griffiths 2010). Other enzymes present in raw milk such as milk proteases and lipoprotein lipase (LPL) have no evidence of aiding in human protein digestion or lipid digestion. These enzymes are denatured by gastric acid and digested by human proteases secreted in the gastrointestinal tract (Olivecrona *et al.* 2003, USFDA 2011).

There is considerable variation in the quality and research rigour of epidemiological studies of early-life exposure to raw milk (MPI 2013b). Case studies have suggested that repeated consumption of raw milk provides some immunity against *Campylobacter* but not from other milk-related pathogens (Blaser *et al.* 1987). However further studies have suggested that increased immunity against *Campylobacter* infection is due to early-life exposure to in-farm environment, and not necessarily through raw milk consumption (McBride and French 2006). The PARSIFAL study is cited with providing a positive association between raw milk consumption, and reduction of asthma and allergies, however in this study, it was estimated that half of the raw milk consumed was boiled before consumption. Authors of the study did not allow evaluation of the effect of pasteurised vs. raw milk consumption, because no objective evidence of the status of the raw milk was available (Waser *et al.* 2007, MPI 2013b). The positive association was further studied in the GABRIELA study by Loss and co-researchers, which confirmed an inverse association between raw milk consumption and asthma and atopy. However these protective mechanisms of action were not fully understood, and the authors advised that 'raw milk consumption cannot be recommended because it might contain pathogens' (Loss *et al.* 2011).

On-farm risk management provisions

Maintenance of hygienic conditions for production is one of the most important public health control measures for raw milk production (Codex Alimentarius Food Standards 2004). Interventions can be applied at the following stages of raw milk production: pre-harvest, harvest and post-harvest (Compton 2008).

Pre-harvest activities for raw milk production include; dietary management, animal health and farm hygiene control. Feeds and water have the ability to contaminate milk with taints and residues. Improved control of storage, preparation and distribution of feed can all help to reduce contamination (MPI 2013a). Control of pathogenic microorganisms through appropriate herd management schemes (salmonellosis and leptospirosis vaccinations, dry cow therapy) will reduce the incidence of clinical disease, herd prevalence, and shedding in clinically normal animals (Ruegg 2003, Compton 2008). Control of the farm environment such as hygienic facilities for feeding supplements and managing dairy effluent irrigation appropriately will reduce the exposure to pathogens via feed and pasture.

Interventions at milking include examination of foremilk, exclusion of unhealthy milking animals, and milking practices that focus on hygiene, including teat disinfection. Foremilk stripping of milking animals helps to quickly identify animals with sub-clinical symptoms of mastitis and other milk abnormalities (e.g. blood) that make the raw milk unfit for human consumption. Soiled udders and teats can lead to increased contamination of raw milk. Teat washing and drying compared to washing but

not drying can lead to a significant reduction in total bacterial counts (Blowey and Edmondson 2010). Hygiene of staff and equipment is important for reducing contamination of raw milk from pathogens, and this includes such basic measures as washing hands and forearms before the start of milking (Compton 2008).

Interventions at post-harvest through control of milking plant hygiene, milk filtering, cooling through an effective cold chain and regular microbiological monitoring will assist in reducing contamination of raw milk (Compton 2008, MPI 2013).

The regulatory framework

Development of policy

Development of the policy for raw drinking milk started in 2009 as part of the NZFSA Domestic Food Review. This was in response to years of correspondence between successive Ministers for Food Safety and raw milk producers and consumers, and several consultation submissions received during the raw milk products review advocating for a change in policy for raw drinking milk.

The first raw drinking milk discussion paper was released in October 2011 and outlined policy options for a regulatory framework (MAF 2011). This received varying views from 1,685 submitters (MPI 2014), including dairy farmers, consumers, scientists, public health officials and dairy companies. Policy options included:

- Keeping the status quo;
- Making limited amendments to conditions of sale and retain the requirement for an RMP;
- 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).

MAF had also considered the options of 'prohibition of raw milk farm gate sales', and 'unrestricted raw milk farm gate sales'. These were not progressed, due to the concerns that prohibition could drive activity underground, and the microbiological risk associated with raw milk was too great to allow no restrictions.

A second discussion paper was released in May 2014 which took into account submissions received from the 2011 paper, the findings of the suite of risk assessment activities, and market research such as consumer surveys (MPI 2014). The second discussion paper included options that expanded on the MPI preferred option from the 2011 paper. This consultation received 1,585 submissions (MPI 2015b). These extended policy options included:

- Sales only from the farm to consumers with restrictions on the quantity a dairy farmer could sell each day and the amount a consumer could purchase;
- Sales only from the farm directly to consumers, and no quantity limits, provided strict requirements are followed;
- Sales from the farm as under option two, plus home deliveries by the farmer directly to the consumer only.

The three options all proposed to frame the requirements for raw milk producers under a Regulated Control Scheme (RCS). The decision to establish the regulatory requirements through an RCS, rather than to require individual producers to develop their own RMPs, was to ensure that a consistent set of risk management measures would be applied and implemented across the industry.

During policy development, maintaining the direct relationship between the 'buyer' and the 'seller' was considered essential to managing risks to public health. The means to achieve this was through allowing sales only from the farm gate or via home delivery by the producer, with the option of utilising a 'transport operator' charged with maintaining the cold chain through to home delivery. Maintaining this direct relationship did not fit with the emerging distribution model involving 'collection points', which are locations where producers would drop off milk for customers to collect at a later point. Further consideration of the controls on distribution in urban settings resulted in the introduction of the concept of 'depots', being a place that raw milk may be temporarily stored during transit to the consumer. The system does not allow for consumers to come and collect the raw milk from depots. However it does allow for a transport operator to store milk at a depot before home delivery to the consumer, which may be by the same transport operator or another transport operator. The producer retains the overall responsibility for the transportation system, including all transport operators and any depots.

Regulations

On 18 June 2015, the Minister for Food Safety, Hon. Jo Goodhew, announced the government's policy intentions for the raw drinking milk regulatory framework, being the development and implementation of an RCS described through over-arching system requirements in secondary legislation (the Regulations) and more detailed technical requirements and specifications in tertiary legislation (the Notice). The Regulations and the Notice were issued under both the Food Act 2014 and the APA to provide a regulatory framework covering the production and sale of raw milk.

The *Raw Milk for Sale to Consumers Regulations 2015* included administrative provisions for registration, reporting requirements, and duties of operators, recognised verifiers and raw milk farm dairy assessors (Parliamentary Council Office 2015). Technical provisions were also included that were designed to minimise pathogenic growth such as the 'supply within 30 hour from commencement of milking' provision and milk cooling requirements. Limits on the quantity for sale and purchase have been removed.

The Regulations were approved by Cabinet on 7 December 2015, and came into effect on 1 March 2016 to align with the Food Act 2014 transitional provisions.

Notice/specifications

Following the signing of the Regulations by cabinet, work commenced on technical requirements and specifications. These were consulted on in the 2014 discussion paper (MPI 2014), and had been socialised at industry workshops held around the country in September 2015. Findings from both the raw milk products policy review and raw drinking milk policy development informed risk management decisions (MPI 2014).

The *Animal Products Notice: Raw Milk for Sale to Consumers* was published on 1 March 2016 (MPI 2016). Since sound farm hygiene minimises environmental contamination of raw milk from microorganisms (Compton CWR 2008), the notice applied Good Hygienic Practice (GHP) through requirements on the design, construction and operation of dairy premises and equipment, maintenance, and cleaning and pest management procedures.

Prevention and control of animal diseases through effective animal health practices

reduces the likelihood of pathogen transmission to milk (MPI 2014, MPI 2013a). Farm dairy operators are therefore required to have procedures for segregating sick animals and managing mastitis. All bovine and cervine herds are required to have a herd Tb status of C5 or higher for Tb management, and any reactors during herd testing must be segregated and isolated (MPI 2016).

The notice provides the frequencies for performance based farm dairy assessments and verification audits. Operators are required to undertake monthly checks of specified systems and procedures and report findings to the recognised verifier. The operator must also comply with conformance testing frequencies for parameters including pathogens, hygiene indicators, and chemical and inhibitory substances. Failures are defined for conformance testing, farm dairy assessments and verification. Serious failures lead to the supply of raw milk being suspended until such time as the farmer has satisfactorily rectified the situation.

The notice also regulates the sale and labelling of raw drinking milk, such as advertising content, and requires mandatory inclusion of warning statements.

Implementation

Implementation of the RCS began on 1 March 2016. The Regulations contain transitional provisions that allow farm dairy operators who sold raw drinking milk between 18 June 2015 and 29 February 2016 exemption from the new requirements until 31 October 2016. These transitional provisions also apply to depot operators that store raw drinking milk, and transport operators who have transported raw drinking milk during this period. All new raw milk producers, transport operators and depot operators must comply with the new requirements from the 1 March 2016.

The Ministry for Primary Industries (MPI) is launching a communications strategy targeting consumers, farm dairy operators, depot operators, and vulnerable populations (children, the elderly, pregnant woman and the immunocompromised) to inform them of the risks of consuming raw milk. This will include issuing guidance to farm dairy operators and depot operators on how to comply with the requirements of the RCS, and holding implementation workshops for industry and consumers.

As part of the implementation of the regulatory framework, MPI will be carrying out a survey of raw milk providers in 2017. This survey will look at specific micro-organisms and chemical contaminants of concern. The results of this survey will be used to support a review of the Regulations that is scheduled to occur 24 months from the RCS coming into force to examine the effect of the legislative framework.

Roles and responsibilities

Under the raw drinking milk regulatory framework, the roles and responsibilities for recognised raw milk farm dairy assessors, recognised verifiers and veterinarians are aligned with the wider dairy regulatory framework.

The role of the raw milk farm dairy assessor is to assess the compliance of the farm dairy business' operation against the RCS. The farm dairy operator will need to contract a farm dairy assessor from a farm dairy assessment organisation. Responsibilities for farm dairy assessors include completing pre-registration checks of farm dairies before they are registered, ongoing raw milk farm dairy assessments, record keeping, and reporting to the farm dairy operator and responsible verifier identification of any critical non-conformances.

Recognised verifiers will verify farm dairy operators and depot operators against the regulated control scheme, and perform all other verification functions relating to the operations of a farm dairy operator or depot operator. The farm dairy operator will request a recognised agency to provide verification services in relation to their farm dairy operation. Responsibilities for verifiers will include pre-registration checks of depot operator's premises before they are registered, ongoing verification visits at the frequency specified in the RCS, record keeping, and reporting duties.

The role of veterinarians remains the provision of professional guidance to farm dairy operators about the health and welfare of milking animals. Operators will be expected to keep records of veterinary advice or diagnoses they receive, veterinary authorisations for restricted veterinary medicines, instructions for segregation or isolation of unhealthy animals, or directions in the case of Tb reactors. Veterinarians are not expected to comment on the quality of milk, however any clinical diagnosis that could affect the suitability of milk for human consumption should be passed on to the farm dairy operator so they can take appropriate action and ensure the milk is withheld from supply. In this regard, the advice given should align with the advice that would be given to any farmer producing milk for supply, whether it will be consumed raw or pasteurised.

Conclusion

The usual process followed when developing risk intervention measures is to:

- assess the risk based on the available science;
- develop options to mitigate the risk, and make risk management decisions based on science, economics and practicality;
- implement the risk management decisions, through clear and unambiguous specification in regulatory or non-regulatory instruments and an appropriate verification framework;
- communicate the nature of the risk to those affected and those who influence the outcome.

Developing and implementing evidence-based risk management in the face of consumer demand that is driven by strongly held beliefs not necessarily founded in good science creates an interesting conundrum for food safety regulators around the world.

In the case of raw drinking milk sales in New Zealand the balance has been struck to make raw milk available to the small but potentially growing proportion of the population intent on purchasing it. The rejection of the most widely accepted risk management option for drinking milk (i.e. pasteurisation) demands a robust risk management framework pre-harvest, during harvest, and post-harvest, along with a strong reliance on risk communication to ensure awareness and understanding of the risks to consumers, particularly those who are vulnerable.

The regulation of raw milk for direct sale to consumers has endeavoured to apply all reasonable risk mitigation measures to manage the known public health risks. The measures applied will come at a cost for producers and only time will tell whether an enduring, compliant, and economically viable trade for the supply of raw drinking milk can be established, and whether the public health outcomes of this system are acceptable to New Zealanders.

References

For formatting purposes, all original long URLs have been condensed using the bit.ly format.

Andrews AT, Anderson M, Goodenough PW. A study of the heat stabilities of a number of indigenous milk enzymes. *Journal of Dairy Research* 54, 237–246, 1987

Arauz LJ, Jozala AF, Mazzola PG, Vessoni Penna TC. Nisin biotechnological production and application: a review. *Trends in Food Science and Technology* 20, 146–154, 2009

Blaser MJ, Sazie E, Williams LP Jr. The influence of immunity on raw-milk associated Campylobacter infection. *Journal of the American Medical association*, 257, 43–46, 1987

Blowey R, Edmondson P. Mastitis control in dairy herds. CABI Publishing, 2010

Boziaris IS, Adams MR. Effect of chelators and nisin produced insitu on inhibition and inactivation of Gram negatives. *International Journal of Food microbiology*. 53, 105–113, 1999

Claeys WL, Cardoen S, Daube G, De Block J, Dewettinck K, Dierck K, De Zutter L, Huyghebaert A, Imberechts H, Thiange P, Vandenplas Y, Herman L. Raw Or Heated Cow Milk Consumption: Review of Risks and Benefits. *Food Control* 31, 251–262, 2012

Codex Alimentarius Food Standards. Code of hygienic practice for milk and milk products. FAO/WHO, 2004. Website: www.fao.org Link: bit.ly/1sNwTmz (accessed 4 April 2016)

Compton CWR, McDougall S. Consideration of on farm provisions for raw milk production. Animal Health Centre, 25 February 2008

Efigenia M, Povoa B, Morae-Santos T. Effect of heat treatment on nutritional quality of milk proteins. *International Dairy Journal* 7, 609–612, 1997

Flynn C. The Optimal Regulatory Model, The application of risk management to government regulation. 10th World Congress on Food Safety, October 1999

Fox PF, Kelly AL. Review: Indigenous enzymes in milk: Overview and historical aspects – Part 1 & 2. *International Dairy Journal* 16, 500–532, 2006

Gilbert S, Lake R, Hudson A, Cressey P. Risk Profile: shiga toxin producing *Escherichia coli* in raw milk. Institute of Environmental Science and Research Limited, July 2007

Gilmour S. History of the New Zealand milk board a study of the corporatist alliance between the state and the domestic milk sector. *Research Report No. 216, Lincoln University, Canterbury,* August 1992

Griffiths MW. Improving the safety and quality of milk. Volume 1: Milk production and processing. *Guelph: Woodhead Publishing Limited,* (pp520), 2010

Hudson A. Minimum Growth Temperatures of Foodbourne Pathogens and Recommended Chiller Temperatures. *MPI Technical Paper No: 2016/04*, January 2011

Hudson A, King N, Lake R, Cressey P. Risk Profile: *Campylobacter jejuni/coli* in Raw Milk. *MPI Technical Paper No: 2014/15,* May 2014

ICMSF. *Micro-organisms in foods 5. Microbiological specifications of food pathogens. International Commission on Microbiological Specifications for Foods, London,* 1996

Kussendrager KD, van Hooijdonk AcM. Lactoperoxidase: physico-chemical properties, occurrence, mechanism of action and application. *British Journal of Nutrition* 84: Suppl. 1, S19–S25, 2000

Lake R, Hudson A, Cressey P, Gilbert S. Risk Profile: *Listeria monocytogenes* in low moisture cheeses. Institute of Environmental Science and Research Limited, July 2005a

Lake R, Hudson A, Cressey P, Gilbert S. Risk Profile: *Listeria monocytogenes* in soft cheeses. Institute of Environmental Science and Research Limited, November 2005b

Lake R, Gilbert S, Wong TL, Cressey P, Risk Profile: *Mycobacterium bovis* in milk. Institute of Environmental Science and Research Limited, Client Report No. FW08031, August 2009

Lejeune JT and Rajala-Schultz PJ. Unpasteurized Milk: A Continued Public Health Threat. *Clinical Infectious Diseases. 48, 93–100, 2009*

Loss G, Apprich S, Waser M, Kneifel W, Genuneit J, Buechele G, Weber J, Sozanska B, Danielewicz H, Horak E, Joost van Nerven RJ, Heederik D, Lorenzen P, Mutius E, Braun-Fahrlaender C, Gabriela study group. The protective effect of farm milk consumption on childhood asthma and atopy: The GABRIELA study. *Journal of Allergy Clinical Immunology* 128, 766–773, 2011

MAF. Proposals for continuing to legally provide for farm gate sales of raw drinking milk. *MAF Public Discussion Paper No:* 2011/11, October 2011

MacDonald L, Brett J, Kelton D, Majowicz SE, Snedekerr K, Sargeant KM. Systematic Review and Meta-Analysis of the Effects of Pasteurization on Milk Vitamins, and Evidence for Raw Milk Consumption and Other Health-Related Outcomes. *Journal of Food Protection* 74 (11), 1814–1832, 2011

McBride G, French NP. Accounting for age-dependant susceptibility and occupation-dependant immune status; a new analytical SIR model. *WSEAS Transactions on Mathematics* 11, 1241–1246, 2006

MPI. Assessment of the microbiological risks associated with the consumption of raw milk. *MPI Technical Paper No: 2014/12*, June 2013a

MPI. An Assessment of the Effects of Pasteurisation on Claimed Nutrition and Health Benefits of Raw Milk**.** *MPI Technical Paper No: 2014/13*, October 2013b

MPI. The sale of raw milk to consumers. *MPI Public Discussion Paper No:* 2014/22, 27 May 2014

MPI. Experiences of Buying, Selling and Consuming Raw Milk: Survey Report. *MPI Information Paper No: 2015/04*, June 2015a

MPI. The Sale of Raw Milk to Consumers: Summary and analysis of submissions on MPI Public Discussion Paper No: 2014/22. *MPI Information Paper No: 2015/05*, June 2015b

MPI. Animal Products Notice: Raw Milk for Sale to Consumers. Website: www.mpi.govt.nz Link: bit.ly/1Rjma76 (accessed 4 April 2016)

NZFSA. Proposed framework for the manufacture, importation and sale of raw milk products. *Public Discussion Document No* 04/08, August 2008

NZFSA. Proposed framework for unpasteurised milk products. *NZFSA Public Discussion Document No* 02/09, May 2009

Olivecrona T, Viraro S, Olivecrona G. Lipases in milk. In P. *F. Fox and P. L.* H. McSweeney (ed), Advanced Dairy Chemistry p473–494. Website: www.books.google.co.nz Link: bit.ly/1TR1upd (accessed 4 April 2016)

Parliamentary Council Office. Biosecurity (National Bovine Tuberculosis Pest Management Plan) Order 1998 (SR 1998/179), 1998. Website: www.legislation.govt.nz Link: bit.ly/1YQBvSQ (accessed 4 April 2016)

Parliamentary Council Office. Raw Milk for Sale to Consumers Regulations 2015. Website: www.legislation.govt.nz Link: bit.ly/1WJZ9T1 (accessed 4 April 2016)

Paulin S, King N, Lake R, Cressey P. Risk Profile Update: *Listeria monocytogenes* in cheese. Institute of Environmental Science and Research Limited, February 2015

Ruegg P. Practical food safety interventions for dairy production. *Journal of dairy Science* 86: E1–E9, 2003

Ryan T, Soboleva T. Farm gate supply of unpasteurised cows' milk: an evaluation of the risk of contamination with Mycobacterium bovis. March 2013

Thomas LV, Clarkson MR, Delves-Broughton J. Nisin. Natural Food Antimicrobial Systems. *In A. S. Naidu (ed), Natural Food Antimicrobial Systems, CRC Press, Boca Raton, Florida.* p463–524, 2000

U.S. Food and Drug Administration. Raw Milk Misconceptions and the Danger of Raw Milk Consumption. *Updated* November 1, 2011. Website: www.fda.gov Link: bit.ly/25aVvDu (accessed 4 April 2016)

Waser M, Michels KB, Bieli, C *et al*. Inverse association of farm milk consumption with asthma and allergy in rural and suburban populations across Europe. *Clinical Experimental Allergy*, 37, 661–670, 2007

Weeks CE, King RL. Bioavailability of calcium in heat-processed milk. *Journal of Food Science* 50, 1101–1105, 1985

Zurera-Cosano, Moreno-Rojas GR, Amaro-Lopez M. Effect of processing on contents and relationships of mineral elements of milk. *Food Chemistry* 51, 75–78, 1994